



Partnerships Clinic

“Innovative Partnerships to Address Research and Treatments for Neglected Tropical Diseases”

Organized by the World Intellectual Property Organization (WIPO)
Wednesday, 24 April 2013
United Nations Headquarters, New York
3:00-5:00 p.m.

Background/Context

One in seven people suffer from at least one Neglected Tropical Diseases and 2.5 billion people are at risk. And yet, because of market failure, for many decades there was little or no research into improved diagnosis and treatment. Much has been done in the past ten years to address this. The key to success, since 2000, has been the creation of new approaches via Product Development Partnerships. New partnerships such as the Drugs for Neglected Diseases Initiative, Medicines for Malaria Venture and WIPO Re:Search are a few examples. These are key to finding solutions for these symptoms of social exclusion. But much more can be done.

What are Neglected Tropical Diseases?

Neglected Tropical Diseases (NTDs), are primarily symptoms of social exclusion. Director General of the World Health Organization, Margaret Chan, calls neglected tropical diseases “ancient companions of poverty” affecting as they do the economically and politically marginalized. While they are a medically diverse group of diseases, they share a number of common features:

Primarily associated with poverty: The most striking common feature of the NTDs is that they affect almost exclusively poor populations¹ living in settings where poverty is widespread and resources, or access to livelihood opportunities, are scarce.

¹Hotez PJ, Fenwick A, Savioli L, Molyneux DH. Rescuing the bottom billion through control of neglected tropical diseases. *Lancet*. 2009;373:1570–1575

The World Health Organization identifies 17 Neglected Tropical Diseases:

Buruli ulcer disease (*Mycobacterium ulcerans* infection), Chagas disease (American trypanosomiasis), cysticercosis, dengue, dracunculiasis (guinea-worm disease), echinococcosis, endemic treponematoses, foodborne trematode infections, human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy (Hansen disease), lymphatic filariasis (elephantiasis), onchocerciasis (river blindness), rabies, schistosomiasis (bilharziasis), trachoma, and soil-transmitted helminthiasis.

Some forms of these diseases (e.g. African sleeping sickness and leishmaniasis) are 100% fatal if not detected and treated in time. All of the other diseases debilitate, blind or maim, permanently curtailing human potential.

[Sustaining the drive to overcome the global impact of neglected tropical diseases](#) World Health Organization January 2013

Affecting politically and economically marginalized groups: Affected populations often live in remote rural areas, in conflict zones, or in urban slums and have little political voice².

Association with Stigma and Discrimination: Many NTDs produce disfigurement and disability, leading to stigma and social discrimination. Their impact disproportionately affects women³

Predominantly tropical: Unlike influenza, HIV/AIDS, and malaria, NTDs generally do not travel and seem to present little threat to the inhabitants of high income countries.⁴

Although medically very diverse, because of their strong link to poverty, they frequently overlap geographically. They tend to cluster together in places where there is poor and substandard housing, drinking water is unsafe, and sanitation is poor. They are prevalent where access to health care is limited or non-existent, and insect vectors are constant household and agricultural companions. This geographical overlap means that people are often affected by more than one disease.

It has been demonstrated that typically diseases associated with extreme poverty are in many cases effectively eradicated as populations grow richer. For example, in 1910 in the United States, hookworm, a soil-based helminth, was endemic, especially in the southern States where in the warm humid climate and with no effective sanitation or sewage treatment, the larvae thrived well. The Rockefeller Sanitary Commission for the Eradication of Hookworm Disease led a programme of public education on "the dangers of soil pollution and how to avoid them" as well as funding school sanitation. By 1915 hookworm had largely been eradicated in the US. However, it is

²Pecoul B. Government action needed to step up research and development for world's most neglected diseases. *Expert Review of Anti-infective Therapy*. 2005;3:841–843

³Hotez PJ. Stigma: The stealth weapon of the NTD. *PLoS Neglected Tropical Diseases*. 2008;2:e230.

⁴Pecoul B. 2005

estimated⁵ that today more than 576 million people are infected, primarily in south Asia and sub Saharan Africa. While it is rarely fatal in developed countries, it is a leading cause of child morbidity in Least Developed Countries.

The World Health Organization has an aggressive strategy to bring these diseases under control using a combination of five public health programmes: preventive chemotherapy; innovative and intensified management; vector control and pesticide management; safe drinking water, basic sanitation and hygiene services, and education; and veterinary public-health services⁶. But this strategy needs to be underpinned by expanded research to ensure that new products are developed for preventing, diagnosing and controlling these diseases.

