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

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- Maria Gloria Vicente
- Adriana Moufarrege
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- Mary Raphael

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- Tony Sant (UK, MHRA)
- Claudius Griesinger (EC/JRC)
- Graham Nash (UK, MHRA)
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WHO: Anita Sands

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- Mari Shirotani
- Madoka Murakami
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- Kaori Ogawa

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- Noriaki Tokunaga

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- Nancy Pressly
- Evan Jacobs

Singapore: HSA
- Wong Woei Jiuang

AHWP: Sasikala Devi Thangavelu

Kazakhstan:
- Gulnar Berkimbayeva
- Nursultan Kalamov
Recent Meetings

• Nov 4, 2016
  13\textsuperscript{th} Teleconference
• Dec 13-16, 2016
  3\textsuperscript{rd} Face to Face meeting in Tokyo, Japan
• Feb 2, 10, 2017
  14\textsuperscript{th} and 15\textsuperscript{th} Teleconference

Coming Meetings

• April – May, 2017
  Teleconference
• June 13-16
  4\textsuperscript{th} 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.
What was the problem at device level? (Annex A)

What were the probable causes of the problem (Annex B)

Which components were involved (Annex D)

What adverse events happened at patient level (Annex C)
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

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Term</th>
<th>Definition</th>
<th>Code</th>
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<tbody>
<tr>
<td></td>
<td>Patient Device Interaction</td>
<td>Problem related to the interaction between the patient and Device.</td>
<td>A01</td>
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<td></td>
<td>Problem</td>
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<tr>
<td></td>
<td>Incompatibility</td>
<td>Problem associated with the interaction between the patient's physiology or anatomy and Device that affects patient and/or Device.</td>
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<tr>
<td></td>
<td>Osseointegration Problem</td>
<td>Problem associated with interconnection between bone tissue and implanted Device.</td>
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<td></td>
<td>Inadequacy of Device</td>
<td>The physical size and/or shape of Device was inadequate with regard to the patient's anatomy.</td>
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<td></td>
<td>Shape and/or Size</td>
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<td>A0103</td>
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<td>Device Appears to Trigger</td>
<td>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.</td>
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<td>Rejection</td>
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<td></td>
<td>Biocompatibility</td>
<td>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.</td>
<td>A0101</td>
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<td></td>
<td>Failure to Osseointegrate</td>
<td>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.</td>
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<td>Loss of Osseointegration</td>
<td>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. &quot;Loosening/Lysis.&quot;</td>
<td>A0102</td>
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Annex B: Cause Investigation Terms and Codes

- Based on FDA terms and ISO terms
- Consist of IMDRF codes, terms and definitions
- 3 sections

**Section 1: Type of Investigation (1 level)**
(e.g., Testing of Actual/Suspected Device, Testing of Device from Same Lot/Batch, Trend Analysis)

**Section 2: Investigation Findings (3 levels)**
(e.g., Biological Problem Identified, Cytotoxicity Problem Identified, Microbial Contamination)

**Section 3: 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
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
2017 Work Plan (as of March 2017)

2017

- Jan
  - MC f2f
- Feb
  - MC TC
- Mar
  - MC f2f

2018

- Apr
  - MC TC
- May
  - MC f2f
- Jun
  - MC TC
- Jul
  - MC f2f

MC review
Public Consultation
MC approval
FD
Publish

- Cause Investigation
- Patient Problem
- Maintenance SOP
- Medical Device Problem
- Italy
- WG f2f

Maintenance phase
Components
Public Consultation
Thank you!