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**Appendix A
Interview Guide**

PPP: _____ Phone #: _____
Name: _____ Date: _____

Hello, my name is Jon Merz. I am a professor at the University of Pennsylvania. I am performing a study for the World Health Organization. I am trying to describe the Intellectual Property positions and other issues facing public/private partnerships (PPP) or other NGO/nonprofit entities' efforts to develop new drugs, vaccines, and other products for diseases that disproportionately affect developing countries. I specifically hope to learn and report information about the different ways these organizations have been set up, as part of a large effort by the WHO examining ways of bringing needed medicines to the developing world.

I would like to hold a 30-45 minute interview with you about your organization. This interview study has been approved by the University of Pennsylvania Committee on Studies Involving Human Beings.

Are you willing to participate in this interview now? YES NO

If **NO**: Would you be willing to do this at another time? YES NO

If **YES**: When may I call you back (date/time)? _____

⇒ If **NO**: Is there someone else in your organization that I could talk to about these issues?

If **YES**: name/phone: _____

If **NO**: Is there a website or other publicly available information that I could access that would give me some information about your organization? _____

Thank you and close.

If **YES**: Great! I intend to publish results without attribution, meaning that what you tell me about your organization, its structure, funding, market position, and intellectual property position will not be reported in any way linking your organization to this information. That is, this interview and any information you give me will be in confidence, and my data will be reported anonymously, and I will only publish or discuss data in a way that it could not be attributed or associated with one organization.

Now, I have about 10 open-ended questions. You are of course free to refuse to answer any question, and to stop this interview at any time.

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First, I'd like to ask you a bit of history and structure of your organization.

- 1) How was your organization formed?
 - i) what/who provided initiative, funding for startup?
 - ii) what is the mission/objective of the organization?
- 2) Can you tell me about the relationships your organization has with industry?
 - i) what are the sources of funding
 - ii) is a collaboration used to gain access to IP
- 3) Can you tell me about the relationships your organization has with governments?
 - i) what governments?
 - ii) have gov't funds been secured? (if yes, which, how much, how secured, prospects/expectations for future gov't funding?)
- 4) Now, can you tell me about the product(s) being pursued by your organization?
 - i) what is the demand for this product
 - ii) where is the market
 - iii) how will the product be distributed
 - a) target price
 - b) who will pay
 - c) physical distribution
 - d) can you tell me about the kinds of licenses that you have or will need to secure for international transport/mfg and sales/distribution?
 - iv) at what stage is your development effort?
 - i) e.g., drug discovery; preclinical studies; clinical trials
 - ii) when do you expect to bring a product to market?
 - v) where does the technical expertise reside
 - a) is it in house or not
 - b) manufacturing will occur where, by whom
 - i) are contracts for mfg in place? with whom?
- 5) Now we get to what I am really interested in here. Can you tell me about the international IP position of the product(s) and your organization?
 - i) can you say something about your organization's overall IP/licensing strategy?
 - a) if not, can I talk to your lawyer or other executive who could tell me about this aspect of the organization?
 - ii) does your organization own any patent(s) or trade secrets/proprietary know-how on the product(s)
 - a) where were the inventions made? who owns them?
 - b) what is your overall strategy regarding ownership of IP resulting from your research?
 - iii) has a freedom to practice analysis been performed

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- if so, with what results? are you willing or able to share this analysis (in confidence)? **cue:** Malaria Vaccine Initiative
- iv) are licenses in place/being sought?
 - a) numbers; from whom; royalties or other compensation structures?
especially: universities: _____; pharma: _____; “biotech”: _____.
 - b) what technologies/patents
 - c) exclusivity / fields of use
 - d) what issues are arising in licensing
cue: market segmentation / ownership of downstream invention
 - e) have any licensing attempts failed
 - if so, explore what happened in detail; what is being done to get around
- 6) Finally, can you talk a little about what problems your organization has faced?
 - i) what are the largest hurdles that have been overcome
 - a) how were they resolved
 - b) general strategies for managing problems
 - ii) what are the largest problems yet to be resolved
- 7) That’s all the questions I had. Do you have any other thoughts about the issue of IP and drug development for developing world needs that you think I missed?

Thank you and close.

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Appendix B **Summary Public Information on US-Based Development PPPs**

Aeras, Global TB Vaccine Foundation	http://www.aeras.org/
Global Vaccines Inc.	http://www.globalvaccines.org/
Children's Vaccine Programme at PATH	http://childrensvaccine.org/
CONRAD	http://www.conrad.org/
Gates Foundation/U. of North Carolina Partnership for the Development of New Drugs	
Global Alliance for TB Drug Development (TB Alliance)	http://www.tballiance.org/
Global Microbicide Project	http://www.gmp.org/
Human Hookworm Vaccine Initiative at Sabin Vaccine Institute	http://www.sabin.org/hookworm_slides.htm
Infectious Disease Research Institute	http://idri.org/
Institute for OneWorld Health	http://www.oneworldhealth.org/
International AIDS Vaccine Initiative	http://www.iavi.org/
International Partnership for Microbicides	http://www.ipm-microbicides.org/
Malaria Vaccine Initiative	http://www.malariavaccine.org/
Pneumococcal Vaccines Accelerated Development and Introduction Plan (PneumoADIP)	http://www.jhsph.edu/Dept/IH/Research/PneumoADIP.html
Program for Appropriate Technology in Health	http://www.path.org/

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Aeras Global TB Vaccine Foundation (Aeras)

<http://www.aeras.org/>

Goal: To develop, test, characterize, license, manufacture and distribute a new TB vaccine within 10 years.

Governance, history, and main activities.

- Founded in 1997 as the Sequella Global TB Foundation by Carol Nacy, MD. Appointment of Jerald Sadoff, MD in 2003 marked a change in direction. Sequella had addressed diagnostics, therapeutics and vaccines for TB. Renamed Aeras at this point and narrowed focus to vaccines exclusively.
- Sadoff's background is in vaccine development for a number of diseases. Came to Aeras from Merck; had worked at Walter Reed before that.
- In 1999, Sequella received a grant of \$25 million from Gates Foundation to create and launch a program called the TB Vaccine Collaboration (TBVC). Goal of TBVC was to accelerate identification, development, and field-testing of new vaccines for TB control.
 - TBVC supported researchers to help move 11 new TB vaccine candidates from laboratory to clinic.
 - One of the vaccines (rBCG30) has emerged as leading candidate to replace existing BCG vaccine.
 - Also prepared site in South Africa for TB vaccine trials.
- Current vaccine development program focuses on candidates that can be used in a “prime-boost” regimen in which primary vaccine injection is followed by a booster injection.
- Scientific model includes extensive external review by advisory groups.
- Aim of Aeras is to do much of the legwork on vaccine candidates (i.e., vaccine-candidate selection screening and clinical trials on candidates) but leave production to other companies.

