

Partnerships in Achieving Manufacturing Excellence

George Robertson

International Workshop
on "Vaccine Quality
Management"

July 10 - 11th 2013 –
Hosted by Birmex,
Mexico D.F.



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

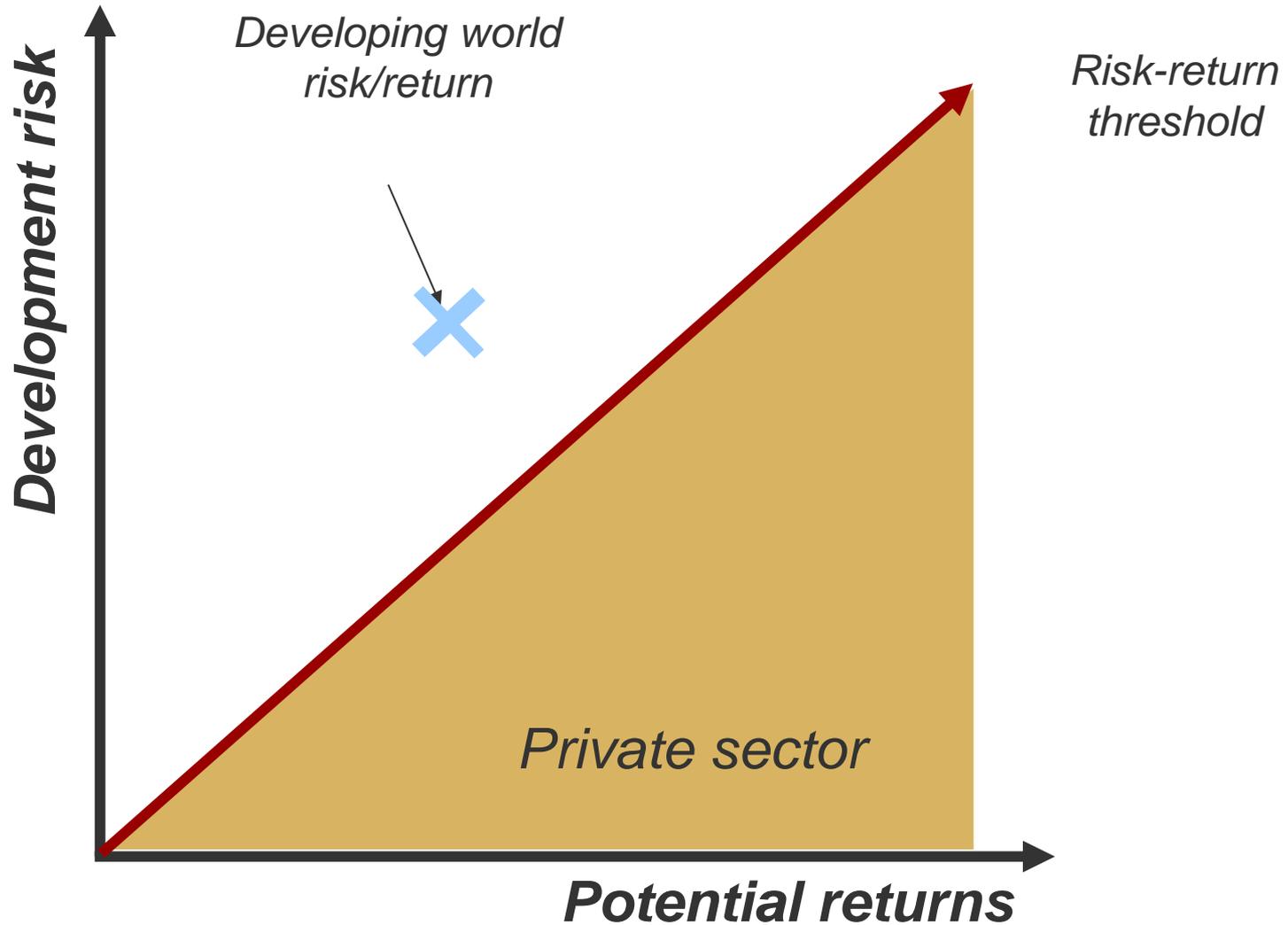


