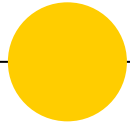


**Working Group 5**

**Clinical Evidence for  
Performance and Safety**



GHWP



## Active Members

Chair : Fikriansyah Bin Irman

Co-Chair : Sumati Randeo

Secretary : Mie Ohama

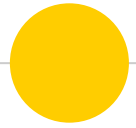
Regulators : 6 Members

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

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**One**

Regulatory Updates

**Two**

Develop & Draft  
Guidance Documents

**Three**

Training



GHWP

# WG 5 Work Plan 2022:



## Regulatory Updates

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### Work Item 1

Regular review of Global clinical regulatory updates

### Target Output

To share and update the WG 5 members of constantly changing regulatory landscape with respect to Clinical Investigation regulations and guidance.

### Status Update

Completed

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- 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	<ul style="list-style-type: none"><li>• Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus</li><li>• Final Guidance: Principles for Selecting, Developing, Modifying and Adapting Patient Reported Outcome Instruments for Use in Medical Device Evaluation</li><li>• Final Guidance: Patient Engagement in the Design and Conduct of Medical Device Clinical Studies</li><li>• Final Guidance: Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)</li></ul>
China	<ul style="list-style-type: none"><li>• Good Clinical Practice for Medical Device</li><li>• Final Guidance - Guidance for Technical Review of the Clinical Evaluation of Intravascular Catheters by Comparison with Predicate Devices</li><li>• Final Regulation-Notice on Issuing 5 technical guidance including Technical Guidance for Clinical Evaluation of Medical Devices (NMPA Notice [2021] No. 73</li><li>• Final Regulation-Notification of Exemption from Clinical Evaluation of Medical Device Catalog (No. 71 of 2021)</li><li>• Final Regulation - Guidance for Technical Review of Clinical Evaluation of the Equivalent Devices of Ultrasonic Scalpel System</li></ul>
Japan	<ul style="list-style-type: none"><li>• Partial Revision of the Ethical Guidelines for Human Life Science and Medical Research</li><li>• 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'.</li></ul>
EU	<ul style="list-style-type: none"><li>• EU MDR – MDCG 2019-9 (rev1March 2022): Summary of Safety and Clinical Performance</li><li>• EU MDR - MDCG 2021-28 Substantial modification of clinical investigation under MDR</li><li>• 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</li><li>• <a href="#">EU-MDR MDCG 2022-2: General principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs).</a></li></ul>
Canada	<ul style="list-style-type: none"><li>• Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations: SOR/2022-18</li></ul>
Egypt	<ul style="list-style-type: none"><li>• Clinical Trials Act</li></ul>

# WG 5 Work Plan 2022:



## Develop & Draft Guidance Documents

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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

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*\*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

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### 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

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# Thanks!

*Any **questions** ?*

You can find me at

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