# Highlights from the Strategic Advisory Group of Experts (SAGE) on Immunization meetings

**11-14 March 2024 (plenary)**

**7 May 2024 (Ebola special)**

**23-26 September 2024 (plenary)**

**Joachim Hombach, Secretary of SAGE**

PDVAC December 2024

# 25 years of the Strategic Advisory Group of Experts (SAGE) on Immunization










# Agenda items SAGE Plenaries 2024

## Agenda March 2024

- Global and regional reports
- Immunization Agenda 2030
- Poliomyelitis (rec)
- Hepatitis E (rec)
- **Covid-19**
- **Immune correlates**
- **Mpox (rec)**
- Respiratory Syncytial Virus

## Agenda September 2024

- Global and regional reports
- Immunization Agenda 2030
- **Respiratory Syncytial Virus (rec)**
- Cholera
- Poliomyelitis (rec)
- **Rubella and Congenital Rubella Syndrome (CRS) (rec)**
- Updates on Mpox and H5N1
- Covid-19

# MAJOR THEME: POLICY ADVICE IN CONTEXT OF EMERGENCIES

## With focus on 2024

| Disease | Policy questions & major issues |
|---|---|
| COVID-19 | • Update on epidemiology and reconfirmation of priority populations for vaccination<br>• Vaccine effectiveness and benefit of strain-adapted monovalent vaccines<br>• Vaccine supply and demand situation |
| Mpox (and smallpox) | • Systematic review of effectiveness and safety of current vaccines<br>• Review of use cases (outbreak response/preventive/post-exposure)<br>• Target populations and vaccine preferences<br>• Call for action |
| Cholera | • Outbreaks remain major concern, and while increasing, supply remains limited<br>• Various policy relevant questions currently unanswered<br>• Need to substantiative preventive vaccination policy |
| Hepatitis E | • Benefit risk assessment of vaccinating pregnant women<br>• Recommendations on reduced dose (2vs. 3) schedule<br>• Research recommendations and data gaps |
| Ebola | • Consolidation of interim recommendations<br>• Strengthening policy for preventive vaccination<br>• Include guidance for long-term excreters |

# RESPIRATORY SYNCYTIAL VIRUS

## Immunization products to protect infants

World Health Organization | IVB

# SAGE recommendations

- SAGE recommended **all countries** introduce passive immunization for preventing severe disease caused by RSV in young infants.
- Decisions to use maternal vaccination and/or the long-acting monoclonal antibody should **consider cost, financing, supply, anticipated coverage and feasibility of implementation** within the existing health system.
- For countries deciding to use the **maternal vaccine**, SAGE recommended a single dose in the **3rd trimester (≥28 weeks GA in most settings)** with no upper GA limit, except for women in active labour. The recommendation to limit to 3rd trimester is a precautionary approach to minimise potential adverse impacts of preterm births before the 3rd trimester, while preserving the benefits and enhancing programmatic feasibility LMICs.
- A **year-round approach** is preferable in most countries in tropical and sub-tropical regions, but a seasonal approach may be considered for countries with clear RSV seasonality based on programmatic and cost-considerations.
- For countries deciding to use the **long acting monoclonal**, SAGE recommended a single dose at birth or the earliest opportunity after birth to all infants if a year-round approach is adopted. In a seasonal approach, administration of the **monoclonal** is recommended for all infants born during the RSV season or those up to the age of 12 months entering the season. Both products can be co-administered with vaccines normally given at the same time.
- SAGE emphasized the critical importance of a **post-licensure**, multicentre, randomized controlled study of the **safety and effectiveness** of the maternal vaccine planned in several African countries.

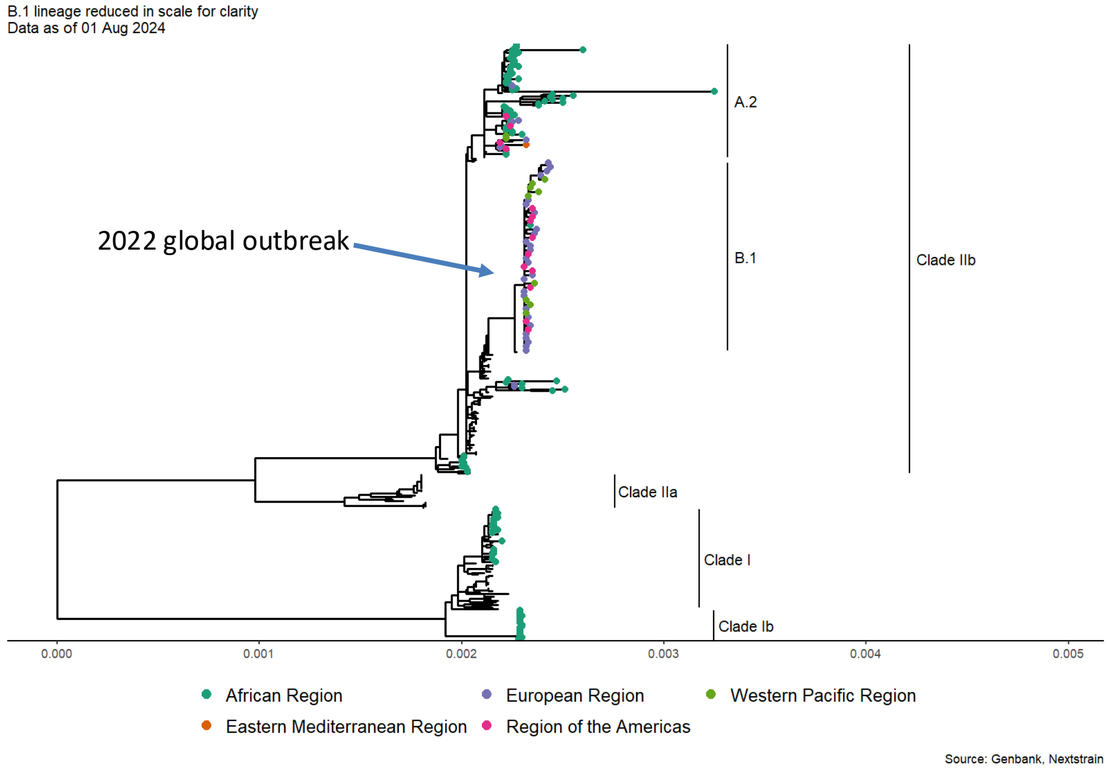
# Mpox

World Health Organization | IVB

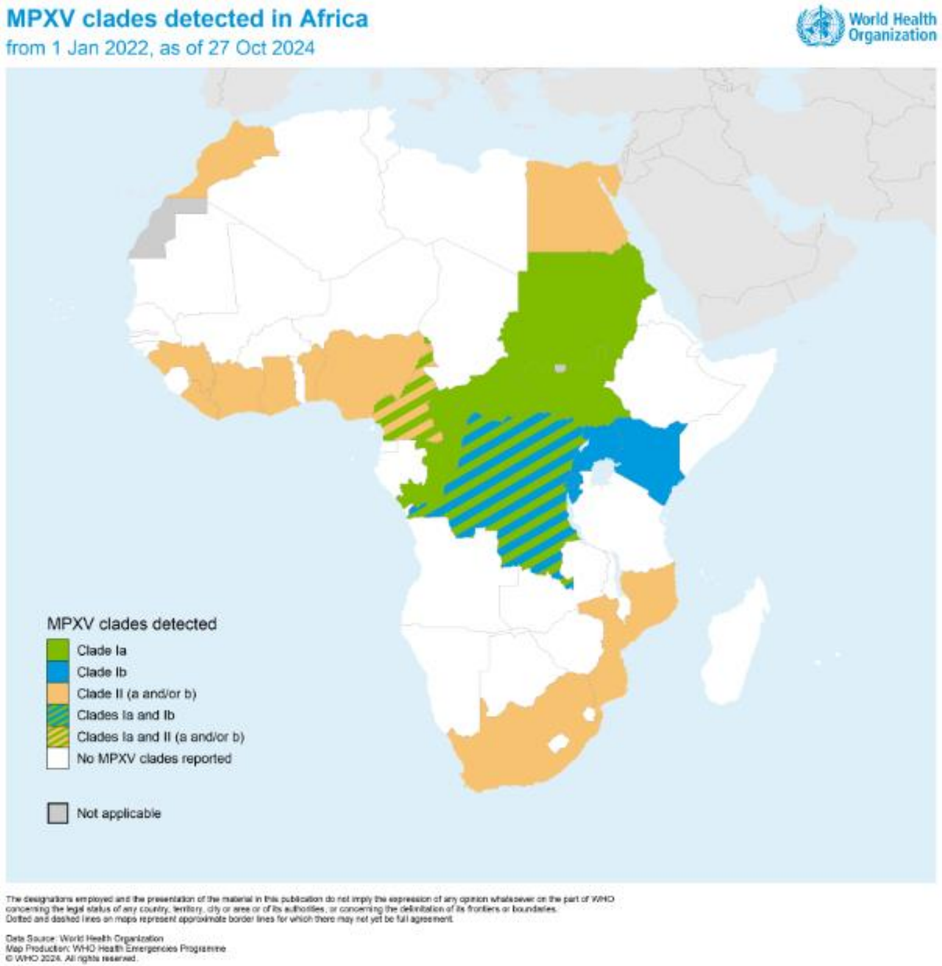
# MPXV clade distribution

There are two mpox virus clades

- Clade I (Central Africa): subclades Ia and Ib
- Clade II (West Africa): subclades IIa and IIb




Source: Genbank, Nextstrain



# Mpox vaccine recommendations (1/2)

- **In context of an outbreak Mpox vaccination may be considered for**:
  - Based on local epidemiology, **members of a geographically defined area or community** (e.g. village), including children, with a **documented high risk of exposure to mpox**.
  - Persons with **repeated intimate physical contacts** such as sex workers; gay, bisexual or other men who have sex with men (MSM) with multiple sexual partners; or other individuals with multiple casual sexual partners.
  - **Health workers at risk of repeated exposure**; clinical laboratory and health care personnel performing diagnostic testing for mpox or providing care, and outbreak response team members (as designated by national public health authorities).
  - **Contacts of persons** with mpox, ideally within the first 4 days of exposure (households, congregate settings, other).

Vaccine position paper released 23 August 2024:

https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers/smallpox-and-mpox-(orthopoxviruses)

# Mpox vaccine recommendations (2/2)

- **In non-outbreak settings,** vaccination is recommended for **laboratory personnel** working with orthopoxviruses. Periodic **revaccination (every 2 to 5 years, depending on risk of exposure)** should be considered for individuals who are at high risk of exposure to more virulent orthopoxviruses.
- **Non-replicating vaccine** (MVA-BN), **minimally replicating vaccines** (LC16-KMB), **replicating** cell-culture derived vaccinia-based vaccines (ACAM2000) or equivalent vaccines that meet WHO standards for quality for vaccinating **immunocompetent, non-pregnant adults**.
- **Specific considerations, including potential off-label use apply to vaccine choice for special population groups** such as immunocompromised individuals, pregnant women and infants, children, and adolescents, noting that the replicating vaccine has significant limitations for use.
- Vaccination should be offered to eligible populations, **irrespective of previous smallpox vaccination and/or visible smallpox vaccine scar**. For individuals previously vaccinated with mpox vaccines, an individual benefit-risk assessment should be done.
- **Additional research is recommended** on disease epidemiology, and the VE, safety, immunogenicity and duration of protection of vaccines. Given the high morbidity and mortality **in children, dedicated effort are required to understand the epidemiology of the disease and performance of vaccines** in this group.

# **Contextualizing** WHO SAGE recommendations with Global mpox SPRP and Continental plan vaccination strategies

## Policy

### WHO SAGE recommendations in outbreak settings


**Pre-exposure:**

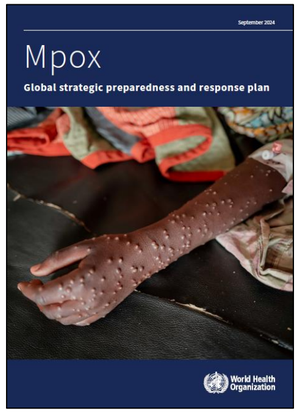
- Members of a **geographically defined area or community**, including children;
- **Health workers** and **outbreak response** team members;
- **Sex workers; gay, bisexual or MSM**; or other with **multiple casual sexual partners**

**Post-exposure:**

- **Contacts:** including children, others in the household, or in congregate settings (e.g.; prisons, schools, health facilities or residential facilities)

## Vaccination strategy

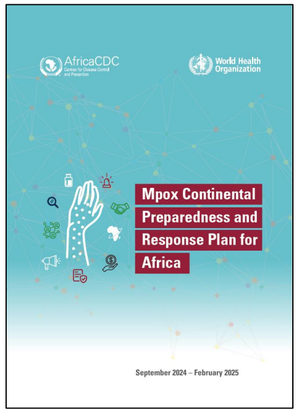
### Mpox Global Strategic Preparedness and Response Plan




**Phased vaccination strategy**

- **Phase 1– stop outbreaks:** by targeting **contacts** of incident cases with onset in the previous 2-4 weeks, and **HCWs/FLWs** in areas with active cases.
- **Phase 2 — expand protection:** individuals at **high risk of severe disease**—based on local epidemiology—in affected areas.
- **Phase 3 – protect for the future: all populations recommended by the SAGE.**

### Mpox Continental Plan for Africa




**Mpox vaccination will be implemented in two phases:**

- **First phase:**
  - exposed group of **contacts and the contacts of contacts**
  - expanded group of **those at risk (healthcare workers, immunocompromised and key populations**).
- **Second phase:** wider targeting **affected communities**, depending on progress in the epidemiology and the availability of vaccines.

