



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)





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1. CURRENT ACTIVITIES



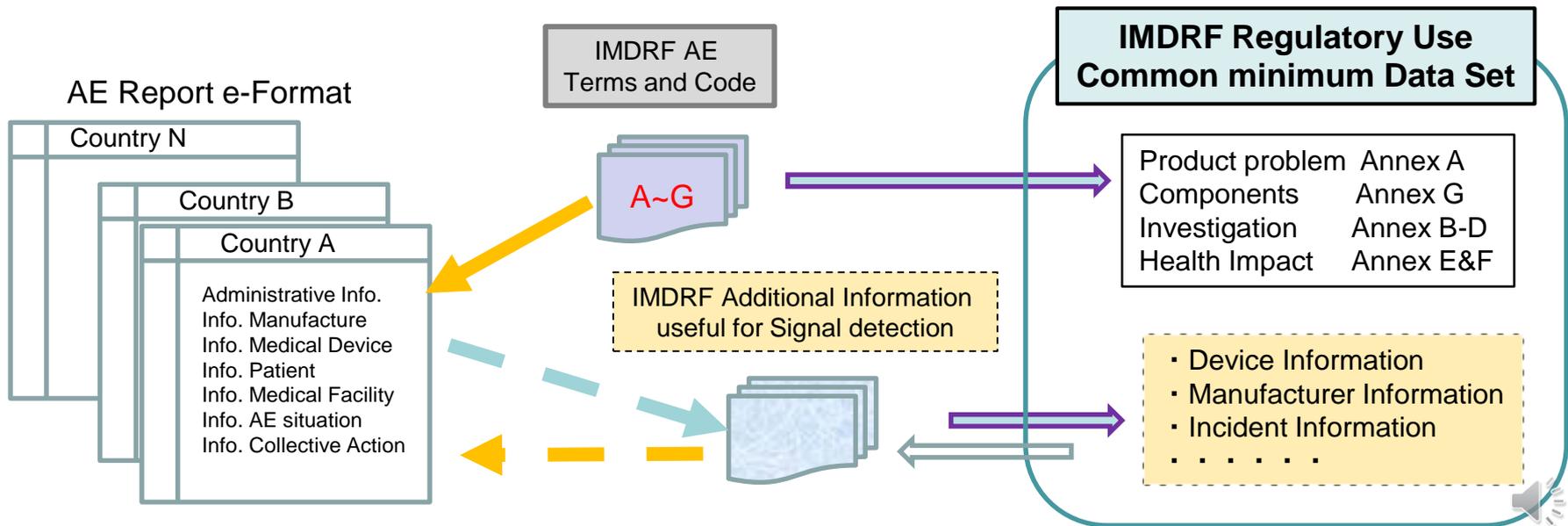
New Work Item Proposal Extension

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





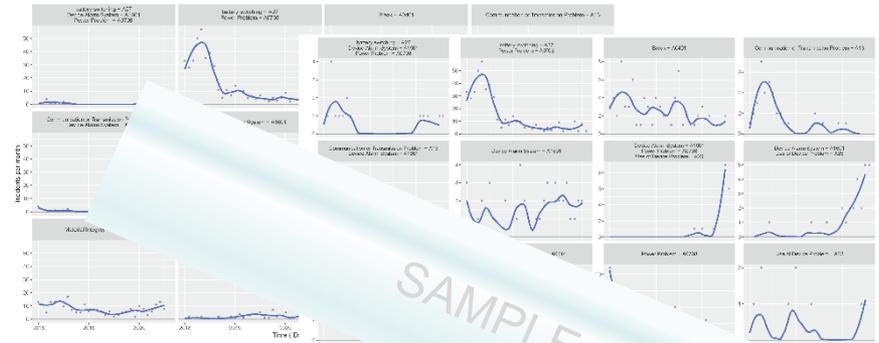
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Finding other necessary terms for signal detection purpose from currently using AER forms in each regulations.

E-Form for AER in each jurisdiction

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

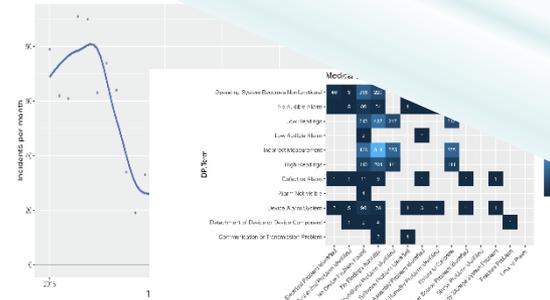
H. DEVICE MANUFACTURERS ONLY	
1. Type of Reportable Event (check all that apply.) <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction <input type="checkbox"/> Summary Report No. of events summarized: <input type="text"/>	2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation
3. Device Evaluated by Manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No (Attach page to explain why not) or provide code:	4. Device Manufacture Date (dd-mm-yyyy)
<input type="checkbox"/> Not Returned to Manufacturer <input type="checkbox"/> Evaluation Summary Attached	5. Labeled for Single Use? <input type="checkbox"/> Yes <input type="checkbox"/> No
6. Adverse Event Problem (Refer to coding manual)	
Health Effect - Clinical Code: <input type="text"/> Medical Device Problem Code: <input type="text"/> Type of Investigation: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> Investigation Findings: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> Investigation Conclusions: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>	Health Effect - Impact Code: <input type="text"/> Component Code: <input type="text"/> Type of Investigation: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> Investigation Findings: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> Investigation Conclusions: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>



