



# Global HIV Vaccine Enterprise

## Strategic Plan 2022-2027

# Foreword

The Global HIV Vaccine Enterprise was conceived in 2003 and formally established in 2005 to accelerate the development of an HIV vaccine by fostering alignment among the scientific community and funders on the scientific agenda – from basic to clinical research. The trial, RV144, provided the first signal in 2009 that an HIV vaccine could have modest efficacy in humans, and planning for late-stage studies commenced. After that the Enterprise broadened its role to support the field in adopting a product development mindset to prepare for the success of late-stage studies. With two pivotal late-stage HIV vaccine studies underway, the 2018-2023 Strategic Plan for the Enterprise brought focus to convening stakeholders to prepare for success, addressing the pivotal regulatory, access and funding challenges of late-stage programmes.

Since the launch of the 2018-2023 strategy, the field has been transformed. The discontinuation of several late-stage clinical trials has redirected emphasis to discovery science and early-stage product development. COVID-19 necessitated extraordinary funder, researcher and government attention (often at the expense of HIV and other infectious diseases) while accelerating capabilities in vaccine research, development, and deployment. And the research community has awakened to the importance of diversity and inclusion in maximizing innovation and research relevance.

For nearly two decades, the Enterprise has been instrumental in identifying gaps, convening stakeholders and fostering collaboration as a response to the evolving needs of the field. This role is as important now as it has ever been. There is an opportunity for the Enterprise to renew momentum in HIV vaccine development by bringing diverse stakeholders together to identify and advance new solutions with the platforms, tools and knowledge that we have today.

The 2022-2027 Strategic Plan positions the Enterprise to apply its strength as a neutral convener to:

- Strengthen the HIV vaccine pipeline.
- Engage and support a diverse scientific community.
- Expand political and financial support for HIV vaccine research and development.
- Encourage the generation and application of new or existing knowledge and tools in HIV vaccine research.

As before, the development of this five-year strategy was a highly collaborative effort. We have benefited from expert input, ideas and feedback from the many stakeholders that we consulted, the Enterprise Advisory Group and leaders at IAS – the International AIDS Society. They helped shape a plan that prioritizes innovation, diversity and speed. We look forward to expanding, strengthening and engaging our global community to make this plan a reality.

The IAS thanks Shift Health for their work in designing the approach to this strategy review, conducting numerous interviews and in-depth desk research, and preparing a summary of their findings and recommendations. We are also grateful for their collaboration in the development of this Strategic Plan.

# Context

The Enterprise has played an enduring role in the HIV vaccine field, convening the community to identify and address priorities and coordinating action critical to advancing a shared commitment to accelerating HIV vaccine research and development. Today, as we move on from the efficacy futility outcomes of HVTN 702 and HVTN 705, the HIV vaccine field must restore emphasis on basic research, vaccine discovery and design, with the imperative of rapidly identifying innovative products and approaches that can move towards late-stage clinical development. The field has faced this challenge before, but it has never encountered it with the benefits of the scientific and clinical knowledge gained from over 40 years of HIV vaccine research and development (R&D) and the unprecedented global infectious disease research progress made during the COVID-19 pandemic.

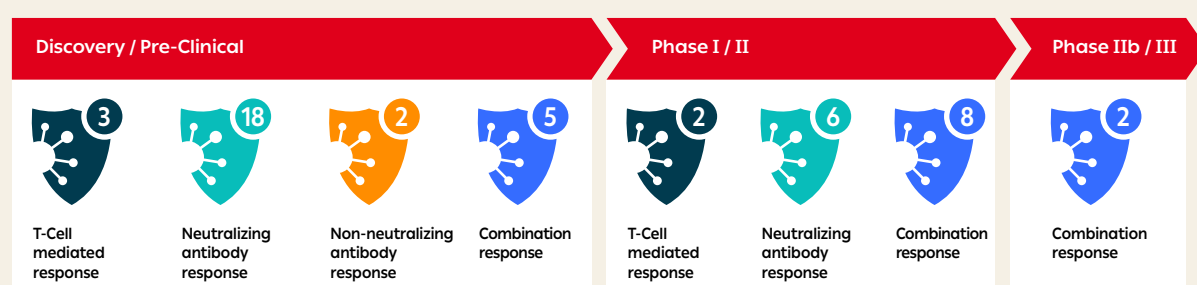
This sense of possibility stemming from COVID-19, coupled with the urgency to rebuild the HIV vaccine product pipeline, will require new ideas and approaches and the engagement of partners from around the world to rebuild momentum. By convening diverse stakeholders and facilitating dialogue and solutions, the Enterprise can help the field strengthen and advance the product pipeline, engage a more global community of researchers, funders and partners, and apply knowledge to foster innovation.

