IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

September 2016

H. Ishikawa

Office of Standard and Guideline Development

Pharmaceuticals and Medical Devices Agency

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Recent Meetings

- April 12-15

  2nd Face to Face meeting in Tokyo, Japan

- May 24, June 17, July 14 and August 26

  9th , 10th, 11th and 12th Teleconference

Coming Meetings

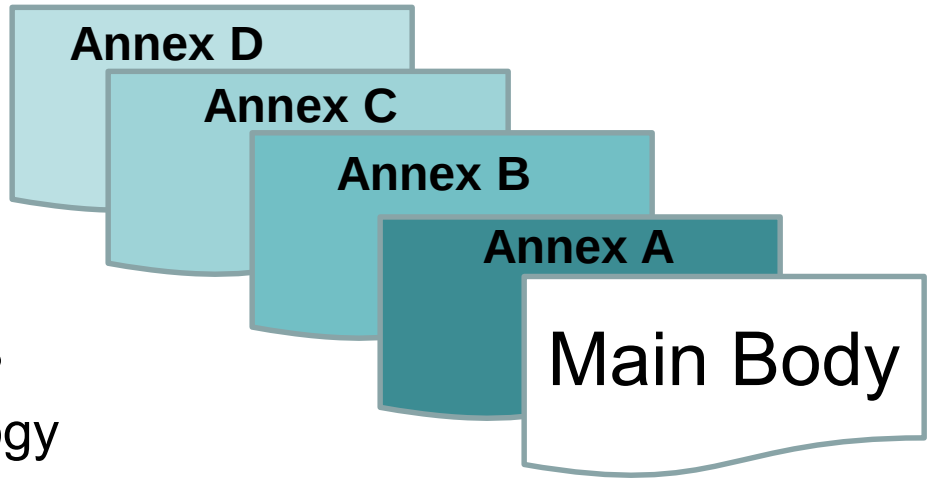
- October - November

  Teleconference

- December 13-16

  3rd Face to Face meeting in Tokyo, Japan

1. Formation of GL document



2. Name of the GL and Annexes

Title: IMDRF Adverse Event Terminology

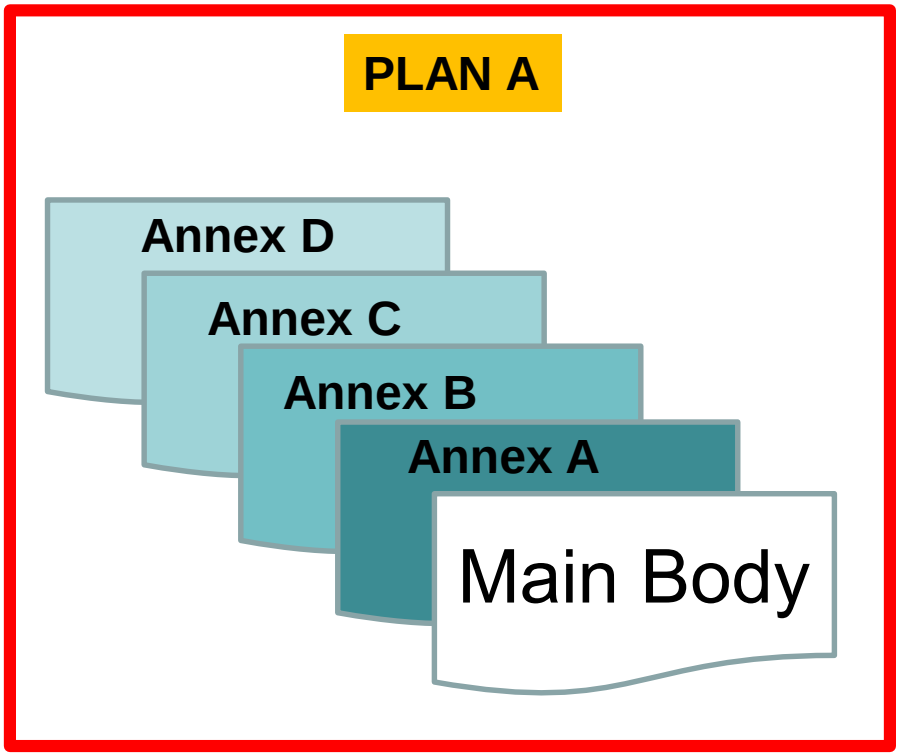
- Annex A: Medical Device Problem terms and codes
  (previously Product Problem)
- Annex B: Cause Investigation terms and codes
  (Previously Evaluation)
- Annex C: Patient Problem terms and codes
- Annex D: Components terms and codes
  (Previously Parts/Components)

