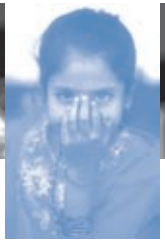

Global Health Partnerships and Academic Technology Transfer

MIHR
A STEP NEARER EQUITY

Centre for the Management of Intellectual Property in Health Research and Development

In collaboration with Technology Managers for Global Health,
A Special Interest Group within the Association of University Technology Managers

This booklet was prepared with the assistance of the Curriculum Planning Workgroup of the Technology Managers for Global Health.

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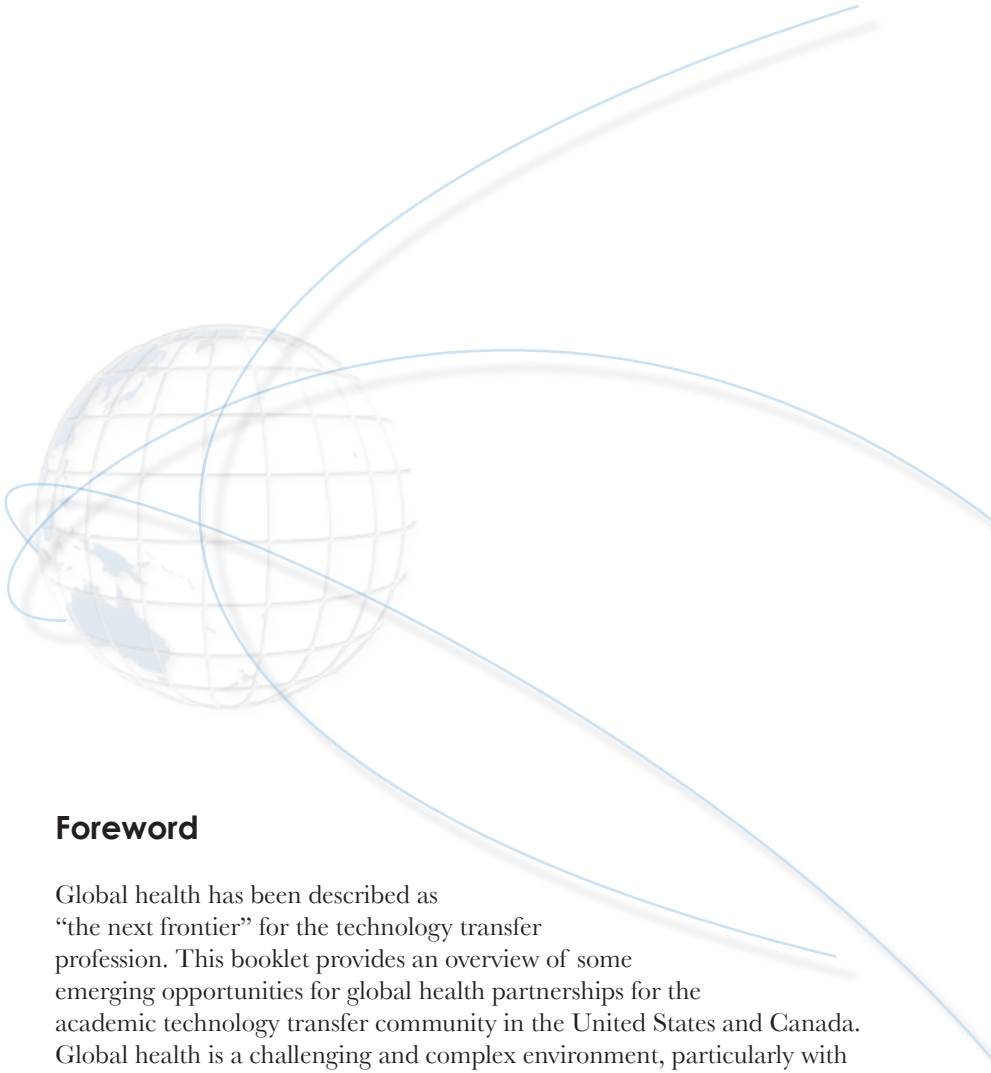


