



IMDRF

International Medical
Device Regulators Forum

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Progress report

March 23
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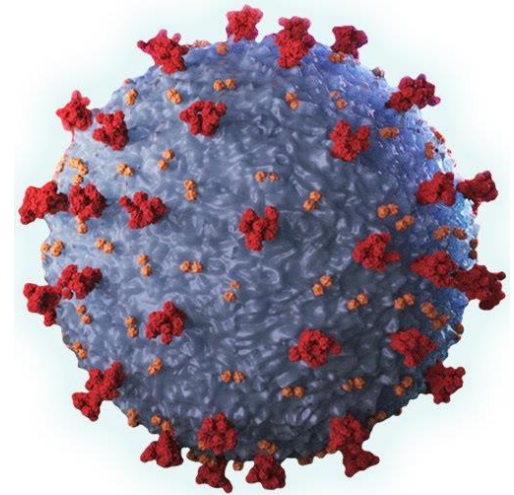
Public consultations

63 comments from public consultation
Over 200 comments and corrections by WG

Comments compiled to the table – each comment
had it's discussion and resolution

Approved changes included in the text

More than **20** WG members participated in weekly Teleconferences





Overall progress



APPROVED

January 2021

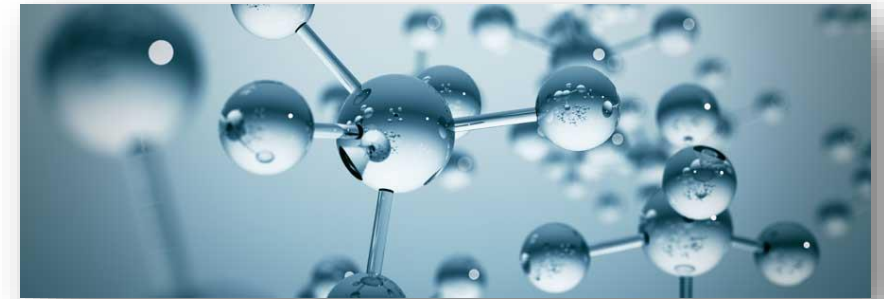
IMDRF/IVD WG/N64 FINAL:2021
**Principles of In Vitro Diagnostic (IVD) Medical
Devices Classification**



Next steps

IMDRF/GHTF documents Systematic Review

- Approved by MC – review and update
- Proposal formulation
- IVD WG discussions (e-mails exchange)
- Teleconferences (draft discussion)
- Final version of NWIP + discussion with MDCE
- Further Teleconferences upon NWIP approval



NWIP on GHTF documents review and update – to be formed

Collaboration with MDCE

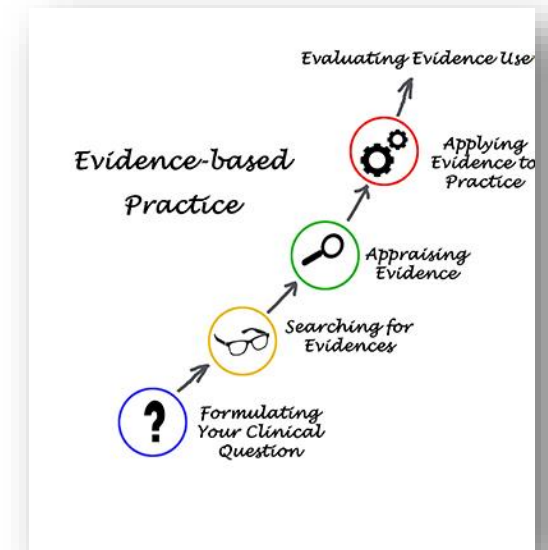


Future work

New Work Item Proposal

Review and update of:

- ❑ 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)



Collaboration with MDCE WG
Proposal to be approved by MC

