World Health Organization Update

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75 HEALTH FOR ALL

Presentation outline

1. Prequalification of IVDs and PQT reorganization
2. GBT Plus and benchmarking
3. Collaborative registration procedure
4. Post-market surveillance
5. Global Diagnostics Coalition
6. EDL
7. Upcoming WHA

WHO Prequalification

New team within PQT: AMD

- IVDs, immunization devices, contraceptive devices and other medical devices

Prequalification of IVDs: new procedure implementation as of 1.1.2026

- Following public consultation
- Strengthened reliance
- Streamlined process
- Strengthened risk-based approach to eligibility for and design of PEs
- Enhanced flexibility for scheduling PE and PQ

Recognized Regulatory Authority	Risk classes undergoing stringent assessment
TGA, Australia	Class 3 and Class 4
Health Canada	Class III and Class IV
Notified bodies designated by EU Member States or other countries under specific agreement	Annex II List A and List B (IVDD) [1] Class C and Class D (IVDR)
MHLW, Japan	Class III
Singapore HSA	Class C and Class D
MHRA, United Kingdom	Annex II List A and List B, (Medical Device Regulations 2002)
US FDA	Class II and Class III

WHO Prequalification cont'd

PQ scope expansion:

In vitro diagnostic medical devices used for the qualitative detection of **Neisseria gonorrhoeae, Chlamydia trachomatis and Trichomonas vaginalis nucleic acid**;

- Rapid diagnostic tests to detect **Chlamydia trachomatis antigen**; and
- Rapid diagnostic tests to detect **Neisseria gonorrhoeae antigen**.

Survey on changes review procedure:

- manufacturers are broadly satisfied with the new guidance
- Recommendations on further streamlining
- Minor revision of the guidance planned in Q2 2026

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WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation...

Revision VI+MD version 2

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- **Assisted self benchmarking in Senegal 8–12 September 2025 (onsite)**
- **Assisted self benchmarking with Bhutan 17 -21 November (SEARO in collaboration with WHO HQ)(online)**

Formal benchmarking of the Health Sciences Authority of Singapore (9 – 13 February 2026)

WHO RSS – GBT Plus workshops

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Objectives:

To strengthen the capacity of NRAs in regulating medical devices to improve access to quality, safe and performant medical products.

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WHO Global Benchmarking Tool pl evaluation...

Revision VI+MD version 2

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To increase knowledge and understanding of the WHO RSS programme and the WHO Global Benchmarking Tool Plus Medical Devices (GBT+MD), Global Model Regulatory Framework for Medical Devices and guidance for post-market surveillance and market surveillance of medical devices.

Two Workshops:

- ✓AFRO 15 -19 September 2025 (in person) special focus on post-market and market surveillance.
- ✓PAHO - 22 to 23 September 2025 and 25 to 26 September 2025 (Online)

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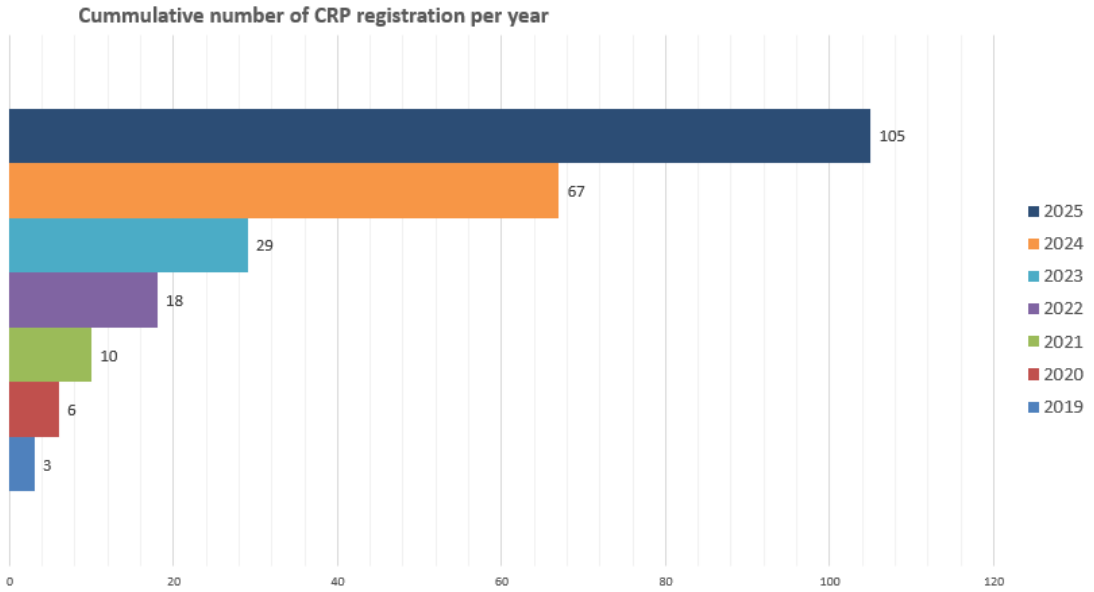
Supporting regulators and manufacturers for post-market and market surveillance

