



IMDRF

International Medical Device
Regulators Forum | 26th Session

Adverse Event Terminology Working Group Update

AET: Committee Meetings and Membership

Membership :

Colleagues from El Salvador have joined the working group

Meetings:

The group continues to meet, via telecon, every 3 weeks

In person meetings are held twice a year :

- 2023: October – Health Canada
- 2024: April – Swiss medic
October - MHRA

AET: IMDRF Code Maintenance

- The 2024 annual review maintenance work will commence in September 2024.
- A review of the Annual Maintenance SOP has been undertaken.
 - Several improved efficiencies and changes to the process have been identified.
 - These changes will be implemented over the coming months.
 - The updated SOP will be ready for endorsement at the January 2025 Management Committee meeting

AET: Documents For Endorsement

- **MedDRA MOU**

- Updates to the current IMDRF / MedDRA MOU to expand the scope to include additional annexes (not just Annex E) has been shared with MedDRA.
- MedDRA has reviewed and shared the updated draft with ICH management.
- The updated MOU is proposed for endorsement

- **Common Data Set for Adverse Event Data Exchange**

- 3 pilot studies have been undertaken
- The process and the supporting documents have been finalised
 - Common Data Set for Adverse Event Data Exchange Guidance Document
 - CDS Request form
 - Data exchange file template
- These documents are proposed for endorsement & publication

AET: Documents For Endorsement

- **A Guidance document to support the practical use of the Adverse Event Terminology**
- ‘Considerations for the selection of IMDRF Adverse Event Terminology, A Guide for Industry Partners and Healthcare Providers’. Guidance Document – This document is proposed for endorsement and publication in draft
- A webinar is planned for October, to explain the document and seek feedback from stakeholders.
- Following the consultation period, the group will finalize the document and develop training material to support the launch/ publication of the document



PUBLIC
MARKET

