

**Public-Private Partnerships for Product Development:
Financial, scientific and managerial issues as challenges to future success**

Research Report

For

The World Health Organization
Commission on Intellectual Property Rights,
Innovation and Public Health

By

Elizabeth Ziemba, JD, MPH
SHARED
One Harvard Street, Suite 303
Brookline, MA 02445-7923
(617) 277 – 7800
eziemba@healthshares.org

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List of Acronyms

AERAS	Aeras Global Tuberculosis Vaccine Foundation
BVGH	BIO Ventures for Global Health
CONRAD	Contraceptive Research and Development Program
CICCR	Consortium for Industry Collaboration in Contraceptive Research
DNDI	Drugs for Neglected Diseases initiative
EMVI	European Malaria Vaccine Initiative
FIND	Foundation for Innovative New Diagnostics
Gates/UNC	Gates Foundation/University of North Carolina Partnership for the Development of New Drugs
GMP	Global Microbicide Project
HHVI	Human Hookworm Vaccine Initiative
IAVI	International AIDS Vaccine Initiative
IDRI	Infectious Disease Research Institute
IOWH	Institute for OneWorld Health
IPM	International Partnership for Microbicides
LAPDAP	LAPDAP Antimalarial Product Development
MDP	Microbicides Development Program
MMV	Medicines for Malaria Venture
MVI	Malaria Vaccine Initiative
MVP	Meningitis Vaccine Project at PATH
PDVI	Pediatric Dengue Vaccine Initiative
PneumoADIP	Pneumococcal Vaccines Accelerated Development and Introduction Plan
RotaADIP	Rotavirus Vaccine Program
SAAVI	South African AIDS Vaccine Initiative
TB Alliance	Global Alliance for Tuberculosis Drug Development

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Executive Summary

Purposes and Objectives:

The purpose of this paper is to examine certain aspects of public-private partnerships for product development to measure their progress as well as challenges in certain key areas. While the concept of Public-Private Partnerships for Product Development (PPP-PDs) is a relatively recent phenomenon, approximately five years have passed since the majority of these entities were created. Issues relating to financial sustainability, governance and accountability, portfolio management of scientific research, capacity development in developing countries, and plans for product delivery are capable of measurement and review at this point in the history of PPP-PDs to identify challenges to future success. In addition, opportunities for collective activity are apparent. The object of this report is to identify for the World Health Organization additional steps to increase the likelihood of product development and distribution for medicines, vaccines and devices for neglected diseases by PPP-PDs. The goal is to ensure that products developed for neglected diseases reach people in developing countries as soon as possible to reduce disease burden and improve health.

Background:

Twenty-four public-private partnerships for product development were selected for in-depth study based on their primary missions being devoted to the development of a drug, vaccine or product to treat and/or cure a neglected disease. Key issues were identified as areas important to the success of PPP-PDs as well as areas where WHO may be able to lend support to accelerate the success of these partnerships.

The issues examined in greater detail are:

- (1) Scale of past, current and future funding and the question of financial sustainability including sources and amounts of funding, funding gap, broadening the base of financial supporters, and creating new methods of funding;
- (2) Portfolio management including scientific challenges and financial sustainability;
- (3) Governance, representation and accountability of PPP-PDs;
- (4) Role of PPP-PDS in developing capacity in low income countries; and
- (5) Product delivery to developing countries including issues, challenges and plans for product distribution.

Collective activities in support of PPP-PDs and related advocacy opportunities are identified and recommendations made for support by WHO.

Methods:

Research was conducted by a literature review as well as a review of materials by and about the 24 selected PPP-PDs. Several individuals within PPP-PDs were contacted for further information and comment.

Key Findings

- (1) Scale of past, current and future funding and the question of financial sustainability

The majority of the 24 PPP-PDs examined were established in the past 5 years with a focus on developing and financing a product of choice for an identified neglected disease. Little evidence of duplication of scientific evidence exists as the PPP-PDs have selected discrete diseases and/or types of products upon which to focus their efforts. Disease-based alliances have been created among all types of public and private entities to coordinate scientific efforts while maximizing the available resources. These alliances facilitate the sharing of scientific information and enable planning for advocacy efforts and product roll out.

Opportunities for WHO: (a) Assist with development and implementation of product roll-out plans working with disease-based alliances; (b) Work to improve coordination among disease-based alliances, PPP-PDs, and other entities to reduce duplication of efforts and maximize resources.

Sources and amounts of funding: More than one billion dollars has been contributed to the 24 PPP-PDs from private foundations, governments and governmental agencies, and private organizations. Foundations provide 76% of total funding with the Gates Foundation being the single largest funding source having contributed more than \$700 million.

Funding Gap: While the actual dollar amounts are in dispute, a sizeable funding gap exists between what has been paid to PPP-PDs and what is needed to bring a product to market. PPP-PDs are at risk of failure if they do not receive the funding necessary to complete the scientific work required to develop products for neglected diseases.

Broadening the base of financial supporters: PPP-PDs current financial sources are identified and, by default, new potential funding sources are identified as targets for support. Additional partners can be drawn from foundations, governments and governmental agencies, as well as private industry.

Opportunities for WHO: Assist PPP-PDs to secure funding by opening or continuing dialogue with new potential funding sources.

Creating new methods of funding: In order to increase the number of participants in PPP-PDs as well as the amount of financing available to PPP-PDs, innovative funding mechanisms are needed to reduce the financial risk of investment. Various “push” and “pull” mechanisms are being explored by the World Bank “Out of the Box” group as well as other organizations to secure money to close the funding gap.

Opportunities for WHO: Assist PPP-PDs to work with the World Bank and other funders to expand the pool of investors and expand the types of investments.

(2) Portfolio Management and the scientific challenges facing PPP-PDs.

PPP-PDs use the portfolio management method to reduce the risk of failure of projects while reducing the time to market. The amount of funding needed and time to market is tied to the scope of the project undertaken. Vaccines being developed are more expensive and take a longer time to bring to market than other products that may have been partially developed in the private sector but shelved due to the lack of a commercial market. Picking the “low hanging fruit” should bring a number of products to market in a relatively short time but the pharmaceutical pipeline feeding the PPP-PDs must be robust in order for portfolios to be balanced. Basic and translational research must be supported to keep the pipeline full.

Opportunities for WHO: Develop new and support existing mechanisms to support basic and translational research to assist the work being done by PPP-PDs.

(3) Governance, Representation and Accountability of PPP-PDs.

Governance of PPP-PDs: “Governance” describes the manner in which PPP-PDs manage themselves and is comprised of formal and informal norms as well as rules and decision-making procedures. “Governing bodies” lead the decision-making process and set priorities and direction for the organizations.

PPP-PDs are identified as “independent” or “hosted” partnerships with distinct methods of operation. PPP-PDs were examined to determine the level of representatives from the South on governing bodies. The composition of governing bodies impacts decision making and should reflect the interests, needs, concerns of all groups to legitimate the governing arrangement.

Representation on Boards of Directors and other advisory groups: Overall, the number of representatives from the South is low and may result in lack of support or cooperation from developing countries as products are developed, tested, and introduced. Increasing the number of representatives from the South should be a key goal of PPP-PDs to ensure success of their missions.

Accountability: The issue of accountability examines the question “To whom are PPP-PDs accountable?” PPP-Ps are certainly responsible for their actions in terms of their funders and Board of Directors but the degree to which they are accountable to the

ultimate beneficiaries of their work, namely people in developing countries, is unclear. Eventual introduction of new products into developing countries will put stresses and strains on already fragile health care systems. Involving and consulting with governments and other representatives from low-income countries from the beginning is vital to ensure that PPP-PDs increase their accountability.

Opportunities for WHO: (a) Work with PPP-PDs to ensure that the fruits of these entities benefit societies equitably in that very poor countries with large populations, unpopular governments or poor infrastructure may be excluded from these partnerships; (b) Facilitate with PPP-PDs to ensure that they are working in harmony and integrated with national health priorities; (c) Lead the development of transparent policy and procedural frameworks to protect the public interest and to ensure that the processes established by PPP-PDs are structured in the public interest; (d) Promote and support research aimed at identifying good partnership practice; (e) Lead the discussion to ensure that developing country governments are given an adequate voice in PPP-PDs; (f) Assist with capacity development in low income countries through coordination with PPP-PDs.

(4) Role of PPP-PDs in developing capacity in low income countries

Capacity building can occur through the transfer of scientific knowledge as well as enhancing the ability of governments to develop and deliver health care services. PPP-PDs are engaged in the *ad hoc* transfer of scientific and technical knowledge by conducting clinical trials in developing countries. Little coordination among PPP-PDs takes place. Networks have evolved in developing countries to identify the level of available expertise. Little infrastructure exists in developing countries to support a regulatory system in terms of Institutional Review Boards.

Substantial work needs to be done in this area to create the infrastructure needed to support research, clinical trials, registration of new drugs and vaccines as well as the integration of those drugs and vaccines into fragile health care systems. Such capacity development is not the role of PPP-PDs but they can play a role in such development especially through the inclusion of representatives from the South on governing boards and other consultative positions.

Opportunities for WHO: Advocate for developing capacity and to establish basic, achievable goals including: regionally harmonized clinical trial guidelines¹; ICH compliant Institutional Review Boards (IRBs) for ethical and safe clinical research, health research requirements and local capacity.

(5) Product delivery to developing countries

The importance of planning for product delivery well in advance of the introduction of a new product is demonstrated by the decade-long time difference between the introduction of the Hepatitis B vaccine in the developed world as opposed to the developing world. Several PPP-PDs have developed or are developing a strategy for introducing products into developing countries but these plans, like the products themselves, are in a nascent

stage. The issues identified for discussion and planning are: Financing; production; delivery; demand; and regulation.

The complexity and financial magnitude of introducing and delivering products into low-income countries is beyond the scope of PPP-PDs capabilities and will require cooperation from all sectors to be successful. PPP-PDs will be valuable to contribute their expertise, knowledge and resources to ensure access to medical products but leadership will have to come from the low-income countries themselves as well as international organizations such as WHO.

Opportunities for WHO: (a) Integrate PPP-PDs into the blueprint for introduction of HIV vaccines and other new medicines; (b) Utilize its authority to engage national governments in the planning for the introduction of new medicines.

Collective activities in support of PPP-PDs:

Engaging in collective activities could enable the work of PPP-PDs to progress faster by pooling their skills and resources in certain areas such as IP information sharing, common systems for clinical trials, collective advocacy to raise awareness about neglected diseases; strengthening regulatory capacity in developing countries and issues related to portfolio management. PPP-PDs could work together to build a broader support base.

Opportunities for WHO: (a) Act as a facilitator for PPP-PDs to collaborate and provide a forum for research and discussion; (b) Evaluate and direct collection of epidemiological data tailored to each country to ensure that decisions about the introduction of new medical products matches the disease burden of individual countries.

Recommendations

In addition to the opportunities set forth above, several key areas can benefit from the skills and expertise of the World Health Organization:

- Advocate for additional traditional and innovative funding mechanisms from current and additional funding sources to support long-term financing of the development and delivery of products for neglected diseases
- Utilize its leadership position and expertise to close the research gap and foster networks while building capacity in low income countries by supporting preclinical and translational research to be conducted collaboratively with institutions in the north and south
- Engage in strategic planning with PPP-PDs to coordinate their efforts between and among PPP-PDs as well as all other interested parties to ensure that duplication of efforts is minimized and financial and other resources are maximized.
- Develop an overarching strategic plan for delivery of new products for neglected diseases by ensuring baseline disease burden information is available for informed decision making and is communicated to leaders at the national level.

- Work with PPP-PDs to develop a plan to increase participation on governing boards by representatives from the South with the long-term goal of accelerating the marketing and delivery of products for neglected diseases.
- Provide a forum for PPP-PDs and other parties to identify and prioritize areas for collaboration.

The assistance of the World Health Organization is invaluable to PPP-PDs to create new products for neglected diseases and to ensure that the people who need them most receive them in the shortest time possible.

Public-Private Partnerships for Product Development: Financial, scientific and managerial issues as challenges to future success

Full Report

The concept of Public-Private Partnerships for Product Development (PPP-PDs) is a relatively recent phenomenon but approximately five years have passed since the majority of these entities were created. Issues relating to financial sustainability, governance and accountability, portfolio management of scientific research, capacity development in developing countries, and plans for product delivery are capable of measurement and review at this point in the history of PPP-PDs to identify challenges to future success. In addition, opportunities for collective activity are apparent. The World Health Organization can take additional steps to increase the likelihood of product development and distribution for medicines, vaccines and devices for neglected diseases by PPP-PDs.

For purposes of this report, the definition of the phrase “Public-Private Partnerships for Product Development” (PPP-PDs) is “a project or portfolio of projects in which public or philanthropic funds and resources are combined to discover and/or develop a product (medicine, vaccine, diagnostics) to meet a public health need”.² The diseases that are the subject of product development by PPP-PDs are collectively referred to within this report as “neglected diseases” as they are prevalent in countries or areas where little or no market incentive exists to encourage commercial development of treatments or preventive measures.

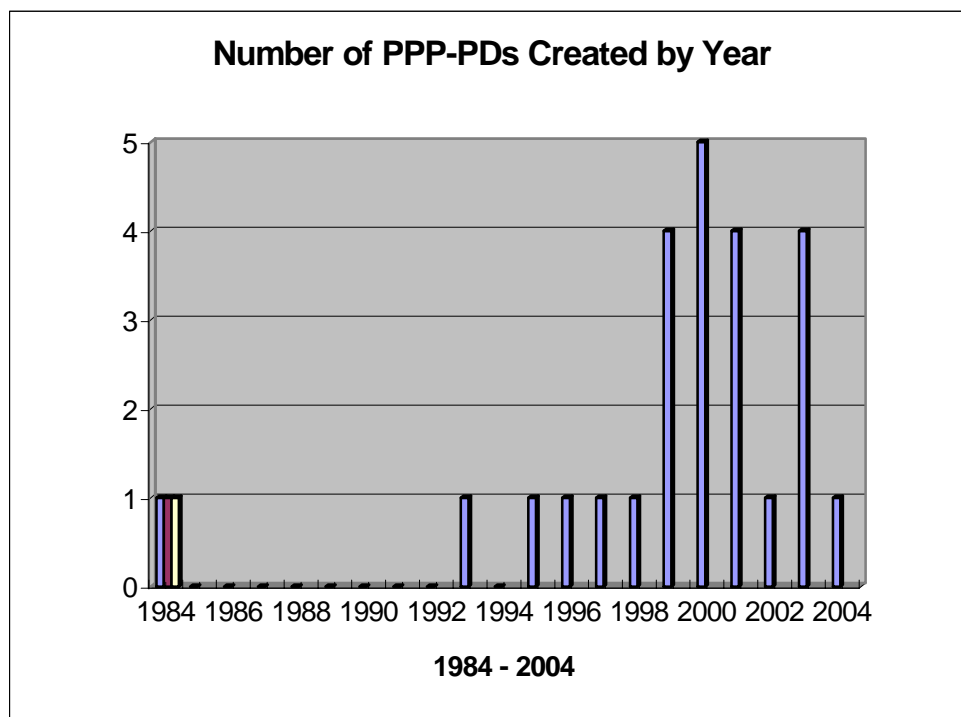
An Overview of Public-Private Partnerships for Product Development

Twenty-four public-private partnerships were selected for review based on the common factor that all of them devote the majority of their efforts to developing medicines, vaccines or diagnostics for diseases of developing countries including malaria, tuberculosis, HIV, leishmaniasis and others collectively referred to as “neglected diseases”. General information about each PPP-PD selected is provided in Appendix 1, Sheet 1.

Of the 24 PPP-PDs, 9 are devoted to developing medicines and/or microbicides, 11 are committed to vaccine development, one is focused on diagnostic products, and three are involved with the development of a combination of medicines, vaccines and/or diagnostics. Five partnerships focus exclusively on reproductive health issues, four focus on malaria and two are committed to tuberculosis and HIV/AIDS respectively. [See Appendix 1, Sheet 2 for a summary of public-private partnerships by candidate product].

As identified in Table 1, below, eighteen of the twenty-four partnerships (75%) have been established within the past five years and one as recently as 2004. [See Appendix 1, Sheet 8 for data table]. Fifteen of the 24 entities (62.5%) have their secretariat in the United States and all but one is located in economically developed countries.

Table 1. Number of PPP-PDs created by year from 1984 to 2004.



Extracted from partnership database found on website for Initiative on Public-Private Partnerships for Health, www.ippph.org, accessed various times December 2004.

Despite the fact that the majority of PPP-PDs have been in existence for five years or less, much has been accomplished by these organizations in terms of mobilizing resources and public opinion in support of developing treatments and preventive measures for neglected diseases.³

The focus of PPP-PDs is the scientific process of developing the product of choice and securing funding for that product. The potential for working at scientific cross-purposes with other similar organizations exists as does the possibility of duplication of other efforts.

In terms of scientific efforts, little duplication of efforts seems to exist as the majority of PPP-PDs have staked out individual territories in terms of disease and the product to be developed. A variety of PPP-PDs focus on the same disease but pursue different approaches. For example, four PPP-PDs are focusing on malaria but two are working on vaccine development (EMVI, MVI), one is working on novel malaria medicines (MMV) and one is focusing on the bringing a developed product through final regulatory stages (LAPDAP).

