Establishing a Patient Centred Medical Device Body

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List of Abbreviations

AI	Artificial Intelligence
CE	Conformité Européenne (European Conformity)
DoC	Declaration of Conformity
EEA	European Economic Area
EHR	Electronic Health Record
EU	European Union
EUDAMED	European Database on Medical Devices
FDA	Food and Drug Administration (America)
GDPR	General Data Protection Regulation
IT	Information Technology
IVD	In Vitro Diagnostic
IVDD	In Vitro Diagnostic Medical Device Directive
IVDR	In-Vitro Diagnostic Medical Device Regulation
KPI	Key Performance Indicator
MDD	Medical Device Directive
MDMS	Medical Device Management System
MDR	Medical Device Regulation
MMA	Malta Medicines Authority
NCA	National Competent Authority
NMPA	National Medical Products Administration (China)
PIP	Poly Implant Prothèse
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMS	Post-Market Surveillance
PRRC	Person Responsible for regulatory compliance
QMS	Quality Management System
SOP	Standard Operating Procedure
TGA	Therapeutic Goods Administration (Australia)
UAT	User Acceptance Testing
UDI	Unique Device Identification

Glossary

Agile Methodology	Agile methodology is a project management approach that emphasises flexibility, collaboration, and customer feedback in the development process of a product. *Adapted from Ghimire & Charters, 2022*
Conformité Européenne, CE	The CE mark indicates that a product complies with EU safety, health, and environmental protection directives and regulations. *Adapted from EUR-Lex, European Commission. Available at: https://eur-lex.europa.eu/EN/legal-content/glossary/ce-marking.html*
Directive	A directive is a legal act of the European Union which requires member states to achieve a particular result without dictating the means of achieving that result. *Adapted from EUR-Lex, European Commission. Available at: https://eur-lex.europa.eu/EN/legal-content/glossary/directive.html.*
EUDAMED	EUDAMED is the IT system established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. EUDAMED is integral part of the implementation of the two Medical Devices Regulations. *Adapted from Public Health, European Commission. Available at: https://health.ec.europa.eu/medical-devices-eudamed/overview_en*
Intended Purpose	Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation. *Adapted from Regulation (EU) 2017/745 of the European Parliament*
In-vitro Medical Device	An in-vitro medical device is a device that is used to perform tests on samples (such as blood, urine, tissue) outside of a living organism to help detect diseases, conditions, or infections. *Adapted from Regulation (EU) 2017/746 of the European Parliament*
Medical Device	A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, for a medical purpose. *Adapted from Regulation (EU) 2017/745 of the European Parliament*
Medical Device Management System	A Medical Device Management System (MDMS) is a framework that encompasses the policies, procedures, and processes used by healthcare institutions to manage their medical device inventory, usage, maintenance, and procurement. *Adapted from Sculz et al., 2016*

National Competent Authority	A National Competent Authority (NCA) is an organisation designated by a country to regulate the approval and monitoring of medical devices within its jurisdiction. *Adapted from European Medicines Agency. Available at: https://www.ema.europa.eu/en/glossary/national-competent-authority*
Notified Body	Notified body means a conformity assessment body designated in accordance with this Regulation. *Adapted from Regulation (EU) 2017/745 of the European Parliament*
Quality Management System	A Quality Management System (QMS) is a structured system of procedures and processes covering all aspects of design, manufacturing, supplier management, risk management, complaint handling, clinical data, and post-market surveillance of a product. *Adapted from Sharma & Luthra, 2023*
Regulation	In the context of medical devices, regulation refers to the legal requirements established by authorities to ensure devices are safe and effective for their intended use. *Adapted from EUR-Lex, European Commission. Available at: https://eur-lex.europa.eu/EN/legal-content/glossary/regulation.html*
Sprint Cycle	In agile methodology, a sprint cycle is a set time period during which specific work has to be completed and made ready for review. *Adapted from Ghimire & Charters, 2022*
Telemedicine	Telemedicine is the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. *Adapted from: Waller & Stotler, 2018*
Unique Device Identifier (UDI)	Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. *Adapted from Regulation (EU) 2017/745 of the European Parliament*

Abstract

In the rapidly evolving landscape of healthcare, the field of medical devices plays a pivotal role in advancing patient safety and enhancing the quality of life. Recent developments in technology and regulatory frameworks have prompted a transition in medical device legislation. The directives governing medical devices and in-vitro diagnostic devices were superseded by the Medical Device Regulation (MDR - (EU) 2017/745) and the In-Vitro Diagnostic Medical Device Regulation (IVDR - (EU) 2017/746), signalling a change in the regulatory landscape. This research endeavours to contribute to this transformative phase by creating a framework for a patient-centred medical device body. The overarching goal is to develop a transition framework for medical device regulation, facilitating stakeholders in understanding and complying with the new regulatory requirements. The methodology is split into four phases. The initial phase focuses on establishing a Medical Device Quality Management System, identifying fundamental regulatory requirements essential for supporting a patient-centred framework. The second phase of the study delves into the development of a centralised Medical Device Incident Reporting System, streamlining processes and procedures for incident reporting functionality in the medical device domain. The third phase is dedicated to setting up a Digital Medical Device Management System (MDMS), addressing production, notification, distribution, vigilance, and surveillance of medical devices placed on the market. The MDMS is designed to enhance transparency and accessibility, allowing stakeholders and the public to verify devices, report adverse events, and contribute to an increased market access for all. The fourth phase focuses on identifying gaps for essential medical device training and continuous professional development, ensuring that medical device operators are well-equipped to navigate the

evolving regulatory landscape. The impact of this study is to put forward a robust framework for bodies to propose innovative legislative transition solutions whilst fostering a patient-centred approach in the implementation of new regulations. This research seeks to contribute to the ongoing enhancement of patient care and well-being through a well-defined, patient-centric medical device regulatory framework.

Chapter 1
Introduction

1.1 Medical device overview

The introductory chapter is intended to present the growth of knowledge in the field of medical devices, focusing on the legislative changes brought by the medical device regulations and the increase in digitalisation in healthcare. The literature review introduces medical devices, with particular attention given to vigilance (Charlesworth & Zundert, 2019), post-market surveillance (Badnjević et al., 2022) and traceability (Regan et al., 2013), while emphasising the roles of the regulator and the patient. The impact on medical device healthcare with reference to digitalisation on daily life is examined, using COVID-19 as an example.

1.1.1 Medical devices and in-vitro diagnostic medical devices

Medical devices and in-vitro medical devices are an essential part of the healthcare industry. These devices revolutionised the way healthcare is delivered, leading to better patient outcomes, increased efficiency, and reduced healthcare costs (Altenstetter & Permanand, 2007). Medical devices and in-vitro medical devices (IVDs) are two groups of devices used in the healthcare industry for diagnosis, treatment, and monitoring of medical conditions.

A medical device is any instrument, apparatus, machine, or other similar article that is intended to be used in the diagnosis, treatment, or prevention of disease or other medical conditions. Medical devices can range from simple tools such as a thermometer or stethoscope to complex technologies like pacemakers, artificial joints, or imaging equipment (Racchi et al., 2016; Aronson et al 2020). In-vitro medical devices are

diagnostic tools that are used to analyse human samples, such as blood, urine, or tissue, outside of the body. In-vitro medical devices can be used to diagnose, monitor, or predict the progression of a disease or medical condition. Examples of IVDs include blood glucose meters, pregnancy tests, and genetic tests. In Europe, both medical devices and IVDs are strictly regulated to ensure a high standard of quality, safety, and effectiveness for patients and healthcare users. Manufacturers are at the core of the regulation and must uphold numerous obligations. The classification system for medical devices and IVDs is one such method of control. (Shermilan & Kamaraj, 2021)

The classification of medical devices and IVDs is based on the intended purpose of the device, the potential risk to the patient or user, and the complexity of the device. The classification system is designed to ensure that the regulatory requirements are appropriate for the level of risk posed by the device (Peter et al., 2020). In Europe, the classification system for medical devices and IVDs is based on four risk classes (De Maria et al., 2018) ranging from low to high risk; see Table 1.1 and 1.2.

Table 1.1 Medical device risk class and certification route

Risk	Class	Type	Certification Route
↓	Class I	This class includes low-risk medical devices, such as bandages, gloves, and tongue depressors	These devices are subject to the least amount of regulation and require a self-declaration of conformity by the manufacturer
	Class IIa	This class includes medium-risk medical devices, such as contact lenses and hearing aids	These devices require a conformity assessment by a notified body and a CE mark before they can be marketed
	Class IIb	This class includes higher-risk medical devices, such as surgical lasers and ultrasound machines	These devices require a conformity assessment by a notified body and a CE mark before they can be marketed
	Class III	This class includes the highest-risk medical devices, such as implantable pacemakers and heart valves	These devices require a conformity assessment by a notified body and a clinical evaluation before they can be marketed

Table 1.1 illustrates how medical devices are classified by risk and certification requirements. Class I devices rely on manufacturer self-declaration, while Classes IIa, IIb, and III demand assessment by notified bodies, a conformity assessment body. These distinctions ensure appropriate regulatory scrutiny, bolstering patient safety and health standards. Adapted from Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20

Table 1.2 In-vitro diagnostic medical device risk class and certification route

Risk	Class	Type	Certification Route
	Class A	This class includes low-risk IVD medical devices, such as those used for blood grouping and pregnancy testing	These devices are subject to the least amount of regulation and require a self-declaration of conformity by the manufacturer
	Class B	This class includes medium-risk IVD medical devices, such as those used for cholesterol testing and some cancer markers	These devices require a conformity assessment by a notified body and a CE mark before they can be marketed
	Class C	This class includes higher-risk IVD medical devices, such as those used for HIV testing and some genetic testing	These devices require a conformity assessment by a notified body and a CE mark before they can be marketed
	Class D	This class includes the highest-risk IVD medical devices, such as those used for the detection of infectious diseases and some genetic testing	These devices require a conformity assessment by a notified body and a clinical evaluation before they can be marketed

Table 1.2 summarises risk classifications and certification routes for in-vitro diagnostic medical devices. Class A devices are low risk, with self-declaration by manufacturers. Classes B, C and D are medium to high-risk devices which require notified body assessment and CE marking. Adapted from Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/746/2023-03-20

The classification system is a critical regulatory process that enhances the safety and efficacy of devices for patient use and is a requirement for medical device certification (Arsonson et al., 2020).

Medical device certification is a legislative requirement conducted to ensure that medical devices comply with regulatory standards which are designed to safeguard the safety and effective use of the device (Marshall et al., 2021). Certification is obtained by undergoing a conformity assessment procedure based on the device's classification (Schoener and Hoxey, 2019). Devices that meet and demonstrate compliance are given the Conformité Européenne (CE) mark. The CE mark is a legal requirement for marketing medical devices in the European Union (EU) and European Economic Area (EEA), with the exception of custom-made devices and devices intended for clinical research. The CE mark allows a device to move freely within the EU and EEA. (Hancher and Foldes, 2013). The responsibility for obtaining the CE mark for medical devices is that of the manufacturer (Shermilan & Kamaraj, 2021). The following are the core principles of medical device certification outlined in the European medical device regulations (Figure 1.1).

- A quality management system (QMS) is a system that ensures that the design, manufacture and distribution of a medical device comply with regulatory requirements and are consistent with the intended purpose of the device. The QMS includes procedures for design, production, testing, and distribution of the device (Sharma & Luthra, 2023; Geetha & Usha, 2020; Holland, 2017).
- Conformity assessment is the procedure used to evaluate whether a medical device complies with pertinent regulatory requirements. The assessment includes

a review of the technical documentation and testing of the device. All medical devices must undergo conformity assessment; the level of the assessment is determined by the device's classification (Mishra, 2017; French-Mowat & Burnett, 2012; Jefferys, 2001).

- Risk assessment is a process that evaluates the potential risks associated with the use of a medical device. The assessment considers the device's intended purpose, the patient population and the prospective risks of the device. The results of the risk assessment impact and affect the design of the device, the labelling, and the instructions for use (Yaqoob et al., 2020; Mahler et al 2020; Starling et al 2017).
- Clinical evaluation is the process by which the safety and performance of a medical device are evaluated in a clinical setting. The evaluation includes the collection and analysis of clinical data and the assessment of the clinical benefits and risks associated with the device (Niemiec, 2022; Wilkinson & van Boxtel, 2020; Egbosimba, 2019).
- Post-market surveillance is a process of ongoing monitoring and evaluation of a device's safety and effectiveness after it has been released to the market. The surveillance includes the collection and analysis of adverse events, complaints, and other data related to the safety and performance of the device (Ren et al., 2023; Badnjević et al 2022; Zippel & Bohnet-Joschko, 2017)

The assessment process of the certification procedure is conducted by notified bodies, which are independent organisations authorised in the EU to evaluate medical devices for compliance with the medical device regulations. A detailed procedural overview of the certification process can be found in Figure 1.2.

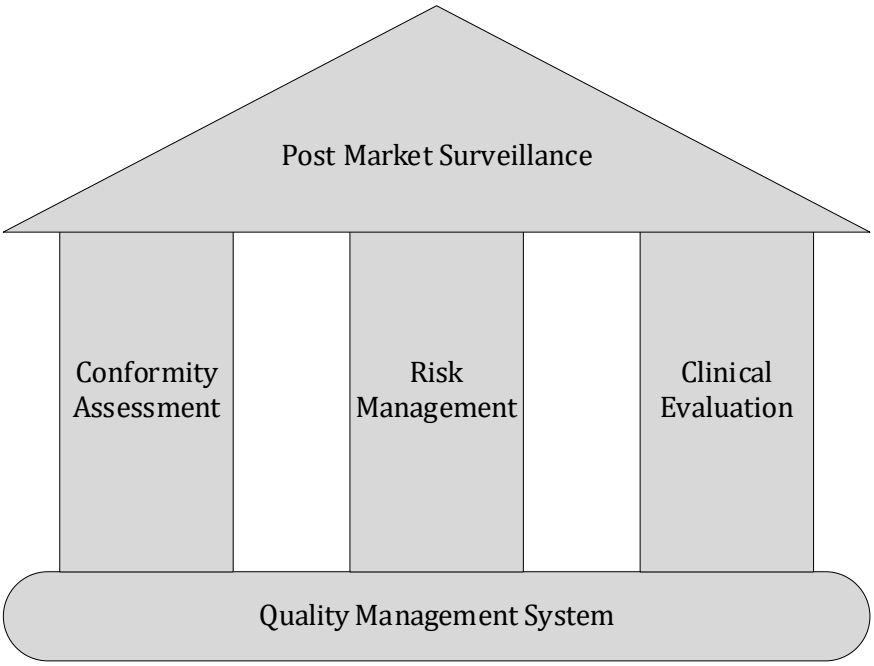


Figure 1.1 The core principles of medical device certification

Figure 1.1 depicts a temple symbolising the structure of medical device certification. The Quality Management System forms the foundation, with three pillars representing Conformity Assessment, Risk Management, and Clinical Evaluation. At the summit is Post Market Surveillance, signifying ongoing monitoring for safety and effectiveness post-approval. Together, these elements ensure robust certification processes in healthcare

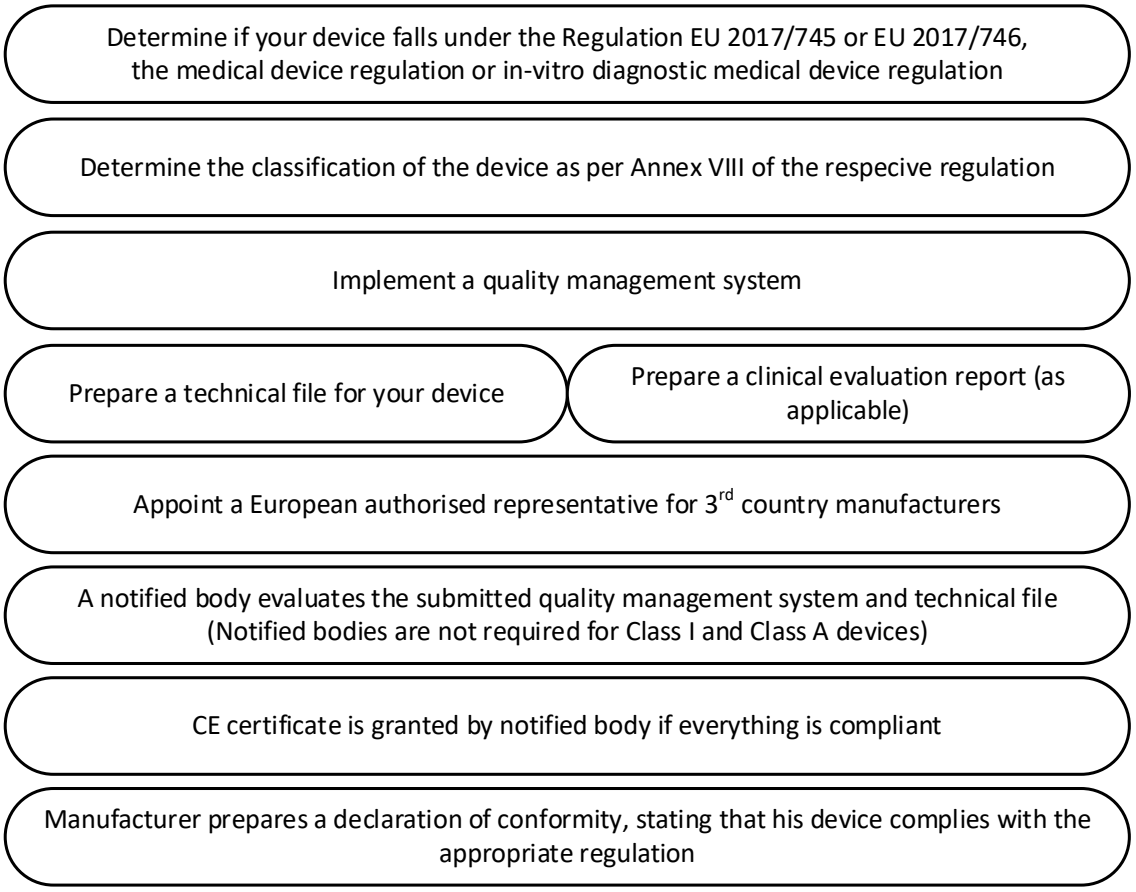


Figure 1.2 illustrates the stepwise procedure of medical device certification for manufacturers. This visual guide assists manufacturers in navigating the rigorous certification process, ensuring compliance with safety and quality standards.

1.1.2 Global regulatory framework

The global regulatory framework for medical devices is a complex system involving of regulations and standards. Manufacturers, suppliers, and distributors must strictly adhere to this complicated framework to assure the safety and effectiveness of medical devices. Globally, governmental health agencies are primarily in charge of regulatory oversight.

Governmental health agencies worldwide include the FDA in the United States, the NMPA in China, the PMDA in Japan, Health Canada's Medical Devices Bureau, the TGA in Australia, and the European Commission within the European Union. (Table 1.3) (Chen et al., 2018).

The regulatory framework in the United States:

The Food and Drug Administration (FDA) in the United States is responsible for the thorough regulation of medical devices. These technologies, which include diagnostic tools, therapeutic equipment, medical software, and mobile applications, are categorised into three classes—Class I, Class II, and Class III—according to the level of risk they pose (Kramer et al., 2012). Devices classified as Class I, which present little risks, are subject to overall regulatory regulations and may not necessitate premarket evaluation. Class II devices, which have a moderate level of risk, are subject to premarket evaluation through a 510(k) application. This application must demonstrate that the device is substantially similar to existing devices (Van Norman, 2016). Premarket approval is required for high-risk Class III devices, which includes the validation of safety and effectiveness through clinical evidence (Maak & Wylie, 2016).

The FDA's regulatory jurisdiction extends beyond the evaluation of products before they enter the market and includes monitoring their performance once they are available for sale, and reporting any negative effects seen by users. Manufacturers are required to record adverse events related to their devices, allowing the FDA to closely monitor device safety and take immediate action, such as issuing recalls or demanding enhanced labelling (Holtzman et al., 2022).

The regulatory framework in China:

The regulatory framework for medical devices in China is overseen by the National Medical Products Administration (NMPA). The NMPA classifies medical devices into three categories based on their level of risk: low-risk (Class I), moderate-risk (Class II), and high-risk (Class III). This classification system is similar to the one used by the FDA in the United States. Manufacturers are required to obtain permission from the NMPA through a three-stage process, which includes product registration, conducting clinical trials, and implementing post-market surveillance. The Chinese government has simplified the regulatory procedure by implementing an expedited assessment for devices that have already received approval from the FDA or Europe (Liu et al., 2017).

Regulatory framework in Japan:

Japan's regulatory framework, supervised by the Pharmaceuticals and Medical Devices Agency (PMDA), categorises medical devices into four risk-based classifications. Devices are categorised into low-risk (Category I), moderate-risk (Category II), and high-risk (Category III) based on complexity and potential harm. Category IV devices, characterised as unique, undergo a more comprehensive regulatory review (Altenstetter, 2012). The general approval process entails the submission of a marketing application, accompanied by clinical evidence that substantiates the safety and effectiveness of the product, similar to the protocols followed by other international organisations. The Japanese system is characterised by the Shonin approach, which approves devices for marketing rather than specific indications, providing manufacturers with flexibility in marketing their devices for a broad range of uses, promoting innovation in the industry (Nakayama et al., 2019).

The regulatory framework in Canada:

Health Canada's Medical Devices Bureau categorises devices in Canada into four risk-based classifications; with Class I devices considered low-risk and Class IV devices representing the highest risk. The approval process entails acquiring a Medical Device Licence by means of submitting technical documents and clinical data. Canada, similar to other legal systems, prioritises post-market surveillance and has implemented expedited review programmes for inventive products (Medical Devices Regulations SOR/98-282, cited 2024).

The regulatory framework in Australia:

The Therapeutic Goods Administration (TGA) of Australia is responsible for regulating medical devices using a risk-based classification system that consists of four classes. This classification system is similar to the frameworks used in other countries worldwide. Manufacturers are required to obtain inclusion on the Australian Register of Therapeutic Goods by submitting technical documentation and clinical data. Australia's regulatory framework is further defined by post-market surveillance and expedited review programmes (McGee et al., 2012).

Table 1.3 Classification of medical devices different countries

Country/Region	Classification	Regulatory Controls
United States (FDA)	Class I (Low risk)	Subject to general controls including labelling requirements, adherence to Good Manufacturing Practices, and registration with the FDA.
	Class II (Moderate risk)	Requires submission of a 510(k) premarket notification to demonstrate substantial equivalence to a legally marketed device, along with adherence to specific performance standards.
	Class III (High risk)	Requires submission of a premarket approval application providing comprehensive scientific evidence of safety and efficacy, including clinical data.
China (NMPA)	Class I (Low risk)	Subject to basic regulatory oversight including product registration and adherence to technical standards.
	Class II (Moderate risk)	Requires additional technical documentation demonstrating safety and efficacy, along with clinical trial data.
	Class III (High risk)	Subject to comprehensive regulatory review, including rigorous assessment of clinical data and manufacturing processes.
Japan (PMDA)	Class I (General medical devices)	Self-declaration of conformity to established standards and technical documentation.
	Class II (Controlled medical devices)	Requires third-party certification to confirm compliance with regulatory requirements and safety standards.
	Class III (Highly Controlled medical devices)	Mandates third-party certification for safety and efficacy, including review by PMDA experts.
	Class IV (Highly Controlled medical devices)	Requires ministerial approval due to significant risks, including life-threatening consequences.

Canada (Health Canada)	Class I (Lowest risk)	Basic regulatory controls including product registration and compliance with applicable standards.
	Class II (Low risk)	Increased scrutiny involving review of safety and performance data, and risk management plans.
	Class III (Moderate risk)	Higher level of regulatory scrutiny necessitating comprehensive evidence of safety, effectiveness, and quality.
	Class IV (High risk)	Stringent requirements for demonstrating safety and efficacy, including clinical trial data and post-market surveillance.
Australia (TGA)	Class I (Low risk)	Basic regulatory controls including conformity assessment procedures and labelling requirements.
	Class IIa (Low to moderate risk)	Increasing regulatory scrutiny involving assessment of safety and performance data, and conformity assessment by the TGA.
	Class IIb (Moderate to high risk)	Heightened scrutiny requiring comprehensive evidence of safety and effectiveness, including clinical data and risk management plans.
	Class III (High risk)	Rigorous assessment involving extensive clinical evidence, post-market surveillance, and ongoing risk management.
European Union (EU Commission)	Class I (Low risk)	Basic regulatory controls including conformity assessment procedures and compliance with essential requirements.
	Class IIa (Low to moderate risk)	Enhanced scrutiny involving review of clinical data and conformity assessment by a notified body.
	Class IIb (Moderate to high risk)	Increased regulatory requirements including comprehensive clinical evaluation and conformity assessment.
	Class III (High risk)	Stringent scrutiny requiring comprehensive clinical data, including evidence of safety and performance, along with ongoing risk management and post-market surveillance

Table 1.3 illustrates the classification of medical devices across the United States, China, Japan, Canada, Australia, and the European Union. It outlines the regulatory controls corresponding to different risk classifications, highlighting variations in scrutiny levels and approval processes. The table offers a comparative overview facilitating insights into global medical device regulatory frameworks. Adapted from Kramer, et al. (2012); Liu, et al. (2017); Altenstetter (2012); Medical Devices Regulations SOR/98-282 (cited 2024) and McGee et al. (2012) and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20

1.1.3 European legislation

The regulatory framework for medical devices in the EU has undergone a significant transformation with the introduction of the Medical Devices Regulation[1] (MDR) and In-Vitro Diagnostic Medical Device Regulation[2] (IVDR) in 2017. Prior to the MDR and IVDR, medical devices in the EU were regulated under the Medical Devices Directive[3] (MDD) and the In-Vitro Diagnostic Medical Device Directive[4] (IVDD), which were introduced in the 1990s (Tarricone et al. 2020). However, in the wake of several high-profile medical device scandals and concerns over the effectiveness of the directives, the EU decided to overhaul its regulatory framework (Jarman et al., 2021). The Poly Implant Prothèse (PIP) silicone breast implants scandal, which occurred in the late 2000s, revolved around the fact that PIP, a French breast implant manufacturer, had been using industrial grade silicone gel in its implants. The implants were more prone to rupturing and leaking, posing health risks to the women who had them (Frumento, 2017; Deva et al., 2019). The metal-on-metal prosthesis incident scandal occurred as a result of growing concerns about the use of metal-on-metal hip implants, which were previously welcomed as a technological advancement. However, it was quickly revealed that these implants had a significant failure rate, typically due to metal particles shedding into the surrounding

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20
[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/746/2023-03-20
[3] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/dir/1993/42/2007-10-11
[4] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/dir/1998/79/2012-01-11

tissues, resulting in painful and severe effects. Patients who had these implants endured significant pain, tissue damage, and, in some cases, metal toxicity (Steinberg et al., 2017; Cohen, 2012). Transvaginal meshes, which were initially introduced as a treatment for pelvic organ prolapse and stress urine incontinence, led to significant controversy. Over time, severe problems, including chronic pain, infection, and organ perforation, were reported among women who received these implants (O'Neill, 2021; Heneghan et al., 2017). With the intent to improve the safety and effectiveness of medical devices, increasing transparency and traceability, and strengthening the regulatory oversight of the industry (Melvin & Torre, 2019), the MDR and IVDR were introduced to address some of the shortcomings of the previous directives (Melvin, 2022),

One of the key changes introduced by the MDR and IVDR is the shift from a directive-based system to a regulation-based system. Under the previous directives, EU Member States were responsible for transposing the requirements into national laws, leading to variations in implementation and enforcement across the EU (Lyapina et al., 2017). However, with the introduction of the regulations, the requirements are now directly applicable in all Member States, reducing the potential for variations in implementation and enforcement (Martelli et al., 2019).

Another significant change introduced by the MDR and IVDR was the introduction of new requirements for robust clinical evidence to support the safety and effectiveness of medical devices. Under the previous directives, medical device manufacturers were able to rely on equivalence to demonstrate that their devices were safe and effective, based on the performance of similar devices on the market. The MDR and IVDR require manufacturers to provide clinical data for a much wider range of devices, particularly higher-risk devices such as implants and in-vitro diagnostic tests. (Ivanovska et al., 2019)

The MDR and IVDR also introduce new requirements for traceability and post-market surveillance, with the aim of improving patient safety and enabling faster identification and response to safety issues. For example, under the regulations, manufacturers are required to provide unique device identifiers (UDI) for each medical device, which will be linked to a publicly accessible database for tracking and monitoring purposes (Bianchini et al 2019).

While the MDR and IVDR have been introduced with the aim of improving the regulatory oversight of medical devices in the EU, there have been concerns over the impact on the industry. The increased requirements for clinical data and post-market surveillance, along with the costs associated with implementing the new regulations, have led to concerns over the availability and affordability of medical devices in the EU (Lubbers et al., 2021). Manufacturers may reduce their portfolios due to rising expenses, resulting in a volatile market. Volatility can manifest itself in two ways: a reduction in product diversity or availability, and a potential price mark-up on the remaining devices. This has a greater impact on niche markets, which naturally have a limited pool of manufacturers. In this type of market, innovation may also be stifled (Maresova et al., 2020). To operate in accordance with the regulations, a greater initial investment is required than to operate in accordance with the directives. As a result of this disparity, fewer companies may attempt to design devices and break into the medical device market. Nevertheless, the EU has stated that the regulations are necessary to ensure the safety and effectiveness of medical devices and protect public health (Bretthauer et al., 2023).

1.1.4 Systems for ensuring quality

Ensuring the quality and safety of medical devices is critical for protecting public health (Lorv et al., 2017). Several systems work in cohesion to help ensure the quality and safety of medical devices. These include regulatory oversight, quality management systems and clinical investigations.

1. Regulatory oversight

The European Commission and each Member State's National Competent Authorities (NCA) are responsible for ensuring that medical devices placed on the EU market meet regulatory standards for safety, efficacy, and quality (Gadotti Martins et al., 2021). The European Commission is the executive body of the European Union, and it is in charge of proposing and enforcing EU laws and policies. Each Member State's NCA is the regulatory body in charge of ensuring that medical devices meet regulatory standards. NCAs are responsible for a number of activities related to medical device regulation such as ensuring compliance with safety and quality standards, evaluating adverse events and incidents, performing manufacturer inspections and audits, and providing guidance to healthcare professionals and the general public on the safe and effective use of medical devices (Van Norman, 2016).

2. Quality management systems

The MDR requires medical device manufacturers to implement a QMS to ensure that their devices meet the necessary regulatory requirements and quality standards (Kheir et al., 2021). These systems typically include procedures for design, development, manufacturing, distribution, and post-market surveillance of medical devices. The QMS

should ensure the safety and performance of the medical devices and be regularly reviewed and updated as necessary to reflect changes in the regulatory requirements or the medical device itself (Luczak, 2012).

A QMS should include the following elements as its core (Sheffer, 2018; Fearis et al., 2017; Razak et al., 2009):

- Documentation: policies, procedures, work instructions, records, and quality manual
- Management responsibility: clear assignment of roles and responsibilities, and effective decision-making processes
- Resource management: identification of resources needed to meet regulatory requirements, such as personnel, infrastructure, and equipment
- Process control: effective control of procedures and the procurement methods
- Monitoring and measurement: ongoing evaluation of processes to ensure they are meeting regulatory requirements.

ISO 13485:2016 Medical devices - Quality management systems[5], is a globally recognised QMS standard for the manufacture of medical devices. It was harmonised to MDD in 2017 and is still the standard used to demonstrate MDR compliance (Table 1.4).

[5] Medical devices - Quality management systems, ISO 13485:2016 [Internet]. [Cited 2024]. Available from URL: https://www.iso.org/standard/59752.html

Table 1.4 Table showing the clauses the ISO 13485:2016 covers from the MDR

MDR QMS Requirements	ISO 13485:2016 clause(s)
A strategy for regulatory compliance	4.1
Safety and performance	7.5
Management responsibility	5.1, 5.5
Resource management	7.4
Risk management	7.3
Clinical evaluation	7.3
Product realisation (planning, design, development, production, and service)	7
Verification of Unique Device Identity assignment	7.5.8, 7.5.9
Post-market surveillance system	8.2.1, 8.2.2
Communication with authorities	8.2.3
Incident reporting	8.2.3
Corrective and preventive actions (with verification of effectiveness)	8.5.2, 8.5.3
Monitoring and measurement, data analysis, and product improvement	8.2

Table 1.4 contrasts the MDR QMS requirements with corresponding ISO 13485:2016 clauses. This tabulated format aids in comprehending the alignment between the regulatory requirements and the ISO standard for effective medical device quality management. Adapted from Medical devices - Quality management systems, ISO 13485:2016 [Internet]. [Cited 2024]. Available from URL: https://www.iso.org/standard/59752.html and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20

It should be noted, however, that ISO 13485:2016 does not replace the MDR requirements for a QMS. To assure the safety, performance, and quality of medical devices on the European market, the MDR incorporates additional standards that go beyond ISO 13485:2016 (Sheffer, 2018). Looking at the particular MDR requirements, it is clear that ISO 13485:2016 does not cover all clauses. These encompass numerous areas of general safety and risk-related performance standards. As an example:

- Annex I, Chapter 1, 2 - minimise risk as much as possible
- Annex I Chapter I, 3 a - develop a risk management plan for each equipment
- Annex I Chapter I, 4 - managing risk to ensure residual risk is acceptable
- Annex 1, Chapter I, Chapter 8 - risk-benefit analysis to warrant that all risks are acceptable when evaluated against advantages
- Annex I, Chapter I, 4 - manufacturers must minimise risk, provide measures such as alarms, and warn patients of any residual danger.

Other MDR provisions not covered by ISO 13485:2016 for example:

- MDR Article 10 4 MDR - the Commission has the authority to issue delegated acts in accordance with Article 115
- MDR Article 10 Ref 16 - manufacturers must have adequate financial coverage for potential liability resulting from defective equipment
- MDR Article 10 6 MDR - after successful conformity evaluation, prepare a Declaration of Conformity (DoC)
- Annex XI A5 A - if the company is based outside the EU, the manufacturer must have an authorised representative who must guarantee that the requirements for the issue of a DoC are met.

Provisions relating to UDI, technical documentation, continuous improvement, post-market surveillance, labelling, recalls, ergonomics, and device lifetimes are among the other MDR criteria that are not covered by ISO 13485:2016.

The MDR specifies processes for medical devices, whereas ISO 13485:2016 specifies a full set of interconnected requirements for developing a QMS (Miclăuş et al., 2020).

3. Clinical investigations

Clinical investigations are an important part of the medical device development process in Europe and are conducted to ensure that devices are safe and effective for use by patients. Clinical investigations involve testing medical devices on human subjects to gather data on their safety, performance, and effectiveness. This information is used to assess the risks and benefits of the device and to determine whether it is suitable for use in patients (Bianco et al., 2017).

In Europe, clinical investigations are regulated by the European Commission and the NCAs of each EU Member State. The regulations aim to ensure that clinical investigations are conducted in an ethical and scientific manner, with the safety and well-being of the participants as the highest priority (Olimid et al., 2018). In addition to ensuring the safety and efficacy of medical devices, clinical investigations can provide valuable data for improving the design and performance of devices, and informing clinical practice and healthcare policy (Campbell et al., 2018).

Overall, these systems work together to ensure that medical devices are safe and effective for use, and to protect public health. By ensuring that medical devices meet the necessary regulatory requirements and quality standards, patients can have confidence in the devices

that they receive and can be assured that they are receiving safe and effective treatments (Jha et al., 2010).

1.1.5 The importance of vigilance, post-market surveillance and traceability

The importance of vigilance, post-market surveillance, and traceability cannot be overstated. These processes help ensure the safety and effectiveness of medical devices and enable regulators and manufacturers to quickly identify and address any safety issues that arise. The protection of patients and the maintenance of the integrity of the medical device market is an ultimate aim of conducting the mentioned processes in a robust manner (Almadi & Alsohaibani, 2019). In the European Union, vigilance, post-market surveillance, and traceability are all key requirements under the MDR and the IVDR. Vigilance and post-market surveillance were hardly distinguishable in the MDD. The Regulations include a number of measures intended to improve the system's robustness and clarity (Jarman et al., 2021).

Vigilance is only one part of the post-market surveillance system, as it refers to the reporting of incidents, field safety corrective actions and recalls (Gagliard et al., 2018). Vigilance involves collecting and analysing information about any issues that arise with the use of medical devices, including adverse events, product defects, and other safety concerns (Gagliard et al., 2017). Adverse events are any unintended events that occur with the use of a medical device, such as injuries or deaths, while product defects may include any manufacturing or design flaws that could impact the safety or performance of a device (Amoore, 2014).

Regulators and manufacturers rely on vigilance to identify and address potential safety issues as quickly as possible. By collecting information about adverse events, product defects, and other safety concerns, regulators and manufacturers can investigate the root cause of these issues and take appropriate action (Pane et al., 2021). This may include issuing warnings or recalls, updating labelling or instructions for use, or making changes to the design or manufacturing of the device (Elbeddini et al., 2020).

The goal of vigilance is to prevent harm to patients by quickly identifying and addressing any safety issues that arise with the use of medical devices. It helps to ensure that medical devices continue to be safe and effective throughout their lifecycle and provides patients and healthcare professionals with the information they need to make informed decisions about the use of medical devices (Polisena et al., 2015). Manufacturers must establish a system for vigilance and report any adverse events, product defects, or other safety issues to the appropriate regulatory authorities (Ward & Clarkson, 2004). This system is critical for ensuring the safety and effectiveness of medical devices for patients in the European Union.

Post-market surveillance (PMS) refers to all activities carried out by manufacturers in collaboration with other economic operators to establish and maintain a systematic procedure for proactively collecting and reviewing experience gained from devices they place on the market, make available on the market, or put into service in order to identify any need to immediately apply any necessary corrective or preventive actions.[6] The goal

[6] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20

of post-market surveillance is to ensure that medical devices continue to meet safety and performance standards throughout their lifetime and to identify any issues that may arise over time (Badnjević et al., 2022).

Post-market surveillance involves following how the device is being used, how well it performs, and any safety concerns that arise. This surveillance involves collecting data from patients, healthcare professionals, and other sources, such as clinical studies and scientific literature (Mower et al., 2020). The data collected includes information about the device's performance, its safety profile, adverse events and any observations that are reported. Manufacturers must establish a system for post-market surveillance and report any issues or adverse events to the appropriate regulatory authorities (Zippel & Bohnet-Joschko, 2017).

Traceability is an essential component of the regulatory framework for medical devices, (Fraser et al., 2018) as it allows for the tracking and locating of devices throughout the supply chain, from manufacturing to end user. This involves creating and maintaining records of the device's journey through the supply chain, including production, distribution, use and post-market surveillance. The records typically include information such as the device's serial number, batch number, and date of manufacture (Bayrak & Özdiler Çopur, 2017).

The ability to trace medical devices through the supply chain is critical for identifying any faulty or unsafe devices that may pose a risk to patients. If a safety issue is identified with a device, traceability enables the rapid and efficient identification of affected devices, allowing for timely recalls and other corrective actions to be taken. This helps to prevent harm to patients and reduces the risk of serious safety incidents (Qouhafa et al.,

2021). By maintaining records of their devices, manufacturers can identify any faulty or unsafe devices, take timely corrective actions, and prevent harm to patients.

1.1.6 Role of the regulator

In the European Union, the role of the regulator in medical devices is fulfilled by the European Commission, with support from various NCAs in individual Member States. NCAs are responsible for implementing and enforcing the MDR and the IVDR within their respective Member States (Parvizi & Kent, 2014). NCAs conduct on-site audits and inspections of stakeholders, including manufacturers and distributors to verify compliance with the regulations and to enforce the recall of devices that do not meet safety and performance requirements (Ball et al., 2018).

As a result of changes in the regulatory landscape, a shift in the underlying role of a medical device NCA is shifting from policing and enforcement to providing a service to patients and stakeholders. The MDR emphasises a risk-based approach, which involves more collaboration and transparency between the NCA and stakeholders. The NCA's primary role is to ensure the safety and effectiveness of medical devices by evaluating the conformity of the device with the applicable regulations, and by monitoring the device's performance on the market. The NCA is expected to provide technical and regulatory expertise to help stakeholders navigate the regulatory landscape.

1.1.7 Patient centred approach

The term ‘patient-centred’ means putting the patient at the core of healthcare decision-making and focusing on meeting their needs, preferences, and values. This approach

recognises that each patient is unique and requires care that is tailored to their specific circumstances, including their medical history, lifestyle, cultural background, and personal beliefs. (ref)

Patient-centred care involves active collaboration between healthcare providers and patients, with a focus on building a trusting and respectful relationship that empowers patients to take an active role in their healthcare. It emphasises open communication, shared decision-making, and a holistic approach to healthcare that considers not just the patient's medical needs and also their emotional, social, and spiritual well-being.

A medical device regulatory body can be patient-centred in multiple ways. For example, patient involvement in regulatory decision-making. Patients must be included in processes such as focus groups, advisory committees, and public consultations. Regulatory bodies must ensure that patients have access to medical devices that are both safe and effective. This includes evaluating device affordability, availability, and accessibility. Patients should be encouraged to provide feedback on medical devices by regulatory bodies. This can be accomplished through the use of surveys, reporting systems, and other feedback mechanisms. Communication and transparency are essential. Regulatory bodies should communicate with patients about medical devices in a clear and transparent manner. They should make information about devices easily accessible to patients and provide clear instructions on how to use them.

Patient safety is a primary concern of the medical device regulations in Europe. The MDR has provisions that are specifically designed to improve patient safety (Shatrov & Blankart, 2022). One of the most significant changes is the introduction of a centralised EU database, called EUDAMED. This database will allow for more effective monitoring of medical devices throughout their lifecycle, from pre-market evaluation to post-market

surveillance. In addition, the MDR requires manufacturers to provide clear and concise information to patients and healthcare professionals about the risks and benefits of using a particular medical device. This information must be provided in a way that is easily understandable and accessible to all. Finally, the MDR encourages patient involvement in the regulatory process by requiring manufacturers to seek patient feedback and opinions during the development and evaluation of medical devices. This input can help manufacturers identify potential safety issues and make improvements to the design and functionality of their devices.

1.1.8 Local scenario

In Malta, the Malta Competition and Consumer Affairs Authority regulated medical devices. In 2020 a national legislation[7] was published to transfer the medical device remit to the Malta Medicines Authority (MMA). The transfer was made in response to the 2019 budget speech.

As a regulator in the pharmaceutical sector, the Maltese Medicines Authority managed to transform the pharmaceutical industry into an innovative and optimised sector which focuses on the patient. This process will continue to be renewed all throughout next year through initiatives aimed at extending the Authority's regulatory mandate on medical

[7] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision on The Maltese Market Regulations [Website] [Cited 2022]. Available from URL: https://legislation.mt/eli/sl/458.59/eng

apparatus, in order to consolidate the skills and expert knowledge available on a national level.[8]

Prior to beginning this research, preliminary findings revealed the absence of a national system for collecting market data on medical devices. There was little to no formal data on a national scale in terms of a list of local stakeholders, a list of marketed medical devices, and any other statistics involving applications. The requirement to establish a reliable system in this area was evident.

A contemporary aspect in medical device regulation is the inclusion of regulating the 'digital component' as since errors or misuse of such aspects may have serious consequences related to safety and efficacy and thus also reflect on the quality of the medical device. The significance of the digital component should be considered in the own spectrum of digitalisation in healthcare rather than considered on their own. Such an outlook on medical devices reflects the tendency to treat medical devices as a holistic part in healthcare in a parallel manner in that medicines are looked at through a patient centred lens rather than solely on the manufacturing component.

1.2 Digitalisation in healthcare

Healthcare digitalisation refers to the application of digital tools and technologies to enhance patient outcomes, healthcare delivery, and overall system effectiveness. The

[8] Scicluna E. Budget Speech 2019 [Website]. Malta: Ministry for Finance; 2018 [cited 2022]. Available from URL: https://finance.gov.mt/en/The-Budget/Documents/The_Budget_2019/Budget_speech_English_2019.PDF

basic premise for healthcare digitalisation is that it can improve efficiency, quality, and safety (Cresswell et al., 2023). According to Ashly Black et al.'s 2011 systematic review, while there is tremendous international interest in leveraging the potential of digital solutions to improve healthcare, there is a gap between the presumed and demonstrated benefits of eHealth technologies. Jamie Ross et al. published a systematic review on eHealth in 2016. The review, which was based on the interpretations of a vast quantity of data from various eHealth systems and healthcare settings, served as an empirical test and recommended areas for further research. El-Sherif et al. addressed the importance of digital health as an integral aspect of public health in his article published in 2022. Fadly et al. conducted another systematic review on the topic of eHealth in 2023. They concluded that successful eHealth implementation was an effective alternative for meeting society's healthcare demands.

1.2.1 The history of digital healthcare and current developments

The history of digital healthcare dates back to the introduction of a new approach to medical record keeping, shifting from paper based to electronic health records (EHR). EHRs were developed and quickly adopted across hospitals and healthcare settings (Zandieh et al., 2008). EHRs were usually only accessible to healthcare providers within the same hospital or healthcare system. The introduction of computer networks and databases in the following years led to the development of more sophisticated EHR systems (Kruse et al., 2016). These systems enabled the electronic storage and sharing of patient data, making it easier for healthcare providers to access and exchange medical records (Thompson, 2021).

Telemedicine refers to remote medical care achieved by telecommunications technology. Patients in remote or underserved areas could receive medical care from specialists in other locations, and healthcare providers could remotely monitor patients and provide follow-up care (LeRouge & Garfield, 2013). Advances in video conferencing and internet connectivity fuelled the growth of telemedicine, making it easier for healthcare providers to communicate with patients and other healthcare professionals in real time (Waller & Chad, 2018).

Mobile healthcare refers to medical and public health applications of mobile network technology such as mobile phones, patient monitoring systems, personal digital assistants, and other wireless devices (Sharma et al., 2022). These technologies allow patients to track their health and communicate with healthcare providers from anywhere (Kumar et al., 2013). For example, patients with chronic conditions such as diabetes or heart disease could use mobile apps to track their symptoms, medication schedules, and other health metrics. Healthcare professionals could then use the information to remotely monitor patients and modify treatment plans as necessary (Sundararaman et al., 2017).

The application of artificial intelligence (AI) and machine learning technology in healthcare is a newly emerging practice (Wani et al., 2022). By analysing large amounts of medical data and identifying patterns that may be invisible to human healthcare providers, these technologies have the potential to improve medical diagnosis and treatment (Huo et al., 2022). AI algorithms, for example, can be used to analyse medical images and detect abnormalities with high accuracy, assisting doctors in diagnosing diseases more quickly and accurately. AI and machine learning can also be used to create personalised treatment plans for patients based on their medical history, lifestyle, and other factors (Nazar et al., 2021).

The pandemic of COVID-19 has sped the adoption of digital healthcare. To provide safe and effective care to their patients while minimising the risk of virus exposure, healthcare providers have turned to telemedicine and remote monitoring. The pandemic has also highlighted the importance of data interoperability and the need for healthcare providers to be able to share patient information easily and securely across multiple systems and platforms (Zeng et al., 2020).

1.2.2 COVID-19 a driver of digital health

The COVID-19 pandemic accelerated the adoption of digital health technologies as healthcare providers and patients sought to adapt to the new realities of healthcare delivery (Taylor et al., 2020). During the pandemic, digital health technologies such as telemedicine, remote monitoring, and digital contact tracing tools were critical in assisting healthcare delivery and public health response (Popov et al., 2022)

The widespread use of telemedicine was one of the most significant advances in digital health during the COVID-19 pandemic. During the pandemic, telemedicine was used to provide a wide range of services, including routine check-ups, chronic disease management, mental health services, and specialty consultations (Chang et al., 2021). One of the primary advantages of telemedicine during the pandemic was the ability to reduce the risk of COVID-19 transmission. Telemedicine reduced the need for in-person visits and the risk of virus exposure by allowing patients to consult with healthcare providers from the comfort of their own homes. This was especially important for vulnerable populations, such as elderly patients and patients with underlying health conditions, who were more likely to suffer from severe illness as a result of COVID-19 (Onishi et al., 2022). The pandemic has also highlighted the value of telemedicine in

underserved and rural areas. Many rural and underserved areas lack access to healthcare, the pandemic only served to make it even more difficult for these patients to receive care. Telemedicine enabled patients in such areas to receive care remotely, reducing travel time and increasing access to healthcare services (Jaffe et al., 2022).

Data analytics and AI were critical tools in the global response to the COVID-19 pandemic. One of the most important applications of data analytics and AI in the COVID-19 response was tracking the virus's spread (Sheng et al., 2021). Governments and public health organisations around the world used data analytics and machine learning algorithms to model the virus's spread and predict the number of cases and deaths in various regions. These models were used to develop strategies for containing the virus's spread, such as social isolation and lockdowns (Alsunaidi et al., 2021).

The COVID-19 pandemic resulted in changes in healthcare policy and regulation, in addition to the rapid adoption of digital health technologies. Policymakers relaxed restrictions on telemedicine and other digital health technologies in response to the pandemic, allowing healthcare providers to adopt these tools and deliver care remotely more easily. The pandemic also highlighted the need for greater investment in digital health infrastructure and cybersecurity to support the rapid adoption of these technologies (Beaulieu & Bentahar, 2021; Rodriguez et al., 2021).

1.2.3 European databank - EUDAMED

EUDAMED[9] stands for '**Eu**ropean **Da**tabank for **Me**dical **D**evices.' EUDAMED is a secure online database system developed by the European Commission to manage and monitor the safety and performance of medical devices throughout the EU. It was established as part of the MDR and the IVDR, which came into force in 2017. This was not the first time the EU established a medical device databank. Eudamed 2 was developed under the MDD and the IVDD, which were in place prior to the adoption of the MDR and the IVDR. Eudamed 2 had limited functionality compared to what was expected from EUDAMED.

Eudamed 2 focused on medical device registration and did not have the same level of functionality and data requirements as EUDAMED. The primary goal of Eudamed 2 was to facilitate information exchange between national authorities and the European Commission in order to ensure compliance with directives. The functionality of Eudamed 2 was limited and did not include a number of the data elements required by the MDR and IVDR. Eudamed 2, for example, did not include the UDI system, which is required under the new regulations. Eudamed 2 was not accessible for all stakeholders in the medical device supply chain. Only certain specific economic operators, such as notified bodies and national competent authorities, had access to Eudamed 2. Overall, while Eudamed 2 was a helpful tool for information exchange under the MDD and IVDD, its capabilities were limited in comparison to the more comprehensive and mandatory

[9]EUDAMED - European Database on Medical Devices [Internet]. [Cited 2024]. Available from URL: https://ec.europa.eu/tools/eudamed/#/screen/home

EUDAMED under the MDR and IVDR regulations. A comparison of the two systems was carried out (Table 1.5).

The databank established under the MDR and the IVDR developed a more robust and comprehensive system in EUDAMED that improved the issues Eudamed 2 presented. EUDAMED's primary goal was to provide a centralised platform for the registration, certification, and monitoring of medical devices in the EU market. The database was intended to enable national competent authorities, notified bodies, manufacturers, and importers to submit and access medical device information. Other stakeholders, such as authorised representatives and the general public were given access to the system, as necessary. Regulatory authorities used the information submitted to EUDAMED to evaluate the safety and performance of medical devices on the market, and to monitor manufacturers' compliance with regulatory requirements. It was also used to facilitate communication between regulatory authorities and manufacturers, and to support market surveillance activity coordination.

Table 1.5 Comparison of Eudamed 2 and EUDAMED

	Eudamed 2	EUDAMED
STAKEHOLDERS	European Commission	European Commission
	National Competent Authorities	National Competent Authorities
		Medical Devices Coordination Group
		Notified bodies
		Economic operators (Manufacturers, Authorised representatives, Importers, Sponsors, Natural or legal persons)
		Experts, Non-EU Competent Authorities
		Public
	Eudamed 2	EUDAMED
SCOPE	Devices	Devices
	Incidents (NCARs)	Vigilance and post-market surveillance
	Certificates	Certificates and Applications for conformity assessment and Summaries of safety and clinical performance
		UDIs
		Notified bodies accreditation/designation
		Clinical Investigations/Performance Studies
		Market surveillance
	Eudamed 2	EUDAMED
FUNCTIONALITIES	Recording	Registration, Recording
	Advanced search	Advanced search
	Download (files, XML, PDF)	Download (files, PDF …)
	Upload (files, XML)	Upload (files …)
	Statistical summary reports	Reports
	Notification emails for information	Notification emails for information and from the Regulations
		Multilingual
		Interoperability (Exchange data through web services)
		Search public data
		Artificial Intelligence (Support, alert and reporting)

Table 1.5 compares Eudamed 2 with EUDAMED under stakeholders, scope, and functionalities. This comparison aids in understanding the differences between the two systems for medical device data management. The changes to the new system under the regulations can be better visualised through this comparison. Adapted from the European Commission https://health.ec.europa.eu/medical-devices-eudamed/overview_en.

EUDAMED was designed as a modular system, with different modules covering various aspects of medical device regulation. The modules include economic operator registration, device registration, notified bodies and certificates, clinical investigations, market surveillance, and vigilance and post-market surveillance. The system can be accessed by all stakeholders via a secure login process, with different access levels granted based on the user's role in the regulatory process. The databank also provides access to information for patients, healthcare professionals, and the general public, such as a list of registered manufacturers and notified bodies, and a list of devices available on the market.

In accordance with the MDR and IVDR legislation, EUDAMED was originally scheduled to go live in May 2020. In April 2020, the European Commission announced that the launch of EUDAMED would be delayed to 2021 due to the COVID-19 pandemic[10]. EUDAMED's implementation timeline was updated numerous times, each time with further postponements on the previously established release date. The end of development was to be followed by an independent audit and publication of a Commission notice in the Official Journal of the European Union. After a 6- or 24-month transitional period, depending on the module as established in the MDR and IVDR, EUDAMED will be released. These delays are expected to have a significant impact on the EU's medical device industry (Billiones, 2020).

[10] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2020/561/oj

EUDAMED's architecture is a complex system with components that work together to support medical device registration, surveillance, and monitoring in the European Union. A high-level overview of the EUDAMED architecture is provided below:

- Core system: The EUDAMED core system is the architecture's central component. It contains the main database and user interfaces that allow authorised users to access and manage the data in EUDAMED.
- Modules: EUDAMED is divided into six modules, each devoted to a specific function or data type.
- Communication infrastructure: EUDAMED relies on a secure communication infrastructure to facilitate data exchange between modules and users. A messaging system, secure data transmission protocols, and access control mechanisms are all part of this infrastructure.
- Technical interfaces: EUDAMED provides technical interfaces that allow external systems and applications to access and exchange data with the core system of the EUDAMED system. APIs, data exchange formats, and integration tools are examples of interfaces.

Based on the preceding literature and using EUDAMED as a case study, medical device database architecture for a system must consider a variety of factors, including data interoperability, security and privacy, and the specific needs of the application. A centralised relational database architecture with a modular design can be an effective approach, but careful consideration must be given to the system's specific needs and requirements (Ganupal et al., 2016).

1.2.4 National databanks and database architecture

National medical device registries are databases that collect data on medical devices used in a specific country. These registries, which are typically run by government agencies or other regulatory bodies, are intended to aid in the monitoring of the safety and effectiveness of medical devices (McGuire et al., 2013). The data collected in national medical device registries may include information about the device's manufacturer and distributor, the intended purpose of the device, the patient population for which the device is intended, and any adverse events or complications that have been reported as a result of the device (El adoubi et al., 2018).

National medical device registries have the potential to assist regulators in identifying potential safety issues with medical devices more quickly. Regulators can identify patterns of adverse events or other issues that may not have been observable during the pre-market testing process by collecting data from a large number of devices in real-world use (Choi et al., 2011). Providers, for example, can use the information in these registries to make more informed decisions about which devices to use for specific patients or conditions. Patients can also use the information to better understand the risks and benefits of various medical devices and make more informed healthcare decisions (Payne et al., 2010)

National medical device registries are not rare, with countries throughout the world having developed such systems to monitor and track medical devices for a variety of purposes, including patient safety, post-market surveillance, and research. Germany has a thorough system for medical device oversight, which includes a registry for of devices called the Devices Information and Database System. The Federal Institute for Drugs and Medical Devices is a prominent regulatory institution in Germany that oversees medical

devices. The Italian Ministry of Health established the Medical Devices System and the Ministry of Health Database to monitor the safety and performance of medical devices. The Portuguese National Authority of Medicines and Health Products, INFARMED, is in charge of the regulation and monitoring of medical devices in Portugal. INFARMED developed an online database for tracking and managing medical devices. Other countries outside of Europe have compiled their own databases, such as the United States' MAUDE- Manufacturer and User Facility Device Experience.

The architecture of these databases varies based on the country's specific requirements, regulations, and healthcare system structure. Common elements often include unique device identifiers, patient data protection measures, and the ability to track device performance over time (Mauch et al., 2021).

Database architecture refers to the overall design and structure of a database system. It involves the organisation of data, the relationships between data entities, and the methods used to access, store, and manage the data (Bernal & Molina, 2022).

There are different types of database architectures, including:

- Hierarchical Architecture: This architecture arranges data in a tree-like structure where each parent record can have multiple child records. It is useful for storing data with a one-to-many relationship but can become complex and difficult to manage as the data grows (Bensaci et al., 2020).
- Relational Architecture: The most widely used architecture, it stores data in tables and defines relationships between tables using keys. It allows for easy data manipulation and querying but can be less efficient when managing large amounts of data (Astrahan et al., 1976; Sculz et al., 2016).
- Object-Oriented Architecture: Stores data as objects, with attributes and methods.

It is useful for representing complex data structures and relationships but can be less efficient when querying data (Naumcheva et al., 2023).

- NoSQL Architecture: This architecture is used for storing unstructured data, such as documents, graphs, and key-value pairs. It is highly scalable and flexible, making it ideal for handling large amounts of data in distributed environments (Khan et al., 2023)

The choice of database architecture depends on the specific requirements of the application and the data being stored. The most appropriate database architecture type for a medical device databank will be determined by multiple factors, including the size and complexity of the data, the database's intended purpose, and the regulatory requirements for data storage and management.

One important consideration for medical database architecture in Europe is the General Data Protection Regulation (GDPR)[11], which sets out strict rules for the collection, storage, and use of personal data. Personal data includes medical data, which the GDPR classifies as a special category of personal data. Medical databases in Europe must ensure that data is stored securely, with appropriate access controls and encryption methods in place, in order to comply with these regulations (Laybats & Davies, 2018). Data interoperability is another critical consideration for medical database architecture in Europe. Medical databases must be able to exchange data with other databanks and systems used in the healthcare sector in order to maximise usefulness and utility. This

[11] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2016/679/2016-05-04

necessitates careful planning and implementation of data exchange protocols, and adherence to common data exchange standards (McCall, 2018).

A common type of database architecture used for medical device databanks is a relational architecture. A relational database organises data into tables, each of which represents a distinct data entity, such as a patient or medical device. Data in the tables is linked together using keys, allowing for simple querying and retrieval of information (Sculz et al., 2016). A NoSQL database architecture is another option for a medical device databank architecture. NoSQL databases are frequently used for storing unstructured or semi-structured data and are built to manage large volumes of data while maintaining high scalability and availability. NoSQL databases are suitable for medical device databanks that must manage a large number of devices and their associated data (Sen & Mukherjee, 2021). Relational databases and NoSQL databases are both viable options, but careful consideration must be given to security and regulatory compliance when designing the architecture.

1.3 Outline and rationale

The MDR and IVDR broadened the legislative focus and established a more stable platform for a patient-centred approach that prioritises safety, quality, and efficacy. The MDR and IVDR impose new requirements on medical device manufacturers, such as stricter clinical evidence, post-market surveillance, and transparency requirements, these regulations also create a new compulsory EU medical device database, EUDAMED. As a result of the complexity of the changes, and the increased responsibility and obligations, stakeholders and regulators have become lost in a sea of laws and regulations. A standard

framework that can be tailored to the needs of individual stakeholders may be capable of satisfying the demands of a large number of stakeholders.

The dissertation titled ‘Establishing a Patient Centred Medical Device Body’ seeks to examine the process of regulating medical devices at an equivalent rigorous level to that established for medicines with emphasis on safety, quality and efficacy. The dissertation attempts to take a leadership role by applying digitalisation tools to develop a robust regulatory framework which would serve as a model for other entities. The findings of the research should serve as an educational tool for an effective use of medical devices in different scenarios and endeavour to empower regulators and other stakeholders to be able to judge on the outcome of the use of the medical device, to detect potentially harmful medical devices and guide in the proper use of a device.

The study proposes a holistic approach to medical devices which includes the whole process from evaluation to vigilance and post-market surveillance. The proposition aims at transposing a complex situation into a simplified scientific and practical innovative endeavour.

1.4 Aim and objectives

The aim of this study is to establish a patient centred medical device body. To achieve this, a framework for the transition of the medical device legislation is required to curate the functions of stakeholders. The framework will facilitate the establishment and transition of medical device centred operators by enabling them to identify their needs and obligations, ensuring proper compliance and execution of the new legislative requirements. The study aims to answer the following objectives:

- Determine and establish the core requirements and framework of a medical device quality management system.
- Analyse current medical device incident reporting functionality and incorporate into a centralised incident reporting platform.
- Setup and maintain a digital medical device management system.
- Identify and cater for necessary training and continuous professional development in the medical device field.

Chapter 2

Methodology

The methodology is divided into four phases, each of which corresponds to a different research objective. The sections serve to create a framework that medical device bodies can adopt and adapt to meet their needs. Figure 2.1 and Figure 2.2 summarise the research design.

Necessary approvals from the Malta Medicines Authority and approval from the Faculty of Medicine and Surgery ethics committee within the University of Malta were obtained.

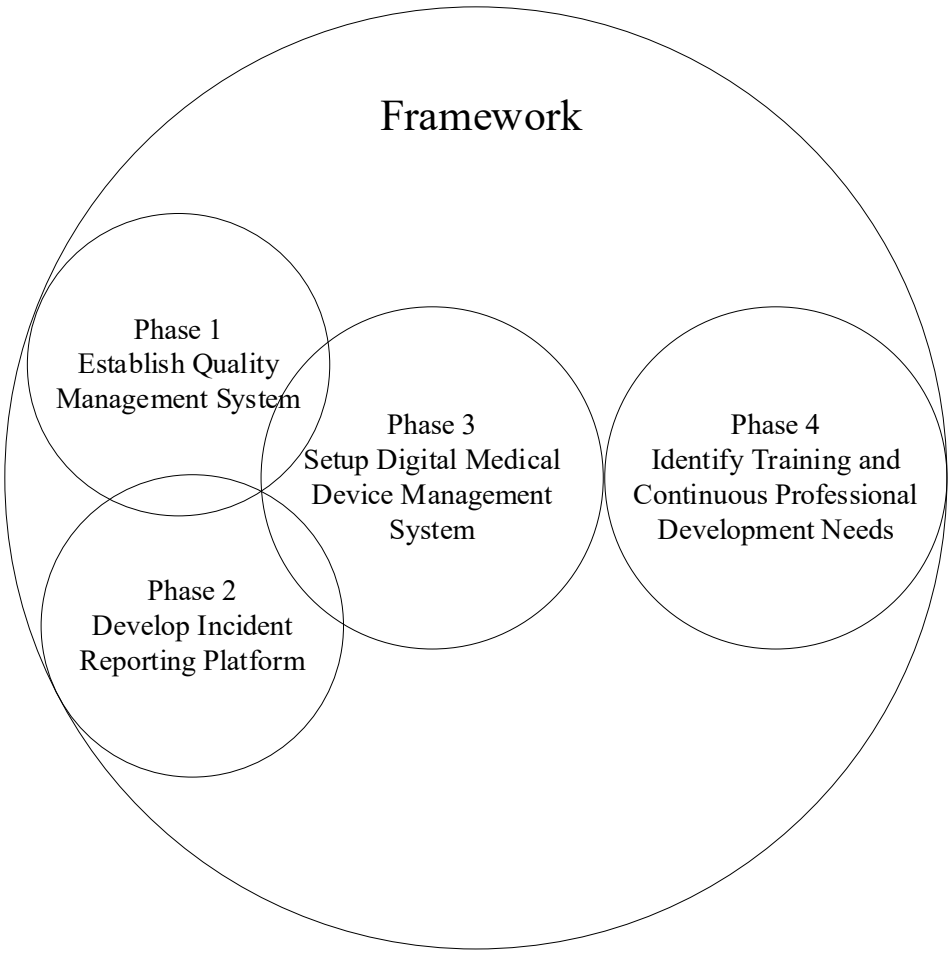


Figure 2.1 Research design

Figure 2.1 outlines the research structure across four key phases. Each phase represents a separate objective. Together the four phases integrate to establish a unified and harmonious medical device body framework.

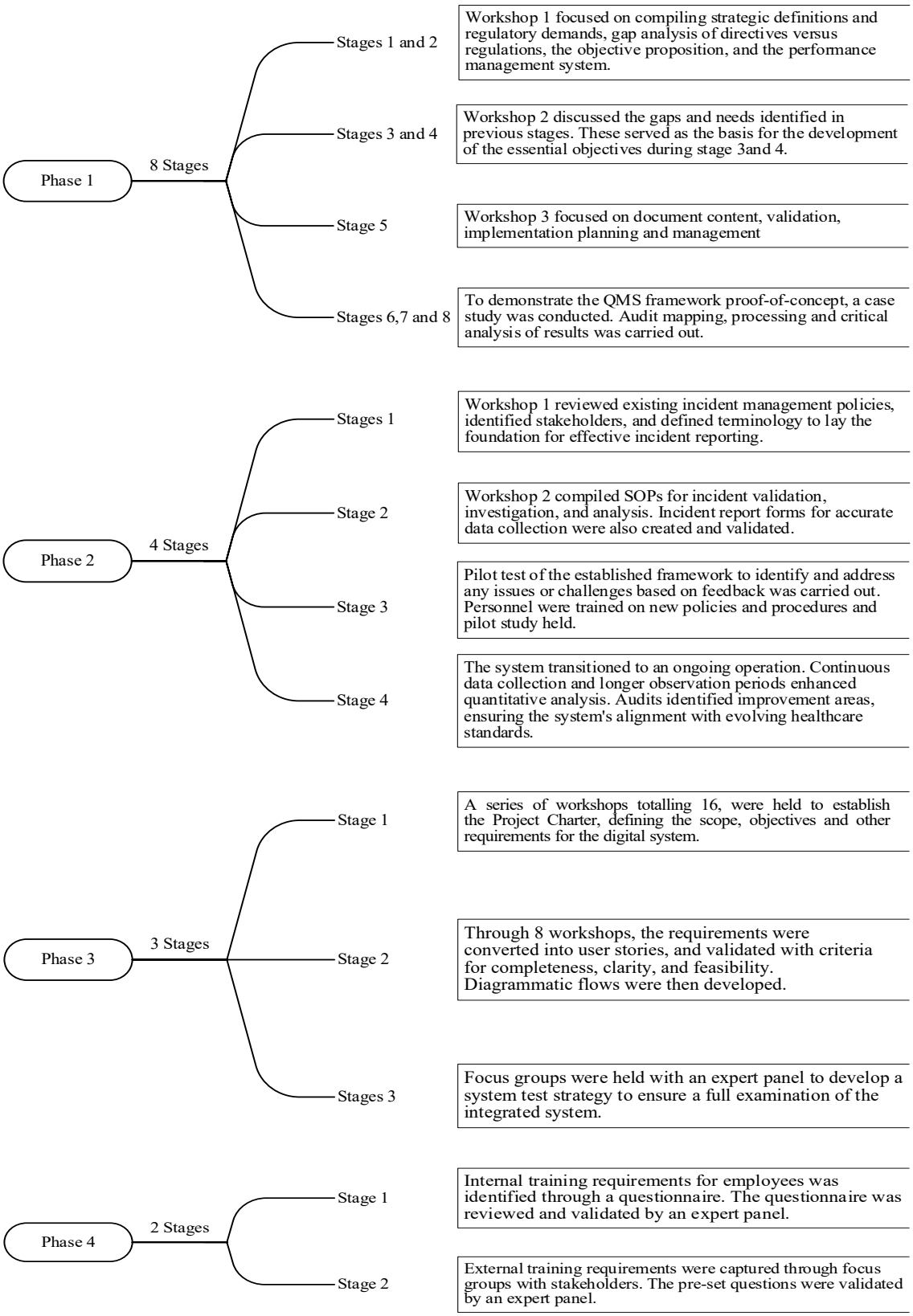


Figure 2.2 Breakdown of each phase

Figure 2.2 illustrates how each phase is further developed and subdivided. Outlining the stages involved and providing a brief description.

2.1 Phase 1: Establishing a medical device quality management system

The deliverable of this phase was to identify the core regulatory requirements required to develop a quality management system that supports a patient centred-approach medical device framework that can be adopted by medical device bodies.

2.1.1 Development of a quality management system

A conceptual quality management system (QMS) framework (Figure 2.3) was identified.

The study used international guidelines such as ISO 13485:2016[12] and ISO 9001:2015[13]. Both standards are concerned with safety and reducing the risk of error by controlling the procedures and implementing quality assurance measures. The medical device regulation (MDR) and in-vitro diagnostic medical device regulation (IVDR) served as another source of content framework. The QMS framework being established was intended to fulfil the regulation provisions as a core requirement.

[12] Medical devices - Quality management systems, ISO 13485:2016 [Internet]. [Cited 2024]. Available from URL: https://www.iso.org/standard/59752.html
[13] Quality management systems Requirements, ISO 9001:2015 [Internet]. [Cited 2024]. Available from URL: https://www.iso.org/standard/62085.html

Figure 2.3 Procedural framework flow

Figure 2.3 outlines the initial process for guiding the quality management system implementation development. The process loops back to allow for an ongoing iterative process.

