

ROADMAP SUMMARY

Vaccine Access Roadmap for Ebola Bundibugyo Virus Disease (BVD) outbreak

A plan to support equitable access to vaccines for the BVD outbreak response

LIVING DOCUMENT VERSION 1: NOVEMBER 18 2026

Developed within the Continental Incident Management Support Team (cIMST) Vaccine Pillar

Includes Africa CDC, CEPI, Gavi, the Vaccine Alliance, WHO and UNICEF

Disclaimer

This document does not constitute technical guidance. It provides a high-level overview of current discussions on access pathways for BVD-specific vaccines across different scenarios for the immediate outbreak response, and identifies key access gaps based on past experience. By outlining these pathways, it aims to strengthen coordination and transparency across the ecosystem, particularly for partners supporting the response outside the cIMST. The scope does not entail solving the identified access gaps; this will be undertaken by a range of stakeholders, including those within the cIMST.

This is a vaccine access plan and not a national implementation plan. It covers at a high-level the needs, funding and roles around country readiness and implementation, but does not detail these operational needs, which are expected to be led by national governments and implementation partners.

This is a living document, which will evolve as the outbreak and clinical development progress, and we receive further inputs. Feedback from stakeholders is welcome at abd@cepi.net so that it can support the next version.

AI tools were used to support the proofreading and design of this document.

Acknowledgements

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The Democratic Republic of Congo stakeholders across Autorité Congolaise de Réglementation Pharmaceutique (ACOREP), National Immunization Technical Advisory Group (NITAG) and EPI were consulted across different initiatives and will be further engaged extensively to inform assumptions.

We would like to thank the following partners for their inputs:

- **Tumaini clinical trial consortium**: Institut National de la Recherche Biomédicale (INRB), University of Antwerp (Global Health Institute) and the Institute of Tropical Medicine Antwerp (ITM)
- **Regulators** via the joint ACOREP-AMA-EMA-WHO platform (AMA - Africa Medicines Agency; EMA - European Medicines Agency)
- **Policy**: WHO Regional Office of Africa (AFRO) Regional Immunization Technical Advisory Group (RITAG)
- **Implementation partners**: Médecins Sans Frontières (MSF) and The International Federation of Red Cross (IFRC)
- **Vaccine developers & manufacturers** including University of Oxford, Serum Institute of India, Moderna, IAVI, Public Health Vaccines, Hilleman Laboratories, Minapharm Pharmaceuticals
- **Other Medical Countermeasure Funders**: UNITAID and The UK Foreign, Commonwealth and Development Office (FCDO)

Further consultations with other high-priority countries, civil society organisations and stakeholders working on BVD response will continue over the next few months, and an updated version will be added if needed to reflect the significant changes.



Picture: A participant is enrolled on the first day of the Tumaini trial in Bunia, Democratic Republic of the Congo.

Credit: © WHO/Dany Bitita

Equitable access to vaccines in the context of the Bundibugyo outbreak means that safe, efficacious and suitable vaccines are available in a ***timely*** *manner and in* ***sufficient*** *volumes, reaching affected populations that need them,* ***regardless of ability to pay****.*

EXECUTIVE SUMMARY

The outbreak of Bundibugyo virus disease (BVD) and subsequent declarations of a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC have triggered a large-scale, nationally led outbreak response supported by regional and global stakeholders. In support of the response, the accelerated development of vaccine candidates against BVD is underway. The aim is to develop safe and efficacious vaccine(s) against BVD that are available, acceptable and usable to help control this outbreak and strengthen preparedness for future ones.

Communities, countries and regional and global partners must, together, advance vaccine development while simultaneously planning for access including evidence needs for policy decisions, regulatory processes, manufacturing, financing and implementation. These activities and decisions must proceed now, navigating the trade-offs and risks associated with the inherent uncertainty both about the outbreak's trajectory and about clinical and regulatory outcomes.

This access roadmap identifies, based on previous experiences, the most critical access priorities and risks; maps progress; and recommends actions by ecosystem partners to address major gaps. Its objective is to build a common approach to enabling access amongst the many partners involved so that vaccine R&D can be translated rapidly into accessible, accepted and implementable vaccination in BVD-affected communities.

This roadmap focuses on vaccine response needs. Separate BVD therapeutics access roadmaps have been developed by Unitaid with WHO, Africa CDC, CEPI and other partners in the PHEIC/PHECS response to identify and anticipate access barriers, so that validated tools reach populations in need without delay. As the therapeutics landscape is evolving rapidly, the latest versions are available at www.unitaid.org.