Similarly, four PPP-PDs are working on the development of microbicides (CONRAD and its subprogram GMP, IPM, and MDP). The two organizations focusing on tuberculosis differ in that one is focusing on developing a vaccine (AERAS) while the other is focused on drug development (TB Alliance). Both HIV/AIDS entities are working the development of an AIDS vaccine. Certain PPP-PDs (FIND, HHVI, MVP, PDVI, PneumoADIP, and RotaADIP) are working on a specific disease or product not shared by other PPP-PDs.

As a response to the need for collaboration and to avoid duplication of scientific and other efforts, alliances have been formed among groups working on HIV/AIDS, microbicides, and malaria. These alliances vary in terms of their goals, membership and development and as such vary in terms of providing a systematic approach to coordinating efforts while maximizing the resources of the PPP-PDs and other organizations.

The Global HIV/AIDS Vaccine Enterprise (Enterprise) was initiated in June 2003 to identify new strategies and mechanisms to develop safe and effective HIV vaccines.⁴ It is an alliance of independent organizations committed to accelerating the development of a preventive vaccine for HIV/AIDS through implementation of a shared scientific strategic plan, mobilization of additional resources, and greater collaboration among HIV vaccine researchers worldwide.⁴ The participants in the Enterprise, including the World Health Organization, are extensive and drawn from all sectors.⁴ The goal of the Enterprise is to stimulate researchers and funders to explore new, collaborative, cooperative and transparent approaches to the obstacles of vaccine development.⁴ Its Strategic Plan identifies scientific opportunities including: expanding the HIV vaccine pipeline; improving animal models; expanding the database of clinical trials; and expanding the availability of new quantitative laboratory tools.⁴

The Enterprise's Strategic Plan has identified issues facing all PPP-PDs: lack of capacity to conduct clinical trials; regulatory considerations; and intellectual property issues. While the Enterprise has a well-defined scientific plan for improving scientific activities, the plan identifies problems relating to capacity development and product rollout issues but fails to provide a detailed plan for addressing these same issues. The opportunity exists for the Enterprise to take a leadership role in formulating a strategy to deal with the non-scientific issues relating to product development and distribution for an HIV/AIDS vaccine.

The Enterprise's Strategic Plan can be used as a model for other existing alliances or as a blue print for other groups or sectors that have not yet formed an alliance.

The Alliance for Microbicide Development⁵ was founded in 1998 to accelerate and coordinate research efforts while increasing the amount of funding available to support the research and development of microbicides. Its coalition of 200 representatives is drawn from all sectors and includes the World Health Organization as well as CONRAD, GMP, and IPM.

Initial research has been conducted to explore the issue of introduction of microbicides in that it is anticipated that products will be entering phase III trials in 2005. Potential delivery strategies are being considered including public sector distribution, social marketing, and commercial providers.^{6 7 8} This research refers to the problems involved with introducing new health technologies in developing countries and the importance of selecting the proper distribution channels while emphasizes the necessity of a “strong role for the public sector in the development and provision” of introducing new health technologies. The reports are silent as to how to garner the support of the public sector needed to ensure successful introduction of microbicides into developing countries.

Alliances dealing with malaria are numerous and include the Multilateral Initiative on Malaria⁹, the Malaria Consortium¹⁰, the Malaria Foundation¹¹, the Japanese Alliance¹² and the Gates Malaria Partnership¹³ as well as the Global Fund for AIDS, TB and Malaria and the Roll Back Malaria program. These and other entities offer some degree of collaboration yet appear to pursue similar goals including improving access to and application of research findings, sustainable research capacity in Africa, advocacy, and promoting global communication and cooperation. While these organizations focus on scientific development of products and building capacity in developing countries, little attention is devoted to planning for the delivery of new products. Coordination between and among these organizations could reduce duplication of efforts, conserve and maximize financial resources, and improve support for the PPP-PDs working on medicines and vaccines for malaria.

PPP-PDs have focused on key areas of scientific research to develop medicines, vaccine and products for neglected diseases with little or no overlap. Much sharing of scientific information takes place formally through alliances and other relationships as well as informally by mutual participation on Boards of Directors, committees and so on. PPP-PDs concentrate on the science needed to achieve their goals of product development and have established channels for sharing the results of their scientific work.

There is a substantial void in terms of planning for distribution once new products are ready to be introduced. While PPP-PDs are identifying issues and conducting preliminary research into solutions to non-scientific matters, more action should be taken now to allow introduction of new products as quickly as possible. An opportunity exists for the World Health Organization to improve coordination between the Alliances and other entities to reduce duplication of efforts and to maximize available resources,

Scale of past, current and future funding and the issue of financial sustainability

Sources and Amounts of Funding

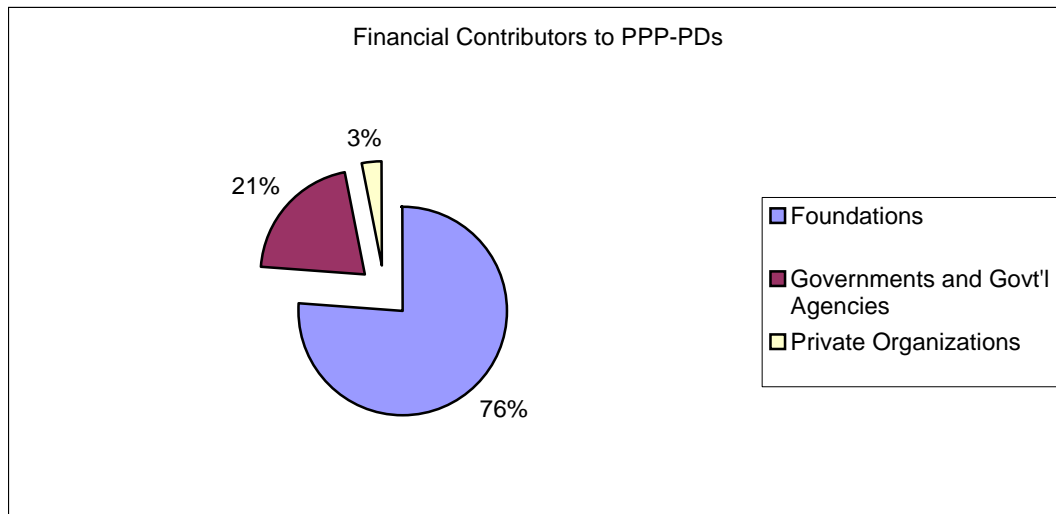
Private foundations, governments and governmental agencies, bilateral and multilateral organizations, and nongovernmental organizations as well as private companies and individuals have funded public-private partnerships for product development. Specifically excluded from consideration are donations of products or other in-kind

donations. Quantifying intangible donations present difficulties in valuation beyond the scope of this report.¹⁴

A summary of the funding sources for PPP-PDs is provided in Appendix 1, Sheets 3, 5, 6, and 7, identifying the major contributors and, if available, the amount supplied to each PPP-PD from the partnership's inception to December 31, 2004.¹⁵ These amounts reflect actual contributions made and do not include future pledges.

Over \$1 billion US has been contributed to these 24 PPP-PDs. Of that total, approximately \$899,433,725.00 has been contributed by private foundations, \$244,462,588.00 by governments and governmental agencies, and \$36,312,547.00 by private entities. [Refer to Appendix A, Sheet 9]. Table 2, below, shows the percentage of total contributions made according to funding source.

Table 2. PPP-PD funding sources by type of financial contributor.



Data assembled from the various websites for PPP-PDs as well as the website for the Initiative on Public-Private Partnerships for Health, www.ippph.org, accessed at various times in November and December 2004.

Of the \$1,180,208,860.00 total amount of contributions made by all donors, the Bill and Melinda Gates Foundation is the largest single contributor with total contributions of \$714,239,419.00 or more than 60% of the total. The Gates Foundation provides funding to 17 of the 24 (71%) of the PPP-PDs. It is the single funding source for 9 of the 24 (37.5%) of the PPP-PDs reviewed. The implications of the magnitude of the contributions of the Gates Foundation cannot be understated. Without its funding, it is possible that 9 PPP-PDs would not exist and several others would be financially compromised. While the Gates Foundation has given no indication that it will withdraw its support from the various PPP-PDs, it is in the best interests of PPP-PDs to enlarge its base of supporters not only for diversity of funding sources but also to address the increasing costs of product development as candidates move into expensive clinical trial phases.

The Funding Gap

The actual amount needed for product development is the subject of debate. Whether one uses the pharmaceutical industry standard amount for the cost of drug development of \$800 million¹⁶ or other measures provided by the PPP-PDs themselves such as “The Economics of Drug Development”¹⁷ conducted for the TB Alliance, substantial additional financial resources will be required to successfully bring products to fruition. It is clear that a funding gap exists between what PPP-PDs have raised to date and the total amount needed to bring a product to the market.^{26 27} The cost estimates do not include costs of marketing and distribution.²⁷

The development of the candidates for an HIV vaccine known as AIDSVAX demonstrates the difficulty of the scientific and financial challenges facing PPP-PDs. AIDSVAX required more than 20 years of development time costing approximately \$200 million.¹⁸ It was evaluated in clinical trials in Thailand demonstrating that world-class clinical trials can be conducted successfully in developing countries; however, the vaccine itself showed minimal efficacy in the Phase III studies so work continues on its development.¹⁸ The scientific hurdles are every bit as challenging as the financial ones.

Substantial amounts of money must be raised by PPP-PDs to ensure the continuation of their work. By segmenting the market of current and potential funding sources, PPP-PDs can identify methods to expand their base of financial support. These segments are: Current funders and traditional funding methods; current funders and novel funding mechanisms; new funders and traditional funding mechanisms; and new funders and novel funding mechanisms.

Table 3. Options for funding sources and types of funding.

Existing funding source with traditional funding mechanism	Existing funding source with novel funding mechanism
New funding source with traditional funding mechanism	New funding source with novel funding mechanism

Broadening the base of financial supporters – Seeking new funding sources

Where can PPP-PDs find additional funding for their ventures? By reviewing the list of current funding sources, it is possible to identify those organizations, governments and other entities that are not participating as financial supporters of PPP-PDs. This approach does not take into account those organizations that provide other types of support such as

in-kind donations or who are involved in other aspects of developing products for neglected diseases.

Broadening the base beyond current funding sources requires focused advocacy, as many potential funders have never invested in medical product development. A great deal of effort may be required to educate and persuade additional funders of the significance of portfolio candidate failures or the magnitude of the investment required.¹⁹ Smaller governments or funders may not have the capacity to conduct an assessment of the opportunities and risks offered by each PPP-PD¹⁹ but they could work collectively to maximize resources and impact of their contributions.

Private foundations are well represented as funding sources of PPP-PDs with the Bill and Melinda Gates Foundation and the Rockefeller Foundations provide 85% of foundation giving and 65% of total funding. PPP-PDs could look to those foundations that have not yet become involved with the partnerships as additional sources of financing.

Governments and government agencies have contributed approximately 21% of the total funding for PPP-PDs. Among governments and governmental agencies, USAID contributes 35% of all government giving and 7% of total funding for PPP-PDs but may be willing to increase its support especially considering that 62.5% of the PPP-PDs maintain their secretariats in the US. Considering the public health impact of neglected diseases, PPP-PDs with the active support of the World Health Organization may be able to exert influence over governments to become generous funding sources of PPP-PDs.

Support from the European Union and its individual member states is modest. There are several individual member states (Belgium, Italy, Luxembourg, Portugal, Spain and the new members of the European Union) that have not provided direct support to PPP-PDs. Additional support from the European Union should be encouraged as the EU has indicated its strong desire to address the lack of medicines for neglected diseases.³

Other developed nations are absent from the list of government supporters. Japan, Australia and other developed countries outside the US and EU can be encouraged by PPP-PDs and the World Health Organization to add their support to PPP-PDs.

The products being developed by PPP-PDs are targeted to the populations in developing countries. Developing countries, especially those with large populations such as the Philippines, India, Brazil, and China, can be encouraged to become active funding sources of PPP-PDs. PPP-PDs can look to those countries that have a vested interest in improving the health of their populations and seek financial support. For example, the “Chinese government has sponsored discovery and development of the artemisinin derivatives” to treat malaria.² While certain developing countries are too poor to make a financial contribution to the work being done by PPP-PDs, others are not. As discussed in later sections, securing the financial support now from developing countries should benefit PPP-PDs throughout the development and distribution process.

Private industry (excluding in-kind and other contributions from the pharmaceutical industry) represents an opportunity for substantially more involvement especially from global companies with operations in disease endemic countries or areas. Industry has a financial stake in the well-being of its work force and may be willing to support efforts to develop products to treat its employees.²⁰ PPP-PDs have ready allies in various non-profit organizations such as Global Business Coalition on HIV/AIDS, (www.businessfightsaids.org) who may assist partnerships bring private industry in the negotiating table. Other corporate initiatives exist, such as the Coca-Cola African Foundation, that are potential partners for funding or for assistance through their extensive global distribution networks.²¹

Strong links exist between PPP-PDs and the major pharmaceutical companies but barriers prevent fuller private sector participation. Understanding those barriers and how to overcome them is required if the private sector is to expand involvement¹⁹ financially and otherwise.

The biotechnology industry is noticeably absent from involvement in PPP-PDs with the unfortunate consequence that neglected diseases have not benefited from the advances in this field. The biotechnology industry does not have the resources that the pharmaceutical industry does but the situation simply presents different opportunities. The newest PPP-PD, BIO Ventures for Global Health, established in 2004, is dedicated to “facilitating the development and distribution of biotech products to treat diseases in the developing world”.^{22, 23, 24} This new PPP-PD has the potential to act as a liaison with biotech companies to bring them into the PPP-PD fold.

Whether addressing the pharmaceutical or biotechnology industries, PPP-PDs face the challenge of encouraging “the private sector to articulate what it will take to get them involved and to explore innovative ways to work together”.¹⁹

WHO can assist PPP-PDs to secure funding by opening or continuing dialogue between partnerships and potential funding sources, especially governments, bilateral and multilateral organizations by “using its respect and prestige to assist with negotiations and discussions”.²⁵

Creating new methods of funding to attract additional funding from current and new supporters of PPP-PDs:

A larger number of funding sources for PPP-PDs should increase the overall amount of money available for partnerships to develop products for neglected diseases. Part of the strategy should be creating innovative financing mechanisms as incentives to fund what is by its very nature a high-risk proposition.³⁰

Providing incentives, especially to the private sector, to encourage participation in the development of medicines and vaccines for neglected diseases is necessary because the financial incentives are low or non-existent.²⁶ Because the countries in which neglected diseases are endemic are too poor to pay for medicines and vaccines, pharmaceutical and

biotechnology companies cannot recoup the return on the investment needed to develop these products.²⁶ The lack of financial incentives for the private sector is a major reason why products have not been developed for the weak commercial market that developing countries represent.²⁶

To date, various push and pull mechanisms have been tried to encourage investment in products for which there is a small or no commercial market. “Push” mechanisms include reducing industry costs through mechanisms such as grants, tax breaks, and fast track approvals.²⁷ “Pull” mechanisms are designed to create effective demands for yet-to-be-developed products via global funds and advance price and purchase commitments.²⁷

The World Bank has assembled the “Out of the Box” (OOTB) group with the mission to “create, improve upon, and validate new strategies and incentives to accelerate the development and use of priority health products for developing countries” by examining the potential for traditional capital market institutions (stock and bond markets, commercial and investment banks) to finance the development activities of PPP-PDs.²⁸ The OOTB group concluded that a strategy of minimizing development costs and risks while guaranteeing revenues is fundamental to accelerating the development of new health technologies targeting the world’s poorest countries.²⁸ Initial recommendations from OOTB include:²⁸

1. Investing in early R&D: The public sector should become more active in reviewing and managing R&D portfolios relevant to priority diseases;
2. Investing in manufacturing plants: The public sector can mitigate risk and influence competition via targeted investments in productive capacity;
3. Establish non-for-profit subsidiaries: Public-private partnerships should explore opportunities to spin off not-for-profit divisions focused on specific vaccines;
4. Long-term purchase guarantees: Given the fundamental barriers of risk and market uncertainty, long term purchase guarantees are likely a necessary part of any solution;
5. Role of World Bank/International Development Association (IDA) in purchase guarantees: Although the World Bank is not involved in the purchase of (sic) the Bank does have tremendous resources available to developing countries and it should continue to explore innovative concepts to facilitate country vaccine purchases;
6. “Venture capital” approach: Money may be invested in companies developing priority vaccines in exchange for equity or “access stakes”;
7. Innovative use of capital markets: The capital markets and related financing mechanisms may be tapped as new sources of funding for global public goods.

The World Health Organization can play an active role in assisting PPP-PDs to work with the World Bank and other existing and potential funding sources to explore and implement the recommendations made by the OOTB group.

New Approach: A “Way out of the box” mechanism

The World Bank’s OOTB group looks at traditional funding mechanisms and offers them for use in a new environment to the strategic benefit of PPP-PDs. Another suggestion targeted to the private sector offers a unique way to involve industry and stockholders in the development of products for neglected diseases.