The procedural framework flow model described is Figure 2.3 was based on the principals outlined in the model developed by Pinheiro de Lima et al. (2015), which provides guidance for defining a company's strategy and performance objectives, and translating them into action plans and performance indicators. It was necessary to define and audit such a strategy in order to create a conceptual QMS framework that could be integrated by multiple medical device bodies. To establish the QMS framework the following were considered: (i) the operational procedures and (ii) the implementation guidelines in accordance with the literature, standards, and regulations. The proposed conceptual QMS framework is detailed in a stage-by-stage procedure (Figure 2.4).

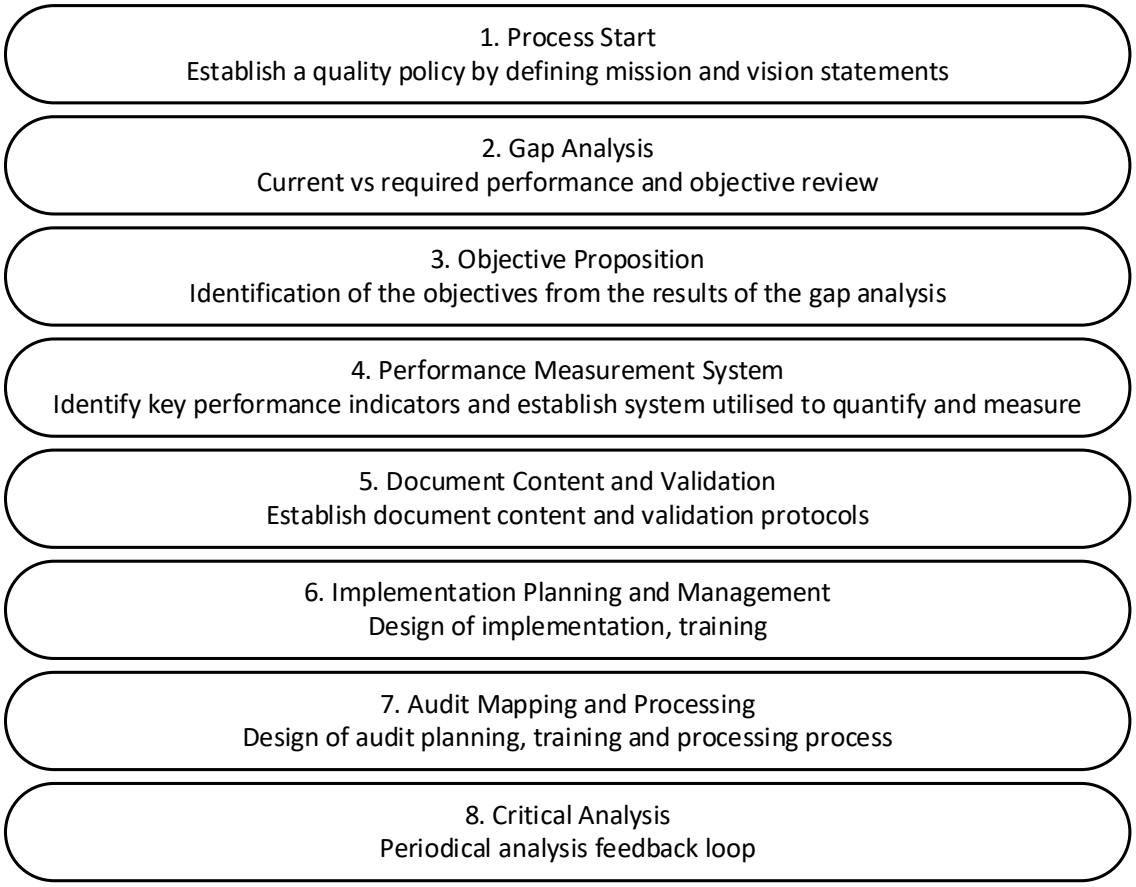


Figure 2.4 Proposed conceptual quality management system framework design

Figure 2.4 presents a quality management system framework design. It begins with defining strategic objectives and regulatory guidelines, progresses through analysing performance gaps, and identifying objectives. Key performance indicators are then determined, documents validated, and implementation plans devised. This structured approach ensures effective quality management.

2.1.2 Stages 1-4: Design and planning

During the design and planning stages 1 to 4, an expert panel of five professionals was formed to ensure the quality of the information being established. The panel included three regulatory experts and two private-sector experts. The goal of this phase was to create a detailed QMS framework process that could be implemented across medical device bodies. The QMS framework was investigated by using the developed procedural framework, which organised the implementation process. At each stage, feasibility,

usability, and utility of the specific process under consideration was assessed. Workshops were organised to facilitate the completion of the tasks. Depending on the data being reviewed and evaluated, a single workshop grouped one or more of the project stages (Figure 2.4).

Workshops used a single focus group methodology, where a single moderator, the researcher, asked an array of pre-determined questions in accordance with the process framework, leading to an organic discussion with the expert panel on the topic. Two workshops were held to cover the initial four stages of the project plan. A third workshop was held for stage 5.

The first workshop focused on compiling the objective propositions, the mission and vision statements and establishing a quality policy. Performing a gap analysis of the directives versus regulations was necessary to determine the basis of the QMS being established. It was necessary to establish the subject matter to the expert panel by clearly stating the project scope and disclosing the desired management system.

A quality policy is the basis of an effective quality programme. A quality policy is defined in ISO 9001:2015 as a brief statement that aligns with an organisation's purpose, mission, and strategic direction. It provides a framework for quality objectives and includes a commitment to meet applicable requirements and to continually improve. The quality policy is the foundation of a quality programme that represents the top management’s commitment.

Following the introduction of the topic and the identification of the quality policy, a gap analysis between the directives and regulations was performed. The gap analysis entailed reviewing the Medical Devices Directive (MDD) and MDR requirements and identifying the differences between them. For example, the MDR broadened the definition of medical

devices compared to the MDD and introduced new classifications for specific devices. The MDR's QMS is aligned closer to the system of the ISO 13485:2016 standard, whereas the MDD was less stringent and alignment to the more generic ISO 9001:2015 standard would have sufficed. To facilitate the discussion, the expert panel was presented with a correspondence between ISO 13485:2016 and ISO 9001:2015 (Appendix 2).

During the second workshop, stages 3 and 4 were discussed. The results of stages 1 and 2, identified the gaps and requirements needed for the QMS framework, these findings served as the basis for the development of the objectives proposed during stage 3.

Stage 4, concentrated on the creation and implementation of a solid framework for managing and monitoring the QMS's performance. The workshop revealed that the performance management system included numerous critical components. First, a system of key performance indicators (KPIs) was established to measure and evaluate the QMS's performance at various levels (Table 3.3). The KPIs were chosen to reflect key aspects of the QMS, such as complaint handling, adverse event reporting, and audit performance, and they covered areas such as process efficiency, customer satisfaction, regulatory compliance, and continuous improvement initiatives.

The expert panel acknowledged the importance of measuring and evaluating performance in order to identify areas for improvement and ensure ongoing compliance with established goals. A structured approach to data collection and analysis was also discussed. This included establishing data collection methods, defining data sources, and determining responsibilities and validation and quality assurance measures.

2.1.3 Stages 5-8: Document content, validation and implementation

Stages 5 to 8 focused on document content, validation, implementation planning and management. Stage 5 was discussed in a third workshop involving the same expert panel as the first two workshops. The initial step in stage 5 was to design the tabulation format for compiling and displaying the list of quality documents (Table 2.1). After compiling the list of objectives and indicators determined in stages 3 and 4, the researcher proposed a list of standard operating procedures (SOP) and quality documents (Appendix 3) that encompassed the identified objectives and collectively were able to function as a quality management framework. This was reviewed and assessed by the expert panel.

Table 2.1 Design of document structure established in stage 5

Document Type	Objectives	Document Name	Indicator
Example 1: Standard Operating Procedure	To define a uniform system for the generation, numbering, review, approval, and obsolescence of documents	Management and Control of Standard Operating Procedures	Periodical review every n years
Example 2: Standard Operating Procedure	To define the procedure for the initiation of medical device incident reports received	The Process of Receiving and Initiating a Medical Device Incident Report	Number of incident reports received
Example 3: Standard Operating Procedure	To establish the process for completing and documenting training	Training and Competence Management	Staff review forms

Table 2.1 illustrates the structured document design established in stage 5 of the process. Example outlines of Standard Operating Procedures, each with specific objectives and indicators are shown.

A protocol for validation of the documents was also assessed. A procedure, which could be applied across different stakeholders, was developed to contribute to the document's accuracy, completeness, consistency, and compliance with the relevant regulations and

standards. The validation process sought to identify any gaps, inconsistencies, or ambiguities and make any necessary changes to improve clarity and compliance. The session stressed the significance of document control and versioning. The findings emphasised the importance of establishing a strong document control system to manage document revisions, approvals, and distribution. This system ensured that all relevant personnel had easy access to the most recent versions of the QMS documentation and that obsolete versions were promptly removed from circulation.

A SOP was designed and validated in order to implement the fundamental principles covered in theory with the expert panel, titled 'Management and Control of Standard Operating Procedures'. This SOP establishes the development, numbering, review, approval, and obsolescence of SOPs. The SOP also defines how to validate, update, and extend the validity of an existing document (Appendix 4). The task of process implementation was debated to be dependent on the specific requirements of the organisation and the type of document being validated. For the purpose of this research, a case scenario was taken where a select number of quality documents of the MMA medical device directorate were used. The documents were created in accordance with the framework highlighted above and implemented into the QMS of the MMA.

2.2 Phase 2: Developing a medical device incident reporting system

The deliverable of this phase of the methodology was the establishment of a patient-centred medical device incident reporting system which focuses on meeting the needs of patients taking into consideration the stakeholders and relevant legislation. Phase 2 was

made up of four stages, Table 2.2 depicts the step-by-step process undertaken for the development of the medical device incident reporting framework. The first stage in the development of the incident reporting framework was a gap analysis done through a needs assessment. The following stages that followed were the compilation of policies and procedures in accordance with quality management systems, the establishment of the incident reporting framework, a pilot implementation of the incident reporting framework and subsequent recurrent audits and evaluation of the framework. The stages were addressed through two workshops and the establishment of an expert panel.

Table 2.2 Stages of developing an incident reporting medical devices framework

Stage	Objectives	Deliverable
Stage 1	**Needs Assessment**	
	Review of existing policies and procedures for incident report management	Identification of common themes
	Identification of key stakeholders involved in incident report management	List of stakeholders involved
	Definition of incident report terminology	Compiled list of definitions
Stage 2	**Compilation of supporting documents and tools**	
	Compilation of SOPs for validating incident reports received, investigating and analysing incident reports	Creation of vigilance procedures
	Creation and validation of incident report forms	Incident report form templates
Stage 3	**Pilot testing**	
	Training of personnel on the new policies, procedures, and reporting system	Training framework established
	Pilot test of system conducted to identify any issues or challenges	IRs received and analysis conducted
	Modify the system based on feedback from staff and stakeholders	
Stage 4	**Evaluate the System**	
	Regular audits of the system planned to identify areas for improvement	Audit and review plan
	Review the system's policies and procedures on a regular basis to ensure compliance and conformity	

Table 2.2 summarises the main tasks undertaken for each stage of the development phase of the medical device incident reporting framework.

2.2.1 Stage 1: Needs assessment

To establish an incident reporting framework, a needs assessment was conducted by looking at evaluating the existing processes, both at a national and international level. Aimed at identifying and classifying incident report templates, in addition to the technical capacity such as resources and capabilities required to implement an innovative robust patient centred medical device framework. Incident reporting management systems of European Member States were taken as a reference point. A list of contact points of all the national competent authorities was obtained from the European Commission website[14]. The website of each National Competent Authorities (NCA) was accessed and the vigilance/incident reporting systems in place for medical devices were reviewed. These systems provided an overview of the medical device incident data fields used by European NCAs. The in-use Maltese national reporting forms were compared to the identified data fields. A gap analysis exercise to determine the local system's weaknesses and strengths was conducted during workshop 1 attended by a panel of six experts consisting of general practitioners, pharmacists, and representatives from medical device stakeholders. A second workshop was conducted for stage two. The agenda for both workshops was drafted (Appendix 6).

In workshop 1, the expert panel was asked to identify key stakeholders related to medical device incident reports. Definitions of terminology related to incident reports were put forward and discussed. The researcher in tandem with the experts reviewed existing lists

[14] European Commission Contacts [Internet]. [Cited 2024]. Available from URL: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

of definitions from various sources such as the MDR, regulatory guidelines, medical device manufacturers' documentation, and other relevant literature. A list of definitions was developed with the experts (Appendix 7). These definitions were chosen due to their vital role in maintaining patient safety, facilitating effective communication, and ensuring regulatory compliance.

The process considered different factors:

- Thorough coverage: The chosen definitions encompassed various aspects of incident reporting, addressing themes such as adverse events, risk management, clinical evaluation, and post-market surveillance.
- Regulatory compliance: Essential terms like CE Marking, notified Body, and recall provided insights into the regulatory landscape, emphasising adherence to rules, certifications, and the execution of corrective measures.
- Patient-centric focus: Definitions like adverse event, serious adverse event, and health institution underscored the patient-centric nature of incident reporting, emphasising the impact on individuals' health and well-being.
- Risk management principles: Terms like risk, risk acceptability, and risk management highlighted proactive measures in identifying, assessing, and managing potential risks associated with medical devices.
- Industry standards: The inclusion of terms like unique device identifier (UDI) aligned with globally accepted standards for device identification and coding, promoting consistency, harmonisation and clear identification of medical devices on the market.
- Communication and reporting: Terms such as vigilance reporting, field safety notice, and post-market surveillance underscored the importance of open communication and reporting pathways.

2.2.2 Stage 2: Compilation of supporting documents and tools

The method used for developing and validating the medical device incident reporting framework involved a needs assessment, followed by the creation of SOPs with accompanying templates. This method aimed to lay a strong basis for the establishment of an effective incident reporting system in the medical device sector. In order to ensure the reliability and effectiveness of the developed documentation, a second workshop was held with an expert panel that included the same specialists that participated in the initial needs assessment. This allowed for a consistent and harmonised perspective throughout the research process.

In stage 1, the needs assessment identified requirements and gaps in the Maltese incident reporting structure in the first workshop. In the second workshop, the findings of the needs assessment were used to establish the framework for the development of two SOPs (Appendices 5 and 6), which were drafted as guidelines for the incident reporting process. Accompanying templates were also designed to help with uniformity and clarity when documenting incidents, ensuring that vital information was consistently documented.

During workshop 2, the expert panel assessed the SOPs and related templates in six key areas: completeness, accuracy, clarity, consistency, accessibility, and data reliability. To quantify their assessments, two validation questionnaires were used, using a Likert scale to measure expert opinions in each category (see Appendix 12 and 13). This systematic evaluation process provided an in-depth appraisal of the documentation's strengths and potential shortcomings.

The researcher included feedback from the expert panel and applied recommendations into the documents, thereby improving the incident reporting structure. This iterative strategy, which included both needs assessment and expert validation, contributed to the

creation of a strong and dependable system for reporting medical device incidents. The incorporation of expert advice in a structured validation process ensured that the framework attained the requirements of completeness, accuracy, clarity, consistency, accessibility, and data reliability in the context of medical device incident reporting.

2.2.3 Stage 3: Pilot testing of the medical device incident reporting system

Mater Dei Hospital was chosen as the location for the pilot implementation. Mater Dei Hospital is the main public acute general hospital on the Maltese islands, offering hospital services in addition to ambulatory specialised services making use of a diverse variety of types and classes of medical devices. During the workshops, the optimal methodology and design of the incident reporting system were discussed. In order to ensure the best possible awareness of the new medical device incident reporting management system, training was provided to the relevant personnel, which included clinical staff, quality and safety personnel, risk managers and other relevant departments.

During the gap analysis and needs assessment in stage 1, the expert panel identified gaps in the Maltese incident reporting structure. The expert panel reviewed these deficiencies and identified training programme objectives, focusing on the need of ensuring MDR compliance while enhancing patient safety. Throughout the iterative development process, the panel provided feedback and recommendations to strengthen the training programme. The expert panel noted the importance of including MDR-specific elements into the training, such as the requirements for incident reporting, post-market surveillance, and vigilance.

The panel proposed an inclusive approach to content development, including modules on incident details and adverse events, legal and regulatory compliance, roles and responsibilities, root cause analysis, corrective and preventive actions, and system navigation. They recommended using case studies and interactive exercises to enhance participant engagement and facilitate comprehension of complex regulatory concepts. The resulting content objectives and modules were expanded to create the *Training Programme for Medical Device Incident Reporting* (Appendix 14). The training programme was designed to use a mixed approach, combining online and face-to-face sessions to accommodate different learning styles and the many roles engaged in incident reporting.

2.2.4 Stage 4: Evaluation

The pilot testing was initially conducted over a one-month period. Following the one month period, a questionnaire was circulated to users to provide feedback and evaluation on the incident reporting system used in the pilot study. The resulting data was evaluated by the same expert panel that was established during the development and validation of the incident report forms. This expert panel included professionals with backgrounds in clinical practice, quality and safety management, risk assessment, and regulatory compliance. The panel's diversity enabled a detailed evaluation that took into account various perspectives and expertise. The incident reporting system was thoroughly analysed using an approach that included both quantitative and qualitative data collection. The raw data, both quantitative and qualitative, was compiled and analysed. Quantitative data captured data on the completion time, error rates, data accuracy, section completion rates, ease of accessibility, user feedback score, and rate of submission. The expert panel

engaged in discussions to provide qualitative insights into the system's functionality, usability, and overall effectiveness.

Following the evaluation of the pilot study, changes were implemented to improve the incident reporting system. The incident report forms were modified based on the input and outcomes of the pilot testing to improve usability and efficacy. A collaborative and iterative approach was used throughout this process to verify that the form matched with the reporting needs, was user-friendly, and conformed with relevant legislation. The goal was to provide a robust and efficient mechanism for medical device incident reports to be accurately reported.

After the completion of the one-month pilot, the system transitioned to an ongoing operation of use. Following the pilot study, continuous efforts were made to collect additional raw data at regular intervals, expanding the sample pool and lengthening the observation period. This increased data collection allowed for a broader quantitative analysis, strengthening the appraisal of the system's performance.

2.3 Phase 3: Setting up a digital medical device management system

The deliverable for this phase was the development of the infrastructure for a digital medical device management system. A digital management system is a complex system comprised of various modules and components designed to collect and process data. A medical device management system (MDMS) concerns the manufacture, notification, distribution, vigilance, and surveillance of medical devices that have been placed on the market. The aim of the digital system was to gather high-quality data, which can then be

processed to generate reports and statistics with the scope of increasing quality, safety and efficacy of medical devices, increasing traceability and visibility of processes related to medical devices regulatory sciences.

The methodology used for project management, whether pure Agile, traditional Waterfall, or a hybrid approach, was determined by a number of factors, including the nature of the project, organisational culture, team dynamics, and unique project requirements. A hybrid Agile methodology was chosen for the creation of the digital medical device management system. Structured planning and documentation are common features of hybrid Agile processes, which are similar to traditional Waterfall project management approaches. This was useful for the research project where specific components required greater forward clarification and planning. By also embracing Agile concepts, the hybrid Agile methodology allowed for flexibility and adaptability, this was useful in the MDMS project where requirements changed, and ongoing input and modifications were continuously required. Finally, hybrid techniques are more easily scaled to accommodate projects of varying sizes. The scope of the research was to establish a framework that can be used by different stakeholders, therefore a hybrid approach that allowed for scalability and adaption to larger and more complicated projects was deemed advantageous.

The methodology for the MDMS framework was split into three stages of database architecture. Stage 1 focused on defining the MDMS scope, objectives, the identification of target stakeholders as end users of the MDMS, feasibility studies including milestones, duration of setting up the digital system and identification of requirements including resources required for establishing a digital MDMS.

In Stage 2 of the project, the Project Charter and drafted process flows were presented to a third-party software development team, with captured requirements

converted into user stories. A review and validation of user stories and process flows involved the researcher, stakeholders, and the development team, using criteria for completeness, clarity, and feasibility. Eight workshops over a month facilitated this validation, focusing on different MDMS modules. Each user story was iteratively refined through collaborative feedback to meet the criteria.

Stage 3 concerned the system User Acceptance Testing (UAT) and implementation. The system was validated through UAT, where the overall functionality and performance were assessed. A process for the ongoing monitoring, maintenance, and support of the system was established. This included response protocols to any issues or defects reported by users, providing regular updates and patches, and ensuring the product's stability and reliability.

2.3.1 Stage 1: Establishing the Project Charter

In line with hybrid Agile methodology, stage 1 focused on defining the scope, objectives, stakeholders, feasibility studies, and identification of other requirements for establishing a digital MDMS. The requirements, collectively called the *Project Charter*, were compiled through discussion and workshops with an expert panel. The expert panel consisted of three external specialists and five MMA members from the area of medical devices, information technology (IT) and finance. The specialists comprised of an external IT consultant and two representatives of the Maltese government IT service provider - MITA.

The development of the *Project Charter* was generated through a series of workshops in collaboration with the expert panel. The expert panel engaged in a continuous discussion

over the course of 16 sessions, each approximately 90 minutes in length. The workshop sessions were seen as a continuous whole, with each succeeding session naturally building on the insights gained from the previous session, resulting in a cohesive and focused discussion.

In the role as a workshop moderator, the researcher provided a set of evolving questions (Appendix 16). These questions served as strategic tools intentionally constructed to prompt detailed information, constructive insights, and professional judgments from the expert panel members. These questions, which served as a guiding framework, were essential in both introducing the subject and driving the conversation towards a predetermined direction.

In contrast to traditional workshop arrangements, in which themes are frequently separated or cut off, our approach embraced a fluid and changing technique. The questions evolved naturally as they were strategically divided across the sixteen seminars. The developing dynamics of each workshop drove this evolution, allowing for an adaptable and responsive improvement of the questioning method. As a result, the first inquiries, which were broad in nature and addressed overarching topics such as resource allocation and stakeholder identification, gradually evolved into highly detailed questions tied to the individual modules established throughout the collaborative sessions. As a result of this approach, each workshop contributed to the immediate topic at hand and also to the ongoing refining of succeeding conversations. Consequently, the list of questions was not static but evolved dynamically over time in parallel to the expert panel's discussion throughout the extended workshops.

As a result, the insights, analyses, and decisive findings generated by these joint workshops were documented and catalogued. The resulting compiled document

(Appendix 17) provides a meaningful foundation for following stages. This document contains the expert panel's collaborative efforts and inputs, serving as a guidepost for the following stages of this phase.

2.3.2 Stage 2: User stories and process flows

The *Project Charter*, identified in conjunction with the expert panel, was presented to a 3rd party software development team. Drafted process flows were also presented. The captured requirements were converted into user stories which were then used to update the process flows of each process that would be used as the foundational processes the system would implement. The validated user stories and flows were compiled. (Appendix 19 and 20).

A comprehensive review and assessment of the user stories and their related process flows was conducted as a validation process. The procedure was collaborative, with both the researcher, relevant stakeholders and the 3rd party software development team participating. To assess the completeness, clarity, and practicality of each user story, validation criteria were developed. Among the criteria were:

- Completeness: Refers to ensuring that each user narrative covers the requested functionality or feature.
- Clarity: Ensuring that each user story's description and tags are clear and unambiguous.
- Feasibility: The possibility of implementing the described functionality within the MDMS is evaluated.

To facilitate the validation process, eight face-to-face workshops were held over the course of a month. Each session concentrated on a different component of the MDMS's identified modules. Table 2.3 summarises the workshop days and their associated themes.

Table 2.3 Breakdown of workshops held for validation of user stories and flows

Task Name	Duration
Device Management & Eudamed	2 days
Case Management & Market Surveillance	2 days
Invoicing & Online Payments	2 days
Portal Requirements including UX/UI, reporting	1 day
Registration & User Management	1 day
Infrastructure	1 day
Integration to Government Services	1 day
EUDAMED technical specification	1 day

Table 2.3 provides a breakdown of workshops dedicated to the validation of user stories and flows. Each task was allocated a specific duration, ranging from one to two days. This structured approach ensured thorough validation across various aspects of the project.

Each workshop day consisted of 6-8 hours of face-to-face discussion. The workshops were designed to enable collaboration between the researcher and key stakeholders such as end users, customers, sponsors, subject matter experts, and members of the 3rd party software development team.

During the workshops, the user stories and process flows were iteratively refined. The user stories were evaluated along the defined format (Table 2.4). Each user story was assessed and validated. This step entailed revisiting the user stories and addressing any uncertainty, ensuring that each narrative met the stated completeness, clarity, and feasibility requirements. If the user story required clarification, the researcher highlighted this, resulting in a collaborative feedback loop. Appendices 16 and 17 contain detailed documentation of the final user stories and process flows that were accepted and validated

during the workshops. This compilation served as the foundation for the MDMS development process's succeeding stages.

Table 2.4 Format of validation of user stories with examples

User Story Title	Flow Correlation	Description	Tags	Accepted by Researcher	Initial Comments by Researcher	Review by 3rd Party	3rd Party Comments	Additional Comments by Researcher
Example 1: As a user I want to reject actor's role registration so that Actor can resubmit required information	2g	Once registration is rejected process should restart and Actor must resubmit correct information without paying again.	Registration of Actors	No	Separate each application per role	Yes	Noted, removed multiple roles description	
Example 2: As a Developer I want to keep track of actions performed by the user so that the system can keep track/generate audits/audit trail.	4f	The following will need to be tracked: - user actions - old content vs new content	Content Management System	No	Missing word in sentence. 'Keep ___ of actions'. As a Developer I want to keep track of actions performed by the user so that the system ...	Yes	Agreed	

Table 2.4 illustrates the format for validating user stories, accompanied by examples. Each user story title is detailed with its flow correlation, description, and associated tags. Researcher acceptance and comments, along with third-party reviews and additional remarks, contribute to refining and finalising the user stories.

2.3.3 Stage 3: Validation and user acceptance testing

Focus groups were held during stage 3. The expert panel's recommendations and understanding of the complexities of the project were used to develop a system test strategy. To ensure a full examination of the integrated system, this test plan detailed the test objectives, defined the scope, and constructed hypothetical test cases. The UAT was incorporated case scenarios, crafted case examples, and established acceptance criteria as an indicator for the efficacy of the system, ensuring that the integrated solution met the standards of functionality, performance, and dependability.

2.4 Phase 4: Identifying continuous professional development needs

The deliverable of this phase was to identify the gaps and needs to allow for continuous professional development to be achieved and maintained on an ongoing basis. Phase 4 was divided into two stages targeting internal personnel and external stakeholder training.

2.4.1 Stage 1: Internal training

Internal training for employees focused on identifying and filling knowledge and skill gaps within the organisation. To facilitate this process, a questionnaire titled 'Employee Skills and Training Needs Assessment' (Appendix 22) was developed. This tool aimed to gauge employees' perceptions of their current skill levels, areas they felt needed improvement, and the types of training in which they were interested. To ensure the questionnaire's efficacy in capturing the varied viewpoints of employees accurately, a validation procedure was conducted before its distribution (Appendix 24). An expert

panel consisting of three individuals with significant experience in the medical devices field reviewed the questionnaire, providing feedback to refine the questions for clarity, relevance, and effectiveness.

Following validation, the questionnaire was disseminated to 12 personnel within the medical device unit at the Malta Medicines Authority. This allowed the participants to highlight their self-perceived competencies and training needs of the internal staff. Participants self-rated their proficiency across different competencies including technical knowledge, communication skills, problem-solving abilities, team collaboration, and project management on a scale of 1 to 5.

After the questionnaire assisted in identifying specific skill gaps within the medical device unit at the Malta Medicines Authority, a curriculum for internal training was established, to specifically cater for the identified gap and enhancing the overall competency and efficiency of the personnel. The curriculum encompassed a series of modules focused on enhancing technical knowledge, communication skills, problem-solving abilities, team collaboration, and project management capabilities. Special attention was given to areas where notable skill gaps were identified, ensuring that the training was directly aligned with the needs of the personnel and the strategic objectives of the medical device unit.

A variety of training methods were discussed to cater to the diverse learning preferences of the staff, combining webinar-based sessions, which were highly favoured, with interactive workshops and hands-on experiences. The different methods aimed to engage participants fully and ensure the effective assimilation of knowledge.

Training sessions were designed to conclude with assessments to gauge the participants' knowledge and the overall success of the program. Those who met the training objectives

were to be awarded certificates or any other equivalent concept, acknowledging their enhanced skill sets. Recognising that professional development is an ongoing journey, the developed curriculum also accounted for continuous learning opportunities, including access to online resources, follow-up sessions, and forums for discussion, thereby fostering an environment of perpetual growth and adaptation.

2.4.2 Stage 2: External training

External training focused on 3rd party stakeholders and individuals connected to the medical device sector. To identify external training needs, a series of focus groups were held. The basis for these focus groups was a set of validated questions (Appendix 23), developed in collaboration with the expert panel that was also used for the internal training stage.

The questions were developed to address the distinct points of view and requirements of three key stakeholder groups:

- Healthcare Professionals
- Regulatory Organisations
- Distributors, and Suppliers

To ensure the questions effectiveness in capturing the varied viewpoints of the stakeholder groups, a validation procedure was conducted through a questionnaire (Appendix 24). Following validation, sessions were held with each stakeholder group.

The external stakeholder curriculum was designed to support the varied individuals and groups involved with the medical device sector, ensuring they are well-equipped to meet the demands of the MDR. The curriculum is composed of targeted modules addressing

core areas such as MDR framework understanding, practical compliance strategies, stakeholder-specific regulatory impacts, and resource utilisation.

Different instructional methods were incorporated to serve the different learning styles and situational needs of external stakeholders. The training embraced webinar sessions for their wide reach, supplemented by e-learning modules for self-paced learning, and in-person seminars for deeper engagement.

Chapter 3
Results

This chapter presents the findings of the research including outcomes of focus groups discussions expert panels, data mining, and validation, leading to the development of a medical device framework. The data gathered through the four different phases of the research is analysed and integrated.

3.1 Phase 1: Medical Devices Quality Management System

This section breaks down the outcomes of the key stages involved in the establishment of a medical devices quality management system, including the identification and analysis of existing regulations and guidelines, the adaptation of the quality management system (QMS) framework to specific organisational needs, and the creation of standard operating procedures (SOP), policies, guidelines, and application forms.

3.1.1 Overview of the QMS framework development process

The process of developing the QMS framework involved conducting a thorough review and analysis of existing medical device quality management regulations, guidelines, and best practises. The goal of this process was to gain a thorough understanding of the regulatory landscape and industry standards. International regulatory bodies such as the FDA and the European Commission, and industry-specific organisations and published literature, were consulted. Key regulatory requirements for quality management were identified during this process. Guidelines for risk management, documentation practises, complaint handling, corrective and preventive actions, incident management, and post-

market activities were included. The analysis revealed common themes and best practises that served as the foundation for the framework's subsequent stages of development.

Based on the insights gained from the analysis of existing regulations and guidelines, the QMS framework was reviewed and adapted to address the specific challenges and specificities of the Medical Devices Regulation's (MDR) operating environment. This included adapting existing procedures, incorporating additional controls, and aligning the framework with the MDR's goals and objectives. Consideration was given to factors such as the organisation's size, the complexity of its operations, and the regulatory environment in which it operates.

The key outcome of the QMS framework development process was the creation of a set of SOPs, policies, guidelines, and application forms. These documents were designed to provide clear instructions and guidance on how to implement the framework and execute various quality management processes.

SOPs were established in a systematic manner, by identifying the stage involved in each process, documenting the specific tasks and responsibilities, and defining the expected outcomes. Policies and guidelines for quality management within an organisation were also developed. These documents outlined the organisation's commitment to quality, approach to risk management, and expectations for regulatory compliance. They established a framework for decision-making and a culture of quality and continuous improvement. Application forms, in addition to SOPs, policies, and guidelines, were developed to aid in the operationalisation of various processes within the QMS framework.

Section 3.1.2 details the specific outcomes of each stage of the QMS framework development process.

3.1.2 Findings from each project stage of the QMS framework

During the three workshops held through the QMS development process, stages 1 to 5 were covered.

Stage 1: Establishment of a quality policy

Based on the MDR Regulations, a quality policy was developed to capture the objectives and intentions of the QMS framework, (Appendix 5). The quality policy established the long-term vision and objectives of the QMS. The mission statement stated the fundamental purpose of the QMS, and the value intended to be provided as a result of the established framework.

Stage 2: Gap analysis

The gap analysis stage sought to identify gaps and discrepancies between existing QMSs based on previous directives and the new regulations' requirements. The gap analysis findings provided valuable insights into the areas that needed to be modified and revealed a number of significant gaps between the directives and regulations. Changes in terminology, documentation requirements, classification rules, and a greater emphasis on risk management and post-market surveillance were the primary causes of these gaps.

The gap analysis findings highlighted the need for detailed staff training and awareness programmes. It was noted that the competence and understanding of personnel was key to the successful implementation of the revised QMS framework. As a result, training sessions to educate staff members about the changes in regulations, their roles and responsibilities, and the impact on daily operations were proposed. This proactive approach was intended to ensure a smooth transition from previous directives to the new regulatory framework.

The MDR is significantly more detailed and comprehensive than the Medical Devices Directive (MDD). The MDD[15] is 60 pages long, with 23 articles and 12 appendices, whereas the MDR[16] is 175 pages long, with 123 articles and 17 appendices. Table 3.1 summarises the key provisions of the MDD and MDR articles, along with comments providing discussion and highlighting the main differences.

[15] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/dir/1993/42/2007-10-11

[16] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20

Table 3.1 Summary of the key differences of the MDD and the MDR articles

Topic	Medical Devices Directive (93/42/EEC), as amended	Medical Devices Regulation (EU 2017/745)	Comments
Scope - Inclusions	**Article 1:** The MDD encompasses medical devices and accessories, including those with ancillary medicinal products and non-viable animal material.	**Article 1:** The MDR expands its scope to cover medical devices and accessories for human use, incorporating active implantable medical devices, devices with ancillary medicinal products from human blood or plasma, devices with non-viable human tissues or cells, devices with non-viable animal tissues or cells, cleaning/disinfection/sterilisation products, and aesthetic products listed in Annex XVI.	The MDR broadens the range of covered devices and products, including various classifications and materials. It notably includes ancillary products from human sources and expands to encompass aesthetic items.
Declaration of Conformity and CE-marking	**Articles 11 and 17:** Under the MDD, manufacturers must draft a declaration of conformity and affix a CE-mark to compliant products. Annex XII details the CE mark's format.	**Article 19 and 20:** The MDR retains the requirement for a declaration of conformity and CE-marking, now specifying that the declaration must be kept current and available in the official language(s) of relevant Member State(s). Annexes IV and V outline information and the CE mark format, respectively.	The MDR adds provisions for updating declarations and linguistic requirements, enhancing clarity and ensuring accessibility across Member States. It specifies the content of the declaration and the format of the CE mark.
Post-Market Surveillance (PMS)	**Annex X of the MDD:** The MDD mentions PMS, allowing clinical data updates through post-production phase reviews. Manufacturers must establish systematic procedures for review and implement corrective actions.	**Articles 83–86:** The MDR mandates manufacturers to institute a PMS system within their Quality Management System (QMS). This system actively collects and analyses data throughout a device's lifetime, facilitating updates to benefit-risk determinations, clinical evaluations, and safety summaries. The MDR requires a detailed PMS plan, including PMCF, with specific reporting obligations based on device class.	The MDR specifies comprehensive requirements for PMS, integrating it into the QMS and emphasising data collection and analysis. It introduces detailed PMS plans, incorporating PMCF, and outlines reporting obligations tailored to device classifications.

Reporting of Incidents	**Article 10:** The MDD requires competent authorities to centrally record and evaluate device recalls and adverse events potentially impacting patient health or safety. Manufacturers follow conformity assessment annexes for reporting requirements.	**Articles 87–92:** The MDR mandates manufacturers to report serious incidents and field safety corrective actions. It defines serious incidents and requires trend reporting for exempt incidents. Reporting deadlines vary based on incident severity.	The MDR enhances incident reporting requirements, extending obligations to serious incidents and trend reporting of exempt incidents. It streamlines reporting categories and tightens reporting timelines, ensuring timely and comprehensive oversight of device safety.

Table 3.1 containes the comparison between the Medical Devices Directive and the Medical Devices Regulation highlighting significant enhancements in scope, conformity declarations, and post-market surveillance. The MDR expands device coverage, updates conformity requirements, and mandates comprehensive post-market surveillance systems, ensuring stricter oversight and improved patient safety across the European Union. Adapted from Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/dir/1993/42/2007-10-11 and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2017/745/2023-03-20

Stage 3: Objective proposition

The objective proposition stage concentrated on developing specific and measurable goals for the QMS framework. The findings of the gap analysis allowed the objectives to be developed in accordance with the organisational goals, regulatory requirements, and industry best practises (Table 3.2).

The objectives were developed using the SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) principle. This ensured that the objectives were clear, measurable, and in line with the overall strategic direction of the regulations. By establishing specific targets and timelines, the framework aimed to increase accountability, track progress, and continuously improve the QMS framework.

Table 3.2 Objectives proposed for QMS framework

Objective	Specific	Measurable	Achievable	Relevant	Time-bound
Ensure regulatory compliance with medical device regulations within the next two years	Track adherence to medical device regulations	Measure compliance levels and track progress	Implement necessary measures and allocate resources for compliance	Align with regulatory requirements and the goals of the organisation	Measure the compliance within a specified timeframe
Reduce the number of non-conformities in the QMS by the end of the next fiscal year	Address and minimise non-conformities within the QMS	Track the number of non-conformities and monitor their reduction	Implement corrective actions and preventive measures to address non-conformities	Enhance the effectiveness and efficiency of the QMS	Achieve the specified reduction in non-conformities within a defined timeframe
Implement a risk-based approach to ensure the safety and efficacy of medical devices, with high-risk devices undergoing thorough risk assessments within the next six months	Apply risk-based assessments to high-risk medical devices	Track the number of high-risk devices undergoing risk assessments	Develop a risk assessment framework and allocate resources for assessments	Enhance patient safety and comply with regulatory requirements	Conduct risk assessments for the specified percentage of high-risk devices within a set timeframe
Enhance stakeholder qualification and management by implementing a stakeholder evaluation system, resulting in an increase in qualified stakeholders within the next nine months	Improve the qualification and management of stakeholders	Track the number of qualified stakeholders and measure the increase	Develop a stakeholder evaluation system and establish criteria for qualification	Ensure the reliability and quality of supplied materials and components	Achieve the specified increase in qualified stakeholders within the defined timeframe

Implement a continuous improvement program, resulting in at least one process improvement initiative implemented every quarter	Foster a culture of continuous improvement	Track the number of process improvement initiatives implemented	Establish a framework for identifying and implementing improvements	Enhance the efficiency and effectiveness of operations	Implement at least one process improvement initiative every quarter
Enhance employee competency through a comprehensive training program, resulting in an increase in employee proficiency scores within the next year	Improve employee competency through training	Assess employee proficiency scores and measure the increase	Develop a training program aligned with identified skill gaps and provide regular training sessions	Ensure employees have the necessary skills to perform their tasks effectively	Achieve the specified increase in employee proficiency scores within the designated timeframe
Ensure regulatory compliance by conducting regular internal audits, confirming with regulatory requirements every quarter	Enhance regulatory compliance through internal audits	Conduct internal audits and measure the compliance rate	Develop an internal audit program, assign qualified auditors, and address any non-compliance issues	Maintain adherence to regulatory standards and avoid penalties or sanctions	Confirm compliance with regulatory requirements on a quarterly basis

Table 3.2 presents objectives formulated using the SMART principles. Each objective is Specific, Measurable, Achievable, Relevant, and Time-bound. Objectives include ensuring regulatory compliance, reducing non-conformities, implementing risk-based approaches, enhancing stakeholder management, fostering continuous improvement, and improving employee competency.

Stage 4: Performance management system

A system of Key Performance Indicators (KPI) was established to measure and evaluate the QMS's performance across various levels (Table 3.3). In conjunction to the KPIs, a structured approach to data collection and analysis was also developed. (Table 3.4). Regular management reviews and audits were part of the performance management system.

Table 3.3 Key performance indicators

Key Performance Indicators
Audit findings closure rate: Percentage of identified audit findings that are successfully addressed and closed
Complaint resolution time: Average time taken to resolve customer complaints from the moment they are received
Compliance rate with medical device regulations: Deviations from regulatory requirements within a given timeframe
Employee proficiency scores: Assessment scores measuring employee competence and proficiency
Number of non-conformities in the QMS: Count of instances where the Quality Management System deviates from specified standards
Number of process improvement initiatives implemented: Count of process improvement initiatives implemented in a given quarter or time period
Response time to inquiries: Average time taken to respond to inquiries or requests
Training effectiveness: Assessment of the impact and effectiveness of training programmes on employee performance

Table 3.3 outlines key performance indicators crucial for evaluating operational effectiveness.

Table 3.4 Structured approach to data collection and analysis

Key Performance Indicator	Data Source	Responsibilities	Validation and Quality Assurance
Audit findings closure rate	Audit reports, internal audit team	Internal audit team	Regular reviews of audit closure status by management
Complaint resolution time	Complaints received	Designated employee/s	Periodic audits of complaint resolution logs to verify accuracy
Compliance rate with medical device regulations	Compliance audit reports, regulatory documents	Regulatory compliance team	External audits by regulatory authorities, periodic reviews by senior management
Employee proficiency scores	Assessment results	Training and development team	Cross-validation of assessment scores, feedback from supervisors
Number of non-conformities in the QMS	Non-conformity reports, internal audits	Quality assurance team, department heads	Regular reviews of non-conformity logs, corrective action tracking
Number of process improvement initiatives implemented	Improvement project documentation, project management system	Process improvement team, project managers	Reviews of project documentation, impact assessments
Response time to inquiries	Inquiries, ticketing system	Designated employee/s, support team	Regular monitoring of response times, feedback surveys
Training effectiveness	Assessment results, training evaluations	Training and development team, trainers	Analysis of assessment scores, feedback analysis for areas of improvement

Table 3.4 outlines a structured approach to data collection and analysis for key performance indicators established in Table 3.3. Responsibilities are assigned to relevant teams or individuals, with validation and quality assurance measures implemented to ensure data accuracy and reliability.

Stage 5: Document content, validation, and implementation

The expert panel recognised the importance of documentation in providing clear guidance, standardising processes, and ensuring consistency within the organisation. Appendix 3 shows the QMS document list using the document structure that was identified in the third workshop and shown in Table 2.1.

To ensure document standardisation, consistency, clarity and relevance, a validation protocol was established (Figure 3.1).

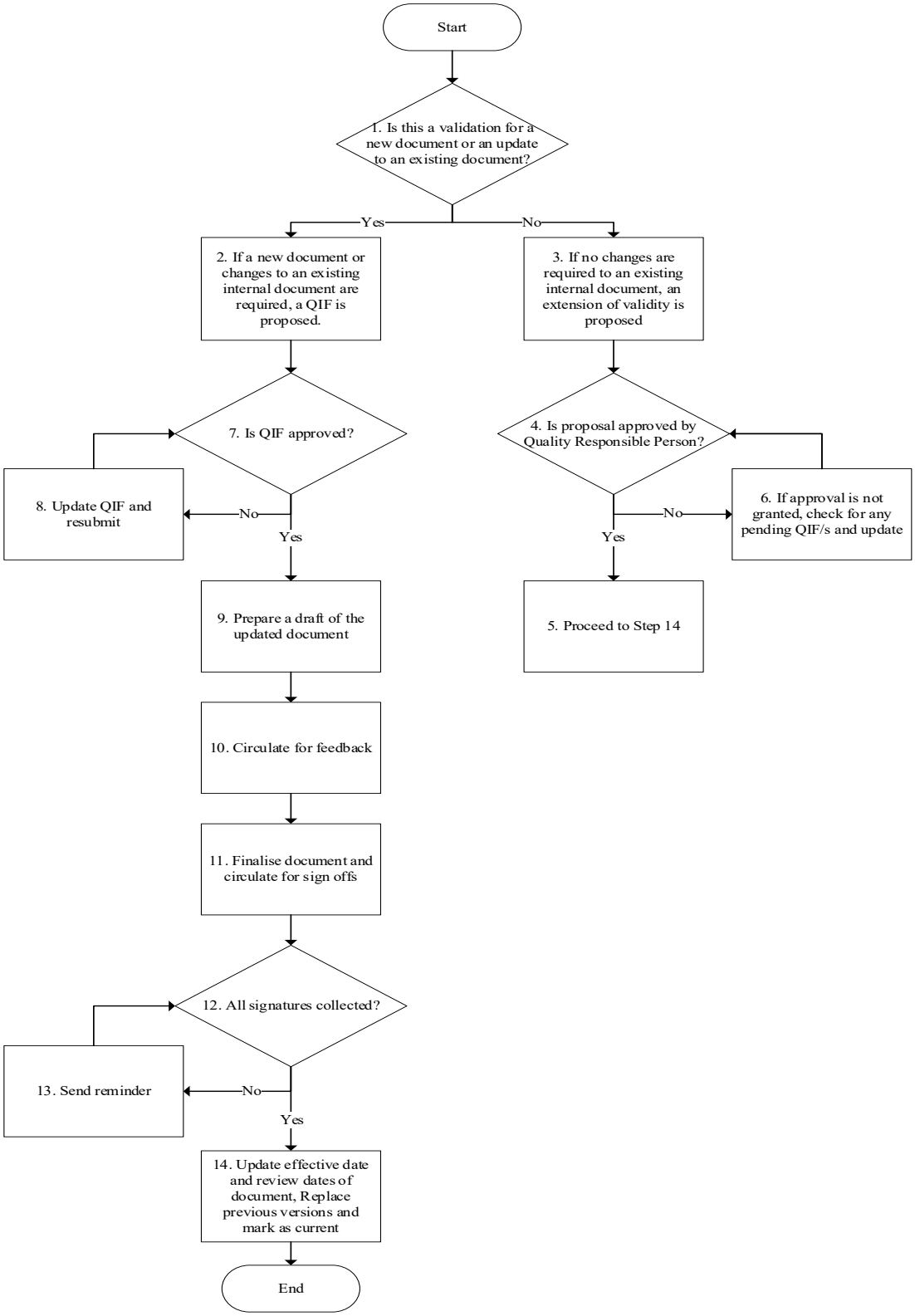


Figure 3.1 Proposed validation process

Figure 3.1 outlines the procedure flow for validating a new or existing quality document.

Stage 6: Implementation planning and management

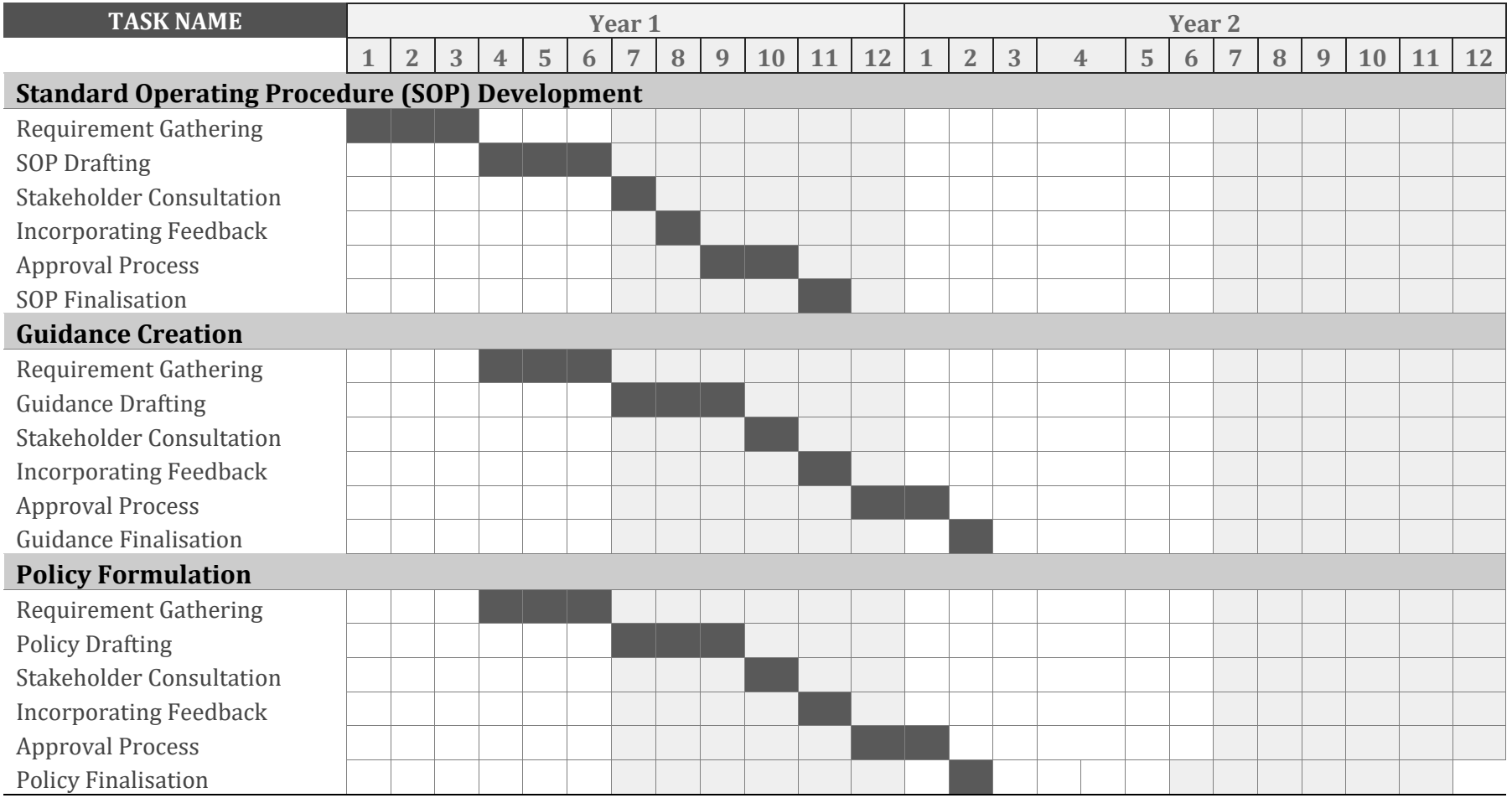
The implementation planning and management stage concentrated on developing a plan for the creation and deployment of a strong QMS based on the established QMS framework. A thorough assessment of the resources, timelines, and dependencies associated with the implementation process was required for effective implementation management. Identifying the necessary human resources, infrastructure, and technologies to support the implementation process was part of this. To demonstrate the QMS framework proof-of-concept, a Malta Medicines Authority (MMA) case study was conducted. In conjunction with the expert panel, a detailed implementation plan (Figure 3.2) outlining the specific activities, milestones, and responsibilities associated with the revised QMS's deployment was compiled. To ensure a systematic and coordinated approach to implementation, the plan considered task sequencing, interdependencies between different processes, and critical timelines.

The study also emphasised the significance of effective change management during the implementation phase. According to the findings, the MMA recognised the importance of engaging and communicating with employees at all levels to help them understand the changes, address any concerns or resistance, and promote buy-in and commitment to the revised QMS. To ensure that employees were well-prepared and supported throughout the implementation process, the MMA implemented a number of change management strategies, including training programmes, workshops, and regular communication channels.

Mechanisms for monitoring and evaluating implementation progress were established. Regular progress reports, milestone reviews, and feedback mechanisms were implemented to identify any issues or deviations from the planned activities. These

monitoring activities would enable the MMA to make timely adjustments, address issues that arose, and ensure that the implementation stayed on track.

Implementation Plan



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Implementation Plan Continued

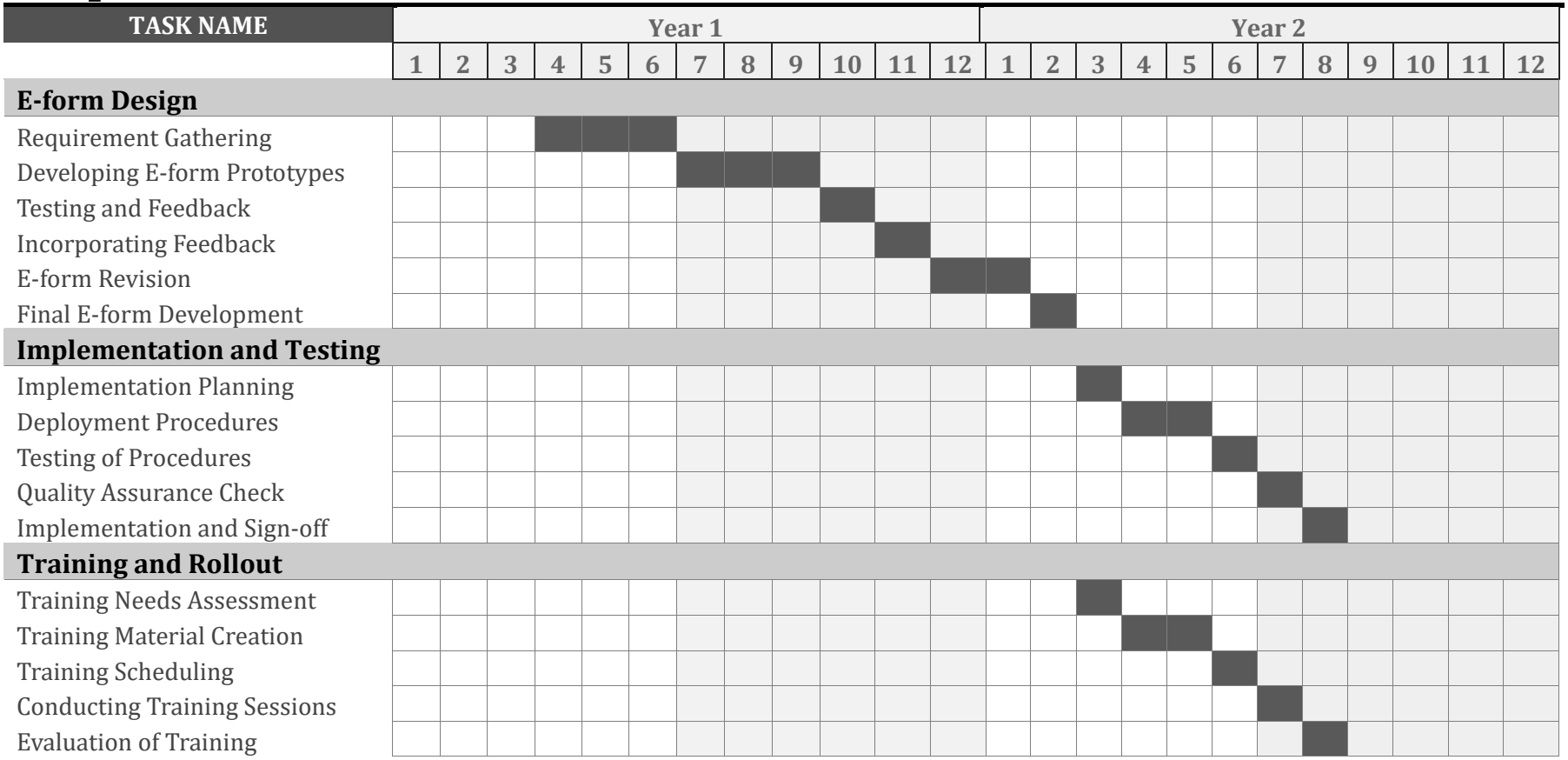

Figure 3.2 GANNT chart showing the timeline of the implementation plan

Figure 3.2 illustrates a Gantt chart detailing the phased implementation plan timeline. The plan spans two years, delineating tasks in sequence and allocated within monthly intervals across the timeline.

Stage 7: Audit Mapping and Processing

The establishment of SOP-001.00 *"Management and Control of Standard Operating Procedures"* (Appendix 2), introduced a systematic and controlled approach towards the generation, numbering, review, approval, and obsolescence of SOPs within the medical device framework. SOP-001.00 contained a structured review and approval process, involving both SOP owners and the personnel responsible for quality, also included was a procedure for validation of new and ongoing active documents.

Stage 8: Critical Analysis

The critical analysis stage involved an examination of the findings stages 1 to 7 to identify strengths, weaknesses, opportunities, and potential areas for improvement within the QMS development process. This stage aimed to provide a holistic view of the QMS framework implementation efforts and shed light on key factors influencing its effectiveness and regulatory compliance.

The validation processes put in place aided in verifying the accuracy and integrity of the documentation, lowering the risk of errors or noncompliance. The analysis did, however, reveal areas that could be considered weaknesses or areas for improvement in the QMS development process. The analysis identified the need for improved audit mapping and processing as a potential area for improvement. While mechanisms were put in place to align the QMS with audit requirements, there was still room to streamline the audit process and improve the effectiveness of corrective actions. Consideration could be made in incorporating technology-enabled audit management systems.

3.2 Phase 2: Medical Device Incident Reporting System

The results pertaining to the development of a medical device incident reporting system are presented in this section.

The medical device incident reporting system's scope emphasises the importance of timely reporting, appropriate information, and compliance with European and national law. It focuses on reporting medical device incidents and in-vitro diagnostic medical device incidents to the National Competent Authority, ensuring that incident reports are complete, accurate, and submitted within the specified timelines, promoting patient safety and regulatory compliance.

3.2.1 Vigilance and incident reporting themes

Findings pertaining to the review of the Competent Authorities' websites and their vigilance/incident reporting systems are categorised according to the common themes identified:

1. *Patient and device information*: Identification of the patient and the medical device involved in the incident, including the device type, model, and serial number.
2. *Incident details*: Description of the incident, including the date, location, and type of incident.
3. *Adverse events*: Identification of any adverse events or harm to the patient, including injuries, complications, or deaths.
4. *Suspected cause*: An assessment of the suspected cause of the incident, including any contributing factors or underlying conditions.

5. *Device performance*: An evaluation of the device's performance during the incident, including any malfunctions or deviations from expected performance.
6. *User error*: An assessment of any user error that may have contributed to the incident, such as improper use or maintenance of the device.
7. *Follow-up actions*: A description of any follow-up actions taken in response to the incident, such as corrective actions, recall of the device, or further investigation.
8. *Reporting information*: Information on the reporter, including contact details and professional affiliation.

3.2.2 Results of the gap analysis

A gap analysis of the Maltese medical device incident report form was conducted with the common identified themes used as a basis for the gap analysis.

- **Patient and Device Information**:
  - The form collected information about the medical device involved, including brand/trade name, model number, catalogue number, and serial/batch/lot number.
  - However, it lacked specific fields for patient identification, such as patient name, identification number, or demographic information. There was also no section dedicated to linking the device with the patient involved.
- **Incident Details**:
  - The form included fields for the date of the incident and the location where it occurred.

- It covered the basic incident details but did not provide space for a detailed description of the incident or the type of incident (e.g., malfunction, misuse, adverse reaction).

- **Adverse Events**:
  - The form asked if an injury was suffered as a result of the incident but did not provide space to describe the nature or severity of the adverse event.
  - There was no specific section to report other adverse events such as complications or deaths related to the incident.
- **Suspected Cause**:
  - The form lacked a dedicated section to assess the suspected cause of the incident or to identify contributing factors or underlying conditions.
  - It did not provide space to describe any investigation or analysis conducted to determine the cause of the incident.
- **Device Performance**:
  - The form did not include specific questions to evaluate the device's performance during the incident or to report any malfunctions or deviations from expected performance.
  - Information on the device's behaviour during the incident could have helped identify potential issues with the device itself.
- **User Error**:
  - The form did not have a section dedicated to assessing user error or improper device use that may have contributed to the incident.
  - Understanding user-related factors could have helped identify areas for improved training or device design.

- **Follow-up Actions**
    - The form lacked a section to describe any follow-up actions taken in response to the incident, such as corrective actions, device recall, or further investigation.
    - Reporting on follow-up actions would have been crucial for ensuring appropriate responses to adverse incidents and preventing similar incidents in the future.
- **Reporting Information**:
    - The form included a section for the reporter's contact details and professional affiliation, covering the basic reporting information.

The incident report form captured essential information about adverse incidents involving medical devices, but it lacked detail in key areas such as patient information, incident description, adverse events, suspected cause, device performance, user error assessment, and follow-up actions. Enhancing the form to include these elements provides a more thorough understanding of adverse incidents and facilitate appropriate responses and preventive measures.

The first workshop discussed the design of the incident reporting system. The topic of using a digital platform for incident reporting was discussed and acknowledged as being the optimal solution. Considering the nature of the study and the need to establish a strong foundation for the system, it was agreed by the expert panel that a paper-based approach would be implemented as an initial phase until a digital solution can be implemented. This paper-based system would serve as a practical starting point to collect data and information while allowing for the smooth transition to a digital platform in the future. Different factors influenced the decision to use a paper-based approach in the first phase.

It provided a tangible and accessible means of developing and refining the incident reporting process. Before implementing a digital solution, the paper-based approach allowed for hands-on experience with the reporting forms, procedures, and workflow, allowing the identification of potential challenges and areas for improvement. This method also made it easier for stakeholders to engage and participate. Incident report forms were drafted and validated to ensure data consistency and uniformity.

The expert panel identified the key stakeholders who form part of a patient-centred incident reporting system (Table 3.5).

Table 3.5 Key stakeholders identified

Key Stakeholders
Healthcare Professionals: Immediate recognition, documentation, and reporting of incidents by frontline healthcare workers are crucial for system efficacy. Their first hand experience and insights are invaluable for incident analysis and improvement initiatives.
Patients: End users' input is vital for identifying device-related issues and enhancing patient engagement. Empowering patients to report incidents fosters transparency and accountability, promoting trust in healthcare.
Manufacturers: Active monitoring and reporting of device performance and safety are essential responsibilities. Manufacturers' commitment to incident reporting is fundamental for detecting flaws and ensuring overall device safety.
Importers and Distributors: Facilitating information exchange and supporting investigations are key roles. Their collaboration with stakeholders helps maintain incident reporting integrity and device market safety.
Regulatory Authorities: Overseeing incident reporting regulations and enforcing compliance are central functions. Their analysis of incident data informs risk assessment and regulatory actions, contributing to public health protection.
National Competent Authorities: Coordination of incident reporting activities ensures proper management and analysis. Their role in disseminating safety alerts and promoting compliance is critical for maintaining effective reporting systems.
Healthcare Facilities: Implementing incident reporting processes and fostering a safety culture are essential. Their collaboration accelerates incident investigation and prevention efforts, enhancing patient safety and regulatory compliance.

Table 3.5 presents key stakeholders identified in the incident reporting system. Each stakeholder plays a vital role in contributing to overall patient safety and regulatory compliance.

3.2.3 Definitions and terminology in incident reporting

Clear and consistent definitions and terminology are considered necessary for effective incident reporting. During the first workshop 28 key definitions were established (Appendix 7).

3.2.4 Incident reporting and investigation processes

During the second workshop, the expert panel assessed the SOPs, guidelines and templates developed. The procedure for incident report management was split into two parts. A SOP was developed for each part. Appendix 8 - SOP-002.00 *The Process of Receiving and Initiating a Medical Device Incident Report and* Appendix 9 - SOP-003.00 *Management of Incident Reports Related to Medical Devices.*

SOP-002 and SOP-003 were validated by the expert group using a questionnaire (Appendix 12). The tabulated results are shown in Table 3.6.

Table 3.6 Results of standard operating procedure validation questionnaire

		Score (1-5)						
Code	**Statement**	**Expert 1**	**Expert 2**	**Expert 3**	**Expert 4**	**Expert 5**	**Expert 6**	**Average**
1.1	Completeness: Is the process for receiving incident reports clearly defined in the SOP documents?	3	4	3	5	4	3	3.7
1.2	Completeness: Are all relevant roles and responsibilities outlined adequately in the documents?	4	3	4	5	3	4	3.8
1.3	Completeness: Does the SOP cover incident reports for both medical devices and in-vitro diagnostic medical devices comprehensively?	3	4	3	4	5	4	3.8
2.1	Accuracy: Are the definitions provided in the SOP consistent with relevant European and national legislation?	4	5	3	4	5	3	4.0
2.2	Accuracy: Are the details provided about the incident classification and risk management tool consistent with the actual implementation and industry best practices?	5	4	3	5	4	3	4.0
2.3	Accuracy: Are the references to applicable regulations, such as EU Regulations 2017/746 and 2017/745, correct and up to date?	4	3	4	5	3	4	3.8
3.1	Clarity: Is the language used in the SOP easy to understand for individuals with varying levels of expertise in the subject matter?	4	5	3	4	5	4	4.2
3.2	Clarity: Are there clear distinctions made between different types of incidents?	5	3	4	5	3	4	4.0
3.3	Clarity: Is the procedure for classifying incident reports through a risk management tool presented in a straightforward manner?	4	5	4	3	5	4	4.2
4.1	Consistency: Are there any conflicting instructions or information within the SOP documents?	4	5	3	4	5	3	4.0
4.2	Consistency: Does the SOP maintain consistency in terminology and definitions throughout the document?	5	4	3	5	4	3	4.0
4.3	Consistency: Is there alignment between the roles and responsibilities outlined in the SOP and those mentioned in related documents or regulations?	4	3	4	5	3	4	3.8

5.1	Accessibility: Are the documents formatted in a way that facilitates easy navigation and readability?	4	5	4	3	5	4	4.2
5.2	Accessibility: Is there a clear table of contents or index for quick reference?	5	3	4	5	3	4	4.0
5.3	Accessibility: Are important sections, such as the procedure for incident report receipt, prominently highlighted for accessibility?	4	5	3	4	5	3	4.0
6.1	Data Reliability: Does the SOP specify how data reliability is ensured during the incident report process?	4	3	4	5	3	4	3.8
6.2	Data Reliability: Are there provisions for validating the accuracy and reliability of data collected during the incident report assessment?	5	4	3	5	4	3	4.0
6.3	Data Reliability: Does the SOP address the steps taken to maintain data integrity and prevent tampering throughout the incident report management process?	4	3	4	5	3	4	3.8

Table 3.6 shows the results of the 18 questions asked during the SOP validation questionnaire. The results are scored on a scale of 1-5.

Two forms for reporting incidents were developed. One for healthcare professionals, and the other for the general public.

Incident report form for healthcare professionals:

The healthcare professional form (Appendix 10) includes fields for documenting device-specific information like the device name, model, serial number, and any clinical implications associated with the incident. The form allowed for detailed incident descriptions, allowing healthcare professionals to provide detailed accounts of events, potential contributing factors, and their professional opinions on the incident.

Incident report form for general public:

The form for the general public (Appendix 11) was designed to be simple and easy to use, with no complex technical jargon or medical terminology. The form included sections for basic incident details, event descriptions, and any observed consequences or effects.

The developed incident forms were validated by the expert group using a questionnaire (Appendix 13). The results were compiled (Table 3.9), positive remarks and suggestions for improvement made by the expert panel were also recorded (Table 3.7 and Table 3.8).

Table 3.7 Positive remarks by expert panel

Positive Remarks
The form captured the most important aspects, ensuring detailed data collection for incident reporting.
The instructions were simple to follow and understand, making it accessible for medical professionals to complete the form correctly and efficiently.
The form ensured consistency in capturing incident details across different reporting instances, promoting uniformity in data collection.
It was easily accessible to healthcare professionals, facilitating straightforward reporting.
The form was reliable in capturing accurate and complete incident data, with safeguards in place to reduce data entry errors or omissions.
It served its purpose well in facilitating the structured collection of incident information, aiding in the analysis and response to reported incidents.

Table 3.7 showcases the positive remarks put forard by the expert panel.

Table 3.8 Suggestions for improvement and amendment by expert panel

Suggestions for Improvement	Amendments Made
The form could have benefited from additional fields to capture device usage context, providing more insights into the conditions under which incidents occurred.	In the final IR form, Section B2 "Device Details" was expanded to include fields for "Functional Use of Product" and "Was the device used in combination with other medical devices?"
There was room for improvement in terms of capturing precise device-related data, which could have enhanced the specificity and utility of the reports for regulatory and safety analysis purposes.	The enhanced IR form introduced specific fields under "B2. Device Details" such as "Product Code/ Reference (Ref)" and "Batch/Lot Number."
Its distribution and availability could have been improved to ensure that it reached all potential users in a timely and efficient manner.	To improve accessibility, the organisation implemented a digital version of the IR form, available through the hospital's internal network. This ensured that healthcare professionals could easily access and submit incident reports, significantly improving the form's distribution and availability.
Incorporating a section for capturing additional supporting documentation, such as images or attachments, would have enhanced the form's utility by allowing for more detailed incident documentation.	The digital version of the revised IR form under "B2. Device Details" was enhanced to include the capability for users to attach documents and images directly to the form.

Table 3.8 lists suggestions for improving the incident report form provided by the expert panel. The amendments made are also included.

