IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

Sept 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

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- Maria Gloria Vicente
- Adriana Moufarrege
- Guilherme Antonio Marques Buss

Canada: Health Canada
- Mary Raphael

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- Tony Sant (UK, MHRA)
- Claudius Griesinger (EC/JRC)
- Graham Nash (UK, MHRA)
- Tim Raemaekers (EC/JRC)
- Robin Seidel (BfArM)

Russia: Roszdravnadzor
- Aysylu Valeeva
- Elena Astapenko

WHO:
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Japan: PMDA
- Hiroshi Ishikawa (Chair)
- Mari Shirotani
- Tsutomu Makino
- Madoka Murakami
- Miho Sato
- Takako Niwa
- Kaori Ogawa

MHLW
- Miki Oota
- Noriaki Tokunaga

US: FDA
- Nancy Pressly
- Evan Jacobs

Singapore: HSA
- Wong Woei Jiuang

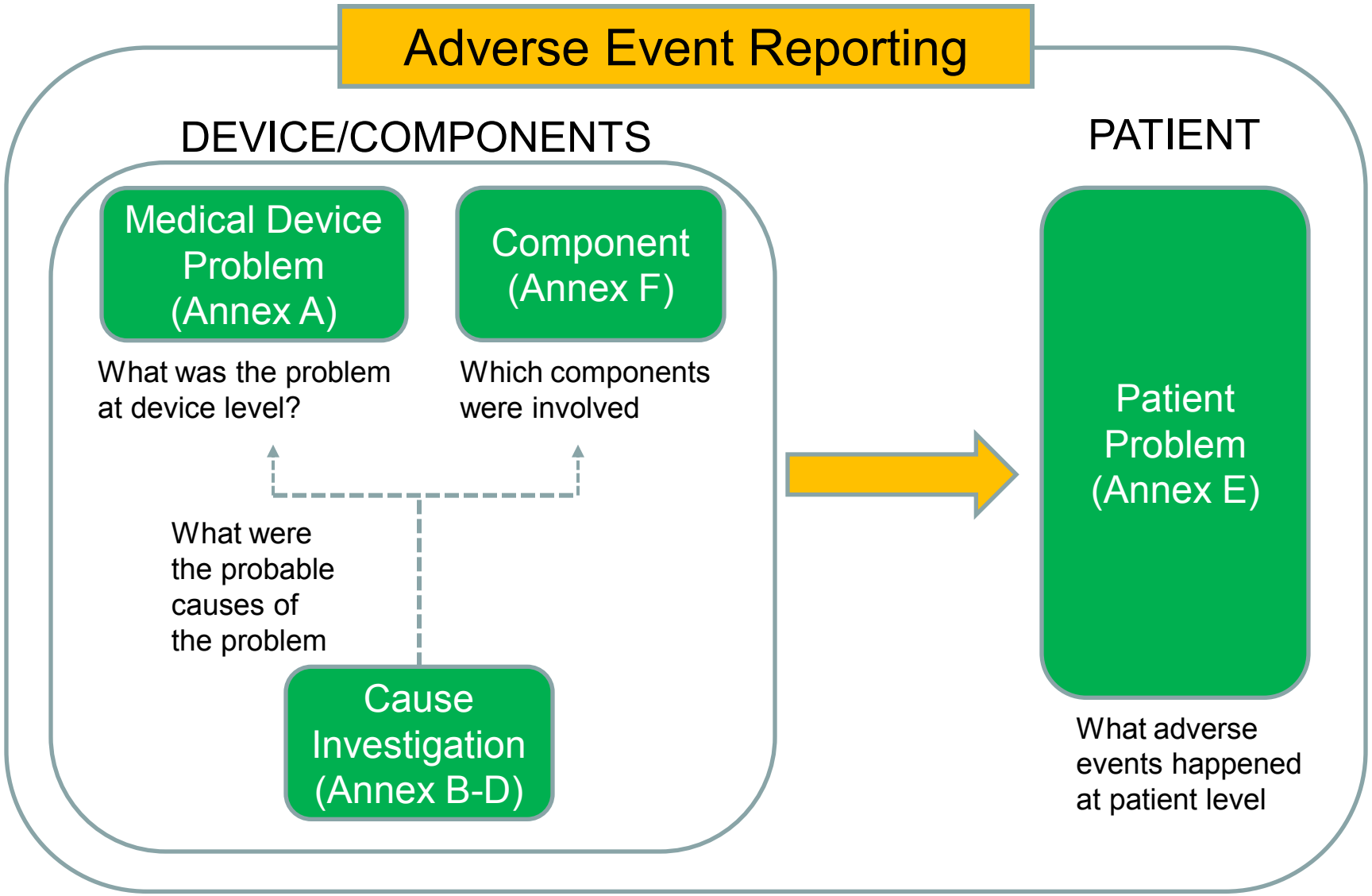
AHWP:
- Sasikala Devi Thangavelu
- Gulnar Berkimbayeva
- Nursultan Kalamov

