IMDRF International Medical Device Regulators Forum

Medical Device Clinical Evaluation (MDCE) Working Group

---- Post-Market Clinical Follow-up Studies

23th March 2021

Work Item

Update existing GHTF documents.

GHTF SG5 N4: *Post-Market Clinical Follow-up Studies*

And following issues need to be addressed (NWIE)

a) Requirements for Clinical Evidence from new sources of Clinical Data (i.e. Real-World clinical experience) for Post-Market Clinical Follow-Up Studies.
b) Basing a Post-Market Clinical Follow-Up Study on clinical experience such as registries or medical records or other sources of data.
c) What clinical issues are appropriate to investigate prior to marketing and what may be investigated post-market.
d) Updates to align guidance on Post-Market Clinical Follow-Up Study to changes in other documents.

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Teleconferences

Develop working draft

2020

3.10 1st WG T-con
3.24 2nd WG T-con
4.07 3rd WG T-con
4.21 4th WG T-con
5.12 5th WG T-con
5.26 6th WG T-con
6.09 7th WG T-con
6.10 8th WG T-con
6.23 9th WG T-con
7.07 10th WG T-con
7.14 11th WG T-con

Public consultation

Received **176** comments

Develop final draft

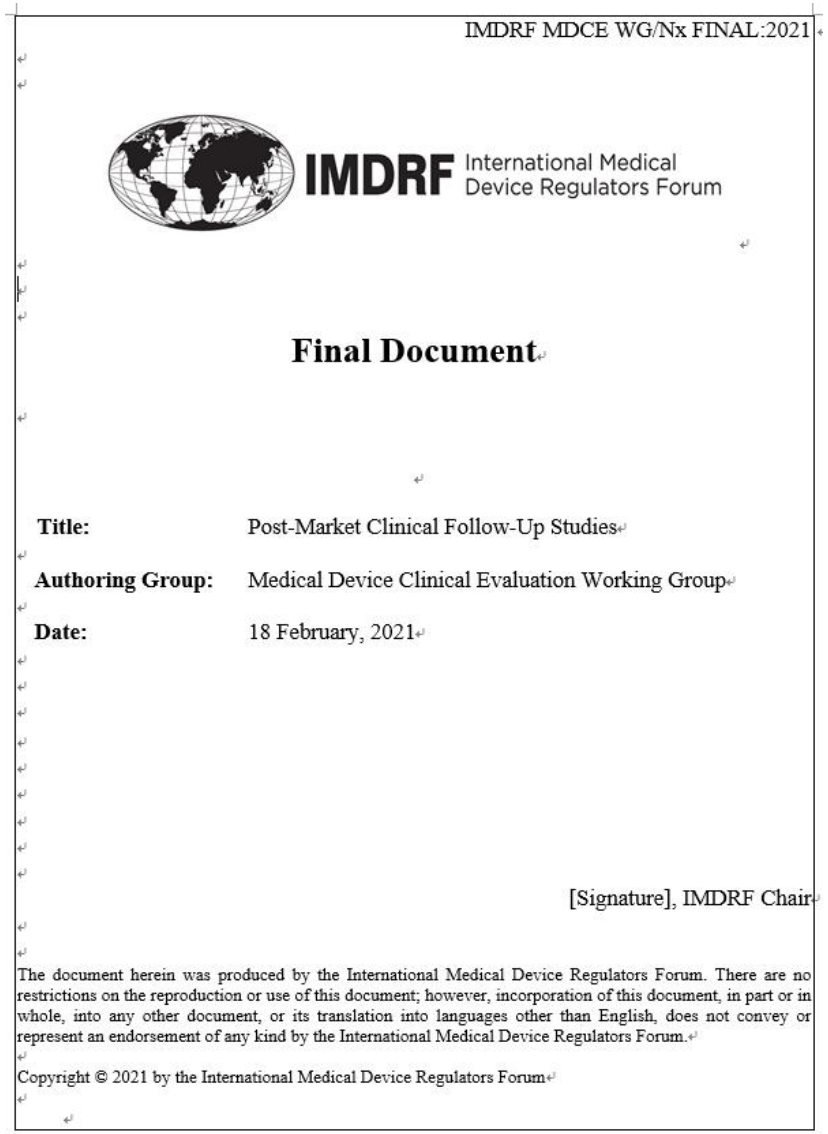
2021

1.19 12th WG T-con
1.26 13th WG T-con
2.02 14th WG T-con
2.09 15th WG T-con

The Final draft

Document Structure:

1.0 Introduction
2.0 Scope
3.0 References
4.0 Definitions
5.0 Circumstances where a PMCF study may be indicated
6.0 Elements of a PMCF study
7.0 The use of information from PMCF studies
Appendix A
Appendix B
Appendix C



IMDRF MDCE WG/Nx FINAL:2021

IMDRF International Medical Device Regulators Forum

Final Document

Title: Post-Market Clinical Follow-Up Studies

Authoring Group: Medical Device Clinical Evaluation Working Group

Date: 18 February, 2021

[Signature], IMDRF Chair

Key changes

- Update the definitions of terms.

Post-market clinical follow-up study: *A study carried out following marketing authorization intended to answer specific questions (uncertainties) relating to Safety, clinical performance and/or effectiveness of a device when used in accordance with its labelling.*

- Update reference documents.

