SP7 - RESEARCH AND INNOVATION
Update on behalf of SP7 WG

Kwaku Poku Asante

A/Prof Meru Sheel

Chinwe Iwu-Jaja

Olwen Wilson

PDVAC Meeting, 6 October 2025

Outline

01	Introduction to IA2030 and SP7	Meru Sheel & K P Asante
02	Pipeline update for priority pathogens	Olwen Wilson
03	Implementation research scoping & project progress	Chinwe Iwu-Jaja
04	Conclusion and next steps	K P Asante

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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

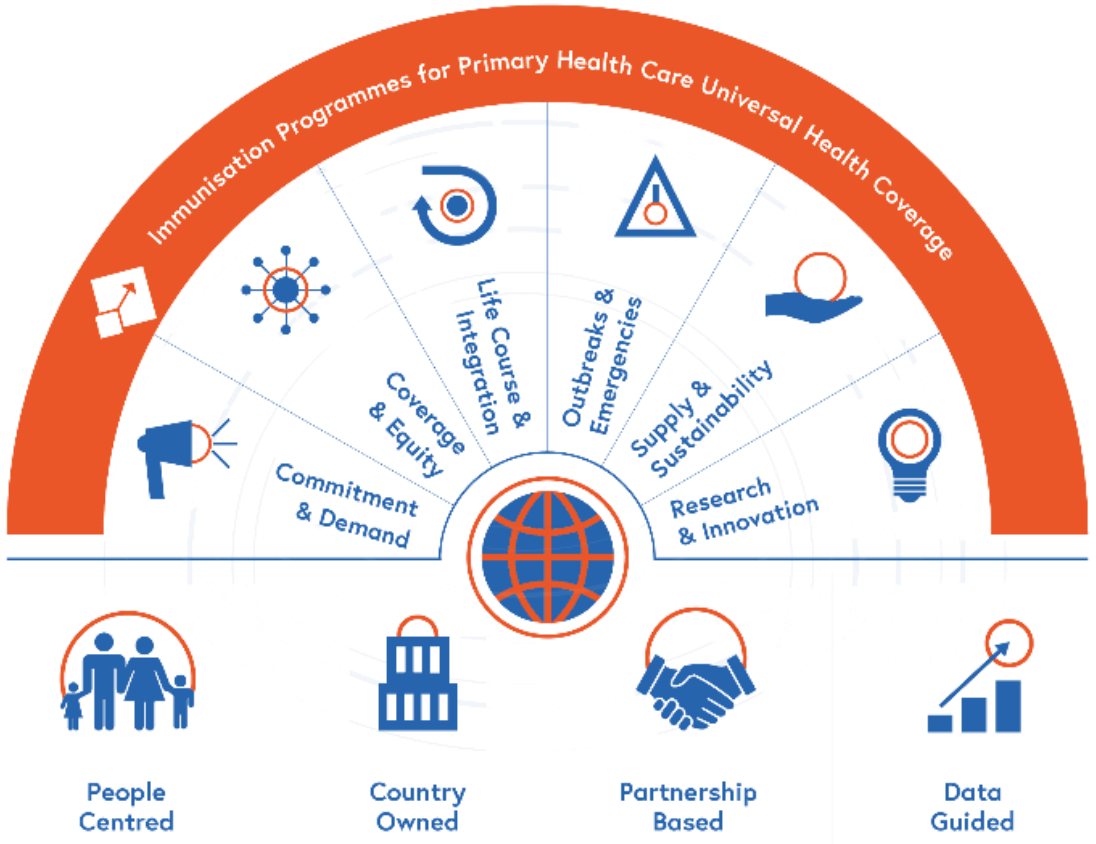
Immunization agenda 2030 (IA2030)

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

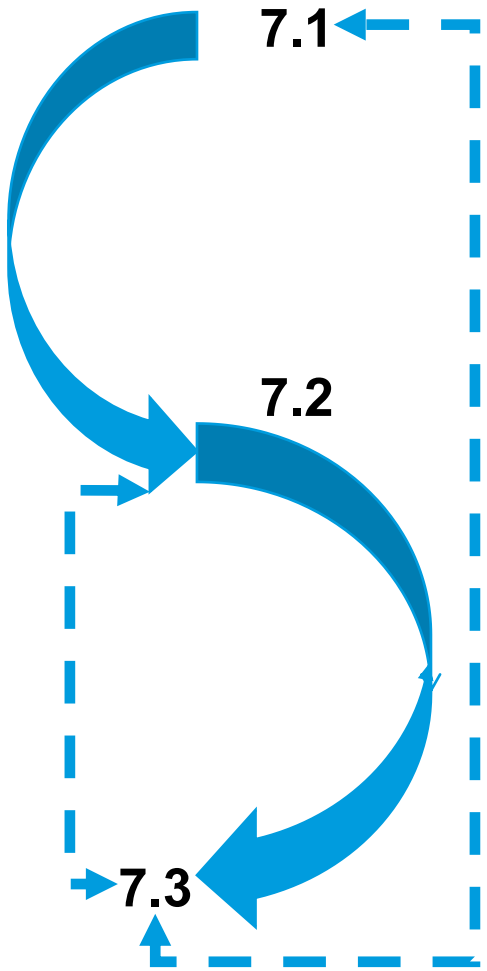
Needs-based Innovation	Strengthen mechanisms to identify vaccine-related research and priorities for innovation according to community needs, particularly for underserved populations, and ensure that the priorities inform innovations in immunization products, services and practices.
New and improved 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