This document describes the context and framework for the Enterprise's new five-year strategy. It begins with an overview of the key opportunities and challenges in the HIV vaccine field today.

## The discontinuation of late-stage HIV vaccine studies has shifted the focus of the field to early-stage development.

Over the past two years, two late-stage HIV vaccine clinical trials have been discontinued due to efficacy futility. **HVTN 702**, led by the Pox-Protein Public-Private Partnership (P5), was discontinued in February 2020; and **HVTN 705**, led by Janssen, was discontinued in September 2021.

With few late-stage candidates in the pipeline, HIV vaccine development activities are now focusing on early-stage discovery and candidate development, a shift that will fundamentally benefit from the exploration of out-of-the-box scientific ideas and innovative vaccine concepts and approaches (for example, understanding and targeting novel immune mechanisms, testing different vaccine platforms and/or adjuvants).



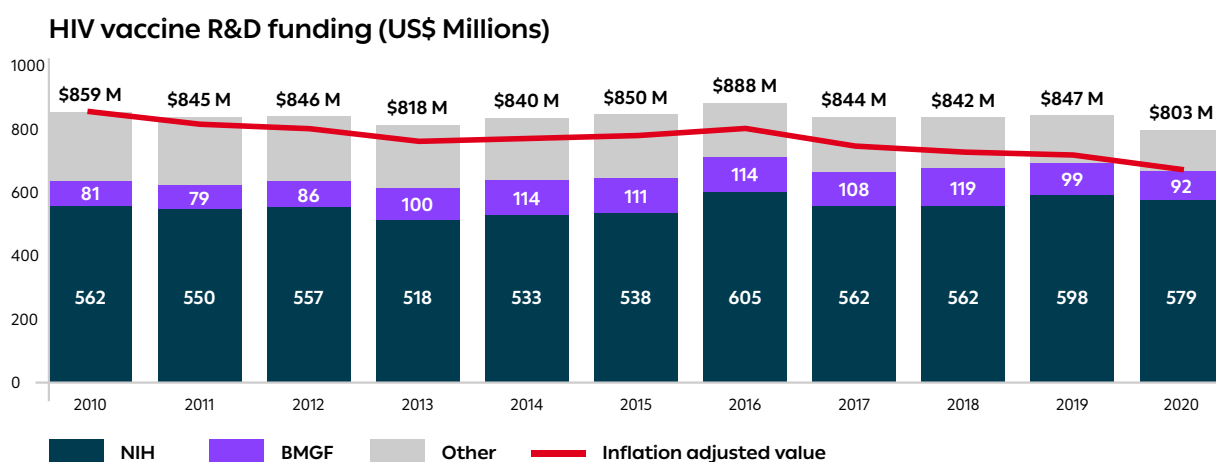
As the field strives to diversify HIV vaccine concepts and maximize the chances of identifying and advancing high-potential candidates, there is an opportunity to strengthen coordination of efforts through a field-wide portfolio approach that guides the distribution of resources and efforts across a diverse set of R&D avenues in parallel.

Finally, with many candidates in the pipeline, integrating approaches to early-stage clinical studies – including adaptive trial designs, combination prevention trials and experimental medicine studies – will be crucial to building a system that can rapidly and iteratively test and advance promising candidates.

