IMDRF International Medical Device Regulators Forum

Medical Device Clinical Evaluation (MDCE) Working Group Update

National Medical Product Administration, China

16th September 2019

Work Item

Update existing 3 GHTF documents.

GHTF SG5 N1R8: 2007*Clinical Evidence – Key Definitions and Concepts*
GHTF SG5 N2R8: 2007 *Clinical evaluation*
GHTF/SG5/N3:2010 *Clinical Investigations*

And 3 topics will be addressed (NWIP)

1. The Essential Requirements of **Demonstrating Equivalence** between the Device under Application and the Comparable Device **for Clinical Evaluation**.
2. **The Decision-Making Principals** for whether a Medical Device Clinical Trial should be Carried Out.
3. Guidelines for the **Acceptance of Overseas Medical Device Clinical Trial Data.**

2018 (2 rounds discussion)

7.17 1st WG T-con Kick-off meeting.

8.07 2nd WG T-con Acceptance of oversea clinical trial data.

8.23 3rd WG T-con Decision-making principals for whether a clinical trial should be carried out.

9.11 4th WG T-con Demonstrating equivalence for clinical evaluation.

10.16 5th WG T-con N2 document.

11.20 6th WG T-con N3 document.

12.10-12.13 WG F2F 1st WG Face to Face meeting in Guangzhou China. Developed working drafts.

2019

1.25 7th WG T-con Working drafts confirmation.

3.19-3.22 3 working drafts were approved and allowed for public consultation.

6.5 Public consultation closed.

6.25 8th WG T-con Public consultation discussion.

7.9-7.11 WG F2F 2nd WG Face to Face meeting in Chengdu China. Developed final drafts.

7.12-7.30 Email Final confirmation.

8.2 Submitted final drafts to MC for consideration.

Comments lists

IMDRF MDCE WG Comment Form	Document:IMDRF MDCE WG (WD)/N55 (formerly GHTF/SG5/N1R8:2007) Clinical Evidence – Key Definitions and Concepts							
Name	Section	Line Number	Type of Comment	Comment	Proposed Change	(Please fill in the forms) Country: e.g. CHINA		
						Accept	Unaccept	Reasons\Final version
Patricia Kultgen	Throughout	Throughout	Technical	Is the term "clinical benefit" specifically avoided? Based on phrase "clinical performance and/or effectiveness" it appears that manufacturers can demonstrate clinical performance, and are not necessarily required to demonstrate effectiveness or benefit?				
Birgitte Berg	1	Introdcution	Technical	There is no mentioning of the European Medical Device Regulation. Please in this section clarify the IMDRF stance on how the relationship of this document is to the MDR and whether applying IMDRF definitions, in this case "General Essential Principles" can be used interchangeably with the MDR "General Safety and Performance Requirements". It is important the manufacturer know whether following IMDRFs recommendations does not make them also need to make separate documents for the EU.				
	Introduction	58	T	The date stamp on the referenced document is February 2010 (rather than May 2007)	Strike and add the following: ~~May, 2007~~ February, 2010 (GHTF/SG5/N3:2010			
Liz Krause	section 3.0		editorial	add IMDRF proposed documents for Clinical Investigation and Clinical Evaluation				
Jessica Yuan\Diana Kanecka	3	88	Technical	Agree with the WG decision to align with the definition of clinical investigation in the ISO 14155 update that is currently in development. Update to remove 2011 version and reference the new version. If the updated ISO 14155 standard is not released when the WG docuemtns are finalized, recommend making mention of the "alignment with ISO/DIS 14155 (under development)" vs. keeping ISO 14155:2011.	(~~ISO 14155:2011~~ alignment with ISO/DIS 14155 under development)			
				ISO 14155 is currently under the revision and in the FDIS phase. The revised version is planned to be released in the end of 2019.				

About public consultation

Comments / Document	Received	Discussed	Accepted
N1 Clinical evidence	47	47	15
N2 Clinical evaluation	161	161	46
N3 Clinical investigation	65	65	33
Total	273	273	94

IMDRF International Medical Device Regulators Forum

The 2nd Face to Face meeting
9th July-11th July
Chengdu, China

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

~~Global Harmonization Task Force~~
International Medical Device Regulators Forum

Title: Clinical Evidence – Key Definitions and Concepts

Authoring Group: ~~Study Group 5~~ Medical Device Clinical Evaluation Working Group

Date: ~~April 26, 2006 5 April~~ July 16 2019

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Clinical Evaluation

Authoring Group: ~~Study~~ Medical Device Clinical Evaluation Working Group ~~5~~

~~**Endorsed by:** The Global Harmonization Task Force~~
Date: ~~May 2007~~ July 16 2019

This document ~~herein~~ was produced by the ~~Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.~~

