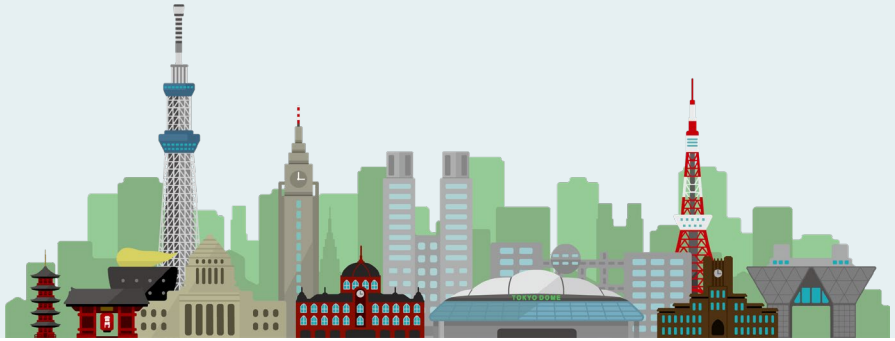
IMDRF International Medical Device Regulators Forum



Adverse Event Terminology and Coding Working Group

Nancy Pressly, Food and Drug Administration, USA.
Andrea Hanson, Health Products Regulatory Authority, Ireland.

IMDRF Management Committee Meeting, Tokyo, March 2025.

About US

The aim of the working group is to:

- Establish an adverse event terminology composed of the following four parts (fully published in 2020)
  - Terms for medical device problems
  - Terms for medical device components
  - Terms for cause investigation (type of investigation, investigation findings, investigation conclusion)
  - Terms for health effects (clinical signs and symptoms, health impact)
- Improve, harmonise and where necessary expand the terminology and underlying structure being used to code information relating to medical device adverse events

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About US

- The Adverse Event Terminology and Coding working group was established in 2015
- The group is composed of members from 12 regions & WHO.
- The group has two Co-Chairs (FDA & HPRA) and a AEWG Maintenance Chair (MHRA 2024 & TGA 2025).
- Convened every 3 weeks via teleconference. A face-to-face meeting is held twice a year.

Focus of Work

1. Leverage post-market monitoring and surveillance

   a) The continued development and improvement of the Adverse Event Terminology and coding system to ensure that it is accurate, agile and moving with innovation, through the management of queries and the **annual maintenance cycle**.

      (The 2024 Review update has been published on the IMDRF website.)

   b) Development of a Common Data Set for Adverse Event Data Exchange between IMDRF Regulators, through the:

      a) Development of the exchange mechanisms.
      b) Development of an “exchange request form”.
      c) Development of a guidance document to explain the system.

Focus of Work

2. Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance

   a) A training presentation / video to reinforce the key principles of the system (N43 document) published under https://www.imdrf.org/imdrf-trainings

   b) A guidance document to support the exchange of the Common Data Set published under IMDRF/AET WG/N85 FINAL: 2024

   c) Development of a **new** guidance document and a video to further support the practical use of the Adverse Event Terminology and coding system (**work in progress – 2025**).

   d) Review of the N43 & N44 documents (**2025 / 2026**)

   e) Website development (**2025**)

Opportunities and Challenges

Opportunities

The AET WG is investigating several areas to enhance and assist with the communication of information relating to the Adverse Event Terminology:

- Restructuring of the AET WG web pages on the IMDRF website to improve usability
- Development of interactive training material/ modules to support the guidance documents
- Use of tools to enhance the submission of change requests from stakeholders

Challenges

Funding is required for the development of quality training materials.

Publications

- IMDRF Annex updates result from the 2024 annual review have been published on the IMDRF website
- Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators IMDRF/AET WG/N85 FINAL: 2024
- IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes IMDRF/AE WG/N43FINAL: 2020 (Edition 4).
- Maintenance of IMDRF AE Terminologies IMDRF/AE WG/N44FINAL:2020 (Edition3).

Resources

IMDRF Terminology

IMDRF AE Terminology Guideline Main Body (N43 Document)

IMDRF AE WG Webpage (Includes links to the terminology web browser)

IMDRF AE Terminology (Current Version)

IMDRF Terminology Maintenance

IMDRF Terminology Maintenance (N44 Document)

IMDRF Terminology Maintenance Webpage

Change Request Form

Related Documents

Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators (N85 document)

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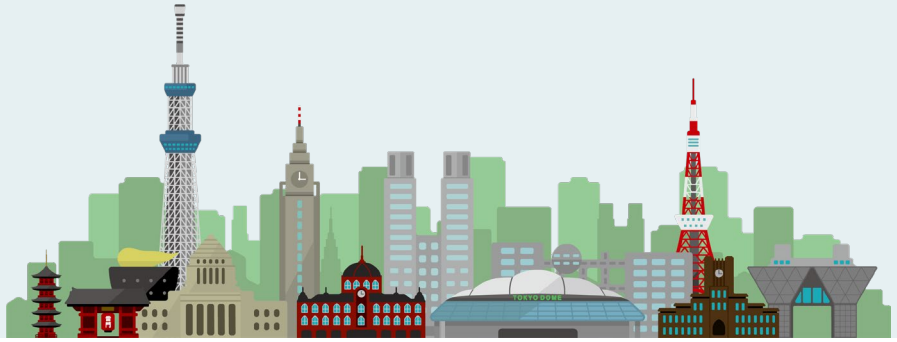

Thank you/Questions