WHO REGULATORY UPDATES

27th IMDRF Management Committee Meeting
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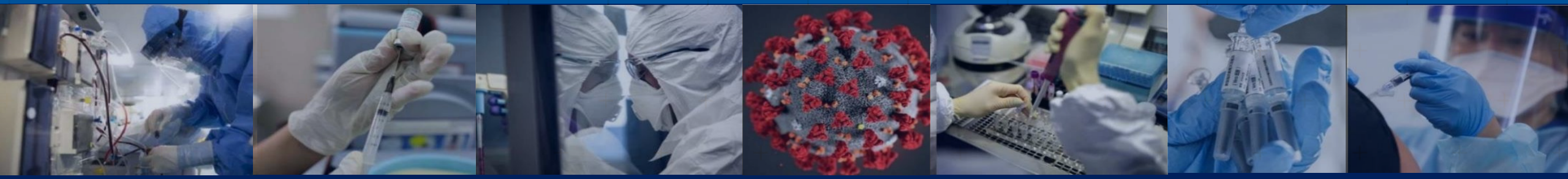

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Outline

- **Regulatory strengthening activities**
  - ✓ GBT Plus
  - ✓ Regulatory reliance and harmonization initiatives
- **Prequalification**
- **Nomenclature**
- **Conclusion**

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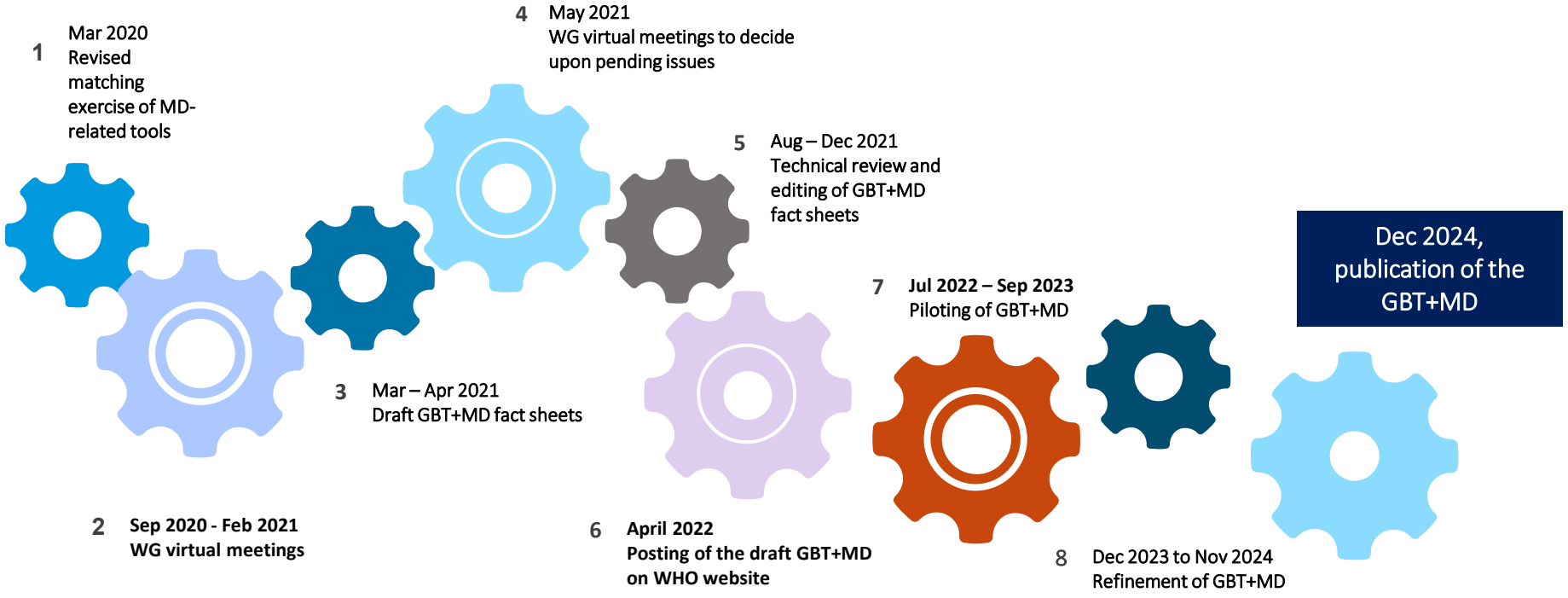
Development of GBT+ for Medical Devices including Invitro Diagnostics



