

# **Innovative approaches to accelerate vaccine development for low-resource countries**

**11<sup>th</sup> Annual General Meeting &  
Conference of DCVMN**

**September 16, 2010**



## **PATH's vision**

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



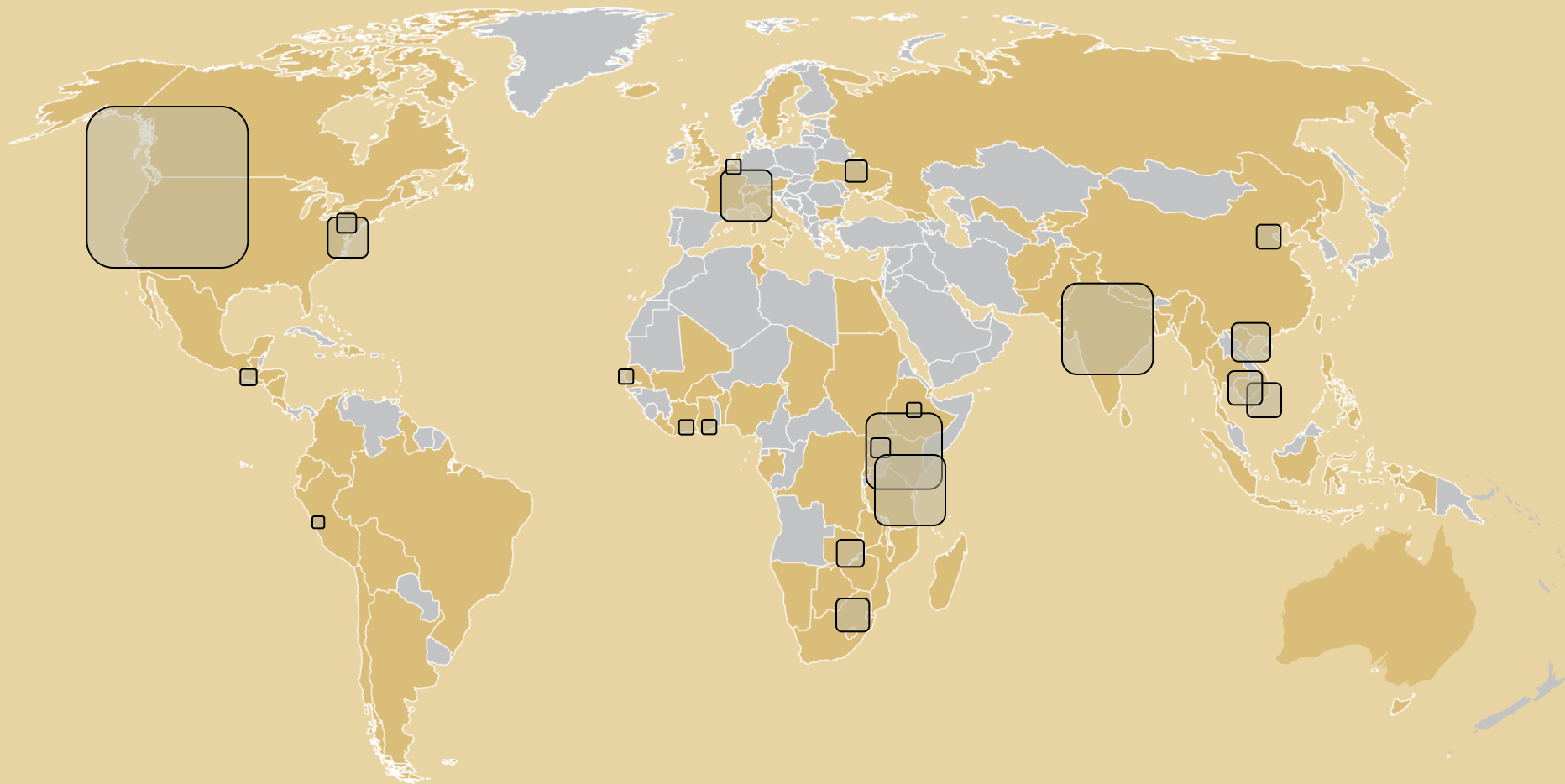
# **PATH's mission**

**Improving the health of people around the world by:**

- **Advancing technologies**
- **Strengthening systems**
- **Encouraging healthy behaviors**



