

DETAILED ROADMAP

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.

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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.

Contents

Executive summary: see the Roadmap Summary document

A INTRODUCTION 4

B ERVEBO ACCESS NEEDS FOR BVD 7

C APPROACH AND METHODOLOGY 8

D KEY ACCESS OBJECTIVES, INTERVENTIONS & ROLES 9

1 Clinical Development 9

2 Regulatory Approvals 13

3 Evidence-Based Policy Recommendations 16

4 Manufacturing and Supply 19

5 Financing, Procurement and Allocation 22

6 Country Readiness & Implementation 25

Annexes 30

A Examples of equitable access provisions covered under CEPI investments 30

Abbreviations and acronyms 31

References 33

A INTRODUCTION

Key Terminology

Bundibugyo virus (BDBV) is a different virus than Zaire Ebola virus (i.e. different species and not a variant). It causes Bundibugyo virus disease, a severe and often fatal viral haemorrhagic fever. Previous Bundibugyo outbreaks in 2007 and 2012 have had case fatality rates of 30 percent and 50 percent respectively, suggesting this virus has around the same lethality as the Zaire ebolavirus species which caused the 2014 – 2016 epidemic in West Africa.

The four Orthoebolaviruses that cause illness in humans:

- Ebola virus (EBOV; species *orthoebolavirus zairense*) causes Ebola virus disease (EVD) [commonly referred to Ebola-Zaire]
- **Bundibugyo virus** (BDBV; species *orthoebolavirus bundibugyoense*) causes Bundibugyo virus disease (BVD)
- Sudan virus (SUDV; species Orthoebolavirus sudanense) causes Sudan virus disease (SVD).
- Taï Forest virus (TAFV; species Orthoebolavirus taiense) causes Taï Forest virus disease (TFVD).

Investigational reserves (IR): Unlicensed, investigational clinical trial-grade vaccine/mAb doses that are produced according to GMP and held in reserve for use in clinical trials during an outbreak (under a research protocol)[a].

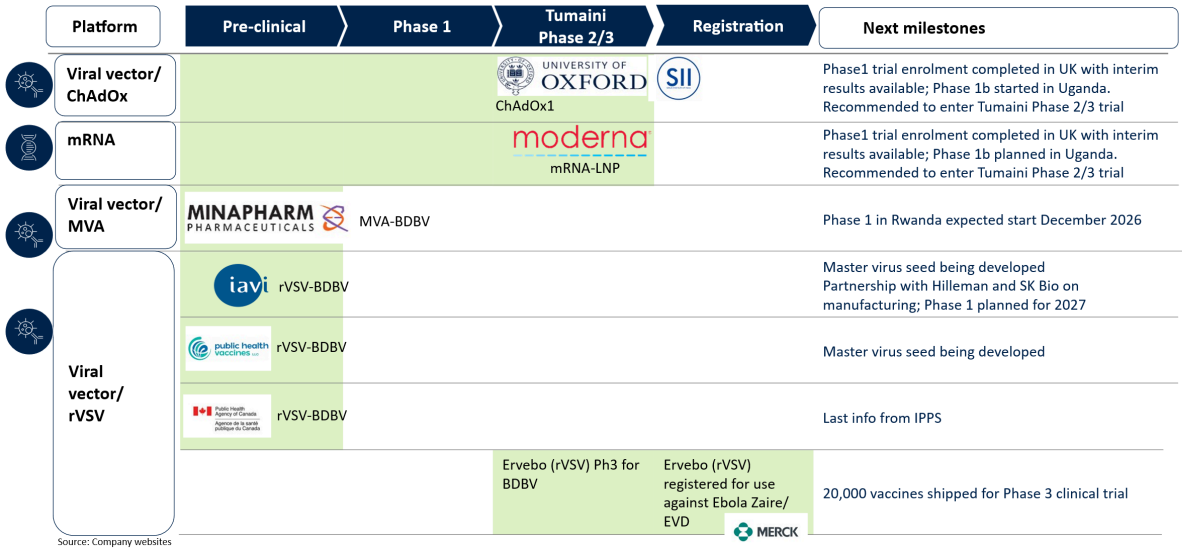
[a] NOTE: These reserves are made "ready" for outbreaks when: the reserves are held in formats and locations that facilitate rapid mobilization in the event of an outbreak; the roles and responsibilities of all actors are clear, and operational plans are in place to fulfil these responsibilities in an emergency; a sufficient number of doses to start a clinical trial are vialled with adequate stability; AND plans are in place for logistics, (re)labelling, and additional fill/finish as necessary.

(Licensed) Stockpile: Commercial material or emergency authorised products held in stock for use in public health emergencies. Other terms used may include 'safety stock.'

1 Background

On May 17, 2026, WHO declared an outbreak of Bundibugyo Virus Disease in the Democratic Republic of the Congo (DRC) a public health emergency of international concern (PHEIC), and Africa CDC declared a Public Health Emergency of Continental Security (PHECS) the following day[1]. The outbreak is the largest Ebola outbreak reported in the DRC[2,] and the second largest on record with high risk of regional spread. As of today, there are no licensed therapeutics or vaccines against Bundibugyo virus disease (BVD). In response, a diverse portfolio of vaccines has been rapidly advanced.

The current BVD vaccine development pipeline includes six investigational candidates across four vaccine platforms, and Ervebo licensed against EVD, as shown in Fig 2.



Sensitivity: Official Use

Figure 2: BVD Vaccine Development Pipeline

2 Roadmap Vision & Objectives

The Bundibugyo Virus Disease (BVD) vaccine access roadmap maps a coordinated pathway to enable equitable access to BVD specific vaccines - outlining what is needed, by when and by whom — across the full vaccine value chain.

The roadmap will enable this vision by:

- **Identifying critical equitable access objectives and enabling transparency**, so that relevant stakeholders can assess priorities and avoid duplication of funding and resources;
- **Serving as a call to action for governments, industry**, funders and global organisations to prioritise the critical access needs;
- **Linking the upstream R&D and downstream access work** on vaccines and other medical countermeasures, and ensuring continuous feedback loops between countries, regional and global partners;
- **Facilitating smooth transitions** between R&D and partners by sharing assumptions and enabling readiness.

3 Strategic questions the access roadmap aims to address:

There are several uncertainties and risks to equitable access for BVD vaccines that the roadmap interventions aim to incorporate:

1. How can vaccine development and manufacturing scale-up efforts line up so that regulatory authorisations are available as quickly as possible to ensure **timely and adequate supply of quality, safe, effective and programmatically suitable vaccines?**
2. When doses are available, how can they be made **accessible to affected and high-priority populations in line with agreed immunisation strategy**, including acceptability of vaccines, vaccine uptake and delivery considering the high number of 'unknown' contact cases, humanitarian contexts, insecure areas and remote populations?

3. At every step, how can **feedback from countries, communities and implementation partners** shape the access approach and inform trade-offs early?
4. How can the vaccine access work fit within the broader response, **being led by local institutions and African organisations**, in a way that it protects existing health services, including routine immunisation, and enables vaccine confidence and capacity building for long-term preparedness?
5. Which **scenarios** in terms of the outbreak trajectory, vaccination strategies and role of different medical countermeasures (MCMs) should be considered to ensure access in the Democratic Republic of Congo (DRC) and other high-priority countries, in the case of cross-border transmission?
6. How should investment priorities, outcomes and activities be weighed against breadth, depth, and **sustainability of access to enable preparedness for future outbreaks**– i.e., what is the impact of short-term decisions on long-term access and sustainability?

4 Scope and limitations of the roadmap

For version 1 - the immediate focus and current scope of the roadmap is equitable access to monovalent BVD vaccines for the outbreak in DRC. Given the high risk of spread to neighbouring countries, the roadmap scope is intended to evolve with the outbreak. Over the medium to long-term, the scope is expected to expand to include the full BVD vaccine portfolio, a move to a licensed stockpile and (if technically feasible) transition to multivalent and/or broadly protective candidates to support sustainability and preparedness across filoviruses.

Ervebo access requirements are outlined in Section C, rather than the different components in the roadmap. This is because Ervebo is currently available for its indicated use of prevention against EVD and the access requirements are distinct from those for novel BVD vaccines given the ready availability of product supply.

While the roadmap focuses on needs for *vaccine* access, equitable access to all medical countermeasures (MCMs) is critical to support early detection, reduce morbidity and mortality, protect health workers, and help break transmission chains. Key synergies that are being explored in parallel:

- Standardizing and sharing information across different MCMs (e.g., on modelling assumptions);
- Scenario mapping across MCMs– i.e., how does the lack of availability of one MCM impact needs for another, how do post-exposure prophylaxis and therapeutics trial outcomes impact vaccine development pathways and use, and what are the ethical and regulatory considerations across different scenarios.

This roadmap does not cover all operational and detailed mechanisms to solve access needs highlighted; rather it provides an end-to-end framework to identify critical gaps to be solved as a priority, by when and by whom, especially highlighting where there are funding or ownership gaps. For example, the roadmap does not detail country readiness and implementation needs, which are being developed by countries and regional partners.

