Medical Device Clinical Evaluation (MDCE) Working Group Update

National Medical Product Administration, China

19th March 2019

Work Item

March 2018 Approved to update existing GHTF documents. 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.**

Proposed Update

Topics	GHTF SG5 documents
1. Demonstrating Equivalence for Clinical Evaluation	GHTF SG5 N1 &N2.
2. Decision-Making Principals for whether a Clinical Trial should be Carried Out	GHTF SG5 N3.
3. Acceptance of Overseas Clinical Trial Data	GHTF SG5 N2 &N3.

Update 3 relevant GHTF SG5 documents

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

Current Status

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.

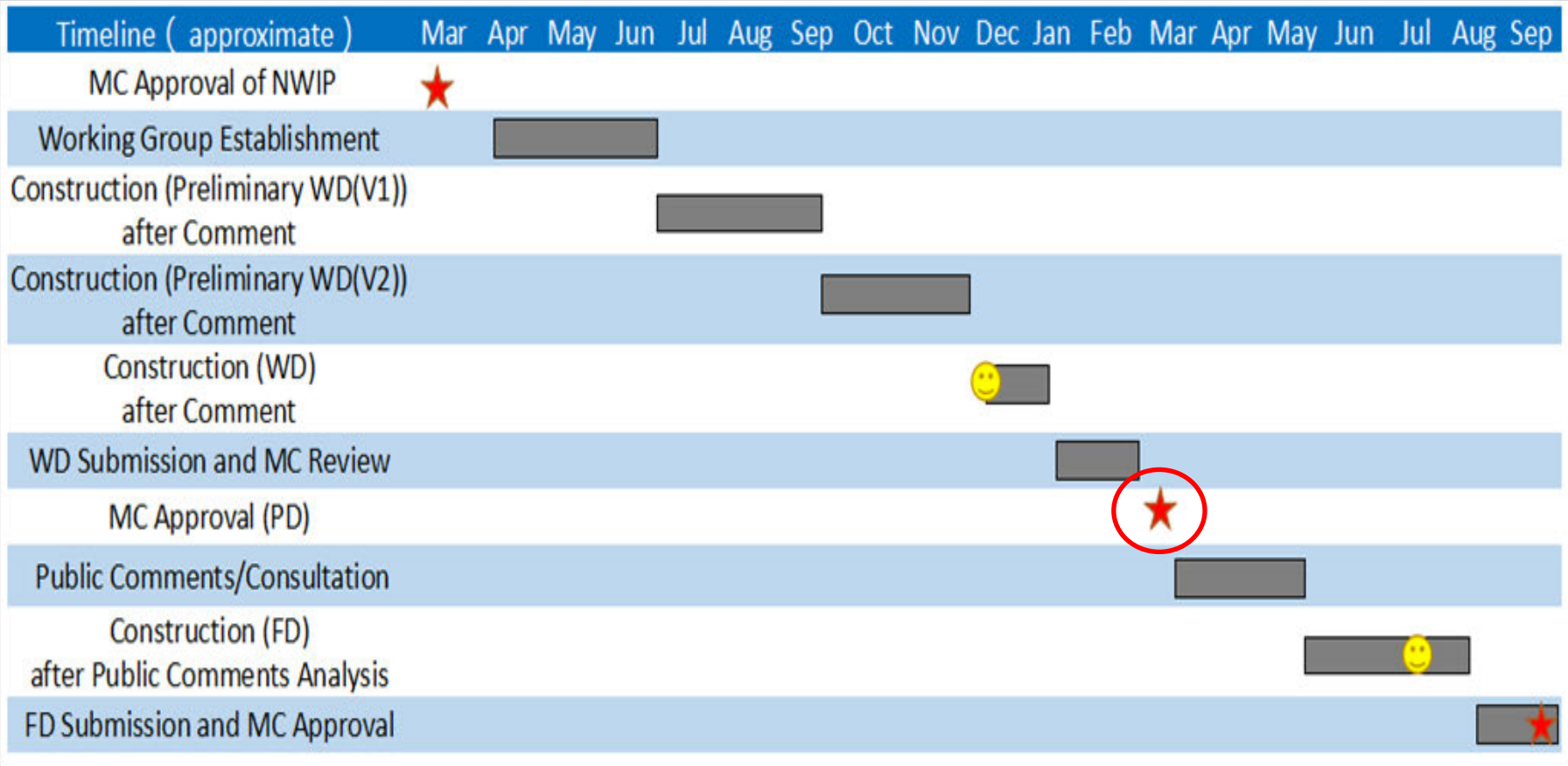
11.20 6th WG T-con N3 document.

