Innovative approaches to accelerate vaccine development for low-resource countries

11th Annual General Meeting & Conference of DCVMN

September 16, 2010





A world where innovation ensures that health is within reach for everyone.



PATH's mission

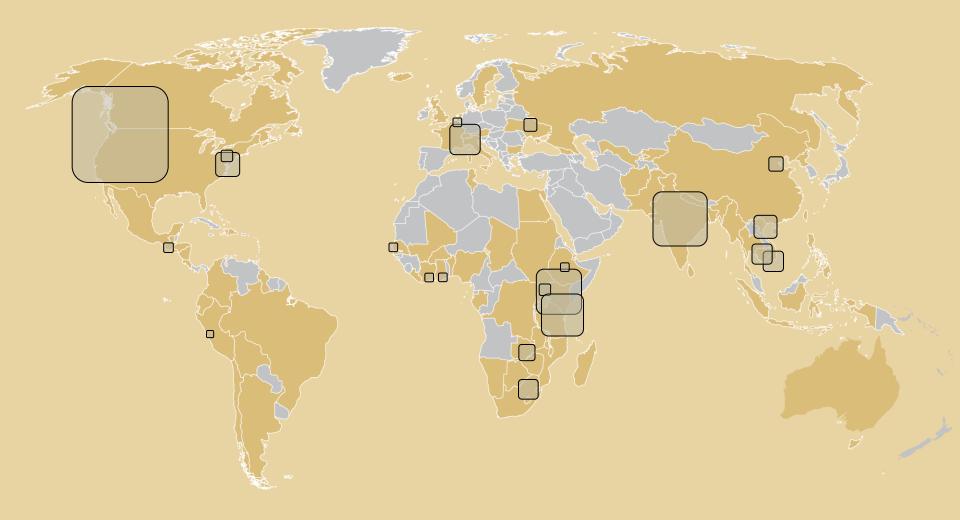
Improving the health of people around the world by:

- Advancing technologies
- Strengthening systems
- Encouraging healthy behaviors



M.Dorgabekova

PATH's global presence



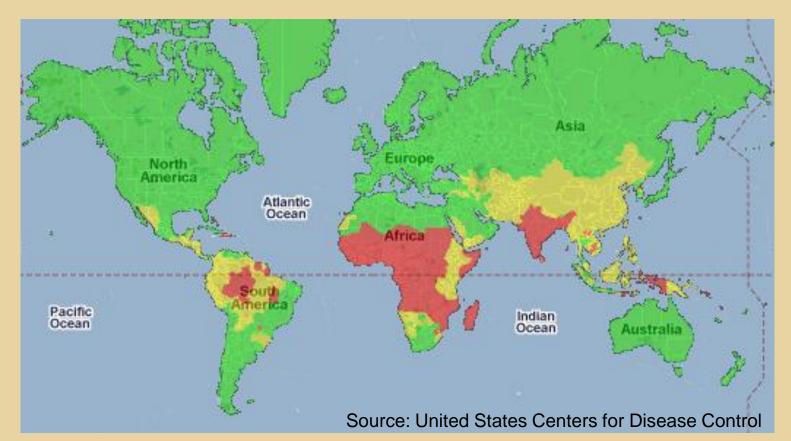
PATH is working in countries shaded orange. Area of square indicates staff per office.

PATH's vaccine development projects

- Pneumococcal disease
- Diarrheal disease
 - Rotavirus
 - Enterotoxigenic *E.* coli and Shigella
- Influenza
- Malaria
- Meningococcal disease



Malaria: market opportunity?



- Each year 350–500 million cases of malaria occur worldwide
- Over one million people die, most of them young children in sub-Saharan Africa
- In 2002, malaria was the fourth cause of death in children in developing countries.

