IMDRF International Medical Device Regulators Forum | 26th Session

Working Group Update Clinical evidence for IVD

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Working group objectives

To update and streamline existing GHTF documents on Clinical evidence for IVDs, including:

- **GHTF/SG5/N6** (Clinical Evidence for IVD Medical Devices-Key Definitions and Concepts)
- **GHTF/SG5/N7** (Clinical Evidence for IVD Medical Devices-Scientific validity determination and Performance Evaluation)
- **GHTF/SG5/N8** (Clinical Evidence for IVD Medical Devices-Clinical Performance studies for IVDs)

Meeting 01 – 20 Jun 2024

1. Introductions and welcome
2. WG objectives and ways of working established
3. Pre-meeting survey result discussion

Key topics identified for further discussions:

- Explore the triangles of "device, analyte and clinical condition" and "scientific validity, analytical performance and clinical performance".
- Review the *State-of-the-art* definition and its application in IVD.
- Align with the updated definition of intended use/purpose from IMDRF/GRRP WG/N47FINAL:2024.
- Explore when clinical data and clinical performance studies are required for IVDs.
- Discuss "established," "standardized," and "novel" tests and their correlation with clinical performance studies.

Meeting 02 – 18 July 2024

1. Presentations on current clinical evidence framework for IVDs by WG members: Australia, Egypt and Ireland (European Commission)
2. Launch of written consultation on GHTF/SG5/N6 and N7 documents

Key topics identified for further considerations:

- Lifecycle approach for clinical evidence of IVDs
- State-of-the-art
- International recognition/reliance
- Documentation templates such as the Clinical evidence Report and Post-market Performance Follow-up Plan and Report

Plan for upcoming meetings

1. Meeting 03 – 12 September 2024: Presentations on current clinical evidence framework for IVDs by WG members: Japan, UK and USA

2. Meeting 04 – 24 October 2024: Thematic analysis of results from the written consultation

3. Meeting 05 – November 2024: Start of deep-dive thematic discussions to agree on updates to N6 and N7 documents

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IMDRF 2024 Chair

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THANK YOU

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