Funding and relationships with academia, industry, and government.

- Aeras is a nonprofit organization. According to strategic plan, must raise \$250 million in order to fully fund its scientific program through 2010.
- In 2004, Gates Foundation gave Aeras an \$82.9 million grant for TB vaccine development (more than doubled the amount spent on TB vaccine development worldwide).
 - Money will be spent on (1) vaccine trials, (2) improved animal models, and (3) development of next-generation vaccines. See more in Products section below.
- In 2003, revenues totaled \$5.8 million. 90% of this came from Gates Foundation
 - Rest came from NIH and interest income.
 - Total program expense in 2003 was \$4.1 million.
- In March 2004, Aeras entered into a partnership with Crucell, a biotechnology company, to improve the current BCG vaccines via proprietary technologies owned by Crucell. Partnership is for \$2.9 million contingent upon Crucell meeting certain development milestones.
- Extensive relationships with scientists in academia, industry, and government evident in composition of Aeras Board and advisory groups.

Product(s).

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- Closest thing to an end product is a prime-boost vaccine composed of rBCG30 as the prime and a fusion protein vaccine as the boost. Phase I trials began in January 2004; Phase II trials planned.
- Crucell BCG+ vaccine (see above).
- Aeras is also conducting more upstream research on so-called 'next-generation' vaccines that use different antigens as starting point for vaccines.

IP position.

- When possible, Aeras seeks to obtain IP rights to vaccine candidates for distribution in the developing world. Essentially, Aeras would in this scenario license out its vaccines to companies for production in the developed world only.
 - Washington Post: “[Aeras] hopes to induce the companies to build big factories, then sell their excess production back to Aeras for distribution in the developing world.”
- If that is not possible (for instance if Aeras has only a share of the IP rights), it seeks agreements whereby partners agree to distribute the vaccines at affordable prices or agree to share the rights with Aeras so other manufacturers can produce vaccines on their behalf.
- 2003 Annual Report: “In all cases Aeras will only support advanced development of TB vaccines where guarantees of adequate supply of the vaccine to meet the projected needs of developing countries in a timely manner are made.”
- No U.S. patents identified.

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Children's Vaccine Program at PATH (CVP at PATH)

<http://childredivaccine.org/>

Goal: To promote equal access to new and lifesaving vaccines worldwide by repairing crumbling immunization programs, building human and financial capacity within countries, and introducing new vaccines and immunization technologies.

Governance, history, and main activities.

- Established by the Program for Appropriate Technology in Health (PATH) in 1998 with a \$100 million grant from the Gates Foundation.
- Directed by Mark Kane, MD from PATH's offices in Seattle. Also has staff in PATH's offices in France, Senegal, India, and Cambodia.
- Other leadership:
 - Sir Gustav Nossal chairs the Strategic Advisory Council for CVP
 - Expert review groups organized around specific vaccines
- Main activities:
 - Direct assistance to countries. Works with national governments and other partners to help assess, plan, and implement improvements to their immunization programs. Conducts training to meet need for regional- and country-level experts for strengthening immunization programs.
 - Philosophy is to work with local colleagues to design and test innovative approaches to immunization delivery at the district level and then encourage partners to replicate them nationally or regionally.
 - Countries assisted: China, India, Indonesia, Cote d'Ivoire, Senegal, Cambodia, Vietnam.
 - Compiling data for decisionmaking. Aims at the lack of information on incidence of lesser-studied diseases that make it difficult for countries to calculate potential benefits of vaccine introduction. Generates data on disease burden and vaccine effectiveness in field conditions.
 - 40 countries assisted.
 - Financing of immunization programs. Works with national governments to develop sustainable immunization financing solutions.
 - Investing in vaccine development.
 - Supports vaccine trials for pneumococcal vaccines in the Gambia and the Philippines.
 - Diversified strategy to speed the progress of several different rotavirus vaccine candidates: trials in Bangladesh, South Africa, and India.
 - Disease burden, cost-effectiveness, and policy studies on Japanese encephalitis. Goal of this project (which is a broader PATH initiative) is to develop a second-generation JE vaccine.
 - Investing in other vaccine technologies.
 - Distribution of proven vaccines such as those for Hib and Hepatitis B.
 - Supporting exploratory work on heat-stable vaccines.
 - Promotion of safe injection solutions.

Funding and relationships with academia, industry, and government.

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- Funded by the Gates Foundation through PATH. \$100 million grant over ten years.
- Nearly 25% of original Gates grant goes to UNICEF, WHO, and the World Bank to refocus on routine immunization.
- CVP is a founding member (1999) of the Global Alliance for Vaccines and Immunization (GAVI). GAVI is a forum where national governments, international organizations, foundations, and vaccine industry representatives work together to improve national immunization programs in the 74 poorest countries in the world.
- CVP helped conceive The Vaccine Fund in 1998 and administered the Fund during first two years of its operation. The Fund provides financial incentive for national governments and GAVI partners to work together to solve biggest problems facing immunization programs.
 - Is an independent, billion-dollar funding resource for countries with a per-capita income of \$1000 or less.
 - Money is disbursed to national governments with few strings attached aside from immunization coverage milestones. Details left to governments.
- Over the longer term, PATH's immunization portfolio is evolving away from broad immunization initiatives and focusing instead on the development of new vaccines.

Product(s).

- No evidence that CVP itself has ownership in any products. Supports the development of vaccines for pneumococcal, rotavirus, and Japanese encephalitis vaccines.

IP position.

- No general stated IP policy by CVP.
- U.S. patents held by PATH:
 - 1 [6,213,980](#) **T** [Fill facilitating unit dose injection cartridge and filling method](#)
 - 2 [5,938,637](#) **T** [Single-use medicine delivery unit for needleless hypodermic injector](#)
 - 3 [5,771,900](#) **T** [Contraceptive diaphragm](#)
 - 4 [5,668,017](#) **T** [Radial absorption device](#)
 - 5 [5,222,948](#) **T** [Injection port for single-use syringe](#)
 - 6 [5,000,737](#) **T** [Single use disposable syringe](#)
 - 7 [4,955,871](#) **T** [Single-use disposable syringe](#)
 - 8 [4,883,473](#) **T** [Single use injection device](#)

CONRAD, Consortium for Industrial Collaboration in Contraceptive Research (CICCR), and the Global Microbicide Project (GMP)

<http://www.conrad.org/>, <http://www.ciccr.org>, <http://www.gmp.org>

Goal: To improve reproductive health, particularly in developing countries, by supporting the development of better, safer, and more acceptable methods to prevent pregnancy and sexually transmitted infections including HIV/AIDS.