**A new era of HIV vaccine development will require collaboration to encourage innovative approaches to vaccine development and foster rapid iteration of new concepts.**

## Attracting investment and talent to the field continues to be a challenge.

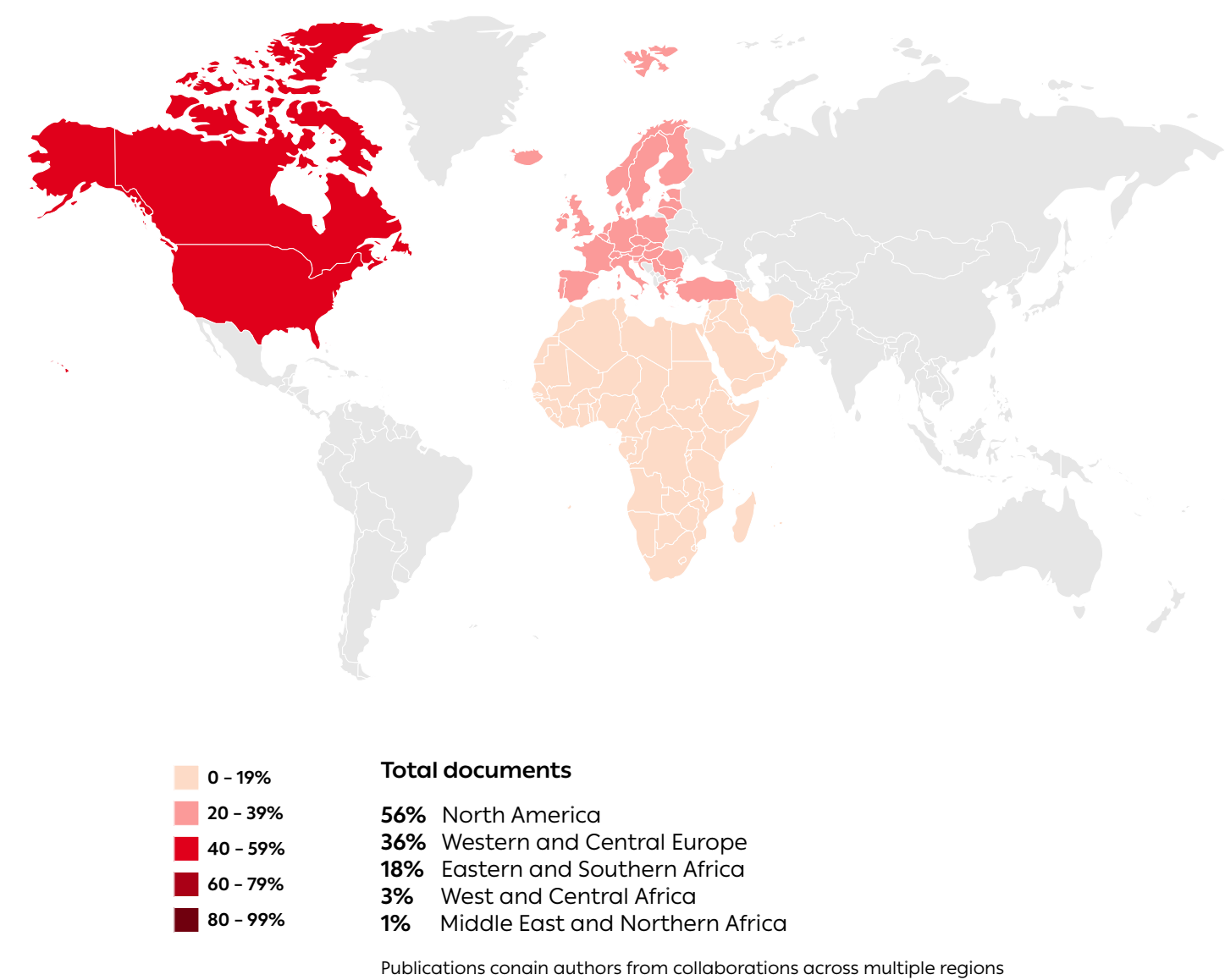
For over a decade, funding for HIV vaccine R&D has remained stagnant (and thus declining in real dollars). It has been dominated by two major US funders: the US Government and the Bill & Melinda Gates Foundation. Smaller financial contributions have been made by other US-based organizations, including USAID and MHRP, and organizations in high-income countries, including the European Commission, the Canadian Institutes of Health Research and the Netherlands Ministry of Foreign Affairs. Without promising late-stage HIV vaccine candidates, funding is most likely to continue to come from government and philanthropic sources for the foreseeable future.