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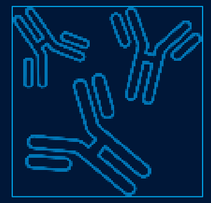

# Immune correlates

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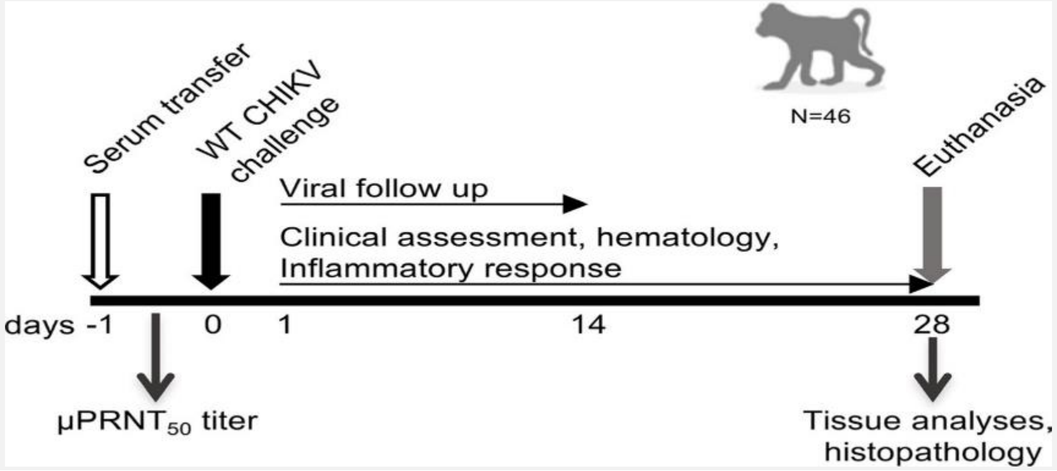
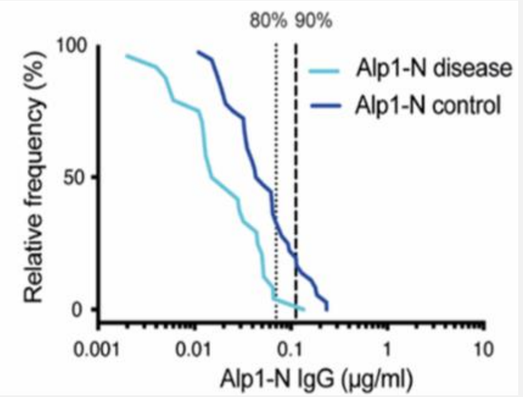
# Immune correlates

- For some vaccines, the **Phase 3 trials with clinical outcomes are challenging** either because they require very **large sample sizes** or because of the **unpredictability of outbreaks** and regulatory approval may be issued based on immunological correlates of protection.
- SAGE was briefed on the proposed **regulatory pathways using this approach for chikungunya and Group B streptococcus (GBS) and vaccines** and the evidence in support of the proposed immunological correlates of protection.
- A chikungunya vaccine (live-attenuated) has been licensed based on immune correlates and GBS vaccines (protein-based and hexavalent glycoconjugate vaccines) are likely to use a similar pathway.

## Chikungunya




## Group B streptococcus



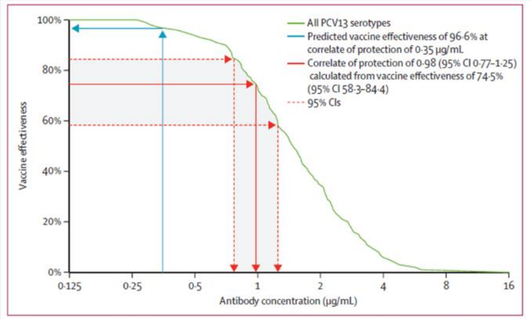




*Figure:* Reverse cumulative distribution curve for the geometric mean of all PCV13 serotype-specific IgG from the PCV13 serology study (EudraCT 2010-023865-22/NCT01425372)
Predicted vaccine effectiveness at a correlate of 0·35 µg/mL and observed vaccine effectiveness against all serotypes for individuals given at least two doses of vaccine before age 12 months or one dose on or after 12 months onwards.

# Immune correlates - SAGE observations

SAGE noted that **in general** prelicensure phase 3 RCT with disease outcomes should remain the **standard for policy recommendations**, and a correlates approach should be considered **case-by-case** only.

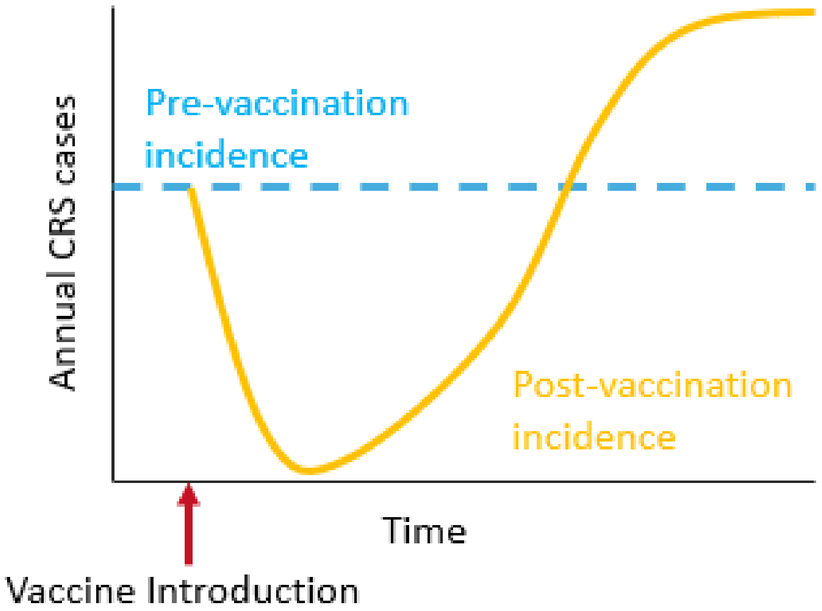
- Since a **chikungunya vaccine** had received regulatory approval and there was interest in introducing this vaccine in several countries, SAGE advised WHO to **initiate a process to conduct a detailed review of the evidence and assess use case scenarios** for the optimal use of this vaccine.

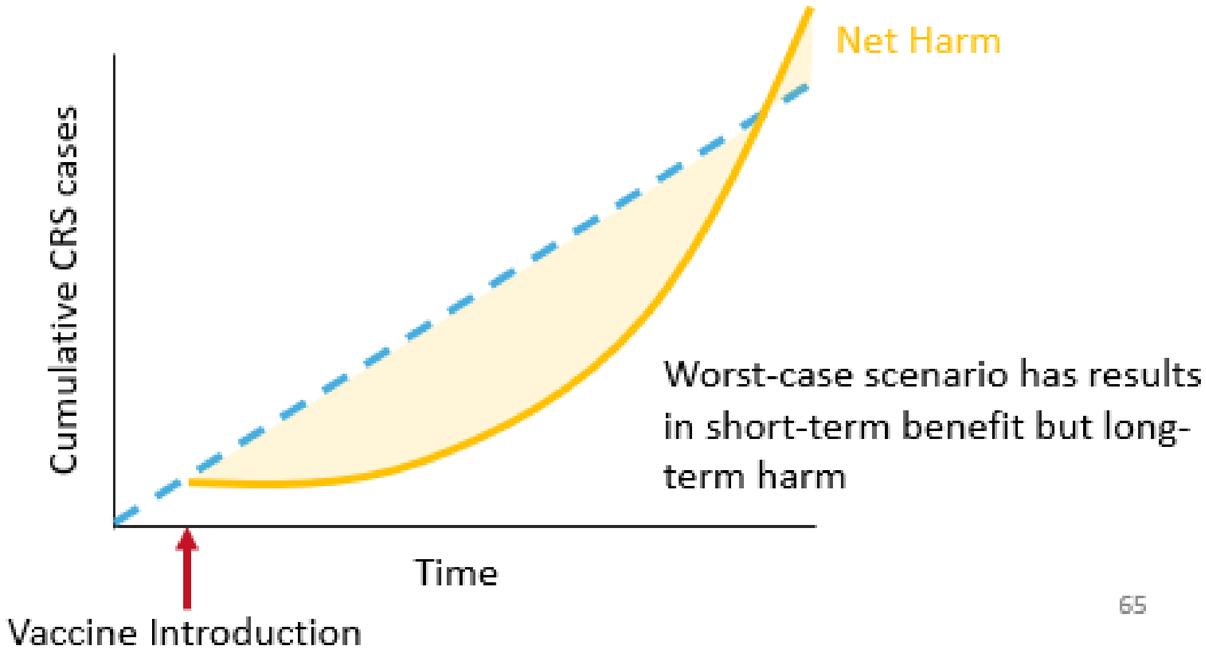
- SAGE also noted that requiring evidence of clinical efficacy for **GBS vaccines** before issuing recommendations could delay registration and ultimately the use of the vaccine in LMICs. SAGE advised WHO to develop guidance on **evidence needed for policy** for vaccines where market authorization is provided in the absence of clinical efficacy data.
- SAGE also advised to develop options for **post-authorization studies** to document vaccine effectiveness, through controlled or observational studies.

# RUBELLA & CONGENITAL RUBELLA SYNDROME (CRS)

# The paradoxical effect of RCV on CRS

- A “paradoxical effect” for rubella occurs when low-to-intermediate RCV coverage leads to a rebound in CRS burden that exceeds no-vaccination levels.
  - Effect has support both theoretically and empirically

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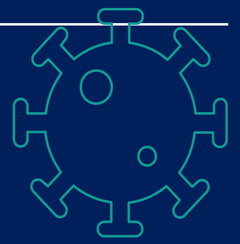
# SAGE recommendations on RCV introduction

- SAGE reviewed extensive **epidemiological data** and **modeling scenarios** on vaccine introduction, including **worst case scenarios**
- SAGE concluded that a universal threshold cannot be defined and **80% appears overly conservative**
- SAGE recommended **lifting the requirement** that countries attain 80% MCV coverage in routine or campaigns before the Rubella Containing Vaccine (RCV) introduction.
- SAGE recommended **universal introduction of RCV** in the 13 countries yet to introduce the vaccine
- SAGE reinforced the current policy for RCV introduction with a **wide age-range campaign** to accelerate the reduction of CRS.
- SAGE reinforced the existing WHO policy for **regular follow-up campaigns** in all countries until they reach 90% routine MCV1/MRCV1 immunization coverage.



# COVID-19

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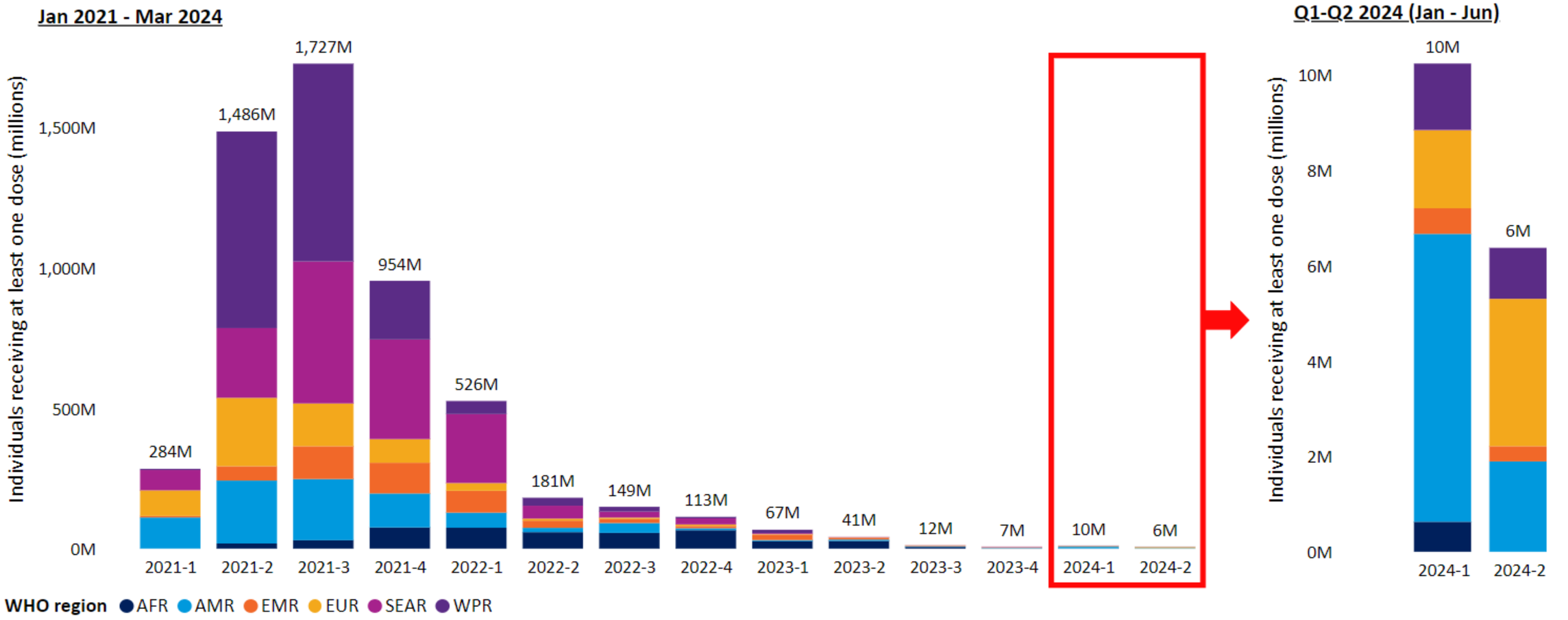
# Individuals having received at least one COVID-19 vaccine dose per quarter across reporting WHO Member States by WHO region




***Sources:*** *WHO-UNICEF Electronic Joint Reporting Form COVID-19 Module & WHO regional reporting systems.* ***Notes:*** *Eritrea and DPR Korea have not started COVID-19 vaccination.*

World Health Organization

# COVID-19 vaccines

Several COVID-19 vaccines have been **updated to target the currently circulating JN.1 and KP.2 subvariants**. The mRNA and protein-based vaccines are in highest use, though access to and demand for these vaccines is low, especially in low- and middle-income countries.