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PATH & GSK: RTS,S malaria vaccine

Background

- GlaxoSmithKline Biologicals (GSK) created RTS,S vaccine candidate in 1987 in close collaboration with Walter Reed Army Institute of Research
- In 2001 GSK and the PATH Malaria Vaccine Initiative (MVI) formed PDP with support from the Bill & Melinda Gates Foundation
- Goal
 - Develop vaccine for infants and young children, with a geographic focus on sub-Saharan Africa





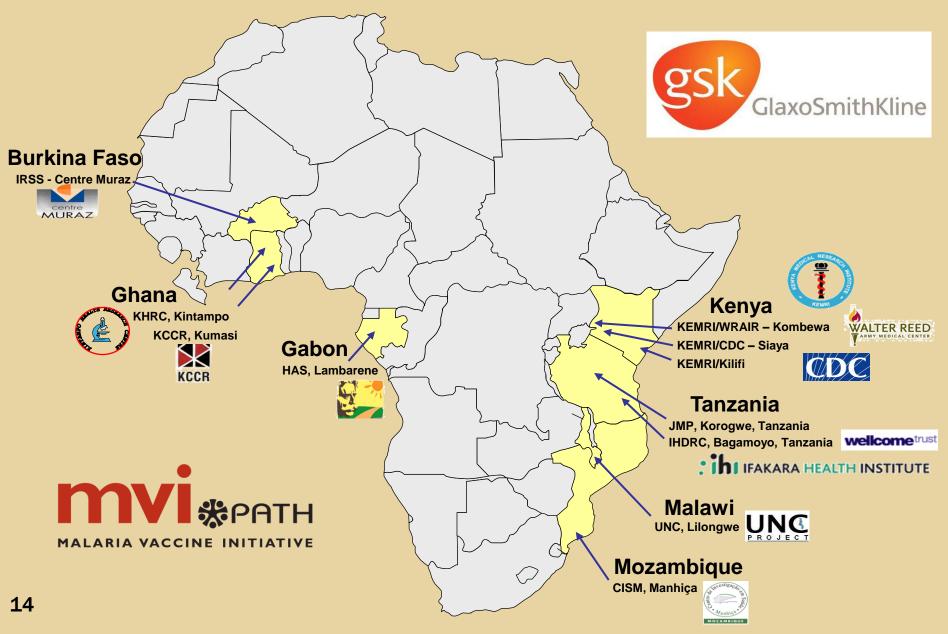
RTS,S malaria vaccine status – Phase 2

Phase 2 clinical trials completed March 2007

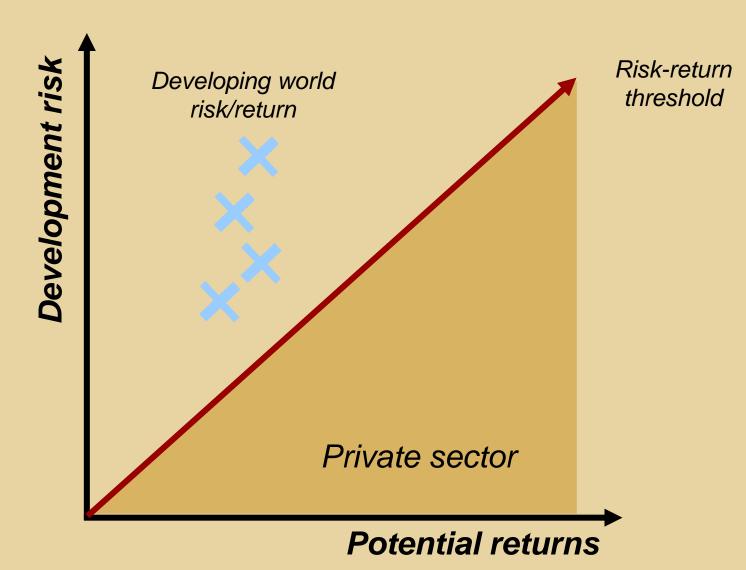
- Beneficial effect on clinical and severe disease over 42 months
- Favorable safety profile (9000 doses to 3000 infants and children)
- Can be coadministered within the infant EPI immunization schedule



