PDVAC General Updates

6th October 2025

Influenza

Pipeline Updates

Phase 3 superiority trials - mRNA seasonal influenza vaccines (very preliminary)

Platform	Superiority Phase 3 trial	Population	Relative Vaccine Efficacy (rVE) vs standard IIV	Primary analysis (Lab-confirmed ILI)
mRNA Moderna	Press release June 2025	≥50 y, ~40,805 11 countries	26.6% (95% CI; 16.7%, 35.4%)	**Superiority met**
mRNA Pfizer	Public Slides, WHO consultation	18-64 y, ~18,607 USA	Unknown	**Superiority met** Immunogenicity non-inferiority not met on B

WHO Activities

- PPC for next-gen influenza vaccine finalized
- SAGE H5N1 policy update (sept 25)
- mRNA TT – TAG meeting to advance H5N1 mRNA R&D (June 25 Argentina)

WHO preferred product characteristics for next generation influenza vaccines,

second edition

World Health Organization

Group A Streptococcus

Pipeline Updates

- 3 M-proteins vaccines in Phase 1

Meeting Updates

Joint Meeting of SAVAC and WHO
Advancing development of Strep A vaccines for populations in need

1) Consider the regulatory and policy pathways for *S. pyogenes* vaccine development for various indications
2) Discuss evidence considerations for possible definitive trial endpoints including pharyngitis, skin and soft tissue infection, etc

WHO Activities

- Update of PPC and Roadmap started in collaboration with SAVAC

Update on measles and rubella MAPs

Manufacturing updates

- A phase 1/2 trial in the Gambia demonstrated similar immunogenicity and safety to MR vaccine delivered SC;
- **Ongoing negotiations** between Micron and SII to establish a site and initiate manufacturing;
- Significant **manufacturing challenges** emerge;
- MR-MAPs **unlikely to be available around 2030**

Other updates

- **Phase 2 trial** of the Micron MAP is **planned** in the Gambia, **2026**, larger sample size;
- Vaxxas Phase 2 trial to start in 2027;
- MR-MAP is thermostable– **CTC for 14 days**;
- MAPs not considered in Gavi 6.0, and for TRS revision

WHO Activities

- Ongoing work to identify anticipated evidence to inform policy decision (**ECVP**)
- Identified **priority pre-implementation research** (in review)
- Published an **RFP for priority pre-implementation research**, selected bidders (contract review pending)

Update on AMR

Overall updates:

- Considerations for outcomes and indicators to measure vaccine impact on AMR– in writing;
- Revision of the Global Action Plan on AMR;

***Klebsiella pneumoniae*:**

- TAG on *K. Pneumoniae* established;
- Uni of Wits to develop a roadmap for vaccines against *K. Pneumoniae*;

***E. Coli* updates**

- Phase 3 trial of the ExPEC 9V vaccine to prevent invasive *E. Coli* failed interim efficacy analysis;
- Trial discontinued;
- No safety signals;
- A setback for bacterial vaccines

Salmonella vaccines

Pipeline Updates

***Salmonella* Typhi**
- Phase III – EuTyphC (Philipines, Senegal, Kenya) – approval imminent

***Salmonella* Paratyphi A**
- Phase 1/2 - CVD1902; SII-TCV(B); TYP03/TYP04

Non-typhoidal *Salmonella*
- Phase 2 – TSCV (U. Maryland & Bharat)
- Phase 1/2a iNTS-TCV (GVGH)
- Phase 2a – iNTS-GMMA (GVGH)

Meeting Updates

***Salmonella* Paratyphi A**
- CVD1902 vaccine CHIM completed
- SII-TCV(B) CHIM +Ph2/3 ongoing
- TYP03/TYP04 CHIM+Phase 3 in preparation

Non-typhoidal *Salmonella*
- CHIM for iNTS using diarrheagenic and invasive strains established