Confidentiality around access obligations: As part of CEPI's investments, there are equitable access commitments from developers and manufacturers embedded into contractual investments. Annex A outlines typical provisions, including data sharing on clinical trial results, affordable and sustainable pricing, preparedness and response obligations, continuity and step-in rights, etc. These are phased by vaccine development stage: for example, phase 1 agreements may focus on data sharing and continuity rights while pricing and allocation requirements are introduced during Phase 2/3 agreements. Due to confidentiality clauses, CEPI is not able to share the specifics of these agreements in a public document.

B ERVEBO ACCESS NEEDS FOR BVD

Technical Guidance and Policy recommendations: On 31st July 2026, the WHO TAG-CVP reviewed data and recommended that Ervebo should be evaluated in a Phase 3 clinical trial[3]. Africa CDC's Emergency Consultive Group (ECG) emphasized that more evidence is needed on the efficacy of Ervebo in preventing BVD but has prioritised use for healthcare workers[4]. Guidance from the Strategic Advisory Group of Experts on Immunization (SAGE) on the use of Ervebo states that there is insufficient evidence to support the programmatic use of Ervebo for the prevention of BVD. If broader use is pursued before results from the Tumaini trial become available, WHO recommends that it be implemented only within the context of a research protocol and accompanied by a comprehensive risk-mitigation plan.[5] Since then, based on a request by DRC, the International Coordinating Group (ICG) on Vaccine Provision released 70,000 doses from the Ebola vaccine stockpile, of which the DRC MoH will use 20,000 doses as part of the Tumaini trial and 50,000 doses for vaccinating frontline and healthcare workers in high-risk areas under a research protocol.

Evidence generation: The Tumaini trial is expected to provide evidence which is essential for policymakers to inform future use of Ervebo in BVD outbreak settings. [6] The first participant has been vaccinated with Ervebo in Tumaini on October 23, 2026[7]. The platform trial will allow several candidate vaccines to be evaluated in parallel, starting with Ervebo.

Policy recommendations and registration: If efficacy of Ervebo against BVD is shown in Tumaini, SAGE could recommend that Ervebo be used more broadly. Although recommended by SAGE, such use of Ervebo would be off-label based on country decision, unless the manufacturer seeks a label extension to include an indication for prevention of BVD.

Supply & allocation of doses: The ICG stockpile contains doses that can be made available to any country undergoing an Ebola Zaire or potentially other filovirus outbreak. The stockpile has a target quantity of 500,000 doses, but allocation for outbreak response and prophylactic vaccination campaigns can cause this quantity to drop before scheduled replenishments. Additional vaccine exceeding stockpile supplies may require waiting for replenishment, arranging out of cycle deliveries and/or productions with the manufacturer, or seeking supply from other stockpiles. Access and allocation of doses is determined by the International Coordinating Group (ICG).

Funding: Additional supply needs for Ervebo doses towards BVD beyond the existing stockpile will need fundraising by Gavi, the Vaccine Alliance.

Community engagement: There is an urgent need to understand community perspectives on use of Ervebo; SAGE recommends that any use of Ervebo against BVD should be accompanied by a carefully designed, culturally appropriate, risk communication and community engagement strategy, supported by social listening and adapted to the local social and cultural context and evolving epidemiologic and social context. It is key that the people offered the vaccine, receive explicit information of the risks given that the efficacy against BVD is unknown, the potential benefits and limitations related to the use of the vaccine in an outbreak of BVD and can provide informed consent[8]. An important consideration is clear messaging for communities where the three vaccination approaches (Tumaini, healthcare workers and possible future off-label use) may occur within a short time span, to explain clearly why some populations may not be eligible for vaccination to minimize or mitigate any perceptions of unfair or unequal administration. UNICEF with support across partners, is currently supporting DRC in their efforts on effective risk communication and community engagement strategies.

C APPROACH AND METHODOLOGY

This roadmap outlines key components of equitable access for BVD vaccines, across three layers — access to the vaccine products, access to enabling systems, and sustainable access. For each component, key risks, interventions to address them, and roles & responsibilities are identified.

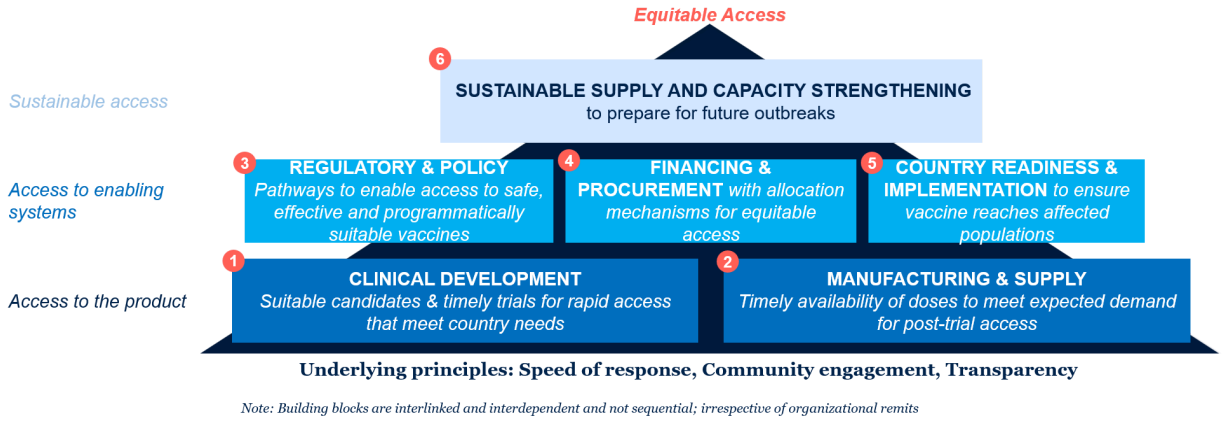


Figure 3: Key components of equitable access

Regional Coordination and Learning

Africa CDC and WHO AFRO will co-lead regional coordination of the roadmap for the current outbreak and to support learning for future outbreaks, including connecting member States, partners and regional institutions to strengthen coordination, share implementation experience and ensure African lessons and priorities inform the evolution of the roadmap.

Operationalisation and Monitoring

The roadmap recommendations and key access priorities were reviewed with the IMST leadership and the iMCM-net Principals. Operationalisation of the gaps will continue in the cIMST vaccine pillar, and other relevant engagements. Key learnings will be fed back to the iMCM working group to support future preparedness efforts.

D KEY ACCESS OBJECTIVES, INTERVENTIONS & ROLES

1 CLINICAL DEVELOPMENT

Programmatically suitable candidates & timely trials that meet country needs

Key access objectives for clinical development are:

a. Clinical trials advanced rapidly for evidence generation to support outbreak response

b. Access embedded in trial design (*trial sites, inclusion of special populations, national sponsor, local researchers & institutions, trial transparency*)

c. Vaccine suitability, acceptability & trust in affected communities prioritized (*vaccines meet WHO TPP critical criteria and are programmatically suitable for deployment in affected countries; social behavioural science & risk communication and community engagement/* RCCE *conducted early*)

d. *Aspirational goal:* Broadly protective/ multivalent candidates advanced; vaccines meet *preferred* WHO TPP characteristics

Background & access risks

Access Risk #1: Delayed access to safe and effective vaccines, including for special populations, limit the opportunity to curtail the outbreak.

There can be no access without a product, and the faster doses become available the faster an outbreak can be curtailed, assuming a product is safe and efficacious and then can be used as part of the broader public health response. Vaccine clinical trials have started at pace across a diverse candidate portfolio, helping to manage technical risk. A broader portfolio including additional candidates beyond the first two vaccines offers resilience if any single candidate does not progress. As of 26 October, two investigational vaccine candidates completed enrolment in phase 1 clinical trials, with initial safety assessment available while others are in preclinical development (see Fig 2).

To rapidly assess safety, immunogenicity and efficacy of candidates prioritised by the TAG-CVP, an adaptive, randomized, controlled Phase 2/3 platform trial (Tumaini) has started[9]. This adaptive platform trial allows several vaccine candidates including Ervebo[b] to be evaluated in parallel within a single trial framework, which saves valuable time during an outbreak. The Institut National de Recherche Biomédicale (INRB) and the University of Antwerp (Global Health Institute) lead and co-sponsor the Tumaini trial. A core clinical trial protocol has been developed, led by the WHO Clinical Trials Writing Group, the trial sponsor and consortium partners, with support from WHO and CEPI. For timeliness, the phase 2 run-in and safety review is in parallel to Phase 3 recruitment. Technical details are available on ClinicalTrials.gov

(NCT07842107)[c]. The WHO TAG-CVP has recommended adding two new investigational BVD-specific vaccine candidates to the ongoing Tumaini clinical trial in the DRC, that includes ChAdOx1, developed by the University of Oxford with the Serum Institute of India, and Moderna's mRNA-1469[10].

b Note: Ervebo is already licensed for EVD and is being assessed for efficacy against BVD, as outlined in section C

c Note: Tumaini is a randomized, blinded, active-controlled adaptive platform trial. The trial will enrol through ring vaccination, which includes contacts of confirmed BVD cases. Eligible participants are randomised to receive a candidate vaccine or an active comparator (a Typhoid vaccine) on Day 1. On Day 29 all participants receive the alternative intervention, so that every participant is offered a candidate vaccine while the comparison between groups remains blinded.

