SP7 - RESEARCH AND INNOVATION

Co-Chair Update on behalf of SP7 WG

A/Prof Meru Sheel, The University of Sydney, Australia
Prof KP Asante, Kintampo Health Research Centre, Ghana

PDVAC Meeting, 9 December 2024

SP7 WORKING GROUP

Region	Member	Organisation	Country
AFRO	Kwaku Poku Asante (Co-lead)	Kintampo Health Research Center	Ghana
	Abdu Abdullahi Adamu	WHO AFRO	Regional office
	Helen Rees (RITAG)	University of the Witwatersrand (WITS)	South Africa
AMRO	Cristiana Toscano (SAGE)	Federal University of Goiás	Brazil
	John Peter Figueroa (RITAG)	University of the West Indies	Jamaica
EMRO	Ghassan Dbaibo (PDVAC)	American University of Beirut	Lebanon
	Ahmed Deemas Al Suwaidi (NITAG-UAE)	United Arab Emirates University	UAE
SEARO	Mimi Lhamu Mynak (RITAG)	Jigme Dorji Wangchuck National Referral Hospital	Bhutan
	Kawser Ali Choudhury (RITAG)	Bangabandhu Sheikh Mujib Medical University	Bangladesh
	Rahul Srivastava	WHO SEARO	Regional office
	Rakesh Aggarwal (RITAG)	Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER)	India
WPRO	Chris Morgan (RITAG)	Jhpiego	Australia/USA
	Meru Sheel (Co-Lead) (IVIRAC)	University of Sydney	Australia/India

Plus IA2030 Core Members

OUTLINE

- IA2030 and SP7 (Research and Innovation) Overview
- Endemic pathogen prioritization exercise
- Introduction to Vaccine and Immunization Implementation Research Strategy and Prioritization exercise

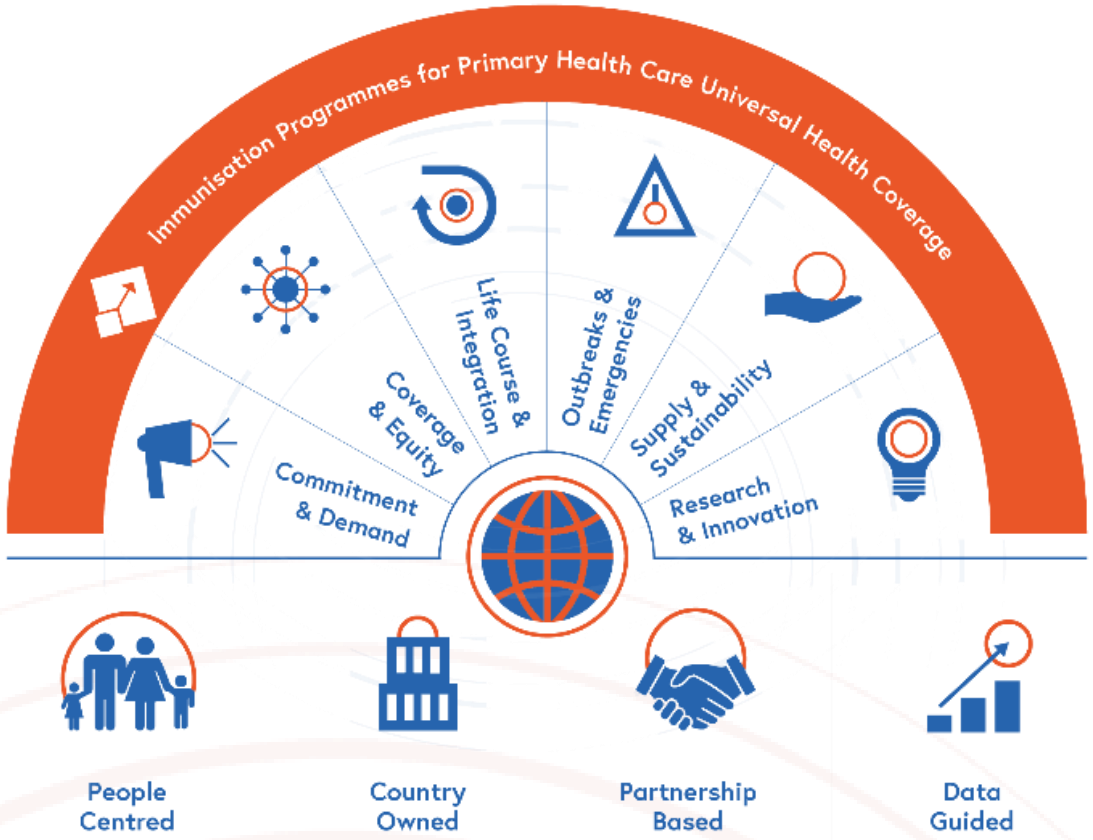
IMMUNIZATION AGENDA 2030 (IA2030)

