

Member States information session on diagnostics capacity

30 April 2025



Report to WHA78

(16) to report on progress in the implementation of this resolution to the Seventy-eighth World Health Assembly in 2025.



SEVENTY-SIXTH WORLD HEALTH ASSEMBLY
Agenda item 13.1

WHA76.5
30 May 2023

Strengthening diagnostics capacity¹

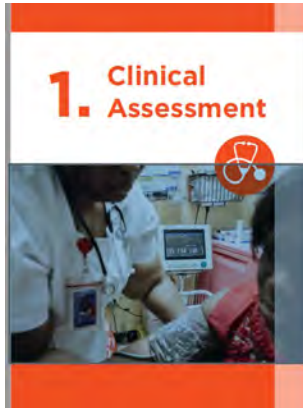
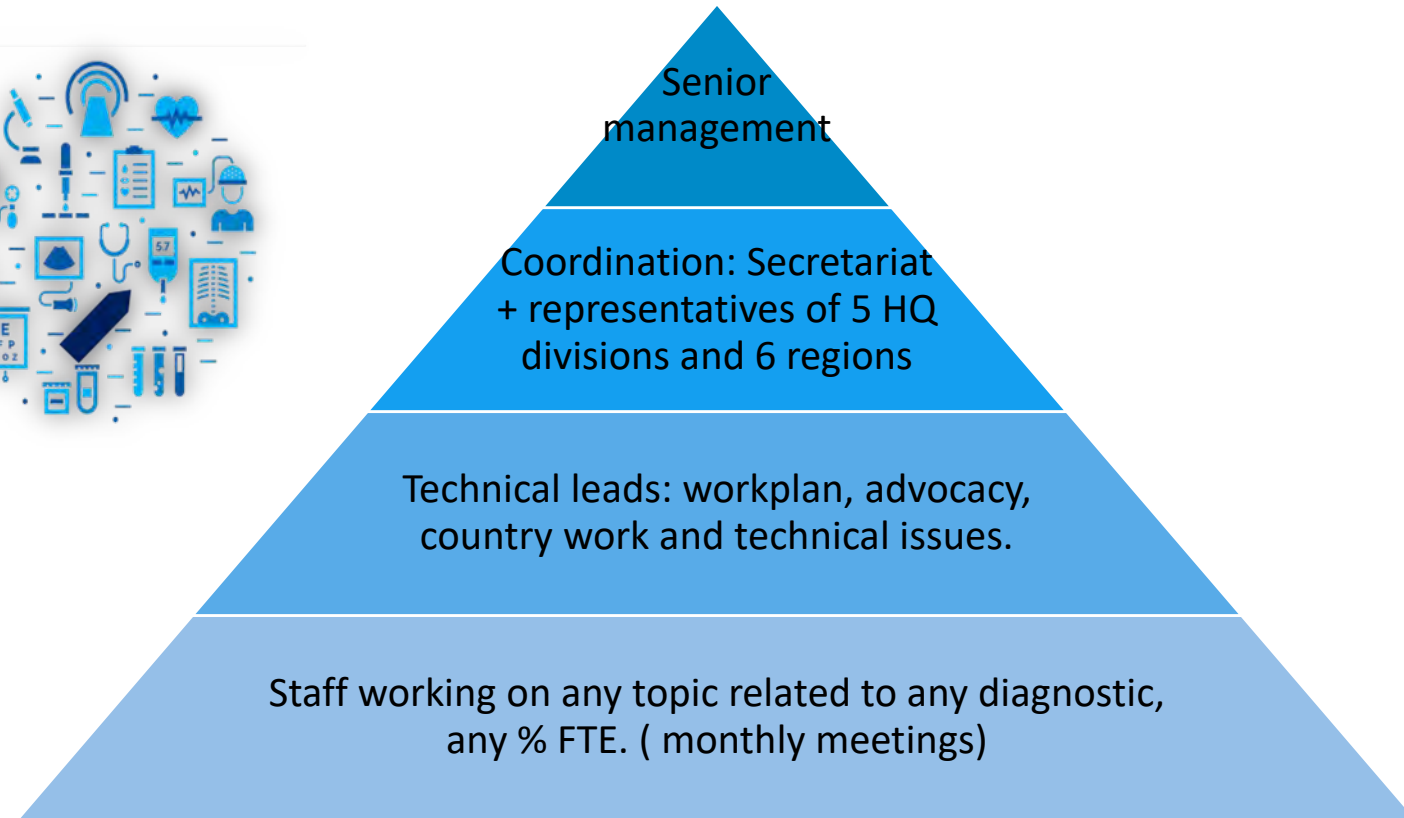
Noting that equitable access to safe, effective and quality assured diagnostics requires a comprehensive health-systems approach that addresses all stages of the value chain;



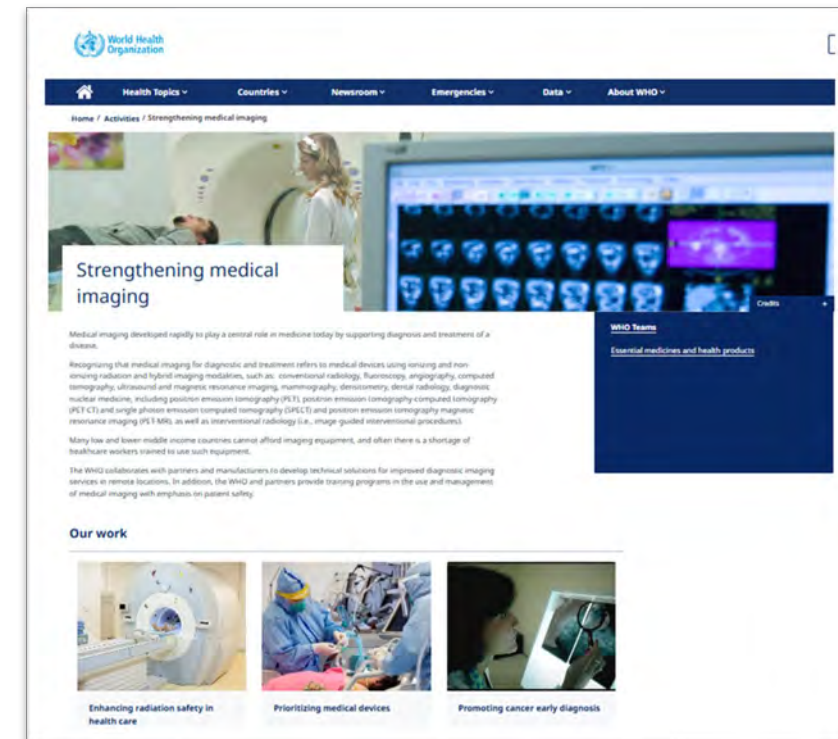
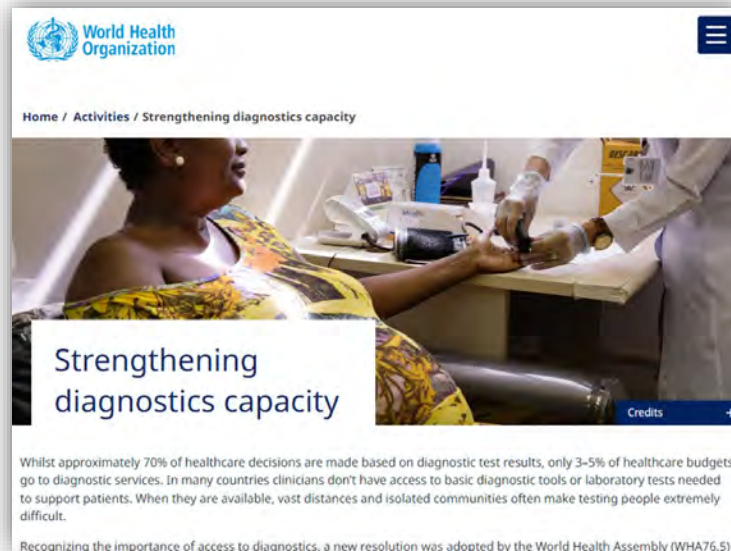
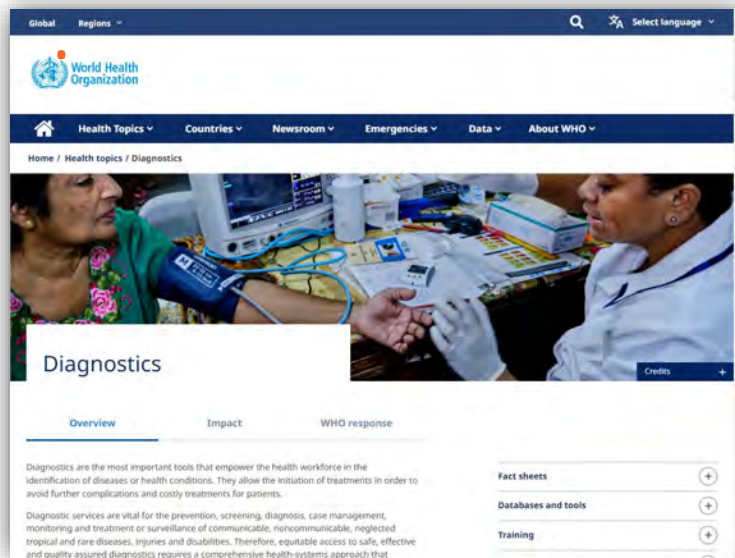
¹ For the purpose of this resolution, the term “diagnostics” includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types.