Table 3.9 Results of incident report validation questionnaire

		Score (1-5)						
Code	**Statement**	**Expert 1**	**Expert 2**	**Expert 3**	**Expert 4**	**Expert 5**	**Expert 6**	**Average**
1.1	Completeness: How would you rate the form's comprehensiveness in capturing all relevant aspects?	4	4	4	5	3	4	4.0
1.2	Completeness: Is the form comprehensive in capturing device details?	5	4	4	5	4	3	4.2
1.3	Completeness: Does the form provide an adequate section for describing the incident in detail?	4	4	5	5	4	3	4.2
2.1	Accuracy: Please rate the accuracy and specificity of the information fields provided in the form.	5	3	4	5	4	3	4.0
2.2	Accuracy: How well does the form align with data protection regulations and guidelines?	3	4	4	3	3	4	3.5
2.3	Accuracy: Is the form clear in terms of ensuring confidentiality of the reporter's information?	4	4	4	4	4	3	3.8
2.4	Accuracy: Does the form capture accurate and reliable information regarding the seriousness of the incident?	4	4	4	5	4	3	4.0
3.1	Clarity: How would you rate the clarity and comprehensibility of the form's instructions?	4	4	5	4	4	4	4.2
3.2	Clarity: Are the form sections organised and structured in a logical and intuitive manner?	4	4	5	4	4	4	4.2
3.3	Clarity: Is the language used in the form easily understandable by healthcare professionals?	3	4	5	4	4	4	4.0
4.1	Consistency: How well does the form ensure consistency in capturing incident details?	5	3	5	5	4	3	4.2
4.2	Consistency: Is the form consistent in its approach to capturing incidents involving multiple medical devices or products?	5	4	5	5	4	3	4.3
4.3	Consistency: Does the form provide consistent guidelines for reporting incidents of varying severity?	4	4	4	5	4	3	4.0

4.4	Consistency: Is there consistency in the terminology and format used throughout the form?	4	4	4	5	4	3	4.0
5.1	Accessibility: Please rate the overall usefulness of the form for reporting medical device incidents.	3	4	4	3	4	3	3.5
5.2	Accessibility: Is the form easily accessible to healthcare professionals in terms of availability and distribution?	4	3	4	4	4	4	3.8
5.3	Accessibility: How well does the form cater to the needs of healthcare professionals with varying levels of technical expertise?	4	4	4	3	4	3	3.7
6.1	Data Reliability: Please rate the overall satisfaction with the medical device incident report form.	4	4	4	5	4	3	4.0
6.2	Data Reliability: How reliable is the form in capturing accurate and complete incident data?	4	4	4	5	4	3	4.0
6.3	Data Reliability: Does the form provide mechanisms to minimise data entry errors or omissions?	4	4	4	4	4	3	3.8
6.4	Data Reliability: Are there provisions in place to ensure the consistency and integrity of the collected data?	4	4	4	5	4	3	4.0

Table 3.9 shows the results of the 21 questions asked during the incident report validation questionnaire. The results are scored on a scale of 1-5.

3.2.5 Pilot Implementation

Following the validation of the developed documents, a pilot implementation study was undertaken. The developed training programme was delivered to staff at Mater Dei Hospital and the Malta Medicines Authority. The training programme (Appendix 14) covered their roles and responsibilities in identifying, reporting, and investigating medical device incident reports.

The training programme was held over multiple sessions with an approximate total duration of 10 hours. This timeframe allowed for in-depth discussion of critical issues while minimising disturbance to normal activities. The training content was documented (Table 3.10). Participants included clinical staff, quality and safety personnel, risk managers and MMA staff.

Table 3.10 Topics of the training program for the incident reporting pilot

Training Topic	Training Content
Introduction to Incident Reporting	Described the significance of incident reporting in ensuring patient safety Provided an understanding of the legal and ethical responsibilities that come with incident reporting
Legal and Regulatory Compliance	Overview of applicable legislation and rules governing incident reporting Ensuring national and international reporting criteria are met.
Roles and Responsibilities	Detailed description of the roles and duties of various incident reporting stakeholders Recognised the importance of each position in the event management process
Medical Device Identification	Instruction on how to correctly identify medical devices involved in events Recognised the significance of documenting device characteristics such as type, model, and serial number
Incident Details and Adverse Events	Detailed coverage of documenting event facts, such as date, location, and incident type Gave information on recognising and reporting adverse events, patient harm, and related problems
Root Cause Analysis	Methods for determining the root causes of occurrences Provided information on contributing elements and underlying circumstances that contribute to events
Corrective and Preventive Actions	Detailed procedures for putting corrective and preventive measures in place Identified the steps performed in response to reported events
System Navigation	Hands-on instruction on how to use the incident reporting system Practice sessions to help participants become acquainted with the data entry and submission processes

Table 3.10 outlines the training program topics for the medical device incident reporting pilot. It covers aspects such as the significance of incident reporting, legal and regulatory compliance and root cause analysis. Training content includes theoretical understanding and practical application exercises.

During the pilot study, medical device incident reports were collected using the developed incident report forms. Any incidents received were anonymised for the purpose of the study and no patient or case details were divulged to the researcher. The number of incident reports collected can be seen in Figure 3.3 and Figure 3.4. The data presented includes retrospective data prior to implementation and reports received following implementation. The pilot was launched in March 2022. Statistics from 2024 were omitted in order to only provide statistics spanning an entire year for ease of comparison. Between January and March 2024, 75 incident reports were received.

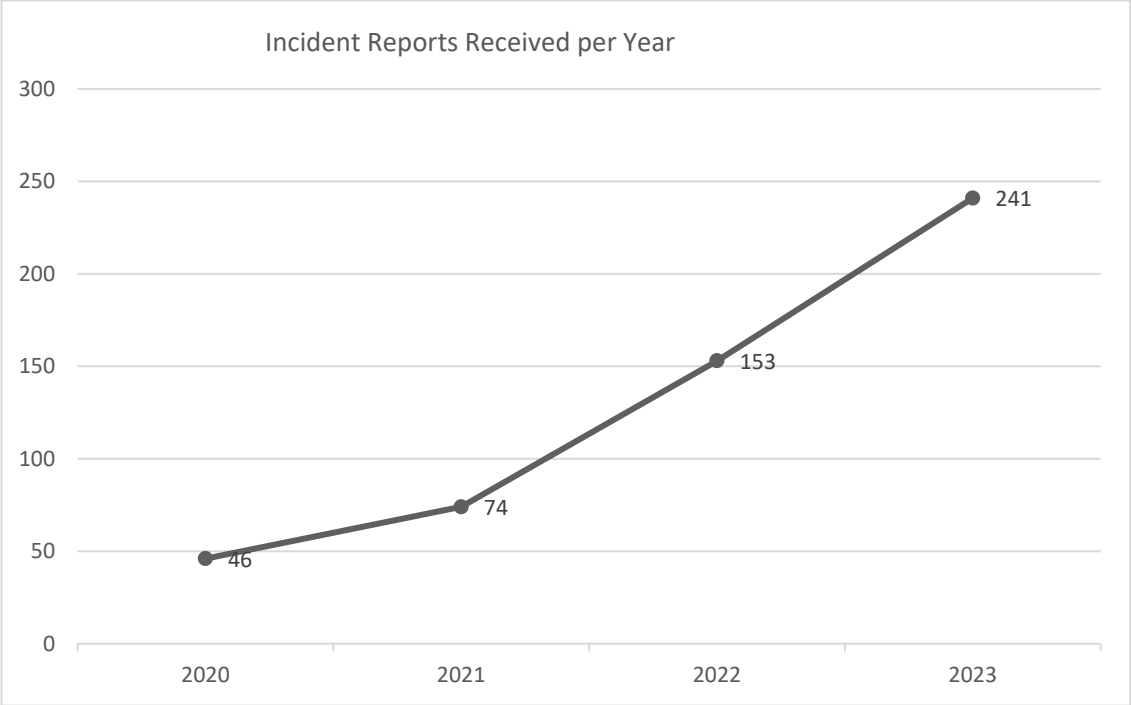

Figure 3.3 Incident reports received per year from 2020 to 2023

Figure 3.3 shows a significant upward trend in the number of incident reports received per year after the implementation of the pilot project in March 2022.

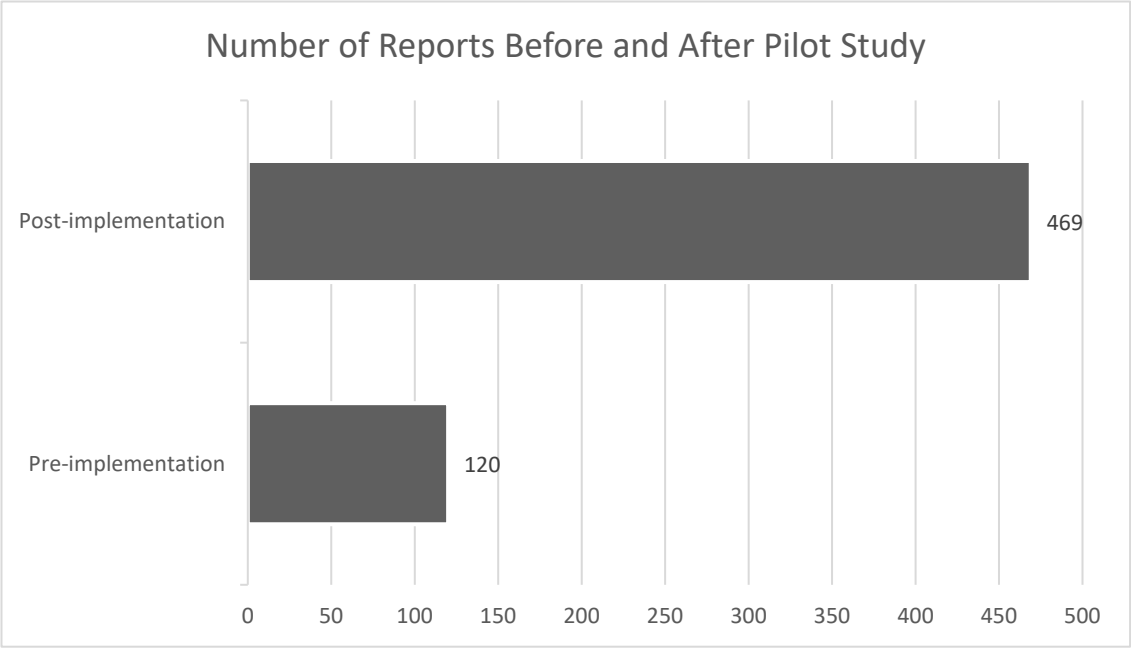

Figure 3.4 Incident reports received prior and post system implementation

Figure 3.4 shows the number of incident reports received prior to implementation in March 2022 and those after implementation up to March 2024.

3.2.6 Data collection of pilot implementation

Following the one-month implementation, an *Incident Report Pilot Study Evaluation Questionnaire* (Appendix 15) was circulated to the users of the system. A total of 28 participants from MDH completed the questionnaire. The results were collated (Table 3.11).

Table 3.11 Results of incident report pilot study evaluation questionnaire

Participant	Completion Time	Ease of Completion	Error Rates	Data Accuracy	Section Completion Rates	Ease of Accessibility	User Feedback Score	Rate of Submission
1	4	5	2	4	4	5	4	5
2	3	4	3	4	3	4	3	4
3	5	5	1	5	5	5	5	5
4	2	3	4	3	2	3	4	3
5	4	4	2	4	4	4	4	4
6	3	5	1	4	3	5	4	4
7	4	4	3	3	4	4	3	3
8	5	4	2	5	5	5	5	5
9	3	3	4	3	3	3	3	4
10	4	5	1	4	4	5	4	4
11	5	4	2	5	5	4	5	5
12	4	5	1	4	4	5	4	4
13	3	4	3	3	3	4	3	4
14	5	5	1	5	5	5	5	5
15	2	3	4	2	2	3	3	3

Participant	Completion Time	Ease of Completion	Error Rates	Data Accuracy	Section Completion Rates	Ease of Accessibility	User Feedback Score	Rate of Submission
16	4	4	2	4	4	4	4	4
17	3	5	1	3	3	5	4	4
18	4	4	3	4	4	4	4	4
19	5	5	1	5	5	5	5	5
20	3	3	4	3	3	3	3	4
21	4	4	2	4	4	4	4	4
22	5	5	1	5	5	5	5	5
23	4	4	3	4	4	4	4	4
24	3	5	1	3	3	5	4	4
25	4	4	2	4	4	4	4	4
26	2	3	4	2	2	3	4	3
27	5	5	1	5	5	5	5	5
28	4	4	3	4	4	4	4	4
Average	3.8	4.2	2.2	3.9	3.8	4.3	4.0	4.1

Table 3.11 containes the results of the *Incident Report Pilot Study Evaluation Questionnaire*. The average scores indicate generally positive feedback across all metrics, with average scores ranging from 3.8 to 4.3 out of 5.

3.2.7 Audit and review plan

Following the successful completion of the pilot study, the system was transitioned from a limited testing period of one-month to an ongoing operation. Data collected at monthly intervals until March 2024 led to a larger sample pool and, as a result of the longer observation time, a richer dataset for a more refined and thorough quantitative analysis.

An audit and review plan were established (Table 3.12). The audits were planned to identify potential areas for improvement, examining processes and functionalities for inefficiencies or bottlenecks that could impede the system's peak performance.

Table 3.12 Audit and review plan

Component	Objective	Frequency	Methodology	Expected Outcomes
Audit	Identify potential areas for improvement within the incident reporting system, enhancing functionality and efficiency	Semi-annual or quarterly	Thorough examination of processes, data collection, and user interactions. Interviews with stakeholders, assessment of data accuracy, and analysis of system metrics	Actionable insights for targeted improvements, streamlined processes, enhanced user experience, and compliance with best practices.
Policy and Procedure Review	Ensure ongoing compliance and conformity with the latest standards and regulations	Annual or bi-annual	Examination of existing policies and procedures in light of updated standards, regulations, and industry best practices. Consultations with legal experts and industry specialists may be included	Updated policies and procedures reflecting the latest standards, ensuring compliance and alignment with the dynamic healthcare environment.

Table 3.12 presents the audit and review plan aimed at improving the incident reporting system and ensuring compliance. Audits, involve thorough process examinations and stakeholder interviews to provide actionable insights. Policy and procedure reviews, ensure alignment with updated standards and regulations, resulting in updated documentation reflecting industry best practices.

3.3 Phase 3: Medical Devices Management System

The results pertaining to the establishment of the Medical Device Management System (MDMS) are presented in this section in the form of a *Project Charter*, user stories and process flows and user acceptance testing.

Table 3.13 Roles and responsibilities of parties participating in phase 3

Parties	Role	Responsibility
Researcher	Design and study of MDMS	Establishing the *Project Charter* Validating the user stories and process flows Developing user acceptance testing and test plan
Expert Panel	Provide expertise, advise and knowledge on the subject matter	Validating the user stories and process flows Developing user acceptance testing and test plan
3rd Party Contractor	Providing technical knowledge and feedback	Compiling the user stories based on the *Project Charter* and process flows provided

Table 3.13 outlines the roles and responsibilities of parties in Phase 3.

3.3.1 Project charter

The expert panel were presented with a series of questions (Appendix 16) over the course of 16 sessions. The following section expands on the workshop responses and themes. A table summarising the below information can be found in Appendix 18. The *Project Charter* was compiled following the questionnaire results (Appendix 17).

Introduction and Context:

Primary Challenges: The expert panel stressed the growing challenge of medical device information management. The integration challenges involved in managing varied medical device data emerged as a recurring subject, emphasising the importance of having a system that can manage a wide range of information types seamlessly.

Regulatory impact: Experts highlighted that, while European legislation established a strong foundation, nuanced implementation is critical. The requirement for a system that can navigate and align with varied regulatory landscapes emerged as an important theme. The need for adaptability to comply with changing regulatory requirements was again emphasised, underlining the need for a versatile MDMS.

Feasibility Studies and Compliance:

Technological Challenges: The expert group expressed concerns regarding existing systems' interoperability with the new MDMS. The focus on seamless integration with existing technologies emerged as a key issue, expressing the relevance of ensuring that the MDMS is compatible with the existing technological environment.

Another significant issue was ensuring data security and privacy in a digital context. The panel's recognition of the necessity for strict security policies to preserve sensitive medical device information came with the topic of emphasising robust cybersecurity safeguards.

Legal Compliance: In terms of legal compliance, the expert panel emphasised strict compliance with European data protection legislation. This theme addressed the importance of legal compliance in system design, suggesting a dedication to designing an

MDMS that meets the highest data protection requirements. The significance of clear documentation and audit trails emerged as a theme, emphasising the requirement of continual legal monitoring and updates to ensure continued compliance.

Stakeholder Engagement:

Key Stakeholders: The panel defined major stakeholders in the medical device area as regulatory authorities, healthcare providers, manufacturers, and the other economic operators as defined in the MDR, and the general public. Each stakeholder group was recognised to have distinct expectations and concerns.

Expectations from MDMS: The expert panel outlined the MDMS expectations of various stakeholder groups. Regulatory organisations, for example, anticipate sophisticated reporting and compliance tools. The theme of adapting features to satisfy varied stakeholder needs was identified. The topic of developing transparent communication channels was essential for manufacturers, showing a focus on fostering open and clear communication between the MDMS and manufacturers.

Resource Allocation:

Human and Technological Assets: The expert panel identified skilled personnel in medical device regulation and database management as essential human assets. The issue of identifying important skill sets for MDMS development emphasised the need for having a team with broad experience to solve the system's multiple difficulties. A strong technology infrastructure for data processing and storage was identified as an important technological asset. The issue of balancing human and technological resources

highlighted the importance of a harmonic integration of these elements to support the MDMS's effective development.

Financial Considerations: System development, maintenance, and update costs were identified as a crucial part of resource allocation. The issue of financial sustainability throughout the MDMS lifecycle implied a strategic approach to ensuring the system's longevity and performance.

Collaborative Approach:

Collaboration with Existing Systems: The need for a seamless connection with existing healthcare databases was emphasised by the expert panel. Prioritising interoperability to improve the overall healthcare ecosystem's efficiency demonstrated a commitment to developing an MDMS that interfaces seamlessly with the larger healthcare infrastructure. Another concern was ensuring that data sharing protocols adhered to industry standards.

Iterative Approaches: Regular reviews and adaptations based on stakeholder feedback emerged as a key theme. The emphasis on an iterative methodology for continuous improvement represented a commitment to improving the MDMS in response to real-world feedback and changing requirements.

Database Architecture:

Designing for Scalability: The theme of scalability as a cornerstone for long-term success emphasised the need for designing a system that can manage expanding data volumes and changing requirements efficiently. The value of cloud-based solutions for accommodating rising datasets was noted.

Actor Registration:

Information and Functionalities: For accurate attribution, the expert group advised full actor profiles. A common subject was ensuring the completeness and accuracy of actor profiles, emphasising the need for gathering extensive and exact information about the actors participating in the medical device domain.

Integration with national identity systems was also emphasised for verification. The theme of reducing the possibility of duplicate or erroneous data shows a dedication to data accuracy and integrity.

Ensuring Accuracy: Regular validation checks for actor information emerged as a theme. Continuous data correctness monitoring and automatic reminders for changing registration details represented a proactive approach to keeping the actor registration module's information accurate and up to date.

Notification Management:

Critical Processes and Workflows: The expert panel emphasised efficient incident reporting protocols. The issue of prioritising efficiency in incident reporting emphasised the significance of building mechanisms that enable speedy and effective event reporting.

It was agreed that automated mechanisms for notifying relevant parties were required. The issue of timely communication as a crucial feature of notification management emphasised the significance of swiftly informing appropriate parties in response to incidents.

Regulatory Compliance: It was essential to adhere to specific regulatory timelines. The issue of harmonising notification management with regulatory requirements emphasised

the need for meeting legal duties when reporting incidents. Integration with regulatory organisations for faster processes appeared as a theme, indicating a dedication to collaborative compliance with regulatory authorities.

Vigilance and Surveillance:

Ticketing System Structure: For incident severity, the expert group advised hierarchical ticketing. The importance of structuring vigilance systems for successful incident response was emphasised, as was the requirement for a methodical approach to addressing incidents based on their severity. Ticketing enabled a complete surveillance system, indicating a strategic focus on establishing a system that delivers a unified and complete view of incidents.

Critical Metrics and Indicators: Monitoring incident resolution times was identified as a key performance indicator. The theme of metrics as indicators of system success reinforced the significance of assessing the overall performance and efficiency of the monitoring system using measurable data points. A theme emerged: tracking the recurrence of specific incident categories, indicating an emphasis on detecting patterns and trends for ongoing development.

Public Website and Communication:

Accessible Information: The expert group suggested that transparency through open communication with the public and other stakeholders was a central theme, showing the dedication to open communication with the public and other stakeholders. The concept of using the website as a medium for regulatory communication recognised the

significance of the public website in quickly communicating critical information to stakeholders.

Stakeholder Engagement: The importance of feedback channels for public participation was recognised. An identified general trend, suggesting a commitment to involving the public in decision-making processes was identified. Educational resources for understanding regulatory procedures were chosen as a manner of creating the website as a two-way communication channel, delivering essential information and encouraging stakeholder knowledge.

User Account Management:

The importance of role-based access for various user categories was emphasised. The importance of personalising user access to ensure that individuals have the proper level of access for their positions emerged as a significant theme. Granular control over sensitive data access was deemed necessary. The importance of ensuring a need-based approach to user permissions emphasised the significance of matching access levels to specific job tasks.

Authentication and Authorisation Protocols: A key proposal was two-factor authentication for increased security. A trend that arose was regular audits of user accounts for compliance, suggesting a commitment to continued oversight for secure user management.

Invoicing and Payment:

Billing and Invoicing Processes: For greater transparency, the expert panel advised itemised charging. Transparency as a guiding concept in financial operations emerged as

a theme, demonstrating a dedication to openness and clarity in regulating financial transactions. The importance of automated invoicing for effective financial operations was recognised. The issue of simplifying financial transactions for regulatory operations emphasised the need for building methods that improve financial transaction efficiency and accuracy.

Integration with safe online payment channels was highlighted in the online payment structures. Aligning with current online payment practices surfaced as a theme, showing a commitment to using current and secure online payment methods.

The replies and themes uncovered during the workshops provided a firm foundation for the MDMS's further stages of development. The expert panel's strategic views, collaborative efforts, and thorough considerations gave useful direction for building the digital system. The *Project Charter* in Appendix 17 served as the groundwork for the MDMS's effective implementation. The expert panel's recommended iterative and adaptive strategy ensured that the system remained resilient and adaptable to the changing landscape of medical device management. The information gathered was used to guide the MDMS's development and refinement, aligning it with the highest standards of efficiency, compliance, and stakeholder involvement.

3.3.2 User stories, process flows, user acceptance testing and test plan

As illustrated in Figure 3.5, a review of 864 user stories was conducted across three assessment sessions. In the initial session, 526 out of the total user stories were approved, leaving 338 needing further clarification. After addressing these clarifications, a second

evaluation approved an additional 299 user stories, while 39 still required further explanation. The third evaluation approved a final 22 user stories. During this review process, 17 user stories were discovered to be either duplicates or redundant and were subsequently removed. This resulted in a final set of 847 approved user stories (Appendix 19).

The process flows linked to these user stories underwent the same validation procedure. Changes and clarifications to the user stories were directly integrated into the corresponding process flows (Appendix 20).

The MDMS test plan and User Acceptance Testing (UAT) execution plan were compiled (Appendix 21).

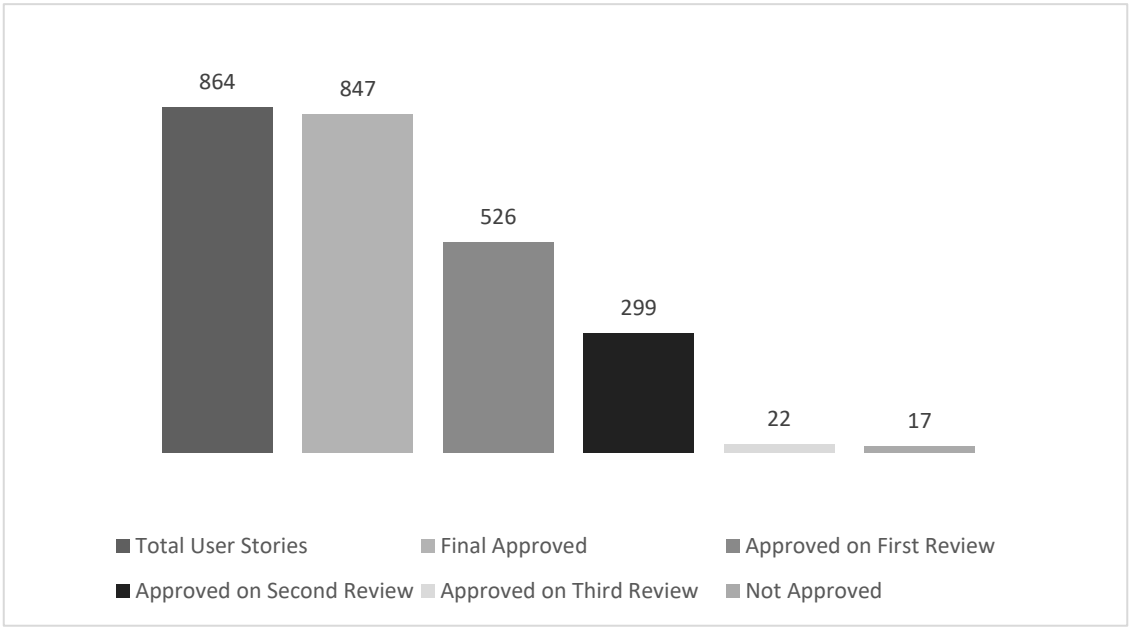

Figure 3.5 Breakdown of validation of user stories

Figure 3.5 shows the validation of user stories approved over the course of three assessments.

3.4 Phase 4: Continuous professional development training

The results for the internal and external training needs identified are presented in this section.

3.4.1 Internal Training

To capture employees' training needs across various skill areas pertinent to their roles within the medical device sector, a questionnaire was developed (Appendix 22). The questionnaire captures the employees' professional competencies, areas for improvement, training preferences, and logistical considerations within the organisation. Following its development, the questionnaire underwent a validation process. The validation was done through a questionnaire that was presented to the expert panel (Appendix 24). The results from the validation questionnaire were collated (Table 3.14).

The validated questionnaire was then disseminated to a group of 12 employees within the medical device unit. The results (Table 3.15) were collated, and the common themes were identified (Table 3.16), highlighting places where employees felt confident and areas where they needed to improve. Employees reported a strong desire for advanced training on issues such as notified bodies and certificates, and they preferred webinar-based training sessions.

Table 3.14 Validation of *Employee Skills and Training Needs* questionnaire

	Score (1-5)			
Question	**1**	**2**	**3**	**Average**
Section 1: Current Skill Levels				
1.1. The questions effectively assess the proficiency of employees in technical knowledge.	4	3	5	4.0
1.2. The questions effectively assess the proficiency of employees in communication skills.	5	4	4	4.3
1.3. The questions effectively assess the proficiency of employees in problem-solving.	3	2	5	3.3
1.4. The questions effectively assess the proficiency of employees in team collaboration.	4	3	5	4.0
1.5. The questions effectively assess the proficiency of employees in project management.	5	4	4	4.3
Section 2: Areas for Improvement				
2.1. The open-ended questions allow employees to express specific areas where they feel they need improvement.	4	3	5	4.0
2.2. The open-ended questions effectively prompt employees to identify challenges or obstacles in their roles that additional training could address.	5	4	5	4.7
Section 3: Training Preferences				
3.1. The open-ended question allows employees to list specific topics or skills they would like to receive training on.	5	4	5	4.7
3.2. The multiple-choice question effectively captures diverse preferences for training delivery methods.	4	3	5	4.0
Overall Impression:				
Please provide an overall assessment of the questionnaire's effectiveness in capturing employee skills and training needs.	5	3	4	4.0
Demographic Information:				
How confident are you in the questionnaire's ability to effectively capture employee skills and training needs?	3	4	5	4.0

Table 3.14 presents the validation results of the Employee Skills and Training Needs Assessment questionnaire. Participants rated the effectiveness of the questionnaire items on a scale of 1 to 5, with 5 being the highest.

Table 3.15 Results of *Employee Skills and Training Needs* questionnaire

	Score (1-5)												
Participant	1	2	3	4	5	6	7	8	9	10	11	12	Average
Technical Knowledge	4	5	3	4	3	4	5	3	4	3	4	5	3.9
Communication Skills	3	4	5	4	5	3	4	5	3	4	5	4	4.1
Problem-Solving	4	4	4	3	4	5	4	4	4	5	4	4	4.1
Team Collaboration	5	4	4	5	4	4	5	3	5	4	4	5	4.3
Project Management	3	3	3	3	2	3	3	3	4	3	3	3	3.0
Economic Operators	3	4	2	3	2	3	4	2	4	3	3	4	3.1
Device Registration	4	5	3	4	3	4	5	3	4	4	4	5	4.0
Notified Bodies	2	3	3	3	4	4	3	4	3	4	4	3	3.3
Clinical Investigations	3	4	4	4	4	5	4	4	5	5	4	4	4.2
Vigilance	4	4	3	4	3	3	4	4	3	4	4	4	3.7
Market Surveillance	3	3	4	4	3	4	4	3	4	3	4	4	3.6
Unique Device Identifier	2	3	2	3	2	3	3	2	3	3	3	3	2.7

Table 3.15 presents the results of the *Employee Skills and Training Needs Assessment* questionnaire. Twelve participants rated their skills from 1 to 5 across various categories. The average scores indicate the perceived proficiency in each skill area.

Table 3.16 Common themes identified

Areas for Improvement	Challenges in Current Role	Training Preferences	Frequency and Time Slot	Additional Comments
Including notified bodies and certificates, unique device identifiers, project management, communication skills, technical knowledge, team collaboration, economic operators and actors and market surveillance.	Navigating complex regulatory processes efficiently, streamlining communication with notified bodies, managing clinical trials and improving communication with economic operators.	Webinars/ online courses workshops and on-the-job training.	Varied preferences, including weekday mornings, evenings, anytime during the workday, late afternoons and flexible schedules.	Expressing gratitude for the emphasis on professional development, the desire to actively contribute, the anticipation of skill enhancement, gratitude for the provided opportunity and genuine excitement about the organisation's commitment to ongoing professional development.

Table 3.16 summarises common themes from open-ended questions of the *Employee Skills and Training Needs Assessment* questionnaire. Participants expressed desire for professional development opportunities and excitement about skill enhancement.

Based on the feedback gathered from the Employee Skills and Training Needs Assessment questionnaire, an internal training curriculum was developed (Appendix 25).

3.4.2 External training

To assess the training requirements of external stakeholders within the medical device sector, focus groups were held for healthcare professionals, regulatory organisations, distributors and suppliers. Questions for each stakeholder group were developed and documented in Appendix 23. After establishing the questions, a validation process was conducted through an expert panel. The validation questionnaire is detailed in Appendix 24. The outcomes from the validation process are recorded in Table 3.17.

Following validation focus groups were held with nine participant stakeholders, three from each stakeholder group. The collated responses were analysed, the results compiled (Table 3.18) and the themes summarised (Table 3.19). A curriculum was developed for external stakeholder training (Appendix 26).

Table 3.17 Validation of external training questions

	Score (1-5)			
Participant	1	2	3	Average
On a scale of 1 to 5 (1 being unclear, 5 being very clear), how clear are the questions for healthcare professionals?	4	5	3	4
Do you find the questions relevant to the challenges and responsibilities faced by healthcare professionals in complying with the MDR? Please provide specific comments.	Yes, the questions are relevant and clear. They address the challenges we face well.	The questions are clear and relevant, capturing the critical challenges faced by regulatory bodies.	The questions are somewhat clear, but some could be more specific to our industry context.	Yes, the questions are relevant and clear. They address the challenges we face well.
Are there any additional topics or aspects related to external training for healthcare professionals that you believe should be included? Please specify.	The questions cover the necessary topics but adding a section on technology integration in healthcare would be beneficial.	No additional topics are needed; the questions cover all necessary aspects.	Additional topics related to supply chain logistics and digital platforms could be included.	The questions cover the necessary topics but adding a section on technology integration in healthcare would be beneficial.
How would you rate the clarity of the questions designed for regulatory bodies on a scale of 1 to 5?	5	4	4	5
In your opinion, are the questions aligned with the critical regulatory challenges faced by organisations in complying with the MDR? Share your insights.	The questions are well-aligned with the regulatory challenges we encounter.	The questions are well-aligned with the regulatory challenges. Adding a subsection on international collaboration could enhance them.	The questions are aligned with the key challenges but adding a section on global distribution challenges would be beneficial.	The questions are well-aligned with the regulatory challenges we encounter.
Do you believe any essential aspects related to external training for regulatory bodies are missing from	The questions are comprehensive, but inclusion of real-	The questions are comprehensive; no	The questions cover the essentials but including a subsection on adapting	The questions are comprehensive, but inclusion of real-world

the questions? If yes, please elaborate.	world case studies would enhance their effectiveness.	essential aspects are missing.	to digital platforms would enhance them.	case studies would enhance their effectiveness.
Evaluate the clarity of the questions for distributors and suppliers on a scale of 1 to 5.	3	4	3	3
Are the questions addressing the key challenges and responsibilities that distributors and suppliers encounter regarding MDR compliance? Provide detailed feedback.	The questions adequately address challenges, but more focus on supplier relationships would be helpful.	The questions effectively address challenges. Consider adding a question on evaluating the impact of training programs.	The questions are good, but more focus on the challenges of small-scale distributors would be helpful.	The questions adequately address challenges, but more focus on supplier relationships would be helpful.
Suggest any additional themes or topics that you think should be covered in the external training questions for distributors and suppliers.	Consider including a section on practical tools for maintaining compliance in the supply chain.	Including a section on emerging trends in the medical device industry could be beneficial.	Consider adding a section on supply chain digitization and cybersecurity.	Consider including a section on practical tools for maintaining compliance in the supply chain.
Overall, how effective do you believe the external training questions are in capturing the essential insights and perspectives of the respective stakeholder groups?	Very Effective	Extremely Effective	Moderately Effective	Very Effective
Please provide any additional comments or suggestions to enhance the external training questions.	The questions are good but including more industry-specific examples could make them even more effective.	Overall, the questions are excellent, and no major changes are necessary.	The questions are decent but refining them to be more industry-specific would increase their effectiveness.	The questions are good but including more industry-specific examples could make them even more effective.

Table 3.17 presents the validation results of the of external training questions. A likert scale from 1-5 was adopted were necessary, the remaining questions were open ended to encourage discussion in the focus group format.

Table 3.18 Results of external training questions

Stakeholder Group	Answers
Healthcare Professionals	Implementing the MDR has been a multifaceted process. Challenges included ensuring medical staff were well-versed in new documentation and reporting requirements, addressed by organizing training and workshops, and adapting to increased post-market surveillance, for which we established a robust monitoring system.
	Healthcare professionals should prioritize understanding the new classification criteria and conformity assessment procedures, keeping updated on labelling and post-market surveillance obligations to align with regulatory standards and ensure patient safety.
	We stay informed through industry conferences, webinars, and reputable regulatory publications, and rely on our hospital's regulatory affairs team for timely updates and interpretations of regulatory changes.
	The MDR has impacted patient care, especially with stricter requirements for clinical evidence. This has involved a more rigorous scrutiny of device performance data and collaboration with manufacturers.
Regulatory Bodies	A critical challenge observed is the complexity of the MDR requirements, especially for smaller organisations. We support them with specialized training programs and workshops and enhance communication channels for timely reporting of adverse events.
	We assess the effectiveness of MDR training through feedback surveys and performance metrics. Improvements could include more interactive learning experiences, such as virtual simulations and case studies, and a centralized platform for sharing best practices.
	Common misconceptions are around the new classification criteria and conformity assessment processes. We address these through regular outreach sessions and have developed detailed guidance documents for navigating compliance intricacies.
Distributors and Suppliers	Ensuring our supply chain aligns with MDR requirements, we have implemented a rigorous supplier qualification process, conduct regular training sessions for suppliers, and share MDR updates through newsletters and workshops.
	Changes in the MDR, particularly in labelling and documentation, required adjustments in business operations. This involved investing in updated systems, streamlining processes, and cross-functional collaboration.
	Communicating MDR-related information is challenging due to its technical nature. We have created user-friendly guides and FAQs, held regular webinars, and had personalised communication channels, alongside a responsive customer support team for queries.

Table 3.18 presents the results of external training questions. Nine participants took part in the focus groups, three from each stakeholder group.

Table 3.19 Common themes identified for external training

Stakeholder Group	Common Themes Identified
Healthcare Professionals	- Training and education for medical staff - Adaptation to increased post-market surveillance - Establishment of robust monitoring systems - Emphasis on classification criteria and conformity assessment - Importance of staying updated on labelling and post-market surveillance - Utilization of industry conferences and webinars for updates - Collaboration with regulatory affairs teams - Importance of reputable regulatory publications - Impact on patient care related to safety and effectiveness - Stricter requirements for clinical evidence - Collaboration with manufacturers to meet regulatory standards
Regulatory Bodies	- Complexity of MDR requirements, particularly for smaller organisations - Tailored training programs and workshops - Emphasis on timely and accurate reporting of adverse events - Evaluation through feedback surveys and performance metrics - Emphasis on interactive learning experiences - Advocacy for a centralized platform for sharing best practices - Common misconceptions related to classification criteria and conformity assessment - Regular outreach sessions for clarification - Development of detailed guidance documents
Distributors and Suppliers	- Implementation of a rigorous supplier qualification process - Regular training sessions for suppliers - Ongoing education and communication of MDR updates - Influence of MDR changes on labelling and documentation requirements - Investment in updated systems and streamlined processes - Cross-functional collaboration for adaptation - Challenges in communicating technical MDR-related information - Creation of user-friendly guides and FAQs - Use of webinars and personalized communication channels - Responsive customer support for prompt query resolution

Table 3.19 summarizes common themes from open-ended questions of the *Employee Skills and Training Needs Assessment* questionnaire. Participants expressed desire for professional development opportunities and excitement about skill enhancement.

Chapter 4
Discussion

The discussion delves into the findings from the study and critical engagement with published work in the field. The conclusions stem from comprehensive research, engagement with stakeholders, and iterative development aimed at achieving operational excellence, enhancing patient safety, and spurring innovation.

4.1 Discussion of findings

The following section describes the analysis and interpretation of the results obtained from the study. It addresses the development and implementation of a quality management system (QMS), the analysis and enhancement of incident reporting functionalities, the planning and setup of a digital medical device management system (MDMS), and the identification and provision of necessary training and continuous professional development for stakeholders within the medical device field.

Collectively the objectives emphasise the importance of an integrated approach to medical device management—one that is compliant with current regulatory standards, and also robust and adaptive to future change. The conclusions presented here are the result of thorough study, stakeholder involvement, and iterative development procedures focused at obtaining operational excellence, improving patient safety, and encouraging innovation in the medical device sector.

1. Establishing the core framework for a medical device quality management system

Phase 1 begins with the conceptualisation of a QMS framework (Figure 2.4), deeply rooted in the principles of ISO 13485:2016[17] and ISO 9001:2015[18] standards. These standards highlight the importance of risk management, customer satisfaction, and the continuous improvement ethos in the quality management scope. Drawing inspiration from the procedural framework flow model developed by Pinheiro de Lima et al. (2015), the study embarked on defining strategic objectives that would comply with regulatory demands and also prioritise patient safety and product quality. The model's emphasis on translating strategic visions into performance indicators and action plans serves as a foundational pillar in crafting a robust QMS framework.

Engagement with an expert panel comprised of regulatory and industry professionals enabled an interactive and collaborative development process of the QMS framework. Using workshops and focus groups, the study used collective expertise to analyse the complexity of the medical device sector, following Tague's (2004) backing of stakeholder engagement in initiatives to improve quality. This collaborative effort highlighted the importance of a robust, stakeholder informed QMS approach that could withstand the ongoing medical device development and regulation.

[17] Medical devices - Quality management systems, ISO 13485:2016 [Internet]. [Cited 2024]. Available from URL: https://www.iso.org/standard/59752.html
[18] Quality management systems Requirements, ISO 9001:2015 [Internet]. [Cited 2024]. Available from URL: https://www.iso.org/standard/62085.html

The regulatory transition from the Medical Devices Directive (MDD) to the Medical Devices Regulation (MDR) presented both challenges and opportunities for the QMS framework. A gap analysis was pivotal in identifying the discrepancies between the existing QMS practices and the enhanced requirements under the MDR. The development of Key Performance Indicators (KPIs) (Table 3.3) and the establishment of a performance management system emerged as strategies in monitoring regulatory compliance and operationalising the QMS framework effectively. This strategic orientation towards performance measurement, resonates with Hristov & Chirico (2019), emphasis on the strategic value of KPIs in achieving organisational excellence.

The validation and implementation stages underscored the crucial role of documentation in ensuring the standardisation of processes and consistency within the organisation (Leotsakos et al,. 2014; Ungan, 2016). A systematic approach to document control, versioning, and validation is essential, mirroring modern perspectives on quality management systems. In line with this, the insights from "Managing Quality: An Essential Guide and Resource Gateway" by Foster (2017) emphasise the significance of maintaining accessible, accurate, and up to date QMS documentation for all stakeholders. This approach to quality management highlights the importance of documentation in establishing clear guidelines and standards, which are pivotal in promoting a culture of quality and regulatory compliance. By integrating such methodologies, the QMS framework adheres to current best practices and also sets a foundation for adaptive and responsive quality management in the rapidly evolving medical device sector.

In assessing the findings from the QMS development process, the critical analysis stage revealed potential areas for improvement, particularly in audit efficiency and the

integration of technology to streamline quality management processes. The exploration of technology-enabled audit management systems represents a forward-looking perspective on enhancing the adaptability and efficiency of the QMS framework. This acknowledgment of areas for enhancement underscores the iterative nature of quality management, where continuous improvement and responsiveness to technological advancements are paramount.

2. Development and implementation of a patient-centred incident reporting system

Starting with a needs assessment, the process highlighted the importance of aligning the incident reporting system with European Member States' standards (European Commission, 2013), revealing discrepancies in the existing Maltese system. This foundational step underscored the necessity for a robust framework that meets regulatory requirements and also addresses the specific needs and capabilities within Malta, paving the way for a system that is both harmonised across borders and tailored to local contexts.

The pilot testing stage (Section 3.2.5) at Mater Dei Hospital transitioned these theoretical frameworks into tangible results, where the real-world efficacy of the system could be gauged. The tailored training programme (Appendix 14) for diverse stakeholders emphasised the significant role of effective education in enhancing incident reporting practices. By employing interactive exercises and case studies, these programs adhered to adult learning principles (Knowles et al., 2020), ensuring engagement and a deepened understanding of complex regulatory concepts.

Evaluation of the pilot study through both quantitative and qualitative methodologies offered a rich understanding of the system's impact, signifying an encouraging increase in incident reporting and identifying avenues for refinement, particularly in system usability and accessibility. This feedback loop, essential for any healthcare system's improvement, points to the significance of user experience in fostering compliance and enhancing safety practices. These findings align with literature emphasising the importance of user-friendly reporting systems in healthcare settings (Blandford et al., 2018).

Looking ahead, the proposed transition to a digital reporting system represents the next phase of efficiency and analytical depth, matching a broader trend of digital transformation in healthcare (Kierkegaard, 2013). This change promises to improve data management skills by streamlining the reporting process, maintaining data quality, and allowing for enhanced incident analysis. The proactive establishment of an audit and review strategy illustrates an effort to continuous enhancement, ensuring that the system is responsive to new insights, technologies, and evolving regulatory landscapes (Takeda et al., 2020).

3. Develop a digital medical device management system

Phase 3, the MDMS objective sought to improve the quality, safety, and efficacy of medical devices through enhanced traceability and visibility of regulatory processes. A hybrid Agile methodology was used, balancing precise planning with the capacity to respond to changing requirements, which suited the project's complex and evolving nature.

The first stage involved discussions and workshops with an expert panel to determine the project's scope, objectives, and stakeholder needs. This collaborative method, undertaken in sixteen sessions, recognised the importance of involving various expertise in establishing a strong and adaptable framework for the MDMS. This method is in line with current project management approaches, which emphasise stakeholder participation and iterative feedback as vital to project success (Schwalbe, 2019).

The user stories reflect the project's attention to an adaptive and responsive design methodology. This is consistent with the principles of Agile methodology (Rubin, 2012), which have been widely used in complex project environments to accept changing needs and improve project outputs (Sutherland & Schwaber, 2020). User stories (Appendix 19) and process flows (Appendix 20) serve as key tools for developing the *Project Charter* (Appendix 17) into practical software functionalities.

Phase 3 concluded with the User Acceptance Testing (UAT) and implementation plan (Appendix 21). This stage assessed the system's readiness for deployment and also established protocols for ongoing monitoring, maintenance, and support. The importance of UAT in guaranteeing system dependability and user satisfaction is crucial in its role in identifying and mitigating potential issues prior to system launch (Lewis, 2014).

Looking beyond the project's lifecycle, multiple themes and findings emerge with implications for the future of medical device management systems. First, the project's hybrid Agile methodology presents a viable model for managing complex, technology-driven projects in the regulatory domain. This model offers a balance between the need for detailed planning and the flexibility to adapt to unforeseen challenges, a balance that is crucial in the rapidly evolving field of medical technology (Conforto et al., 2014).

Second, the project's emphasis on stakeholder engagement and iterative feedback underscores the significance of user-centric design in crafting systems that aptly cater to the diverse requirements of its users. Recent studies affirm this perspective, indicating that projects which prioritise user feedback and participation throughout the development process are more likely to meet or exceed stakeholder expectations and achieve higher satisfaction rates (Bano & Zowghi, 2015).

Third, the project's focus on creating a scalable and adaptable system architecture addresses a key challenge in medical device management: the need to accommodate an ever-expanding volume of data and evolving regulatory requirements. This challenge is echoed in the literature, which underscores the importance of designing systems with the flexibility to grow and adapt over time (Hassan & Bahsoon, 2016).

As the field continues to evolve, the lessons learned from this project will undoubtedly inform future initiatives aimed at enhancing the regulation and management of medical devices. Future research could explore the long-term impacts of such systems on regulatory compliance, device safety, and patient outcomes, further contributing to the body of knowledge in this domain.

4. Identify and cater for necessary training and continuous professional development

The internal training assessment highlighted a need for skill enhancement across various areas including technical knowledge, communication skills, problem-solving, team collaboration, and project management. Such findings resonate with existing literature emphasising the importance of a well-rounded skill set for professionals navigating the

complex regulatory landscape of medical devices (McDermott et al., 2022). The identification of specific training desires, notably regarding notified Bodies and certificates, mirrors the industry's call for specialised knowledge in navigating MDR complexities (Trubetskaya et al., 2022).

The approach to curriculum development, tailored to address these identified gaps, exemplifies a strategic alignment with best practices in adult learning theory, advocating for diverse instructional methods to cater to varied learning preferences (Lieser et al., 2018). This is further exemplified by the inclusion of webinar-based sessions, interactive workshops, and hands-on experiences, aiming to ensure the effective assimilation of knowledge and skills (Ebner & Gegenfurtner, 2019).

External training findings illuminate the challenges and educational needs of key stakeholders in the medical device ecosystem. The focus on healthcare professionals, regulatory organisations, and distributors and suppliers underscores the multi-stakeholder impact of MDR compliance (Shah et al., 2023). The adaptation to increased post-market surveillance and the emphasis on understanding new classification criteria and conformity assessment procedures underscore the pressing need for ongoing education and support to navigate regulatory changes (Huusko et al., 2023).

Comparatively, the literature highlights the role of continuous professional development in ensuring regulatory compliance and enhancing patient safety within the medical device sector (Rashid, 2013; Hanlon et al., 2021). This is particularly relevant in the context of MDR's stringent requirements, where the capacity to adapt and integrate new knowledge is paramount (Davis & Rayburn, 2016; Merry et al., 2023).

The combination of internal and external training assessments reveals a picture of the educational landscape within the medical device sector. The findings indicate a clear trajectory towards enhanced competency, regulatory compliance, and patient safety. The developed curricula, both internal (Appendix 25) and external (Appendix 26), address immediate skill gaps and also lay the groundwork for continuous learning and adaptation, echoing the sentiments of a dynamic and evolving regulatory environment (Kwame & Petrucka, 2021; Zaitoun et al., 2023)

4.2 Methodological critique and study limitations

The methodological approach used to establish a patient centred medical device framework incorporated a multi-phase strategy. This methodology was designed to address the complex regulatory, technical, and operational dimensions mandated by the transition to the new legislative landscape outlined by the MDR and the IVDR. While the methodology, offered a detailed examination of the necessary aspects for transitioning, it was not without limitations. These limitations were not just procedural but were linked with the rapidly changing environment of medical device regulation and technological advancements, further complicated by global factors such as the COVID-19 pandemic. Such an environment imposed a unique set of methodological challenges, impacting the study's design, execution, and the overall applicability and relevance of its findings. The limitations can be grouped under the following:

1. Rapid evolution of regulatory landscape and technological advancements
2. Impact of legislation, COVID-19 and time constraints
3. Sample size and generalisability of study findings
4. Implementation and adoption challenges.

1. Rapid evolution of regulatory landscape and technological advancements

The landscape of medical device regulation is continually evolving, the pace at which regulatory changes and technological advancements occur in the medical device sector significantly influenced the study's design, methods, and outcomes. Notably, the amendments of the MDR and the IVDR within the European Union, such as Regulation 2020/561[19] and Regulation 2023/607[20], introduced substantial updates that necessitated continuous adaptation of the study's framework. Regulation 2020/561 was published as a result of COVID-19, its main scope was to extend the date of application of the MDR by one year from 26 May 2020 to 26 May 2021. This transitional provision aimed at addressing challenges faced by manufacturers and helped facilitate a smooth transition to the new regulatory framework established by the MDR. Regulation 2023/607 introduced a further extension of the transition period of CE certificates provided for in the MDR. These legislative shifts, aimed at safeguarding patient safety and streamlining the regulatory landscape, directly impacted the study's application and applicability over time. Future legislative amendments could impact the established framework, potentially

[19] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 [Internet]. [Cited 2024]. Available from URL: http://data.europa.eu/eli/reg/2020/561/oj

[20] Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 [Internet]. [Cited 2024] Available from URL: http://data.europa.eu/eli/reg/2023/607/oj

resulting in the developed framework would not covering the latest legislative requirements.

The integration of modern technologies within medical devices, including digital health solutions, presented both opportunities and challenges. Technological progress, while offering innovative approaches to patient care and device management, required the study to employ broad methodologies that could remain applicable amidst rapid innovation (Ventola, 2014). The agility to incorporate these advancements was paramount; however, the study faced challenges in maintaining pace with these developments, impacting the findings' long-term relevance.

2. Impact of legislation, COVID-19 and time constraints

The COVID-19 pandemic has resulted in a fundamental change across various sectors, including medical research and device regulation, necessitating innovative approaches to circumvent the restrictions imposed by the crisis. The advent of COVID-19 and subsequent legislative responses, particularly Regulation 2020/561 that extended the application date of the MDR, illustrate the volatile nature of the regulatory environment and its direct effect on the study’s execution. This period of legislative flux, coupled with the global pandemic, imposed considerable time constraints, affecting sample size and data collection methods.

Adaptations made to the study design in response to these factors included pivoting to online platforms for stakeholder engagement and data collection. The transition to virtual environments for stakeholder interactions, necessitated by COVID-19, limited the reach

of the study. This digital shift potentially resulted in a compromised depth of discussion and lack of non-verbal cues inherent in face-to-face interactions, aspects that are vital for nuanced understanding and stakeholder feedback. A study by Greenhalgh et al. (2020) highlighted the effectiveness and challenges of virtual consultations in healthcare, underscoring the trade-offs between accessibility and the richness of communication. This reflects the need for future research methodologies to be designed in a way that can more effectively capture the nuances of stakeholder feedback in virtual settings, possibly through advanced virtual reality technologies or more interactive online platforms.

3.Sample size and generalisability of study findings

The study faced limitations in terms of sample cohort and generalisation of findings. The study's reliance on a limited cohort, specifically within Mater Dei Hospital and the Malta Medicines Authority, underscored challenges related to sample size and the representation of broader populations. (Alvarez et al., 2021). Geographical variation in healthcare infrastructure means that different regions or countries have unique healthcare systems, regulatory frameworks, and patient care standards. As a result, the characteristics and experiences captured in the study may not have fully captured the complexities and variations found in other healthcare settings (Levac et al., 2010).

The methodology's reliance on select panels of experts and stakeholders for consultations during the development and validation phases also potentially limited the generalisability of the findings. This limitation is particularly noticeable in areas requiring diverse input

to create universally applicable solutions, such as in the development of a patient-centred quality management system. The experiences and perspectives of a broader stakeholder group could imbue the research with a richer, more diverse set of insights, enhancing the applicability and effectiveness of the proposed frameworks (Collins & Varmus, 2015).

The pilot study conducted at Mater Dei Hospital offered insights into the practical implementation and immediate impacts of the medical device incident reporting system. However, the limitation of conducting this study at a single site may not fully represent the diverse healthcare environments, thus potentially restricting the generalisability of the findings. The promising results from the pilot study underscore the necessity of multi-site studies to assess the system's effectiveness across various settings, enhancing the robustness and applicability of research findings.

4. Implementation and adoption challenges.

The successful implementation and adoption of new frameworks and systems within the medical device sector hinge on different factors, including stakeholder engagement, regulatory approval, and the availability of resources. Resistance to change and the complexity of integrating new systems into existing workflows present significant challenges.

Operational challenges, including participant compliance and the adoption of modern technologies, significantly influenced the study outcomes. Factors such as resistance to change, technological literacy among participants, and integration of new systems into existing workflows presented hurdles that required strategic mitigation efforts (Kotter,

1995). Overcoming these challenges requires an inclusive approach that includes stakeholder education, the demonstration of value, and the provision of resources to facilitate transition. Engaging stakeholders early in the development process and maintaining open lines of communication can help mitigate resistance and foster a collaborative environment conducive to successful implementation.

While the methodological approach undertaken in this study was robust and structured, aiming to navigate through the complexities of transitioning to a new legislative framework under MDR and IVDR, it was not impervious to the dynamic and often unpredictable challenges presented by the evolving landscape of medical device regulation, technology, and global crises. The critique highlights the adaptability required to overcome these limitations, underscoring the necessity for ongoing innovation, broader replication across various settings, and the importance of iterative updates to keep pace with technological and regulatory advancements. Through acknowledging these limitations, the study contributes valuable insights into the complexities of establishing a patient centred medical device framework.

4.3 Practical implications

The project's practical implications represent substantial advances towards improving patient safety and regulatory management of medical devices. The implications range from the adoption of continuous quality improvement activities within medical device organisations to the streamlining, standardisation, and accuracy of incident reporting. The

research had led to the development of tailored training programmes to address identified knowledge and skill gaps. These initiatives reinforce the importance of an integrated approach to medical device safety, and also emphasise the role of technological advancements and educational innovations in promoting a culture of compliance and safety in the healthcare sector. Through these practical implications, the research illustrates methods that can significantly boost patient participation and empowerment.

The implications can be grouped under the following headings:

1. Continuous quality improvement
2. Incident reporting system enhancements
3. Digitisation through the medical device management system
4. Educational and training innovations

1. Continuous quality improvement

The study emphasises the importance of continuous quality improvement within medical device organisations. Data analysis, feedback loops, and key performance indicators are important techniques that enable process improvements. This approach is consistent with literature that advocates for continuous quality improvement as a cornerstone of healthcare excellence (Keel et al., 2017; Carayon et al., 2014). The dependence on self-reported data from organisations can produce biases, limiting the objectivity of the findings. Future research could benefit from including third-party audits to validate organisational reports, to strengthen the quality improvement framework.

2. Incident reporting system enhancements

Following the introduction and integration of SOP-002 and SOP-003 (Appendices 8 and 9) into the Malta Medicines Authority's quality management system, a marked improvement in the incident report processing was observed. The implementation of these standard operating procedures (SOP) addressed and resolved the previously existing backlog of incident reports, validating their effectiveness within the system. These procedures were adopted directly into the quality framework and upheld through annual audit reviews, demonstrating their efficacy and relevance without necessitating modifications until the next audit cycle.

An enhancement in the incident reporting process was observed through the revision of SOP-003, which empowered the significance of patient involvement and safeguarding. This revision related to the formation of an advisory committee for medical device that was aimed at adjudicating incident reports. The committee is composed of the Malta Medicines Authority (MMA) CEO, the CEO of Mater Dei Hospital (MDH), clinical director of MDH, the clinical risk manager of MDH, MMA staff, a clinical expert and, importantly, a patient representative. The inclusion of a patient representative within this committee emphasises a patient-centred approach in the decision-making process, aligning with contemporary healthcare trends that advocate for patient involvement in healthcare decisions.

The deployment of the incident reporting training program and the adoption of the structured framework significantly improved the reporting process. Healthcare professionals, equipped with the necessary tools and knowledge, demonstrated enhanced decision-making capabilities concerning medical device usage. The notable increase in

incident reporting post-implementation (Figure 3.3), can be attributed to either a genuine rise in incidents or the facilitated ease of the reporting process, encouraging more submissions from healthcare providers (Hutchinson et al., 2009; Lamb & Piper, 2015). This enhancement, coupled with a user satisfaction rating of 4.0 out of 5, illustrates the positive impact of the system on increasing the volume and quality of incident reports.

3. Digitisation through the medical device management system

The MDMS is designed to enhance the decision-making and management processes through a digital framework, aiming for an overhaul in medical device healthcare management. The effort towards digitisation, echoing the findings of Buntin et al. (2011), underscores the potential of digital systems to substantially uplift healthcare efficiency and outcomes.

The MDMS's proposes a centralised platform that spans a public interface to advanced backend infrastructure for economic operators. This framework delineates process flows systematically and also offers stakeholders the flexibility to tailor the system to their unique needs. The incorporation of MDMS into daily operational workflows brings benefits, including enhanced decision-making capabilities and immediate access to detailed medical device data. Such integration is pivotal for healthcare providers, enabling informed decision-making and efficient information retrieval, thereby directly impacting patient care quality and safety.

Moreover, the MDMS serves as a consolidated data repository, empowering stakeholders to employ advanced analytical tools for trend analysis, risk detection, and proactive

quality improvement measures. This capability facilitates evidence-based decision-making, allowing regulatory bodies and healthcare providers to implement interventions that bolster patient safety and enhance the delivery of healthcare services. The collaborative nature of the MDMS fosters a culture of open communication, transparency, and continuous learning, ensuring a steadfast focus on safety, quality, and effectiveness within the medical device industry.

4. Educational and training innovations

The introduction of tailored training programs for healthcare professionals represents a proactive approach to improving device safety. A pivotal step in the ongoing development of medical device education can be seen through the establishment of a study unit on medical devices at the university of Malta. The curriculum for the study unit PHR2612 - Medical Devics[21] taught to second year pharmaceutical technologists was developed as a result of the research done in this study. The material is delivered via the use of face-to face lectures and interactive e-learning modules is in line with modern educational strategies that leverage technology for enhanced learning outcomes (Ruiz et al., 2006).

Under the regulations of the MDR and IVDR, it is required that manufacturers and authorised representatives must designate a Person Responsible for Regulatory Compliance (PRRC). The primary duty of the PRRC is to ensure that the medical devices

[21] https://www.um.edu.mt/courses/studyunit/PHR2612

produced by their organisation meet the regulatory standards set forth by the MDR or IVDR. However, there is no similar requirement placed upon importers and distributors. Recognising this discrepancy, and as a continuation of the initiatives in Phase 4, a national equivalent to the PRRC was established for local importers and distributors, termed as the Medical Device Registered Person (MDRP). To qualify for the MDRP role, a set of criteria were defined, which include the need for a certificate from an accredited course on medical devices. In collaboration with applicable academic bodies, a number of courses were developed and accredited to provide the necessary training to local stakeholders.

4.4 Future directions

This thesis aims to contribute to field of medical devices by exploring current practices and challenges and also by outlining a detailed path for future research directions. Future research directions can be grouped under the following headings:

1. Evaluating Regulatory Policies
2. Exploring Patient-centred Approaches for Incident Reporting
3. Diversifying and Expanding Participant Pools in Future Studies
4. Implementing and Evaluating the Medical Device Management System (MDMS)
5. Investigating Long-term Impacts and Cross-cultural Studies

1. Evaluating regulatory policies

The landscape of medical device regulation is complex and varied, reflecting the diverse healthcare systems and regulatory environments across the globe. Future research in this area should focus on assessing the efficacy of current regulatory frameworks, identifying best practices, and pinpointing areas where improvements are necessary. Comparative studies across different regulatory contexts are crucial for this endeavour. For instance, Fink and Akra (2023) highlight the disparities in medical device approval processes between the FDA in the United States and the EMA in Europe, suggesting that these differences can lead to variations in patient safety outcomes. Similarly, Marešová et al. (2020) emphasise the need for harmonising regulatory policies to facilitate global medical device surveillance and improve patient safety. These studies underscore the importance of a nuanced understanding of regulatory impacts and the potential for policy improvements.

2. Exploring patient-centred approaches for incident reporting

The call for a more patient-centred approach to incident reporting is both timely and essential. Developing tools and strategies that empower patients to report incidents and concerns about medical devices can foster a culture of transparency and trust. For example, Webber et al. (2022) demonstrated how patient-reported outcomes could be leveraged to improve device safety monitoring. The deployment of digital platforms that facilitate easy reporting and feedback mechanisms (Ruscio et al., 2020; Rahman et al., 2023) and could significantly enhance patient engagement and safety outcomes. These efforts should be complemented by education campaigns that inform patients about their

crucial role in reporting and safety oversight, thereby bridging the gap between healthcare providers and recipients.

3. Diversifying and expanding participant pools in future studies

Expanding and diversifying participant pools to include a broader range of geographical locations, healthcare infrastructures, and demographic backgrounds is essential. This approach can uncover valuable insights into how different populations interact with and are impacted by medical devices. By embracing diversity, future research can address the nuanced challenges of medical device regulation and usage in various contexts, leading to more universally applicable solutions (Allmark, 2004; Oh et al., 2015).

4. Implementing and evaluating the medical device management system

The Medical Device Management System (MDMS) represents a significant advance in the field, promising to streamline decision-making processes, enhance patient treatment protocols, and improve overall device oversight. The full implementation and evaluation of this digital platform are essential. Completing user acceptance testing and launching the MDMS would provide a real-world assessment of its effectiveness. Digital platforms like the MDMS can play a crucial role in enhancing the safety and efficacy of medical device management (Tun et al., 2020). This research direction aligns with the technological advancements in healthcare and also with the increasing need for systems that can dynamically adapt to the changing landscape of medical device oversight.

5. Investigating long-term impacts and cross-cultural studies

Finally, the thesis underscores the importance of long-term and cross-cultural studies in understanding the impacts of patient-centred medical device oversight. Such research could provide insights into the sustainability of patient-centred approaches and their adaptability across diverse cultural and regulatory environments. For instance, studies focusing on the economic evaluations of patient-centred reporting systems (De La Perrelle et al., 2020; Fu et al., 2023) , could offer a detailed view of the cost-effectiveness of these approaches. Cross-cultural studies, can elucidate the challenges and opportunities of implementing patient-centred oversight in diverse healthcare systems, providing a roadmap for global adaptation and scalability (Wong et al., 2020).

The future directions outlined in this thesis contribute to a growing body of research that seeks to enhance medical device safety and oversight through innovative regulatory policies, patient-centred approaches, and technological advancements. By addressing these areas with a clear focus on inclusivity, transparency, and technological integration, future research can build upon the foundational work established in this research.

4.5 Conclusion

The primary aim was to craft a framework conducive to establishing or transitioning medical device organisations to a more patient-centred focus. This entailed a methodological approach segmented into four distinct phases, each targeting a key aspect

of medical device regulation - from quality management and incident reporting to the implementation of a digital management system and addressing training needs within the sector. This study yielded key findings: the formulation of a quality management system rooted in core regulatory requirements advocating a patient-centred ethos, the conceptualisation and integration of an incident reporting mechanism into a centralised platform enhancing operational transparency and efficiency, the establishment of a digital medical device management system designed to streamline regulatory processes and strengthen stakeholder engagement, and the identification of fundamental training and professional development gaps alongside proposed strategies to bridge these gaps.

The first phase, focused on establishing a quality management system, the study identified and utilised fundamental regulatory requirements that were in compliance with international standards such as ISO 13485:2016 and ISO 9001:2015, and the medical device regulation and in-vitro medical device regulation. A conceptual quality management system framework was developed. The quality management system framework fulfils regulatory requirements and incorporates a patient-centred orientation into the operational foundation for medical device stakeholders.

The quality management system document list presents a template document that medical device stakeholders can follow to compile and maintain their quality management system. Among these documents, SOP-001: Management and Control of Standard Operating Procedures was drafted. The study provides stakeholders with a direct, actionable document for establishing the procedural standards that will support the entire quality management system. The creation of this framework, specifically SOP-001, displays a

proactive approach to regulatory compliance, one that satisfies patients' needs and concerns, promoting the patient-centred ethos of the medical device regulation.

The second phase, centred on the development of a centralised incident reporting system, focused on the creation of a system that streamlined the reporting process, making it more efficient and accessible. The system was designed to enable quicker identification and response to device-related incidents, ensuring that potential risks to patients are mitigated in a timely manner. By providing a straightforward mechanism for reporting incidents, the study enhanced the vigilance and post-market surveillance capabilities of regulatory bodies and safeguarding patient interests.

The pilot study implementation of the incident reporting system demonstrated its efficacy. It illustrated the system's capabilities in a real-world setting. The data obtained shows an increase in the number of incident reports following implementation (Figure 3.3). This suggested that the system could facilitate faster and more coherent communication among healthcare providers, patients, and regulatory bodies.

The implementation of the pilot study and the data and feedback obtained highlighted the system's significance in establishing a proactive regulatory environment that prioritises swift incident response and thorough post-market surveillance. This phase of the study illustrated the practical steps taken to enhance patient safety and device reliability, demonstrating the tangible benefits of an incident reporting system in the continuous effort to safeguard patient interests in the dynamic field of medical device regulation.

The third phase of the study involved developing the framework for a digital medical device management system. This phase employed a hybrid Agile methodology to balance detailed planning with the agility to react to evolving regulatory needs, allowing for

precision and flexibility in the face of the complex nature of medical device regulation. The collaborative approach employed in this phase was crucial, where extensive collaborations with an expert panel through workshops established the groundwork for the medical device management system. This phase highlighted the critical role of stakeholder engagement in driving project success.

User stories and process flows provide a comprehensive framework for the implementation of a digital medical device management system. The user acceptance testing and test plan templates established cater for the testing and validation of the medical device management system prior to deployment, safeguarding system reliability and user satisfaction.

The fourth phase focused on the identification of training gaps and the need for continuous professional development within the medical device sector. This phase identified the existing deficiencies in knowledge and skills among professionals engaged in the lifecycle of medical devices.

The establishment and implementation of the medical device registered person into national legislation, marking a pivotal step towards formalizing the need for structured professional development in the field. The establishment of a study unit on medical devices at the University of Malta represents a forward-thinking approach to embedding medical device education within academic curricula.

This study establishes methods and frameworks to enhancing medical device regulation that prioritises patient well-being. The integration of digital tools, alongside the refinement of quality management and professional development practices, sets a new

standard for how medical devices are regulated, prioritizing safety, efficacy, and patient-centred care at every step.

References

Allmark P. Should research samples reflect the diversity of the population? J Med Ethics 2004;30(2):185-189. DOI: 10.1136/jme.2003.004374

Almadi MA, Alsohaibani FI. Reporting Adverse Medical Device Events Is an Obligation and Not a "Fashion". Obes Surg 2019;29(9):2974-2975. DOI: 10.1007/s11695-019-03974-6

Alsunaidi SJ, Almuhaideb AM, Ibrahim NM, Shaikh FS, Alqudaihi KS, Alhaidari FA, et al. Applications of big data analytics to control covid-19 pandemic. Sensors (Basel, Switzerland) 2021;21(7):2282. DOI: 10.3390/s21072282

Altenstetter C, Permanand G. EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective. The Review of policy research 2007;24(5):385-405. DOI: 10.1111/j.1541-1338.2007.00291.x

Altenstetter C. Medical device regulation in the European Union, Japan and the United States. Commonalities, differences and challenges. INNOVATION-ABINGDON 2012;25(4):362-388. DOI: 10.1080/13511610.2012.723328

Alvarez G, Núñez-Cortés R, Solà I, Sitjà-Rabert M, Fort-Vanmeerhaeghe A, Fernández C, et al. Sample size, study length, and inadequate controls were the most common self-acknowledged limitations in manual therapy trials: A methodological review. J Clin Epidemiol 2021;130:96-106. DOI: 10.1016/j.jclinepi.2020.10.018

Amoore JN. A Structured Approach for Investigating the Causes of Medical Device Adverse Events. Journal of medical engineering; J Med Eng. 2014;2014:314138-13. DOI: 10.1155/2014/314138

Aronson JK, Heneghan C, Ferner RE. Medical Devices: Definition, Classification, and Regulatory Implications. Drug Saf. 2020;43(2):83-93. DOI: 10.1007/s40264-019-00878-3

Arsad FS, Syed Soffian SS, Megat Kamaruddin P,Sofia Nadira, Nordin NR, Baharudin MH, Baharudin UM, et al. The Impact of eHealth Applications In Healthcare Intervention: A Systematic Review. Journal of health research 2023;37(3):178-189. DOI: 10.56808/2586-940X.1020

Astrahan M, Blasgen M, Chamberlin D, Eswaran K, Gray J, Griffiths P, et al. System R: relational approach to database management. ACM transactions on database systems 1976;1(2):97-137. DOI: 10.1145/320455.320457

Badnjević A, Pokvić LG, Deumić A, Bećirović LS. Post-market surveillance of medical devices: A review. Technology and health care 2022;30(6):1315-1329. DOI: 10.3233/THC-220284

Ball GP, Shah R, Donohue K. The decision to recall: A behavioral investigation in the medical device industry. J Oper Manage 2018;62(1):1-15. DOI: 10.1016/j.jom.2018.07.003

Bano M, Zowghi D. A systematic review on the relationship between user involvement and system success. Information and software technology 2015;58:148-169. DOI: 10.1016/j.infsof.2014.06.011

Bayrak T, Özdiler Çopur F. Evaluation of the unique device identification system and an approach for medical device tracking. Health policy and technology 2017;6(2):234-241. DOI: 10.1016/j.hlpt.2017.04.003

Beaulieu M, Bentahar O. Digitalization of the healthcare supply chain: A roadmap to generate benefits and effectively support healthcare delivery. Technological forecasting & social change 2021;167:120717. DOI: 10.1016/j.techfore.2021.120717

Bensaci C, Zennir Y, Pomorski D, Innal F, Liu Y, Tolba C. STPA and Bowtie risk analysis study for centralized and hierarchical control architectures comparison. Alexandria engineering journal 2020;59(5):3799-3816. DOI: 10.1016/j.aej.2020.06.036

Bernal MC, Molina Y. A test model for database architectures: an assessment for job search engine systems. Journal of applied research and technology 2022;20(3):306-319. DOI: 10.22201/icat.24486736e.2022.20.3.1169

Bianchini E, Francesconi M, Testa M, Tanase M, Gemignani V. Unique device identification and traceability for medical software: A major challenge for manufacturers in an ever-evolving marketplace. J Biomed Inform. 2019;93:103150. DOI: 10.1016/j.jbi.2019.103150

Bianco S, Nunziata A, Pozzoli G. Clinical Investigations on Medical Devices, after the New European Regulation (2017/745). Clinical Trials and Practice Journal. 2017;1(1):10-14.DOI: 10.17140/CTPOJ-1-102

Billiones R. Eudamed's delay and its impact on disclosure of clinical investigations under the EU MDR. Medical writing (Leeds). 2020;29(3):12-5.