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There are 17 global priority endemic pathogens, with a combined total of 34 use cases

The global list is a compilation of the top-10 priority pathogens in each WHO region

Global list of priority endemic pathogens for new vaccine R&D

- Cytomegalovirus
- Dengue virus
- Extra-intestinal pathogenic *E coli* (ExPEC)
- Hepatitis C virus
- HIV-1
- Influenza[1]
- *Klebsiella pneumoniae*
- *Leishmania* spp
- *Mycobacterium tuberculosis* (TB)[1]
- Norovirus
- *Plasmodium falciparum*[1]
- Respiratory syncytial virus (RSV)[1]
- *Salmonella* (non-typhoidal)
- *Shigella* spp
- *Staphylococcus aureus*
- *Streptococcus agalactiae* (group B streptococcus)
- *Streptococcus pyogenes* (group A streptococcus)

Use Case Examples[2]

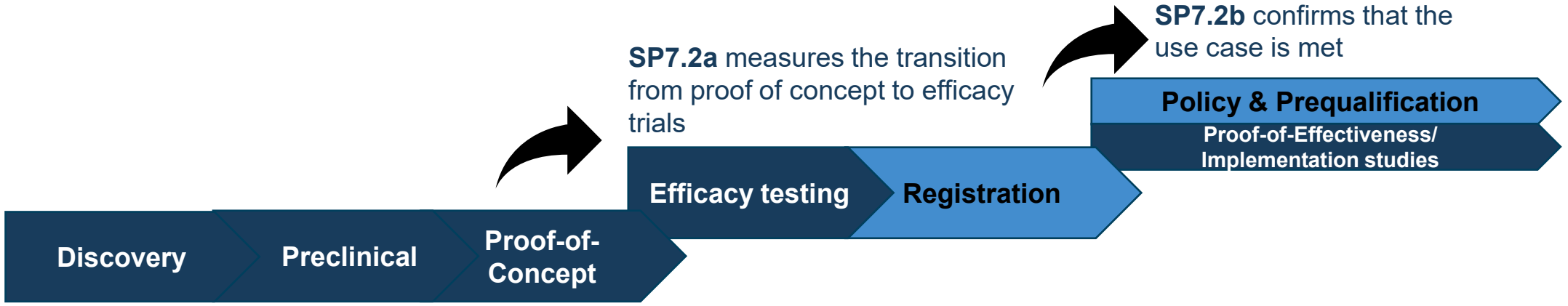
Tuberculosis	1. Prevention of active disease in adults[3] 2. Prevention of TB disease in infants & young children[2] 3. Adjunctive treatment of TB, or to prevent relapse following cure
Group B Strep	1. Maternal immunisation during pregnancy 2. Prevention of Group B streptococcal infections in older adults

Lists are alphabetical. Note: [1] Pathogen has licensed vaccine(s), but existing vaccine(s) do not meet the needs of certain population. [2] For selected pathogens only. The wording of these use cases has been shortened or simplified to fit on the slide. A full list of all use cases per pathogen is available in the Annex. [3] These use cases include people living with HIV.

SP7.2 measures progress in two ways: Phase 3 trials, and licensed & WHO recommended product

Out of 34 use cases, SP7.2 (a) and (b) track the percentage which meet either of these milestones

Full Value of Vaccines Continuum (R&D elements)



Metric	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*

Figure adapted from Hutubessy R, Lauer JA, Giersing B, Sim SY, Jit M, Kaslow D, et al. The Full Value of Vaccine Assessments (FVVA): a framework for assessing and communicating the value of vaccines for investment and introduction decision-making. BMC Med 2023;21:229. https://doi.org/10.1186/s12916-023-02929-0.

In both 2024 & 2025, only 13/34 use cases (38%) met the SP7.2a metric with candidate in Phase 3 trials

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Use cases which meet SP7.2a or SP7.2b, page 1/2

Pathogen	Use Case	7.2a?	7.2b?
Cytomegalovirus	Prevention and/or modification of sequelae associated with congenital CMV, by vaccinating women and girls prior to pregnancy (NCT05085366)	✓	
Dengue virus	Vaccine for dengue naïve and seropositive individuals, to prevent dengue febrile illness induced by any dengue serotype (NCT07013487)	✓	
Influenza	Improved seasonal influenza vaccines, with a duration of protection of at least one year (NCT07013487)	✓	
Mycobacterium tuberculosis (TB)	Prevention of active pulmonary TB disease (with or without evidence of latent infection), including in those with HIV infection (NCT06062238)	✓	
Mycobacterium tuberculosis (TB)	Prevention of TB disease in infants and young children, including in infants with HIV infection (NCT04975178)	✓	
Norovirus	Prevention of norovirus acute gastroenteritis for children in all countries from 6 weeks of age (NCT06524947)	✓	
Norovirus	Prevention of norovirus acute gastroenteritis for adolescents, adults, and/or older persons in all countries (including travellers) (NCT06592794)	✓	