# PATH's global presence



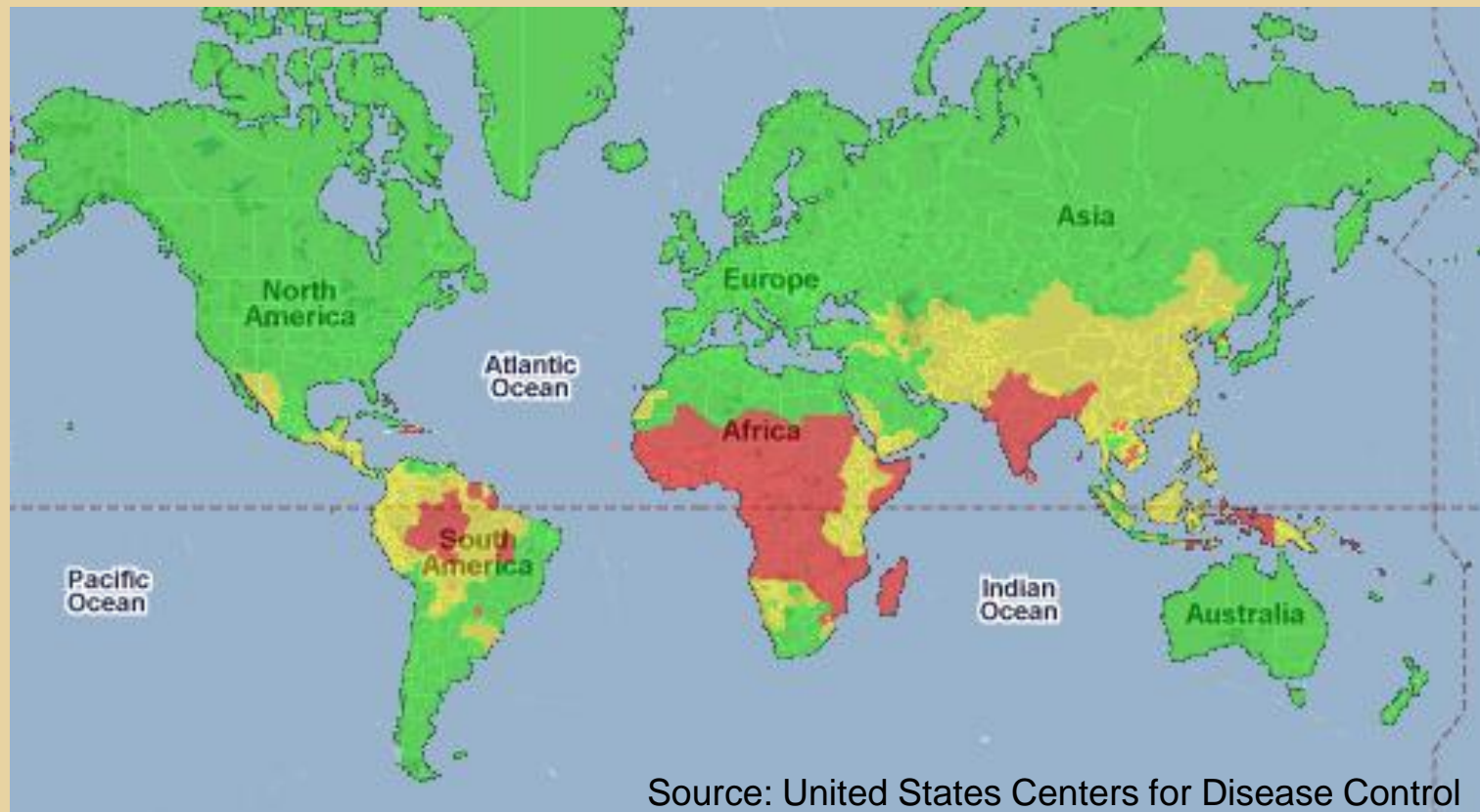
PATH is working in countries shaded orange.  
Area of square indicates staff per office.