Black AD, Car J, Pagliari C, Anandan C, Cresswell K, Bokun T, et al. The impact of ehealth on the quality and safety of health care: A systematic overview. PLOS MED 2011;8(1):e1000387. DOI: 10.1371/journal.pmed.1000387

Blandford A, Gibbs J, Newhouse N, Perski O, Singh A, Murray E. Seven lessons for interdisciplinary research on interactive digital health interventions. Digital health 2018;4:2055207618770325. DOI: 10.1177/2055207618770325

Bretthauer M, Gerke S, Hassan C, Ahmad OF, Mori Y. The New European Medical Device Regulation: Balancing Innovation and Patient Safety. Ann Intern Med 2023;176(6):844-848. DOI: 10.7326/M23-0454

Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information technology: a review of the recent literature shows predominantly positive results. Health Aff (Millwood) 2011 Mar;30(3):464-471. DOI: 10.1377/hlthaff.2011.0178

Campbell B, Campbell M, Dobson L, Higgins J, Dillon B, Marlow M, et al. Assessing the Value of Innovative Medical Devices and Diagnostics: The Importance of Clear and Relevant Claims of Benefit. Int J Technol Assess Health Care 2018;34(4):419-424. DOI: 10.1017/S0266462318000466

Carayon P, Wetterneck TB, Cartmill R, Blosky MA, Brown R, Kim R, et al. Characterising the complexity of medication safety using a human factors approach: an observational study in two intensive care units. BMJ QUAL SAF 2014;23(1):56-65. DOI: 10.1136/bmjqs-2013-001828

CHANG JE, LAI AY, GUPTA A, NGUYEN AM, BERRY CA, SHELLEY DR. Rapid Transition to Telehealth and the Digital Divide: Implications for Primary Care Access and Equity in a Post-COVID Era. Milbank Q 2021;99(2):340-368. DOI: 10.1111/1468-0009.12509

Charlesworth M, Zundert AAJ. Medical device regulation: the need for clinical vigilance and oversight. Anaesthesia. 2019;74(6):693-695. DOI: 10.1111/anae.14603

Chen Y, Chiou C, Huang Y, Tu P, Lee Y, Chien C. A Comparative Study of Medical Device Regulations: US, Europe, Canada, and Taiwan. Ther Innov Regul Sci. 2018;52(1):62-69. DOI: 10.1177/2168479017716712

Choi JS, Lee JH, Park JH, Nam HS, Kwon H, Kim D, et al. Design and implementation of a seamless and comprehensive integrated medical device interface system for outpatient electronic medical records in a general hospital. INT J MED INFORM 2011;80(4):274-285. DOI: 10.1016/j.ijmedinf.2010.11.007

Cohen D. How safe are metal-on-metal hip implants? BMJ 2012;344(7846):e1410. DOI: 10.1136/bmj.e1410

Collins FS, Varmus H. A New Initiative on Precision Medicine. N Engl J Med 2015;372(9):793-795. DOI: 10.1056/NEJMp1500523

Conforto EC, Salum F, Amaral DC, da Silva SL, de Almeida L,Fernando Magnanini. Can Agile Project Management Be Adopted by Industries Other than Software Development? PROJ MANAG J 2014;45(3):21-34. DOI: 10.1002/pmj.21410

Cresswell K, Anderson S, Montgomery C, Weir CJ, Atter M, Williams R. Evaluation of Digitalisation in Healthcare and the Quantification of the "Unmeasurable". Journal of general internal medicine : JGIM 2023. DOI: 10.1007/s11606-023-08405-y

Davis DA, Rayburn WF. Integrating Continuing Professional Development With Health System Reform: Building Pillars of Support. Academic medicine 2016;91(1):26-29. DOI: 10.1097/ACM.0000000000001002

De La Perrelle L, Radisic G, Cations M, Kaambwa B, Barbery G, Laver K. Costs and economic evaluations of Quality Improvement Collaboratives in healthcare: A systematic review. 2020;20(1):155. DOI: 10.1186/s12913-020-4981-5

De Maria C, Di Pietro L, Díaz Lantada A, Madete J, Makobore PN, Mridha M, et al. Safe innovation: On medical device legislation in Europe and Africa. Health policy and technology. 2018;7(2):156-165. DOI: 10.1016/j.hlpt.2018.01.012

Deva AK, Cuss A, Magnusson M, Cooter R. The "Game of Implants": A Perspective on the Crisis-Prone History of Breast Implants. Aesthet Surg J. 2019;39:S55-65. DOI: 10.1093/asj/sjy310

Ebekozien A, Aigbavboa CO, Ramotshela M. A qualitative approach to investigate stakeholders' engagement in construction projects. Benchmarking : an international journal 2023. DOI: 10.1108/BIJ-11-2021-0663

Ebner C, Gegenfurtner A. Learning and Satisfaction in Webinar, Online, and Face-to-Face Instruction: A Meta-Analysis. Frontiers in education (Lausanne) 2019;4. DOI: 10.3389/feduc.2019.00092

Egbosimba D. Medical devices industry: the problem of clinical evaluation reports. Ann Biol Clin (Paris) 2019;77(5):514-516. DOI: 10.1684/abc.2019.1473

El aboudi N, Benhlima L. Big Data Management for Healthcare Systems: Architecture, Requirements, and Implementation. Advances in bioinformatics 2018;2018:4059018-10. DOI: 10.1155/2018/4059018

Elbeddini A, Yeats A, Lee S. Amid COVID-19: The importance of developing an positive adverse drug reaction (ADR) and medical device incident (MDI) reporting culture for

Global Health and public safety. Journal of pharmaceutical policy and practice 2020;13(1):18.

El-Sherif D, Abouzid M, Elzarif MT, Ahmed AA, Albakri A, Alshehri MM. Telehealth and Artificial Intelligence Insights into Healthcare during the COVID-19 Pandemic. Healthcare (Basel) 2022;10(2):385. DOI: 10.3390/healthcare10020385

Embracing the cloud for better cyber security. : IEEE; 2011. DOI: 10.1109/PERCOMW.2011.5766877

Fearis K, M.S., Petrie A, M.A. Best practices in early phase medical device development: Engineering, prototyping, and the beginnings of a quality management system. Surgery 2017;161(3):571-575. DOI: 10.1016/j.surg.2016.08.052

Fink M, Akra B. Comparison of the international regulations for medical devices–USA versus Europe. 2023;54:110908. DOI: 10.1016/j.injury.2023.110908

Fraser AG, Butchart EG, Szymański P, Caiani EG, Crosby S, Kearney P, et al. The need for transparency of clinical evidence for medical devices in Europe. The Lancet 2018;392(10146):521-530. DOI: 10.1016/S0140-6736(18)31270-4

French-Mowat E, Burnett J. How are medical devices regulated in the European Union? J R Soc Med 2012;105(1):22-28. DOI: 10.1258/jrsm.2012.120036

Frumento C. French breast implants, the medical device regulation, and a theoretical case study. Medical writing (Leeds). 2017;26(2):39-40.

Fu R, Ng V, Liu M, Wells D, Yurga E, Nauenberg E. Considering patient perspectives in economic evaluations of health interventions. Frontiers in public health 2023;11:1212583. DOI: 10.3389/fphar.2020.01234

Gadotti Martins E, Pinheiro de Lima E, Gouvea da Costa S,E. Developing a quality management system implementation process for a medical device manufacturer. Journal of manufacturing technology management 2015;26(7):955-979. DOI: 10.1108/JMTM-12-2012-0119

Gagliardi AR, Ducey A, Lehoux P, Turgeon T, Ross S, Trbovich P, et al. Factors influencing the reporting of adverse medical device events: qualitative interviews with physicians about higher risk implantable devices. BMJ quality & safety 2018;27(3):190-198. DOI: 10.1136/bmjqs-2017-006481

Gagliardi AR, Ducey A, Lehoux P, Turgeon T, Ross S, Trbovich P, et al. Factors influencing the reporting of adverse medical device events: qualitative interviews with

physicians about higher risk implantable devices. BMJ quality & safety; BMJ Qual Saf. 2018;27(3):190-8. DOI: 10.1136/bmjqs-2017-006481

Geetha VG, S U. Risk Based Approach In Medical Device Quality Management System In Covid-19 Pandemic. International Journal of Economics and Management Studies 2020;7(5):175-179.

Ghimire D, Charters S. The impact of Agile development practices on project outcomes. 2022. DOI: 10.3390/app122110698

Gordon S, Crager J, Howry C, Barsdorf AI, Cohen J, Crescioni M, et al. Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically. Ther Innov Regul Sci 2022;56(3):442-453. DOI: 10.1007/s43441-021-00363-z

Greenhalgh T, Wherton J, Shaw S, Morrison C. Video consultations for covid-19. BMJ (Online) 2020;368:m998. DOI: 10.1136/bmj.m998

Gremyr I, Lenning J, Elg M, Martin J. Increasing the value of quality management systems. International journal of quality and service sciences 2021;13(3):381-394. DOI: 10.1108/IJQSS-10-2020-0170

Gunapal PPG, Kannapiran P, Teow KL, Zhu Z, Xiaobin You A, Saxena N, et al. Setting up a regional health system database for seamless population health management in Singapore. Proceedings of Singapore healthcare. 2016;25(1):27-34. DOI: 10.1177/2010105815611440

Hancher L, Földes ME. Revision of the Regulatory Framework for Medical Devices in the European Union: The Legal Challenges. European journal of risk regulation; Eur.j.risk regul. 2013;4(4):429-435. DOI: 10.1017/S1867299X0000307X

Hanlon HR, Prihodova L, Russell T, Donegan D, O'Shaughnessy A, Hoey H. Doctors' engagement with a formal system of continuing professional development in Ireland: a qualitative study in perceived benefits, barriers and potential improvements. BMJ Open 2021;11(11):e049204. DOI: 10.1136/bmjopen-2021-049204

Heneghan C, Aronson JK, Goldacre B, Mahtani KR, Plüddemann A, Onakpoya I. Transvaginal mesh failure: lessons for regulation of implantable devices. BMJ. 2017;359:j5515. DOI: 10.1136/bmj.j5515

Holland A. Risk Based Approach for Medical Device Quality Management. Quality (Wheaton) 2017;56(10):55-57.

Holtzman J, Lalani C, Redberg RF. FDA Regulation of Medical Devices—Moving Beyond the Horse and Buggy. JAMA internal medicine 2022;182(1):8-9. DOI: 10.1001/jamainternmed.2021.6633

Hristov I, Chirico A. The role of sustainability key performance indicators (KPIs) in implementing sustainable strategies. Sustainability (Basel, Switzerland) 2019;11(20):5742. DOI: 10.3390/su11205742

Huo W, Zheng G, Yan J, Sun L, Han L. Interacting with medical artificial intelligence: Integrating self-responsibility attribution, human–computer trust, and personality. Comput Hum Behav 2022;132:107253. DOI: 10.1016/j.chb.2022.107253

Hutchinson A, Young TA, Cooper KL, McIntosh A, Karnon JD, Scobie S, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. QUAL SAF HEALTH CARE 2009;18(1):5-10. DOI: 10.1136/qshc.2007.022400

Huusko J, Kinnunen U, Saranto K. Medical device regulation (MDR) in health technology enterprises - perspectives of managers and regulatory professionals. BMC health services research 2023;23(1):310. DOI: 10.1186/s12913-023-09316-8

Ivanovska E, Ribarska JT, Lazova J, Popstefanova N, Jovanoska MD, Jolevska ST. Providing clinical evidence under the MDR 2017/745 – new challenges for manufacturers in medical device industry. Arhiv za farmaciju 2019;69(1):39-49. DOI: 10.5937/arhfarm1901039I

Jaffe TA, Hayden E, Uscher-Pines L, Sousa J, Schwamm LH, Mehrotra A, et al. Telehealth use in emergency care during coronavirus disease 2019: a systematic review. Journal of the American College of Emergency Physicians Open 2021;2(3):e12443-n/a. DOI: 10.1002/emp2.12443

Jarman H, Rozenblum S, Huang TJ. Neither protective nor harmonized: The crossborder regulation of medical devices in the EU. Health economics, policy and law; Health Econ Policy Law. 2021;16(1):51-63. DOI: 10.1017/S1744133120000158

Jefferys DB. The regulation of medical devices and the role of the Medical Devices Agency: Regulation of medical devices. Br J Clin Pharmacol 2001;52(3):229-235. DOI: 10.1046/j.0306-5251.2001.01416.x

Jha AK, Prasopa-Plaizier N, Larizgoitia I, Bates DW. Patient safety research: an overview of the global evidence. QUAL SAF HEALTH CARE 2010;19(1):42-47. DOI: 10.1136/qshc.2008.029165

Keel G, Savage C, Rafiq M, Mazzocato P. Time-driven activity-based costing in health care: A systematic review of the literature. Health policy (Amsterdam) 2017;121(7):755-763. DOI: 10.1016/j.healthpol.2017.04.013

Khan W, Kumar T, Zhang C, Raj K, Roy AM, Luo B. SQL and NoSQL Database Software Architecture Performance Analysis and Assessments—A Systematic Literature Review. Big data and cognitive computing 2023;7(2):97. DOI: 10.3390/bdcc7020097

Kheir O, Smedts S, Jacoby A, Verwulgen S. Efficient quality management in medtech start-ups (Based on iso 13485). Medical devices (Auckland, N.Z.) 2021;14:313-319. DOI: 10.2147/MDER.S320583

Kierkegaard P. eHealth in Denmark: A Case Study. J Med Syst 2013;37(6):9991. DOI: 10.1007/s10916-013-9991-y

Knowles, M.S., Holton III, E.F., Swanson, R.A., SWANSON, R., & Robinson, P.A. (2020). The Adult Learner: The Definitive Classic in Adult Education and Human Resource Development (9th ed.). Routledge. https://doi.org/10.4324/9780429299612

Kotter JP. Leading change: why transformation efforts fail. EMR 2009;37(3):42-48. DOI: 10.1109/EMR.2009.5235501

Kramer DB, Xu S, Kesselheim AS. Regulation of Medical Devices in the United States and European Union. NEW ENGL J MED 2012;366(9):848-855. DOI: 10.1056/NEJMhle1113918

Kruse CS, Kristof C, Jones B, Mitchell E, Martinez A. Barriers to Electronic Health Record Adoption: a Systematic Literature Review. J Med Syst 2016;40(12):252. DOI: 10.1007/s10916-016-0628-9

Kumar S, Nilsen WJ, Abernethy A, Atienza A, Patrick K, Pavel M, et al. Mobile health technology evaluation: The mHealth evidence workshop. Am J Prev Med 2013;45(2):228-236. DOI: 10.1016/j.amepre.2013.03.017

Kwame A, Petrucka PM. A literature-based study of patient-centered care and communication in nurse-patient interactions: barriers, facilitators, and the way forward. BMC nursing 2021;20(1):1-10. DOI: 10.1186/s12912-021-00684-2

Lamb D, Piper N. Automating patient safety incident reporting to improve healthcare quality in the defence medical services. BMJ military health 2015;161:i39-i45. DOI: 10.1136/jramc-2015-000543. DOI: 10.1136/jramc-2015-000543

Laybats C, Davies J. GDPR. Business Information Review 2018;35(2):81-83. DOI: 10.1177/0266382118777808

Lee Ventola C. Mobile devices and apps for health care professionals: Uses and benefits. P&T (Lawrenceville, N.J.) 2014;39(5):356-364.

LeRouge C, Garfield MJ. Crossing the telemedicine chasm: Have the U.S. barriers to widespread adoption of telemedicine been significantly reduced? INT J ENV RES PUB HE 2013;10(12):6472-6484. DOI: 10.3390/ijerph10126472

Levac D, Colquhoun H, O'Brien KK. Scoping studies: Advancing the methodology. IMPLEMENT SCI 2010;5(1):69. DOI: 10.1186/1748-5908-5-69

Lieser P, Taff SD, Murphy-Haga A. The webinar integration tool: A framework for promoting active learning in blended environments. Journal of Interactive Media in Education 2018;2018(1):7. DOI: 10.5334/jime.453

Liu W, Shi X, Lu Z, Wang L, Zhang K, Zhang X. Review and approval of medical devices in China: Changes and reform: REVIEW AND APPROVAL OF MEDICAL DEVICES IN CHINA. Journal of biomedical materials research.Part B, Applied biomaterials 2017;106:2093-2100. DOI: 10.1002/jbm.b.34031

Ljapina M, Kisselova–Yaneva A. Why new regulations of the European Parliament on medical devices are needed? Journal of Medical and Dental Practice. 2017;4(1):591-596. DOI: 10.18044/Medinform.201741.591

Lorv B, Horodyski R, Welton C, Vail J, Simonetto L, Jokanovic D, et al. The Development of a Quality Management Framework for Evaluating Medical Device Reprocessing Practice in Healthcare Facilities. Healthcare quarterly (Toronto, Ont.); Healthc Q 2017;19(4):37-43. DOI: 10.12927/hcq.2016.24903

Lubbers BR, Schilhabel A, Cobbaert CM, Gonzalez D, Dombrink I, Brüggemann M, et al. The New EU Regulation on in Vitro Diagnostic Medical Devices: Implications and Preparatory Actions for Diagnostic Laboratories. HemaSphere; Hemasphere. 2021;5(5):e568. DOI: 10.1097/HS9.0000000000000568

Luczak J. Establishing a small company's medical device quality system. TQM journal 2012;24(4):363-373. DOI: 10.1108/17542731211247382

Maak TG, Wylie JD. Medical Device Regulation: A Comparison of the United States and the European Union. J Am Acad Orthop Surg. 2016;24(8):537-543. DOI: 10.5435/JAAOS-D-15-00403

Mahler T, Elovici Y, Shahar Y. A New Methodology for Information Security Risk Assessment for Medical Devices and Its Evaluation. arXiv.org 2020.

Maresova P, Hajek L, Krejcar O, Storek M, Kuca K. New regulations on medical devices in europe: Are they an opportunity for growth? Administrative sciences. 2020;10(1):16. DOI: 10.3390/admsci10010016

Marešová P, Klímová B, Honegr J, Kuča K, Ibrahim WNH, Selamat A. Medical Device Development Process, and Associated Risks and Legislative Aspects-Systematic Review. Frontiers in public health 2020;8:308. DOI: 10.3389/fpubh.2020.00308

Marshall J, Morrill K, Gobbe M, Blanchard L. The Difference between Approval Processes for Medicinal Products and Medical Devices in Europe. Ophthalmologica. 2021;244(5):368-378. DOI: 10.1159/000517522

Martelli N, Eskenazy D, Déan C, Pineau J, Prognon P, Chatellier G, et al. New European Regulation for Medical Devices: What Is Changing? Cardiovasc Intervent Radiol. 2019;42(9):1272-8. DOI: 10.1007/s00270-019-02247-0

Mauch H, Kaur J, Irwin C, Wyss J. Design, implementation, and management of an international medical device registry. Current controlled trials in cardiovascular medicine 2021;22(1):845. DOI: 10.1186/s13063-021-05821-5

McCall B. What does the GDPR mean for the medical community? The Lancet (British edition) 2018;391(10127):1249-1250. DOI: 10.1016/S0140-6736(18)30739-6

McDermott O, Foley I, Antony J, Sony M, Butler M. The Impact of Industry 4.0 on the Medical Device Regulatory Product Life Cycle Compliance. Sustainability (Basel, Switzerland) 2022;14(21):14650. DOI: 10.3390/su142114650

McGee RG, Webster AC, Rogerson TE, Craig JC. Medical device regulation in Australia: safe and effective? MED J AUSTRALIA 2012;196(4):256-260. DOI: 10.5694/mja11.11261

McGuire MJ, Noronha G, Samal L, Yeh H, Crocetti S, Kravet S. Patient Safety Perceptions of Primary Care Providers after Implementation of an Electronic Medical Record System. J Gen Intern Med 2013;28(2):184-192. DOI: 10.1007/s11606-012-2153-y

Medical Devices Regulations, SOR/98-282 [Internet]. [Cited 2024]. Available from URL: https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/Melvin T, Torre M. New medical device regulations: The regulator's view. EFORT Open Reviews; EFORT Open Rev. 2019;4(6):351-356. DOI: 10.1302/2058-5241.4.180061

Melvin T. The European Medical Device Regulation-What Biomedical Engineers Need to Know. JTEHM. 2022;10:1-5. DOI: 10.1109/JTEHM.2022.3194415

Merry L, Castiglione SA, Rouleau G, Létourneau D, Larue C, Deschênes MF, et al. Continuing professional development (CPD) system development, implementation, evaluation and sustainability for healthcare professionals in low- and lower-middle-income countries: a rapid scoping review. BMC medical education 2023;23(1):498. DOI: 10.1186/s12909-023-04427-6

Miclăuş T, Valla V, Koukoura A, Nielsen AA, Dahlerup B, Tsianos G, et al. Impact of Design on Medical Device Safety. Ther Innov Regul Sci. 2020;54(4):839-49. DOI: 10.1007/s43441-019-00022-4

Mishra S. FDA, CE mark or something else?—Thinking fast and slow. Indian Heart J 2017;69(1):1-5. DOI: 10.1016/j.ihj.2016.11.327

Mower J, Cohen T, Subramanian D. Complementing Observational Signals with Literature-Derived Distributed Representations for Post-Marketing Drug Surveillance. Drug Saf 2020;43(1):67-77. DOI: 10.1007/s40264-019-00872-9

Nakayama M, Tanaka S, Hamada S, Uchida T, Kawakami K. Recalls and Premarket Review Systems for High-Risk Medical Devices in Japan. Ther Innov Regul Sci 2019;53(6):775-780. DOI: 10.1177/2168479018812812

Naumcheva M, Ebersold S, Naumchev A, Bruel J, Galinier F, Meyer B. Object-Oriented Requirements: a Unified Framework for Specifications, Scenarios and Tests. arXiv.org 2023. DOI: 10.48550/arxiv.2209.02189

Nazar M, Alam MM, Yafi E, Su'ud MM. A Systematic Review of Human-Computer Interaction and Explainable Artificial Intelligence in Healthcare With Artificial Intelligence Techniques. Access 2021;9:153316-153348. DOI: 10.1109/ACCESS.2021.3127881

Niemiec E. Will the EU Medical Device Regulation help to improve the safety and performance of medical AI devices? Digital health; Digit Health 2022;8:20552076221089079. DOI: 10.1177/20552076221089079

Oh SS, Galanter J, Thakur N, Pino-Yanes M, Barcelo NE, White MJ, et al. Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. PLoS medicine 2015;12(12):e1001918. DOI: 10.1371/journal.pmed.1001918

Olimid D, Olimid AP, Chen FI. Ethical governance of the medical research: clinical investigation and informed consent under the new EU Medical Devices Regulation (2017⁄745). Rom J Morphol Embryol. 2018;59(4):1305-1310.

O'Neill J. Lessons from the vaginal mesh scandal: enhancing the patient-centric approach to informed consent for medical device implantation. Int J Technol Assess Health Care 2021;37(1):e53. DOI: 10.1017/S0266462321000258

Onishi Y, Ichihashi R, Yoshida Y, Tahara T, Kikuchi T, Kobori T, et al. Substitution of telemedicine for clinic visit during the COVID-19 pandemic of 2020: Comparison of telemedicine and clinic visit. Journal of Cutaneous Immunology and Allergy 2022;13(9):1617-1625. DOI: 10.1111/jdi.13826

Pane J, Verhamme KMC, Villegas D, Gamez L, Rebollo I, Sturkenboom MCJM. Challenges associated with the safety signal detection process for medical devices. Medical devices (Auckland, N.Z.) 2021;14:43-57. DOI: 10.2147/MDER.S278868

Parvizi N, Woods K. Regulation of medicines and medical devices: Contrasts and similarities. Clin Med 2014;14(1):6-12. DOI: 10.7861/clinmedicine.14-1-6

Payne TH, tenBroek AE, Fletcher GS, Labuguen MC. Transition from paper to electronic inpatient physician notes. J AM MED INFORM ASSN 2010;17(1):108-111. DOI: 10.1197/jamia.M3173

Peter L, Hájek L, Maresova P, Augustynek M, Penhaker M. Medical devices: Regulation, risk classification, and open innovation. Journal of open innovation 2020;6(2):1-12.

Petkovic J, Magwood O, Lytvyn L, Khabsa J, Concannon TW, Welch V, et al. Key issues for stakeholder engagement in the development of health and healthcare guidelines. Research involvement and engagement 2023;9(1):27. DOI: 10.1186/s40900-023-00433-6

Polisena J, Gagliardi A, Clifford T. How can we improve the recognition, reporting and resolution of medical device-related incidents in hospitals? A qualitative study of physicians and registered nurses Quality, performance, safety and outcomes. BMC health services research 2015;15(1). DOI: 10.1186/s12913-015-0886-0

Popov VV, Kudryavtseva EV, Katiyar NK, Shishkin A, Stepanov SI, Goel S. Industry 4.0 and Digitalisation in Healthcare. Materials 2022;15(6):2140. DOI: 10.3390/ma15062140

Qouhafa, Meryem ; Benaji, Brahim ; Lebbar, Souad ; Soulaymani, Abdelmajid ; Moukhtari, Abdelrhani Soulaymani, A. ; Mokhtari, A. ; Slimani, K. ; Hami, H. ; Bourekkadi, S. DOI: 10.1051/e3sconf/202131901086

Racchi M, Govoni S, Lucchelli A, Capone L, Giovagnoni E. Insights into the definition of terms in European medical device regulation. Expert review of medical devices; Expert Rev Med Devices. 2016;13(10):907-917. DOI: 10.1080/17434440.2016.1224644

Rahman Jabin MS, Steen M, Wepa D, Bergman P. Assessing the healthcare quality issues for digital incident reporting in Sweden: Incident reports analysis. Digital health 2023;9:20552076231174307. DOI: 10.1177/20552076231174307

Rashid ARA. Continous professional development and the pharmaceutical industry-education or marketing? Bangladesh journal of medical science (Ibn Sina Trust) 2013;12(1):5-9. DOI: 10.3329/bjms.v12i1.13347

Razak IHA, Kamaruddin S, Azid IA, Putra Almanar I. ISO 13485:2003: Implementation reference model from the Malaysian SMEs medical device industry. TQM journal 2009;21(1):6-19. DOI: 10.1108/17542730910924718

Regan G, Mc Caffery F, Mc Daid K, Flood D. Medical device standards' requirements for traceability during the software development lifecycle and implementation of a traceability assessment model. COMPUT STAND INTER. 2013;36(1):3-9. DOI: 10.1016/j.csi.2013.07.012

Ren Y, Bertoldi M, Fraser AG, Caiani EG. Validation of CORE-MD PMS Support Tool: A Novel Strategy for Aggregating Information from Notices of Failures to Support Medical Devices' Post-Market Surveillance. Ther Innov Regul Sci 2023;57(3):589-602. DOI: 10.1007/s43441-022-00493-y

Rodriguez JA, Shachar C, Bates DW. Digital Inclusion as Health Care — Supporting Health Care Equity with Digital-Infrastructure Initiatives. N Engl J Med 2022;386(12):1101-1103. DOI: 10.1056/NEJMp2115646

Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: A systematic review of systematic reviews (an update). Implementation science : IS 2016;11(1):146. DOI: 10.1186/s13012-016-0510-7

Ruiz JG, Mintzer MJ, Leipzig RM. The impact of e-learning in medical education. Acad Med 2006;81(3):207-212. DOI: 10.1097/00001888-200603000-00002

Ruscio E, Bianchet B, Scarpis E, Del Pin M, Degan S, De Corti D, et al. Incident reporting digitalization: the experience of an Italian academic hospital, 2019. Eur J Public Health 2020;30. DOI: 10.1093/eurpub/ckaa165.190

Schoener B, Hoxey E. Comparing attributes of the ASEAN medical device directive and EU 2017/745 regulation. Biomed Instrum Technol. 2019;53(3):208-213. DOI: 10.2345/0899-8205-53.3.208

Schulz WL, Nelson BG, Felker DK, Durant TJS, Torres R. Evaluation of relational and NoSQL database architectures to manage genomic annotations. J Biomed Inform 2016;64:288-295. DOI: 10.1016/j.jbi.2016.10.015

Sen, PS; Mukherjee, N. Designing a NoSQL Database for Efficient Storage and Retrieval of Health Data. Piscataway: Piscataway: The Institute of Electrical and Electronics Engineers, Inc. (IEEE); 2021. DOI: 10.1109/FiCloud49777.2021.00045

Shah P, Snitman A, McCaney J, Rose LM, Sheridan D, Espinoza Salomon J. PMDedu: Assessing the educational needs of startups and academic investigators focused on pediatric medical device development. Journal of clinical and translational science 2023;7(1):e235. DOI: 10.1017/cts.2023.633

Sharma A, Luthra G. Implementing a Risk-Based Approach to Quality Management System ISO-13485 Processes in Compliance with EUMDR 2017/745 for Medical Device Industry. Journal of Pharmaceutical Research International 2023;35(13):8-19.

Sharma SK, Al-Wanain MI, Alowaidi M, Alsaghier H. Mobile healthcare (m-Health) based on artificial intelligence in healthcare 4.0. Expert Syst 2022. DOI: 10.1111/exsy.13025

Shatrov K, Blankart CR. After the four-year transition period: Is the European Union's Medical Device Regulation of 2017 likely to achieve its main goals? Health policy (Amsterdam). 2022;126(12):1233-1240. DOI: 10.1016/j.healthpol.2022.09.012

Sheffer J. Embarking on a quest for quality. Biomedical instrumentation & technology 2018;52(3):172. DOI: 10.2345/0899-8205-52.3.172

Sheng J, Amankwah-Amoah J, Khan Z, Wang X. COVID-19 Pandemic in the New Era of Big Data Analytics: Methodological Innovations and Future Research Directions. Br J Manage 2021;32(4):1164-1183. DOI: 10.1111/1467-8551.12441

Shermilan P A, Kamaraj R. Regulatory Obligation and Challenges faced by the medical device manufacturer in Europe, United States & India. International journal of pharmaceutical research 2021;13(2). DOI:https://doi.org/10.31838/ijpr/2021.13.02.376

Standardization in patient safety: the WHO High 5s project https://academic.oup.com/intqhc/article/26/2/109/1803803?login=false International Journal for Quality in Health Care, Volume 26, Issue 2, April 2014, Pages 109–116, https://doi.org/10.1093/intqhc/mzu010

Starling RC, Estep JD, Horstmanshof DA, Milano CA, Stehlik J, Shah KB, et al. Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and

Medical Management in Ambulatory Heart Failure Patients: The ROADMAP Study 2-Year Results. JACC.Heart failure; JACC Heart Fail 2017;5(7):518-527. DOI: 10.1016/j.jchf.2017.02.016

Steinberg J, Shah KM, Gartland A, Zeggini E, Wilkinson JM. Effects of chronic cobalt and chromium exposure after metal-on-metal hip resurfacing: An epigenome-wide association pilot study. J Orthop Res. 2017;35(10):2323-2328. DOI: 10.1002/jor.23525

Stoumpos AI, Kitsios F, Talias MA. Digital Transformation in Healthcare: Technology Acceptance and Its Applications. International journal of environmental research and public health 2023;20(4):3407. DOI: 10.3390/ijerph20043407

Sundararaman LV, Edwards RR, Ross EL, Jamison RN. Integration of Mobile Health Technology in the Treatment of Chronic Pain: A Critical Review. Reg Anesth Pain Med 2017;42(4):488-498. DOI: 10.1097/AAP.0000000000000621

Tarricone R, Ciani O, D'Acunto S, Scalzo S. The rise of rules: Will the new EU regulation of medical devices make us safer? Eur J Intern Med. 2020;80:117-120. DOI: 10.1016/j.ejim.2020.07.012

Taylor CB, Fitzsimmons-Craft EE, Graham AK. Digital technology can revolutionize mental health services delivery: The COVID-19 crisis as a catalyst for change. Int J Eat Disord. 2020;53(7):1155-1157. DOI: 10.1002/eat.23300

The European Commission Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 8, January 2013

Thompson M. The geographies of digital health – Digital therapeutic landscapes and mobilities. Health Place. 2021;70:102610. DOI: 10.1016/j.healthplace.2021.102610

Trubetskaya A, Manto D, McDermott O. A Review of Lean Adoption in the Irish MedTech Industry. Processes 2022;10(2):391. DOI: 10.3390/pr10020391

Tun S, Spainhower CJ, Cottrill CL, Lakhani HV, Pillai SS, Dilip A, et al. Therapeutic Efficacy of Antioxidants in Ameliorating Obesity Phenotype and Associated Comorbidities. Frontiers in pharmacology 2020;11:1234. DOI: 10.3389/fphar.2020.01234

Ungan MC. Standardization through process documentation. Business process management journal 2006;12(2):135-148. DOI: 10.1108/14637150610657495

Van Norman GA. Drugs and Devices: Comparison of European and U.S. Approval Processes. JACC.Basic to translational science; JACC Basic Transl Sci 2016;1(5):399-412. DOI: 10.1016/j.jacbts.2016.06.003

Van Norman GA. Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices. JACC.Basic to translational science 2016;1(4):277-287. DOI: 10.1016/j.jacbts.2016.03.009

Wafa R, Khan MQ, Malik F, Abdusalomov AB, Cho YI, Odarchenko R. The Impact of Agile Methodology on Project Success, with a Moderating Role of Person's Job Fit in the IT Industry of Pakistan. 2022;12(21):10698. DOI: 10.3390/app122110698

Waller M, Stotler C. Telemedicine: a Primer. Curr Allergy Asthma Rep 2018; 18(10):54-59. DOI: 10.1007/s11882-018-0808-4

Ward JR, Clarkson PJ. An analysis of medical device-related errors: prevalence and possible solutions. J Med Eng Technol. 2004;28(1):2-21. DOI: 10.1080/0309190031000123747

Webber CM, Caldwell B, Bocell FD, Saha A, Tarver ME. Patient-reported outcomes and medical device evaluation: from conception to implementation. J Patient Rep Outcomes 2022;6(1):53. DOI: 10.1186/s41687-022-00463-w

Wilkinson B, van Boxtel R. The Medical Device Regulation of the European Union Intensifies Focus on Clinical Benefits of Devices. Ther Innov Regul Sci 2020;54(3):613-617. DOI: 10.1007/s43441-019-00094-2

Wong E, Wong E, Mavondo F, Fisher J. Patient feedback to improve quality of patient-centred care in public hospitals: A systematic review of the evidence. BMC health services research 2020;20(1):530. DOI: 10.1186/s12913-020-05383-3

Yaqoob T, Abbas H, Shafqat N. Integrated Security, Safety, and Privacy Risk Assessment Framework for Medical Devices. JBHI 2020;24(6):1752-1761. DOI: 10.1109/JBHI.2019.2952906

Zaitoun RA, Said NB, de Tantillo L. Clinical nurse competence and its effect on patient safety culture: a systematic review. BMC nursing 2023;22(1):173. DOI: 10.1186/s12912-023-01305-w

Zandieh SO, Yoon-Flannery K, Kuperman GJ, Langsam DJ, Hyman D, Kaushal R. Challenges to EHR Implementation in Electronic- Versus Paper-based Office Practices. J Gen Intern Med 2008;23(6):755-761. DOI: 10.1007/s11606-008-0573-5

Zeng Z, Chen P, Lew AA. From high-touch to high-tech: COVID-19 drives robotics adoption. Tourism geographies 2020;22(3):724-734. DOI: 10.1080/14616688.2020.1762118

Zippel C, Bohnet-Joschko S. Post market surveillance in the german medical device sector – current state and future perspectives. Health Policy 2017;121(8):880-886. DOI: 10.1016/j.healthpol.2017.06.005

List of Publications

Fearne J, Camilleri Agius Decelis D, Serracino Inglott A. Medical Devices Directive in the European Union adapting to the EU Regulation. 12th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Vienna, Austria 2020

Grech L, Fearne J, Farrugia K, Gatt Baldacchino E, Serracino-Inglott A. Good Distribution Practice Training for Medical Device Industry. Pharmacy Education. 2022; 22(3):24.

Fearne J, Catania J, Grech L, Serracino-Inglott A. Developing a Patient Centred Incident Reporting Medical Device Framework. Pharmacy Education. 2023; 23(6):402

Grech L, Fearne J, Farrugia K, Gatt Baldacchino E, Zarb Adami M, Wirth F, Serracino-Inglott A, Azzopardi LM. Medical Devices Study Unit in the Pharmaceutical Technology Course. EAFP annual conference, Valencia, 2023.

Catania J, Fearne J, Farrugia K, Grech L, Serracino-Inglott A. Implementation of patient-centred incident reporting framework. MedinPharma, Malta, 2023.

Fearne J, Catania J, Farrugia K, Grech L, Serracino Inglott A. Establishing a patient-centred incident reporting medical device framework in Malta. MedinPharma, Malta, 2023.

Farrugia K, Tanti S, Portughese A, Fearne J, Grech L, Serracino Inglott A. Development of clinical investigations and performance studies in Malta. MedinPharma, Malta, 2023.

Galea L, Farrugia K, Fearne J, Grech L, Serracino Inglott A. Identification of Medical Devices application templates in Malta. MedinPharma, Malta, 2023

List of Appendices

Establishing a Patient Centred Medical Device Body

Submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

Julian Fearne

Department of Pharmacy
2024

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Appendix 1

University research ethics committee (UREC) approval

From: FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt>
Sent: 23 June 2021 15:54
To: Julian Fearne
Cc: Louise Grech; Anthony Serracino Inglott
Subject: Re: FRECMDS_2021_142 - ID: 8742_11052021_Julian Fearne

Dear Mr Fearne,

Good afternoon and thank you for the submitted documents.

Since your self-assessment resulted in no issues being identified, FREC will file your application for record and audit purposes but will not review it.

Any ethical and legal issues including data protection issues are your responsibility.

Kindly **confirm** that you sent all the documents which you attached to the UREC form together with other documents related to your study.

Kindly note that these documents are also requested for audit purposes.

Regards,
Annalise

L-Università ta' Malta

Annalise Mallia Duca | Secretary

Faculty Research Ethics Committee
Faculty of Medicine and Surgery
Medical School, Mater Dei Hospital
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https://www.um.edu.mt/ms/students/researchethics

Appendix 2

Correspondence between ISO 13485:2016 and ISO 9001:2015

Annex B
(informative)

Correspondence between ISO 13485:2016 and ISO 9001:2015

Tables B.1 and B.2 show the correspondence between ISO 13485:2016 and ISO 9001:2015.

Table B.1 — Correspondence between ISO 13485:2016 and ISO 9001:2015

Clause in ISO 13485:2016	Clause in ISO 9001:2015
1 Scope 4.1.1 (no title)	1 Scope 4.3 Determining the scope of the quality management system
4 Quality management system	4 Context of the organization 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes 8.4 Control of externally provided processes, products and services
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes 7.5.1 General
4.2.3 Medical device file	*No equivalent clause*
4.2.4 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented information
4.2.5 Control of records	7.5.2 Creating and updating 7.5.3 Control of documented information
5 Management responsibility	5 Leadership
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy 5.2.1 Establishing the quality policy 5.2.2 Communicating the quality policy

5.4 Planning	6 Planning
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6 Planning 6.1 Actions to address risks and opportunities 6.3 Planning of changes
5.5 Responsibility, authority and communication	5 Leadership
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	5.3 Organizational roles, responsibilities and authorities
5.5.3 Internal communication	7.4 Communication
5.6 Management review	9.3 Management review
5.6.1 General	9.3.1 General
5.6.2 Review input	9.3.2 Management review inputs
5.6.3 Review output	9.3.3 Management review outputs
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General 7.1.2 People
6.2 Human resources	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment and contamination control	7.1.4 Environment for the operation of processes
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Requirements for products and services
7.2.1 Determination of requirements related to product	8.2.2 Determining the requirements for products and services
7.2.2 Review of requirements related to product	8.2.3 Review of the requirements for products and services 8.2.4 Changes to requirements for products and services
7.2.3 Communication	8.2.1 Customer communication
7.3 Design and development	8.3 Design and development of products and services
7.3.1 General	8.3.1 General
7.3.2 Design and development planning	8.3.2 Design and development planning
7.3.3 Design and development inputs	8.3.3 Design and development inputs
7.3.4 Design and development outputs	8.3.5 Design and development outputs
7.3.5 Design and development review	8.3.4 Design and development controls
7.3.6 Design and development verification	8.3.4 Design and development controls
7.3.7 Design and development validation	8.3.4 Design and development controls
7.3.8 Design and development transfer	8.3.4 Design and development controls

7.3.9 Control of design and development changes	8.3.6 Design and development changes 8.5.6 Control of changes
7.3.10 Design and development files	7.5.3 Control of documented information
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing process	8.4 Control of externally provided processes, products and services 8.4.1 General 8.4.2 Type and extent of control
7.4.2 Purchasing information	8.4.3 Information for external providers
7.4.3 Verification of purchased product	8.4.2 Type and extent of control 8.4.3 Information for external providers 8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
7.5.2 Cleanliness of product	*No equivalent clause*
7.5.3 Installation activities	*No equivalent clause*
7.5.4 Servicing activities	*No equivalent clause*
7.5.5 Particular requirements for sterile medical devices	*No equivalent clause*
7.5.6 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier system	*No equivalent clause*
7.5.8 Identification	8.5.2 Identification and traceability
7.5.9 Traceability	8.5.2 Identification and traceability
7.5.10 Customer property	8.5.3 Property belonging to customers or external providers
7.5.11 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8 Measurement, analysis and improvement	9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Feedback	8.5.5 Post-delivery activities 9.1.2 Customer satisfaction
8.2.2 Complaint handling	9.1.2 Customer satisfaction
8.2.3 Reporting to regulatory authorities	8.5.5 Post-delivery activities
8.2.4 Internal audit	9.2 Internal audit
8.2.5 Monitoring and measurement of processes	9.1.1 General

8.2.6 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs
8.3.1 General	10.2 Nonconformity and corrective action
8.3.2 Actions in response to nonconforming product detected before delivery	8.7 Control of nonconforming outputs
8.3.3 Actions in response to nonconforming product detected after delivery	8.7 Control of nonconforming outputs
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 General	10.1 General 10.3 Continual improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	0.3.3 Risk-based thinking 6.1 Actions to address risks and opportunities 10.1 General 10.3 Continual improvement

Table B.2 — Correspondence between ISO 9001:2015 and ISO 13485:2016

Clause in ISO 9001:2015	Clause in ISO 13485:2016
1 Scope	1 Scope
4 Context of the organization	4 Quality management system
4.1 Understanding the organization and its context	4.1 General requirements
4.2 Understanding the needs and expectations of interested parties	4.1 General requirements
4.3 Determining the scope of the quality management system	4.1 General requirements 4.2.2 Quality manual
4.4 Quality management system and its processes	4.1 General requirements
5 Leadership	5 Management responsibility
5.1 Leadership and commitment	5.1 Management commitment
5.1.1 General	5.1 Management commitment
5.1.2 Customer focus	5.2 Customer focus
5.2 Policy	5.3 Quality policy
5.2.1 Establishing the quality policy	5.3 Quality policy
5.2.2 Communicating the quality policy	5.3 Quality policy
5.3 Organizational roles, responsibilities and authorities	5.4.2 Quality management system planning 5.5.1 Responsibility and authority 5.5.2 Management representative
6 Planning	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 8.5.3 Preventive action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2 Quality management system planning
7 Support	6 Resource management
7.1 Resources	6 Resource management
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.2 Human resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4.1 Work environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.5.1 General	7.6 Control of monitoring and measuring equipment
7.1.5.2 Measurement traceability	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	6.2 Human resources
7.2 Competence	6.2 Human resources
7.3 Awareness	6.2 Human resources
7.4 Communication	5.5.3 Internal communication

7.5 Documented information	4.2 Documentation requirements
7.5.1 General	4.2.1 General
7.5.2 Creating and updating	4.2.4 Control of documents 4.2.5 Control of records
7.5.3 Control of documented Information	4.2.3 Medical device file 4.2.4 Control of documents 4.2.5 Control of records 7.3.10 Design and development files
8 Operation	7 Product realization
8.1 Operational planning and control	7.1 Planning of product realization
8.2 Requirements for products and services	7.2 Customer-related processes
8.2.1 Customer communication	7.2.3 Communication
8.2.2 Determining the requirements for products and services	7.2.1 Determination of requirements related to product
8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to product
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	7.3.1 General
8.3.2 Design and development planning	7.3.2 Design and development planning
8.3.3 Design and development inputs	7.3.3 Design and development inputs
8.3.4 Design and development controls	7.3.5 Design and development review 7.3.6 Design and development verification 7.3.7 Design and development validation 7.3.8 Design and development transfer
8.3.5 Design and development outputs	7.3.4 Design and development outputs
8.3.6 Design and development changes	7.3.9 Control of design and development changes
8.4 Control of externally provided processes, products and services	4.1 General requirements (see 4.1.5) 7.4.1 Purchasing process
8.4.1 General	7.4.1 Purchasing process
8.4.2 Type and extent of control	4.1 General requirements (see 4.1.5) 7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information 7.4.3 Verification of purchased product
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision 7.5.6 Validation of processes for production and service provision

8.5.2 Identification and traceability	7.5.8 Identification 7.5.9 Traceability
8.5.3 Property belonging to customers or external providers	7.5.10 Customer property
8.5.4 Preservation	7.5.11 Preservation of product
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision 7.5.3 Installation activities 7.5.4 Servicing activities 8.2.2 Complaint handling 8.2.3 Reporting to regulatory authorities 8.3.3 Actions in response to nonconforming product detected after delivery
8.5.6 Control of changes	7.3.9 Control of design and development changes
8.6 Release of products and services	7.4.3 Verification of purchased product 8.2.6 Monitoring and measurement of product
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product
9 Performance evaluation	8 Measurement, analysis and improvement
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement
9.1.1 General	8.1 General 8.2.5 Monitoring and measurement of processes 8.2.6 Monitoring and measurement of product
9.1.2 Customer satisfaction	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaint handling
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal audit	8.2.4 Internal audit
9.3 Management review	5.6 Management review
9.3.1 General	5.6.1 General
9.3.2 Management review inputs	5.6.2 Review input
9.3.3 Management review outputs	5.6.3 Review output
10 Improvement	8.5 Improvement
10.1 General	8.5.1 General
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual improvement	5.6.1 General 8.5 Improvement

Correlation table taken from ISO 13485:2016

Appendix 3

Quality management system document list

Decision Area	Document Type	Objectives	Document Name	Indicator
Document Control	Standard Operating Procedure	To establish a systematic process for evaluating, approving, and implementing changes in order to effectively assess and manage their impact on quality, safety, and efficacy.	Change Control Management	Periodical review every n year
Document Control	Standard Operating Procedure	To define the process for developing, approving, and maintaining standard operating procedures (SOPs) in order to ensure consistency, clarity, and regulatory compliance.	Creation and Management of SOPs	Periodical review every n year
Document Control	Standard Operating Procedure	Establishing the steps and guidelines for preparing and submitting regulatory approval applications while ensuring accuracy, completeness, and adherence to applicable regulations.	Creation of Applications	Periodical review every n year
Document Control	Standard Operating Procedure	To create a system for documenting, investigating, and resolving deviations from established procedures in order to ensure product quality, safety, and compliance.	Deviation Management	Number of un/controlled changes
Document Control	Standard Operating Procedure	To provide guidelines for the creation, organisation, and maintenance of accurate and complete documentation in order to support regulatory compliance and traceability.	Good Documentation Practices	Periodical review every n year
Document Control	Standard Operating Procedure	To ensure that labelling and instructions for use (IFU) documents are created, reviewed,	Labelling and Instructions for Use (IFU) Control	Periodical review every n year

		approved, and controlled accurately in order to comply with regulatory requirements and provide clear and appropriate information to users.		
Document Control	Standard Operating Procedure	To define the procedures for processing incoming applications efficiently and effectively, ensuring proper handling, tracking, and timely completion.	Processing of Applications Received	Periodical review every n year
Document Control	Standard Operating Procedure	To develop a risk-based approach for classifying and managing medical devices based on potential patient safety risks and regulatory requirements.	Risk-Based Classification and Management of Medical Devices	Periodical review every n year
Human Resources	Standard Operating Procedure	To provide guidelines for assigning responsibilities, delegating tasks, and ensuring clear communication within the organisation in order to achieve efficient and effective work distribution.	Delegation of Work	Periodical review every n year
Human Resources	Standard Operating Procedure	To define the process for recruiting, onboarding, and offboarding employees in order to maintain a consistent and compliant approach while fostering a positive employee experience.	Recruitment, Onboarding and Off-Boarding Procedure	Staff review forms
Human Resources	Standard Operating Procedure	To put in place a comprehensive training and competency management system to ensure that employees are properly trained,	Training and Competence Management	Staff review forms

		qualified, and competent to perform their assigned tasks.		
Regulatory Oversight	Standard Operating Procedure	The procedures for conducting post-market clinical follow-up studies to collect and evaluate clinical data on the safety and performance of medical devices after they have been placed on the market are to be defined.	Management of Post-Market Clinical Follow-up (PMCF)	Periodical review every n year
Regulatory Oversight	Standard Operating Procedure	To ensure compliance with post-market surveillance requirements, processes for monitoring, analysing, and reporting adverse events and other safety-related information related to medical devices must be established.	Management of Regulatory Compliance with Post-Market Surveillance Requirements	Periodical review every n year
Regulatory Oversight	Standard Operating Procedure	To establish procedures for ensuring regulatory compliance in medical device distribution, importation, and exportation, including adherence to applicable laws, regulations, and licencing requirements.	Management of Regulatory Compliance for Distribution, Importation and Exportation of Medical Devices	Periodical review every n year
Regulatory Oversight	Standard Operating Procedure	To ensure clinical evaluation and investigation requirements are met, processes for planning, conducting, and documenting clinical studies and evaluations for medical devices must be established.	Management of Regulatory Compliance with Clinical Evaluation and Investigation Requirements	Periodical review every n year
Regulatory Oversight	Standard Operating Procedure	Developing procedures for implementing and maintaining a UDI	Management of Regulatory Compliance with Unique Device	Periodical review every n year

		system in order to meet regulatory requirements for identifying and tracking medical devices throughout their lifecycle.	Identification (UDI) Requirements	
Regulatory Oversight	Standard Operating Procedure	To define the processes and responsibilities for managing regulatory inspections and audits conducted by regulatory authorities or notified bodies, with the goal of ensuring readiness, cooperation, and compliance.	Management of Regulatory Inspections and Notified Body Audits	Periodical review every n year
Regulatory Oversight	Standard Operating Procedure	Ensure regulatory compliance by implementing robust processes and controls, as well as conducting periodic audits to assess adherence to applicable regulations and guidelines.	Regulatory Compliance and Audit	Periodical review every n year
Regulatory Oversight	Standard Operating Procedure	In order to improve product quality and regulatory compliance, a systematic process for identifying, investigating, and implementing corrective and preventive actions to address nonconformities, deviations, and systemic issues must be established.	Management of Corrective and Preventive Actions (CAPA)	Number of CAPAs recorded
Market Surveillance	Standard Operating Procedure	To define the procedures for conducting internal audits and inspections in order to assess the effectiveness of the quality management system, identify areas for improvement, and	Internal Audits and Inspections	Periodical review every n year

		ensure regulatory compliance.		
Market Surveillance	Standard Operating Procedure	To develop a risk-based approach for conducting medical device inspections and testing to ensure their safety, efficacy, and compliance with applicable regulations and standards.	Risk-Based Inspection and Testing of Medical Devices	Periodical review every n year
Surveillance	Standard Operating Procedure	To provide guidelines for identifying, documenting, and investigating potential cases of counterfeit and/or falsified medical devices, with the goal of ensuring timely and appropriate action is taken to protect patient safety and regulatory compliance.	Handling and Investigation of Potential Counterfeit and/or Falsified Medical Devices	Number of recorded investigations
Vigilance	Standard Operating Procedure	To define the procedures for receiving, documenting, investigating, and resolving medical device complaints, as well as reporting adverse events to regulatory authorities as necessary.	Complaint Handling and Medical Device Reporting	Number of recorded complaints
Vigilance	Standard Operating Procedure	To establish a systematic process for dealing with and investigating potential serious adverse events and public health threats associated with medical devices, with the goal of ensuring that appropriate actions are taken to mitigate risks and protect public health.	Handling and Investigation of Potential Serious Adverse Events and Public Health Threats	Periodical review every n year

Vigilance	Standard Operating Procedure	To address safety-related issues with medical devices, define the procedures for managing field safety corrective actions and field safety notices, including their identification, communication, implementation, and tracking.	Management of Field Safety Corrective Actions (FSCA) and Field Safety Notices (FSN)	Periodical review every n year
Vigilance	Standard Operating Procedure	To establish a systematic process for initiating, carrying out, and documenting product recalls and withdrawals in order to ensure that non-compliant or unsafe medical devices are removed from the market in a timely and effective manner.	Management of Product Recalls and Withdrawals	Periodical review every n year
Vigilance	Standard Operating Procedure	To define the procedures for reporting, handling, and investigating adverse events related to medical devices in accordance with vigilance reporting requirements, in order to ensure the devices' ongoing safety and performance monitoring.	Vigilance Reporting, Handling and Investigation of Adverse Events	Number of vigilance reports received

Appendix 4

SOP-001.00 Management and control of standard operating procedures

CONTENTS

1.0 PURPOSE

1.1 The purpose of this SOP is to establish and maintain a systematic and controlled approach to the generation, numbering, review, approval, and obsolescence of Standard Operating Procedures (SOPs) within the framework of the Medical Device Quality Management System (QMS). This SOP ensures compliance with current Good Documentation Practices (GDP) and facilitates the efficient processing of document revisions and extensions of validity. Furthermore, it aims to promote consistency, accuracy, and regulatory compliance in the creation and management of SOPs.

2.0 SCOPE

2.1 This SOP applies to all personnel involved in the creation, review, approval, and maintenance of SOPs within the medical device framework. This includes but is not limited to, authors, reviewers, approvers, and the Document Control Officer responsible for overseeing the SOP management process. Adherence to this SOP is critical to maintaining the integrity of the QMS and ensuring that all SOPs are developed and maintained in a standardized manner.

3.0 DEFINITIONS

3.1 cGxP – cGxP stands for current Good Practices; the ‘x’ can stand for various things such as manufacturing, distribution, laboratory, and documentation. GMP is a system for ensuring that products are consistently produced and controlled according to quality standards whilst always safeguarding the quality of life of the patient.

3.2 SOP – Standard Operating Procedures are GMP documents which are the tested, verified, approved, and documented way of executing operations.

3.3 SOP Owner – The person who is responsible that the respective SOP is followed (Normally the respective area manager or area owner).

3.4 Quality Responsible – The person designated by job description and organogram to

have overall responsibility over the Quality Management System.

4.0 RESPONSIBILITIES

4.1 All personnel that have been authorised either to issue, review or approve SOPs are responsible for following this SOP.

4.2 Final approval of all SOPs must be carried out by the releasing Quality Responsible.

4.3 The Quality Responsible is responsible for ensuring that all SOPs follow the guidelines stipulated within this SOP and any applicable regulatory requirements.

4.4 It is the responsibility of the respective SOP owner to ensure that all applicable SOPs are reviewed prior to their review due date.

4.5 The Quality Responsible is responsible for controlling and maintaining a list of approved SOPs.

4.6 The Quality Responsible is responsible for keeping all superseded SOPs archived and not accessible to other personnel, whilst being accessible to the quality team in case of any investigations.

5.0 PROCEDURE

5.1 **Introduction**

5.1.1 Every activity being carried out has to be defined by a specific SOP.

5.1.2 All SOPs have to be reviewed by the respective owner which is being directly impacted by the SOP and have to be approved by a pre-determined Quality Responsible.

5.1.3 The approval of an SOP alone does not permit its usage, the SOP has to be made effective before being used. Unless justified, the effective date of the SOP should not be more than 2 weeks from the respective approval date.

5.1.4 All personnel that have read and understood this SOP and have adequate knowledge on the respective subject can write SOPs.

5.1.5 **Training on all relevant SOPs must be performed and documented before the respective procedure is carried out by the personnel.** Section owners are responsible for deciding who requires training on a particular SOP. This shall be included in a Training Matrix that shall be verified by the Quality Responsible.

5.2 **SOP Numbering**

5.2.1 SOPs are numbered using the following format:

SOP-XXX.RR

Where:

SOP is a constant prefix referring to Standard Operating Procedures

XXX refers to a sequential number starting from '001' to '999' which is unique to every SOP

RR refers to the revision number of the SOP, starting from '00'

5.2.2 To number a new SOP, the Quality Responsible must be informed, which then provides the next unique SOP number.

5.2.3 If an SOP number is not used after the Quality Responsible has listed it in the SOP Reference List, the Quality Responsible must be informed so that the unique SOP number provided is made available again.

5.2.4 This system is to be maintained by the Quality Responsible or deputy only.

5.3 **SOP Format and Content**

5.3.1 SOPs should be written in justified format using Calibri font size 12 with multiple (1.15) line spacing.

5.3.2 Every SOP should be structured as stipulated in Appendix I (SOP Template).

5.3.3 Company logo, SOP name, SOP number, page number and total number of pages must be visible on all pages.

5.3.4 Each SOP must include the following headings:

- **Purpose:** outlines the aim and objectives of the respective SOP.

- **Scope:** specifies the main areas, procedures, and equipment covered by the respective SOP.

- **Definitions:** a glossary of terms or abbreviations used within the text.

- **Responsibilities:** identifies the different responsibilities detailed in the SOP and the personnel responsible to follow them.

- **Procedure:** The step-by-step method which clearly explains the respective operations. Ideally, the structure of this section is in sequential point form for ease of understanding.

- **References:** a list of all materials, documents, articles, and SOPs used or which may be affected by the current SOP.

- **Revision History:** an account of the changes carried out when modifying the SOP. If a change control or CAPA was the reason for the change, it has to be specified in the revision history. The revision history table is carried over in all revisions of the respective SOP; for example, if the SOP was revised 4 times, all the previous revision histories are retained and clearly visible to keep an optimal audit trail.

- **Appendices:** The SOP may contain additional information such as forms and templates, associated with the procedure within the SOP.

5.4 **Issuing a new SOP**

5.4.1 The author drafts a new SOP and circulates it for review (if needed; if a review is not needed, the SOP is sent directly for approval instead).

5.4.2 The SOP owner decides the personnel required to train on the specific SOP which is then approved by the Quality Responsible.

5.4.3 The training matrix is then updated by the Quality Responsible.

5.4.4 When the SOP is reviewed and/or approved, the Quality Responsible will issue the final version of this SOP and will write the review due date which is maximum 3 years after the SOP is made effective.

5.4.5 The SOP is marked with a '**MASTER'** stamp on each page, scanned and stored into the company's QMS.

5.4.6 The original hardcopy of the SOP is retained by the Quality Department.

5.4.7 The quality department records the steps taken for an SOP to be approved and effective in a logbook (Appendix II).

5.5 **Revision of an existent SOP**

6.5.1 The SOP author has to request a soft copy of the editable word document from the Quality Department.

6.5.2 The author issues the updated SOP for review.

6.5.3 When the SOP is reviewed and/or approved, the Quality Responsible will issue the final version of this SOP.

5.6 **Extension of validity**

5.6.1 All SOPs shall be reviewed after a period of not more than three years. If the SOP is still deemed valid after such a period, then no changes shall be applied and can be extended as is for another three years.

5.6.2 The below criteria need to be satisfied for an SOP to qualify for validity extension:

- Procedure still reflects current practices
- It is still relevant with respect to cGxP
- It is still relevant with respect to any relevant company policies

5.6.3 Once agreed upon by the respective document owner and Quality Responsible, the 3-year validity extension field on the front page of the SOP is filled in and signed accordingly.

5.6.4 SOP validity extension can be granted only once.

5.6.5 No re-training is required in the case of SOP validity extension.

5.7 **SOP use and end of lifecycle**

5.7.1 Reading copies and working forms can be printed by all personnel. Printed copies have an expiry of 5 days, print date included, except for working documents. The latter should include a footer that requires the user to verify that the governing SOP version is still effective at time of use (Refer to **Appendix I**).

5.7.2 When an SOP is no longer required, it should be made obsolete via change control and the list of active SOPs is to be updated accordingly.

6.0 REFERENCES

N/A

7.0 REVISION HISTORY

SOP Revision	Reference	Reason for Revision
		•

8.0 APPENDICES

8.1 **Appendix I** – SOP Template

8.2 **Appendix II** – Template & Legend for the Logbook for Control of SOP Distribution

APPENDIX I – SOP Template

SOP-XXX.RR	STANDARD OPERATING PROCEDURE [TITLE]	

Prepared by:	Role:	Signature:	Date:
Reviewed by: Add or remove reviewer sections as necessary	Role:	Signature:	Date:
Approved by:	Role:	Signature:	Date:
Effective Date:		Review Due Date: *3 years from effective date*	

3-Year Validity Extension			
Reviewed by: Add or remove reviewer sections as necessary	Role:	Signature:	Date:
Approved by:	Role:	Signature:	Date:
Extension Effective Date:		Review Due Date: *3 years from effective date*	

CONTENTS

SOP Revision	Reference	Reason for Revision
		•

APPENDIX I – XXX

(Each appendix should start on a fresh page)

APPENDIX II – XXX (Working Forms, worksheets, *etc.*)

Working forms should include this footer:

(Make sure that there is a section break and the footer is not linked to the previous section)

I hereby verify that the governing SOP version is still effective at time of use: _____ Date: _____

APPENDIX II – Template & Legend for the Logbook for Control of SOP Distribution

SOP no. & version	Master	Scan	Coming into Force	Training Updated	HC removed	HC cancelled	HC replaced	SC removed	SC replaced

Legend

SOP Approval stage		**Summarised Heading**
Stamping every page of new approved SOP, as *Master*.		**Master**
Scanning of new SOP and insertion of relevant control forms on each page.		**Scan**
Placement of new SOP in QMS		**Coming into Force**
Alerting of personnel who require training on new SOP.		**Training**
SOP Effective stage		
Removal of hardcopy/hardcopies of SOP/s to be superseded, from active SOP file (does not apply in case of new SOPs).		**HC removed**
Stamping of SOP/s to be superseded, as *Cancelled* (does not apply in case of new SOPs).		**HC cancelled**
Placement of new SOP into relevant active SOP file.		**HC replaced**
Transfer of SOP to the superseded folder		**SC removed**
Transfer of effective SOP to the effective SOP folder		**SC replaced**

Appendix 5

Quality policy

Mission

The mission is to protect public health by developing a quality management system that supports a patient-centred medical device framework that medical device bodies can use.

Vision

The vision of the QMS framework is to develop best practises that can be used to establish a centre of excellence for advancing innovative and effective regulation and developing high standards and scientific rigour in the work performed. Striving for excellence for the benefit of patients and stakeholders and endeavouring to be internationally recognised, as an efficient framework system for the promotion of development and sustainable growth.

The objectives of the QMS framework are to:

- Ensure that medical device stakeholders follow applicable regulations, directives, and guidelines.
- Establish consistent and standardised processes for evaluating medical device compliance with regulatory requirements, including evaluation of technical documentation, clinical data, and quality management systems.
- Assess and manage the risks associated with medical devices, such as potential safety hazards, performance issues, and noncompliance with regulatory requirements.
- Facilitate effective communication between competent authorities and medical device stakeholders in order to exchange information, address inquiries, and provide regulatory guidance.
- Monitor the safety and performance of medical devices on the market by performing market surveillance activities such as post-market surveillance, adverse event reporting, and recall management.
- Enforce regulatory compliance by auditing, inspecting, and evaluating the facilities, processes, and quality management systems of medical device stakeholders.

- Continuously improve the regulatory framework and processes by incorporating stakeholder feedback, identifying areas for improvement, and enacting necessary changes to ensure effective and efficient regulatory oversight.
- Prioritise public health and safety by ensuring that medical devices on the market are safe, effective, and of high quality.

Appendix 6

Agenda for stakeholder workshop on incident reporting system

Workshop 1

Agenda Item	Details
1. Welcome and introduction	• Participant introductions • Workshop objectives overview
2. Presentation on needs assessment	• Overview of *Stage 1: Needs assessment* • Presentation of common themes identified
3. Gap analysis exercise and discussion on incident data fields	• Analysis of Maltese national reporting forms and data fields • Interactive discussion on gaps and strengths
4. Identifying key stakeholders	• Identification and discussion on key stakeholders
7. Definitions and discussion of incident reporting steps	• Clarification of key terms and concepts • Discussion on the steps taken when incident reports are received
7. Open discussion	• Participants' input, questions, and feedback
8. Closing remarks	• Thanking the participants. • Encouragement to continue working together.

Workshop 2

Agenda Item	Details
1. Welcome and introduction	• Participant introductions • Workshop objectives overview
2. Presentation on supporting documents and tools	• Overview of *Stage 2: Compilation of supporting documents and tools*
3. Incident report SOP framework	• Compilation of SOP for validating incident reports received • Compilation of SOP for investigating and analysing incident reports
4. Incident report forms	• Compilation of template incident report forms
5. Validation Questionnaire	• Validation of all documents created
6. Open discussion	• Participants' input, questions, and feedback
7. Closing remarks	• Thanking the participants. • Encouragement to continue working together.

Appendix 7

List of identified incident report related definitions

Term	Definition
Adverse Event	Any undesired medical occurrence, unintended disease, injury, or clinical signs, including abnormal laboratory findings, observed in subjects, users, or other individuals during a clinical investigation. It encompasses events, whether or not related to the investigational device.
Benefit-Risk Determination	The analysis encompassing all assessments of benefit and risk relevant to the device's use for its intended purpose, conducted in accordance with the manufacturer's specified intended purpose.
CE Marking	A marking affixed by a manufacturer to indicate that a device complies with the applicable requirements outlined in regulations and other relevant Union harmonization legislation.
Clinical Evaluation	A systematic and ongoing assessment of clinical data relevant to a medical device's safety and performance, supporting the conformity assessment process.
Device Deficiency	Any inadequacy in the identity, quality, durability, reliability, safety, or performance of an investigational device. This includes malfunctions, use errors, or deficiencies in information supplied by the manufacturer.
Device Lifecycle	The entire span of a medical device's existence, from design and development through manufacturing, distribution, use, and ultimately disposal. Vigilance activities, including monitoring and reporting, are integral components throughout the device's lifecycle.
Field Safety Corrective Action	Corrective actions taken by a manufacturer, for technical or medical reasons, to prevent or reduce the risk of a serious incident associated with a device available on the market.
Field Safety Notice	A communication issued by a manufacturer to inform users and stakeholders about a safety-related issue with a medical device, including instructions for corrective actions.
Health Institution	An organization primarily dedicated to the care or treatment of patients or the promotion of public health.
Incident	Any malfunction, deterioration in characteristics, or performance issues of a device available on the market. This includes use-errors related to ergonomic features, inadequacies in information provided by the manufacturer, and undesirable side-effects.
Medical Device	Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer for use in humans. It serves one or more specific medical purposes such as diagnosis, prevention, monitoring, prediction, prognosis, treatment, alleviation of disease; diagnosis, monitoring, treatment, alleviation, or compensation for an injury or disability; investigation, replacement, or modification of the anatomy or physiological/pathological processes; and providing information through in vitro examination of specimens derived from the human body. It does not achieve its primary intended action through pharmacological, immunological, or metabolic means but may be assisted in its function by such means. Certain products related to conception control and cleaning, disinfection, or sterilization of devices are also considered medical devices.
Notified Body	An independent third-party organization designated by regulatory authorities to assess the conformity of medical devices with regulatory requirements.

Periodic Safety Update Report	A comprehensive document submitted by the manufacturer to regulatory authorities at specified intervals, providing an overview of the safety and performance of a medical device.
Post-Market Clinical Follow-Up	A continuous process of gathering and evaluating clinical data related to the safety and performance of a medical device after it has been placed on the market.
Post-Market Surveillance	All activities conducted by manufacturers in collaboration with other economic operators to establish and maintain a systematic procedure for proactively collecting and reviewing experiences gained from devices placed on the market. The purpose is to identify any need for immediate application of corrective or preventive actions.
Recall	Any measure aimed at retrieving a device already made available to the end user.
Risk	The combination of the probability of harm occurrence and the severity of that harm.
Risk Acceptability	The determination, based on risk management principles, of whether the level of risk associated with a medical device is acceptable within the context of its intended use.
Risk Management	A proactive and systematic process that identifies, assesses, and manages potential risks associated with the use of a medical device.
Serious Adverse Event	Any adverse event leading to death; serious deterioration in subject health resulting in life-threatening illness or injury, permanent impairment, hospitalization, medical or surgical intervention to prevent life-threatening conditions, chronic disease, foetal distress, foetal death, or congenital physical or mental impairment or birth defect.
Serious Incident	Any incident directly or indirectly leading to death, temporary or permanent serious deterioration of a patient's, users, or other person's state of health, or posing a serious public health threat.
Signal Detection	The systematic process of identifying potential safety concerns or emerging issues related to a medical device through the analysis of various data sources.
Trend Reporting	The practice of analysing and reporting patterns or trends in adverse events or device deficiencies over time, facilitating preventive actions.
Unique Device Identifier (UDI)	Means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market
User Feedback	Information provided by users, healthcare professionals, or other stakeholders regarding their experiences, concerns, or observations related to the use of a medical device. User feedback is valuable for identifying potential issues and improving device safety.
Vigilance Reporting	The process of promptly notifying regulatory authorities about adverse events or incidents associated with a medical device, as part of the vigilance system.
Vigilance System	A systematic process implemented by manufacturers to continuously monitor and assess the safety and performance of their medical devices throughout their lifecycle.
Withdrawal	Means any measure aimed at preventing a device in the supply chain from being further made available on the market

Appendix 8

SOP-002.00 The process of receiving and initiating a medical device incident report

CONTENTS

1.0 PURPOSE

1.1 The purpose of this standard operating procedure is to describe the process of receiving incident reports involving medical devices.