In both 2024 & 2025, only 2/34 use cases (6%, both RSV) met the SP7.2b metric with a licensed product

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Use cases which meet SP7.2a or SP7.2b, page 2/2

Pathogen	Use Case	7.2a?	7.2b?
Plasmodium falciparum	mAbs for prevention of blood-stage infection due to P falciparum at the individual level, and/or reduction of clinical malaria, including severe malaria and death due to P falciparum (PACTR202409607254081)	✓	
Respiratory syncytial virus (RSV)	Active immunisation of women during pregnancy, for prevention of severe RSV disease in offspring during the neonatal period and early infancy (Abrysvo)	✓	✓
Respiratory syncytial virus (RSV)	mAbs for prevention of severe RSV disease for all infants in the first 6 months of life and for high-risk young children entering their second RSV season (e.g with chronic heart or chronic lung disease) (Enflonsia, Beyfortus)	✓	✓
Shigella spp	Prevention of moderate to severe diarrhoea due to Shigella in infants from 6 months and children up to 36 months of age (NCT06838195)	✓	
Staphylococcus aureus	Prevention of severe infection in populations at risk, such as children, those over 60 years of age, and/or those in all age groups who are immunocompromised, experiencing recurrent skin and soft tissue infections, suffering from relevant comorbidities, exposed to epidemic strains, diabetics, or undergoing elective surgery or other invasive procedures with high risk of S. aureus infection (ChiCTR2200062998)	✓	
Streptococcus agalactiae (group B streptococcus)	Maternal immunisation during pregnancy to prevent GBS-related stillbirth and invasive GBS disease in neonates and young infants (NCT03765073)	✓	

Despite a lack of change in the SP7.2a and SP7.2b scores since 2024, there is significant activity in pathogen pipelines

In mid-2024, use cases were categorized as Phase 1, pre-efficacy data, or having some efficacy signal

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19 use cases were in the Phase 2 pre-efficacy category, and a further 5 had efficacy data

Phase 1[1]

- **ExPEC** – Maternal immunisation to prevent disease in neonates & young infants
- **Hep C** – Prevent chronic Hep C infection for persons at risk
- **Hep C** – Therapeutic vaccines for chronic Hep C
- **HIV-1** – Prevent HIV in high-risk populations (via active immunization)
- **HIV-1** – Treatment/cure of HIV
- **HIV-1** – Preventive mAbs in HIV-neg. individuals
- **Klebsiella** – Maternal vaccination during pregnancy to prevent neonatal sepsis
- **Klebsiella** – Prevent disease in high-risk populations
- **Group B Strep** – Prevent infection in older adults
- **Group A Strep** – Prevent GAS disease in young children (potentially including sequelae)

10 use cases

Phase 2 and Pre-Efficacy Data[1]

- **CMV** – Prevent congenital CMV by vaccinating women & girls prior to pregnancy
- **Influenza** – Universal type vaccine
- **Influenza** – Improved seasonal vaccine
- **Leishmania** – Prevent VL, CL, and/or PKAD in all ages
- **TB** – Adjunctive treatment / prevention of relapse
- **TB** – Prevent disease in infants & young children
- **Noro** – Prevent acute gastroenteritis in children 6wks+
- **Noro** – Prevent acute gastro in adolescents & adults
- **Malaria** – Prevent disease
- **Malaria** – Prevent community transmission
- **Malaria** – mAbs to prevent disease
- **RSV** – Active immunization of infants
- **NTS** – Pediatric vaccine
- **NTS** – High risk individuals
- **Shigella** – Infants aged 6-36 months
- **Shigella** – Prevention in travellers & military
- **Staph A** – Active vaccine for high-risk individuals
- **Staph A** – mAbs for treatment or prevention
- **Group B Strep** – Immunization during pregnancy

19 use cases

Efficacy data available[1]

- **Dengue** – prevention of disease due to any serotype
- **ExPEC** – high-risk populations
- **TB** – prevention in adults
- **RSV** – maternal immunization
- **RSV** – mAbs to prevent severe RSV disease for all infants & high-risk young children

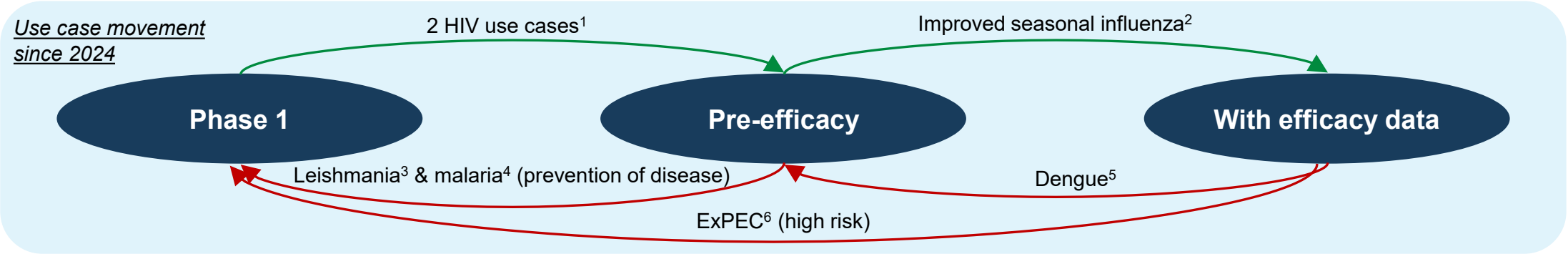
5 use cases

[1] The wording of these use cases has been shortened or simplified to fit on the slide. A full list of all use cases per pathogen is available in the Annex.