PATH's vaccine development projects

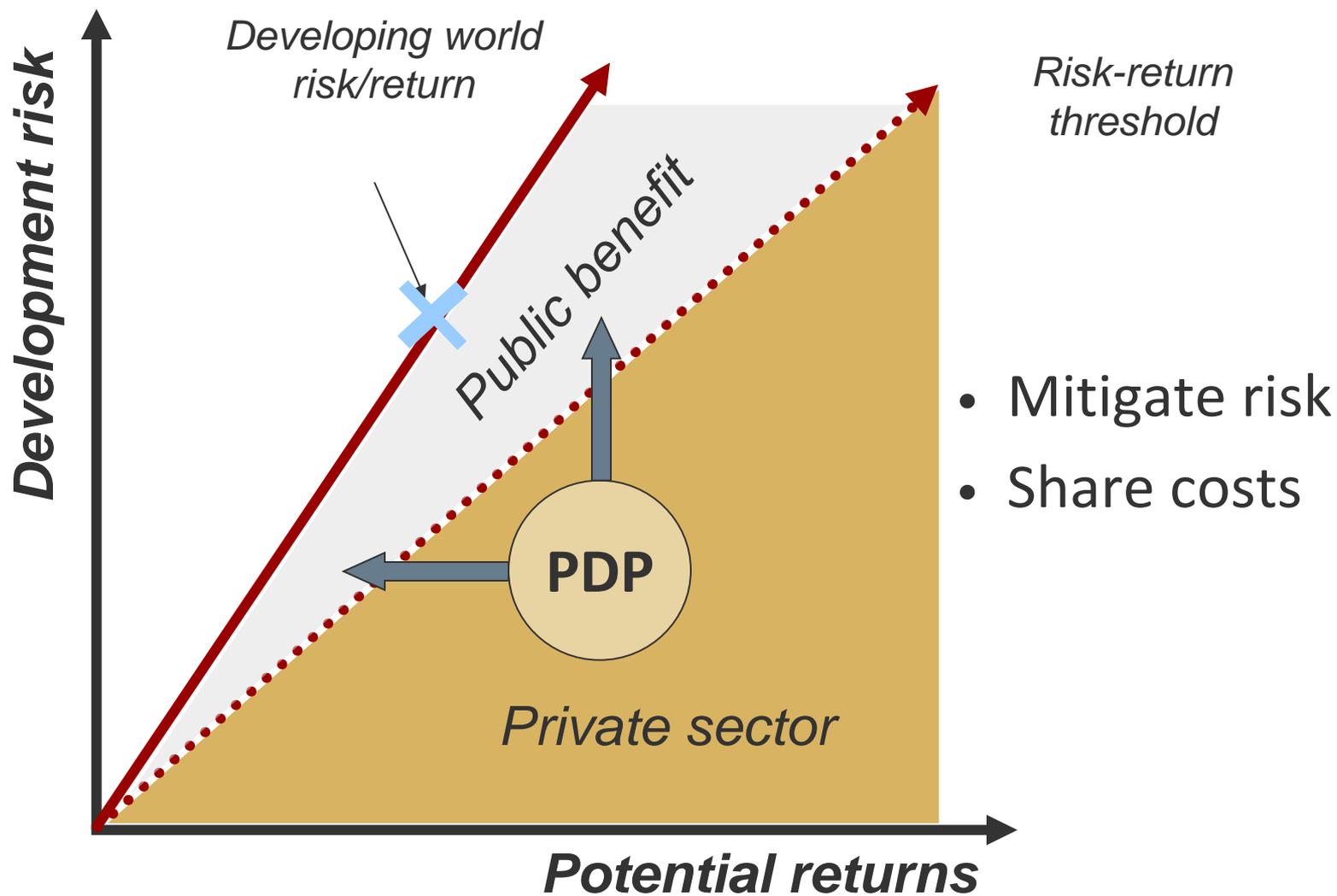
- Pneumococcal disease
- Diarrheal disease
 - Rotavirus
 - Enterotoxigenic *E. coli* and *Shigella*
- Influenza/RSV
- Polio
- Malaria
- Meningococcal disease



