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Bringing Vaccine Manufacturing Capabilities to the Developing World

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Bringing Vaccine Manufacturing Capabilities to the Developing World

**Vaccine Technology IV
May 20-25, 2012
Albufeira, Portugal**



Outline

- About PATH
- Vaccine Development at PATH
- Vaccines against pneumonia
- Vaccines against diarrheal diseases
- Vaccines against influenza
- Assessing Chinese Vaccine Manufacturers

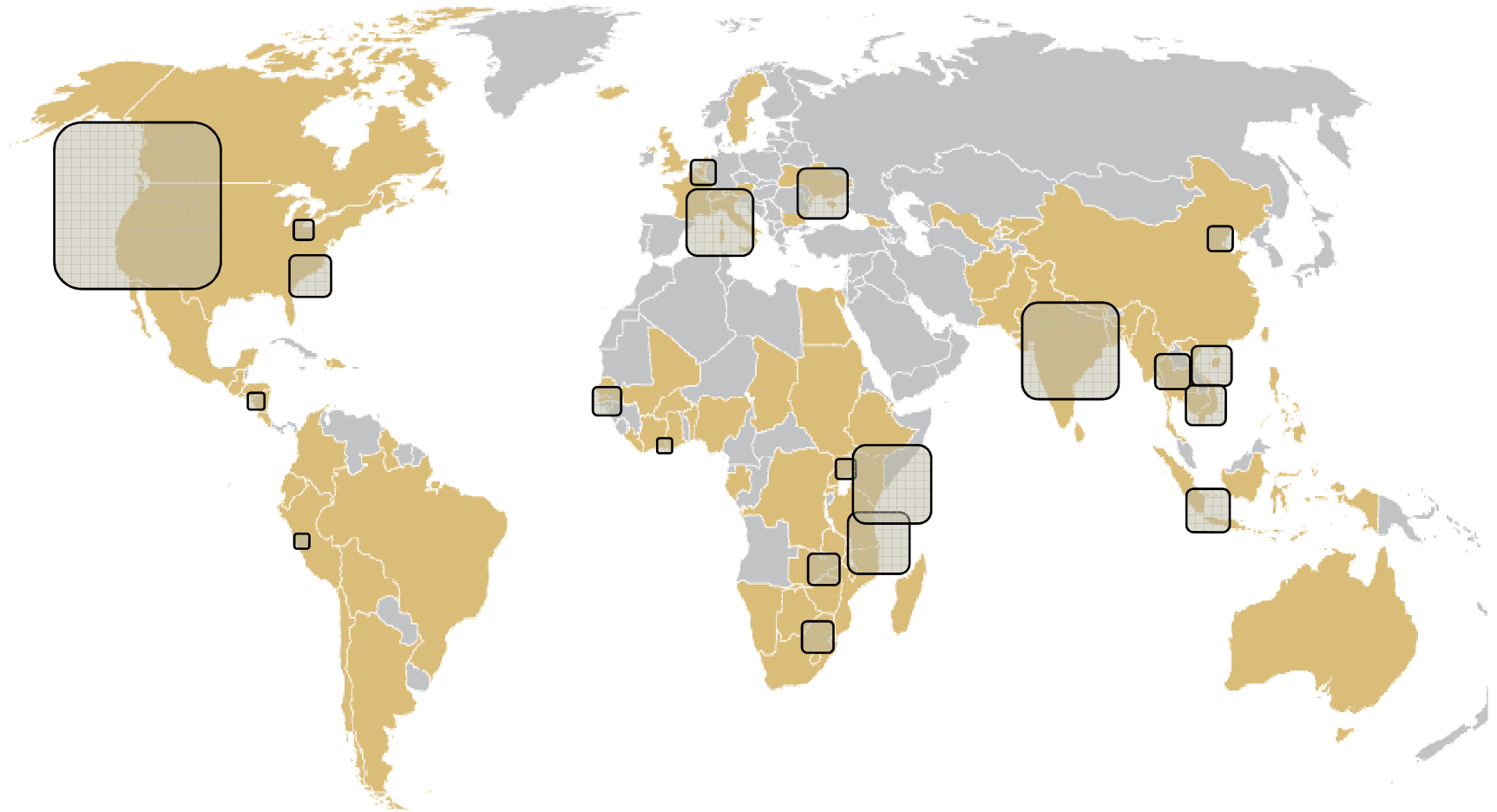


PATH: A catalyst for global health

PATH's mission is to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors.



