



**WIPO Re:Search
Strategic Plan 2017–2021**



WIPO | Re:Search

Sharing Innovation
in the Fight Against
Neglected Tropical Diseases

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WIPO Re:Search Strategic Plan 2017–2021

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First published 2017

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CH-1211 Geneva 20, Switzerland



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Printed in Switzerland

Vision:

Improved global health through innovation that mobilizes intellectual property and the power of private and public sector collaborations.

Mission:

Accelerate the discovery and development of technologies for neglected tropical diseases, malaria and tuberculosis by sharing intellectual property with the global health research community, catalyzing and fostering global health collaborations, and contributing to capacity-building in developing countries.

Foreword by Francis Gurry, Director General, WIPO

I am pleased to provide this brief introduction to the WIPO Re:Search Strategic Plan, 2017-2021. The World Intellectual Property Organization (WIPO), BIO Ventures for Global Health (BVGH) and the original 31 Members launched WIPO Re:Search with great ambition and more than a little hope in the fall of 2011. It is rare that one can honestly say that even one's greatest expectations have been exceeded. Thanks to the dedication and efforts of everyone involved in the project, this is indeed the case. Of particular note are the tireless work of BVGH, the Partnership Hub Administrator, the commitment of the Members, the direct support of several Member States, and of course the dedication of WIPO staff to this instructive example of how the United Nations can bring together a range of public and private entities in pursuit of a common, humanitarian goal.

In the case of global health, a legitimate role of the United Nations is to sponsor partnerships that address human and social needs neglected by market forces. WIPO is the United Nations specialized agency providing the global forum for intellectual property (IP) services, policy, information and cooperation. WIPO believes that IP is a powerful tool for stimulating innovation. WIPO Re:Search is our principal effort to ensure that IP supports and stimulates advances in global health research, and the IP policies of WIPO Re:Search are designed to ensure access by the poor in developing countries. Neglected tropical diseases (NTDs), malaria, and tuberculosis (TB) are examples of devastating conditions that disproportionately affect the poorest and most disadvantaged among us. Indeed, a wide body of literature describes NTDs as both a cause and effect of the vicious cycle that keeps people entrapped in poverty. In this case, the market-based incentives that drive much of

pharmaceutical research and development (R&D) are inadequate to attract the necessary investment into new product development.

WIPO Re:Search fills an important gap by facilitating access to valuable IP and by stimulating early stage research on promising leads. The project's Members, particularly the private sector companies, have vast inventories of compounds, stores of knowledge including scientific expertise, regulatory data, and much more, that they are willing to share with qualified researchers working on NTDs, malaria and TB. Yet, without an organizing framework, the matching of providers of pharmaceutical IP with researchers is inefficient, or does not happen at all. With the organizing framework of WIPO, and the matchmaking services of BVGH, WIPO Re:Search acts as a catalyst for increasing the amount of global R&D directed at NTDs, malaria and TB.

In its first five years, WIPO Re:Search has quadrupled its membership, facilitated 112 collaborations, each of which involve valuable IP, and supported capacity building through research sabbaticals of six developing country scientists at the laboratories of developed country Members. Going forward, the challenges, as detailed in the Strategic Plan, are to build on these achievements and to determine how to provide further support to collaborations that show promise for further development.

WIPO is proud to make its contribution to the global efforts, building on its expertise in IP to ensure that the IP system delivers benefits to all and especially the poor.

Francis Gurry

Foreword by Jennifer Dent, President, BVGH

WIPO Re:Search was launched in October 2011 with the bold and ambitious mission of demonstrating the vital role of intellectual property (IP) in catalyzing innovation and product development for malaria, tuberculosis and neglected tropical diseases.

More than five years later, I am very proud to say that WIPO Re:Search – now a global network of more than 120 organizations across over 35 countries – is meeting this mission, while also advancing United Nations Sustainable Development Goals 3 (Good Health and Well-Being) and 17 (Global Partnerships). Importantly, WIPO Re:Search is sending a strong message to governmental, policy, and non-profit research communities worldwide that IP is a critical tool in the arsenal against poverty-related diseases. Specifically, Member’s IP assets have been deployed in 112 research collaborations spanning 14 diseases; 15 of these collaborations have advanced to the next stage of product development. Further, six African scientists have received high-level training in neglected disease product discovery and development at leading biopharmaceutical companies and universities.