Link: https://www.who.int/tools/global-benchmarking-tools

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Updated Figures of the WHO GBT+MD

Item \ Function	RS	MA	PS	LI	RI	LA	CT	Grand Total
Number of Sub-Indicators	68	35	44	19	26	29	29	250
Sub-Indicators measuring maturity level 1	8	7	9	2	3	2	2	33
Sub-Indicators measuring maturity level 2	10	3	11	3	3	3	9	42
Sub-Indicators measuring maturity level 3	27	22	16	12	12	17	15	121
Sub-Indicators measuring maturity level 4	23	3	8	2	8	7	3	54

Minimal capacity

Advanced/ reference NRAs

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Rollout of the WHO Global Benchmarking Tool + Medical Devices (GBT + MD)

- **November 2024:** Formal benchmarking of Nigeria regulatory system
- **February 2025:** Regional assisted self-benchmarking workshop for SEAR countries: Bangladesh, Bhutan, India, Indonesia, Maldives, Sri Lanka, Thailand and Timor Leste

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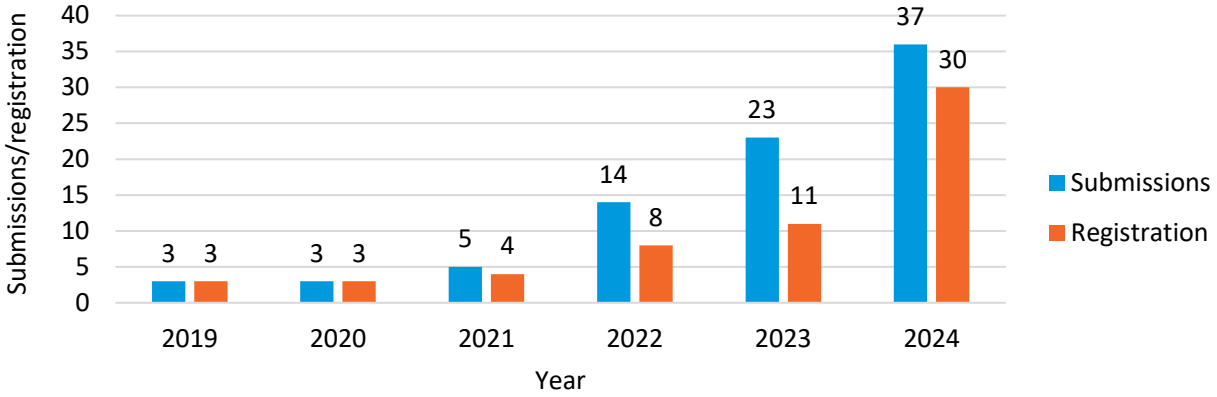
Promoting regulatory reliance for medical devices regulation