Neglected Tropical Diseases: A market failure

While new products are a critical element in tackling these diseases of poverty, historically R&D investment has been very low. Between 1975 and 2000 it is estimated that only 10% of global R&D resources were directed at diseases accounting for 90% of the global disease burden⁷. The result was that in this 25 year period, only 13 new drugs for neglected diseases were approved for use.

A number of reasons accounted for this market failure. The marginalized nature of the affected populations is one. Ineffective regulatory infrastructures are another. But the prime reason was that while these diseases affect millions of patients, their lack of ability to pay for market-financed innovative products meant there was no market for drug developers to exploit. The market incentives were insufficiently strong to drive investment in innovation.

Partnership as a solution

In the past 15 years, there has been a transformation in the approach to research into NTDs. Driven by a changing public perception about global equity and global social inclusion, and increasing public awareness, there was a raised political pressure to address the health needs of the worlds poorest communities. This happened at a time when research departments from a diverse set of private sector actors were consolidated into a few privately funded centres of excellence capable of carrying out leading edge research. There was also a new influx of public and philanthropic funds into NTD research. These combined in new ways to create a new range of public-private Product Development Partnerships (PDPs), either tackling specific diseases - such as the Medicines for Malaria Venture – or using specific tools such as the Medicines Patent Pool.

⁵Bethony J, Brooker S, Albonico M, et al. (May 2006). "Soil-transmitted helminth infections: ascariasis, trichuriasis, and hookworm". *Lancet* 367

⁶Sustaining the drive to overcome the global impact of neglected tropical diseases" World Health Organization, January 2013

⁷Nwaka S and Ridley R (2003). 'Virtual drug discovery and development for neglected diseases through public-private partnerships.' *Nature* 2 (November): 924.

Overcoming market failure: The role of partnerships

These new PDPs have come to occupy an extremely important place in the landscape of NTD research. PDPs have been successful in mobilizing resources focused on NTDs both from public and private sectors – and notably too from philanthropic organizations – to the extent that they now 38% of global funding (\$1.2billion). But PDPs are also important because they allow development risk to be shared by the private sector in two key ways⁸. Firstly, a new ‘no profit-no loss’ model adopted by companies required them to reduce their R&D costs to a minimum in order to deliver neglected disease products at low or no markup. Companies therefore changed their approach to PDPs in order to maximize the impact of their R&D spend. Secondly, late stage clinical trials, drug registration and dissemination become progressively more expensive. So while early stage research remained in house, partnership with PDPs became essential to bring products successfully to the market.

Today PDPs are involved in the vast majority of NTD research. The International Federation of Pharmaceutical Manufacturing Associations estimates that in 2012, of 132 R&D projects listed in its status report, 112 were PDPs involving IFPMA member companies, the remaining 20 (15%) projects were company-only undertakings.⁹

The result is an increasingly promising pipeline of new products to tackle NTDs. The total number of active R&D projects on NTDs, malaria and tuberculosis has progressively risen since 2005 from 32 to 132 in 2012. Furthermore, since 2005, six new medicines and vaccines have been approved for use.

Growing R&D pipeline by industry and partners for neglected diseases

	2005	2006	2007	2008	2009	2010	2011	2012
Medicines	32	43	50	58	75	91	82	117
Vaccines	(not counted)	6	8	9	9	11	11	15
Total projects	32	49	58	67	84	102	93	132

Source: International Federation of Pharmaceutical Manufacturing Associations

Catalyzing partnerships: Doing more with more

The World Health Organization (WHO) is clearly at the centre of United Nations efforts to combat these diseases. However, in order to provide sufficient incentive to promote research the partnership approach is essential. To catalyze such partnerships, there is a responsibility on all UN programmes, funds and agencies to work with philanthropic partners, academia and the private sector to build the necessary networks. As an example of what can be achieved, at the World Intellectual Property Organization (WIPO), we have established a new partnership, WIPO Re:Search, with WHO as Technical

⁸Moran M. et al “The new Landscape of Neglected Disease Drug Development” September 2005

⁹ “Pharmaceutical R&D Projects to Discover Cures for Patients with Neglected Conditions”, IFPMA December 2012

Advisor, in order to spur collaborative research into NTDs. Through WIPO Re:Search, several of the world's leading research and development-based pharmaceutical companies and other research and academic institutions make available results and know how that might be of value to other researchers in the field. The searchable, public database provides information on the intellectual property available for licensing, as well as services and other technology or materials not necessarily protected by intellectual property. Researchers working to advance the development of new drugs, vaccines, or diagnostics for neglected tropical diseases can explore the database for any assets that can help advance their work.

The WIPO Re:Search database of available intellectual property assets and resources, facilitates the creation of new partnerships. The challenge across the UN System is to take the next steps to facilitate more partnerships for research into Neglected Tropical Diseases.