



# WHO Product Development for Vaccines Advisory Committee (PDVAC)

Context for and goals of this meeting

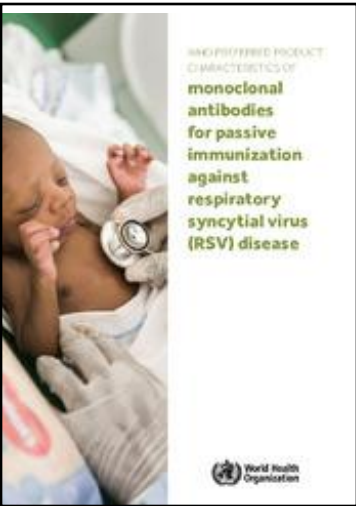
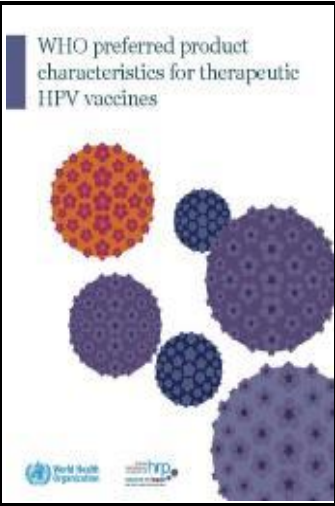
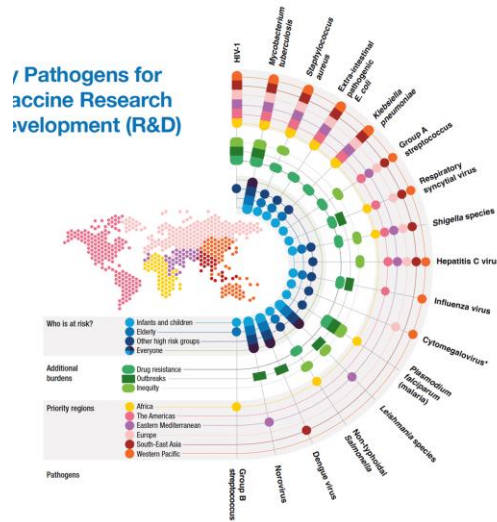


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Team Lead  
Product & delivery research unit  
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9-11 December 2024



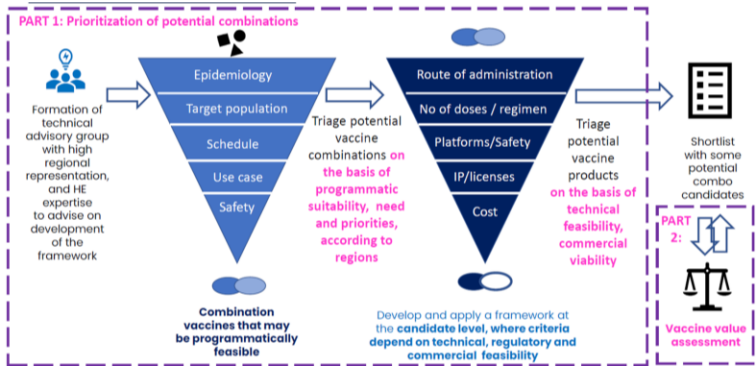
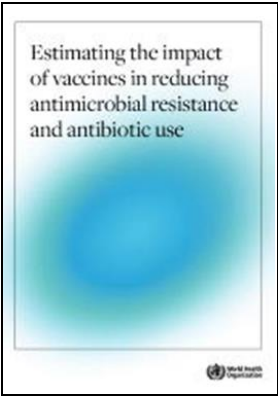
# What does PDVAC do?



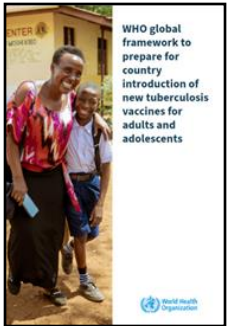
Prioritization of new vaccines in the pipeline

