IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

March 2017

Working Group Chair:

H. Ishikawa

Office of Standards and Guidelines Development

Pharmaceuticals and Medical Devices Agency

Member list

Australia: TGA
- Pamela Carter
- Jorge Garcia

Brazil: ANVISA
- Maria Gloria Vicente
- Adriana Moufarrege
- Guilherme Antonio Marques Buss

Canada: Health Canada
- Mary Raphael

European Union:
- Jean-François Roche (EC)
- Tony Sant (UK, MHRA)
- Claudius Griesinger (EC/JRC)
- Graham Nash (UK, MHRA)
- Tim Raemaekers (EC/JRC)

Russia: Roszdravnadzor
- Aysylu Valeeva
- Elena Astapenko

WHO: Anita Sands

Japan: PMDA
- Hiroshi Ishikawa (Chair)
- Mari Shirotani
- Madoka Murakami
- Takako Niwa
- Kaori Ogawa

MHLW
- Miki Ota
- Noriaki Tokunaga

US: FDA
- Nancy Pressly
- Evan Jacobs

Singapore: HSA
- Wong Woei Jiuang

AHWP: Sasikala Devi Thangavelu

<Obsever>

Kazakhstan:
- Gulnar Berkimbayeva
- Nursultan Kalamov

Recent Meetings

- Nov 4, 2016

  13th Teleconference

  - Dec 13-16, 2016

  3rd Face to Face meeting in Tokyo, Japan

- Feb 2, 10, 2017

  14th and 15th Teleconference

Coming Meetings

- April – May, 2017

  Teleconference

- June 13-16

  4th Face to Face meeting in Ispra, Italy

NWIP: Adverse Event Terminology and Coding

Initial submission: September 2014

Not adopted

Followed by discussions in the small expert WG

Adoption: March 2015

Mission;

Development of a harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics (IVDs).

Purpose;

To improve the efficiency of the adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single, appropriate adverse event terminology and coding system.