WHO Activities

- Regulatory consultation bivalent typhoidal *Salmonella* (July 2024)
- (https://pubmed.ncbi.nlm.nih.gov/40318346)

- Published Typhi/PPC and R&D for bivalent *S.* Paratyphi A & iNTS (https://pubmed.ncbi.nlm.nih.gov/40964609)

- Working with QNS on updating TRS for TCV and conjugate vaccines
- Collaborating with ECBS & partners on the development of *Salmonella* research standards

- Active discussions on combination vaccines (https://www.ivi.int/wp-content/uploads/2025/08/4.-INTS-Combination-Vaccine-Geneva-meeting-report-18FEB2025-FINAL.pdf)

Rotavirus (Next-generation vaccines)

Pipeline Updates

- WHO PQ – Rotarix; RotaVac; RotaSiil; RotaTec
- Licensed – Rota-V-Aid (India; Russia); RotaVin (Viet Nam)
- Phase 1 – CDC9; Zhifey-IRV
- Phase 2** – Sinovac-HSRV; MaxVax; IMBCAMS
- Phase 3 – RV3-BB

Meeting Updates

- Several next-generation vaccines on pipeline
- RV3-BB expected **reg. approval Q12026** for pilot; Q12027 for large scale
- New vaccines in development likely to go through **CHIM** – prioritize products & de-risk investments

WHO Activities

- Increased participation and visibility on Rotavirus vaccine fora
- Update rotavirus vaccine pipeline and information on website (PDR)
- Further discussion in regard to a PPC and R&D Roadmap to follow

Next Generation Cholera Vaccines (NGCV)

Pipeline Updates

NGCVs are being designed to overcome limitations of current killed whole-cell oral cholera vaccines (OCVs), including short duration of protection in young children and global supply shortages. Development focuses on three major platforms:

- **Live-attenuated oral vaccines (PanChol, CVD 103-HgR/Vaxchora™)**
- **Improved killed OCVs (Euvichol-S, Hillchol®, DuoChol)**
- **Cholera conjugate vaccines (CCVs, e.g., OSP:rTTHc)**

Meeting Updates

- **OSP:rTTHc:** Completed **Phase I** adult safety/immunogenicity, yielding immunologic signals (anti-OSP IgG, memory B cells) that support pediatric bridging trials—if field efficacy in infants is confirmed, CCVs could be integrated into routine EPI schedules.
- **PanChol: Phase I** data demonstrate acceptable safety/tolerability and immunogenicity signals in adults, supporting further clinical development.
- **CVC 103-HgR** in use for travelers aged >6 years. Mali trial in endemic population recommended furthering development targeting endemic populations
- **Euvichol-S:** WHO **prequalification granted** and manufacturer scale-up announced together with peer-reviewed safety/immunogenicity and multiple field effectiveness evaluations from outbreak settings showing two-dose protection and variable single-dose effectiveness in emergency campaigns.
- **Hillchol completed phase III in India** with good results for safety and immunogenicity
- **DuoChol** reformulation of Dukoral into easy to handle lyophilized capsules. **Phase I ongoing** and licensure expected by 2028

