



**IMDRF**

International Medical  
Device Regulators Forum

# **Adverse Event Terminology and Coding Working Group**

March 2019

**Working Group Chair:**

**H. Ishikawa**

**Office of Standards and Compliance for Medical Devices**

**Pharmaceuticals and Medical Devices Agency**



## Overview of IMDRF AE WG

NWIP

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.



## Member list

### Australia: TGA

Pamela Carter  
Jorge Garcia

### Brazil: ANVISA

Maria Gloria Vicente  
Adriana Moufarrege  
Sheila Martins Cordovil  
Carla Cruz

### Canada: Health Canada

Richard McAteer  
Tanya Hiebert  
Leanne Moore

### European Union:

Jean-François Roche (EC)  
Tony Sant (UK, MHRA)  
Claudius Griesinger (EC/JRC)  
Graham Nash (UK, MHRA)  
Tim Raemaekers (EC/JRC)  
Juan Antonio Blasco Amaro (EC/JRC)  
Dimitrios Panidis (EC/JRC)  
Robin Seidel (BfArM- Germany)

### Russia: Roszdravnadzor

Aysylu Valeeva  
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Yaroslav Kurtukov

### WHO:

Anita Sands

### Japan: PMDA

Hiroshi Ishikawa (Chair)

Mari Shirodani

Madoka Murakami

Miho Sato

Tsutomu Makino

Takako Niwa

Toru Takahashi

Kaori Ogawa

Yukari Namba

