IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

March 2018

Working Group Chair:

H. Ishikawa

Office of Standards and Guidelines Development

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

Canada: Health Canada
- Mary Raphael
- Richard McAteer

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
- Elena Astapenko

WHO:
- Anita Sands

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

MHLW
- Ryo Iwase
- Akimasa Takeuchi

US: FDA
- Nancy Pressly
- Evan Jacobs

Singapore: HSA
- Wong Woei Jiuang
- Lailing Liew

AHWP:
- Sasikala Devi Thangavelu
- Azat Iskaliyev
- Dinara Esbolatova
- Gulnar Berkimbayeva

Recent Meetings

- Oct. 11th, 2017

  18th Teleconference
- Nov. 28th – Dec. 1st, 2017

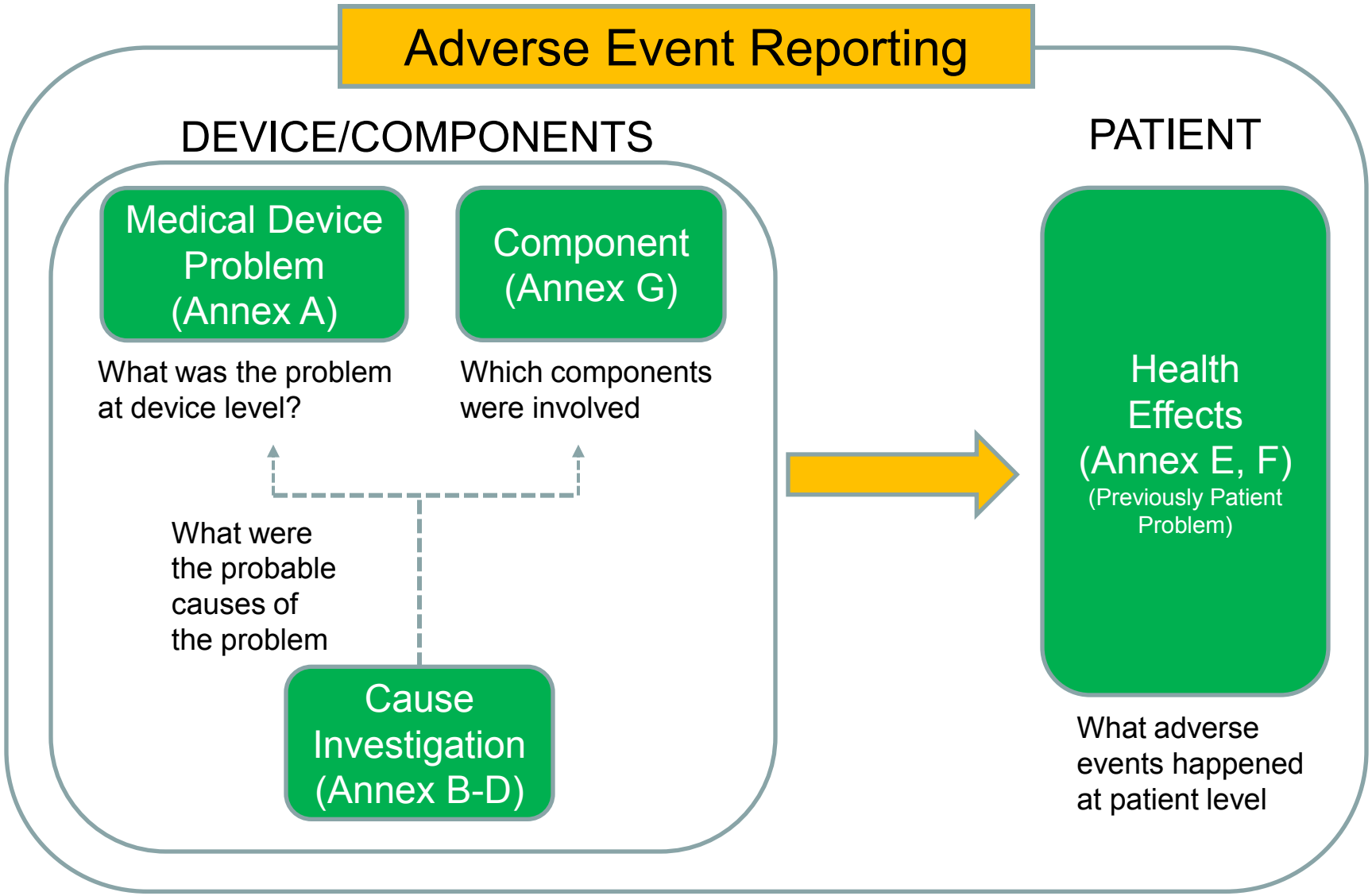
  5th Face to Face meeting in Moscow, Russia
- Feb. 7th, 2018

