IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

IMDRF Open Stakeholders Forum Webinar
Sept 14th 2021

Presented by
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Pharmaceuticals and Medical Devices Agency (PMDA)

1. CURRENT ACTIVITIES

IMDRF International Medical Device Regulators Forum

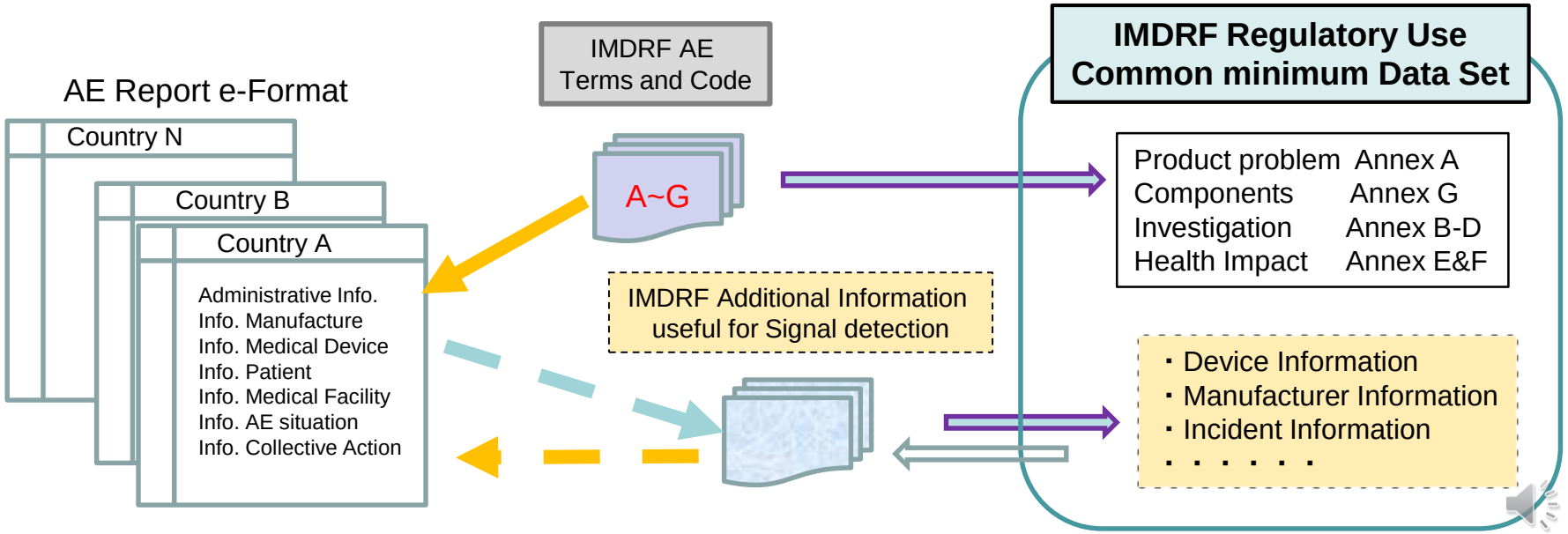
New Work Item Proposal Extension

Finding the harmonization of adverse event terminology

Purpose

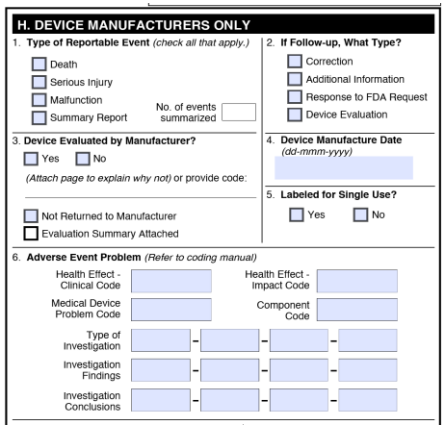
- Expand the harmonisation of adverse event terminology, and
- Standardize data fields across jurisdictions
- To be able to fully exploit adverse event reporting for signal detection.

