

Clinical evidence for IVD Working Group Update

Co-chairs: UK and EC



About Us

Established: May 2024

Goals: 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

Consultations: on N6 and N7 with both regulators and stakeholders finalised in September 2024.

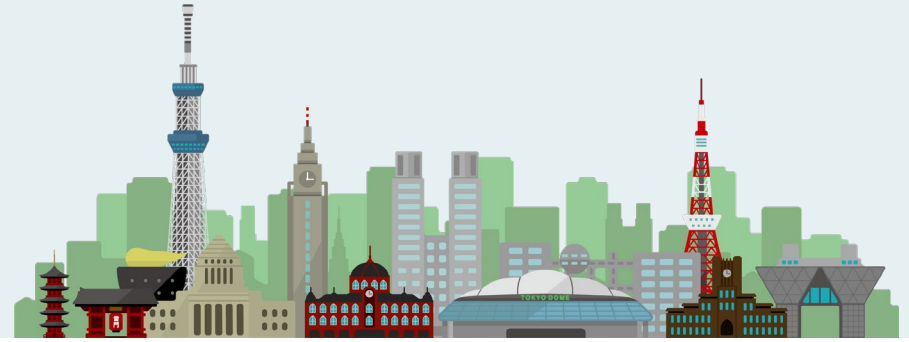


Ongoing Work and Future Work

- Group meetings: so far, eight meetings between regulators which focused on: exchange of knowledge and experience (2-3 meetings) and analysis of first comments received.
- Discussed and finalized analysis of comments from the WG members and stakeholders on **N6** (Devices-Key Definitions and Concepts)
- After completion of regulators discussion on **N7** (Scientific validity determination and Performance Evaluation) - scheduled for the end of Q1, the WG has agreed on **holding a workshop with stakeholder participation on 10 April, and is asking each country about candidate companies, organizations,** etc. to be requested.



IMDRF International Medical Device
Regulators Forum



Thank you/Questions