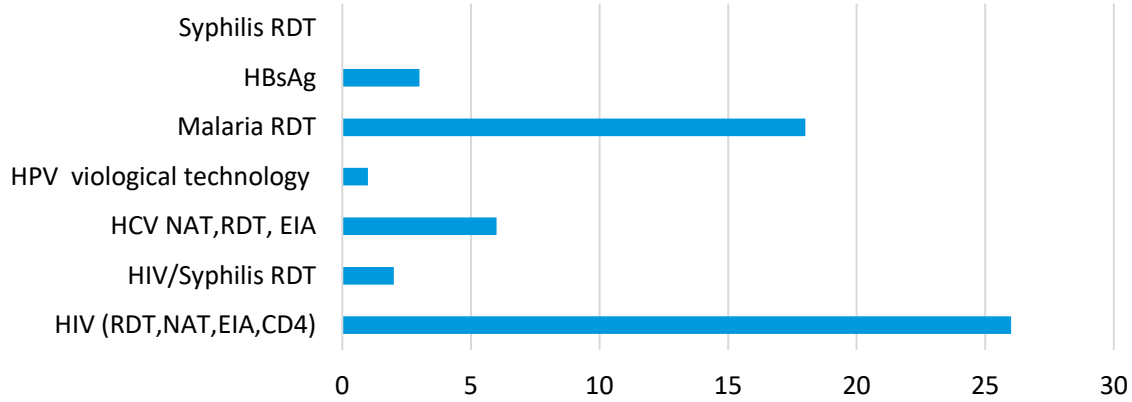
WHO Collaborative registration procedure for IVDs

- ✓ 37 national regulatory authorities signed agreement to participate in CRP for PQ IVDs
- ✓ 62 IVD products registered in countries through CRP with average time of 89 days (within 90 days)

Number of submission against registration



Type of Assays Registered under CRP



Support to NRAs

- ✓ CRP 12th Annual hybrid meeting held in November 2024, in Jakarta, Indonesia, with over 200 participants (*100 in person)*
- ✓ SEARN NRAs in developing a reliance model based on the WHO Global Model Regulatory Framework (GMRF)
- ✓ Global Webinar on the Facilitated Procedure for EUL MPXV Assays in Oct 2024 *(4 NRAs signed CRP, submissions in NRAs awaiting decision*)
- ✓ Conducted a specific workshop on EUL for MPXV for SEARN members in January 2025 *(preparedness)*

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Support| NRAs and regional harmonization initiatives

AMDF reform (to MDA-TC)

- Ongoing support to AMRH - medical devices assessment technical committee (MDA-TC)
- MDA -TC will also facilitate harmonization of requirements and standards for assessments, registration and marketing authorization activities at REC and NRA levels in Africa

Technical support

- WHO training materials for assessment of IVDs technical files finalized - pilot in Q2 2025
- Contributed to the review of the AU Model Law to include specific requirements for medical devices and development Model Regulations

Southeast Asian Regulatory Network (SEARN), W5

- Development of a strategy to facilitate reliance for medical devices and regulatory capacity building framework
- Workshop on regulation of MDs (GMRF, Reliance and initial assessment using GBT plus MDs)

