IMDRF International Medical Device Regulators Forum

Medical Device Clinical Evaluation (MDCE)Working Group Update

National Medical Product Administration,China

September 18th, 2018

Purpose

- Improve the effectiveness and efficiency of premarket review by promoting increased global harmonization in approach and requirements on leveraging and evaluating the available clinical evidence,

- Reduce the number of redundant clinical trials, integrate the principles of post-market clinical follow up and real world evidence, as applicable,

- Accelerate the introduction of new safe and effective medical devices/technologies to the patients in variable jurisdictions.

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 Investigations*

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Working Group

April

Apr. 6th

Submit Final NWIP to MC

April

Apr. 10th

Sent out official invitation letters.

May

April.11th - May.11th

Received nominees from MC members

May

May. 28th

Submitted proposed member list to MC.

June

May.30th - June 7th

Received nominees and resubmitted to MC

June

June. 27th

Reported working group progress on MC T-con, and WG established.

Australia: Simon Singer
Brazil: Alessandro Ferreira do Nascimento, Leticia Barel Filier
Canada: Amanda Jones
China: Yinghui Liu (Chair), Shan Ju, Yawen Wang
EU: Camilla Fleetcroft, Gwennaelle EVEN
Japan: Yumiko Aoyagi, Daisuke Tanaka, Mami Ho, Daisuke Fujisawa
Russia: Valeeva Aisylu, KurtukovYaroslav
Singapore: Low Lai Peng
South Korea: Youngsook Choi, Youngmin Han
the United States: Soma Kalb, Minerva Hughes
WTO/PAHO: Micaela Dominguez
DITTA: Keiichiro Ozawa, Leo Hovestadt, Bradley Matsubara
GMTA: Michael Pfleger, Robin Newman, Theodore Lystig

Current Status

6.27 MC T-con Working group establishment.

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.

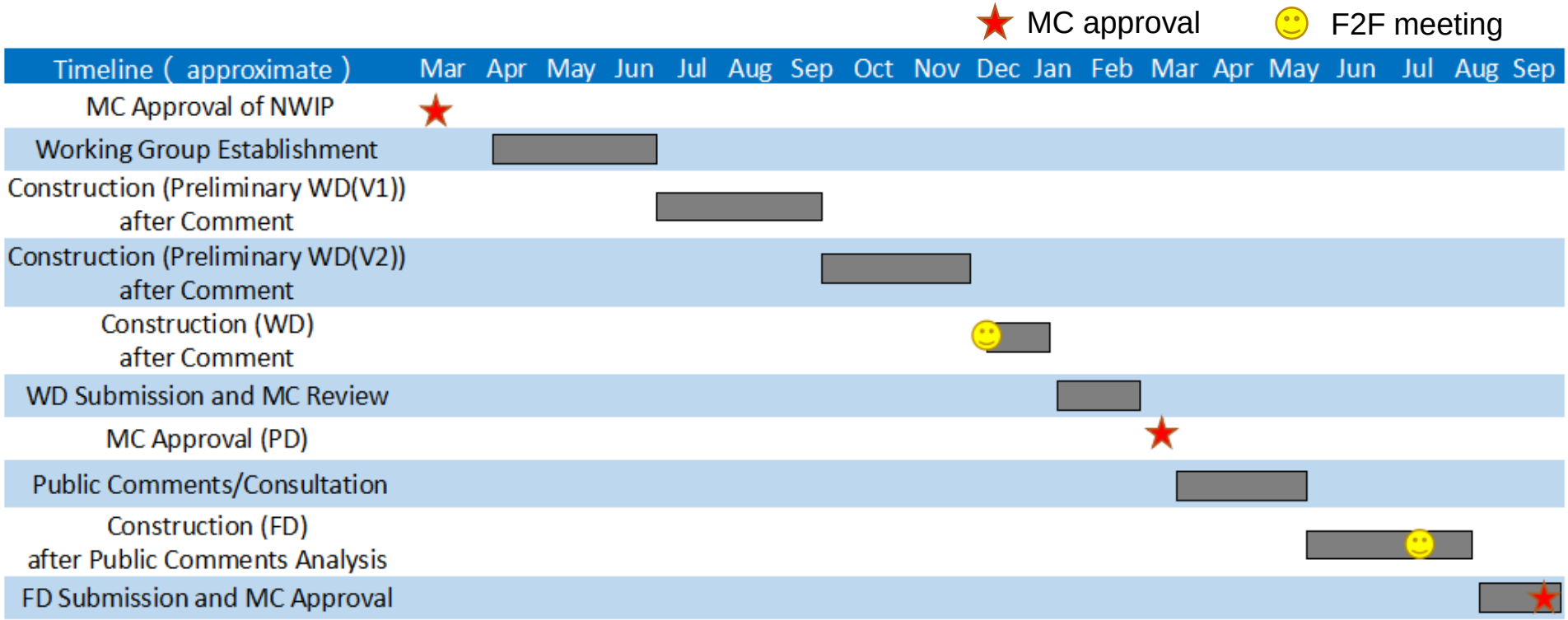
9.11 4th WG T-con Demonstrating equivalence for clinical evaluation.