Updated Data

Since mid-2024, three use cases have progressed and four have moved down due to various reasons

There are now 11 use cases in Phase 1, 19 in pre-efficacy, and 4 with efficacy data



New use cases per category	• Leishmania (all spp.) • Vaccine mediated prevention of *P. falciparum* malaria • ExPEC infection in high-risk individuals	• Treatment or cure of HIV in HIV positive individuals • mAb-mediated prevention of HIV in HIV-negative individuals • Dengue due to any dengue serotype	• Improved seasonal influenza
Use cases which remained in the same category	ExPEC (maternal immunisation) Hep C (both use cases) Vaccine-mediated HIV-1 prevention Klebsiella (both use cases) Group B Strep (older adults) Group A Strep	CMV Influenza (universal vaccine) TB (prevention in children & adjunct therapy) Norovirus (both use cases) Malaria (preventing community transmission and mAbs to prevent disease) RSV (active immunization of infants) Non-typhoidal salmonella Shigella (both use cases) Staph aureus (both use cases) Group B Strep (maternal immunization)	TB (prevention of disease in adults & adolescents) RSV (both use cases)

See Annex slides for explanation of category changes

Full use case wording for pathogens that moved is: [1] 2 HIV use cases: a) Treatment and/or cure of HIV infection in HIV-1 positive individuals including with vaccines or mAbs, and 2) Preventive mAbs for HIV-1 infection in confirmed HIV-negative individuals at substantial risk of HIV infection. [2] Improved seasonal influenza vaccines, with a duration of protection of at least one year [3] Prevention of visceral leishmaniasis and/or cutaneous leishmaniasis in all age groups in endemic regions starting from 6 months of age, and/or prevention or treatment of post-kala azar dermal leishmaniasis [4] Prevention of blood-stage infection due to P falciparum malaria at the individual level, for populations or age groups who experience high incidence of infection [5] Vaccine for dengue naïve and seropositive individuals, to prevent dengue febrile illness induced by any dengue serotype [6] Prevention of invasive E coli disease, including urinary tract infections or bacteraemia, in high-risk populations. Full use case wording for all pathogens is available in the Annex.

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WHO SP7 Scoping Project – project overview

Context

2023: SP7-WG agenda shifts focus to country needs & Implementation Research

2024: WHO designs **multi-phased Exemplar Pilot** with Wellcome Trust, basing much of **Phase 1 Scoping Project** on SP7-WG requests for Objective 7.1 re. **implementation research**

2025: **SP7 Scoping Project** launched and activities initiated, with focus on 2 test cases: **mat.RSV** & **Comb.Vacc.**

Project end date:
31 December 2025

Objective: Examine & characterize the vaccine and immunization research ecosystem with particular focus on how the role of implementation research can be enhanced

Outputs

- ✓ Insights on types of evidence & capacity required for effectively informed country-level decisions → test case (i.e., new combination vaccines)
- ✓ Roadmap to regionally coordinated research agenda

Goal: a responsive, equitable, and impactful research ecosystem

WHO SP7 Scoping Project – project structure

Across 3 workstreams

1. Clarify vaccine and immunization research taxonomy, nomenclature, and stakeholders
   - Global level / led by SEARO (by sub-contract with partner institution)

METHODS: literature review + expert consultation

2. 2.1: Assess current practices and opportunities to identify & address evidence needs related to implementation research in context of 2 designated innovations / test cases
   - Country level / led by AFRO (through country-level partner institutions)

   2.2: Identify and define components of a research proposal for primary test case (ie. combination vaccines) to address prioritized evidence gaps
   - Regional level / led by AFRO & TDR (through University of Ghana)

METHODS: landscape analysis / focus group discussions

3. Coordinate consultations with relevant research experts to review findings and agree on roadmap for next phase of pilot, focused on research agenda-setting & capacity building
   - Global & Regional level convening (involving community of experts engaged throughout VIRECo, incl. SP7 WG)

METHODS: forum discussions + virtual FGDs + workshop

Project Team

Technical Leads:

Naor Bar-Zeev (WHO- HQ/**IVB**-IAI)
Anna Thorson (WHO-HQ/**TDR**-RCS)

Project Managers:

Anna-Lea Kahn (WHO-HQ/**IVB**)
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Workstream 1

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Workstream 2

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Aschalew Teka Bekele (WHO-**AFRO**/VPD)
Sidy Ndiaye (WHO-**AFRO**/VPD)

Workstream 3

Chinwe Iwu-Jaja (WHO-**AFRO**/VPD)