2.0 SCOPE

2.1 This procedure applies to and is to be followed by all members of staff dealing with incident reports received.

3.0 DEFINITIONS

3.1 ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Medical Device Regulation and other applicable Union harmonisation legislation providing for its affixing.

3.2 ‘Economic operator’ means a manufacturer, an authorised representative, an importer, a distributor, or the person referred to in Article 22(1) and 22(3) of Regulation (EU) 2017/745.

3.3 ‘Incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

3.4 ‘In vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- concerning a physiological or pathological process or state;
- concerning congenital physical or mental impairments;
- concerning the predisposition to a medical condition or a disease;

- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

3.5 ‘Line Head’ for this SOP is the Director, Senior Head, or Head of the department.

3.6 ‘Medical Device’ means any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

3.7 ‘Serious Incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other

person's state of health, (c) a serious public health threat.

3.8 ‘User’ means any healthcare professional or lay person who uses a device.

For the scope of this SOP, any mention of a medical device also refers to an in vitro diagnostic medical device.

4.0 RESPONSIBILITIES

4.1 The **Line Head** is responsible for**:**

- Consulting on case management when this is required.
- Reviewing the Quality Risk Management Tool.
- Ensuring process continuity in the absence of the designated employee, as well as compliance with and implementation of the procedure.

4.2 The **Designated Employee** is responsible for:

- Following the designated process upon receipt of report.
- Recording and updating any and all databases with all correspondence and information about the incident report.
- Ensuring that actions are taken in a timely manner.
-

5.0 PROCEDURE

5.1 Receipt of report.

5.2 Receipt of Incident Report (IR) form (Appendix 1 or Appendix 2), through phone calls or filled-in forms, and equivalent. If a report is received in any other form, the reporter is asked to fill in the appropriate form.

5.3 Register the Incident Report.

5.3.1 Assign reference numbers as IRXXX-YYYY. XXX is a chronological number, and YYYY is the year of receipt of the IR.

5.3.2 Include details of IR in the database.

5.4 Is the report related to a medical device? If no, proceed to Step 5.5. If yes, proceed to Step 5.6.

5.5 Reply to the concerned party that IR is not related to medical devices and cannot be processed further.

5.6 Classification of incident report through a risk management tool worksheet as per Appendix 3. To be completed for each incident report received.

5.7 Contact stakeholder related to device/s in IR to provide applicable documentation.

5.7.1 Has the stakeholder acknowledged receipt of IR and sent documentation? If no, proceed to Step 5.8. If yes, proceed to Step 5.9.

5.8 Send a reminder email to stakeholder. Communicate directly with the manufacturer/ NB (as applicable). If the requested documentation is not received following the first reminder. Proceed to Step 5.9.

5.9 Acknowledge receipt of documentation.

5.10 Update the database with all the collated data and follow the procedure outlined in SOP-003.00.

6.0 REFERENCES

6.1 Regulation (EU) 2017/746 on in-vitro diagnostic medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0746-20230320

6.2 Regulation (EU) 2017/745 on medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20230320

7.0 REVISION HISTORY

SOP Revision	Reference	Reason for Revision
		•

8.0 APPENDICES

8.1 Appendix 1 – Healthcare Professionals: Medical Devices & In-Vitro Diagnostics Report Form

If 'Yes' add all relevant details of other products	Brand name: Batch Number: _____ Other (e.g. dose/ flow rate): _____
Was a serious incident[1] suffered?	☐ Yes ☐ No

If 'Yes', indicate the type of incident:

❑ Causal relationship between the incident and the medical device

❑ Serious public health threat

❑ Death of a patient, user or other person

❑ Unanticipated serious deterioration in a person's state of health

❑ Other (please specify):

_____

_____

_____

Classify the severity of the incident	❑ High Risk ❑ Medium Risk ❑ Low Risk

[1] 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.

Section B: Incident Details			
B1. Place of Incident			
Entity/ Hospital			
B2. Device Details – *Please include all the known/ visible details of the device*			
Brand Name			
Generic Name			
Product Code/ Reference (Ref)			
Batch/Lot Number		Quantity known to be defective (if any)	
Manufacturer			
Is the product CE Marked	❑ Yes ☐ No	Sterile	❑ Yes ☐ No
A sample of the defective device must be retained where possible. If a sample cannot be retained, support this report with photos.			
Has a sample been retained?	❑ Yes ☐ No	If 'NO' specify reason:	
B3. Incident Details			
Date of Incident (DD-MM-YYYY)		Name of the ward/unit of where the incident occurred	
Functional Use of Product			
Was the device used in combination with other medical devices?		☐ Yes	❑ No
If 'Yes', add all relevant details of other products	Brand name: Product Code/Reference (Ref): _____ Serial/ Batch/ Lot Number: _____		
Was the device used in combination with a medicinal product?		☐ Yes	❑ No

Healthcare Professionals

Medical Devices & In-Vitro Diagnostics Report Form

Section A: Details of Reporter ☐ Tick the box if you wish to keep the below information confidential.	
Name & Surname	
Contact Number	
Position	
Email Address	
Signature of Reporter	
Date	

Description of Incident:
If a sample cannot be retained, support this report with photos or any other relevant information.

Other comments:

8.2 Appendix 2 – General Public: Medical Devices & In-Vitro Diagnostics Report Form

General Public

Medical Devices & In-Vitro Diagnostics Report Form

Section A: Details of Reporter ☐ Tick the box if you wish to keep the below information confidential.	
Name & Surname	
Contact Number	
Email Address	
Date	
Section B: Details of the medical device. *Please include all the known/ visible details of the device*	
Brand Name	
Generic Name	
Intended Use of the medical device (Example: blood glucose meter to monitor glucose levels)	
Name of Manufacturer	
Batch Number / Lot Number	
Device obtained from:	☐ Public Institution ☐ Private Institution ☐ Pharmacy ☐ Online ☐ Other If Other, please specify:
Name of institution / outlet	
Address (if known)	
Telephone (if known)	

Section C: Incident Details	
Date of Incident (DD-MM-YYYY)	

Description of Incident:
If a sample cannot be retained, support this report with photos or any other relevant information

Was the device retained?	☐ Yes ☐ No
Was an injury incurred?	☐ Yes ☐ No

If 'Yes', description of injury:

8.3 Appendix 3 – Quality Risk Management Tool

Quality Risk Management Tool

PART A – Preliminary Information about the Incident Report	
Manufacturer	
Product Brand Name	
Generic Name	
Catalogue Number	
Local Supplier	
Applicable Legislation	
Risk Class	

PART B – The Intrinsic Risk Associated with the Incident Report

Risk Factor	Risk Score	Matrix for Estimating the Intrinsic Risk
The Complexity of the incident refers to: reported quantities affected, causality, detectability, probability of occurrence of direct/indirect harm and risk class of device.	1 2 3 **Circle one**	
The Criticality of the incidents refers to clinical risk assigned (severity), past incident reports on the same device/ recurrence of incident report submitted locally, number of batches affected, reporting entity's assigned level of harm, actual or potential, consequential to the incident, intended and potential users and population affected.	1 2 3 **Circle one**	

	Criticality		
Complexity	1	2	3
1	1 (Low)	2 (Low)	3 (Med)
2	2 (Low)	4 (Med)	6 (High)
3	3 (Med)	6 (High)	9 (High)

Use the above matrix and record the Intrinsic Risk associated with the site below:

Low ☐ Medium ☐ High ☐

PART C – Risk Timeline Score

If Intrinsic Risk is Low – Inform stakeholder within 4 days.

If Intrinsic Risk is **Medium** – Inform stakeholder within 3 days.

If Intrinsic Risk is **High** - Inform stakeholder within 2 days.

PART D – The Intrinsic Risk Rating Criteria

Each risk factor is assigned a risk score from 1 to 3 based on individual criteria.

Risk criteria for each risk factor are as follows:

Reported quantities affected - 1, more than 5 or more than 10.
Causality - nil/ unassessable, possible or probable/ likely.
Detectability – low, medium, high.
Probably of recurrence of direct/indirect harm – low, medium, high.
Risk Class of device – class I/A, class IIa/ IIb/ B/ C.
Clinical risk assigned (severity) – low, medium, high.
Past incident reports on the same device/ recurrence of incident report submitted locally – none, more than 5, more than 10.
Number of batches affected – 1 batch, more than 2, more than 3.
Reporting entity's assigned level of harm, actual or potential, consequential to the incident – low, medium, high.
Intended and potential users and population affected – universal, adults, paediatric/ ICU patients/ immunocompromised.

Healthcare Professionals

Medical Devices & In-Vitro Diagnostics Report Form

Section A: Details of Reporter **☐ Tick the box if you wish to keep the below information confidential.**	
Name & Surname	
Contact Number	
Position	
Email Address	
Signature of Reporter	
Date	

Section B: Incident Details			
B1. Place of Incident			
Entity/ Hospital			
B2. Device Details - *Please include all the known/ visible details of the device*			
Brand Name			
Generic Name			
Product Code/ Reference (Ref)			
Batch/Lot Number		Quantity known to be defective (if any)	
Manufacturer			
Is the product CE Marked	☐ Yes ☐ No	Sterile	☐ Yes ☐ No
A sample of the defective device must be retained where possible. If a sample cannot be retained, support this report with photos.			
Has a sample been retained?	☐ Yes ☐ No	If 'NO' specify reason:	
B3. Incident Details			
Date of Incident (DD-MM-YYYY)		Name of the ward/unit of where the incident occurred	
Functional Use of Product			
Was the device used in combination with other medical devices?			☐ Yes ☐ No
If 'Yes', add all relevant details of other products	Brand name: _____ Product Code/Reference (Ref): _____ Serial/ Batch/ Lot Number: _____		
Was the device used in combination with a medicinal product?			☐ Yes ☐ No

If 'Yes' add all relevant details of other products	Brand name: _____ Batch Number: _____ Other (e.g. dose/ flow rate): _____
Was a serious incident[1] suffered?	☐ Yes ☐ No

If 'Yes', indicate the type of incident:

☐ Causal relationship between the incident and the medical device

☐ Serious public health threat

☐ Death of a patient, user or other person

☐ Unanticipated serious deterioration in a person's state of health

☐ Other (please specify):

Classify the severity of the incident	☐ High Risk ☐ Medium Risk ☐ Low Risk

[1] serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.

Description of Incident:
If a sample cannot be retained, support this report with photos or any other relevant information.

Other comments:

General Public

Medical Devices & In-Vitro Diagnostics Report Form

Section A: Details of Reporter **☐ Tick the box if you wish to keep the below information confidential.**	
Name & Surname	
Contact Number	
Email Address	
Date	
Section B: Details of the medical device. *Please include all the known/ visible details of the device*	
Brand Name	
Generic Name	
Intended Use of the medical device (Example: blood glucose meter to monitor glucose levels)	
Name of Manufacturer	
Batch Number / Lot Number	
Device obtained from:	☐ Public Institution ☐ Private Institution ☐ Pharmacy ☐ Online ☐ Other If Other, please specify: _____
Name of institution / outlet	
Address (if known)	
Telephone (if known)	

Section C: Incident Details	
Date of Incident (DD-MM-YYYY)	

Description of Incident:
If a sample cannot be retained, support this report with photos or any other relevant information

Was the device retained?	☐ Yes ☐ No
Was an injury incurred?	☐ Yes ☐ No

If 'Yes', description of injury:

Quality Risk Management Tool

PART A – Preliminary Information about the Incident Report	
Manufacturer	
Product Brand Name	
Generic Name	
Catalogue Number	
Local Supplier	
Applicable Legislation	
Risk Class	

<table>
<tr><th colspan="3">PART B – The Intrinsic Risk Associated with the Incident Report</th></tr>
<tr><th>Risk Factor</th><th>Risk Score</th><th>Matrix for Estimating the Intrinsic Risk</th></tr>
<tr><td>The Complexity of the incident refers to: reported quantities affected, causality, detectability, probability of occurrence of direct/indirect harm and risk class of device.</td><td>1 2 3
Circle one</td><td rowspan="2"><table>
<tr><th></th><th colspan="3">Criticality</th></tr>
<tr><th>Complexity</th><th>1</th><th>2</th><th>3</th></tr>
<tr><td>1</td><td>1 (Low)</td><td>2 (Low)</td><td>3 (Med)</td></tr>
<tr><td>2</td><td>2 (Low)</td><td>4 (Med)</td><td>6 (High)</td></tr>
<tr><td>3</td><td>3 (Med)</td><td>6 (High)</td><td>9 (High)</td></tr>
</table>
Use the above matrix and record the Intrinsic Risk associated with the site below:

Low ❑ Medium ❑ High ❑</td></tr>
<tr><td>The Criticality of the incidents refers to clinical risk assigned (severity), past incident reports on the same device/ recurrence of incident report submitted locally, number of batches affected, reporting entity’s assigned level of harm, actual or potential, consequential to the incident, intended and potential users and population affected.</td><td>1 2 3

Circle one</td></tr>
</table>

PART C – Risk Timeline Score
If Intrinsic Risk is **Low –** Inform stakeholder within **4 days.** If Intrinsic Risk is **Medium –** Inform stakeholder within **3 days.** If Intrinsic Risk is **High -** Inform stakeholder within **2 days.**

PART D – The Intrinsic Risk Rating Criteria
Each risk factor is assigned a risk score from 1 to 3 based on individual criteria. **Risk criteria** for each **risk factor** are as follows: Reported quantities affected - 1, more than 5 or more than 10. Causality - nil/ unassessable, possible or probable/ likely. Detectability – low, medium, high. Probably of occurrence of direct/indirect harm – low, medium, high. Risk Class of device – class I/A, class IIa/ IIb/ B/ C. Clinical risk assigned (severity) – low, medium, high. Past incident reports on the same device/ recurrence of incident report submitted locally – none, more than 5, more than 10. Number of batches affected – 1 batch, more than 2, more than 3. Reporting entity's assigned level of harm, actual or potential, consequential to the incident – low, medium, high. Intended and potential users and population affected – universal, adults, paediatric/ ICU patients/ immunocompromised.

Appendix 9

SOP-003.00 Management of Incident Reports Related to Medical Devices

CONTENTS

1.0 PURPOSE

1.1 This standard operating procedure details the management of incident reports related to medical devices made available on the local market. The purpose is for this process management to be timely, appropriate and in accordance with the European and national legislation.

2.0 SCOPE

2.1 Further management of incidents related to medical devices and in-vitro diagnostic medical devices received as per SOP002.

3.0 DEFINITIONS

3.1 ‘Authorised Representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer’s behalf in relation to specified tasks with regard to the latter’s obligations under this regulation.

3.2 ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.

3.3 ‘Distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

3.4 ‘Economic Operator’ means a manufacturer, an authorised representative, an importer, a distributor, or the person referred to in Article 22 (1) and 22 (3) of the MDR.

3.5 ‘EUDAMED’ refer to the European databank for medical devices. It is a secure, web-based portal which enables the exchange of information between National Competent Authorities and the European Commission.

3.6 ‘Field safety corrective action’ means corrective action taken by a manufacturer for

technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

3.7 'Field safety notice' means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action.

3.8 'Importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.

3.9 'Incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

3.10 In vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- concerning a physiological or pathological process or state;
- concerning congenital physical or mental impairments;
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic *medical devices*;

3.11 'Line Head' for this SOP is the Director, Senior Head, or Head of the department.

3.12 'Making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

3.13 'Manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and

markets that device under its name or trademark.

3.14 ‘Medical Device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state,

3.15 providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

3.16 ‘Notified Body’ means a conformity assessment body designated in accordance with this Regulation.

3.17 Recall’ means any measure aimed at achieving the return of a device that has already been made available to the end user.

3.18 ‘Risk’ means the combination of the probability of occurrence of harm and the severity of that harm.

3.19 ‘Serious Incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.

3.20 ‘User’ means any healthcare professional or lay person who uses a device.

3.21 ‘Withdrawal’ means any measure aimed at preventing a device in the supply chain

from being further available from the market.

4.0 RESPONSIBILITIES

4.1 The **Line Head** is responsible for:

- Consulting on case management.
- Ensuring updates to the centrally recording system of incident reports related to medical devices and IVDs.
- Ensuring process continuity in the absence of the designated employee, as well as compliance with and implementation of the procedure.

4.2 The **Designated Employee** is responsible for:

- Reviewing the incident reports and requesting any missing documentation that is necessary for a better understanding of the incident.
- Liaising with the reporter entity where and when deemed fit.
- Ensuring that pending cases are being followed-up regularly.
- Recording and updating the databases with all correspondence and information about the incident.
- Ensuring that actions are taken in a timely manner.

5.0 PROCEDURE

5.1 Initiation after finalizing SOP-002

5.2 Following receipt of documentation, root cause analysis is carried out internally for IR.

5.3 Has risk assessment been issued by the stakeholder entity?

5.3.1 If yes, proceed to step 5.8.

5.3.2 If no, proceed to step 5.4.

5.4 Did stakeholder entity request for further information on IR?

5.4.1 If yes, proceed to step 5.5.

5.4.2 If no, proceed to step 5.7.

5.5 Forward received request to the end-user.

5.6 Did the end-user submit the requested information?

5.6.1 If no, proceed to step 5.7.

5.6.2 If yes, send to stakeholder entity and proceed to step 5.3.

5.7 Send reminder email and proceed to 5.3.

5.8 IR, risk assessment and collected data are reviewed with root cause analysis.

5.9 Final outcome of the IR assessment is attained.

5.10 Inform all entities with the outcome.

5.11 Consider the Incident Report as closed and update the database.

6.0 REFERENCES

6.1 Regulation (EU) 2017/746 on in-vitro diagnostic medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0746-20230320

6.2 Regulation (EU) 2017/745 on medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20230320

7.0 REVISION HISTORY

SOP Revision	Reference	Reason for Revision
		•

8.0 APPENDICES

N/A

Appendix 10

Health care professional incident report form

Health Care Professional Incident Report Form

Section A: Details of Reporter **☐ Tick the box if you wish to keep the below information confidential.**	
Name & Surname	
Contact Number	
Position	
Email Address	
Signature of Reporter	
Date	

Section B: Incident Details			
B1. Place of Incident			
Entity/ Hospital			
B2. Device Details - *Please include all the known/ visible details of the device*			
Brand Name			
Generic Name			
Product Code/ Reference (Ref)			
Batch/Lot Number		Quantity known to be defective (if any)	
Manufacturer			
Is the product CE Marked	☐ Yes ☐ No	Sterile	☐ Yes ☐ No
A sample of the defective device must be retained where possible. If a sample cannot be retained, support this report with photos.			
Has a sample been retained?	☐ Yes ☐ No	If 'NO' specify reason:	
B3. Incident Details			
Date of Incident (DD-MM-YYYY)		Name of the ward/unit of where the incident occurred	
Functional Use of Product			
Was the device used in combination with other medical devices?			☐ Yes ☐ No
If 'Yes', add all relevant details of other products	Brand name: _____ Product Code/Reference (Ref): _____ Serial/ Batch/ Lot Number: _____		
Was the device used in combination with a medicinal product?			☐ Yes ☐ No

If 'Yes' add all relevant details of other products	Brand name: _____ Batch Number: _____ Other (e.g. dose/ flow rate): _____
Was a serious incident[1] suffered?	☐ Yes ☐ No

If 'Yes', indicate the type of incident:

☐ Causal relationship between the incident and the medical device

☐ Serious public health threat

☐ Death of a patient, user or other person

☐ Unanticipated serious deterioration in a person's state of health

☐ Other (please specify):

Classify the severity of the incident	☐ High Risk ☐ Medium Risk ☐ Low Risk

Description of Incident:
If a sample cannot be retained, support this report with photos or any other relevant information.

[1] serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.

Other comments:

Appendix 11

General public incident report form

Public Incident Report Form

Section A: Details of Reporter **☐ Tick the box if you wish to keep the below information confidential.**	
Name & Surname	
Contact Number	
Email Address	
Date	
Section B: Details of the medical device. *Please include all the known/ visible details of the device*	
Brand Name	
Generic Name	
Intended Use of the medical device (Example: blood glucose meter to monitor glucose levels)	
Name of Manufacturer	
Batch Number / Lot Number	
Device obtained from:	☐ Public Institution ☐ Private Institution ☐ Pharmacy ☐ Online ☐ Other If Other, please specify: _____
Name of institution / outlet	
Address (if known)	
Telephone (if known)	
Section C: Incident Details	
Date of Incident (DD-MM-YYYY)	

Description of Incident:
If a sample cannot be retained, support this report with photos or any other relevant information

Was the device retained?	☐ Yes ☐ No
Was an injury incurred?	☐ Yes ☐ No

If 'Yes', description of injury:

Appendix 12

Validation questionnaire for SOP-002 and SOP-003

Validation Questionnaire for SOP-002 and SOP-003

The Likert scale 1-5 depicts the varying degrees of agreement or disagreement, with 1 being the most negative and 5 being the most positive. Examples of response options represented include:

- Strongly Disagree, Disagree, Neutral, Agree and Strongly Agree
- Poor, Fair, Satisfactory, Good and Excellent
- Not Useful, Somewhat Useful, Neutral, Useful and Very Useful

Statement	1	2	3	4	5
Completeness					
Is the process for receiving incident reports clearly defined in the SOP documents?					
Are all relevant roles and responsibilities adequately outlined in the documents?					
Does the SOP cover incident reports for both medical devices and in-vitro diagnostic medical devices comprehensively?					
Accuracy					
Are the definitions provided in the SOP consistent with relevant European and national legislation?					
Are the details provided about the incident classification and risk management tool consistent with the actual implementation and industry best practices?					
Are the references to applicable regulations, such as EU Regulations 2017/746 and 2017/745, correct and up to date?					
Clarity					
Is the language used in the SOP easy to understand for individuals with varying levels of expertise in the subject matter?					
Are there clear distinctions made between different types of incidents?					
Is the procedure for classifying incident reports through a risk management tool presented in a straightforward manner?					
Consistency					
Are there any conflicting instructions or information within the SOP documents?					
Does the SOP maintain consistency in terminology and definitions throughout the document?					
Is there alignment between the roles and responsibilities outlined in the SOP and those mentioned in related documents or regulations?					
Accessibility					
Are the documents formatted in a way that facilitates easy navigation and readability?					
Is there a clear table of contents or index for quick reference?					
Are important sections, such as the procedure for incident report receipt, prominently highlighted for accessibility?					
Data Reliability					
Does the SOP specify how data reliability is ensured during the incident report process?					
Are there provisions for validating the accuracy and reliability of data collected during the incident report assessment?					
Does the SOP address the steps taken to maintain data integrity and prevent tampering throughout the incident report management process?					

Additional Comments:

Appendix 13

Validation questionnaire for incident reporting forms

Validation Questionnaire for Incident Reporting Forms

The Likert scale 1-5 depicts the varying degrees of agreement or disagreement, with 1 being the most negative and 5 being the most positive. Examples of response options represented include:

- Strongly Disagree, Disagree, Neutral, Agree and Strongly Agree
- Poor, Fair, Satisfactory, Good and Excellent
- Not Useful, Somewhat Useful, Neutral, Useful and Very Useful

Statement	1	2	3	4	5
Completeness					
How would you rate the form's comprehensiveness in capturing all relevant aspects of a medical device incident?					
Is the form comprehensive in capturing device details such as brand name, generic name, product code/reference, and batch/lot number?					
Does the form provide an adequate section for describing the incident in detail?					
Accuracy					
Please rate the accuracy and specificity of the information fields provided in the form.					
How well does the form align with data protection regulations and guidelines?					
Is the form clear in terms of ensuring confidentiality of the reporter's information?					
Does the form capture accurate and reliable information regarding the seriousness of the incident?					
Clarity					
How would you rate the clarity and comprehensibility of the form's instructions?					
Are the form sections organized and structured in a logical and intuitive manner?					
Is the language used in the form easily understandable by healthcare professionals?					
Consistency					
How well does the form ensure consistency in capturing incident details across different reporting instances?					
Is the form consistent in its approach to capturing incidents involving multiple medical devices or products?					
Does the form provide consistent guidelines for reporting incidents of varying severity?					
Is there consistency in the terminology and format used throughout the form?					
Accessibility					
Please rate the overall usefulness of the form for reporting medical device incidents.					
Is the form easily accessible to healthcare professionals in terms of availability and distribution?					
How well does the form cater to the needs of healthcare professionals with varying levels of technical expertise?					
Data Reliability					
Please rate the overall satisfaction with the medical device incident report form.					
How reliable is the form in capturing accurate and complete					

incident data?					
Does the form provide mechanisms to minimize data entry errors or omissions?					
Are there provisions in place to ensure the consistency and integrity of the collected data?					

Additional Comments:

Appendix 14

Training programme for medical device incident reporting

Training Programme for Medical Device Incident Reporting Pilot

Julian Fearne

Topics

Introduction to Incident Reporting

Legal and Regulatory Compliance

Roles and Responsibilities

Medical Device Identification

Incident Details and Adverse Events

Topics

Root Cause Analysis

Corrective and Preventive Actions

System Navigation

Participants' Evaluation

Q&A Session

Introduction to Incident Reporting

Welcome to the Medical Device Incident Reporting Training Program

- **Objective:** Understand the importance of incident reporting in ensuring patient safety
- Incident reporting is a critical aspect of our commitment to patient well-being
- Legal and ethical considerations are paramount when dealing with medical device incidents.

4

Emphasize the critical role of incident reporting in ensuring patient safety.

•Highlight that incident reporting is not just a process but a legal and moral obligation.

•Illustrate the importance of incident reporting through an example: a malfunctioning medical device that poses a potential risk to patients.

•Stress that incident reporting involves a systematic approach to identifying, documenting, and analyzing events that deviate from standard procedures.

Legal and Regulatory Compliance

- **Objective:** Gain an overview of the legislation and rules governing incident reporting.
- Understanding the regulatory landscape is crucial for compliance.
- We'll explore national and international reporting criteria to align our practices with the prevailing regulations.

Stress the importance of compliance for maintaining high standards in healthcare.

- Explain that national and international regulations guide incident reporting practices.
- Provide examples of regulations, such as national health regulations and international standards like ISO 13485.
- Discuss the consequences of non-compliance, including legal repercussions and potential harm to patient safety.
- Emphasize that understanding legal and regulatory frameworks is crucial for building a robust incident reporting system.

Roles and Responsibilities

- **Objective:** Understand the roles and duties of various incident reporting stakeholders.
- Different positions play vital roles in the incident management process.
- Recognise the importance of each position in the event management process.
- Highlight how every team member, from clinical staff to quality and safety personnel, plays a crucial role.

6

Introduce the various stakeholders involved in incident reporting.

- Explain the unique roles each stakeholder plays in the incident management process.
- Provide specific examples, such as clinical staff witnessing incidents and quality and safety personnel ensuring adherence to protocols.
- Emphasize that recognizing the importance of each role avoids gaps in the reporting process.
- Highlight that clearly defined roles help establish accountability and streamline the incident reporting workflow.

Medical Device Identification

- **Objective:** Learn how to correctly identify medical devices involved in events.
- Recognise the significance of documenting device characteristics, including type, model, and serial number.
- Accurate identification is fundamental for effective incident documentation and subsequent analysis.
- Comprehensive documentation aids in root cause analysis and preventive measures.

7

Stress the foundational importance of accurate identification of medical devices.

- Explain the significance of documenting device characteristics such as type, model, and serial number.
- Use an example to illustrate how proper identification aids in assessing the history of a malfunctioning device.
- Emphasize that comprehensive documentation supports root cause analysis and facilitates corrective actions to prevent future incidents.

Incident Details and Adverse Events

- **Objective:** Understand the importance of documenting event facts such as date, location, and incident type.
- Clear and comprehensive documentation is crucial for effective incident reporting.
- Gain information on recognising and reporting adverse events, patient harm, and related problems.
- Adverse events can have a significant impact on patient safety; recognising and reporting them promptly is essential.

8

- Highlight the essential nature of comprehensive documentation of incident details.
- Explain the importance of documenting date, location, and incident type for a contextual understanding.
- Emphasize that reporting adverse events promptly allows for swift intervention to minimize harm.
- Provide examples of adverse events and the impact on patient safety.
- Stress that thorough incident details contribute to a more accurate analysis, leading to effective preventive measures.

Root Cause Analysis

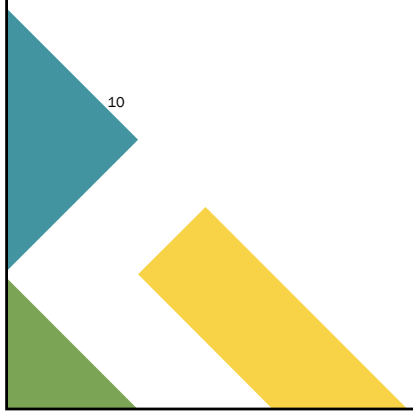
- **Objective:** Learn methods for determining the root causes of incidents.
- Understanding why incidents occur is fundamental for implementing effective corrective and preventive actions.
- We'll explore factors that may contribute to incidents and delve into the importance of identifying these elements.

Emphasize that determining root causes is vital for preventing the recurrence of incidents.

- Explain the concept of identifying contributing elements that enhance incident understanding.
- Provide examples of systemic issues revealed through root cause analysis, such as insufficient staff training.
- Stress that recognizing contributing elements, like equipment calibration issues, provides a holistic perspective.
- Highlight that root cause analysis is a proactive approach to address the underlying issues that lead to incidents.

Corrective and Preventive Actions

- **Objective:** Understand the detailed procedures for putting corrective and preventive measures in place.
- We'll discuss the immediate actions taken upon incident reporting and the subsequent follow-up procedures.
- A timely and well-planned response is crucial for minimizing potential harm.



Stress the key role of implementing effective actions in preventing the recurrence of incidents.

- Explain that timely and well-planned responses are crucial for minimizing harm.
- Provide examples of corrective actions, such as updating training protocols, and preventive measures, such as routine equipment maintenance.
- Emphasize that corrective and preventive actions form the backbone of incident response, ensuring continuous improvement.

System Navigation

Welcome to the System Navigation training segment.

- **Objective:** Gain hands-on instruction on how to use the incident reporting system.
- Practice sessions are designed to enhance user familiarity with the system's data entry and submission processes.
- User proficiency is crucial for the successful implementation of the incident reporting framework.

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- Emphasize the essential nature of hands-on instruction for system proficiency.
- Explain that practice sessions enhance user familiarity with the incident reporting system.
- Encourage participants to actively engage in simulated incidents during practice sessions.
- Stress that hands-on sessions ensure a smoother transition to real incident reporting scenarios.
- Highlight that user proficiency is vital for the successful implementation of the incident reporting framework and fosters a culture of reporting.

Participants' Evaluation

- Welcome to the Participants' Evaluation segment.
- **Objective:** Participants will be evaluated on their grasp of the training content through a series of ongoing questions.
- Continuous assessment ensures a comprehensive understanding of incident reporting responsibilities.

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Participants' Evaluation

Introduction to Incident Reporting

1. **Question:** Why is incident reporting considered a legal and moral obligation in healthcare?
2. **Question:** Provide an example of a situation where incident reporting would be crucial for maintaining patient safety.

Participants' Evaluation

Legal and Regulatory Compliance

1. **Question:** How does compliance with national and international regulations contribute to effective incident reporting?
2. **Question:** Can you identify one specific national or international regulation governing incident reporting in healthcare?

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1. **Expected Response:** Participants should explain how adherence to regulations ensures standardization, legal conformity, and the promotion of patient safety within incident reporting practices.
2. **Expected Response:** Participants should mention a relevant regulation, such as ISO 13485, and briefly describe its significance in the context of incident reporting.

Participants' Evaluation

Roles and Responsibilities

1. **Question:** Explain the importance of having clearly defined roles in incident reporting. How does this contribute to the overall incident management process?
2. **Question:** Provide an example of a role played by a stakeholder other than clinical staff in incident reporting.

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1.Expected Response: Participants should discuss the significance of accountability, efficient workflow, and avoiding gaps in the reporting process through well-defined roles. **2.Expected Response:** Participants should mention roles such as those of quality and safety personnel, emphasizing their contributions to incident reporting protocols.

Participants' Evaluation

Medical Device Identification

1. **Question:** Why is accurate identification of medical devices considered foundational in incident reporting?
2. **Question:** Can you provide an example of information that should be documented when identifying a medical device involved in an incident?

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1. **Expected Response:** Participants should highlight the importance of accurate identification in assessing device history, conducting root cause analysis, and implementing effective corrective actions.
2. **Expected Response:** Participants should mention details such as device type, model, and serial number, emphasizing their role in incident documentation.

Participants' Evaluation

Incident Details and Adverse Events

Question: Why is documenting comprehensive incident details essential for effective incident reporting?

Question: Provide an example of an adverse event that should be promptly reported. Why is prompt reporting crucial in such cases?

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Expected Response: Participants should discuss how detailed documentation contributes to accurate analysis, preventive measures, and an understanding of adverse events.

1. **Expected Response:** Participants should describe an adverse event and explain the significance of prompt reporting in minimizing harm and facilitating swift intervention.

Participants' Evaluation

Root Cause Analysis

Question: How does root cause analysis contribute to preventing the recurrence of incidents in healthcare?

Question: Provide an example of a systemic issue that could be revealed through root cause analysis in incident reporting.

1. **Expected Response:** Participants should discuss how identifying root causes helps address underlying issues and implement effective preventive measures.
2. **Expected Response:** Participants should mention systemic issues like insufficient staff training and explain their impact on incident occurrences.

Participants' Evaluation

Corrective and Preventive Actions

Question: Why are timely and well-planned corrective and preventive actions crucial in incident reporting?

Question: Can you give an example of a corrective action and a preventive measure in response to an incident? Briefly describe their roles.

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1.Expected Response: Participants should highlight the role of these actions in preventing recurrence, minimizing harm, and ensuring continuous improvement in incident response. **2.Expected Response:** Participants should provide examples, such as updating training protocols (corrective action) and routine equipment maintenance (preventive measure) and explain their roles in incident response.

Q&A Session

- Thank you for your attention. We'll now open the floor for any questions you may have.
- Your input is valuable in ensuring clarity and understanding of the incident reporting framework.

Thank you

A heartfelt thank you for your active participation in the training program.

Together, we are making strides toward a more effective and patient-centric incident reporting system.

Julian Fearne julian.fearne.11@um.edu.mt

Appendix 15

Incident report pilot study evaluation questionnaire

Incident Report Pilot Study Evaluation Questionnaire

Instructions: Please provide your feedback on each question using the Likert scale (1-5), where 1 indicates Strongly Disagree and 5 indicates Strongly Agree.

Additionally, feel free to provide comments or suggestions for improvement where necessary.

Thank you for your valuable feedback. Your input is crucial in enhancing the effectiveness of the Incident Reporting System.

Statement	1	2	3	4	5
Completion Time:					
How long did it take you, on average, to complete an incident report?					
Please rate the ease of completing incident reports on a scale of 1 to 5 (1 being very difficult, 5 being very easy).					
Error Rates:					
Did you encounter any errors while completing incident reports? If yes, please specify.					
How would you rate the frequency of errors encountered during incident reporting? (1 being very rare, 5 being very frequent)					
Data Accuracy:					
How confident are you in the accuracy of the data recorded in incident reports? (1 being not confident at all, 5 being very confident)					
Have you noticed any inaccuracies or inconsistencies in the data recorded?					
Section Completion Rates:					
Did you complete all sections of the incident reports? If not, which sections did you find challenging to complete?					
On average, what percentage of incident reports do you complete in full?					
Ease of Accessibility:					
How easy is it for you to access the incident reporting system?					
Are there any difficulties or challenges you face when accessing the system?					
User Feedback Score:					
Based on your experience, how would you rate the incident reporting system overall? (1 being very poor, 5 being excellent)					
Do you have any feedback or suggestions for improving the incident reporting system?					
Rate of Submission:					
How frequently do you submit incident reports?					
Have you experienced any obstacles or delays in submitting incident reports?					

Additional Comments:

Appendix 16

Project Charter questions

Project Charter Workshop Questions

1. Introduction and Context:
    a. What, in your expert opinion, are the primary challenges currently faced in managing medical device information and processes?
    b. How do you perceive the impact of current regulatory frameworks, both at the European and national levels, on medical device management?
2. Feasibility Studies and Compliance:
    a. From a technological standpoint, what potential challenges do you foresee in implementing a digital medical device management system?
    b. In terms of legal compliance, which specific aspects of European legislation do you believe are most critical for the success of this project?
3. Stakeholder Engagement:
    a. Who do you identify as the key stakeholders in the medical device domain, and how should their interests be considered in the MDMS development?
    b. In your experience, what key functionalities and features do different stakeholders typically expect from a system like the MDMS?
    c. What strategies do you recommend for ensuring ongoing collaboration and engagement with stakeholders throughout the project?
4. Resource Allocation:
    a. From a resource perspective, what human and technological assets do you consider indispensable for the successful development of the MDMS?
    b. Are there any financial considerations or constraints that should be factored into the resource planning?
5. Collaborative Approach:
    a. How do you envision collaboration between the MDMS and existing healthcare systems, particularly regarding actor registration and information exchange?
    b. What iterative approaches do you recommend to refine the system requirements and ensure alignment with evolving legal and industry standards?
6. Database Architecture:
    a. Given your knowledge, how would you recommend designing the database architecture to ensure scalability, performance, and data integrity?

b. Are there specific data security and privacy considerations that you believe are paramount in the database design?

7. System Requirements:
    a. In your experience, what are the critical functionalities that should be incorporated into the MDMS to meet European legalisation and national requirements?
    b. Can you prioritize the identified modules in terms of their importance and potential impact on the overall system?
8. Actor Registration:
    a. What information and functionalities, in your expert opinion, should be included in the actor registration module?
    b. How can the system ensure accurate and up-to-date registration, based on your experience with similar systems?
9. Notification Management:
    a. Based on your expertise, what are the critical processes and workflows in medical device notification management that the MDMS should address?
    b. How can the MDMS ensure efficient and timely notification processes in line with regulatory requirements, in your view?
10. Vigilance and Surveillance:
    a. From your experience, how should the ticketing system for vigilance and post-market surveillance be structured to enhance incident reporting and response?
    b. What, in your expert opinion, are the critical metrics and indicators that the system should track for effective surveillance?
11. Public Website and Communication:
    a. Drawing on your expertise, what information do you believe should be accessible through the operational public website?
    b. How can the website contribute to transparent communication with the public and other stakeholders, based on your experience?
12. User Account Management:
    a. In your expert opinion, what levels of user access and permissions are necessary, and how should user account management ensure data security?
    b. Are there specific authentication and authorization protocols that, based on your experience, should be integrated into the system?
13. Invoicing and Payment:

a. Considering your expertise, what billing and invoicing processes are typically in place, and how can the MDMS streamline these financial transactions?
b. What online payment structures align with the financial requirements of medical device regulatory activities, based on your knowledge?

Appendix 17

Project Charter

Project Charter

Executive Summary

The development of the Medical Device Management System (MDMS) is a pivotal initiative aimed at addressing the complex challenges associated with managing medical device information in the digital landscape. This Project Charter serves as a comprehensive guide, outlining the strategic plan and considerations that underpin the entire project lifecycle.

Project Background

The MDMS project evolved through a series of workshops facilitated by an expert panel. Over 16 sessions, the panel engaged in continuous and immersive debates, providing valuable insights and professional judgments. The workshops, marked by a fluid and changing technique, allowed for the evolution of questions and discussions, contributing to a cohesive and focused exploration of the project's intricacies.

Objectives

The primary objective of the MDMS project is to develop a robust system for managing medical device information, ensuring seamless integration, regulatory compliance, stakeholder engagement, and efficient resource allocation.

Scope of Work

General

- Develop a system for exchanging information related to National and European Legislation on medical devices.
- Store regulatory data, including actor information, medical device registry, adverse effects reports, certificates, and market surveillance data.

Geographical Area

- The system will cover the Maltese Islands.

Stakeholders/Actors

- Economic Operators, Notified Bodies, Public/Healthcare Providers, and Contracting Authority.
- Each stakeholder has specific tasks related to the MDMS.

Specific Modules

- **Entity Registration Module**

The Entity Registration Module is fundamental for accurate reporting within the MDMS, ensuring a robust foundation for managing medical device information.

- Comprehensive Actor Profiles:
  - Develop a user-friendly interface for creating comprehensive actor profiles, capturing extensive information about participants in the medical device domain.
  - Emphasize the importance of accuracy and completeness in actor profiles to enhance data integrity.
- Integration with National Identification Systems:
  - Implement a seamless integration with national identification systems for efficient verification of actor information.
  - Minimize the potential for duplicate or inaccurate data by utilizing authoritative sources for identity verification.
- Continuous Data Accuracy Monitoring:
  - Introduce regular validation checks for actor information to ensure ongoing data accuracy.
  - Establish automated notifications for updating registration details, streamlining processes for maintaining accurate and up-to-date information.

- **Device Notification Module**

The Device Notification Module focuses on efficient workflows and timely communication, essential for managing incidents and regulatory compliance.

- Streamlined Incident Workflows:
  - Prioritize the development of workflows that enable the efficient reporting and handling of incidents related to medical devices.
  - Emphasize the significance of speedy and effective incident resolution through streamlined processes.
- Automated Stakeholder Notifications:
  - Implement automated processes for notifying relevant stakeholders promptly when incidents are reported.
  - Ensure timely communication is a key aspect of the notification management process.
- Adherence to Regulatory Timelines:

        - Design the module to adhere strictly to specific regulatory timelines for incident reporting and resolution.
        - Align notification processes with regulatory requirements to facilitate compliance.

- **Vigilance Module**

  The Vigilance Module plays a critical role in ensuring the comprehensive surveillance and efficient response to incidents related to medical devices.

  - Hierarchical Ticketing System:
    - Develop a hierarchical ticketing system that categorizes incidents based on severity, providing a structured approach to incident response.
    - Ensure that the system prioritizes and addresses incidents according to their level of severity.
  - Integration with Incident Reporting:
    - Establish seamless integration with the incident reporting functionality to create a unified surveillance system.
    - Enable the Vigilance Module to gather real-time data from incident reports, offering a holistic and detailed view of incidents.
  - Monitoring Incident Resolution Times:
    - Implement a key performance indicator (KPI) for monitoring and analysing incident resolution times.
    - Provide stakeholders with insights into the efficiency of incident resolution processes.
  - Metrics for System Effectiveness:
    - Define and track metrics that serve as indicators of the overall effectiveness of the Vigilance Module.
    - Analyse data to continuously improve the system's ability to detect patterns, trends, and recurring incident types.
  - Collaboration with Regulatory Authorities:
    - Ensure the module's seamless integration with regulatory bodies for efficient collaboration.
    - Align incident reporting and surveillance processes with regulatory requirements to facilitate a coordinated response.
  - Continuous Improvement Mechanism:

        - Establish a mechanism for regular reviews and adaptations based on stakeholder feedback and evolving regulatory standards.
        - Emphasize an iterative approach to continuously enhance the Vigilance Module in response to real-world feedback.

- **Market Surveillance Module**

  The Market Surveillance Module of the MDMS is designed to gather, record, and analyse comprehensive data on the quality, performance, and safety of medical devices within the regulatory landscape. This module plays a pivotal role in ensuring a proactive and vigilant approach to monitoring medical devices throughout their lifecycle.

  - Data Collection and Recording:
    - Establish mechanisms for systematic and real-time data collection from various sources, including manufacturers, healthcare providers, and regulatory authorities.
    - Record and categorize information on adverse events, product defects, and other relevant incidents.
  - Analysis and Evaluation:
    - Implement advanced analytics tools to assess the significance and potential impact of reported issues.
    - Conduct thorough evaluations to identify trends, patterns, and emerging risks in the market.
  - Risk Management:
    - Develop a risk assessment framework to categorize and prioritize market surveillance findings.
    - Implement protocols for timely communication and collaboration with relevant stakeholders in addressing identified risks.
  - Communication and Reporting:
    - Establish clear and transparent communication channels for disseminating market surveillance outcomes to regulatory bodies, manufacturers, and other stakeholders.
    - Generate comprehensive reports outlining market trends, risk assessments, and recommendations for regulatory actions.
  - Continuous Improvement:

        - Implement iterative processes for continuous improvement based on feedback, emerging industry standards, and evolving regulatory requirements.
        - Conduct regular reviews of the Market Surveillance Module to enhance its effectiveness and responsiveness.

- **Invoicing & Payments Module:**
    - Itemized billing for transparency will be a guiding principle in financial processes. Automated invoicing will streamline financial transactions, ensuring efficiency for regulatory activities.
    - Integration with secure online payment gateways will align the financial systems with contemporary online payment practices. Real-time transaction tracking will be implemented for accountability, ensuring financial systems support broader regulatory goals.
    - Generate and send pro-forma invoices, track payments, and manage penalties.
- **Systems Management Module**

  The Systems Management Module focuses on ensuring secure and efficient system operation, administration, and user access.
    - Role-Based Access Control:
        - Implement role-based access control to define and manage user permissions based on their responsibilities.
        - Balance data accessibility with security by assigning granular control over sensitive data access.
    - Two-Factor Authentication:
        - Enhance system security by incorporating two-factor authentication for user authentication.
        - Regularly audit user accounts for compliance to ensure continuous oversight and adherence to security protocols.
    - User Training and Support:
        - Provide comprehensive training and support resources for users to navigate the Systems Management Module effectively.
        - Establish a feedback mechanism for users to contribute insights and recommendations for continuous improvement.

- **Reporting Module**

  The Reporting Module within the MDMS is a robust tool designed to extract, analyse, and present various types of information crucial for regulatory decision-making and operational efficiency.

  - Customizable Reporting:
    - Provide a user-friendly interface for stakeholders to generate customized reports based on their specific requirements.
    - Enable flexible report configurations, allowing users to select data elements, apply filters, and tailor reports to their needs.
  - Data Aggregation and Calculation:
    - Implement functionalities for aggregating and calculating data, facilitating the generation of summary reports and key performance indicators.
    - Ensure the reporting tool supports statistical data analysis for in-depth insights.
  - Reference and Temporal Fields:
    - Allow referencing any data element within the system to maintain data integrity and consistency across reports.
    - Support the addition of temporary fields to accommodate ad-hoc reporting needs.
  - Minimal Performance Impact:
    - Optimize the reporting tool to have negligible impact on the overall system performance, even when handling complex queries and large datasets.
    - Utilize efficient data retrieval and processing mechanisms to ensure timely report generation.
  - User Training and Support:
    - Provide comprehensive training resources and support for users to maximize the utility of the Reporting Module.
    - Establish a feedback loop for users to suggest enhancements and improvements to the reporting functionalities.

Specific Activities

- Successful analysis, design, development, delivery, installation, and configuration of the MDMS.
- Set up live, test, and development environments.

- Analysis, development, testing, and deployment of enhancements.
- Provision of maintenance and support.
- Operation, administration, and management of the Solution.
- Provision of required technical documentation in English.
- Design workflows aligned with the Contracting Authority's business processes.
- System testing, assistance in UAT sessions, and preparation of necessary testing documentation.

Technical Requirements

The MDMS solution shall:

- Have a common look and feel with a user-friendly, efficient, and intuitive graphical user interface (GUI).
- Be one integrated system accessible through a central portal with single sign-on.
- Be modular, scalable, configurable, and offer a degree of customisability.
- Be web-based for 24/7 access from any location with an internet connection.
- Have cross-browser compatibility (Internet Explorer, Edge, Safari, Firefox, Google Chrome, Opera).
- Be responsive to adapt to various screen sizes.
- Have front- and back-ends in the English language.
- Handle Maltese language characters for accessibility in both Maltese and English.
- Have real-time updates.
- Abide by technology guiding principles such as abstraction, interoperability, loose coupling, generality, virtualization, and open standards.
- Allow multiple concurrent users (100+ users) without individual user licensing.

Data Exchange Requirements

- Implement file upload to EUDAMED via XML, validated against provided XSDs.
- Implement file downloads from EUDAMED in XML format.
- Allow automated generation of XML files for data submission to EUDAMED.

Reporting Generation Requirements

- Develop a reporting tool with functionalities like reference to any data element, temporary field addition, aggregation, calculation, statistical data analysis, and data sorting.
- Ensure the reporting tool has a negligible impact on overall system performance, even with complex queries.

Appendix 18

Summary table of *Project Charter* responses and themes

1. Introduction and Context:	
Primary Challenges: *Responses:*	*Themes:*
Increasing complexity of medical device information management.	Integration challenges in managing diverse medical device data.
Ensuring compliance with evolving regulatory frameworks.	The need for adaptability to dynamic regulatory landscapes.
Regulatory Impact: *Responses:*	*Themes:*
European regulations create a robust framework but require nuanced implementation.	Emphasis on harmonizing local and European regulations.
National regulations may introduce specific challenges in harmonization.	Need for flexibility to accommodate changing regulatory requirements.

2. Feasibility Studies and Compliance:	
Technological Challenges: *Responses:*	*Themes:*
Interoperability of existing systems with the new MDMS.	Focus on seamless integration with existing technologies.
Ensuring data security and privacy in a digital environment.	Emphasis on robust cybersecurity measures.
Legal Compliance: *Responses:*	*Themes:*
Stringent adherence to European legislation on data protection.	Prioritizing legal compliance in system design.
Importance of clear documentation and audit trails.	Need for continuous legal monitoring and updates.

3. Stakeholder Engagement:	
Key Stakeholders: *Responses:*	*Themes:*
Regulatory bodies, healthcare providers, manufacturers, and the public.	Importance of a multifaceted approach to stakeholder engagement.
Each stakeholder group has unique expectations and concerns.	Strategies for balancing diverse stakeholder interests.
Expectations from MDMS: *Responses:*	*Themes:*
Regulatory bodies expect robust reporting and compliance features.	Tailoring functionalities to meet diverse stakeholder needs.
Manufacturers seek streamlined processes for notifications and surveillance.	Establishing transparent communication channels.

4. Resource Allocation:	
Human and Technological Assets: *Responses:*	*Themes:*
Skilled personnel in medical device regulation and database management.	Identifying critical skill sets for MDMS development.
Robust technological infrastructure for data processing and storage.	Balancing human and technological resources.
Financial Considerations: *Responses:*	*Themes:*
Consideration of costs for system development, maintenance, and updates.	Financial sustainability throughout the MDMS lifecycle.
Budgetary allocations for cybersecurity measures.	Prioritizing investments in cybersecurity.

5. Collaborative Approach:	
Collaboration with Existing Systems: *Responses:*	*Themes:*
Seamless integration with existing healthcare databases.	Prioritizing interoperability to enhance overall healthcare ecosystem efficiency.
Ensuring data exchange protocols align with industry standards.	Adaptive approaches for evolving legal and industry standards.
Iterative Approaches: *Responses:*	*Themes:*
Regular reviews and adaptations based on stakeholder feedback.	Emphasizing an iterative model for continuous improvement.
Flexibility in accommodating changes in legal and industry standards.	Balancing rigidity with adaptability.

6. Database Architecture:	
Designing for Scalability: *Responses:*	*Themes:*
Distributed database architecture for scalability.	Scalability as a cornerstone for long-term success.
Cloud-based solutions to accommodate growing datasets.	Strategies for accommodating increasing data volume.
Data Security and Privacy: *Responses:*	*Themes:*
Encryption protocols for data security.	Making data security and privacy integral to database design.
Incorporating anonymization features for privacy.	Striking a balance between accessibility and security.

7. System Requirements:	
Critical Functionalities: *Responses:*	*Themes:*
Robust incident reporting and tracking functionalities.	Prioritizing functionalities critical to regulatory compliance.
Adherence to European legalisation and national requirements.	Balancing diversity in functionalities to meet various requirements.
Module Importance: *Responses:*	*Themes:*
Actor registration seen as foundational for accurate reporting.	Establishing a hierarchy of importance among modules.
Invoicing and payment modules essential for financial transparency.	Aligning module importance with regulatory and operational needs.

8. Actor Registration:	
Information and Functionalities: *Responses:*	*Themes:*
Comprehensive actor profiles for accurate attribution.	Ensuring completeness and accuracy in actor profiles.
Integration with national identification systems for verification.	Minimizing the potential for duplicate or inaccurate data.
Ensuring Accuracy: *Responses:*	*Themes:*
Regular validation checks for actor information.	Continuous monitoring for data accuracy.
Automated notifications for updating registration details.	Streamlining processes for maintaining accurate information.

9. Notification Management:	
Critical Processes and Workflows: *Responses:*	*Themes:*
Streamlined workflows for incident reporting.	Prioritizing efficiency in incident reporting.
Automated processes for notifying relevant stakeholders.	Timely communication as a key aspect of notification management.
Regulatory Compliance: *Responses:*	*Themes:*
Ensuring adherence to specific regulatory timelines.	Aligning notification management with regulatory requirements.
Integration with regulatory bodies for streamlined processes.	Enhancing collaboration with regulatory authorities.

10. Vigilance and Surveillance:	
Ticketing System Structure: *Responses:*	*Themes:*
Hierarchical ticketing for incident severity.	Structuring vigilance processes for effective incident response.
Integration with incident reporting for a holistic view.	Enabling a comprehensive surveillance system through ticketing.
Critical Metrics and Indicators: *Responses:*	*Themes:*
Monitoring incident resolution times.	Metrics as indicators of system effectiveness.
Tracking the recurrence of specific incident types.	Prioritizing key performance indicators for surveillance.

11. Public Website and Communication:	
Accessible Information: *Responses:*	*Themes:*
Transparent display of incident reports.	Fostering transparency through accessible information.
Timely updates on regulatory changes.	Using the website as a channel for regulatory communication.
Stakeholder Engagement: *Responses:*	*Themes:*
Feedback mechanisms for public input.	Engaging the public as stakeholders in the regulatory process.
Educational resources for understanding regulatory processes.	Establishing the website as a two-way communication channel.

12. User Account Management:	
Role-based access for different user types.	Balancing data accessibility with security.
Granular control over sensitive data access.	Ensuring a need-based approach to user permissions.
Authentication and Authorization Protocols: *Responses:*	*Themes:*
Two-factor authentication for heightened security.	Incorporating industry-standard security protocols.
Regular audits of user accounts for compliance.	Ensuring continuous oversight for secure user management.

13. Invoicing and Payment:	
Billing and Invoicing Processes: *Responses:*	*Themes:*
Itemized billing for transparency.	Transparency as a guiding principle in financial processes.
Automated invoicing for efficient financial transactions.	Streamlining financial transactions for regulatory activities.
Online Payment Structures: *Responses:*	*Themes:*
Integration with secure online payment gateways.	Aligning with contemporary online payment practices.
Real-time transaction tracking for accountability.	Ensuring financial systems support the broader regulatory goals.

Appendix 19

Validated user stories

Work Item Type	Title	State	Tags
User Story	As a Designer I want to conduct an accessibility test so that I make sure that the integrated HTML still allows the site to be accessible and accessibility was not hindered in any way	Approved	
User Story	As a Distributor Actor I want to notify individual device in MDMS so that Devices would be registered in MDMS	Approved	Device Management; Needs attachment; Phase 2; shared with client
User Story	As a Distributor Actor I want to notify devices in bulk in MDMS so that Devices would be registered in MDMS	Approved	Device Management; Needs attachment; Phase 2; shared with client
User Story	As a System I want to notify Actor via an email when the bulk upload fails so that Actor can correct the bulk upload file	Approved	Device Management; Phase 2; shared with client
User Story	As a Distributor Actor I want to pay the fee so that I can notify devices	Approved	Device Management; Needs Linking; Phase 2; shared with client
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to generate local identifier code for devices so that I can save the link between actor and device	Approved	API; Device Management; Phase 2; shared with client
User Story	As a Distributor or Importer Actor I want to select if devices are Legacy devices or not so that I can use basic UDI-DI for MDR devices	Approved	Device Management; Phase 2; shared with client
User Story	As a Distributor or Importer Actor I want to insert device's basic UDI-DI so that I can notify MDR devices	Approved	Device Management; Phase 2; shared with client
User Story	As a Distributor or Importer Actor I want to insert legacy device details so that I can notify legacy devices	Approved	Device Management; Phase 2; shared with client
User Story	As a System I want to send notification to MA that there is device notification pending approval so that MA can approved device notification	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to store notification in MDMS so that Data can be audited	Approved	API; Device Management; Phase 2; shared with client
User Story	As a User I want to verify legacy devices so that devices would be notified	Approved	Backend; Device Management; Phase 2; shared with client

User Story	As a User I want to reject verification of legacy devices so that Distributor Actor would resubmit information	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a User I want to generate xml request to EUDAMED so that I can verify MDR devices	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a User I want to reject verification of MDR devices so that Distributor or Importer Actor would resubmit information	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to notify Actor that device notification is rejected so that Actor can resubmit information	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to link devices to an Actor (Importer/Distributor) so that MDR devices would be notified	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to notify Actor of successful device notification so that devices are notified	Approved	API; Device Management; Phase 2; shared with client
User Story	As a User I want to reject the notification of a single device when devices are uploaded in bulk so that only the marked devices are rejected	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As an Actor I want to group single devices under one notification so that I can notify devices as one application	Approved	Device Management; Phase 2; shared with client
User Story	As a Distributor Actor I want to modify individual device in MDMS so that Devices would be registered in MDMS	Approved	Device Management; Needs attachment; Phase 2; shared with client
User Story	As a Distributor Actor I want to modify devices in bulk in MDMS so that Devices would be registered in MDMS	Approved	Device Management; Needs attachment; Phase 2; shared with client
User Story	As a System I want to notify Actor if bulk upload fails so that Actor can correct the bulk file for upload	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to store modifications in MDMS so that Data can be audited	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to send a notification to User notifying that there is a pending device modification so that User can be notified of a pending action	Approved	API; Device Management; Phase 2; shared with client
User Story	As a User I want to generate XML request to EUDAMED so that User can download amended / withdrawn device details	Approved	Backend; Device Management; Phase 2; shared with client

User Story	As a User I want to upload XML response from EUDAMED so that User can approve modifications	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a User I want to approve device modifications so that Actor is notified of successful modification	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to send unsuccessful modification notification to Actor so that Actor can resubmit modification	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to send successful modification notification so that Actor is informed of successful modifications	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to provide a way to upload device information from EUDAMED and replace existing information so that I am able to refresh the information stored about devices since editing of non-legacy devices is not allowed	Approved	API; Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to have a search facility where I can search for devices so that I can check device information	Approved	Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to search for devices by name so that I can view device details	Approved	Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to search for devices by basic UDI-DI so that I can view device details	Approved	Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to search for devices by model so that I can view device details	Approved	Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to search for devices by Nomenclature code so that I can view device details	Approved	Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to search for devices by Risk class so that I can view device details	Approved	Device Management; Phase 2; shared with client
User Story	As a Public or logged in user I want to search for devices by device status so that I can view device details	Approved	Device Management; Phase 2; shared with client
User Story	As a Developer I want to keep track of audits so that the system can keep of actions performed by the user	Approved	API; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide searching and filtering so that the end user is able to search and filter	Approved	Backend; Device Management; NFR; Phase 2; shared with client

User Story	As a Developer I want to provide PDF and CSV export functionality so that the end user is able to export the whole list to a CSV or PDF	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide a way where templates for PDF export can be provided so that the header and footer can be added to the PDF on export	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide bulk upload CSV file sample so that end-users have a guidance on what file should be provided to the system	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to check uploaded bulk devices files so that to report any files which are not as expected	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to have files uploaded asynchronously so that there is no need to wait for a reply and the end-user can continue with other work	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to send out a notification to the end user who uploaded the file so that the end user can take any necessary action if required	Approved	API; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to check for duplicate data and notify users accordingly so that they can review the uploaded file and remove any duplicate information	Approved	Device Management; Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to the system to provide the CSV line number where the error originated from where possible so that the end user can fix the issues	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to the system to only allow CSV file uploads where bulk upload is expected so that to avoid having files which are not useable	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I need to provide multilingual error messages so that in case Maltese language is enabled, I can provide error messages in Maltese	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I need to provide multilingual forms so that in case Maltese language is enabled, I can provide forms in Maltese	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide a portal which provide a score of at least 60 in Google lighthouse measuring tool so that I can guarantee good web portal performance and good user experience	Approved	Device Management; NFR; Phase 2; shared with client

User Story	As a Developer I want to provide support to all major browsers so that end users can access the portal using their favourite browser	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide only logical deletes in the system so that when deleting items, these can be retrieved back	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide a section where the end user can view the deleted items so that items can be restored back	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to keep track of the different file versions so that previous files can be viewed upon request	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to make use of frameworks such as Polly so that I am able to retry API calls automatically so that to avoid failures due to connection issues	Approved	Device Management; NFR; Phase 2
User Story	As a Developer I want to audit API calls including the amount take to process the request so that it is easier to identify processes which are taking long	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I need to validate the XML generated so that to confirm it complies with the schema provided by EUDAMED	Approved	API; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to validate the XML provided by the user when this is uploaded so that to confirm it complies with the schema provided by EUDAMED	Approved	API; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to store public data on Redis cache so that make sure that the response times are reduced as much as possible	Approved	Device Management; NFR; Phase 2
User Story	As a Developer I need to provide the facility to upload files so that these are stored within the system bound to the respective entity they pertain to	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I need to limit file uploads to a maximum of 5Mb so that we can limit the storage used	Approved	Backend; Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to scan files uploaded with Windows Defender before entering the storage so that we can reduce the risk of having malicious files uploaded and accessed by users	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a Developer I want to make sure that I use regular expressions, max length, required fields and placeholders so that I can guide end users in filling the correct information in the forms	Approved	Backend; Device Management; NFR; Phase 2; shared with client

User Story	As a Developer I want to set a timeout of around 15 seconds (configurable) for APIs so that the system does not keep waiting for a response indefinitely	Approved	Backend; Device Management; NFR; Phase 2
User Story	As a Developer I want to show a loader when retrieving the data so that the system can notify the end user that something is happening in the background	Approved	Device Management; NFR; Phase 2; shared with client
User Story	As a non-distributor Actor, I want to submit required information so that I can register as a non-distributor	Approved	Registration of Actors (Non-Distributors)
User Story	As a non-distributor Actor, I want to select the roles so that I can register as a non-distributor	Approved	Registration of Actors (Non-Distributors)
User Story	As a non-distributor Actor, I want to fill in required forms so that I can register as a non-distributor	Approved	Registration of Actors (Non-Distributors)
User Story	As a non-distributor Actor, I want to Upload required documents so that I can register as a non-distributor	Approved	Registration of Actors (Non-Distributors)
User Story	As a non-distributor Actor, I expect system to check if SAGE account using key exists in MDMS so that MAA can create my profile if it does not exist in Sage	Approved	Registration of Actors (Non-Distributors)
User Story	As a non-distributor Actor, I expect system to check if SAGE account using key exists in MDMS so that I can proceed to the payment section if my profile exist in Sage	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to generate XML request to EUDAMED so that I can download XML response	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to upload XML into MDMS system so that information is saved in MDMS system	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to verify information between Actors submitted data and EUDAMED data so that I can approve or reject role registration	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to approve actor's role registration so that Actor is registered in MDMS system	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to reject actor's role registration so that Actor can resubmit required information	Approved	Backend; Phase 2; Registration of Actors; shared with client

User Story	As a System I want to send notification to non-distributor so that Actor is notified of successful registration	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to send notification to non-distributor that registration is not approved so that Non-Distributor Actor can resubmit required information	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have data audited in the system so that I can have data stored in the system	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a Distributor Actor I want to submit required information so that I can register as Distributor	Approved	Registration of Actors (Distributors)
User Story	As a non-distributor Actor, I expect system to send notification to MA finance to create new Actor details in Sage so that MAA can create my profile if it does not exist in Sage	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to create Actor in Sage and provide SAGE account Identifier so that Actors details are registered in Sage	Approved	Registration of Actors (Non-Distributors)
User Story	As a Distributor Actor I want to pay registration fee so that I can register as a Distributor	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to send a notification to User that there is registration pending approval so that User can approve pending registration for distributor and non-distributor actors	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to approve a distributor actor's role registration so that Actor is registered in MDMS system	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to send registration approval notification to Distributor actor so that Distributor actor is notified of successful registration	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have data audited in the system so that I can track changes	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to reject a distributor actor's role registration so that Actor can resubmit required information	Approved	Backend; Phase 2; Registration of Actors; shared with client

User Story	As a System I want to save initially submitted data so that Actor can amend data accordingly	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a non-distributor Actor, I want to pay registration fee so that I can apply as a non-distributor	Approved	Registration of Actors (Non-Distributors)
User Story	As a User System to start tickler so that I can monitor process duration	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to generate XML request to EUDAMED so that I can download XML response	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to upload XML to EUDAMED so that EUDAMED can generate file for download	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want EUDAMED to notify me of a file available for download so that MAA can download the file	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to download a file from EUDAMED so that I can upload XML file to MDMS	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to upload XML file from EUDAMED into MDMS so that I can update non-distributor information	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have XML file stored in MDMS so that I can track changes	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to send notification from MDMS so that non-distributor actor is informed that changes are done in MDMS	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have notification audited in MDMS so that I can track changes	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to upload XML to MDMS so that XML file can be processed in MDMS	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want XML provided to be processed in the system so that Data can be stored in MDMS	Approved	Registration of Actors (Non-Distributors)
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to approve Distributors modified information so that I can approve modification	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to stop tickler when status changed to approved so that I can monitor process duration	Approved	API; Phase 2; Registration of Actors; shared with client

User Story	As a System I want to have amended information stored in MDMS so that MA can review changes	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to send notification to MA that there is registration pending approval so that MA can approve changes	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a User I want to approve changes to the Distributors information so that Distributors information is up to date	Approved	Backend; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to stop tickler when status changed to approved so that I can monitor process duration	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have approval notification sent to distributor actor so that Distributor actor is informed of approved changes	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have rejected notification sent to distributor actor so that Distributor actor can resubmit information	Approved	API; Needs Linking; Phase 2; Registration of Actors; shared with client
User Story	As a System I want to have notification audited in MDMS so that I can track changes	Approved	API; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to keep track of audits so that the system can keep track of actions performed by the user	Approved	API; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to provide searching and filtering so that the end user is able to search and filter within the various lists provided by the system	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to provide PDF and CSV export functionality so that the end user is able to export the whole list to a CSV or PDF	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to provide a way where templates for PDF export can be provided so that the header and footer can be added to the PDF on export	Approved	NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I need to provide multilingual error messages so that in case Maltese language is enabled, I can provide error messages in Maltese	Approved	NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I need to provide multilingual forms so that in case Maltese language is enabled, I can provide forms in Maltese	Approved	NFR; Phase 2; Registration of Actors; shared with client

User Story	As a Developer I want to provide a portal which provide a score of at least 60 in Google lighthouse measuring tool so that I can guarantee good web portal performance and good user experience	Approved	NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to provide support to all major browsers so that end users can access the portal using their favourite browser	Approved	NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to provide only logical deletes in the system so that when deleting items, these can be retrieved back	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to provide a section where the end user can view the deleted items so that items can be restored back	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to keep track of the different file versions so that previous files can be viewed upon request	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to make use of frameworks such as Polly so that I am able to retry API calls automatically so that to avoid failures due to connection issues	Approved	NFR; Phase 2; Registration of Actors
User Story	As a Developer I want to audit API calls including the amount take to process the request so that it is easier to identify processes which are taking long	Approved	NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to validate the XML generated so that to confirm it complies with the schema provided by EUDAMED	Approved	API; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to validate the XML provided by the user when this is uploaded so that to confirm it complies with the schema provided by EUDAMED	Approved	API; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to store public data on Redis cache so that make sure that the response times are reduced as much as possible	Approved	NFR; Phase 2; Registration of Actors
User Story	As a Developer I want to provide the facility to upload files so that these are stored within the system bound to the respective entity they pertain to	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to limit file uploads to a maximum of 5Mb so that we can limit the storage used	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to scan files uploaded with Windows Defender before entering the storage so that we can reduce the risk of having malicious files uploaded and accessed by users	Approved	NFR; Phase 2; Registration of Actors; shared with client

User Story	As a Developer I want to make sure that I use regular expressions, max length, required fields and placeholders so that I can guide end users in filling the correct information in the forms	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a Developer I want to set a timeout of around 15 seconds (configurable) for APIs so that the system does not keep waiting for a response indefinitely	Approved	NFR; Phase 2; Registration of Actors
User Story	As a Developer I want to show a loader when retrieving the data so that the system can notify the end user that something is happening in the background	Approved	Backend; NFR; Phase 2; Registration of Actors; shared with client
User Story	As a developer I want to set up the Umbraco portal so that we can start development	Approved	CMS; Phase 2; shared with client
User Story	As a developer I want to set up the standard content required such as contact us pages, error pages, etc so that a skeleton site is available	Approved	CMS; Phase 2; shared with client
User Story	As a Developer I want to provide a means how featured news can be viewed on the frontend so that User are able to provide information to the end-users	Approved	CMS; Phase 2; shared with client
User Story	As a Developer I want to keep track of actions performed by the user so that the system can keep track/generate audits/audit trail.	Approved	CMS; Phase 2; shared with client
User Story	As a Developer I want to make use of Hotjar and Google Analytics so that User can get analytics on the use of the portal	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a Developer I want to incorporate captchas when forms can be accessed without having a login so that to avoid being spammed by robots	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a Developer I want to make sure that Blob storage, database and webapps make use of ZRS so that provide business continuity	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to make sure data at rest is encrypted using inbuilt azure functionality so that data remains encrypted at all times when not in use	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to provide two types of error pages so that end user so that the user is notified that an error happened	Approved	CMS Frontend; NFR; Phase 2; shared with client