Advices on vaccine and monoclonal antibody product development for LMIC use

Advices on development of vaccine platforms

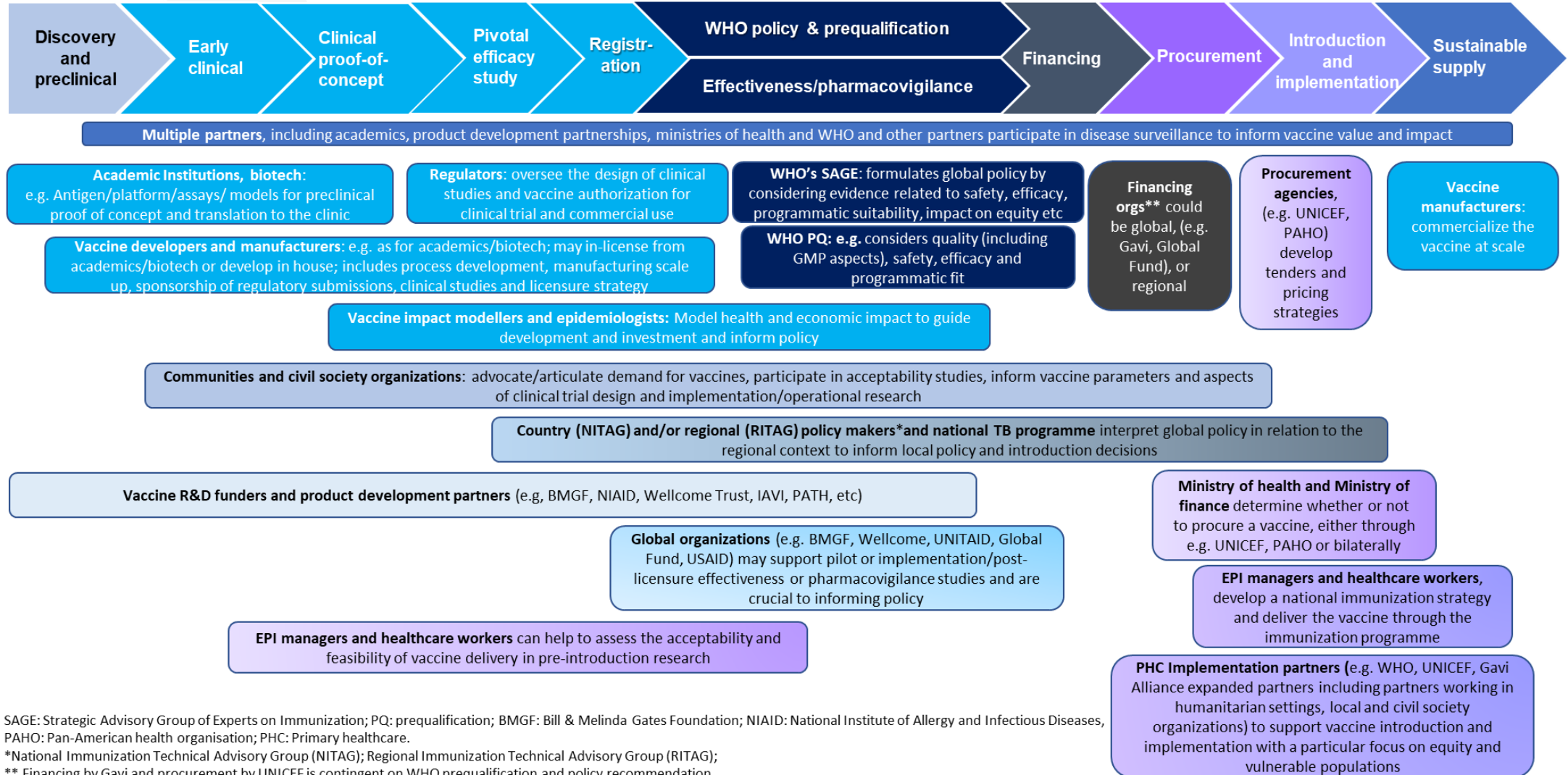


Develop strategic value frameworks for research decision making across country, regional and global level stakeholders

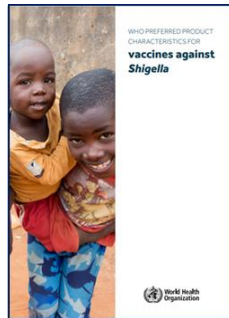
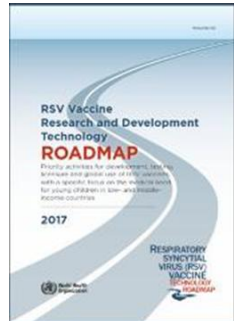
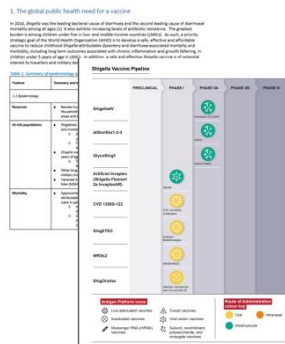