Timeline/Milestones: Progress to date

	Q1 Jan-Mar 2025	Q2 Apr-Jun 2025	Q3 Jul-Sep 2025	Q4 Oct-Dec 2025
Workstream 1: Taxonomy & Stakeholder Mapping (SEARO)	✓ SEARO RFP for sub-contract	✓ Lit review (scoping review) ✓ Expert interviews	• **Draft report** for technical review by VIRECo	• **Final report** on Taxonomy & Stakeholders
Workstream 2: Landscape Analysis + Test case evidence & capacity needs (AFRO)	✓ Development of generic protocol for mapping & SWOT assessment (landscape analysis) ✓ Selection of target countries for country-level assessments	✓ Test case selection concluded ✓ Target countries confirmed and engaged	• Country-level data collection ◦ FGDs with regional experts / prioritization of evidence gaps for test case	• **Final consolidated report of** country-level findings & recommendations • **Regional report** on research & capacity needs for test case • **Study plan** on prioritized research for test case
Workstream 3: Expert consultation (AFRO)	✓ AFRO webinar on Project objectives and plans ✓ AFRO Survey on innovations to inform test case selection ✓ GVIRF: presentation + SP7 WG mtg	✓ AFR-RITAG Consultation on test case + lands.analysis ✓ AFR-RITAG update	✓ VIRECo launch + consultations	• VIRECo consensus & **validation workshop** on objectives & activities for next phase • **Regional Roadmap** for research agenda & Capacity Bldg

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Conclusions and next steps

SP7 activities presented remain relevant in vaccine development however,

- the knowledge generated are quite dynamic I.e products are being developed and we need to continue to identify approaches and evidence for their introduction and implementation needs to be carefully designed within the new emerging landscape.

Key next steps

- update priority list and communicate with stakeholders
- enhance engagement with LMICs on research gaps identified from the scoping review with focus on capacity building for research agenda development and implementation in line with the pathogen prioritisation agenda

Acknowledgements

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

SP7 Working Group Members
IA2030 Secretariat

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Gates Foundation

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Annex

The PDVAC Secretariat designed a systematic, consultative process to identify priority pathogens

Using literature reviews, multi-criteria decision analysis, and regional consultations

Landscape review

- **Time**: Mid 2022
- **Method**: Literature review
- **Goals**:
  - Understand existing priorities
  - Learn from previous prioritization exercises

Regional surveys

- **Time:** Nov 2022 – May 2023
- **Method:** Regional MCDA surveys for criteria
- **Goals:**
  - Identify criteria weighting for prioritization
  - Combine with pathogen data to give Top 10 lists for each region

Global synthesis

- **Time**: May – Dec 2023
- **Method**: Data analysis & expert consultation
- **Goals**:
  - Combine regional Top 10 lists into a global priority list
  - Define IA2030 M&E metrics

Regional consultations

- **Time**: July 2023 – May 2024
- **Method**: Expert consultation
- **Goals**:
  - Consult with regional stakeholders at RITAG meetings
  - Gain endorsement of outcomes from RITAG chairs

Narrowing list of priority pathogens by region

PDVAC: Product Development for Vaccines Advisory Committee. MCDA: Multi criteria decision analysis. RITAG: Regional Immunization Technical Advisory Group.

Both Leishmania and the ExPEC use case in high-risk individuals fell back to Research due to trial failures

Leishmaniasis was previously in Phase 2 & pre-efficacy; ExPEC was in a Phase 3 trial

Leishmania (*all spp.*)

- **Clinical Trial Number:** NCT03969134
- **Developer:** University of York
- **Trial failure:** Phase 2 trial in Sudan failed to reach therapeutic end point. Planned further studies were cancelled due to the security situation.[1]
- **Future of the pipeline:** A new consortium (University of York, HDT Bio, ITM Antwerp, and clinical centres in Ethiopia), is exploring a new RNA-based candidate, which could enter trials as early as 2026, pending funding availability.[1]

