



IMDRF International Medical Device
Regulators Forum

IMDRF ADVERSE EVENT TERMINOLOGY AND CODING WORKING GROUP UPDATE

Co-Chairs: EU and US

AE Working Group

Goal

Develop harmonized terminology to code information relating to medical device adverse events.

Benefits

- Improves the efficiency of adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single harmonized adverse event terminology and coding system
- Improved accuracy of capturing and reporting of medical device related adverse events
- Reduced ambiguity
- Better usability
- More sophisticated signal detection

Current Work Items

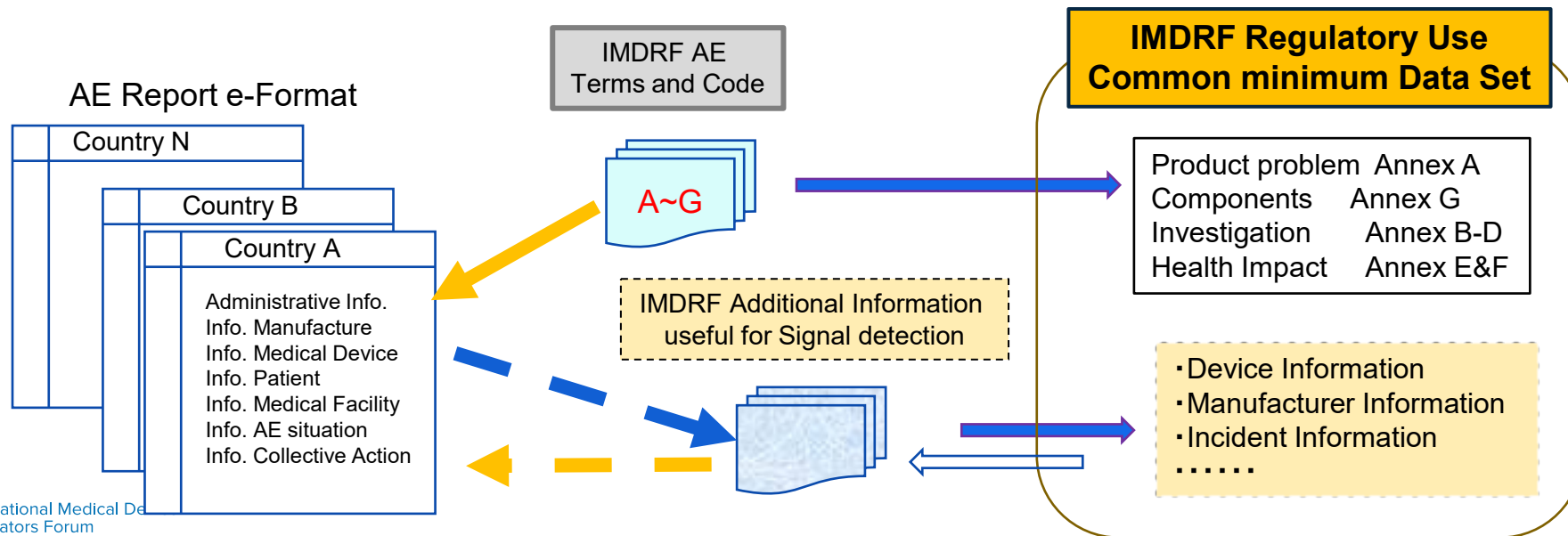
1. NWIE on harmonizing AE terminology for signal detection
2. AE terminology maintenance

NWIE - Harmonizing Adverse Event Terminology

Purpose

Harmonize additional AE data to be able to utilize adverse event reporting for signal detection

- **Phase 1** Define additional sets of harmonized adverse event terms and codes
- **Phase 2** Develop common minimum data requirements for reporting that are standardized across jurisdictions