13. WHO task force to address horizontal approach

To align all WHO staff members dealing with all types of diagnostics, to work together towards the implementation of the resolution **WHA76.5** in a harmonized integrated way.



New WHO websites integrating all information on diagnostics



Diagnostics



Contact us

The WHO Diagnostic Task Force includes senior management, a coordination group and 5 working groups: advocacy; country strategy and support; technical issues; resource mobilization and; resolution implementation workplan.

If you are a stakeholders working with countries on strengthening diagnostics capacity contact us using the email below.

diagnostics-taskforce@who.int



Strengthening
diagnostics capacity

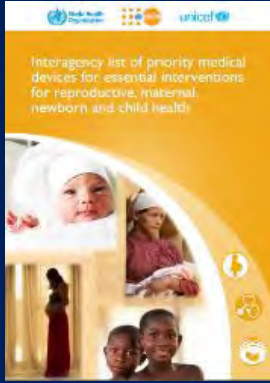
<https://www.who.int/activities/strengthening-medical-imaging>

WHA76.5 Requests to DG	status
(1) to collect data on affordability, availability	In development
(2) technical advice for procurement	Ongoing
(3) cross-references between EDL and PMD,	Achieved and will continue
(4) to update WHO Model Lists EDL and PMD	Achieved and will continue
(5) health technology management of diagnostics	On going
(6) local production of diagnostics	On going
(7) regulatory system	On going
(8) Member States national lists	On going
(9) Diagnostics for emergency	In development
(10) MeDevIS and "e-EDL"	Achieved and will continue
(11) Laboratory networks	Various
(12) definitions of Dx	In consultation
(13) horizontal health program approach not silos	WHO Diagnostic Taskforce
(14) integrated diagnostic networks	In development

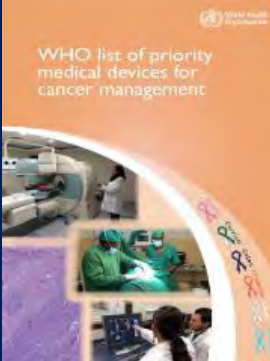
4. WHO selects Priority medical devices and essential diagnostics test for MS to include in the national list.



MeDEVIS



Interagency list of priority medical devices for reproductive, maternal, newborn and child health

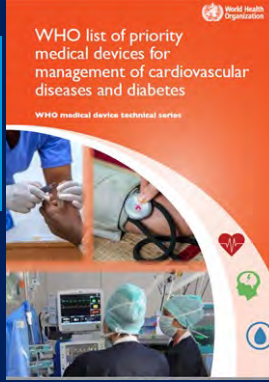


WHO list of priority medical devices for cancer management

Oxygen related med devices are described in all of them!



Priority medical devices list for the COVID-19 response and associated technical specifications

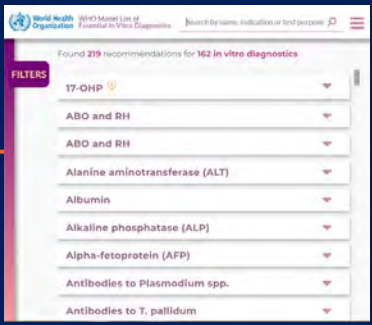


WHO list of priority medical devices for management of cardiovascular diseases and diabetes

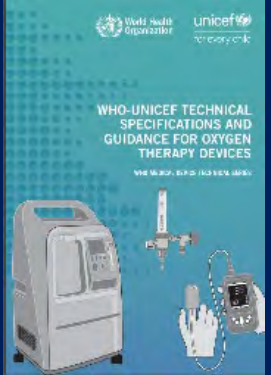
List of essential/
priority



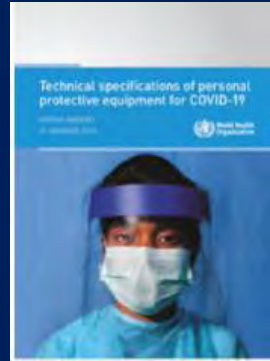
The selection and use of essential in vitro diagnostics



WHO Model List of Essential In Vitro Diagnostics



WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES



Technical specifications of personal protective equipment for COVID-19



Technical specifications of radiotherapy equipment for cancer treatment

Technical specifications



Technical specifications for personal protective equipment for COVID-19

2015 2017 2020 2021 2018-2019-2021-2023

(4) to update the WHO Model List of Essential In Vitro Diagnostics and the WHO lists of priority medical devices, to include innovative diagnostics, following a review of the latest evidence and/or health technology assessments;

The Strategic Advisory Group of Experts on IVDs (SAGE IVD) met in November 2024, to review the latest evidence towards the update of the WHO model list of essential IVDs (EDL)

- The report of the 5th SAGE IVD meeting, including the EDL 5 will be published in mid-2025.
- The electronic EDL is being updated accordingly and will include 13 new tests, codes and terms from nomenclature systems EMDN and GMDN and links to laboratory instruments in MeDevIS.
- The SAGE IVD panel will be renewed as per its TOR in July 2025.
- The current application-based process will be reviewed during 2025.

10. WHO digital platforms

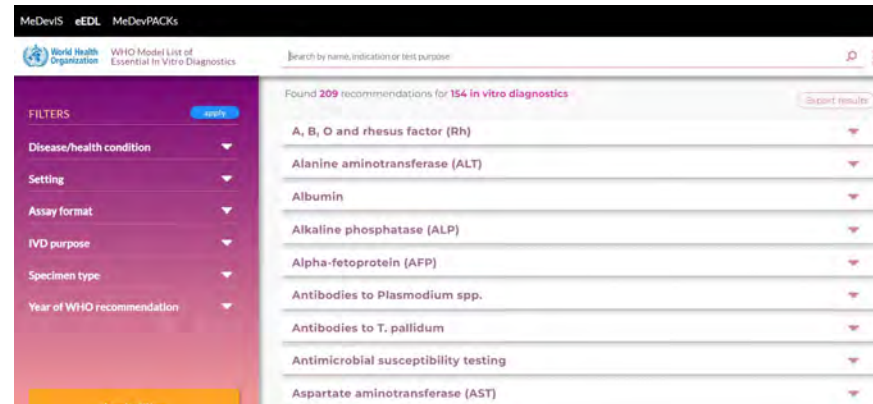
WHO list of Priority Medical Devices (technologies)

Updates every year, (@2,500 devices)



WHO model list of Essential in vitro diagnostics (type of tests)

Updates every 2 years (@200 tests)



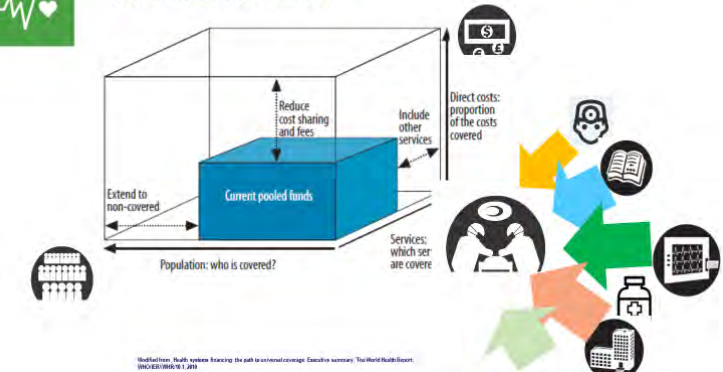
Access the MeDeViS

Universal Health Coverage compendium.

(Retrieves information from eEDL and MedeviS, same case would be for ICD 11)



Health Technologies are required to achieve SDG3: universal health coverage, including financial risk protection, access to quality essential health-care services.