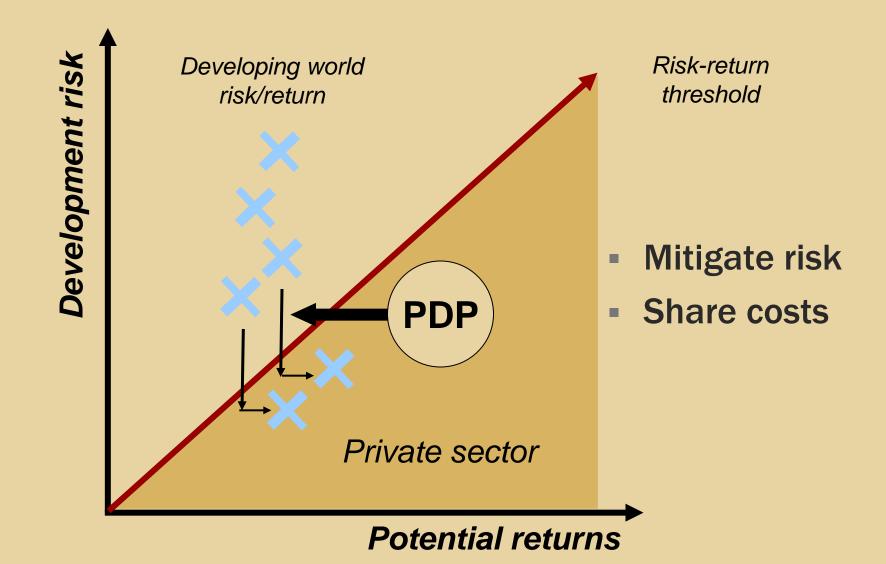
RTS,S malaria vaccine status - Phase 3 trial



Role of product-development partnerships



Role of product-development partnerships



Mutually beneficial, collaborative partnerships

Mutual benefit

WHAT PATH BRINGS

- Expertise in developing country health systems
- Presence in poor countries
- Ability to strengthen clinical trial capacity
- Financial support
- Technical expertise
- Strategic relationships
- Intellectual property

WHAT PARTNERS BRING

- Expertise in product development
- Scientific and technical capacity
- Intellectual property
- Manufacturing facilities & equipment
- Large-scale distribution systems
- Market-based approach

