L-Università ta' Malta
Faculty of Medicine & Surgery
Department of Pharmacy

CLINICAL INVESTIGATIONS FOR MEDICAL DEVICES IN SMALL MEMBER STATES

Shirley Tanti, Anthony Serracino-Inglott, Louise Grech

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

email: shirley.tabone.11@um.edu.mt

INTRODUCTION

The rapid advancement of innovative medical technologies particularly those incorporating big data analytics, robotics, and artificial intelligence (AI) has significantly increased the complexity of modern medical device designs. These technologies enable unprecedented capabilities such as real-time patient monitoring, predictive diagnostics, autonomous surgical assistance, and adaptive therapeutic interventions. As medical devices become more sophisticated and capable of independently processing large volumes of data or executing automated functions, the challenges associated with ensuring their safety, effectiveness, and reliability grow proportionally.

AIM

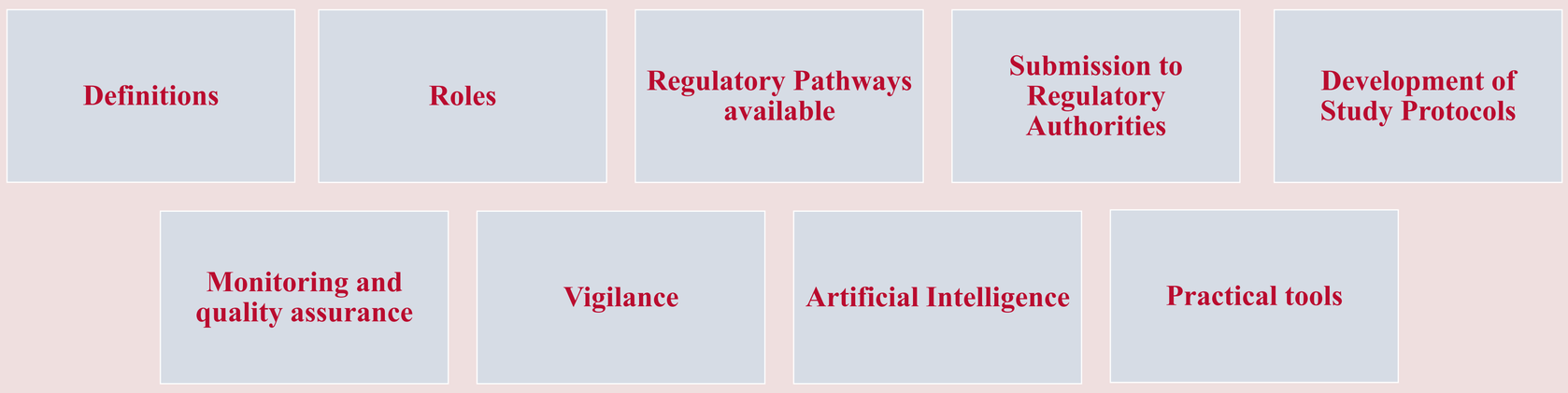
To produce a tool that supports harmonisation and optimisation of best practice standards in medical device clinical investigations with the goal of ensuring consistency, quality, and efficiency across study processes.

METHOD

Phases	Methodology: Data Collection Tools
Phase 1	A systematic literature review was carried out using PubMed, HyDi, and Google Scholar. Official websites of European regulatory authorities, documents issued by the Medical Devices Coordination Group, relevant International Organisation for Standardisation (ISO) standards, and the European Regulations for Medical Devices and In Vitro Diagnostics were reviewed.
Phase 2	Data obtained from Phase 1 were analysed to identify recurring themes and elucidate gaps within the current regulatory frameworks and guidelines. The *Guidebook on Good Practice for Medical Device Clinical Investigations* was developed.
Phase 3	The *Guidebook on Good Practice for Medical Device Clinical Investigations* was validated by an expert panel (n=4) consisting of National and European Experts, using SWOT Analysis to assess accuracy, relevance, and alignment with current regulatory standards.

RESULTS

The *Guidebook on Good Practice for Medical Device Clinical Investigations* consists of 11 sections (Figure 1)



The expert panel agreed that the Guidebook:

- **complies with the Regulations, supports more efficient operations, offers educational benefits, promotes the harmonisation of best practices, incorporates risk minimisation strategies, and introduces the use of artificial intelligence in the conduct of clinical investigations.**
- **requires timely revisions to reflect latest updates in Regulations and emerging technologies; and potentially restricts capacity to accommodate the individual characteristics of different clinical investigations.**
- **should incorporate supporting material with relevant resources tailored for stakeholders participating in the conduct of clinical investigations.**

CONCLUSION

The increasing sophistication of medical devices necessitates equally advanced regulatory assessment processes that safeguard patient safety and public health. The developed *Guidebook on Good Practice for Medical Device Clinical Investigations* establishes a concise baseline to outline a framework which delineates the expectations for clinical investigations and performance studies involving medical devices and In Vitro diagnostics supporting innovation. This structured approach ensures clarity, coherence, and ease of use, allowing stakeholders to navigate complex regulatory expectations and adopt harmonised, best-practice methodologies throughout the lifecycle of a clinical investigation.

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