12.10-12.13 1st WG Face to Face meeting in Guangzhou China.

2019

1.25 7th WG T-con drafts confirmation.

Current Status



Key changes

N1: *Clinical Evidence – Key Definitions and Concepts*

- Update the definitions and explanations of terms

- Update reference documents

Key changes

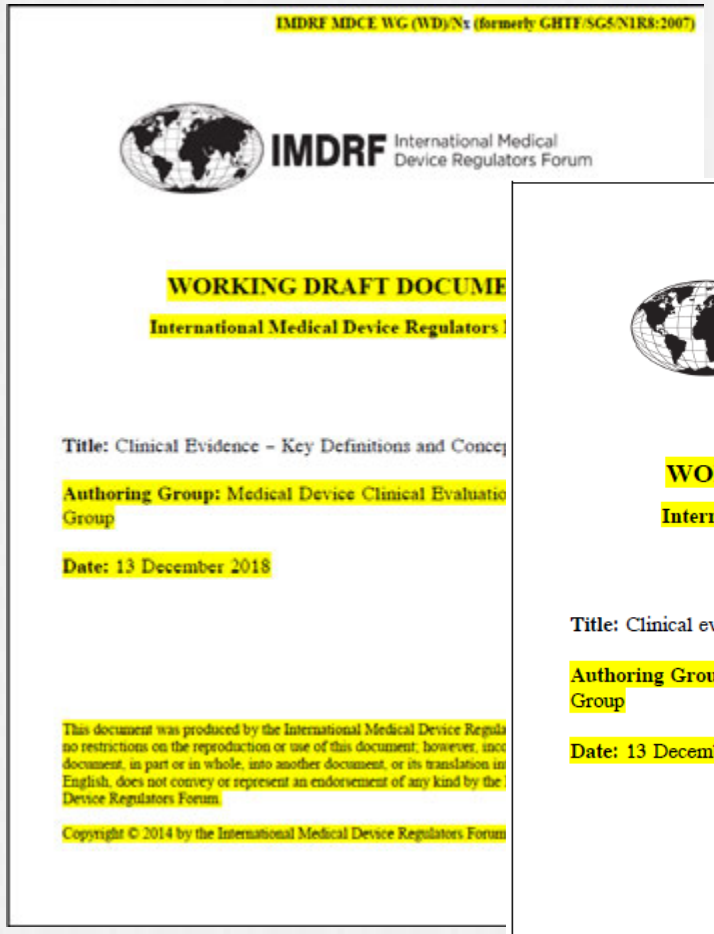
N2: *Clinical evaluation*

- Update the several definitions such as “comparable devices" , "intended use/purpose“, “effectiveness”.
- New paragraphs introducing the latest IMDRF documents relates to SaMD and registry data
- 2 new appendixes including: the considerations of comparability & considerations of overseas clinical investigation data

Key changes

N3: *Clinical Investigations*

- A new figure of key considerations of clarifying the need for clinical investigations
- Combine the paragraphs of risk management and risk analysis
- Update the considerations for device study protocols
- Introduced concept of multi-regional clinical investigation.



IMDRF MDCE WG (WD)/Nx (formerly GHTF/SG5/N1R8:2007)