Vaccine **effectiveness against severe disease remains** high and relatively stable. However, the **effectiveness against symptomatic disease is lower and wanes quickly**; the effectiveness of vaccines matched to the currently circulating Omicron variants is higher than mismatched vaccines.

SAGE reaffirmed the validity of the existing **WHO SAGE Roadmap for prioritising uses of COVID-19 vaccines and the priority-use groups** defined and emphasised the importance of revaccination of the priority-use groups as recommended in the Roadmap.

A WHO COVID-19 **vaccine position paper** will be developed, and publication is expected in **2025**.

# SAGE – plan of work & deliverables (draft)

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# Proposed SAGE proposed new activities starting 2025

| Topic | Expected outcome; main items |
|---|---|
| Chikungunya | New vaccine position paper, outbreak response, endemic use |
| Yellow Fever | Update 2013 Vaccine position paper, address pediatric dose-scheduling, fractional dose vaccination |
| COVID-19 | Consolidate existing interim guidance into a vaccine position paper |
| Japanese Encephalitis | Update 2015 vaccine position paper, need for booster doses, new vaccine products |
| Pertussis | Update 2015 vaccine position paper; discuss booster needs, maternal vaccination, outbreak response |
| Avian influenza | Review/update on guidance of use of vaccine during the interpandemic |

# Proposed non-policy items 2025

| Topic | Expected outcome; main items |
|---|---|
| NITAGs and vaccine prioritization | Discussion item on capacity development and decision-assistance |
| New TB vaccines | Update on TB vaccine landscape and global support measures |
| Combination vaccines | Advise on framework for preferred combination options based on public health considerations |

## Longer list items*:

Typhi – paratyphi bivalent vaccines,
Group B streptococcus vaccines,
Maternal immunization (platform),
Older adult vaccination (platform/schedule)

*not exhaustive

# Technical Advisory Group on Market Access for Vaccines (TAG MVAC)

**PDVAC meeting**

09 December 2024

Geneva

Tara Prasad
Team Lead, Global Access
Department of Immunization, Vaccines & Biologicals (IVB)
Universal Health Coverage/Lifecourse Division
World Health Organization

# WHO Market Information for Access Initiative

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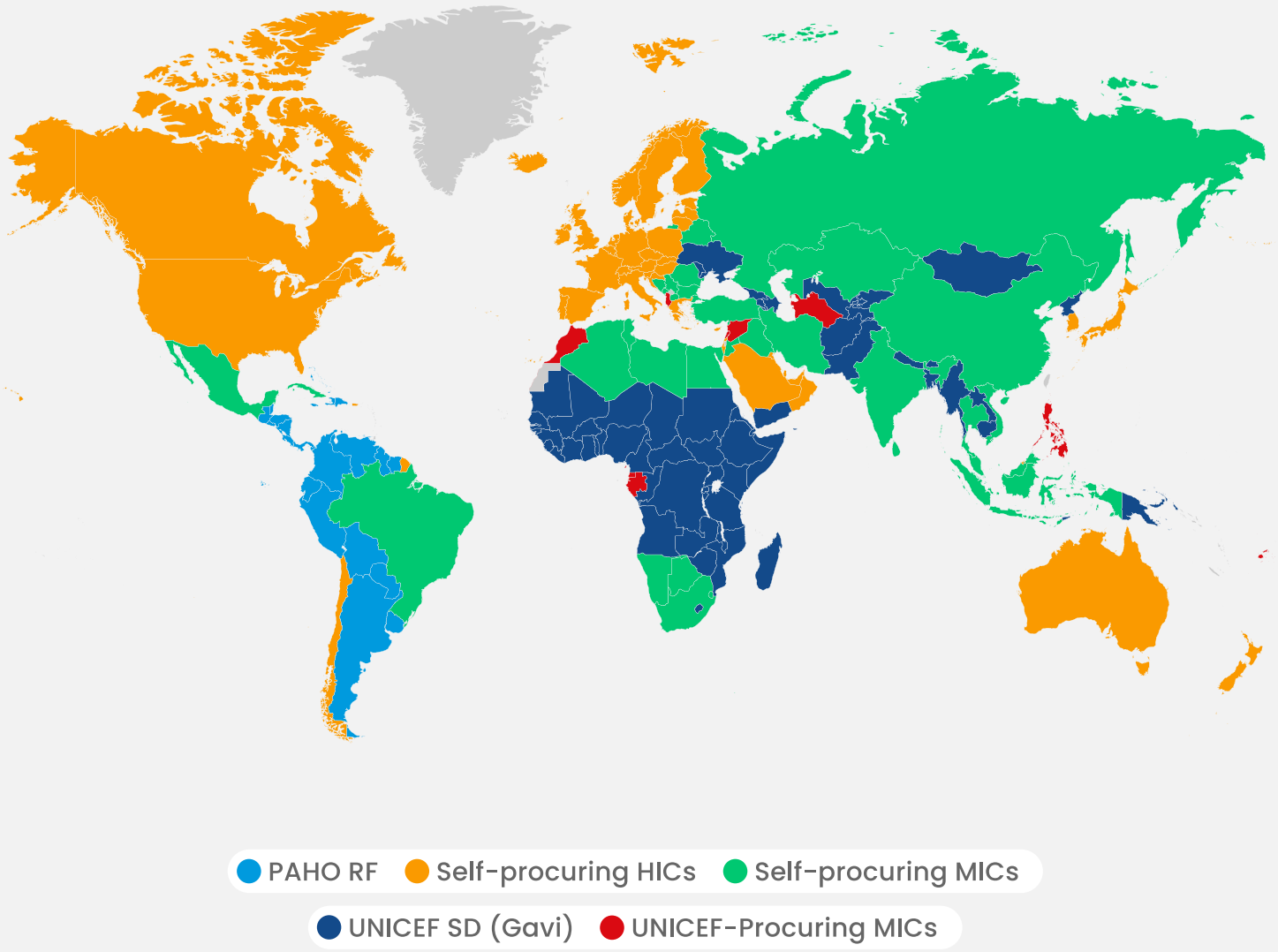
# WHO has a global mandate to support equitable access to vaccines for all

Vaccine supply is planned and distributed to serve a **global market** – consumption in one country impacts others

Historical focus limited to UN procured vaccines leaves out 60% of the vaccine ecosystem, limiting visibility on full risks and opportunities

Global scope includes:

- **All vaccines**
- **All countries**
- **All suppliers**
- **All procurement channels**
- **All financing channels**

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# Market Information for Vaccine Access (MI4A) to shape global and local vaccine access strategies & actions

MI4A
MARKET INFORMATION FOR ACCESS TO VACCINES

Enhance the understanding of **global vaccine demand, supply and pricing dynamics** and identify access barriers and risks

Convene global health experts and partners on **strategies and guidance** to address identified risks and opportunities

Strengthen **national and regional capacity** for improved access to vaccines supply

**Every year, WHO publishes:**

**1. MI4A Public Vaccine Purchase Dataset** to improve market transparency

**2. Global Vaccine Market studies** to assess market-specific dynamics that may impact supply, affordability and access

- 11 studies since 2017 *(Meningococcal meningitis, Pneumococcal, Human rabies, Typhoid, Hepatitis A, BCG, D&T containing, HPV, Measles containing, Malaria, Seasonal Influenza)*
- **12th Study:** Global Market Study on RSV Immunization Products

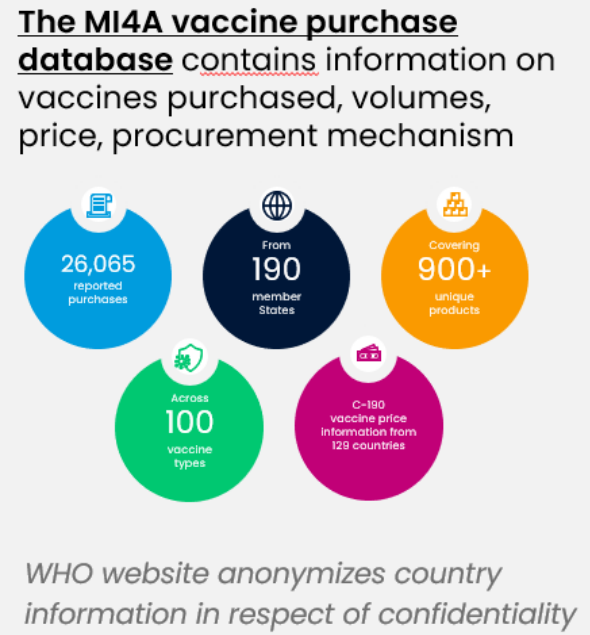
**3. Global Vaccine Market Report** to assess cross-antigen global vaccine market dynamics

**Source:** WHO Market Information for Access to Vaccines Initiative

# 1. Every year WHO collects data from countries

- MI4A Vaccine purchase database published in September 2024, with information on 2023 purchases from **169 countries**; historical data from **2005**

- Table containing price ranges as reported by countries

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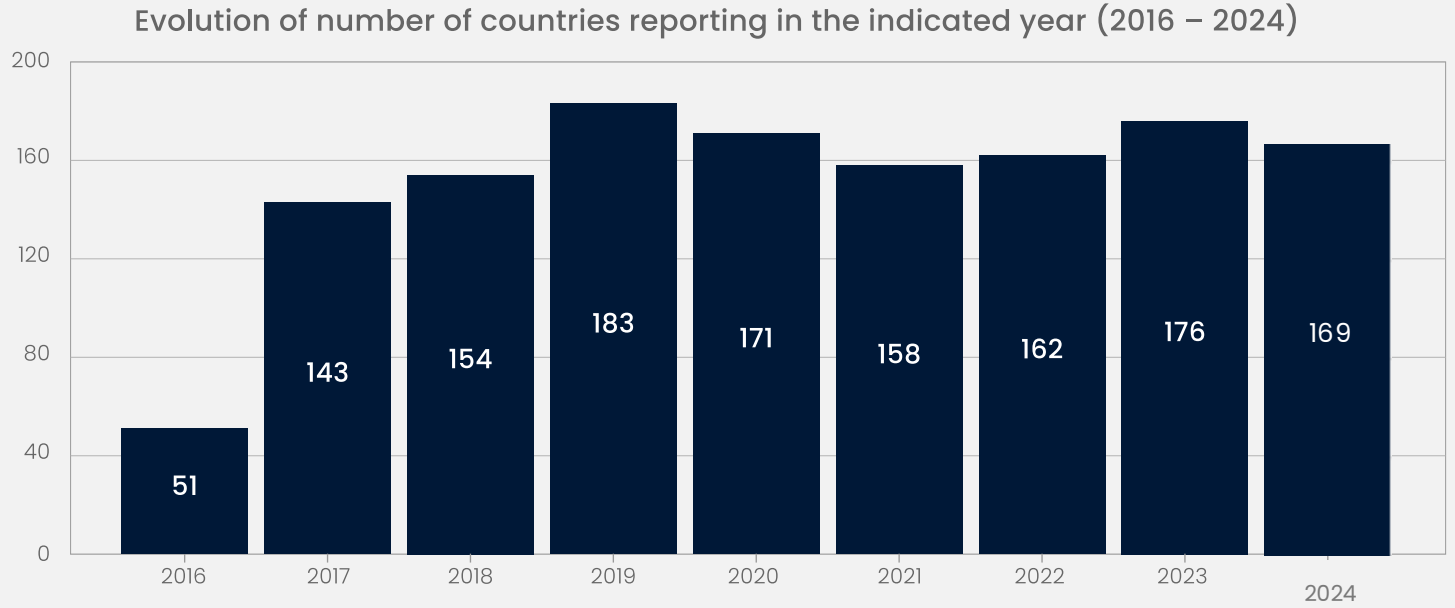