An innovative funding mechanism, called “PharmaShares”,²⁹ has been proposed by SHARED, a Boston based non-profit organization dedicated to improving access to essential medicines to the world’s poorest. The concept behind “PharmaShares” is to create a tax-deductible check off mechanism associated with the sale or purchase of pharmaceutical stocks with the proceeds to be paid into an independent entity. This “PharmaShares” check off mechanism is designed so that when an individual purchases pharmaceutical company stocks, the shareholder is offered the option to add a tax-deductible amount to the total transaction for contribution to the “PharmaShares” fund. Upon sale of pharmaceutical shares, the same tax-deductible option applies. The independent “PharmaShares” entity collects and administers these tax-deductible funds to be used solely to assist with the development and/or delivery of essential drugs to developing countries. This type of mechanism allows direct participation by shareholders of pharmaceutical companies and gives shareholders an opportunity to participate in improving global health. The funds could be used to support PPP-PDs who apply to receive funds. Alternatively, a single PPP-PD could enter into an arrangement with a pharmaceutical company to use the “PharmaShares” mechanism with the donations used to fund its own development goals.²⁹

While traditional funding mechanisms remain the most attractive to current and potential funders, novel funding mechanisms should be explored to encourage substantially greater investment in PPP-PDs. The World Health Organization can encourage the creation and development of non-traditional funding mechanisms for PPP-PDs through its relationship with the World Bank and other entities.

Portfolio Management: Scientific Challenges and Financial Sustainability

While much progress has been made by PPP-PDs, products have not yet been developed. Projections of the likelihood of success involve a combination of overcoming scientific hurdles and maintaining financial support.

The amount of funding for each project is tied to the scope of the project undertaken. For example, it is much costlier to develop vaccines as opposed to medicines²⁷ just as it is more expensive to produce a product involving novel scientific discoveries such as an AIDS vaccine as opposed to developing a product that may have been previously worked on in the private sector but shelved because of lack of a commercial market. Based on the degree of scientific difficulty and the extreme cost, the development of novel vaccines are the highest risk but also have a substantial public health benefit especially the AIDS and malaria vaccines which affect millions of people.

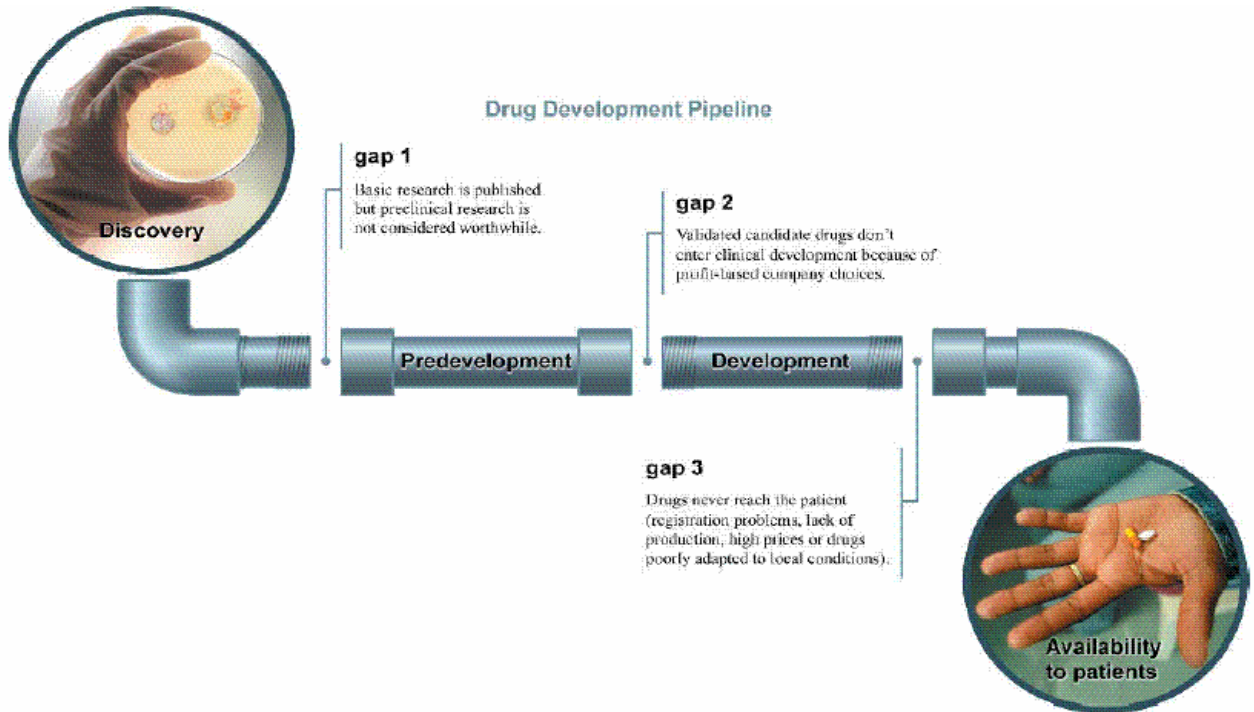
To reduce scientific risk, PPP-PDs use the portfolio method to balance their projects and manage the likelihood of failure of projects. Product portfolio management is a risk reduction technique developed by the pharmaceutical industry and utilized by PPP-PDs to maximize the likelihood of taking an idea to market while limiting the cost of development as well as time to market.³⁰ Key performance indicators (e.g. survival rates) are used prospectively and retrospectively to continually optimize the portfolio's content and performance to meet three objectives: (1) balance risk between high and low risk projects; (2) maximize the chance for a new medicine, - the lower the risk of the project the fewer projects are needed; and (3) manage the time to market by having a combination of projects at various stages of maturity.³⁰ Portfolio projects are continuously evaluated by commercial opportunity, technical feasibility and development feasibility. Given that on average only 1 in 10 new project ideas delivers a development candidate and that only 1 in 20 development candidates will reach the market as a medicine,³⁰ the portfolio approach increases the likelihood for success.

For example, DNDi currently has a portfolio of nine long-, medium, and short term projects that fill identified gaps in the drug development pipeline for each disease: (1) the early discovery stage, (2) the stage before drugs enter clinical development, and (3) at the point where drugs should reach patients but do not.³¹ Four are long-term projects to identify new lead compounds that can kill trypanosomiasis and/or leishmaniasis-causing parasites, and one focuses on combining existing anti-leishmanial drugs.³¹ The remaining four are short-term projects working with existing drugs at end of the pipeline. For instance, the registration of paromomycin, an old antibiotic, for visceral leishmaniasis in Africa (in collaboration with Institute of One World Health and WHO/TDR); the evaluation of nifurtimox, a drug used for Chagas disease, in combination with eflornithine to treat second stage sleeping sickness (in collaboration with WHO/TDR and Bayer); and two fixed-dose artesunate combination therapies (FACT) of artesunate/amodiaquine and artesunate/ mefloquine against chloroquine-resistant malaria in Africa and Asia respectively (in collaboration with seven medical research institutes across the world).³¹

Picking the proverbial low hanging fruit by modifying existing products increases the likelihood of producing a product while reducing costs and time to market. These short time projects contrast with the long-term projects that have substantially higher risk of failure at greater cost. It remains to be seen if funding sources will remain with PPP-PDs for the many years that are required to develop products.

A healthy portfolio of projects depends upon a steady flow of pharmaceutical product concepts or leads that support that pipeline. Without a commercial incentive to ensure that the pipeline is full, PPP-PD portfolios are at risk themselves of running dry either because there is inadequate funding for basic research or failure to translate basic research into plausible candidates.³²

Figure 1. Identifying the gaps in the Drug Development Pipeline.



Pecoul, B. New Drugs for Neglected Diseases: From Pipeline to Patients, PloS Medicine, Vol. 1, Issues, 020, October 2004.

The size of the gap along the research and development continuum is not known but appears to be significant and could constrain PPP-PDs in the long run.³² The PPP-PDs have seized the most promising candidates for development and as these candidates move through the development portfolio, replacement candidates are needed.³² Less attractive product candidates may impact the PPP-PDs chances for success.³²

Opportunities exist to repair the gap in the research continuum for neglected diseases such as:³²

- Creation of a funding strategy to support the translation of basic research into early product leads
- Increase investment in enabling technologies such as rodent models
- Foster interaction between academic laboratories and industrial entities
- Create a strategy to increase participation and integration of researchers in endemic countries in early research projects
- Sponsor networking between basic researchers for neglected diseases
- Create and/or encourage partnerships among investigators, institutions and private sector especially those in developing countries

Closing the research gap will increase the probability that PPP-PDs will develop products for neglected diseases over the long term. In its “Priority Medicines for Europe and the World” report, the World Health Organization recommends to the European Union to develop a mechanism to support “translational and preclinical research” done by PPP-PDs and others.³ The World Health Organization can continue to press for support from the European Union and other entities.

Governance, Representation and Accountability of PPP-PDs

The concepts of governance, representation and accountability are intertwined and have a direct impact on the success of PPP-PDs especially in terms of their relationship with the governments, institutions and people in low income countries. Participation in the leadership of PPP-PDs by representatives from developing countries will ease the constraints to implementation, increase “local ownership”, and improve the chances of sustaining partnership activities including product development initiatives.³³

Governance of PPP-PDs

“Governance” concerns the manner in which an organization manages itself and is comprised of formal and informal norms as well as rules and decision-making procedures that bring order and structure cooperation.³³ Themes relating to the concept of governance include: legitimacy or the extent to which authority is considered valid by those affected by it; representation and participation by those who are affected by the exercise of power; the degree to which individuals are accountable for their decisions and actions; transparency; and the effectiveness, efficiency and sustainability of the governing body.³³

Governing bodies direct the decision-making process and power relationships in PPP-PDs. A governance structure that fits the needs of the partnership is necessary to ensure that the public health objectives and the objectives of the partners are being met.³⁴ The PPP-PDs have selected one of two general models of governance: independent or hosted.

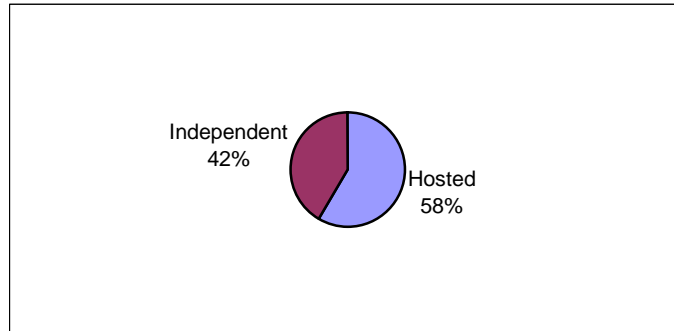
“Independent” partnerships are based on a business model with management structures similar to a private company. The governing body is a Board of Directors with representatives drawn from the public, private and civil sectors. The organizations generally have a lean executive management team as well as a scientific advisory committee and a stakeholder council.³⁵ This model is favored in situations where the partnership is going to work with many separate entities.³⁶ As the governing body, the Board of Directors of “independent” PPP-PDs has the responsibility to develop policies and principles for the partnership: review and guide corporate strategy; appoint, monitor, and advise key executives; assure financial integrity by reviewing finance and budgeting; and fundraise.³³

“Hosted” partnerships create an affiliation with an existing organization such as a university or government funded research institute to benefit from existing infrastructure and science. This type of arrangement determines where the PPP-PD will be housed and

the terms of the hosting arrangement, typically operating by their hosts policies and procedures.³⁸ Hosted partnerships have “governing bodies” provided by the hosting organization that maintains fiduciary responsibility for the partnership which may restrict the partnership in terms of decision-making.³³

Of the 24 PPP-PDs reviewed, 14 are hosted and 10 are independent. [Refer to Summary Sheet number 1 for independent v. hosted status].

Table 4. Hosted v. Independent PPP-PDs.



The composition of governing bodies of independent and hosted partnerships determines the mix of public and private representation as well as North – South representation. These and other factors have a direct impact on the shared-decision making conducted by governing bodies. Deliberately structuring the governing body in such a way as to ensure that seats and voting rights are provided to both public and private sector organizations or North – South organizations increases the chances that the decisions taken reflect the interests, needs, and concerns of all groups.³³ In addition, participation in Board representation may “increase the perceived fairness and legitimacy of the governing arrangement”.³³

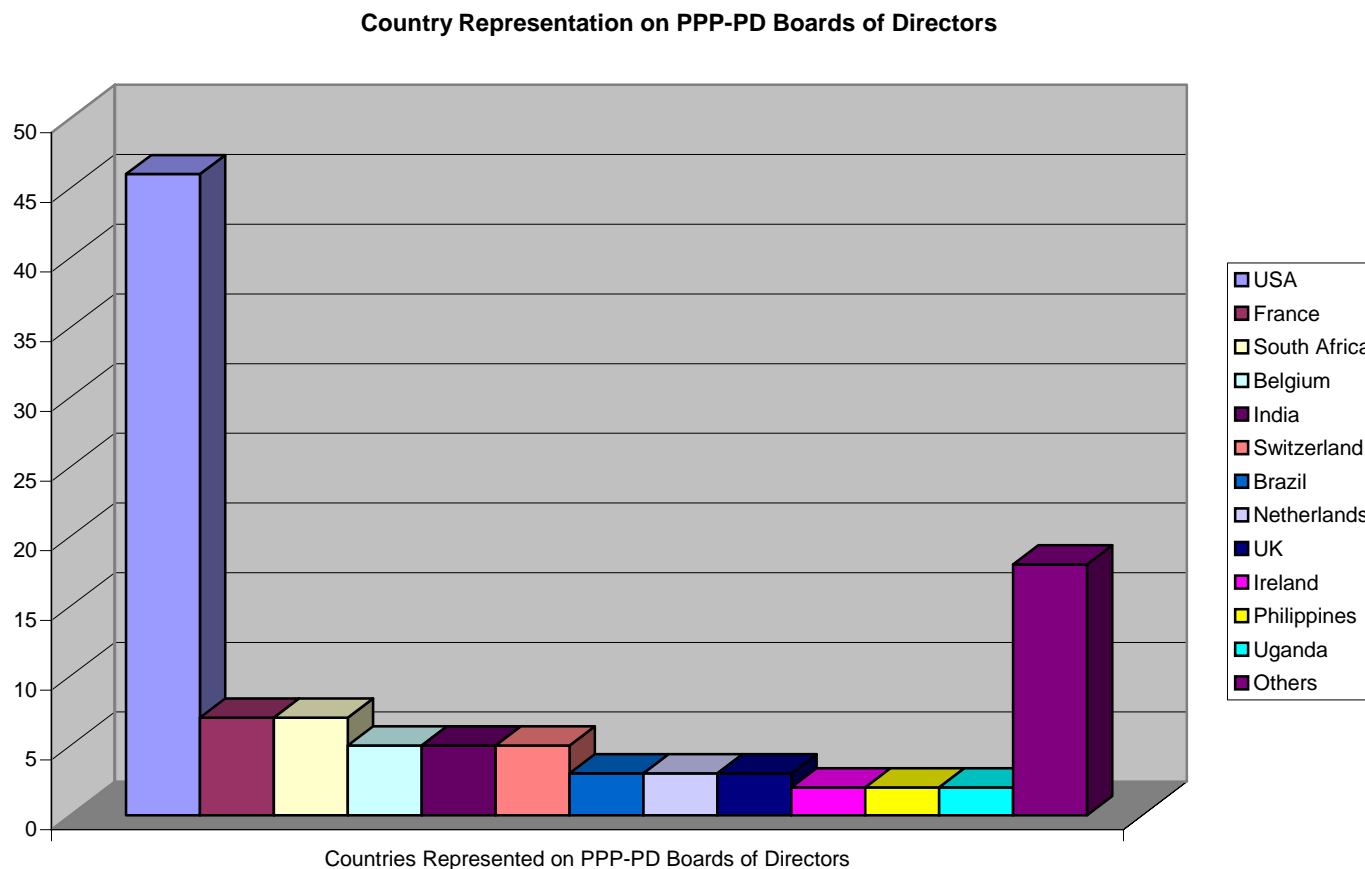
Representation on Boards of Directors and other advisory committees:

A review of the composition of representatives of the governing bodies of PPP-PDs by examining who sits on the Board of Directors/Governing Bodies, Scientific Advisory Committees and other bodies that govern these partnerships is set out on Appendix 1, Sheet 4.³⁷

As of December 31, 2004, there were a total of 109 available positions on the Boards of Directors/Governing Bodies (Boards) for PPP-PDs. Of the total, 108 seats are filled with one vacancy. Thirty countries are represented on the Boards with 15 countries having developed economies while 15 are less developed economies. Table 5, below, shows the number of Board members per country. Of all Board members, 79 (72%) are from developed economies. The United States has 46 Board representatives or 42% of all Board members. Please refer to Appendix 1, Sheet 10 for a complete listing of countries and representatives for each country.

Table 5. Number of PPP-PD Board of Directors members by country.

Information about Board representation was collated from the websites of the various PPP-PDs as well as the website of the Initiative on Public-Private Partnerships on Health, www.ippph.org, accessed at numerous times in November and December 2004 as well as January 2005.



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While some PPP-PDs have deliberately ensured representation from the South (DNDi), other Boards have no or few participants from low or middle-income countries or organizations (AERAS, IDRI). This pattern is reflected in the membership of Scientific Advisory Committees and other advisory boards as well. Please refer to Appendix 1, Sheet 4 for further detail on the composition of Boards of Directors and Advisory Committees.

It can be argued that “genuine deference to local decision-making would acknowledge that the elected governments of poorer countries are better placed than NGOs based in richer ones to decide what is in the interests of their populations”.³⁸ The same can be said of “northern-based foundations, firms, governments and academics”.³³ Broader representation from the South increases the likelihood that proposed solutions will meet the needs of the populations to be served.

