Pox-Protein Public Private Partnership (P5)
Access Planning

Global HIV Vaccine Enterprise
PD Bootcamp

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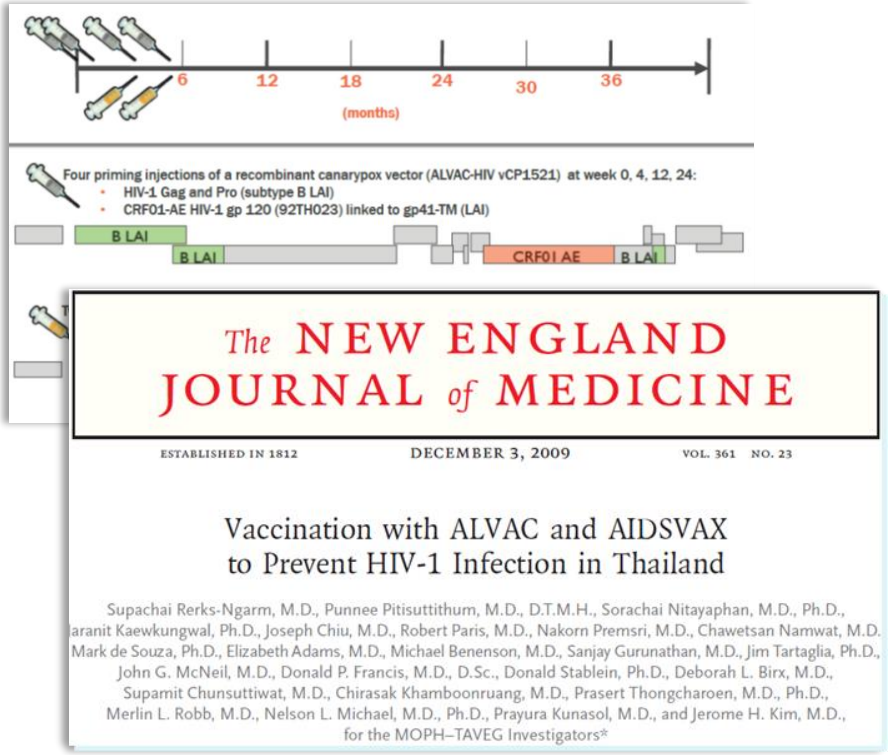
BILL & MELINDA GATES *foundation*

RV144 was the first Phase 3 trial to suggest that an HIV vaccine may be achievable



- Partnership among US Military, NIAID, Sanofi Pasteur, GSID and the Government of Thailand
- Pox-protein prime-boost regimen of two vaccine candidates lowered the rate of HIV infection by 31.2% in a study of 16,000 Thai adult volunteers
- Yielded unprecedented scientific insight into the immune responses associated with a reduced risk of HIV infection

Interest in building on the results of RV144 led to the establishment of the Pox-Protein Public Private Partnership (P5).

The P5 is a public-private partnership committed to building on the findings from RV144

- Testing modified vaccine components from RV144 with the goal of enhancing efficacy and prolonging protection
- Early safety and immunogenicity studies in South Africa are currently underway; efficacy studies are being planned
- Parallel P5 research studies

Given HIV incidence in RSA, even a modestly efficacious vaccine might achieve impact in high-risk populations.

Planning for future access to a successful vaccine is a priority for the P5.

An efficacious result from the P5 development track studies may set the stage for vaccine licensure

If there is a clear efficacy result from HVTN 702, the path from VE to licensure and rollout will be multi-year and complex.

P5 aims to build upon the access planning lessons learned in RV144

The process takes time: start early

Plan judiciously for all outcomes—aspirational, expected and unlikely

Develop a meticulous stakeholder engagement strategy

Codify and manage the effort as a defined project with clear deliverables

Acknowledge and manage diverse partner expectations

Prior to launch of an efficacy trial, the P5 is building a proactive, transparent and highly collaborative access planning process.

Access Planning is a key element of planning for success

The P5 has established a Global Access Committee to guide development of an Access Plan that will define expectations and outline commitments essential to making a successful vaccine available to target populations in RSA and ultimately Southern Africa.

Each P5 partner represented on the GAC has equal say in the decision-making process.*

The GAC has been charged with engaging stakeholders in RSA to develop an Access Plan that reflects the interests of South Africa and P5 partners.

* The GAC is guided by terms of reference endorsed by all P5 partners.