# 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.

# **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 co-administered within the infant EPI immunization schedule**





# RTS,S malaria vaccine status – Phase 3 trial



## Burkina Faso

IRSS - Centre Muraz



## Ghana

KHRC, Kintampo

KCCR, Kumasi



## Gabon

HAS, Lambarene



## Kenya

KEMRI/WRAIR – Kombewa

KEMRI/CDC – Siaya

KEMRI/Kilifi



## Tanzania

JMP, Korogwe, Tanzania

IHDRC, Bagamoyo, Tanzania



ih IFAKARA HEALTH INSTITUTE

## Malawi

UNC, Lilongwe

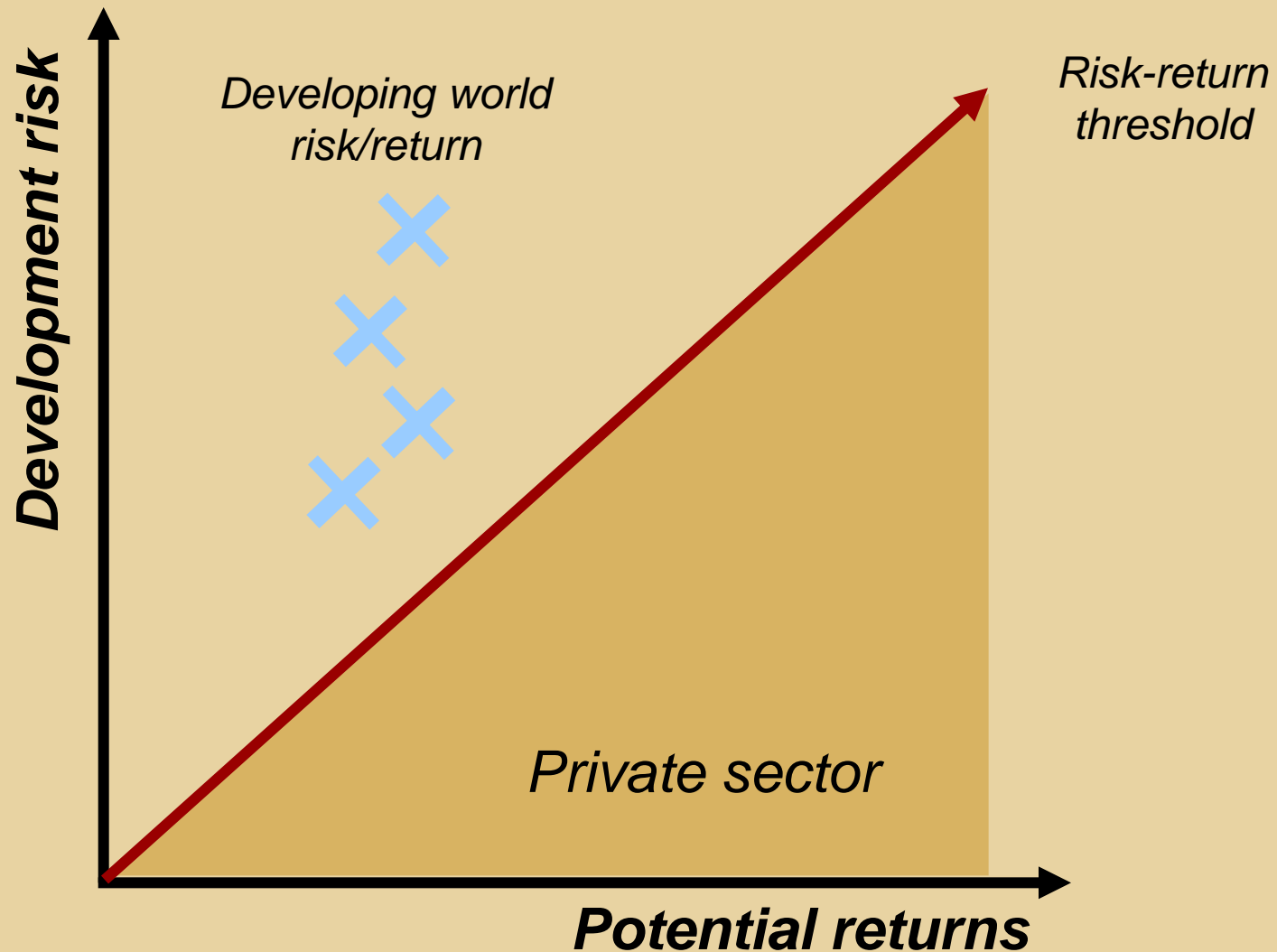


## Mozambique

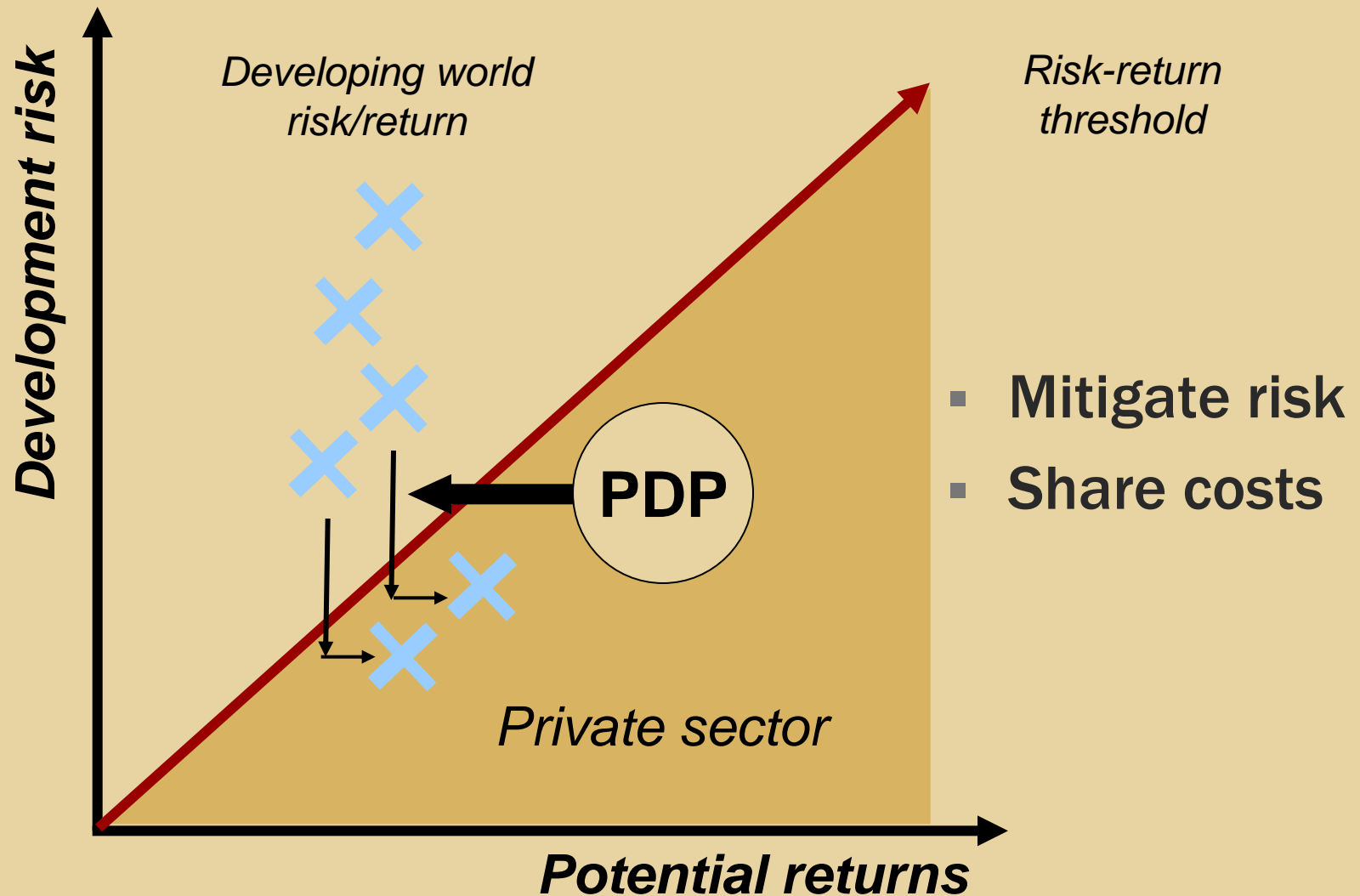
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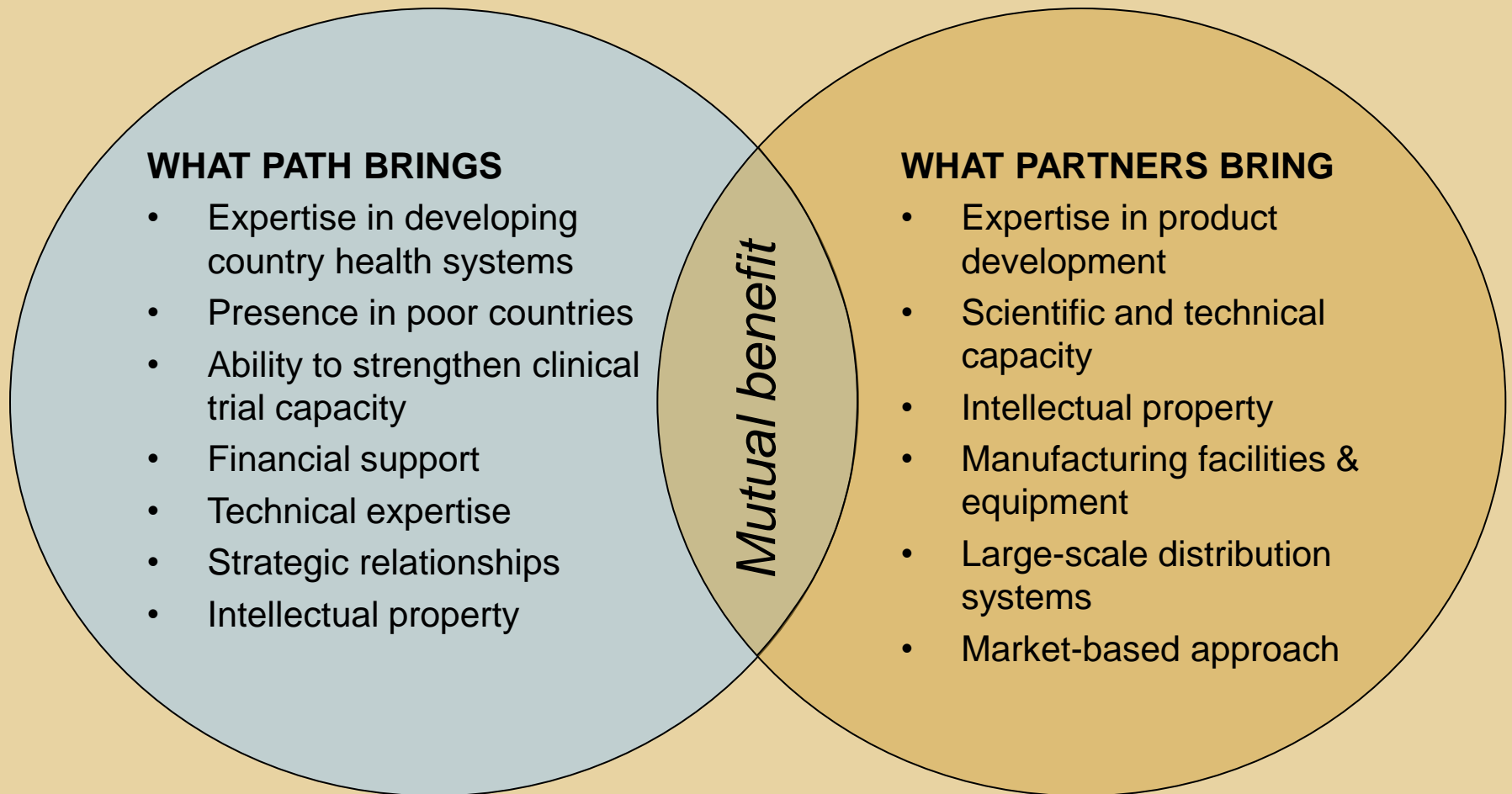
# Role of product-development partnerships