Logistics may play a part in the low representation from developing countries. Fifteen of the 24 PPP-PDs (62.5%) are headquartered in the United States and only one (SAAVI) is located in Africa. Twenty-three of the twenty-four PPP-PDs are situated in developed countries putting individuals from developing countries at a disadvantage in terms of ease and cost of travel.

Public-private partnerships are a product of developed countries, are housed in developed countries, funded by developed countries, and governed primarily by people from developed countries. While it can be argued that PPP-PDs need to be located in places that have easy access to the institutions in the North that fund them, the “symbolic importance of the locale (as well as the prevailing work cultures in these cities) may give the impression that these are not as ‘global’ as their names often suggest”.³³

“If developing countries genuinely believe they are true stakeholders then they may also be inclined to contribute more themselves to product R&D projects and organizations, both through financial and in-kind resources”.² The legitimacy of the authority of PPP-PDs involving developing countries increases.

The low participation of individuals from developing countries on Boards of Directors and other advisory groups raises concerns about the future of PPP-PDs. The cooperation and participation of developing countries is key to ensuring that once products are developed that they will be delivered to populations in developing countries. Their goal may be undermined because targeted recipients of PPP-PDs products may not be involved in “formulating policies, discussing priorities or considering the problems around delivery”.^{39 40 41} Involving national and community policy makers as well as key promoters such as individuals from professional associations can assist PPP-PDs in identifying gaps in research and other issues that can assist with the introduction of products into developing countries if consulted early in the process.⁴⁰

PPP-PDs are presented with clear challenges to increase the number of partners from the South. The majority of the PPP-PDs are less than five years old and representation from less developed countries can increase over time if PPP-PDs make it a priority to develop “innovative, cost-effective models for deeper southern and other stakeholder input”.³³

Accountability: Expanding the role of representation of the South

A question related to governance and representation is that of accountability. To whom are the PPP-PDs accountable? Are they “accountable to their own structures (boards, funding sources, councils) or to their constituencies (governments, shareholders, member states, beneficiaries including the intended recipients of the products being developed)?³⁹

Accountability is defined as “being held responsible for one’s actions”.⁴² Both the private and public sectors have well-developed systems of accountability. In the private sector, management is accountable to its shareholders while in the public sector, administrative structures report to political structures that are ultimately accountable to voters.⁴²

Accountability within PPP-PDs is less clear for several reasons. First, the PPP-PDs do not have any mechanisms for holding a partner accountable since the partners are autonomous entities. No system of sanctions exists to apply to negligent partners.⁴² Second, responsibility to governments and intended recipients in developing countries, referred to as “downward accountability”, is ill-defined and limited, posing a challenge to cooperation between international and local organizations.⁴³

PPP-PDs have adopted mechanisms for accountability that mirror their independent or hosted status. Independent PPP-PDs such as MMV have senior management that is appointed by and accountable to the Board of Directors.³³ A hosted PPP-PD operates so that the management and scientific groups report directly to the corporate sponsor such as those organizations housed at the Program for Appropriate Technology in Health (PATH) that report directly to its sponsor, the Bill and Melinda Gates Foundation.^{33, 42} In both models, PPP-PDs are accountable first to their donors and then indirectly to the public sector organizations and even more remotely, intended beneficiaries in developing countries.⁴³

Overall, the governing bodies of PPP-PDs are held accountable primarily to “funders and stakeholders directly involved in the specific R&D problem”.³³ An opposing view contends that “stakeholders such as peoples from low-income countries need to be in a position to hold PPP[-PDs] accountable and one mechanism for so doing involves systems of representation together with access to information.”³³ By defining accountability more narrowly, PPP-PDs may be doing themselves a disservice in the future when it is time to request more extensive cooperation from low-income countries to test, market and deliver their products.

Once products are developed and introduced in developing countries, increased costs and systems demands will be made on developing countries. Administrative demands for implementation, funding for obtaining and distributing products as well as opportunity costs are issues for developing countries.³⁹ System demands include reinforcing or establishing new systems for specific diseases, training staff in particular interventions, and introducing them to new drug regimens”.³⁹ Initiatives from PPP-PDs may divert resources to health problems considered of lower national priority and may create or exacerbate internal rivalries for control over funds and other resources.⁴⁴ These additional demands will divert attention from other country level priorities and will certainly put stresses on already fragile health care systems.³⁹

Little is known about the perspectives of governments in low-income countries regarding PPP-PDs; however, when partnerships have excluded ministry officials, problems have arisen. For example, Namibia and South Africa initially rejected the UNAIDS/Bristol-Myers Squibb’s “Secure the Future” program because they had not been consulted in its design.⁴⁴ Ethical issues have been raised about conducting clinical trials in Africa where drugs will be unaffordable as well as the training of African doctors in the US on drug regimens, methods and equipment that are unavailable in Africa.⁴⁴

It is unclear at this time what, if any, role PPP-PDs will provide in addressing accountability issues; however, WHO with its global focus can take steps to assist PPP-PDs, governments, funding sources and other interested parties engage in addressing these issues. The World Health Organization can:

- Work with PPP-PDs to ensure that the fruits of these entities benefit societies equitably. Very poor countries with large populations, unpopular governments or poor infrastructure may be excluded from these partnerships.⁴³
- Facilitate with PPP-PDs to ensure that they are working in harmony and integrated with national health priorities.⁴⁵
- Lead the development of transparent policy and procedural frameworks to protect the public interest and to ensure that the processes established by PPP-PDs are structured in the public interest.⁴⁵
- Promote and support research aimed at identifying good partnership practice.⁴⁶
- Lead the discussion to ensure that developing country governments are given an adequate voice in PPP-PDs.⁴⁷
- Assist with capacity development through coordination with PPP-PDs.⁴⁵

Role of PPP-PDs in developing capacity in low income countries

“Developing capacity” can be thought of in two broad categories: (1) transfer of scientific and technical knowledge and (2) ability of the governments of low-income countries to develop health care services and ensure access to the products PPP-PDs strive to create.

PPP-PDs have the potential to develop capacity in areas where clinical trials are conducted. With their major focus on core research and development activities, PPP-PDs are developing products that must under go clinical trials before registration is completed. Many of the PPP-PDs have clinical trials underway in developing countries presenting

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challenges in terms of selecting and managing trial sites, regulatory capacity and ethical review capacity.

To date, PPP-PDs have taken a solo approach to find sites for clinical testing, finding resources to manage clinical data and provide biostatistical analysis as well as using the capacity offered by the European and Developing Countries Clinical Trial Partnership (EDCTP).¹⁹

For example, IAVI has pursued a vigorous site development approach for phase 1 trials with 16 potential sites in 7 countries.⁴⁸ Aeras has engaged in clinical site development designed to enhance the capabilities of physicians, scientists, and public health workers in TB endemic areas of the Western Cape region.⁴⁹ Global Alliance for TB Drug Development working in collaboration with International Union Against TB and Lung Diseases (IUATLD) organized in South Africa to engage and strengthen potential clinical sites, especially laboratory skills and the preparatory work before clinical testing can take place⁴⁸. MMV is pursuing the course testing the product at site that is represented in the portfolio of program development partners for the specific project, thereby optimizing the project for the sponsor's needs.⁴⁸

The overarching mission of PPP-PDs is to develop appropriate products for neglected diseases and the issue of capacity building in Africa is not the top priority for these organizations or for their funders that require the attainment of certain scientific and business goals.⁴⁸ An understanding of the current level of expertise available in Africa confirms that much work needs to be done before these resources will be at a level where they can be full participants in the process. Specifically, there is “no consistent criteria for assessing current trials capacity or future needs and no organization has maintained an overview on which to base coordinated efforts to strengthen capacities to match future needs”.⁴⁸ This void represents an opportunity for coordination and direction from an international health organization such as WHO.

Research networks exist in Africa to identify available resources for PPP-PDs to utilize. The African Malaria Network Trust (AMANET) is a collection of approximately 30 institutions in 20 countries engaged in malaria research reflecting a wide range of available equipment and clinical trials experience.⁵⁰ The Pan African Bioethics Initiative (PABIN) and the African Health Research Forum (AHRF) are involved in efforts to strengthen capacity in Africa.⁵¹ INDEPTH is a network involved in long-term intensive demographic surveillance systems in 16 countries. Each site has basic infrastructure and potential for clinical trials including access to participants in malaria, tuberculosis and HIV/AIDS endemic communities.

Little has been done in Africa to systematically develop research capacity especially in sub-Saharan Africa “where health research in most countries has an allocation of less than 0.5% of national budgets, and health budgets are funded with less than 1% of gross domestic product but innovative schemes for financing research are in place in Colombia and the Philippines”⁵². Government research institutes such as the National Institute for Medical Research, Tanzania, the Joint Clinical Research Center, Uganda, the Kenya

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Medical Research Institute and the National Institute for Pharmaceutical Research, Nigeria provide opportunities for local scientists and to influence public policy⁴⁸. In general, there is evidence of general political will to boost creativity within the scientific community but the “lack of capacity is one of the reasons many industry players choose not to run trials” in developing countries.¹⁹

“Regional health research networks have been established in Asia (Asia Pacific Health Research Forum, <http://www.aphrf.org>), Latin America and the Caribbean to consolidate efforts on health research priorities common to the respective regions” but obtaining long-term support and sustaining networking has been difficult.⁵²

The role of the pharmaceutical industry in participation in clinical trials in developing countries has been primarily through public-private partnerships. For example, Merck is conducting trials in 58 countries in Eastern Europe, Asia and Latin America and GSK is working to facilitate testing in developing countries but opportunities exist to engage the pharmaceutical industry more fully in building clinical capacity in developing countries.⁴⁸ Bilateral aid donors tend to support institutions, local missions or global funding rather than research development.⁴⁸ The opportunity exists for government and international organizations to raise capacity and standards including training to build capacity in implementing clinical trials and to establish regulatory structures.⁴⁸

Other major challenges exist in developing capacity in Africa. First, African countries do not have Institutional Review Boards and of those who do the standard of quality is good to poor.⁵¹ Developing countries must work with each other as well as with industrialized nations on the full range of access issues.⁵³ Establishing regional regulatory networks would enable countries to share expertise and harmonize processes to expedite product review.

Other shortcomings hamper the capacity building process. Clinical studies take place in 1 or 2 locations within a country and exclude medical practitioners in isolated, rural areas; by global standards, facilities for handling and managing clinical data are minimal; inadequate travel and communication infrastructures impede communication; developing support from the local level takes a long time to establish trust among sponsor, research team, community and participants.⁴⁹ The issue of informed consent is complicated by low levels of literacy, difficulties with understanding and communication compounded by the use of translators; and cultural issues including the tradition of seeking the consent of the village chief and the family head before an individual gives consent. Building capacity within the African scientific community to demonstrate credibility in managing research funds is needed.⁵¹

Research efforts can be hampered by the low number of people willing to participate in clinical trials. For example, South African HIV vaccine research efforts are threatened by the inability to enroll people in clinical trials. “According to researchers from the Medical Research Council, the fear of stigma and discrimination for their communities prevented people from taking part in the trials”.⁵⁴

Opportunities exist for an organization, possibly WHO or a regional WHO office, to advocate for developing capacity and to establish basic, achievable goals including: regionally harmonized clinical trial guidelines⁵⁵; ICH compliant Institutional Review Boards (IRBs) for ethical and safe clinical research, health research requirements and local capacity⁴⁹. This role requires material and financial support, training, coordination of resources within the region, governance structures as well as administrative and management skills. If WHO takes on this or any other role, it will need to carefully consider the issues of “under funding and understaffing”²⁵ that may hamper its effectiveness.

Increasing the role of developing countries in capacity building is crucial but should not be left to PPP-PDs alone as it may pull them off mission.¹⁹ Support is needed from government, multilateral and bilateral agencies, as well as private and public institutions. “A challenge for the [PPP-PDs] is how to leverage their collective voice to facilitate increased focus and momentum from organizations such as WHO, which can help by working in parallel with them”.¹⁹

Many aspects of access to medicines are out of the control of PPP-PDs such as health systems issues including the quality and competency of health personnel, government procurement practices and efficiency, government budgeting for health care, national policies regarding product choice and drug policy, and other related issues.⁵⁶ In addition, low-income countries need the tools necessary to make informed decisions about the introduction of any new medicine or vaccine. Factors to be considered in making such a decision in regards to any of the neglected diseases include: current disease burden; cost-effectiveness of existing treatments compared to the cost-effectiveness of any new treatment; economic disease burden; the capacity of the existing delivery infrastructure; and availability of financing.⁵⁷

PPP-PDs, along with their stakeholders and national citizens must insist that “governments and intergovernmental institutions fulfill their responsibility in properly funding and directing needs-based R&D. Governments have a duty to ensure that appropriate resources and capacity exist in independent national and intergovernmental institutions to set, drive, monitor and critically evaluate the national and global health agenda”.⁴⁷

It is clear that many challenges exist to develop capacity in developing countries and that these challenges far exceed the scope, skills or mission of PPP-PDs. Leadership opportunities exist for pan-African or international organizations led by WHO to set out the framework and guidelines for the long-term commitment needed to develop research and clinical capabilities in low income countries.

Product delivery to developing countries: Issues, challenges, plans for product distribution

Public health history shows the importance of planning for the introduction of products well in advance of those products being ready for distribution. While challenges for

medicines, vaccines and diagnostics are unique and present their own sets of issues, the case of vaccines is a good example. “The historical approach to developing an introduction strategy has been to start thinking about it only after the product is available – a Hepatitis B (HepB) vaccine was introduced in the developing world in the late 1980s, nearly 10 years after the developed world; the vaccine of Haemophilus influenza type b (Hib) has a similar story. By 2001, 126 countries had introduced HepB vaccine; only 77 countries had introduced Hib. The cost of this approach has been estimated in hundreds of thousands of preventable deaths”.⁵⁸

Ensuring access to finished products in developing countries requires demand for those products, adequate financing and infrastructure. Clearly the magnitude of these issues prevents PPP-PDs from tackling them alone. “PPPs may be able to play a role in critical areas relating to access by ensuring availability of the products as well as ensuring that the products are adopted. To ensure availability, PPP-PDs can assist in the development of appropriate regulatory approval and licensure infrastructure; manufacturing capability and sufficient capacity; and logistics and delivery networks in-country.”¹⁹

To ensure adoption of new products, PPP-PDs can participate in end-user awareness about the product and its benefits; effective pricing and financing mechanisms to ensure affordability; and engage in building a supportive social and policy environment.¹⁹

Several PPP-PDs have prepared strategies for dealing with the delivery of newly developed products. For example, IAVI has set out a blueprint for access to an AIDS vaccine which touches on issues relevant to other vaccines as well as medicines and diagnostics. These issues are: (1) Financing – Mobilize political support to price vaccines by ability to pay and secure donor resources to purchase vaccines for poor countries; (2) Production – Forge public-private partnerships to share the risk of building capacity in advance of a licensed vaccine; (3) Delivery – Establish innovative systems for delivering AIDS vaccines to at-risk and hard-to- reach adolescents and adults; (4) Demand – Secure reliable demand forecasts that can guide arrangements for financing, production and delivery; and (5) Regulation – Streamline and coordinate licensure procedures, scale up regulatory expertise in developing countries.⁵⁹

Another PPP-PD engaging in planning for product distribution is the Meningitis Vaccine Project (MVP) that has identified 4 areas of focus: vaccine development; research and surveillance; vaccine rollout and distribution; and communications, advocacy and resource mobilization.⁵⁸ At the same time that MVP is negotiating an off-take agreement for the future vaccine in order to secure long-term supply at low and predictable transfer prices, it is preparing the ground for uptake by working with Ministers of Health and Finance in Africa to build awareness and demand. Efforts are made to work with the donor community to secure financial support.⁵⁸

The Rotavirus Vaccine Project (RVP) is working to reduce the time from development of a vaccine to distribution in developing countries. RVP’s model is designed to harness the resources and commitment of the vaccine industry, public health organization, donors, and governments to address “barriers to vaccine introduction. The model focuses on both

sides of the vaccine/supply demand equation to achieve stable vaccine supply at a feasible price established through predictable demand”.⁶⁰

This model depends on the successful achievement of the following Strategic Goals⁶⁰:

- Provide information that enables national and international decision-makers to make an evidence-based decision regarding use of vaccine.
- Accelerate the availability of affordable, new vaccines appropriate for use in developing countries.

