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Medical Device Clinical Evaluation (MDCE) Working Group Update

National Medical Product Administration, China

September 23th, 2020



Work Item

16th MC meeting Approved NWIE to address some issues including:

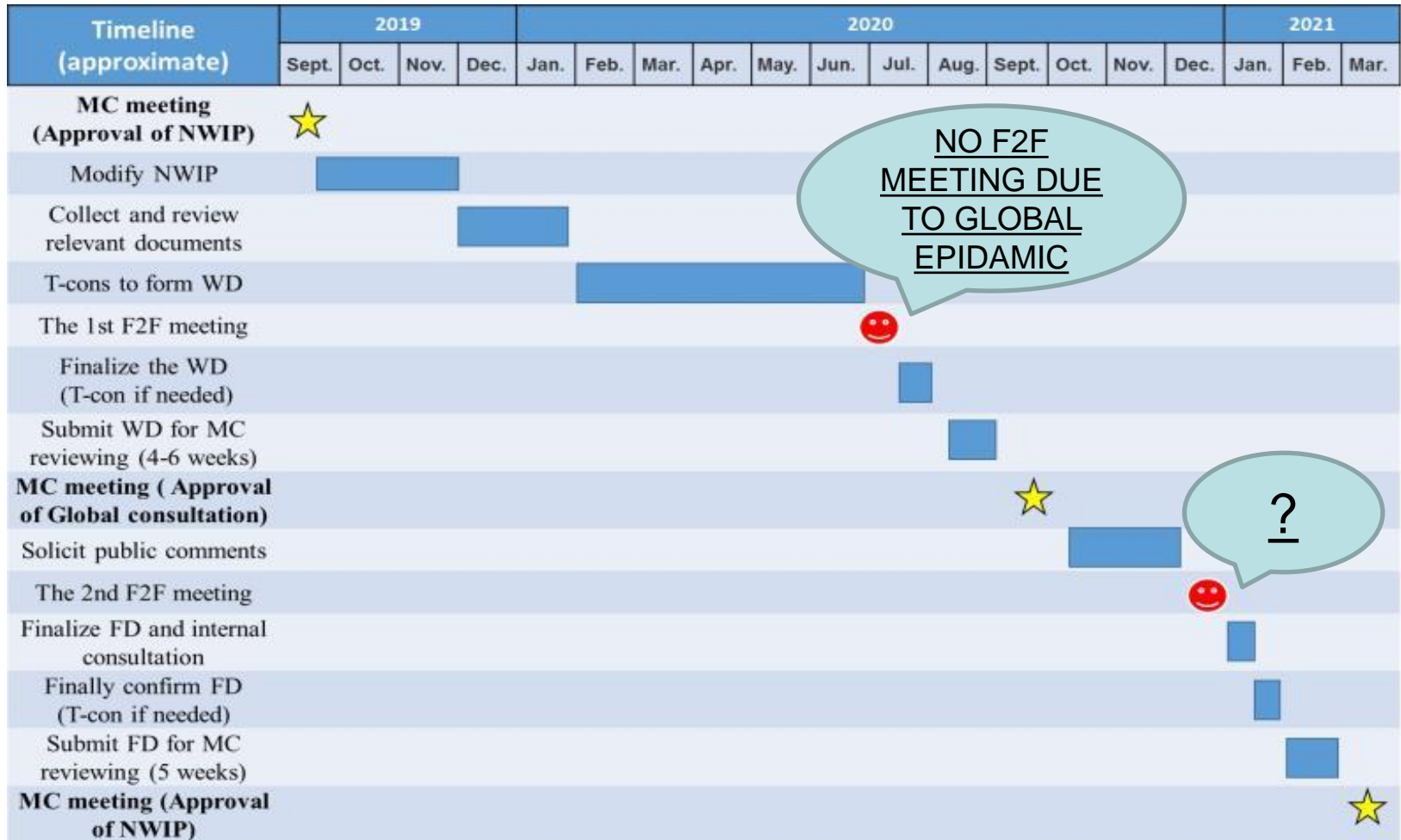
1. The requirements for clinical evidence from new sources of clinical data.
2. Basing a PMCF study on clinical experiences.
3. What clinical issues are appropriate to investigate prior to marketing and what may be investigated post-market.
4. Update to align guidance to changes in other documents.

update

GHTF/SG5/N4:Post-Market Clinical Follow-Up Studies



Work plan & progress



NO F2F MEETING DUE TO GLOBAL EPIDAMIC

?



Preparation

- Modify NWIE form.
- Literature reviews from **81** relative documents of all 10 jurisdictions.

Draft document

- **3** Rounds of discussion
- **11** Tele-conferences
- **5** Versions

Discussion	Comments	
1 st round	160	
2 nd round	65	
3 rd round	20	plus 120 editorial comments



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Examples of proposed changes

- 1. What issues can be addressed via PMCF studies?**
change “Residual risks” to “Uncertainties”.
- 2. Circumstances where a PMCF study may be indicated.**
9 examples describe the circumstances.
- 3. The use of information from PMCF studies.**
9 examples describe the utilization.



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4. Elements of a PMCF study design & implementation

5. New appendixes (informative)

Appendix A: Examples of clinical experience data sources

Appendix B: Considerations of using clinical experience data

Appendix C: Potential bias and control methods



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Timeline

Tele-conference

2020

Aug. Submit working draft to MC (milestone 1)

Sep. Working draft to be considered during MC meeting

Sep. – Nov. Public consultation period

Nov. – Dec. Discuss the comments

2021

Jan. Finalize draft document

Feb. Submit final documents to MC

Mar. Final documents to be considered during MC meeting
(milestone 2)



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Working Draft

IMDRF MDCE WG(WD2)/Nx (formerly GHTF/SG5/N4:2010)



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Working Draft

Title: Post-Market Clinical Follow-Up Studies

Authoring Group: Medical Device Clinical Evaluation Working Group

Endorsed by: IMDRF Management Committee

Date: 7 August, 2020 February 18, 2010

Dr. Larry Kelly, GHTF Chair

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Thank you