Develop new tools / guidance to facilitate and de-risk product development for investment

# PDVAC takes a strategic view of the end-to-end process



# PDVAC Technical Advisory Groups develop WHO guidance to inform vaccine development and investment decisions



Technical guidance documents are developed by groups of subject matter experts, as PDVAC Technical Advisory Groups (TAGs)

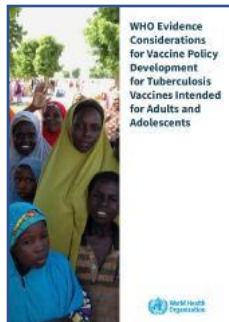
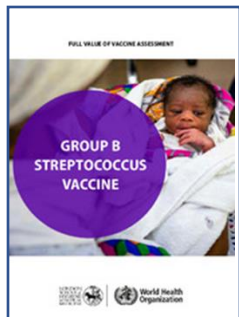
Current / imminent PDVAC TAGs:

- GBS (clinical and policy)
- Vaccines and AMR
- Influenza (value assessment)
- Salmonella (PPCs and Roadmaps)
- TB (clinical and policy)
- Combination vaccines
- Klebsiella

What's known?

What's needed?

What attributes?



What impact?

What evidence for policy-makers?

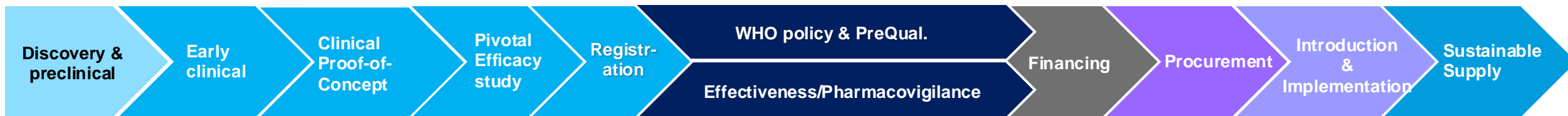
Please note: PDVAC's scope is **endemic vaccines** where there is a disproportionate LMIC burden

# Overview of existing technical guidance documents

Vaccine	Preferred Product Characteristics (PPC)	Vaccine Value Profile (VVP)*	Full Vaccine Value Assessment (FVVA)	R&D Roadmap	Evidence Considerations for Vx policy (ECVP)	Other
TB	Vaccines for infants, adults and adolescents, therapeutic	In progress	✓	✓	✓	Global framework for country introduction
HIV	Monoclonals					
Shigella	Vaccines for infants	✓	✓ *			
Gonococcus	Vaccines for young people	✓				
RSV	Monoclonals for infants Vaccines for infants	✓		✓		
ETEC	Vaccines for infants	✓		✓ *		
HSV	Vaccines for young people	✓				
GAS	Vaccines infants and young children To be revised		✓ *	✓		
Next-generation Influenza	Improved influenza vaccines Universal-type influenza A vaccines Revised – version 2 to be discussed		In progress			
GBS	Vaccines for pregnant women	✓	✓	✓	In progress	
Malaria	Monoclonals for children Vaccines (falciparum & vivax)	In progress				
MR-MAPs*	Vaccines		✓ *	✓	In progress	VIPS Action plan
tHPV	Vaccines to clear infection Vaccines to treat cervical precancers					

VVPs also for Norovirus, cytomegalovirus, Salmonella enterica serovar Paratyphi A, Leishmaniasis, Chikungunya, Hookworm, Schistosomiasis, Klebsella, Non- thypoidal salmonella; \* developed by partners.

# The PDVAC ecosystem



**IA2030 envisions a world where everyone, everywhere, at every age, fully benefits from vaccines to improve health and well-being.**