Generation of evidence on vaccine safety and efficacy in special populations is critical to inform policy recommendations, especially for children and pregnant and lactating women. Inclusion of special populations has historically followed initial clinical trials, and their inclusion into initial, pivotal clinical trials requires careful, contextualised justification. A stepwise approach for such inclusion in the clinical trial protocol has been approved by ACOREP:

- **Age**: Children are among those hardest hit by the Ebola outbreak in certain regions. Children over one year of age are included in the Tumaini protocol. For vaccine candidates not licensed in younger children, enrolment of children under 12 years is subject to the availability of supportive Phase 1/2 data in the relevant age group and recommendation by the WHO TAG-CVP. Both Moderna and Oxford are planning Phase 1b studies in Uganda with age de-escalation to be conducted in parallel to the Phase 2/3 to generate this supportive evidence. Mitigation strategies are needed to prepare for a scenario where evidence is not be generated in sufficient time for children to be included in the Moderna and Oxford arms of the trial.
- **Women of childbearing potential (defined as age 15–45 years),** including those pregnant and breastfeeding, are included in the Tumaini protocol. Known contraindications of a specific vaccine in pregnant women will exclude them from receiving that specific vaccine. Further follow up for pregnant women is planned.
- **Immunocompromised people:** Subjects with known or suspected immunosuppression will be included in the trial and vaccinated where feasible based on the profiles of individual vaccine candidates.

Enabling access to research data in an outbreak is critical for evidence informed decision-making. As part of its investment obligations and in line with international trial funding standards, CEPI-funded vaccine candidates have made a commitment to register trial results (including negative clinical trial results) in a register listed on the WHO International Clinical Trials Registry Platform (ICTRP)[11]. In outbreak contexts, developers are expected to rapidly and responsibly share interpretable results, including negative results, with national Ministry of Health or equivalent in the countries where trials are held, as well as submit clinical trial data for publication within thirty days after study completion in an open sharing platform. CEPI also plays a facilitating role to support the outputs of trials to inform global and regional decision-making.

Access Risk #2: Lack of vaccine programmatic suitability may limit uptake and can create barriers to access

Vaccines advanced for trials must include country inputs around programmatic suitability.

The WHO Target Product Profile for BVD vaccines[12] details the preferred and critical criteria for vaccines intended for reactive/outbreak use and preventive use. Beyond safety and an appropriate risk-benefit ratio, no single characteristic is considered more important than another. Based on several country and regional inputs, a single-dose vaccine is considered important for the outbreak response, and both investigational vaccines as well as Ervebo entering the Tumaini trial will be evaluated for their potential to be used as a single-dose vaccine.

WHO SAGE is expected to consider product suitability (e.g., thermostability, and implications of vaccines needing ultra-cold chain) in the context of expanded access or emergency use and for access to remote populations (a recent VIPS study identified the programmatic needs and trade-offs for heat-stable vaccines [13]). In the SAGE evidence to recommendations (ETR) table, SAGE considers whether vaccines meet community values and preferences. A risk-benefit and acceptability assessment will be needed around known platform safety signal, particularly if large populations are expected to be vaccinated. Evidence to support this risk-benefit assessment should be made available to SAGE in advance.

Access Risk #3: Vaccine hesitancy, local acceptability and mistrust may undermine vaccine confidence and reduce uptake

Strategic community engagement should start as early as possible and continue throughout vaccine development and deployment planning. Engagement is essential to ensure trial designs reflect the perspectives, concerns and practical realities of affected communities, while supporting trust, transparency and informed participation.

The DRC, UNICEF, Africa CDC, WHO and IFRC, among other partners are already conducting Risk Communication and Community Engagement (RCCE) activities in DRC, with technical content available around key messages for Ebola vaccine studies in the context of the BVD outbreak.. The Tumaini trial consortium includes dedicated activities for community engagement and social and behavioural research (SBS). The selection of the consortium, including INRB and MSF, reflects established presence and expertise in DRC, including outbreak-related community engagement. The trial also includes a full work package on social science led by ITM under a dedicated protocol. INRB and Africa CDC are also expected to include targeted approaches for communities in conflict settings.

Finally, timely, evidence-based policy recommendations will play a key role in reinforcing vaccine confidence and trust; this is addressed further in Section 3.

Summary of Clinical Development interventions

Key Access risks	Interventions to mitigate risks/ enable equitable access	Known/ anticipated roles F: Funding; L: Leading; S: Supporting
1. Delayed access to safe and effective vaccines, including for special populations, limit the opportunity to curtail the outbreak.	■ Vaccine portfolio investments optimised for speed ■ Phase 2/3 platform efficacy trial (Tumaini) conducted towards EUL/PQ with ≥1 developers ■ Inclusion of special populations in Tumaini protocol ■ Transparency commitments to register data (including negative clinical trial results) in public clinical trial registers ■ Continuity plans if outbreak obligations unmet	F: CEPI (including funding from European Commission, the U.S. Department of State, the Fund for Science and Technology; and the Republic of Korea); Biomedical Advanced Research and Development Authority (BARDA) –investments in IAVI and PHV. L: Vaccine Developers: U. Oxford/SII, Moderna – currently in scope for Tumaini; others TBD L: DRC MoH, Tumaini trial co-sponsors: The Institut National de Recherche Biomédicale (INRB) and the University of Antwerp (Global Health Institute), WHO S: Africa CDC, Epicentre, Médecins Sans Frontières (MSF), the Institute of Tropical Medicine Antwerp (ITM)
2. Lack of vaccine programmatic suitability may limit uptake and can create barriers to access	■ Country-level acceptability and programmatic suitability considerations assessed via alignment with WHO TPP and accounted in future market shaping and investment decisions	L: WHO SAGE; Gavi S: Africa CDC, DRC INSP/ Ethics Committee
3. Vaccine hesitancy, acceptability and mistrust may undermine vaccine confidence and reduce uptake	■ Embed access in trial design – efficacy studies in affected communities & locations, sponsor to be country-led, vaccine aims to meet WHO TPP critical criteria	F: CEPI L: WHO Clinical Trials Writing Group; Tumaini trial consortium; Vaccine Developers
	■ Social & Behavioural Science principles & RCCE part of clinical trials	F: CEPI L: Vaccine Developers, INRB, Africa CDC, MSF, ITM
4.Vaccine candidates should meet preferred WHO TPP for long-term preparedness	■ Investments made towards preferred WHO TPP (e.g. thermostability, dose schedule, dose volume, etc) ■ Broadly protective/ multivalent candidates advanced	To be decided

■ Indicates confirmed or planned funding ■ Indicates funding or ownership gaps

■ Deprioritized for ongoing outbreak response

2 REGULATORY APPROVALS

Key access objectives for timely regulatory approvals are:

a. Conditions and trade-offs for emergency/conditional authorisations and full licensure clarified early across all regulators, with a streamlined process for joint reviews

b. Timely emergency use authorisations by National Regulatory Authorities (e.g., DRC ACOREP), with national authorisations recognised as independent and contingent for access to doses locally.

c. Timely WHO Emergency Use Listing (EUL) – pending data availability

d. Timely marketing authorization/ full licensure in all high-priority countries and WHO PQ

e. Regulatory authorities and public health agencies have the capacity and systems in place before deployment to detect, investigate, assess and respond to adverse events following immunisation (AEFIs), adverse events of special interest (AESIs), serious adverse events (SAEs) and other emerging safety signals.

f. *Aspirational goal:* AMA provides recommendations, DRC Regulatory NRA reaches WHO Maturity Level 3 (ML3) status; at least one WLA (WHO-Listed Authority) in Africa that can rapidly support future WHO EUL pathways

Background terminology used in this section:

1. **Authorisation**: Can mean any type of authorisation issued by a national regulatory or international technical agency that provides guidance or official authority for a vaccine to be used in a country and describes the conditions surrounding that use (e.g., whether it required informed consent). This is a pre-requisite for and different from a policy recommendation.
2. **AMA:** The Africa Medicines Agency (AMA) provides continental leadership for regulatory harmonisation, reliance, and emergency coordination so that African countries can review, authorize, monitor, and access medical products more rapidly and consistently. AMA is working closely with the World Health Organization (WHO), Africa CDC, and national regulatory authorities (NRAs) in Africa to ensure that any emergency use of investigational medical products meets strict regulatory, safety, and ethical standards.[14] AVAREF, a network of African national regulatory authorities and ethics committees, is part of AMA and is expected to support joint reliance of clinical trial applications. AMA provides a technical recommendation to NRAs and it will be up to the countries to decide to approve.
3. **ACOREP EUA:** ACOREP is the national authority responsible in DRC for determining how efficacy trials will be conducted, whether Expanded Access will be used, and what will be required for EUA in DRC.
4. **Reference authority**: The NRA that provides the initial regulatory assessment of a vaccine candidate and that is "referenced" by WHO in their EUL assessments.
5. **EMA CMA:** The European Medicines Agency (EMA) is a WHO Listed Authority (WLA) and supports the development of medicines that address unmet medical needs. The applicable process for EMA to grant a regulatory authorisation for BVD vaccines is under discussion – i.e., whether a conditional

marketing authorisation (CMA) or an opinion issued through the 'EU-M4all' (former article 58 for products to be used outside of Europe) pathway will be used.

