

ABOUT PATH AND ITS MALARIA VACCINE INITIATIVE



PATH is an international nonprofit organisation that transforms global health through innovation. Its

mission is to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. **PATH's** work spans five platforms: vaccines, devices, diagnostics, drugs, and system and service innovations.

PATH is known for partnering with the private sector to develop lifesaving health technologies with global impact and has five large programmes dedicated to product development. **PATH** works across the R&D spectrum, from development to delivery, channeling the tremendous potential of inventive ideas, scientific discovery, and groundbreaking collaborations into better health and opportunity for all.

One of **PATH's** flagship product development programmes is the **PATH** Malaria Vaccine Initiative (MVI). MVI was established in 1999 to accelerate the development of malaria vaccines and catalyze timely access in endemic countries, toward realizing its vision of a world free from malaria. MVI identifies potentially promising malaria vaccine approaches and systematically moves them through the development process. Since its founding, MVI has moved dozens of projects through its pipeline, with half a dozen in clinical development in 2014—including the RTS,S malaria vaccine candidate, under development with GlaxoSmithKline, which is currently in late-stage development. Looking forward, MVI's R&D strategy is to develop a second-generation malaria vaccine that would support achievement of the longer-term goals of malaria elimination and eradication.

www.path.org

ABOUT SABIN PDP



The Sabin Vaccine Institute Product Development Partnership (Sabin PDP) focuses on creating safe, effective, and

low-cost vaccines to prevent human suffering from infectious and neglected tropical diseases that infect more than 1 billion people worldwide. The **Sabin PDP** collaborates with private, academic, and public institutions in low- and middle-income countries, Australia, the United States, and Europe for preclinical development, vaccine manufacturing, and clinical testing. It is the first and only vaccine development programme targeting human hookworm infection. In addition, the **Sabin PDP** is developing vaccines for schistosomiasis, leishmaniasis, Chagas disease, ascariasis, trichuriasis, and severe acute respiratory syndrome (SARS)—diseases that primarily affect people living in poverty around the world.

www.sabin.org

ABOUT TB ALLIANCE



TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

TB Alliance is a not-for-profit organisation dedicated to the discovery and development of better, faster-acting, and affordable drugs for TB. Today's TB drug regimen takes too long to cure, is too complicated to administer, and can be toxic. Despite the flaws with and growing resistance to current TB treatments, no new TB drugs have been developed in nearly 50 years. Through innovative science and with partners around the globe, we lead a global effort to ensure development of and equitable access to faster, better TB cures that will advance global health and prosperity. We combine the unparalleled R&D expertise of our staff with the skills and resources of our highly accomplished network of partners to efficiently leverage the most promising science around the world. Since its founding in 2000, the **TB Alliance** has assembled the largest portfolio of potential new drugs in history and the greatest concentration of TB drug development expertise in the world. The **TB Alliance** currently manages more than 20 projects in its pipeline, including several multi-drug regimens in late-stage clinical trials. The **TB Alliance** harnesses the power of global innovation, expertise, and partnerships to discover and develop new and better TB treatments to transform the treatment of TB and drug-resistant TB, and reduce the world's burden.

www.tballiance.org

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PRODUCT DEVELOPMENT PARTNERSHIPS (PDPS)

Background

Despite the many advances in research and development (R&D) in global health over the past half-century, an estimated 10 million people die every year from infectious diseases¹, of which the vast majority are poor people living in low and middle income countries. The poverty-related and neglected diseases (PRNDs) causing this high burden of disease include tuberculosis (TB), HIV/AIDS, malaria and neglected tropical diseases.

The toll of this disease burden comes in the form of increased mortality and morbidity, inability to follow education, and lost work productivity, thus threatening the ability to reach economic and other development goals. The absence of an effective market and resulting lack of financial incentives to private sector investment has contributed to limited private sector engagement and restricted innovation in the field of global health R&D technologies. As a consequence, only 10 percent of global health research is devoted to conditions that account for 90 percent of the global disease burden—a “fatal imbalance”² often referred to as the “10/90 gap”³. This fatal imbalance triggered the creation of product development partnerships (PDPs) that have the objective to fill existing R&D gaps. PDPs research, develop, and facilitate access to new health technologies that target diseases disproportionately affecting populations in low- and middle-income countries across Latin America, Africa, and Asia.

