Medical Device Clinical Evaluation (MDCE) Working Group Update

National Medical Product Administration, China

September 23th, 2020
**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.

GHTF/SG5/N4: Post-Market Clinical Follow-Up Studies
# Work plan & progress

<table>
<thead>
<tr>
<th>Timeline (approximate)</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
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<tr>
<td>MC meeting (Approval of NWIP)</td>
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<tr>
<td>Modify NWIP</td>
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<tr>
<td>Collect and review relevant documents</td>
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<td>T-cons to form WD</td>
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<td>Finalize the WD (T-con if needed)</td>
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<td>Finalize FD and internal consultation</td>
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- MC approval
- F2F meeting
- WD = Working draft
- FD = Final Document.

**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

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<td>3&lt;sup&gt;rd&lt;/sup&gt; round</td>
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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.
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
Timeline

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)
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, 2016

Dr. Larry Kelly, GHTF Chair

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