Attracting and diversifying funding after the COVID-19 crisis and post-HVTN 702/705 will require a compelling case for investment that addresses the concerns and interests of a wide range of potential funders. In some countries, the declining prevalence of HIV, rising rates of other infectious diseases, prioritization of pandemic preparedness in general and/or the uptake and effectiveness of available treatment options (notably, PrEP) raise questions about the need for investment in a preventive HIV vaccine. While PrEP has become more widely available and is helping to curb the HIV epidemic, it presents long-term cost and access concerns that can only practically be addressed with a preventive vaccine.

New opportunities also exist to communicate the extraordinary benefits that past investment in HIV vaccine R&D has generated for other infectious diseases (including COVID-19) and to pursue funding opportunities where HIV vaccine research intersects with other infectious diseases, co-morbidities or pandemic preparedness.

Finally, the HIV vaccine talent pool is dominated by world-class researchers in the late stages of their careers, exposing an important need to engage and develop early-stage researchers, particularly from regions most affected by HIV. Indeed, between 2010 and 2017, researchers from Africa and the Middle East participated in less than a quarter of the scientific production of HIV and AIDS research compared with over 80% for researchers from North America and Europe <sup>1</sup>. It will be critical for stakeholders to work together to attract and retain the next generation of HIV vaccine researchers who will reinvigorate the field with new ideas, intellectual energy and experience from the regions most impacted by HIV.



The field must renew the case for HIV vaccine research to broaden the funding base and attract a diverse and engaged community of researchers.

1. González-Alcaide et al. (2020). [HIV/AIDS research in Africa and the Middle East: participation and equity in North-South collaborations and relationships](#)

## There are new opportunities to close scientific gaps and apply knowledge and approaches from other infectious diseases.

While the field is looking ahead to new approaches to HIV vaccine R&D, a lot remains to be learned from previous and ongoing HIV vaccine studies. For example, the recent trial results (such as HVTN 702/705 and AMP) have not yet been analysed in full; an opportunity remains for the field to prepare for sharing and interpreting these results to inform early-stage vaccine efforts. In addition, some observations from previous HIV vaccine studies are not yet well understood, including declining antibody durability following immunization, as well as the discrepancy in vaccine efficacy between animal and human studies. Addressing scientific knowledge gaps such as these can provide important insights with the potential to improve HIV vaccine development.

