International Medical Device Regulator Forum (IMDRF) Adverse Event Terminology

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Virtual Regional Workshop on Good Regulatory Practices and Medical Device Regulation

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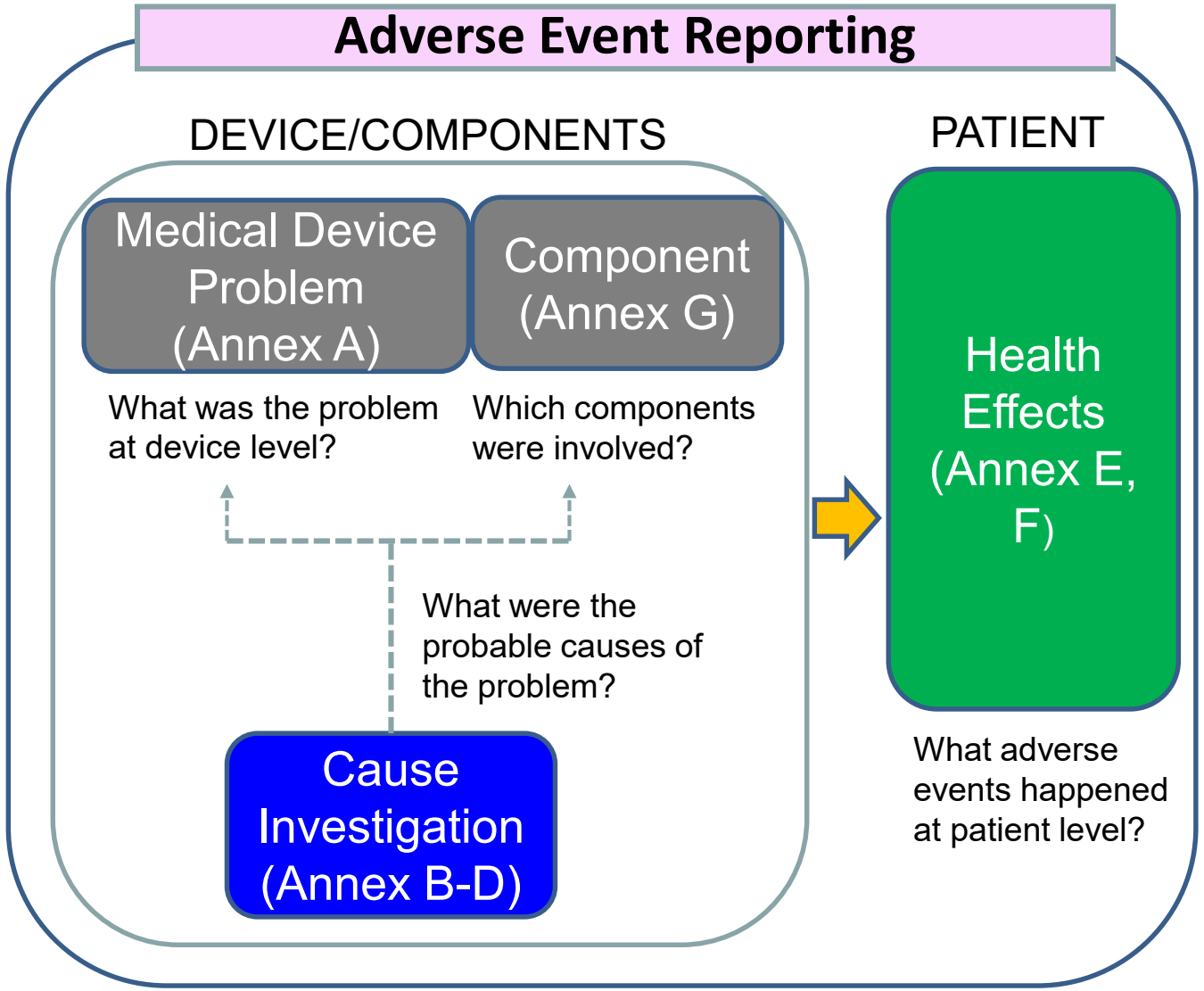
IMDRF AE Terminology Working Group

- **Mission**:
  - Development of a **harmonized terminology for reporting adverse events** related to medical devices including in-vitro diagnostics (IVDs).
- **Purpose**:
  - To improve the **efficiency** of the adverse events management systems for faster response by both industry and regulatory agencies, with the use of a **single, appropriate adverse event terminology and coding system**.
- **Benefits**:
  - Improves accuracy of capturing and reporting of MD-related adverse events;
  - Reduces ambiguity and increases effectiveness of the evaluation process;
  - Readily usable (in contrast to narrative text) for more sophisticated signal detection and trending analysis by querying functions and data visualization enabling faster response by both regulatory agencies and industries.