- **Phase 1** Define additional sets of harmonised terms and codes
- **Phase 2** Common minimum data requirements for reporting



Finding other necessary terms for signal detection purpose from currently using AER forms in each regulations.

E-Form for AER in each jurisdiction



H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** *(check all that apply.)*
   - ☐ Death
   - ☐ Serious Injury
   - ☐ Malfunction
   - ☐ Summary Report

   No. of events summarized

2. **If Follow-up, What Type?**
   - ☐ Correction
   - ☐ Additional Information
   - ☐ Response to FDA Request
   - ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?** ☐ Yes ☐ No

   (Attach page to explain why not) or provide code:

   ☐ Not Returned to Manufacturer
   ☐ Evaluation Summary Attached

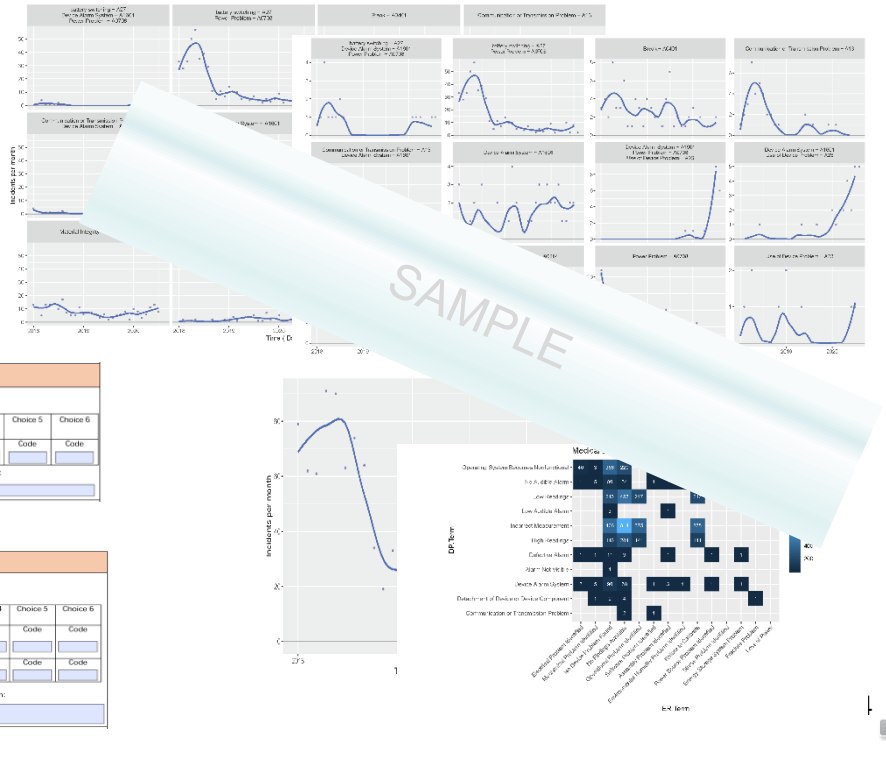
4. **Device Manufacture Date** *(dd-mmm-yyyy)*