AIMS

PDPs work to address the particular needs for new products for PRNDs. They drive R&D with patients' needs in mind and facilitate access to appropriate and affordable tools in disease-endemic countries. PDPs are able to advance global health goals by accelerating the development of products that may not otherwise have been created. Today there are 16 major PDPs operating globally, each with a specialised focus on vaccines and other preventive tools, microbicides, treatments, or diagnostics.

What are PDPs?

PDPs are:

- Nonprofit organisations that develop appropriate and affordable innovative tools for populations affected by PRNDs.
- Public health-driven and focused on patients' needs in designing product for use in low- and middle-income countries with a high disease burden.
- Are working along the product development continuum from early discovery to product implementation, covering specific research gaps or the full innovation cycle.
- Employing a portfolio approach to R&D to accelerate product development by pursuing multiple strategies for a disease area and allowing only the most promising products to move forward.
- Engaged as partners with academic and public research institutions, the private sector, governments, and civil society organisations—including partners in developing countries, stimulating medical research in developing countries and linking scientists across the North-South divide.

Creating impact: achievements to date

PDPs have helped to create the largest product development pipeline ever for drugs, vaccines, and diagnostic tools addressing global health needs. They have re-catalysed the development of global health tools.

Prior to the creation of PDPs, the neglected disease R&D pipeline was noticeably empty. A 2001 study estimated that only 1.1 percent of new drugs approved between 1975 and 1999 were for PRNDs, though they represented 12 percent of the global disease burden.⁴

To date PDPs have contributed to the development and introduction of 42 products⁵ for use by affected populations. Thus they contribute to the World Health Organisation's (WHO) goals of preventing, eliminating, and eradicating several diseases, and to achieving the health-related targets in the Millennium Development Goals.

With a focus on diseases that disproportionately affect developing countries, PDPs are committed to conducting research with and in these countries, and as they integrate partners from the North and South, they have made important contributions to building and sustaining capacity for health research. The organisations currently support research centers and scientists across Africa, Asia, and Latin America.

Advantages and strengths of PDPs

PDPs reduce industry and donor risks for investment in research in PRNDs. Funding is spread across the portfolios to support broad product pipelines, allowing partners—including governments and private sector players—to contribute to the R&D enterprise without having to bear the entire cost and risk themselves.

Strong governance structures and professional portfolio management ensures programmes are conducted effectively and efficiently by reviewing projects as they progress through defined transition points. Using this portfolio model, PDPs select winners and eliminate non-performers, thus ensuring that only the most promising candidates are accelerated through the development process.

CREATED WITH THE SUPPORT OF:

AERAS Advancing Tuberculosis Vaccines for the World

DNDi NORTH AMERICA
Drugs for Neglected Diseases Initiative



FIND
Foundation for innovative new diagnostics

iavi
International AIDS Vaccine Initiative

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

MMV
Medicines for Malaria Venture

PATH

SABIN
VACCINE INSTITUTE

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

PDPs leverage resources from public and private sector partners, including co-financing of costly late-stage clinical trials, in kind contributions, and access to intellectual property. PDP agreements with industry foresee provisions to ensure affordable pricing and adequate levels of supply, and include provisions for technology transfer or access to intellectual property.

Need for sustained financial support for R&D for PRNDs

Paradoxically, just as many PDPs are on the cusp of achieving significant results, public funding for product development has dropped markedly during the last two years. According to the G-FINDER 2013 report,⁶ there has been a 20 percent cut in public funding by international donor governments since the financial crisis and a 20 percent funding drop for product development—the largest ever. The report also showed a shift towards basic research and national research efforts. While critical basic research questions need to be answered, it is crucial to translate these

insights and research results into new, affordable, and adapted health technologies for people affected in endemic countries. These new tools will have significant impact on public health and contribute to economic development.