User Story	As a Developer I want to limit the session to remain available for 20 minutes (standard session timeout) from the last activity so that end user is logged out after 20 minutes	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide forgot password and reset password functionality so that users can reset their password without the intervention of the user	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to create a function to validate passwords so that so that users are guided to use strong passwords	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to lock user's email address from being edited so that this can be used as the primary identifier	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide users with a facility to change user's profile so that after manual verification the user's email address can be changed	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to keep track of actions performed by the user so that the system can keep track/generate audits/audit trail.	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide searching and filtering so that the end user is able to search and filter	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide a way where templates for PDF export can be provided so that the header and footer can be added to the PDF on export	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I need to provide multilingual error messages so that in case Maltese language is enabled, I can provide error messages in Maltese	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I need to provide multilingual forms so that in case Maltese language is enabled, I can provide forms in Maltese	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide a portal which provide a score of at least 60 in Google lighthouse measuring tool so that I can guarantee good web portal performance and good user experience	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to provide support to all major browsers so that end users can access the portal using their favourite browser	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to make use of GraphQL so that only required data is obtained when querying data from the database and improve performance	Approved	CMS Frontend; NFR; Phase 2

User Story	As a Developer I want to keep track of the different file versions so that previous files can be viewed upon request	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to make use of frameworks such as Polly so that I am able to retry API calls automatically so that to avoid failures due to connection issues	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to audit API calls including the amount take to process the request so that it is easier to identify processes which are taking long	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I need to provide the facility to upload files so that these are stored within the system bound to the respective entity they pertain to	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I need to limit file uploads to a maximum of 5Mb so that we can limit the storage used	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to scan files uploaded with Windows Defender before entering the storage so that we can reduce the risk of having malicious files uploaded and accessed by users	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to make sure that I use regular expressions, max length, required fields and placeholders so that I can guide end users in filling the correct information in the forms	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to create a unique password to be used in conjunction with the case number so that users who are not registered can log in the system using the case number and unique password combination	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to set a timeout of around 15 seconds (configurable) for APIs so that the system does not keep waiting for a response indefinitely	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to show a loader when retrieving the data so that the system can notify the end user that something is happening in the background	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I need to validate the XML provided by the end-user when this is uploaded so that to confirm it complies with the schema provided by EUDAMED	Approved	CMS Frontend; NFR; Phase 2; shared with client

User Story	As a Developer I want to provide a means how users can authenticate using two factor authentication (2FA) so that users can log in securely	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to cache public content (output cache) for 15 minutes so that the system performance is improved	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to make use of a CSP (Content security policy) so that it can help securing the site	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to make use of a cookie policy so that users get to know what cookies are in use and be in line with GDPR compliance	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to make use of the OWASP top 10 portal so that I can be guided on how to develop the portal in a secure manner	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to make sure that TLS 1.2 is being used so that transmission of data is secured	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to build the portal in a responsive manner so that it can scale up or down nicely to any device and screen	Approved	CMS Frontend; NFR; Phase 2; shared with client
User Story	As a Developer I want to make sure that all links are pointing to using TLS over http (https) so that I can secure connection for any used assets	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to make use of CI/CD and allow scripting of ARM, Database and Code so that they can be deployed as artifacts when using pipelines	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to promote code once approval is provided so that to avoid issues being raised on the UAT environment	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to allow access to blob storage, APIs, databases, azure functions, configuration manager and vaults to internal network only so that to safeguard the data	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to publish the Umbraco web application for public access on the UAT and Live environment only so that users can access the web portal from anywhere	Approved	CMS Frontend; NFR; Phase 2
User Story	As a Developer I want to want to use 2 keys where applicable so that key rotation can happen without interrupting the service	Approved	CMS Frontend; NFR; Phase 2

User Story	As a Developer I want to use read-only keys in all components except to where configuration needs to be performed so that configurations cannot be altered	Approved	CMS Frontend; NFR; Phase 2
User Story	As a User I want to have CMS functionality so that I can update web site content	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a User I want to be able to create web site pages so that I can update web site content	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a User I want to be able to create web site news so that I can update web site content	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a User I want to be able to create web site banners so that I can update web site content	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a User I want to be able to create web site online forms so that I can update web site content	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a User I want to be able to upload content to web site so that I can update web site content	Approved	CMS Frontend; Phase 2; shared with client
User Story	As a System I want to have device status 'Pending' so that I can monitor device notification approval	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device status 'Active' so that I can monitor device notification approval	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device status 'Recalled' so that I can mark the status of the device post approval	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device status 'Withdrawn' so that I can mark the status of the device post approval	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device status 'On Hold' so that I can mark the status of the device post approval	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to not allow device status change so that device status cannot be changed by the actors when the status is set to the statuses in the description	Approved	API; Device Management; Phase 2; shared with client
User Story	As a System I want to have medical device risk classification 'Class1s' so that I can determine devices risk status	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device risk classification 'Class1m' so that I can determine devices risk status	Approved	Backend; Device Management; Phase 2; shared with client

User Story	As a System I want to have medical device risk classification 'Class2' so that I can determine devices risk status	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device risk classification 'Class2b' so that I can determine devices risk status	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a System I want to have device risk classification 'Class3' so that I can determine devices risk status	Approved	Backend; Device Management; Phase 2; shared with client
User Story	As a Developer I want to keep track of audits so that the system can keep of actions performed by the user	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide searching and filtering so that the end user is able to search and filter	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide PDF and CSV export functionality so that the end user is able to export the whole list to a CSV or PDF	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide a way where templates for PDF export can be provided so that so that the header and footer can be added to the PDF on export	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide multilingual error messages so that in case Maltese language is enabled, I can provide error messages in Maltese	Approved	Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide multilingual forms so that in case Maltese language is enabled, I can provide forms in Maltese	Approved	Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide a portal which provide a score of at least 60 in Google lighthouse measuring tool so that I can guarantee good web portal performance and good user experience	Approved	Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide support to all major browsers so that end users can access the portal using their favourite browser	Approved	Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide a facility to delete a message within the correspondence so that User can recall a message.	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client

User Story	As a Developer I want to send a notification to the end user that he has an unread message in the correspondence but not the actual text so that the end user is notified	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to provide with the functionality to edit a message so that user can amend messages sent	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to keep track of the different file versions so that previous files can be viewed upon request	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to make use of frameworks such as Polly so that I am able to retry API calls automatically so that to avoid failures due to connection issues	Approved	Market Surveillance; NFR; Phase 3
User Story	As a Developer I want to audit API calls including the amount take to process the request so that it is easier to identify processes which are taking long	Approved	Market Surveillance; NFR; Phase 3
User Story	As a Developer I want to store public data on Redis cache so that make sure that the response times are reduced as much as possible	Approved	Market Surveillance; NFR; Phase 3
User Story	As a Developer I want to provide the facility to upload files so that these are stored within the system bound to the respective entity they pertain to	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to limit file uploads to a maximum of 5Mb so that we can limit the storage used	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to scan files uploaded with Windows Defender before entering the storage so that we can reduce the risk of having malicious files uploaded and accessed by users	Approved	Market Surveillance; NFR; Phase 3
User Story	As a Developer I want to make sure that I use regular expressions, max length, required fields and placeholders so that I can guide end users in filling the correct information in the forms	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to create a unique password to be used in conjunction with the case number so that users who are not registered can log in the system using the case number and unique password combination	Approved	Backend; Market Surveillance; NFR; Phase 3

User Story	As a Developer I want to set a timeout of around 15 seconds (configurable) for APIs so that the system does not keep waiting for a response indefinitely	Approved	Backend; Market Surveillance; NFR; Phase 3
User Story	As a Developer I want to show a loader when displaying the data so that the system can notify the end user that something is happening in the background	Approved	Backend; Batch 2 user stories; Market Surveillance; NFR; Phase 3; shared with client
User Story	As a Developer I want to keep track of audits so that the system can keep track of actions performed by the user	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide searching and filtering so that the end user is able to search and filter	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide PDF and CSV export functionality so that the end user is able to export the whole list to a CSV or PDF	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide a way where templates for PDF export can be provided so that so that the header and footer can be added to the PDF on export	Approved	Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide multilingual error messages so that in case Maltese language is enabled, I can provide error messages in Maltese	Approved	Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide multilingual forms so that in case Maltese language is enabled, I can provide forms in Maltese	Approved	Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide a portal which provide a score of at least 60 in Google lighthouse measuring tool so that I can guarantee good web portal performance and good user experience	Approved	Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide support to all major browsers so that end users can access the portal using their favourite browser	Approved	Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide a facility to delete a message within the correspondence so that User can recall a message.	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to send a notification to the end user that he has an unread message in the correspondence but not the actual text so that the end user is notified	Approved	API; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to provide with the functionality to edit a message so that user can amend messages sent	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance

User Story	As a Developer I want to provide a section where the end user can view the deleted items so that items can be restored back	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to keep track of the different file versions so that previous files can be viewed upon request	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to make use of frameworks such as Polly so that I am able to retry API calls automatically so that to avoid failures due to connection issues	Approved	NFR; Phase 3; Vigilance
User Story	As a Developer I want to audit API calls including the amount take to process the request so that it is easier to identify processes which are taking long	Approved	NFR; Phase 3; Vigilance
User Story	As a Developer I want to validate the XML generated so that to confirm it complies with the schema provided by EUDAMED	Approved	API; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to validate the XML provided by the end-user when this is uploaded so that to confirm it complies with the schema provided by EUDAMED	Approved	API; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to store public data on Redis cache so that make sure that the response times are reduced as much as possible	Approved	NFR; Phase 3; Vigilance
User Story	As a Developer I want to provide the facility to upload files so that these are stored within the system bound to the respective entity they pertain to	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to limit file uploads to a maximum of 5Mb so that we can limit the storage used	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to scan files uploaded with Windows Defender before entering the storage so that we can reduce the risk of having malicious files uploaded and accessed by users	Approved	Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to make sure that I use regular expressions, max length, required fields and placeholders so that I can guide end users in filling the correct information in the forms	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a Developer I want to create a unique password to be used in conjunction with the case number so that users who are not registered can log in the system using the case number and unique password combination	Approved	Backend; NFR; Phase 3; Vigilance

User Story	As a Developer I want to set a timeout of around 15 seconds (configurable) for APIs so that the system does not keep waiting for a response indefinitely	Approved	NFR; Phase 3; Vigilance
User Story	As a Developer I want to show a loader when displaying the data so that the system can notify the end user that something is happening in the background	Approved	Backend; Batch 2 user stories; NFR; Phase 3; shared with client; Vigilance
User Story	As a User I want to Bulk search for Basic UDI-DI on EUDAMED so that I am able to match Devices when new notification of devices happen.	Approved	Backend; Batch 3 user stories; Phase 2; Search Devices; shared with client
User Story	As a User I want to Bulk search for Basic UDI-DI on EUDAMED so that I am able to take a snapshot of local devices when a new case is opened.	Approved	Backend; Batch 3 user stories; Phase 2; Search Devices; shared with client
User Story	As a User I want to Search for Actors on EUDAMED so that I am able to match details when local EOs register	Approved	Backend; Batch 3 user stories; Phase 2; Search Devices; shared with client
User Story	As a User I want to Export vigilance cases to EUDAMED so that I update EUDAMED records	Approved	Backend; Batch 3 user stories; Phase 2; Search Devices; shared with client
User Story	As a User I want to Import FSN/Manufacturer Report in the EUDAMED report format so that I can start investigation based on EUDAMED report	Approved	Backend; Batch 3 user stories; Phase 2; Search Devices; shared with client
User Story	As a User I want to be able to generate XML file for actor search on EUDAMED so that I can save data in MDMS as snapshot when opening case	Approved	Backend; Batch 3 user stories; Phase 2; Search Devices; shared with client
User Story	As a User I want to have tickler functionality so that I can monitor process deadlines	Approved	Backend; Batch 3 user stories; Phase 2; shared with client; Tickler Functionality
User Story	As a User I want to create tickler against process workflow so that I can define tickler in days to expire	Approved	Backend; Batch 3 user stories; Phase 2; shared with client; Tickler Functionality
User Story	As a User I want to define tickler in number of calendar days so that I can have notifications before tickler expires	Approved	Backend; Batch 3 user stories; Phase 2; shared with client; Tickler Functionality
User Story	As a User I want to be able to pause tickler so that tickler would pause the count until manually released	Approved	Backend; Batch 3 user stories; Phase 2; shared with client; Tickler Functionality
User Story	As a User I want to be able to stop tickler so that tickler would be stopped	Approved	Backend; Batch 3 user stories; Phase 2; shared with client; Tickler Functionality

User Story	As a System I want to be able to restart tickler so that tickler would be stopped	Approved	API; Batch 3 user stories; Phase 2; shared with client; Tickler Functionality
User Story	As a System I want to archive data so that data can be used in case an audit needs to happen or for legal purposes	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a System I want to have data archived for 15 years so that the most current data is kept for the specified time	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a System I want to have data archived in separate DB so that I can audit data	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a System I want to have data logically deleted so that I can have data removed but still accessible	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a System I want to have deleted data moved to separate DB so that performance of the system is not affected	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to logically delete recalled devices data so that Data details are not shown on the screen but can still be accessible	Approved	Audit Data; Backend; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to have deleted recalled devices data saved in separate DB so that performance of the system is not affected	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to enquire data in separate DB so that I can review data	Approved	Audit Data; Backend; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to track user activity so that I can audit user activity	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to delete data older than 15 years so that I can permanently delete data	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to view audits so that I can enquire Audit actions	Approved	Audit Data; Backend; Batch 3 user stories; Phase 2; shared with client
User Story	As a System I want to remove the audits (history) records from the audits DB so that I can actually delete archived audit records after a period of time	Approved	Audit Data; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to be able to create ad-hoc forms so that I can publish forms	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to be able to view submitted forms so that I can view the forms	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client

User Story	As a User I want to be able to convert ad-hoc forms to tabular format so that I can extract data	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to select fields in ad-hoc form so that I can create form	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to edit ad-hoc form so that I can amend form fields	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to delete ad-hoc form not previously approved so that form is deleted	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to approve ad-hoc form so that form is published	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a User I want to save ad-hoc form in system so that I can refer to it at later stage	Approved	Adhoc Forms; Batch 3 user stories; Phase 2; shared with client
User Story	As a system I want to send payment notification so that Actor is notified of PENDING/PAID(or approved) payment.	Approved	API; Batch 3 user stories; Notifications; Phase 2; shared with client
User Story	As a System I want to I would like to provide functionality to be able to manage templates for notifications so that MA can change the templates as required	Approved	Batch 3 user stories; Notifications; Phase 2; shared with client
User Story	As a System I want to send notification of rejection to Distributor/Importer so that Distributor/Importer is notified of rejection	Approved	API; Batch 3 user stories; Notifications; Phase 2; shared with client
User Story	As a System I want to send notification of Device amendments including status changes so that Distributor/Importer is notified of Device amendments including status changes	Approved	API; Batch 3 user stories; Notifications; Phase 2; shared with client
User Story	As a System I want to send notification of Device amendments rejection so that Distributor/Importer is notified of Device amendments rejection	Approved	API; Batch 3 user stories; Notifications; Phase 2; shared with client
User Story	As a System I want to send notification of device approval so that Distributor/Non-distributor is notified of the approval/rejection	Approved	API; Batch 3 user stories; Notifications; Phase 2; shared with client
User Story	As a User I want to be able to set up registration fees so that I can charge the fee	Approved	Backend; Batch 3 user stories; Phase 2; Registration Fee Manager; shared with client

User Story	As a User I want to be able to set up device notification fees so that I can charge the fee	Approved	Backend; Batch 3 user stories; Phase 2; Registration Fee Manager; shared with client
User Story	As a User I want to be able to set up market surveillance fees so that I can charge the fee	Approved	Backend; Batch 3 user stories; Phase 2; Registration Fee Manager; shared with client
User Story	As a User I want to be able to set up recurring fees so that I can charge the fee	Approved	Backend; Batch 3 user stories; Phase 2; Registration Fee Manager; shared with client
User Story	As a User I want to be able to change the fee amount and frequency so that I can amend fees	Approved	Backend; Batch 3 user stories; Phase 2; Registration Fee Manager; shared with client
User Story	As a User I want to have search functionality so that I can search for devices, actors and cases in Vigilance and Market surveillance module	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As an Actor I want to search for devices so that System will display on screen search results	Approved	Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As a User I want to search for devices so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As a System I want to display search results for devices so that User can view the results	Approved	API; Batch 3 user stories; Phase 2; Search Devices; Search functionality; shared with client
User Story	As a User I want to search for actors so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Phase 2; search actors; Search functionality; shared with client
User Story	As a System I want to display search results for actors so that User can view the results	Approved	API; Batch 3 user stories; Phase 2; search actors; Search functionality; shared with client
User Story	As an Actor I want to search for cases so that System will display on screen search results	Approved	Batch 3 user stories; Phase 2; Search functionality; shared with client; Vigilance
User Story	As a User I want to search for cases so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client; Vigilance

User Story	As a System I want to display search results for cases so that User can view the results	Approved	API; Batch 3 user stories; Phase 2; Search functionality; shared with client; Vigilance
User Story	As an Actor I want to search for correspondence so that System will display on screen search results	Approved	Batch 3 user stories; Correspondence; Phase 2; Search functionality; shared with client
User Story	As a User I want to search for correspondence so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Correspondence; Phase 2; Search functionality; shared with client
User Story	As a System I want to display search results for correspondence so that User can view the results	Approved	API; Batch 3 user stories; Correspondence; Phase 2; Search functionality; shared with client
User Story	As a User I want to search for text matching file names or tags so that User can view the results	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As a System I want to display search results for text matching file names or tags so that User can view the results	Approved	API; Batch 3 user stories; Frontend; Phase 2; Search functionality; shared with client
User Story	As an Actor I want to search for invoices so that System will display on screen search results	Approved	Batch 3 user stories; Phase 2; Search functionality; search invoices; shared with client
User Story	As a User I want to search for invoices so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As an Actor I want to search for credit notes so that System will display on screen search results	Approved	Batch 3 user stories; payments; Phase 2; Search functionality; shared with client
User Story	As a User I want to search for credit notes so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As an Actor I want to search for payments so that System will display on screen search results	Approved	Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As a User I want to search for payments so that System will display on screen search results	Approved	Backend; Batch 3 user stories; Phase 2; Search functionality; shared with client
User Story	As a System I want to display search results for payment so that User can view the results	Approved	Batch 3 user stories; Phase 2; Search functionality; shared with client

User Story	As a User I want to be able to manage internal users in MDMS so that I can assign access user rights	Approved	Batch 3 user stories; Permissions for Malta Users; Phase 2; shared with client
User Story	As a User I want to be able to create Case Manager user profile so that I can assign access rights	Approved	Batch 3 user stories; Permissions for Malta Users; Phase 2; shared with client
User Story	As a User I want to be able to create Case Officer user profile so that I can assign access rights	Approved	Batch 3 user stories; Permissions for Malta Users; Phase 2; shared with client
User Story	As a User I want to be able to create Documentation Officer user profile so that I can assign access rights	Approved	Batch 3 user stories; Permissions for Malta Users; Phase 2; shared with client
User Story	As a User I want to be able to create Administrator user profile so that I can have access to all modules	Approved	Batch 3 user stories; Permissions for Malta Users; Phase 2; shared with client
User Story	As a User I want to be able to create Manager user profile for Market surveillance and Vigilance so that I can have the appropriate access rights	Approved	Batch 3 user stories; Market Surveillance; Permissions for Malta Users; Phase 2; shared with client; Vigilance
User Story	As a User I want to be able to create data officer user profile so that I can have access rights	Approved	Batch 3 user stories; Permissions for Malta Users; Phase 2; shared with client
User Story	As a User I want to be able to create Enquirer user profile for Market surveillance and Vigilance so that I can have access rights	Approved	Batch 3 user stories; Market Surveillance; Permissions for Malta Users; Phase 2; shared with client; Vigilance
User Story	As a User I want to have Vigilance module access to following functions so that I can perform my work	Approved	Backend; Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a Public I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a Health professional I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a Healthcare provider I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a Manufacturers I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance

User Story	As an Authorised Representative I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a Notified Bodies I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a Distributors I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As an Importers I want to have Vigilance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Phase 3; shared with client; Vigilance
User Story	As a User I want to view payment invoices	Approved	Backend; Payments and Invoices; Phase 2
User Story	As a developer I want to integrate Google Analytics so ADMIN can track and view reports regarding the website traffic.	Approved	
User Story	As a System I want to have In-Vitro Devices risk classification 'Class A' so that I can determine devices risk classification	Approved	Backend; Device Management; Phase 2
User Story	As a System I want to have In-Vitro Devices risk classification 'Class B' so that I can determine devices risk classification	Approved	Backend; Device Management; Phase 2
User Story	As a System I want to have In-Vitro Devices risk classification 'Class C' so that I can determine devices risk classification	Approved	Backend; Device Management; Phase 2
User Story	As a System I want to have In-Vitro Devices risk classification 'Class D' so that I can determine devices risk classification	Approved	Backend; Device Management; Phase 2
User Story	As a User I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As a Public I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As a Manufacturers I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As an Authorised Representative I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As a Notified Bodies I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client

User Story	As a Distributors I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As an Importers I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As a Line Head (case manager) I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As an Inspectors (Case officer) I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As a Documentation Officer (team member of case officer) I want to have Market surveillance module access to following functions so that I can perform my work	Approved	Batch 5 user stories; Market Surveillance; Phase 3; shared with client
User Story	As a system I want to send Payment Reminders to the actor 2 days after the payment is due, then after 1 week and then every month to both the actor and ADMIN	Approved	API; Batch 3 user stories; Notifications; Phase 2
User Story	As an Actor I want to Login to portal so that B2C can authenticate my credentials	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a B2C I want to validate authentication so that I can authenticate user	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a B2C I want to send token and any available claims so that User can log in to the system	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a System I want to check if record for this user exist so that I can insert new record if record does not exist	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a System I want to insert new user record in the database if user does not exist so that I can authenticate logged in user	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a System I want to authenticate logged in user so that I can display general public dashboard	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a System I want to prompt user to input missing details so that I can display general public dashboard	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a System I want to Not allow user to proceed without providing missing information together with confirmation of data so that I can display general public dashboard	Approved	B2C; Frontend; Phase 2; User Stories Batch 5

User Story	As a System I want to allow user to login and display general public dashboard so that User is logged in	Approved	B2C; Frontend; Phase 2; User Stories Batch 5
User Story	As a User I want to log in to the portal so that I have access to Backend portal with proper role permissions	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a User I want to submit log in details on B2C so that I can log in to the portal	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a User I want to automatically log in user with machine credentials so that I can log in to the portal	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a B2C I want to validate details so that I can send token and respective claims	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a B2C I want to send token and respective claims so that User can log in	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a System I want to check is user record exist in backend so that I can authenticate user	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a System I want to check if user has been assigned any roles if record exist in the backend so that I can assign respective access rights	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a System I want to assign respective access rights so that User have access to backend	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a System I want to display general public dashboard if user record exist without roles so that Admin can assign respective roles	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a User I want to have access to backend portal with proper role permissions so that I can have respective dashboard when logged in	Approved	B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As an ADMIN user I want to assign permissions/roles to user so that User can log in to MDMS with proper role	Approved	Admin assign Corp account; B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As an ADMIN user I want to input the CORP account details in login screen and assigns the required permissions/roles so that User can log in to MDMS with proper role	Approved	Admin assign Corp account; B2C; Backend; CMS; Phase 2; User Stories Batch 5
User Story	As a System I want to notify user that his account is created in MDMS so that User can log in to MDMS with proper role	Approved	Admin assign Corp account; B2C; Backend; CMS; Phase 2; User Stories Batch 5

User Story	As an Actor I want to assign representatives to an actor so that Representative can act on behalf of actor	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As an Actor I want to log in to MDMS frontend using B2C so that I can invite representative to act on my behalf	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As an Actor I want to submit representative's email address so that Representative can be linked to the actor	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to check if representative's email address is already bound with the same actor so that I can send notification invitation	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to generate error if email is already bound to the actor so that I cannot allow for the same representative to be bound to the actor	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to check if representative's email address has pending invitation so that I can send notification invitation	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to clear any pending invitations so that I can send notification invitation	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to generate email invitation if there is no pending invitation so that Representative can receive invitation	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to audit data in the system so that I can refer to data at later stage	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a Representative user I want to receive an email and click on the link so that I can verify email address	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a Representative user I want to input email address for verification so that I can verify email address	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to check that random identifier match email in system and organization record so that Email address is verified	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a B2C I want to validate authentication so that user log in details are verified	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a B2C I want to send token and any available claims so that System will display registration screen	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to display registration screen with prepopulated available information so that Representative user can log in	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2

User Story	As a System I want to check if there is required information missing so that Representative can populate required information	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to prompt user to input missing details so that Representative user can fill in required information	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to not allow user to proceed without providing missing information together with confirmation of data so that Representative user can fill in required information	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a Representative user I want to insert required information so that I can proceed with log in	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to save and audit data in the system so that I can refer to data at a later stage	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to bind representative user to the actor so that Representative user is linked to the actor	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a System I want to display user dashboard so that Representative user can act on behalf of actor	Approved	Batch 5 user stories; Frontend; Invite Actor Representatives; Phase 2
User Story	As a User I want to log in to portal using B2C so that I can log in	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a User I want to submit username and password so that I can log in	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a B2C I want to validate authentication so that User can log in to portal	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a B2C I want to send token and any available claims so that User can log in to portal	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a System I want to check if user record exist so that User can log in to portal	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a System I want to check if user is bound to an Actor so that User can log in to portal	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a System I want to display screen to enable the user to choose the selected actor or the general public profile in case user is already bound to an actor so that User can select appropriate dashboard	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5
User Story	As a System I want to display general public dashboard in case user is not bound to an actor.	Approved	Frontend; Login to portal using B2C; Phase 2; User Stories Batch 5

User Story	As a User I want to edit my profile so that I can update profile details	Approved	Edit Actor Profile; Frontend; Phase 2; User Stories Batch 5
User Story	As a User I want to click on 'Edit' profile tab on dashboard so that I can update profile details	Approved	Edit Actor Profile; Frontend; Phase 2; User Stories Batch 5
User Story	As a User I want to update personal / work profile details so that I can update profile details	Approved	Edit Actor Profile; Frontend; Phase 2; User Stories Batch 5
User Story	As a System I want to save and audit data in the system so that Data is saved and audited	Approved	Edit Actor Profile; Frontend; Phase 2; User Stories Batch 5
User Story	As a User I want to manage representative of an organisation so that I can add remove Admin	Approved	Frontend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As an Admin User (Permission only for ADMIN user) I want to click on ‘Manage representatives’ tab on dashboard so that I can add remove Admin	Approved	Frontend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As an Admin User (Permission only for ADMIN user) I want to manage representatives’ details so that I can add remove Admin	Approved	Frontend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As a System I want to save and audit data in the system so that Data is saved and audited	Approved	Frontend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As an Administrator I want to give/remove Admin rights to a particular representative of an actor so that I can add/remove administrator rights	Approved	Backend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As an Administrator I want to set myself as part of the organisation with admin rights so that I can invite new representative	Approved	Backend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As an Administrator I want to select actor from a list so that I can add/remove administrator rights	Approved	Backend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As an Administrator I want to provide Administrator rights as needed for selected representatives so that I can add/remove administrator rights	Approved	Backend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As a System I want to save and audit data in the system so that Data is saved and audited	Approved	Backend; Organisation Representative; Phase 2; User Stories Batch 5
User Story	As a user I want to receive email notification so that I can download FSN/MIR xml file from EUDAMED	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance

User Story	As a User I want to download FSN/MIR xml file from EUDAMED so that I can open a case	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a User I want to upload XML file to MDMS so that I can open a case	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a User I want to manually submit FSN/MIR form so that I can open a case	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to parse XML file so that I can create the case	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to use data from the form so that I can create the case	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to open case and assign case number so that System can assign case to case manager	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to assign 'created' status to the case so that System can assign case to case manager	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to determine if investigation is triggered by a vigilance case manager so that case can be approved/rejected	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to send notification to all case managers if case is not initiated by case manager so that case can be reviewed for approval/rejection	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a Case manager I want to approve case so that Case status will change to 'Approved'	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance

User Story	As a Case manager I want to reject case so that Case status will change to 'Rejected'	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to send notification to case officer that case is rejected so that case officer is notified	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to audit notification so that data can be audited	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a Case officer I want to receive notification of rejection so that I am notified	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to stop tickler if investigation is triggered by case manager so that Case can be approved	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to automatically change status of the case to 'Approved' so that case can be assigned to case officer	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a Case manager I want to assign case to case officer so that case officer can initiate investigation	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to send notification to case officer so that case officer is informed of assignment	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a System I want to audit notification so that data can be audited	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a Case officer I want to receive notification so that case officer is notified of assignment	Approved	Backend; Batch 5 user stories; Incident Report Management Initiation from FSN/MIR; Phase 3; Vigilance
User Story	As a Health Professionals/General Public or Health institutions I want to select the form from the list so that I can fill in Vigilance request	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance

User Story	As a Health Professionals/General Public or Health institutions I want to fill in an online form so that I can submit the case	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to assign case number to the case so that ADMIN can assign case to the case manager	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to change status of the case to 'created' so that I can send notification to case managers	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to send notification to the case Manager so that Case manager can approve the case	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to save data in MDMS so that I can audit data	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to send email notification of new case creation to Manager so that Case manager can approve/reject the case	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a Case manager I want to determine if case can be approved so that Case can be opened	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance

User Story	As a Case manager I want to approve the case so that Case can be opened	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a Case manager I want to reject the case	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to stop tickler if case is approved so that Case can be assigned to case officer	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to change status of the case to 'approved' so that Case can be assigned to case officer	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to change status of the case to 'rejected' so that Actor (health professional/general public) is notified of rejection	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to send notification of rejection to Actor (health professional/general public) so that Actor is notified of rejection	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to audit notification so that data can be audited	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As an Actor (health professional/general public) I want to receive notification of rejection so that actor is notified	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance

User Story	As a Case manager I want to assign case to case officer so that case officer can proceed with investigation	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to send notification to the case officer so that Case officer is informed	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a System I want to save data in MDMS so that data can be audited	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a Case officer I want to receive notification so that Case officer is informed	Approved	Batch 5 user stories; Frontend; Incident Report Management Initiation from Health Professionals/General Public or Health institutions; Phase 3; Vigilance
User Story	As a Case officer I want to receive email notification so that I am informed of the new case	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to start tickler so that I can monitor process	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to perform initial review of the case so that I can assign severity	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to Assign severity to opened case so that case can be assessed	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to determine in MDMS if the case is affecting Malta so that case can be opened	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to automatically assign 'Closed' status if case does not affect Malta so that case is closed	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance

User Story	As a System I want to stop tickler function so that tickler is stopped	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to assign 'open' status to the case if case effect Malta so that case can be opened	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to Link FSN/MIR with Actor and Device /All devices so that system can assign deadlines according to severity	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to select legacy devices in relation to the case so that I can upload a request to EUDAMED in case this exists	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to select regular devices in relation to the case so that I can upload a request to EUDAMED	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Case officer I want to generate request to send to EUDAMED using UDI-DI if it is not legacy device so that I can upload a request to EUDAMED in case this exists	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a User (ADMIN) I want to Upload request to EUDAMED so that I can download XML response	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a Eudamed I want to notify MA of available download so that I can download XML response	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a User (ADMIN) I want to Log in to EUDAMED so that I can download XML response	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a User (ADMIN) I want to Upload file to MDMS portal (logged in as ADMIN), and details of devices are created in MDMS DB so that I can link FSN/MIR with actor and devices	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to assign deadlines according to severity provided by the case officer so that I can initiate correspondence with Actor	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance

User Story	As a Case officer I want to initiate correspondence / internal notes with Actor so that I can assign 'active' status to the case	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to assign 'Active' status to the case so that I can receive Actors feedback	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to check if target SRN is not registered in MDMS so that I can send notification to the Actor that there is pending correspondence	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to check if target SRN is registered in MDMS so that I can send notification to the Actor that there is pending correspondence	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to send notification to Actor providing the unique case password and specify that there is some correspondence to be actioned so that Actor can receive notification	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As a System I want to send notification to Actor, if target SRN is registered in the system, that there is some correspondence to be actioned so that Actor can receive notification	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As an Actor I want to receive notification of pending action so that Actor can reply to correspondence	Approved	Backend; Batch 5 user stories; Case officer Incident Report Management; Phase 3; Vigilance
User Story	As an Actor I want to be provided with a login functionality in MDMS so that I can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As an Actor I want to log into the system using B2C so that I can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a System I want to determine if actor already logged in once in the system so that I can show the case correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As an Actor I want to see case correspondence in case I am registered user so that I can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance

User Story	As an Actor I want to Input generated unique number which would have been supplied in the email sent so that I can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a System I want to link case to login so that I can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As an Actor I want to see case correspondence in case so that I can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As an Actor I want to provide necessary comments and / or documents so that Case officer would receive feedback	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a System I want to send notification to the case officer so that Case officer can review feedback	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case officer I want to review messages and / or documents so that I can advise Actor that feedback is satisfactory	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case officer I want to review messages and / or documents so that I can advise Actor that feedback is not satisfactory	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case officer I want to reply to correspondence and advise that feedback is not satisfactory so that Actor can provide additional information	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a System I want to send notification to Actor so that Actor can provide additional information	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a System I want to audit data notification so that Data can be audited	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case officer I want to change status of the case to the appropriate status so that case status would be set to closed, in remediation, on hold	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance

User Story	As a Case officer I want to determine if FSN needs to be initiated via EUDAMED in case the case was raised locally so that EUDAMED request could be generated	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case officer I want to Determine if FSN needs to be initiated via EUDAMED in case the case was raised locally so that FSN is submitted to EUDAMED	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case officer I want to generate XML for EUDAMED so that FSN is submitted to EUDAMED	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Phase 3; Vigilance
User Story	As a Case manager I want to re-assign case so that case officer is assigned to the case	Approved	Backend; Batch 5 user stories; Phase 3; Re-Assign to Case officer; Vigilance
User Story	As a Case manager I want to select the case officer from drop down menu so that case officer is assigned to the case	Approved	Backend; Batch 5 user stories; Phase 3; Re-Assign to Case officer; Vigilance
User Story	As a System I want to assign the case officer to the case so that I can send notification to the case officer	Approved	Backend; Batch 5 user stories; Phase 3; Re-Assign to Case officer; Vigilance
User Story	As a System I want to send notification to the case officer so that case officer is informed of new case assigned to him	Approved	Backend; Batch 5 user stories; Phase 3; Re-Assign to Case officer; Vigilance
User Story	As a System I want to audit data notification so that data can be audited	Approved	Backend; Batch 5 user stories; Phase 3; Re-Assign to Case officer; Vigilance
User Story	As a Case officer I want to receive notification so that I can work on case	Approved	Backend; Batch 5 user stories; Phase 3; Re-Assign to Case officer; Vigilance
User Story	As a Case officer I want to receive a reply to some correspondence outside of the system so that I can update correspondence in MDMS	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a Case officer I want to PDFs the correspondence to upload it to the system so that I can update correspondence in MDMS	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a System I want to prompt for file upload, date of correspondence and target SRN so that I can update correspondence in MDMS	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance

User Story	As a Case Officer I want to provide the necessary information so that system can store information	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a System I want to audit data correspondence so that data can be audited	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a System I want to link correspondence with the case so that Actor can access correspondence	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As an Actor / MA I want to delete correspondence so that I can replace the text that was put in the correspondence with 'Message has been deleted'	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a User I want to see all uploaded / received files per case so that I can view all files uploaded / received in one place	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a User I want to create internal notes per case so that I can have internal notes visible only to MA user	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a User I want to view all internal notes per case so that I can view all internal notes in one place	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a User I want to view all activity history of the case so that I can review all case activity in one place	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a User I want to view all linked cases so that I can review all cases linked to my case	Approved	Backend; Batch 5 user stories; Case officer uploads offline correspondence; Phase 3; Vigilance
User Story	As a Case manager/officer I want to schedule annual Market Surveillance so that I can have calendar scheduler functionality	Approved	Backend; Batch 5 user stories; Create Schedule; Market Surveillance; Phase 3
User Story	As a Case manager/officer I want to create a schedule of site visits so that site visits will be planned	Approved	Backend; Batch 5 user stories; Create Schedule; Market Surveillance; Phase 3
User Story	As a Case manager/officer I want to input site visits into scheduler so that site visits will be planned	Approved	Backend; Batch 5 user stories; Create Schedule; Market Surveillance; Phase 3

User Story	As a Case manager/officer I want to Plan scheduled Market surveillance and inputs the scheduled date for the visit so that site visits will be planned	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case manager/officer I want to link actor and all devices to investigation so that I can create investigation	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to create Investigation and assign Investigation number so that Status of the investigation is changed to 'create'	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to change status to 'Created' so that Investigation can be approved	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to determine if investigation is triggered by an Investigation manger so that investigation can be approved automatically	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to send notification to all Case managers if investigation is not triggered by Case manager so that investigation can be approved or rejected	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case manager I want to approve the case so that I can assign case to Case officer	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case manager I want to reject the case so that I can assign case to Case officer	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to stop tickler if case is approved so that case status can be changed to 'approved'	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to change case status to 'Rejected' if case is not approved	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3

User Story	As a System I want to send notification to case officer that case is rejected so that Case officer is informed of rejection	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to audit data notification so that data can be audited	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case officer I want to receive notification of rejection so that Case officer is informed of rejection	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to change case status to 'approved'	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case manager I want to assign case to Case officer	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case officer I want to receive notification so that I can plan investigation	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to send notification to Users of upcoming scheduled visit 60 days before or less so that Actor can be notified of planned investigation	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to audit data notification so that data can be audited	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As an Actor I want to be notified of upcoming investigation so that date of investigation can be agreed upon	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to start tickler for Case officer to kick off process so that process duration is monitored	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case officer I want to kick off process and propose investigation dates via correspondence so that investigation date can be agreed upon	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3

User Story	As a System I want to Start Tickler for Actor to agree on dates (10 days). so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a user want to contact Actor so that I can agree on dates of investigation	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case officer I want to set the investigation date so that I can start the investigation	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to stop tickler for the Actor so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to notify ADMIN of scheduled investigation 15 days before actual investigation takes place so that investigation can commence	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to notify Actor of scheduled investigation 15 days before actual investigation takes place so that investigation can commence	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a user want to contact Actor so that investigation can start	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a Case officer I want to receive notification that investigation is due so that I am informed of the due date	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As an Actor I want to receive notification that investigation is due so that I am informed of the due date	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to Assign “Open” status to investigation on the date of investigation so that investigation can commence	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a System I want to start tickler so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3

User Story	As an Actor I want to submit online subcontracting form so that I can open investigation	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to create Investigation and assign Investigation number so that I can notify ADMIN of a new case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to change status of the case to “created” so that I can notify ADMIN of a new case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to send notification to Case managers so that Case manager can approve or reject the case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to Audit data notification so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to Start Tickler (10 days) so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case manager I want to approve the case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case manager I want to reject the case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to Change status of the case to 'rejected' if not approved by Case manager	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to Audit data notification so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As an Actor I want to receive notification of the rejection including comments so that I am notified of rejection	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3

User Story	As a System I want to Automatically change status of the case to 'approved' if initiated by Case manager so that Actor is notified of approval	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case manager I want to provide a price for the job so that Actor can pay for the investigation	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to set payment status to 'Pending' so that Actor can pay for the investigation	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case manager I want to assign case to Case officer so that Case officer can link actor / devices to the case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to send notification to case officer so that Case officer is informed	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to receive notification so that Case officer is informed	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to link actor/ devices to investigation so that I can schedule investigation	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to Send payment notification to actor so that Actor can pay investigation fee	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As an Actor I want to receive payment notification so that I can pay investigation fee	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to start tickler for payments so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3

User Story	As an Actor I want to pay investigation fee online so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As an Actor I want to pay investigation fee manually so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to determine if payment is affected so that I can assign respective status to the payment	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to set payment status as 'Paid' if payment has been affected so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to stop tickler for payments so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to start tickler for Case officer to kick off process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to initiate process and propose investigation dates via correspondence so that I can agree with actor on investigation date	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to manually assign 'cancelled' status to investigation if payment is not affected so that payment status would be changed to 'cancelled'	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to set payment status to 'cancelled' so that process would end	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to stop tickler for Case officer to kick off process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to start tickler for investigated EO to agree on investigation date so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3

User Story	As an ADMIN I want to contact EO so that investigation date can be agreed upon	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As an Actor I want to provide availability for dates so that investigation date can be agreed upon	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to set investigation start date so that investigation can start	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to notify ADMIN and EO of scheduled investigation 15 days before actual investigation takes place so that EO can be contacted	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to contact EO so that investigation can start	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to send notification to Case officer that investigation is due so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case officer I want to receive notification to Case officer that investigation is due so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As an Actor I want to receive notification that investigation is due so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to Assign “Open” status to investigation on the date of investigation so that Investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a System I want to start tickler for investigation so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open Investigation Subcontracting; Phase 3

User Story	As an ADMIN I want to create investigation case so that Case officer can link actor / devices to the investigation	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case officer I want to link actor and all devices to investigation so that system can create investigation and assign investigation number	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to change status of the investigation to 'created' so that I can link incident with investigation	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to link incident with investigation so that case manager can approve or reject investigation	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to send a notification to all Case Managers for approval or rejection	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to determine if the investigation is triggered by a case manager so that case manager can assign case to case officer	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case manager I want to assign case to case officer if investigation is triggered by a case manager so that system can send notification to case officer.	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to start tickler if case investigation is not triggered by case manager so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case manager I want to reject case so that status of the case is changed to 'Rejected'	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case manager I want to approve the case so that I can change status of the case to 'Approved'	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to Change status of the case to 'rejected' if not approved by Case manager so that I can inform case officer	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3

User Story	As a System I want to send notification of rejection to case officer so that case officer is informed	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to audit notification so that I can refer to it at later stage	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case officer I want to receive rejection notification so that I am informed	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to Change status of the case to 'approved' so that case manager can assign case to case officer	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to send notification to the Actor about unplanned investigation so that Actor can be contacted	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to audit notification so that I can refer to it at later stage	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As an assigned case officer, I want to contact Actor so that I can agree on a date of investigation	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to start tickler for Case officer to kick off process so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case officer I want to start process and propose investigation dates via correspondence so that I can agree on a date with Actor to commence investigation	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to stop tickler for Case officer to kick off process so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3

User Story	As a System I want to start tickler for Actor to agree on dates so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case officer I want to contact Actor so that I can agree on a date to start investigation	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As an Actor I want to provide availability for dates via correspondence so that investigation can be opened	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to stop tickler so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a Case officer I want to set investigation start date so that investigation can be opened	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to assign 'open' status to investigation so that investigation can commence	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a System I want to start tickler for investigation so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Inspection Following an Incident; Market Surveillance; Phase 3
User Story	As a General Public/ Health institution I want to fill in online form so that Investigation can be created	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to send notification to Case managers so that Case manager is informed about new investigation report	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to audit notification data so that I can refer to it at later stage	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case manager I want to receive email notification of investigation report so that I am informed of new investigation report	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3

User Story	As a System I want to create investigation and assign investigation number so that investigation is created	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to change status of the investigation to 'created' so that case manager can approve/reject investigation	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to start tickler for approval process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case manager I want to approve case so that I can assign case officer to the case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case manager I want to reject case so that I can reject case	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to send notification to Actor that the case is not approved so that Actor is informed about rejection	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to Change status of the case to 'rejected' if not approved by Case manager so that Actor is informed about rejection	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to stop tickler for approval process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to audit notification data so that I can refer to it at later stage	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As an Actor I want to receive notification of rejection including comments so that I am informed about rejection	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to change status of the case to 'approved' so that case manager can assign case to case officer	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3

User Story	As a System I want to stop tickler for approval process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case manager I want to assign case to case officer so that case officer can link actor / devices to the investigation	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case officer I want to link actor / devices to investigation so that I can initiate investigation process	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to start tickler for Case officer to kick off process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case officer I want to start process and propose investigation dates via correspondence so that I can agree with actor on investigation date	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to stop tickler for case officer to kick off process so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to start tickler for investigated EO to agree on investigation date so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As an Actor I want to provide availability dates via correspondence so that I can agree on investigation start date	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to stop tickler for actor so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case officer I want to set investigation start date so that investigation can be opened	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a System I want to assign 'open' status to investigation on the day of investigation so that investigation can commence	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3

User Story	As a System I want to start tickler so that I can monitor process duration	Approved	Batch 5 user stories; Frontend; Market Surveillance; Open investigation as General public; Phase 3
User Story	As a Case officer I want to report findings to the Actor so that I can set the risk	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As a System I want to provide facility to record findings related to investigation so that case officer and report findings	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As a Case officer I want to set risk so that I can prioritise case findings	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As a System I want to allocate the respective tickler functionality for each finding so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As a System I want to send a notification to Actor of any pending findings requiring action so that Actor is informed about required actions	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As a System I want to start tickler to reach findings so that I can monitor process duration	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As an Actor I want to receive notification so that I am informed about required actions	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report findings
User Story	As an Actor I want to receive notification of findings so that I am informed about corrective actions	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to log in to the system using B2C so that I can reply to correspondence	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to list findings related to the investigation so that Actor can reply to correspondence	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to provide facility to provide CAPA's related to findings so that Actor can reply to correspondence	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to provide facility to provide deadlines for each finding so that I can calculate ticklers for each finding	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to configure findings so that Actor can submit findings in MDMS	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3

User Story	As a System I want to send internal notifications for findings so that ADMIN is informed	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to provide CAPA's information and upload required information so that ADMIN can review feedback	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to stop tickler for individual finding reported so that I can monitor process duration	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to receive notification so that I am informed about feedback	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to determine if feedback is satisfactory so that I can provide feedback if needed	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to start tickler if feedback is required so that I can monitor process duration	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to provide feedback to CAPA's so that Actor can provide additional information	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to change status of the case to the appropriate status if no feedback is required so that system can assign status accordingly	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to assign status accordingly to case so that CAPA's can be finalised	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an ADMIN I want to be able to pause / resume tickler so that CAPA's can be finalised	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to determine if CAPA's are finalised so that ADMIN can submit final report	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to submit final report if CAPA's are finalised so that I can determine if investigation needs to be sent to EUDAMED	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to notify Actor that there is feedback on submission so that Actor can provide CAPA's information	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to receive email notification that feedback is not satisfactory so that I can provide additional feedback	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3

User Story	As an Actor I want to provide CAPA's information and upload required information so that ADMIN can review feedback	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to stop tickler for the findings reported so that I can monitor process duration	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to receive notification so that I can review feedback	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to determine if investigation needs to be sent to EUDAMED so that system can generate request XML for EUDAMED	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to generate XML request to EUDAMED so that case officer set status of the case to 'close'	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an ADMIN I want to set status of the case to 'closed' so that I can send report to concerned entities	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an ADMIN I want to send report to concerned entities so that Actors are informed	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to input the number of hours taken on site so that payment based on the rate can be calculated	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to assign case to the case manager where the input of the payment is done and pre-populated by the system so that Case manager can set payment fee	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case manager I want to determine if payment is required related to investigation findings so that Case manager can set payment fee	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case manager I want to confirm/set payment fee if payment is required so that system can assign case to the case officer	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to assign case to the case officer	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to set payment status to 'pending' so that Actor can settle the payment	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to send notification to actor so that Actor is informed about pending payment	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3

User Story	As an Actor I want to receive notification so that I am informed about pending payment	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to start tickler for payment so that I can monitor process duration	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to pay the fee online so that I can settle the fee	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to pay the fee manually so that I can settle the fee	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to set payment status to 'Paid' so that ADMIN can close the case	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to be able to manually assign payment status to 'Cancelled' so that ADMIN can close the case	Approved	Batch 5 user stories; Create CAPAs; Frontend; Market Surveillance; Phase 3
User Story	As an ADMIN I want to contact Actor so that system can notify actor that there is some correspondence pending	Approved	Backend; Batch 5 user stories; EO to be contacted; Market Surveillance; Phase 3
User Story	As a System I want to check if target SRN is registered in the system so that system can notify actor that there is some correspondence pending	Approved	Backend; Batch 5 user stories; EO to be contacted; Market Surveillance; Phase 3
User Story	As a System I want to send notification to Actor that there is some correspondence to be actioned if target SRN is registered in the system so that Actor can receive notification	Approved	Backend; Batch 5 user stories; EO to be contacted; Market Surveillance; Phase 3
User Story	As a System I want to send notification to EO providing the unique number to be used in order to link the case to the user after first login if target SRN is not registered in the system so that Actor can receive notification	Approved	Backend; Batch 5 user stories; EO to be contacted; Market Surveillance; Phase 3
User Story	As an Actor I want to receive notification of pending action so that I can provide required information	Approved	Backend; Batch 5 user stories; EO to be contacted; Market Surveillance; Phase 3
User Story	As a Case manager I want to re-assign an investigation so that case manager can select case officer	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3

User Story	As a Case manager I want to select case officer so that I can assign case officer to an investigation	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3
User Story	As a System I want to assign case officer to an investigation so that I can send notification to assigned case officer	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3
User Story	As a System I want to send notification to case officer so that case officer is informed	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3
User Story	As a Case officer I want to receive notification so that I am informed about investigation	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3
User Story	As a Case officer I want to have access to the case so that I can work on a case	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3
User Story	As a System I want to remove old access to the case so that newly assign case officer can work on a case	Approved	Backend; Batch 5 user stories; Investigation Manager re-assign investigation to Investigation officer; Market Surveillance; Phase 3
User Story	As a Case officer I want to receive a reply to some correspondence outside of the system so that I am informed	Approved	Backend; Batch 5 user stories; Investigation officer uploads offline correspondence; Market Surveillance; Phase 3
User Story	As a Case officer I want to upload correspondence (PDF files)	Approved	Backend; Batch 5 user stories; Investigation officer uploads offline correspondence; Market Surveillance; Phase 3

User Story	As a System I want to ask for file upload, date of correspondence and target SRN so that I can link correspondence with investigation	Approved	Backend; Batch 5 user stories; Investigation officer uploads offline correspondence; Market Surveillance; Phase 3
User Story	As a Case officer I want to provide the information so that system can store correspondence	Approved	Backend; Batch 5 user stories; Investigation officer uploads offline correspondence; Market Surveillance; Phase 3
User Story	As a System I want to store correspondence and link it with the investigation so that information can be reviewed	Approved	Backend; Batch 5 user stories; Investigation officer uploads offline correspondence; Market Surveillance; Phase 3
User Story	As a Case officer I want to create a report so that Actor would receive report of the investigation	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation
User Story	As a Case officer I want to have facility to select document template from file repository so that I can fill in the report	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation
User Story	As a Case officer I want to download a document template from the common file repository so that I can fill in the report	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation
User Story	As a Case officer I want to have document pre-filled if details are related to investigation / case so that I can fill in the report	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation
User Story	As a Case officer I want to modify the file locally on the desktop so that I can upload the file to the system	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation
User Story	As a Case officer I want to upload report to the system so that Actor can receive final investigation report	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation
User Story	As a System I want to keep versioning of report so that I can refer to different report versions if needed	Approved	Backend; Batch 5 user stories; Market Surveillance; Phase 3; Report Generation Preparation

User Story	As an Actor I want to log into the system using B2C so that I can see correspondence related to a particular case	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to determine if Actor has already logged in once in the system so that I can display relevant correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to input generated unique number which would have been supplied in the email sent in case actor is logging in for the first time so that system would link case to login	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to link case to login so that I can display relevant correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to show case correspondence related to a particular case so that Actor can provide required feedback	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As an Actor I want to provide necessary comments / documents so that ADMIN can reply to correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to send notification to the case officer so that case officer can review feedback	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to review feedback so that I can determine if feedback is satisfactory	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to determine if feedback is satisfactory so that I can finalise the correspondence	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a Case officer I want to reply to the correspondence if feedback was not satisfactory so that Actor can submit additional information	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3
User Story	As a System I want to send notification to the Actor about additional information needed so that Actor can submit additional information	Approved	Batch 5 user stories; EO replies to correspondence within system; Frontend; Market Surveillance; Phase 3

User Story	As a System I want to stop tickler if case is rejected so that case status can be changed to 'rejected'	Approved	Backend; Batch 5 user stories; Market Surveillance; Open investigation Scheduled; Phase 3
User Story	As a system I want to send notification of rejection to Actor so that Actor is informed	Approved	Backend; Batch 5 user stories; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As a Case Manager I want to write comments for rejection	Approved	Backend; Batch 5 user stories; Market Surveillance; Open Investigation Subcontracting; Phase 3
User Story	As an Actor I should be presented with the option's 'manual' or 'credit card' when submitting a payment	Approved	Frontend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a user, I expect to see the payment details and the reference number when opening the application	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a user, I expect the data to be stored and audited for MDMS so that I have traceability of any changes to the submitted records	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor, I should receive a prompt asking me to attach the proof of payment before I submit my application	Approved	Frontend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User I want to check if the proof of payment is attached to the application so that the payment can be processed	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User I want to have the option to change the payment status from 'pending' to 'paid' so that I can identify a paid record	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User I want to send a notification to the Actor asking them for the 'payment reference number' if the proof of payment is not attached so that I can process the payment	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor, I expect to receive a notification from the user if the 'payment reference number' is required	Approved	Frontend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor, I should be presented with a free-text area where I can input the payment reference number prior to submitting the application.	Approved	Frontend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User, if the Actor selected 'manual payment', I should receive the payment before processing.	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client

User Story	As a User, I want to send a notification to the Actor advising them the payment was unsuccessful if the proof of payment was not attached.	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor, I expect to receive a notification requesting me to submit the proof of payment if I receive a notification informing me it was unsuccessful.	Approved	Frontend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User I want to I expect system to store information in MDMS if the proof of payment is attached so that Data can be audited	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User, I want to verify that the payment was received so that I can generate a proof of payment receipt.	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User, I expect the pro-forma invoice to be generated and stored on MDMS	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a User, I expect the proof of payment and pro-forma invoice to be stored on MDMS	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As a user, I expect all required fields needed for the sage integration are stored as expected.	Approved	Backend; Manual Payments; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor, I expect system to determine if payment is manual or by credit card so that I can submit payment	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I expect system to notify GPG using a 'prepare for payment' request so that I can submit payment	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect the data to be stored on MDMS so that Data can be audited	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I expect to be presented with a screen showing GPG payment details so that I can submit payment	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I expect to I expect GPG to process the payment so that GPG can generate payment notification	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client

User Story	As an Actor I expect to I expect GPG to generate payment notification so that Payment can be processed	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect GPG reference number to be recorded so that payment number within the system can be related with the external GPG reference number	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I expect to be presented with a screen showing GPG payment details so that I can verify if payment is processed	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect system to determine if payment is successfully processed so that Pro-forma invoice can be generated	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I want to receive notification of successful payment so that Actor can submit the payment	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I expect system to send notification of successful payment so that I can receive notification	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect system to I expect system to generate pro-forma invoice so that Data can be stored in MDMS	Approved	Credit Card Payment; Frontend; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect system to process payment notification so that System can generate pro-forma invoice	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect system to Store data on MDMS so that Data can be audited	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect system to store all required fields so that Data can be exchanged with Sage	Approved	Backend; Credit Card Payment; Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect System to get transactions details so that Transactions can be exported from MDMS	Approved	Backend; Export Transactions to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client

User Story	As a User I expect data to be mapped between MDMS and Sage so that Transactions can be imported to Sage	Approved	Backend; Export Transactions to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect transactions to be exported to Sage every 15 minutes so that Sage will receive transaction information	Approved	Backend; Export Transactions to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect transactions to be received by MDMS so that Data can be reconciled	Approved	Backend; Export Transactions to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a System I want to get the required transactions from Sage so that Data can be saved on MDMS	Approved	Backend; Import Transactions to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a System I want to Show transaction details in Frontend so that User can refer to those details	Approved	Backend; Import Transactions to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a System I want to map the data between MDMS and Sage so that Transactions can be imported to Sage	Approved	Backend; Import Transactions to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a System I want to save data into MDMS so that Data can be audited	Approved	Backend; Import Transactions to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a System I want to export transaction to Sage every 15 minutes so that Sage will receive transaction information	Approved	Backend; Import Transactions to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect MDMS to Get customers data from Sage by identifier so that Data can be saved on MDMS	Approved	Backend; Import Actor to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect that details, pertaining to the Actor such as Name, Address, VAT No…., between Sage and MDMS, are checked before generating pro forma invoices so that Data can be kept up to date	Approved	Backend; Import Actor to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect data to be transform into MDMS format so that Data can be saved on MDMS	Approved	Backend; Import Actor to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client

User Story	As a User I expect system to Store data on MDMS so that Data can be audited	Approved	Backend; Import Actor to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect pro-forma invoice to be saved so that it can be referred to in the future	Approved	Backend; Import Actor to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect scheduler to run every 15 minutes so that data is kept coordinated with Sage	Approved	Backend; Import Actor to MDMS (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect to get all new actors or actors which data have been modified from MDMS so that Data is reconciled	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect to get actor's data from Sage so that System can check if record exist in MDMS	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect to be checked if actor exist in Sage so that Actor data is updated/created	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect actor's information to be updated on Sage so that Actor data is updated	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect new Actor to be created on Sage so that Actor data is created if it does not exist	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect Sage account reference ID to be updated with the details received from SDK so that Data is synchronised with Sage	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect scheduler to run every 15 minutes so that data is kept coordinated with Sage	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As a User I expect to get all new actors or actors which data have been modified from MDMS so that Data is reconciled	Approved	Backend; Export Actor to Sage (Scheduler); shared with client
User Story	As a User I expect to get actor's data from Sage so that System can check if record exist in MDMS	Approved	Backend; Export Actor to Sage (Scheduler); shared with client

User Story	As a User I expect to be checked if actor exist in Sage so that Actor data is updated/created	Approved	Backend; Export Actor to Sage (Scheduler); shared with client
User Story	As a User I expect actor's information to be updated on Sage so that Actor data is updated	Approved	Backend; Export Actor to Sage (Scheduler); shared with client
User Story	As a User I expect new Actor to be created on Sage so that Actor data is created if it does not exist	Approved	Backend; Export Actor to Sage (Scheduler); shared with client
User Story	As a User I expect Sage account reference ID to be updated with the details received from SDK so that Data is synchronised with Sage	Approved	Backend; Export Actor to Sage (Scheduler); shared with client
User Story	As a User I expect scheduler to run every 15 minutes so that data is kept coordinated with Sage	Approved	Backend; Export Actor to Sage (Scheduler); shared with client
User Story	As a User I expect customer details to be updated so that data is kept coordinated with Sage	Approved	Backend; Export Actor to Sage (Scheduler); Payments and Invoices; Phase 2; shared with client
User Story	As an Actor I want to update profile details so that my profile details are up to date	Approved	Frontend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As an Actor I expect notification to be sent to MA so that MA can approve profile detail changes	Approved	Frontend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As a User I want to receive notification that profile details have been amended so that I can approve the changes	Approved	Backend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As a User I want to approve Actors user profile changes so that Actors profile details changes are amended	Approved	Backend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As a User I want to not to approve Actors user profile changes so that Actor can revise changes	Approved	Backend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As a User I expect approved changes to be saved to the user profile so that Changes can be audited	Approved	Backend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As a User I expect that approved changes are sent to the 'export to Sage' queue so that Changes can be exported to Sage as per defined schedule	Approved	Backend; Payments and Invoices; Phase 2; shared with client; User profile update
User Story	As a User I want data to be stored on MDMS so that Data can be audited	Approved	Registration of Actors (Non-Distributors)

User Story	As a User I want to approve actor's role registration so that Actor is registered in MDMS system	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I want to reject actor's role registration so that Actor can resubmit required information	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I expect system to stop tickler so that I can monitor process duration	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I expect system to send notification to non-distributor so that Actor is notified of successful registration	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I expect system to send notification to non-distributor that registration is not approved so that Actor can resubmit required information	Approved	Registration of Actors (Non-Distributors)
User Story	As a User I expect system to have data audited so that I can have data stored in the system	Approved	Registration of Actors (Non-Distributors)
User Story	As a Distributor Actor I want to Upload required documents so that I can register as a Distributor	Approved	Registration of Actors (Distributors)
User Story	As a Distributor Actor I expect system to check if SAGE account using key exists in MDMS so that MAA can create my profile if it does not exist in Sage	Approved	Registration of Actors (Distributors)
User Story	As a Distributor Actor I expect system to check if SAGE account using key exists in MDMS so that I can proceed to the payment section if my profile exist in Sage	Approved	Registration of Actors (Distributors)
User Story	As a Distributor Actor I expect system to send notification to MA finance to create new Actor details in Sage so that MAA can create my profile if it does not exist in Sage	Approved	Registration of Actors (Distributors)
User Story	As a User I want to create Actor in Sage and provide SAGE account Identifier so that Actors details are registered in Sage	Approved	Registration of Actors (Distributors)
User Story	As a Distributor Actor I want to pay registration fee so that I can apply as a Distributor	Approved	Registration of Actors (Distributors)
User Story	As a User I expect system to send a notification to User that there is registration pending approval so that User can approve pending registration for distributor actors	Approved	Registration of Actors (Distributors)
User Story	(Distributors) As a User I want to approve actor's role registration so that Actor is registered in MDMS system	Approved	Registration of Actors (Distributors)

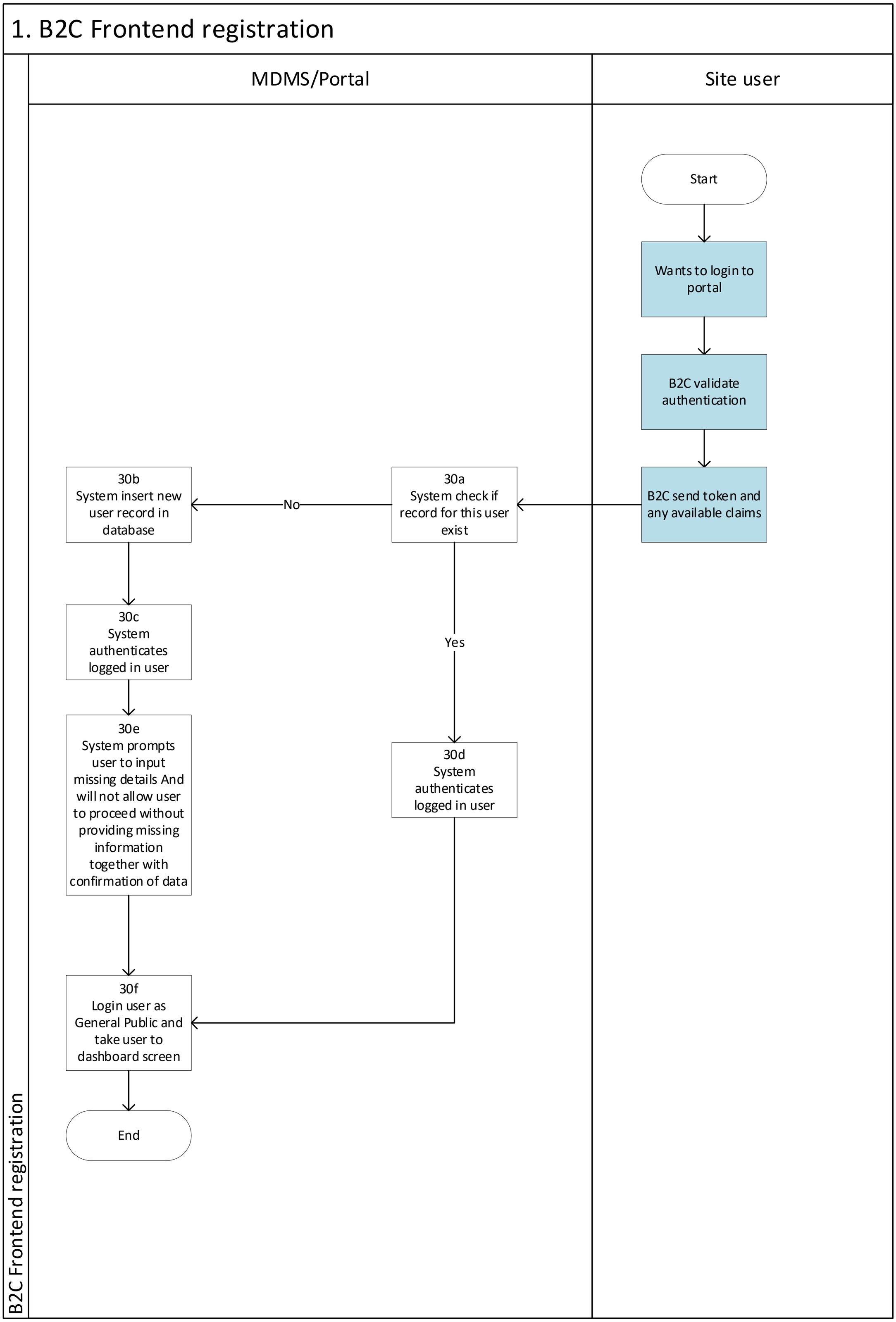
User Story	(Distributors) As a User I want to reject actor's role registration so that Actor can resubmit required information	Approved	Registration of Actors (Distributors)
User Story	As a User I expect system to send notification to Distributor so that Actor is notified of successful registration	Approved	Registration of Actors (Distributors)
User Story	As a User I expect system to send notification to Distributor that registration is not approved so that Actor can resubmit required information	Approved	Registration of Actors (Distributors)
User Story	(Distributors) As a User I expect system to have data audited so that I can have data stored in the system	Approved	Registration of Actors (Distributors)
User Story	(Distributors) As a User I expect system to stop tickler so that I can monitor process duration	Approved	Registration of Actors (Distributors)
User Story	As an Actor I want to modify all registration information so that I can update all my information	Approved	Actor Modification (Non-Distributor)
User Story	As a User uploads XML to MDMS so that Data can be stored in MDMS	Approved	Actor Modification (Non-Distributor)
User Story	As a User I expect system to have XML file stored in MDMS so that I can track changes	Approved	Actor Modification (Non-Distributor)
User Story	As a User I expect MDMS to send notification to MA finance to update Sage manually so that Sage is updated	Approved	Actor Modification (Non-Distributor)
User Story	As a User I expect system to send notification from MDMS so that non-distributor actor is informed that changes are done in MDMS	Approved	Actor Modification (Non-Distributor)
User Story	As a User I expect system to save notification in MDMS so that Notification is audited	Approved	Actor Modification (Non-Distributor)
User Story	As a Distributor Actor I want to modify all registration information so that I can update all my Distributor information	Approved	Distributor Detail Amendments
User Story	As a User I expect system to start tickler so that I can monitor process duration	Approved	Distributor Detail Amendments
User Story	As a User I expect data to be stored on MDMS so that Data can be audited	Approved	Distributor Detail Amendments
User Story	As a User I want system to send notification to ADMIN finance to update details in Sage manually so that ADMIN can update Sage records manually	Approved	Distributor Detail Amendments

User Story	As a User I expect system to send notification to ADMIN that there is pending approval so that Changes can be approved	Approved	Distributor Detail Amendments
User Story	As a User I want to approve actor's amendments so that Actor details are updated in MDMS system	Approved	Distributor Detail Amendments
User Story	As a User I want to reject actor's amendments so that Actor can resubmit required information	Approved	Distributor Detail Amendments
User Story	As a User I expect system to start tickler so that I can monitor process duration	Approved	Distributor Detail Amendments
User Story	As a User I want to have approval notification sent to distributor actor so that Distributor actor is informed of approved changes	Approved	Distributor Detail Amendments
User Story	As a I want to have rejected notification sent to distributor actor so that Distributor actor can resubmit information	Approved	Distributor Detail Amendments
User Story	As a User I expect system to save notification in MDMS so that Notification is audited	Approved	Distributor Detail Amendments
User Story	(Distributors) As a User System to start tickler so that I can monitor process duration	Approved	Registration of Actors (Distributors)