(10) to publish publicly available information on diagnostic products and technologies⁵ from the WHO Model List of Essential In Vitro Diagnostics and the WHO lists of priority medical devices, through the open electronic platforms eEDL and MeDeViS;

3. Links between the WHO electronic EDL and the medical devices information system MeDevIS are **now available** for a set of IVD tests and laboratory instruments

<https://medevis.who-healthtechnologies.org/search?query=HIV>

WHO MedDevIS Essential In vitro Diagnostics (EDL) ICD-11 UHCC

WHO list of priority medical devices

General vs. specific use (health condition)

Primary use

Intended population age

Intended population sex

Service delivery platforms / Healthcare levels

Healthcare unit

Type of medical device or related product

Capital Equipment

Reusable

Knowledge level

Nomenclature

Training materials available

Technical specifications available

Innovative technology available

Related WHO Essential in vitro diagnostic test

Related IVDs Technical Specifications available

HIV

Found 9 results:

Enzyme Immuno Assay (EIA), Human Immunodeficiency Virus (HIV), kit

HIV1/HIV2/Treponema pallidum antibody IVD, kit, rapid ICT, clinical

Rapid Diagnostic Immunodeficiency Virus (HIV), kit

Reagents, HIV qualitative NAT

Reagents, HIV quantitative NAT

Reagents, HIV-1/2 (antigen and antibody) EIA

Reagents, HIV-1/2 RDT

Reagents, HIV-1/2 supplemental assay

Test, HIV 1 & 2, rapid

https://medevis.who-healthtechnologies.org/devices/RMN_098

Test, HIV 1 & 2, rapid

Primary use:

Type of medical device or related product:

General vs. specific use (health condition):

Intended population age:

Intended population sex:

Level of technical knowledge:

Capital:

Reusable:

Requirements:

WHO list of priority medical devices:

Service delivery platforms / Healthcare levels:

Healthcare unit:

EMDN related code(s):

GMDN related code(s):

WHO related resources: https://apps.who.int/iris/bitstream/handle/10665/75206/9789241193877_eng.pdf;sequence=1 https://www.who.int/health-topics/diagnostics#tab=tab_1 <https://youtu.be/D77Ycn5GGXc> <https://apps.who.int/iris/handle/10665/338095>

WHO resources on medical devices: [Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health](#) [WHO list of priority medical devices for cancer management](#) [WHO List of Priority Medical Devices for management of cardiovascular diseases and diabetes](#) [WHO List of Priority medical devices list for the COVID-19 response and associated technical specifications](#) [Package of eye care interventions](#)

<https://edl.who-healthtechnologies.org/recommendations/2475>

MeDevIS eEDL MeDevPACKs

WHO Model List of Essential In Vitro Diagnostics

Search by name, indication or test article

Antibodies to HIV-1/2 (anti-HIV Ab), RDT

Indication - HIV infection

Antibodies to HIV-1/2 (anti-HIV Ab)

Facility level: 3, Blood screening laboratory

Purpose	To screen blood donations for HIV
Specimen types	Capillary whole blood, Venous whole blood, Plasma, Serum
WHO prequalified or recommended products	Public reports of WHO prequalified IVDs https://extranet.who.int/pqweb/vitro-diagnostics/prequal-reports/wfopr?field_whopr_category=58
WHO supporting documents	Screening donated blood for transfusion-transmissible infections: recommendations (2009) http://app.who.int/iris/handle/10665/44202
Related Medical Devices in MeDevIS	Test, HIV 1 & 2, rapid



(3) to provide cross-references between the WHO Model List of Essential In Vitro Diagnostics and the diagnostic devices already included in the WHO priority medical devices lists, in order to facilitate the identification of relevant diagnostics for comprehensive diagnostic services, in particular through the open electronic platforms eEDL¹ and MeDevIS;²

Dengue and chikungunya

Reference Packages

Filter

Copy

Export

> Prevention of dengue and chikungunya

1 of 1 core actions included

▼ Screening and diagnosis of dengue and chikungunya

3 of 3 core actions included

COM PHC 1RL 2RL 3RL MHU

> History and physical examination

▼ Basic laboratory tests

Tasks

Provide counselling and information and obtain consent

Conduct diagnostic testing

Document examination findings

Medical devices

In vitro diagnostic tests

Medicines

Type Of Care

Curative

Action Category

08. Laboratory

Life stage

All ages

Programmes

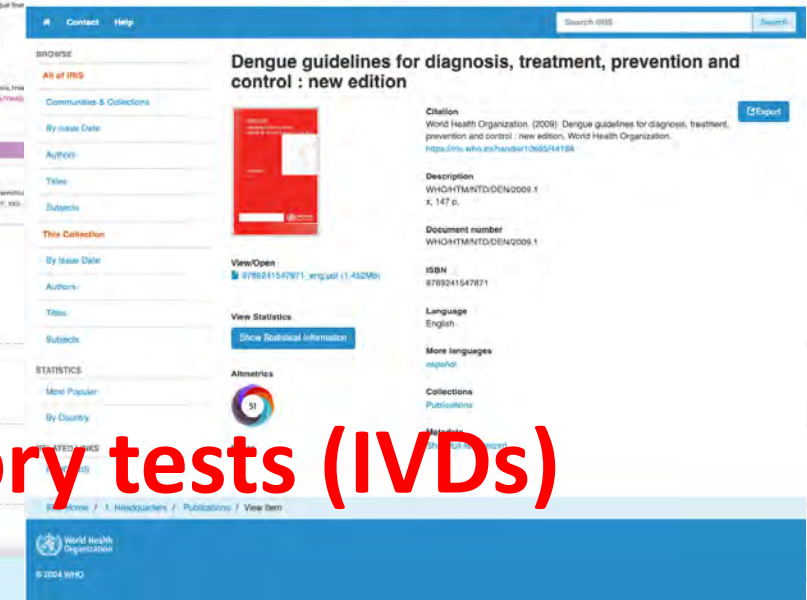
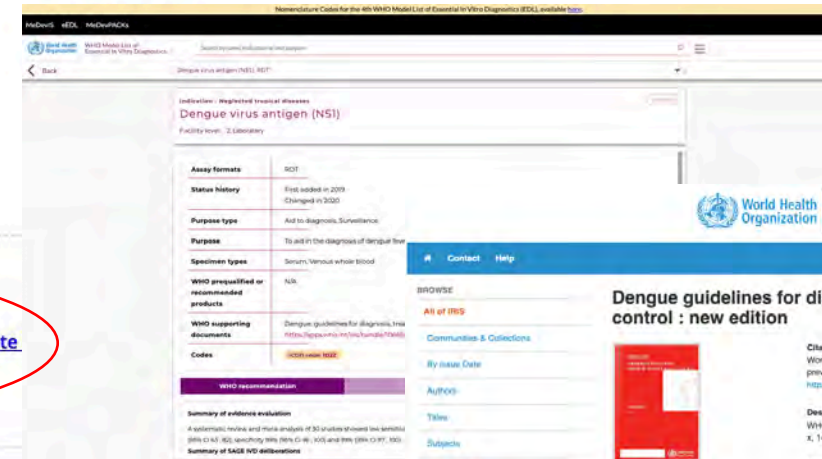
Dengue fever and chikungunya

Included in

[core] Diagnosis of dengue and chikungunya and management with medication

Core bundles

Additional bundles



Linking service delivery to laboratory tests (IVDs)

Antenatal care

> Fetal biophysical profile

> Screening for substance use

> Point of care testing

> Basic laboratory tests

> Advanced laboratory tests

▼ Ultrasound

Tasks

Provide counselling and information and obtain consent

Document examination findings

Conduct radiological examination

Medical devices [Reusable Clinical assessment Module](#), [Physical examination with ultrasound Module](#), [OB/GYN Ultrasound C](#)

In vitro diagnostic tests

Medicines

Type Of Care Curative

Action Category 09. Imaging studies

Life stage e) Later adolescence/early youth (15-19 years), f) Later youth (20-24 years), g) Early adulthood (25-49 years)

Programmes Sexual and reproductive health, Maternal and newborn health

Included in [core] Routine care during pregnancy
[core] Management of antenatal complications

WHO references [World Health Organization. \(2016\). WHO recommendations on antenatal care for a positive pregnancy experience](#)
[World Health Organization, United Nations Population Fund, World Bank & United Nations Children's Fund \(UNICEF\)](#)

> Oral iron and folic acid supplementation

Physical examination with ultrasound Module

Module type: Module

Module action: Physical examination with ultrasound

Healthcare setting: Diagnostic ultrasound

Reusable: Yes

Disease areas: All Areas

Resources: To be defined

Service delivery platforms / Healthcare levels: First-level (district) hospital services

Devices

[Stethoscope](#) Item quantity: 1

[Blood Pressure \(BP\) measurement device](#) Item quantity: 1
Aneroid, adult / paediatric

[Thermometer](#) Item quantity: 1

[Ophthalmoscope](#) Item quantity: 1

[Ultrasound scanner](#) Item quantity: 1

[Probe, ultrasound, general purpose, 4d/phased array](#) Item quantity: 1

[Probe, ultrasound, general purpose, curvilinear/convex](#) Item quantity: 1
3-5 MHz

WHO MeDevS MeDevPacks Essential in vitro Diagnostics (EDL) ICD-11 UHCC

World Health Organization MeDevS 2016 2.0 Search by keyword or click "enter" to display available filters

Export device

Ultrasound scanner, Doppler, general purpose and ob/gyn, portable

Primary use: Diagnosis / Measurement / Monitoring

Type of medical device or related product: Imaging / nuclear medicine equipment

Multiple vs. specific use (health condition): Multiple

Intended population age: Later adults (over 64 years)
Adults (20 to 64 years)