Drivers of partnership diversity

State of Science or Technology

Intellectual Property

Time to Market

Clarity of Market

Distribution System Readiness

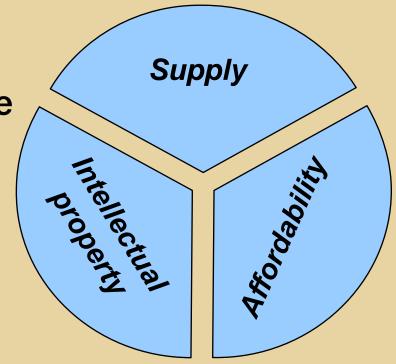
Partnership Complexity



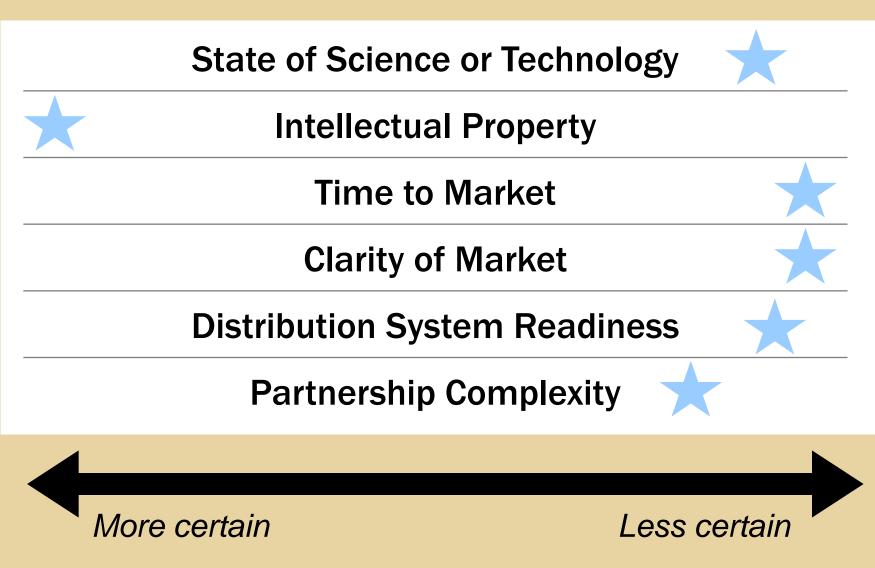
Less certain

Global access: critical terms

- Ensuring product supply
 - Impact requires scale
- Making products affordable
 - Market segmentation enables tiered pricing structures
- Managing intellectual property
 - Relative value of supply and price concessions vs royalties
 - Reserve rights if supply/pricing commitments not met



Case: RTS,S malaria vaccine



Case: RTS,S malaria vaccine

Partnership terms

- GSK to supply and provide preferred pricing for infants and children in malaria-endemic regions of Africa
- MVI to research and project demand in Africa
- MVI and GSK work together with government and other partners to ensure that clinical trials adhere to the highest clinical, ethical, and safety standards.





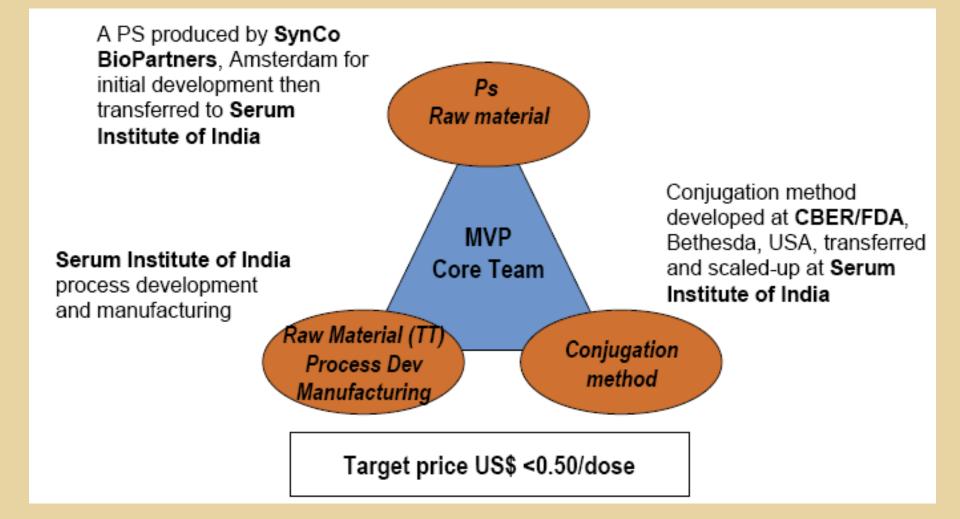
PATH Meningitis Vaccine Project (MVP)

Background

- Created in June 2001 by a grant from the Bill & Melinda Gates Foundation as a 10-year partnership between WHO and PATH
- Goal
 - Eliminate epidemic meningitis as a public health problem in Sub-Saharan Africa through the development, testing, licensure and widespread use of conjugate meningococcal vaccines



MVP Men A vaccine development model



Men A conjugate vaccine- "MenAfriVac"



MVP status

MenAfriVac[™], the Men A Conjugate Vaccine (PsA-TT) developed by MVP & Serum Institute of India has shown:
Equivalent safety profile to the licensed polysaccharide and Hib vaccines in 1-29 year-olds in Africa and India
The characteristics of a conjugate vaccine:

- Superior immunogenicity (rSBA & hSBA) in 12-23 month olds vs. the licensed polysaccharide vaccine
- Effective inducement of immunological memory in 12-23 month olds
- Inducement of bactericidal antibodies persisting at sustained levels in 12-23 month olds vs. polysaccharide vaccine
- Superior immunogenicity (rSBA) confirmed in 2-29 year olds in Africa & in 2-10 year olds in India vs. polysaccharide vaccine