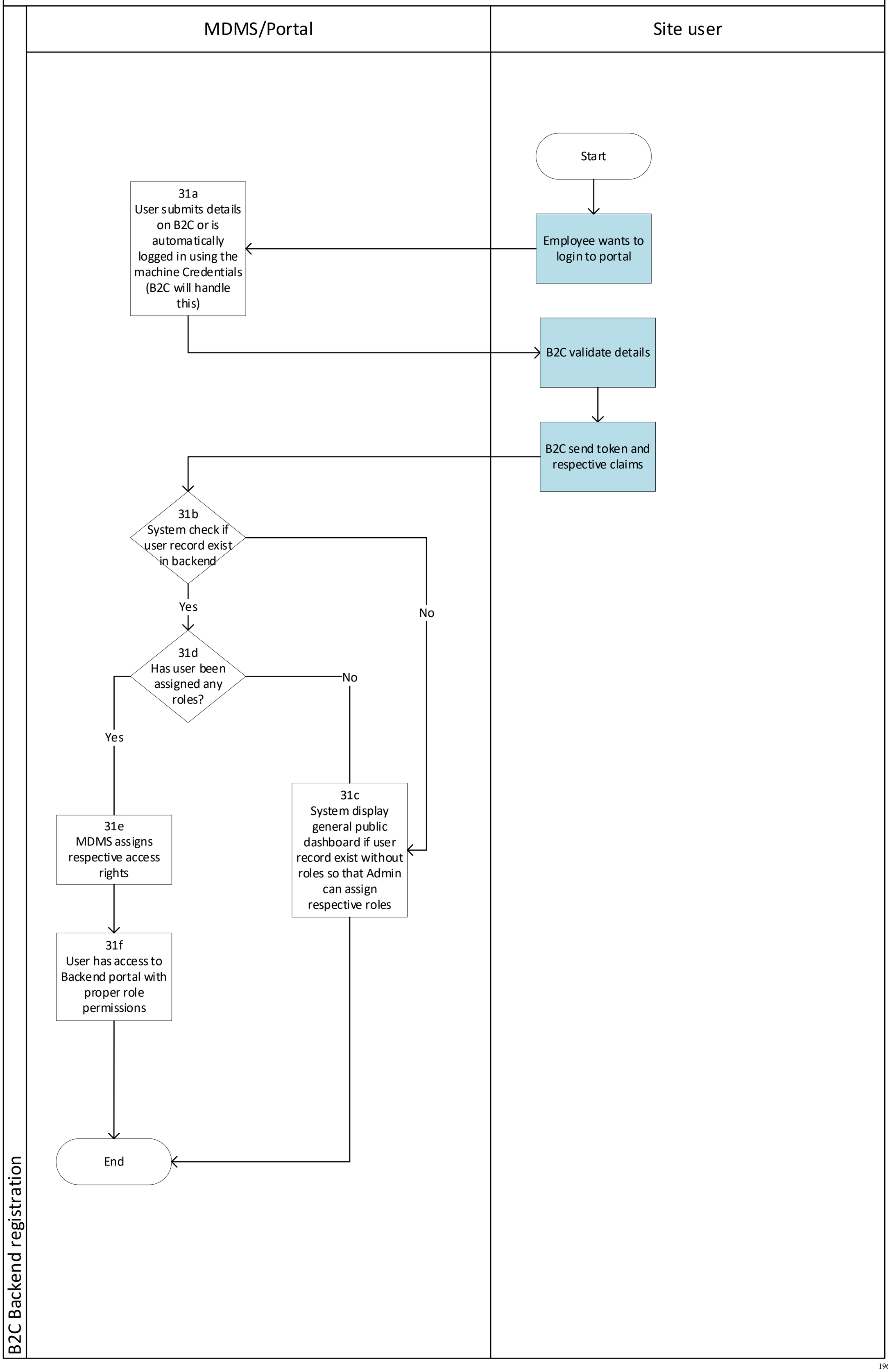
Appendix 20

Validated process flows

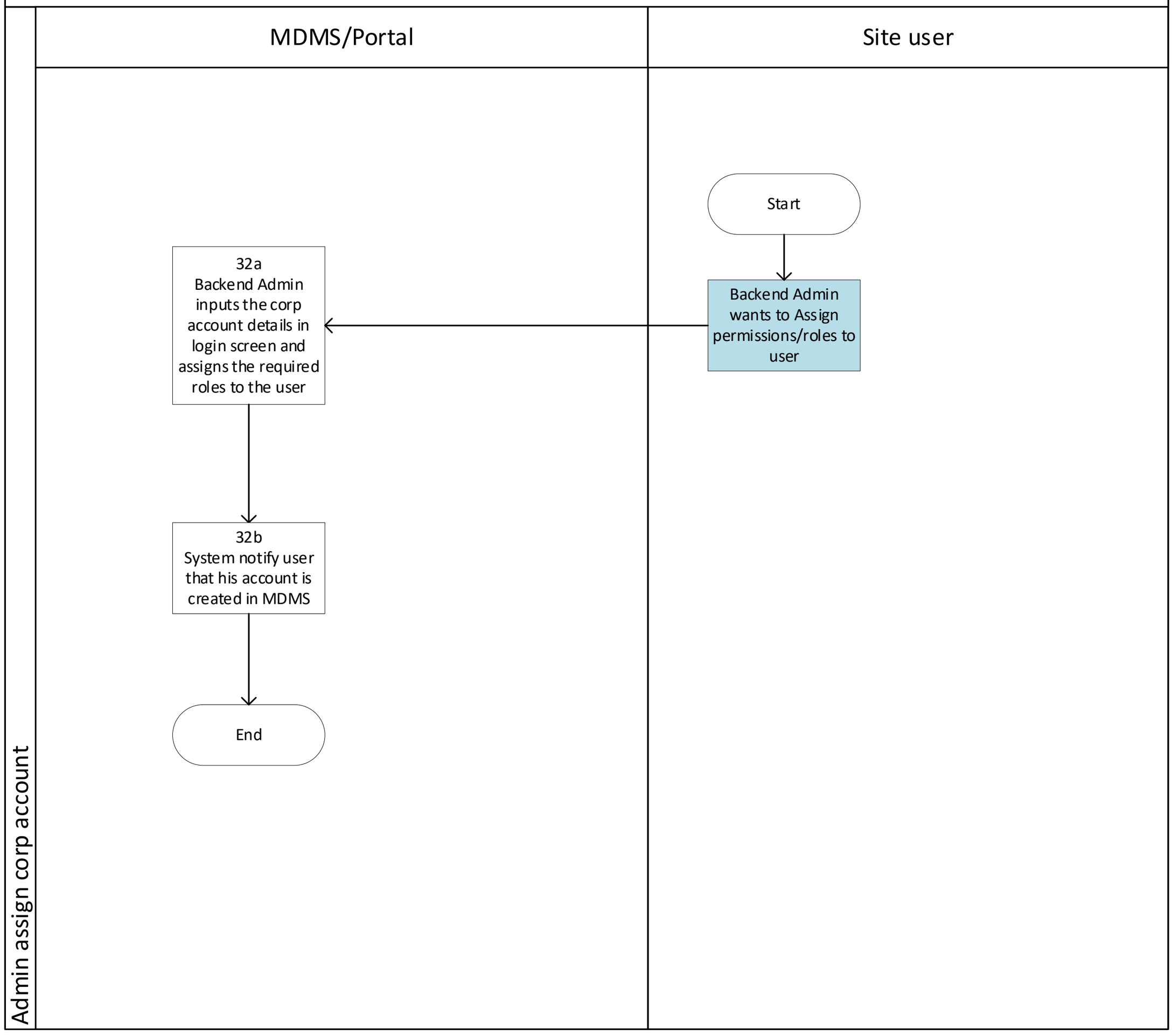
1. B2C Frontend registration



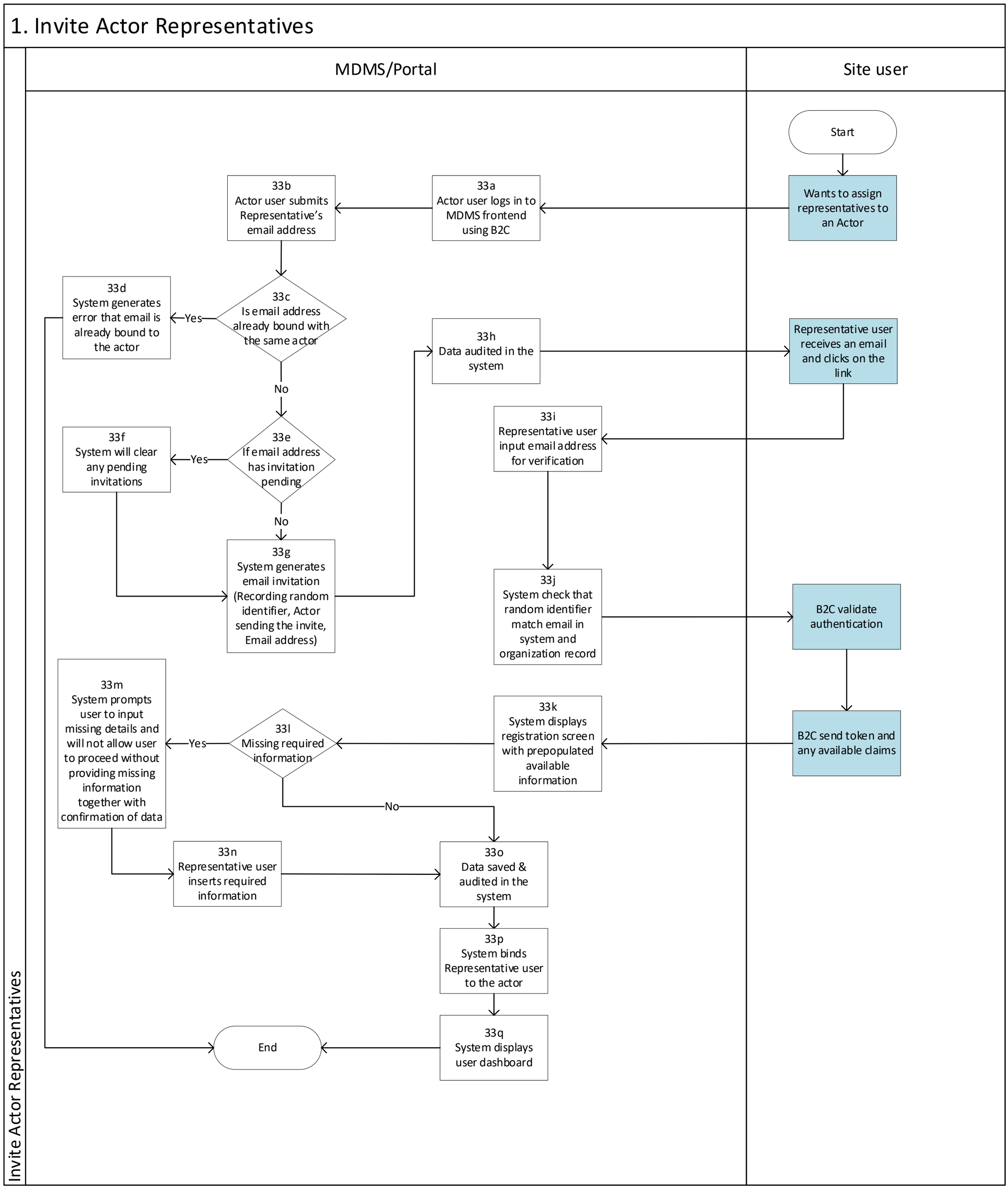
1. B2C Backend registration



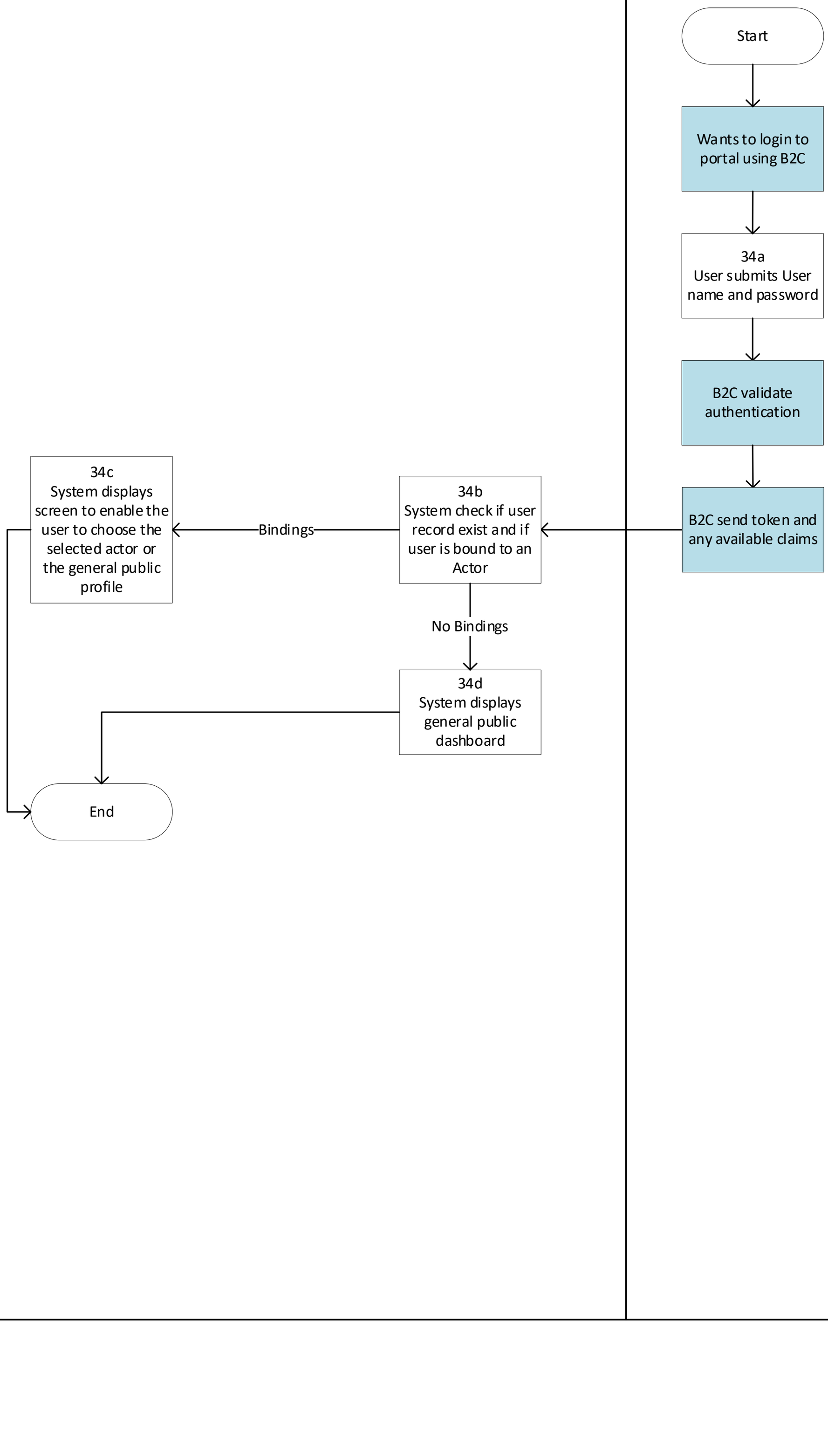
1. Admin assign corp account



1. Invite Actor Representatives

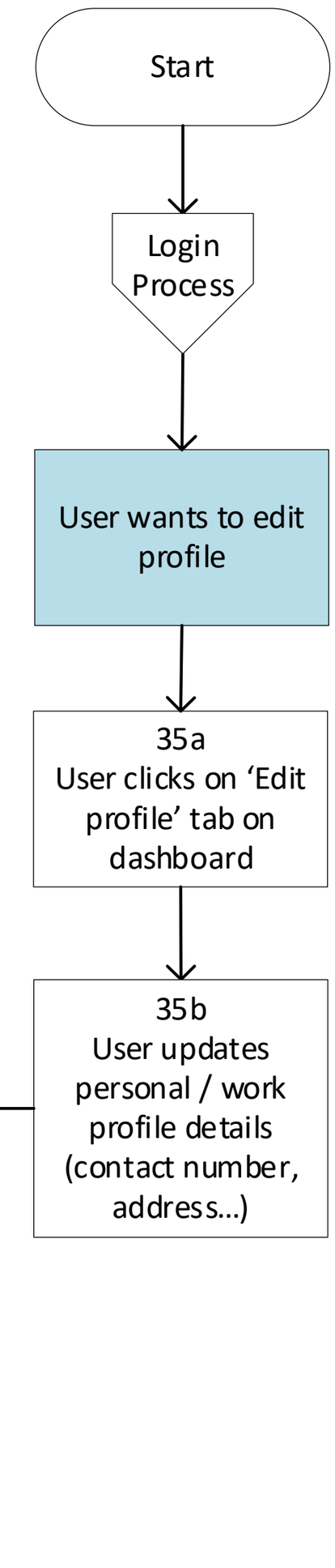


1. Login to portal using B2C

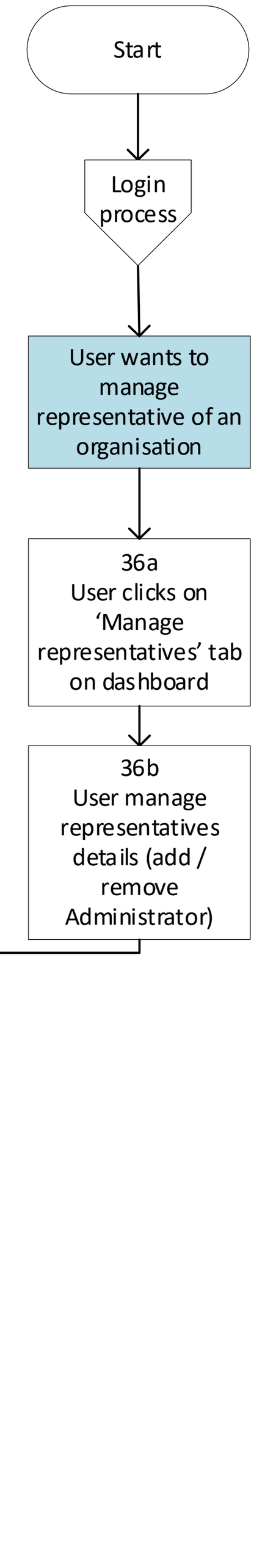
MDMS/Portal	Site user
	

Login to portal using B2C

1. Edit profile

MDMS/Portal	Site user
	

1. Manage representatives (Make Admin / remove)

MDMS/Portal	Site user
	

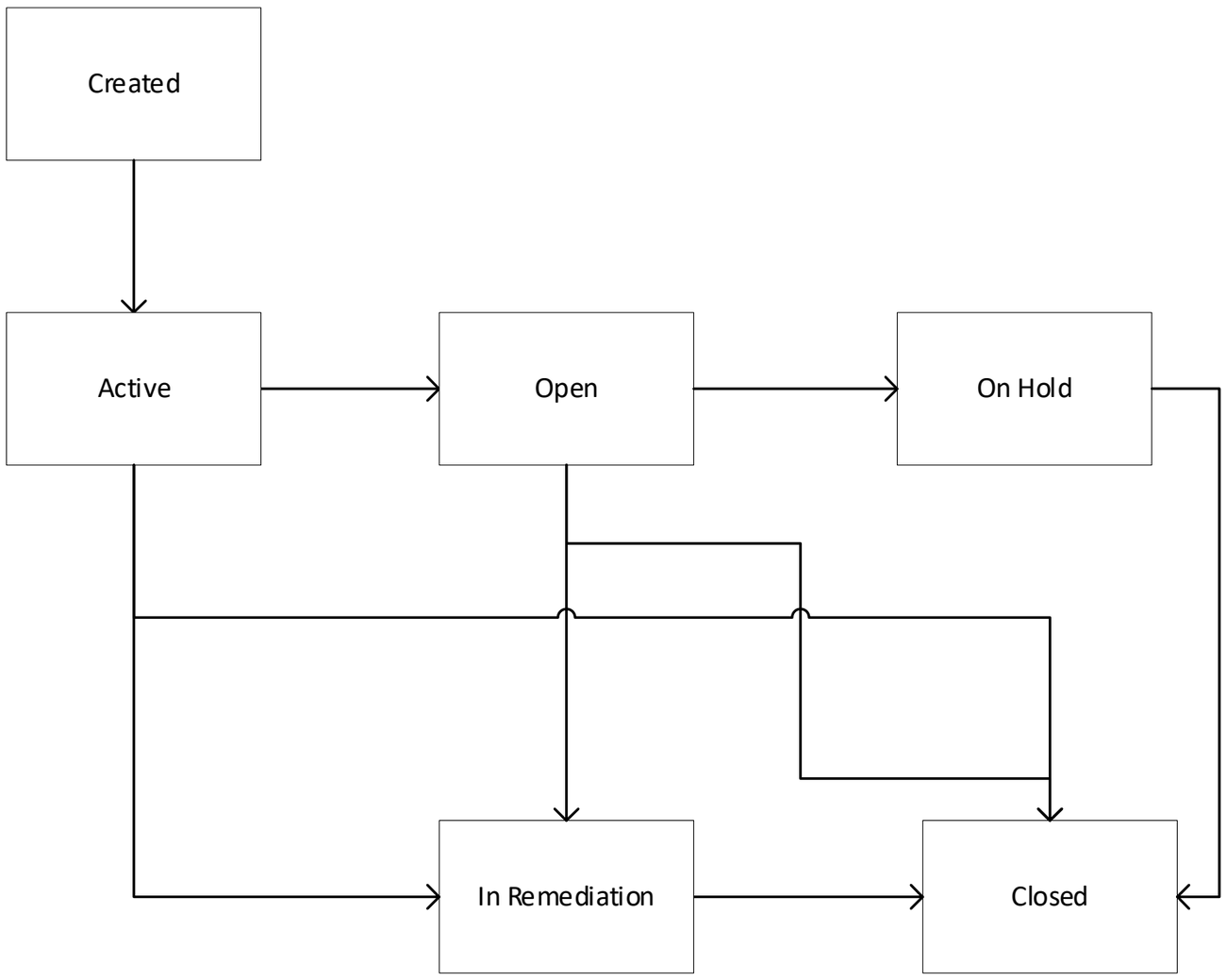
Manage representatives (Make Admin / remove)

1. Backend Administrator Manages Representatives

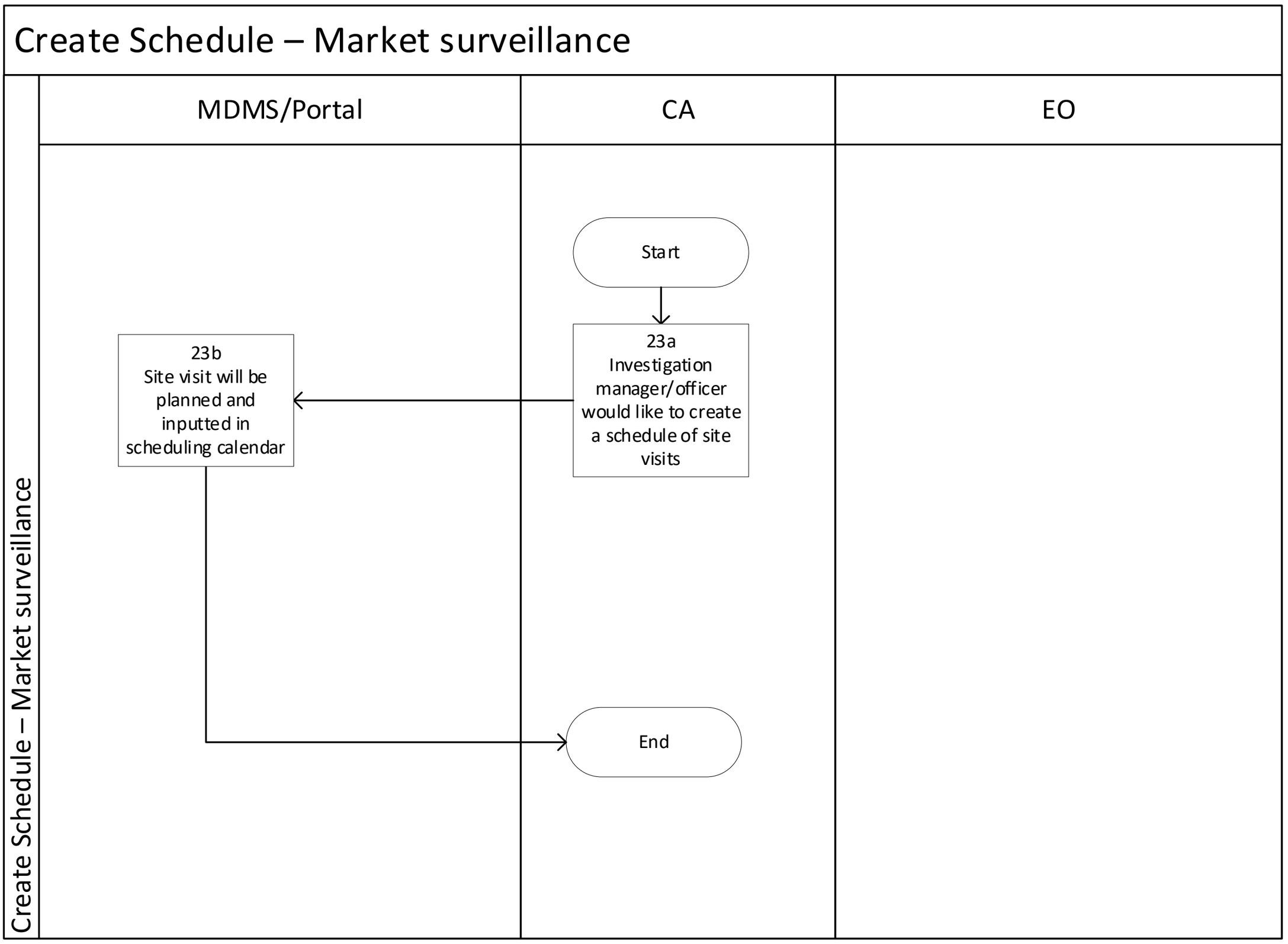
MDMS/Portal	MMA Administrator
Backend Administrator	Start Backend Admin wants to give Admin rights to a particular representative of an organisation 37a Backend Admin link himself to an organisation with Admin rights 37b User Selects representative from a list 37c User provide Admin rights as needed for selected representatives 37d Data saved & audited End

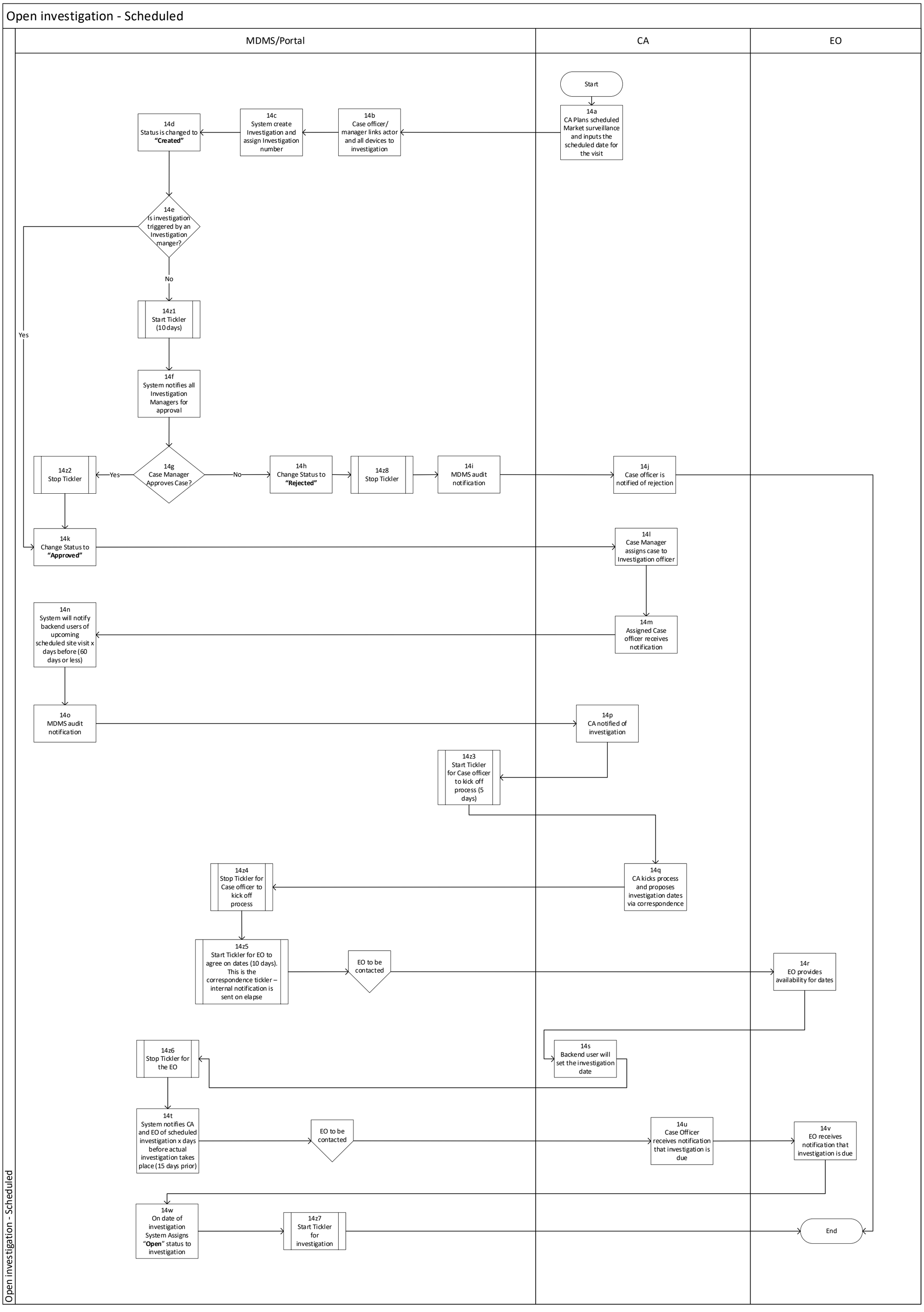
1. Internal Case statuses

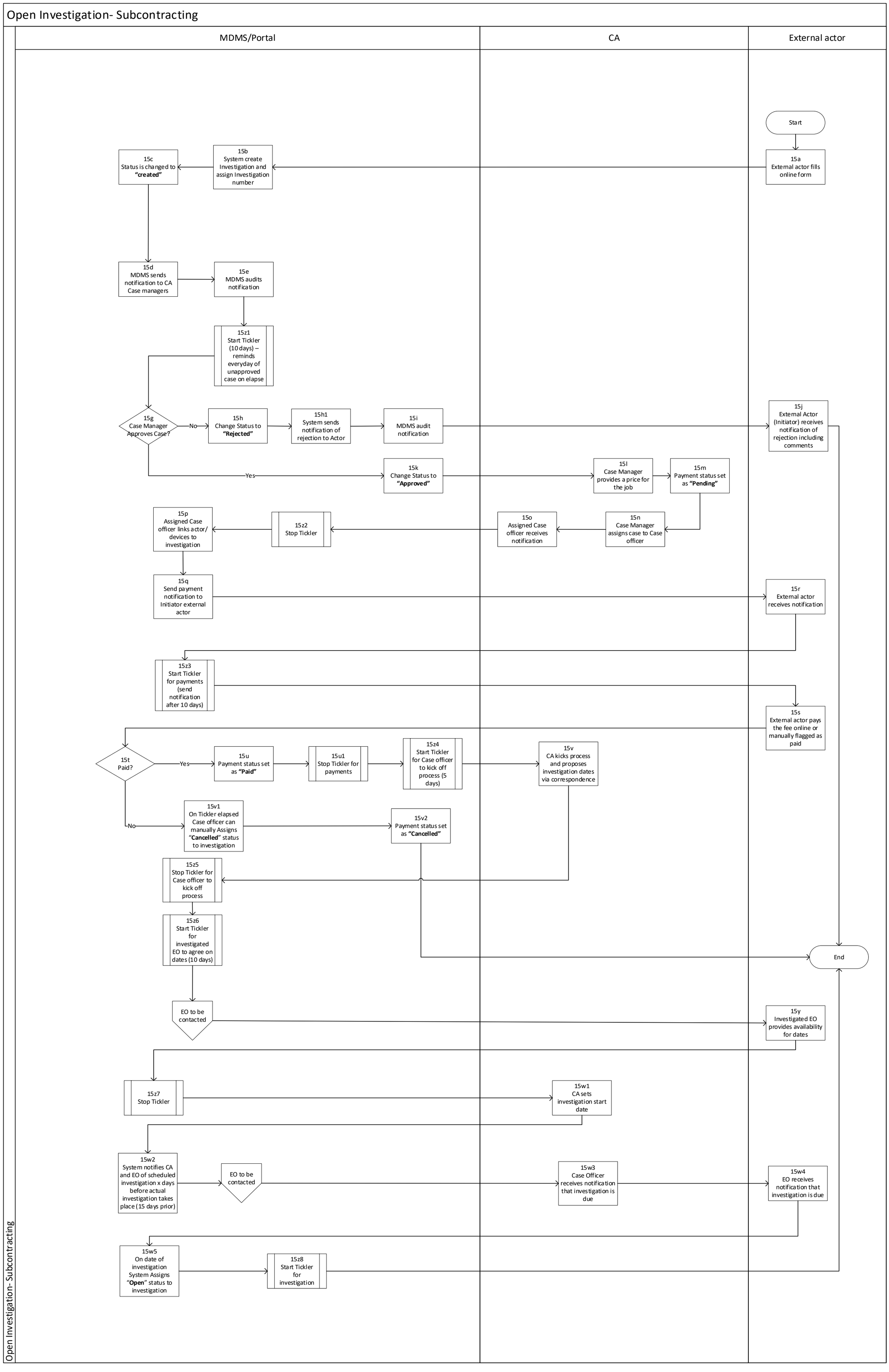
Case statuses



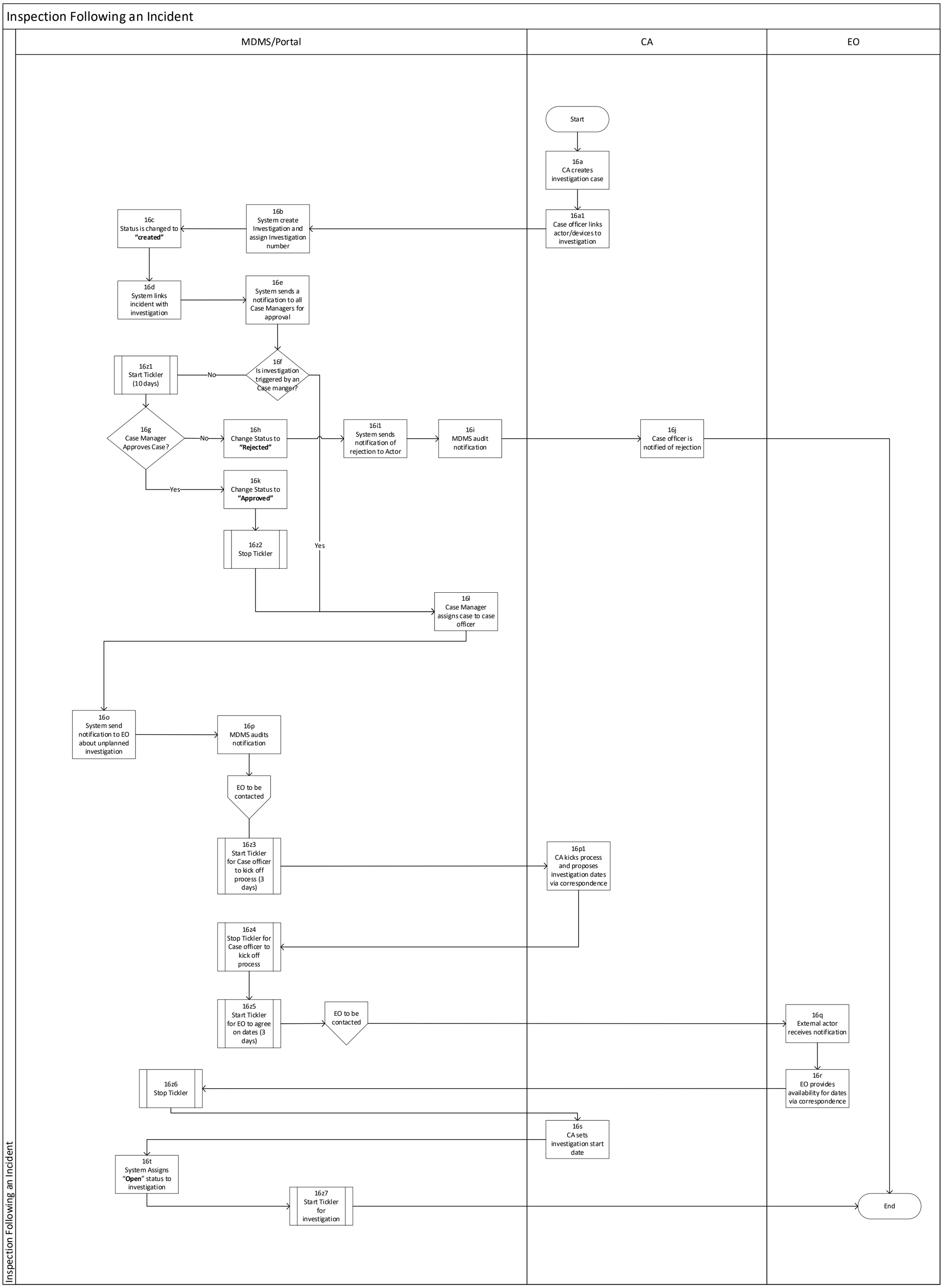
Create Schedule – Market surveillance

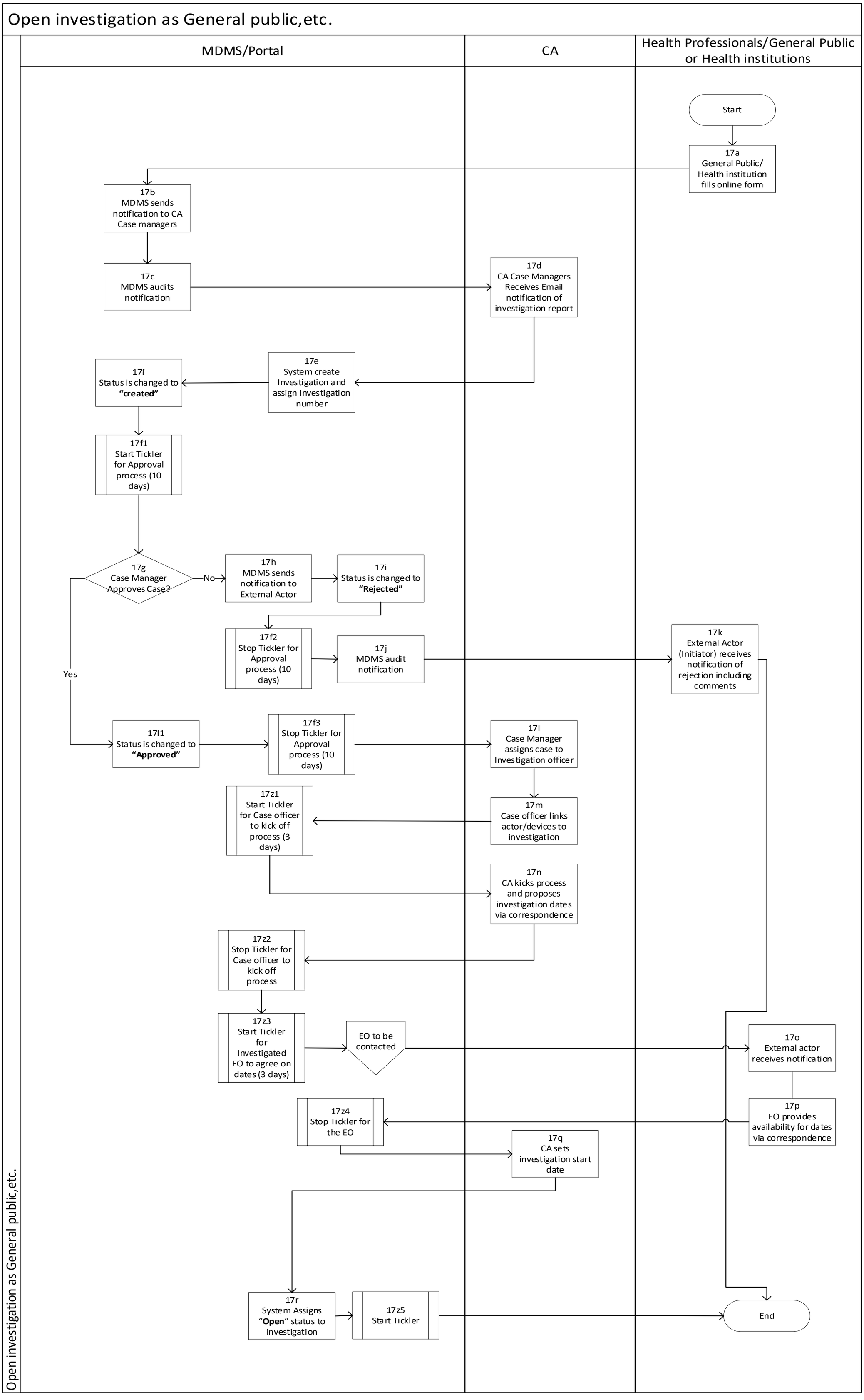



Open investigation - Scheduled
MDMS/Portal
CA
EO
Start
14a
CA Plans scheduled Market surveillance and inputs the scheduled date for the visit
14b
Case officer/ manager links actor and all devices to investigation
14c
System create Investigation and assign Investigation number
14d
Status is changed to **"Created"**
14e
Is investigation triggered by an Investigation manger?
Yes
No
14z1
Start Tickler (10 days)
14f
System notifies all Investigation Managers for approval
14g
Case Manager Approves Case?
Yes
No
14z2
Stop Tickler
14h
Change Status to **"Rejected"**
14z8
Stop Tickler
14i
MDMS audit notification
14j
Case officer is notified of rejection
14k
Change Status to **"Approved"**
14l
Case Manager assigns case to Investigation officer
14m
Assigned Case officer receives notification
14n
System will notify backend users of upcoming scheduled site visit x days before (60 days or less)
14o
MDMS audit notification
14p
CA notified of investigation
14z3
Start Tickler for Case officer to kick off process (5 days)
14q
CA kicks process and proposes investigation dates via correspondence
14z4
Stop Tickler for Case officer to kick off process
14z5
Start Tickler for EO to agree on dates (10 days). This is the correspondence tickler – internal notification is sent on elapse
EO to be contacted
14r
EO provides availability for dates
14s
Backend user will set the investigation date
14z6
Stop Tickler for the EO
14t
System notifies CA and EO of scheduled investigation x days before actual investigation takes place (15 days prior)
EO to be contacted
14u
Case Officer receives notification that investigation is due
14v
EO receives notification that investigation is due
14w
On date of investigation System Assigns "**Open**" status to investigation
14z7
Start Tickler for investigation
End

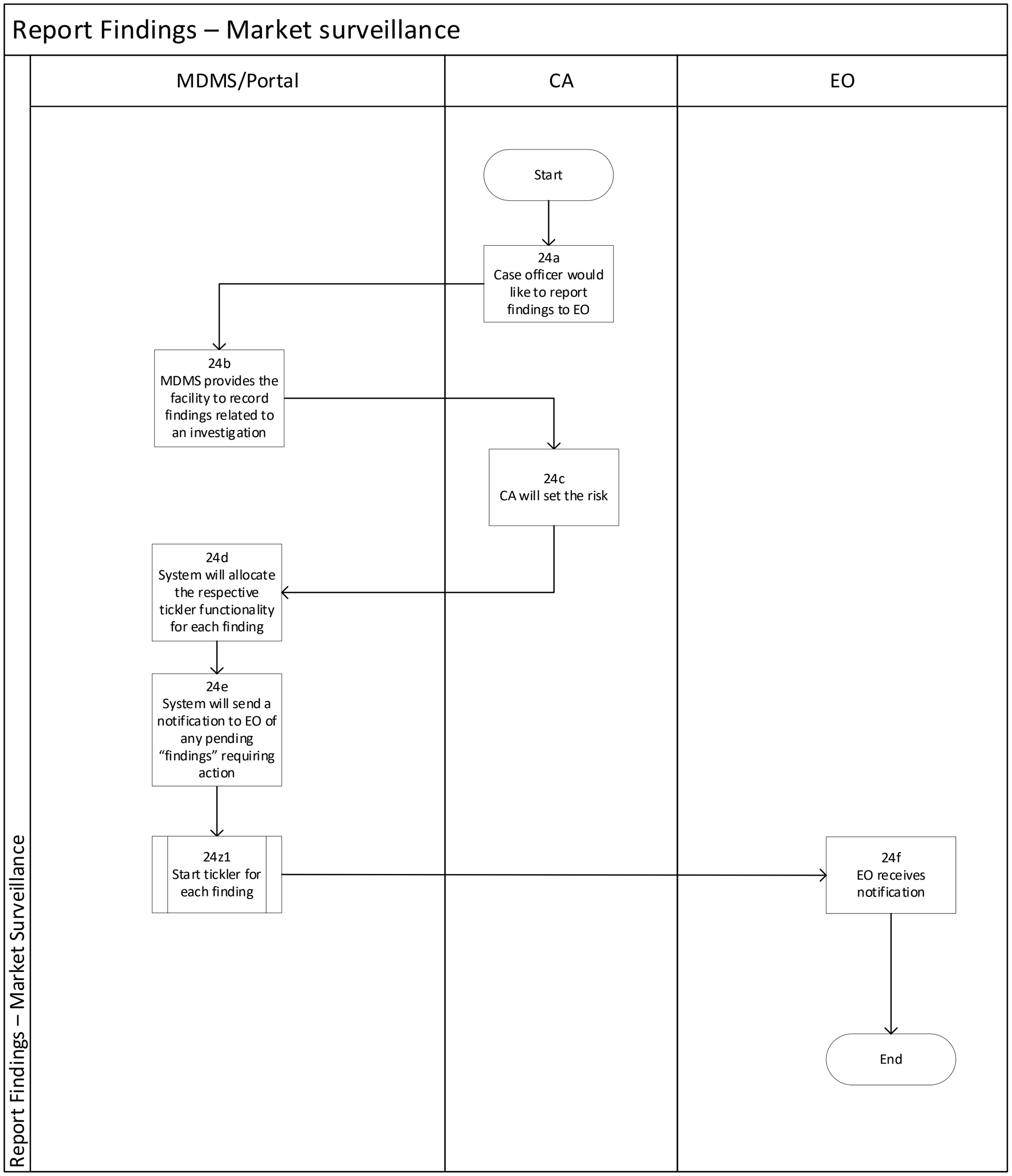

Open Investigation- Subcontracting
MDMS/Portal
CA
External actor
Start
15a
External actor fills online form
15b
System create Investigation and assign Investigation number
15c
Status is changed to **"created"**
15d
MDMS sends notification to CA Case managers
15e
MDMS audits notification
15z1
Start Tickler (10 days) – reminds everyday of unapproved case on elapse
15g
Case Manager Approves Case?
No
15h
Change Status to **"Rejected"**
15h1
System sends notification of rejection to Actor
15i
MDMS audit notification
15j
External Actor (Initiator) receives notification of rejection including comments
Yes
15k
Change Status to **"Approved"**
15l
Case Manager provides a price for the job
15m
Payment status set as **"Pending"**
15n
Case Manager assigns case to Case officer
15o
Assigned Case officer receives notification
15z2
Stop Tickler
15p
Assigned Case officer links actor/ devices to investigation
15q
Send payment notification to Initiator external actor
15r
External actor receives notification
15z3
Start Tickler for payments (send notification after 10 days)
15s
External actor pays the fee online or manually flagged as paid
15t
Paid?
Yes
15u
Payment status set as **"Paid"**
15u1
Stop Tickler for payments
15z4
Start Tickler for Case officer to kick off process (5 days)
15v
CA kicks process and proposes investigation dates via correspondence
No
15v1
On Tickler elapsed Case officer can manually Assigns "**Cancelled**" status to investigation
15v2
Payment status set as **"Cancelled"**
15z5
Stop Tickler for Case officer to kick off process
15z6
Start Tickler for investigated EO to agree on dates (10 days)
End
EO to be contacted
15y
Investigated EO provides availability for dates
15z7
Stop Tickler
15w1
CA sets investigation start date
15w2
System notifies CA and EO of scheduled investigation x days before actual investigation takes place (15 days prior)
EO to be contacted
15w3
Case Officer receives notification that investigation is due
15w4
EO receives notification that investigation is due
15w5
On date of investigation System Assigns "**Open**" status to investigation
15z8
Start Tickler for investigation

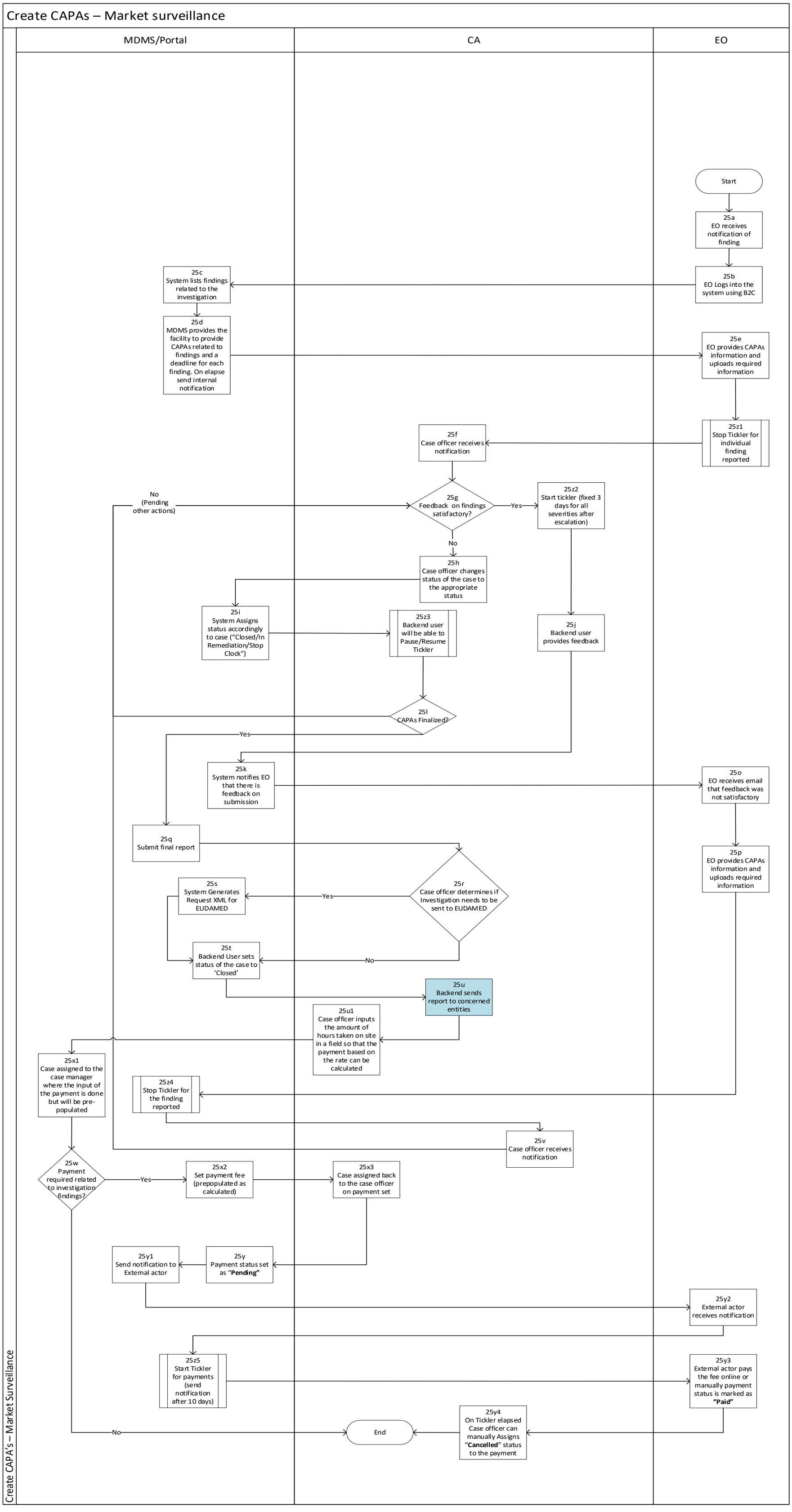
Inspection Following an Incident

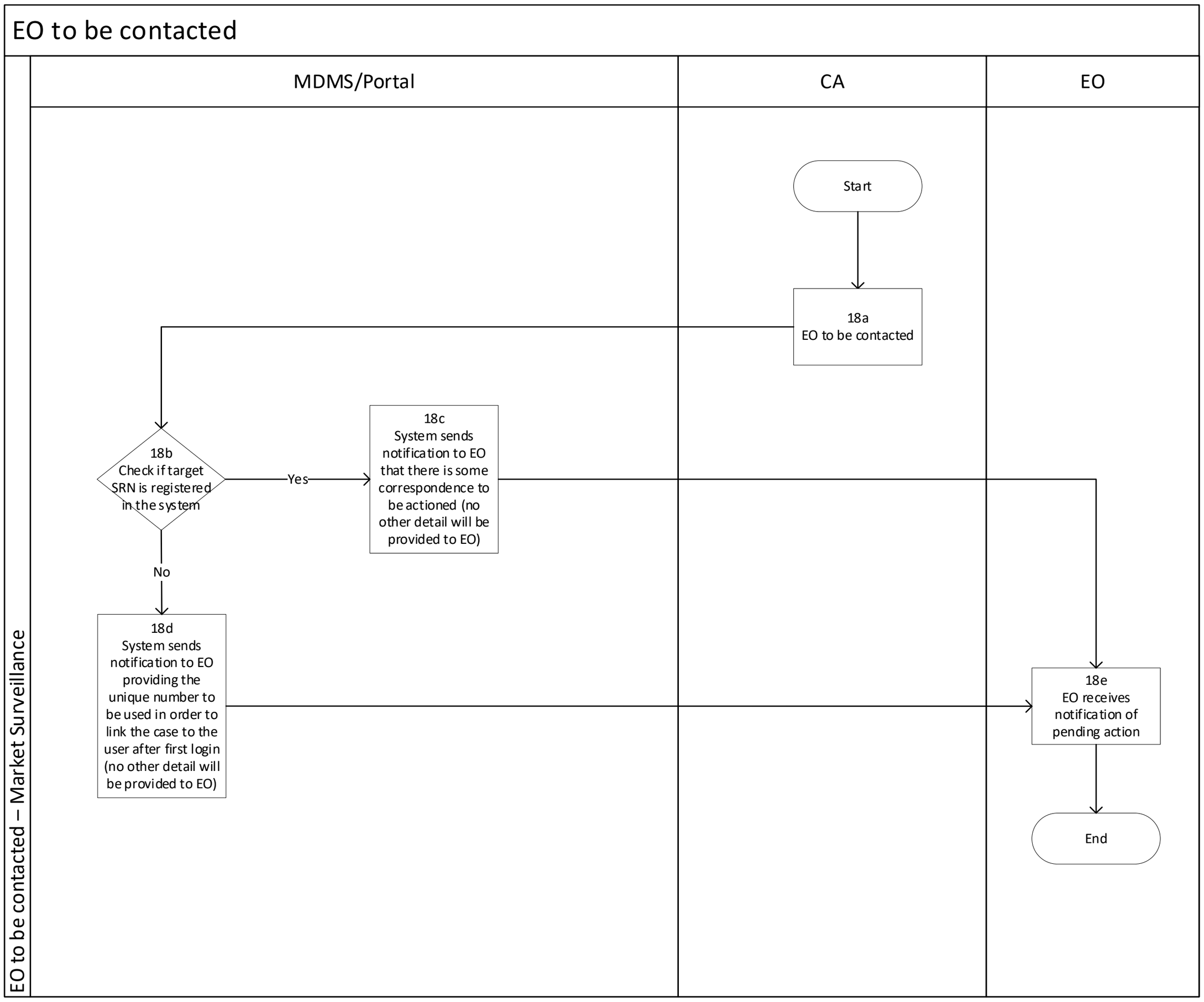



Open investigation as General public,etc.
MDMS/Portal
CA
Health Professionals/General Public or Health institutions
Start
17a
General Public/ Health institution fills online form
17b
MDMS sends notification to CA Case managers
17c
MDMS audits notification
17d
CA Case Managers Receives Email notification of investigation report
17e
System create Investigation and assign Investigation number
17f
Status is changed to **"created"**
17f1
Start Tickler for Approval process (10 days)
17g
Case Manager Approves Case?
No
Yes
17h
MDMS sends notification to External Actor
17i
Status is changed to **"Rejected"**
17f2
Stop Tickler for Approval process (10 days)
17j
MDMS audit notification
17k
External Actor (Initiator) receives notification of rejection including comments
17l1
Status is changed to **"Approved"**
17f3
Stop Tickler for Approval process (10 days)
17l
Case Manager assigns case to Investigation officer
17z1
Start Tickler for Case officer to kick off process (3 days)
17m
Case officer links actor/devices to investigation
17n
CA kicks process and proposes investigation dates via correspondence
17z2
Stop Tickler for Case officer to kick off process
17z3
Start Tickler for Investigated EO to agree on dates (3 days)
EO to be contacted
17o
External actor receives notification
17p
EO provides availability for dates via correspondence
17z4
Stop Tickler for the EO
17q
CA sets investigation start date
17r
System Assigns "**Open**" status to investigation
17z5
Start Tickler
End
Open investigation as General public,etc.

Report Findings – Market surveillance

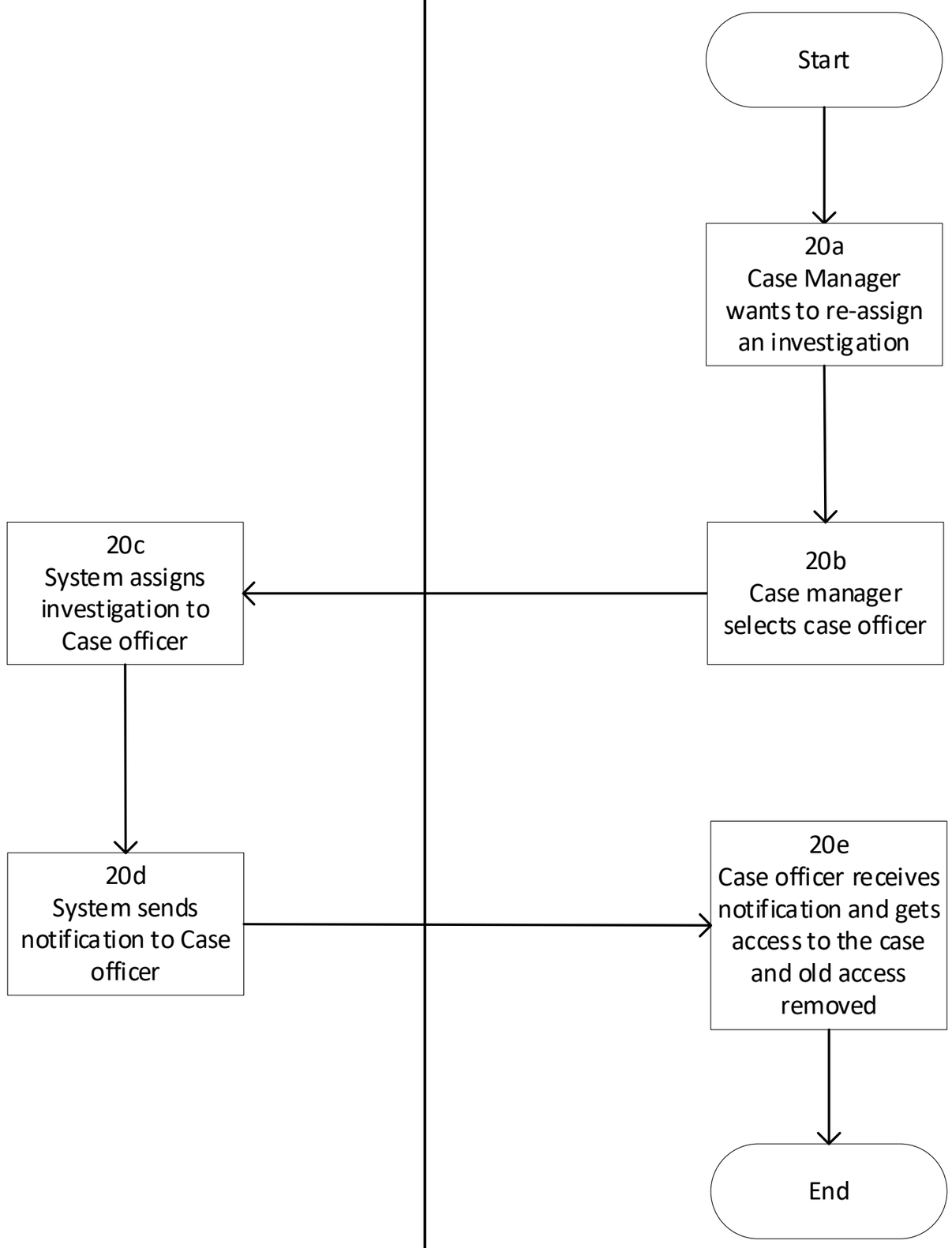



Create CAPAs – Market surveillance
MDMS/Portal
CA
EO
Start
25a
EO receives notification of finding
25b
EO Logs into the system using B2C
25c
System lists findings related to the investigation
25d
MDMS provides the facility to provide CAPAs related to findings and a deadline for each finding. On elapse send internal notification
25e
EO provides CAPAs information and uploads required information
25z1
Stop Tickler for individual finding reported
25f
Case officer receives notification
25g
Feedback on findings satisfactory?
Yes
25z2
Start tickler (fixed 3 days for all severities after escalation)
No
(Pending other actions)
No
25h
Case officer changes status of the case to the appropriate status
25i
System Assigns status accordingly to case (“Closed/In Remediation/Stop Clock”)
25z3
Backend user will be able to Pause/Resume Tickler
25j
Backend user provides feedback
25l
CAPAs Finalized?
Yes
25k
System notifies EO that there is feedback on submission
25o
EO receives email that feedback was not satisfactory
25q
Submit final report
25p
EO provides CAPAs information and uploads required information
25r
Case officer determines if Investigation needs to be sent to EUDAMED
Yes
25s
System Generates Request XML for EUDAMED
No
25t
Backend User sets status of the case to ‘Closed’
25u
Backend sends report to concerned entities
25u1
Case officer inputs the amount of hours taken on site in a field so that the payment based on the rate can be calculated
25x1
Case assigned to the case manager where the input of the payment is done but will be pre-populated
25z4
Stop Tickler for the finding reported
25v
Case officer receives notification
25w
Payment required related to investigation findings?
Yes
25x2
Set payment fee (prepopulated as calculated)
25x3
Case assigned back to the case officer on payment set
25y1
Send notification to External actor
25y
Payment status set as “Pending”
25y2
External actor receives notification
25z5
Start Tickler for payments (send notification after 10 days)
25y3
External actor pays the fee online or manually payment status is marked as “Paid”
No
End
25y4
On Tickler elapsed Case officer can manually Assigns “Cancelled” status to the payment
Create CAPA’s – Market Surveillance


EO to be contacted
MDMS/Portal
CA
EO
EO to be contacted – Market Surveillance
Start
18a
EO to be contacted
18b
Check if target SRN is registered in the system
Yes
18c
System sends notification to EO that there is some correspondence to be actioned (no other detail will be provided to EO)
No
18d
System sends notification to EO providing the unique number to be used in order to link the case to the user after first login (no other detail will be provided to EO)
18e
EO receives notification of pending action
End

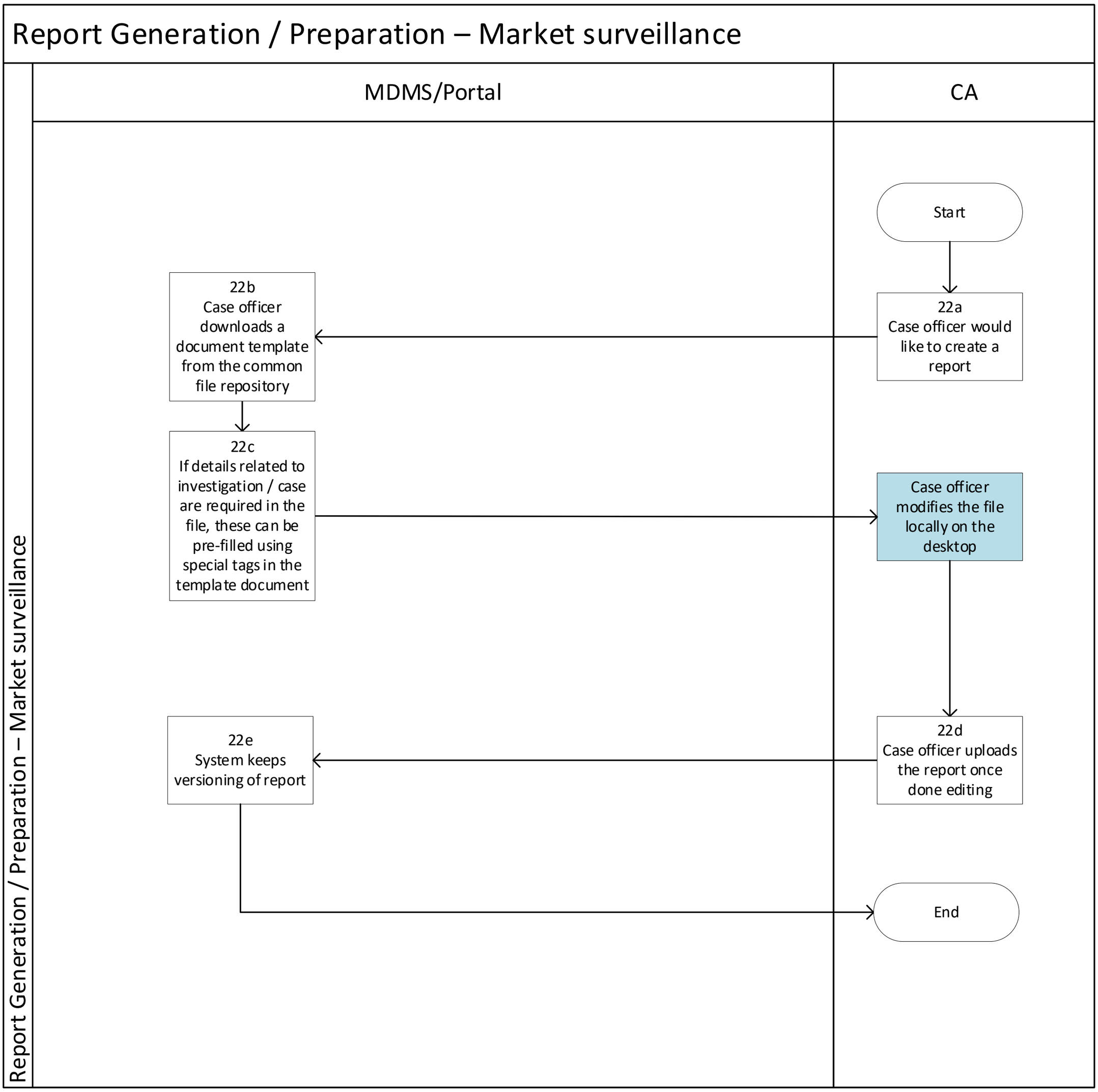
Investigation Manager re-assign investigation to Investigation officer

Investigation Manager re-assign investigation to Investigation officer	MDMS/Portal	CA



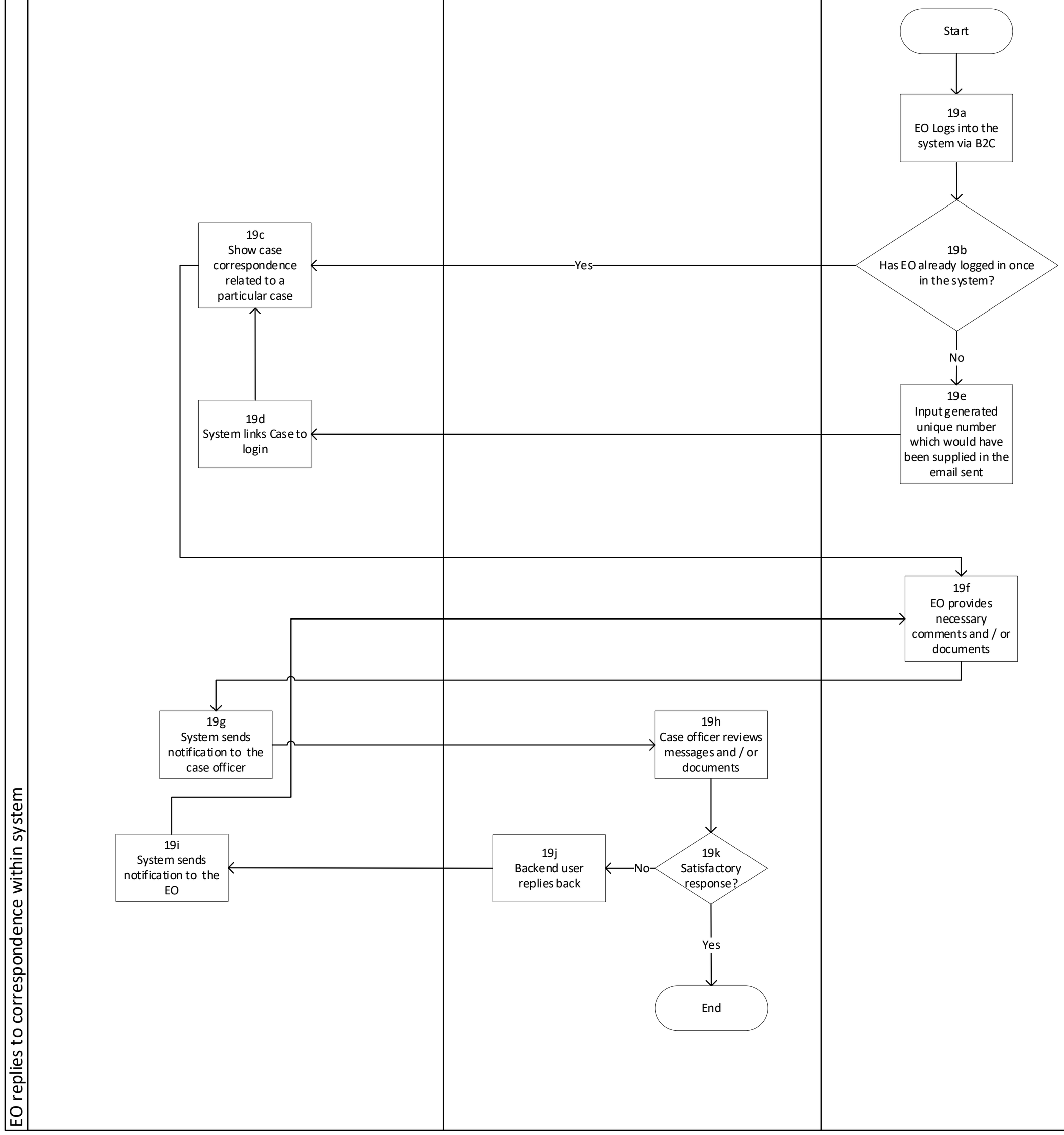
Investigation officer uploads offline correspondence