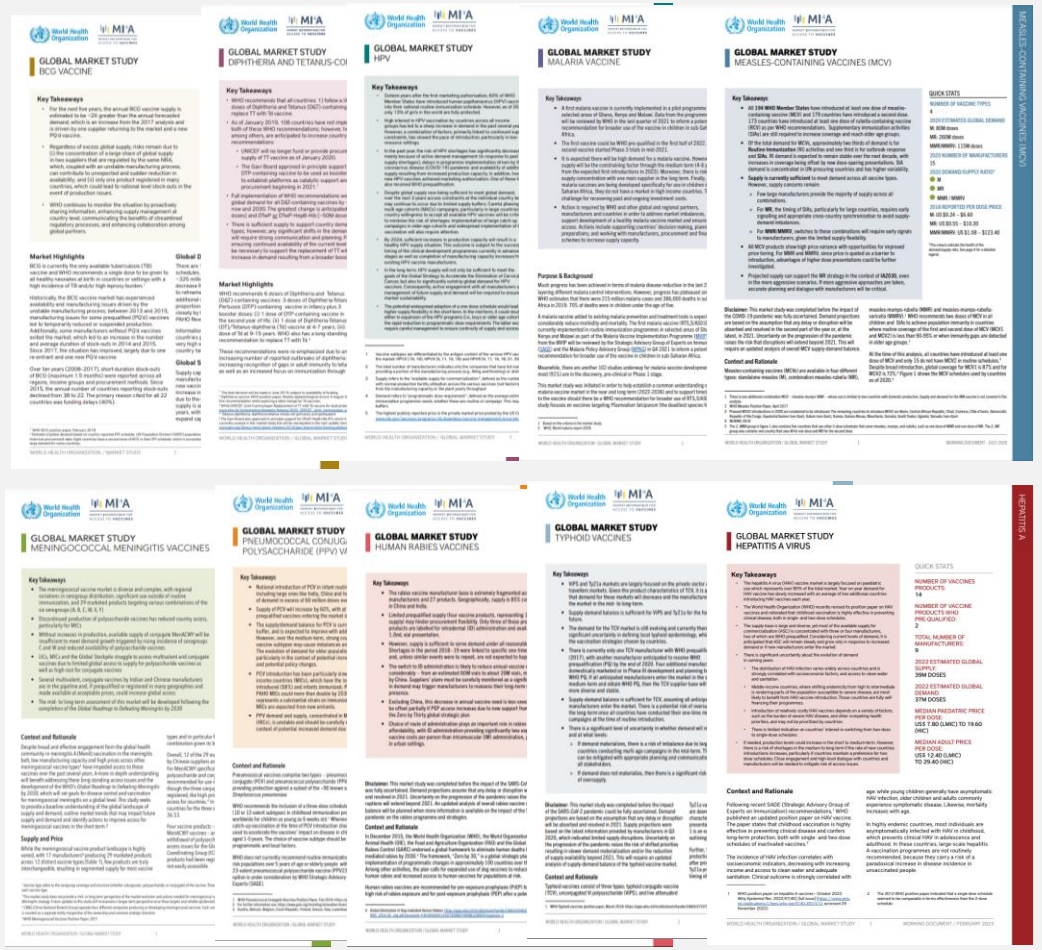

| VACCINE | UNICEF Supply Division (incl. COVAX) | | | | | | PAHO Revolving Fund | | Self-procurement | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Gavi | | Non-Gavi | | | | | | | | | | | |
| | | | LMIC | | UMIC | | | | LMIC | | UMIC | | HIC | |
| | Min | Max | Min | Max | Min | Max | Min | Max | Min | Max | Min | Max | Min | Max |
| BCG | $0.10 | $0.20 | $0.10 | $0.22 | $0.10 | $0.27 | $0.12 | $0.33 | $0.16 | $0.80 | $0.03 | $1.24 | $0.25 | $29.53 |
| bOPV | $0.11 | $0.20 | $0.14 | $0.23 | $0.14 | $0.20 | $0.13 | $0.20 | $0.18 | $0.18 | $0.16 | $0.38 | $0.25 | $4.94 |
| COVID-19 | $3.70 | $20.00 | $6.70 | $7.50 | $4.00 | $12.00 | $12.00 | $12.00 | | | $4.00 | $15.00 | $17.68 | $93.54 |
| Dengue | | | | | | | | | | | | | $95.18 | $95.18 |
| Diphtheria | | | | | | | | | | | $0.04 | $0.04 | | |
| DT | $0.18 | $0.21 | $0.17 | $0.38 | $0.20 | $0.21 | $0.18 | $0.18 | $0.24 | $0.47 | $0.09 | $1.13 | $0.78 | $1.42 |
| DTaP | | | | | | | $18.20 | $18.20 | | | $0.81 | $0.81 | $13.04 | $20.81 |
| DTaP-HepB-Hib-IPV | | | | | | | $20.00 | $21.54 | | | $19.92 | $39.20 | $20.99 | $96.86 |
| DTaP-HepB-IPV | | | | | | | | | | | | | $63.48 | $63.48 |
| DTaP-Hib | | | | | | | | | | | $0.81 | $0.81 | | |
| DTaP-Hib-IPV | | | | | | | $17.61 | $19.00 | | | $12.75 | $26.41 | $17.75 | $67.11 |
| DTaP-IPV | | | | | | | $13.49 | $13.66 | | | $15.47 | $24.50 | $14.08 | $46.52 |
| DTwP | $0.18 | $0.19 | $0.17 | $0.19 | $0.18 | $0.19 | $0.18 | $0.18 | $0.46 | $0.61 | $0.11 | $0.11 | $0.34 | $0.68 |
| DTwP-HepB | $0.85 | $0.85 | | | | | | | | | $1.42 | $1.42 | | |
| DTwP-HepB-Hib | $0.78 | $1.29 | $0.78 | $1.29 | $0.80 | $3.77 | $1.19 | $1.19 | $1.63 | $2.29 | $1.25 | $1.25 | $6.47 | $11.69 |
| HepA (adult) | | | | | $7.45 | $8.30 | $10.99 | $13.50 | | | $33.13 | $33.13 | $17.50 | $39.11 |
| HepA (ped.) | | | $6.99 | $6.99 | | | | $8.03 | $11.09 | $11.09 | $4.13 | $21.08 | $11.42 | $27.71 |
| HepA+B | | | | | | | | | | | | | $46.65 | $72.05 |
| HepA-Typhoid | | | | | | | | | | | | | $87.94 | $89.74 |
| HepB (adult) | | | $0.70 | $0.70 | | | $0.33 | $0.78 | $1.40 | $1.40 | $0.97 | $7.85 | $2.29 | $74.94 |

*The table is non-exhaustive and only representative of min-max prices as they are reported by countries. Variations can be attributed to different vaccine presentations, manufacturers and other factors.*

# 2. 12 Global Market Studies performed so far covering key vaccines

## MI4A Market Studies

- Meningococcal meningitis
- Pneumococcal
- Human rabies
- Typhoid
- Hepatitis A
- BCG
- D&T containing
- HPV
- Measles containing
- Malaria
- Seasonal Influenza
- **RSV**


**Download here:**

[WHO Global Market Study on RSV Immunization Products]

# 3. WHO Global Vaccine Market Report (GVMR)


## What is the GVMR?

- A report including analyses on global vaccine market dynamics, issued since 2018
- The global scope allows for a more comprehensive understanding of the demand/supply landscape for specific antigens and across antigens
- It is a snapshot of last year's vaccine market, capturing trends from one year to the next
- Mainly uses data provided by countries through the Joint Reporting Form, complemented by other public sources[1]

## What topics does it cover?

1. Volume and value
2. Manufacturing and supply
3. National stock-outs
4. Vaccine specific supply dynamics and supply security
5. Procurement and pricing
6. Vaccine regulation

1. GVMM, Chinese Lot release data, UNICEF SD, PAHO RF, ICG, The World Bank Group, Gavi, The Vaccine Alliance, OWID, US CDC, UNOPS, publicly reported sales

# Role of the TAG MVAC

World Health Organization

# The TAG MVAC was established in 2023 and plays a critical role in advising WHO on global access to vaccines

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## Technical Advisory Group on Market Access for Vaccines (who.int)

### Members


Anna Mia Eckström


Ezzeddine Mohsni


Pradeep Haldar


Nathan Mulure


Els Torreele


Eiichi Shimizu


Michel Zaffran


Anthony So

### Newly appointed Members 2H 2024


Julie Barnes Weise


Ruben Proano


Heather Deehan


Michael Schunk


Emma Hannay


Sheetal Sharma

# In its capacity as an advisory body to WHO, the Technical Advisory Group has the following functions on priority topics

**Provide an independent recommendation on technical and/or strategic aspects** of key global vaccine market topics

**Deliver recommendations on proposed areas for action by WHO** to enhance global access to vaccines resulting from market analyses and as proposed by the WHO Secretariat;

**Advise WHO on data sources, data quality, methodologies and overall market assessments** with a key focus on supply demand balance, pricing dynamics, supply sustainability, regional supply security and other relevant aspects related to global vaccine market access.

# TAG MVAC Meeting #4 (26-27 Nov, 2024)
# Meeting objectives

1. Present the **findings of the Global Market Study on RSV immunization products** and discuss the related areas for action

2. Discuss the **2024 update of the WHO Global Vaccine Market Report (GVMR)** and seek TAG feedback on **IA2030 indicator on market health**

3. Update the TAG MVAC on **WHO support to countries** to improve equitable access to vaccines

4. Present WHO proposal for **categorization of vaccines for trade**

5. Present **the 2025 areas of work and priorities** and collect feedback from the TAG on **next market study**

# Observers

- Per WHO rules: WHO may invite external individuals from time to time to attend the **open sessions** as “observers”.
- Observers may be invited either in their personal capacity, or as representatives from an institution.
- At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization
- **Observers are invited to attend TAG meetings to contribute to the discussions.**

**Participants**

**Partner Institutions:**

- African Centre for Disease Control (Africa CDC)
- Bill and Melinda Gates Foundation
- Centre for Disease Control and Prevention (CDC)
- China Centre for Disease Control
- CEPI
- European Commission
- Gavi, the Vaccine Alliance
- Knowledge Ecology International (KEI)
- MedAccess
- Medecins Sans Frontieres (MSF)
- PAHO Revolving Fund
- UNICEF Supply Division
- Wellcome Trust

**Manufacturers Associations:**

- IFPMA
- DCVMN
- AVMI

# TAG MVAC Priority topic 2024: Global Market Study on RSV Immunization Products

World Health Organization

# Importance of connection across the access value chain

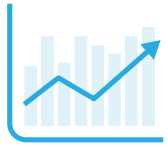
**Supply access & pricing strategies, investments, scale up and allocation**

Research & development of products from early stage to marketing authorization

Develop policies for optimal use of vaccines & advance evidence-based introduction of vaccines

Prequalification/ Regulatory approval

Country interest, product choice and demand signals



Market shaping including co-financing, pooled procurement and demand aggregation

Supplies to countries

Global market study for early market shaping

**Demand and supply planning and coordination are key**

*This figure is illustrative and non-exhaustive*

# Key takeaways from RSV market study

World Health Organization

## Supply likely sufficient to meet demand in the next 10 years but with limited access in LICs and MICs

**Adoption of RSV products in LICs and LMICs is expected to evolve at a much slower pace,** with introductions several years later than HICs

**Country pace will depend on an unfolding of a sequence of events**

## High supply-demand interdependencies

**Evolution of available and affordable supply** for the different RSV immunisation products **will influence country demand**

Global, regional, and national **policy recommendations** and the materialisation of **funded country demand** will **influence manufacturer investments** and **scale of supply** for different products

## Dual-market for RSV vaccines and mAbs

**Greater demand certainty and commercial attractiveness in HICs & UMICs (e.g., adult vaccines and mAbs).** Access to maternal vaccines & mAbs may be limited in LICs & LMICs if competition for supply

**Risks product segmentation between different country groups based on countries' ability to pay** rather than public health priorities

## Concentrated supply base

**Current and future manufacturer base is not sufficiently diversified,** with a limited number of suppliers for RSV mAbs and maternal vaccines

Products developed by companies HQ in U.S., U.K., France, China, Japan, and South Korea, **limited DCVMNs in the market.**

## Country pace of adoption uncertain

**Country challenges** include competing priorities, financial constraints, lack of capacity in life-course immunization, outstanding introductions of other vaccines, etc.

**Uncertain affordability and supply timing** likely compound with country challenges & influence country adoption decisions and product preferences

# Actions to support access to RSV vaccines and mAbs

## Country demand, policy, and uptake

- **Generation of comprehensive evidence base** to help increase countries' awareness of RSV and inform their decision-making and product choice
- **Engagement with developers and manufacturers during clinical trial planning** to increase representation of LICs and MICs in clinical trials
- **Early indications on size of funded demand from LICs and LMICs** to inform suppliers' planning
- **Transparency of product prices and market information across all market segments** to reduce information asymmetries and inform country decisions
- **Strengthening of country vaccine delivery infrastructure across the life course**
- **Development of products with simplified programmatic requirements** to help address country implementation barriers
- **Financial support for countries with limited budgets** to support product introduction, with considerations of longer-term domestic financing sustainability

## Supply availability and affordability

- **Engagement with suppliers with authorized and pipeline products** to support the development of equitable access strategies for LICs and MICs
- **Engagement with originator and DCVMN suppliers about the potential opportunity to identify if technology transfer and regional diversification** of manufacturing may be viable to improve supply and affordability of vaccines
- **Monitoring of global RSV market dynamics** including supply and demand to mitigate potential knock-on effects between HICs, MICs and LICs
- **Monitoring of RSV vaccine and mAb clinical development pipeline** and engagement with developers to support product suitability in all settings and early global access planning
- **Active market shaping** interventions to enable accessible and affordable supply, including for non-Gavi MICs