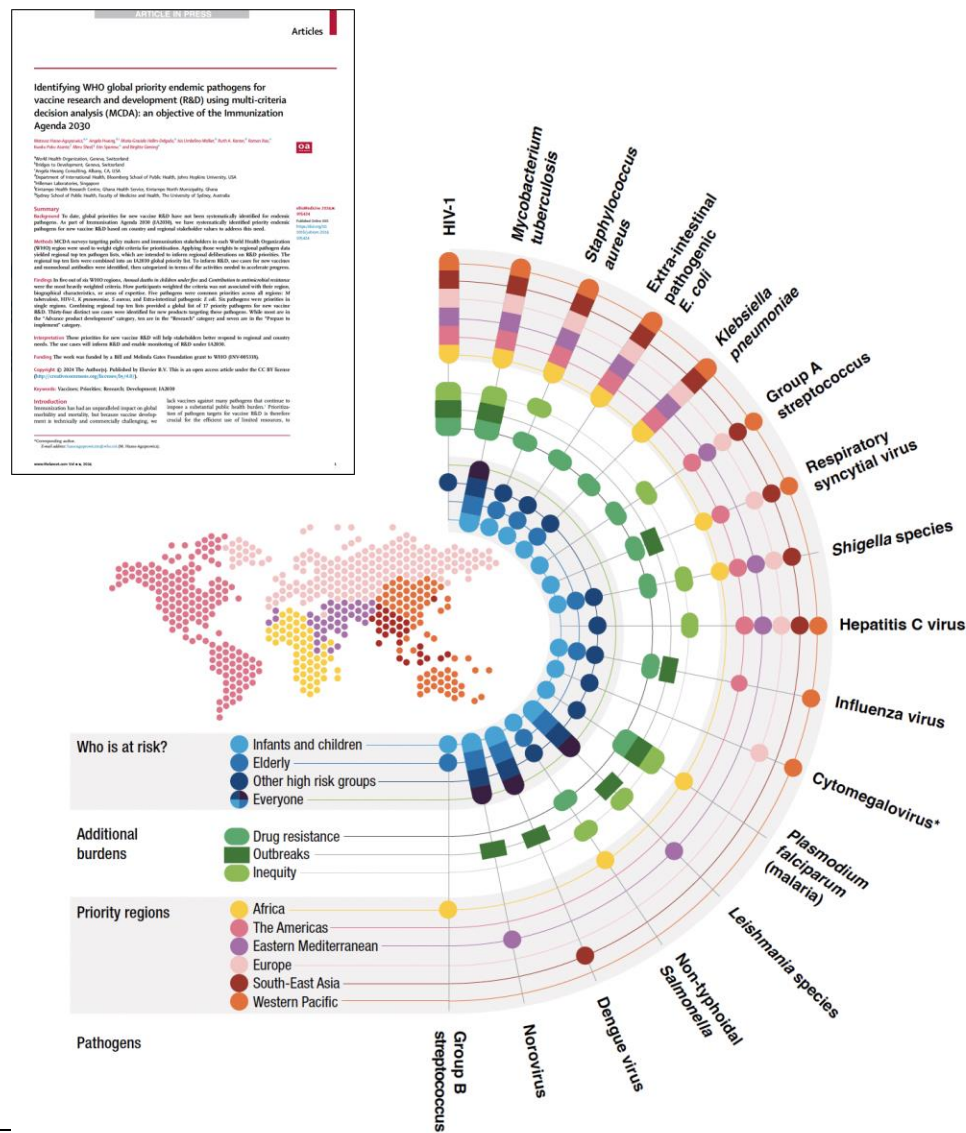
PDVAC: product development





# PDVAC's link to IA2030 Strategic Priority 7

**Objective 7.2: To identify R&D priorities: list of global endemic pathogen targets for new vaccines**



Action categories:	Research	Advance Product Development	Prepare to Implement
Pathogens:	<ul style="list-style-type: none"> <li>Group A streptococcus</li> <li>Hepatitis C virus</li> <li>HIV-1</li> <li><i>Klebsiella pneumoniae</i></li> </ul>	<ul style="list-style-type: none"> <li>Cytomegalovirus</li> <li>Influenza virus (broadly protective vaccine)</li> <li><i>Leishmania</i> species</li> <li>Non-typhoidal <i>Salmonella</i></li> <li>Norovirus</li> <li><i>Plasmodium falciparum</i> (malaria)</li> <li>Shigella species</li> <li><i>Staphylococcus aureus</i></li> </ul>	<ul style="list-style-type: none"> <li>Dengue virus</li> <li>Group B streptococcus</li> <li>Extra-intestinal pathogenic <i>E. coli</i></li> <li><i>Mycobacterium tuberculosis</i></li> <li>Respiratory syncytial virus</li> </ul>