IMDRF International Medical Device Regulators Forum

WORKING DRAFT DOCUME

International Medical Device Regulators

Title: Clinical Evidence – Key Definitions and Concep

Authoring Group: Medical Device Clinical Evaluatio Group

Date: 13 December 2018

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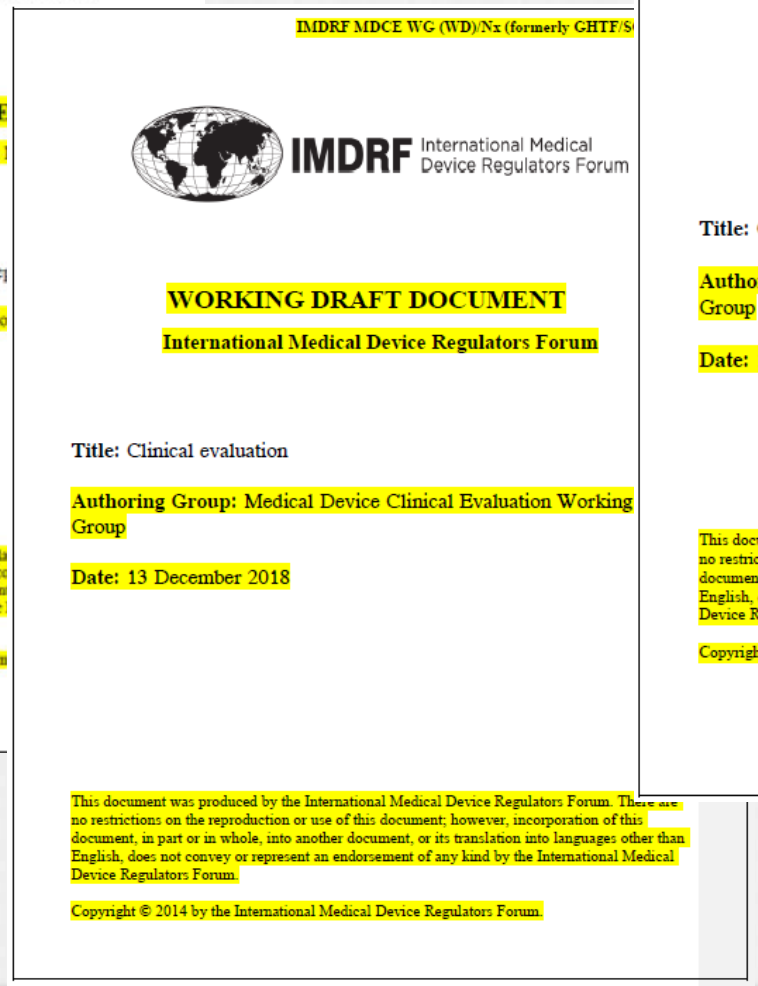

IMDRF MDCE WG (WD)/Nx (formerly GHTF/S

IMDRF International Medical Device Regulators Forum

WORKING DRAFT DOCUMENT

International Medical Device Regulators Forum

Title: Clinical evaluation

Authoring Group: Medical Device Clinical Evaluation Working Group

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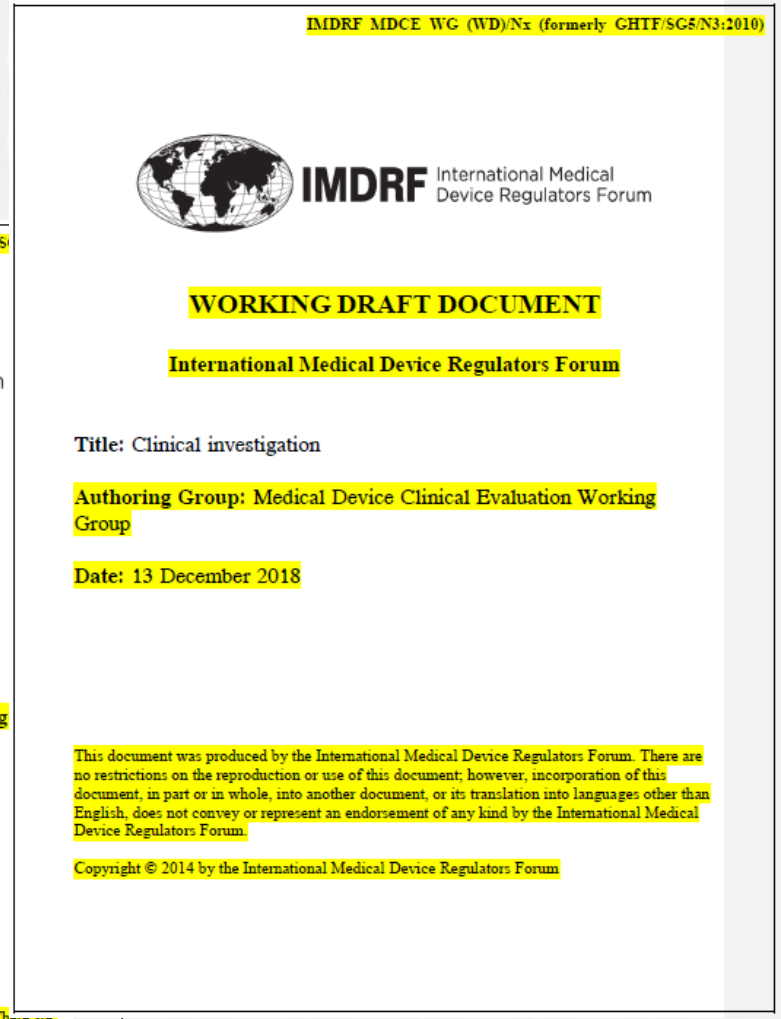

IMDRF MDCE WG (WD)/Nx (formerly GHTF/SG5/N3:2010)

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