Foreword

Global health has been described as "the next frontier" for the technology transfer profession. This booklet provides an overview of some emerging opportunities for global health partnerships for the academic technology transfer community in the United States and Canada. Global health is a challenging and complex environment, particularly with regard to invention and intellectual property management issues. It is an evolving area, which can only benefit from the experience and expertise of a diverse body of university technology managers. Therefore, there is a need for a new cadre of university-based professionals to join forces and together identify, develop and implement new and creative strategies to promote global health equity. Raising awareness about global health disparities and highlighting some opportunities for individual managers are first steps in exploring how we may extend the impact of our professional work to global health settings. We are pleased to share with you a booklet that is intended for this purpose.

This booklet is not comprehensive in its coverage of these issues, but rather provides a brief overview that will hopefully encourage a wider dialogue within your institution and in your professional circles. In general, we seek to address global health disparities via creative management of:

(**a**) **Research outcomes:** New technologies and inventions that may lead to treatments for neglected diseases and other diseases that disproportionately affect the poor;

(**b**) **Partnership prospects:** New partners in different sectors and/or regions of the world that can further develop technologies of particular relevance to the developing countries, especially with those partners that facilitate research collaborations between and among public, private and/or non-profit entities that are addressing global health problems;

(**c**) **Licensing provisions:** Mechanisms that may assure access and promote further development and/or utilization of such technologies for the benefit of the poorer populations in developing countries; and

(**d**) **Professional development and networking:** Resource development and training programs that foster good practices in the ethical stewardship of intellectual property to promote global health equity.

To prepare this booklet, the Centre for the Management of IP in Health R&D (MIHR), teamed up with the Technology Managers for Global Health (TMGH), a special interest group within the Association of University Technology Managers. We are grateful to the Rockefeller Foundation for providing financial support toward this collaboration.

We hope that you find this booklet useful, and that you will join us in our TMGH efforts to connect up with a network of technology licensing professionals seeking to advance global health causes. Please feel free to contact Usha Balakrishnan at usha-balakrishnan@uiowa.edu with any feedback, comments or inquiries.

"MIHR, through its collaboration with TMGH, aims to advance innovative practices in the management of intellectual property to promote global health equity."

Richard Mahoney
Acting CEO, MIHR and member, MIHR Board of Trustees

"We are at a critical point in history where science, health and intellectual property meet. University technology managers can play a valuable role by using the tools of their trade to encourage the development of technologies that can have a profound impact on global health."

Maria Freire
President & CEO,
Global Alliance for Tuberculosis Drug Development,
and recipient of AUTM's 2002 Bayh-Dole award

For over a century, research universities and academic institutes and hospitals (collectively "universities") have advanced the frontiers of knowledge for the benefit of humankind. Valuable contributions to biomedical science have led to technologies that have improved the quality of life for many people. Despite these advances, diseases disproportionately burden the world's poor, resulting in tragically high mortality rates in the developing countries. Effective vaccines and drugs could save lives, reduce poverty, and help economies develop.

HIV/AIDS, tuberculosis, and malaria are among the world's biggest killers, and have a horrific impact on poor countries and poor people. Neglected diseases such as Chagas' disease or visceral leishmaniasis kill or disable millions of people, yet treatment options for all these diseases and more, are inadequate or non-existent because there is little economic incentive for the private sector to develop new drugs. Prevalence of all leading non-communicable diseases—such as diabetes, and heart disease—also is projected to increase substantially over the next two decades, with the majority of the burden falling on developing countries.

HIV/AIDS kills more people worldwide than any other infectious disease. Currently, 40 million people are living with HIV, 95 percent of whom live in the developing world. In many African countries, half of all 15-year-olds will die of AIDS before their 50th birthday.