6. **WHO EUL**[15]**:** Acts as an international assurance of quality, safety and efficacy for UN procurement agencies, international agencies, and Member States for emergency procurement/use of unlicensed vaccines based on an essential set of quality, safety, efficacy, and programmatic suitability data.
7. **Licensure:** Full licensure/registration/marketing authorisation for a marketing authorisation holder to freely sell a product within a country or geographic area.
8. **In the long-term a WHO prequalification (PQ)** acts as an international assurance of quality, safety, efficacy and suitability for procurement and use in LMICs immunisation programmes. PQ is currently unlikely for BVD specific vaccines during this outbreak given the limited data on the vaccines that may be available; however, WHO EUL clearly indicates that manufacturer/developers should commit to continue generating data to support licensure by a national regulatory authority and PQ.

Access risks

Access Risk #1. Lack of early national authorisations may cause delays in national deployment

Use of doses in DRC and other affected countries depends on national regulatory authorisations (i.e., DRC ACOREP), facilitated via AMA and other regulatory recommendations. Early consultations are ongoing to ensure vaccine developers and manufacturers understand the conditions for timely authorisations and likely pathways. This is also critical for trust in regulatory authorisations of vaccines and communication that fosters vaccine confidence. Parallel submission to all interested African regulators, AMA, WLA reference authority, WHO and regulator for manufacturing country (as needed) is recommended.

In the mid-term, AMA's technical recommendation can support participating NRAs for emergency use authorisation. EMA and AMA have provided guidance on the regulatory considerations around clinical development of Bundibugyo vaccines.[16]

Timely registration in high-risk and trial host countries will be critical to ensure timely access to vaccine doses in the context of an outbreak and preparedness for future outbreaks. For vaccines developed with CEPI funding, CEPI requests timely submissions for licensure in countries at highest risk of outbreaks.

Access Risk #2. Regulatory authorisations (WLA authorisations and WHO EUL) may delay access to doses

Access to doses depends on demonstration of quality, safety and efficacy for timely regulatory authorisations. Pathways and conditions to facilitate rapid WHO EUL should be clearly understood by vaccine developers and activated, as WHO visibility on the regulatory dossier can support SAGE policy guidance for programmatic use of vaccine doses. WHO Emergency Use Listing (EUL) or Prequalification (PQ) is needed to enable UNICEF procurement of vaccines. WHO EUL could also facilitate country Emergency Use Authorisations (EUA) if not already in place.

The preference is to have expedited reviews by a WHO Listed Authority (WLA)[17]**, as WHO EUL could be granted rapidly after an emergency regulatory authorisation (EUA) by WLA, if WHO Emergency Guidance is in place.** It is currently unclear which WLA (e.g., the European Medicines Agency, Health Canada, etc) would serve as the reference authority across the different candidates, if these assessments can be conducted in an expedited manner and which pathways would be applicable. Joint discussions across ACOREP, WHO, EMA and AMA are being conducted to clarify these questions. A WHO EUL could

also be granted based on approval by WHO Regulatory Maturity Level 3 or 4 (ML3 or ML4) authorities (e.g., Egypt and South Africa); however this will take longer. Good Manufacturing Practices (GMP) assessments will be required for manufacturing.

Regulatory pathways that enable timely WHO EUL should be clarified, outlining the likely reference authority across candidates and streamlining the joint reviews.

An expanded access pathway could be activated in parallel as a mitigation strategy (as detailed in the policy section below), as this can also support additional evidence generation of safety data to support licensure. However, the goal is for as short a period of expanded access as feasible to speed the pathway to licensure and PQ.

Finally, in the scenario that the data collected in the current outbreak does not support any conditional or emergency regulatory authorisation for reasons other than non-performance, alternative regulatory pathways to achieve licensure will be needed so that licensed vaccines are available for the next outbreak (e.g., via immunobridging).

Summary of Regulatory interventions

Key Access risks	Interventions to mitigate risks/ enable equitable access	Known/ anticipated roles F: Funding; L: Leading; S: Supporting
1. Lack of early national authorisations may cause delays in national deployment and may contribute to vaccine mistrust	Early engagement with all regulators on conditions/pathways for regulatory authorisations	L: Vaccine Developers, DRC ACOREP & other NRAs in high-risk countries, AMA, WLA (e.g., EMA, Health Canada)
	MAHs submit rolling applications to relevant regulators as soon as possible for joint reviews	L: MAHs
	Priority licensure in high-priority countries	L: MAHs, NRAs
2.Regulatory authorisations may delay access to doses	Regulatory pathway for timely WHO EUL defined and activated, with streamlining for joint reviews	L: Joint ACOREP-AMA-EMA-WHO platform
3. Risk of delayed regulatory authorisations if outbreak winds down before sufficient data can be collected	Regulatory pathways identified for EUL/ licensure/PQ for remaining candidates Support AMA, support DRC NRA towards WHO Regulatory Maturity Level 3 (for importation of vaccines and medicines) that can accelerate the approval of essential vaccines and medicines during public health emergencies in the future Regulatory strengthening efforts to identify WLA in Africa for future preparedness	Joint ACOREP-AMA-EMA-WHO platform ACOREP, WHO, AMA, Africa CDC WHO

Indicates confirmed or planned funding/roles Indicates funding or ownership gaps

Deprioritized for ongoing outbreak response

3 EVIDENCE-BASED POLICY RECOMMENDATIONS

Key access objectives for policy recommendations are:

1. Evidence generated to support SAGE and NITAG policy recommendations, with clear triggers for any expanded access or emergency use deployment (BVD-specific vaccines)
2. Evidence generated to support policy recommendations on vaccination strategies that enable equitable access to BVD vaccines

Background terminology used in this section[18]:

Expanded access (US/FDA) or Compassionate use (EU/EMA) allows individuals with serious or life-threatening diseases to receive investigational medicines with benefit known to exceed the risk outside clinical trials.

The term Expanded Access 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'. Further context on the terms is provided in the WHO document on Emergency use of unproven clinical interventions outside clinical trials (MEURI).

Expanded access requires a Phase 3 Randomized Controlled Trial (RCT) that shows the vaccine to be safe and efficacious against BVD. Emergency use data complements RCTs (it does not replace them).

Other requirements for expanded access (at a high-level and details to be clarified by WHO):

1. Approved protocol by the regulatory authority and Ethics Committee
2. Principal Investigator and sponsor (legally responsible);
3. Standard Operating Procedures (SOPs);
4. Insurance for Adverse Events (AEs), safety follow up; medical care by physicians provided if adverse events;
5. Patients / participants informed consent;
6. Data is kept confidential;
7. Investigators have to be certified in Good Clinical Practices (GCPs)
8. Doses need to be GMP released

Access Risk #1: Lack of robust evidence to inform timely policy recommendations may delay access to vaccine doses

Clarity on the evidence and processes required to support rapid SAGE recommendations for BVD vaccine use—including considerations of vaccine safety, efficacy, quality and programmatic suitability—can strengthen early access planning, as a SAGE recommendation to WHO is required to enable Gavi funding

of doses. WHO has provided initial considerations on potential pathways for policy recommendations for use of vaccines against BVD below:

Preferred policy pathway:

WHO and SAGE may recommend deployment of doses under **off-label (Ervebo) or emergency use conditions** as soon as there is an efficacy signal from the TUMAINI trial.

Parallel policy pathway:

While collection of data and regulatory reviews for emergency authorisations are being done, SAGE may recommend vaccine use under **expanded access protocols**[19]. These recommendations could be triggered, among other considerations, by an interim efficacy signal emerging from the Tumaini trial, potentially enabling faster access to more communities. An expanded access protocol allows individuals with or at known risk of serious or life-threatening diseases to receive investigational medicines with benefit likely to exceed the risk outside clinical trials but entails significant operational and legal challenges. WHO is currently developing a protocol for expanded access use as well as a framework for funding and implementation. In this scenario investigational doses would need to be donated from manufacturers to the sponsor of the expanded access protocol and an insurance/ I&L mechanism would need to be in place (detailed in section 4). **Expanded access use is likely to be the first mechanism for vaccine access and requires confirmation on funding and roles- including sponsorship, insurance, and evidence generation strategy**.