# Role of product-development partnerships



# Mutually beneficial, collaborative partnerships



# Drivers of partnership diversity

**State of Science or Technology**

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**Intellectual Property**

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**Time to Market**

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**Clarity of Market**

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**Distribution System Readiness**

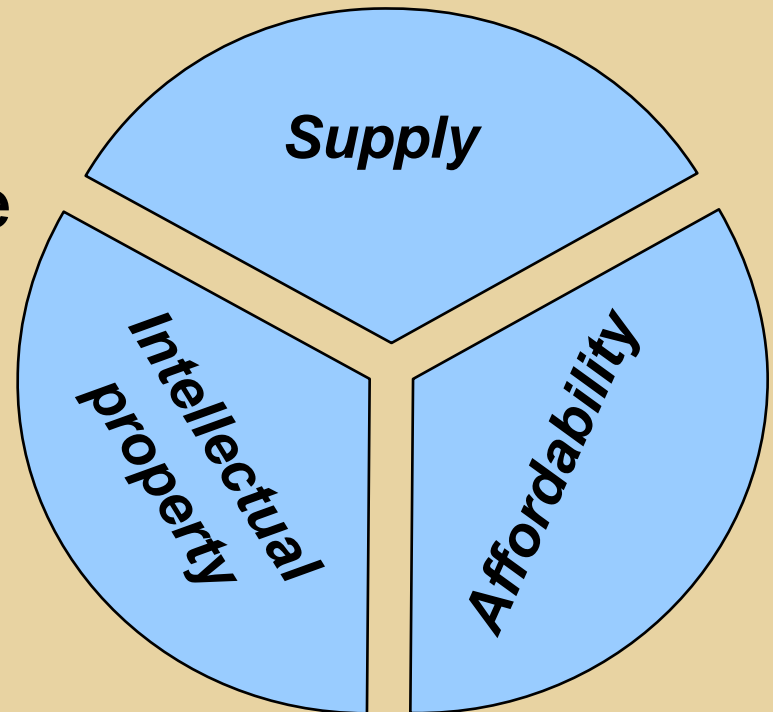
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**Partnership Complexity**



# 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

State of Science or Technology



Intellectual Property



Time to Market



Clarity of Market



Distribution System Readiness



Partnership Complexity



*More certain*

*Less certain*



# 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**

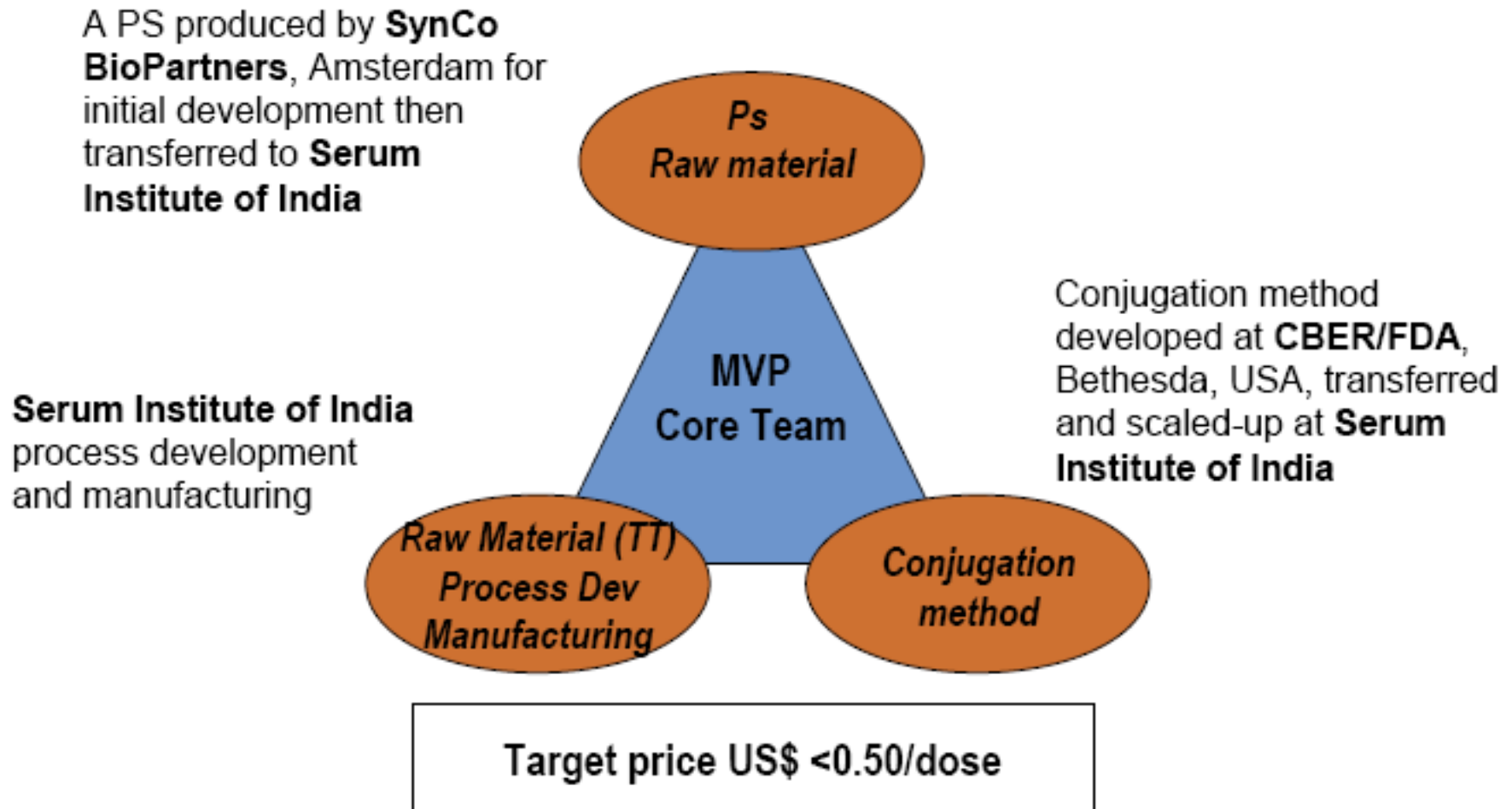
- Created in June 2001 by a grant from the Bill & Melinda Gates Foundation as a 10-year partnership between WHO and PATH