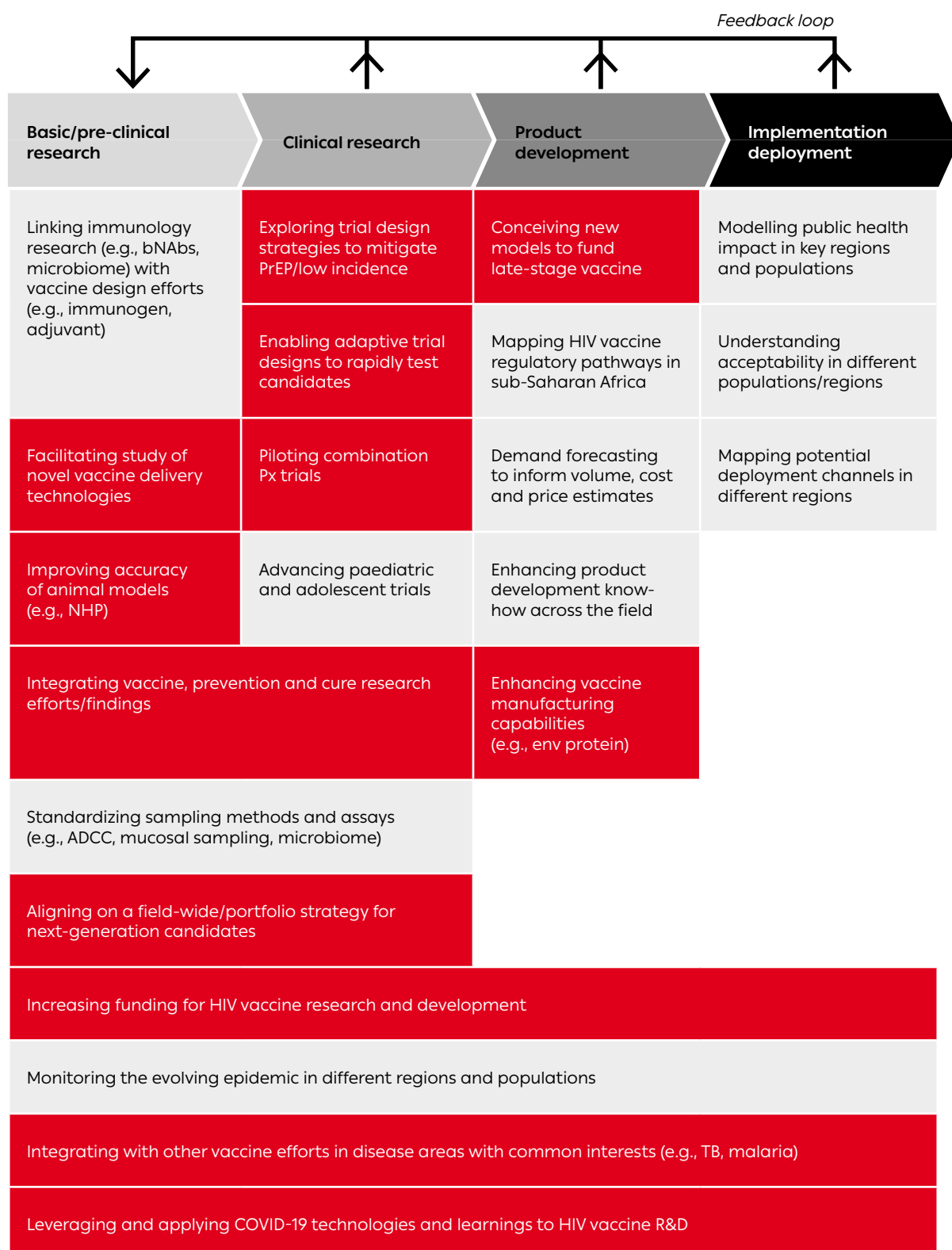
If applied judiciously and thoughtfully, many advances in vaccine R&D stemming from COVID-19 (including agile collaborations, accelerated development of new technologies and innovative data-sharing platforms) have the potential to propel HIV vaccine R&D. In addition to COVID-19, other infectious diseases may also offer unique scientific insights, technologies or approaches (including vaccine platforms, access considerations and funding models) that can be applied to HIV vaccine development and vice versa.



Accelerating HIV vaccine R&D will require stakeholders to come together to fill scientific gaps and leverage knowledge, tools, technologies and approaches developed for other infectious diseases.

## Updated areas of greatest unmet need and potential impact

Given changes to the HIV vaccine landscape since 2018, recent consultations with stakeholders have reinforced a need for the Enterprise to focus on critical issues in earlier stages of the research and innovation continuum. Issues highlighted in bright red represent those that would benefit most from greater coordination, invigorated collaboration and facilitated multi-stakeholder approaches.



# Our strategy

## Vision

A safe and effective HIV vaccine that is available to the world.

## Mission

To unite diverse stakeholders to share knowledge, foster collaboration, enable solutions and expand support critical to accelerating the discovery and development of – and future access to – an HIV vaccine.

## Commitments

1. Strengthening and advancing the HIV vaccine pipeline
2. Expanding and diversifying engagement and resources
3. Mobilizing knowledge to accelerate product development

## The Enterprise approach

Because the Enterprise is neither a funding body nor a direct participant in R&D, it is uniquely poised to serve as a neutral convener of the field, driven by the following guiding principles:



**Facilitate stakeholder alignment** in a neutral & impartial manner



**Focus on complex issues** that cannot be addressed by any single entity



Identify issues and coordinate responses proactively & efficiently



Mobilize collaborative action and decision making toward solutions



Promote accountability of the field to its collective resolve



## Structure of the strategy

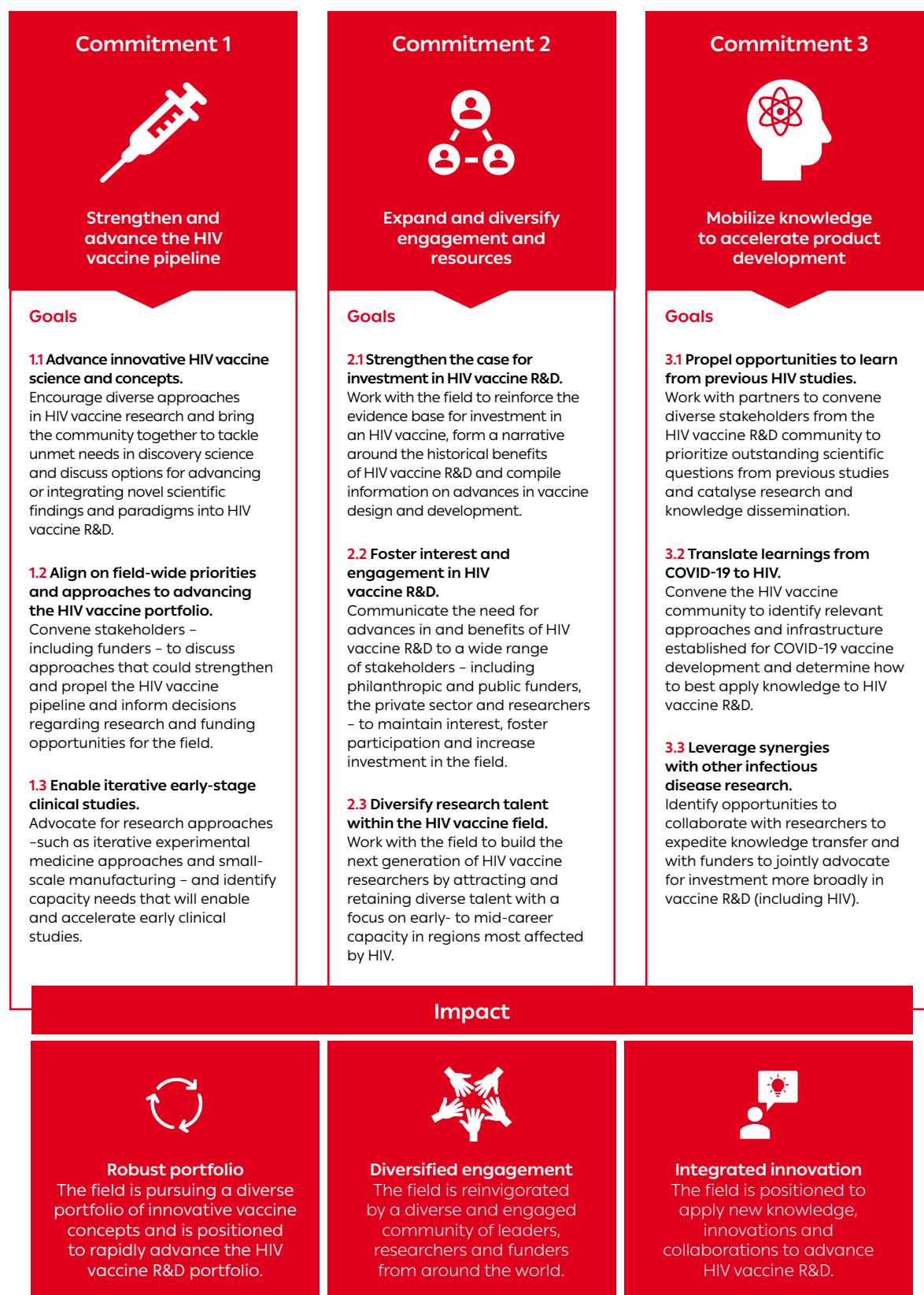
Each **commitment** will be advanced by a set of **goals** that will be achieved through **priority activities** (specific projects on which the Enterprise will focus effort to advance goals). Progress towards these goals and activities will contribute to the **impact** of the Enterprise on the global HIV vaccine research arena.

# Global HIV Vaccine Enterprise

## Strategic Plan 2022-2027

**Vision:** A safe and effective HIV vaccine that is available to the world.

**Mission:** To unite diverse stakeholders to share knowledge, foster collaboration, enable solutions and expand support critical to accelerating the discovery and development of—and future access to—an HIV vaccine.