Role of product-development partnerships

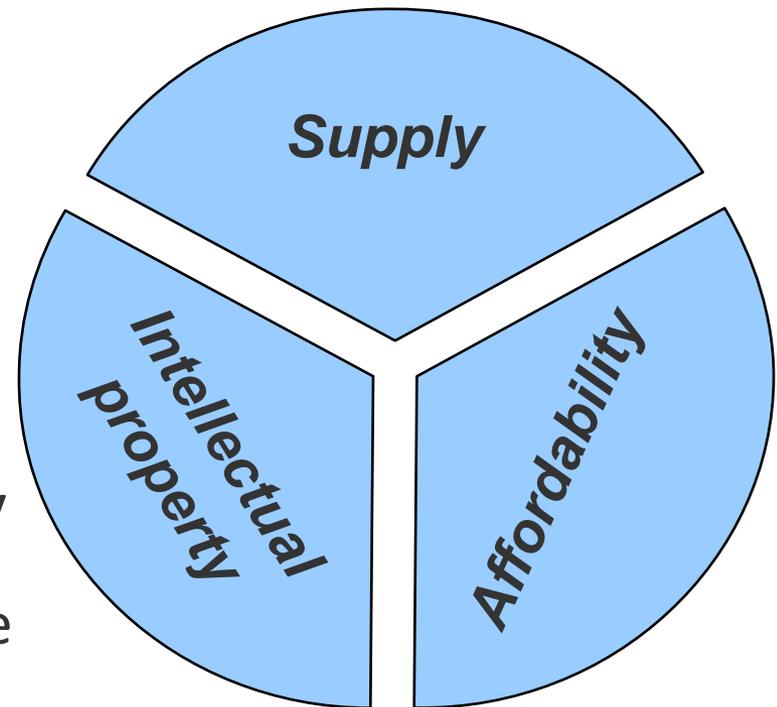


Role of product-development partnerships



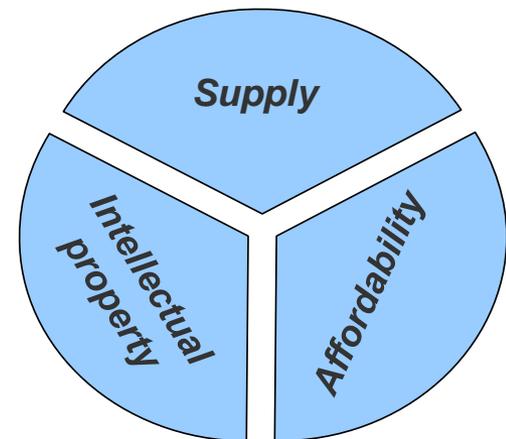
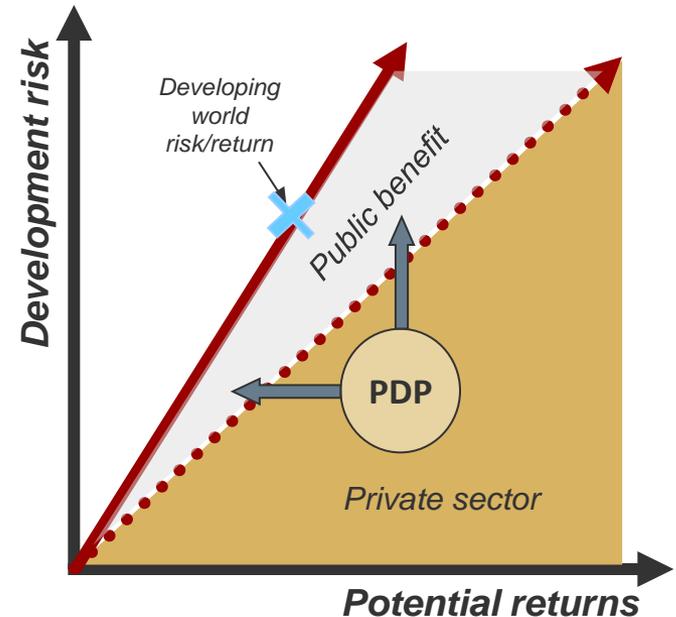
Global access: critical terms

