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Harmonising Terminology for Signal Detection in Medical Device Vigilance

Project brief

Medical device safety, quality, and efficacy are fundamental to patient protection and public health. Signal detection plays a key role in post-market surveillance by enabling the early identification and management of emerging safety concerns. This research aims to develop harmonised definitions and terminology for signal detection and management in medical device vigilance.

Methodology

Scenario analysis of signal detection practices

- Literature review of signal detection practices focusing on legislation, guidelines and international approaches within materiovigilance.

Establishment and validation of definitions

- Development of a questionnaire to establish harmonised definitions and terminology within signal detection.

Focus Group Validation

- Dissemination of questionnaire to experts within competent authorities, economic operators and potential users of medical devices.

Results & conclusions

The study identifies a lack of harmonised and standardised approaches to signal detection and management in the medical devices field. In response, a List of Signal Detection Terminology and Definitions containing 30 terms was developed. Validation by a focus group of 10 experts showed consensus that the proposed terminology was clear, relevant, and appropriate for regulatory use.

These findings contribute toward a harmonised approach to materiovigilance across EU Member States. Further research is ongoing to validate the terminology with stakeholders, including economic operators, notified bodies, clinicians, and users, to support framework development.