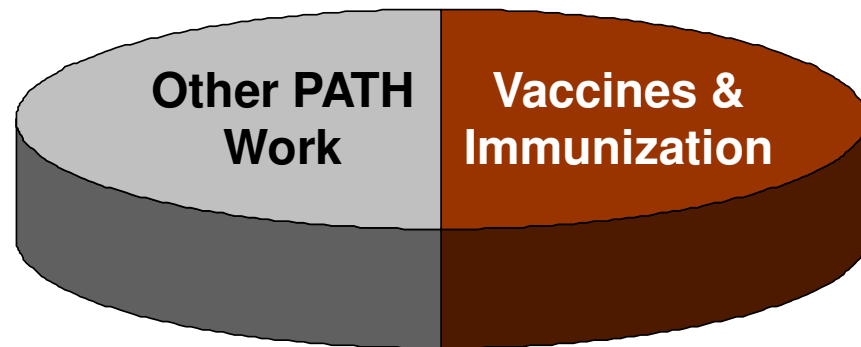
Global presence



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



PATH's work in vaccines and immunization



Comprehensive approach encompassing research and development, advocacy, financing, distribution, administration, and uptake.

RANGE OF ACTIVITIES

- Increasing availability of existing vaccines.
- Closing the gap in uptake of newly available vaccines.
- Developing technology in support of vaccines and immunization.
- Working with partners to develop new vaccines.



Vaccine development at PATH

WHY

Some vaccines are not available while others are not affordable or available in sufficient quantity.

HOW

Identify candidates and partner with industry, academia, public health organizations, and developing-world manufacturers.

WHAT

PATH's key contributions are financial resources, technical expertise, and partnership facilitation.

GOAL

To accelerate the development of new, lifesaving vaccines against selected major disease threats in the developing world.



PATH's vaccine development projects

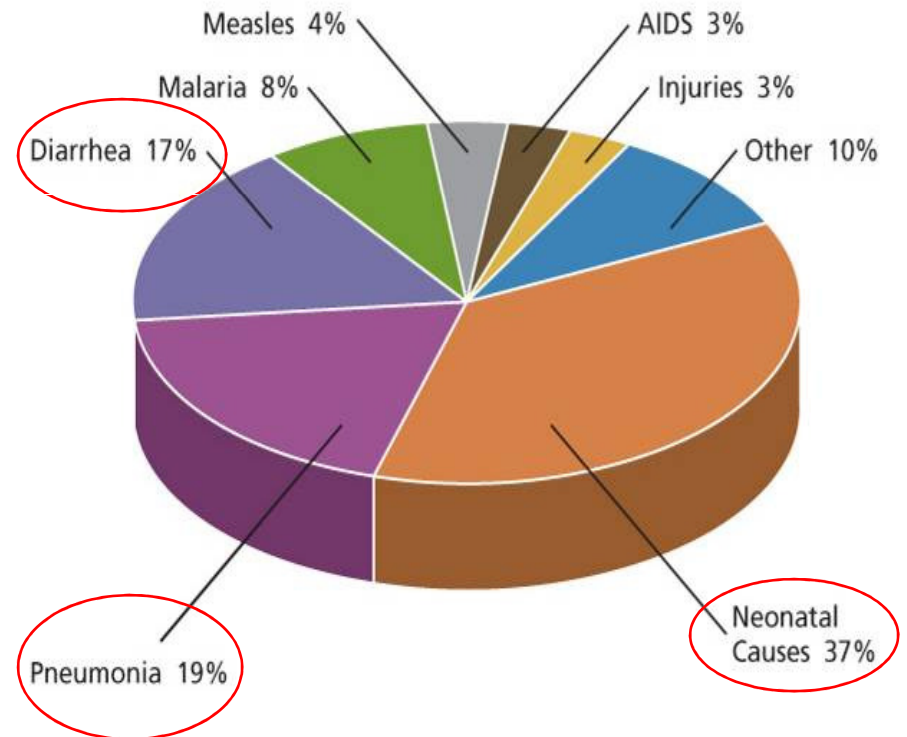
- Pneumococcal disease
- Diarrheal disease
 - Rotavirus
 - Enterotoxigenic *E. coli* and *Shigella*
- Influenza
- Malaria
- Meningococcal disease



Focus on major disease threats

- 2.5 million children die from vaccine-preventable diseases each year.
- Pneumonia and diarrhea are the two leading causes of under-five deaths in the developing world.