The Access Plan will set expectations and provide a roadmap for the deployment of an efficacious vaccine

Ensuring timely, sustainable access to a safe and efficacious vaccine requires a strategy that:

- Projects the ***public health impact and identifies target population(s) for which the highest impact may be achieved*** under different levels of efficacy
- Identifies and outlines potential solutions to ***commercial, regulatory, manufacturing, policy and deployment*** considerations
- Defines ***conditions, processes and provisions (e.g. funding, manufacturing) for access*** based on vaccine characteristics and public health objectives

Vaccine Access Plan is a critical to defining partner commitments required to ensure a clear, feasible and impactful public health strategy.

The P5 Access Plan will address a range of key questions in the context of an evolving HIV landscape

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Priority Populations/ Targets

Target population(s)?
Bridging studies?
Public health objective?

Regulatory Requirements

Licensure requirements?
Regulatory strategy?
Implications for future studies?

Market Conditions

Public/private delivery?
Forecasted demand?
Cost of goods?

Technology Sharing

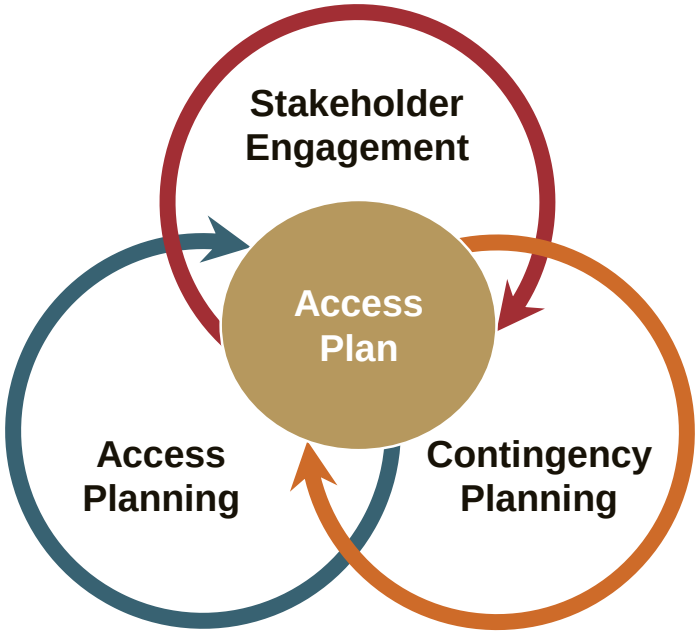
Tech sharing expectations?
Manufacturer capabilities?
Transfer agreements?

Manufacturing/ Product Development

Funding commitments?
Manufacturing responsibility?
Volume/timing expectations?

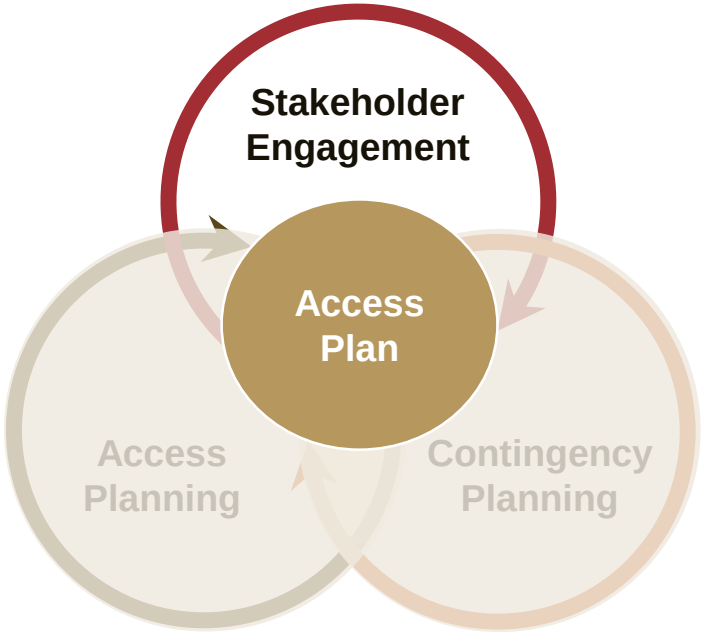
Addressing these questions requires ongoing partner, stakeholder and community engagement.

The P5 is pursuing a three-pronged approach to the development of the Access Plan



Access planning is an iterative process informed by stakeholder interests and the need to plan for different contingencies.