### MHLW Ryo Iwase

Akimasa Takeuchi

### US: FDA

Nancy Pressly

Evan Jacobs

### Singapore: HSA

Woei Jiuang Wong

Lailing Liew

### South Korea: MFDS

Hyeonho Kim

### AHWP:

Sasikala Devi Thangavelu

Azat Iskaliyev

Dinara Esbolatova

Gulnar Berkimbayeva

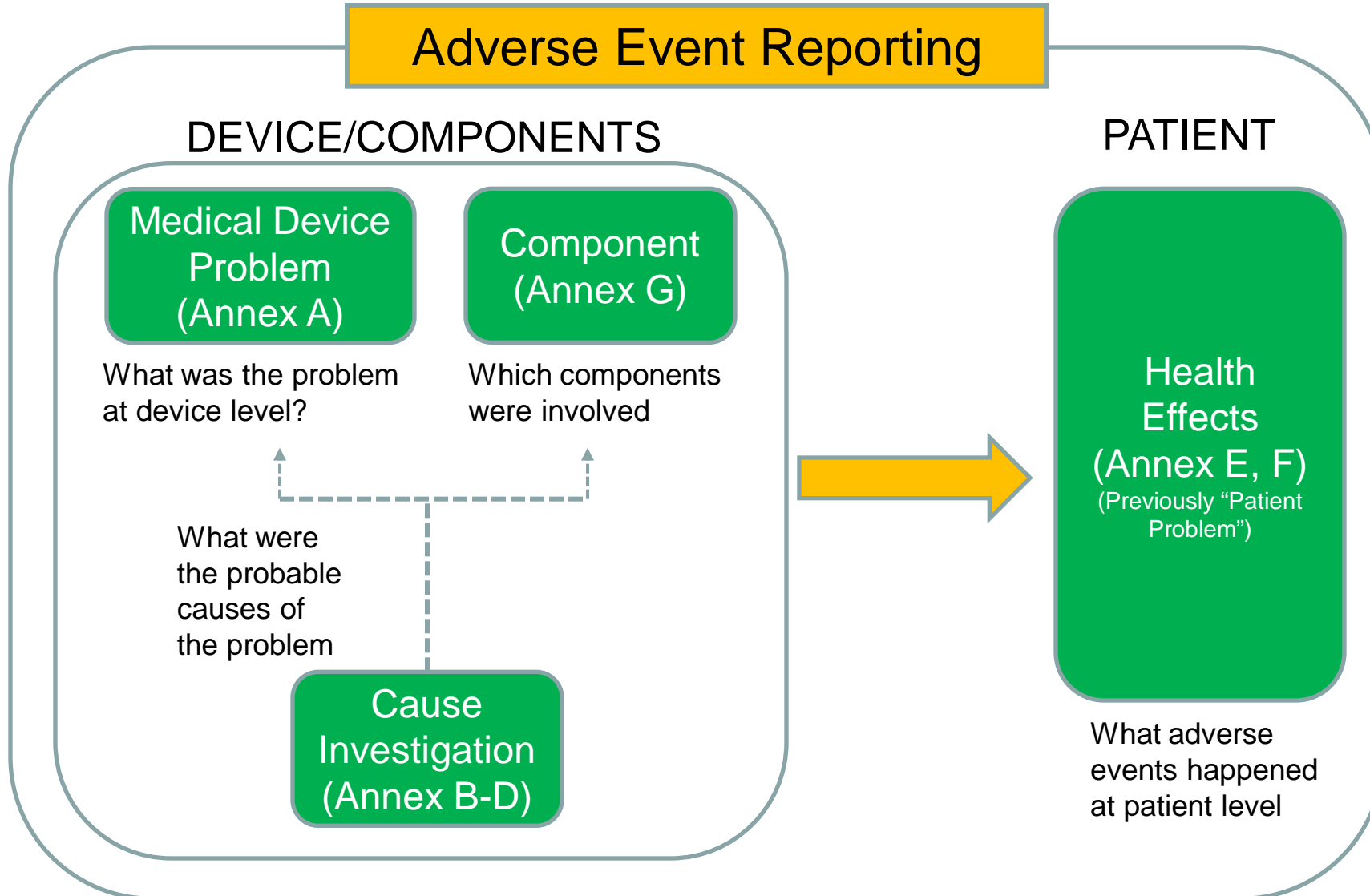


## Recent Meetings

- April 16<sup>th</sup> – 20<sup>th</sup>, 2018  
6<sup>th</sup> Face to Face meeting in Canberra, Australia
- Nov 14<sup>th</sup>, 2018  
21<sup>st</sup> Teleconference
- Nov 26<sup>th</sup> – 30<sup>th</sup>, 2018  
7<sup>th</sup> Face to Face meeting in Singapore
- Feb 20<sup>th</sup>, 2019  
22<sup>nd</sup> Teleconference

## Coming Meetings

- March 26<sup>th</sup>- 29<sup>th</sup>, 2019  
8<sup>th</sup> Face to Face meeting in Brazil





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

Main Body: published on April 10<sup>th</sup> in 2017 revised with the addition of Annexes B, C and D and published as Edition2 on Sep. 21<sup>st</sup> in 2017.

Annex A (Medical Device Problem):

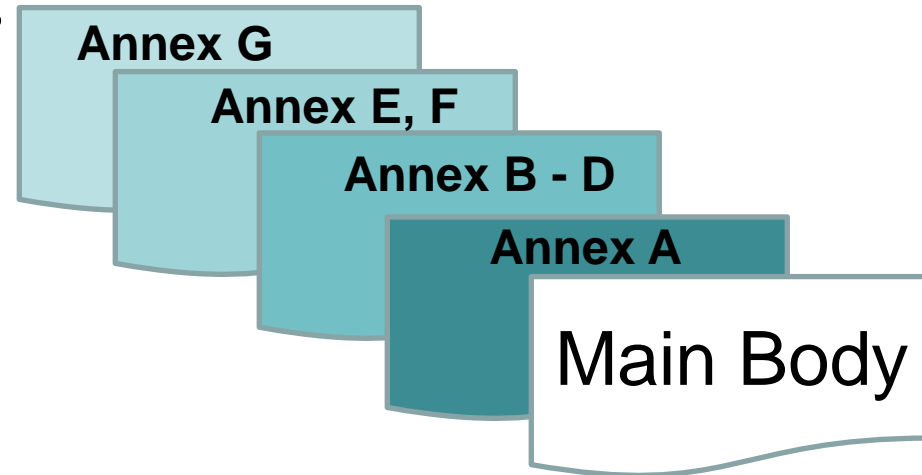
published with mapping on April 10<sup>th</sup> in 2017; Sep. 21<sup>st</sup> in 2017 (Edition2)

