

Clinical Evidence for In Vitro Diagnostic Medical Devices Working Group Update

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About the Working Group

Objective: To update and streamline existing GHTF documents on Clinical evidence for IVD medical devices, 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)



Our progress

- Review of the first two GHTF documents - N6 (Key Definitions and Concepts) and N7 (Scientific Validity Determination and Performance Evaluation) - has been completed.
 - A new IMDRF document has been developed that consolidates content from both GHTF documents, with updated definitions and principles of clinical evidence to ensure alignment with other IMDRF documents and recent developments in the field.
 - Additional sections addressing novel types of IVD medical devices have been included, including software IVDs and companion diagnostics.
 - The new draft IMDRF document has been accepted for public consultation at the January IMDRF management committee meeting. The consultation is expected to go live in March 2026 and will be open for 60 days.
- Plans to commence review of the final GHTF document - N8 (Clinical Performance Studies for IVD Medical Devices) starting in March 2026.



Consultation Clinical Evidence
for IVD Medical Devices –
Definitions and Principles of
Performance Evaluation