# Commitment 1

## Strengthening and advancing the HIV vaccine pipeline

**Convene the field to embed innovation, coordination and speed in early-stage candidate development.**

The field has shifted from a period of unprecedented late-stage clinical activity to replenishing the pipeline and accelerating vaccine development. Success in this new phase will hinge on novel approaches (including immune mechanisms and vaccine platforms) to R&D to expand beyond the traditional concepts that have been the focus of past efforts.

**"The next 3-5 years are going to require the field to explore new product concepts and reach beyond the same old players and approaches if we are going to make any significant progress in the near term."**

EAG Member and Past Member of P5

The Enterprise can support this new imperative by bringing stakeholders (such as researchers and funders) together to identify and explore diverse and innovative vaccine concepts (including combinations of concepts and components) that can help fill the early stages of the pipeline. It can also facilitate information sharing to keep the field abreast of plans, outcomes and progress of products toward the later stages of the pipeline.

This commitment will help develop a diverse pool of candidates that reflect the innovative potential of the field and bring stakeholders together to ensure that the approach to advancing the portfolio is rapid, iterative and coordinated.

### GOAL 1.1

**Advance innovative HIV vaccine science and concepts:** Encourage diverse approaches in HIV vaccine research and bring the community together to tackle unmet needs in discovery science and discuss options for advancing or integrating novel scientific findings and paradigms into HIV vaccine R&D.

### GOAL 1.2

**Foster a field-wide portfolio approach to advancing the HIV vaccine pipeline:** Convene stakeholders, including funders, to discuss approaches that could strengthen and propel the HIV vaccine pipeline and inform decisions regarding research and funding opportunities for the field.

### GOAL 1.3

**Enable iterative early-stage clinical studies:** Advocate for research approaches, such as iterative experimental medicine approaches and small-scale manufacturing, and identify capacity needs (personnel, for example) that will enable and accelerate early clinical studies.

#### Priority activities:

- Convene stakeholders around new knowledge and novel paradigms to foster partnerships and seek opportunities to integrate findings into HIV vaccine research.
- Convene researchers and funders to share progress on R&D efforts in the pre- and early-clinical phases and inform research policy and funding directions that optimize progress across the portfolio.
- Develop a policy paper that advocates for the need for health research and innovation systems to support experimental medicine studies (for example, small-scale manufacturing, mRNA or gene-based technology development).

# Commitment 2

## Expanding and diversifying engagement and resources

**Reinvigorate engagement in HIV vaccine R&D through a compelling case for investment and development of a diverse scientific community.**

With flat (if not declining) interest from an already limited number of funders and a perception that an HIV vaccine may not be needed in the context of declining HIV incidence and increasing uptake of PrEP, the field requires an updated narrative and approach to communicating the importance of an HIV vaccine to a breadth of stakeholders.

**"Anything we can do field-wide to help create visibility and opportunities for a diverse pool of talent is critically important because we really need to build the next generation of HIV researchers."**

EAG Member and Past Member of P5

The Enterprise can help maintain momentum in the context of the evolving prevention landscape by supporting the field in articulating the broad benefits of HIV vaccine research (for example, accelerating COVID-19 vaccine R&D) and the continued need for an HIV vaccine while advocating for and attracting diverse stakeholders to the field, including researchers, the private sector, philanthropists and public funders.

This commitment will help diversify and engage a pool of committed funders, researchers and partners, driving the field's HIV vaccine R&D priorities.

### GOAL 2.1

#### **Strengthen the case for investment in HIV vaccine R&D:**

Work with the field to reinforce the evidence base (for example, monitoring incidence, modelling studies and Full Vaccine Value Assessment (FVVA) for investment in an HIV vaccine, form a narrative around the historical benefits of HIV vaccine R&D and compile information on advances in vaccine design and development.

### GOAL 2.2

#### **Foster interest and engagement in HIV vaccine R&D:**

Communicate the need for advances in and benefits of HIV vaccine R&D to a wide range of stakeholders, including philanthropic and public funders, the private sector and researchers, to maintain interest, foster participation and increase investment in the field.