RVP will pursue this model over the next few years with the aim of demonstrating and creating a model to ensure global rotavirus vaccine access.⁶⁰

PneumoADIP is taking an approach similar to RVP. Working closely with GAVI and other organizations, PneumoADIP seeks to use innovative financing mechanisms such as demand creation, manufacturing incentives, and predictable funding to meet goals.⁶¹ It hopes to provide affordable vaccines in developing countries; encourage a fair return on investment in the research, development, and production of vaccines, leading to a strong and healthy global vaccine industry; create incentives for manufacturers to invest in expanding capacity by ensuring demand for the vaccines; improve skills and infrastructure in countries to better forecast and plan long-term vaccine needs; and optimize the impact of vaccines and reduce long-term wastage.⁶¹

One of the first steps in ensuring accelerated introduction of vaccines into developing countries is to establish the value of the value of vaccinating children in individual countries. This process requires that the disease burden is known and articulated.⁵⁸ Disease burden studies, efficacy trials and other fact gathering activities must be done to define the baseline of disease prevalence and the information must be communicated to national and community leaders.^{58 41} This information will also paint a picture of latent demand to be used as an initial price estimate.⁵⁸

Education and advocacy coupled with demonstration trials will be necessary to convince decision makers on the national level to prioritize the introduction of the vaccines where appropriate.⁵⁸ Sustainable funding must be available to ensure a reliable supply of the vaccines.⁵⁸

PneumoADIP and RVP are working to “identify ‘early adopter’ countries which will be the first introducers of their respective vaccines. These adopters will become the priority focus in terms of enhanced disease surveillance, demonstration projects, and eventual introduction. Success in these countries will then lead to introduction and success in ‘early majority’ and ‘later majority’ countries. This user segmentation reflects the varied need, capacity and willingness of countries to adopt new vaccine technologies; it adapts commercial approaches to market segmentation and phased introduction”.⁵⁸

The early adopter countries will most likely have “stable political environments, respect for intellectual property rights, and a strong national commitment to testing a vaccine that might benefit the population.”⁶² This selection process raises the issue of increasing inequalities in developing countries as countries that the populations of the least organized and least stable may have the populations that are most needy.³⁹

Both ADIPs are “working with multinational pharmaceutical companies – the suppliers closest to market for both Pneumococcus and Rotavirus vaccines for the developing world – to negotiate pricing arrangements. All of this is being done while products are still in development so the ADIPs are potentially shaping the products being created and explicitly trying to influence future supply dynamics”.⁵⁸

The goal of PPP-PDs is to ensure that within developing countries their products are “used and understood by the consumers and are put into use within national health systems, whether within the private or public sectors”.²

To ensure marketing and distribution of products, Ridley points to the model of the non-profit organization, The Concept Foundation, which “was initiated to handle IPR and licensing issues associated with the new contraceptive developed through the Human Reproductive Health Programmed at WHO”.² The Concept Foundation has “engaged with local manufacturers and distributors to ensure widespread availability of affordable product”.²

Several PPP-PDs have actions plans and strategies for introducing new products into developing countries and have begun the process of building support within these countries; however, it is clear that the task of delivery is outside the mission of most PPP-PDs. It is such a huge undertaking that cannot be accomplished without the support of international organizations such as WHO, national governments, multilateral and bilateral entities, and all members of the public and private sectors. WHO, UNAIDS and CDC have produced a blueprint for the introduction of a first generation HIV vaccine⁶³ but the role of PPP-PDs is not identified. PPP-PDs must be involved in this process to utilize their expertise, knowledge and resources to reach the desired public health goal of ensuring greater access to vaccines and medicines for neglected diseases. The governments of low income countries will need the expertise of WHO and PPP-PDs to help them make the best health choices for their people based on accurate disease burden information and treatment options within the available finances.

Collective activities in support of PPP-PDs: Advocacy Opportunities

The work of PPP-PDs could progress faster if they participated in collective activities using their resources and skills to further their respective missions. Areas for possible collective action include communication and coordination such as information sharing relating to deal making and IP management; coordinated action such as common systems for clinical trials; collective advocacy to raise awareness about neglected diseases; strengthening of regulatory capacity in developing countries; and issues relating to portfolio management.¹⁹ Because PPP-PDs operate with small administrative staffs, they

are “so busy and focused on their mission that they haven’t paid attention to ways to work together”.²⁵

An even larger challenge is for PPP-PD is to “communicate the core strengths and perceived benefits of the model with simple messages that cut across the entire field of [PPP-PDs] to encourage a broader support base.¹⁹ The “Priority Medicines for Europe and the World” emphasized the importance of public-private partnerships in addressing neglected diseases and advocated for specific actions to be taken by the European Union. PPP-PDs can continue and expand this work independently and with the cooperation of the World Health Organization.

“As the [PPP-PDs] plan for the success of their development efforts, they must also work in parallel with other organizations and groups to ensure that public policy, financing and infrastructure are ready once a product has been successfully developed”.¹⁹ Gaps in resources or capacity including translational capabilities, regulatory capacity, delivery infrastructure, regulatory harmonization could be addressed through existing public sector organizations such as WHO.¹⁹ PPP-PDs working together is necessary to ensure access in developing countries. With their competing goals and increasing demands on fragile health systems, they may meet with resistance if they cannot build up national health systems and integrate their products into strained systems.³⁹

The opportunity exists for PPP-PDs to work together to “develop and deliver a simple set of messages about the [PPP-PD] field” that may be more effective than individual efforts.¹⁹ Dialogue between and among PPP-PDs takes place on an ad hoc basis but no formal mechanism yet exists to create and implement a plan of action for PPP-PDs.

With the unfortunate demise of the Initiative on Public-Private Partnerships for Health,¹ data collection and research on public-private partnerships will have to take place elsewhere or not at all. It is unclear what entity will take the initiative to bring together the leaders of PPPs to discuss issues that are of mutual importance. It is up to PPP-PDs working individually and together to ensure their own success.

The World Health Organization may act as a facilitator for PPP-PDs to collaborate and provide a forum for research and discussion. If new products are to be successfully adopted by low income countries, further action is required to ensure that fragile health systems are supported and advised based on epidemiological data tailored to each country.

Recommendations for further action by the World Health Organization:

Public-private partnerships for product development have accomplished much in terms of mobilizing resources, focusing research and public opinion in support of developing treatments and preventive measures for neglected diseases. The World Health

¹ IPPPH closed its doors effective 31 December 2004. www.ipph.org.

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Organization can continue to foster and support the work of PPP-PDs in several key areas:

- Advocate for additional traditional and innovative funding mechanisms from current and additional funding sources to support long-term financing of the development and delivery of products for neglected diseases
- Utilize its leadership position and expertise to close the research gap and foster networks while building capacity in low income countries by supporting preclinical and translational research to be conducted collaboratively with institutions in the north and south
- Engage in strategic planning with PPP-PDs to coordinate their efforts between and among PPP-PDs as well as all other interested parties to ensure that duplication of efforts is minimized and financial and other resources are maximized.
- Develop an overarching strategic plan for delivery of new products for neglected diseases by ensuring baseline disease burden information is available for informed decision making and is communicated to leaders at the national level.
- Work with PPP-PDs to develop a plan to increase participation on governing boards by representatives from the South with the long term goal of accelerating the marketing and delivery of products for neglected diseases.
- Provide a forum for PPP-PDs and other parties to identify and prioritize areas for collaboration.

By continuing its work with PPP-PDs, the World Health Organization can assist them to achieve their goals of developing products for neglected diseases. These products will have a positive impact on the health of millions of people worldwide.

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¹¹ Website for the Malaria Foundation International, www.malaria.org, accessed 9 February 2005.

¹² Website for the Japanese Alliance, www.jpma.or.jp, accessed 8 February 2005.

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APPENDIX 1, Sheet 1										
Public-Private Partnerships for Product Development (PPP-PD)										
Summary Information										
	Acronym	Full Name	Year Established	Secretariat	Executive Officer	Headquarters	Website	Telephone	Disease Focus	Email
1	Aeras	Aeras Global Tuberculosis Vaccine Foundation	1997	USA	Jerald Sadoff	7500 Old Georgetown Road, Suite 800, Bethesda, MD 20814 USA	www.aeras.org	301-547-2900	Tuberculosis	info@aeras.org
2	BVGH	BIO Ventures for Global Health	2004	USA	Wendy Taylor	1225 Eye Street NW, Suite 400, Washington DC 20005 USA	www.bvgh.org	202-312-9260	Neglected diseases	info@bvgh.org
3	CONRAD	Contraceptive Research and Development Program	1984	USA	Henry Gabelnick	Eastern Virginia Medical School, 1611 North Kent St., Suite 806, Arlington, VA 22209 USA	www.conrad.org	703-524-4744	Reproductive health	info@conrad.org
4	CICCR	Consortium for Industrial Collaboration in Contraceptive Research	1995	USA	Michael J.K. Harper	Eastern Virginia Medical School, 1611 North Kent St., Suite 806, Arlington, VA 22209 USA	www.ciccr.org	703-524-4744	Reproductive health	mharper@conrad.org
5	DNDi	Drugs for Neglected Diseases <i>initiative</i>	2003	Switzerland	Bernard Pecoul	1, place Saint Gervais, 1201 Geneva, Switzerland	www.dndi.org	41 (0) 22 906 9230	Neglected diseases	dndi@dndi.org
6	EMVI	European Malaria Vaccine Initiative	1998	Denmark	Soren Jepsen	The Hague, The Netherlands	www.emvi.org	45 32 68 3188	Malaria	sje@ssi.de
7	FIND	Foundation for Innovative New Diagnostics	2003	Switzerland	Giorgio Roscigno	71, av. Louis-Casai Case postale 93 1216 Cointrin/Geneva Switzerland	www.finddiagnostics.org	41 (22) 710 05 90	Diagnostic tests for infectious diseases	info@finddiagnostics.org
8	Gates/UNC	Gates Foundation/University of North Carolina Partnership for the Development of New Drugs	2000	USA	Richard Tidwell	UNC-Chapel Hill, 805 Brinhaus-Bullitt Bldg., Chapel Hill, NC 27599 USA	www.pathology.unc.edu/faculty_labs/tidwell_lab/newintrest.htm	919-966-4294	Leishmaniasis, African trypanosomiasis	tidwell@med.unc.edu
9	GMP	Global Microbicide Project	2000	USA	Michael J.K. Harper	1611 N. Kent St., Suite 806, Arlington, VA 22209-2111 USA	www.gmp.org	703-276-4022	Reproductive health	mharper@conrad.org
10	HHVI	Human Hookworm Vaccine Initiative	2000	USA	Dean Mason and Fran Sonkin, Interim Management Team	161 Cherry Street, New Canaan, CT 06840-5408 USA	www.sabin.org	203-972-7907	Hookworm	sabin@sabin.org
11	IAVI	International AIDS Vaccine Initiative	1996	USA	Seth Berkeley	110 William Street, Floor 27, New York, NY 10038-3901 USA	www.iavi.org	212-847-1111	HIV/AIDS	info@iavi.org
12	IDRI	Infectious Disease Research Institute	1993	USA	David Webster	1124 Columbia St, Suite 600, Seattle, WA 98104	www.idri.org	206-381-0883	Chagas, leprosy, TB, malaria, leishmaniasis	dwebster@idri.org
13	IOWH	Institute for OneWorld Health	2000	USA	Victoria Hale	580 California Street, Suite 900, San Francisco, CA 94104 USA	www.oneworldhealth.org	415-421-4700	Neglected diseases	info@oneworldhealth.org
14	IPM	International Partnership for Microbicides	2002	USA	Zeda Rosenberg	1010 Wayne Avenue, Suite 1450, Silver Spring, MD 20910 USA	www.ipm-microbicides.org	301-608-2221	Reproductive health	info@ipm-microbicides.org

15	LAPDAP	Lapdap Antimalarial Product Development	2001	UK	Prof. Peter Winstanley	Univ. of Liverpool, Ashton Street, Liverpool L69 3GE UK		(44) 151-794-5544	Malaria	peterwin@liverpool.ac.uk
16	MDP	Microbicides Development Programme	2001	UK	Jonathan Weber	Imperial College, South Kensington, SW7 2AZ UK	No separate legal status		Reproductive health	
17	MMV	Medicines for Malaria Venture	1999	Switzerland	Chris Hentschel	20, route de Pre-Bois, 1215 Geneva 15, Switzerland	www.mmv.org	41 22 799 4060	Malaria	info@mmv.org
18	MVI	Malaria Vaccine Initiative	1999	USA	Melinda Moree	6290 Montrose Road, Suite 1000A, Rockville, MD 20852 USA	www.malariavaccine.org	301-770-5377	Malaria	mmoree@malariavaccine.org
19	MVP	Meningitis Vaccine Project at WHO/PATH	2001	France	Marc LaForce	Batiment Avant Centre, 13 Cehmin du Levat, Fernay Voltaire 01210 France	www.meningvax.org	33 4 5028 2563	Meningitis	fmlaforce@path.org
20	PDVI	Pediatric Dengue Vaccine Initiative	2001	South Korea	Scott Halstead	5824 Edson Lane, North Bethesda, MD 20852 USA	www.pdvi.org	301-984-8704	Dengue fever	halsteads@erols.com
21	PneumoADIP	Pneumococcal Vaccines Accelerated Development and Introduction Plan	2003	USA	Orin Levine	Johns Hopkins, PneumoAdip, 615 N. Wolfe St., Baltimore, MD 21205 USA	www.preventpneumo.org	443-287-2019	Pneumonia & Meningitis	olevine@jhsph.org
22	RotaADIP	Rotavirus Vaccine Programme	2003	USA	John Wecker	1455 NW Leary Way Seattle, WA 98107 USA	www.rotavirusvaccine.org	206-285-3500	Rotavirus	RVInfo@path.org
23	SAAVI	South African AIDS Vaccine Initiative	1999	South Africa	Tim Tucker	Francie van Zyl Drive, Cape Town, South Africa	www.saavi.org.za	27-21-938-0262	HIV/AIDS	saavi@mrc.ac.za
24	TB Alliance	Global Alliance for TB Drug Development	2000	USA	Maria Freire	80 Broad Street, 31st floor, New York, NY 10004 USA	www.tballiance.org	212-227-7540	Tuberculosis	info@tballiance.org

Public Private Partnerships by Candidate Products				
	Acronym	Medicines/Microbicides	Vaccines	Diagnostic Products
1	Aeras		X	
2	BVGH	X	X	X
3	CONRAD	X		
4	CICCR	X		
5	DNDi	X		
6	EMVI		X	
7	FIND			X
8	Gates/UNC	X		
9	GMP	X		
10	HHVI		X	
11	IAVI		X	
12	IDRI	X	X	X
13	IOWH	X	X	
14	IPM	X		
15	LAPDAP	X		
16	MDP	X		
17	MMV		X	
18	MVI		X	
19	MVP		X	
20	PDVI		X	
21	PneumoADIP		X	
22	RotaADIP		X	
23	SAAVI		X	
24	TB Alliance	X		

Apendix 1, Sheet 3, Summary of Public Private Partnerships for Product Development by Funding Sources							
	Type of Funder:	Foundations					
		Gates	Rockefeller	Mellon	Various Foundations and Trusts	Anonymous	Total Foundation Giving
1	Aeras	\$107,900,000.00					
2	BVGH	\$1,000,000.00	\$100,000.00				
3	CONRAD	\$38,412,100.00					
4	CICCR	\$38,400,000.00	\$7,800,000.00	\$7,700,000.00	\$2,700,000.00	\$4,000,000.00	
5	DNDi						
6	EMVI	\$0.00					
7	FIND	\$30,000,000.00					
8	Gates/UNC	\$15,100,000.00					
9	GMP	\$25,000,000.00					
10	HHVI	\$18,000,000.00					
11	IAVI	\$26,500,000.00	\$8,961,000.00		\$117,362,906.00		
12	IDRI	\$15,000,000.00					
13	IOWH	\$8,800,000.00					
14	IPM	\$60,127,319.00	\$15,027,000.00				
15	LAPDAP						
16	MDP						
17	MMV	\$30,000,000.00	\$4,300,000.00		\$1,018,400.00		
18	MVI	\$150,000,000.00					
19	MVP	\$70,000,000.00					
20	PDVI	\$55,000,000.00	\$1,000,000.00		\$75,000.00		
21	PneumoADIP						
22	RotaADIP	Requested - not provided					
23	SAAVI	Requested - not provided					
24	TB Alliance	\$25,000,000.00	\$15,000,000.00		\$150,000.00		
	Totals:	\$714,239,419.00	\$52,188,000.00	\$7,700,000.00	\$121,306,306.00	\$4,000,000.00	\$899,433,725.00

Appendix 1, Sheet 4, Developing Country Representatives on Management and Advisory Committees										
Individuals were identified by nationality or in the alternative according to the nationality of their current employment or affiliation										
Acronym	Board of Directors Number of Directors	Countries Represented								
		USA	India	France	Brazil	Switzerland	Kenya	Malaysia	Sweden	
Aeras	8	8								
BVGH	6	5	1							
CONRAD	No separate legal status									
CICCR	No separate legal status									
DNDi	9	0	1	4	1	1	1	1	1	
EMVI	9	0								1
FIND	4	1					1			
Gates/UNC	No separate legal status									
GMP	No separate legal status									
HHVI	No separate legal status									
IAVI	14	4	1	1	1					
IDRI	7	7								
IOWH	8	7								
IPM	9	4		1						
LAPDAP	No separate legal status									
MDP	No separate legal status									
MMV	9	2	1				2			
MVI	No separate legal status									
MVP	Joint Management Committee with PATH									
PDVI	9	6		1						
PneumoADIP	Managed by a committee at GAVI									
RotaADIP	Joint Management Committee with PATH									
SAAVI	6									
TB Alliance	11	2	1		1		1			
Total	109	46	5	7	3		5	1	1	1