Intended population sex: All

Level of technical knowledge: Specialized clinical

Capital: Yes

Requirements: electricity (mains)
emergency power supply
HIS/LMIS/RIS/PACS

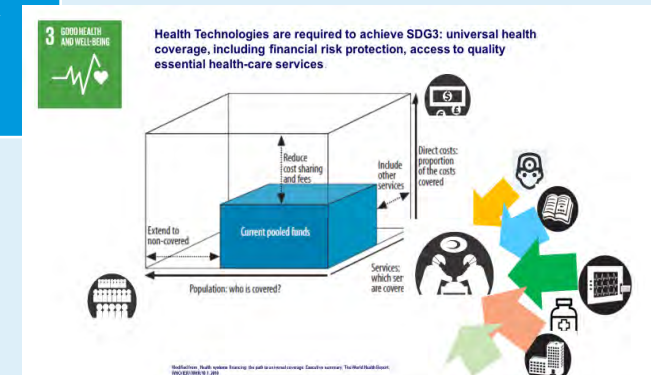
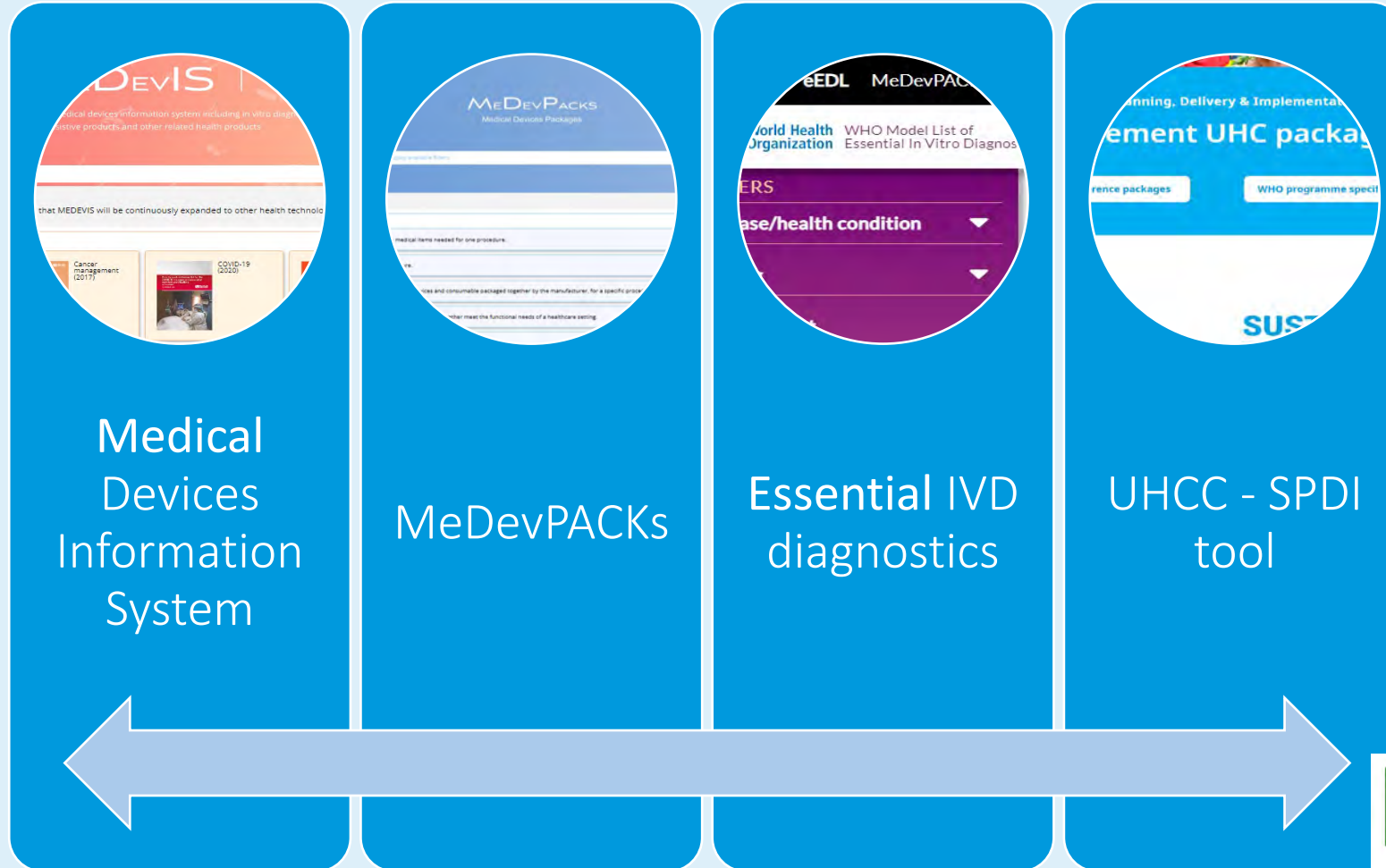


Linking service delivery to imaging diagnostics

3bis. Interconnected, WHO information in **open** platforms, for Member States

UHC reference

Using naming
EMDN and
GMDN



- The Strategic and technical advisory group of Medical Devices (STAG MEDEV) has approved the inclusion of other diagnostics in the Priority medical devices and updated the Medevis platform including nomenclature

May 2022, World Health Assembly 75 decision

- to 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**, ...to serve as a reference to stakeholders and Member States;
- (2) to submit a substantive report on progress made in implementing this decision to the Executive Board at its **152nd session in 2023**, and its **156th session in 2025**.

February 2025, report to the Executive Board EB156

[EB156/13](#) describes the road map for implementation of the WHA75.25 decision and to 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](#)

The screenshot displays the MeDevIS platform interface. At the top, there are navigation tabs: WHO UHCC, MeDevIS, MeDevPacks, and Essential in. Below the navigation bar, the WHO logo and 'MeDevIS 2025 v2.0' are visible. A search bar contains the text 'Pulse oximeter, table top'. To the right of the search bar, there are two input fields: 'EMDN related code(s)' with the value 'Z1203020408' and 'PULSE OXIMETERS', and 'GMDN related code(s)' with the value '45607'. Below these fields, there is a detailed description of a pulse oximeter. At the bottom of the screenshot, there is a list of nomenclature codes and their counts: EMDN (2471), EMDN not available (115), GMDN (2397), and GMDN not available (189). A blue box in the bottom right corner contains the text: 'In MEDEVIS Adding MD nomenclatures: EMDN codes and terms GMDN codes terms and definitions'.



World Health
Organization

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

7. The update of WHO Global Model Regulatory Framework for Medical Devices including IVDs

First edition 2017



- Describe the role and responsibilities of a country's NRAs for implementing and enforcing the regulations;
- Describes circumstances in which a regulatory authority may either: "rely on", or "recognize" the work products from trusted regulatory sources;
- Recommends two steps i.e. basic regulatory controls towards an expanded level; at three stages (premarket, placing on market and post market) ;
- Provides recommendations throughout the medical device's life cycle.

Revised in 2022-2023 to address: rapidly changing field, updated guidance documents, Integration of sub indicators in the GBT+ MDs tool, experience with implementation, COVID 19 pandemic.

Main revisions (2023)

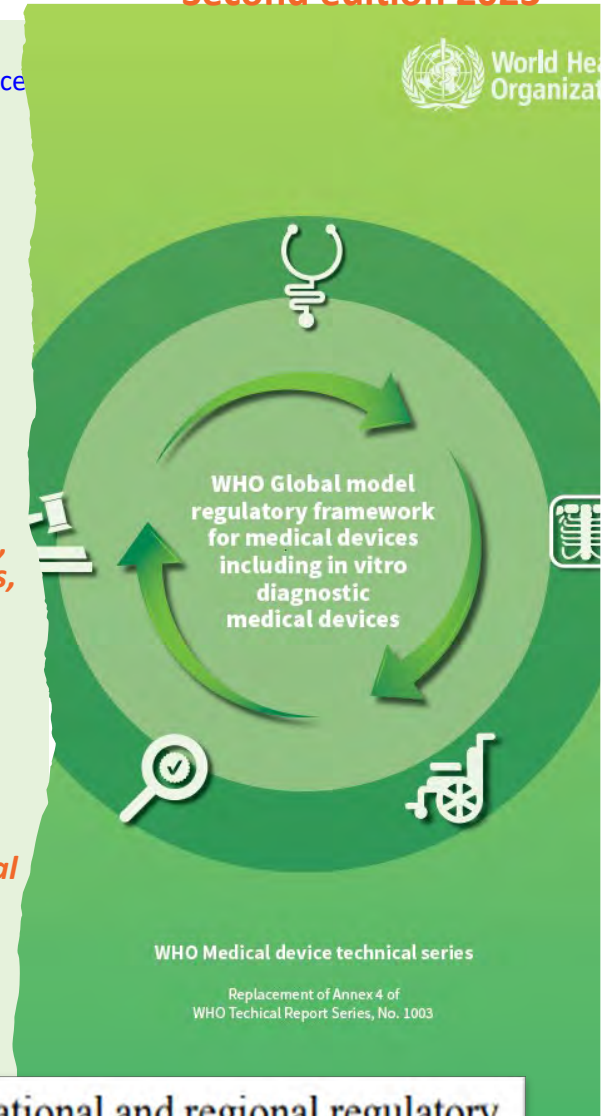
▪ Expanded text:

- a) Definition, essential principles, conformity assessment, companion diagnostics, good regulatory practice, good reliance practice and local production
- b) Additional topics: *reprocessing of single use medical devices, Software as Medical Device (SaMD), Companion diagnostics, Collaborative Registration Procedure, EUL by WHO as an example to Member States*

▪ New topics

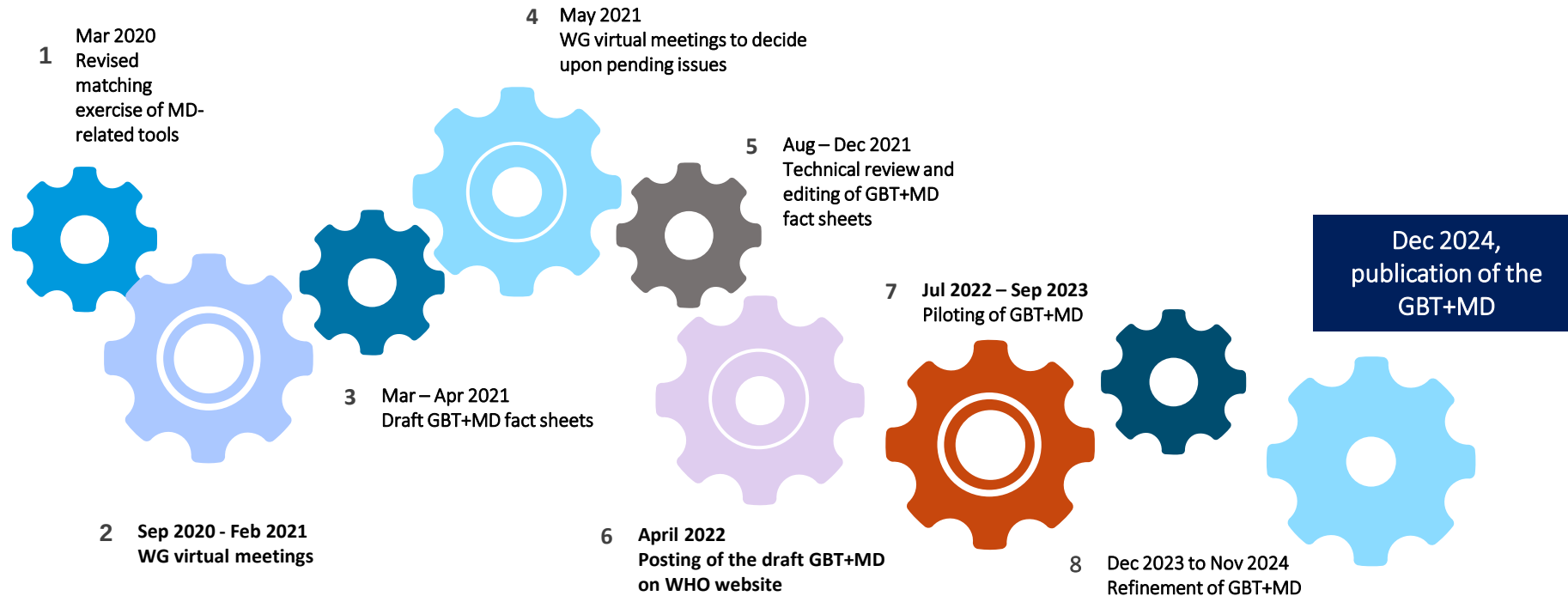
- a) Regulatory pathways : *conformity assessment according to risk class, reliance, emergency use authorization, combination products, borderline products, donated medical devices*
- b) Implementation: *stakeholders' involvement, developing a road map, regulatory capacity building*

Second edition 2023

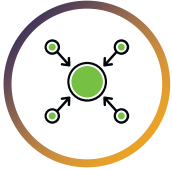


(7) to support Member States upon their request to strengthen national and regional regulatory systems for diagnostics;

Development of Global Benchmarking Tool + for Medical Devices including In Vitro Diagnostics



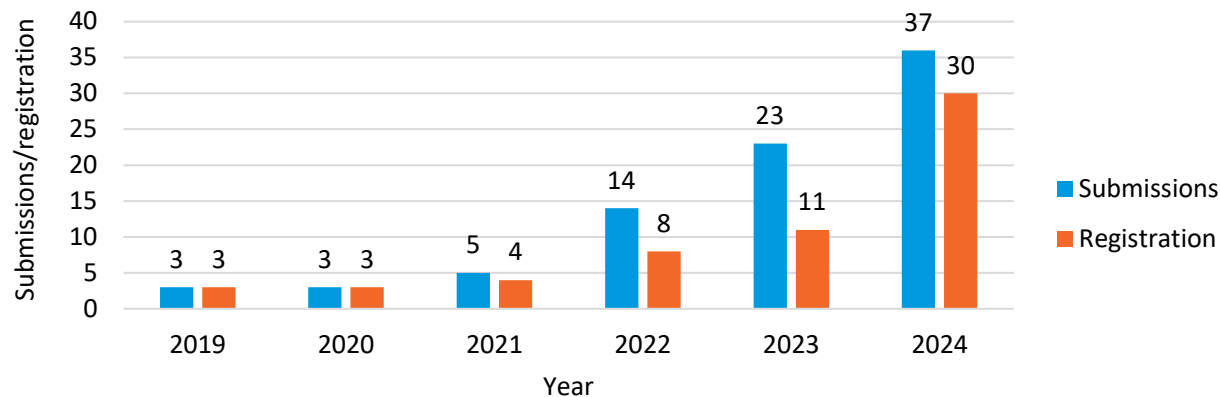
Promoting regulatory reliance for medical devices regulation



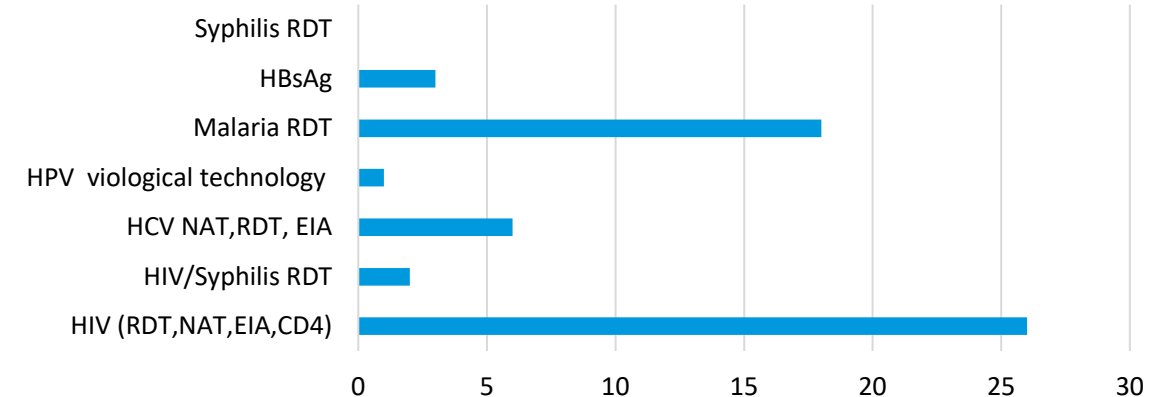
WHO Collaborative registration procedure for IVDs

- ✓ 37 national regulatory authorities signed agreement to participate CRP for PQ IVDs
- ✓ 62 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 conducted in November 2024 Workshop for in Jakarta, Indonesia, with over 200 attending (100 people in the room + 110 online).
- ✓ SEARN NRAs on regulation on medical devices in developing a reliance model based on the WHO Global Model Regulatory Framework.
- ✓ Global Webinar for NRAs on the Facilitated Procedure on EUL MPXV assays in October 2024 (4 NRAs have signed and successful submissions in two NRAs, awaiting regulatory decision).
- ✓ Conducted a specific workshop on EUL for MPXV for SEARN members in January 2025 (preparedness).