- **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



**State of Science or Technology**



**Intellectual Property**



**Time to Market**



**Clarity of Market**

**Distribution System Readiness**



**Partnership Complexity**



*More certain*

*Less certain*

# 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



**State of Science or Technology**



**Intellectual Property**

**N/A**

**Time to Market**



**Clarity of Market**



**Distribution System Readiness**



**Partnership Complexity**



*More certain*

*Less certain*

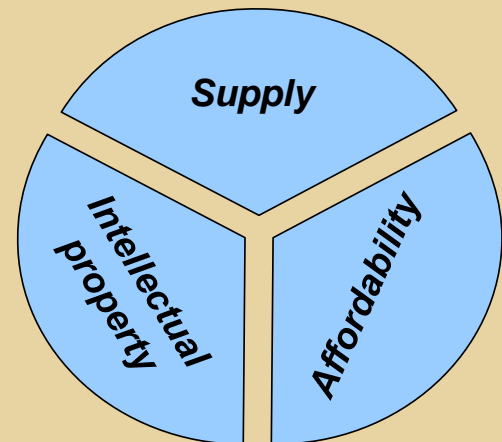
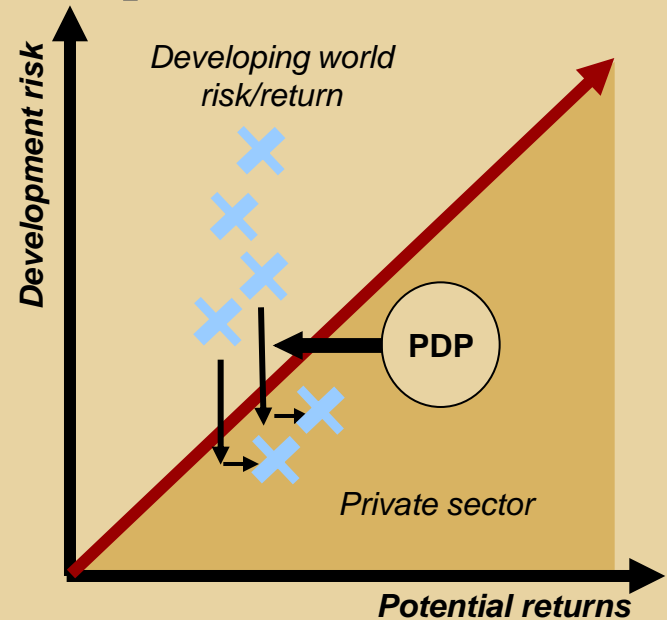


# **Case: Japanese Encephalitis Vaccine**

- **Partnership terms**
  - **CDIBP caps public-sector price until 2026 for low-income 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



# 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.



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