MVP introduction strategies

- Single dose in catch up vaccination campaigns for 1 to 29 year olds to rapidly induce herd immunity
 - Start with Burkina Faso, Mali and Niger
 - Other belt countries are prioritized on the basis of epidemiologic need and absorptive capacity
- Protect birth cohorts
 - Single dose at 9-12 months or two doses (14 weeks and 9 months) within the EPI schedule

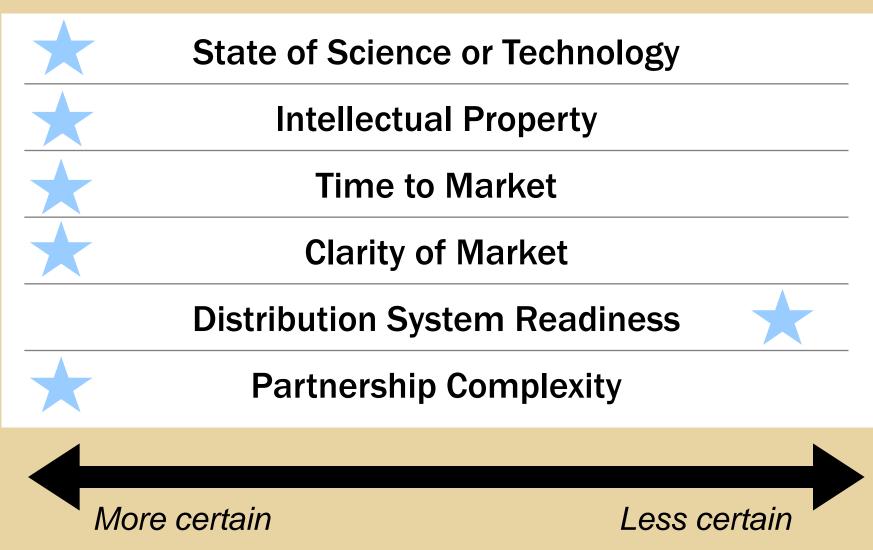
or

 Follow-up campaigns targeted at 1-4 year olds every 5 years

MVP 2010 timelines for introduction

- Market authorization by the Indian National Regulatory Agency in Q1 2010
- WHO Prequalification achieved June 23, 2010
- Introduction in Burkina Faso, Mali, and Niger in Q4 2010

Case: Men A conjugate vaccine



Case: Men A conjugate vaccine

Partnership terms

- Serum Institute of India to supply guaranteed volume vaccine/year at USD<.50/dose
- WHO to assist in registration activities in Sub-Saharan Africa
- WHO to assist in vaccine introduction activities in Sub-Saharan Africa



Case: Japanese Encephalitis Vaccine

Background

- Efforts to control vector, the Culex mosquito, have been ineffective
- Inactivated vaccine exists, but cost out of reach for public sector programs; millions of children at risk
- Chengdu Institute of Biological Products had manufactured improved vaccine to protect over 200 million children in China over a 20-year period
- Goal
 - Ensure equitable access to a safe, efficacious vaccine





Case: Japanese Encephalitis Vaccine

\star	State of Science or Tech	nology
$\mathbf{\star}$	Intellectual Proper	ty
N/A	Time to Market	
$\mathbf{\star}$	Clarity of Market	
\star	Distribution System Readiness	
\star	Partnership Comple	xity
More certain		Less certain