# Updates from IVIR-AC

**Philipp Lambach, MD, MBA, PhD**
**Value of Vaccines**

World Health Organization | IVB

# IVIR-AC within IVB advisory framework and actions across the three levels of WHO

# IVIR-AC is managed by the Value of Vaccine team (Analysis and Insights unit)

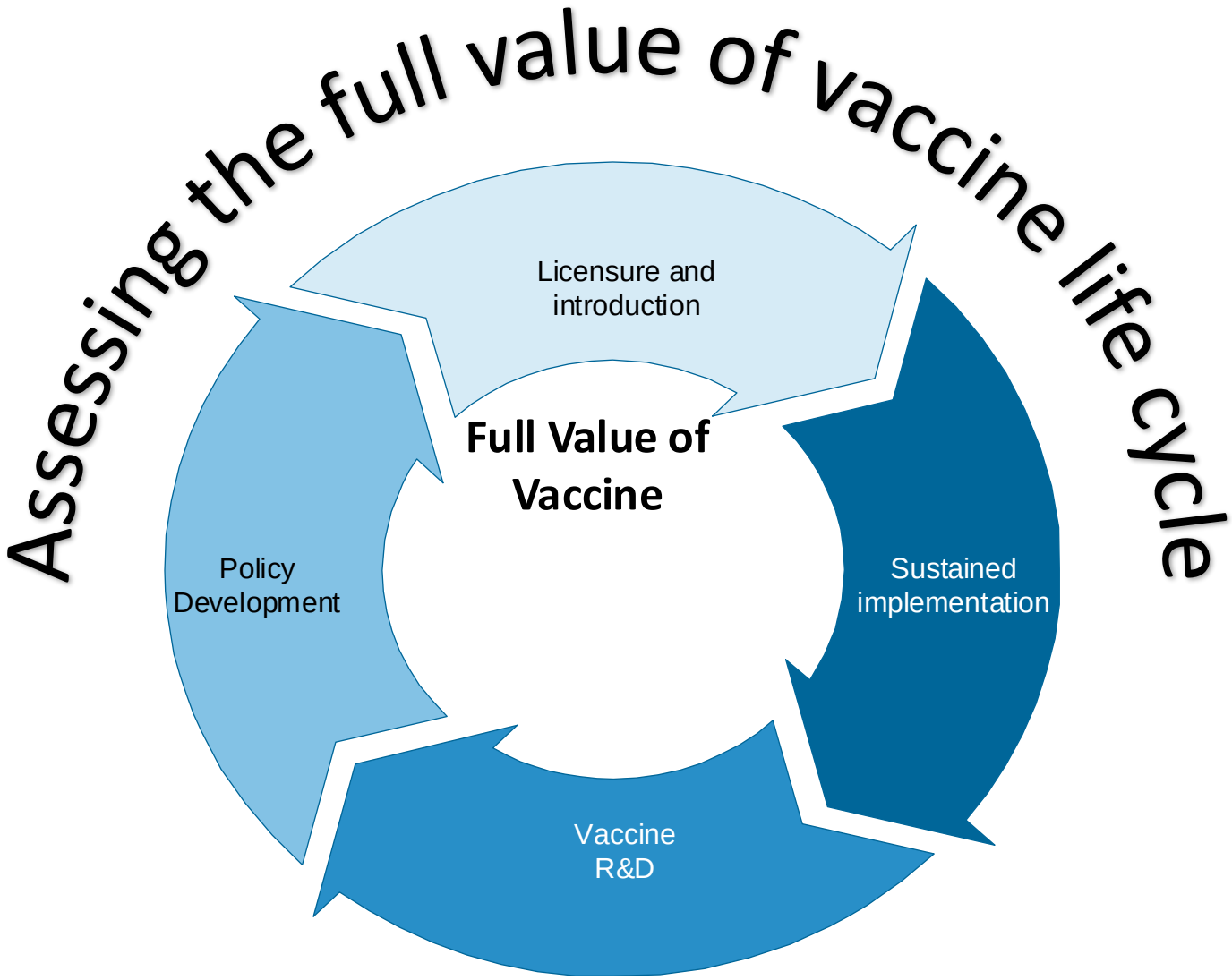
**Normative guidance – IVIR-AC**

**Support decision making**

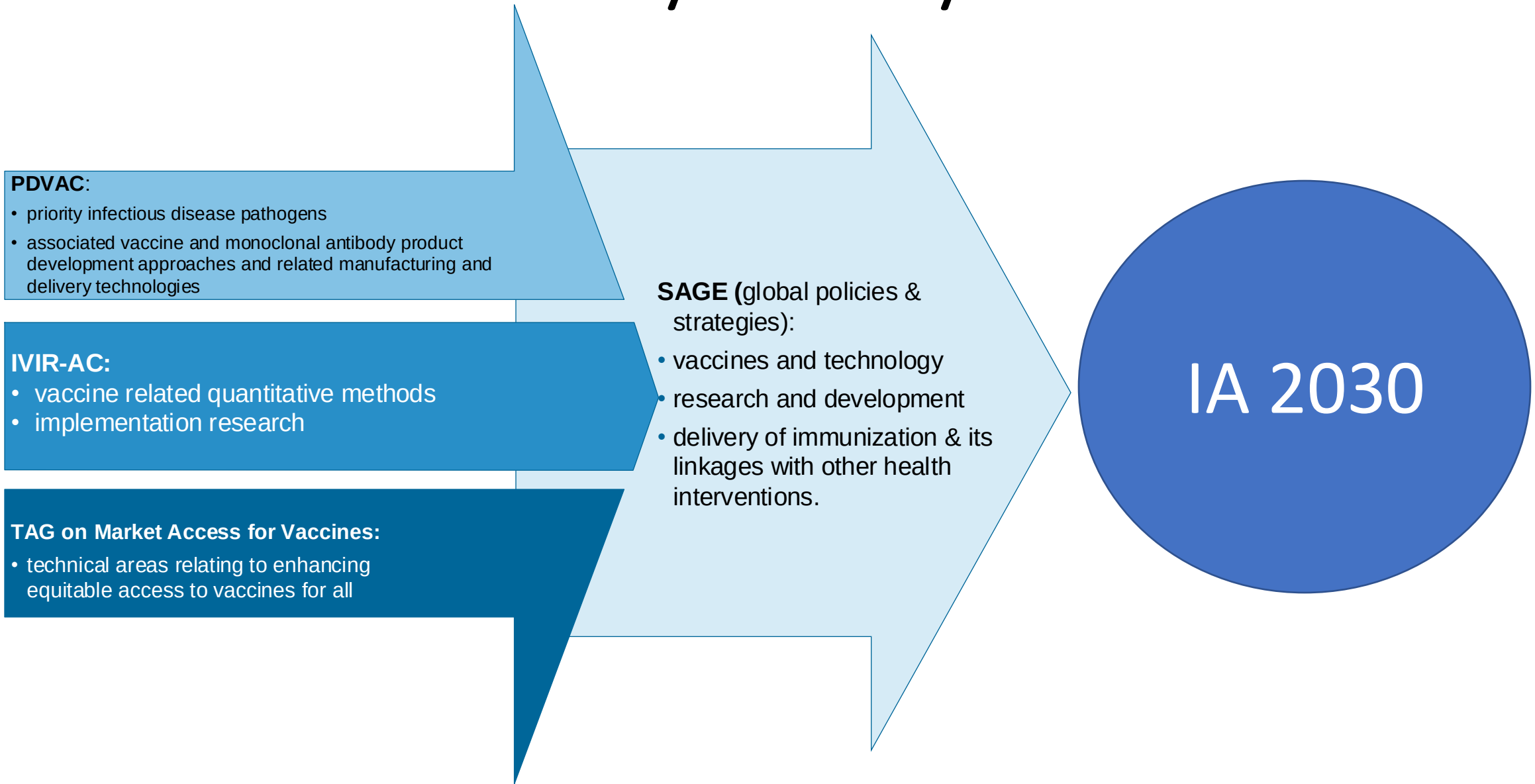
- Modelling
- Economic assessments
- Country support Tools

**Value frameworks**

- Full Value of Vaccine Assessments
- Vaccine value profiles (PDR led)

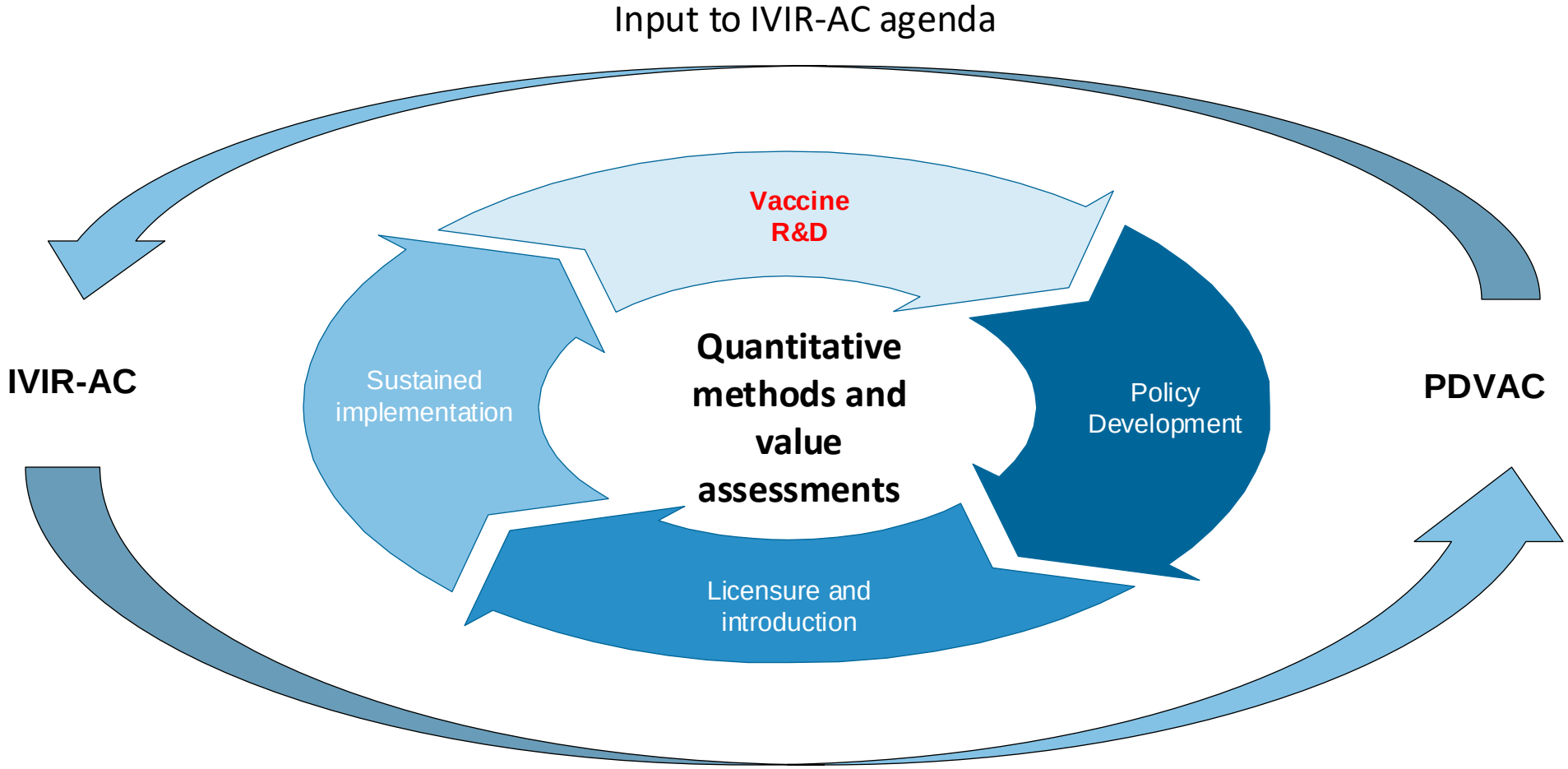


# IVB's Research to Policy advisory value chain



# Close collaboration between PDVAC and IVIR-AC

**To optimize informed policy development, IVIR-AC and PDVAC Secretariats work closely together to coordinate vaccine development agenda setting in particular related to value and impact of novel vaccines**



# Continuous information sharing PDVAC and IVIR-AC

- Coordination of agenda setting:
  - Coordination meetings IVIR-AC and PDVAC Secretariats discuss joint priorities & setting of PDVAC/IVIR-AC agenda
  - PDVAC Secretariat involved in IVIR-AC director brief to be aware of main strategic priorities of the director towards departmental priorities
- PDVAC presence at IVIR-AC meeting (and vice versa):
  - *Secretariats* have access to all sessions of each other's meetings
  - For sessions of specific interest: *PDVAC Secretariat or chair* can suggest participation of additional PDVAC members
- Joint meetings and dissemination strategy
  - Where needed PDVAC and IVIR-AC Secretariats jointly the review of vaccines (e.g. Group A Strep review, 2022)
  - Joint co-ordination strategy to convey the purpose of the various technical products overseen by both committees, and to align information on the two websites
- Rapid feedback loops on outputs:
  - Early-sharing of meeting reports to ensure rapid transmission recommendations

# IVIR-AC Three level engagement

## Global level

- Formal joint PDVAC, SAGE and IVIR-AC review mechanism
- Engagement of stakeholders, WHO departments: modelling, economic and impact analysis
- Leadership role as platform to Economic, Modelling and Impact analysis world wide

## Regional level

- Regional Offices/RITAG increased engagement in IVIR-AC agenda setting and methods review
- IVIR-AC meetings as platform to discuss research and evidence with regional stakeholders
- IVIR-AC facilitates link-up with international stakeholders (VIMC, WHO Pandemic hub, etc)

## Country level

- Secretariat & Country Offices engage in modelling, economic and IR analysis, capacity building
- Platform to provide advice to national stakeholders and link-up national stakeholders with decision-support available

# Committee composition

- Expertise
  - Mathematical modelling/quantitative methods in vaccine research
  - Economic analysis of vaccine development, planning and/or implementation
  - Methodologic approaches to vaccine performance and impact
  - Value estimation of vaccines Health systems and programme deliver

## Chair

## Experts

| | |
|---|---|
| Professor Rakesh Aggarwal ›  | Professor William Moss ›  |
| Professor Habib Hasan Farooqui ›  | Patrick Munywoki ›  |
| Professor Stefan Flasche ›  | Allison Portnoy ›  |
| Doctor Alexandra Hogan ›  | Meru Sheel ›  |
| Professor Sun-Young Kim ›  | Professor Sheetal Silal ›  |
| Kathy Leung ›  | Professor Xuan-Yi Wang ›  |

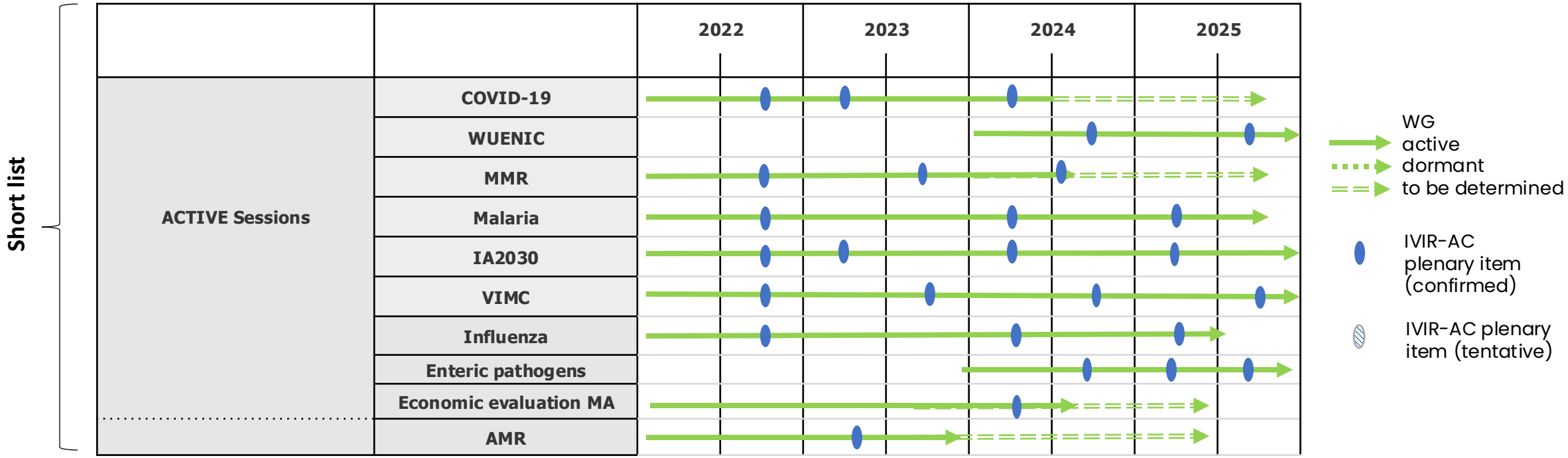
## Secretariat

| | |
|---|---|
| Philipp Lambach |  |
| Mitsuki Koh |  |
| Rola Egloff |  |

https://www.who.int/groups/immunization-and-vaccines-related-implementation-research-advisory-committee/current-members