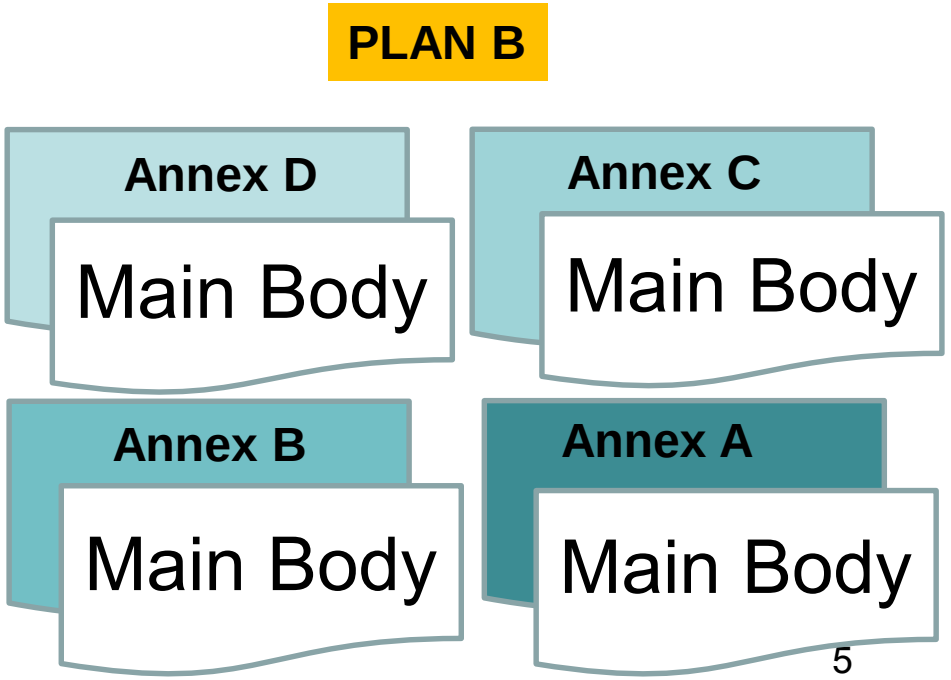
(Reference) Formation of GL document

Structure of GL document

Plan A One GL including all terms

Plan B GL for each Annex





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
- Codes have meaning with one alphabetical letter (A for Medical Device Problem, B for Cause Investigation, C for Patient Problem, D for Components) and 6 digits* Arabic numbers (first 2-digit for level 1, second 2-digit for level 2, and third 2-digit for level 3).
  Ex) A 01 00 00

*Numbers of digits will be decided annex by annex

Annex A: Medical Device Problem Terms and Codes

Level 1			Level 2			Level 3		
Term	Definition	Code	Term	Definition	Code	Term	Definition	Code
Activation, Positioning or Separation Problem	Problem associated with any deviations from device documented performance specifications relating to the sequence of events for activation, positioning or separation of the device or one of its components into a specific body location. NOTE 1 "Deployment" is synonymous with "activation".	A010000	Activation Problem	Problem associated with the activation of the device and/or device components.	A010100	Activation Failure Including Expansion Failures	Problem associated with the device and/or device components failing to be activated including expansion.	A010101
						Difficult or Delayed Activation	Problem associated with delayed or difficult activation of the device and/or device component(s).	A010102
						Premature Activation	Problem associated with early and unexpected activation of the device and/or device component(s).	A010103
						Self-Activation or Keying	Problem associated with the unintended activation of device, or device having been unexpectedly turned on during use.	A010104
			Positioning Problem	Problem associated with the movement of the device and/or device components to an intended location.	A010200	Difficult or Delayed Positioning	Problem associated with users experiencing difficulty or delay to position device and/or device components to a specified location.	A010201
						Difficult to Advance	Problem associated with difficulty moving the device or its components to an intended location (e.g. difficulty in	A010202

Code Mapping: Reference for Public Consultation

ISO	NCI	FDA	IMDRF
1000	C63013	2906	A010000
1001	C63244	1157	A010201
1002	C96715	3270	A010101
1003	C63159	2547	A010303
1004	C62863	1484	A010103
1005	C63035	2577	A010102
1100	C63270	2898	A080300
1102	C64349	2879	A080100
1200	C63269	1112	A080000
1201	C63305	2880	A080200
1300	C62952	2900	A090000
1302	C63223	1171	A090300
1303	C63180	2541	A090400
1304	C63142	2183	A090500
1305	C63055	1371	A090600
1306	C62915	1399	A090700

ISO Order

ISO	NCI	FDA	IMDRF
1000	C63013	2906	A010000
		NEW	A010100
1002	C96715	3270	A010101
1005	C63035	2577	A010102
1004	C62863	1484	A010103
	C62844	1557	A010104
	C63034	3009	A010200
1001	C63244	1157	A010201
	C63235	2920	A010202
	C63233	1316	A010203
	C63228	1528	A010204
	C63210	1212	A010205
	C63198	2524	A010206
	C63043	2616	A010207
	C63183	1158	A010208