Governance, history, and main activities.

- CONRAD was established in 1986 under a cooperative agreement between Eastern Virginia Medical School (EVMS) and the U. S. Agency for International Development (USAID). Headquartered in Arlington, VA.
- Director of CONRAD is Henry L. Gabelnick, PhD; he has held this position since 1990. Background in contraceptive research with the NIH.
- CONRAD seeks to move potential contraceptive/microbicide leads through all phases—pre-clinical testing, clinical testing, final Phase III human testing, providing data to the FDA for approval, and collaborating with a manufacturing firm for production of the final product.
- In 1995, CONRAD established CICCR to increase the pharmaceutical industry's commitment to develop new contraceptives. Promotes collaboration between not-for-profit entities and industry in three areas of research: contraceptives for men, monthly regimens for women, and vaginal barriers to prevent pregnancy and STIs.
 - CICCR makes two major types of grants:
 - Feasibility grants support high-risk research that results in preliminary findings to make a project more attractive to a financial partner.
 - Matching funds awarded to not-for-profit research institutions working in collaboration with industrial partners.
- In 2001, CONRAD established GMP to expedite the development of microbicides that may or may not be contraceptive. GMP provides funds for both pilot and major projects. No cost-sharing requirement with industrial partners exists, although it is encouraged.
- Together, CONRAD/CICCR/GMP main activities organized around:
 - Chemical barriers and HIV/STI prevention
 - Mechanical barriers for women (objective of developing a one-size-fits-all device)
 - Systemic hormonal contraceptives for men

Funding and relationships with academia, industry, and government.

- Receives funding from Eastern Virginia Medical School, USAID, the National Institute of Child Health and Human Development, the Centers for Disease Control and Prevention, and the National Institute of Allergy and Infectious Diseases.
- Approximately \$60 million contributed by USAID and \$37 million by the Gates Foundation (top two funders).
- Extensive links with academia through grants administered: 43 by CONRAD, 61 by CICCR, and 27 by GMP from 2002-04.
- Several physicians have joint appointments between CONRAD and the Eastern Virginia Medical School.

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- In August 2004, CONRAD and the Indian Council of Medical Research signed a Memorandum of Understanding to facilitate cooperation on the development of microbicides to be used in developing countries.

Product(s).

- Cellulose sulfate (chemical contraceptive). Preclinical trials have revealed potential of cellulose sulfate as a contraceptive and microbicide. Two Phase II contraceptive trials initiated in 2004; Phase III HIV prevention trials will begin in 2004 and 2005.
- CONRAD supplied the developers of two intravaginal devices, Lea's Shield and FemCap, with key clinical trial data required for FDA approval.
- Expanded multicenter trial of a long-acting androgen/progestin combination (NET-EN plus TU) in 2005 for male contraception; Phase I studies of progestagen delivery systems (also for male contraception).
- UC-781 is being tested as a vaginal microbicide for the prevention of HIV transmission. CONRAD has completed the first Phase I safety trial and is working with CDC as well as CONRAD to design a series of additional Phase I trials.
- ACIDFORM and BufferGel: vaginal gels with high buffering capacity. CONRAD has supported Phase I tests.
- Other mechanical vaginal barriers: CONRAD supports testing of the SILCS intravaginal barrier device, the BufferGel Duet, and a better female condom.

IP position.

- All grant applications (CONRAD, CICCR, GMP) state the following:
 - "All potential recipient institutions must document their technology transfer capability, including:
 - Statement of already existing patent rights relevant to the proposed studies
 - The patent policy of the potential recipient institution
 - Any written procedure for processing invention disclosures

All subproject agreements contain a patent clause in which the recipient institution is granted patent rights for invention disclosure; however, the U.S. Government reserves certain rights. The CONRAD Program also reserves the right to share in intellectual property rights when substantive input has been contributed by CONRAD Program staff."

- Intellectual property rights to cellulose sulfate owned by a Canadian company, Polydex Pharmaceuticals, which has worked closely with CONRAD throughout development process.
- No U.S. patents identified for CONRAD; Polydex patent:

2 [6,063,773](#)  [Cellulose sulfate for use as antimicrobial and contraceptive agent](#)

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

Goal: To develop new drugs to fight African sleeping sickness and leishmaniasis.

Governance, history, and main activities.

- Led by Dr. Richard Tidwell, a UNC professor of medicine and pharmacy; founded in 2000.
- Involves a consortium of more than a dozen faculty and scientists from UNC-Chapel Hill, Georgia State University, the London School of Hygiene and Tropical Medicine, Ohio State University, the Swiss Tropical Institute, the Kenya Trypanosomiasis Research Institute and Immtech International, Inc.
- In 1990, Tidwell and colleagues showed that drugs synthesized to fight AIDS-related infections were effective against sleeping sickness and leishmaniasis.
- Tidwell and Dr. David Boykin of Georgia State University experimented with a compound called DB289 which allows medication to be orally absorbed and converted to an active state through the body's normal enzyme systems.
- Advanced clinical studies on DB289 are ongoing; consortium is also searching for new drugs to treat leishmaniasis.

Funding and relationships with academia, industry, and government.

- Initial grant of \$15.1 million for the consortium over five years.
- An additional \$2.7 million was given to the consortium specifically to advance trials on DB289's effectiveness against sleeping sickness; \$2.4 million of this given to Immtech.
- Immtech, Inc. is a biopharmaceutical firm that conducts clinical trials and would manufacture and distribute drugs produced.
- Consortium scientists have a stake in Immtech through share ownership.

Product(s).

- The lead drug of this partnership, DB289, has received Fast Track status from the FDA for treating sleeping sickness.
 - The World Health Organization estimates that there are 500,000 to 750,000 active cases of human Trypanosomiasis in central Africa and another 60 million people that are at risk of contracting the disease.
- DB289 is also in late stage Phase II trials for treating malaria and pneumocystis carii pneumonia.

IP position.

- No general stated IP policy.
- UNC-CH team developed and patented DB289 and then licensed the drug to Immtech, Inc.
- Patents held by Dr. Tidwell relating to leishmaniasis or trypanosomiasis:

1 [6,737,440](#) **T** [Synthesis and antimicrobial activity of novel dicationic "reversed amidines"](#)

2 [5,206,236](#) **T** [Method for the treatment of malaria](#)

3 [5,202,320](#) **T** [Method for treating leishmaniasis](#)

4 [4,963,589](#) **T** [Methods for treating Giardia lamblia](#)

Global Alliance for TB Drug Development

<http://www.tballiance.org/>

Goal: To accelerate the discovery and development of faster-acting and affordable drugs for tuberculosis; aim to have marketable drug(s) by 2010.