Recent Meetings

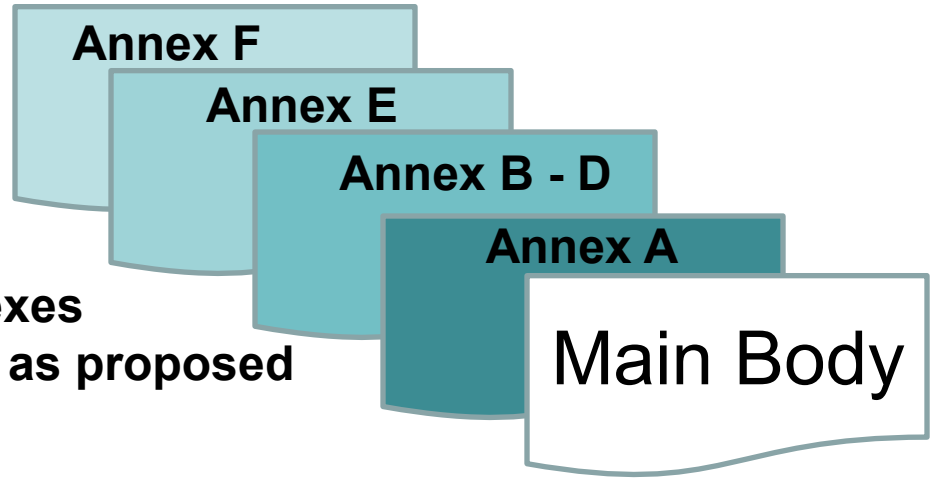
- Apr 5th, 2017
  16th Teleconference
- June 13th – 16th, 2017
  4th Face to Face meeting in Ispra, Italy
- July 6th, 2017
  17th Teleconference

Coming Meetings

- Oct 11th, 2017
  18th Teleconference
- Nov 28th – Dec 1st, 2017
  5th Face to Face meeting in Moscow, Russia


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

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



Main Body: published on April 10th in 2017
revised with the addition of Annexes B, C and D, and presented to MC as proposed final document (Edition 2)

Annex A (Medical Device Problem):
published with mapping on April 10th in 2017

Annex B – D (Cause Investigation):
presented to MC as proposed final document

Annex E (Patient Problem): under discussion

Annex F (Component): to be discussed after Annex E takes shape

Annex B-D: Cause Investigation Terms and Codes

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

Annex B: Type of Investigation

Annex B: Type of Investigation

Note: Select as many terms as necessary/appropriate to characterise the investigation

Device (bold): For the purpose of this Annex B, a **device** means a medical device including accessories and compo