Tuberculosis. The World Health Organization estimates that 200 million people will develop the disease and 35 million will die of it in the next 20 years. More effective, easier to use, and affordable treatments for multi-drug resistant TB are desperately needed, as TB patients worldwide are still treated with the same drugs that were discovered 40 years ago.

"Although intellectual firepower and research are the most potent weapons in a university's global health arsenal, the fruits of that research cannot be fully realized unless discoveries are managed skillfully in the larger context of international health research and global health needs."

Gerald T. Keusch
Assistant Provost for Global Health, Medical Campus
and Associate Dean for Global Health, Boston University, and member, MIHR Board of Trustees

Role of the University Technology Manager

While numerous factors contribute to today's global health disparities, modern research universities have a unique opportunity to build on their public missions and help lead the way in harnessing science to improve global health. Universities generate many new discoveries and embody a strong tradition of generating and disseminating knowledge for the public good. This tradition offers an opportunity to develop new management frameworks that address global health challenges.

Technology managers can support the translation of university-based discoveries into products that benefit global health through invention evaluation, patent filing decisions, licensing efforts and negotiating strategies. Given that technologies primarily useful to the poor in developing countries do not carry significant financial promise, university technology managers need to use new and innovative intellectual property (IP) management strategies and practices.

For example, they need to:

- Craft license terms designed to promote the development of—and assure access to—new technologies for the benefit of the poorer populations in developing countries

- Include license clauses that help ensure benefits to the public sector such as free samples for clinical evaluation in developing countries

- Explore an expanded landscape of potential technology development and licensing partners to include entities with a global health focus

Technology managers can also help to raise awareness among their faculty members, students, and administration on these issues, such that when IP arises that may be of importance to global health, proper consideration is given to access issues in deciding on strategies for development and in crafting agreements for the IP.

Technology Managers for Global Health (TMGH)

The need for technology managers to discuss, develop and implement new best practices for IP management was the rationale behind the formation in 2003 of the "Technology Managers for Global Health" (TMGH) as a Special Interest Group within the Association of University Technology Managers (AUTM). TMGH meets during the association's annual meeting with the goals of serving as a professional resource and a network for sharing experiences.

Centre for the Management of IP in Health R&D (MIHR)

MIHR was established in the United Kingdom in 2002 on the principle that "improved management of IP by the public sector is one way to achieve the goal of improving availability of health products needed in developing countries by the poor." MIHR has undertaken technology transfer training programs in South Africa, Egypt, and India. In addition, MIHR serves as a resource for licensing strategies and specific provisions that enhance public sector goals. These are described in greater detail in the "MIHR Handbook of Best Practices for the Management of Intellectual Property in Health Research and Development" (a hard copy of the Handbook is available upon request from MIHR at admin@mihr.org). Under a recent grant from the Rockefeller Foundation, MIHR and TMGH have teamed up to design and deliver new training curricula aimed at U.S. and Canadian university technology managers.

"Technology managers are key "gatekeepers," and their managerial role in facilitating timely interactions within the continuum of scientific R&D, discovery, and product development cannot be underestimated."

Usha R. Balakrishnan
Director, Office of Corporate Partnerships, The University of Iowa
and Founder, Technology Managers for Global Health

"Today, with all the wonders and promise of modern medicine, there is a growing sense that these inequities cannot be allowed to continue. University technology managers can play a valuable role in this effort."

Lita Nelsen
Director, MIT Technology Licensing Office,
and Past President, AUTM,
and member, MIHR Board of Trustees

Malaria. This parasitic disease is endemic in large parts of the developing world and is a leading killer in many poor corners of the world, especially sub-Saharan Africa. Malaria infects between 300 and 500 million people worldwide and kills between 1 and 2 million people each year.

Chagas' disease. A leading health concern throughout South and Central America, this disease infects between 16 and 18 million people each year and kills an estimated 45,000 people a year.

Visceral leishmaniasis. Afflicting roughly 1.5 million people, if left untreated, this disease is almost always fatal. Almost all of the 500,000 new cases arising from recurrent epidemics each year occur in the rural areas of the Indian subcontinent, Brazil, and Sudan.