Collating field safety notices

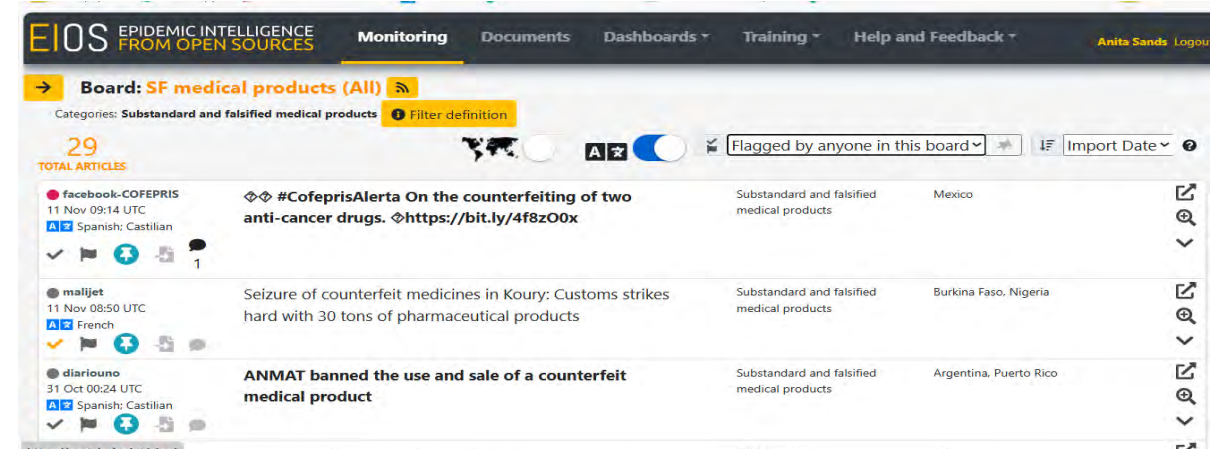
Use of WHO EIOS to create a global repository of field safety notices of medical devices

• Benefits

- Emerging regulators can consider reliance when another regulator has reviewed a FSCA and FSN

• Expected challenges

- Detecting content published in PDF format

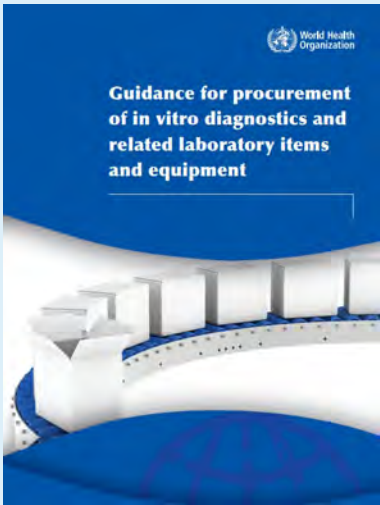


- *Epidemic Intelligence from Open Sources (EIOS) is web-based system designed to support public health intelligence activities using natural language processing and machine learning*
- *Scrapes 45,000 news sources in any language continuously, translates summary to English*

2. Procurement of quality assured IVD diagnostics, QMS toolkit, AI

Procurement advice for Member States

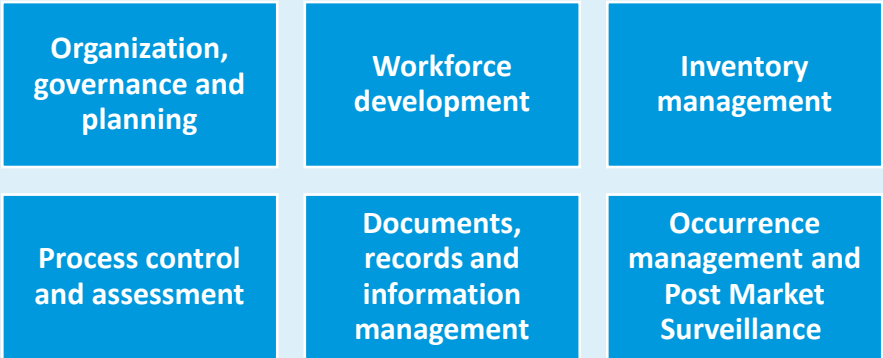
- Development of tool for QA of IVD diagnostics procured by WHO for Member States, *on-going*
- Aligning with QA policy of implementing partners
- Update of WHO procurement of IVD diagnostics and laboratory items, *planned*



Quality mangement systems for non-lab settings

Adaptation of existing lab QMS tools to non-lab settings context:

- Minimum package of QMS activities
- Simplification of the 12 QSE to 6 pillars
- Practical guidance, implementation tools and resources
- Multi-disease approach (starting with qualitative serology RDTs)

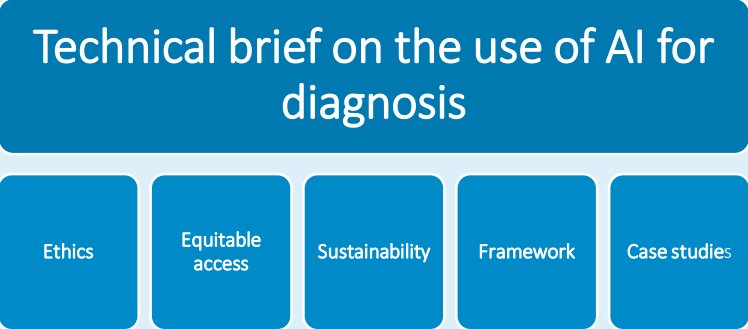


Artificial intelligence enabled IVD diagnosis

Development of technical brief on the use AI for diagnosis (starting with HIV, STIs viral hepatitis)

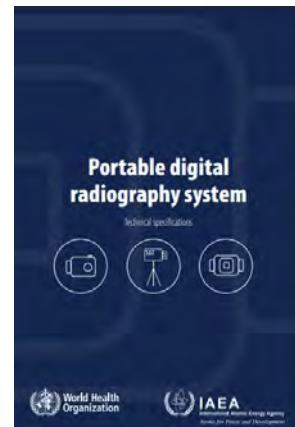
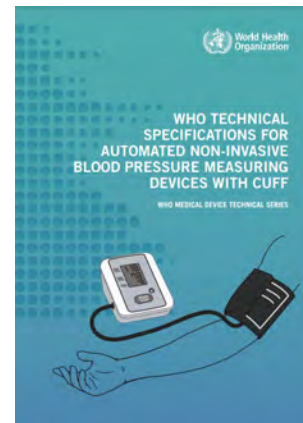
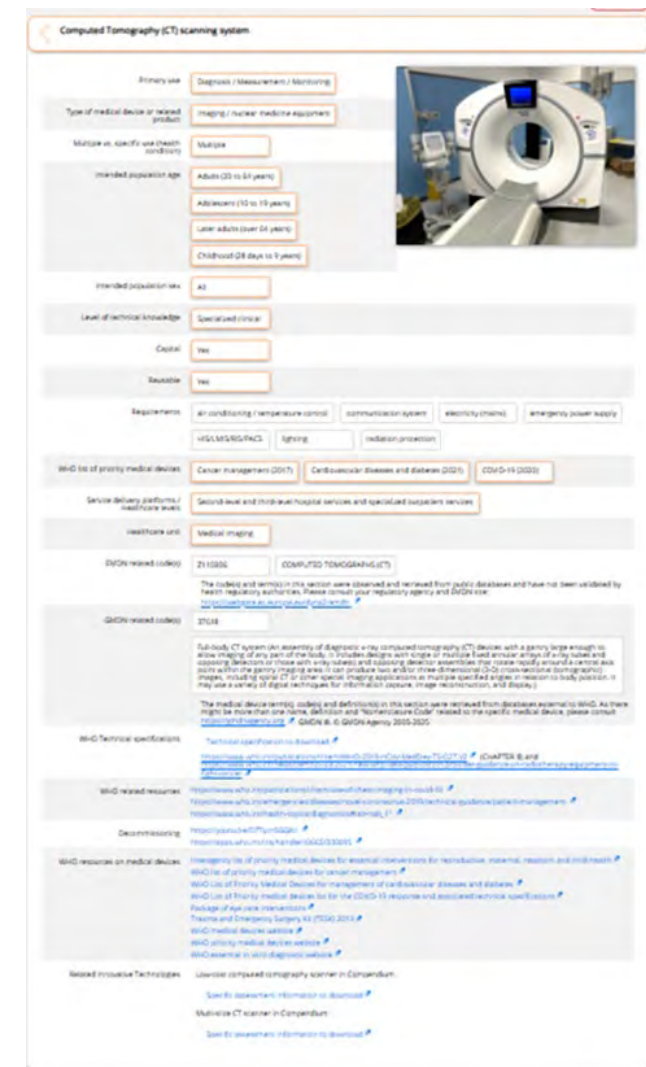
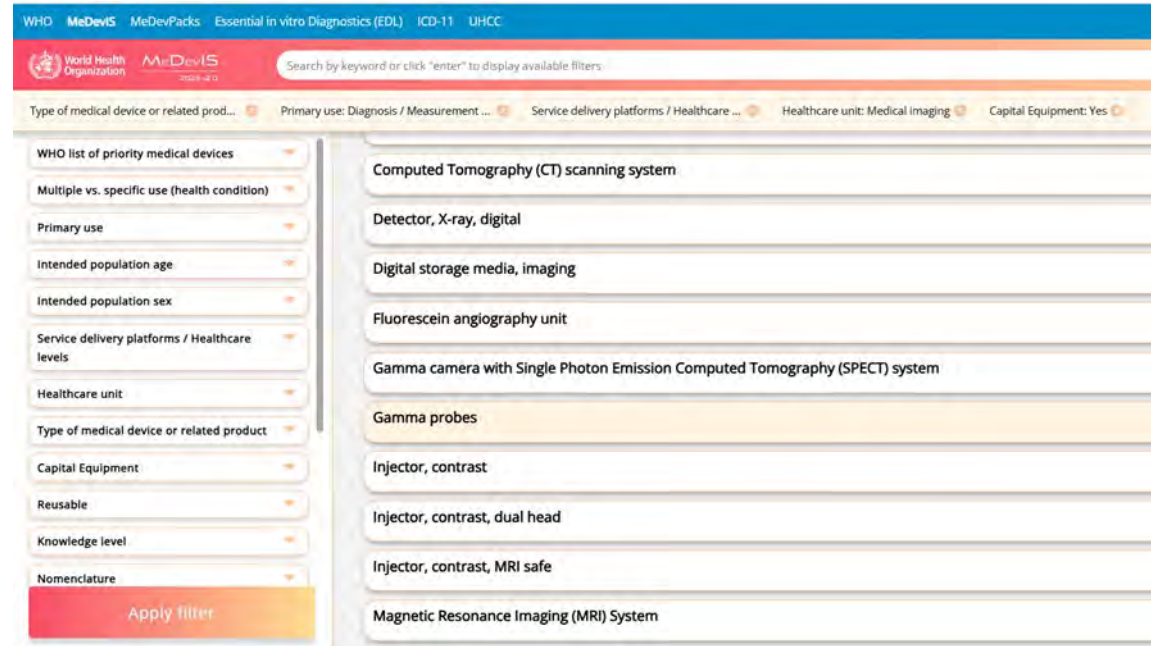
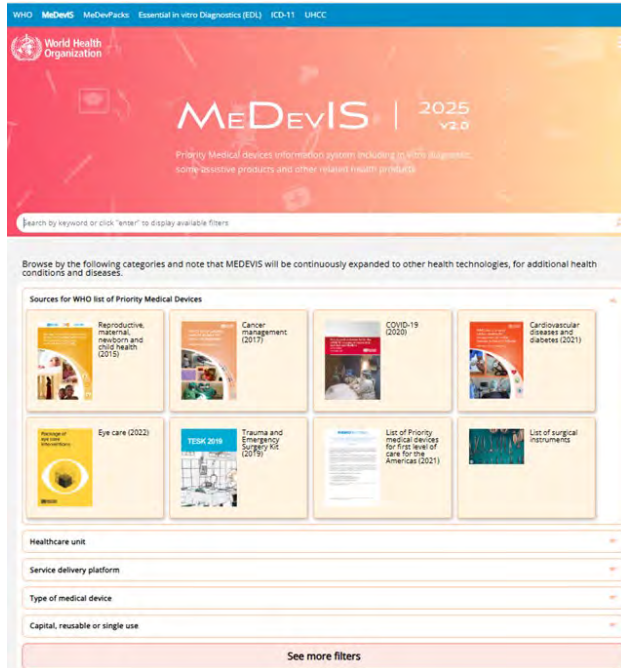
Time-lines:

- Formation of a working group (10-12 members external WHO), *on-going*
- Q2-Q4 2025: WG consultations, *on-going*
- Q4 2025: Technical brief draft available, *planned*



(2) to support Member States, upon their request and as appropriate, with technical advice for procurement that will enable access to good quality, affordable diagnostics for all Member States;²

2 bis. Technical specifications for procurement of other diagnostic devices



(2) to support Member States, upon their request and as appropriate, with technical advice for procurement that will enable access to good quality, affordable diagnostics for all Member States;²

6. The Health Technology Access program (HTAP) plays a neutral broker, matchmaking, coordinating and convening role for support to specific technology leveraging expertise internally and by partner organizations

- Foster R&D and innovation of new products with potential for emergencies and unmet need
- Facilitating tech. transfer opportunities to existing health products that can be applied for health emergencies

*i.e. SD Biosensor license:
RDT technology transfer*

Provides rights, know-how and material required to produce rapid diagnostic tests (RDT) based on the licensed technology



- Goal of sublicensing: contribute to sustainable manufacture of quality-assured RDTs at competitive prices.
- Assessment of potential TT recipients (identification of gaps/enablers aligned with an ecosystem approach)
- TT/development plan on unique needs/gaps of the manufacturer, country, region
- There is a need for a coordinated approach to providing support which draws on the strengths and mandates of relevant programs, if success is to be realized

(6) to continue to support Member States upon their request in promoting quality and sustainable local production of diagnostics, including, as appropriate, by facilitating research and development and technology transfer on voluntary and mutually agreed terms, and by coordinating with relevant international intergovernmental organizations and agencies to promote local production in a strategic and collaborative approach;³

Reflections to date – relevant to RDT technology transfer

SMEs in most LMICs have limited experience with the manufacture of RDTs (incl. technology transfer)

=> Most are transitioning from health product distribution to manufacturing

As expected with an “emerging” industry, manufacturers would benefit from support with

- Translation R&D and scientific know-how to complement manufacturing process
- Technology transfer and business agreement negotiations
- Establishing QMS aligned with RDT manufacturing that meets the necessary technical requirements
- Regulatory compliance - specialized technical assistance to reach prequalification status

For selected technology under the HTAP framework, the team supports engagement with govt. and regional stakeholders to identify ecosystem enablers and partnerships.

- ✓ Assessed and identified 3 potential sublicensee candidates
 - ✓ Selected one sublicensee – to be announced in May 2025
- ⇒ *Additional Sublicensee is under consideration pending analysis of market and demand enablers*
- ⇒ Mapping of tech transfer initiatives would facilitate synergies and complementarities

8. Development of national essential diagnostics lists (NEDL).

- By 2021 only 2 countries had published a NEDL based on the evidence-based recommendations of the WHO EDL, however, after the publication of [WHO guidance on how to develop and update national lists of essential IVDs](#) the uptake of the EDL by countries increased exponentially.
- During 2024, 5 more countries published their NEDLs towards increasing access to essential in vitro diagnostics for their population
- 26 other countries are actively working on their NEDLs.
- WHO support MS with technical assistance by organizing webinars and workshops on NEDL development in collaboration with the ROs and external partners; and by reviewing NEDL drafts in collaboration with COs.

8 bis. Development of national essential diagnostics lists (NEDL)

- With the support of PAHO, the [guidance document on NEDLs](#) was published in [Spanish](#) and [Portuguese](#)
- This document will be updated during 2026 and will include best practices on development and implementation of NEDLs from countries.



9. Essential Diagnostics List for Humanitarian and Public Health Emergencies

- Development of EDL for emergencies is a joint project between the EDL Secretariat and WHE Laboratory and Diagnostic team
- WHO has established a working group comprised of members of the WHO Strategic Advisory Group of Experts on IVDs (SAGE IVD) and WHO staff to draft the EDL subset list for emergencies



Public health emergencies

Outbreaks, epidemics, pandemics



Environmental or natural disasters

Earthquakes, hurricanes, tsunamis, floods



Complex humanitarian crises and armed conflicts

Conflict, refugee/internal displacement, migration

- Scope of EDL - need to take into consideration the wide variability in diverse emergencies and broad spectrum of test types
- Prioritization and a staged approach - First phase should focus on IVDs, and diagnostic imaging included in Phase 2
- Methodology - combined Scoping review and Delphi approach
- Gather and synthesize evidence on diagnostic services in emergencies including relevant lists of diagnostics
- Initial list drafted as a subset of those already in the EDL 4
- For those diagnostics not already in the EDL need to be added as new complementary list via the rigorous process used for the EDL, including public consultations
- Final version based on recommendations from both SAGE IVD and STAG MEDEV will be published alongside EDL 6

Timeline for Development of EDL Emergencies



12. WHO definition of "diagnostics"

1st phase:
collect
information on
definitions

2nd phase: SAGE
IVD and
STAGMEDEV
and WHO Dx Tf

3rd phase: Non
State Actors

4th Open
consultation

5th phase:
consensus and
publication

(12) to develop and/or update WHO definitions of diagnostics, through a group of experts and public consultations, and to publish revised definitions before the 156th session of the Executive Board;

Background: Current definitions do not define “diagnostics”

Medical device

- Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:
 - ■ diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - ■ diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;
 - ■ investigation, replacement, modification or support of the anatomy or physiological process;
 - ■ supporting or sustaining life;
 - ■ control of conception;
 - ■ cleaning, disinfection or sterilization of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body;
- and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

In vitro diagnostic medical device (IVD)

- a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

NOTE 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Open consultation

As published in WHA 76.5

Strengthening Diagnostics capacity.

- “For the purpose of this resolution, the term “diagnostics” includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types”

Proposed definition

- Diagnostics are medical devices that provide information about diseases, physiological status, or health conditions in medicine and public health, with any of the following test purposes : screening , detection, prevention, surveillance, diagnosis or aid to diagnosis, monitoring, prediction, investigation, prognosis, or staging .
- They range from simple devices to complex systems, including: in- vitro devices, medical imaging, endoscopic systems, electrophysiology equipment, amongst others. They are indispensable to health care, emergency and pandemic preparedness and response, health security, combating antimicrobial resistance and, in general, supporting universal health coverage.