  19th Teleconference

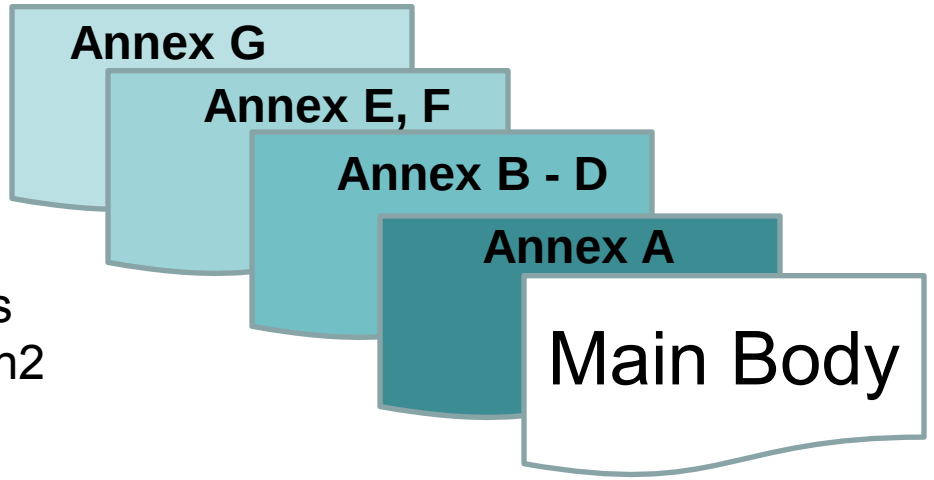
Coming Meetings

- April 16th – 20th, 2018

  6th Face to Face meeting in Canberra, Australia


Adverse Event Reporting
DEVICE/COMPONENTS
PATIENT
Medical Device Problem (Annex A)
What was the problem at device level?
Component (Annex G)
Which components were involved
What were the probable causes of the problem
Cause Investigation (Annex B-D)
Health Effects (Annex E, F)
(Previously Patient Problem)
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 published as Edition2 on Sep. 21st in 2017.

Annex A (Medical Device Problem):
published with mapping on April 10th in 2017; Sep. 21st in 2017 (Edition2)