Governance, history, and main activities.

- A meeting in Cape Town in February 2000 resulted in a Declaration for TB Drug Development calling for the accelerated development of new treatments for TB. Signatories also agreed to create the Global Alliance for TB Drug Development at that meeting.
- CEO Maria C. Freire, PhD heads an eleven-member board of directors representing international and national government agencies, pharmaceutical and biotechnology companies, private foundations and non-governmental organizations.
 - Dr. Freire previously led the Office of Technology Transfer at the U.S. National Institutes of Health for seven years where she was responsible for all the patenting and licensing activities of the NIH, as well as for the Food and Drug Administration.
- Main activities. Building a drug portfolio to:
 - Shorten the duration of TB treatment
 - Be effective against multi-drug resistant TB (MDR-TB)
 - Improve the treatment of latent TB infection
- Stakeholders Association. The TB Alliance also includes in its governance framework a group of institutions who join in a "Stakeholders Association" and have certain roles and responsibilities of advising, guiding and supporting the organization. Provisions were made for close coordination between the TB Alliance, its Board of Directors, and its Stakeholders; including the election of a member of a Stakeholders representative to sit ex-officio on the Board of Directors.
- 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. Members serve three-year terms.
- Research is not conducted in-house; rather, however, it is funded and managed by the TB Alliance. Offices in New York, Brussels, and Cape Town.

Funding and relationships with academia, industry, and government.

- \$25 million five-year unrestricted grant by Gates Foundation in 2000; remaining conditional balance of \$5 million was to be paid to the TB Alliance by Gates in one annual payment in 2005.
- \$15 million grant from Rockefeller Foundation; 2 million euro grant from World Health Organization; 2 million euro grant from Netherlands Department of Development.
- At the end of 2004, TB Alliance had \$20.7 million cash on hand.
- Chiron Corp. exclusively licensed the compound PA-824 to the TB Alliance. TB Alliance paid an undisclosed amount up front and will follow up with milestone payments if the drug succeeds in clinical testing.
- In 2004, signed agreements with Brazil's Oswaldo Cruz Foundation, India's Council of Scientific and Industrial Research, South Africa's MRC Tuberculosis Lead Research

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Program, and a Peruvian governmental group to use their R&D facilities to develop new TB drugs.

- Also in 2004, began a joint research program with the Novartis Institute of Tropical Diseases (NITD) to identify the next generation of nitroimidazopyran compounds related to PA-824. A modified form of the compound could result in a drug whose required dosage is easier to comply with than current TB drug regimens.
- Portfolio consists of work with a number of partners:
 - Drug candidates in the *discovery* stage of research: quinolones (KRICT, Yonsei University), nitroimidazole analogs (NITD, NIAID), macrolides (University of Illinois-Chicago), carboxylates (Wellesley College).
 - Drug candidates in the *preclinical* stage of research: non-fluorinated quinolone (Proctor & Gamble), PA-824 (Chiron), and Pyrrole LL-3858 (Lupin Ltd.).
 - Drug candidates in the *clinical* stage of research (in partnership with but not licensed to the TB Alliance): quinolone and moxifloxacin (Bayer AG) and diarylquinoline R207910 (Johnson & Johnson).
 - Platform technologies: murine model of TB (Johns Hopkins University) and Biomedical Information Resources (Intellectual Limited).

Product(s).

- PA-824, licensed to the TB Alliance from Chiron Corp., is a novel lead compound related to nitroimidazoles, a family of compounds used to treat a range of infections. PA-824 has demonstrated in vitro activity against both drug-sensitive and multidrug resistant strains of TB. Early research into PA-824 highlighted important properties that may have the potential to permit significant reduction in the duration of TB treatment from its present course of 6-9 months.
 - Scheduled to enter clinical trials in 2005.
 - Contracted research organizations have conducted a full range of preclinical, pharmacokinetic, toxicology, safety pharmacology, and production assessments.
- Moxifloxacin. Studies supported by the TB Alliance and conducted at Johns Hopkins using a mouse model indicate that moxifloxacin markedly shortens the duration of TB therapy. Bayer AG, the TB Alliance, and the European and Developing Countries Clinical Trials Partnership are in discussion to formalize moxifloxacin's development as an anti-TB agent with a comprehensive clinical development program. This will build on a recently completed Phase II trial.
- TB Alliance economics report indicates that the global market for anti-TB drugs is \$450 million and is expected to increase to \$700 million by 2010

IP position.

- "Affordability, adoption, and access"
- Pursues intellectual property rights "to ensure the availability of novel technologies for public benefit. This approach allows us, at each stage of negotiations, to balance affordability and health equity with effective incentives for collaboration and win-win agreements."
- Negotiates terms and conditions based on: public health impact of the technology; level of investment, stage of scientific and clinical development; pipeline requirements, timing and other business, economic and public health considerations.

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- In deal with Chiron, TB Alliance stipulated that Chiron has the option to manufacture and commercialize end products in developed-world markets but would receive no royalties for drug sales in developing countries.
- NITD has committed the Novartis Group to make any TB drugs resulting from the NITD-TB Alliance collaboration available to patients, without a profit, in developing countries where TB is endemic.

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Human Hookworm Vaccine Initiative at the Sabin Vaccine Institute (HHVI at SVI)

Goal: To develop a genetically engineered recombinant hookworm vaccine.

Governance, history, and main activities.

- Research is led by vaccinologist, Peter Hotez, M.D., Ph.D., a Senior Fellow at the Sabin Institute and the Professor and Chair of the Department of Microbiology and Tropical Medicine at The George Washington University.
- Governance is organized as follows:
 - Program management: SVI
 - Scientific support: George Washington University
 - Process development: Biological Process Development Facility, U. of Nebraska, Dept. of Chemical Engineering
 - Antigen validation: George Washington University
 - Pilot production: Walter Reed Army Institute of Research
- Main activities:
 - Antigen selection for hookworm vaccine on the basis of immune response test results of animal models that were challenged with hookworm parasites. (Antigen Na-ASP-2 was selected).
 - Investigational New Drug application filed and approved by the FDA.
 - Phase I testing of hookworm vaccine began in Washington DC in January 2005.

Funding and relationships with academia, industry, and government.