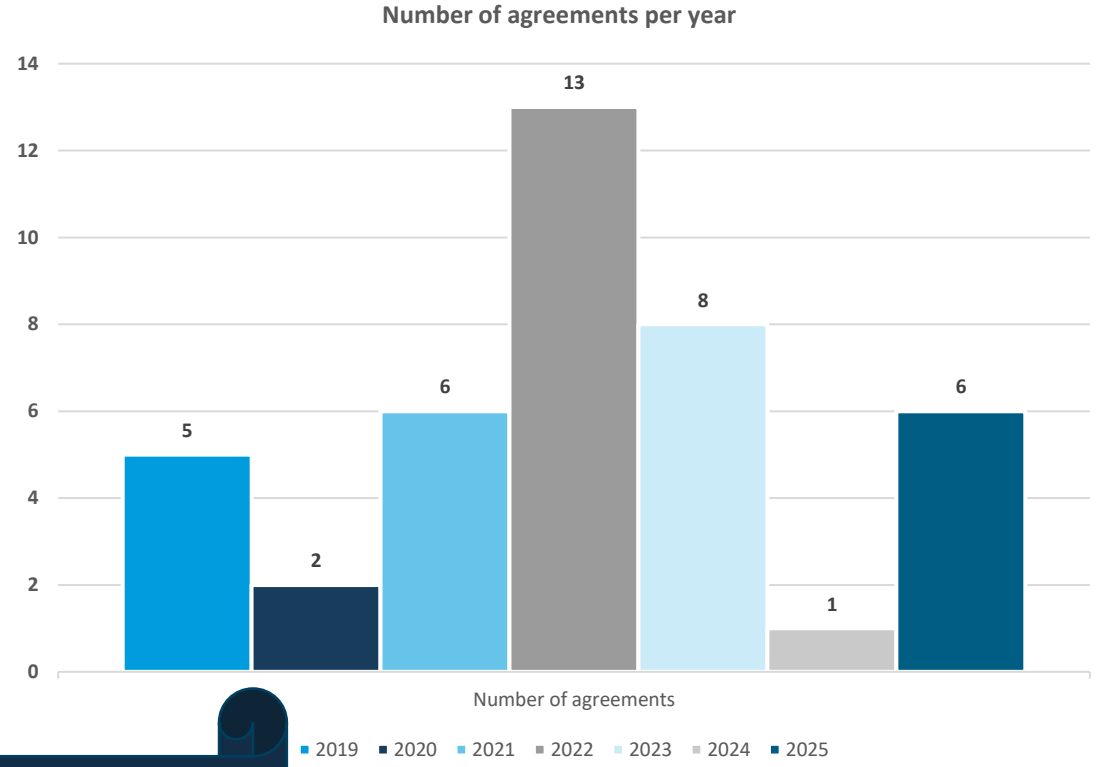
Improving access to safety and quality information

- ✓ WHO is working towards a global database on field safety notices (and certain regulatory decisions)
  - WHO's Epidemic Intelligence via Open Sources uses text mining, natural language processing, named entity recognition and machine learning algorithms, to sort and categorize the articles/notices posted online.
  - Many regulators posts FSN as PDFs making it difficult to use AI to detect and aggregate.