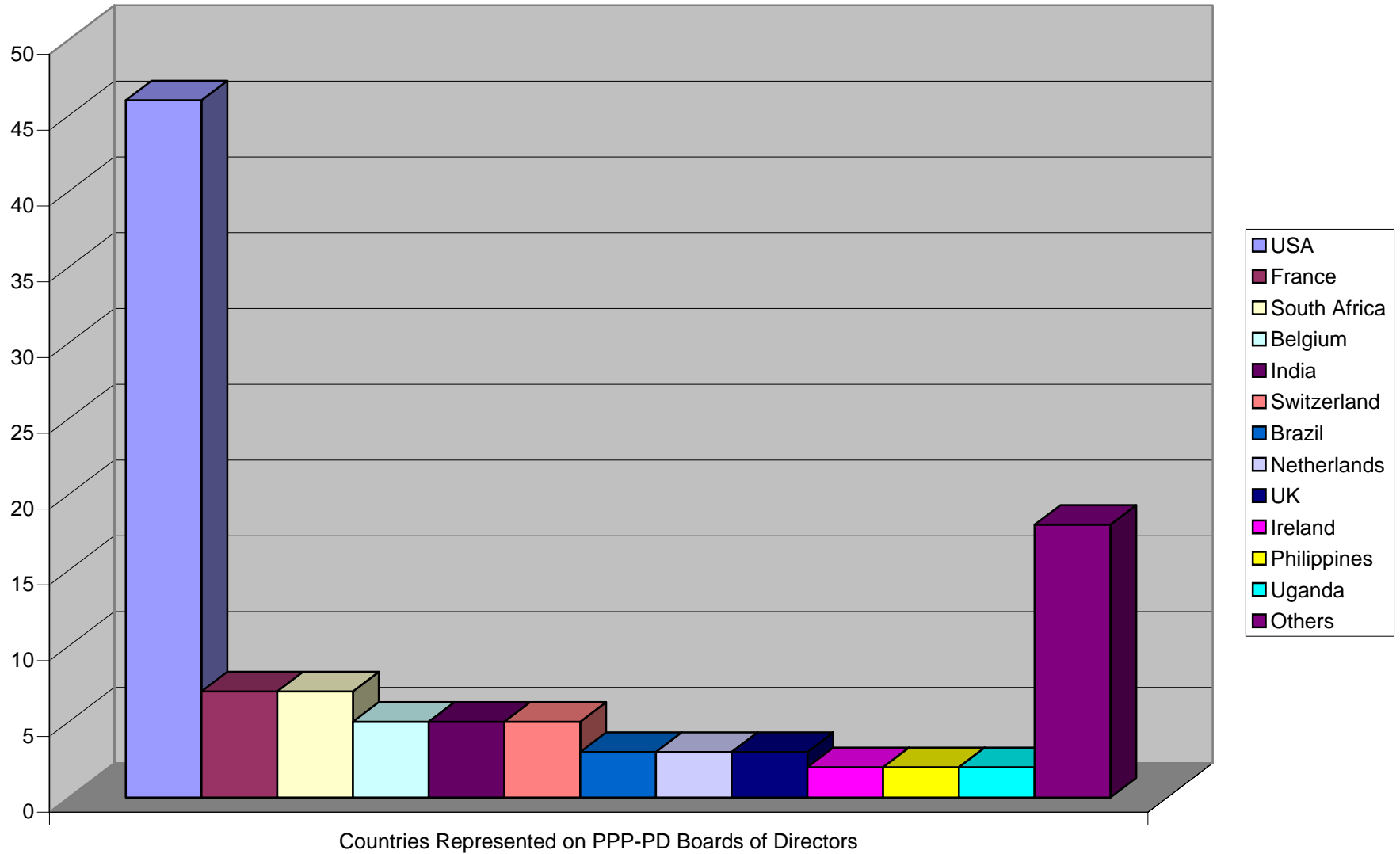
presented													
India	South Africa	Switzerland	Venezuela	Japan	Thailand	Sweden	Germany	Cameroon	Ireland	Australia	Netherlands	UK	Vietnam
2	1	1	1	1	1				7				
		1				1	1	1	4				
	2	1							3	1	1		
2									2			1	1
					1				1			4	
1	1	1		1								2	
5	4	4	1	2	2	1	1	1	21	1	1	7	1

List of Individual Foundations and Amounts of Contributions to IAVI

Foundation Name	Amount
Starr Foundation	\$9,000,000.00
Alfred P. Sloan Foundation	\$5,000,000.00
Global Forum for Health Research	\$400,000.00
Angel Music Ltd.	\$115,662.00
Vincent P. Belotsky Jr. Foundation	\$325,000.00
Crusaid (UK)	\$321,402.00
Ittleson Foundation	\$40,000.00
Levi Strauss Foundation	\$50,000.00
John M. Lloyd Foundation	\$20,000.00
Mercury Phoenix Trust	\$151,070.00
James B. Pendleton Charitable Trust	\$250,000.00
Tides Foundation	\$5,000.00
Vanderbilt Family Foundation	\$4,000.00
John D. and Catherine T. MacArthur Foundation	\$25,000.00
New York Community Trust	\$100,000.00
Elton John AIDS Foundation	\$321,090.00
Bill and Melinda Gates Foundation Challenge Grant	\$100,000,000.00
Until There's a Cure Foundation	\$850,000.00
All other donors	\$384,682.00
Total	\$117,362,906.00

Appendix 1, Sheet 6	
Government Support for IAVI by country and amount	
Country	Amount
Netherlands	\$23,686,718.00
Sweden (SIDA)	\$487,287.00
Norway	\$2,413,779.00
Ireland	\$4,605,288.00
Denmark	\$1,798,469.00
Total	\$32,991,541.00

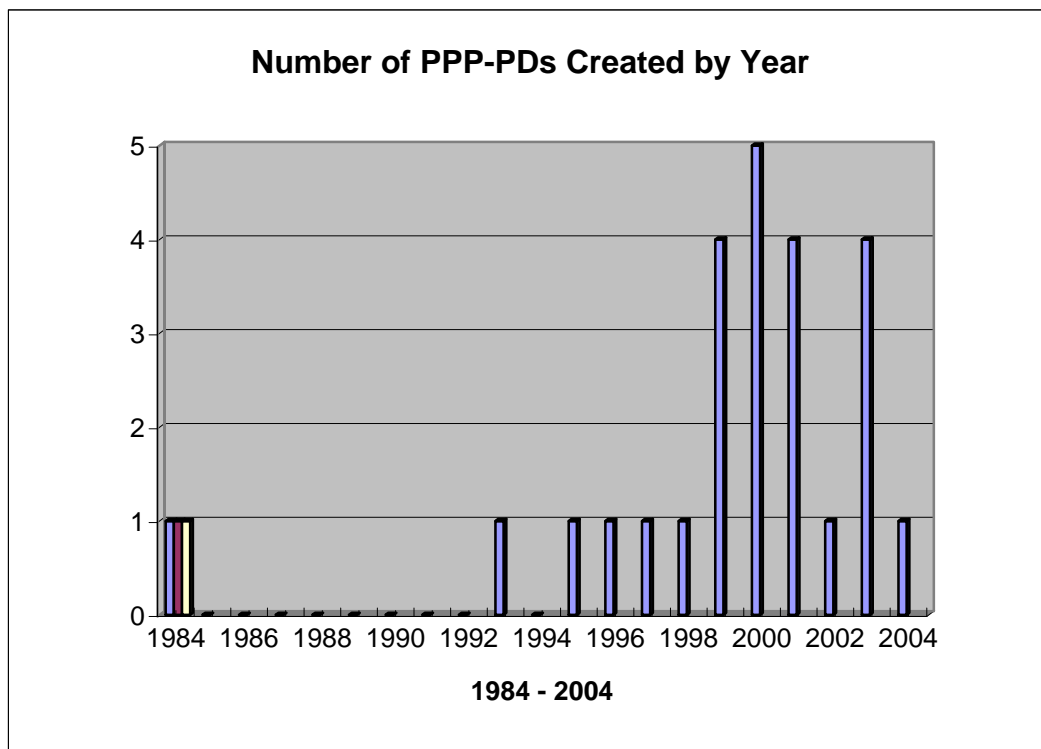
Country Representation on PPP-PD Boards of Directors



Appendix 1, Sheet 7	
Government Support of IPM by Country and Amount	
Government	Amount
Ireland	\$6,614,250.00
Norway	\$1,442,745.00
Denmark (DANIDA)	\$774,355.00
Netherlands	\$8,205,000.00
Total	\$17,036,350.00

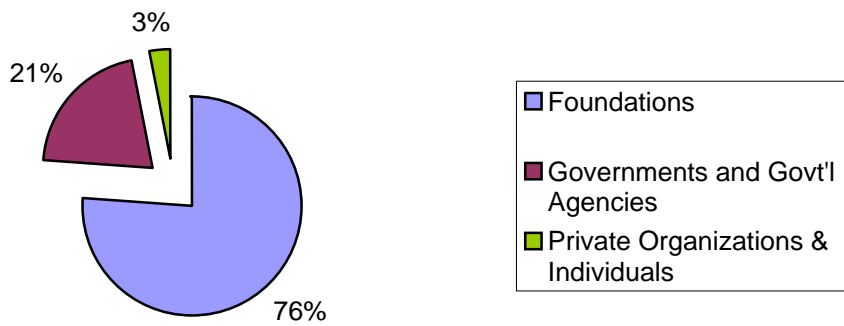
Appendix 1, Sheet 8
Number of Public-Private Partnerships Established by Year

1	1984
0	1985
0	1986
0	1987
0	1988
0	1989
0	1990
0	1991
0	1992
1	1993
0	1994
1	1995
1	1996
1	1997
1	1998
4	1999
5	2000
4	2001
1	2002
4	2003
1	2004



Appendix 1, Sheet 9		
Breakdown of Total Financial Contributions to PPP-PDs		
Foundations		\$899,433,725.00
Governments and Govt'l Agencies		\$244,462,588.00
Private Organizations & Individuals		\$36,312,547.00

Financial Contributors to PPP-PDs



Appendix 1, Sheet 10		
Number of Directors By Country of Nationality		
Country	Number of Members	Developed Economy?
USA	46	y
France	7	y
South Africa	7	n
Belgium	5	y
India	5	n
Switzerland	5	y
Brazil	3	n
Netherlands	3	y
UK	3	y
Ireland	2	y
Philippines	2	n
Uganda	2	n
Kenya	1	n
Malaysia	1	n
Sweden	1	y
Norway	1	y
Tanzania	1	n
Germany	1	y
Senegal	1	n
Spain	1	y
Australia	1	y
Wales	1	y
Chile	1	n
Egypt	1	n
Ghana	1	n
Mozambique	1	n
Korea	1	y
Japan	1	y
Mexico	1	n
Peru	1	n
Vacancy	1	n/a
	0	

				Private Organizations and Individuals		
World Bank	WHO	Total Gov't Giving		MSF	GAVI	Beckton Dickinson
				\$5,000,000.00		
\$4,765,000.00						\$1,000,000.00
\$370,000.00						
X						
\$2,500,000.00	\$3,500,000.00					
					\$30,000,000.00	
\$7,635,000.00	\$3,500,000.00	\$244,462,588.00		\$5,000,000.00	\$30,000,000.00	\$1,000,000.00

GSK	ExxonMobil	Total Private		Total Contributions
				\$107,900,000.00
				\$1,100,000.00
				\$98,412,100.00
				\$61,000,000.00
				\$5,000,000.00
				\$30,000,000.00
				\$15,100,000.00
				\$25,000,000.00
				\$18,000,000.00
\$12,547.00				\$271,578,987.00
				\$15,000,000.00
				\$8,800,000.00
				\$94,577,255.00
X				\$27,000,000.00
	\$300,000.00			\$55,515,518.00
				\$150,000,000.00
				\$70,000,000.00
				\$56,075,000.00
				\$30,000,000.00
				\$40,150,000.00
\$12,547.00	\$300,000.00	\$36,312,547.00		\$1,180,208,860.00

Appendix 2:

Governance of PPP-PDs: Representation on Board of Directors and other advisory committees

Individuals were identified by their nationality or in the alternative according to the nationality of their current employer or organization of professional affiliation as of December 31, 2004.. The country of nationality is at the end of each individual's description. Also, please refer to Addendum A, Sheet 4 for a summary of the following information:

Aeras:

Board of Directors: (<http://www.aeras.org/about/board/index.html>, accessed 12/28/2004)

(1) R. Gordon Douglas, Jr., MD, Chairman:

R. Gordon Douglas, Jr. currently serves as consultant to the Vaccine Research Center at the National Institutes of Health. He is director of the following biotech companies: Advancis Pharmaceuticals, Elusys Therapeutics, Vical (chairman), VaxInnate, Iomai. USA

(2) Richard E. Chaisson, MD:

Richard E. Chaisson is Professor of Medicine, Epidemiology and International Health at the Johns Hopkins University in Baltimore. He also directs the Johns Hopkins Center for Tuberculosis Research. USA

(3) Ann M. Ginsberg, MD, PhD:

Ann M. Ginsberg is Head of Clinical Development at the Global Alliance for TB Drug Development. Immediately prior to assuming this position, she was Director of Project Management at Merck Research Laboratories, Merck & Co, Inc. USA

(4) Michel Greco, MS, MBA:

Michel Greco is currently a board member of several international institutions as well as biotechnology companies involved in vaccine policy, research and development. USA

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(5) M. Michele Hogan, PhD:

M. Michele Hogan is Executive Director of the American Association of Immunologists, Inc., and is the managing editor of The Journal of Immunology. USA

(6) David McMurray, MS, PhD:

David McMurray serves as the Regents Professor of the Department of Medical Microbiology and Immunology, College of Medicine, Texas A&M University. USA

(7) Vijay Samant, MS, MBA:

Vijay Samant is President and CEO of Vical Incorporated. Based in San Diego, California, Vical develops biopharmaceutical products based on patented non-viral DNA delivery technologies for the prevention and treatment of life-threatening diseases. India

(8) Kenneth H. Silverberg, J.D., Board Secretary:

Kenneth Silverberg joined the Washington office of Nixon Peabody LLP in 1990 as a partner following 20 years of practice as a CPA and tax partner at Arthur Andersen & Co. USA.

ADVISORY GROUPS: (<http://www.aeras.org/about/sag/index.html>, accessed 12/28/2004)

All clinical research protocols and informed consent forms for clinical trials conducted by Aeras are approved by Aeras' [Research in Human Subjects Review Committee \(Institutional Review Board\)](#) as well as the IRB of each local research site. Aeras' IRB is composed of experts in TB, vaccines, ethics, statistics and non-scientific aspects of clinical research. The IRBs, as well as a Safety Monitoring Committee and other in-house and outside monitors, will provide continuing safety oversight throughout the trials. A number of outside scientific committees will review the progress, milestones, major decision points, and clinical safety issues for each major project conducted by Aeras. Some of these groups are formed and operating, while others are in the process of being organized. Current and planned advisory groups include the [Vaccine Selection Advisory Committee](#) consisting of experienced vaccine industry experts, the [Animal Models Technical Advisory Group \(TAG\)](#) consisting of TB vaccine animal model experts, the [Immunology TAG](#) consisting of industrial, public sector and academic immunologists with expertise in assay design and evaluation, the Clinical Trials and Site Development TAG consisting of prominent statisticians, clinicians and epidemiologists with expertise in trial design and implementation, and the Process Development and Release Assay TAG consisting of industry-experienced process engineers and assay specialists.