The participation of many organisations and countries in the development of new products for PRNDs is a remarkable and welcome change from past decades. However, there is still a lack of incentives for the pharmaceutical industry to invest in R&D for PRNDs. We need a sustainable environment for research and innovation for such diseases with new funding and incentive mechanisms that support activities in the long term. This is reflected by the governmental discussion at the WHO following advice from the Consultative Expert Working Group on Research and Development: Financing and Coordination to set up a global R&D observatory, as well as assessing a pilot pooled funding mechanism for R&D. This is more important than ever in tough economic times if we are to ensure that those most in need do not end up paying the highest price.

BRIEF PROFILES OF SELECTED PDPs

ABOUT AERAS

AERAS

Advancing Tuberculosis Vaccines for the World

Aeras is a nonprofit biotech advancing the development of new TB vaccines that will be accessible and affordable to all who need them, with a particular focus on developing countries where the need is most urgent. In collaboration with partners worldwide, **Aeras** is supporting the clinical testing of six experimental vaccines, as well as the development of a robust portfolio of second generation vaccine candidates. These new vaccines are being developed in collaboration with pharmaceutical and academic partners and represent the most innovative and cutting edge technology in the field of TB vaccine R&D. **Aeras** is a fully integrated R&D organisation with the expertise to conduct the full spectrum of vaccine development—vaccine construction, vaccine evaluation, manufacturing, clinical development, and regulatory submission for licensure. In collaboration with partners, **Aeras** has conducted over 30 clinical trials of new TB vaccines, enrolling thousands of subjects at multi-country trial sites. Together with experts from around the world, **Aeras** has established comprehensive, measurable, and globally acceptable criteria for selecting, assessing and advancing only the most promising vaccine candidates through the pipeline with the goal of bringing more effective TB vaccines to the market. New vaccines sit at the center of future TB elimination efforts. A vaccine that protects individuals from TB would be the single most cost-effective tool in mitigating this epidemic.

www.aeras.org

ABOUT DRUGS FOR NEGLECTED DISEASES INITIATIVE (DNDi)



As not-for-profit R&D organisation, **DNDi** works to deliver new treatments for neglected diseases, in particular leishmaniasis, human African trypanosomiasis (sleeping sickness), Chagas disease, malaria, specific filarial infections, and paediatric HIV. **DNDi** has established regional disease-specific platforms, which bring together partners in disease-endemic countries to strengthen existing clinical research capacity, as well as to build new capacity where necessary.

In Africa, two platforms have been set up: the Leishmaniasis East Africa Platform (LEAP) and the HAT platform, and in Latin America, **DNDi** has created the Chagas Platform. Since its inception in 2003, **DNDi** has delivered six treatments: two fixed-dose anti-malarials (ASAQ and ASMQ), nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness, sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa, a set of combination therapies for visceral leishmaniasis in Asia, and a pediatric dosage form of benznidazole for Chagas disease. **DNDi** was established in 2003.

www.dndi.org

ABOUT EUROPEAN VACCINE INITIATIVE (EVI)



EVI is a leading European nonprofit PDP that has the principal objective to develop effective, accessible, and affordable vaccines against malaria and other diseases of

poverty. Since its inception in 1998, it has contributed to the development of 32 malaria vaccine candidate formulations with 16

vaccine candidates being advanced into Phase I clinical trials, three of which have been transitioned for further clinical development in sub-Saharan Africa. **EVI** leads global efforts in the development of vaccines against diseases of poverty, while also acting as coordinator of several initiatives to create harmonisation between global stakeholders in vaccine research. **EVI** is co-founder of the Malaria Vaccine Funders Group and is hosted by Heidelberg University in Germany.