Level 1		
Term	Definition	Code
Testing of Actual / Suspected Device	The investigation employed relevant empirical testing of the actual **device** suspected in the reported adverse event in order to establish their functional and other properties and to identify possible causes for the adverse event. Relevant testing would typically be based on test methods used for evaluating safety and performance as described in the latest relevant standards.	B01
Testing of Device from Same Lot/ Batch Retained by Manufacturer	The investigation employed relevant empirical testing of the **device** of the same lot or batch than that of the suspected **device** in the reported adverse event in order to support the identification of possible causes for the adverse event. Testing was performed using the **device** retained by the manufacturer (i.e. was not shipped). Relevant testing would typically be based on test methods used for evaluating safety and performance as described in the latest relevant standards.	B02
Testing of Device from Same Lot/ Batch Returned from User	The investigation employed relevant empirical testing of the **device** of the same lot or batch than that of the suspected **device** in the reported adverse event in order to support the identification of possible causes for the adverse event. The **device** was returned from the user. Relevant testing would typically be based on test methods used for evaluating safety and performance as described in the latest relevant standards.	B03
Testing of Device from Other Lot/ Batch Retained by Manufacturer	The investigation employed relevant empirical testing of the **device** of another lot or batch than that of the suspected **device** in the reported adverse event in order to support the identification of possible causes for the adverse event. This includes **devices** without a lot/ batch designation. Testing was performed using the **device** retained by the manufacturer (i.e. was not shipped). Relevant testing would typically be based on test methods used for evaluating safety and performance as described in the latest	B04

Annex C: Investigation Findings

Annex C Investigation Findings ("what were the findings?")

Device (bold): For the purpose of this Annex C, a **device** means a medical device including accessories and components.

Level 1			Level 2			Level3		
Term	Definition	Code	Term	Definition	Code	Term	Definition	Code
Biological Problem Identified	Problems relating to, caused by or affecting biological processes or living organisms.	C01	Biocompatibility Problem Identified	The **device** causes cellular or tissue responses that elicit an undesirable local or systemic effect in the recipient or beneficiary of that therapy. (See ISO 10993)	C0101			
			Biological Contamination	The undesirable presence of living organisms such as bacteria, fungi, or viruses or their products (enzymes or toxins).	C0102	Endotoxin Contamination	The undesirable presence of toxins associated with certain bacteria (e.g. gram negative bacteria).	C010201
						Microbial Contamination	The undesirable presence of microorganisms or microbes such as bacteria and fungi (yeasts and molds).	C010202
			Material or Material Leachate Pyrogenic Problem	The undesirable presence of pyrogens or fever-producing organisms caused by materials that permeate through the **device**.	C0103			
			Cytotoxicity Problem Identified	The **device** was found to have an undesirable level of toxicity to living cells.	C0104			
			Genotoxicity Problem	The **device**'s ability to cause	C0105	Carcinogenic	The **device**'s ability to trigger	C010501

Annex D: Investigation Conclusion

Annex D: Investigation Conclusion ("why did the incident/adverse event occur?")

Device (bold): For the purpose of this Annex D, a **device** means a medical device including accessories and components.

Level 1			Level 2		
Term	Definition	Code	Term	Definition	Code
Cause Traced to Device Design	Problems traced to the design specifications (e.g. in the requirements, testing processes, hazard analysis, implementation strategy).	D01	Design Inadequate for Purpose	Problems traced to design/design features of the **device** that do not support or interfere with the intended purpose of the **device**.	D0101
			Human Factors Engineering - Device Difficult to Operate	Problems traced to inappropriate and/or inadequate assessment and engineering design of the **device** to accommodate how or where the **device** will be used.	D0102
			Human Factors Engineering - Device Difficult to Assemble	Problems traced to inadequate design of the component parts and/or assembly steps resulting in the **device** not being able to be assembled correctly.	D0103
			Human Factors Engineering - Device Difficult to Reprocess	Problems traced to inadequate design of the reprocessing steps and/or the **device** resulting in the **device** remaining unclean.	D0104
			Missing or Inadequate Safety Measures	Problems traced to inadequate design or complete lack of safety measures leading to **device** malfunction or unintended properties of the **device** including possible hazards for persons using the **device**.	D0105
			Design Change Validation Inadequate	Problems traced to inadequate or lack of validation of design changes of the **device** leading to malfunction or unintended properties of the **device** including possible hazards for persons using the **device**.	D0106
Cause Traced to Component Failure	Expected or random component failure without any design or manufacturing issue.	D02			
Cause Traced to Manufacturing	A defect in the processes or systems used in the	D03	Manufacturing Deficiency	Problems traced to manufacturing process.	D0301

