IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

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Office of Standards and Guidelines Development

Pharmaceuticals and Medical Devices Agency

WG Member

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- Nancy Pressly
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Original Proposal

- **Purpose**

- To improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events.
- The AE terminology will be composed of three parts: terms for medical device malfunction, terms for patient/user outcome and terms for part/component of medical device. (Note: Evaluation terms and code is not the scope of this WG)

Original Proposal

- **Proposal**

First Step : establishment of the harmonized hierarchy concept for AE terms

- Review existing AE terms.
- (pick several samples of terms from each member)
- Find difficulties or differences
- Review the hierarchies concept and reach a consensus of it

Second Step : Further discussion towards implementation

- Discuss how to utilize existing systems such as ISO/TS 19218, FDA's system and etc.
- For the parts and components level, we may review Global Medical Device Nomenclature (GMDN).
- Find possibility for collaboration with ISO TC 210.
- Discuss single code concept or alternative ways such as to create a map with other codes.
- Discuss the maintenance issue
- Publish the IMDRF recommendation document

Developing evaluation terms and codes can be discussed later as the Work Item Extension of this proposal.

Meetings

1. April 23 & May 28, 2015
   - 1st and 2nd Teleconference
2. June 4 and 5, 2015
   - 1st Face to Face meeting in Silver Spring, US
3. June 8 and 9, 2015
   - ISO/TC210/WG3 meeting in Denver, US
4. June 18, July 9 , Aug 6 and Oct 8, 2015
   - 3rd to 6th Teleconference
5. Nov 17 – 20, 2015
   - ISO/TC210/WG3 meeting in Seattle, US
6. Dec 9, 2015 & Mar 1, 2016
   - 7th and 8th Teleconference

ISO/TC210/WG3 (Seattle 2015)

Followings are reported by the WG3

- Answers from the IMDRF MC jurisdictions to the questionnaire by ISO TC210 (incl. some detailed request from ANVISA and TGA)
- IMDRF AE WG's current undergoing request to ISO TC210 WG3

Followings recommendation has been presented to the plenary

- Reconfirm 19218-1 and -2, then modify once IMDRF GL documents are published.
- Once IMDRF GL has been adopted, ISOTC210 should conduct a systematic review with a recommendation that 19218-1,-2 be withdrawn.

Resolution at the plenary Resolution 91

ISO/TC210 accepts the proposal from WG3 to reconfirm ISO 19218-1,and ISO19218-2

NWI Extension Proposal

- **Evaluation Terms**
  Based on the ISO resolution it is necessary to start developing evaluation terms with the same manner as Product problem.

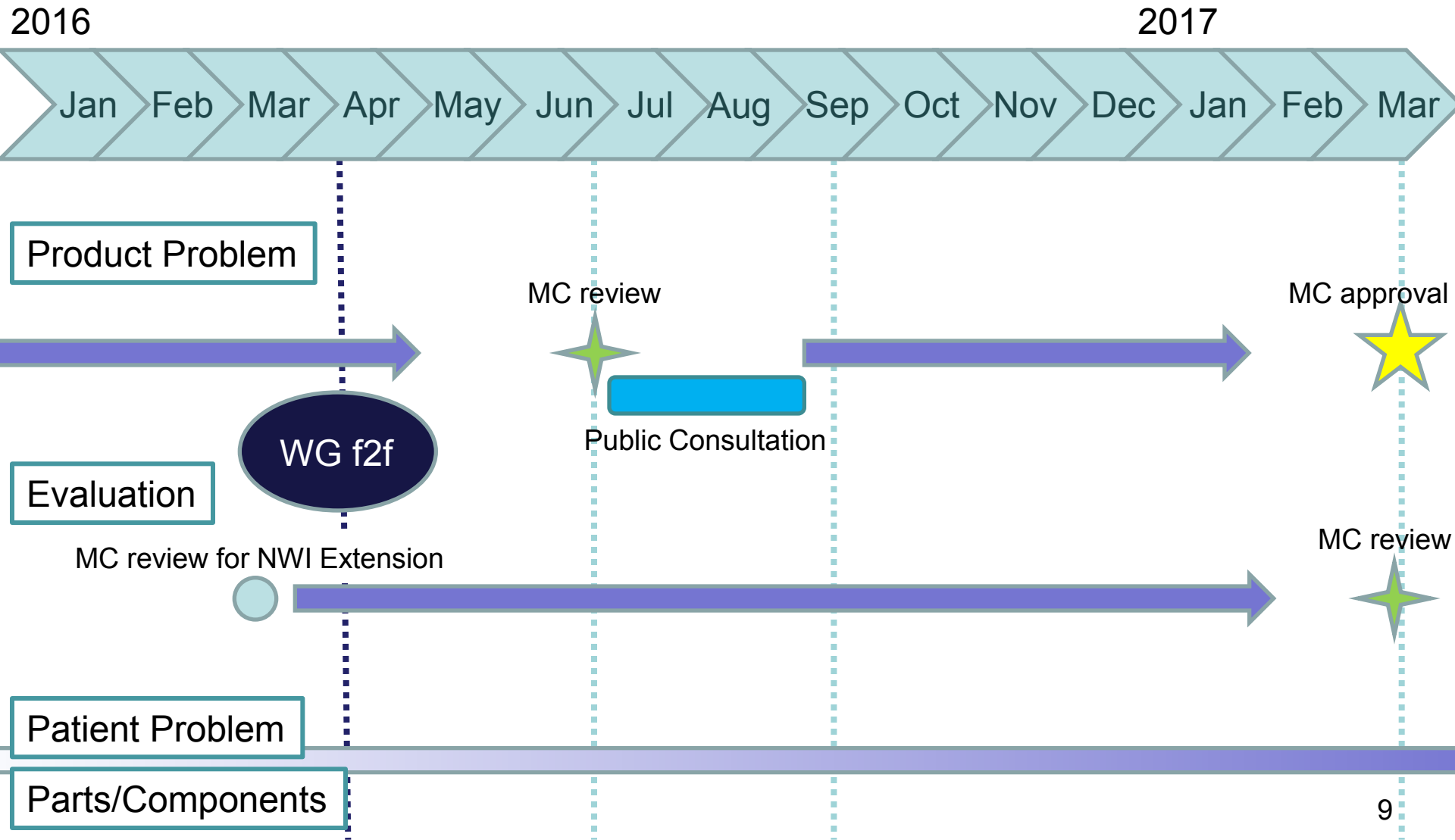
of Terms discussed in WG

As of Jan 2016

	Terms from ISO/TS	Terms not found in ISO/TS	Total number of terms
Device Problem terms (Event-type codes: TS19218-1)	107	391	493
Evaluation codes : TS19218-2	117	TBD	(149)
Patient Problem terms	N/A	(640)	(640)
Parts & Components terms	N/A	(578)	(578)

Note: Terms are under discussion and numbers are subject to change.
Some ISO terms may not suitable to use as IMDRF terms.
(i.e. include evaluation terms)

2016 Work Plan (as of Feb 2016)



Thank you