IMDRF International Medical Device Regulators Forum

Clinical Evidence for IVDs

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About Us

Clinical evidence is foundational in the:

- evaluation of clinical performance,
- safety, and
- effectiveness

of in vitro diagnostic (IVD) medical devices.

Scan to learn more

In an innovation landscape for IVDs that is rapidly evolving, fit-for-purpose principles for clinical evidence are essential.

About Us

Objective: 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)

Ongoing work

- Group meetings: since June update, meetings with working group members and stakeholders to discuss and agree on draft proposal text for the new IMDRF document has concluded. The new IMDRF document will combine GHTF documents ***N6*** (Devices-Key Definitions and Concepts) and ***N7*** (Scientific validity determination and Performance Evaluation).
- In July-August, experts were invited to input directly on outstanding sections (methods for lit review appraisal) and new sections on novel types of IVD devices (software IVD, companion diagnostics).
- A final meeting is scheduled in September to discuss the additional sections and gain agreement from members and stakeholders to submit the draft IMDRF document for public consultation at the January MC meeting.

Opportunities/Challenges

Opportunities:

- Consolidating GHTF documents ***N6*** and ***N7*** into one IMDRF technical document
- Alignment with relevant IMDRF documents (e.g. definitions, principles)
- Updating and harmonising, where possible, essential principles for establishing scientific validity, analytical and clinical performance for IVD medical devices
- Considerations and convergence on expectations for specific types of IVDs, such as companion diagnostics, IVD software

Challenges:

- Different approaches to certain aspects (e.g. established/standardized and novel tests, weighting of different sources of evidence)
- Scope and time constraints

Thank you/Questions