In advance of our fifth anniversary, the World Intellectual Property Organization (WIPO, the Secretariat), BIO Ventures for Global Health (BVGH, the Partnership Hub), and the WIPO Re:Search Advisory Committee initiated a strategic planning process, to ensure that WIPO Re:Search continues to achieve its mission and contribute to the dialogue around IP and access in a global health landscape that has changed significantly since 2011.

Following internal discussions and input from Members and external stakeholders, we are pleased to present the WIPO Re:Search Strategic Plan 2017-2021. As noted within, BVGH will implement

a more targeted approach to collaboration formation to address priority global health needs. We will prioritize and provide enhanced support to the most promising product development collaborations within the WIPO Re:Search portfolio. Other key objectives include supporting the development of research and IP management capacity at Member organizations in low- and middle-income countries, and increasing public visibility around the role of WIPO Re:Search in global health innovation.

We are confident that this strategic roadmap will position WIPO Re:Search to celebrate even greater successes at the 10-year milestone, and we look forward to continuing to partner with our valued Members and external stakeholders as we work toward our common goals.

Jennifer Dent

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Executive Summary

Vision:

Improved global health through innovation that mobilizes intellectual property and the power of private and public sector collaborations.

Mission:

Accelerate the discovery and development of technologies for neglected tropical diseases, malaria and tuberculosis by sharing intellectual property with the global health research community, catalyzing and fostering global health collaborations, and contributing to capacity-building in developing countries.

WIPO Re:Search Strategic Plan 2017–2021

This Strategic Plan is both the result of extensive internal discussions involving the World Intellectual Property Organization (WIPO, the Secretariat), BIO Ventures for Global Health (BVGH, the Partnership Hub Administrator) and the WIPO Re:Search Advisory Committee, and of several rounds of consultations with Members of WIPO Re:Search. The preparation of the plan also benefitted from inputs from external stakeholders, and is anchored in, and builds on, the WIPO Medium-Term Strategic Plan (2016-2021).

The creation of WIPO Re:Search was driven by two inter-related goals. The first is to demonstrate that the intellectual property (IP) system can and does work to stimulate investment in innovation. It largely explains why WIPO, as an organization with no direct responsibility for health, sponsors a global health program. The second is to catalyze more research on neglected tropical diseases (NTDs), malaria and tuberculosis (TB). There is a dearth of investment in new and better medicines for these diseases.

It is timely to prepare a strategic plan to ensure that WIPO Re:Search contributes effectively to the continuing debate on IP and health; takes account of the changing global health research and development (R&D) landscape; and contributes to the achievement of the United Nations (UN) Sustainable Development Goals (SDGs).

There is continuing debate about IP, innovation and access, with disagreement as to whether IP is a barrier or a facilitator. WIPO Re:Search contributes to the policy discussion by providing tangible evidence that the IP framework facilitates access to health technologies and thus enables more R&D, even in neglected fields. Moreover, on the issue of R&D itself, WIPO Re:Search adds to the range of investments in NTDs, malaria, and TB, precisely because its Members are reassured about sharing IP assets within a mechanism that respects IP. While important progress has been made in some NTDs, malaria and TB, major challenges remain and there is a continuing need for new vaccines, drugs and diagnostics. By contributing tangible results, WIPO Re:Search serves the direct need for more products while also sending a constructive message about IP and health.

WIPO Re:Search bases its continuing activities on a belief in the positive value of IP, the need for partnering among various actors in innovation, a long-term perspective of potential contribution to product development, the opportunity to mobilize resources, and the value of research. After five years of operation, it is timely to build on the achievements of WIPO Re:Search and devise a strategy for its continued success.

WIPO Re:Search has an outstanding record of success. As of April 2017, it has established 112 collaborations, of which 34 are ongoing. The establishment of these collaborations and the continuation of many have demonstrated that IP is not a barrier to upstream research on NTDs, malaria and TB. Furthermore, membership has grown from 31 to 126 organizations, representing 35 countries. WIPO Re:Search has carried out a comprehensive communication and advocacy program and has funded and undertaken capacity-building for developing country scientists.