- \$18 million grant from the Gates Foundation in 2000.
- Also funded by the NIH, the March of Dimes, and the China Medical Board of New York.
- Sabin Vaccine Institute signed a memorandum of understanding this past fall with federal and state vaccine production facilities in Brazil for clinical development of the vaccine. A Human Hookworm Vaccine Initiative team based in Brazil is now assembling baseline data in a rural area impacted by hookworm disease. Phase I trials planned for the end of 2005.
- Phase II trials likely to take place in Brazil, Honduras, and China.

Product(s).

- Vaccine based on cocktail of: L3 antigen (Na-ASP-2) + adult-stage hookworm antigen + adjuvant. In clinical testing as described above.
- No current vaccine in place. Estimated market: 740 million cases in areas of rural poverty.

IP position.

- No stated IP policy.
- Patents for the lead antigen candidates have been filed on behalf of the Sabin Vaccine Institute by Michael E. Whitham, Esq, Whitham, Curtis & Christofferson, P.C., Reston, VA. Other relevant patents held by Dr. Hotez:

1 [5,753,787](#)  [Nucleic acids encoding ancylostoma secreted protein](#)

2 [5,427,937](#)  [Hookworm anticoagulant](#)

N.B.: The Cancer Vaccine Consortium does not appear to be a PDPPP in the same sense as the other organizations listed here; it is a consortium of private companies organized by the SVI.

See: http://www.sabin.org/CV_Consortium.htm

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Infectious Disease Research Institute (IDRI)

<http://idri.org/>

Goal: To create vaccines, diagnostics, and therapeutics for neglected diseases.

Governance, history, and main activities.

- Founded in 1993 by Stephen Reed, PhD, in partnership with Seattle biotech Corixa Corp., which Dr. Reed co-founded. Dr. Reed is currently President and CEO of IDRI but is no longer officially affiliated with Corixa.
 - Board of directors under Dr. Reed includes: John H. Dawson, Jr., M.D., FACS, Cynthia Healy, Ph.D., Franklyn G. Prendergast, M.D., Ph.D., Steven G. Reed, Ph.D., Mark Smith, MBA, Patricia Wahl, Ph.D., David Webster, MBA
 - Has twenty five scientific and technical personnel and three support staff and maintains laboratory and office space in the Seattle Life Sciences Center. Most of the space is devoted to research laboratories. Corixa is located in the same building.
- Main activities:
 - Research and development activities organized around six diseases: tuberculosis, leishmaniasis, Chagas disease, malaria, leprosy, and Buruli ulcer.

Funding and relationships with academia, industry, and government.

- Received \$15 million grant from Gates Foundation in March 2000.
- Other funders include the NIH, the Cancer Research Institute, and private donors.
- Extensive links with industry, academic, and public health organizations:
 - With Corixa Corp. to develop vaccines against leishmaniasis and tuberculosis.
 - With the American Leprosy Missions to develop a therapeutic vaccine and a test for early diagnosis of leprosy.
 - With CompleGen Inc. to develop new therapeutics against malaria and Chagas disease.
 - With UNDP - World Bank - WHO Special Programme for Research and Training in Tropical Diseases (TDR) on the development of vaccines both for prevention and therapy of leishmaniasis. IDRI also maintains a collaborative office at the WHO – TDR in Geneva.

Product(s).

- Vaccine for leishmaniasis: Scientists from IDRI and Corixa, under the leadership of Dr. Reed, discovered, formulated, and developed a defined vaccine for the first time (second generation recombinant vaccine), which was shown to be safe and protective against leishmaniasis in experimental animals. Vaccine (Leish-111f + MPL-SE) is now being tested for safety and immunogenicity in healthy volunteers (in collaboration with Northwest Kinetics, Tacoma, WA, USA). Another safety/immunogenicity trial to follow soon after assessment of safety in healthy volunteers will be conducted in patients with active cutaneous leishmaniasis in collaboration with Dr. Jacinto Convit, and his group at the Instituto de Biomedicina, Caracas, Venezuela.
- Diagnostic test for leishmaniasis: Detects antibodies that arise during the fatal internal form of leishmaniasis. Test is reaching routine use in India, Latin America, and Africa. Through a collaborative arrangement, InBios Corp (Seattle) is producing and distributing this test based

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on a recombinant antigen (K-39). WHO is conducting a multinational trial to compare and validate our test with other methods

- Vaccine for tuberculosis: IDRI has helped Corixa Corporation and GlaxoSmithKline develop a prototype tuberculosis vaccine. Corixa, GlaxoSmithKline and IDRI scientists, working together, developed a monkey model for testing human vaccines. In a recent experiment in monkeys, it was shown that the prototype TB vaccine can induce protection more effectively than the current TB vaccine, BCG. First time monkeys have been effectively vaccinated for TB. Now beginning the process of manufacturing and clinical testing.
- Malaria therapeutics: IDRI and CompleGen scientists have identified over a dozen new therapeutic targets and screening assays.
- Diagnostic test for Chagas: IDRI and Corixa scientists have developed an effective blood test for Chagas disease. The test is now being implemented in South America.
- Scientists from IDRI and Corixa Corp. have developed a rapid serological test based on a defined recombinant protein of Leishmania (k39) which requires only a small blood sample and can be performed in remote places under field conditions. This test is manufactured by Inbios Corp and is being evaluated and compared with other tests in a multi-center trial involving several countries under the auspices of WHO/TDR
- IDRI estimates that six million people per year would benefit from the successful design of vaccines, drugs, and diagnostics that they are undertaking.

IP position.

- No stated IP policy.
 - IDRI holds no patents in the United States. Relevant patents granted to Dr. Reed are given below. Most appear to be assigned to Corixa.
- 1 [6,709,661](#) **T** [Leishmania antigens for use in the therapy and diagnosis of leishmaniasis](#)
 - 2 [6,638,517](#) **T** [Leishmania antigens for use in the therapy and diagnosis of leishmaniasis](#)
 - 3 [6,627,198](#) **T** [Fusion proteins of Mycobacterium tuberculosis antigens and their uses](#)
 - 4 [6,613,337](#) **T** [Leishmania antigens for use in the therapy and diagnosis of leishmaniasis](#)
 - 5 [6,607,731](#) **T** [Leishmania antigens for use in the therapy and diagnosis of leishmaniasis](#)
 - 6 [6,592,877](#) **T** [Compounds and methods for immunotherapy and diagnosis of tuberculosis](#)
 - 7 [6,500,437](#) **T** [Leishmania antigens for use in the therapy and diagnosis of leishmaniasis](#)
 - 8 [6,458,366](#) **T** [Compounds and methods for diagnosis of tuberculosis](#)
 - 9 [6,375,955](#) **T** [Leishmania antigens for use in the therapy and diagnosis of leishmaniasis](#)
 - 10 [6,365,165](#) **T** [Leishmania antigens for use in the therapy and diagnosis of Leishmaniasis](#)
 - 11 [6,350,456](#) **T** [Compositions and methods for the prevention and treatment of M. tuberculosis infection](#)
 - 12 [6,338,852](#) **T** [Compounds and methods for diagnosis of tuberculosis](#)
 - 13 [6,290,969](#) **T** [Compounds and methods for immunotherapy and diagnosis of tuberculosis](#)
 - 14 [5,912,166](#) **T** [Compounds and methods for diagnosis of leishmaniasis](#)
 - 15 [5,834,592](#) **T** [Leishmania antigens for use in the therapy and diagnosis of Leishmaniasis](#)

Institute for OneWorld Health (IOWH)

<http://www.oneworldhealth.org/>

Goal: To develop new medicines for infectious diseases predominantly affecting those in the developing world.