Strategic framework for decade; all countries & partners on vaccines & immunization

7 Strategic Priorities

informed by

4 Core Principles for action



SP7

https://www.immunizationagenda2030.org/

SP7 RESEARCH AND INNOVATION GOALS

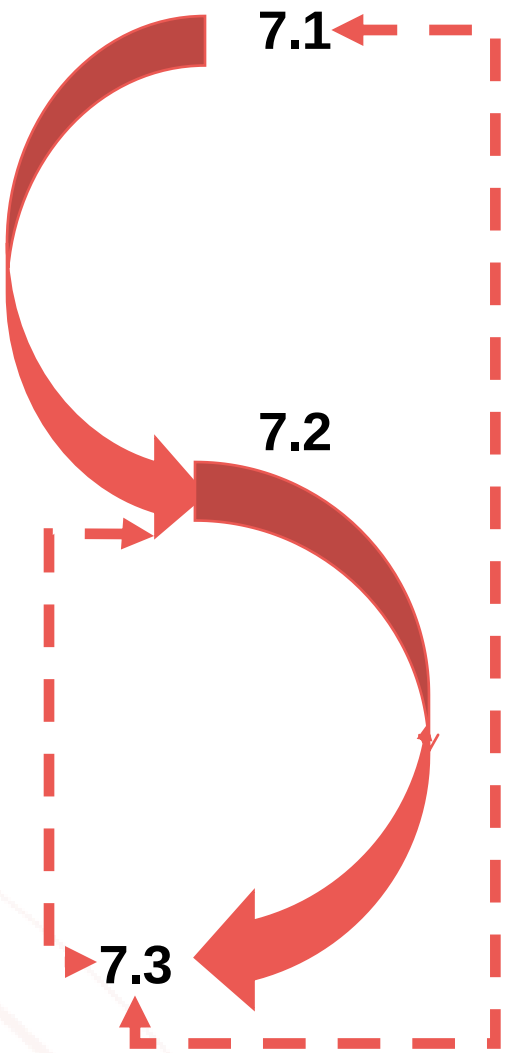
Needs-based Innovation	Strengthen mechanisms to identify vaccine-related research and priorities for innovation according to community needs, particularly for underserved populations, and ensure that the priorities inform innovations in immunization products, services and practices.
New and improved products, services and practices	Accelerate the development of new vaccines, technologies and improved products, services and practices, while ensuring continued progress in the development of vaccines for priority targets
Evidence for implementation	Shorten the path to maximum vaccine impact by implementation and operational research and through evidence-informed decisions on policy and implementation based on sound evidence of needs, benefits and risks.
Local capacity	Build local capacity to address programme challenges and maximize impact by cooperative creation, sourcing, adopting and scaling-up of innovations.

SP7 WORKING GROUP OBJECTIVES

7.1 Develop strategies to identify and communicate evidence and research needs to strengthen immunization policy and practice in LMICs