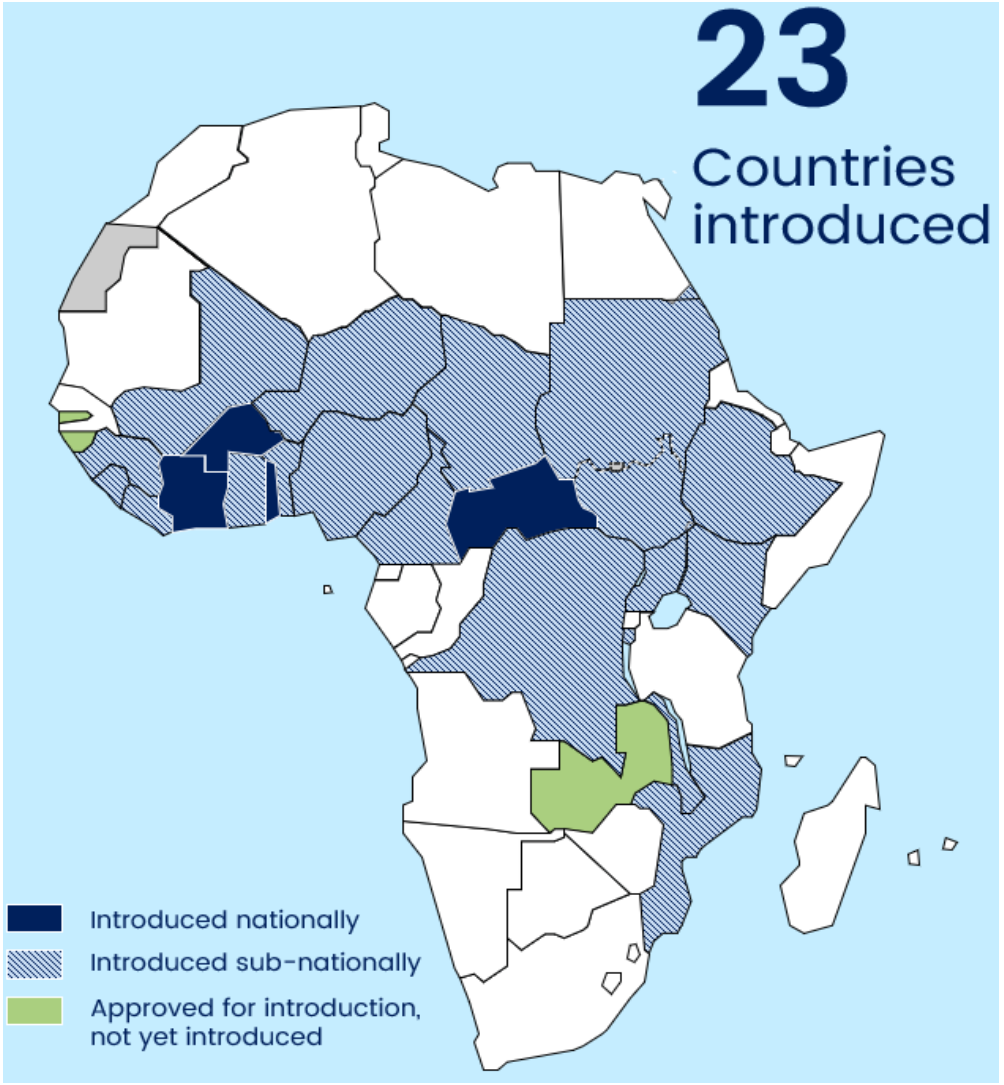
WHO Activities

- Shaping Use Cases and Priority Product Characteristics (PPCs) for Next-Generation Cholera Vaccines
- Enhancing Coordination for Cholera Vaccine Research and Policy Alignment
- Optimizing OCV Campaign Delivery through CTC Implementation and Guidance

