Adverse Event Terminology Working Group

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Adverse Event Terminology Working Group

Purpose:

- 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

Adverse Event Terminology Working Group

Current Activities:

- **The WG continues to meet every 3 weeks to progress the ongoing work items**
  - Reinstated in-person meetings. Met 10/2023 in Ottawa, Canada
  - Upcoming meetings
    - 4/2024 Bern, Switzerland
    - 10/2024 London, England
  - Added new representatives to the WG from Egypt
- **2024 terminology updates to publish in March**
  - Total change requests received – 123
  - Change requests rejected – 44
  - Change requests resulting in modification – 12
  - Change requests resulting in new term/code – 67

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Current Activities

- **Work continues on a common data set for adverse event report exchange between regulators**
  - Conducting pilot exchanges between a sub-group of regulators to identify areas that need clarification or modifying.
  - First pilot exchange resulted in changes to how data is requested
  - Second pilot exchange resulted in the successful sharing of small data sets to 2 regulators.
  - Third pilot, currently underway, will share larger data sets among all participants in the pilot to assure larger data sets can be sent, accepted and combined into useful data.
- **Work is underway on the new document on points to consider for code selection**
  - Document will provide additional guidance on how to use the coding sets in conjunction with one another to properly code an adverse event.
  - Considering additional options for sharing this information in the future such as additional training modules that can be accessed on-demand.


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