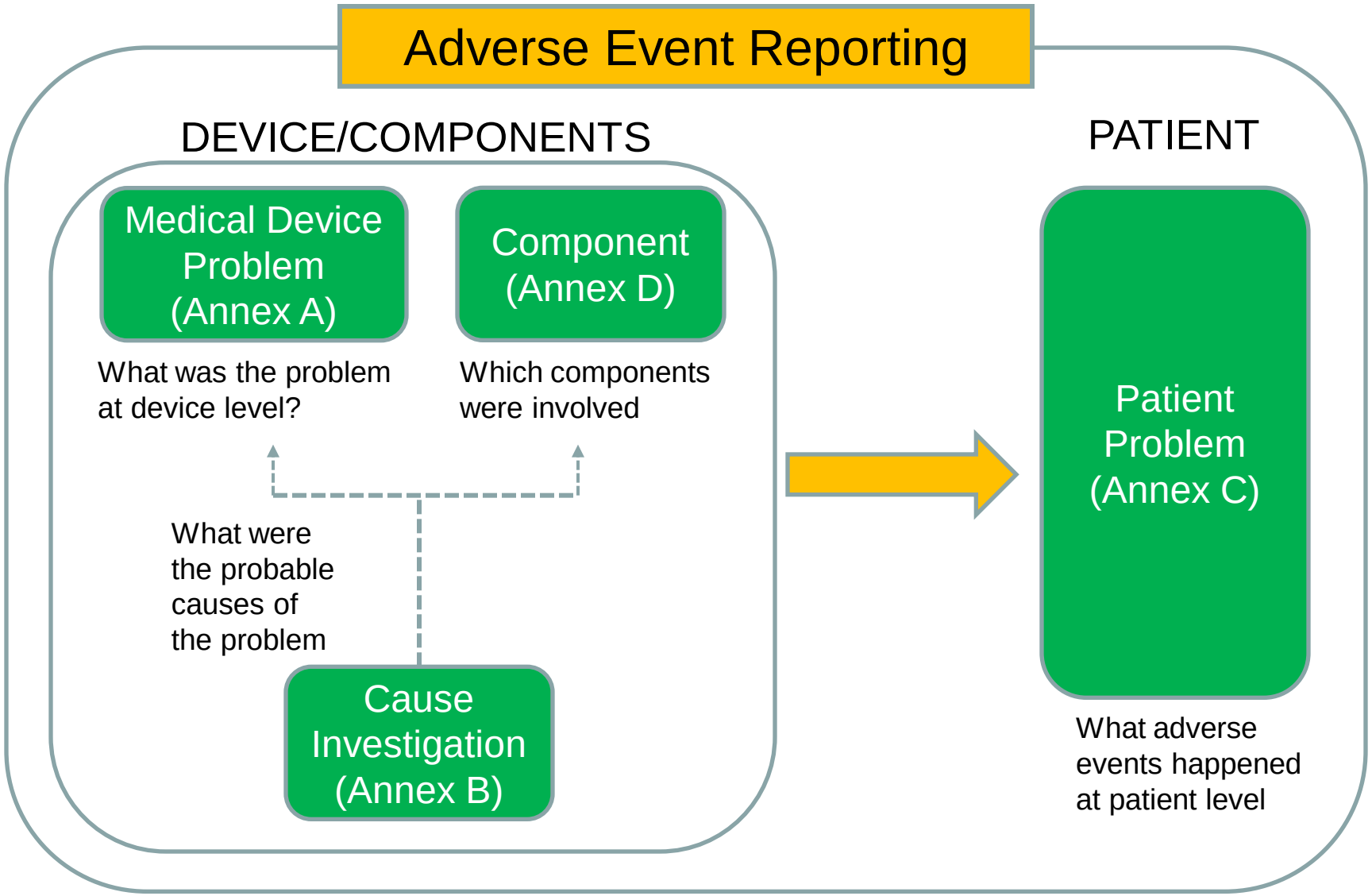
Benefits;

- Improved accuracy of capturing and reporting of medical device related adverse events,
- Reduced ambiguity, hence increased effectiveness of the evaluation process, and
- Better usability, in contrast to narrative text;

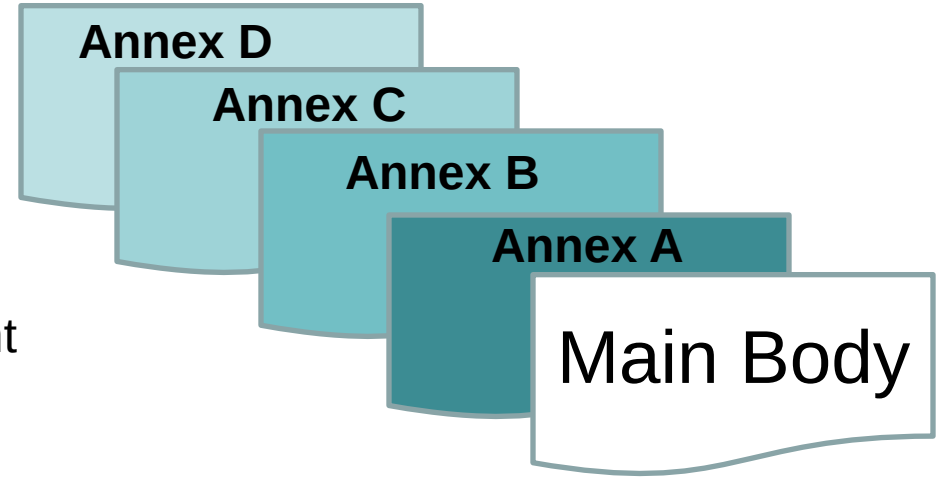
for

- More sophisticated signal detection (i.e. the identification of potential novel risks), and
- Trending analysis by incident management systems including advanced querying functions and data visualization.

