Adverse Event Terminology and Coding Working Group

Sep 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
- Tanya Hiebert

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
- Yaroslav Kurtukov

WHO: Anita Sands

Japan:

PMDA
- Hiroshi Ishikawa (Chair)
- Mari Shirotani
- 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

- Oct. 11th, 2017

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

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

  19th Teleconference
- April 16th – 20th, 2018

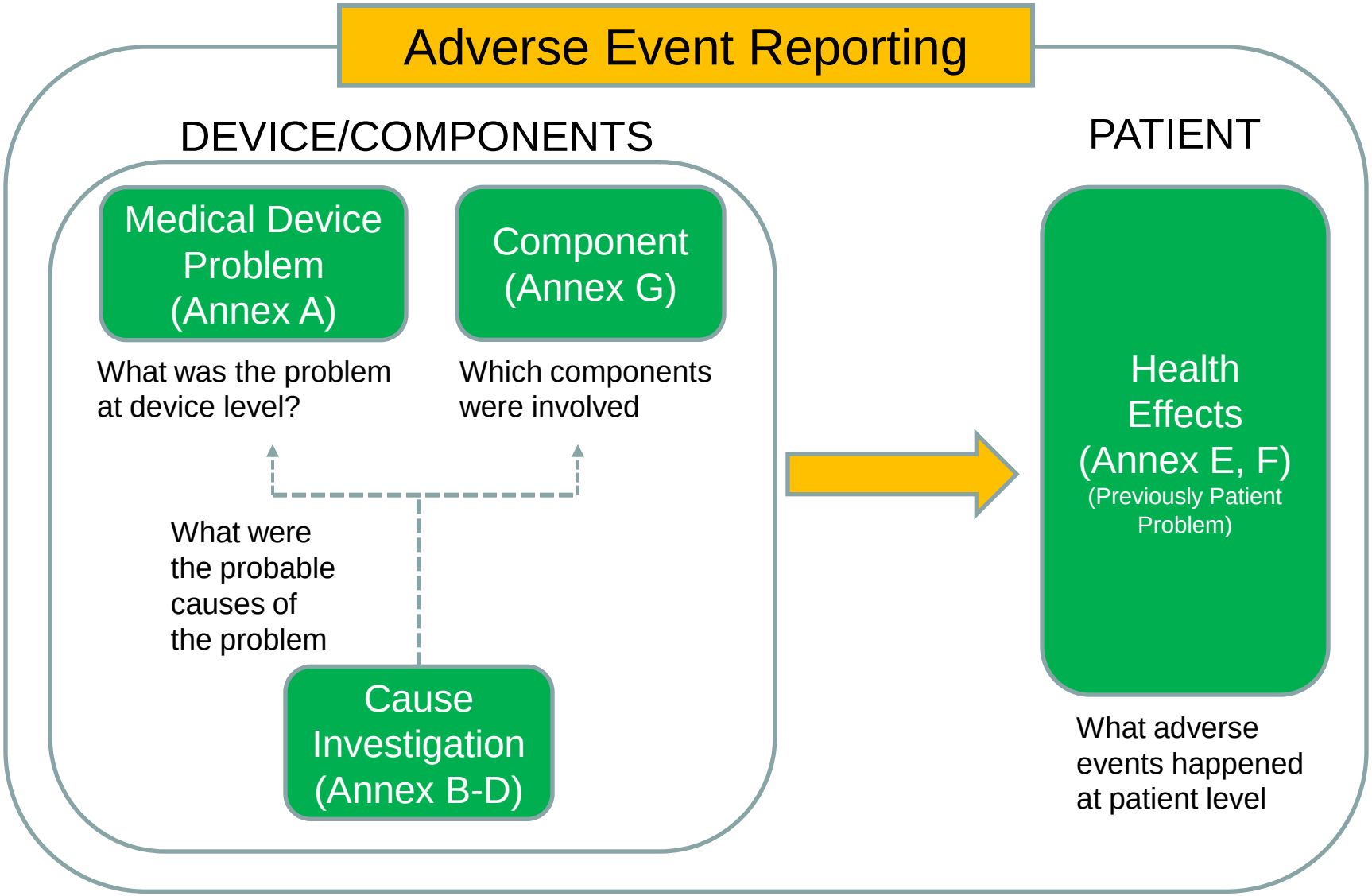
  6th Face to Face meeting in Canberra, Australia

