



IMDRF

International Medical
Device Regulators Forum

Adverse Event Terminology and Coding Working Group

IMDRF Open Stakeholders Forum Webinar
Sept 14th 2021

Presented by
H. Ishikawa, Working Group Chair
Pharmaceuticals and Medical Devices Agency (PMDA)





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1. CURRENT ACTIVITIES





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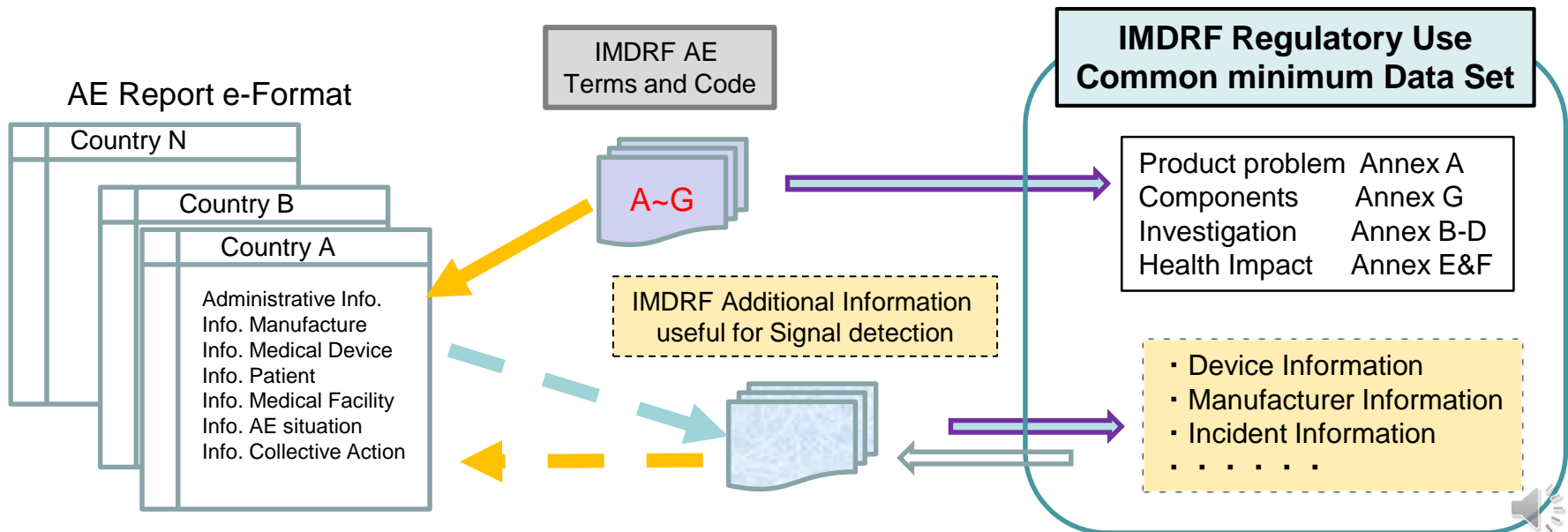
New Work Item Proposal Extension

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.)

☐ 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-mm-yyyy)

5. Labeled for Single Use?

☐ Yes ☐ No

6. Adverse Event Problem (Refer to coding manual)

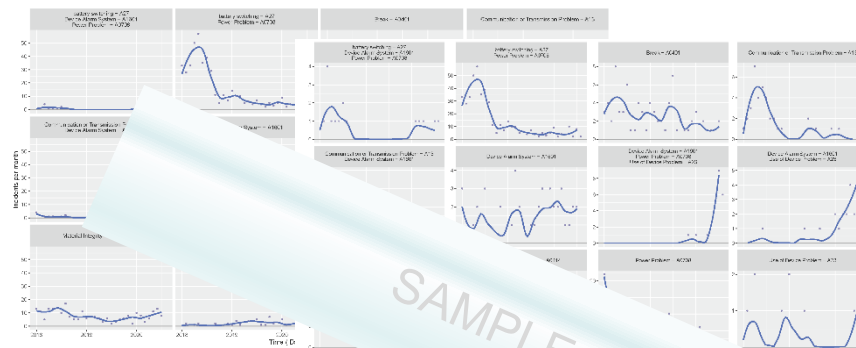
Health Effect - Clinical Code: Health Effect - Impact Code:

Medical Device Problem Code: Component Code:

Type of Investigation:

Investigation Findings:

Investigation Conclusions:



IMDRF Cause Investigation* terms and codes (Annex B, C, D)

a. Coding with IMDRF terms is a mandatory requirement.

IMDRF Cause Investigation: Type of investigation (Annex B)

Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
Code	Code	Code	Code	Code	Code	Code	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:

f. IMDRF Component codes (Annex E)

Coding with IMDRF terms is a mandatory requirement.

IMDRF Component codes (Annex E)

Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

3.2 Medical device problem information

a. IMDRF Medical device problem codes (Annex A)

Coding with IMDRF terms is a mandatory requirement.