Annex B – D (Cause Investigation):

published with mapping on Sep. 21<sup>st</sup> in 2017

Annex E, F (Health Effects): submitted for approval as Final Document

Annex G (Component): Under discussion





## Annex E and F: Health Effects Terms and Codes

- Based on FDA terms and refers to MedDRA
  - As a response to some public comments, the WG has decided to provide mapping information with MedDRA terms/codes, cooperating with MedDRA.
- 2 annexes
  - Annex E: Clinical Signs, Symptoms and Conditions (3 levels)  
(Structured according to Organ / Physiological system)
  - Annex F: Health Impact (3 levels)  
(e.g., death, hospitalization, unexpected medical intervention)
- Consists of IMDRF codes, terms and definitions
- Coding principles are the same as Annex A-D.





## Annex E and F: Health Effects Terms and Codes

### Annex E Clinical Signs, Symptoms and Conditions

e.g. Paralysis  
Keratitis  
Burn  
Fracture

Category (Level 1)  
(Organs, Systems, Disorders, Concepts)

### Annex F Health Impact

e.g. Death  
Delay to Diagnosis/Treatment/Therapy  
Hospitalisation or Prolonged Hospitalisation  
Inadequate/Inappropriate Treatment  
Minor Injury/ Illness/Impairment  
Serious Public Health Treat/Injury/Illness/Impariment  
Misdiagnosis/Misclassification  
Intervention/Medical Intervention



### Annex E: Clinical Signs, Symptoms and Conditions

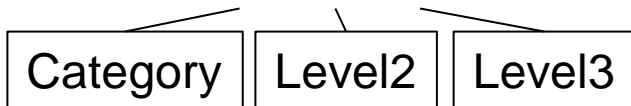
No./ Category (Level 1) (Organs, Systems, Disorders, Concepts)	
1. Nervous System	14. Reproductive System and Breast
2. Mental, Emotional and Behavioural Disorders	15. Pregnancy, Childbirth and the Puerperium
3. Blood and Lymphatic System	16. Musculoskeletal System
4. Immune System	17. Skin and Subcutaneous Tissue
5. Vascular System	18. Neoplasms Benign, Malignant and Unspecified
6. Heart	19. Infections
7. Respiratory System	20. Injury
8. Eye	21. Procedural Complications
9. Ear and Labyrinth	22. Investigations and Diagnostic Tests
10. Gastrointestinal System	23. General Disorders
11. Hepatic and Biliary System	24. Others
12. Metabolism and Nutrition	LIST (all terms in one sheet)
13. Kidney and Urinary Tract	



## Annex E Coding system

- Categories are treated as Level 1 with codes but not used for reporting. Categories do not have definitions.
- Basic coding principle is the same as other Annexes.

E XX XX XX



- The Annex E excel file has a tab with all terms (LIST) and tabs for each category.
- For term which exists in a secondary place, its code is linked to the primary code.



## Annex F: Health Impact

Level 1 terms	
Change in Therapeutic Response	Recognised Device or Procedural Complication
Death	Reduction in Life Expectancy
Brain Death	Sedation
Delay to Diagnosis	Rehabilitation
Delay to Treatment/ Therapy	Surgical Intervention
Disruption of Subsequent Medical Procedure	Serious Public Health Threat
Exacerbation of Existing Condition	Unexpected Deterioration
Hospitalization or Prolonged Hospitalization	Unexpected Diagnostic Intervention
Fetal Harm	Unexpected Medical Intervention
Inadequate/Inappropriate Treatment or Diagnostic Exposure	Insufficient Information
Minor Injury/ Illness / Impairment	Unanticipated Adverse Device Effect
Serious Injury/ Illness/ Impairment	No Health Consequences or Impact
Misdiagnosis/ Misclassification	No Patient Involvement
Prolonged Episode of Care	Appropriate Term/Code Not Available

