IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

13:00 – 13:15

Adverse Event Terminology (USA / EU)

Andrea Hanson

Market Analysis Lead, Health Products Regulatory Authority

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

Nancy Pressly, Working Group Co-Chair, US Food and Drug Administration (FDA)

Andrea Hanson, Working Group Co-Chair, Health Products Regulatory Authority (HPRA)

28th March 2023

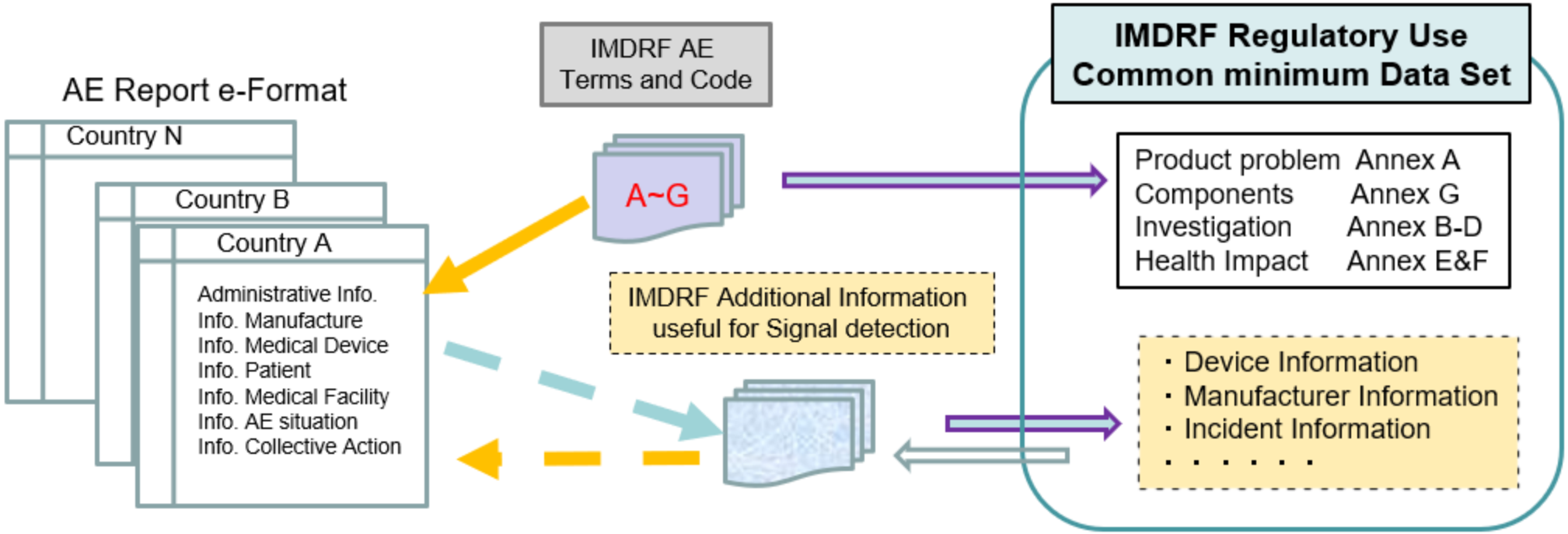
1. CURRENT ACTIVITIES

Work in Progress

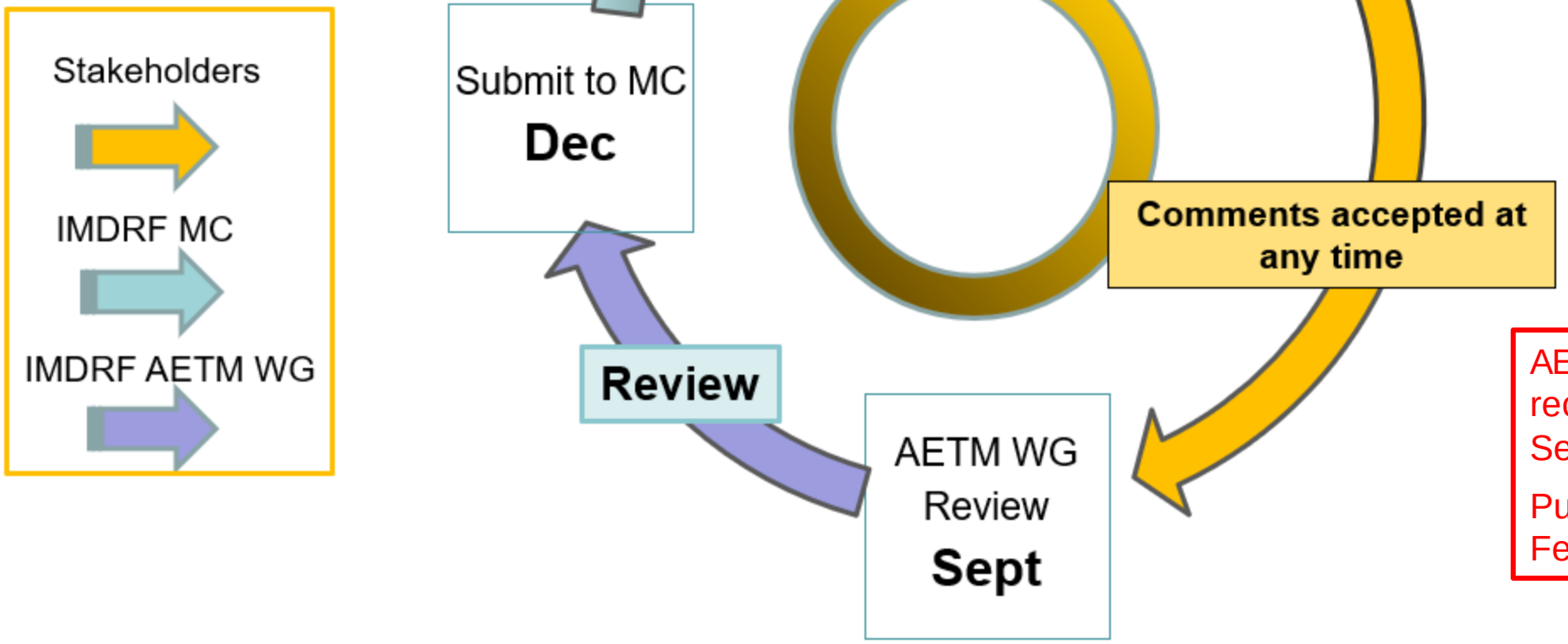
Expanding the Harmonization of Adverse Event Terminology

Issues being addressed:

- Common minimum data requirements for reporting, including defined data fields, data requirements, and data structure.
- Common format for data exchange between jurisdictions.



2. TERMINOLOGY MAINTENANCE



149 change requests were reviewed

- 48 accepted
- 20 modified
- 81 rejected

AETM WG reviews comments received by the 1st of September

Publication of updates – February 2023

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)

IMDRF International Medical Device Regulators Forum

Thank you/Questions