IMDRF Cause Investigation* terms and codes (Annex B, C, D)								
Coding with IMDRF terms is a mandatory requirement. IMDRF Cause Investigation: Type of investigation (Annex B)	Choice 1 (most relevant) Code	Choice 2 Code	Choice 3 Code	Choice 4 Code	Choice 5 Code	Choice 6 Code	Choice 7 Code	Choice 8 Code
IMDRF Cause Investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code	Code	Code
IMDRF Cause Investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code	Code	Code
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:								
IMDRF Component codes (Annex E) Coding with IMDRF terms is a mandatory requirement.								
IMDRF Component codes (Annex E)	Choice 1 (most relevant) Code	Choice 2 Code	Choice 3 Code	Choice 4 Code	Choice 5 Code	Choice 6 Code	Choice 7 Code	Choice 8 Code
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:								

3.2 Medical device problem information						
IMDRF Medical device problem codes (Annex A) Coding with IMDRF terms is a mandatory requirement.						
IMDRF Medical device problem codes	Choice 1 (most relevant) Code	Choice 2 Code	Choice 3 Code	Choice 4 Code	Choice 5 Code	Choice 6 Code
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:						

3.3 Patient information						
IMDRF Health Effect* terms and codes (Annex E, F) Coding with IMDRF terms is a mandatory requirement.						
IMDRF Clinical signs, symptoms, and conditions codes (Annex E)	Choice 1 (most relevant) Code	Choice 2 Code	Choice 3 Code	Choice 4 Code	Choice 5 Code	Choice 6 Code
IMDRF Health impact codes (Annex F)	Code	Code	Code	Code	Code	Code
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:						





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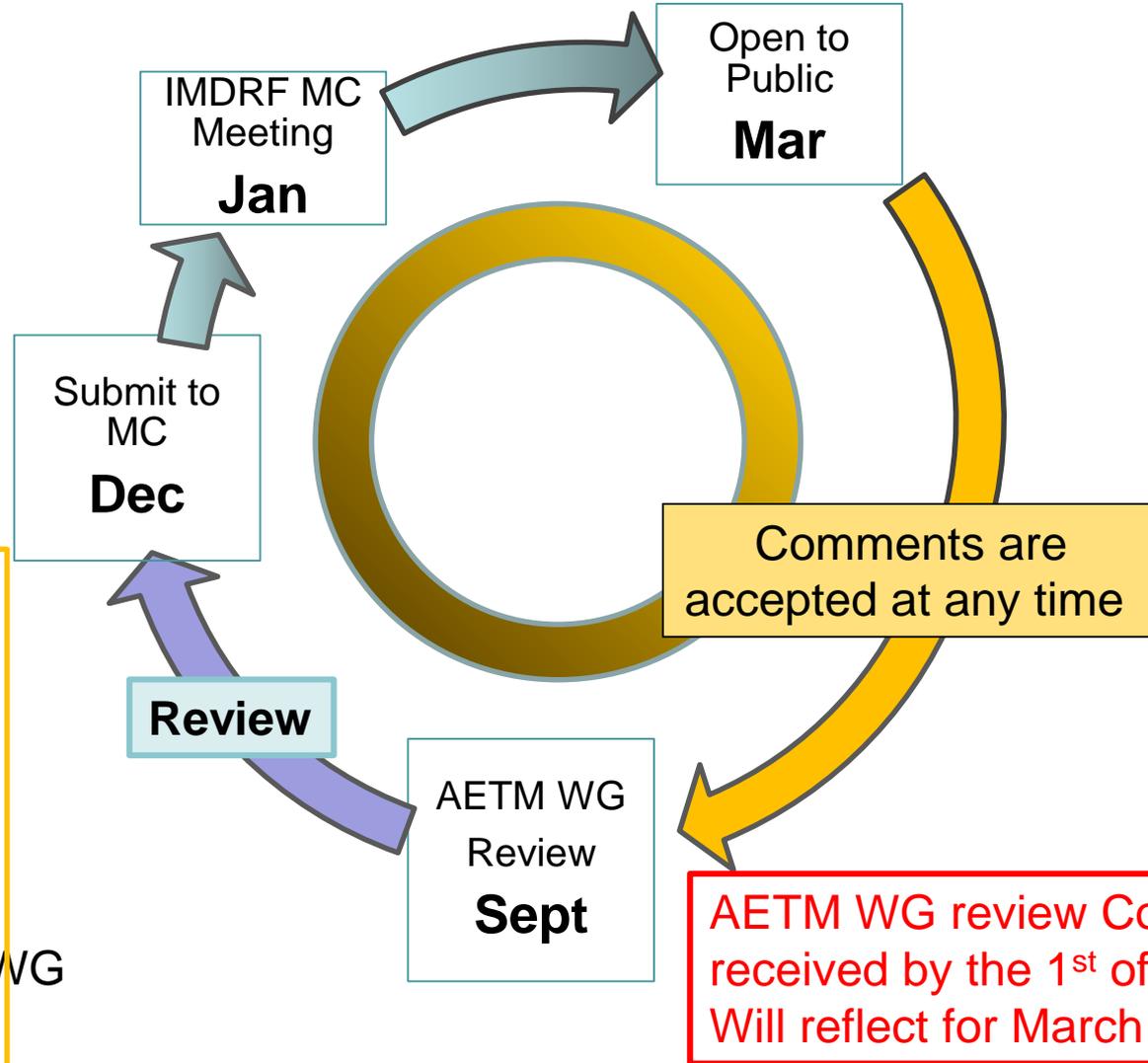
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2. MAINTENANCE





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Stakeholders



IMDRF MC



IMDRF AETM WG





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 \(N44 Document\)](#)