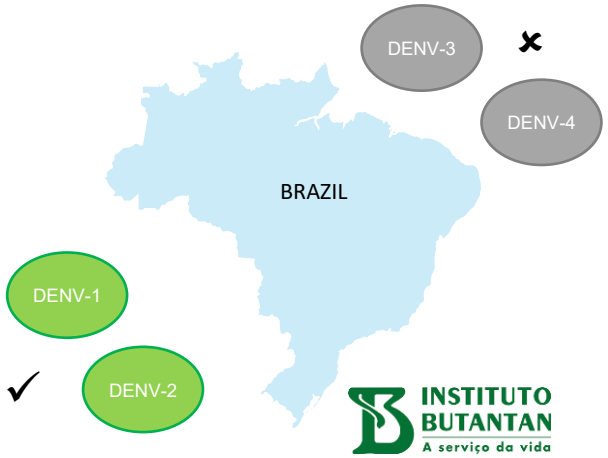
ExPEC

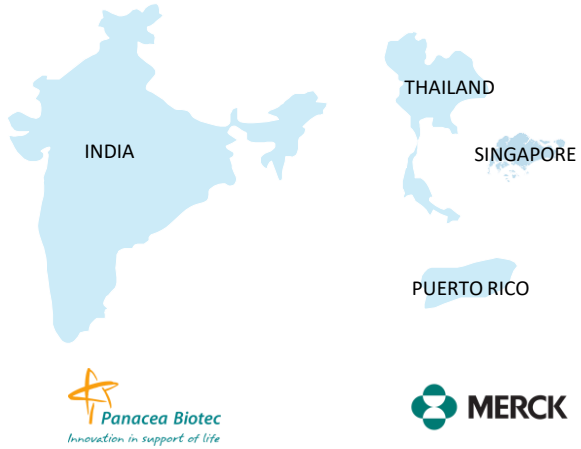
- **Clinical Trial Number**: NCT04899336
- **Developer**: Sanofi and Johnson & Johnson
- **Trial failure**: In February 2025, the independent data monitoring committee determined that the vaccine candidate was not sufficiently effective compared to placebo and the Phase 3 study was discontinued.[2]
- **Future of the pipeline**: The pipeline is currently in "Research" stage. There are no known Phase 1 candidates which meet the use case.

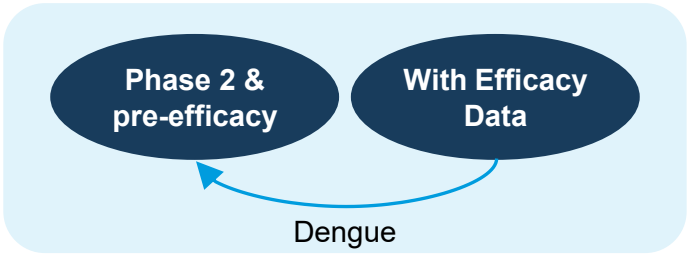
Source: [1] Conversation with Professor Paul Kaye, University of York, Lead researcher on Leishmaniasis. [2]: Sanofi press release. Link: https://www.sanofi.com/en/media-room/press-releases/2025/2025-02-13-06-00-00-3025576

The Dengue use case has reverted to Phase 2 & pre-efficacy data due to hitches during its Phase 3 trial

A lack of circulating DENV-3 and DENV-4 prevented Butantan from gathering data on efficacy against these serotypes







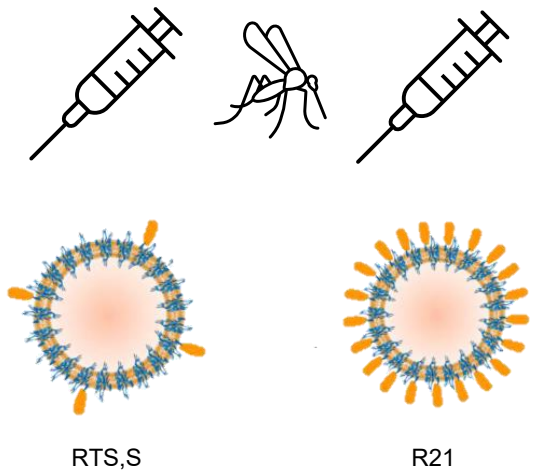
1
- In Butantan's Phase 3 trial in Brazil, the candidate protected against DENV-1/2 – but DENV-3/4 were not present.[1]
- Butantan submitted a dossier to ANVISA based on these results.[2]
- If approved, the vaccine will be licensed only in Brazil (due to an agreement with Merck).

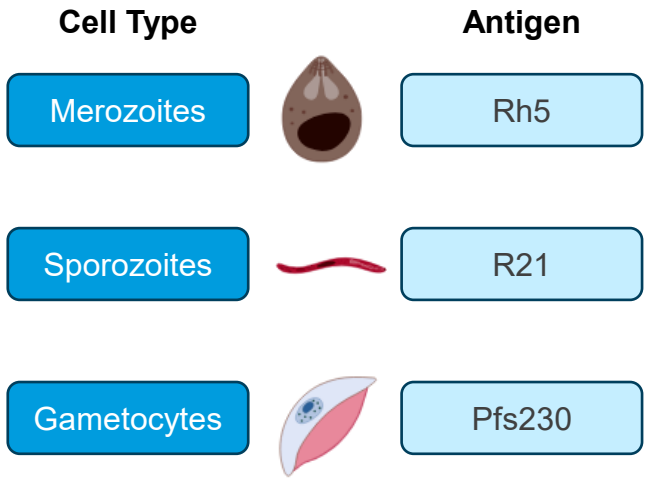
2
- Merck & Panacea's candidates are in Phase 3 trials, aiming to show efficacy against all 4 serotypes. [3]
- They are based on the same underlying TV003 formulation from the NIH.

3
- Dengue's use case calls for a vaccine which protects against all serotypes.
- It will remain in Phase 2 & pre-efficacy until a candidate has proven efficacy against all four serotypes.

Sources: [1] https://www.sciencedirect.com/science/article/abs/pii/S1473309924003761 [2] https://fundacaobutantan.org.br/noticias/instituto-butantan-pede-a-anvisa-registro-da-sua-vacina-contra-a-dengue-primeira-do-mundo-em-dose-unica?lang=en [3] Merck Clinical Trial: https://trialsearch.who.int/Trial2.aspx?TrialID=NCT07013487 Panacea Clinical Trial: https://trialsearch.who.int/Trial2.aspx?TrialID=CTRI/2024/03/064910

The Malaria prevention of disease use case moved to Research due to iterative multi-antigen vaccine R&D





Pfs230[3]
- Alone: Phase 2
- Combi Phase 1
- Combi candidate (with R21) aims to block disease & transmission

Rh5[4]
- Alone: Phase 2b
- Combi: Phase 1
- Combi candidate (with R21) targets stronger disease protection

1
- Two vaccines for malaria already exist – RTS,S[1] and R21.
- These single-antigen vaccines prevent disease – but breakthrough infections still occur.