Malaria

Status of malaria vaccine roll-out, as of September 2025

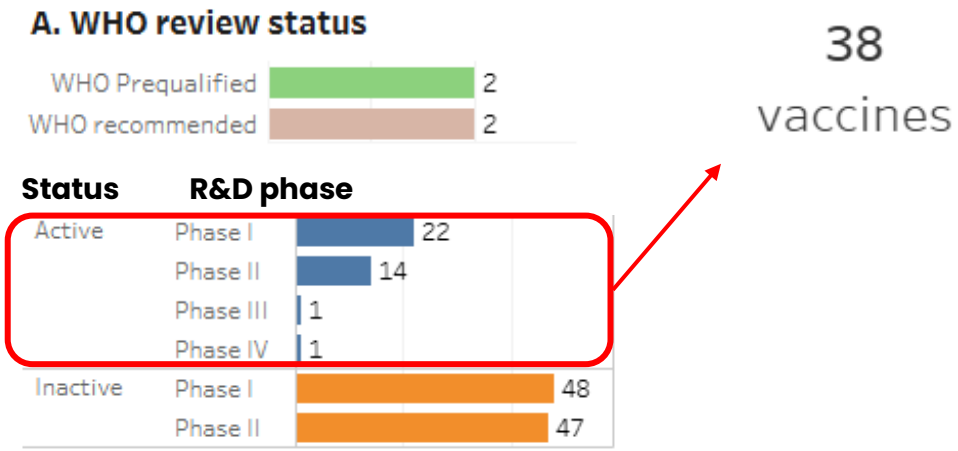
- **23 countries introduced**[1]**:** 4 nationally, 19 sub-nationally. Additional introductions and scale up in 2025 and 2026
- **More than 47 million doses delivered by UNICEF**[2] for a cumulative annual target population of **>10 million children** …rapidly increasing. **Supply sufficient to meet demand.**
- **But, limited geographic reach due to funding constraints:** Gavi support limited to a maximum of **85% vaccine volume for target population** in moderate and high transmission areas. Risk of further cuts due to funding gap for 2026-2030 strategy period
- **Market shaping ongoing:** GSK and Bharat Biotech commit to progressive RTS,S/AS01 price reductions to < US$5/dose by 2028.[3] SII to reduce R21/Matrix-M price (depending on volumes procured)



Sources: [1] WHO Malaria Vaccine Introduction Dashboard (24 Sep 2025) [2] UNICEF Immunization Market Dashboard + doses delivered during MVIP [3[GSK press release (25 Jun 2025)