Why a BVD vaccine access roadmap is needed

- Clinical trials to evaluate vaccine candidates against BVD are rapidly progressing. Tumaini, a pivotal Phase 2/3 clinical trial of BVD vaccine candidates is underway[1]. **In parallel, work to strengthen readiness to access and deploy vaccine doses across different scenarios must now be accelerated,** so vaccines are used as quickly as possible when the data support it.
- **Lessons learned from past epidemics and pandemics, including COVID-19, mpox and previous Ebola outbreaks**, demonstrate the importance of ensuring that equitable access is planned from the outset of vaccine development and coordinated across the end-to-end value chain.
- **No organisation can achieve access alone**. This access roadmap prioritises needs across the ecosystem and maps the pathway to equitable access

1 First participant vaccinated in pivotal Phase 2/3 Bundibugyo vaccine trial in DRC https://cepi.net/first-participant-vaccinated-pivotal-phase-23-bundibugyo-vaccine-trial-drc

Recommendations for governments, vaccine response partners and funders

Partners have identified the following urgent priorities on access to vaccines against BVD:

- **Sustain clinical trial momentum and inclusion of special populations:** Completing the Tumaini Phase 2/3 trial and ensuring availability of data that can enable access remains key. Specifically, generating evidence in special populations, including pregnant and lactating women, children and immunocompromised people is critical, to ensure that these populations are not inadvertently excluded from timely access to an efficacious vaccine[2].
- **Continue to prioritise risk communication and community engagement and integrate social and behavioural science into trials and beyond:** DRC, UNICEF, Africa CDC, WHO, IFRC and other partners are conducting community engagement activities for clinical research associated with the outbreak. The Tumaini trial also incorporates social and behavioural science research, led by the Institute of Tropical Medicine Antwerp (ITM), and community engagement, led by Institut National de la Recherche Biomedicale (INRB) and Africa CDC, to build trust and inform trial design. Sustained systemic engagement led by local institutions and by trusted community leaders to build long-term vaccine confidence beyond clinical trials will remain critical.
- **Prepare urgently for any expanded access[a] use of vaccines:** Sponsors need to be identified, a protocol developed, country readiness needs identified and funding allocated as a matter of urgency.

> *a* Note: The term Expanded Access (US/FDA) refers to use of a vaccine following evidence of efficacy but before a formal regulatory determination; this will be used throughout the document encompassing the parallel term 'Compassionate Use' (EU/EMA). Further context on the terms is provided in the WHO document on Monitored emergency use of unregistered and experimental Intervention (MEURI).

- **Streamline regulatory pathways and prioritise evidence needs for timely SAGE and NITAG policy recommendations:** Outline sequencing and conditions for national and global regulatory authorisations and policy recommendations for use of the vaccines and their implementation strategies. National recommendations and regulatory authorisations are contingent for access to doses and should be recognized as independent of other regulatory processes to foster vaccine confidence.
- **Ensure that product liability and indemnification (I&L) is not a barrier to access for post-trial use of BVD vaccines across different regulatory scenarios:** While vaccine manufacturers hold liability for vaccine use post full licensure, prior use may require bespoke I&L mechanisms. This includes insurance held by the sponsor for any expanded access protocols for use of investigational BVD vaccines, and any indemnification mechanisms to be agreed with countries for emergency use. All these efforts must take into account delivery to humanitarian populations of concerns, and I&L waivers should be sought for humanitarian organizations who will be delivering vaccinations.
- **Incorporate programmatic suitability considerations into vaccine funding decisions:** A WHO Target Product Profile (TPP) is available for BVD vaccines and the WHO Technical Advisory Group on Candidate Vaccine Prioritization (TAG-CVP) has prioritized vaccine candidates for the Tumaini trial[3]. In addition, developers, manufacturers and funders will assess further investments in R&D, manufacturing and procurement. All these efforts must consider local perspectives to ensure that vaccines remain programmatically suitable for deployment under outbreak conditions in the Democratic Republic of the Congo (DRC) and other high-priority countries.
- **Define and communicate assumptions around a multi-country allocation mechanism** for future BVD vaccines as a contingency measure, applying lessons from previous outbreaks.