Governance, history, and main activities.

- Founded in July 2000 in San Francisco by Victoria Hale, PhD. IOWH was the first nonprofit pharmaceutical company in the United States.
- Dr. Hale currently serves as CEO and Chair of the Board of Directors. Dr. Hale formerly worked at the FDA, Genentech, and co-founded Axiom Biomedical Inc.
 - 7 members of the Board of Directors (most are PhD-qualified, includes pharmaceutical executives and a former FDA Commissioner).
 - 16 members of the Scientific Advisory Group (most are PhD-qualified; from academia or industry).
 - 20 staff members at IOWH in San Francisco.
- Touts a new business model revolving around “partnering and collaborating with industry and researchers, securing donated intellectual property, and utilizing the scientific and manufacturing capacity of the developing world.”
- Scientific expertise extends from drug and vaccine lead identification and optimization to conducting clinical trials and securing regulatory approval of new medicines for patients in the developing world.
- Main activities centered around leishmaniasis, Chagas disease, schistosomiasis, diarrheal disease, and malaria.

Funding and relationships with academia, industry, and government.

- Main funding source is the Gates Foundation with \$4.6 million in grants for Chagas and leishmaniasis, \$1.4 million for a malaria vaccine, and \$42.6 million for developing a microbial factory for artemisinin (to treat malaria).
- Other funders include a variety of foundations, corporate donors, and individual donors.
- IOWH sees itself as a ‘catalyst’ for new opportunities involving industry; government and academia; and developing-world institutions:
 - Industry. Takes responsibility for markets in least developed countries; obtains resources from private foundations and governments; provides international regulatory expertise; provides tax deduction for donated IP; creates viable path for off-patent drugs that would otherwise not be pursued.
 - Government and academia. Provides the bridge between novel bench science and its conversion to applications for the developing world; advocates to government and foundation funders in support of specific basic research that will later become new drug development projects; advises academicians in translational science – such as high-throughput screening and lead optimization of potential new drugs.
 - Developing-world institutions. Works with developing country partners in clinical trials, pharmaceutical manufacturing, and distribution of new medicines for neglected diseases; advocates for increased funding for academic laboratories in the developing world and building capacity by training health care workers and scientists in clinical

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drug development through each of our projects; transfers knowledge and technology to improve local efforts to address disease threats.

- Actual partners include a host of academic, governmental, and industry research groups. See *IP position* below for a description of some of these partnerships.
- IOWH is organizing a community of volunteer scientists to share their ideas, skills, accumulated research or contacts to advance the development of developing-world medicines. Seed grant provided by the Sapling Foundation.

Product(s).

- Paromomycin. Paromomycin is an off-patent aminoglycoside antibiotic that was previously approved by the U.S. FDA and is marketed in the U.S. as an oral formulation to treat intestinal parasites. In June 2003, OneWorld Health initiated the largest phase 3 clinical trial ever performed for visceral leishmaniasis (VL), treating 667 VL patients in India in collaboration with the Special Programme for Research and Training in Tropical Diseases of the World Health Organization (WHO/TDR). The clinical trial will concluded in November 2004. IOWH will submit an application for approval to the Indian regulatory agency in 2005. Looking for manufacturers and distributors.
- Drug for Chagas disease. IOWH is developing and commercializing the compound K777 as an antiparasitic agent. It is currently conducting the necessary pharmacological and toxicological preclinical studies on this orally active cysteine protease inhibitor to determine if it can enter human clinical trials. If K777 is not successful, IOWH plans to develop an effective drug for Chagas disease from a series of highly active azole compounds.
- Drug for pediatric diarrhea. IOWH is finalizing the selection of a late-stage candidate that fits criteria for a pediatric diarrhea treatment. Strategy is to conduct the final clinical testing of these products in diarrhea hospitals or diarrhea centers of excellence such as the Centre for Health and Population Research (ICDDR,B) in Bangladesh.
- Artemisinin (malaria drug) manufacturing system. IOWH is collaborating with the California Institute of Quantitative Biomedical Research (QB3) at the University of California, Berkeley, and Amyris Biotechnologies to use *E. coli* bacteria to manufacture artemisinin. Under the five-year grant, UC Berkeley will complete development of the synthetic process to create artemisinin, Amyris will develop the process for pilot-scale and industrial fermentation, and IOWH will perform the drug development and regulatory work to show that the microbially produced artemisinin derivative is equivalent to the natural form.
- Malaria vaccine. IOWH is working with Sanaria Inc. which has developed a novel approach to a malaria vaccine using a substance extracted from weakened, infected mosquitoes. Still in preclinical stages.
- IOWH estimates for relevant disease burdens (annual morbidity): visceral leishmaniasis, 1.5 million; diarrheal diseases, 1.25 billion; malaria, 300 million; Chagas, 10 to 12 million; schistosomiasis, 200 million.

IP position.

- IOWH is explicit about using donated intellectual property for its products. Its business plan calls for manufacturing and distribution to be outsourced to quality corporations in the developing world.
- An examination of various products and partnerships gives a glimpse at how IOWH seeks intellectual property:

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- Paromomycin was an off-patent drug still marketed in the U.S.
- In 2002, Celera Genomics granted IOWH an exclusive license to develop K777 (also known as CRA-3316) free of any royalty or cash payments. IOWH is developing K777 as a treatment for Chagas. The compound was originally worked on by scientists at both Celera and UCSF.
- In 2003, IOWH licensed a novel class of high-potency compounds called azoles from Yale University and the University of Washington to treat Chagas. The agreement granted an exclusive license for IOWH in developing countries but also creates an opportunity in which the universities could seek a pharmaceutical partner to develop the same compounds for fungal infections in industrialized countries.
- In 2004, the University of California-Santa Barbara donated all rights for its patent on the use of calcium channel-blockers against parasitic diseases to IOWH. IOWH plans to develop the science into a drug against schistosomiasis.
- No U.S. patents assigned to IOWH.