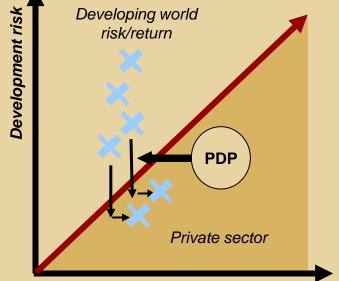
Case: Japanese Encephalitis Vaccine

Partnership terms

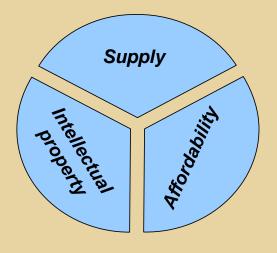
- CDIBP caps public-sector price until 2026 for lowincome countries; gains access to international markets
- PATH builds evidence base for use by collecting data required for country-by-country licensure and eventually for WHO prequalification
- Collaboration supports construction of new facility to ensure sufficient, sustainable, and affordable supply.
 PATH provides technical assistance to confirm that equipment, installation and production meet global standards

Product development partnerships and global access

- Expand the risk/return threshold for the private sector
- Identify unique partnership characteristics
- Negotiate global access consistent with partnership



Potential returns



Conclusions

- Vaccines represent one of the most successful and cost-effective public health interventions available today.
- Millions of children remain underimmunized or unimmunized because of the shortage of affordable and available vaccines.
- PATH is working to close the immunization gap by partnering to develop new vaccines and ensuring access to those vaccines for developing-country populations.

For further information

Maximizing the benefits of public-private partnerships

- **Availability** н,
- Accessibility
- Affordability

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Maximizing the benefits of public-private partnerships

An overview of PATH's approach to maximizing the availability, accessibility, and affordability of global health technologies through private-sector collaboration

Recent increases in global health resources have prompted new models for solving global health oblems. Creative partnerships between the public and private sectors have been one successful punce and private sectors have been one successful approach. Because many of these partnerships receive support from public or philanthropic sources, it is important to ensure that the resulting products are available as "global public health goods"—that is, roads that are available accessible and affordable to one as a means to improve health.

Since 1977, PATH has partnered successfully with many organizations, including dozens of commercial firms. We typically collaborate with a commercial firms. We typically collaborate with a company to develop a specific product that will help to overcome a global health challenge, especially for people living in resource-poor settings. This document shares our experience working with our partners—whether commercial, academic, ment, research, or nonprofit-to ensure that the products we develop together are best made available to improve public health.

Mutually beneficial partnerships

MULGING DETERTION PATTORShips PATTH goal in any patternship is to fulfill our mission: to improve the health of people around the world by asknonic technologics, strengthening systems, and encouraging healthy behaviors. PATTH looks for alignment between our global health goals and our pattern's goals to create a successful patternship har providers mutual heanfit. We doign the project so the goals of both PATTH and our sentence on hear the Theoremet for mutual heanfit partner can be met. The greater the mutual benefit, e stronger the partnership and the more likely that global health goals will be achieved.

PATH actively engages in developing and commercializing health products with our partners. We work collaboratively, helping to solve problems, make decisions, and track progress. Working closely

with partners is critical when several partnerships must be coordinated to develop a single product. PATH codifies our negotiations with partners in legal agreements. These agreements are essential regal agreements. Inese agreements are essential to protecting our investment and ensuring global health goals will be reached. They establish a framework and are one component of our ongoing, collaborative relationships. Unique partnerships

PATH develops a unique, strategic approach to each partnership. We carefully consider a number of issues and weigh a range of options. In developing our approach, PATH builds an understanding of the risks and barriers that have prevented a particul global health problem from being solved. For example, what is the status of the research? Has the manufacturing process been developed? Is the market for the product clear? Are there complex partnership or intellectual property networks that must be navigated? PATH also takes time to understand the constr

that define how potential partners can engage. For that define how potential partners can engage. Yor example, what market pressures are they facing? Where are they succeeding or being challenged? Are they being considered for acquisition or divestiture? How does this potential partnership relate to other products or intellectual property the partner owns? PATH also considers how to best ensure that the partnership's discoveries can be applied to improve health, even if the partnership doesn't proceed as anticipated.

PATH's specific approach to a partnership is a function of the factors outlined in the "Drivers of partnership diversity" figure. Our tailored appr to each partnership allows us to address the variability in these and other factors.

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