2 https://www.who.int/news-room/events/detail/2026/10/05/default-calendar/strategic-advisory-group-of-experts-on-immunisation-october-2026
3 Two new candidate vaccines to join Ebola trial as treatment research advances https://www.who.int/news/item/04-11-2026-two-new-candidate-vaccines-to-join-ebola-trial-as-treatment-research-advances

- **Ensure country-level operational readiness** to authorize, receive, deliver and administer vaccine doses, including timely NRA authorisations, NITAG policy recommendations, training of healthcare workers, storage of vaccines, safety surveillance, monitoring and reporting, coverage, effectiveness and impact monitoring, development of demand, communication and community mobilization strategy and materials, etc. A clear and coordinated **guidance on vaccination strategies** is also needed to ensure planning around vaccine supply and deployment needs.
- **Integrate special access approaches for humanitarian populations of concern:** Some communities will need tailored access approaches, including humanitarian channels – such as those run by UNHCR and humanitarian partners – rather than relying solely on national delivery mechanisms. Lessons from challenges faced by the COVID-19 humanitarian buffer, as outlined in this joint report, should be leveraged to define a concrete strategy for access to BVD vaccines for these populations.
- **Continue efforts to improve country-level active surveillance and community listening systems** to support access for affected communities and populations and enable a more effective outbreak response.
- **Coordinate access efforts across all medical countermeasures:** Together with partners working on therapeutics and diagnostics, it is acknowledged there are several common areas for vaccines, therapeutics and diagnostics access roadmaps, and the urgent need to continue and reinforce collaboration, particularly on regulatory pathways, financing needs, joint procurement mechanisms and aligned community engagement messages.





Photo: *Arrival of ChAdOx vaccine doses in Kinshasa, DRC on 10th Nov 2026 for the Tumaini trial. © INRB*

Summary of Access Objectives and Current Status

A detailed assessment of access risks across the end-to-end vaccine chain has identified the following objectives for vaccine access, and the current progress.

1 Clinical development

Objectives

- Trials advanced rapidly for evidence generation
- Access embedded in trial design, including data for special populations
- Suitability, acceptability and trust in affected communities prioritised, including RCCE/SBS
- *Aspirational: Broadly protective vaccine candidates advanced*

Progress

- ✓ Tumaini started 23 Oct with Ervebo; two BVD-specific vaccines recommended to enter by WHO TAG-CVP
- ✓ Phase 1 enrolment complete for two candidates; Phase 1b in Uganda (underway for U.Oxford and expected for Moderna)
- ✓ Special populations included in Tumaini Phase 2/3 trials

Uncertainties

- ? Vaccine efficacy against BVD
- ? Programmatic suitability for deployment

2 Regulatory

Objectives

- Authorisation conditions clarified early; streamlined joint reviews
- Timely NRA Emergency Use Authorisations and WHO EUL
- Timely marketing authorization/ full licensure in all high-priority countries and WHO PQ
- Safety monitoring in place before deployment
- *Aspirational: AMA recommendations provided, DRC NRA reaches ML3, at least one WLA in Africa*

Progress

- ✓ Joint ACOREP-AMA-EMA-WHO, EMA platform for streamlined reviews

Uncertainties **Gaps**

- ? Reference authority per candidate and expedited review mechanism
- ? Regulatory approval of the expanded access protocol

3 Policy

Objectives

- Evidence generation for SAGE and NITAG, with clear triggers for expanded access protocols and emergency use (BVD specific vaccines) or off-label (Ervebo)
- Evidence generation to support recommendations on vaccination strategies

Progress

- ✓ WHO developing protocol for expanded access

Uncertainties **Gaps**

- ? Timing of efficacy signal and SAGE recommendation trigger for expanded access use
- ? Vaccination strategy - ring vs broader vaccination
- ⚠ Expanded access funding and roles including sponsor, insurance and evidence generation strategy

4 Manufacturing

Objectives

- MAH identified for each candidate before Phase 2/3 trials
- Timely at-risk scale-up of doses in sufficient quantities
- Price post-licensure supports equitable access
- African manufacturing incentivised

Progress

- ✓ MAHs for two lead candidates and manufacturing pathways for multiple forthcoming candidates in place
- ✓ Initial modelling estimates available to inform outbreak supply needs in 2027
- ✓ Gavi APCs nearing finalisation

Uncertainties

- ? Supply of Ervebo if needed beyond current stockpile (pending efficacy against BVD)

5 Funding, Procurement and Allocation

Objectives

- Push and pull funding to incentivize EUL/PQ
- Product Liability and Indemnification not a barrier to access
- Multi-country vaccine allocation mechanism defined
- *Aspirational: long-term stockpiles funded*

Gaps

- ⚠ Insurance for expanded access use
- ⚠ I&L needs for emergency use post WHO EUL, including any indemnification mechanisms and I&L waivers for humanitarian organisations
- ⚠ Vaccine allocation mechanism