Major causes of death in children under age five



Source: WHO estimates of the causes of death in children, Lancet 2005.



Establishing partnerships

- Partners: industry, academia, nongovernmental organizations, and government agencies.
- Partnerships direct R&D, manufacturing, and distribution strengths toward novel technologies.
- Collaborations must lead to improved **availability**, **accessibility**, and **affordability** of vaccines.
- PATH negotiates partnerships to ensure global access.



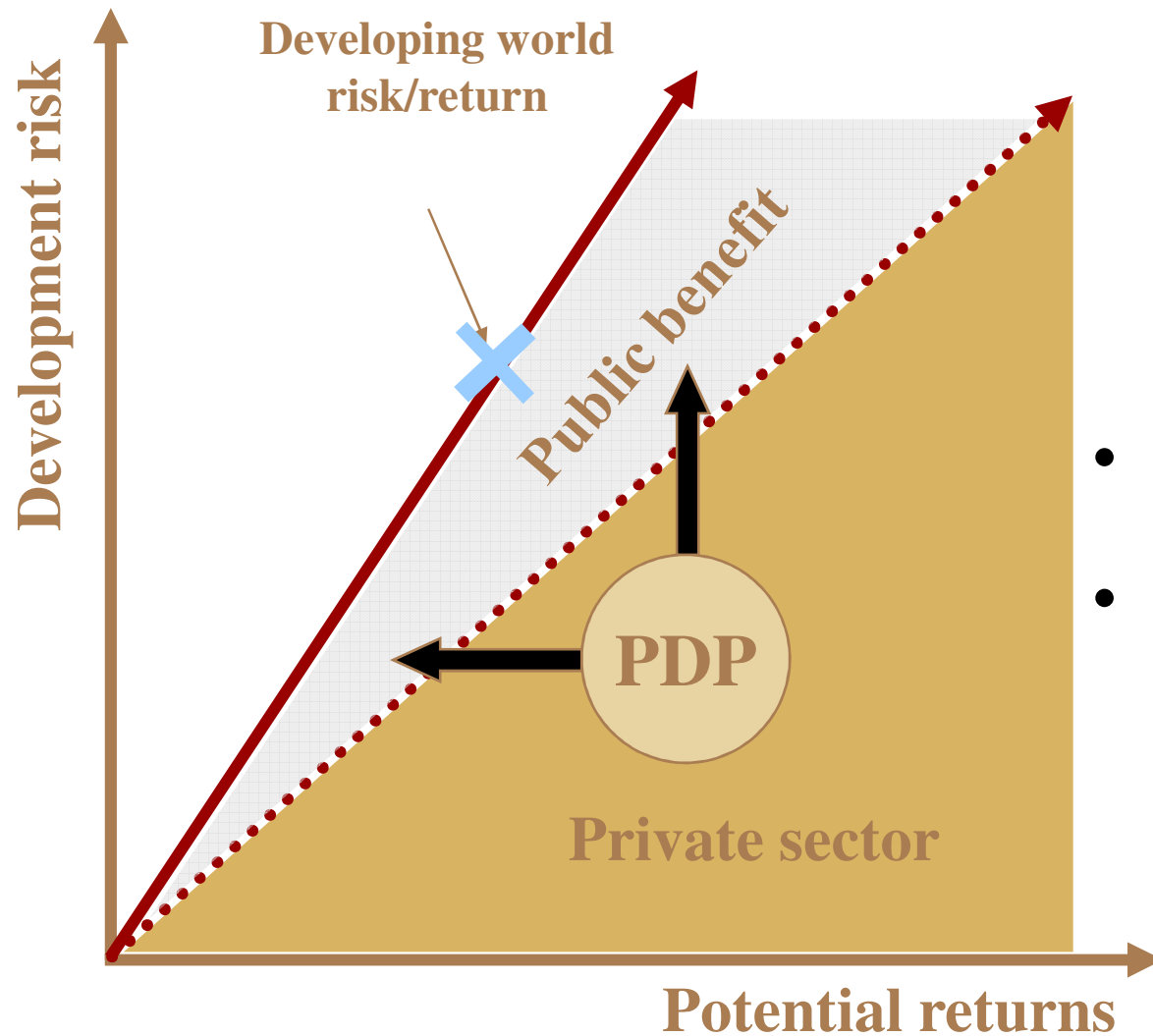
Global access

Key components of commercial terms:

- Affordability/pricing
- Manufacturing capacity
- Accessibility
- Quality



Role of product-development partnerships

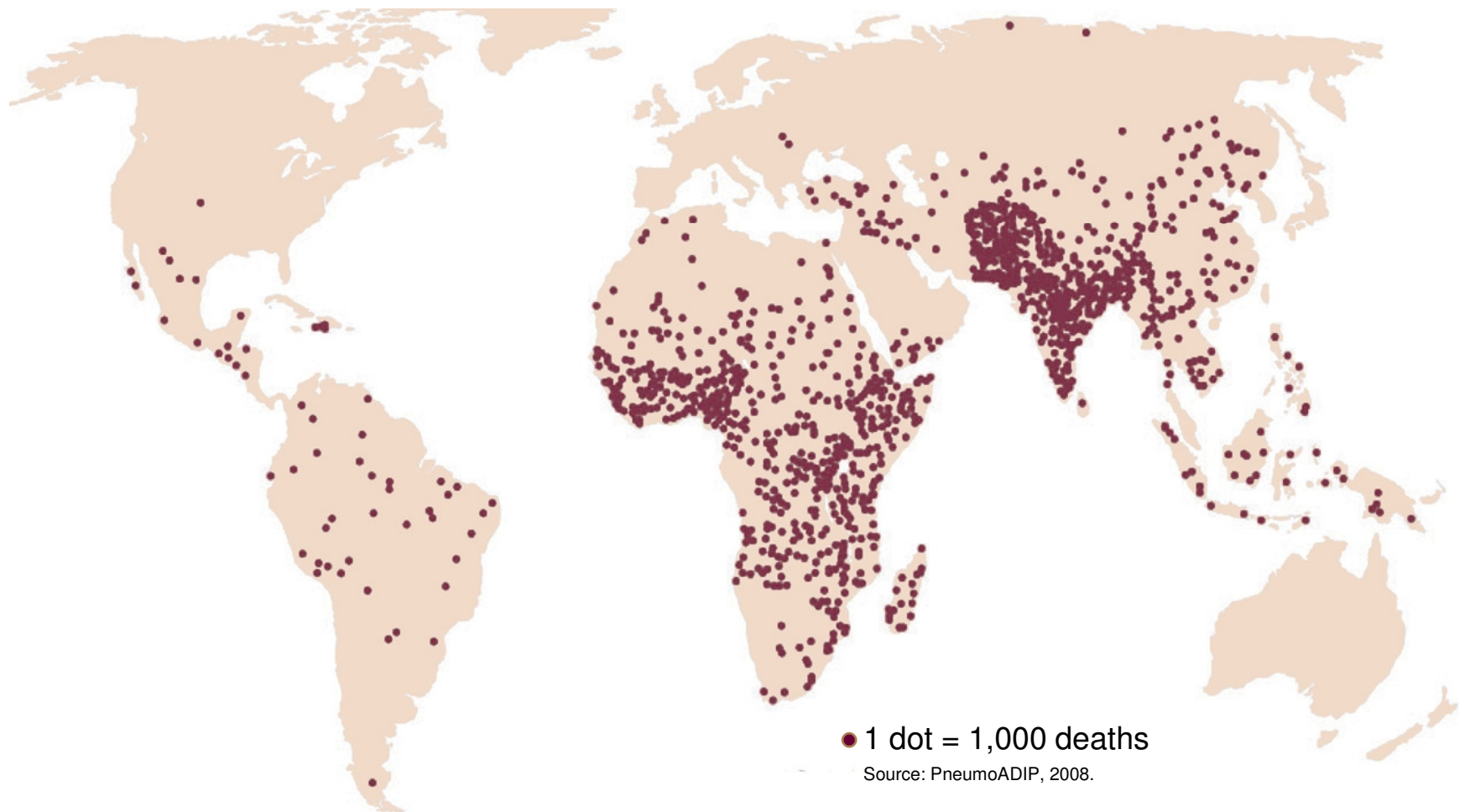


- Mitigate risk
- Share costs



Vaccines against pneumonia

Up to 1 million children under age five die each year from pneumococcal disease—the number one cause of childhood pneumonia.



Pneumococcal partnerships



Children's Hospital Boston
The Hospital for Children



University of Glasgow

PURDUE UNIVERSITY

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

MUCOSIS
Vaccines that mimic nature



Infectious Disease Research Institute
The Non-profit Biotech SM

UNIVERSITY of MARYLAND SCHOOL of MEDICINE

Institute for Genome Sciences