Malaria vaccine R&D pipeline

WHO malaria vaccine R&D dashboard



Clinical trials by country

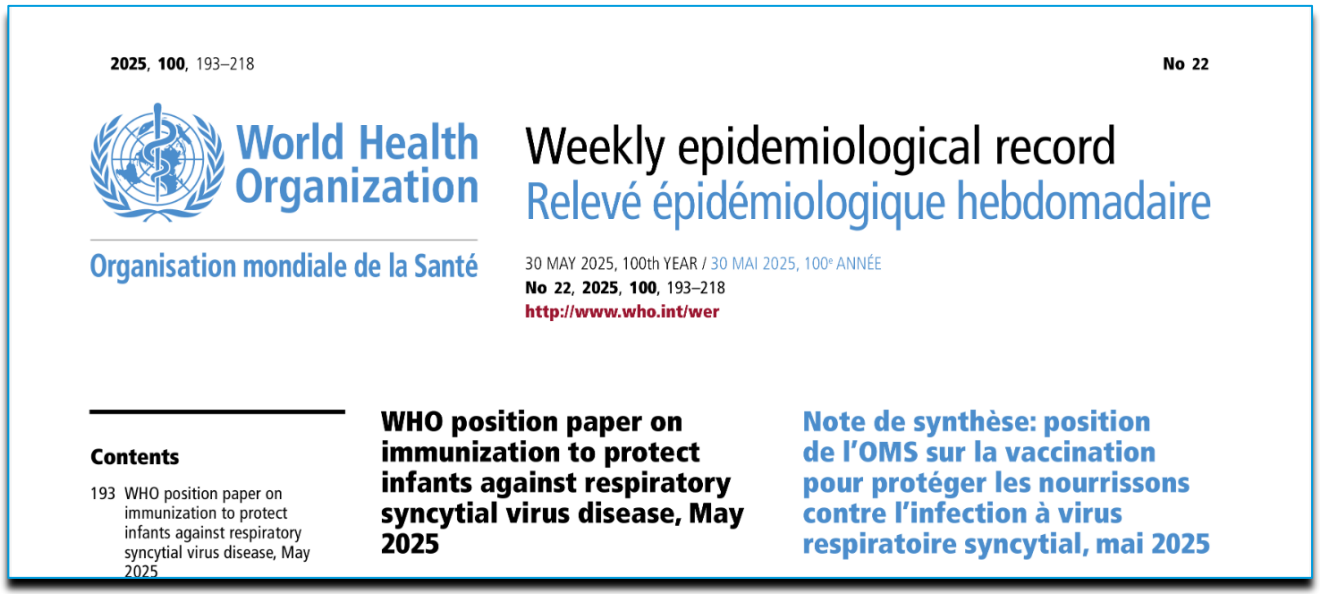
Notable candidates & trials

- **Rh5 prevention of disease & death in young children**
  - Phase 2b Burkina Faso (expected completion 2026)
  - Combined w/ R21 – Phase 1b (expected completion 2025, plans for Phase 2b in 2026)
- **R21 all-age seasonal vaccination** The Gambia & Burkina Faso, SERVAL trial (Phase 3, expected completion Dec 2025)
- **Malaria in pregnancy** (women of child-bearing age)
  - PfSPZ Phase 2 completed
  - R21 Phase 2 planned, Mali
- **Pfs230 transmission blocking with R21** (Phase 2/3 planned)

WHO malaria vaccine research activities 2025-2026

- **Technical consultations on next generation vaccine R&D:** transmission blocking vaccines and modelling-informed preferred product characteristics