A SAGE recommendation is a pre-condition for Gavi APC-funded doses to be used. In a scenario where national authorities move in advance of the global policy process, a delay in deploying Gavi APC-funded doses may occur. This scenario is unlikely as it implies lack of sufficient evidence for a SAGE recommendation. Nevertheless, different policy pathways that facilitate access to vaccine doses in countries should be outlined, and their trade-offs, including risks around safety or efficacy, should be clarified early with national stakeholders. SAGE can convene an emergency meeting whenever there is sufficient evidence to support a policy decision and the Working Group has completed its review. Close coordination with the SAGE Secretariat on the trial progress is therefore essential.

Following SAGE recommendations, the RITAG advises the WHO Regional Director and Member States on regional adaptation of SAGE guidance and the NITAG ultimately considers the national policy recommendation for deployment of doses within the local context. RITAG/NITAG participation as observers in the SAGE Ebola vaccines working group[20] and any extraordinary SAGE meetings helps ensure that regional and national bodies receive the evidence at the same time. This can streamline efforts and to support timely adaptation of SAGE recommendation. An ad-hoc emergency-session by NITAG could support timely recommendations for use in DRC and other countries.

Access Risk #2: Policy recommendations for vaccine deployment may be limited to ring vaccination, which may be challenging in the current outbreak context

Ring vaccination has been the recommended deployment strategy in Ebola outbreak response, requiring vaccination of contacts of confirmed cases and, where appropriate, contacts of contacts. However, contact tracing challenges in the current DRC BVD outbreak have resulted in many “unknown cases” outside established contact lists, which may limit the effectiveness of a purely ring-based approach. To reach affected populations more effectively, broader vaccination strategies, including geographically targeted approaches, may need to be considered, and these have been used in previous outbreaks when needed.

SAGE, RITAG and NITAG will recommend the appropriate deployment strategy. These recommendations on vaccination strategies should not be delayed by lack of sufficient evidence or limited by vaccine doses available.

To support timely decision-making, the evidence requirements for these recommendations should be clarified early, with modelling and other relevant data used, where appropriate, to complement clinical evidence. This evidence will likely include an assessment of operational capacity in DRC and other affected countries to implement ring vaccination.

Early assessment of likely vaccination strategies will also inform dose requirements and manufacturing scale-up needs, helping ensure that deployment decisions are not constrained by vaccine supply. These scenarios are expected to be modelled under the CEPI- and Gavi-funded project with Imperial.

Summary of Policy interventions

Key Access risks	Interventions to mitigate risks/ enable equitable access	Known/ anticipated roles F: Funding; L: Leading; S: Supporting
1. Lack of robust evidence for timely policy recommendations may delay access to vaccine doses	Readiness for expanded access use including identification of sponsors, funding, evidence generation strategy and development of protocol	F: TBD Lead for expanded access protocol development and framework for funding and implementation: WHO
	Robust evidence for timely SAGE recommendations for off-label, emergency or expanded access use, highlighting interdependencies around national/ regional policy pathways RITAG/NITAG participation as observers in the SAGE BVD working group and any extraordinary SAGE session	L: WHO SAGE, NITAGs, AFRO RITAG
2.Policy recommendations on vaccination strategies to enable equitable access to doses should not be constrained by limited number of vaccine doses.	Identify likely vaccination strategies, estimate vaccine doses needed across vaccination strategies to inform policy recommendations	F: CEPI, WHO; L: Imperial S: WHO SAGE, NITAG, AFRO RITAG

Indicates confirmed or planned funding Indicates funding or ownership gaps

4 MANUFACTURING AND SUPPLY

availability of doses for use beyond clinical trials

Key access objectives for manufacturing are:

a. Marketing Authorisation Holder (MAH) identified for each candidate before they enter the Tumaini trial
b. Timely supply of sufficient quantity of vaccine doses for outbreak response ensured through early at-risk manufacturing scale-up of investigational doses
c. African manufacturing for licensed vaccine doses incentivized for all candidates
d. *Aspirational goal:* Strategies explored to support sustainable pathways for tech transfer/ regional manufacturing (especially vaccines meeting WHO preferred TPP)

Background & risks:

Access Risk #1: Vaccines may not be available in adequate quantities when recommended for use beyond clinical trials

Early access to doses depends on early, at-risk manufacturing scale-up so that sufficient doses are available for clinical trials and outbreak needs, including for emergency or expanded access use. Manufacturing agreements including contract manufacturing organisations (CMOs) and Marketing Authorisation Holder (MAHs) will need to be in place before the candidate enters phase 2/3 trials, with capacity reserved for scale-up of BVD vaccine doses. These efforts have been accelerated based on previous investments made into CEPI's rapid response platforms. Serum Institute of India (SII) is the manufacturing partner and MAH for the ChAdOx1 vaccine and has stockpiled approximately 620,000 finished doses of the vaccine candidate [21]. Moderna is expected to manufacture and license its LNP-mRNA vaccine, with capacity to quickly scale-up manufacturing of doses - as part of its agreement with CEPI, the company will make available at a minimum 500,000 doses for timely supply to low- and middle-income countries under access pricing[22]. However, both SII and Moderna doses will need to be purchased (e.g., via Gavi APCs). Further manufacturing scale-up could be conducted based on supply needs.

For the IAVI rVSV candidate and under ASPR/BARDA funding, Hilleman Laboratories is expected to manufacture *clinical trial doses* and transfer the technology to SK bioscience for manufacturing scale-up activities to generate a supply of the investigational vaccine [2324]. For the Minapharm MVA-BDBV vaccine, the vaccine candidate is designed by Minapharm's Berlin-based subsidiary ProBioGen, which will initially produce the drug substance. In parallel, Minapharm is transferring drug substance manufacturing to Cairo, enabling fully local drug substance and drug product end to end manufacturing at Minapharm's novel plant in Egypt[25]. Drug product manufacturing is already certified by EDA (Egyptian Drug Authority), drug substance commissioning is in progress.

Modelling is ongoing to estimate vaccine supply needs for emergency use, assuming vaccination following the earliest interim efficacy signal. This exercise estimates vaccine supply needed across different epidemiological scenarios and vaccination strategies[26]. Based on *initial* modelled outputs from Imperial, the true unconstrained demand for BVD vaccines is high but the limiting factor for vaccination roll-out is likely to be vaccination capacity on the ground.

- Epidemiological scenarios and absorption capacity (maximum daily consumption rate of doses) are key determinants of necessary volumes of doses.
- The modelling suggests that a fair assumption would be the need for **1-2 million doses over the first 6 months of vaccination**.
- In the event that the epidemiologic outlook remains stable (in terms of number of cases, no real improvements in other control measures, largely "steady state") – and assuming a daily absorption **of 3-15k doses per day**, the volume of doses required is in the range of **550k-2.7m doses over six months**.
    - In the 2018-2020 North Kivu outbreak, the maximum rate of vaccination peaked at about 1500 doses per day. However, given the greater geographic spread in this outbreak and involvement of other countries, the range of 3-15k doses per day is plausible.
- In the event that the epidemiologic outlook improves (modestly), the modelling suggests around **1 million doses** within 6 months could meet demand.
- The modelling does not consider demand under an expanded access scenario. This would alter vaccination strategies and delivery.

These assumptions and scenarios continue to be validated and revised as needed. Further clarity is needed on doses needed across the different vaccine candidates including pipeline vaccines that have not yet entered the Tumaini trial. These will depend on the clinical evidence and policy recommendations for use. Given these uncertainties, manufacturing capacity planning for these pipeline candidates is currently challenging.

Utilization of these doses will depend on the demand from countries, regulatory status, policy recommendations, product suitability, trust, perception of risk and community readiness, etc; therefore, evidence generation, community engagement, communication and vaccination strategies are needed alongside quantitative forecasting.

To meet this supply, at-risk manufacturing investments in the form of advance purchase commitments (APCs) are currently under consideration by Gavi, to assure supply of doses in a timely manner and fund future procurement of vaccines as soon as relevant policy and regulatory approvals are granted[27].

Access Risk #2. If vaccines are not manufactured regionally in Africa, it could impact continental supply resilience and long-term global health security

Regional capacity can be strengthened by incentivising African manufacturing and technology transfer through push and pull incentives, although should be balanced with considerations around supply sustainability. CEPI has committed funding towards leading African biopharmaceutical company Minapharm group, which if successful can serve as the basis for future African-manufactured filovirus vaccines[28].

Incentives are currently in place for tech-transfers to regional manufacturers across all candidates. This includes Gavi African Vaccine Manufacturing Accelerator (AVMA) incentives for any African manufactured BVD vaccine that receives WHO EUL to be eligible for US $25 million payment for drug-substance production and US $10million milestone payment for fill-finish, if it is manufactured on a pandemic platform – i.e., viral-vector or mRNA or if it meets the product characteristics underpinning the prioritisation of Ebola vaccines (i.e. multivalent, thermostable, etc.).