MDMS/Portal	CA
Investigation officer uploads offline correspondence	Start Case officer receives a reply to a correspondence outside of the system Case officer PDFs the correspondence to upload it to the system 21a System asks for file upload, date of correspondence and target SRN 21b Case officer provides the information 21c System stores correspondence and links it with investigation End

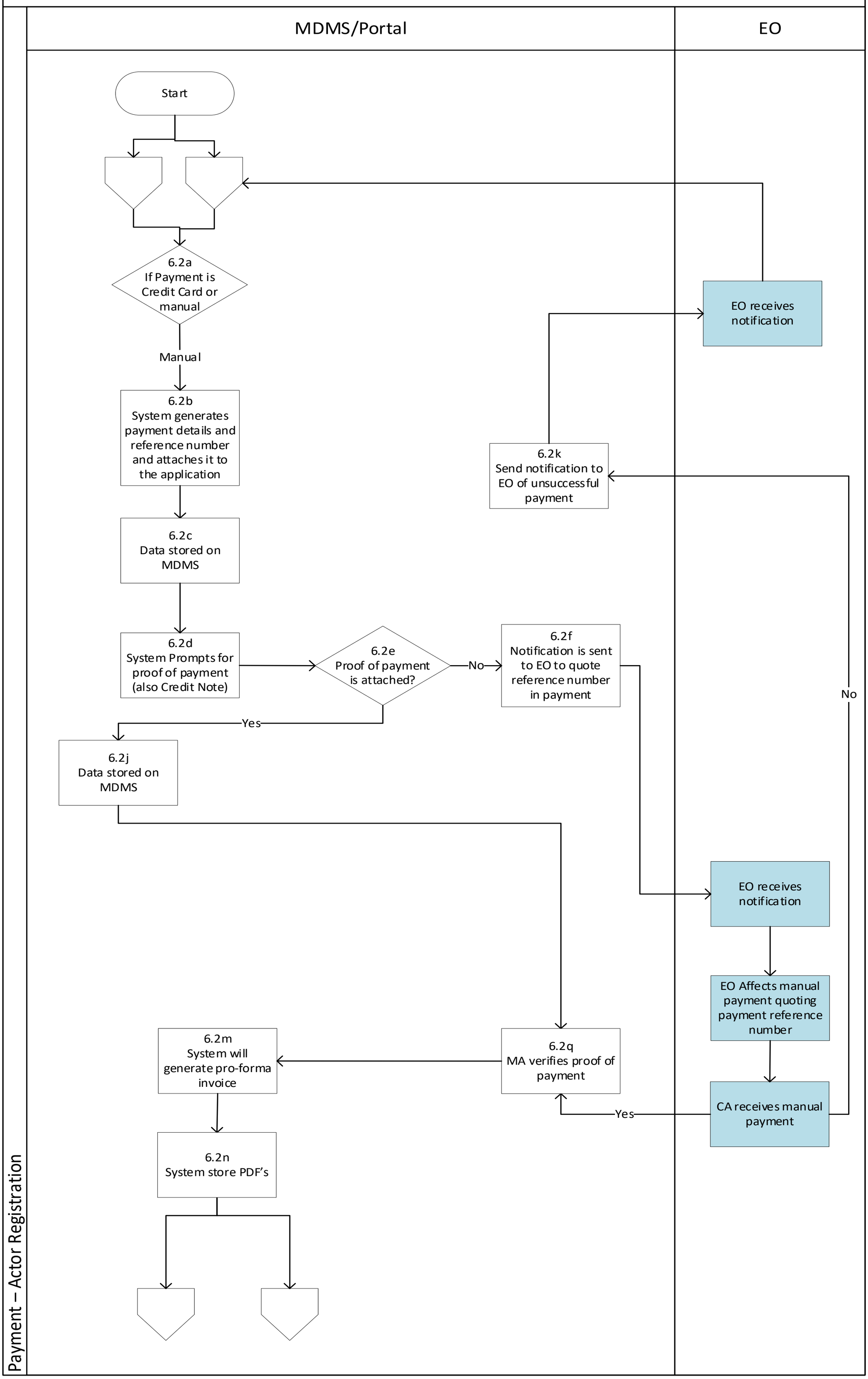

Report Generation / Preparation – Market surveillance
MDMS/Portal
CA
Start
22a
Case officer would like to create a report
22b
Case officer downloads a document template from the common file repository
22c
If details related to investigation / case are required in the file, these can be pre-filled using special tags in the template document
Case officer modifies the file locally on the desktop
22d
Case officer uploads the report once done editing
22e
System keeps versioning of report
End

EO replies to correspondence within system

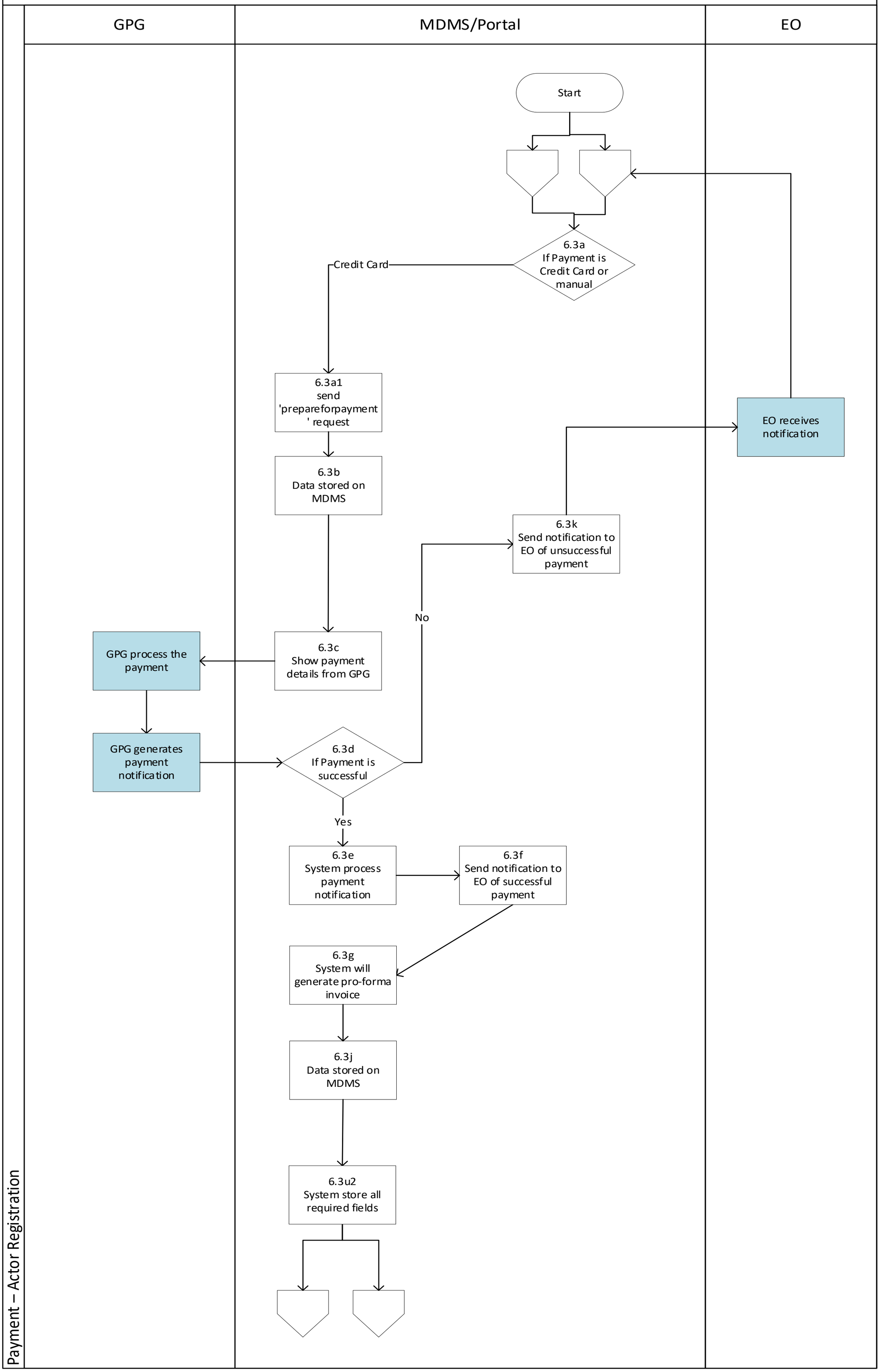
MDMS/Portal	CA	EO



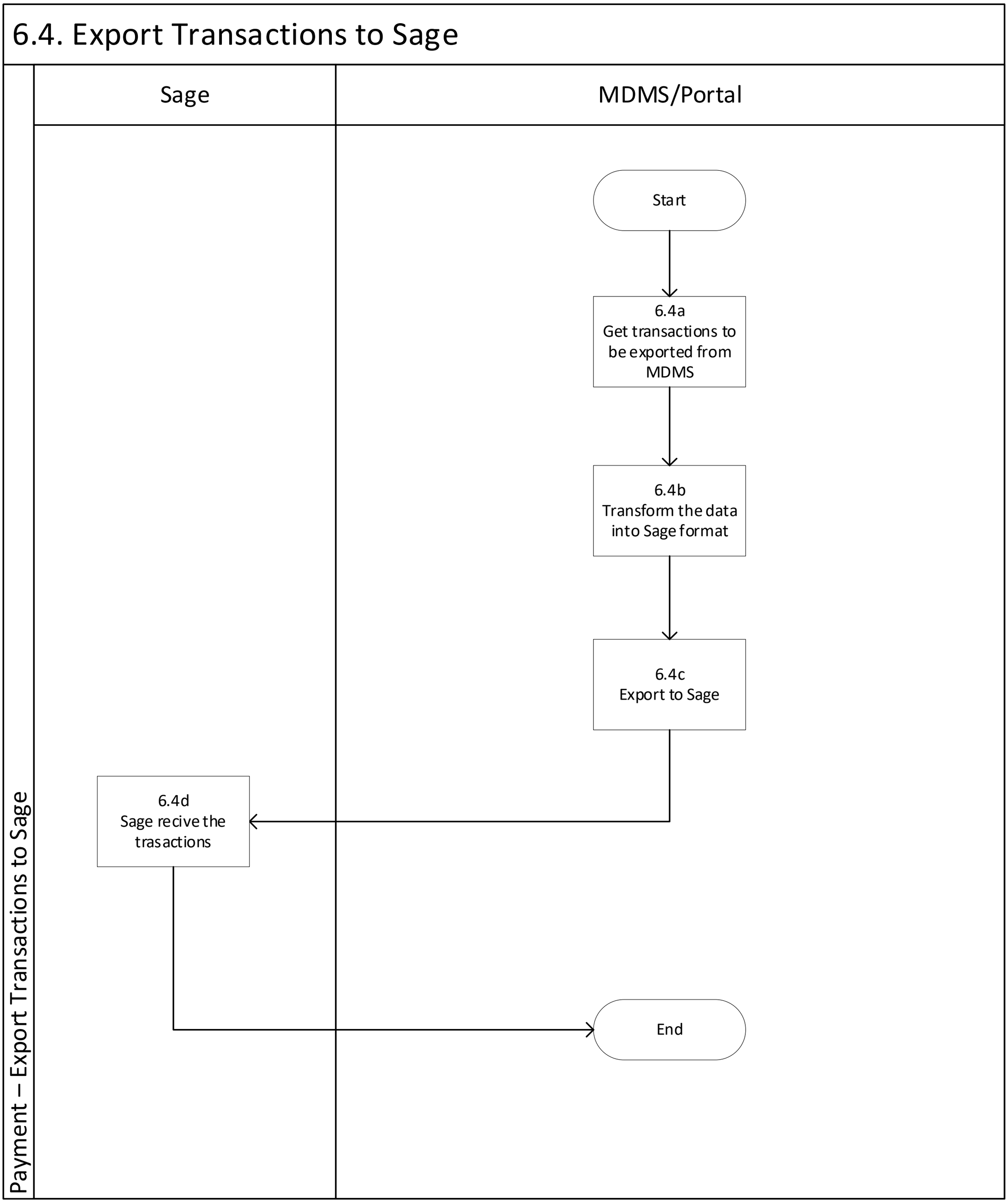
6.2. Manual Payment – Actor Registration



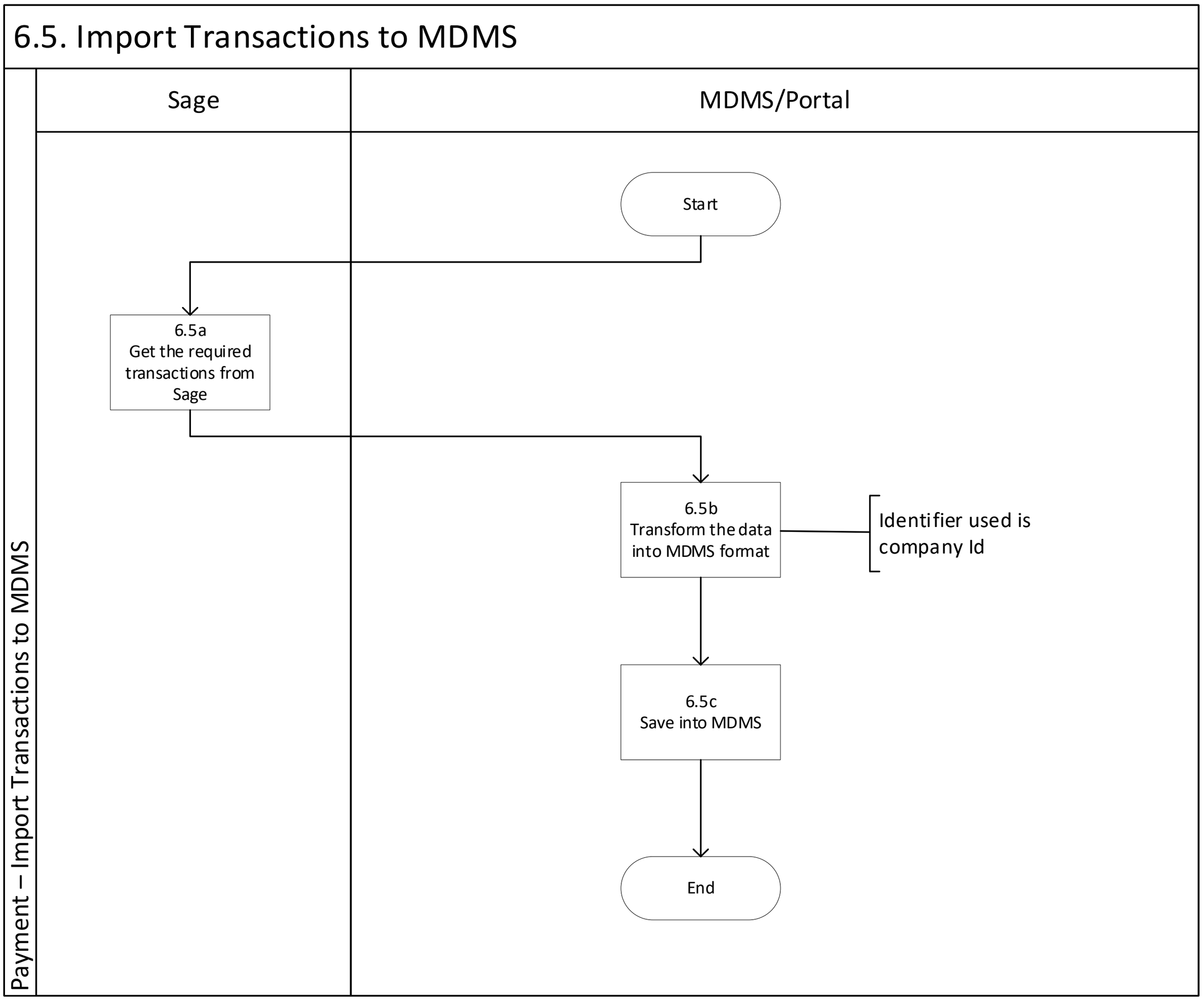
6.3. Credit Card Payment – Actor Registration



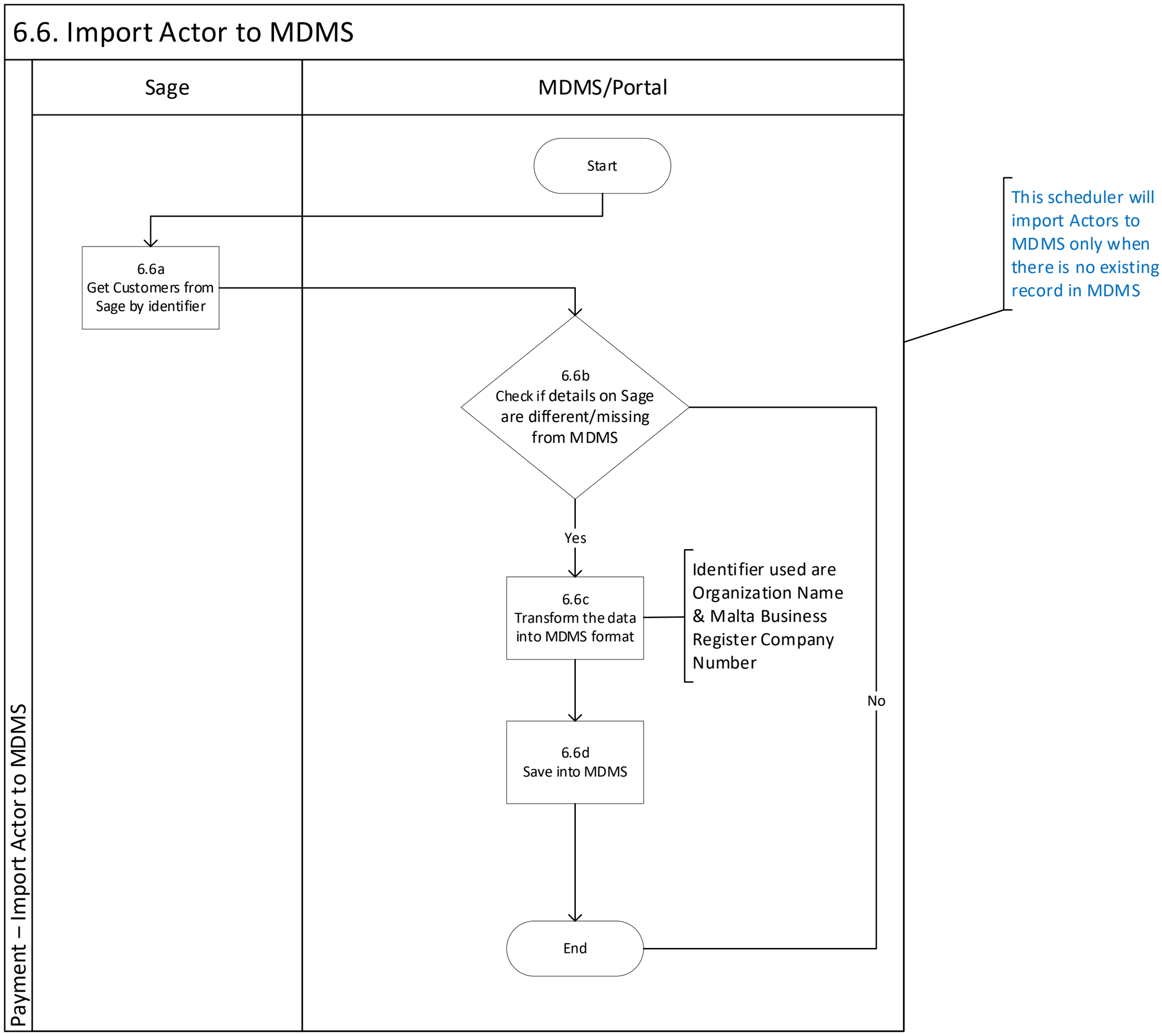
6.4. Export Transactions to Sage



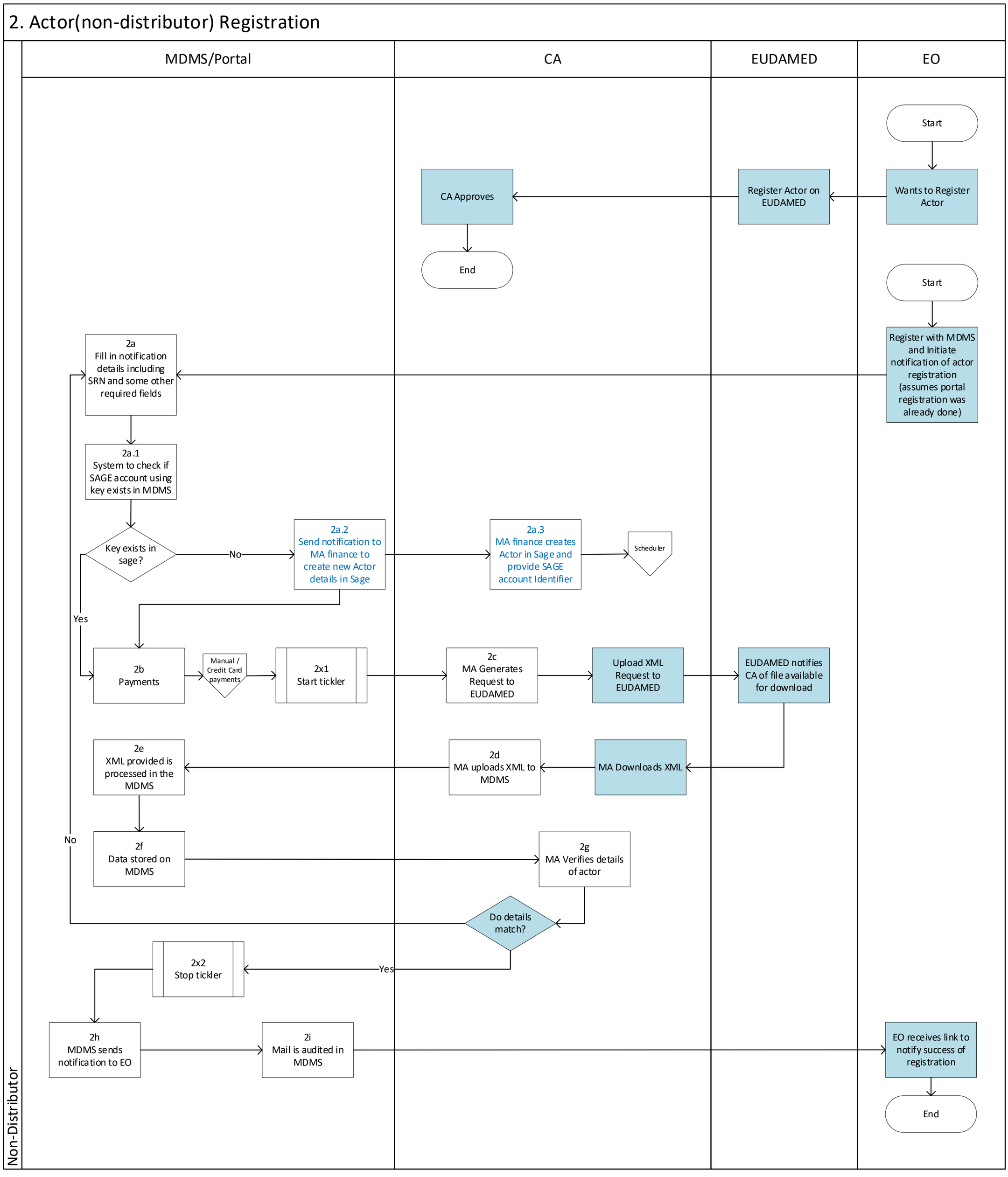
6.5. Import Transactions to MDMS



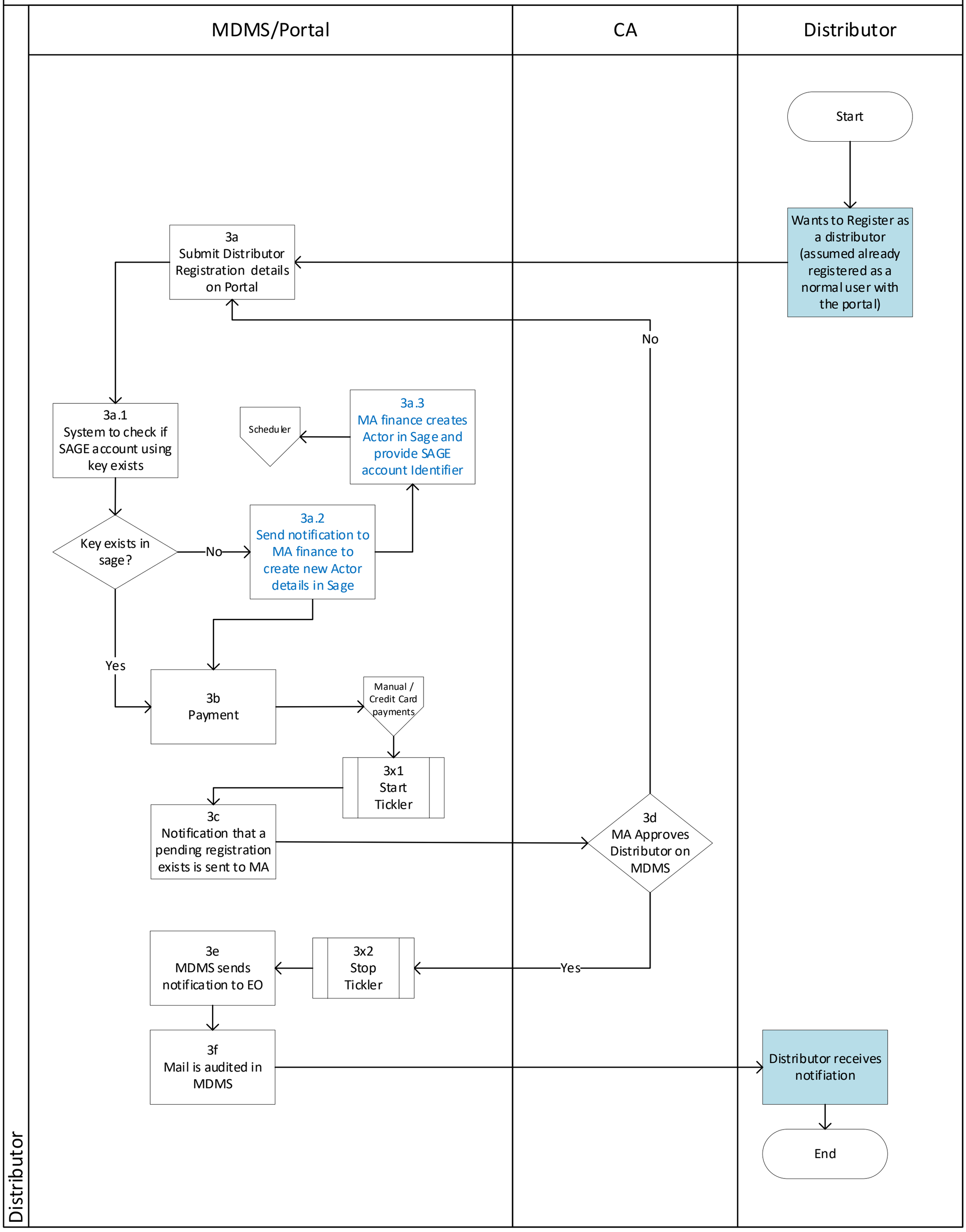
6.6. Import Actor to MDMS



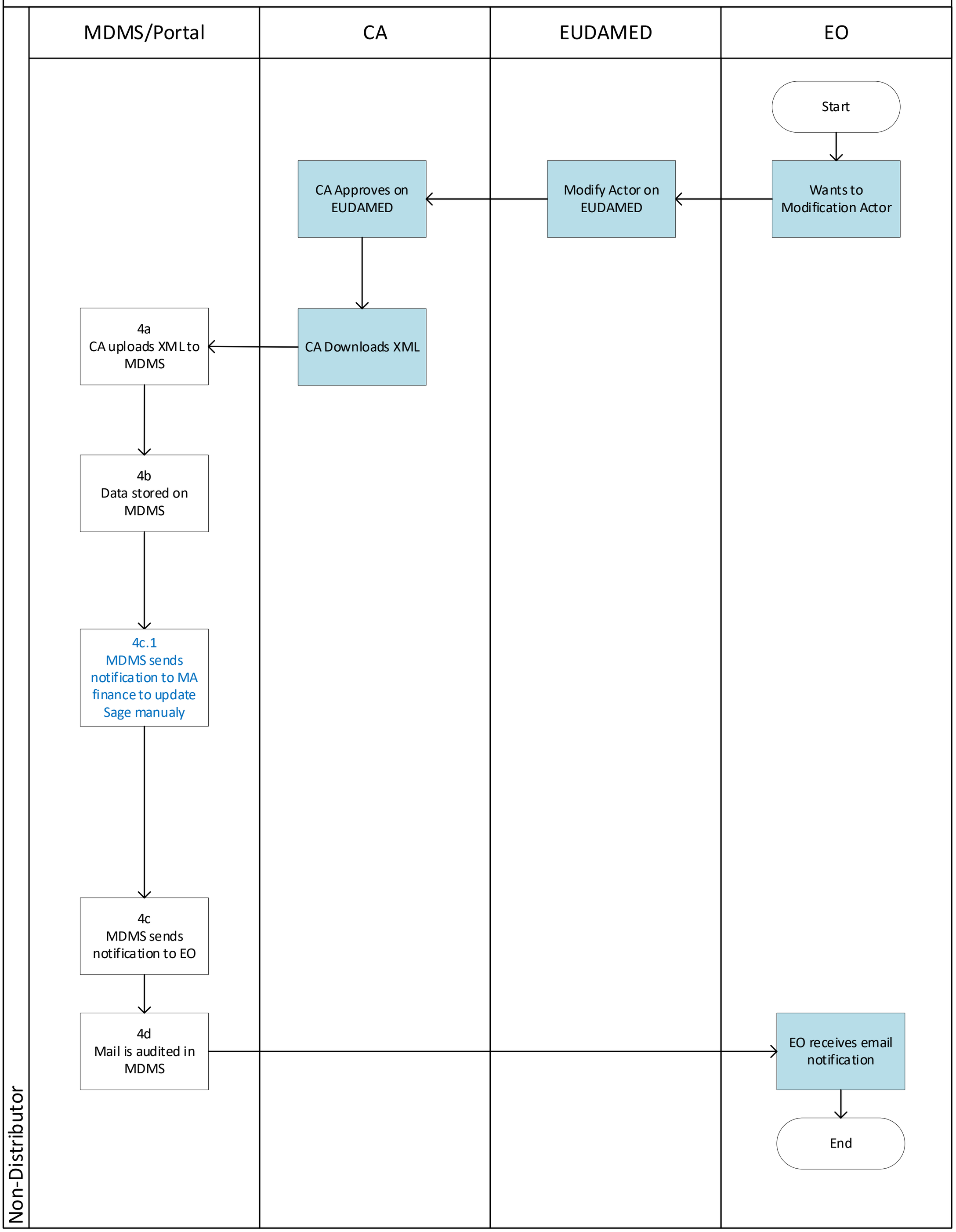
2. Actor(non-distributor) Registration



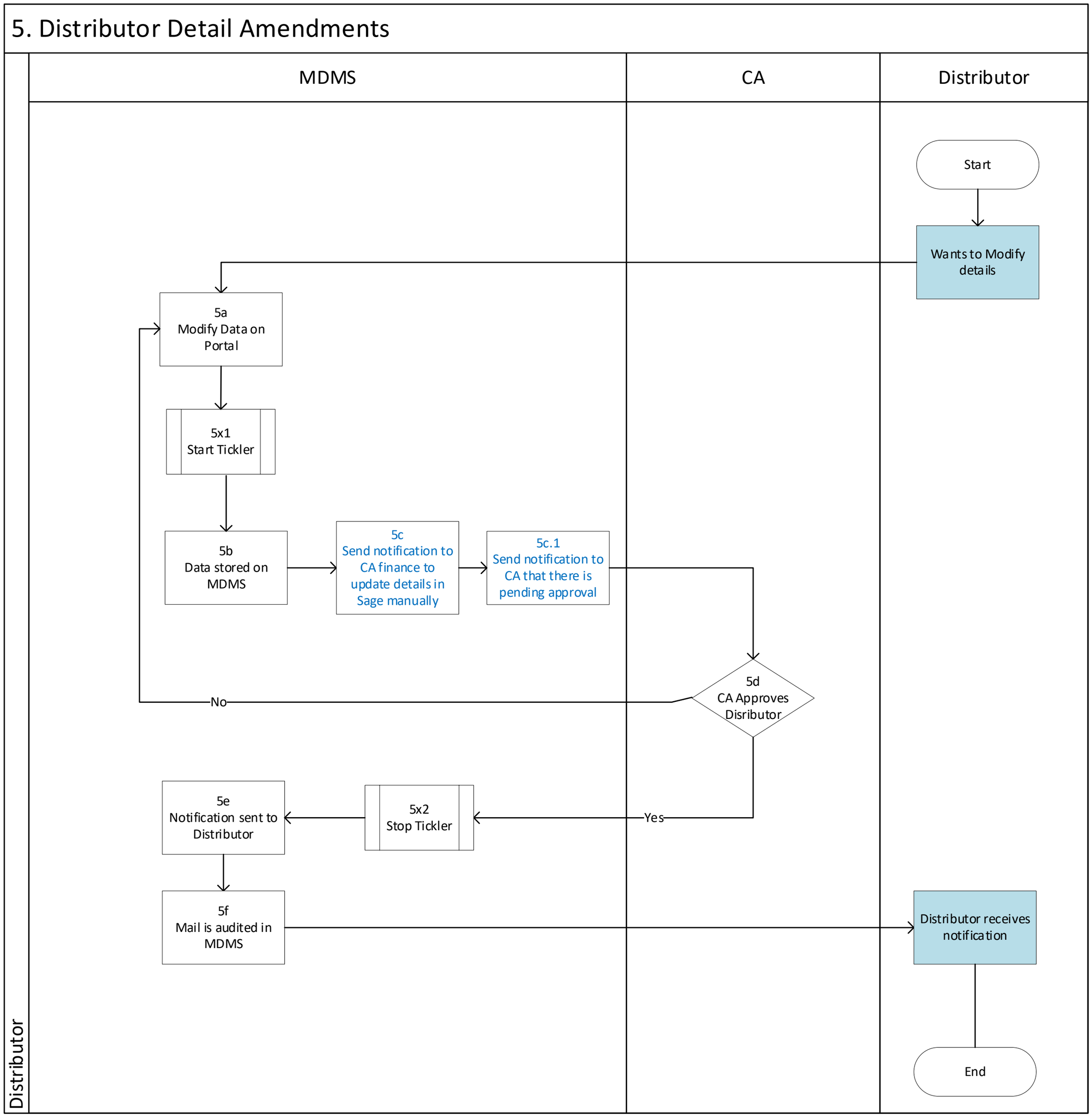
3. Distributor Registration



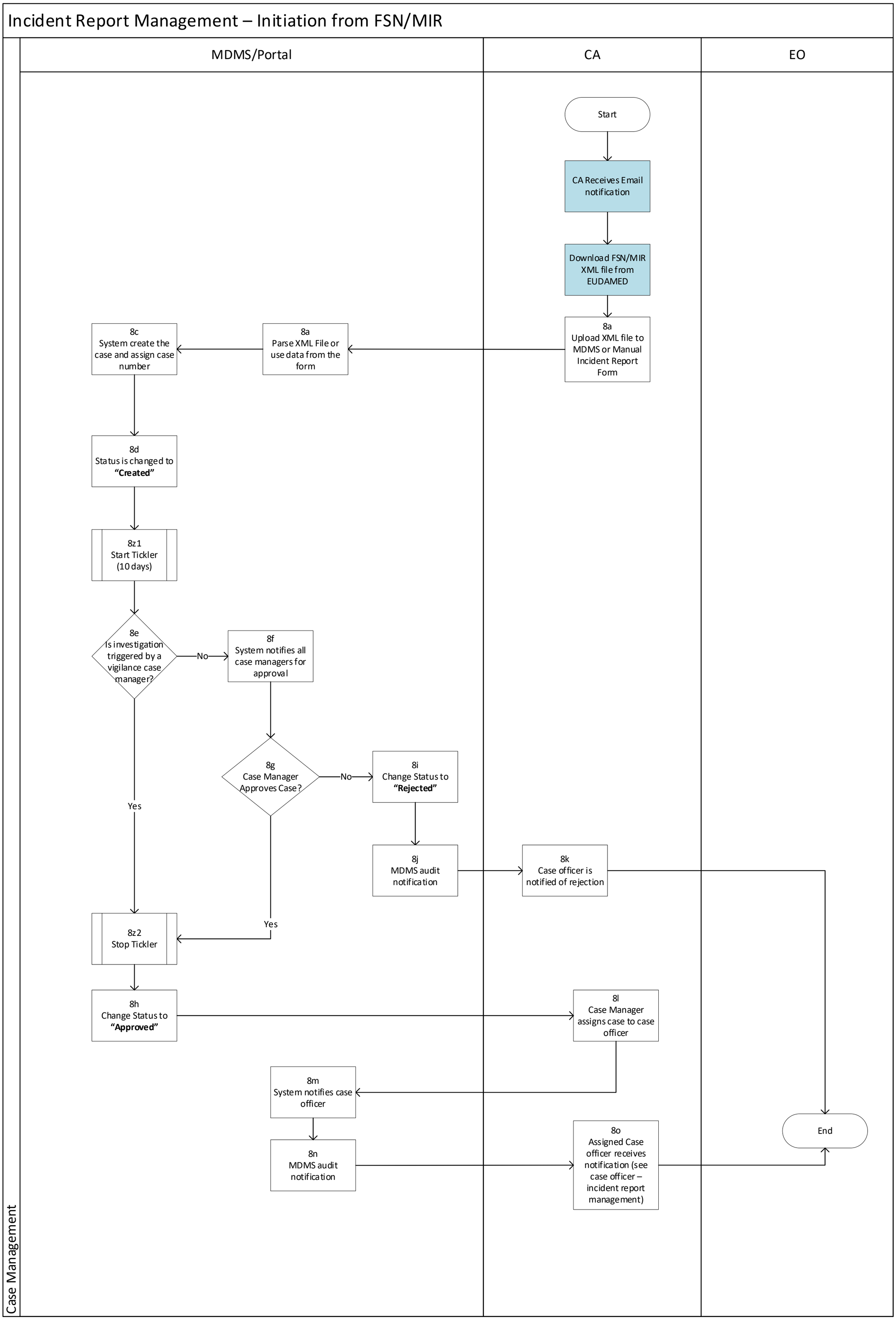
4. Actor (non-distributor) Modification

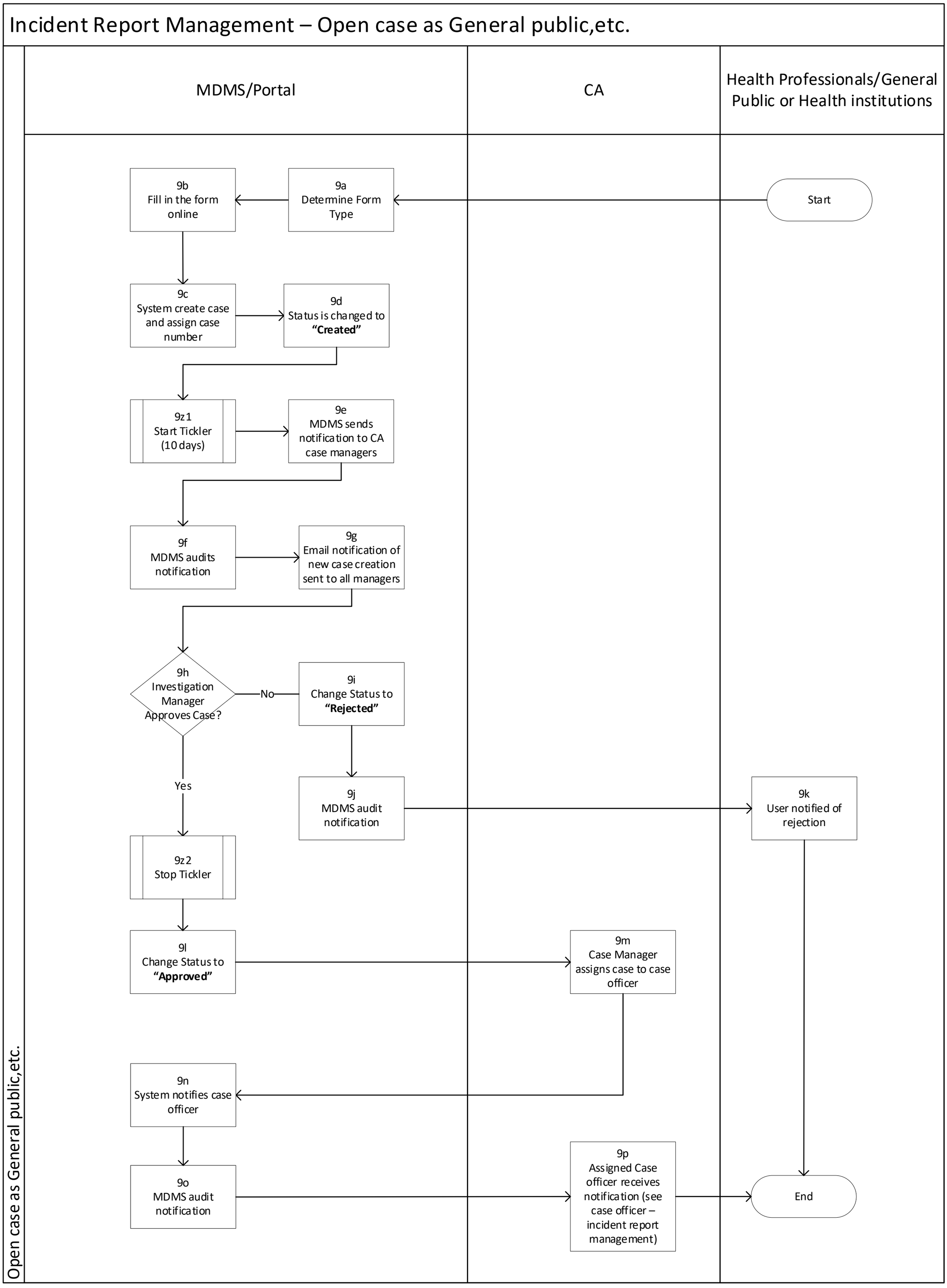


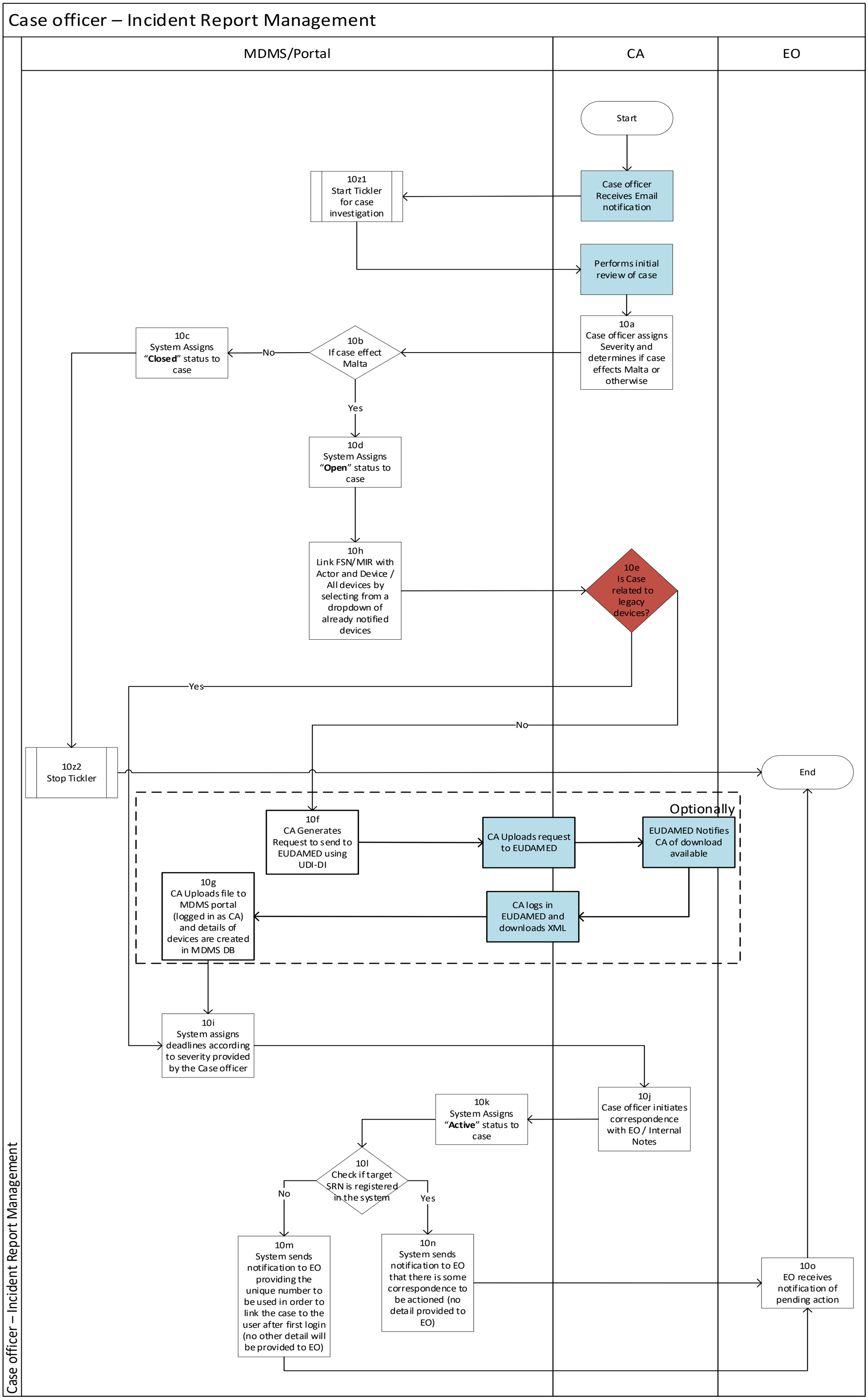
5. Distributor Detail Amendments

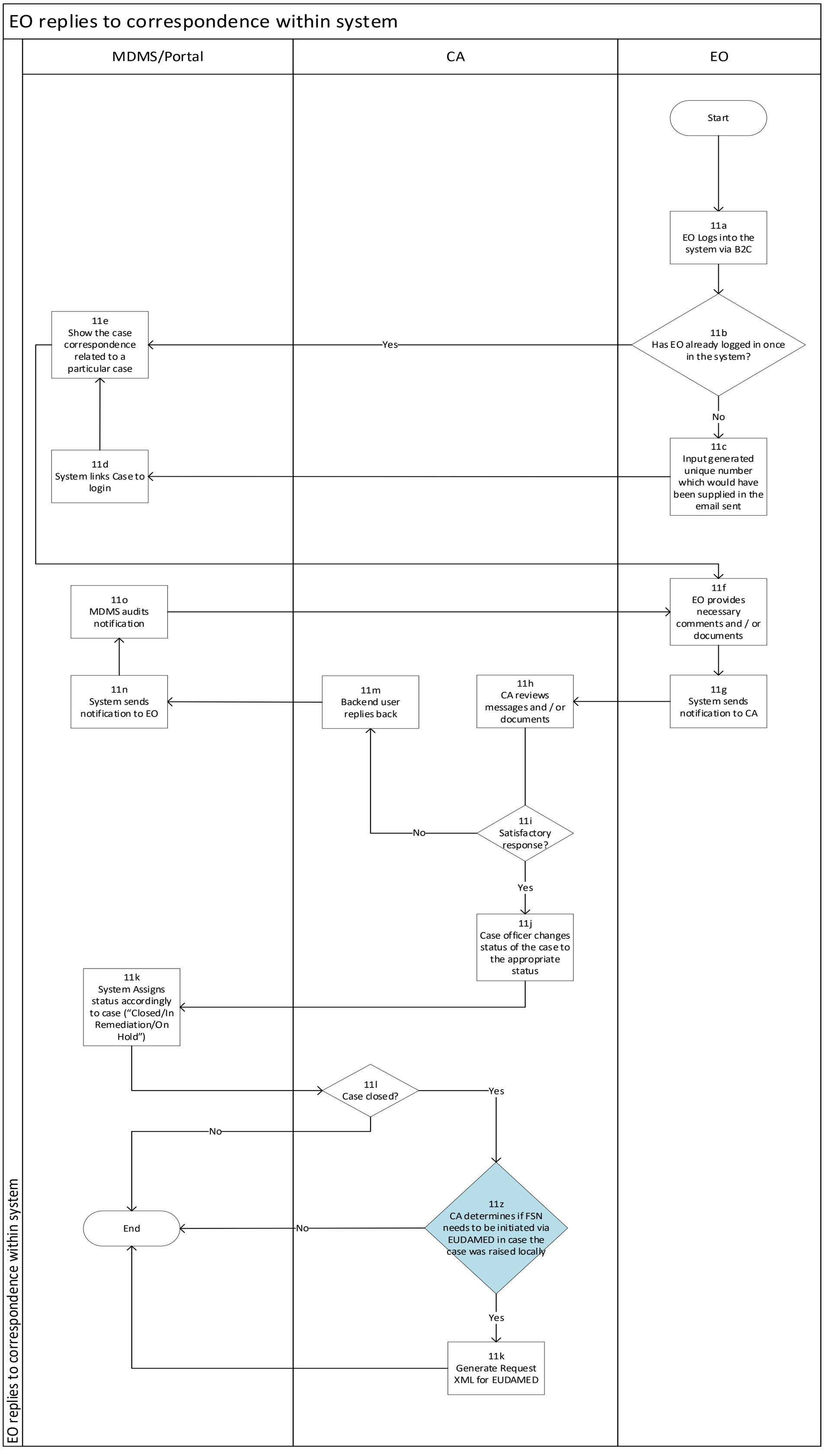


Incident Report Management – Initiation from FSN/MIR




Incident Report Management – Open case as General public,etc.
MDMS/Portal
CA
Health Professionals/General Public or Health institutions
Start
9a Determine Form Type
9b Fill in the form online
9c System create case and assign case number
9d Status is changed to "Created"
9z1 Start Tickler (10 days)
9e MDMS sends notification to CA case managers
9f MDMS audits notification
9g Email notification of new case creation sent to all managers
9h Investigation Manager Approves Case?
No
9i Change Status to "Rejected"
Yes
9j MDMS audit notification
9k User notified of rejection
9z2 Stop Tickler
9l Change Status to "Approved"
9m Case Manager assigns case to case officer
9n System notifies case officer
9o MDMS audit notification
9p Assigned Case officer receives notification (see case officer – incident report management)
End
Open case as General public,etc.


Case officer – Incident Report Management
MDMS/Portal
CA
EO
Start
Case officer Receives Email notification
10z1 Start Tickler for case investigation
Performs initial review of case
10a Case officer assigns Severity and determines if case effects Malta or otherwise
10b If case effect Malta
No
10c System Assigns "Closed" status to case
Yes
10d System Assigns "Open" status to case
10h Link FSN/MIR with Actor and Device / All devices by selecting from a dropdown of already notified devices
10e Is Case related to legacy devices?
Yes
No
10z2 Stop Tickler
End
Optionally
10f CA Generates Request to send to EUDAMED using UDI-DI
CA Uploads request to EUDAMED
EUDAMED Notifies CA of download available
CA logs in EUDAMED and downloads XML
10g CA Uploads file to MDMS portal (logged in as CA) and details of devices are created in MDMS DB
10i System assigns deadlines according to severity provided by the Case officer
10j Case officer initiates correspondence with EO / Internal Notes
10k System Assigns "Active" status to case
10l Check if target SRN is registered in the system
No
Yes
10m System sends notification to EO providing the unique number to be used in order to link the case to the user after first login (no other detail will be provided to EO)
10n System sends notification to EO that there is some correspondence to be actioned (no detail provided to EO)
10o EO receives notification of pending action


EO replies to correspondence within system
MDMS/Portal
CA
EO
Start
11a
EO Logs into the system via B2C
11b
Has EO already logged in once in the system?
Yes
No
11e
Show the case correspondence related to a particular case
11d
System links Case to login
11c
Input generated unique number which would have been supplied in the email sent
11f
EO provides necessary comments and / or documents
11o
MDMS audits notification
11n
System sends notification to EO
11m
Backend user replies back
11h
CA reviews messages and / or documents
11g
System sends notification to CA
11i
Satisfactory response?
No
Yes
11j
Case officer changes status of the case to the appropriate status
11k
System Assigns status accordingly to case (“Closed/In Remediation/On Hold”)
11l
Case closed?
Yes
No
11z
CA determines if FSN needs to be initiated via EUDAMED in case the case was raised locally
End
No
Yes
11k
Generate Request XML for EUDAMED

Re-Assign to Case officer

Case management

MDMS/Portal	CA
	Start
	12a Case Manager wants to re-assign a case
	12b Case manager selects case officer
12c System assigns case to case officer	
12d System sends notification to Case officer	
12e MDMS audits notification	
	12f Case officer receives notification
	End

Case officer uploads offline correspondence

MDMS/Portal	CA
	Start
	Case officer receives a reply to a correspondence outside of the system
	Case officer PDFs the correspondence to upload it to the system
13a System asks for file upload, date of correspondence and target SRN	
	13b Case officer provides the information
13c System stores correspondence and links it with case	
End	

Appendix 21

User acceptance testing and test plan templates

MDMS Test Plan Template

Section	Description
Test Objectives:	
Validate Overall Functionality	• Validate the overall functionality of the MDMS system.
Assess Performance	• Assess the performance of the MDMS under varying conditions.
Evaluate Reliability	• Evaluate the reliability and stability of the integrated MDMS.
Ensure UAT Alignment	• Ensure that User Acceptance Testing (UAT) verifies alignment with user expectations.
Scope:	
Functionality Testing	• Verify the core features and functionalities of the MDMS. • Ensure accurate data input, processing, and output. • Confirm proper integration of software components. • Validate user permissions and access rights. • Test field visibility, field names, and lists.
Performance Testing	• Evaluate system response times under normal and peak loads. • Assess the system's ability to handle a specified number of concurrent users. • Test the MDMS performance with different data volumes. • Measure resource utilization and identify potential bottlenecks.
Reliability Testing	• Verify system stability over an extended period of continuous operation. • Assess the system's recovery from failures. • Test the MDMS under stressful conditions to identify potential points of failure. • Assess the reliability of data storage and retrieval processes.
User Acceptance Testing (UAT)	• Validate alignment with user scenarios and expectations. • Assess usability, navigation, and overall user experience. • Verify user feedback mechanisms. • Ensure acceptance criteria are met.
Test Cases:	
Functionality Testing	• Verify login functionality with valid and invalid credentials. • Test data input and processing for accuracy. • Check integration points between modules. • Validate user roles and permissions. • Ensure proper display of fields, field names, and lists.
Performance Testing	• Conduct load testing to simulate concurrent user activity. • Measure response times for common transactions. • Test the MDMS under varying network conditions. • Evaluate system scalability by increasing data volumes.
Reliability Testing	• Perform continuous operation testing over an extended period. • Simulate system failures and assess recovery mechanisms. • Conduct stress testing to determine system limits.

	• Verify data integrity and reliability during and after system interruptions.
User Acceptance Testing (UAT)	• Validate UAT scenarios representing real-world usage. • Test cases covering positive, negative, and boundary scenarios. • Evaluate system behaviour against acceptance criteria. • Assess overall user satisfaction and feedback.

Assumptions:

Test Environment	• The test environment accurately represents the production environment.
Test Data	• Test data is comprehensive and covers various scenarios.
MDMS System Stability	• The MDMS system is in a stable state before testing begins.

Dependencies:

Testing Tools and Resources	• Availability of necessary testing tools and resources.
Development and IT Teams	• Cooperation from development and IT teams for any required configurations.

UAT Execution Timeline	• Define the schedule for executing UAT, including start and end dates for testing phases.
UAT Participants	• Identify and enlist participants, including sample users and stakeholders involved in the UAT process.
UAT Feedback and Issue Resolution	• Establish a process for collecting and addressing user feedback during UAT.

User Acceptance Testing (UAT) Execution Plan

Section	Description
UAT Scenarios:	
a. Login and User Access	• Validate user authentication and authorization processes. • Verify access rights for different user roles.
b. Data Input and Processing	• Test the accuracy and completeness of data input. • Verify data processing and system response.
c. Functionality Validation	• Validate core functionalities based on user requirements. • Ensure proper integration of software components.
d. Field Visibility and Lists	• Verify the visibility of fields based on user roles. • Confirm the accuracy and completeness of field names and lists.
e. Permissions and Access Controls	• Validate user permissions and access controls. • Test the system's response to unauthorized access attempts.
f. User Feedback Mechanism	• Evaluate the system's feedback to user actions. • Verify the effectiveness of error messages.
Test Cases:	
a. Positive Test Cases	• Confirm that the system behaves as expected under normal conditions. • Validate successful execution of typical user scenarios.
b. Negative Test Cases	• Test error handling and system response under unexpected inputs. • Verify the system's behaviour when users attempt unauthorized actions.
c. Boundary Test Cases	• Validate the system's behaviour at the limits of its capabilities. • Test the system's response to extreme or maximum input values.
d. User Interface Testing	• Verify the usability and intuitiveness of the user interface. • Test navigation and clarity of information presented.
e. Integration Testing	• Validate the interaction between different modules during user actions. • Confirm that integrated features work seamlessly.
Acceptance Criteria:	
a. Login and User Access	• Users can log in with valid credentials. • Access rights are enforced according to predefined roles.
b. Data Input and Processing	• Data input is accurate and complete. • System processes data within an acceptable timeframe.
c. Functionality Validation	• Core functionalities align with user requirements. • Software components integrate seamlessly.
d. Field Visibility and Lists	• Fields are visible based on user roles. • Field names and lists are accurate and complete.
e. Permissions and Access Controls	• User permissions are enforced. • Unauthorized access attempts result in appropriate responses.
f. User Feedback Mechanism	• System provides clear and helpful feedback. • Error messages are informative and user-friendly.

UAT Execution Timeline	• Define the schedule for executing UAT, including start and end dates for testing phases.
UAT Participants	• Identify and enlist participants, including sample users and stakeholders involved in the UAT process.
UAT Feedback and Issue Resolution	• Establish a process for collecting and addressing user feedback during UAT.

Appendix 22

Employee skills and training needs assessment

Employee Skills and Training Needs Assessment

Thank you for participating in this survey. Your feedback is crucial in helping us understand your skills, training needs, and preferences.

Please provide honest and thoughtful responses. Your input will be used to tailor training programs that align with your professional development goals.

Section 1: Current Skill Levels

1.1. On a scale of 1 to 5, with 1 being "Novice" and 5 being "Expert," please rate your proficiency in the following skills:

Technical Knowledge: _____

Communication Skills: _____

Problem-Solving: _____

Team Collaboration: _____

Project Management: _____

1.2. On a scale of 1 to 5, with 1 being "Novice" and 5 being "Expert," please rate your knowledge on the following topics:

Economic Operators and Actors: _____

Medical Device Registration and Notification Processes: _____

Notified Bodies and Certificates: _____

Clinical Investigations and Performance Studies: _____

Vigilance and Post-Market Surveillance: _____Market Surveillance

Unique Device Identifier: _____

Other (please specify) : _____

Section 2: Areas for Improvement

2.1. Are there specific areas where you feel you need improvement? Please provide details.

[Open-ended response]

_____
_____
_____
_____
_____

2.2. Do you encounter any challenges or obstacles in your current role that you believe additional training could address?

[Open-ended response]

_____
_____
_____
_____
_____

Section 3: Training Preferences

3.1. What topics or skills would you like to receive training on? Please list specific areas of interest.

[Open-ended response]

_____
_____
_____
_____
_____

3.2. How do you prefer to receive training? (Select all that apply)

In-Person Workshops _____

Online Courses _____

Webinars _____

On-the-Job Training _____

Other (please specify):

_____
_____

3.3 Do you have any preferred time slots and/or frequency of the training sessions?

[Open-ended response]

_____
_____
_____
_____
_____

Section 4: Additional Comments

4.1. Do you have any additional comments or suggestions regarding training and professional development within the organization?

[Open-ended response]

_____
_____
_____
_____
_____

Job Title: _____

Years of Experience: _____

Department/Team: _____

Preferred Contact Method for Training Updates: _____

Thank you for taking the time to complete this questionnaire. Your input is highly valued.

Appendix 23

Questionnaire for external training questions

For Healthcare Professionals:

1. Can you share your experiences with implementing the MDR requirements in your clinical practice? What challenges have you encountered, and how have you addressed them?

2. In your opinion, what are the key aspects of the MDR that healthcare professionals should prioritize for successful compliance?

3. How do you stay informed about updates and changes in the MDR, and what resources do you find most helpful in understanding and applying regulatory requirements?

4. Can you provide examples of situations where the MDR has had a direct impact on patient care, and how have you navigated these changes?

For Regulatory Bodies:

1. From your perspective, what are the most critical regulatory challenges organizations face in complying with the MDR, and how do you support them in overcoming these challenges?

2. How do you assess the effectiveness of MDR training programs currently available to industry stakeholders, and what improvements do you think can be made?

3. In your interactions with medical device companies, what common misconceptions or gaps in understanding about the MDR do you often observe, and how do you address them?

For Distributors and Suppliers:

1. How do you ensure that your supply chain aligns with MDR requirements, and what steps have you taken to educate your partners on compliance matters?

2. Can you share instances where changes in the MDR have influenced your business operations, and how have you adapted to these changes?

3. What challenges have you faced in communicating MDR-related information to your clients or customers, and how do you overcome these challenges?

Appendix 24

Questionnaires for the validation of the internal assessment and external training questions

Expert Panel Validation Questionnaires:

Instructions: Please provide your feedback on each question using the Likert scale (1-5), where 1 indicates Strongly Disagree and 5 indicates Strongly Agree.

Additionally, feel free to provide comments or suggestions for improvement where necessary.

Thank you for your valuable feedback. Your input is crucial in enhancing the effectiveness of the Employee Skills and Training Needs Assessment questionnaire.

Validation Questionnaire for Internal Training

Statement	1	2	3	4	5
Section 1: Current Skill Levels					
1.1. The questions effectively assess the proficiency of employees in technical knowledge.					
1.2. The questions effectively assess the proficiency of employees in communication skills.					
1.3. The questions effectively assess the proficiency of employees in problem-solving.					
1.4. The questions effectively assess the proficiency of employees in team collaboration.					
1.5. The questions effectively assess the proficiency of employees in project management.					
Section 2: Areas for Improvement					
2.1. The open-ended questions allow employees to express specific areas where they feel they need improvement.					
2.2. The open-ended questions effectively prompt employees to identify challenges or obstacles in their roles that additional training could address.					
Section 3: Training Preferences					
3.1. The open-ended question allows employees to list specific topics or skills they would like to receive training on.					
3.2. The multiple-choice question effectively captures diverse preferences for training delivery methods.					
Section 4: Additional Comments					
4.1. The open-ended question allows employees to provide any additional comments or suggestions regarding training and professional development within the organization.					
Overall Impression:					
Please provide an overall assessment of the questionnaire's effectiveness in capturing employee skills and training needs.					

Additional Comments:

Validation Questionnaire for External Training

Statement	1	2	3	4	5
On a scale of 1 to 5 how clear are the questions for healthcare professionals?					
Do you find the questions relevant to the challenges and responsibilities faced by healthcare professionals in complying with the MDR? Please provide specific comments.	**Open-ended response**				
Are there any additional topics or aspects related to external training for healthcare professionals that you believe should be included? Please specify.	**Open-ended response**				
How would you rate the clarity of the questions designed for regulatory bodies on a scale of 1 to 5?					
In your opinion, are the questions aligned with the critical regulatory challenges faced by organizations in complying with the MDR? Share your insights.	**Open-ended response**				
Do you believe any essential aspects related to external training for regulatory bodies are missing from the questions? If yes, please elaborate.					
Evaluate the clarity of the questions for distributors and suppliers on a scale of 1 to 5.					
Are the questions addressing the key challenges and responsibilities that distributors and suppliers encounter regarding MDR compliance? Provide detailed feedback.	**Open-ended response**				
Suggest any additional themes or topics that you think should be covered in the external training questions for distributors and suppliers.	**Open-ended response**				
Overall, how effective do you believe the external training questions are in capturing the essential insights and perspectives of the respective stakeholder groups?					
Please provide any additional comments or suggestions to enhance the external training questions.	**Open-ended response**				

Additional Comments:

Appendix 25

Internal training curriculum

Curriculum Overview

Objective: To equip employees with enhanced skills and knowledge in key areas identified as critical for their roles, including technical knowledge, communication, problem-solving, team collaboration, project management, and specialised topics relevant to the medical devices sector.

Duration: The curriculum is structured as a series of modules to be delivered over a period of 6 months, allowing for flexibility in scheduling and minimising disruption to work commitments.

Delivery Modes: The curriculum incorporates a mix of in-person workshops, online courses, webinars, and on-the-job training sessions. This hybrid approach facilitates broad participation and accommodates different learning styles.

Curriculum Modules

- Foundational Skills
    - Technical Knowledge in Medical Devices: Covering the basics to advanced concepts in medical device technology, regulatory standards, and industry practices.
    - Communication Skills: Enhancing interpersonal communication, presentation skills, and technical writing for clarity and effectiveness in a regulatory environment.
    - Problem-Solving Techniques: Strategies and tools for effective decision-making and creative solutions to complex challenges.
    - Team Collaboration: Building high-performance teams through effective collaboration, conflict resolution, and leadership skills.
- Project Management
    - Comprehensive training in project management methodologies, tools, and best practices tailored to the regulatory aspects of medical devices.
- Specialised Topics
    - Economic Operators and Actors: Deep dive into the roles and responsibilities within the medical device market.

    - Medical Device Registration and Notification Processes: Understanding the regulatory framework and practical steps for compliance.
    - Notified Bodies and Certificates: Insight into working with Notified Bodies, including preparation for audits and maintaining certifications.
    - Clinical Investigations and Performance Studies: Best practices in designing and conducting studies, and how to navigate regulatory submissions.
    - Vigilance and Post-Market Surveillance: Techniques for monitoring and reporting to ensure ongoing compliance and patient safety.
    - Unique Device Identifier (UDI) System: Implementing and managing UDIs in line with global regulatory requirements.
- Training Preferences and Logistics
    - Sessions scheduled to accommodate employee availability, with options for live and recorded webinars to enhance accessibility.
    - Utilisation of interactive platforms for online courses and workshops to foster engagement and facilitate hands-on learning experiences.

Assessment and Certification

- Participants will undergo assessments at the end of each module to measure knowledge acquisition and application.
- Certificates of completion will be awarded to recognise proficiency and encourage ongoing professional development.

Continuous Learning and Feedback

- The curriculum includes mechanisms for ongoing feedback, allowing for real-time adjustments and ensuring the training remains relevant and effective.
- Participants will have access to a resource library for continuous learning and support beyond the structured training sessions.

This curriculum is designed as a dynamic, responsive framework to foster professional growth, address current challenges, and anticipate future needs within the medical device

unit, ensuring that the Malta Medicines Authority remains at the forefront of regulatory excellence and innovation.

Appendix 26

External training curriculum

External Training Curriculum for MDR Compliance

Objective: To empower external stakeholders in the medical device sector with the knowledge and skills necessary to navigate and comply with MDR effectively.

Duration: An ongoing program with initial intensive training sessions followed by regular updates and refresher courses.

Format: A combination of live webinars, interactive workshops, e-learning modules, and in-person seminars, complemented by a suite of digital resources.

Module 1: Understanding the MDR Framework

- Overview of MDR
- Key changes from previous regulations
- Classification criteria and conformity assessment
- Legal implications and enforcement

Module 2: Practical Compliance Strategies

- Documentation requirements and best practices
- Labelling requirements and strategies for implementation
- Vigilance and post-market surveillance systems
- Adverse event reporting procedures

Module 3: Navigating MDR for Different Stakeholder Groups

- Tailored sub-modules for healthcare professionals, regulatory organizations, distributors, and suppliers
- Case studies and role-specific compliance scenarios
- Collaboration and communication across the supply chain

Module 4: Effective Utilization of MDR Resources

- Guidance on utilizing regulatory publications and resources
- Leveraging feedback from regulatory affairs teams
- Utilizing FAQs and quick-reference guides

Module 5: Continuous Learning and Adaptation

- Regular updates on MDR amendments and interpretations
- Workshops on emerging topics and challenges
- Creating a community of practice for shared learning and support

Module 6: Interactive Learning and Skill Building

- Virtual simulations of compliance-related tasks
- Problem-solving workshops for case studies and real-world scenarios
- Performance support tools, such as checklists and decision trees

Module 7: Communication and Outreach

- Strategies for communicating MDR-related changes to various audiences
- Creating customer-oriented guides for MDR compliance
- Developing and maintaining responsive customer support channels

Module 8: Supplier and Distributor Specific Training

- Supplier qualification and education on MDR obligations
- Distributor-led initiatives for ensuring end-to-end supply chain compliance
- Regular briefings on MDR updates impacting the supply chain

Additional Resources

- Access to a digital platform for ongoing learning and community engagement
- Newsletters providing regular MDR updates and insights
- Access to regulatory advisory for addressing specific compliance questions

Assessment and Certification

- Participants will complete assessments to validate their understanding and application of MDR compliance strategies.
- Certification of completion for various modules, endorsing stakeholder proficiency in MDR-related competencies.

This curriculum is designed to be dynamic and responsive to the evolving landscape of the medical device regulatory environment. It provides stakeholders with the tools to stay current, make informed decisions, and maintain compliance with the MDR.