Adverse Event Terminology and Coding Working Group

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WG Member

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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
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.
1\textsuperscript{st} 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

<table>
<thead>
<tr>
<th>Terms from ISO/TS</th>
<th>Terms not found in ISO/TS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Problem terms (Event-type codes: TS19218-1)</td>
<td>107</td>
</tr>
<tr>
<td>Patient Problem terms</td>
<td>n.a.</td>
</tr>
<tr>
<td>Parts &amp; Components terms</td>
<td>n.a.</td>
</tr>
<tr>
<td>Evaluation codes : TS19218-2</td>
<td>117</td>
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</tbody>
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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