2
- The *P. falciparum* parasite goes through many changes within the human body.
- New research is investigating multi-antigen vaccines to improve efficacy against disease and reduce malaria community transmission.

3
- However, combinations must be re-trialed in early stages, even when single candidates are safe in advanced trials.

[1] https://clinicaltrials.gov/study/NCT02251704 [2] https://clinicaltrials.gov/study/NCT06068530 [3] https://clinicaltrials.gov/study/NCT06507605 [4] https://clinicaltrials.gov/study/NCT05357560

Two HIV use cases progressed from Research to Phase 2 & pre-efficacy due to bnAbs work

Broadly neutralizing antibodies (bnAbs) may be a powerful tool to prevent and treat HIV

Two HIV use cases have a bnAb in Phase 2

- **Use cases for treating and preventing HIV are in Phase 2 due to bnAbs**
- Treatment use case: A ViiV healthcare bnAb candidate in Phase 2 was safe and well tolerated. Patients experienced a decline in viraemia which warrants further investigation
- Prevention use case: The CAPRISA 012C Phase 2 trial of a combination of two bnAbs[1] is still ongoing. One bnAb targets the V1/V2 region of Env gp120, the other targets the CD4 binding site

bnAbs are important for HIV treatment and prevention…

- **bnAbs could be powerful approaches to HIV prevention and treatment**
- Delivering bnAbs directly (i.e., passive immunization) could rapidly control or prevent HIV infection
- Cocktails of bnAbs offer better protection against the high genetic diversity of HIV

… and for HIV vaccine R&D

- **bnAbs may also help to accelerate research for a traditional HIV vaccine**
- Active vaccination has struggled to induce immunogenicity – more so than for other diseases
- Identifying effective bnAbs helps identify key protective antigens, saving wasted effort engineering vaccines against non-protective or subdominant antigens

Note: [1] The two bnAbs trialed are CAP256V2LS and VRC07-523LS

The seasonal influenza vaccine has some efficacy signal due to a strong Phase 3 readout

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Influenza use cases	
	
1. Universal Influenza: Phase 2 & pre-efficacy	2. Seasonal Influenza: with efficacy signal

- There are 2 influenza use cases
- The seasonal vaccine use case now has some efficacy signal due to a strong readout from a Moderna Phase 3 trial[1,2]

Moderna mRNA-1010 Phase 3 Announced Results

Strain		Avg. rVE
Influenza A H1N1	→	29.6%
Influenza A H3N2	→	22.2%
Influenza B / Victoria lin.	→	29.1%

- Candidate mRNA-1010 trialed in adults aged 50+
- Relative vaccine efficacy (rVE) was 26.6% vs. a licensed flu vaccine
- Full results not yet published[2] – once they are published, engagement with NITAGs likely needed

[1] Moderna mRNA-1010 Phase 3 Trial: https://clinicaltrials.gov/study/NCT06602024 [2] Press release with initial results: https://news.modernatx.com/news/news-details/2025/Moderna-Announces-Positive-Phase-3-Results-for-Seasonal-Influenza-Vaccine/default.aspx

Use cases for priority endemic pathogens (1/3)

Pathogen	Use Case	2025 Action Category
Cytomegalovirus	Prevention and/or modification of sequelae associated with congenital CMV, by vaccinating women and girls prior to pregnancy	Pre-efficacy
Dengue virus	Vaccine for dengue naïve and seropositive individuals, to prevent dengue febrile illness induced by any dengue serotype	Pre-efficacy
Extra-intestinal pathogenic *E coli* (ExPEC)	Prevention of invasive E coli disease, including urinary tract infections or bacteraemia, in high-risk populations	Research
Extra-intestinal pathogenic *E coli* (ExPEC)	Maternal immunisation during pregnancy to prevent invasive E coli disease, such as neonatal sepsis and meningitis, in neonates and young infants (informed by PDVAC deliberations)	Research
Hepatitis C virus	Prevention of chronic hepatitis C infection for persons at risk	Research
Hepatitis C virus	Therapeutic vaccines to improve treatment outcomes for chronic HCV infections8	Research
HIV-1	Prevention of HIV in high-risk populations (informed by clinical trials)	Research
HIV-1	Treatment and/or cure of HIV infection in HIV-1 positive individuals (includes vaccines, mAbs, and combined approaches) (informed by clinical trials)	Pre-efficacy
HIV-1	Preventive mAbs for HIV-1 infection in confirmed HIV-negative individuals at substantial risk of HIV infection and their sexual partners and/or prevention of HIV-1 infection in neonates and infants with HIV exposure	Pre-efficacy
Influenza	Universal-type (“broadly protective”) influenza A vaccines for prevention of severe influenza illness caused by human influenza A virus infection in persons aged 6 weeks and older belonging to a group at high risk for severe influenza illness (children aged 6 weeks through 59 months, elderly adults, persons with chronic medical conditions, and pregnant women). Duration of efficacy should be a minimum of 5 years	Pre-efficacy
Influenza	Improved seasonal influenza vaccines, with a duration of protection of at least one year	With efficacy
Klebsiella pneumoniae	Vaccine administered during pregnancy to prevent neonatal sepsis caused by the major disease-causing serotypes of K pneumoniae	Research
Klebsiella pneumoniae	Preventing K pneumoniae-attributable disease, including pneumonia, bloodstream infections, and/or urinary tract infections in high-risk populations such as older adults, the immunocompromised, and those with anticipated prolonged hospital stay or planned surgeries	Research