International AIDS Vaccine Initiative (IAVI)

<http://www.iavi.org/>

Goal: To speed the search of a vaccine to prevent HIV infection.

Governance, history, and main activities.

- IAVI was founded in 1996 after a landmark meeting of global vaccine and public health experts convened by the Rockefeller Foundation.
- IAVI operates in 23 countries to research and develop vaccine candidates. Offices in New York, Europe, East Africa, and India.
- Seth Berkley, MD serves as President and CEO. He chairs the 14-member Board of Directors consisting of a variety of academic, government, industry, and field representatives.
- There are also a 13-member Scientific Advisory Committee and a 16-member Policy Advisory Committee.
- Main activities:
 - Provides financial and technical support to scientific partnerships joining industry, academia and government to accelerate the research and development of promising vaccine concepts for the developing world from preliminary laboratory studies to clinical trials in humans.
 - Advocates for public policies that would make vaccine research a political and economic priority and ensure rapid global access once a vaccine is developed.
 - Supports the development and implementation of strategies to increase understanding of the clinical trial process at the community level.
- IAVI's vaccine research and development program is tailored to meet the specific needs of developing countries. For this reason, IAVI conducts human trials of its vaccine candidates in Africa and Asia, regions where a vaccine is needed most urgently. To date, IAVI-sponsored vaccines have been developed based on subtypes of the HIV virus most prevalent in these regions.
- IAVI advocates for innovative global finance mechanisms to close the gap between anticipated demand for a preventive AIDS vaccine in the hardest hit countries and limited purchase and delivery capabilities. Stimulating an innovative approach to IP that protects industrial investment in research yet recognizes an AIDS vaccine as a public good is another of IAVI's advocacy objectives.
- Wrote and is now implementing the widely acclaimed Scientific Blueprint for AIDS Vaccine Development, a strategic plan to guide the world's scientific effort.
- Established the first periodical devoted to chronicling HIV vaccine research, IAVI Report, which has more than 10,000 readers in 115 countries.

Funding and relationships with academia, industry, and government.

- Total of \$350 million donated to IAVI thus far. IAVI's major financial supporters include the Gates Foundation (\$100 million); the Rockefeller, Starr and Sloan foundations; the World Bank; BD (Becton, Dickinson & Co.); the European Union; and the governments of Canada, Denmark, Ireland, the Netherlands, Norway, Sweden, the United Kingdom and the United States.

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- IAVI collaborates with more than 30 private companies and academic and government agencies worldwide. Has invested more than \$100 million in vaccine R&D. It is also a collaborating center for UNAIDS.
- IAVI works with scientists in Africa and Asia to study how an AIDS vaccine can be safe and effective in populations where most new HIV infections are occurring; also studying how a vaccine can be designed so that it is inexpensive to manufacture.
- In Africa and India, IAVI has established capacity for small-scale vaccine trials by building clinics and laboratories and training staff.


Product(s).

- To date, IAVI has developed eight vaccine candidates, five of which are already in clinical trials in eight countries. These five candidates are:
 - A pair of vaccine candidates, named HIVA.DNA and HIVA.MVA, designed by the UK Medical Research Council and the University of Nairobi. IAVI-sponsored Phase I and II trials are underway in Kenya, South Africa, Switzerland, Uganda and the United Kingdom. Results have been disappointing thus far.
 - A vaccine candidate named ADVAX designed by the Aaron Diamond AIDS Research Center; an IAVI-sponsored Phase I trial is underway in the United States.
 - A potentially single-shot vaccine candidate named tgAAC09 designed by Targeted Genetics Corp. and Columbus Children's Research Institute; an IAVI-sponsored Phase I trial is underway in Belgium. Phase I and II studies planned for southern Africa and India in 2005.
 - IAVI provided significant support for the early development of a vaccine candidate named AVX101, designed by AlphaVax Inc. AlphaVax and the US government are conducting a trial in South Africa and the United States.
- A vaccine being developed by an IAVI-sponsored partnership between a US biotechnology company and the government of India should enter clinical trials soon. IAVI has several other promising candidates in earlier stages of development, including: a bacterial vector vaccine, which could be produced in large scale at low cost and administered orally and a Semliki Forest Virus (SFV) replicon DNA vaccine, which also might provide immunity from HIV with only a few doses.

IP position.

- Patents are property of the developers, while IAVI owns a royalty-free license to any successful vaccine to assure it is available at reasonable prices in developing countries.
- “Unlike traditional venture capitalists, who seek equity in return for their investments, IAVI finances AIDS vaccine development in exchange for a commitment that a successful vaccine will be provided in poor countries at a reasonable price.” –Seth Berkley
- IAVI's IP agreements are tailored for each partner and program, but all define “reasonable price” for developing countries as based on the income level of the country among other factors. In IAVI's current agreements, developing countries are those meeting World Bank criteria for lower and middle income countries.
- Should a company funded by IAVI decline to produce a vaccine for developing countries in reasonable quantities at reasonable prices, IAVI will have certain rights to obtain licenses to contract with other manufacturers.
- Challenges related to IP:

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- “Some of challenges to an IP policy implementation include: broad umbrella and vaccine component patents; stacking of royalties; negotiations typically starting at the private sector level of royalty rates and milestone payments; lack of IAVI ownership of IP to cross-license; countries now requiring transfer of technology to local manufacturers; US export laws preventing technology transfer, or even product transfer without licenses being in place. IAVI’s IP policy works in a flexible manner, respects IP rights, analyses IP and obtains freedom to operate as required. IAVI will pursue reduction in trade barriers where appropriate. An analysis of possible instruments showed that owning the IP was the best alternative, whereas licensing IP rights gave much less control, and an access commitment was of minimal use.”
(<http://www.who.int/intellectualproperty/events/en/Dip-789-screen.pdf>)
- Holds one patent:
 - 1 [6,531,313](#)  [Invasive bacterial vectors for expressing alphavirus replicons](#)

International Partnership for Microbicides (IPM)

<http://www.ipm-microbicides.org/>

Goal: To accelerate the discovery, development and accessibility of microbicides to prevent transmission of HIV.

Governance, history, and main activities.