Annex B – D (Cause Investigation):
published with mapping on Sep. 21st in 2017

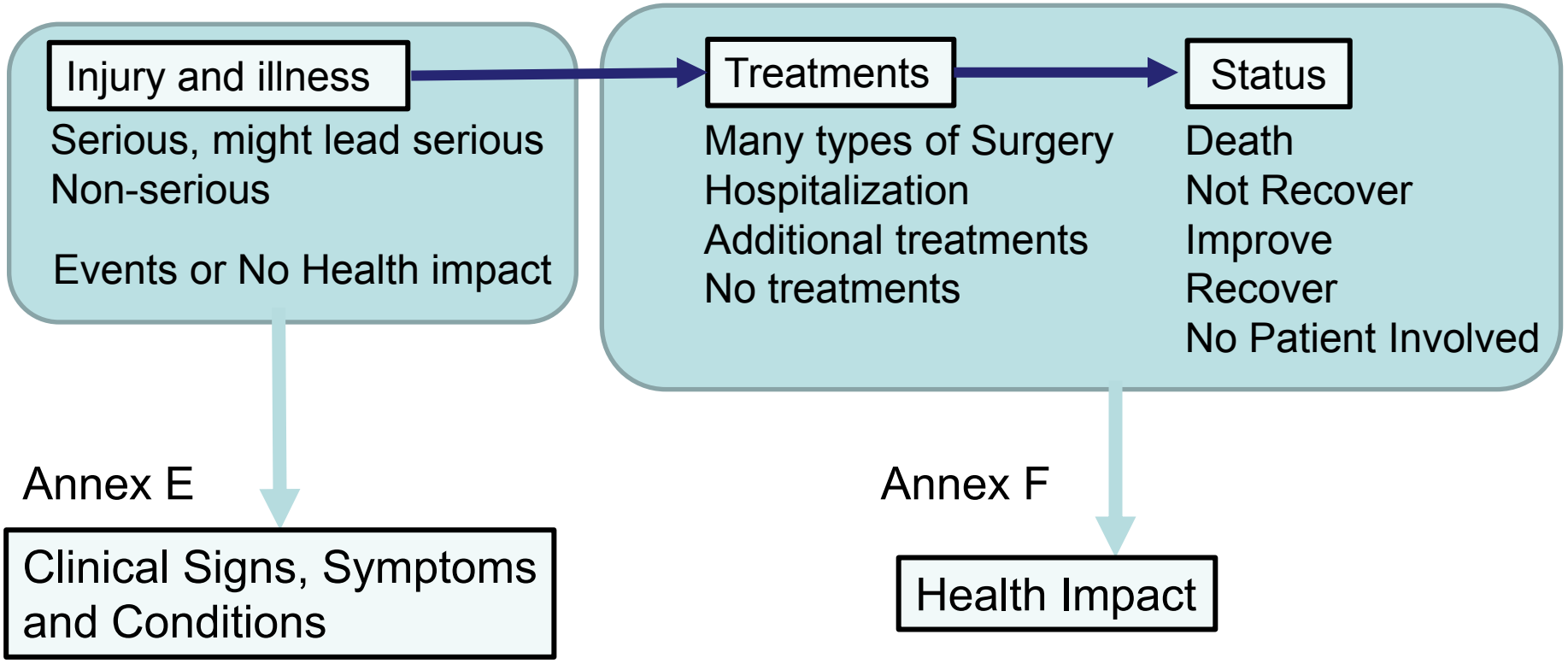
Annex E, F (Health Effects): under discussion

Annex G (Component): to be discussed after Annexes E, F take shape

Annex E and F: Health Effects Terms and Codes

- Based on FDA terms and refers to MedDRA
- Consists of IMDRF codes, terms and definitions
- 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, wrong intervention due to incorrect diagnosis)

Annex E and F: Health Effects Terms and Codes



Annex E: Clinical Signs, Symptoms and Conditions

No./ Category (Organs, Systems, Disorders, Concepts)	
1. Nervous system~~: central~~	15. Kidney and urinary tract
~~2. Nervous system: peripheral~~ merged with No. 1	16. Reproductive system
3. Mental, emotional and behavioural disorders	~~17. Breast~~ moved to other section
4. Blood and lymphatic system	18. Pregnancy, childbirth and the puerperium
5. Immune system	19. Musculoskeletal system and connective tissue
6. Vascular system	20. Skin and subcutaneous tissue
7. Heart	21. Neoplasms benign, malignant and unspecified (incl cysts polyps)
8. Respiratory system	22. Infections
9. Eye	23. Injury
10. Ear and labyrinth	~~24. Toxicity~~ moved to other section
11. Gastrointestinal system	25. Procedures and procedural complications
12. Hepatic and biliary system	26. Investigations and diagnostic tests
13. Metabolism and nutrition	27. General disorders
14. ~~Endocrine system~~ moved to other section	

Annex E: Basic concept

- Terms belonging to categories below are commonly names of organ. Those terms may also exist in the suitable organ categories.

No.	Category Name
21	Neoplasms benign, malignant and unspecified (incl. cysts and polyps)
22	Injury
23	Infection
25	Procedural complications
26	Investigations and diagnostic tests
27	Generalized disorders

- If a same term exist in more than two categories, the code for the term in the organ category will take a priority.

e.g. 9. Eye

Level 1	Code	Level 2	Code	Level 3	Code
Eye	E090000	Burn, corneal	E091500		

23. Injury

Level 1	Code	Level 2	Code	Level 3	Code
Injury	E230000	Burn	E232100	Burn, corneal	E091500

Annex F: Health Impact

Level 1 terms

Death	Change in Therapeutic Response
Serious Injury/ Illness/ Impairment	Delay to Diagnosis
Minor Injury/ Illness / Impairment	Delay to Treatment/ Therapy
Serious public health threat	Hospitalisation or Prolonged Hospitalisation
Reduction in life expectancy	Rehabilitation
Misdiagnosis	Surgical Intervention
Misclassification	Unexpected deterioration
Recognised procedural complication	Sedation
Inadequate/inappropriate treatment	Insufficient Information
Prolonged episode of care	Newly Identified Complication
Unexpected medical intervention	No Health Consequences Or Impact
Unexpected diagnostic intervention	No Patient Involvement
	No Code Available