Annex E : Patient Problem

- Based on FDA terms and refers to MedDRA
- Consists of IMDRF codes, terms and definitions
- JRC contributed the results of their own research on “the patient problem nomenclatures” at F2F in Ispra, and now organizing the structure of Annex E with mapping to MedDRA terms
- Communicating with MedDRA, SNOMED and ICD closely

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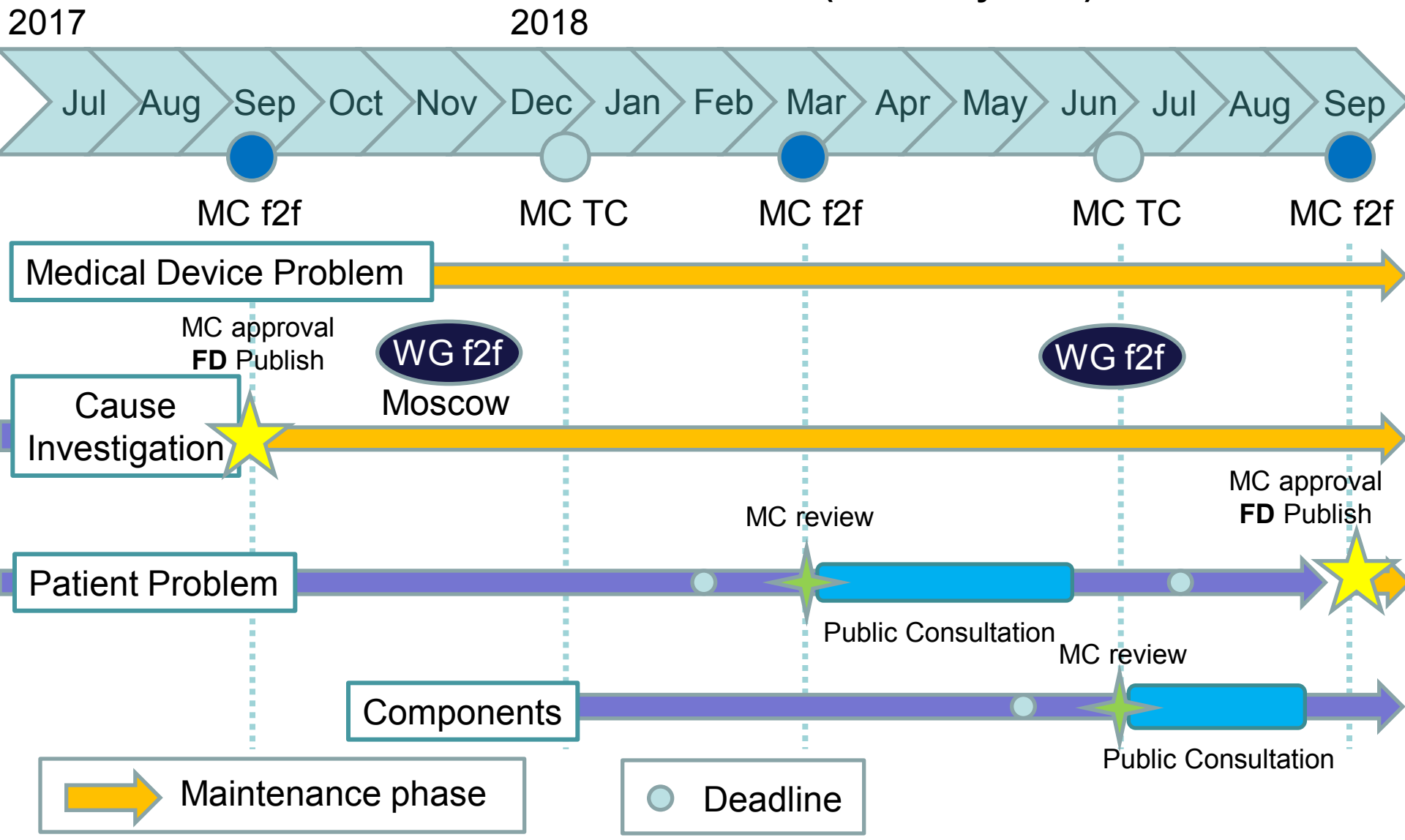
2017 Work Plan (as of July 2017)



Thank you!