IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

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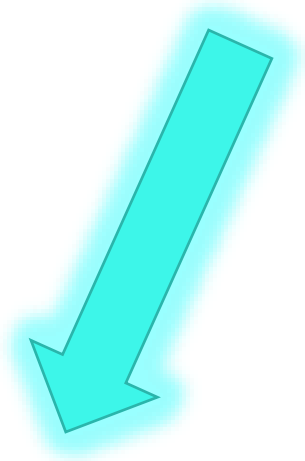

Provide your feedback on this Working Group!

Follow this link and let us know:

https://forms.office.com/e/nJNdyjGQMN

IMDRF 24th Session – Berlin, Germany

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 (FDA & HPRA) and a AEWG Maintenance Chair (MHRA).
- The group convenes every 3 weeks via teleconference. A face-to-face meeting will be held in October 2023.

About Us

The aim of the working group is to:

- Improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events, and
- Establish and maintain IMDRF adverse event terminology composed of the following three parts: terms for medical device malfunction, terms for patient/user outcome and terms for part/component of medical device.

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

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)

Ongoing work

1. Leverage post-market monitoring and surveillance

   a) The 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.
      d) The implementation of a pilot study.

   b) 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**.

Ongoing work

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

   a) The development of a training presentation / video to reinforce the key principles of the system (N43 document).

   b) The development of a guidance document to support the exchange of the Common Data Set.

   c) The development of a **new** guidance document and a video to further support the practical use of the Adverse Event Terminology and coding system.

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.

- More guidance is needed to support the practical use of the codes.
- Confidentiality arrangement and EU General Data Protection Regulation (GDPR) need to be factored into the use and the exchange of the Common Data Set.
- Further development of analytical algorithms is required.

Resources

IMDRF Terminology

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

IMDRF AE Terminology (Current Version)

IMDRF Terminology Maintenance

IMDRF Terminology Maintenance Webpage

Change Request Form

Related Documents

IMDRF AE Terminology Guideline Main Body (N43 Document)

IMDRF Terminology Maintenance (N44 Document)

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Thank you/Questions

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