Africa CDC will aim to advance and shape African Manufacturing readiness by supporting selection of African manufacturers and end-to-end lead-time mapping of vaccine supply, cold-chain mapping and gap resolution, supply-chain strengthening, communicating readiness requirements to countries, last-mile delivery and reverse logistics, that can further support and incentivize vaccine manufacturing in Africa.

To support future decision-making on licensed stockpiles, and selection of vaccine candidates across Filoviruses, strategies should be explored to determine sustainability of regional manufacturing for outbreak vaccines with low and unpredictable demand. Defining a position that navigates trade-offs around economic sustainability of vaccines, regional resilience, speed of access, lower COGS, etc; can help donors and funders enable selection of the right vaccine candidates for a future stockpile, especially one that meets WHO preferred TPP characteristics.

Summary of Manufacturing and Supply interventions

Key Access risks	Interventions to mitigate risks/ enable equitable access	Known/ anticipated roles F: Funding; L: Leading; S: Supporting
1. Vaccines may not be available in adequate quantities when recommended for use beyond clinical trials	Manufacturing agreements/ capacity in place for candidates before entering phase 2/3 trials, with MAH	F: CEPI L: Vaccine developers and Manufacturers
	Assess supply for outbreak response needs across several epidemiologic scenarios & vaccination strategies	F: CEPI and Gavi; L: Imperial; S: WHO, UNICEF, Africa CDC
	Early at-risk manufacturing scale-up for access to doses outside of clinical trials	F: Gavi (in progress for lead candidates); funding for remaining candidates TBD L: Vaccine Manufacturers
2. If vaccines are not manufactured regionally in Africa, it could impact continental supply resilience and long-term global health security	At least one African manufacturing/ tech transfer in place for BVD vaccines	L: Minapharm
	Tech transfers incentivized across eligible candidates	L: Gavi AVMA S: Africa CDC supporting selection of African manufacturing candidates
	End-to-end lead-time mapping of vaccine and cold-chain supply, readiness and gap assessment	L: Africa CDC, WHO, UNICEF
	Strategies to explore sustainability of regional manufacturing across different candidates to support long-term stockpile decisions	TBD

5 FINANCING, PROCUREMENT AND ALLOCATION

Key access objectives for procurement and funding are:

a. Manufacturers incentivized to pursue WHO EUL/PQ through push and pull funding mechanisms

b. Post-licensure access to doses secured for affected countries at a price that supports equitable access and is sustainable

c. Product Liability and Indemnification is not a barrier to access across different regulatory scenarios

d. Allocation mechanisms defined for future BVD vaccines as contingency measures

e. *Aspirational goal:* Long-term vaccine stockpiles funded to enable preparedness for future outbreaks

Background & risks:

Access Risk #1. Vaccine manufacturers need demand signals/ procurement guarantees to advance vaccine development efforts

Similar to Ebola Zaire, Bundibugyo vaccines lack sustainable demand and there is not yet an established market for vaccines against it. This creates uncertainty for manufacturers to pursue and prioritize late-stage clinical development and manufacturing at risk. To supplement push funding, demand guarantees or procurement signals can therefore **incentivise** development, manufacturing and access and ensure that manufacturers pursue WHO PQ for long-term preparedness.

UNICEF and Gavi launched an Expression of Interest (EoI) in June 2026 to gather information from developers and manufacturers on their specific needs and inform how financing (through e.g. Gavi-funded APCs at the start) can best support access to vaccine doses.[29] Pull funding for procurement of doses post-EUL/PQ has been mobilised and Gavi-funded APCs are being negotiated.

Access risk #2. Vaccine pricing could prohibit access to emergency authorized or licensed vaccines in affected countries and/or vaccine supply could be hoarded by HICs restricting supply

Vaccine pricing must be accessible for LMICs; vaccines developed with CEPI funding are expected to ensure access to licensed vaccines for low-and-middle-income countries, and that procurement of licensed vaccines is at a price that does not limit equitable access and is sustainable to the manufacturer[30]. CEPI vaccine development funding agreements typically explicitly acknowledge that the price of project vaccines is critical to achieving Equitable Access and commit to a methodology to determine the pricing, considering the need to balance availability and affordability for populations in need, with financial sustainability for manufacture and supply. The pricing commitment may include a COGS + X% model, or

tiered pricing or price-volume ladder. Where possible, CEPI also requires transparency on pricing.[31] In turn, Gavi funded APCs are expected to firm up supply delivery timelines for initial doses under APCs to ensure LMIC access.

Access Risk #3: Product liability and indemnification should not be a barrier to access across different regulatory scenarios

Clinical trial insurance is expected to cover the Principal Investigators, sponsors and the medical care and indemnification in case of claims related to adverse events experienced by people following vaccination for the duration of a clinical trial and any post-trial claim reporting period specified in the policy. While vaccine manufacturers hold liability for vaccine use post full licensure of vaccine, 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.

Access Risk #4: Allocation of doses for populations should be equitable balancing needs, implementation readiness and supply

If the outbreak spreads beyond DRC as well as for contingency, an allocation mechanism will need to be defined for equitable allocation of doses, covering both investigational vaccine allocation under expanded access and EUL/ PQ vaccines. It is currently unclear whether new BVD vaccines fall under the remit of ICG mechanism to manage and coordinate the provision of emergency vaccine supplies, or if there will be another allocation mechanism. For example, the Access and Allocation Mechanism (AAM) could be a potential model to replicate in the short-term, building on lessons from mpox.

An allocation mechanism should ideally consider an epidemiologically driven approach, with prioritisation based on:

- Outbreak-affected populations
- Endemic and high-risk countries
- Humanitarian settings and vulnerable populations.

Access Risk #5: Current financing mechanisms may not support licensed stockpile funding

In the long-term, licensed stockpile funding decisions will need to be made for suitable candidate(s). For Gavi funding eligibility, there is an existing vaccine investment case and vaccine program – the ICG-managed Ebola stockpile which in principle covers all Ebola strains although currently holds vaccines against Ebola (Zaire). The inclusion of another Ebola vaccine in the stockpile would require mobilizing additional resources but no new Vaccine Investment Strategy case. An ongoing economic evaluation being conducted by Imperial will model the health-economic impact and cost-effectiveness of BVD vaccine candidates and optimal portfolio strategies to inform future funding support (e.g., a potential stockpile). Further evidence will be needed to inform stockpile funding decisions (by Gavi or other funders), and candidate selection criteria such as optimal stockpile sizes and optimal use case as part of broader disease control efforts. In addition, regional procurement mechanisms such as Africa Pooled Procurement Mechanism (APPM) should be explored to define scope and conditions of (co-)funding licensed vaccine stockpiles. Assessment of sustainability (manufacturer, donor and country-level sustainability) will be needed to support long-term preparedness and inform investment efforts across all filovirus vaccine stockpiles.

Summary of financing and procurement interventions

Key Access risks	Interventions to mitigate risks/ enable equitable access	Known/ anticipated roles F: Funding; L: Leading; S: Supporting
1. Vaccine manufacturers need demand signals/ procurement guarantees to advance vaccine development efforts	Gavi activates funding, signs advance purchasing commitments (APCs) with MAHs	F: Gavi; L: MAHs
	UNICEF readiness for procurement of EUL/PQ vaccines	L: UNICEF
2. Vaccine pricing could prohibit access to emergency authorized or licensed vaccines in affected countries and/or vaccine supply could be hoarded by HICs restricting supply	Pricing formula defined with manufacturers before phase 2/3 investments (whilst ensuring sustainability for the manufacturer) – e.g., via COGS + X% or tiered pricing Licensed products are available for public procurement and LMIC access is prioritized	CEPI, Gavi, UNICEF
3. Product liability and indemnification should not be a barrier to access across different regulatory scenarios	Insurance for use of investigational vaccines in expanded access protocols	TBD (Sponsors of the expanded access)
	I&L mechanisms as relevant for emergency use: Indemnification needs understood with countries; I&L waivers for humanitarian organisations, etc	L: Gavi, WHO and UNICEF S: DRC, Vx Manufacturers
4. Allocation of doses for populations should be equitable balancing needs, implementation readiness and supply	Equitable allocation mechanisms defined and communicated as contingency measure (involving operational bodies, ToR, decision-making steps and lead times)	TBD (ICG or another mechanism)
5. Current financing mechanisms may not support licensed stockpile funding	Health-economic impact modelling across BVD vaccine candidates to inform future decision-making on funding	F: CEPI; L: Imperial
	Assessment of stockpile needs – i.e., size, financing needs, and sustainability (manufacturer, donor and country-level) to support long-term preparedness and inform investment efforts across all filovirus vaccine stockpiles (overlaps with section 4 on regional manufacturing) Plans made for maintenance of the Investigational Ready Reserves (IRR)/ stockpile post outbreak Long-term sustainable financing in place for future outbreaks	L: TBD S: Gavi, Africa CDC, WHO, UNICEF, CEPI, MAHs