## 17 Pathogens; 34 total use cases

Indicator	Definition
SP 7.2 a	% of use cases that have vaccines or monoclonal antibodies (mAbs) in Phase 3 trials
SP 7.2 b	% of use cases with licensed vaccines or mAbs that have supportive or permissive policy recommendations <ul style="list-style-type: none"> <li>• <i>Licensed: by WHO-listed authority (WLA) or transitional WLA</i></li> <li>• <i>Policy recommendations: by SAGE if within SAGE scope, by a NITAG if not in SAGE scope</i></li> </ul>

Webinar posted at:  
<https://youtu.be/b0AbwShNuV0?si=e0SA6AUOHD4kwtTf>

# Contributors to the IA2030 Endemic Pathogen Prioritization

## Strategic discussions and guidance

PDVAC Members and meeting participants  
SAGE Members and meeting participants  
SP7 Working Group members and meeting participants  
WHO IVB and AFRO VPD  
Gavi policy team

## SP7 Working Group Chairs

KP Asante  
David Kaslow

## Methodology advice

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Paul Hansen  
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Stacey Knobler  
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Yot Teerawattanon

## Global Burden of Diseases data

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Kelly Bienhoff  
Eve Wool

## Translation review

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Annie Mo  
Irina Morozova  
Ana Paula Szylovec  
Megan Williamson  
Dina Youssef

## Review of pathogen scores

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Muhammed Afolabi	Michelle Groome
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Alan Barrett	Sonali Kochhar
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Jeffrey Cannon	Jean C. Lee
Chris Chadwick	Katharine Looker
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Hannah Clapham	Niklas Luhmann
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David Durrheim	Kathleen Neuzil
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Pat Fast	Helen Rees
Peter Figueroa	Andrew Steer
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Nebiat Gebreselassie	Anh Wartel
Birgitte Giersing	

## Survey dissemination

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Rajinder Suri  
Yoshihiro Takashima  
Ole Wichmann  
*and many others at regional and country levels*

## Consultation partners

African CDC  
Global NITAG Network  
PAVMN, Africa  
HITAP, Thailand  
WHO regional offices,  
CEPI, WHO R&D Blueprint team members

## Project team

### WHO

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Erin Sparrow

### Bridges to Development

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Ísis Umbelino  
Alan Brooks  
Anastasia Pantelias  
Maria Dreher

Maria-Graciela Hollm-  
Delgado



# Objectives of this meeting

- PDVAC endorsement of:
  - the approach to develop a strategic framework for development of combination vaccines.
  - the revised PPC for next generation influenza vaccines;
  - the R&D roadmap and PPC for S. Typhi/Paratyphi A bivalent vaccines.
- Building on the endemic pathogen prioritization list, identification of priority vaccines and vaccine use cases for IVB and PDVAC focus
- Proposed areas/actions/priorities where IVB and PDVAC should engage to guide product development for vaccines and monoclonals for global endemic pathogen priorities.

## Three types of session:



For endorsement – related to approval of guidance documents, such as PPCs, that have been developed by technical advisory groups and been through public consultation



For discussion: request to provide technical and strategic advice; some specific questions may be posed.



For information: relevant information that is helpful to know.

# Orientation to the PDVAC website: All slides and reports

Global Regions Select language

World Health Organization

Health Topics Countries Newsroom Emergencies Data About WHO

## Product Development for Vaccines Advisory Committee

PDVAC is an independent standing WHO committee of experts which provides external advice to WHO related to priority infectious disease pathogens, associated vaccine and monoclonal antibody product development approaches and related manufacturing and delivery technologies.

[About >](#)

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### Meetings

- [PDVAC Home](#)
- [Members](#)
- [Meetings](#)

PDVAC meeting materials including executive summaries, agendas, list of participants and presentations can be found below. PDVAC normally meets once a year in-person however the committee meetings are currently being convened virtually with each meeting covering a particular subject matter. Additional meetings for 2023/24 will be announced here in due course.

### Upcoming events

9 - 12 December 2024

**2024 meeting: WHO Product Development for Vaccines Advisory Committee Meeting (PDVAC)**

### Past Events

2023

12 - 13 December 2023

**2023 meeting: WHO Product Development for Vaccines Advisory Committee Meeting (PDVAC)**

21 June 2023 13:00 - 16:00 CET

**PDVAC (virtual) meeting on measles and rubella microarray patches (MR-MAPS) - June 2023**

2022

5 - 6 December 2022

**Development for Vaccines Advisory Committee (PDVAC) - December 2022**

7 February 2022 13:00 - 15:15 UTC Time

**PDVAC (virtual) meeting on invasive non-typhoidal Salmonella (iNTS) vaccines**