The P5 GAC is committed to timely, consistent and transparent stakeholder engagement



ONGOING ACTIVITIES

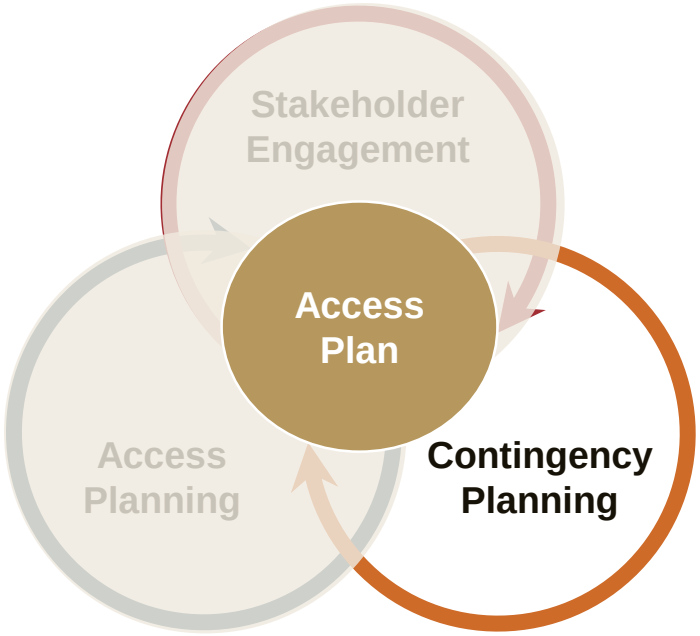
- Engage key stakeholders from different sectors
- Identify access questions and policy considerations
- Understand stakeholder and community interests

FUTURE ACTIVITIES

- Inform vaccine impact model parameters and assumptions
- Contribute to future access discussions
- Validate the Access Plan

Having completed extensive outreach to introduce the GAC process and secure buy-in, our stakeholder engagement effort is now focused on gathering insights and data critical to the vaccine impact modelling effort.

Contingency Planning prepares all partners for potential risks and outcomes of the trial



ONGOING ACTIVITIES

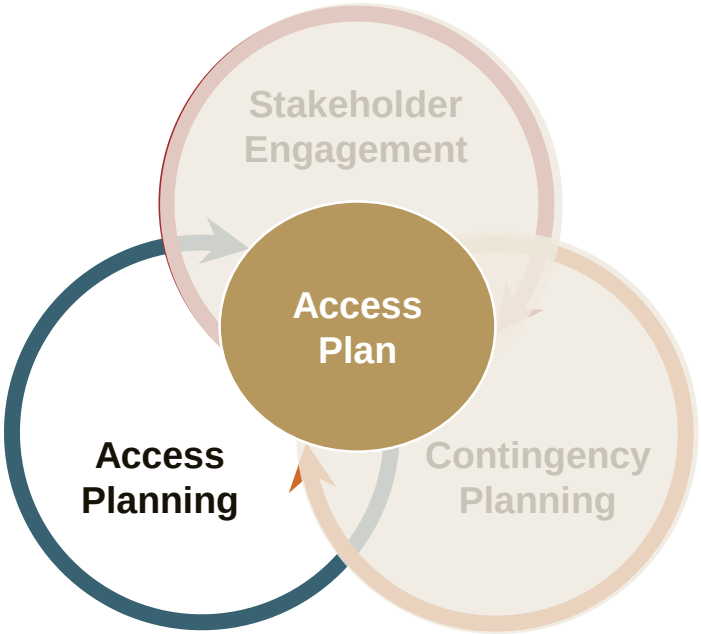
- Assembly of a Roadmap Working Group (RWG)
- Development of RWG terms of reference

FUTURE ACTIVITIES

- Identify different safety, operational and efficacy outcomes
- Define strategies to manage/respond to outcomes
- Coordinate partners around a single consensus-based agenda and communications plan

Contingency Planning compels partners to plan for success—and for potential challenges —and in doing so clarifies the conditions under which vaccine access provisions will be triggered.

Access planning is an iterative process that needs to evolve with the changing HIV prevention landscape



ONGOING ACTIVITIES

- Identify access issues at different VE ranges
- Determine assumptions & parameters for impact modelling
- Understand government & regulatory expectations related to vaccine access

FUTURE ACTIVITIES

- Public health impact modelling to inform the Access Plan
- Develop access roadmap & implementation plan
- Define commitments required for vaccine access
- Modify Plan as circumstances evolve

Access planning is informed by impact modelling, contingency planning and iterative stakeholder engagement.

Access Plan will aim to position the P5 to meet vaccine access requirements under predefined scenarios

THE ACCESS PLAN WILL AIM TO:

- Outline the regulatory, market demand, technology transfer, manufacturing and pricing requirements for vaccine access
- Define timelines, principles, activities and provisions required for access
- Secure sustainable commitments to making the vaccine available to key populations

P5 partners are committed to constructing a plan that will define requirements for achieving timely and sustainable access for populations where a significant public health impact can be achieved.