5. **Labeled for Single Use?** ☐ Yes ☐ No

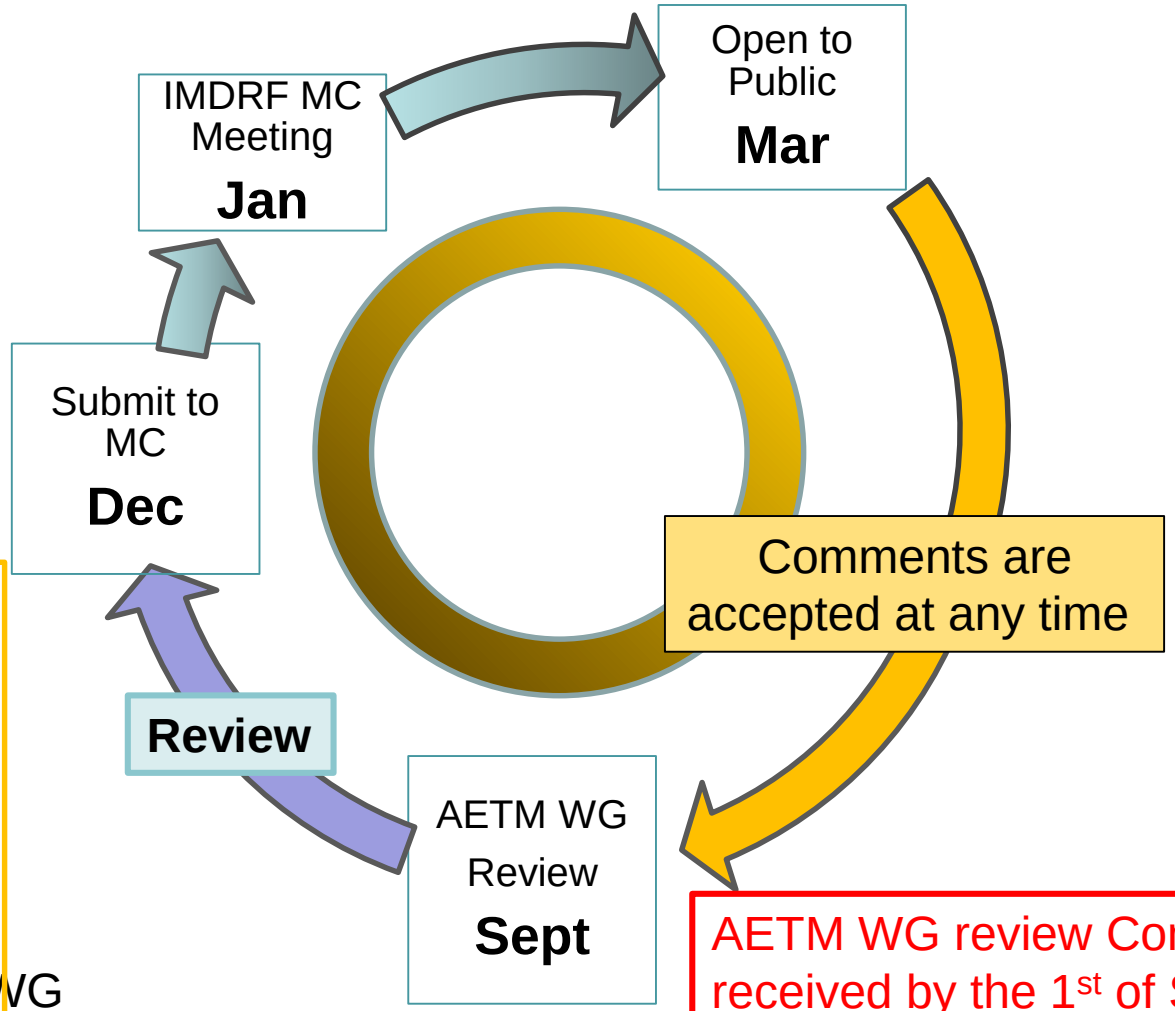
6. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect - Clinical Code		Health Effect - Impact Code	
Medical Device Problem Code		Component Code	
Type of Investigation	– – –		
Investigation Findings	– – –		
Investigation Conclusions	– – –		

Image of Signal detection
By each jurisdiction by their own way using the IMDRF common term



2. MAINTENANCE



Stakeholders

IMDRF MC

IMDRF AETM WG

AETM WG review Comments received by the 1st of September Will reflect for March Publication

Thank you for your kind attention!

Resources

IMDRF Terminology

- IMDRF AE WG Webpage (Includes links to the terminology web browser)
- IMDRF AE Terminology (Current Version)
- IMDRF AE Terminology (Archived Versions)

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)