Thus enabling a faster response by both regulatory agencies and device manufacturers.


Adverse Event Reporting
DEVICE/COMPONENTS
PATIENT
Medical Device Problem (Annex A)
Component (Annex D)
What was the problem at device level?
Which components were involved
What were the probable causes of the problem
Cause Investigation (Annex B)
Patient Problem (Annex C)
What adverse events happened at patient level

Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes



Annex A (Medical Device Problem):
to be published as a final document

Annex B (Cause Investigation):
to be published for public consultation

Annex C (Patient Problem), Annex D (Component):
under discussion

Annex A: Medical Device Problem Terms and Codes

- Based on FDA terms and ISO terms
- 3 level hierarchical coding structure
- Consist of IMDRF codes, terms and definitions
- First letter of the code indicates the annex, followed by 2 to 6 digits Arabic numbers, reflecting the hierarchical orders. (2 for level 1, 4 for level 2, and 6 for level 3). e.g., A 01, A 0201, A 030102

Annex A: Medical Device Problem Terms and Codes

Level 1			Level 2			Level 3		
Term	Definition	Code	Term	Definition	Code	Term	Definition	Code
Patient Device Interaction Problem	Problem related to the interaction between the patient and Device.	A01	Patient-Device Incompatibility	Problem associated with the interaction between the patient's physiology or anatomy and Device that affects patient and/or Device.	A0101	Biocompatibility	Problem associated with undesirable local or systemic effects due to exposure to medical device materials or leachates from those materials by a patient who has an implant or is receiving treatment with Device made from them.	A010101
						Device Appears to Trigger Rejection	Device appears to elicit undesired response in the patient to the presence of an implanted or invasive Device, without inherent Device failure, e.g. fibrous encapsulation, or inflammation of the tissue around the Device, or extrusion of the Device.	A010102
						Inadequacy of Device Shape and/or Size	The physical size and/or shape of Device was inadequate with regard to the patient's anatomy.	A010103
			Osseointegration Problem	Problem associated with interconnection between bone tissue and implanted Device.	A0102	Failure to Osseointegrate	Problem associated with the failure to see direct anchorage of an implant by the formation of bony tissue around the implant without the growth of fibrous tissue at the bone-implant interface.	A010201
						Loss of Osseointegration	Problem associated with weakened integration of Device at the bone-implant interface due to loss of fibrous and/or bony tissue and leading to compromised anchorage of Device. i.e. 'Loosening/Lysis.' "	A010202