- Completed the 1st round discussion for all 3 topics by teleconferences.
- Developed preliminary working drafts version1.

Outcome of T-cons

Date	Topic	Comments	Outcome
June 27th	Kick-off Meeting	/	Reached agreement on the work plan and decided 3 documents to be updated.
July 17th	Acceptance of Oversea Clinical Trial Data	38	Generally met the agreement, the working draft may be finished after a few modification and check of wording.
August 7th	Decision-Making Principals for Clinical Trial	65	Had a full communication, needs modifications according to comments.
August 23th	Equivalence Demonstration	46	Reached agreement on most of changes, needs modifications and new adding according to comments.

Work Plan



*** WD**: Working draft, **PD**: Proposed document, **FD**: Final document

Examples of proposed changes

1. Equivalence Demonstration

- "Whether data from comparable devices to support the safety and/or performance of the device in question."

  e.g.

  -- Clinical data from multiple comparable devices

  -- Explanation of the "same intended use"

- Update definitions and quoted latest relevant IMDRF documents.

  e.g.

  -- Definition of clinical evaluation, comparable device, intended use/Purpose

  -- Quote IMDRF document of SaMD, registry data

2. Decision-Making Principle for Clinical Trial

- Update the crucial considerations in clarifying the need for clinical investigation

  e.g.

  -- Novelty of the device

  -- Risk level of the device

  -- Sufficiency of data from sources other than CI

  -- Balance in pre-market and post-market clinical data collection

  -- Data from CI generated in other jurisdiction(s)

- Update reference ISO14155-1:2003 &ISO14155-2:2003

3. Acceptance of Overseas Data

- Adding on N2

  A new appendix of “considerations when data form clinical Investigation are generated in different jurisdiction(s)”

  -- Regulatory requirements differences

  -- Internal and external factors

- Adding on N3

  -- Introduce Multi Regional Clinical Investigation as a consideration of clinical design.

  --A series of definition related on MRCI

  MRCI\Region\Regulatory Region

Foundation of updates

- Regulations and guidelines from 10 member jurisdictions.
- The agreements of group members.

Timeline

Teleconference

2018

- **Oct-Nov** Discussion and modification of preliminary working drafts(V1)
- **Dec 11th~14th** Face to face working group meeting to finalize 3 working drafts

2019

- **Jan-Feb** Submit working drafts to MC (milestone 1)
- **Mar** Woking drafts to be considered during MC meeting
- **Mar-May** Public consultation period
- **June-July** Analysis and discuss comments Face to face working group meeting to finalize draft documents
- **Aug** Submit final documents to MC
- **Sep** Final documents to be considered during MC meeting (milestone 2)

Thank you