Indicates confirmed or planned funding Indicates funding or ownership gaps

Deprioritized for ongoing outbreak response

6 COUNTRY READINESS & IMPLEMENTATION

to ensure vaccine reaches affected populations

Key access objectives for country readiness and implementation are:

a. **Surveillance, case-finding, case investigation, and contact tracing efforts improved** and **sustained**, to support ring vaccination efforts or recommended vaccination strategy
b. **Country readiness assessment made & operational funding needs identified early**, including core components identified below
c. Tailored strategies for vaccine access to **humanitarian populations of concern** identified
d. **Continuity of routine immunisation ensured**
e. **Funding and capacity for vaccine delivery and uptake** in place for rollout of vaccine doses, including core components identified below
f. *Aspirational goal:* Novel and effective community engagement approaches explored (outside of vaccine trials or MCM-specific RCCE) to foster trust ahead of future outbreaks

Background & risks

This section highlights high-level needs around country readiness, but a detailed implementation plan is needed to cover all operational needs, roles & funding requirements. This is expected to be led by MoHs with support from WHO, UNICEF, Africa CDC and other relevant partners and in high-priority countries leveraging the Africa CDC and WHO-led continental plan.[32]

Access risk #1: Even if vaccine doses are available, lack of early country readiness plans may delay access to affected populations

Implementation readiness and community engagement are needed to translate vaccine supply and policy into impact. A substantial scaling up of the existing response coordinated by DRC, in collaboration with WHO and partners, is needed to contain the outbreak. There is a need to maintain or scale up heightened surveillance, preparedness and control measures, and the vaccine supply chain particularly in view of continued population movement and the risk of cross-border transmission.[33] As BVD spreads through close contact, vaccines will only have an impact if they reach the people most at risk at the right time; therefore, immediate improvements in surveillance are critical.

Immediate focus on country readiness for vaccine deployment is to prepare for any expanded access recommendations. This includes identification of sponsor(s), development of a protocol, identification of appropriate insurance & liability mechanisms, and making operational support plans for deployment.

For use of emergency authorized vaccines, country-level operational readiness plans need to be made urgently and in advance of vaccine availability. The Africa CDC and WHO led Continental Preparedness and Response Plan has provided a strategic framework to guide coordinated preparedness, readiness, and response efforts across African Union Member States, the implementation of which requires an estimated budget of approximately US $518 million over six months, based on updated costing[34], across different scenarios and at-risk countries. Gavi has committed initial $10M from the First Response Fund to

"protect and prepare". Of this $10M, Gavi has committed US$ 6 million to protect routine immunisation services, health care workers and to support preparedness for future Ebola vaccination. US $4million has been disbursed to the DRC, US $500,000 to Uganda and US $1.5million has been committed to Africa CDC, WHO and UNICEF to support regional coordination and cross-country preparedness work. UNICEF is expected to procure and deliver vaccines (once WHO EUL granted) and ancillary supplies to affected areas. The World Bank is also supporting outbreak response, by helping the DRC sustain national response and by supporting neighbouring countries to strengthen regional preparedness, coordination, and cross-border health security through the ongoing Health Emergency Preparedness, Response and Resilience (HEPRR) program[35].

Immediate country readiness plans are expected to be led by countries (DRC INSP as well as MoHs in other high-risk countries) and may need to be adapted in view of final vaccination strategy recommendations. These plans should include the following aspects:

- **Community engagement & demand generation** to understand and address concerns, and approaches to build trust before and during outbreaks.
- Readiness for national regulatory authorisations and policy recommendations to facilitate timely vaccine authorization, importation, and deployment
- **Supply chain considerations** including:
  - Timely operational funding synced with vaccine shipments
  - Deployment capacity (cold-chain capacity, vaccine management, vaccine distribution plan, protecting routine immunisation, etc)
  - Administration data systems, including how data flows back to the level of the allocation mechanism
  - Vaccine waste management. Vaccine disposal and the requirement of reverse logistic.
- **Operational deployment** considerations including:
  - Training of health care workers and vaccinators (potentially with digital aides)
  - Vaccination strategy and service delivery, including access to remote and insecure areas
  - National and microplanning activities, including development of WHO programmatic guidance and training tools for Health care workers
  - Special deployment needs for expanded access
- **Monitoring, Safety & Effectiveness**, including:
  - Monitoring of coverage (on a real-time daily basis)
  - Support to countries to monitor not only safety but also quality and effectiveness of deployed doses. This is a condition for EUL and ensuring that Risk Management Plan (RMP) addressing country needs is well adapted.
  - Evidence generation for pharmacovigilance, requiring early planning at the programmatic level deployment. Strong pharmacovigilance should be accompanied by adequate risk communication.
  - Establishing or strengthening vaccination monitoring and data systems, including vaccine registries, monitoring of coverage and uptake, AEFI reporting, and linkage with surveillance and laboratory data to support implementation and evidence generation.

- Clear monitoring and reporting plans drafted – with clarity on core metrics to be collected and reported, via which data systems (e.g.: DHIS2)
-

- **Knowledge Management & Learning**
  - Identification of bottlenecks and incorporation of lessons from implementation of vaccines in previous responses

Access Risk #2: Humanitarian populations of concern may remain underserved without efficient, tailored access mechanisms

Insecurity, population displacement and mobility, last-mile delivery constraints, and cross-border movement complicate response operations and increase the risk of further geographic spread within and beyond DRC. Some communities will therefore require tailored access approaches, including humanitarian channels operated by UNHCR and other humanitarian partners, rather than reliance on national delivery mechanisms.

An effective mechanism will require coordinated action between financing partners, including Gavi, and humanitarian organisations such as MSF, IRC, IFRC, and other international and national NGOs. Its design should incorporate lessons from the COVID-19 Humanitarian Buffer, for further streamlining and accessibility by humanitarian organisations.

Access Risk #3: Implementing vaccine rollout constitutes financial and operational challenges

Beyond readiness, once vaccines are authorized and recommended for use, attention will need to shift to implementation and delivery of these doses to affected populations. It will be imperative to track roll-out of the vaccines – with strong monitoring systems and structures in place. Key metrics should include uptake (disaggregated), drop-out (if multiple doses), stock reporting and wastage. Securing additional funding to support the deployment of vaccines and the critical systems and health workers required to ensure these vaccines reach affected populations will be essential. Once vaccines are recommended for use, Gavi's Board will consider whether additional funding should be allocated to support vaccine delivery and roll-out.

Finally, community engagement outside of vaccine trials or therapeutics trials needs to continue beyond the outbreak, and a robust RCCE strategy is needed, as covered in section 1. However, it is important to note that RCCE alone in the context of outbreak response may not address the critical barriers to trust in public health systems, and novel approaches that reach communities, address their concerns and priorities are needed for future preparedness.

Summary of country readiness interventions

Key Access risks	Interventions to mitigate risks/ enable equitable access	Known/ anticipated roles F: Funding; L: Leading; S: Supporting
1. Even if vaccine doses are available, lack of early and adequate country readiness plans may delay access to affected populations	Early country operational readiness for deployment of vaccines under expanded access or emergency use (i.e., plans made and implemented so that countries are ready for implementation)	F: Gavi; World Bank Pandemic Fund L: DRC MoH/INSP, WHO, Africa CDC S: Country MoH (DRC INSP) + other partners as relevant including implementation partners such as MSF, IFRC, local NGOs and CSOs and UNICEF; + supply chain partners such as UNICEF
2.Humanitarian populations of concern may remain underserved without efficient, tailored access mechanisms	Targeted approaches for access to humanitarian populations of concern identified, including an effective humanitarian buffer.	L: TBD S: Humanitarian organisations (TBD - UN Refugee Agency (UNHCR), MSF, IFRC, International Committee of the Red Cross (ICRC); International Council of Voluntary Agencies (ICVA), INTERSOS, International Organization for Migration (IOM). UNICEF, Africa CDC, WHO
3. Implementing authorized vaccine rollout constitutes financial and operational challenges	Operational Funding for vaccine **implementation** available and vaccines rolled out for use (once authorized)	F: TBC (Gavi pending Board decision + other funders) L: DRC MoH/INSP, WHO, Africa CDC S: Other partners as relevant including implementation partners such as MSF, IFRC, local NGOs and CSOs, UNICEF; + supply chain partners such as UNICEF