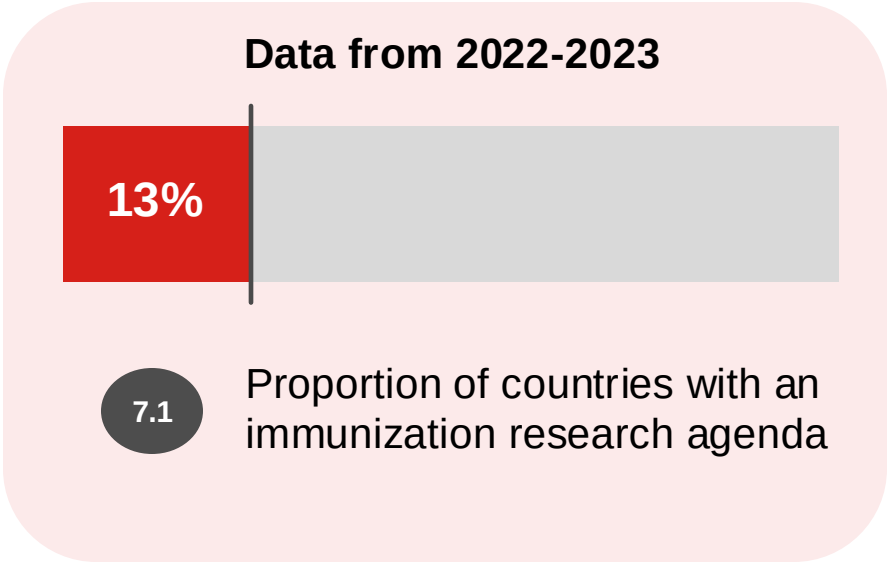
7.2 Facilitate R&D to create new and better vaccines and related products and services that are designed for use in LMIC contexts

7.3 Develop regional operational and implementation research prioritization framework and identify capacity building needs



INDICATORS TO TRACK PROGRESS

- Two original indicators
  - No. of countries with national agenda for research on immunization
  - Progress towards global research and development targets
- Early reporting through eJRF had poor responses



- Feedback from RITAGs and SP7 working group members that indicator may not be appropriate at country-level
- In 2024, efforts to review & revise indicators without increasing reporting needs

ACTIVITY ONE UPDATE
SP7.2 R&D PRIORITIES FOR ENDEMIC PATHOGENS

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

- Focus efforts on developing vaccines for the pathogens that most impact communities across the world
- Accelerate vaccine development by aligning immunization stakeholders
- Track progress in vaccine and immunization R&D under IA2030

Work led by Drs Mateusz Hasso-Agopsowicz and Birgitte Giersing

SP7.2 IDENTIFY R&D PRIORITIES FOR ENDEMIC PATHOGENS

Mid 2022

Landscape review

- Understand existing priorities
- Learn from previous prioritization exercises

Nov 2022 – May 2023

Regional surveys

- Regional MCDA surveys to weight criteria for prioritization
- Combine with pathogen data to generate top 10 lists for each region

May – Dec 2023

Global synthesis

- Combine regional Top 10 lists into a global priority list
- Define IA2030 M&E

July 2023 – May-2024

Regional consultations

- Discussion with regional stakeholders at RITAG meetings and endorsement of outcomes from RITAG chairs

2024 onwards

Monitor, update

- Global monitoring as part of IA2030 and regional strategies
- Update analysis as new data emerge

MCDA: Multi-criteria decision analysis, PDVAC: Product Development for Vaccines Advisory Committee, IVB: WHO Headquarters Immunization, Vaccines, and Biologicals

Work led by Drs Mateusz Hasso-Agopsowicz and Birgitte Giersing

17 PRIORITY ENDEMIC PATHOGENS FOR VACCINE R&D

IMMUNIZATION AGENDA 2030

Identifying WHO global priority endemic pathogens for vaccine research and development (R&D) using multi-criteria decision analysis (MCDA): an objective of the Immunization Agenda 2030

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Summary

Background To date, global priorities for new vaccine R&D have not been systematically identified for endemic pathogens. As part of Immunisation Agenda 2030 (IA2030), we have systematically identified priority endemic pathogens for new vaccine R&D based on country and regional stakeholder values to address this need.

Methods MCDA surveys targeting policy makers and immunisation stakeholders in each World Health Organization (WHO) region were used to weight eight criteria for prioritisation. Applying those weights to regional pathogen data yielded regional top ten pathogen lists, which are intended to inform regional deliberations on R&D priorities. The regional top ten lists were combined into an IA2030 global priority list. To inform R&D, use cases for new vaccines and monoclonal antibodies were identified, then categorized in terms of the activities needed to accelerate progress.

