GHWP 26th Annual Meeting

Feb 15th, 2023

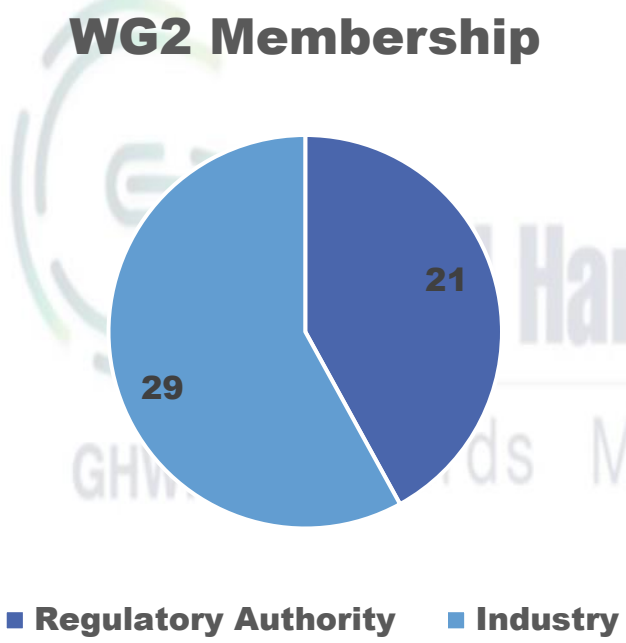
WG2 – Pre-market: IVDD

Chair: Dr. Wen-Wei TSAI

Co-Chair: Ir Prof. Albert KF POON

Advisor: Ms. Shelley TANG

WG2 Membership Updates



50 members from 20 economies

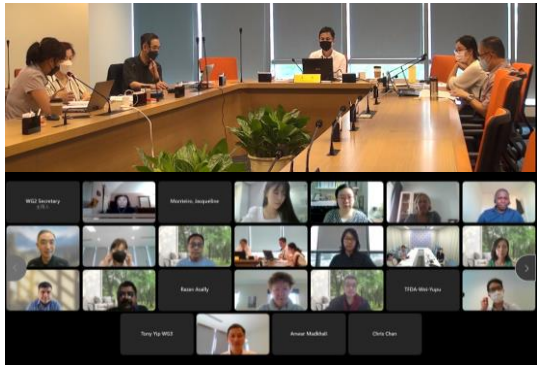
- **Incl. 1 advisor and 2 observers**
- **3 new members:**

1. Mr. Shang-Ching LIN
   (Regulatory Authority, Chinese Taipei)
2. Ms. Ning Zhen Justina Lee
   (Industry, Singapore)
3. Ms. Yon Ju Kang
   (Industry, Republic of Korea)

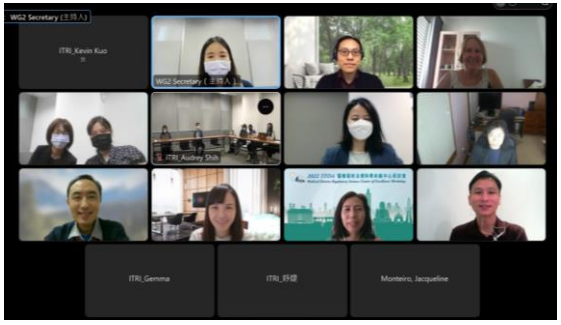
WG2 Project Activities in 2022

Date	Activity
Feb. 15	**WG2 1st Teleconference**
Jun. 17	WG2-5 Initial Meeting for “Guidance document on Clinical Evaluation for IVD related to COVID 19 PCR testing devices”
Jul. 21	WG1-2-3 Initial Meeting for ”Revisit a GHWP Document (Categorisation of Changes to a Registered Medical Device, AHWP/WG2-WG1-WG3/F001:2019)”
Aug. 24	**WG1-2-3 Joint Work Group meeting (Taipei FTF + WebEx)**
Oct. 18	WG1-2-3 Joint meeting for WG1 Work Item 2: eIFU document revisit
Oct. 19	**WG2 meeting: 19th October (Taipei FTF + WebEx)**

- Project Core member discussion: Jul. 4 & 19, Aug. 23, Dec. 6



WG1-2-3 Joint Work Group meeting (Aug. 24)



WG2 meeting (Oct. 19)

WG2 Progress in 2022

Work Item	Deliverables	Timeline	Progress Update
Development of GHWP Guidance Document	**Categorisation of Changes to a Registered Medical Device** **(collaboration with WG1 & WG3)**	**Jan. 2022 – Jan. 2023**	**Under the document endorsement procedure**
	Survey on Good Reliance Practice across GHWP members	May 2022 – 2023	**Drafting in progress** Designing the questionnaire, including the definition of reliance
	Regulatory Requirements for Electronic Instructions for Use (eIFU) **(collaboration with WG1 & WG3)**	2022 – 2023	**Drafting in progress**