Paragraph



(12) to develop and/or update WHO definitions of diagnostics, through a group of experts and public consultations, and to publish revised definitions before the 156th session of the Executive Board;

13 and 14. The Global Diagnostics Coalition aims to convene organizations globally, complementary to the WHO's internal diagnostics efforts

Catalyst for greater Dx engagement	WHA Resolution 76.5	
Resulting Dx bodies	WHO Dx Task Force	Global Dx Coalition
Relation to WHO	Internal WHO body	External body, with WHO-led Secretariat hosting and convening global organizations
Mission	To align all WHO staff members dealing with all types of diagnostics, to work together towards the implementation of the resolution WHA76.5: Strengthening Diagnostics Capacity, in a harmonized integrated way.	To act as a collaborative platform and/or convening body to provide strategic direction and coordinate efforts to strengthen diagnostics capacity

- (13) to take a horizontal health programme approach for all diagnostics (both in vitro and non-in vitro) across diseases and to avoid siloed guidance, policy and funding streams;
- (14) to support Member States in creating optimized, integrated diagnostic networks and services that best serve country programmes to tackle all diagnostic systems needs, removing the oftentimes siloed programmatic and diagnostic services;

Global Diagnostics Coalition (GDC) to be launched in Q2 - 2025

Goal of Coalition

- **To support implementation of WHA resolution 76.5**, through advocacy, implementation in countries, resource mobilization, and monitoring impact
- **To act as a collaborative platform** and/or convening body to provide strategic direction and coordinate efforts to strengthen diagnostics capacity
- **To provide a horizontal approach to improve access to diagnostics** as a fundamental pillar of healthcare systems towards achieving universal health coverage and emergency preparedness/response

Governance¹

- A **WHO-led Secretariat** will coordinate the efforts of a **Steering Committee (SC) of 10-20 organizations**
- The SC will select focus areas **based on Member States' input**, supported by several **Working Groups**

Partners who have voiced interest in joining the GDC



Potential focus areas for the Coalition to provide support

- | |
|--|
| A. Support in establishing national diagnostic strategies |
| B. Support in developing national essential diagnostic lists |
| C. Support in making diagnostics available, accessible, and affordable at the PHC level |
| D. Support in developing skilled workforce at all healthcare levels, with training to support advances in Dx technology |
| E. Support in establishing routine data collection systems to monitor Dx market shaping and the effective use of diagnostics |
| F. Support across other interest areas (to be determined) |

1. More detail on governance structure to be provided upon request

WHA 76.5 recommendations to act as a foundation for scoping discussion

Preliminary focus areas highlighted in yellow – final areas of focus to be determined by Steering Committee based on additional input

WHA76.5 Requests to Member States (simplified)
1: Establish national diagnostic strategies
2: Establish health technology assessment systems
3: Develop national essential diagnostic list
4: Expand accessibility of diagnostics at PHC level
5: Invest in and train skilled workforce
6: Apply standards for the safe use of diagnostic imaging
7: Invest in diagnostic R&D and promote local production
8: Facilitate access through funding for diagnostic R&D
9: Take policy measures to ensure equitable and timely access to diagnostics
10: Leverage the TRIPS agreement to promote diagnostic access
11: Promote policies to prevent anti-competitive practices that hinder access
12: Harmonize and promote twinning practices and reliance mechanisms for the regulation, manufacturing and supply of all types of diagnostics
13: Establish routine data collection to monitor and improve the diagnostic market
14: Invest in diagnostic services, including selection and use of essential dx
15: Strengthen international collaboration and assistance, incl. during epidemics

WHA76.5 Requests to WHO Director General (simplified)
(1) to collect data on affordability, availability
(2) technical advice for procurement
(3) cross-references between EDL and PMD,
(4) to update WHO Model Lists EDL and PMD
(5) health technology management of diagnostics
(6) local production of diagnostics
(7) regulatory system
(8) Member States national lists
(9) Diagnostics for emergency
(10) MeDevIS and "e-EDL"
(11) Laboratory networks
(12) Definition of Dx
(13) horizontal health program approach not silos
(14) integrated diagnostic networks

WHO Diagnostics Taskforce members supporting (3), (4),



Note: we will also consider an additional product-specific focus area

On going work by WHO Diagnostics Taskforce members.

Thank you!
All joining our efforts
to support prompt
diagnosis for
everyone
everywhere!



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WHO

20, Avenue Appia
1211 Geneva

Switzerland

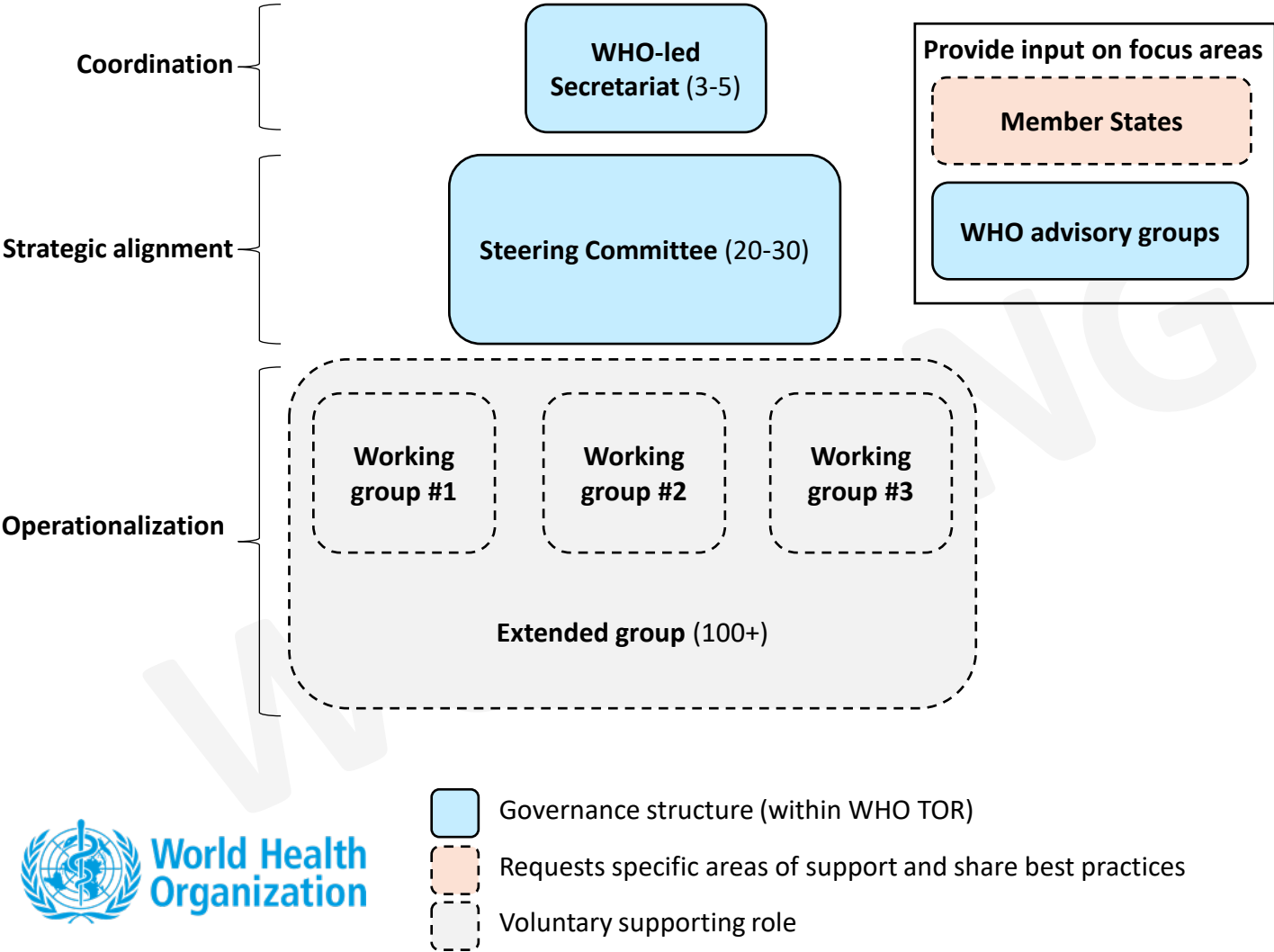
Medical devices

Email: medicaldevices@who.int

website: https://www.who.int/health-topics/medical-devices#tab=tab_1

Extra slides

Coalition operating model designed to promote agility, limiting formal structure and enabling working group flexibility outside of TOR



Group	High-level responsibility
Secretariat	Propose focus areas annually, based on input from Member States and WHO advisory groups. Includes WHO representative and is supported by voluntary commitments from members of Steering Committee
Steering Committee	Meets bi-annually to confirm long-term strategy and short-term focus areas and working groups. Includes leadership-level members of selected organizations with sustained multi-year engagement on diagnostics
WHO Advisory groups	Engage with secretariat on determining areas of focus on an annual basis. Includes WHO SAGE/STAG representatives
Working groups	Responsible for delivering outputs that align with the Coalition’s workplan and focus areas, reporting back to the Steering Committee bi-annually. Comprised of both steering and extended group members
Extended group	Open forum; meets annually, contributes to respective working groups