Indicates confirmed or planned funding Indicates funding or ownership gaps

Full Access roadmap with tentative timelines and roles

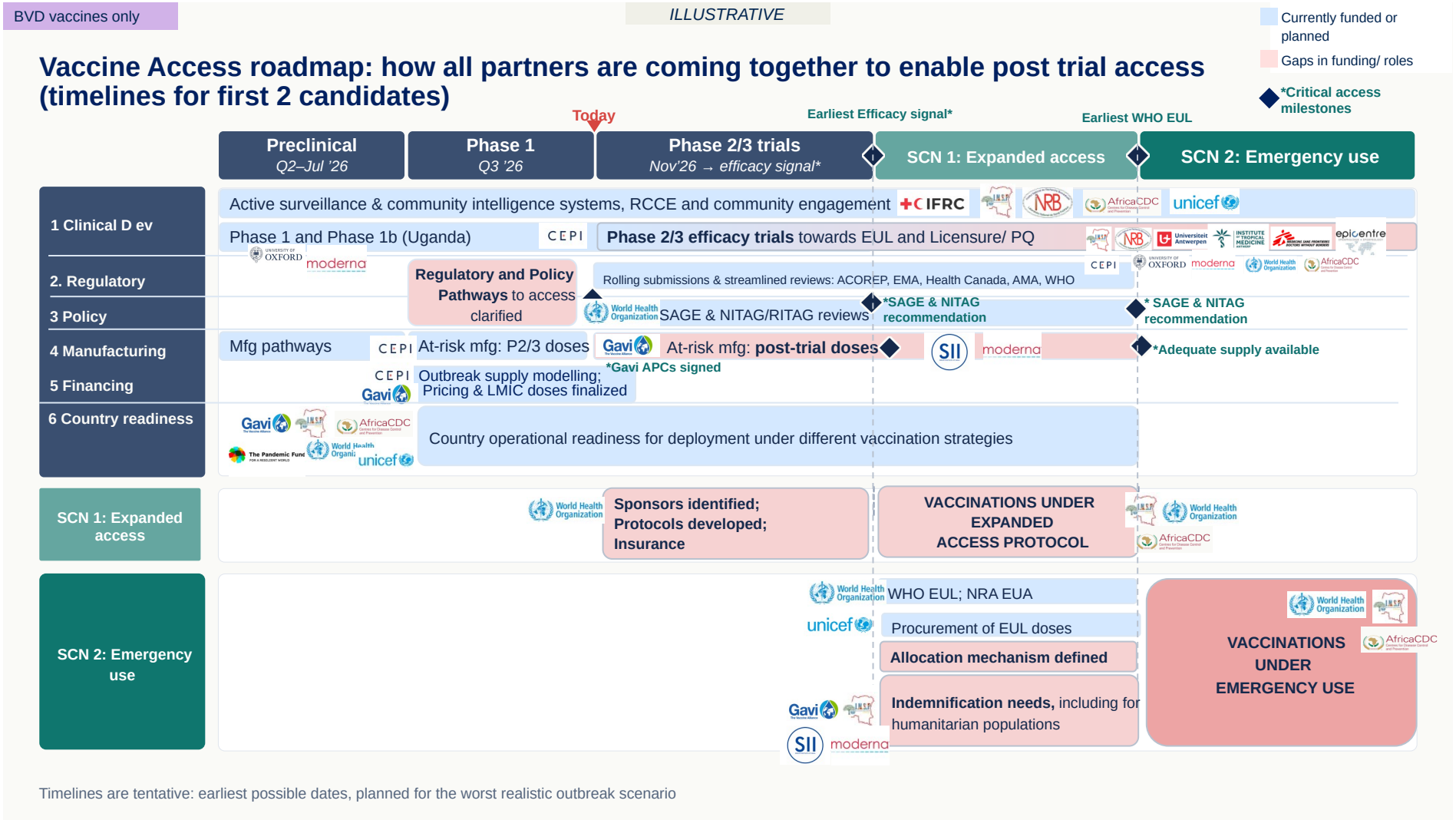


Figure 1: Illustrative Vaccine Access Roadmap

A Annex A: Examples of equitable access provisions covered under CEPI investments

Some examples of how equitable access is included in CEPI agreements – not candidate specific[36]:

Access to and sharing of data and information, publication (open access): Requirements for data sharing, e.g., mandated registration of data in public clinical trial registers and publication in open access journals in a timely fashion so that all developers can benefit from current knowledge of a disease and interventions. Providing public access to the outputs of the funded research can accelerate scientific research in this field.

Affordable & sustainable pricing: CEPI funding agreements typically explicitly acknowledge that the price of project vaccines is critical to achieving Equitable Access and commit to a methodology to determine the pricing formula, considering the need to balance availability and affordability for populations in need, with financial sustainability for manufacture and supply. The pricing commitments may include a COGS + X% model, or tiered pricing or price-volume ladder. Where possible, CEPI also requests transparency on pricing.

Preparedness and response obligations: Obligations in the case of future outbreaks, with defined triggers, such as scaling up production, allocation of manufacturing capacity, or access to platforms through mandated technology transfers to trusted partners.

Continuity in product development, manufacture and supply: Traditionally CEPI relies on step-in rights enabled by CEPI's public health license to ensure continuity in product development, manufacture and supply. Intended as a measure of last resort in the event of non-performance or in response to an outbreak, in practice, exercising these rights can also be challenging if there is a funding gap and an awardee continues development independently of CEPI. Recent funding agreements strengthen continuity and bridge the gap with this measure of last resort by contemplating additional work packages subject to further funding by CEPI, or by securing a "first right to fund" that ensures CEPI shall have the first right (but not the obligation), to further fund the development, manufacture and deployment of a project vaccine.

Abbreviations and acronyms

AAM	Access and Allocation Mechanism
ACOREP	Autorité Congolaise de Réglementation Pharmaceutique (DRC's national medicines regulatory authority)
AEFI	Adverse Event Following Immunization
AESI	Adverse Event of Special Interest
AMA	African Medicines Agency
APC	Advance Purchase Commitment
AVMA	African Vaccine Manufacturing Accelerator
Africa CDC	Africa Centres for Disease Control and Prevention
AFRO	WHO Regional Office for Africa
APPM	African Pooled Procurement Mechanism
ASPR	Administration for Strategic Preparedness and Response (United States)
AVAREF	African Vaccine Regulatory Forum
BARDA	Biomedical Advanced Research and Development Authority (United States)
BVD	Bundibugyo Virus Disease
BDBV	Bundibugyo virus, species Orthoebolavirus bundibugyoense
CEPI	Coalition for Epidemic Preparedness Innovations
cIMST	Africa CDC & WHO-led Continental Incident Management Support Team
CMA	Conditional Marketing Authorisation
CMC	Chemistry, Manufacturing and Controls
CMO	Contract Manufacturing Organization
COGS	Cost of Goods Sold
CSO	Civil Society Organization
DHIS2	District Health Information Software 2
DRC	Democratic Republic of the Congo
EMA	European Medicines Agency
ECG	Emergency Consultative Group (Africa CDC)
EUA	Emergency Use Authorisation
EUL	Emergency Use Listing
FRF	Gavi First Response Fund
FDA	Food and Drug Administration (United States)
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
I&L	Indemnification and Liability
ICG	International Coordinating Group (on Vaccine Provision)
IFRC	International Federation of Red Cross and Red Crescent Societies
ICRC	International Committee of the Red Cross
ICTRP	WHO International Clinical Trials Registry Platform
ICVA	International Council of Voluntary Agencies
IRIDs	Internationally held Reserves of Investigational Doses
ITM	Institute of Tropical Medicine (Antwerp)
LMIC	Low- and Middle-Income Country
LNP	Lipid Nanoparticle
mAb	Monoclonal Antibody
iMCM-net	Interim Medical Countermeasures Network
IMST	Incident Management Support Team
INRB	Institut National de la Recherche Biomédicale (DRC)
INSP	Institut National de Santé Publique (DRC)
IOM	International Organization for Migration
IPC	Infection Prevention and Control
MAH	Marketing Authorisation Holder
MCM	Medical Countermeasure(s)
ML3 / ML4	WHO Regulatory Maturity Level 3 / 4
MoH	Ministry of Health
MSF	Médecins Sans Frontières
NITAG	National Immunisation Technical Advisory Group
NRA	National Regulatory Authority
PHEIC	Public Health Emergency of International Concern
PHECS	Public Health Emergency of Continental Security
PHV	Public Health Vaccines
PQ	WHO Prequalification
R&D	Research and Development
RCT	Randomized Controlled Trial
rVSV	Recombinant vesicular stomatitis virus
RCCE	Risk Communication and Community Engagement
RITAG	Regional Immunisation Technical Advisory Group

RMP	Risk Management Plan
SAGE	Strategic Advisory Group of Experts on Immunisation
SAE	Serious Adverse Event
SBS	Social and Behavioural Science
SII	Serum Institute of India
TAG-CVP	WHO Technical Advisory Group on Candidate Vaccine Prioritization
TPP	Target Product Profile
UNHCR	United Nations High Commissioner for Refugees (UN Refugee Agency)
UNICEF	United Nations Children's Fund
VIPS	Vaccine Innovation Prioritisation Strategy
WHO	World Health Organization
WLA	WHO Listed Authority

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