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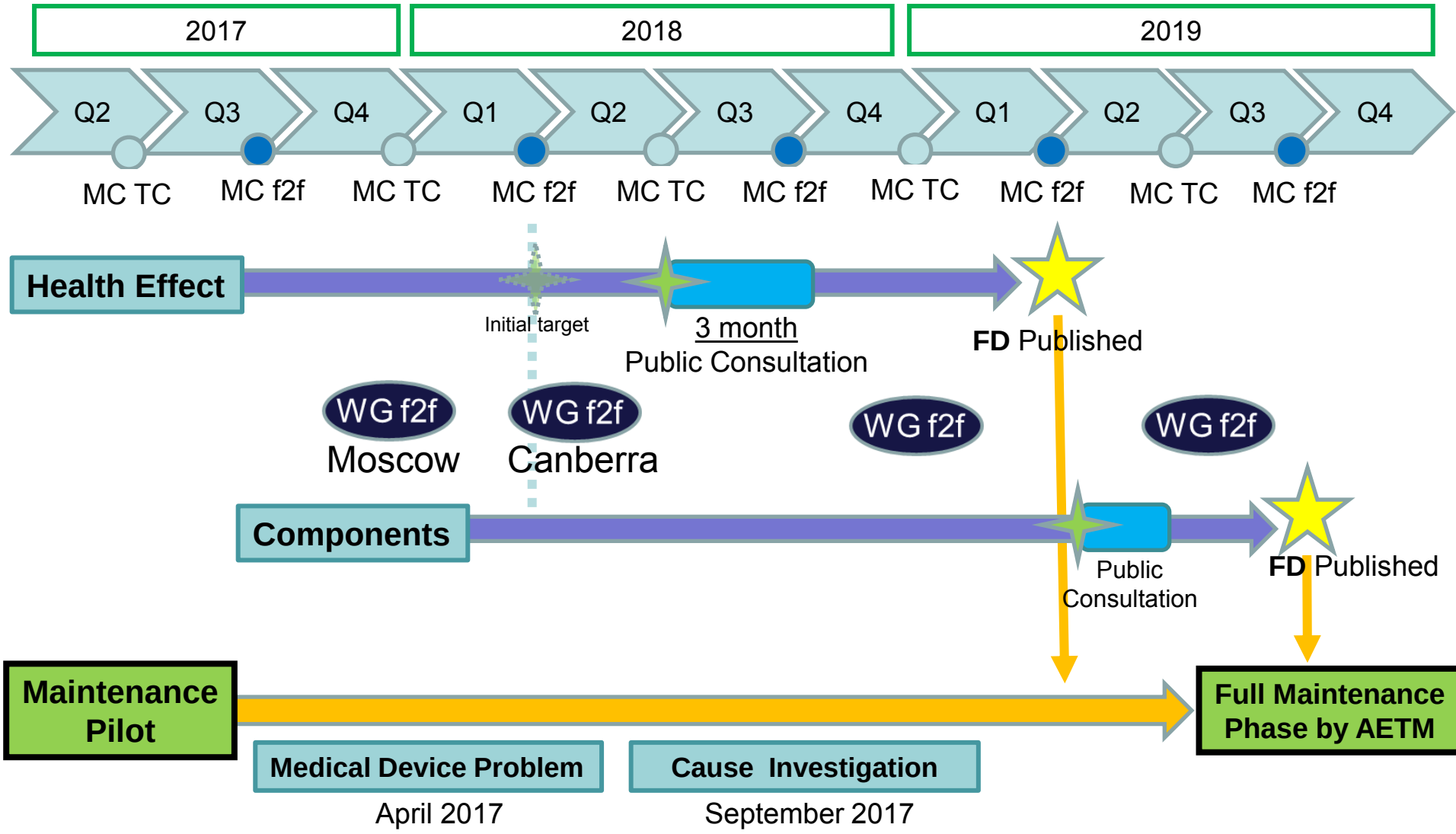
AE terminology Working Plan (as of Dec 2017)



Thank you!