Coming Meetings

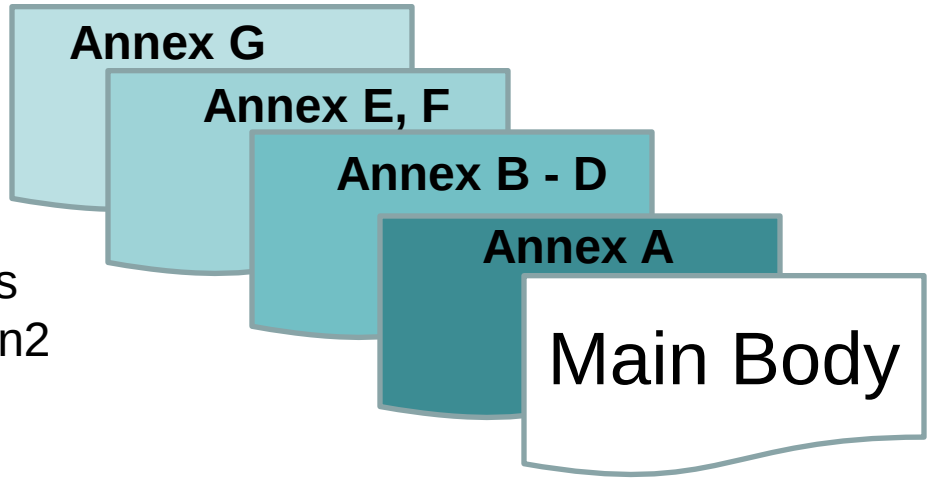
- Nov 26th – 30th, 2018

  7th Face to Face meeting in Singapore, Singapore

Adverse Event Reporting



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 public consultation until Oct. 12th in 2018

Annex G (Component): Under discussion

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

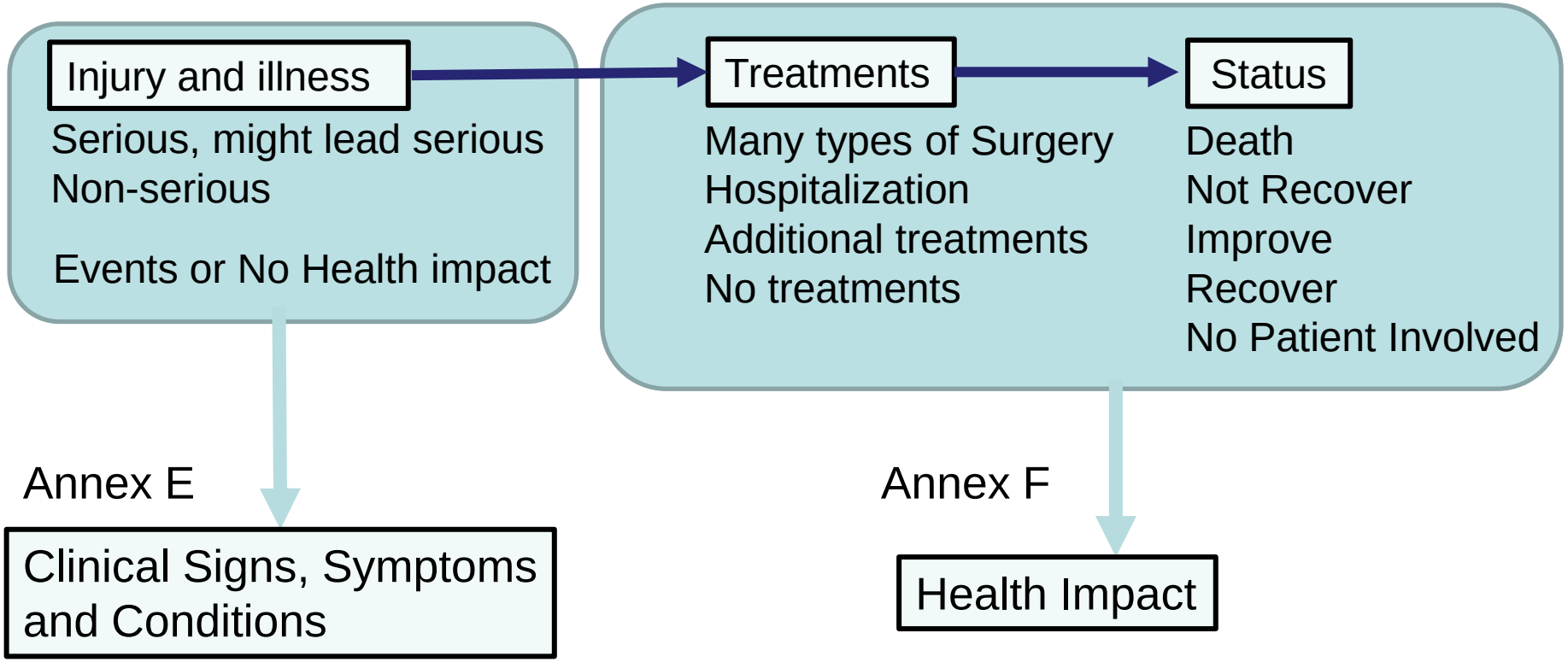
  Annex E: Clinical Signs, Symptoms and Conditions (3 levels)

  (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)
- Codes will be assigned after reviewing public comments. Coding principles will be the same as Annex A-D.