IMDRF Adverse Event Terminology

- **Annex A:** Medical Device Problem
- **Annex B:** Cause Investigation - Type of Investigation
- **Annex C:** Cause Investigation - Investigation Findings
- **Annex D:** Cause Investigation – Investigation Conclusion
- **Annex E:** Health Effects - Clinical Signs and Symptoms or Conditions **(aligned to MedDRA)**
- **Annex F:** Health Effects - Health Impact
- **Annex G:** Medical Device Component



Reference : IMDRF N43 document

IMDRF AE Terminology Working Group

Annex	Name of terminology	Description
A	**Medical device problem**	Describing problems (malfunction, deterioration of function, failure) of medical devices that have occurred in pre- or post-market contexts (e.g. clinical studies, clinical evaluation or post-market surveillance)
B	**Cause investigation** *Type of Investigation*	Includes what was investigated and what kind of investigation was conducted
C	**Cause investigation** *Investigation Findings*	Findings that are keys to identifying the root cause
D	**Cause investigation** *Investigation Conclusion*	Conclusions derived from the investigation and specifies the root cause of the specific adverse event
E	**Health Effects** *Clinical Signs, Symptoms and Conditions*	Describing the clinical signs, symptoms and conditions of the affected person appearing as a result of the medical device adverse event/incident.
F	**Health Effects** *Health Impact*	Describing the consequences of the medical device adverse event/incident on the person affected.
G	**Component**	Describing the parts and components which were involved in, or affected by, the medical device adverse event/incident.

IMDRF AE Terminology

IMDRF Adverse Event Terminology (Excel Format)

IMDRF AE terminology is provided in Excel format under IMDRF/AE WG/N43.

Since Edition 4 published on 20 April 2020, all annexes are provided in a new common format. The contents of each column are explained in a README file.

IMDRF Adverse Event Terminology Web Browser

The web browser for IMDRF AE terms ensures user-friendly searching and hence better and more adequate use of terms by reporters/regulators.

- Annex A: Medical Device Problem
- Annex B: Cause Investigation - Type of Investigation
- Annex C: Cause Investigation - Investigation Findings
- Annex D: Cause Investigation – Investigation Conclusion
- Annex E: Health Effects - Clinical Signs and Symptoms or Conditions
- Annex F: Health Effects - Health Impact
- Annex G: Medical Device Component

IMDRF AE Terminology

- Available in excel and json formats

IMDRF code: IMDRF/AE WG/N43FINAL:2020 (Edition 4) **Published date**: 20 April 2020

Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes
PDF (1.22 mb) DOCX (279.8 kb)

IMDRF code: IMDRF/AE WG/N43FINAL:2023 (Release No. 2023) **Published date**: 16 February 2023

Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem
XLSX (60.21 kb) JSON (167.95 kb)

Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Type of Investigation
XLSX (21.98 kb) JSON (14.08 kb)

Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Findings
XLSX (31.55 kb) JSON (52.26 kb)

Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Conclusion
XLSX (23.4 kb) JSON (16.22 kb)

Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions (Version 1 - 23Feb23)
XLSX (190.29 kb) JSON (392.24 kb)

Annex F: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Health Impact
XLSX (24.08 kb) JSON (22.2 kb)

Annex G: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Component
XLSX (41.36 kb) JSON (86.71 kb)

IMDRF AE Terminology

- Web Browser

Annex A: Medical Device Problem

Release Number: 2023

Working Group: Adverse Event Terminology

By typing text in the free text field, elements not matching the text are removed. The text inserted is searched in all the fields composing each term. The text found is highlighted in red.

If the element containing the desired text is not visible, it could be necessary to expand the parent term. To make this operation automatic, select the check box Expand/collapse automatically.

The button "Expand all/Collapse all" allows to collapse or collapse all the terms in order to visualize the entire structure.

To reset the search and restore the initial status of the IMDRF web browser, click the Reset button.

IMDRF Terms and Definitions use American spelling.

Expand all | Reset

☐ Expand/collapse automatically

Search Here

- A01 - Patient Device Interaction Problem
Problem related to the interaction between the patient and the device.

+ A0101 - Patient-Device Incompatibility
Problem associated with the interaction between the patient's physiology or anatomy and the device that affects the patient and/or the device.

+ A0102 - Osseointegration Problem
Problem associated with interconnection between the bone tissue and the implanted device.

A0103 - Loosening of Implant Not Related to Bone-Ingrowth
Problem associated with the loss of direct anchorage of an implanted device over time or due to an injury.

+ A0104 - Migration or Expulsion of Device
Problem with an implanted or invasive device moving within the body, or being completely expelled from the body.

Maintenance of IMDRF AE Terminology

- The terms in the Annexes are maintained by the AE Working Group.
- The IMDRF AE terminology is always open for Change Requests.
- The **cutoff date** for inclusion in the next release is **1 September**. The Change Requests will then be reviewed by IMDRF, and the updated terminology and outcome of Change Requests will be **published in March**.
- Proposal of addition/modification/deletion of the terms must be submitted to AE WG by either **National Competent Authorities or Stakeholder Organizations**, using the **Change Request form**.

Maintenance of IMDRF AE Terminology

Things to Note

- For change request submissions, it is important to include the **rationale** and provide a **specific example of an incident** that would require the requested term. This will enable AEWG to better understand the need for a new term or to modify an existing term.
- Annex E: Health Effects - Clinical Signs and Symptoms or Conditions, should **not** be used for clinical conditions that are **existing clinical conditions/illnesses.** It is meant to describe clinical signs and symptoms or conditions that are a **consequence of device use/failure.**

Appendix B: Change Log

Requester information		Change Proposal Information										
		Identification of code / term for which proposal is made						Proposal of change				
Date submitted (DD/MM/YYYY)	Submitter (organisation name)	Terminology (Annex A, B, C, D, E, F, G)	Version of Annex	Code	Term	Location in the hierarchy	Definition	Category of change (Select: Add, delete, modify)	Description of change (e.g. "modification of definition ...")	Rationale for change (e.g. "the change is necessary to accommodate a new type of device...")	Impact on other existing terms	Example of an incident which would be coded using the proposed term

Thank you