NWIE - Current Progress

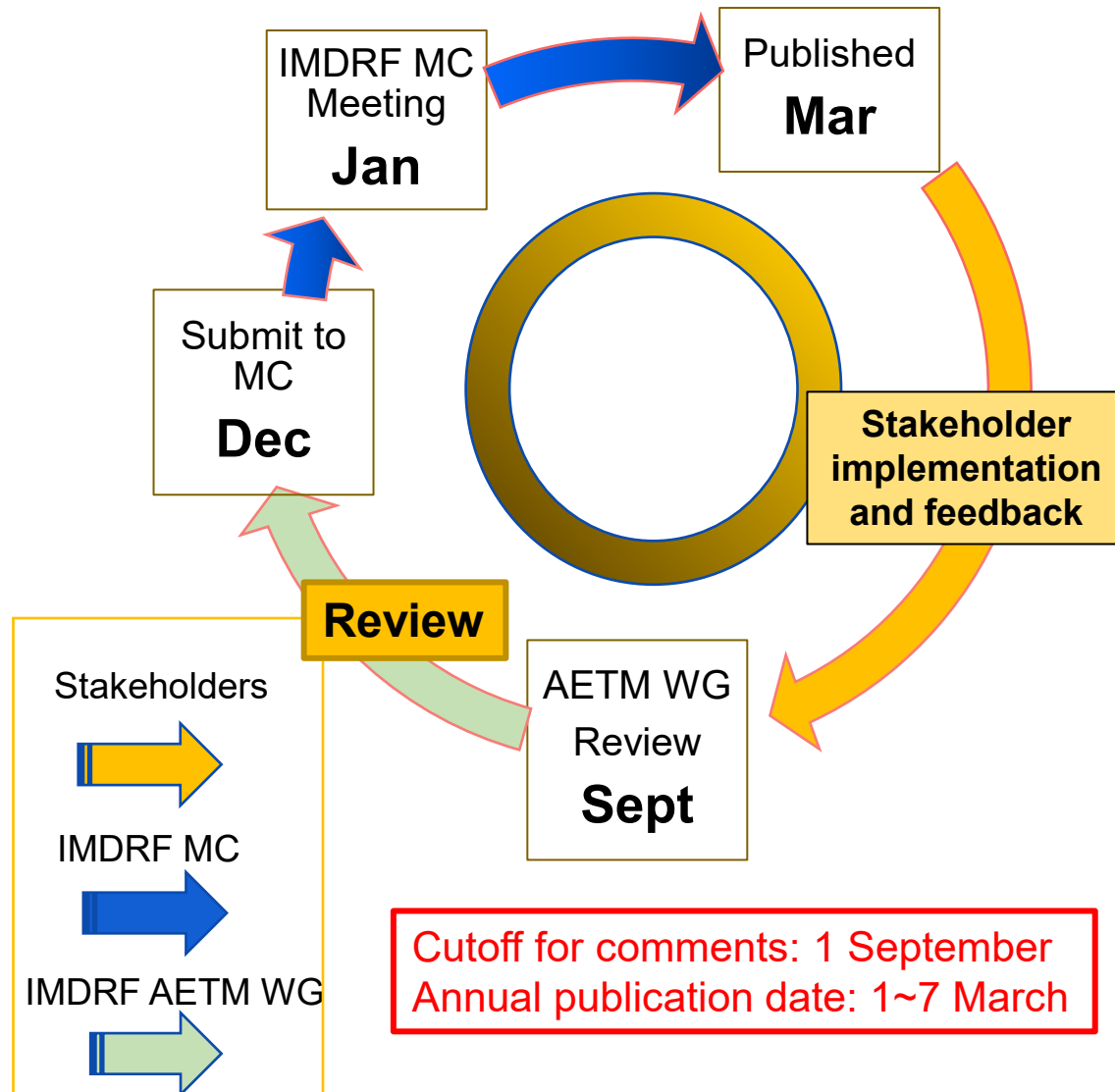
The WG compiled a “common data set” for sharing of adverse event report information among IMDRF jurisdictions based on the reporting formats used by member jurisdictions. The WG extensively discussed each field to determine if including such a field would aid in signal detection using this common data set.

The WG has begun drafting guidelines which lay out the “common data set” and provide guidelines for the sharing of report among IMDRF jurisdictions.

Next steps

1. The working group will focus on Terminology Maintenance from September to January.
2. Beginning in early 2023 the working group expects to begin testing of the methodology for sharing reports and completing the draft guideline.

AE Terminology Maintenance



Report to the MC

1. Maintenance leadership

Following the procedures in IMDRF N44 "Maintenance of IMDRF AE Terminologies," the WG agreed to rotate the chair every 2 years. Singapore is beginning its second year as Maintenance Lead.

2. Comments for review

The deadline for the WG to receive comments from various stakeholders was Sept 1. The WG will review these comments and submit a Change Log and updated annexes for MC approval in January and expected publication in March.

Thank you!

Questions?

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