Annex E and F: Health Effects Terms and Codes

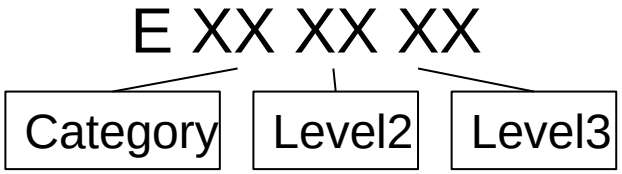


Annex E: Clinical Signs, Symptoms and Conditions

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.



- 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 E: Special case for coding

- One term has one code.
  - Some terms belongs to two categories. In such case, the only code assigned to the term in the category taking priority is also applied to the same term in the other category.
  - Other applicable category for the term is shown in the term list and the prioritized category is written in red and bold.

e.g.

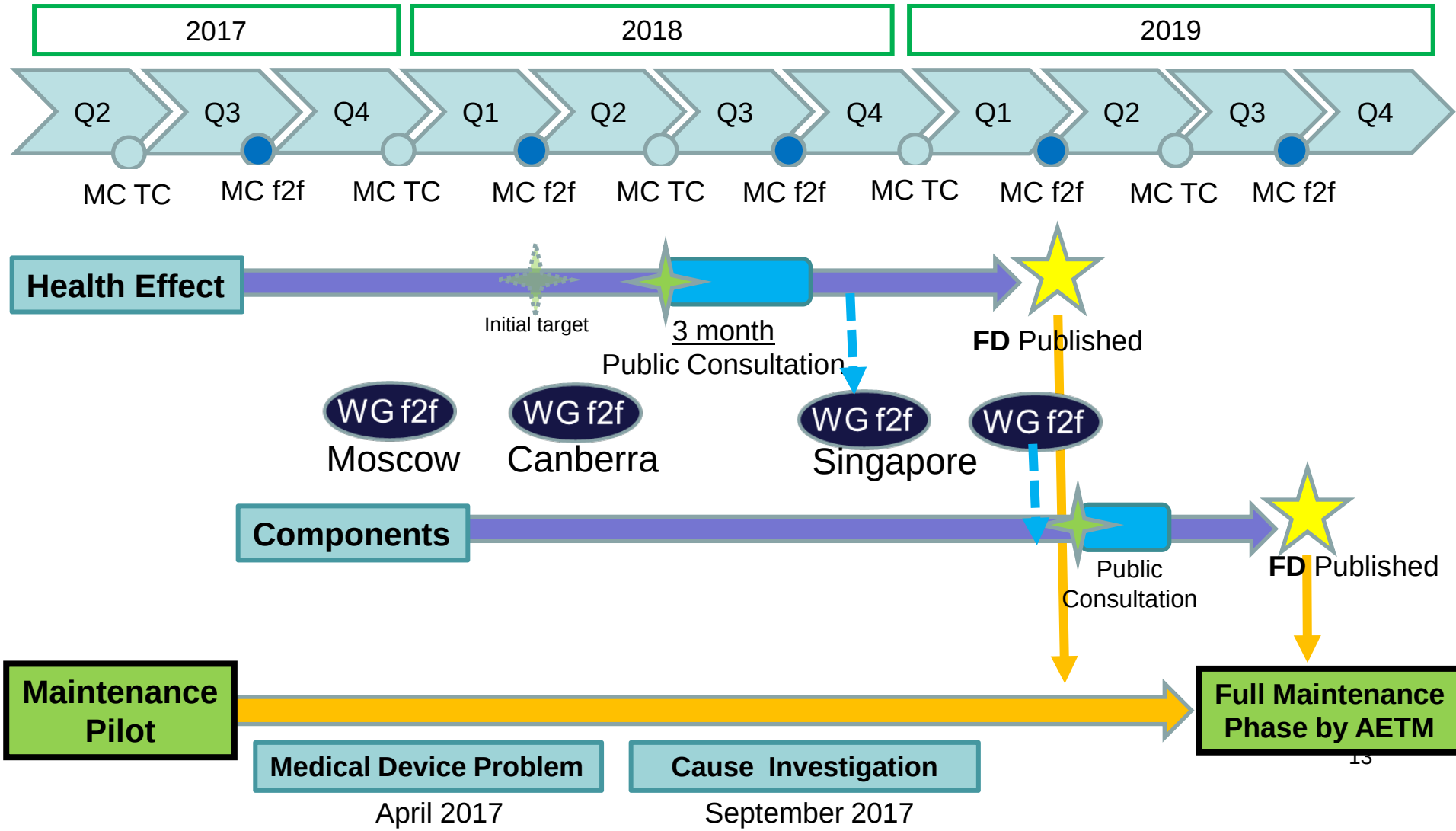
Category 17. Skin and Subcutaneous Tissue

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Skin Erosion	E17XX	20. Injury	3				

Category 20. Injury

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Erosion	E20YY			Skin Erosion	E17XX Not E20YYZZ	**17. Skin and Subcutaneous Tissue**	**2**

AE terminology Working Plan (as of Dec 2017)



Thank you!