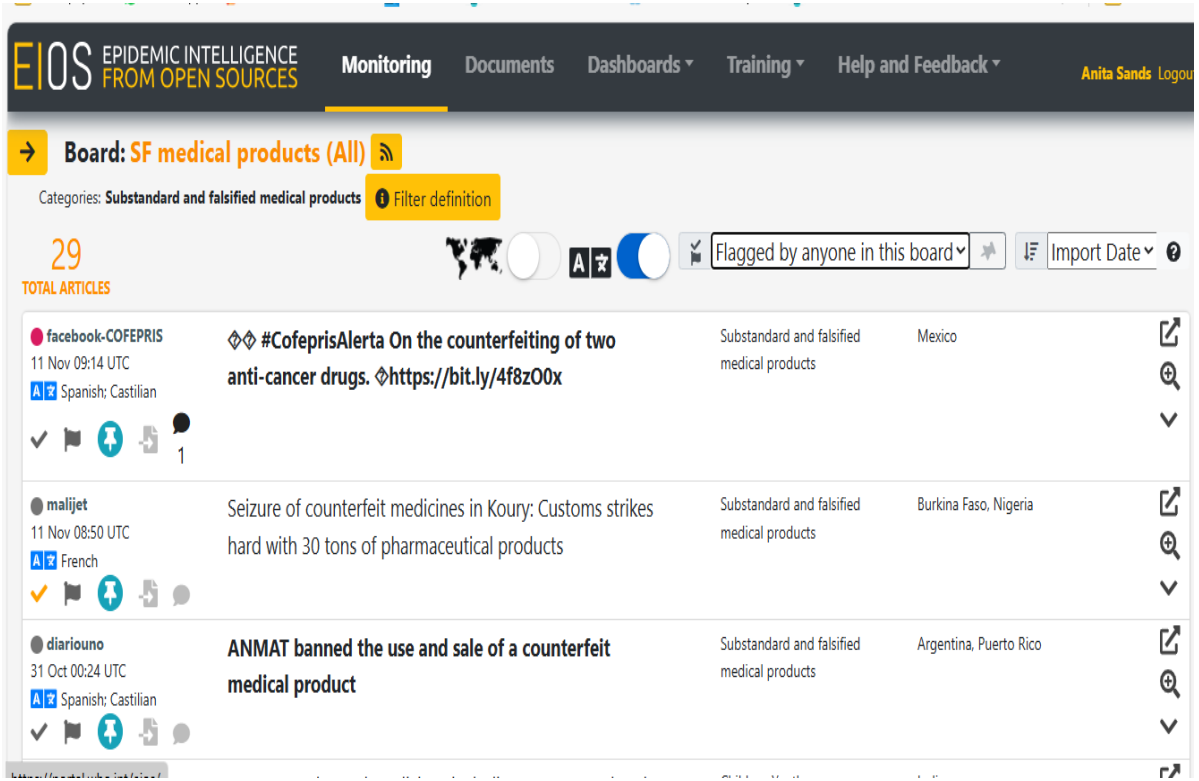
GMRF: https://cdn.who.int/media/docs/default-source/biologicals/ecbs/annex3-gmrf-who_trs_1045.pdf?sfvrsn=88867b3a_3&download=true

GBT +: Evaluation of national regulatory systems of medical devices (GBT+ Medical devices)

Collating field safety notices

Use of WHO EIOS to create a global repository of field safety notices of medical devices

- **Benefits**
  - Emerging regulators can consider reliance when another regulator has reviewed a FSCA and FSN
- **Expected challenges**
  - Detecting content published in PDF format



- *Epidemic Intelligence from Open Sources (EIOS) is web-based system designed to support public health intelligence activities using natural language processing and machine learning*
- *Scrapes 45,000 news sources in any language continuously, translates summary to English*

Prequalification: Main achievements

- In 2024: Three “first-time” listings: the first **HCV self-test**, the first **TB NAT** assay and first **G6PD test**;
- Expansion of the PQ pipeline to **non-communicable diseases & first time QA assessments of NTDs**
- Expanded use of the Expert Review Panel for Diagnostics (**ERPD**) assessments, across several disease areas
- Emergency Use Listing (EUL) assessments of **MPXV NAT** assays with listing of 3 products
- Full implementation of assessment sessions as a new operating model, with 6 sessions per year
  - **Many thanks to all IMDRF member NRAs who have supported this activity**
    - ✓ **TGA Australia, ANVISA Brazil, Health Canada, NMPA China, HSA Singapore, MFDS R. Korea, MHRA UK**
- Development of several new or amended **TSS** documents, including the finalization of the **TB-LAM TSS**
- Development of a new guidance on **change assessments**; and
- Finalization and imminent launch of **ePQS** – a new IT platform

Prequalification: Coming next

- **Revision of the PQDx process: to be implemented in Q2 2025**
  - ✓Strengthened reliance
- **TSS under development:**
  - ✓STIs
  - ✓TB: NGS and IGRA
- **New changes guidance:**
  - ✓Strengthened risk-based approach
  - ✓Strengthened reliance
  - ✓Implementation in March 2025

Nomenclature of medical devices

- Has been discussed by Member States since May 2019 during the Executive Board 145 meeting
- **«principles:** transparent governance and methodology, freely available and global public good, to be referenced and used by regulators, procurers, managers and all users of medical devices»
- Agreement in 2024 to use EMDN and GMDN in WHO for public reference