# IVIR-AC highlights and biennium workplan 2024/5

# Some examples of IVIR-AC Strategic Workplanning 2024-2025




**Long list**

**Long list topics**: HPV, JE, Yellow fever, Cholera, Varicella / Zoster, Group B Strep., Chikunguniya, TB

# Select Highlights 2024-5: Malaria impact estimations

## IVIR-AC meeting February 2024

**Background:** Individual countries, with varying transmission intensities, seasonal patterns, and existing packages of non-vaccine malaria interventions, will need to decide which vaccine to introduce among communities with high malaria risk

**Public health impact and CE of R21/Matrix-M malaria vaccine**

- IVIR-AC reviewed Imperial College and Swiss TPH modelling analyses of Phase II and III trial data across different delivery strategies, transmission intensities & seasonal transmission settings
- Across both modeling analyses, IVIR-AC suggests
  - inclusion of more comprehensive sensitivity analyses for economic analysis and a budget impact analysis.
  - both modeling efforts are useful to guide implementation but do not replace detailed country-level analyses.

**Impact of different dose schedules for RTS,S in seasonal settings**

- Problem: ideal schedule for optimal effectiveness, including interval between 3rd & 4th doses and added benefit of seasonal or hybrid over age-based schedules, is unknown.
- Swiss TPH/Telethon Kids Institute and PATH presented impact modeling analyses timing of 4th dose across various settings and schedules
- Overall, IVIR-AC agrees that **both models used are generally well-suited to address the questions at hand** and concludes that the models support notion that there is currently insufficient evidence to strongly advocate for any specific timing of a fourth dose.

## IVIR-AC meeting February 2025

**Background:** WHO Global Malaria Programme currently recommends use of Subnational tailoring (SNT) of malaria interventions as a country-led evidence-driven process to facilitate targeting of each population with a mix of interventions to achieve maximum possible impact. However, global recommendations based cost-effectiveness in are lacking

**Problem:**

- WHO "Guiding principles for prioritizing malaria interventions in resource-constrained country contexts to achieve maximum impact" supports countries in SNT process
- However, they do not yet include selection of intervention mix to achieve maximal impact at lowest costs in different epidemiological settings

**WHO Response**

- WHO Malaria programme and Immunization department together with Science Division joined forces to use diverse consensus modelling approach to characterize intervention mixes, with assumptions about performance and coverage, that can maximize impact at minimal costs in different scenarios

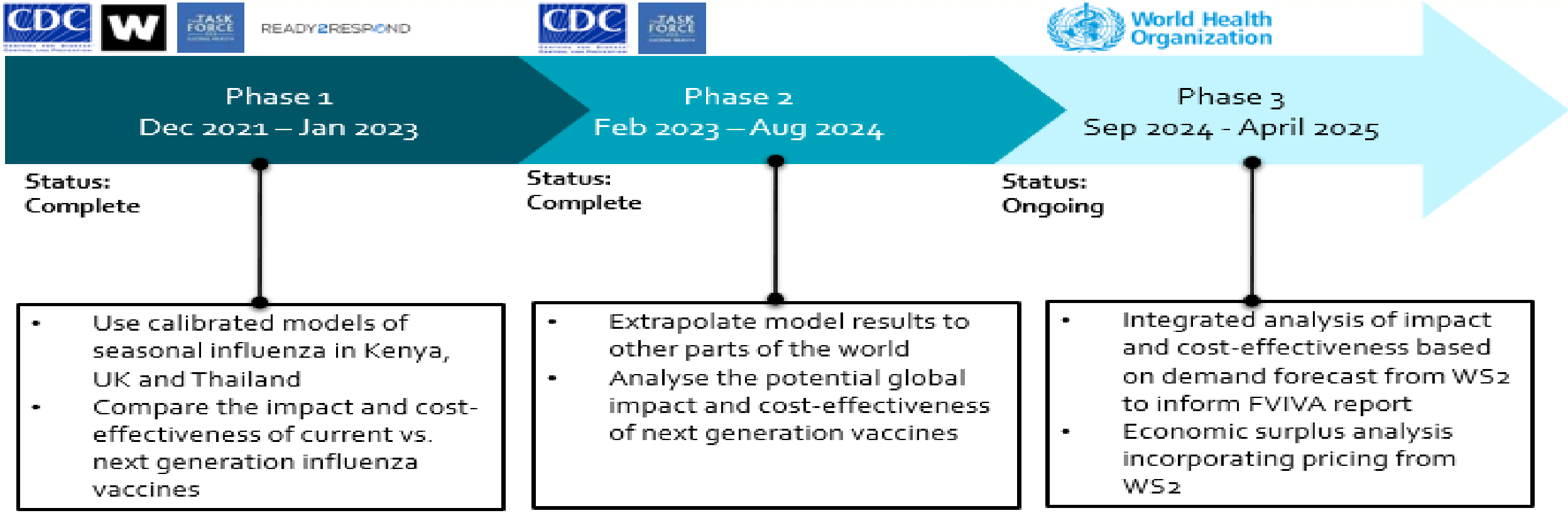
**Expectations to IVIR-AC**

- Ensure the robustness of modelling efforts by reviewing quality of its methods for using modeled evidence on the mix of interventions as an input to WHO policy recommendations from MPAG and SAGE

# Select Highlights 2024-5:

## Full Value of improved Influenza vaccine Assessment (FVIVA)

- Project run in close coordination to the update of PPCs for improved influenza vaccines by PDVAC




- Request to IVIR-AC:
  - **IVIR-AC meeting Feb 2025**: Review preliminary results (e.g. key analyses estimating health and economic impact of influenza vaccines)
  - **IVIR-AC subgroup**: Review final results (FVIVA report)

# IVIR-AC recommendations

- **Meeting reports**
  - Shared as draft with SAGE Secretariat within a week after IVIR-AC meeting
  - Finalized within 2 weeks for online publication with Vaccine journal and at WHO webpage
- **Pink books**:
  - Include all relevant background information
  - Draft vailable to director IVB and SAGE before IVIR-AC meeting
  - Finalized and published online 2 weeks after meetings


https://www.who.int/groups/immunization-and-vaccines-related-implementation-research-advisory-committee/meeting-reports-and-executive-summaries

# Future IVIR-AC meeting dates – aligned with SAGE workplan

- IVIRAC: 17-21 February 2025
- SAGE: 10-13 March 2025

- IVIRAC: 2-5 September 2025
- SAGE: 22-25 September 2025

- IVIRAC: 23-27 February 2026
- SAGE: 9-12 March 2026

- IVIRAC: 21-25 September 2026
- SAGE: 5-8 October 2026

# Thank you

PDVAC meeting, 9-11 December 2024

# WHO Biological Standardization: Updates

Dr Ivana Knezevic, WHO/MHP/HPS/TSS/NSB

9 December 2024, Geneva

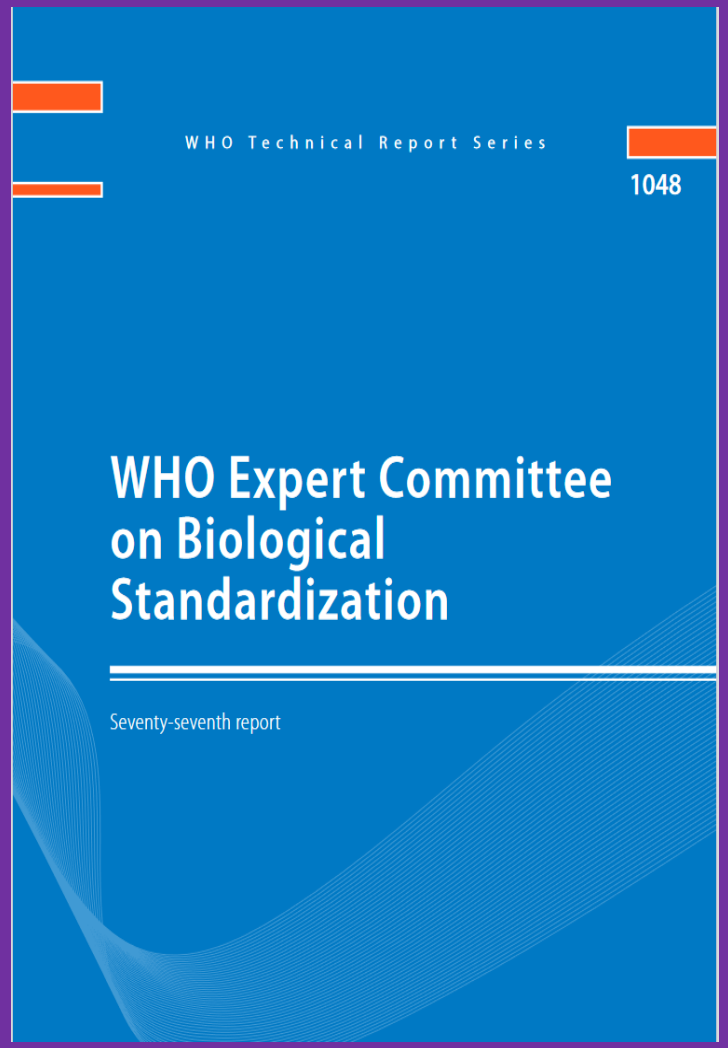
# Outline of the presentation

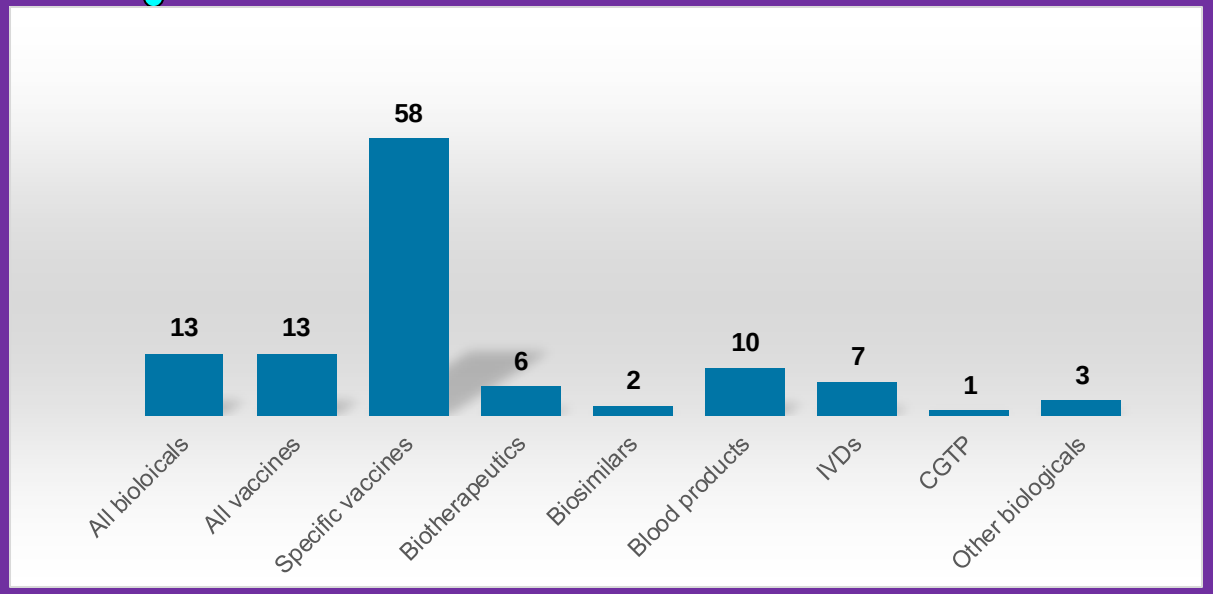
- WHO standards for biological products
  - written standards
  - measurement standards
- Expert Committee on Biological Standardization
- WHO Collaborating Centers and Custodian Laboratories
- Plan for written standards in coming years
- Requests for new/revised standards: A template
- Forthcoming events

# WHO norms and standards for biologicals

## Global written standards (113)

https://www.who.int/groups/expert-committee-on-biological-standardization




## Global measurement standards (more than 500)

**Measurement standards: essential elements for development, licensing and lot release**

## Scientific evidence

1) Standardization of assays
2) Further development and refinement of QC tests
3) Scientific basis for setting specifications