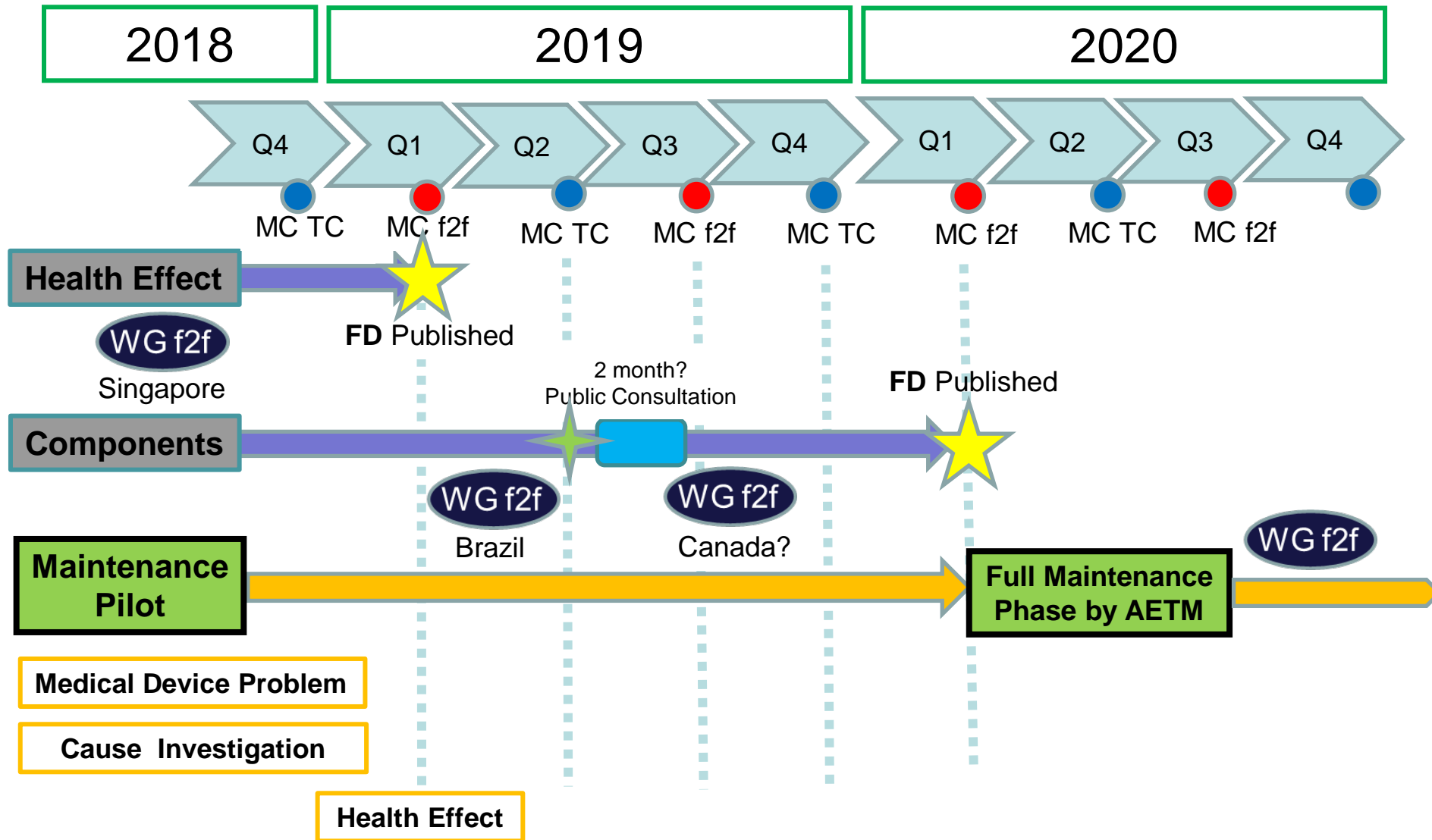


## Annex G: Parts and Components

- Based on FDA terms
- Reviewed the terms based on practical usage
- Proposed WD to be submitted for the MC September meeting in 2019
- After 2 month consultation, proposed final document will be submitted to the MC early 2020



## AE terminology Working Plan (as of Mar 2019)





Thank you!

