Working Group 5

Clinical Evidence for Performance and Safety

GHWP

Active Members

Chair : Fikriansyah Bin Irman
Co-Chair : Sumati Randeo
Secretary : Mie Ohama
Regulators : 6 Members
Industry : 7 Members

Kindly note the GHWP WG membership application procedures as follows:

1) Please complete the membership registration form and send along with the applicant's CV to Secretariat email.
2) Application will be forwarded to related WG Chair & Co-Chair for approval.
3) Application will then be sent to the TC Chair & Co-Chairs for approval.

Work Items 2022

GHWP

Work Items

One
Regulatory Updates

Two
Develop & Draft Guidance Documents

Three
Training

GHWP

WG 5 Work Plan 2022:

Regulatory Updates

Work Item 1	Target Output	Status Update
Regular review of Global clinical regulatory updates	To share and update the WG 5 members of constantly changing regulatory landscape with respect to Clinical Investigation regulations and guidance.	Completed

- Updates from the IMDRF meeting as shared by advisors.
- The following new and changing regulations were reviewed.

Regular review of Global clinical regulatory updates

Country	Title
USA	• Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus • Final Guidance: Principles for Selecting, Developing, Modifying and Adapting Patient Reported Outcome Instruments for Use in Medical Device Evaluation • Final Guidance: Patient Engagement in the Design and Conduct of Medical Device Clinical Studies • Final Guidance: Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)
China	• Good Clinical Practice for Medical Device • Final Guidance - Guidance for Technical Review of the Clinical Evaluation of Intravascular Catheters by Comparison with Predicate Devices • Final Regulation-Notice on Issuing 5 technical guidance including Technical Guidance for Clinical Evaluation of Medical Devices (NMPA Notice [2021] No. 73 • Final Regulation-Notification of Exemption from Clinical Evaluation of Medical Device Catalog (No. 71 of 2021) • Final Regulation - Guidance for Technical Review of Clinical Evaluation of the Equivalent Devices of Ultrasonic Scalpel System
Japan	• Partial Revision of the Ethical Guidelines for Human Life Science and Medical Research • Enforcement of ministerial ordinance to revise a part of 'the ordinance for enforcement of the act for ensuring the safety, etc. of regenerative medicine, etc.' and 'regulations for enforcement of clinical research act'.
EU	• EU MDR – MDCG 2019-9 (rev1March 2022): Summary of Safety and Clinical Performance • EU MDR - MDCG 2021-28 Substantial modification of clinical investigation under MDR • EU Commission Implementing Regulation: 2021/2078 lawing down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (EudaMed) Nov 2021 • EU-MDR_MDCG 2022-2: General principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs).
Canada	• Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations: SOR/2022-18
Egypt	• Clinical Trials Act

WG 5 Work Plan 2022:

Develop & Draft Guidance Documents

Work Item 2	Target Output	Target & Status Update
GHWP guidance document on Clinical Evaluation for IVD related to Covid 19 PCR testing devices.	Collaboration with WG2 to finalize the guidance documents*	On hold
Gap analysis between IMDRF and GHWP Guidance	To understand the gap between IMDRF and GHWP guidance on Clinical Evidence for Medical Device - Key Definitions and Concepts, Clinical Evaluation and Clinical Investigation	Completed

**Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for In Vitro Diagnostic Medical Devices endorsed on 1 Dec 2021*

The gaps analysis between IMDRF and GWHP guidance were completed, and the result of the gap analysis was reviewed. Based on the gap analysis, the following GHWP guidance was finalized:

Clinical Evidence for Medical Device – Key Definitions and Concepts
Clinical Evaluation
Clinical Investigation

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WG 5 Work Plan 2022:

Training

Work Item 3	Target Output	Target & Status Update
For training for WG 5 and AHWP members, WG5 will organize a workshop during AHWP annual meeting in 2022.	• ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice • ISO 20916: 2019 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice	Postponed

Thanks!

Any questions ?

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