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

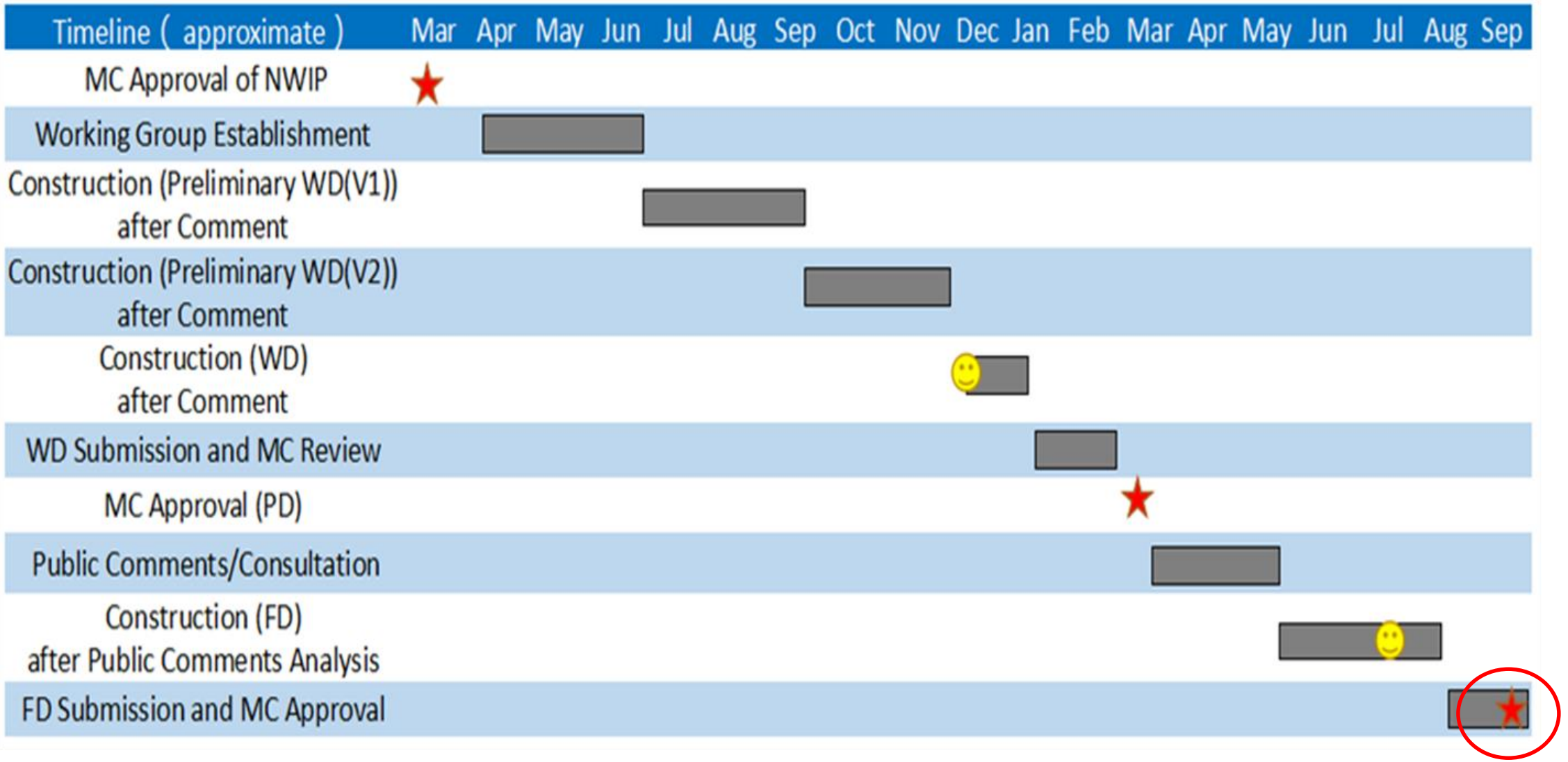
Title: Clinical Investigation
~~**Authoring Group**: Study Group 5~~
~~**Endorsed by**: The Global Harmonization Task Force~~
Authoring Group: Medical Device Clinical Evaluation Working Group

Date: ~~12, 2010 5 April~~ July 16, 2019

~~Dr. Larry Kelly, GHTF Chair~~

Key changes

- Update the definitions and explanations of terms.
- Update reference documents.
- New paragraphs introducing the latest IMDRF documents related to clinical evaluation.
- 2 new appendixes including: the considerations of comparability & considerations of overseas clinical investigation data.
- A new figure of key considerations of clarifying the need for clinical investigations.
- Update the considerations for clinical investigation protocols.
- Introduced concept of multi-regional clinical investigation.
- Other revision of original contents.


Timeline (approximate)
Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep
MC Approval of NWIP
Working Group Establishment
Construction (Preliminary WD(V1)) after Comment
Construction (Preliminary WD(V2)) after Comment
Construction (WD) after Comment
WD Submission and MC Review
MC Approval (PD)
Public Comments/Consultation
Construction (FD) after Public Comments Analysis
FD Submission and MC Approval

What we did during the public consultation…

Develop Possible New Work Item Extension(NWIE)

~~a) Multi-Regional Clinical Investigation (develop a new IMDRF document)~~

b) Clinical Performance Evaluation of IVDs (update of GHTF SG5 N6/N7/N8)

c) Post Market Clinical Follow-up Studies (update of GHTF SG5 N4)

13th August 2019

NWIE b) and c) were submitted to Management Committee.

Thank you