### GOAL 2.3

#### **Diversify research talent within the HIV vaccine field:**

Work with the field to build the next generation of HIV vaccine researchers by attracting and retaining diverse talent with a focus on early- to mid-career capacity in the regions most affected by HIV.

#### **Priority activities:**

- Bring together HIV experts to align on analyses (such as modelling studies and FVVA) that will help the field strengthen the case for continued investment in HIV vaccine R&D.
- Work with partners to leverage and supplement research and analysis conducted by the Enterprise to develop a narrative articulating the benefits of investment in HIV vaccine R&D to the HIV field and to other infectious diseases (for example, COVID-19).
- Advance and expand the Enterprise's African research network programme to engage early- to mid-career researchers from diverse geographic regions.

# Commitment 3

## Mobilizing knowledge to accelerate product development

**Apply knowledge from HIV and other infectious diseases to advance HIV vaccine development.**

As the field transitions to the next chapter of HIV vaccine R&D, it has the opportunity to look within and beyond the HIV vaccine field to harness new paradigms, knowledge, tools and approaches to accelerate HIV vaccine R&D.

**"We need to be opportunistic on what is emerging from other disease areas and whether there are commonalities and cross learnings that can be applied based on what works best first."**

EAG Member

The Enterprise can bring stakeholders together to identify the most crucial questions to be answered from previous HIV vaccine studies. Further, the Enterprise can help the field identify and apply relevant knowledge and approaches from other HIV prevention and cure studies, as well as from COVID-19 and other infectious disease research to advance vaccine research.

Commitment 3 will ensure that the field applies available knowledge, expertise and resources within HIV and the broader infectious disease arena to generate new solutions that can help accelerate the development of a safe and effective vaccine.

### GOAL 3.1

**Propel opportunities to learn from previous HIV studies:** Work with partners to convene diverse stakeholders from the HIV vaccine R&D community to prioritize outstanding scientific questions from previous studies (such as 702, 705 and AMP) and catalyse research and knowledge dissemination.

### GOAL 3.2

**Translate learnings from COVID-19 to HIV:** Convene the HIV vaccine community to identify relevant approaches and infrastructure established for COVID-19 vaccine development (including technologies, agile collaborations, data-sharing platforms and research infrastructure) and determine how to best apply knowledge to HIV vaccine R&D.

### GOAL 3.3

**Leverage synergies with other infectious disease research:** Identify opportunities to collaborate with researchers to expedite knowledge transfer (for example, vaccine platform optimization and access considerations) and with funders to jointly advocate for investment more broadly in vaccine R&D (including HIV).

#### Priority activities:

- Work with partners to convene stakeholders involved in HVTN 702 and HVTN 705 to prioritize analyses to be conducted as a follow-up to the pivotal studies.
- Bring HIV and COVID-19 experts together to identify and assess knowledge, tools and approaches from COVID-19 with potential value to HIV vaccine R&D.
- Convene stakeholders on a regular basis to scan the broader infectious disease and/or pandemic preparedness research environment and surface opportunities for partnership and knowledge transfer to HIV.

# Impact

The Enterprise has played a critical role in the HIV vaccine arena as a neutral convener focused on addressing challenges and opportunities central to accelerating the development of an HIV vaccine. Orienting the Enterprise's efforts around issues most relevant to the field today, the 2022-2027 Strategic Plan will enable it to help reinvigorate the field and achieve the following key impacts:



## Robust portfolio

The field is pursuing a diverse portfolio of innovative vaccine concepts and is positioned to rapidly advance the HIV vaccine R&D portfolio.



## Diversified engagement

The field is reinvigorated by a diverse and engaged community of leaders, researchers and funders from around the world.



## Integrated innovation

The field is positioned to apply new knowledge, innovations and collaborations to advance HIV vaccine R&D.

**Now more than ever, a well-coordinated and collaborative approach is crucial to unlocking the promise of new solutions to enduring challenges in the HIV vaccine field.**

**Our 2022-2027 Strategic Plan reinforces the Enterprise's role in helping the field accelerate the discovery and development of a safe and effective HIV vaccine for the world.**