- **Shared reference materials** and **lab proficiency testing** for immuno-assays
- **Correlates of protection**: 1) prioritization of biomarkers and assays and 2) harmonized statistical approaches to validate
- Global research agenda on **implementation research**, monitoring **R21 and RTS,S post-licensure research studies**.

Updates on RSV



2025, 100, 193–218 No 22

World Health Organization

Organisation mondiale de la Santé

Weekly epidemiological record

Relevé épidémiologique hebdomadaire

30 MAY 2025, 100th YEAR / 30 MAI 2025, 100e ANNÉE

No 22, 2025, 100, 193–218

http://www.who.int/wer

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193 WHO position paper on immunization to protect infants against respiratory syncytial virus disease, May 2025

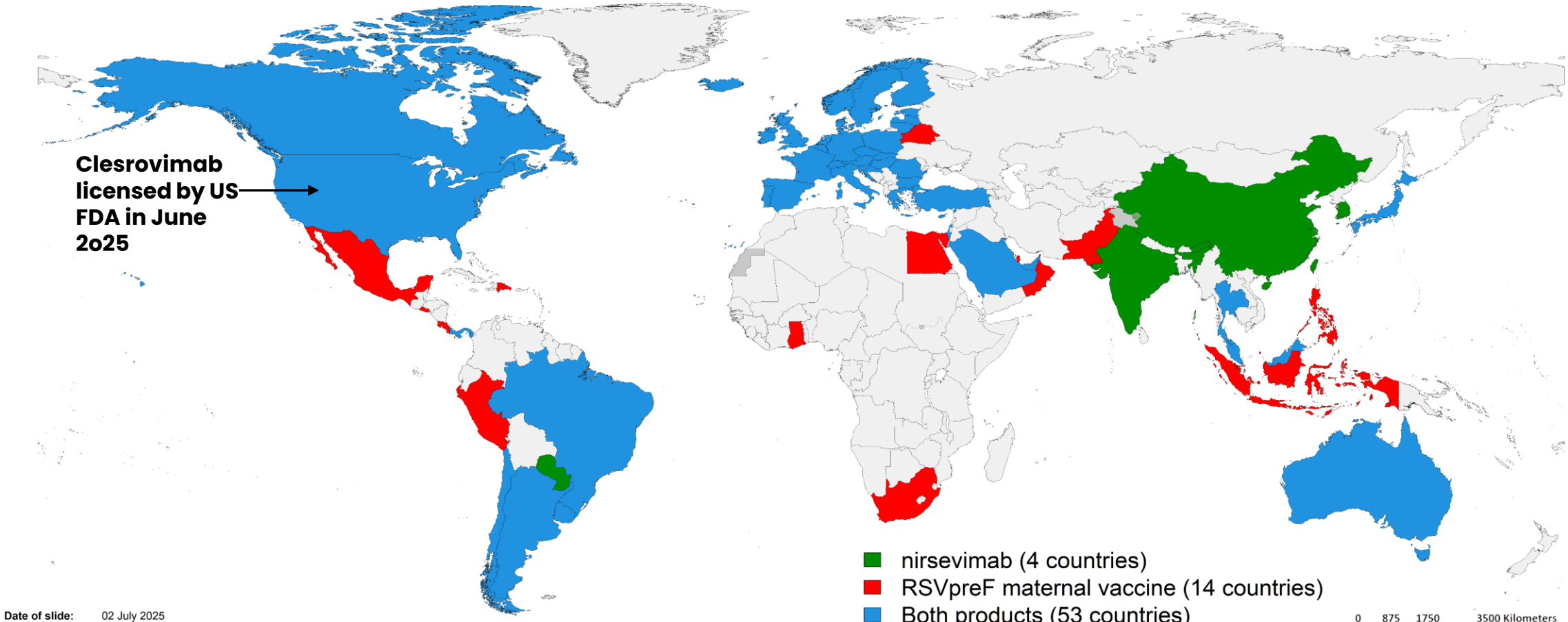
WHO position paper on immunization to protect infants against respiratory syncytial virus disease, May 2025