WG2 Proposed Work Plan in 2023

- **Meetings in 2023 (tentative schedule)**
  - WG2 kick-off meeting (online): late February
  - WG2 FTF meeting: July
  - WG2 online meeting: October
- **Work Items**

	Work Item	Deliverables	Timeline	Progress Updates
1	**Confirmation of WG membership**	WG2 member list	– Jun. 2023	Contact members who have not participated in any WG2 activities for a certain period (e.g., 2 years) to confirm their memberships

WG2 Proposed Work Plan in 2023

	Work Item	Deliverables	Timeline	Planned Progress
2	**Development of GHWP Document (*Tentative*)**	Good Reliance Practices for MD, IVD and SaMD across the life cycle • **Survey** on Good Reliance Practice across GHWP members • Guidance document for Good Reliance Practices	2022 – **(*Tentative*)**	Drafting in progress (NWIP of the survey approved on 24th May 2022)
		Review and update GHWP/WG1-WG2-WG3/F002:2019- Regulatory Requirements for Electronic Instructions for Use (eIFU) **(cooperate with WG1 & WG3)**	2022 – 2023	Drafting in progress (NWIP approved on 29th August 2022)
		Review and update **Merge** GHWP/WG2-WG1-WG3/F001:2019- Categorisation of Changes to a Registered Medical Device **and** GHWP/WG1/F001:2020 Guidance for Minor Change Reporting **(cooperate with WG1 & WG3)**	2023	Will be determined by late February
		Review and update GHWP/WG2/F001:2017 - Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices	TBD	

WG2 Further Work Plan

Work Item	Deliverables	Timeline
Development of GHWP Document (*Tentative*)	Grouping of IVD for Product Registration	2024 – 2025 (***Tentative***)
	Review and update GHWP/WG2/F001:2016 - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	2025 (***Tentative***)
	Regulatory Practices on "RUO" Labelled Products and Laboratory Developed Products / Requirements and specifications for in-house developed and produced in vitro diagnostic medical devices	TBD
	Review and update GHWP/WG2/F001:2014 - Comparison between CSDT and STED IVDDs	TBD
	Conformity Assessment of AI-based Digital Pathology Software	TBD

WG2 Achievements (since 2018) (1/3)

	Work Item	Deliverables	Endorsed in
1	**Development of GHWP Guidance Document**	Labelling for In Vitro Diagnostic Medical Devices	2018
		Categorisation of Changes to a Registered Medical Device **(collaboration with WG1 & WG3)**	2019
		Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) **(collaboration with WG1 & WG3)**	2019
		Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices **(collaboration with WG5)**	2021
		Replacement Reagent and Instrument Family Policy	2021
		Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency **(collaboration with WG1 & WG3)**	2021

WG2 Achievements (since 2018) (2/3)

	Work Item	Contribution to	Period	Achievements
2	**Participation in International / Global Organization collaboration and activities**	**International IVD Standards**	2018 – 2022	WG2 has joined **ISO/TC 212** as liaison member to participate in standard discussion and contribution from regulators and industry's point of view.
		IMDRF, in IVD Guidance	2019 – 2022	➢ Participated in IMDRF Working Group on "Principles of IVD medical devices Classification" ■ IMDRF/IVD WG/N64FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification ➢ Participating in IMDRF New Working Group on "Clinical evidence for IVD medical devices"

WG2 Achievements (since 2018) (3/3)

	Work Item	Contribution to	Period	Achievements
2	**Participation in International/ Global Organization collaboration and activities**	**WHO Technical Specification Documents**	2018 –	➢ Continuous contact with WHO IVD PQ team to maintain technical communication ➢ Collect and consolidate comments from WG2 members on the WHO documents, including: ■ TSS-6: Syphilis Rapid diagnostic tests ■ TSS-7: Rapid diagnostic tests to detect hepatitis C antibody or antigen. ■ TSS-8: Immunoassays to detect hepatitis C antibody and/or antigen ■ TSS-10: In vitro diagnostic (IVDs) medical devices used for the qualitative and quantitative detection of Hepatitis C ribonucleic acid ■ TSS-11: In vitro diagnostic (IVDs) medical devices used for the quantitative detection of HIV-1 nucleic acid ■ TSS-12: In vitro diagnostic (IVDs) medical devices used for the qualitative detection of HIV-1 and HIV-2 nucleic acid ■ SS-13: Rapid diagnostic tests to detect hepatitis B surface antigen ■ TSS-14: Immunoassays to detect hepatitis B virus surface antigen ■ TSS-15: In vitro diagnostics (IVDs) medical devices used for the quantitative detection of Hepatitis B nucleic acid ■ TSS-17: In vitro diagnostic (IVD) medical devices used for the qualitative detection of Mycobacterium tuberculosis complex (MTBC) and mutations associated with drug-resistant tuberculosis (DR-TB) ■ **TSS-18: Haemoglobin A1c point of care analysers for professional use (DRAFT)**

Thank you for your attention