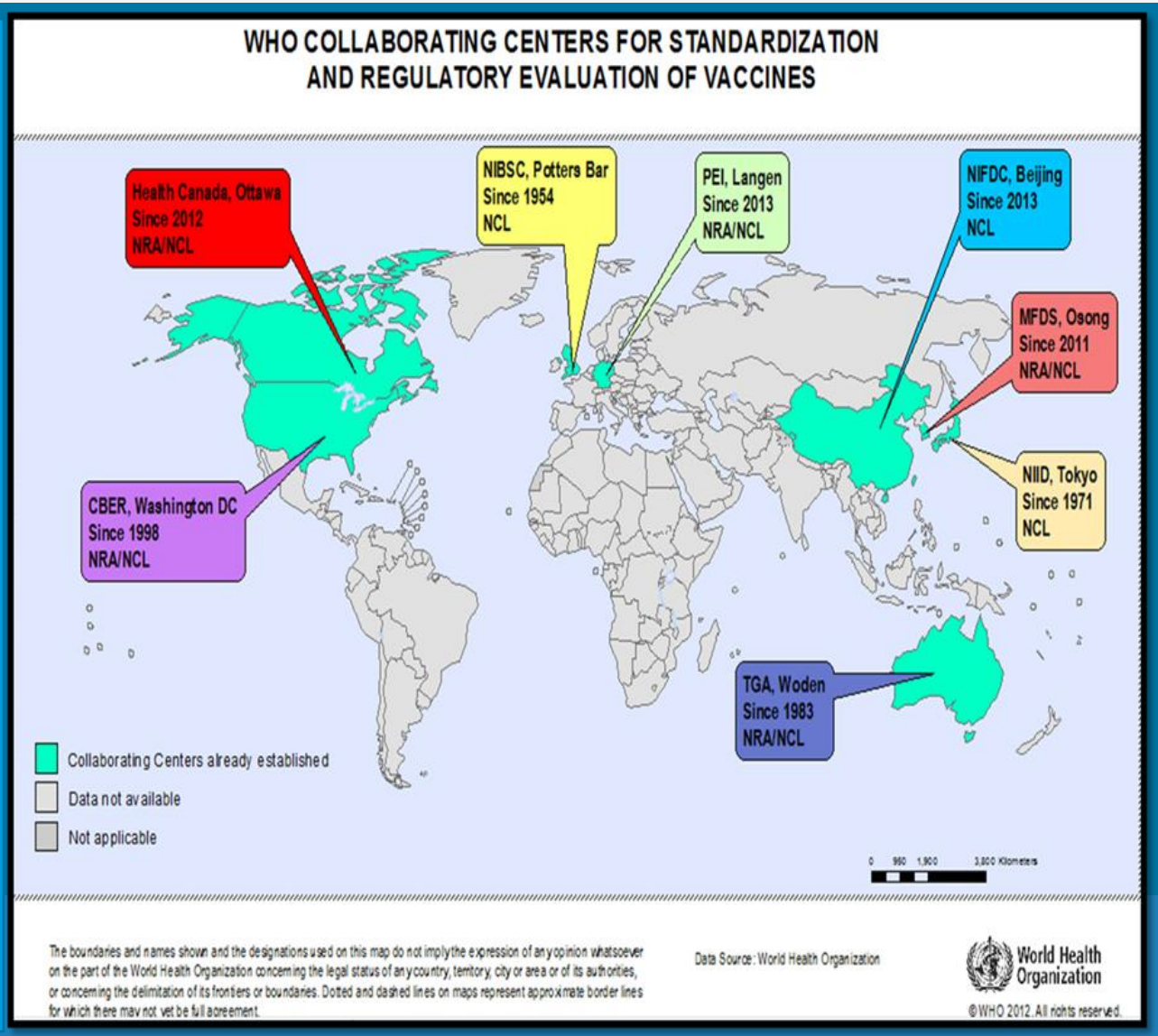
# WHO CCs and Custodian Laboratories for Biological Standardization

- **Input provided to the following:**
  - Measurement standards: MHRA (NIBSC) with the input from CCs and other laboratories
    - Vaccines and related substances
    - Biotherapeutics
    - Blood products and related substances
    - In vitro diagnostics
    - Cell and gene therapies
    - PHE (eg, SARS-CoV-2)
    - high-throughput sequencing standards
  - Written standards
  - Implementation workshops

- **CBER re-designation completed in February 2024**
- **Health Canada re-designation completed in Oct 2024**

- **WHO custodian laboratories for measurement standards:**

**1) MHRA (NIBSC), 2) PEI, 3) CBER/US FDA and 4) EDQM (antibiotics)**



# Concept of WHO written standards (Recommendations/ Guidelines)

1) Key principles for evaluation of biologicals as a basis for setting national requirements;

2) Basis for WHO Prequalification and support to NRA strengthening and capacity building

3) Leave space to NRAs to formulate additional/ more specific requirements;

4) Living document that will be developed further in line with the progress in scientific knowledge and experience

5) Assistance with the implementation of the guidelines into regulatory and manufacturers practice through:

- Global, regional and national workshops involving regulators, manufacturers and other relevant experts
- Trainings, advisory groups

**Science based regulation**

6) Consider guidance issued by other bodies – intention to complement them, not to create a conflict.

# WHO written standards for regulatory evaluation of vaccines

1. WHO Guidelines on NC and C evaluation that apply to vaccines:

1.1. Nonclinical evaluation of vaccines (TRS 927, ECBS 2003)
1.2. Nonclinical safety evaluation of DNA vaccines (TRS 941, ECBS 2005) - discontinued
1.3. Nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines (TRS 987, 2013)
1.4. Clinical evaluation of vaccines (TRS 1004, ECBS 2016)
1.5. Guidelines for assuring the quality, safety and efficacy of plasmid DNA vaccines (TRS 1028, ECBS 2020)
1.6. Evaluation of the quality, safety and efficacy of messenger RNA vaccines for the prevention of infectious diseases: regulatory considerations (TRS 1039, ECBS 2021)
1.7. Guidelines on regulatory preparedness for the oversight of pandemic or other emergency use vaccines in importing countries (TRS 1054, Annex 2, ECBS, Oct 2023), Replacement of Annex 7 of WHO TRS, No. 1004

2. WHO Good Practices: GMP, GLP, GCP

3. Cell substrates for vaccine production, stability evaluation of vaccines, vaccine lot release, post-approval changes etc

4. Guidelines/ Recommendations for specific types of vaccines: polio, rabies, influenza, pneumo, DTP and combined vaccines, rotavirus, malaria, typhoid, HPV, RSV etc

# 78th ECBS meeting held on 16 - 19 Oct 2023

1. Executive Summary published on WHO web site on 26 October 2023: https://www.who.int/publications/m/item/78th-ecbs-meeting-october-2023

2. ECBS report (TRS) published on 25 April 2024

# 79th ECBS meeting held on 11-14 March 2024

1. Executive Summary published on WHO web site on 20 March 2024:

Page link:

https://www.who.int/publications/m/item/79th-ecbs-meeting-march-2024

Document link:

https://www.who.int/publications/m/item/79th-ecbs-meeting-march-2024

2. ECBS report (TRS 1059) published on 5 August 2024 on WHO web site

# Main outcomes of 79th ECBS meeting (11-14 March 2024)

World Health Organization

Table 1
**WHO international reference materials established by the ECBS in March 2024**

| Material | Unitage | Status |
|---|---|---|
| **Biotherapeutics other than blood products** | | |
| Golimumab | 500 IU/ampoule TNF neutralizing activity<br>500 IU/ampoule of TNF binding activity<br>500 IU/ampoule of FcγRIII binding activity<br>500 IU/ampoule of ADCC activity<br>50 µg/ampoule for therapeutic drug monitoring | First WHO International Standard |
| **In vitro diagnostics** | | |
| HIV-1 p24 antigen | 44 IU/ampoule | First WHO International Standard |
| Lassa virus RNA for NAT-based assays<br><br>Lineages II, III, V and VII | No unitage assigned | First WHO International Reference Panel |
| **Standards for use in high-throughput sequencing technologies** | | |
| Adventitious virus detection in biological products using HTS technologies | CBER-FSCUST-90 (hCoV)<br>2.6 x $10^{10}$ genome copies/mL<br>CBER-FSCUST-91 (PCV1)<br>8.1 x $10^{9}$ genome copies/mL<br>CBER-FSCUST-92 (REO)<br>1.5 x $10^{10}$ genome copies/mL<br>CBER-FSCUST-93 (FeLV)<br>4.0 x $10^{10}$ genome copies/mL<br>CBER-FSCUST-94 (EBV)<br>2.8 x $10^{7}$ genome copies/mL<br>CBER-FSCUST-95 (RSV)<br>5.5 x $10^{10}$ genome copies/mL<br>CBER-FSCUST-96 (MVM)<br>1.2 x $10^{10}$ genome copies/mL | First WHO International Reference Panel |
| **Vaccines and related substances** | | |
| Diphtheria antitoxin for use in flocculation test (equine) | No unitage assigned | WHO International Reference Reagent |

Table 2
**WHO international reference materials proposed for discontinuation in March 2024**

| Material | Rationale | Proposed discontinuation pathway |
|---|---|---|
| First WHO International Standard for calcitonin, ASU 1–7 eel calcitonin analogue (elcatonin)<br>**NIBSC code 84/614** | Low, and highly geographically restricted, demand | Decision by the ECBS in October 2024 based on the outcomes of stakeholder consultation and feedback |
| First WHO International Standard for human C-reactive protein<br>**NIBSC code 85/506** | Low demand as a result of limited adoption of the assigned IU | Decision by the ECBS in October 2024 based on the outcomes of stakeholder consultation and feedback |
| WHO international reference reagents for adventitious virus detection by high-throughput sequencing<br>Porcine circovirus type 1<br>**CBER code SC-VR-6000P**<br>Mammalian orthoreovirus type 1<br>**CBER code SC-VR-6001P**<br>Feline leukaemia virus<br>**CBER code: SC-VR-6002P**<br>Human respiratory syncytial virus<br>**CBER code: SC-VR-6003P**<br>Epstein-Barr virus<br>**CBER code: SC-VR-6004P** | Superseded by the establishment of the First WHO International Reference Panel (see Table 1 above) | Recommendation by the ECBS to establish the reference panel at the current meeting resulted in immediate discontinuation of all five WHO international reference reagents and their reassignment as CBER reagents for research purposes only |

# 80th ECBS meeting held on 7-11 October 2024

1. Executive Summary published on WHO web site on 18 October 2024:

Main outcomes of the meeting of the WHO Expert Committee on Biological Standardization held from 7 to 11 October 2024

2. ECBS report is in preparation and will be published in 2025 on WHO web site

# Main outcomes of 80th ECBS meeting (7-11 October 2024)

World Health Organization

**Table 1. WHO international reference materials established by the ECBS in October 2024**

| Material | Unitage | Status |
|---|---|---|
| **In vitro diagnostics** | | |
| Epidermal growth factor receptor variant T790M (c.2369C>T) genomic DNA | Variant allele frequency = 100% | WHO International Reference Reagent |
| Epidermal growth factor receptor variant L858R (c.2573T>G) genomic DNA | Variant allele frequency = 100% | WHO International Reference Reagent |
| Epidermal growth factor receptor variant p.E746_A750del (c.2235_2249del) genomic DNA | Variant allele frequency = 100% | WHO International Reference Reagent |
| Serum amyloid A | 56 µg per ampoule | Second WHO International Standard |
| Thyroglobulin antibodies (human serum) | 735 IU/ampoule | First WHO International Standard |
| Tissue transglutaminase autoantibodies (human serum) | 200 IU/vial anti-tTG IgA<br>100 IU/vial anti-tTG IgG | First WHO International Standard |
| **Vaccines and related substances** | | |
| Marburg virus antibodies for binding assays (human serum) | 250 IU/ampoule anti-glycoprotein IgG | First WHO International Standard |
| SARS-CoV-1 antibodies for neutralization assays (human immunoglobulin) | 250 IU/ampoule | First WHO International Standard |

# WHO written standards for biologicals: recently established by the ECBS

**1. COVID-19 related documents (from 2020 to 2024):**

1.1. Guidelines for assuring the quality, safety and efficacy of plasmid DNA vaccines (TRS 1028, ECBS, Aug 2020)

1.2. Evaluation of the quality, safety and efficacy of messenger RNA vaccines for the prevention of infectious diseases: regulatory considerations (ECBS, Oct 2021)

1.3. Guidelines for the production and QC of mAbs for use in humans, replacement of Annex 3 of WHO TRS 822 (TRS 1043, ECBS, Apr 2022)

1.4. Guideline for the preclinical and clinical evaluation of mAbs and related products for the prevention and treatment of infectious diseases (ECBS, Apr 2023). Disease specific supplements for COVID-19 (ECBS, 2024), **RSV (ECBS, Oct 2024)**

1.5. Manual for the establishment of national and other secondary standards for antibodies against infectious agents focusing on SARS-CoV-2 (ECBS, Apr 2022)

# WHO written standards: revision/new/ from 2024 onwards

**2. Revision of PIP guidelines (TRS 1004, Annex 7)** – expanded scope and guidance for vaccines for pandemic and emergency use **(ECBS, Oct 2023)**

**3. Revision of Guidelines for rota vaccines (TRS 941, annex 3),** comprehensively revised Recommendations **(ECBS, Oct 2024)** now reflect current manufacturing and quality control practices for LA rotavirus vaccines, while its nonclinical and clinical recommendations are more broadly applicable to any type of rotavirus vaccine, including prospective non-replicating viral-vectored products.

**4. Good practices for blood establishments,** replacement of the 2011 WHO Guidelines on GMP for blood establishments. The revised document now reflects a broad range of developments in key administrative procedures, quality assurance and regulatory compliance.