NIST
National Institute of Standards and Technology



Tulane University



SERUM INSTITUTE OF INDIA LTD

JOHNS HOPKINS UNIVERSITY

THE UNIVERSITY OF KANSAS



St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder
Finding cures. Saving children.



THE UNIVERSITY OF ADELAIDE AUSTRALIA

genocea
BIOSCIENCES



University of BRISTOL



EMORY UNIVERSITY



中生集团成都生物制品研究所
Chengdu Institute of Biological Products, CNBG



Developing vaccines against diarrheal diseases

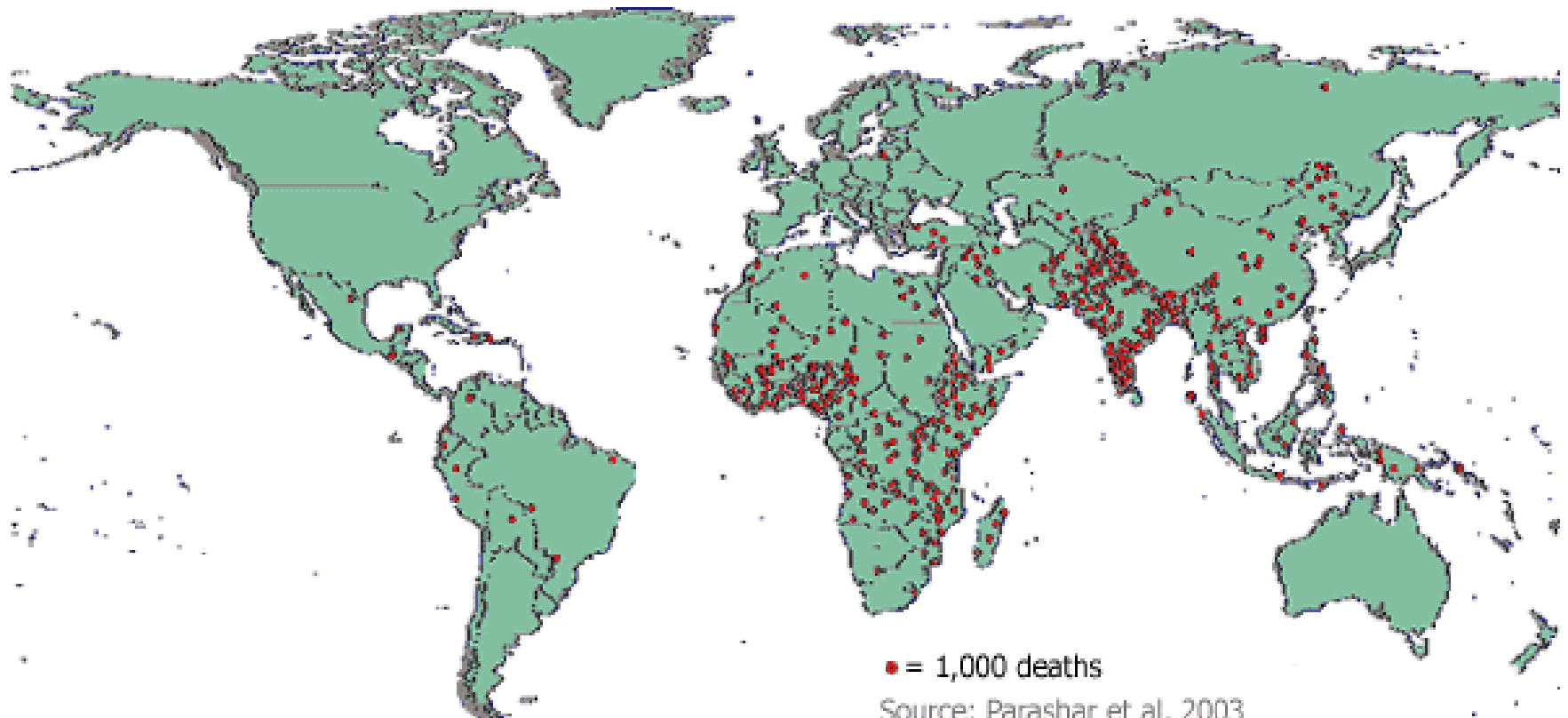
PATH is tackling diarrheal disease by addressing the most common cause of severe diarrhea, rotavirus, and the two leading bacterial causes of diarrhea, enterotoxigenic *E. coli* and *Shigella*.