Findings In five out of six WHO regions, *Annual deaths in children under five* and *Contribution to antimicrobial resistance* were the most heavily weighted criteria. How participants weighted the criteria was not associated with their region, biographical characteristics, or areas of expertise. Five pathogens were common priorities across all regions: *M tuberculosis*, HIV-1, *K pneumoniae*, *S aureus*, and Extra-intestinal pathogenic *E coli*. Six pathogens were priorities in single regions. Combining regional top ten lists provided a global list of 17 priority pathogens for new vaccine R&D. Thirty-four distinct use cases were identified for new products targeting these pathogens. While most are in the "Advance product development" category, ten are in the "Research" category and seven are in the "Prepare to implement" category.

Interpretation These priorities for new vaccine R&D will help stakeholders better respond to regional and country needs. The use cases will inform R&D and enable monitoring of R&D under IA2030.

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Keywords: Vaccines; Priorities; Research; Development; IA2030

Introduction

Immunization has had an unparalleled impact on global morbidity and mortality, but because vaccine development is technically and commercially challenging, we lack vaccines against many pathogens that continue to impose a substantial public health burden.[1] Prioritization of pathogen targets for vaccine R&D is therefore crucial for the efficient use of limited resources, to

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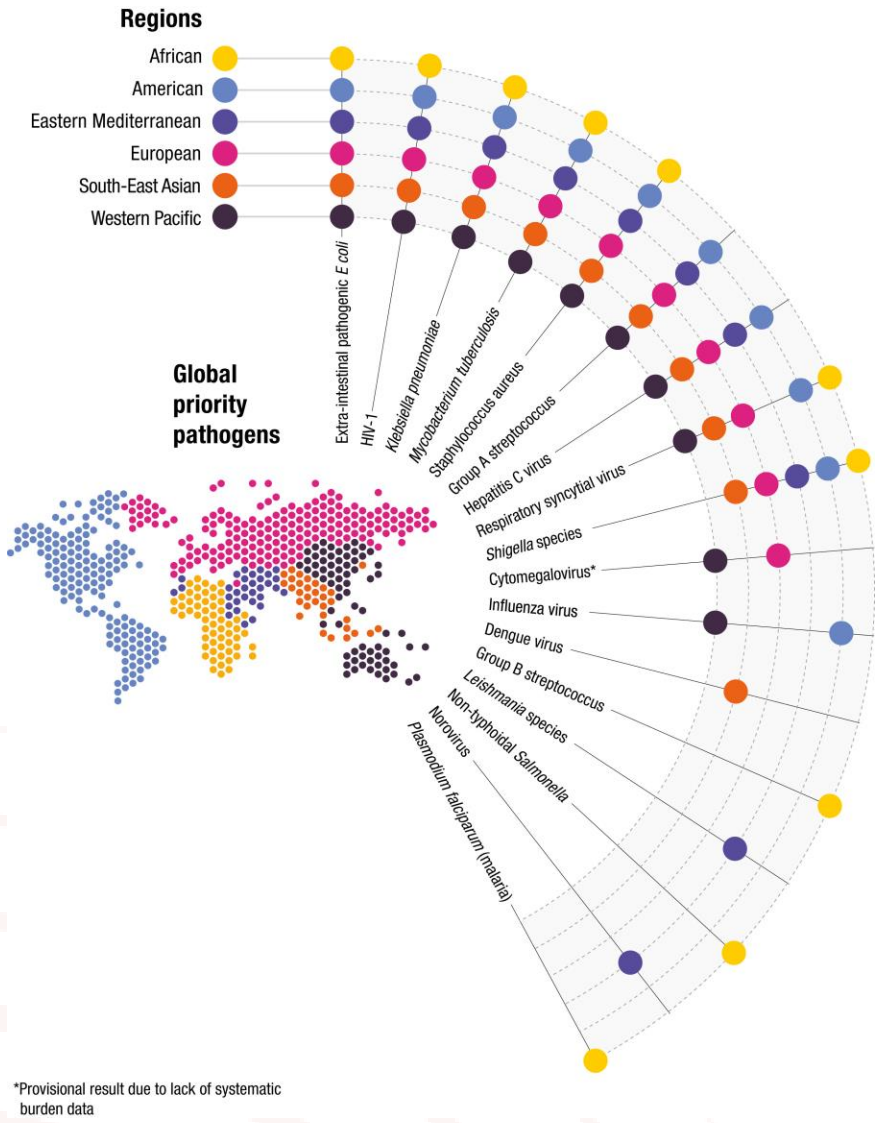