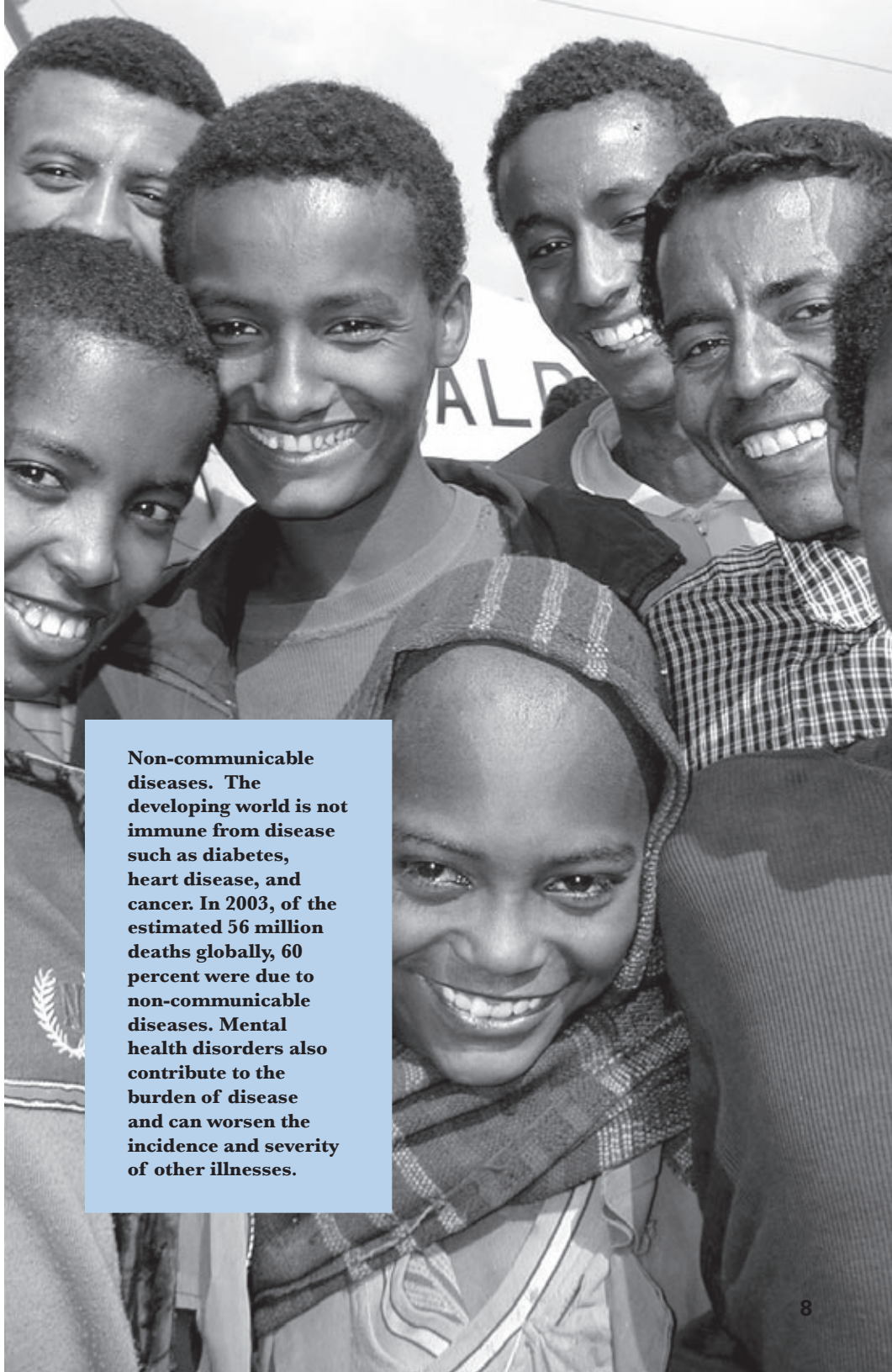
Emerging Opportunities in Global Health Partnerships