- IPM was formed in spring of 2002 as a result of the Rockefeller Foundation's Microbicide Initiative.
- Nine-member Board of Directors chaired by Mahmoud Fathalla, MD, former director of WHO's Special Programme of Research, Development, and Research Training in Human Reproduction.
- Zeda F. Rosenberg, ScD is CEO of IPM. Formerly a senior scientist at NIAID.
- IPM is organized into four areas: research and development; regulatory and clinical affairs; access; external affairs and policy.
- R&D philosophy is to establish collaborations for cost-efficient development of promising drugs; in some cases, this means that IPM will carry out a project internally.
- Main activities:
 - Assessing candidates across the microbicide portfolio
 - Technically and financially supporting high-priority candidates
 - Creating capacity for the microbicide field to optimize formulations and delivery technologies
 - Expanding clinical trial capacity
 - Developing new manufacturing facilities
 - Streamlining regulatory pathways and strengthening regulatory agency capacity to review and approve products
 - Coordinating efforts to prepare for worldwide access

Funding and relationships with academia, industry, and government.

- Has received about \$100 million total to date. Biggest funders include the Gates Foundation (\$60 million), Rockefeller Foundation (\$15 million), the UN, the World Bank, and the governments of Denmark, Iceland, the Netherlands, Norway, and the UK.
- In 2004, IPM entered into a material transfer agreement with GlaxoSmithKline (GSK) under which GSK will select and provide proprietary anti-HIV compounds to be tested for possible use as microbicides.
- Collaboration with Tibotec Pharmaceuticals to develop TMC120 (see *Products* below).
- Collaborates with the St. Georges Hospital in London for screening of potential microbicides.
- Hopes to build six to eight new phase III clinical trial sites in partnership with developing countries. Collaboration with the University of Ghent, the WHO, the University of Witwatersrand, the UK Microbicide Development Program, the European and Developing Countries Clinical Trials Partnership, the CDC, the Harvard School of Public Health, and IAVI is ongoing to identify and assess sites in countries including Rwanda, Ethiopia, Kenya, and Vietnam.

Product(s).

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- In March 2004, IPM and Tibotec Pharmaceuticals, a Belgian company, entered an agreement to develop TMC120. TMC120 was originally developed as an oral AIDS drug but has now been adapted into a gel that is in Phase I clinical trials.
- Supports the development of topical PMPA, an antiviral HIV drug in a broad collaboration including CONRAD, the NIH, and Gilead Sciences, Inc.

IP position.

- Requires that in exchange for investment in a product, private sector partners agree that a successful product will be made available in developing countries at a reasonable cost.
- Secured a royalty-free license from Tibotec Pharmaceuticals to develop and distribute TMC120 in poor countries.
- No U.S. patents held by IPM.

Malaria Vaccine Initiative (MVI)

<http://www.malariavaccine.org/>

Goal: To speed the development of an effective malaria vaccine.

Governance, history, and main activities.

- Launched in 1999; administered within PATH, with offices in Rockville (MD) and Seattle.
- Directed by Melinda Moree, PhD. Formerly worked at PATH and USAID.
- A Strategic Advisory Council composed of experts 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. Dr. Philip Dubovsky, MVI's Scientific Director, chairs the TAGs.
- Focuses more on vaccine development as opposed to vaccine discovery; also more on the parasite *P. falciparum* (more deadly, but less widespread) than *P. vivax*.
- Main activities. MVI has ten vaccine development projects around the globe. Two of those have clinical trials in Africa underway. Each project is managed by a Joint Product Development Committee, with representation from MVI and the partner(s) involved in that particular project. Nine projects target *P. falciparum* while one focuses on *P. vivax*.

Funding and relationships with academia, industry, and government.

- Initial grant of \$50 million from the Gates Foundation. Additional grant of \$100 million allocated in 2003. \$8 million from USAID.
- Extensive network of relationships through academia, industry and government. These are usually centered around each specific vaccine development project. For example, for pediatric clinical trials in Mozambique and The Gambia, MVI teamed with GSK, the Hospital Clinic of the University of Barcelona, Centre de Investigacao em Saude de Manhica, and Mozambique's Ministry of Health.

Product(s).

- Clinical trials in endemic countries:
 - Pediatric clinical trials on GSK's advanced malaria vaccine candidate. Previously shown to be safe and efficacious with adults and children. Phase II trial in Mozambique confirmed vaccine's safety and partial efficacy.
 - Phase I trials on adults and children in Kenya complete for MSP1 vaccine candidate developed by the Walter Reed Army Institute of Research.
- Clinical trials in developed countries:
 - Phase I clinical trials on Apovia Inc.'s MalariVax candidate vaccine were completed in Germany, the U.S., and the U.K.
 - Phase I clinical trials begun on several blood- and sexual-stage malaria vaccine candidates developed in partnership with the Malaria Vaccine Development Branch of NIAID.
 - Phase I trials on a series of malaria vaccines based on Oxxon Pharmaccines' "prime-boost" technology. In partnership with Oxford University.

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- Preclinical development and manufacturing
 - Three partnerships in Australia are moving forward five vaccine constructs designed to reduce the severity of malaria in children. Current focus is to optimize formulations and devise methods for manufacture before taking them into clinical trials.
 - MVI is working with the International Centre for Genetic Engineering and Biotechnology in New Delhi, India to develop a vaccine against *P. vivax*. Bharat Biotech International Ltd. Will manufacture the vaccine for pre-clinical testing.
 - Partnership with GenVec, Inc. and the US Navy Medical Research Center to develop and test multivalent, multi-stage malaria vaccines using GenVec's adenovirus vector technology.

IP position.

- Patents belongs to private partners; if they abandon commercialization, MVI retains back-up development and manufacturing rights.
- MVI is undertaking a study to explore how best to implement a patent pool for malaria-specific IP.
- Challenges related to IP:
- MVI has discovered, for example, that vaccine developers are reluctant to work with the MSP-1 malaria antigen. MSP-1 is a leading antigen with good immunogenicity and animal model data, but the presence of multiple patents with overlapping claims reduces its attractiveness. Engaging in MSP-1 commercialization would require a lengthy and complicated technology transfer process. Researchers tend to favor antigens that are in the public domain or that are owned by a single organization. Why does the IP landscape for MSP-1 not sort itself out through traditional channels such as technology transfer and the courts? Developers who want assurance of the rights to use MSP-1 would have to obtain licenses from no less than eight organizations. Though theoretically possible, a licensing transaction of this type would take years, require significant staff time, and cost hundreds of thousands of dollars in attorney fees. While companies routinely make such efforts on behalf of commercial products, the economics of malaria vaccines make developers more reluctant to invest in such cumbersome technology acquisition.
(<http://www.who.int/intellectualproperty/events/en/Dip-789-screen.pdf>)
- No U.S. patents held.