6 Country Readiness and Implementation

Objectives

- Surveillance and contact tracing sustained
- Plans and funding for country operational readiness and deployment available
- Tailored strategies for access to humanitarian populations of concern
- Routine immunisation protected and sustained
- *Aspirational: novel community engagement approaches*

Gaps

- ⚠ Operational readiness plans for vaccine deployment under different scenarios
- ⚠ Deployment funding
- ⚠ Strategies for humanitarian populations
- ⚠ Role/ use case of vaccines vs PEP

Full Access roadmap with tentative timelines and roles

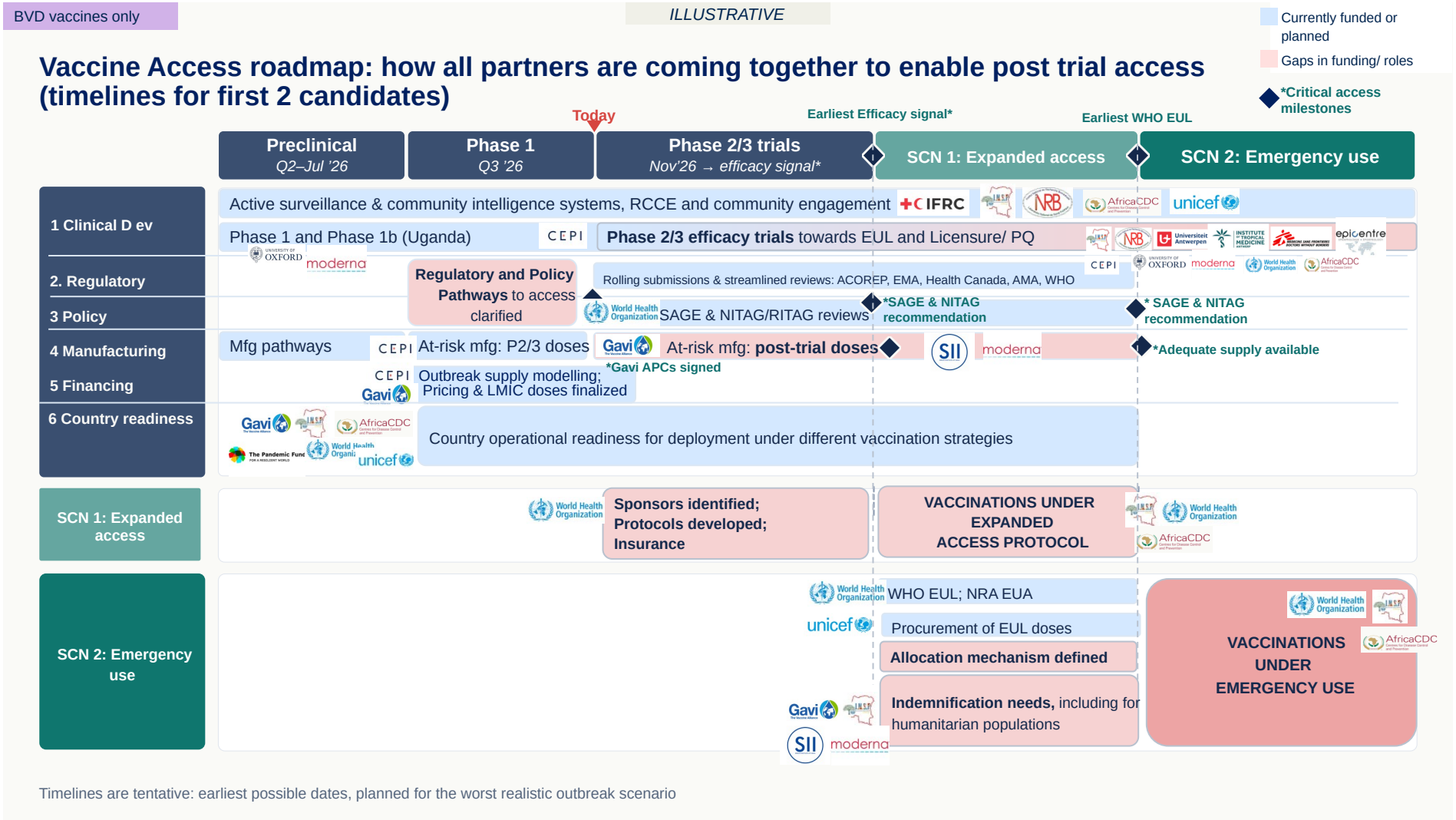


Figure 1: Illustrative Vaccine Access Roadmap

A Detailed Roadmap outlining risks, interventions and roles across the six access components is also available on the webpage