- **Research in Human Subjects Review Committee (Institutional Review Board):** (<http://www.aeras.org/about/sag/irb/index.html>, accessed 12/28/2004)

(1) **Naomi E. Aronson, MD**, Director, Infectious Diseases Division, Uniformed Services University of the Health Sciences, Bethesda, Maryland, *Chairman*

(2) **Ronald Bayer, PhD**, Joseph P. Mailman School of Public Health, Columbia University, New York, New York

(3) **William C. Blackwelder, PhD**, Biostatistical Consultant, Bethesda, Maryland

(4) **Patrick Chaulk, MD**, Senior Associate for Health, Annie E. Casey Foundation, Baltimore, Maryland

(5) **Jacqueline S. Coberly, MHS, PhD**, Johns Hopkins University Bloomberg School of Public Health, Bethesda, Maryland

(6) **Christine Grady, MS, PhD**, National Institutes of Health, Department of Clinical Bioethics, Bethesda, Maryland

(7) **Carla Kidd**, Kidd and Company, Greenwich, Connecticut

(8) **Paul D. Parkman, MD**, Parkman Associates, Kensington, Maryland

(9) **Michael A. Stoto, PhD**, Senior Statistical Scientist, RAND, Arlington, Virginia

(10) **Natalie Waugh**, Aeras Global TB Vaccine Foundation, Bethesda, Maryland

(11) **Henry Yeager, Jr., MD**, Professor of Medicine, Georgetown University Hospital, Washington, DC

(12) **Lewellys F. Barker, MD**, Senior Medical Advisor, Aeras Global TB Vaccine Foundation, *Committee Staff*

- **Vaccine Selection Advisory Committee:**
(<http://www.aeras.org/about/sag/vsac/index.html>, accessed 12/28/2004)

(1) **R. Gordon Douglas, Jr., MD**, Chairman, Board of Directors, Aeras Global TB Vaccine Foundation; Consultant, Niantic, Connecticut, *Chairman*

(2) **Paul-Henri Lambert, MD**, Professor, CMU-Centre of Vaccinology, Geneva, Switzerland

(3) **Paul Parkman, MD**, Parkman Associates, Kensington, Maryland

(4) **Stanley Plotkin, MD**, Medical and Scientific Advisor, University of Pennsylvania

(5) **Vijay Samant, PhD**, President and CEO, Vical, Inc., San Diego, California

(6) **Carmen Wagner, PhD**, President, Strategic Compliance International, Cary, North Carolina

(7) **Lewellys F. Barker, MD**, Senior Medical Advisor, Aeras Global TB Vaccine Foundation, *Committee Staff*

- **Animal Models Technical Advisory Group:**
(<http://www.aeras.org/about/sag/amtag/index.html>, accessed 12/28/2004)

(1) William R. Bishai, MD, PhD, Associate Professor, Division of Infectious Diseases, Johns Hopkins University School of Medicine, Baltimore, Maryland

(2) JoAnne L. Flynn, PhD, Associate Professor, Department of Molecular Genetics and Biochemistry, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania,

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(3) Angelo Izzo, PhD, Assistant Professor, Department of Microbiology, Immunology and Pathology, Colorado State University, Fort Collins, Colorado

(4) Jan A.M. Langermans, PhD, Director, Experimental Animal Services, Wageningen UR, The Netherlands

(5) David Lewinsohn, MD, PhD, Department of Pulmonary and CCM PVAMC, Oregon Health and Science University, Portland, Oregon

(6) Keith G. Mansfield, DVM, DACVP, Harvard Medical School, New England Regional Primate Center, Southborough, Massachusetts

- **Immunology Technical Advisory Group:**

(<http://www.aeras.org/about/sag/itag/index.html>, accessed 12/28/2004):

(1) John Shiver, PhD, Executive Director, Viral Vaccine Research, Merck, Inc., Rahway, New Jersey

(2) Rafi Ahmed, PhD, Director, Vaccine Research, Emory University School of Medicine, Atlanta, Georgia

(3) Susan L. Swain, PhD, Director, Trudeau Institute, Inc., Saranac Lake, New York

(4) Mario Roederer, PhD, Director, Immunology and Flow Cytometry Core Laboratory, NIAID/NIH, Bethesda, Maryland

(5) Richard Koup, MD, Director, Human Immunology Program, Vaccine Research Center, NIAID/NIH, Bethesda, Maryland

(6) Robert A. Seder, MD, Chief, Cellular Immunology Section, Vaccine Research Center, NIAID/NIH, Bethesda, Maryland

(7) Helen McShane, MD, Nuffield Department of Clinical Medicine, University of Oxford, John Radcliffe Hospital, Oxford, United Kingdom

(8) T. Mark Doherty, PhD, Coordinator, Research and Strategy, Infectious Disease Immunology, Statens Serum Institut, Copenhagen, Denmark

BIO Ventures for Global Health:

Board of Directors: (<http://www.bvgh.org/about/directors/default.asp>, accessed 12/28/2004):

(1) Robert B. Chess, BS, MBA, Chairman of Nektar Therapeutics, USA.

(2) Carl B. Feldman, BS, JD, President of Biotechnology Industry Organization, Washington DC, USA.

(3) Kiran Mazumdar-Shaw, Managing Director of BioCon India.

(4) Melinda Moree, PhD., Director of the Malaria Vaccine Initiative, USA.

(5) Stelios Papadopoulos, PhD, MBA, is Vice Chairman of SG Cowen & Co, USA.

(6) J. Leighton Read, MD, is a General Partner in Alloy Ventures, USA.

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Advisory Committee: (<http://www.bvgh.org/about/advisors/default.asp>, accessed 12/28/2004):

BVGH is in the process of assembling an expert Scientific Advisory Committee (SAC). The SAC will review and recommend projects for BVGH support and guide BVGH's portfolio management.

CONRAD:

No separate legal status, part of Virginia Medical School. (Website of IPPPH, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=50&typobj=0&id_chapter=organization, accessed 12/28/2004).

CICCR:

CICCR is a project of the CONRAD Program at the Eastern Virginia Medical School. CONRAD is supported by the U.S. Agency for International Development (USAID), National Institutes of Health (NIH), and Centers for Disease Control and Prevention (CDC). (Website of IPPPH, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=17&typobj=0&id_chapter=organization, accessed 12/28/2004).

DNDi:

Board of Directors:

(http://www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=143&ArticleId=191&TemplateId=1, accessed 12/28/2004).

- (1) BRUN Reto, Director, Swiss Tropical Institute, Switzerland
- (2) CHAMPEY, Yves, Chair, DNDi Board of Directors, France
- (3) FERREIRA Jose Roberto, Director International Cooperation, Fiocruz (Secretary), Brazil.
- (4) KANT Lalit, Senior Deputy Director General, ICMR, India.
- (5) KOECH Davy, Director, KEMRI, Kenya.
- (6) KOURILSKY Philippe, Director General, Institut Pasteur, France
- (7) MAHIN Bruce, financial Director, MSF France (Treasurer), France.
- (8) MERICAN Dato (Dr) Ismail, Deputy Director General of Health, Malaysian MoH, Malaysia
- (9) ROSTRUP Morten, President, MSF International, France.

Scientific Advisory Committee:

http://www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=143&ArticleId=275&TemplateId=2, accessed 12/28/2004).

Chair

(1) WIRTH Dyann Professor, Harvard School of Public Health, Chair of the TDR Strategic Research Committee, USA

Members representing Founding Partner institutions

(2) BHATT Kirana (KEMRI) Associate Professor, Department of Medicine, University of Nairobi, Kenya

(3) BOECHAT Nubia (FIOCRUZ) Director, Far Manguinhos, Brazil

(4) BOELAERT Marleene (MSF), Scientist at the Antwerp Leopold Tropical Diseases Institute, France

(5) BOST Pierre-Etienne (Institut Pasteur) Director, Medicinal Chemistry Unit, CNRS, France

(6) FAIRLAMB H. Alan (TDR) Professor and Head, Division of Biological Chemistry & Molecular Microbiology, University of Dundee, Scotland

(7) NAVARATNAM Visweswaran (Malaysian Ministry of Health) Professor, Clinical Pharmacology, University Sains, Malaysia

(8) SETH Shiv Dayal (ICMR) Chair, Clinical Pharmacology Department, ICMR, India

Members from external institutions

(9) FOLB Peter Professor of Pharmacology, Director WHO Collaborating Centre for Drug Policy, University of Cape Town, South Africa

(10) GUPTA Chhittar Mal Director, Central Drug Research Institute, Lucknow, India

(11) HERRLING Paul Head, Corporate Research, Novartis, Basel, Switzerland

(12) SHAPIRO Bennett Executive VP External Research and Worldwide Licensing, Merck, USA

(13) URBINA Julio Director, Biological Chemistry Laboratory, Instituto Venezolano de Investigaciones

Cientificas, Caracas, Venezuela

(14) YAMADA Haruki Vice President Research, The Kitasato Institute,
Tokyo

(15) YUTHAVONG Yongyuth Chair of Pharmacology, Director Thailand
Graduate institute of Science and Technology,
Bangkok, Thailand

European Malaria Vaccine Initiative:

Board of Directors: (<http://www.emvi.org/>, accessed 12/28/2004):

- (1) Hannah Akuffo (Vice Chairperson), Sweden
- (2) Marc De Bruycker, Belgium
- (3) Joe D. Cohen, Belgium
- (4) Andreas Holtel, Belgium
- (5) Anna Karaoglou, Belgium
- (6) Renée van Kessel (Chairperson), The Netherlands
- (7) Bernt Lindtjørn, Norway
- (8) Charles Mgone, Tanzania
- (9) Diarmuid O'Donovan, Republic of Ireland

Scientific Advisory Committee: (http://www.emvi.org, accessed 12/28/2004)

- (1) Marita Troy Blomberg, Sweden
- (2) Paul Hagan, Scotland
- (3) Peter Kremsner, Germany
- (4) Rose Leke, Cameroun
- (5) Pierre Meulien, Republic of Ireland
- (6) Louis Molineaux, Switzerland
- (7) Artur Scherf, France

Foundation for Innovative New Diagnostics (FIND):

Board of Directors: (<http://www.finddiagnostics.org/about/board/default.htm>, accessed 12/28/2004)

- (1) Gerard H. Moeller, PhD, Germany
- (2) Peter Small, MD, USA
- (3) Maneul Dayrit, MD, Philippines
- (4) Bernard Mach, PhD, MD, Switzerland.

Scientific Advisory Committee:

([http://www.finddiagnostics.org/about/team/committee.htm#Scientific Advisory Committee](http://www.finddiagnostics.org/about/team/committee.htm#Scientific_Advisory_Committee), accessed 12/28/2004):

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The Scientific Advisory Committee (SAC) is composed of 6 to 10 leading scientists with expertise in each of the key areas: development, evaluation, and demonstration, across some of the leading technologies and indications FIND plans to address.

The SAC will fill several primary roles in FIND:

- Support the CSO in the creation and implementation of the Scientific Strategic Plan
- Assist in the mapping of technologies to tests needed in different market segments
- Refine prioritization process of portfolio selection
- Evaluate and select the most promising projects, using deep knowledge of science, models for success, technologies, and requirements for success in DEC's
- Bring latest technologies and developments to the attention of the CSO
- Provide scientific expertise to accelerate, reduce the cost of, and increase the effectiveness of diagnostic test development and demonstration

Each SAC member will serve a maximum of three terms of three years each. SAC meetings will take place twice a year and individual members are expected to interact informally with the Chief Scientific Officer and Scientific Heads of FIND on a more frequent basis, as their expertise is needed. SAC members will be expected to reclude themselves from situations posing a potential conflict of interest.

No individuals names are provided on the website.

Gates Foundation/U. of North Carolina Partnership for the Development of New Drugs (GFUNC)

No separate legal status. Hosted at University of North Carolina, a government supported institution. (IPPPH website, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=85&typobj=0&id_chapter=organization, accessed 12/28/2004)

Global Microbicide Project (GMP):

No separate legal status. GMP is a project of the CONRAD Program at the Eastern Virginia Medical School. CONRAD is supported by the U.S. Agency for International Development, National Institutes of Health, and Centers for Disease Control and Prevention. (IPPPH website, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=20&typobj=0&id_chapter=organization, accessed 12/28/2004)

Human Hookworm Vaccine Initiative:

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No separate legal status. HHVI is an initiative of the Albert B. Sabin Vaccine Institute, a U.S. tax-exempt organization under Section 501(c)(3).

(<http://www.sabin.org/hookworm.htm>, accessed 12/28/2004).

IAMI:

Board of Directors: (<http://www.iami.org/lists/roster.cfm?show=board>, accessed 12/28/2004)

(1) Dr. Seth F. Berkley, M.D., President and Chief Executive Officer, Executive Office, International AIDS Vaccine Initiative, USA

(2) Dr. Awa Marie Coll Seck, M.D., Ph.D., Executive Secretary, Roll Back Malaria Partnership, Former Minister of Health and Prevention, Former Director, Policy, Strategy and Research, Joint United Nations Programme on HIV/AIDS, Senegal

(3) Dr. Ciro de Quadros, M.D., MPH, Director, International Programs, Albert B. Sabin Vaccine Institute, Former Director, Vaccines and Immunization, Pan American Health Organization, Brazil

(4) Mr. John D. Evans (Treasurer), Chairman and CEO, Evans Telecommunications Co. & The John D. Evans Foundation, USA

(5) Ms. Angela Gómez de Mogollón, President, Profamilia, Spain

(6) Mr. Michel Greco, Former President, COO and Deputy CEO, Aventis Pasteur Former President and Chief Operating Officer, Pasteur Mérieux MSD, France

(7) Dr. Ian Gust, M.D. (Ex-Officio, Secretary), Professorial Fellow, Department of Microbiology & Immunology, University of Melbourne, Australia

(8) Ms. Glenys Kinnock, Member of the European Parliament, Wales, European Parliament, Wales

(9) Dr. Chrispus Kiyonga, M.D., Minister Without Portfolio, Government of Uganda Former Minister of Health, Uganda

(10) Mr. Paul H. Klingenstein, General Partner, Aberdare Ventures, USA

(11) Mr. Geoffrey Lamb (Chair), Vice President, Concessional Finance and Global Partnerships, The World Bank Group, Ireland/South Africa

(12) Dr. Peter Piot, M.D., Ph.D. (Ex-Officio), Executive Director, Joint United Nations Programme on HIV/AIDS, Belgium

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(13) Mr. Kapil Sibal, J.D., Minister of Science & Technology and Ocean Development,
Council for Scientific and Industrial Research, India

(14) Mr. Lee C. Smith (Founding Chair) - Former President, Levi Strauss International
Former Chair, US National Leadership on AIDS, USA

Scientific Advisory Committee: (<http://www.iavi.org/lists/roster.cfm?show=sac>,
accessed 12/28/2004)

(1) Dr. John G. Curd, President & Chief Medical Officer, Novacea, Inc. , USA

(2) Dr. Michel De Wilde
Research and Development,
Aventis Pasteur, France

Dr. Ian Gust, M.D. (Chair)
Professorial Fellow, Department
of Microbiology & Immunology,
University of Melbourne,
Australia

(2) Dr. Joep Lange
Universiteit van Amsterdam, Netherlands

(3) Dr. Antonio Lanzavecchia
Institute for Research in Biomedicine, Switzerland

(4) Dr. Rosemary Mubanga Musonda
Acting Director General, National AIDS Council, USA

(5) Prof. Helen Rees,
Executive Director, University of Witwatersrand,
Reproductive Health Research Unit, South Africa

(6) Dr. Douglas D. Richman, M.D.
Departments of Pathology & Medicine , VA Medical
Center, San Diego, USA

(7) Dr. Philip K. Russell, M.D.
Principle Science Advisor, Office of Public Health
Emergency Preparedness, U.S. Department of Health and
Human Services, USA

(8) Dr. Jerald C. Sadoff

President & CEO, AERAS Global Tuberculosis
Foundation, USA

(9) Dr. Mauro Schechter, M.D.
Head, AIDS Research Laboratory, Universidade Federal
do Rio de Janeiro, Brazil

(10) Dr. Bruce Walker, M.D.
Director of AIDS Research Center, Massachusetts
General Hospital, USA

(11) Dr. Carolyn Williamson
University of Cape Town , South Africa

Infectious Disease Research Institute (IDRI):

Board of Directors: (http://www.idri.org/page.php?pg_page_id=61, accessed
12/29/2004)

- (1) John H. Dawson, Jr., M.D., FAC
- (2) Cynthia Healy, Ph.D.
- (3) Franklyn G. Prendergast, M.D., Ph.D.
- (4) Steven G. Reed, Ph.D.
- (5) Mark Smith, MBA
- (6) Patricia Wahl, Ph.D.
- (7) David Webster, MBA

No advisory committees are identified but the organization does work with Collaborating Centers worldwide on specific projects. (http://www.idri.org/page.php?pg_page_id=9, accessed 12/29/2004).

Institute for One World Health (IOWH):

Board of Directors: (<http://www.oneworldhealth.org/about/directors.php>, accessed
12/28/2004)

- (1) Victoria G. Hale, Ph.D. (Chair)
Founder and Chief Executive Officer, Institute for OneWorld Health, USA
- (2) Leslie Z. Benet, Ph.D.
Professor, Biopharmaceutical Sciences, University of California, San Francisco, USA
- (3) Jere Goyan, Ph.D.
Former Commissioner, United States Food & Drug Administration (FDA), USA

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(4) William A. Haseltine, Ph.D.
Chairman and Chief Executive Officer, Haseltine Associates, USA

(5) Frederick W. Kyle
Chairman, BioRexis Pharmaceutical Corporation, USA

(6) Bernardita Mendez, Ph.D.,
President, Fundación Ciencia para la Vida (Science for Life Foundation), Chile

(7) Herbert D. Montgomery
Chief Financial Officer and Director, Media Arts Group, Inc., USA

(8) H. Kyle Webster, Ph.D.
Vice President, Becton Dickinson Asia Pacific, USA

Scientific Advisors: (<http://www.oneworldhealth.org/about/advisors.php>, accessed 12/29/2004)

(1) Aftab Ahmed Ansari, Ph.D.
Professor, Emory University, Atlanta, GA

(2) Keith Bailey, Ph.D.
Retired Director, Bureau of Biologics and Radiopharmaceuticals, Canadian Health Protection Branch (CHP), CANADA

(3) Joy Cavagnaro, Ph.D.
President, Access BIO, Leesburg, VA

(4) Daniel G. Colley, Ph.D.
Professor, Department of Infectious Diseases, University of Georgia, Atlanta, GA

(5) Le Dinh Cong, M.D., Ph.D.
Retired Director, National Institute of Malariaology, Parasitology and Entomology, (NIMPE) Hanoi, VIETNAM

(6) Gary Gamerman, M.S, J.D.
President, Seraphim Life Sciences Consulting, Vienna, VA

(7) Eric M. Gordon, Ph.D.
Retired Sr. VP of Research, Sunesis, Inc.

