IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

Daisuke Koga
Deputy Director for Medical Devices
Office of International Programme
Pharmaceuticals and Medical Devices Agency

WG Member

Australia: TGA
- Pamela Carter
- Jorge Garcia

Brazil: ANVISA
- Maria Gloria Vicente
- Guilherme Antonio Marques Buss
- Stela Candioto Melchior

Canada: Health Canada
- Mary Raphael

Europe: EC
- Jean-François Roche

UK: MHRA
- Tony Sant

Russia: Roszdravnadzor
- Aysylu Valeeva
- Elena Astapenko

Japan: PMDA
- Daisuke Koga (Chair)
- Hiroshi Ishikawa
- Madoka Murakami
- Yutaka Matsui
- Miho Sato
- Mai Okamoto
- Mari Shirotani

MHLW
- Tomomi Satomi

US: FDA
- Nancy Pressly
- Evan Jacobs

WHO
- Anita Sands

AHWP
- WONG Woei Jiuang
- SASIKALA Devi Thangavelu

Meetings

1. April 23 & May 28
   - 1st and 2nd Teleconference
2. June 4 and 5
   - 1st Face to Face meeting in Silver Spring, US
3. June 8 and 9
   - ISO/TC210/WG3 meeting in Denver, US
4. June 18, July 9 and Aug 6
   - 3rd to 5th Teleconference

1st Face to Face meeting (1)

- Compared ISO/TS19218-1 (L1,L2) and FDA Device Problem terms (L2,L3 and L4).
- Agreed
  - to use FDA L2 and ISO L1 and some L2 as parent terms
  - to propose FDA L3 as IMDRF terms for AE reporting
  - to further discuss on FDA L4 and lower level terms to propose as IMDRF terms for AE reporting
- Hierarchy like structure of those terms will be proposed as a model structure. (similar to ISO terms)
- Agreed to assign IMDRF codes to terms sequentially.

1st Face to Face meeting (2)

- Agreed to discuss also on FDA Patient Problem terms and FDA Parts & Components terms to propose as IMDRF terms. IMDRF code will also be assigned to those terms separately
- Agreed to discuss Evaluation terms, which corresponds to TS19218-2, after the discussions on above terms
- Agreed on table of contents of AEWG Document and to start drafting

1st Face to Face meeting (3)

- Agreed to propose ISO/TC210/WG3 to have collaborative scheme such as joint working group
- Agreed to discuss with ISO/TC210/WG3 on maintenance of terms taking timeliness into consideration
  - ISO/TC210/WG3 is a primal candidate of Maintenance body (at least) for Event and Evaluation terms
  - Maintenance scheme for Patient Problem terms and Parts & Components terms has to be discussed

ISO/TC210/WG3

- Explained purpose and current activity of AEWG
- Proposed to input from IMDRF, from the perspective of regulatory authorities
- WG3 decided to send a letter from Chair to IMDRF Chair to request information on how TS19218-1 and -2 is recognized among member jurisdictions and suggested additions/revisions by mid-October.
- WG3 agreed to defer discussion of -2 until next meeting.
- WG3 will have a next meeting in November in Seattle.

of Terms discussed in WG

	Terms from ISO/TS	Terms not found in ISO/TS
Device Problem terms (Event-type codes: TS19218-1)	107	385
Patient Problem terms	n.a.	640
Parts & Components terms	n.a.	578
Evaluation codes : TS19218-2	117	TBD

Note: Terms are under discussion and numbers are subject to change.

Work Plan

1. September
   - Progress report to the MC
   - Propose to start discussion about Evaluation terms with ISO/TC210 to the MC
   - Continue to discuss on Device Problem terms and other terms
   - Continue to discuss on AEWG document with Device Problem terms, Patient Problem terms and Parts & Components terms with codes.
2. October
   - Finalize drafting Device Problem terms by AEWG
   - Propose Device Problem terms to ISO/TC210/WG3 as suggested additions/revisions from IMDRF AEWG
3. November
   - ISO/TC210/WG3 meeting
4. March 2016
   - Propose Working Draft of AEWG document to the MC

Thank you