Annex B: Cause Investigation Terms and Codes

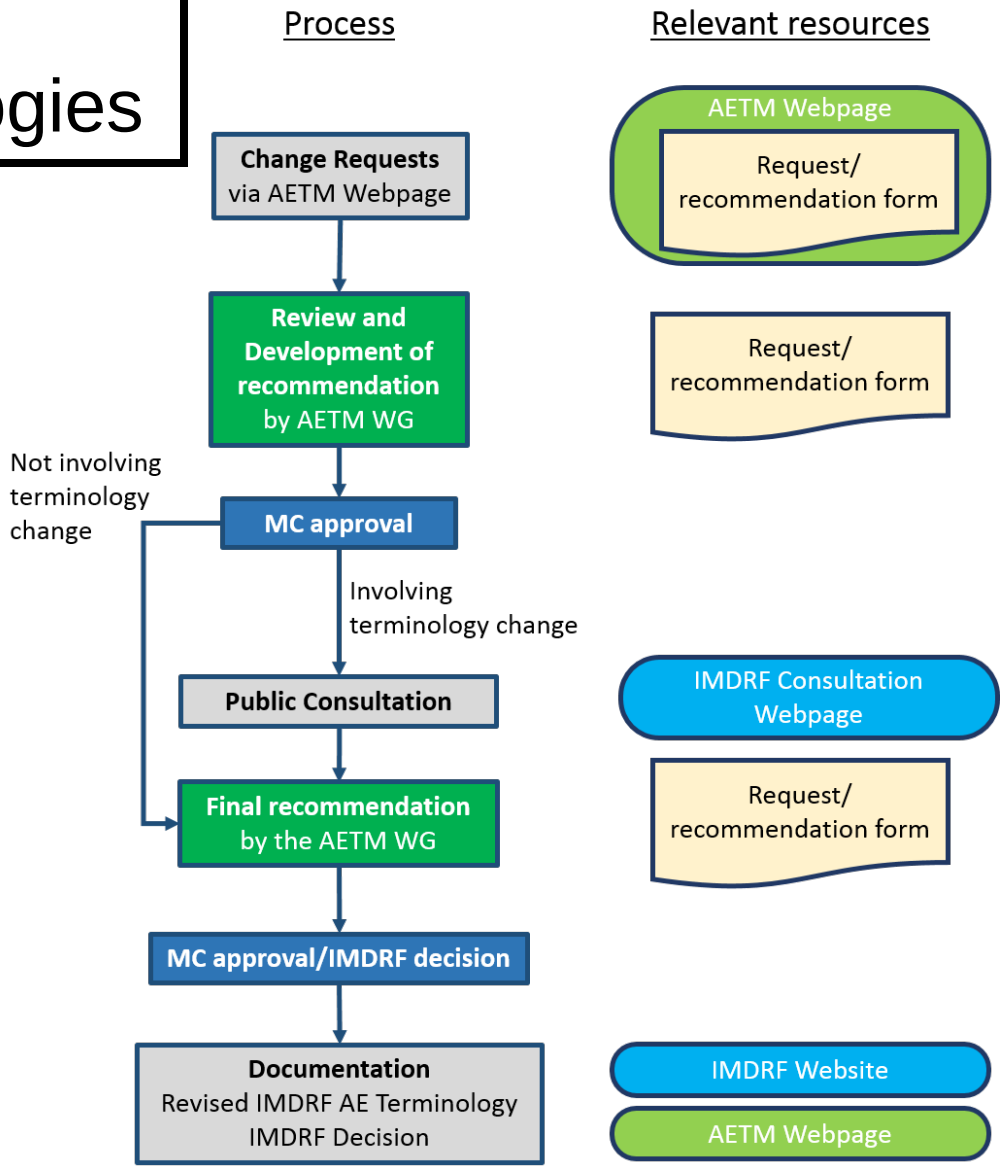
- Based on FDA terms and ISO terms
- Consist of IMDRF codes, terms and definitions
- 3 sections
  - Section1: Type of Investigation (1 level)
    (e.g., Testing of Actual/Suspected Device, Testing of Device from Same Lot/Batch, Trend Analysis)
  - Section2: Investigation Findings (3 levels)
    (e.g., Biological Problem Identified, Cytotoxicity Problem Identified, Microbial Contamination)
  - Section3: Investigation Conclusion (2 levels)
    (e.g., Cause Traced to Device Design, Cause Traced to Manufacturing, Quality Control Deficiency)

Annex B: Cause Investigation Terms and Codes

- First letter of the code indicates the annex, next number indicates the section, followed by 2 to 6 digits Arabic numbers, reflecting the hierarchical orders. (2 for level 1, 4 for level 2, and 6 for level 3).
  e.g., B1 01, B2 01, B2 0105, B2 010501,
  B3 01, B3 0101

