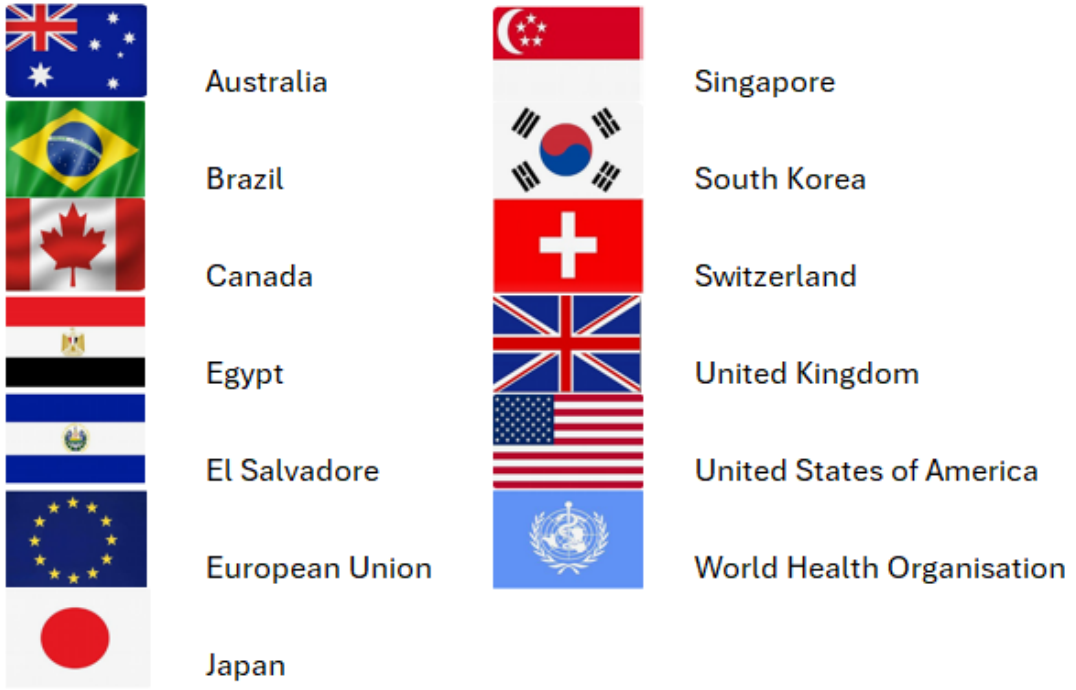
IMDRF International Medical Device Regulators Forum

# IMDRF Adverse Event Terminology WG

Andrea Hanson, Health Products Regulatory Authority (HPRA), Ireland, European Union
Evan Jacobs, Food and Drug Administration (US FDA), United States of America

# About US

- The Adverse Event Terminology and Coding working group was established in 2015.
- The group is composed of members from 11 regions.
- The group has two Co-Chairs (HPRA & FDA) and a AEWG Maintenance Chair (TGA).
- The group convenes every 3 weeks via teleconference. The next in person meeting will be held in October 2025.



# About US

The aim of the working group is to:

- Establish IMDRF adverse event terminology including terms for medical device malfunction, evaluation result/conclusion, patient/user outcome, and part/component of a medical device.
- Support the implementation and the use of the terminology through the provision of guidance documents and training materials.
- Improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events.

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# About US

Strategic Plan - IMDRF Key Objectives 2021-2025

1. Managing regulatory challenges for medical devices and innovative technologies by providing **timely and appropriate guidance**
2. **Strengthening post-market surveillance** for medical devices and implementing regulatory life cycle processes

- **Priority 2: Post-Market** - Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients.
- Topic: **Adverse Event Terminology Harmonize adverse event terminology** to expand terminology and systems being used to code information relating to medical device adverse events

# Publications (if any)

- IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes IMDRF/AE WG/N43FINAL: 2020 (Edition 4).
    - Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem
    - Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER) – Type of Investigation
    - Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Findings
    - Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER) – Investigation Conclusion
    - Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions
    - Annex F: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Health Impact
    - Annex G: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Component
- Maintenance of IMDRF AE Terminologies IMDRF/AE WG/N44FINAL:2020 (Edition3)
- Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators IMDRF/AET WG/N85 FINAL: 2024

# Ongoing work (or upcoming work if new work item)

## Adverse Event Terminology Website Pages and Web Browers

The Working group has reviewed the Adverse Event Terminology website pages and the IMDRF Code browser. The changes and improvements that have been identified have been shared with the Webmaster and will be implement over the coming period.

## MedDRA Codes

A subgroup of the AET Working group has had several meetings with MedDRA representatives to discuss the mapping of MedDRA codes to the IMDRF Annex A codes.
To date Annex A level 1 and level 2 codes have been reviewed and discussed. The review of level 3 codes is currently under consideration.

## Adverse Event Terminology Annual Maintenance

Work on the review of the change requests received during the 2025 Annual maintenance cycle will commence in September 2025.

# Ongoing work (or upcoming work if new work item)

## Guidance on Consideration for the selection of IMDRF Adverse Event Terminology codes and terms

The group has reviewed the feedback from the consultation on the draft Guidance Document. The document has been amended to reflect the feedback.
The group is currently exploring the possible options for the development of training material to support the launch/ publication of the document (e.g. a training video and online test).

## Review of the N43 and N44 Guidance Documents

The working group conducted a review of the N43 *Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes* and N44 *Maintenance of IMDRF AE Terminologies* during the in-person meeting in April 2025. The first draft of a combined/ merged document was compiled and a list of further changes for consideration was recorded.

Further work will continue on this work item in Q4 2025.

# Opportunities and Challenges

- Regulatory convergence with increased use of the Adverse Event Terminology and coding system.
- Increased harmonisation with use of common terminology.
- Opportunity for increased oversight and signal detection.
- Easier exchange of information.

- Additional tools for the implementation of training material would be beneficial.
- Further development of analytical algorithms is required.

# Thank you/Questions