- Updated the circumstances where a PMCF study may be indicated, including:

a) Unanswered questions of long-term Safety, clinical performance and/or effectiveness.
b) Novel technologies or new intended use.
c) Higher-risk device and use scenarios.
d) Uncertainties in generalizing clinical investigation results.
e) Devices approved with clinical data from comparable devices.
f) Emergence of new information relating to Safety, clinical performance and/or effectiveness.
g) Urgent market access in public health emergencies.
h) Rare anticipated adverse events.
i) Effectiveness of the mitigation for a known risk.

- Revised the elements of a PMCF study, added the requirements and considerations about the objective, design and implementation of PMCF studies that based on clinical experience data. 3 new informative appendixes are introduced in the design of PMCF studies.

Appendix A Examples of Clinical Experience Data Sources for PMCF Studies

Appendix B Considerations for Using Clinical Experience Data for PMCF Studies

Appendix C Potential Biases and Confounding in PMCF Studies and Controlling Methods

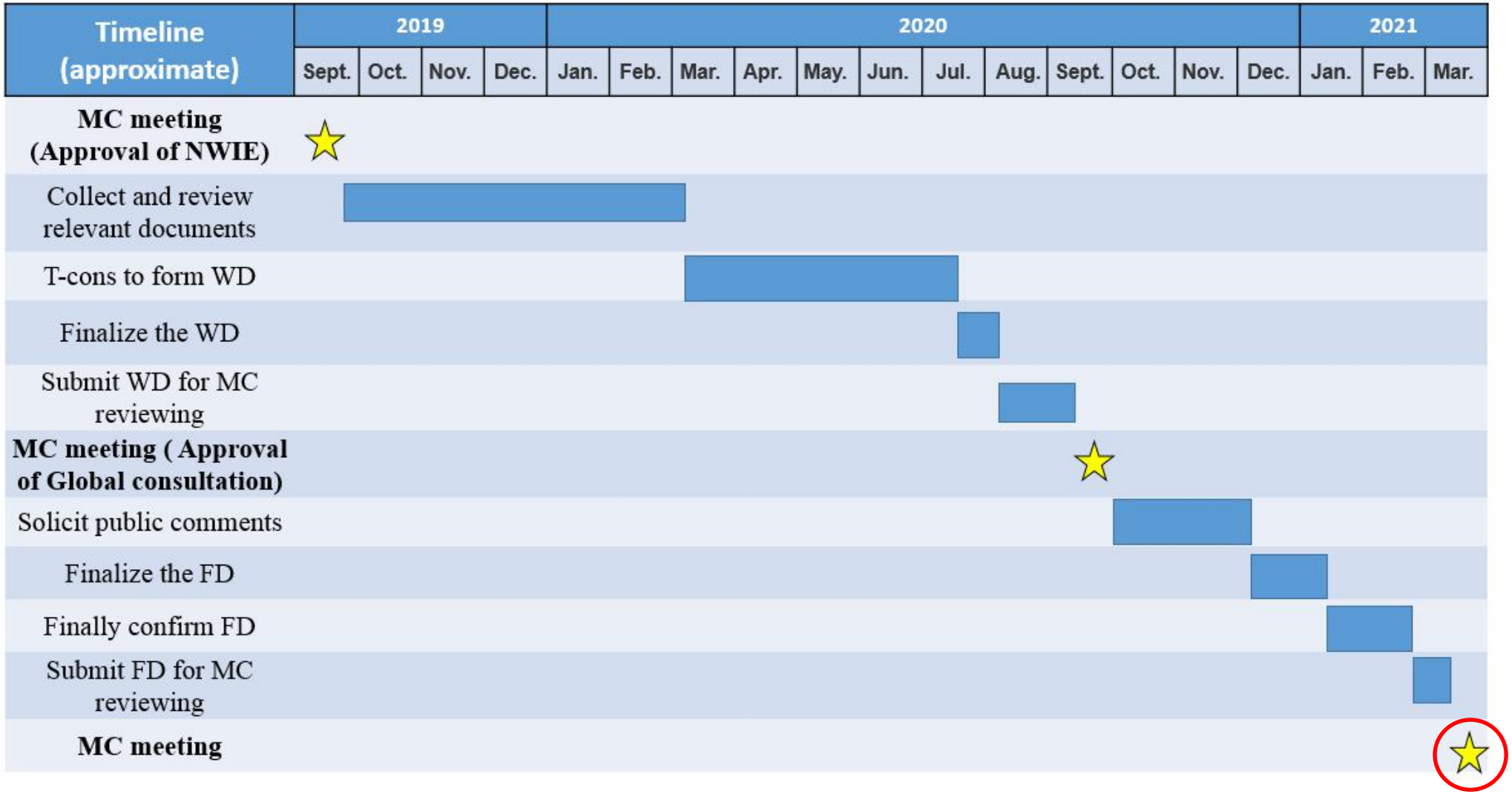
- Update the use of information from PMCF studies

"*The data and conclusions derived from the PMCF studies are part of the post-market surveillance program and used as input to the clinical evaluation and risk management process. This may result in the need to reassess whether the device continues to comply with the Essential Principles. Such assessment may result in corrective or preventive actions, for example：*

- *changes to the labelling/instructions for use,*
- *changes to manufacturing processes,*
- *changes to the device design,*
- *public health notifications, or*
- *product removal.*

In addition, clinical data/evidence generated from PMCF studies can be used to:

- *become the part of premarket clinical evidence, or supplementary data for next- generation or similar technologies when applying for marketing authorization,*
- *develop objective performance criteria and performance goals,*
- *form control/comparison groups."*



MC approval WD = Working draft FD = Final Document.

Thank you