IMDRF Medical device problem codes

Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

3.3 Patient information

a. IMDRF Health Effect* terms and codes (Annex E, F)

Coding with IMDRF terms is a mandatory requirement.

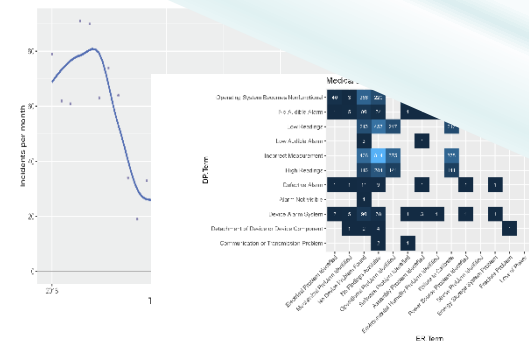
IMDRF Health Effect* terms and codes (Annex E, F)

Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
Code	Code	Code	Code	Code	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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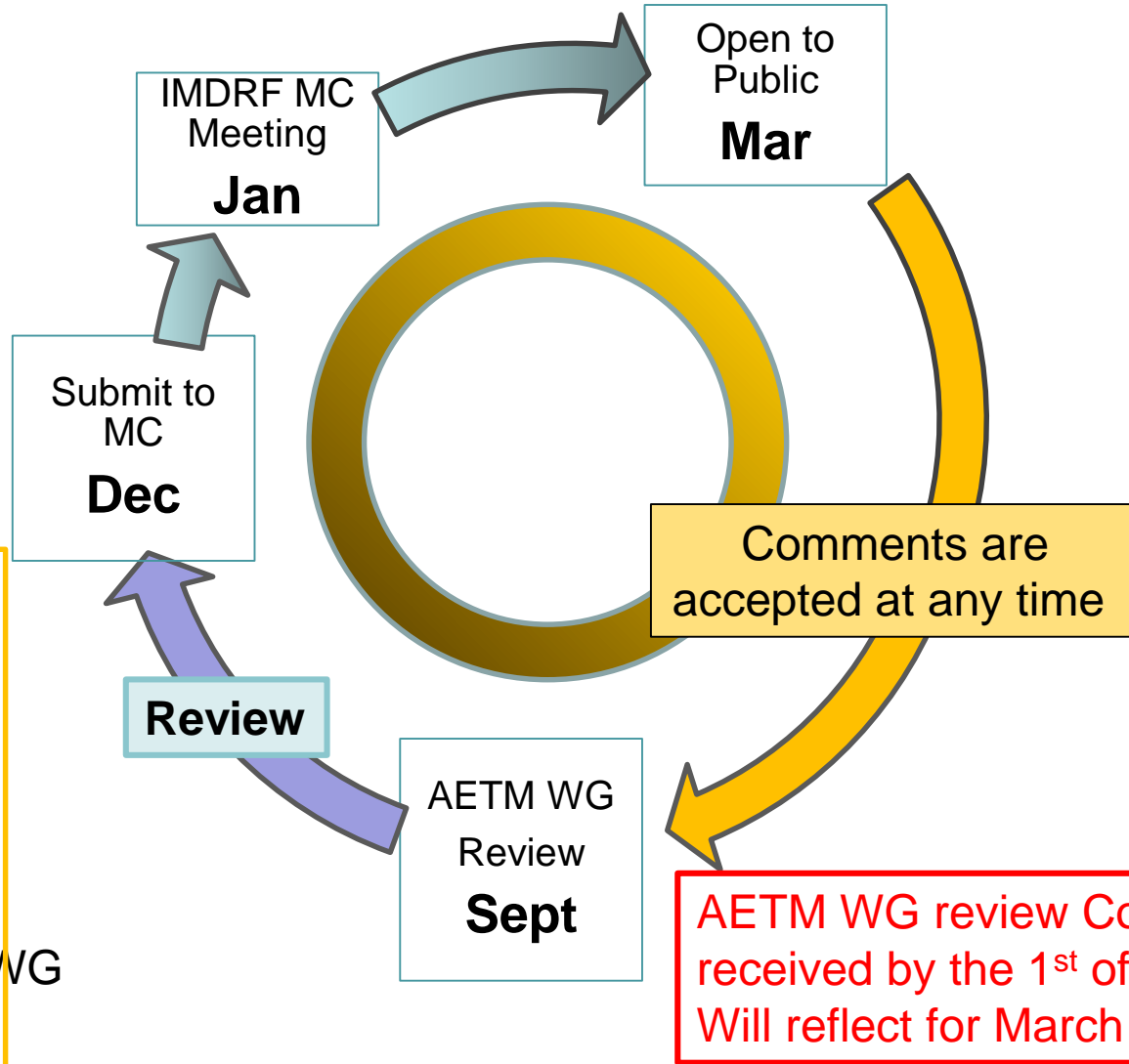
2. MAINTENANCE





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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 \(N44 Document\)](#)

