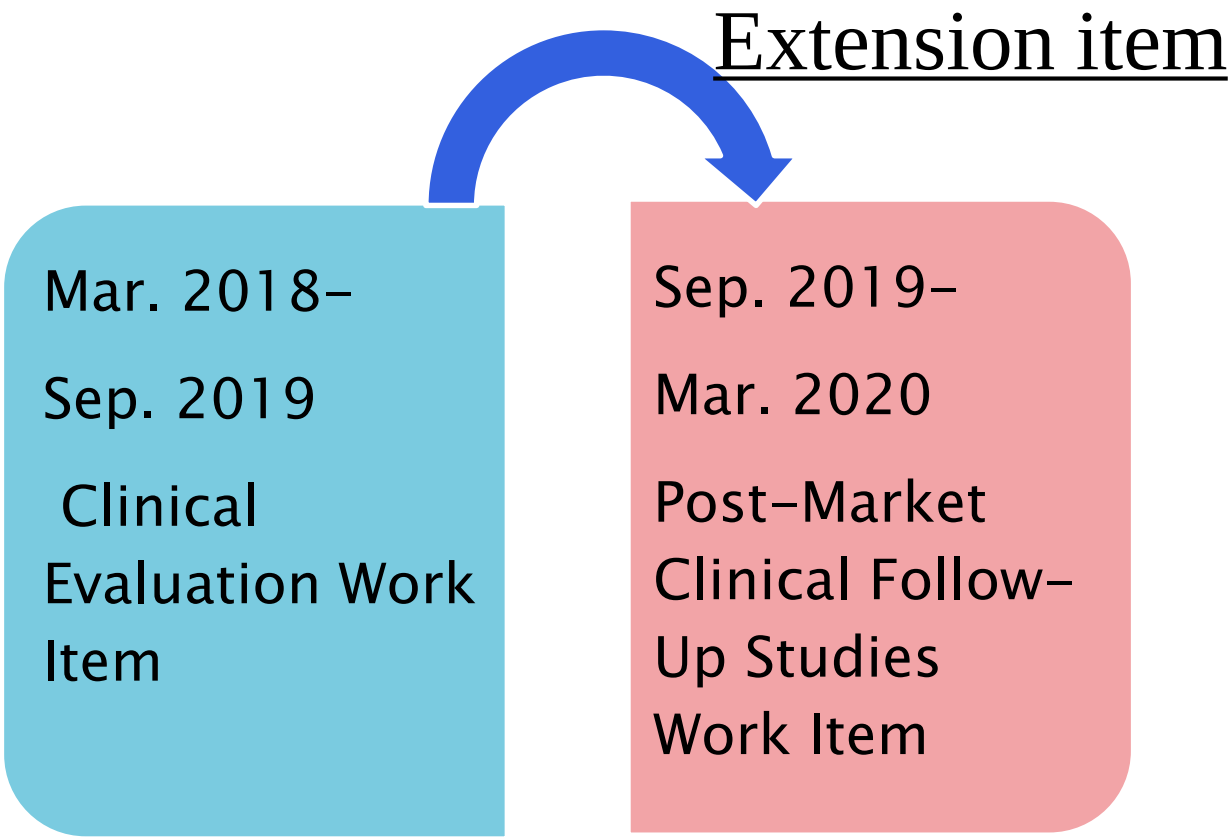
IMDRF International Medical Device Regulators Forum