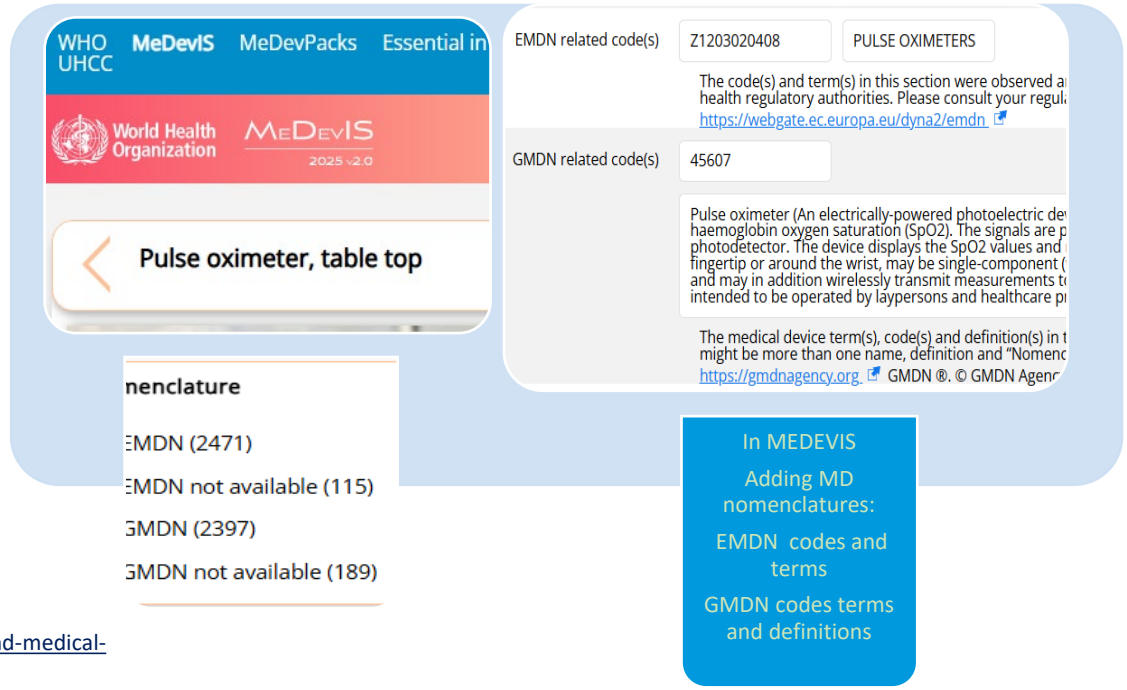
WHA75 Decision in May 2022

- integrate **available** information related to medical devices, including **terms, codes, and definitions**, in the web-based database and clearinghouse established in line with Resolution WHA60.29 (2007)… **MeDevIS;** and to **link this to other WHO platforms**, as a reference to member states and stakeholders;
- submit a substantive report on progress made in implementing this decision to the Executive Board at its **152nd session in 2023,** and **156th session in 2025, respectively**

Report to the Executive Board EB156 in Feb 2025

- EB156/13 describes the roadmap for implementation of the WHA75.25 Decision
- promote only the use of these two systems and avoid multiple other developments

Standardization of medical devices nomenclature
International classification, coding and nomenclature of medical devices



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More information: https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature

Conclusions

- Publication of WHO GBT in 2024 considered a game changer for regulatory capacity building in countries
  - ✓ useful tool for identifying areas for improvement
  - ✓ opportuntiy for IMDRF members to contribute/benefit in line with GMRF

- Stable, well-functioning and integrated regulatory strong system (ML 3)
  - ✓ensures quality, safety and performance of medical devices

- Opportunity for WHO Listed Authorities + Medical Devices (WLA+MD)
  - ✓building on existing capacity and lessons from medicines and vaccines

Thank you