Vaccines against rotavirus

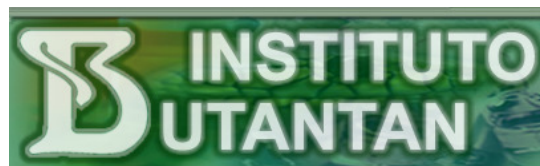
More than 500,000 children under five die each year from rotavirus infection—the number one cause of childhood diarrhea.

Global Distribution of Rotavirus Mortality



Source: Parashar et al, 2003

Rotavirus partnerships

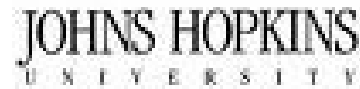


Vaccines against bacterial diarrhea

- At least one million children under five die each year from enterotoxigenic *Escherichia coli* (ETEC) and *Shigella*, combined, the leading bacterial causes of diarrhea.
- Currently, no licensed vaccines against ETEC or *Shigella* are available.



Enteric partnerships



EndoBiologics, Inc.



Vaccines against influenza

- Between 250,000 and 500,000 people die each year from seasonal influenza, and the most severe pandemic caused up to 50 million deaths.
- A gap of nearly 6 billion courses exists between current influenza vaccine production capacity and what is needed to protect the global population in a pandemic.
- Current influenza vaccines are difficult to produce quickly and in large quantities.



Influenza partnerships



Neugenesis Corporation
Biomedicines for the 21st Century



Building influenza vaccine capacity in Vietnam

- Human vaccine development in Vietnam against pandemic influenza has been a high priority for several years in response to H5N1.
 - Strongly supported by the governments of Vietnam, the United States, Japan, the WHO, and others.
 - Three entities initially engaged in human influenza A/H5N1 vaccine development and production.
 - Surveillance system to identify prevalence and seasonality of influenza.
 - Progress towards identifying gaps and establishing steps to continue development towards licensure.



IVAC – new influenza facility



A factory of approx. 800 m² will be built including Production division, QC and offices

Chicken farm and other facilities will be nearby

➤ *Building site: Suoi Dau farm (20km far from HQ of IVAC)*



CNBG institutes



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
- Accessibility
- Affordability

www.path.org

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 problems. Creative partnerships between the public 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, goods that are available, accessible, and affordable to everyone 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 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, government, research, or nonprofit—to ensure that the products we develop together are best made available to improve public health.

Mutually beneficial partnerships
PATH's goal in any partnership is to fulfill our mission: to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. PATH looks for alignment between our global health goals and our partner's goals to create a successful partnership that provides mutual benefit. We design the project to be the goal of both PATH and our partner can be met. The greater the mutual benefit, the 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 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 particular 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 constraints that define how potential partners can engage. For 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 approach to each partnership allows us to address the variability in these and other factors.






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