Medical Device Clinical Evaluation (MDCE)Working Group Update

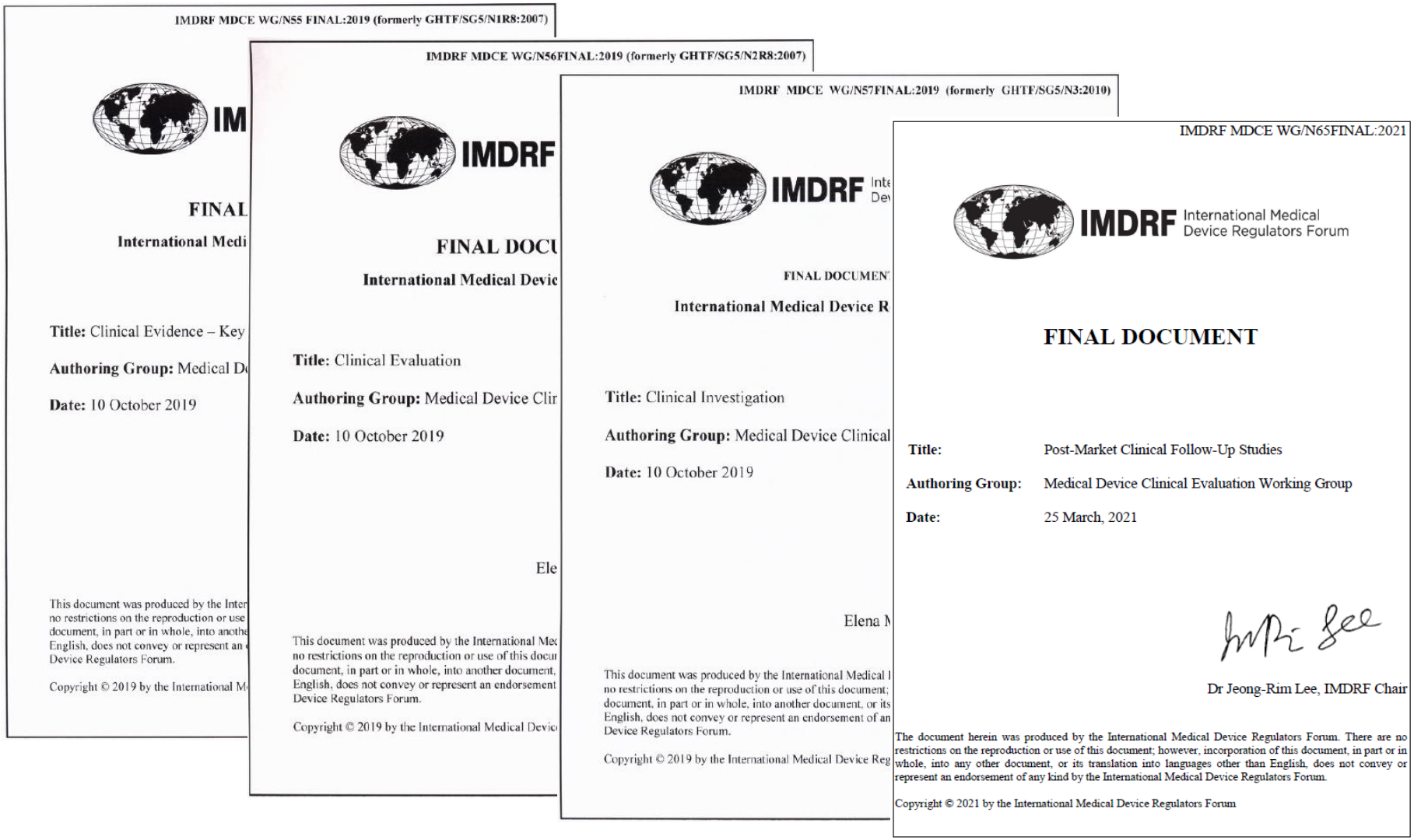
National Medical Product Administration,China

September 14th, 2021

Summary of previous work



Documents developed



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Title: Clinical Evidence – Key

Authoring Group: Medical D

Date: 10 October 2019

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FINAL DOCUMENT

Title:	Post-Market Clinical Follow-Up Studies
Authoring Group:	Medical Device Clinical Evaluation Working Group
Date:	25 March, 2021

Dr Jeong-Rim Lee, IMDRF Chair

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NWIE/NWIP submitted – MRCI & N5

- **Multi-Regional Clinical Investigation (MRCI)**

Aim to increase the efficiency and effectiveness during pre-market medical device review by promoting global harmonization in general requirements on the planning, design and conduct of the MRCIs.

- **Reportable Events During Pre-Market Clinical Investigations(N5)**

Aim to Harmonize a more tailored and fit for purpose regulatory model for recording and reporting adverse events that may occur during a clinical investigation. Adapt the requirements to current situation of IMDRF members, such as scope of reporting events, timing to report, contents of reports etc. Transfer detailed requirements from main body into informative attachment with necessary modification, reflecting the representative requirements of different jurisdictions.

Unfortunately, the NWIP/NWIE did not discussed at MC meeting, because the MC considered that IVD work item has higher priority under current global situation.

Further work plan

- MDCE working group will consider to apply for the MRCI & GHTF N5 work items after IVD work item is done.

OR

- Working group is also exploring new work items to consider, aligned with the IMDRF strategic plan 2021-2025.

Thanks for your attention