Use cases for priority endemic pathogens (2/3)

Pathogen	Use Case	2025 Action Category
Leishmania *spp*	Prevention of visceral leishmaniasis and/or cutaneous leishmaniasis in all age groups in endemic regions starting from 6 months of age, and/or prevention or treatment of post-kala azar dermal leishmaniasis	Research
Mycobacterium tuberculosis (TB)	Prevention of active pulmonary TB disease (with or without evidence of latent infection), including in those with HIV infection	With efficacy
Mycobacterium tuberculosis (TB)	Prevention of TB disease in infants and young children, including in infants with HIV infection	Pre-efficacy
Mycobacterium tuberculosis (TB)	Adjunctive treatment of TB, or to prevent relapse following cure in patients being treated for active TB, both drug sensitive and drug resistant strains	Pre-efficacy
Norovirus	Prevention of norovirus acute gastroenteritis for children in all countries from 6 weeks of age	Pre-efficacy
Norovirus	Prevention of norovirus acute gastroenteritis for adolescents, adults, and/or older persons in all countries (including travellers)	Pre-efficacy
Plasmodium falciparum	Prevention of blood-stage infection due to P falciparum malaria at the individual level, for populations or age groups who experience high incidence of infection	Research
Plasmodium falciparum	Prevention of malaria transmission at the community level for children and adults, including women of childbearing age, who represent the infectious reservoir and will need to be targeted to maximize the vaccine's impact on transmission	Pre-efficacy
Plasmodium falciparum	mAbs for prevention of blood-stage infection due to P falciparum at the individual level, and/or reduction of clinical malaria, including severe malaria and death due to P falciparum	Pre-efficacy
Respiratory syncytial virus (RSV)	Active immunisation of women during pregnancy, for prevention of severe RSV disease in offspring during the neonatal period and early infancy	With efficacy
Respiratory syncytial virus (RSV)	Active immunisation of infants, for prevention of RSV disease in infants and young children	Pre-efficacy
Respiratory syncytial virus (RSV)	mAbs for prevention of severe RSV disease for all infants in the first 6 months of life and for high-risk young children entering their second RSV season (e.g with chronic heart or chronic lung disease)	With efficacy
Salmonella (non-typhoidal)	Paediatric vaccines for prevention of invasive disease caused by non-typhoidal Salmonella in children aged 6 – 36 months	Pre-efficacy

Abbreviations: APD = Advance Product Development; P2I = Prepare to Implement

Use cases for priority endemic pathogens (3/3)

Pathogen	Use Case	2025 Action Category
Salmonella (non-typhoidal)	Prevention of invasive disease caused by non-typhoidal Salmonella in other individuals at high risk, including immunocompromised individuals, children over 36 months, the elderly, immunocompromised individuals, and persons living or traveling in settings with poor sanitation and hygiene	Pre-efficacy
Shigella spp	Prevention of moderate to severe diarrhoea due to Shigella in infants from 6 months and children up to 36 months of age	Pre-efficacy
Shigella spp	Prevention of Shigella-attributable dysentery and diarrhoea for high-risk populations such as travellers and the military, communities with high incidence, elderly and institutionalized individuals, and/or pregnant women	Pre-efficacy
Staphylococcus aureus	Prevention of severe infection in populations at risk, such as children, those over 60 years of age, and/or those in all age groups who are immunocompromised, experiencing recurrent skin and soft tissue infections, suffering from relevant comorbidities, exposed to epidemic strains, diabetics, or undergoing elective surgery or other invasive procedures with high risk of S aureus infection	Pre-efficacy
Staphylococcus aureus	mAbs for prevention or treatment of disease caused by S aureus, such as severe pneumonia and/or superinfection in conjunction with viral pneumonia	Pre-efficacy
Streptococcus agalactiae (group B streptococcus)	Maternal immunisation during pregnancy to prevent GBS-related stillbirth and invasive GBS disease in neonates and young infants	Pre-efficacy
Streptococcus agalactiae (group B streptococcus)	Prevention of Group B streptococcal infections in older adults	Research
Streptococcus pyogenes (group A streptococcus)	Prevention of GAS disease: pharyngitis, impetigo and invasive disease in young children. Potential for prevention of GAS immune-mediated sequelae: acute rheumatic fever and rheumatic heart disease	Research

Abbreviations: APD = Advance Product Development; P2I = Prepare to Implement