*Provisional result due to lack of systematic burden data

Work led by Drs Mateusz Hasso-Agopsowicz and Birgitte Giersing

17 PRIORITY ENDEMIC PATHOGENS FOR NEW VACCINE R&D & THEIR ACTION CATEGORIES

IMMUNIZATION AGENDA 2030

Action categories:	Research	Advance Product Development	Prepare to Implement
Pathogens:	• Group A streptococcus • Hepatitis C virus • HIV-1 • *Klebsiella pneumoniae*	• Cytomegalovirus • Group B streptococcus • Influenza virus • *Leishmania* species • Non-typhoidal *Salmonella* • Norovirus • *Plasmodium falciparum* (malaria) • *Shigella* species • *Staphylococcus aureus*	• Dengue virus • Extra-intestinal pathogenic *E coli* • *Mycobacterium tuberculosis* • Respiratory syncytial virus
Characteristics:	Few candidates in early clinical development or substantial technical challenges	Diverse candidates in development, including those in phase 2 studies	Candidates with high potential for approval by a WHO-listed authority before 2030
Recommended actions:	• **Identify research gaps** • **Improve surveillance** and burden estimates • Develop **target product profiles** • Assess **potential vaccine value** • **Develop tools** to improve technical feasibility	• **Stimulate investment** by raising awareness of opportunities for impact • **Develop tools** to inform decision-making (such as correlates of protection and economic models) • **Create consensus** on regulatory and policy pathways	• **Build awareness** of emerging products • **Assemble evidence** needed for policy decisions • Establish mechanisms for **long-term, equitable access** to approved products

Actions continue to introduce new vaccines and improve existing ones

Work led by Drs Mateusz Hasso-Agopsowicz and Birgitte Giersing

MOVING FORWARD WITH THE PRIORITY PATHOGEN LIST

Priorities will **inform** stakeholder strategies
Priorities should be **considered** in the context of existing global, regional and country R&D strategies

Regional stakeholders

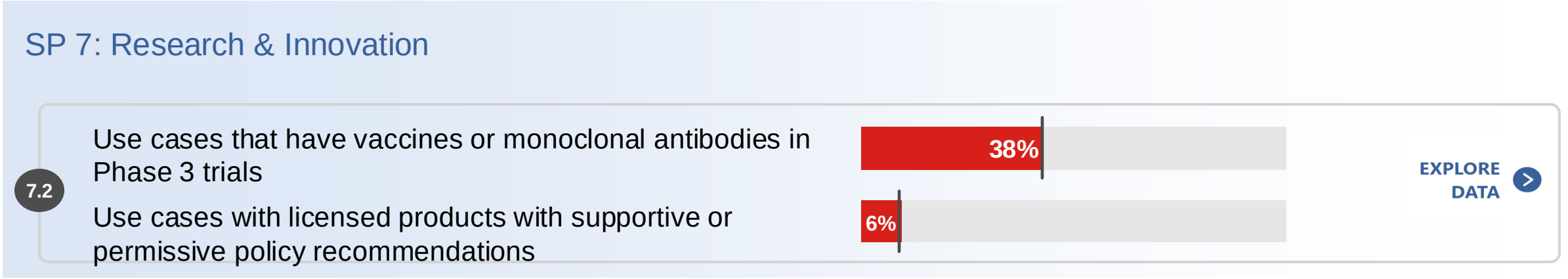
- **Industry**: inform investments in vaccine R&D
- **Funders**: inform funding for vaccine R&D
- **Researchers**: inform evidence generation
- **Policy makers**: build awareness of R&D pipelines, and prepare for introduction

Global stakeholders

- **WHO:** inform activities to accelerate evidence generation, R&D, and policy making to serve low-resource settings
- **Gavi**: inform Vaccine Investment Strategy (VIS)
- **IA2030:** to monitor progress in global R&D for new vaccines