Note de synthèse: position de l'OMS sur la vaccination pour protéger les nourrissons contre l'infection à virus respiratoire syncytial, mai 2025

WHO position paper on RSV, 30 May 2025:
https://www.who.int/publications/i/item/who-wer-10022-193-218

Maternal RSV PreF SDV prequalified in March 2025:
https://www.who.int/news/item/19-03-2025-who-prequalifies-first-maternal-respiratory-syncytial-virus-vaccine

Global regulatory market authorizations for RSV immunization products to protect infants



Date of slide: 02 July 2025
Map production: Immunization, Vaccines and Biologicals (IVB), World Health Organization (WHO)
Data source: IVB database as at 02 July 2025

Disclaimer:

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area nor of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Country introductions – national programmes

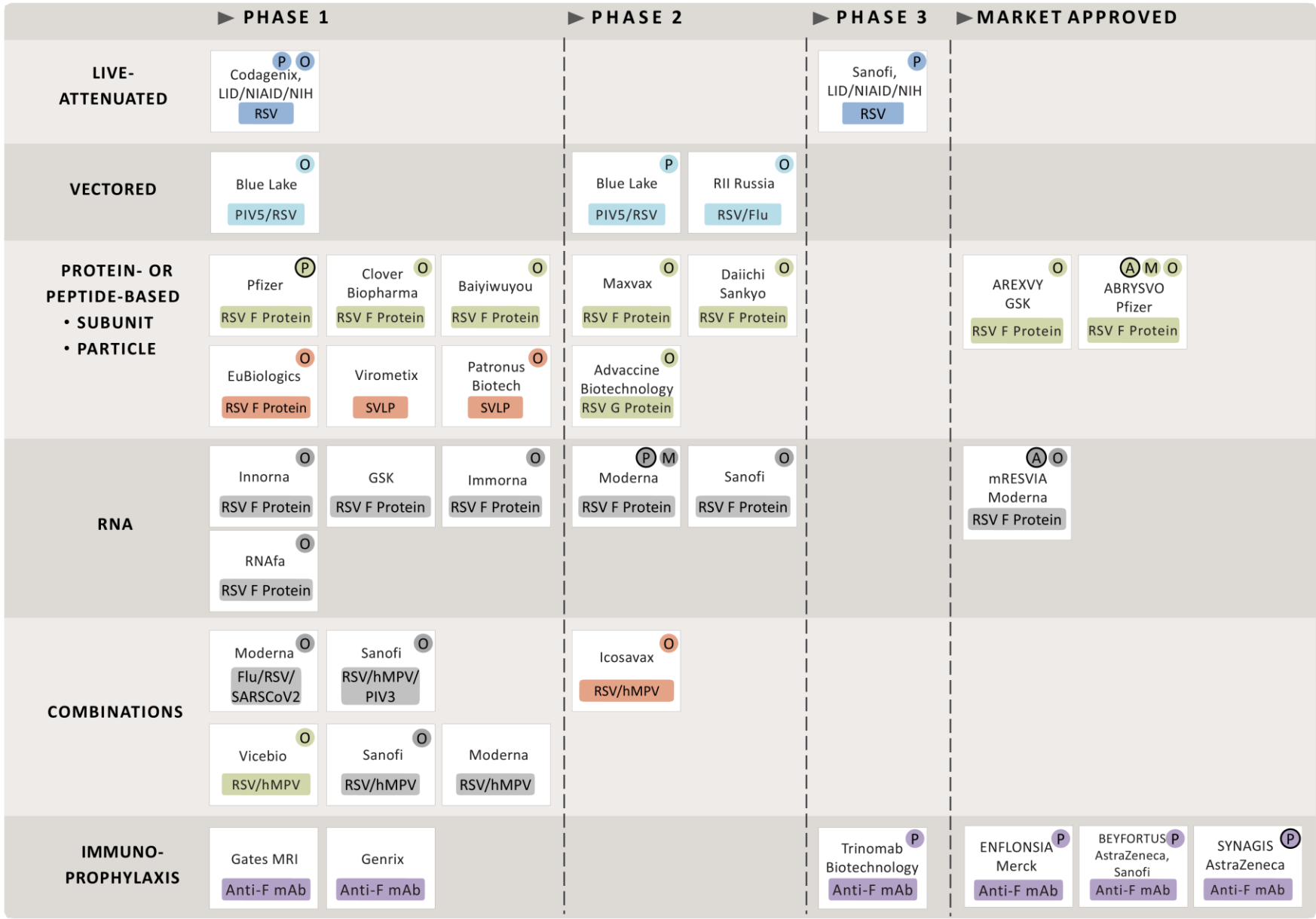
- 73 have licensed these products through their NRAs*
- 24 countries have started to use these products within their national immunization systems (in some other countries products are only available on the private market)*
- The majority of countries are high-income (21 countries) and 3 upper middle-income countries (all in Latin America).
- Use in countries varies: some use maternal immunization as the primary strategy, some the mAb & some both products. Recommendations on when in pregnancy to give the vaccine differ (e.g 24-36 weeks, from 28 weeks, 32-36 weeks gestation); and how the mAb is used (e.g newborns, all-infants, only high-risk)
- No low income or lower-middle Income countries have yet introduced these products
- In July 2026, the Gavi board approved an RSV maternal immunization programme with country introductions expected to start in 2028

* Data provided by manufacturers

RSV Vaccine and mAb Snapshot

P =PEDIATRIC M =MATERNAL ◯ =LIMITED TO INCREASED RISK
A =ADULT O =OLDER ADULT

PLATFORM KEY:
=LIVE/CHIMERIC =mAb
=VECTORED =PARTICLE
=SUBUNIT =NUCLEIC ACID



*SVLP = Synthetic virus-like particle

UPDATED: June 17, 2025

https://www.path.org/resources/rsv-vaccine-and-mab-snapshot/

PATH

Updates on HIV

Pipeline updates

- Breakthroughs have concentrated in bnAbs: bnAb candidates from ViiV healthcare to treat HIV and the CAPRISA to precent HIV (012C) are both in Phase 2. The CAPRISA 012C trial is ongoing; the ViiV trial found the bnAb was safe and effective.
- Long acting ARVs

Meeting updates

- WHO consultation on the use of broadly neutralizing antibodies for postnatal prophylaxis against vertical transmission of HIV, 2024. Meeting report in finalization.

WHO Activities

- PPC for HIV bNAbs published in 2022
- WHO recommends injectable lenacapavir for HIV prevention in May 2025