IMDRF Order

Proposal for Maintenance of the IMDRF AE terminology

- Evolve the AE WG to AE terminology Maintenance 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

Details to be discussed

- Create webpage for AE terminology maintenance in the IMDRF website and set recommendation form for industry to collect their opinion.
- Each jurisdiction is also to review existing or new terms and bring up ideas to the Maintenance WG.
- Chair including Secretariat of Maintenance WG rotates yearly base
- Chair will call regular meetings (TC or F2F).

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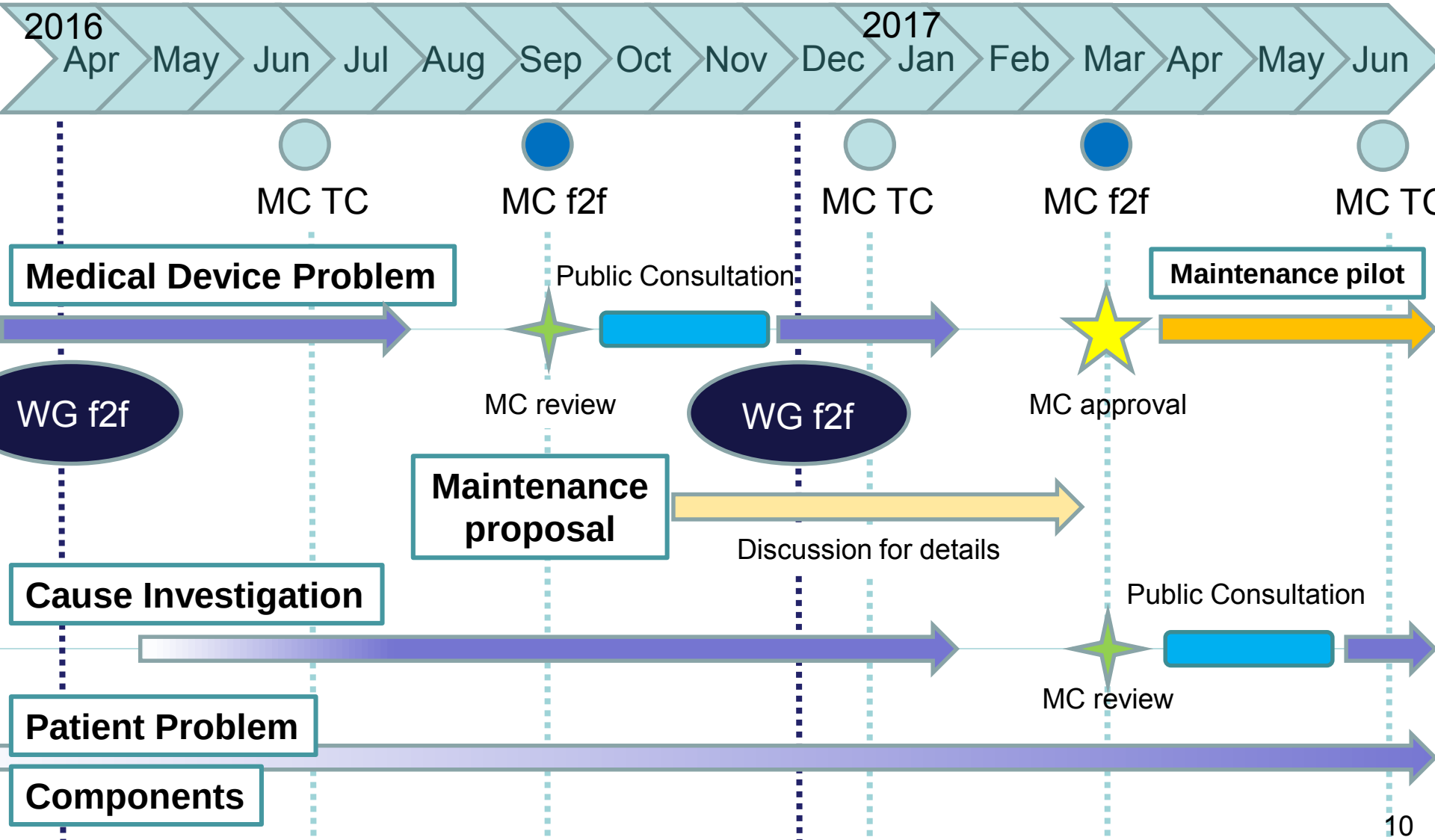
Work Plan (as of Sep 2016)



Thank you