www.euvaccine.eu

ABOUT FIND



FIND is an international nonprofit founded in 2003 to save lives and fight diseases of poverty through innovative diagnostics solutions. With programs in TB, malaria,

and neglected tropical diseases, **FIND** works across development, delivery, and implementation. Over the past 11 years, **FIND** has delivered 11 new tests and created an enabling environment for countless more through specimen banks, reagent development, and better market visibility. It has conducted clinical trials and supported the development of policy guidances for 6 novel TB diagnostics and the new human African trypanosomiasis rapid test. It has also supported quality assured scale-up of diagnostics through implementation, quality assurance, and lab-strengthening work. These achievements have helped increase the global prioritization of diagnostics and—in many cases—have revolutionized the landscape in their respective fields. Despite this, critical gaps remain for almost all diseases of poverty. **FIND** operates as facilitator, mobilizer, and bridge builder to support complete diagnostic solutions, with linkage to treatment and care paramount in everything that we do.

www.finddiagnostics.org

ABOUT INTERNATIONAL AIDS VACCINE INITIATIVE (IAVI)



IAVI is a global not-for-profit organisation whose mission is to ensure the development of safe, effective, accessible, preventive AIDS vaccines for use throughout the world. Founded in 1996, **IAVI** works

with governments, academia, civil society, and the private sector in 25 countries to design and evaluate novel AIDS vaccine candidates, advancing a portfolio of the most promising approaches in clinical testing, based on the latest scientific insights. It has a strong focus on the countries where HIV/AIDS has greatest impact, coordinating a network of research laboratories in five African countries and in India, building clinical research capacity, engaging with local communities and providing services such as free HIV testing and counselling. **IAVI** is dedicated to ensuring that a future AIDS vaccine will be available and accessible to all who need it, including those vulnerable groups (such as women and girls) who are often poorly served by existing HIV prevention tools. It also conducts policy analysis and serves as an advocate for the AIDS vaccine field, supported by generous donations from governments, private individuals, corporations, and foundations.

www.iavi.org

ABOUT INTERNATIONAL PARTNERSHIP FOR MICROBICIDES (IPM)



IPM was founded as a nonprofit organisation in 2002 and leverages public, philanthropic, and private sector resources to

spur development of life-saving technologies for women. **IPM's** mission is to prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries. Microbicides in the form of vaginal rings, films, and gels could help empower women with discreet, safe, effective, and long-acting tools they can use to protect their own health. **IPM's** most advanced product is a monthly vaginal ring that slowly releases the antiretroviral drug dapivirine. The dapivirine ring is now in two parallel Phase III studies—the first efficacy studies of a microbicide ring for HIV prevention. These studies are expected to provide the evidence needed to secure regulatory approvals and licensure when results become available in 2016. In addition, **IPM** is expanding the microbicide pipeline with the development of multipurpose prevention technologies that provide simultaneous protection against HIV infection and unintended pregnancy in order to address women's multiple sexual and reproductive health needs.

www.ipmglobal.org

ABOUT MEDICINES FOR MALARIA VENTURE (MMV)



MMV is a leading PDP in the field of antimalarial drug research and development. Its mission is to reduce the

burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs. Since its foundation in 1999, **MMV** has developed and brought to registration four new medicines with its partners: Pyramax[®], co-developed with Shin Poong; Eurartesim[®] with Sigma-Tau; Guilin's artesunate injection for the treatment of severe malaria, Artesun[®]; and Coartem[®] Dispersible, a child-friendly formulation developed with Novartis. Since 2009, over 200 million courses of Coartem Dispersible treatment have been supplied to 50 malaria-endemic countries; and since prequalification in 2010, an estimated 12 million vials of artesunate injection have been delivered, saving 80,000- 90,000 additional lives. Managing the largest portfolio of antimalarial R&D projects ever assembled, of over 65 projects, **MMV** has seven new drugs in clinical development addressing unmet medical needs in malaria, including medicines for children, pregnant women and relapsing malaria, and drugs that could support the elimination/eradication agenda. **MMV's** success in research and access & product management comes from its extensive partnership network of over 300 pharmaceutical, academic and endemic-country partners in 50 countries. **MMV's** vision is a world in which innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria, and ultimately help to eradicate this terrible disease.

www.mmv.org