The past several years have seen the creation of unprecedented coalitions of institutions devoted to global health. Nonprofit organizations, foundations, pharmaceutical and biotechnology companies, government agencies, and volunteer charities are working to bring the benefits of medical science to developing countries. In particular, nonprofit international public-private partnerships (PPPs) have emerged, which mobilize the strengths of the private sector to develop technologies while ensuring accessibility for low-income populations. The Rockefeller Foundation and the Bill & Melinda Gates Foundation have played a leading role in supporting these PPPs, which serve as valuable partners for universities that are looking to transfer technologies with global public health potential. These PPPs have also garnered financial support from several governments and other foundations. For example:

- The Malaria Vaccine Initiative, based at PATH, seeks to accelerate the development of promising malaria vaccines and ensure their availability and accessibility in the developing world. Collaborating with government, academic and industry partners, as well as with other vaccine development programs and organizations, this initiative is engaged with more than a dozen partners in 10 vaccine development programs.

- The Global Alliance for Tuberculosis Drug Development seeks to develop new drugs that reduce the course of treatment to two months or less, overcome drug-resistant strains, and effectively treat latent TB. Since its creation in 2000, the TB Alliance has acquired and now manages a portfolio of 10 candidate TB drugs, half of which originated from university-based research.

- The International AIDS Vaccine Initiative (IAVI) is supporting a number of programs to accelerate the development and clinical testing of preventive vaccines for HIV, among them the Neutralizing Antibodies Consortium with five universities and the National Institutes of Health (NIH). The Consortium's university members entered into IP agreements providing IAVI with the option for a license to develop any invention from the consortium, to fulfill the mission of ensuring that developing countries can access future AIDS vaccines at reasonable costs.



Non-communicable diseases. The developing world is not immune from disease such as diabetes, heart disease, and cancer. In 2003, of the estimated 56 million deaths globally, 60 percent were due to non-communicable diseases. Mental health disorders also contribute to the burden of disease and can worsen the incidence and severity of other illnesses.

In addition to the work of global health PPPs, U.S. and Canadian institutions are working directly with developing country licensing and drug development partners. For example:

- The NIH Office of Technology Transfer licensed to PATH a vaccine conjugation technology for the development of a meningococcal vaccine in collaboration with the World Health Organization. The Serum Institute in India will manufacture the vaccine for eventual distribution in sub-Saharan Africa, the Middle East, Latin America and the Caribbean, and Eastern Europe.