**5. New document with the guidance for phasing out animal testing in the evaluation of biologicals** – Draft document has been prepared and PC planned for Nov-Dec 2024 and Consultation on 27-28 Feb 2025 (ECBS, Oct 2025)

**6. Recommendations for the preparation, characterization and establishment of international and other biological reference standards (TRS 932, annex 2)** – Consultation on 24-26 Feb 2025 (ECBS, 2026)

**7. Revision of Guidelines for PAC for vaccines and biotherapeutic products (TRS 993, Annex 4)** to review reporting categorization of some PACs and to include risk-based approach and reinforce reliance mechanism (ECBS, 2026)

# WHO written standards: implementation workshops 2023-2025

**Implementation workshops (Meeting reports/Executive Summary of the workshops held published at WHO web site):**

1. Polio vaccines: 31 October – 2 Nov 2023, Indonesia
2. Manual for secondary standards: 14 – 16 November 2023, Indonesia
3. Cell and gene therapy products: 14-16 May 2024, Oman
4. Cell and gene therapy products: April 2025, Botswana
5. Biosimilars: July 2025, Tunisia

# mAb Guidelines for infectious diseases

- ECBS endorsed the development of **mAb guidelines broadly applicable to mAbs** intended for **prevention or treatment of infectious diseases** (Oct. 2020)
  - Considered a high priority during COVID-19 pandemic with clinical and manufacturing benefits of mAbs
  - Reflect the advances in technologies and growing importance of mAbs for infectious disease

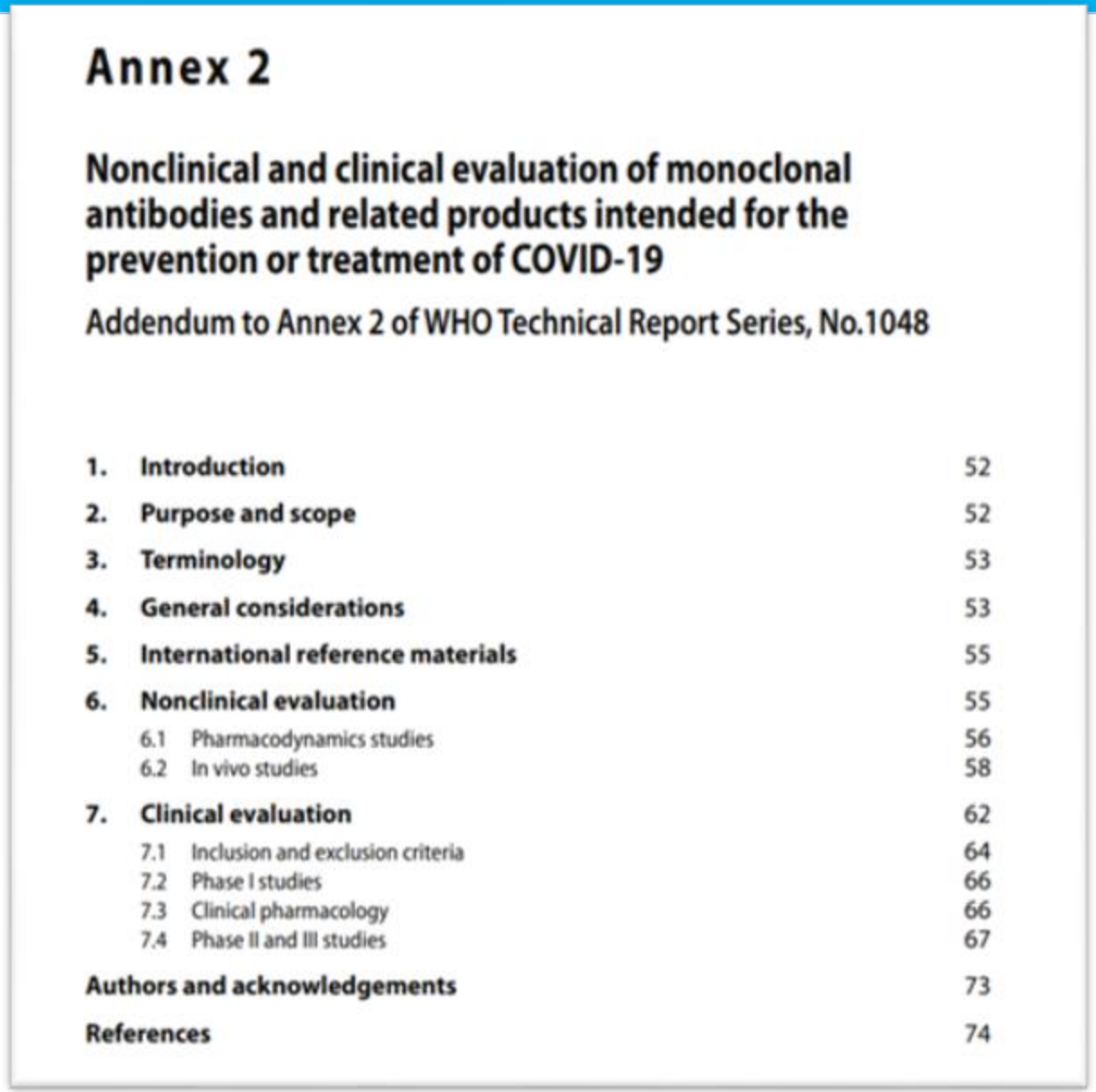
- **Guidelines for the production and quality control of mAbs for medicinal use** (WHO TRS 1043, Annex 4, 2022)
  - Apply to mAbs regardless of expression system, route of administration or clinical indication

- **Guidelines on the nonclinical and clinical evaluation of mAbs intended for the prevention and treatment of infectious diseases** (WHO TRS 1048, Annex 2, 2023)
  - Provide general guidance for evaluating mAbs regardless of the target pathogen or toxin
  - **Addenda on disease-specific regulatory considerations** need to be developed.

# Disease-specific mAb addenda : COVID-19

**Adopted by ECBS in March 2024** (WHO TRS 1059, annex 2, published)

- Provide supplementary considerations for evaluating the safety and efficacy of mAbs
  - Directed specifically against SARS-CoV-2 antigens
  - Intended for pre- and post-exposure prophylaxis and treatment of COVID-19
  - Applicable primarily to parenterally administered mAbs, including single and co-formulated mAbs



## Annex 2

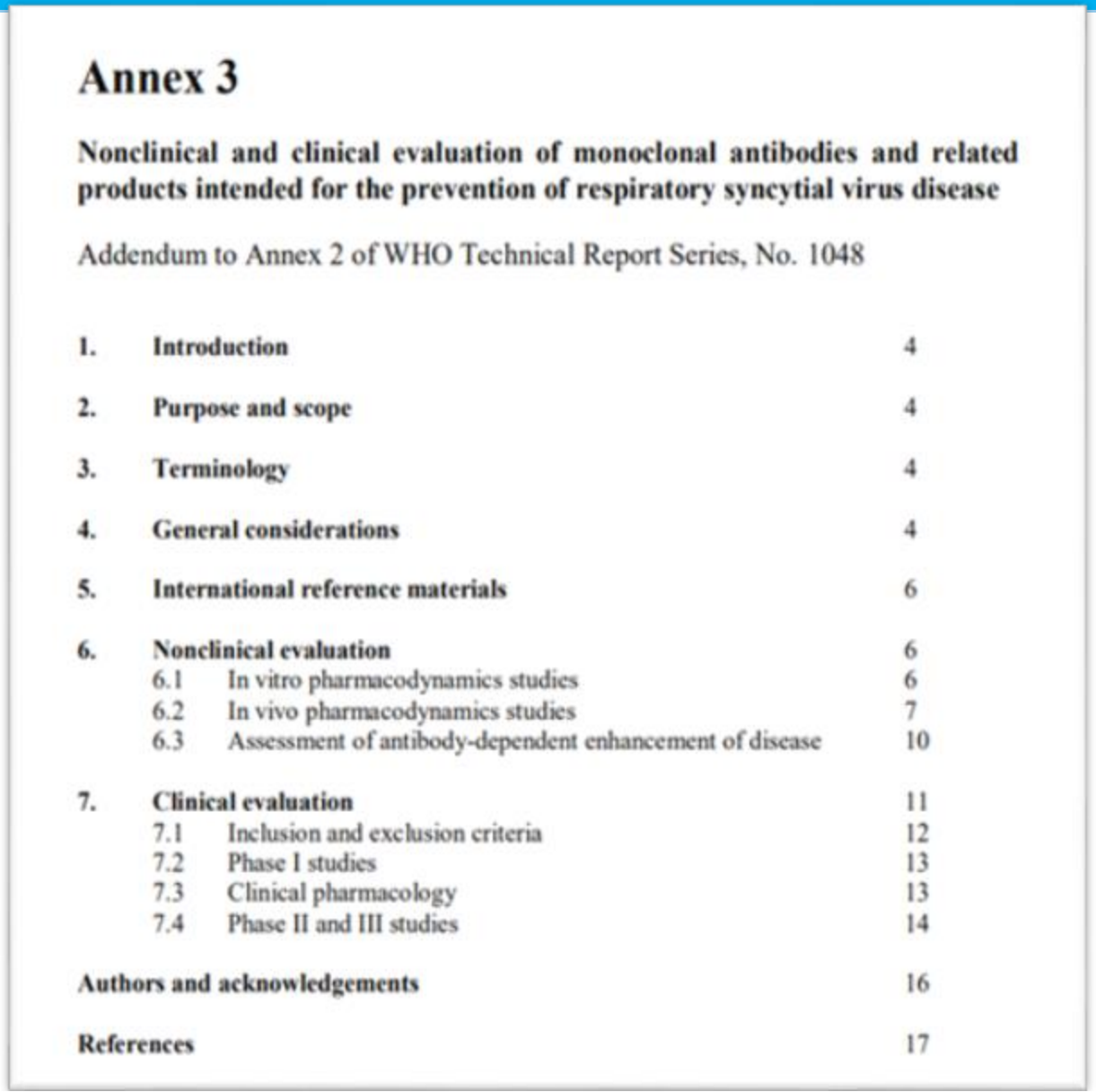
**Nonclinical and clinical evaluation of monoclonal antibodies and related products intended for the prevention or treatment of COVID-19**

Addendum to Annex 2 of WHO Technical Report Series, No.1048

# Disease-specific mAb addenda : RSV disease

**Adopted by ECBS in October 2024** (Post-ECBS document is available)

- Provide supplementary considerations for evaluating the safety and efficacy of mAbs
  - Directed specifically against respiratory syncytial virus (RSV) antigens
  - Intended primarily for pre-exposure prophylaxis in infants and young children, with applicability to immunocompromised individuals
- Provide immediate protection against severe RSV disease, particularly in high-risk infants
  - Long-acting mAbs and/or maternal vaccines were recommended for passive immunization by SAGE (September 2024)



## Annex 3

**Nonclinical and clinical evaluation of monoclonal antibodies and related products intended for the prevention of respiratory syncytial virus disease**

Addendum to Annex 2 of WHO Technical Report Series, No. 1048

# WHO written standards- pipeline under consideration

**I. Revision of existing WHO written standards**

1. Vero-cell adapted Yellow fever vaccine (vYF)
2. Guidelines on the quality, safety and efficacy of pneumococcal conjugate vaccines
3. Recommendations to assure the quality, safety and efficacy of tetravalent live attenuated dengue vaccines
4. Recommendations for MMR vaccines
5. Guidelines for Vaccine Lot Release
6. Guidelines for stability evaluation of vaccines
7. Guidelines for sterility
8. Recommendations for TB vaccines
9. Guidelines for malaria vaccines

**II. Proposal for developing new WHO written standards**

1. Recommendations to assure the quality, safety and efficacy of bivalent Salmonella Typhi/Paratyphi A conjugate enteric fever vaccines
2. Guidelines on the quality, safety and efficacy of GBS vaccines
3. Guidelines for multivalent meningococcal conjugate vaccines
4. Recommendations to assure the quality, safety and efficacy of multivalent Shigella vaccines
5. Guidelines on the quality, safety and efficacy of new TB vaccines
6. Guidelines on invasive non-typhoidal Salmonella (iNTS) vaccines
7. Guidelines for Chikungunya vaccines
8. Guidelines for the development of measles and rubella vaccines delivered by microarray patches (MR-MAP)
9. Guidelines for HTS for evaluation of vaccines and other biologicals

# Template for written standards - new or revised

- Requests for new written standards/ revision of existing documents
- Details regarding the following:
  - Requestor
  - Rationale
  - Public health importance
  - Status of the development
  - Plan for submission to PQ

WHO Expert Committee on Biological Standardization (ECBS)

| | | | |
|---|---|---|---|
| Proposal (title) | | | |
| Proposer (name of Institution) | | Principal contact | |
| Rationale | | | |
| Anticipated uses and users | | | |
| Issues raised by the proposal | | | |
| Action required | | | |
| Proposer's project reference | | Date proposed: | |
| CONSIDERATIONS FOR ASSIGNMENT OF PRIORITIES | | | |
| Approval status and PQ plan | | | |
| Status of the clinical development | | | |
| Public health importance | | | |
| Global importance | | | |
| Global need from regulatory & scientific considerations | | | |
| ECBS outcome | | | |

# WHO events in 2024 and 2025

- 80th meeting of the Expert Committee on Biological Standardization (ECBS): 7-11 October 2024, Geneva
- 19th International Conference of Drug Regulatory Authorities: 14 - 18 October 2024, New Delhi, India
- WHO Drafting Group meeting to discuss revision of Recommendations for the preparation, characterization, and establishment of international and other biological reference standards, 24-26 February 2025, WHO, Geneva, Switzerland
- Informal consultation on WHO Guideline on the phasing out animal tests for the quality control of biological products, 27-28 February 2025, WHO, Geneva, Switzerland – Public consultation from 2 December 2024 to 10 January 2025 **New**
- Implementation workshop on cell and gene therapy products – April 2025
- Implementation workshop on the evaluation of biosimilars – July 2025
- 81st meeting of the Expert Committee on Biological Standardization (ECBS): 13-17 October 2025, Geneva

# Many thanks to:

…WHO colleagues

…members of the Expert Advisors Panel on Biological Standardization including the ECBS members

…members of WHO drafting and Working Groups

…colleagues from Collaborating Centers and Custodian Laboratories

…many individual experts

…stakeholders

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Biological standardization website: Expert Committee on Biological Standardization (who.int)