Adverse Event Terminology Working Group

Stephanie Shedd
International Policy Analyst
U.S. FDA
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
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
  o Conducting pilot exchanges between a sub-group of regulators to identify areas that need clarification or modifying.
  o First pilot exchange resulted in changes to how data is requested
  o Second pilot exchange resulted in the successful sharing of small data sets to 2 regulators.
  o 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
  o Document will provide additional guidance on how to use the coding sets in conjunction with one another to properly code an adverse event.
  o Considering additional options for sharing this information in the future such as additional training modules that can be accessed on-demand.