(8) Win Gutteridge, Sc.D.
Retired Chief, Product R&D, WHO Special Program for Research and Training in Tropical Diseases (TDR), Geneva, Switzerland - UK

(9) T. K. Jha, M.D., FRCP (E), DTMH

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Retired Prof of Medicine, University of Bihar; Founder, Kalazar Research Centre, India

(10) John Kilama, Ph.D.
President, Global Bioscience Development Institute

(11) James McKerrow, Ph.D.
Professor, Pathology, University of California, San Francisco

(12) Col. Wil Milhous, Ph.D.
Director, Experimental Therapeutics, Walter Reed Army Institute of Research, Forest
Glen, MD

(13) Michael Powell, Ph.D.
Managing Director, Sofinnova Ventures

(14) Shyam Sundar, M.D.
Professor of Medicine, Banaras Hindu University, Varanasi, INDIA
Director, Kala Azar Medical Clinic, Muzaffarpur, INDIA

(15) Alan S. Taylor, Ph.D.,
V.P., Regulatory Affairs, Gilead Sciences

(16) Daniel F. Veber, Ph.D.
Drug Discovery Consultant

(17) Judith C. Wilber, Ph.D.
Senior Director of XDx Reference Laboratory

International Partnership for Microbicides (IPM):

Board of Directors: (http://www.ipm-microbicides.org/about_ipm/board.cfm, accessed 12/29/2004):

(1) Mahmoud M. Fathalla, Chair
Dr. Fathalla is a professor of Obstetrics and Gynecology and former Dean of the Medical School at Assiut University in Egypt.

(2) Quarraisha Abdool Karim
Dr. Abdool Karim is the Director of the Southern African Fogarty International HIV/AIDS Training and Research Programme. South Africa.

(3) Els Borst-Eilers

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Dr. Borst-Eilers served as Minister of Health, Welfare and Sport of the Government of the Netherlands from August 1994 through July 2002, and as Deputy Prime Minister from 1998. Netherlands.

(4) Alex G. Coutinho

Dr. Coutinho is Chief Executive Officer of TASO, The AIDS Service Organization of Uganda. TASO is the largest AIDS care and support organization in sub-Saharan Africa supporting 22,000 HIV+ clients with an annual budget of \$6,000,000 and a staff of 270. Uganda

(5) Henry L. Gabelnick

Dr. Gabelnick is the director of the CONRAD Program that was established under a cooperative agreement with the U.S. Agency for International Development (USAID) at the Eastern Virginia Medical School where he is also a professor in the Department of Obstetrics and Gynecology. USA

(6) Seth L. Harrison

Dr. Harrison has been a life sciences venture capitalist since 1991. USA

(7) A.N. "Jerry" Karabelas

Dr. Karabelas (Jerry) is a Partner at Care Capital, a life-sciences investment firm. USA

(8) Zeda F. Rosenberg

Dr. Rosenberg is the Chief Executive Officer of the IPM, responsible for providing vision, leadership, and direction to the organization. USA

(9) H  l  ne Rossert-Blavier

Dr. Rossert-Blavier has been the Director General of AIDES in France since 1997. France.

No information about advisory committees is available at this time.

LAPDAP Antimalarial Product Development (LAPDAP):

No separate legal status. A project under the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (WHO/TDR) with a joint product development agreement between TDR and GlaxoSmithKline (GSK). (IPPPH website,

http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=21&typobj=0&id_chapter=organization, accessed 12/29/2004).

Microbicides Development Program (MDP):

No separate legal status, housed at the Imperial College of Science, Technology and Medicine. An International Scientific Advisory Group provides guidance and expertise on strategy and direction. A Programme Management Board, made up of principal investigators and representatives of the clinical sites, monitors scientific progress.

(IPPPH website,

http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=90&typobj=0&id_chapter=organization, accessed 12/28/2004).

Medicines for Malaria Venture (MMV):

Board of Directors:

(http://www.mmv.org/pages/content_frame.asp?ThePage=page1_0002_1.htm&Nav=0002, accessed 12/29/2004)

(1) Dame Bridget Ogilvie FRS, University College London, United Kingdom (*Chair of MMV Board*), UK

(2) Dr Enriqueta Bond, President, Burroughs Wellcome Fund, USA

(3) Dr Jack Chow, Assistant Director-General, HIV/AIDS, TB and Malaria, World Health Organization, Switzerland

(4) Dr Chris Hentschel, Chief Executive Officer, Medicines for Malaria Venture (MMV), Switzerland

(5) Prof. Trevor Jones, Director General, The Association of the British Pharmaceutical Industry (ABPI), United Kingdom

(6) Dr R. A. Mashelkar, Director General, Council of Scientific and Industrial Research (CSIR), India

(7) Dr Pascoal M. Mocumbi, High Representative of the European and Developing Countries Clinical Trials Partnership (EDCTP); former Prime Minister of Mozambique

(8) Prof. Francis Nkrumah, Former Director, Noguchi Memorial Institute for Medical Research, University of Ghana, Ghana

(9) Prof. Leon Rosenberg, Department of Molecular Biology, Princeton University, USA

Observers:

Dr Winston E. Gutteridge, former Chief, Product R&D, Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization, Switzerland; served as full MMV Board Member from 1999-2003; took over Chair of MMV Expert Scientific Advisory Committee (ESAC) in 2003.

Expert Scientific Advisory Committee (ESAC):

(http://www.mmv.org/pages/content_frame.asp?ThePage=page1_0002_1.htm&Nav=0002, accessed 12/29/2004)

Chair:

(1) Dr Win Gutteridge, former Chief, Product R&D, Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization, Switzerland - UK

Members:

(2) Dr George Aynilian, PhD Pharmacist with expertise in clinical research (Phase I – IV), international regulatory affairs and 15 years' drug development experience in leadership roles of strategic operations and project management in pharmaceutical and hospital product divisions.

(3) Dr David Floyd, former Vice-President, Discovery Chemistry, Bristol-Myers Squibb; currently Head of Focus Consulting. UK

(4) Dr Alan Hudson, Chemist, former Head of Cancer Research, Wellcome plc (UK) with additional expertise in parasitology and malaria chemotherapy. UK

(5) Dr Zulfiqarali Gulamhussien Premji, Clinical Parasitologist with over 25 years of experience in teaching, research and clinical work combined with extensive experience in laboratory work involving diagnosis and molecular biology techniques. Tanzania.

(6) Dr David Roos, Professor of Biology and Director, University of Pennsylvania Genomics Institute. Expertise in the cell biology of apicomplexan parasites and joint coordinator of the Plasmodium genome database, USA

(7) Dr John A Salmon, Senior Pharmaceutical Research Scientist with expertise in bioanalysis, drug metabolism and pharmacokinetics. Consultant in biopharmacy to the pharmaceutical industry and visiting lecturer at King's College, London and the University of Greenwich, UK

(8) Dr Dennis Schmatz, Biologist with expertise in parasitology, including malaria. Vice President, Infectious Disease and Immunological Research, Merck Research Laboratories, USA

(9) Professor Robert (Bob) William Snow, Head, Malaria Public Health Group, KEMRI/Wellcome Trust Programme, Nairobi, Kenya

(10) Dr Henrietta Ukwu, Vice President, Global Regulatory Policy, Merck & Co., Inc. Over 10 years of senior pharmaceutical industry and regulatory experience. Nigeria

(11) Dr Thomas E. Wellems, Biologist with expertise in cell and molecular biology of malaria and mechanisms of drug resistance. National Institute of Allergy and Infectious Diseases/National Institutes of Health, USA

(12) Dr Kitima Yuthavong, Clinician/Paediatrician; former Medical Director, Aventis Pharma Thailand; Clinical Co-ordinator, Clinical Monitoring Unit, Thailand

Malaria Vaccine Initiative (MVI):

No separate legal entity. MVI is a program of PATH, an international, non-profit organization dedicated to improving health. (IPPPH website, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=30&typobj=0&id_chapter=organization, accessed 12/29/2004)

A Strategic Advisory Council composed of highly respected individuals in the vaccine field provides MVI with overall programmatic and strategic guidance. MVI seeks technical input on individual projects from Technical Advisory Groups (TAGs). Each TAG is constituted to provide advice on the specific vaccine strategy, drawing from a global panel of experts in vaccine development, malaria, pharmaceutical production, project management, regulatory affairs, and clinical trials. (<http://www.malariavaccine.org/ab-strategic.htm>, accessed 12/29/2004)

Meningitis Vaccine Project at WHO/PATH (MVP):

MVP is a partnership between the World Health Organization (WHO) and the Program for Appropriate Technology in Health (PATH) created with the technical advice of the U.S. Centers for Disease Control and Prevention. Its parent organization is PATH and MVP is governed by a Joint Management Committee with various advisory groups. (IPPPH website, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=29&typobj=0&id_chapter=organization, accessed 12/29/2004).

According to the MVP website, the following advisory groups assist the organization: (<http://www.meningvax.org/team.htm#advisory>, accessed 12/29/2004):

- **Project Advisory Group (PAG)**

- (1) Prof. Hagos Beyene, Dean and Associate Professor of Pediatrics and Child Health, Defense University, College of Health Sciences, Addis Ababa, Ethiopia
- (2) Dr. Samuel Z. Bugri, Program Manager, WHO/AFRO, MDSC, Burkina Faso
- (3) Dr. Mohamed-Mahamoud Hacen, WHO Representative, Burkina Faso
- (4) Dr. Alphonsine Kouassi Mbengue, Assistant, Faculté de Médecine d'Abidjan, Laboratoire de bactériologie, Abidjan, Ivory Coast

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- (5) Prof. Moussa Maiga, Deputy Director General, West African Health Organization (WAHO), Burkina Faso
- (6) Dr. Idris Mohammed, Chairman, National Programme on Immunization (NPI) Board, Nigeria
- (7) Prof. Francis Nkrumah, Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Ghana

- **MVP Expert Panel**

- (1) Dr. Ronald W. Ellis, Senior Vice President, R&D and General Manager, Shire Biologics Inc.
- (2) Dr. Lance K. Gordon, Chief Executive Officer, VaxGen, Inc.
- (3) Dr. Emil C. Gotschlich, M.D., V.P. for Medical Sciences, The Rockefeller University
- (4) Prof. Brian Greenwood, Manson Professor of Clinical Tropical Medicine, London School of Hygiene and Tropical Medicine, University of London
- (5) Prof. Francis Nkrumah, Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Ghana
- (6) Dr. Regina Rabinovich, Director of Infectious Diseases, Global Health Program, Bill & Melinda Gates Foundation
- (7) Dr. Anne Schuchat, M.D., Chief, Respiratory Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention

- **Project Management Committee**

- (1) Dr. Anarfi Asamoah-Baah, Assistant Director - General, Communicable Diseases, WHO
- (2) Dr. Christopher Elias, President, PATH
- (3) Dr. Mark Kane, Director, Children's Vaccine Program at PATH
- (4) Ms. Joy Phumaphi, Assistant Director - General, Family and Community Health, WHO

Pediatric Dengue Vaccine Initiative (PDVI):

Board of Councilors: (PDVI website, http://www.pdvi.org/about_us/organization.html, accessed 12/29/2004):

CHAIRMAN

(1) Duane Gubler, Sc.D., USA

CO-CHAIR

(2) Jane Cardosa, Ph.D., USA

MEMBERS

(3) John Clemens, M.D., Korea
(4) Dean Jamison, Ph.D., USA
(5) Ichiro Kurane, M.D., Ph.D., Japan.

- (6) Richard Mahoney, Ph.D.,
USA
- (7) Stanley Plotkin, M.D., USA
- (8) Donald Shepard, Ph.D., USA
- (9) Marie-Paule Kieny, Ph.D.,
France

Technical Advisory Groups provide support on selected projects. (PDVI website, http://www.pdvi.org/about_us/organization.html, accessed 12/29/04).

PneumoADIP:

The Pneumococcal Vaccines Accelerated Development and Introduction Plan (PneumoADIP) is a project located at the Johns Hopkins Bloomberg School of Public Health.

The Pneumo ADIP is reporting its activities and progress directly to a Management Committee that is composed of a sub-group of members of the GAVI Board. (IPPPH website, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=100&typobj=0&id_chapter=organization, accessed 12/29/2004).

RotaADIP:

Joint management committee with PATH.

SAAVI:

The structure of the organization is as follows: (SAAVI website, <http://www.saavi.org.za/structure.htm>, accessed 12/29/2004)

The SAAVI Directorate is responsible for the management of the initiative. The Directorate reports to a Steering Committee, which comprises the primary funders as well as the President of the Medical Research Council (MRC). The SAAVI Advisory Board offers regular strategic advice on individual programmes as well as the overall direction of the initiative. Research and implementation groups are led by principal investigators (PIs). The Medical Research Council is the legal persona and host organisation for SAAVI. SAAVI is therefore subject to the MRC's rules, regulations and financial management systems and also has access to its services such as financial, human resources, IT and the MRC's Legal Office.

The Directorate

The SAAVI Directorate is based at the Medical Research Council and comprises a small team which co-ordinates the funding and activities of all the SAAVI research groups. Principal investigators act as the senior management team and decide on important scientific and clinical matters.

The SAAVI Directorate encompasses scientific leadership, business and communications expertise.

(1) Dr Tim Tucker
SAAVI Director

(2) Dr Gatsha Mazithulela
SAAVI Deputy Director (Scientific Affairs)

(3) Michelle du Toit
PA to Director

(4) Danie Eksteen
SAAVI Business Manager

(5) Michelle Galloway
SAAVI Media and Communications Manager

(6) Elise Levendal
SAAVI Community Preparedness Programme Manager

Global Alliance for TB Drug Development (TB Alliance):

The Board of Directors (BOD) numbers 12 with all sectors evenly represented. The Scientific Advisory Committee (SAC) consists of 9 to 15 scientific experts representing a diverse array of technical fields from academia, public health research and private industry. A Stakeholders Association of relevant organizations (worldwide: public research institutes, the pharmaceutical industry, nonprofit organizations, public policy and independent sectors) recommends candidates to the Board of Directors and elects a Stakeholders President who sits ex-officio on the BOD. (IPPPH website, http://www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=10&typobj=0&id_chapter=organization, accessed 12/29/2004).

Dr. Gijs Elzinga, *Chairman of the Board*
Deputy Director-General, Netherlands' National Institute of Public Health and the Environment, Netherlands

Dr. Paul Herrling, *Vice Chair*
Head of Corporate Research, Novartis International AG, Switzerland

Dr. Ariel Pablos-Méndez, *Treasurer*

Director, Knowledge Management and Sharing, World Health Organization, Mexico

Dr. John La Montagne, *Secretary**

Deputy Director, U.S. National Institute of Allergy and Infectious Diseases/National Institutes of Health

(*Dr. La Montagne died unexpectedly on November 2, 2004) – Position is vacant

Dr. Gail Cassell

Vice President, Scientific Affairs, Eli Lilly and Company, USA

Dr. Maria C. Freire

President and Chief Executive Officer, Global Alliance for TB Drug Development, Peru

Dr. Carlos Morel

Scientific Coordinator, Oswaldo Cruz Foundation (FIOCRUZ), Brazil

Mr. Parag Saxena (2005)

Chief Executive Officer, Invesco, India

Dr. Lee Reichman

Executive Director, New Jersey Medical School National Tuberculosis Center, USA

Sir David Weatherall

Founding Director Emeritus, Weatherall Institute of Molecular Medicine, University of Oxford, UK

Dr. Charles Yu

President, TB Alliance Stakeholders' Association

Board Member, Philippines Coalition Against Tuberculosis (PhilCAT), Philippines

Scientific Advisory Committee: (Alliance website, http://www.tballiance.org/1_2_3_scientific.asp, accessed 5 January 2005)

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The TB Alliance established a Scientific Advisory Committee to assist in evaluating proposals and projects under consideration for investment as part of its TB drugs portfolio.

The Scientific Advisory Committee provides technical expertise on drug research, development, manufacturing, and distribution, as well as other medical and scientific issues, and consists of 15 scientific experts from a wide range of relevant disciplines, including:

Basic science: genomics, microbiology molecular biology, and pharmacology

Clinical expertise: internal medicine, infectious diseases, and clinical trials

Drug development: preclinical, medicinal chemistry, formulation and manufacturing experts

TB-endemic country clinical trials

Epidemiology

Ethics

The pharmaceutical and biotechnology industries

Statistics

Members of the Scientific Advisory Committee are selected for three-year terms. To address myriad scientific and technical needs, the Chair has the flexibility to invite scientists to serve as ad hoc members for limited periods of time or on a project-by-project basis.

Current members:

Dr. Clifton Barry, III
National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA

Dr. Ken Duncan
GlaxoSmithKline, UK

Dr. Bernard Fourie, *Secretary*
Medical Research Council of South Africa, South Africa

Dr. Maria C. Freire
Global Alliance for TB Drug Development, Peru

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Dr. Jacques Grosset
The Johns Hopkins University, Maryland - France

Dr. Yoshiaki Kiso
Kyoto Pharmaceutical University, Japan

Dr. Barbara Laughon, *Chair*
National Institute of Allergy and Infectious Diseases, National Institutes of Health,
USA

Dr. Christopher Lipinski
Pfizer Inc., USA

Dr. Denis Mitchison
St. George's Hospital Medical School, UK

Dr. Richard O'Brien
Foundation for Innovative New Diagnostics, Switzerland

Dr. Ramesh Panchagnula
Indian National Institute of Pharmaceutical Education and Research, India

Dr. Philippe Prokocimer
Johnson & Johnson, France

Dr. Christine Sizemore
National Institute of Allergy and Infectious Diseases, National Institutes of Health,
USA

Dr. Mel Spigelman
Global Alliance for TB Drug Development, USA

Dr. C. Kendall Stover
Pfizer Inc., USA

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Streefland PH. Introduction of a HIV vaccine in developing countries: social and cultural dimensions. Vaccine. Volume 21, Issues 13-14, 28 March 2003, pages 1304-1309.

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