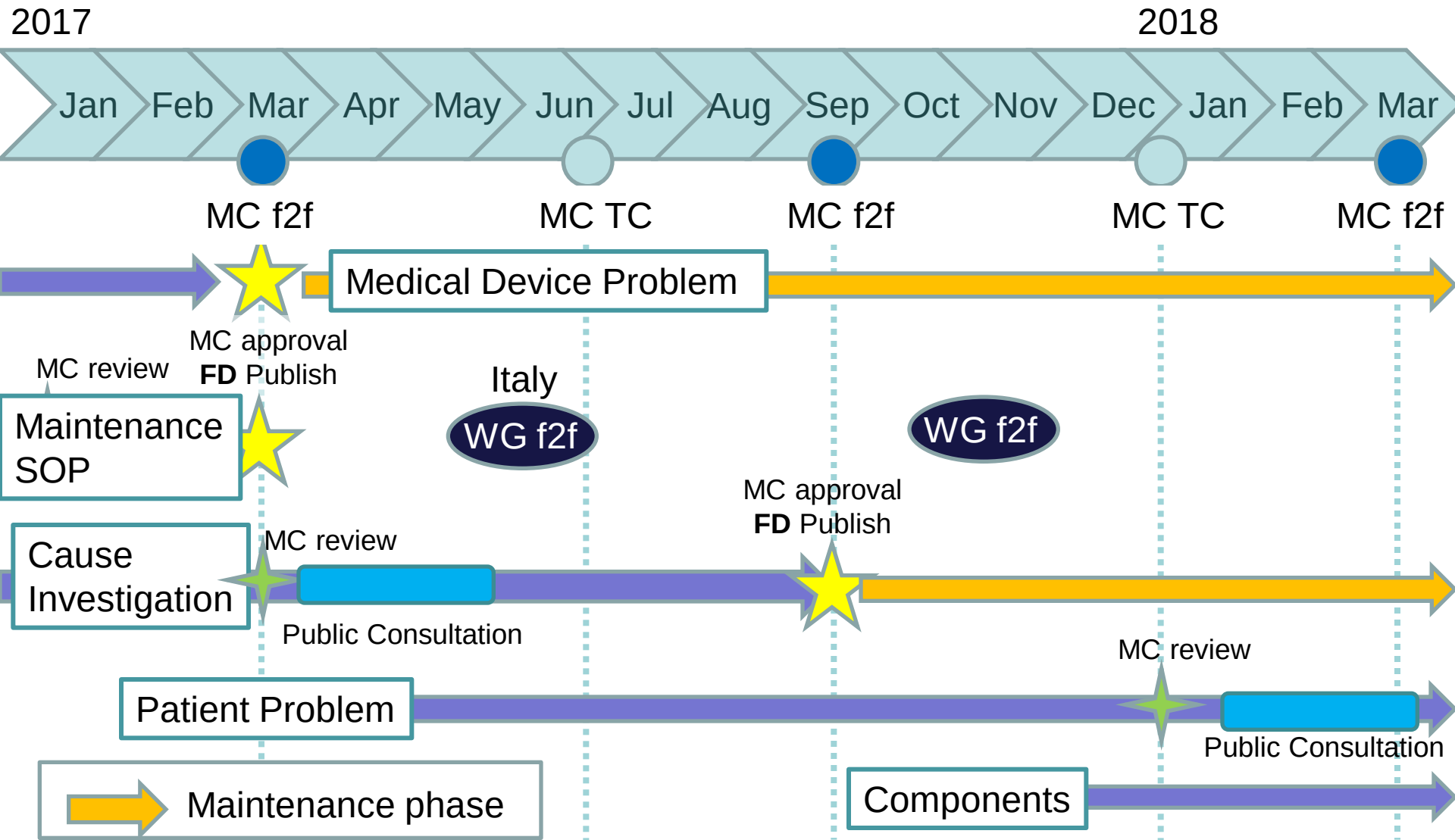
Maintenance of the IMDRF AE terminologies

- Evolve the AE WG to AE Terminology Maintenance (AETM) permanent WG after publication of the 4 annexes (Medical Device Problem T/C, Cause Investigation T/C, Patient Problem T/C, Components T/C)
- Once Annex A is published, current IMDRF AE WG will maintain the IMDRF AE terms as a pilot



IMDRF International Medical Device Regulators Forum

2017 Work Plan (as of March 2017)



Thank you!