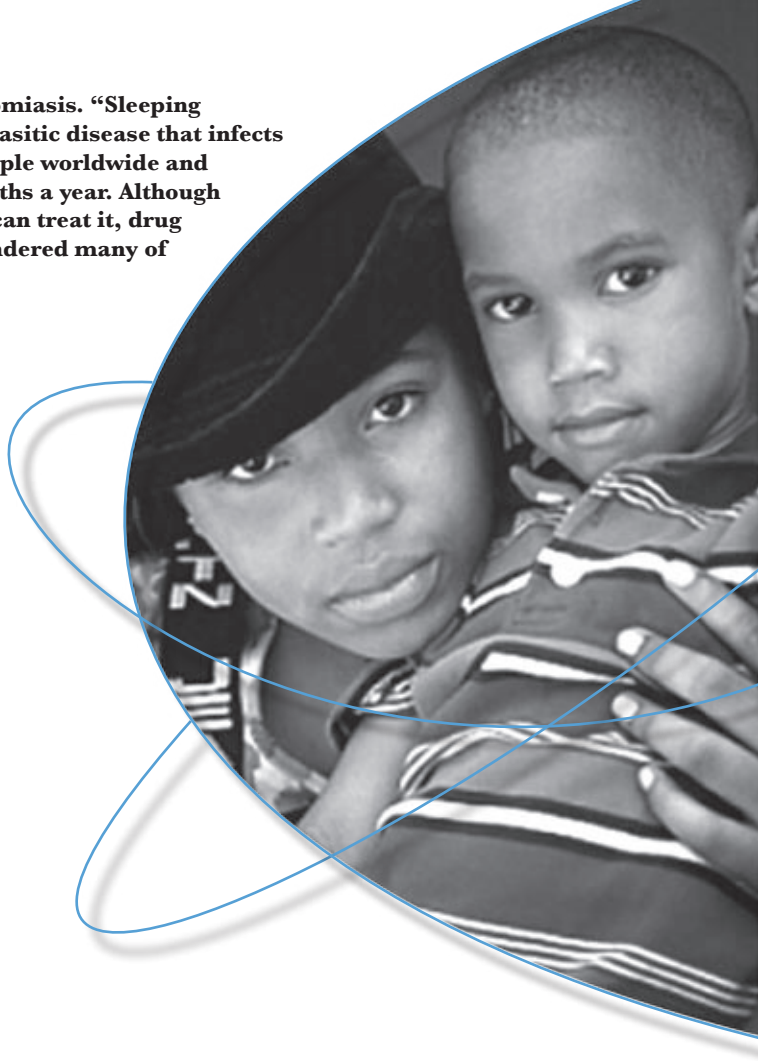
- In 2004, MIT licensed to Indian Immunologicals Ltd. (IIL) a human antibody production technology which IIL plans to use to develop an inexpensive rabies vaccine. India alone experiences over 30,000 deaths a year from rabies.

- Immtech International Inc., under license from a consortium of four U.S. universities (University of North Carolina at Chapel Hill, Georgia State, Duke, and Auburn) is developing certain dicationic compounds as therapies for various infectious diseases. One such compound is currently in clinical trials in the Democratic Republic of the Congo for the treatment of trypanosomiasis (African sleeping sickness).

- University of California, Berkeley and the Samoan government entered into an agreement for the development of antivirals from the bark of the mamala tree, which is indigenous to Samoa. Should Berkeley genetically engineer low-cost prostatin, an antiviral compound that could cure AIDS and other viral scourges, it will share revenue with villages, experts, and others in Samoa by distributing revenue to Seacology Foundation that in turn, distributes the revenue according to a specified formula.

Some private sector entities and industry trade associations have also launched significant new initiatives for neglected diseases. For example, BIO Ventures for Global Health, an offshoot of the Biotechnology Industry Organization, seeks to break traditional barriers to development by identifying viable market opportunities that may address unmet health needs of the developing world and encouraging new companies to enter the global health space.

African trypanosomiasis. "Sleeping sickness" is a parasitic disease that infects half a million people worldwide and causes 50,000 deaths a year. Although a range of drugs can treat it, drug resistance has rendered many of them ineffective.



"Despite the acute need for new drugs and vaccines to combat communicable diseases, historic mechanisms for the creation of new health technologies are unlikely to ensure the development and deployment of new and more effective products."

Chad Gardner
Associate Director for Health Equity,
The Rockefeller Foundation

Managerial Creativity to Promote Global Health Equity

In light of these innovative initiatives and successful experiences of university technology transfer offices, there are several ways technology managers can utilize novel vehicles for technology that has little financial return, but may have critical public health impact. These include:

- Assess current inventories of technologies that might be useful to organizations that are targeting health products for the developing world
- Incorporate creative licensing terms and conditions to support development for high impact/low profit technologies
- Expand beyond traditional strategies to include the global public-private partnerships and new research and development players in global health
- Seek out resources that guide the crafting and development of new licensing strategies
- Share your experiences with other professional colleagues.

Professional Technology Managers:

Are you intrigued by these topics and would like more information?

Send your inquiries, suggestions and comments.

Would you like to share your experiences with interested colleagues?

Volunteer to speak at professional society meetings or provide brief summaries/case studies.

Would you like to join a network of colleagues seeking to advance global health causes?

Participate in Technology Managers for Global Health.

For further information go to www.tmgh.org or contact:

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