- 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

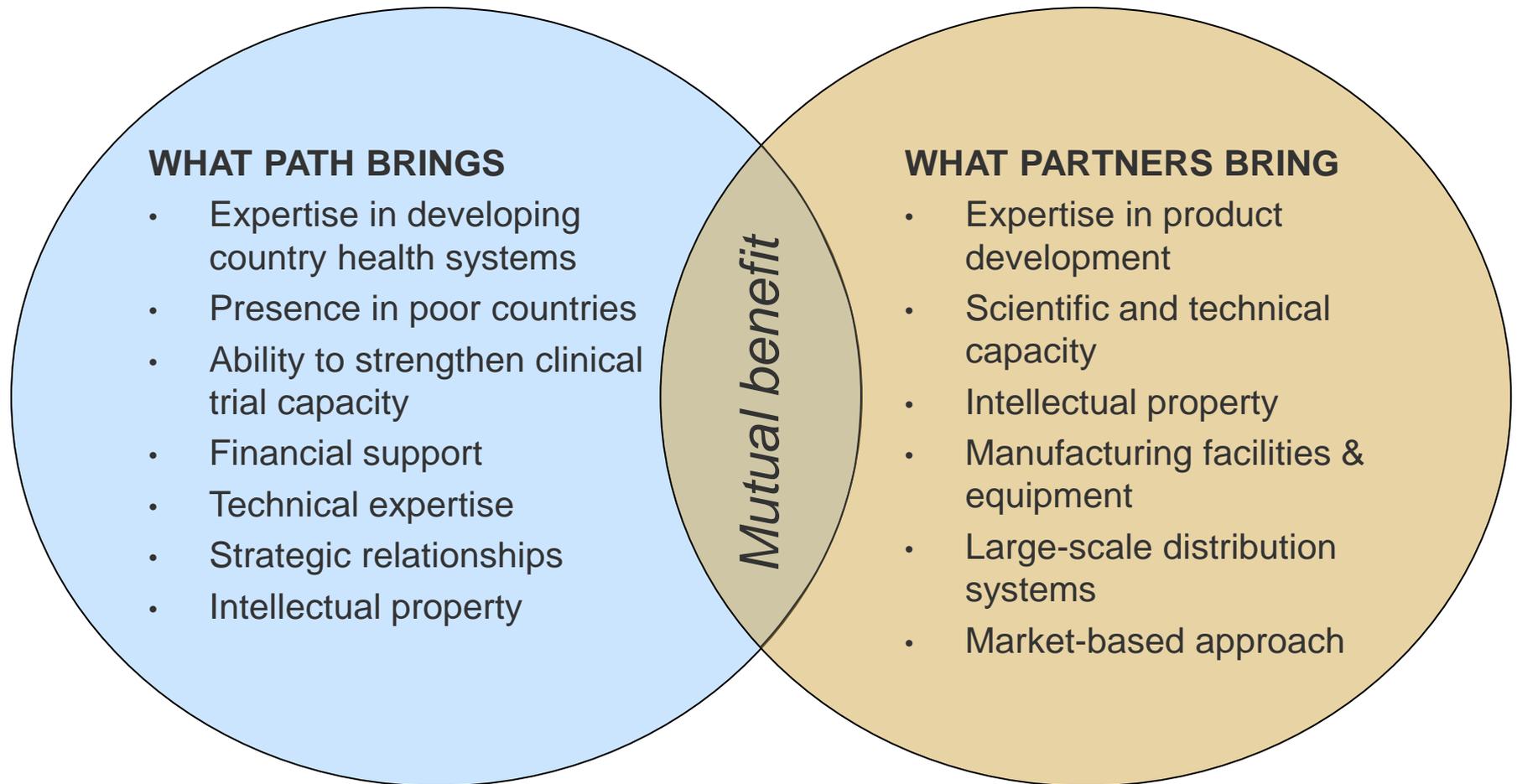


Product development partnerships and global access

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



Mutually beneficial, collaborative partnerships



PATH support to manufacturing

- Vaccine product support
 - Meningococcal Type A conjugate
 - Pneumococcal polysaccharide conjugate*
 - Japanese Encephalitis
 - Influenza
 - Rotavirus*
 - Polio / hexavalent
- Country-level support
 - Brasil
 - China
 - Viet Nam

How do you manage?

ICH Q10 says, *“Performance indicators should be identified and used to monitor the effectiveness of processes within the QS.”* and *“Performance indicators that measure progress against quality objectives should be established, monitored, communicated regularly, and acted upon as appropriate.”*

- Management needs to establish the metrics, act on them to improve the QS and communicate the results and goals to everyone.
- QA needs to facilitate the collection of the data, its analysis (root cause and risk analysis) and present the data in a usable form to top management

How do you measure performance?

- The ICH Q10 Quality System consists of these four key elements:
 - Process Performance and Product Quality Monitoring,
 - Corrective Action and Preventive Action (CAPA),
 - Change Management, and
 - Management Review of Process Performance and Product Quality.

If you don't measure, how can you improve?

An example of a process performance and product quality monitoring system are Key Performance Indicators (KPIs):

- Corrective Action Preventive Action (CAPA) System
- Deviation/Investigation System
- Change Control System
- Training Program
- Internal Audit Program
- Documentation Management System
- Supplier Control Program
- *A KPI can also be defined at any level. For instance, as part of a manufacturing process, yield at a particular step or the performance of a cleanroom during aseptic operations can be KPIs on the shop floor.*

Management support

- Clear definition of responsibilities within the organization – this includes global, regional, and/or local, as appropriate for the business
- Sufficient qualified resources to perform tasks and activities associated with processes and systems
- Clear definition of information and communication flow within all levels of the organization
- Integration of risk management into all activities, particularly design and process operations
- Support of initiatives for continuous improvement throughout the organization

Managing the Quality System using Performance Indicators

10 – 11 October 2013 in Hanoi

This two-day workshop is intended for senior manufacturing and quality management executives. A key to successful to effective quality management knows what to manage; which data to gather and how to assess the risk to the product, the company and most importantly, the patient.

George Robertson
Vaccine Development Global Program

grobertson@path.org

+202 540 4452

<http://sites.path.org/vaccinedevelopment/>
www.path.org