- ✓ Ensuring use of IMDRF adverse event reporting terminology.
  - Used by WHO database for medical device incidents for WHO recommended IVDs
  - Used by WHO International Classification of Diseases (ICD-11)

Collaborative Registration Procedure for in vitro diagnostics

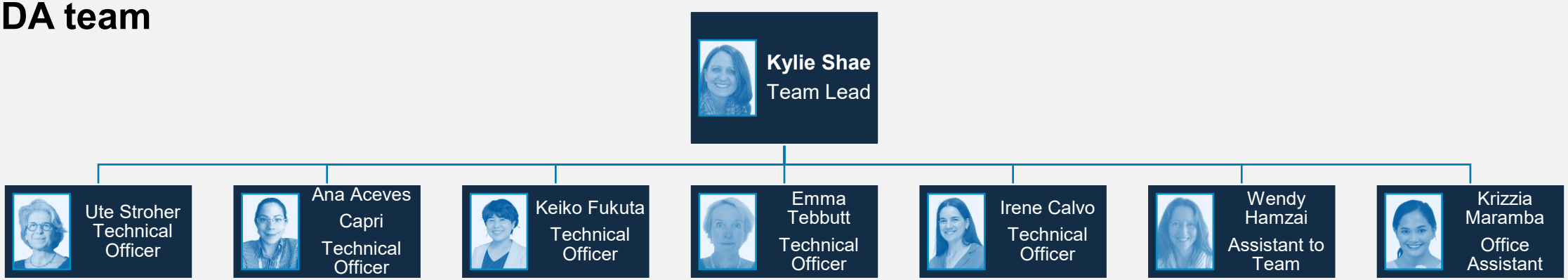




- ✓ Increased registrations in 2025 (41)
- ✓ 41 Signed agreements
- ✓ Median time = 71 days
- ✓ Registrations updated in the ePQS

Medical devices and Assistive technology (MDA) Team

MDA team



Activities update

Global Diagnostics Coalition

- ✓ Following its launch in May 2025, a call for membership and key meetings were held, an in-person meeting is planned on the side lines of WHA 79

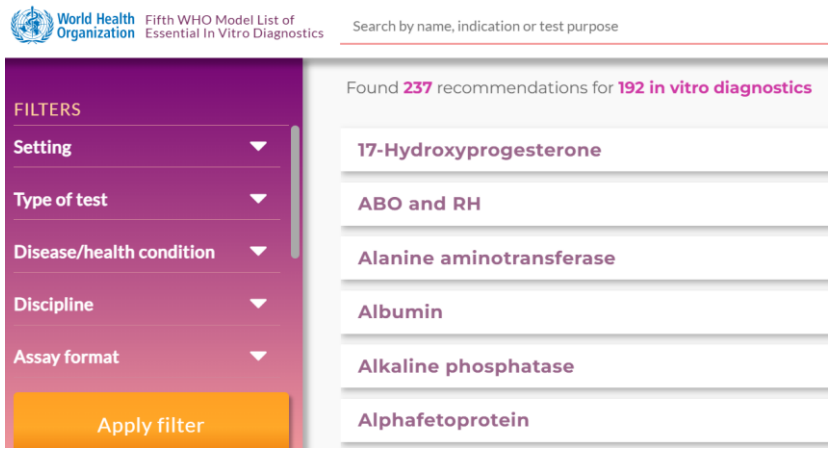
MDA activities update……cont

- ✓ **Medical Devices Information System（MeDevIS）and Medical Device Packages (MEDEVPACKS)**
  MeDevIS 2.1 released, including medical devices related to hearing, meningitis, oral health, and tuberculosis and updated version of MEDEPACKS

- ✓ **5th Essential In Vitro Diagnostics List (EDL 5)**
  EDL5 is now available online, and the report of the 5th SAGE IVD meeting will be available soon

- ✓ **Essential Diagnostics List for emergencies**
  Work in progress towards developing a list including in vitro tests and non in vitro diagnostic technology (devices) tailored for emergencies

- ✓ **Resolution on Strengthening Equitable Access to Diagnostic Imaging through Teleradiology – pending adoption at WHA79**
  A new resolution on teleradiology was introduced at the recent WHO EB meeting, and the EB confirmed the resolution be tabled at WHA, May 2026.



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