Adverse Event Terminology Working Group Update

Working Group Chair(s):
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About the Working Group

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

Focus of Work

1) The continued development and improvement of the Adverse Event Terminology and coding system to ensure that it is accurate, agile and moving with innovation. **Annual maintenance cycle** for 2025 was completed and updates to the terminology and coding system were published on the IMDRF website in March. **380** change requests were received and **128** changes were accepted:

43 changes to Annex A	**28 changes to Annex E**
11 changes to Annex B	**17 changes to Annex F**
14 changes to Annex C	**10 changes to Annex G**
5 changes to Annex D	

This year's update also includes a mapping of IMDRF Annex A level 1 and level 2 codes to MedDRA, which was developed by a joint subgroup of the IMDRF AET WG and MedDRA MSSO.

Focus of Work

2) The development of Guidance to support the use of the Adverse Event Terminology and coding system

- **"*Considerations for the selection of IMDRF Adverse Event Terminology A Guide for Industry Partners and Healthcare Providers*. "** IMDRF/AET WG/N86 FINAL:2026 was finalised and published in February.

- Four online quizzes were developed and published to support the introduction of this new guidance document

- The working group is conducting a review of the ***N43 Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*** and ***N44 Maintenance of IMDRF AE Terminologies*** with the intention of combining them into a single guidance document that is consistent with the content of the newly-published considerations for selection (N86) guidance document. Work continues on this item.

Adverse Event Terminology Quizzes

N86