7.2 MONITORING AND EVALUATION TO MONITOR PROGRESS (UNDER DISCUSSION)

Example M&E score card



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 • *Licensed: by WHO-listed authority (WLA) or transitional WLA* • *Policy recommendations: by SAGE if within SAGE scope, by a NITAG if not in SAGE scope*

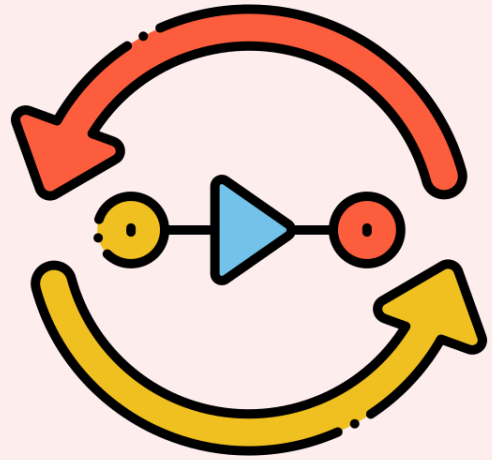
ACTIVITY TWO UPDATE
SP7 VACCINE AND IMMUNIZATION IMPLEMENTATION RESEARCH STRATEGY AND PRIORITIZATION

Rationale/ problem statement

Vaccine and Immunization Implementation Research Strategy and Prioritization

In support of IA2030 SP7 objectives

- Research investments that are informed by local and national immunization program needs
- Need for greater and better regional and country level data
- Enhanced stakeholder engagement to identify research gaps and priorities
- Supporting vaccine introduction, improvements to vaccine schedules, and programme implementation



End to End For Vaccines & Immunization

VACCINE AND IMMUNIZATION IMPLEMENTATION RESEARCH STRATEGY AND PRIORITIZATION

PHASE 1 (SP7.1)

Examine & characterize the vaccine and immunization research ecosystem

- focus on implementation research to identify research priorities to inform policy and practice
- **identify evidence and capacity gaps using a test case (TBD)**

Underway

PHASE 2 (SP7.3)

Regional vaccine implementation research prioritization

- **Support development of research agenda + capacity building**

PHASE 3 (SP7.2)

Generate evidence using tools and processes (phase 1 & 2)

- **translate into policy and practice**

SCOPING PROJECT FOR VACCINE AND IMMUNIZATION IMPLEMENTATION RESEARCH STRATEGY AND PRIORITIZATION (PHASE 1)

SP7 Working Group

To examine and characterize the immunization implementation research ecosystem

- WS1: Terminology & types of evidence needed
- WS2: Analysis of evidence-based decision-making and existing structures, processes and practices to determine implementation research needed to inform policy and practice at local level
- WS3: Regional consultations and validation workshop with immunization stakeholders

Coordinated approach to prioritizing vaccine research needs country, regional and global level

- **WHO HQ, AFRO and SEARO**
- **Local institutions (AFRO & SEARO) to lead country-level work**

PRIORITIES FOR 2025

- Finalise progress indicators to track progress
- Track progress across SP7 objectives
  - Monitor progress against pathogens with vaccines in phase 3 trials, vaccines with policy decision, and mAbs
  - Need and use of implementation research for evidence-based immunisation policy and practice
- Identify synergies across other IA2030 strategic prioritises for greater impact

WHAT IS THE ROLE FOR IMPLEMENTATION RESEARCH IN VACCINE PRIORITIZATION AND PRODUCT DEVELOPMENT?

Over the course of the PDVAC presentations and deliberations, please contemplate:

- How/whether understanding country and regional research priorities and perspectives is useful for your product development planning?
- What are the key ‘end goal’ questions that you have to inform your investments in vaccine development?
- How can you get involved and support the goals of IA2030 SP7?
- Please seek out the SP7 Chairs and Secretariat with your thoughts!

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Dr Birgitte Giersing
Dr Naor Bar-zeev
Ms Anna-lea Kahn
Dr Erin Sparrow

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IA2030 Secretariat

Wellcome Trust

Activity leads

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