Over the next five years, partnerships will continue to be central to WIPO Re:Search. BVGH will implement a more process-driven and targeted partnership development approach to link R&D programs with gaps and disease burdens. WIPO Re:Search, however, may significantly expand activities with respect to IP by working, upon request, with partners to provide input regarding appropriate IP management strategies. Contingent upon additional funding, WIPO Re:Search hopes to expand capacity-building programs and provide limited financial support to some collaborations to advance their research.

WIPO Re:Search will seek to achieve four Strategic Goals by executing the following Implementing Activities:

Strategic Goal No. 1:

Use IP assets to advance R&D for NTDs, malaria, and TB through collaborations

Implementing Activity 1.1:

Establish and maintain, in collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR) and others, as appropriate, a landscape analysis of technologies (including target product profiles [TPPs]) for each priority disease to help guide priority setting and collaboration formation.

Implementing Activity 1.2:

Establish new collaborations that address priority needs and provide assistance and support to ongoing partnerships, as required.

Implementing Activity 1.3:

Expand the number of company Providers who can offer assets and support for the operations of WIPO Re:Search and expand the number of Members, especially from developing countries, that contribute needed capabilities. New Members will be recruited to meet needs for addressing particular diseases or technologies and to increase membership from Africa, Asia and Latin America.

Implementing Activity 1.4:

Provide comprehensive IP management assistance to partnerships that are moving toward downstream product development.

Strategic Goal No. 2:

Accelerate the advancement of promising compounds or leads

Implementing Activity:

Accelerate progress in a selected group of collaborations by assisting collaborators to obtain grants from donor agencies. The highest priority will be those projects with the potential for the compound or lead to move rapidly to later stages of evaluation.

Strategic Goal No. 3:

Enhance global capacity for IP management and biomedical R&D

Implementing Activity:

Support capacity development of Member organizations, from developing countries and academic institutions, by strengthening IP management capabilities. Also provide to them research fellowships for capacity-building at leading research centers.

Strategic Goal No. 4:

Communicate the beneficial role of IP in innovation for NTDs, malaria, and TB

Implementing Activity:

Increase dissemination of information about the role of IP for R&D in NTDs, malaria, and TB; the potential technologies to combat these diseases; and the specific contributions of WIPO Re:Search. Also leverage the capacity of Members to disseminate information about WIPO Re:Search.

WIPO Re:Search will set priorities according to burden of disease, need for new or improved technologies, shortfalls in resources, availability of IP, technological potential of available resources, and capabilities of potential partners. For the near-term, WIPO Re:Search intends to maintain its current disease priorities.

To achieve its Strategic Goals, WIPO Re:Search will have programs in partnering, IP management, funding of research projects, capacity-building and communications. The funding of research projects and capacity-building will be subject to raising additional resources. It will continue to collaborate with key organizations in both the public and private sectors. The programs of WIPO Re:Search are carried out through the coordinated work of WIPO and BVGH.

WIPO Re:Search will continue to be evaluated against Milestones through WIPO mechanisms, and regularly reviewed by Members, the Advisory Committee, and the Board of BVGH.

The WIPO Re:Search expenditures have grown since its launch in late 2011, with a direct program expenditure of 1.7 million Swiss Francs in 2016. These expenditures are composed of allocations from WIPO's regular budget, contributions from Member States through the Funds-in-Trust program (Governments of Australia and Japan), and substantial contributions from the funding Members of WIPO Re:Search (Eisai, GlaxoSmithKline, Johnson & Johnson, Merck KGaA, MSD, Novartis, Pfizer, Sanofi and Takeda) to the Partnership Hub at BVGH. To implement this Strategic Plan, WIPO Re:Search will need to substantially expand this funding base.

1. Introduction

1.1 Context

Over a billion individuals globally are afflicted with one or more neglected tropical diseases (NTDs). However, because the majority of those affected are poor and reside in low- and middle-income countries (LMICs), investment in research and development (R&D) for new products for these conditions is not commercially viable for the private sector. As a result, many of the 19 NTDs lack modern, safe, effective and affordable products to prevent, diagnose and treat them (see Section 1.2). Given that the private sector's priorities lie elsewhere (in non-communicable diseases [NCDs], for example), new models of partnership and product development have evolved in the last 20 years to stimulate R&D for NTDs.

The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations (UN) with 189 Member States¹ and is the global forum for intellectual property (IP) services, policy, information and cooperation. WIPO is committed to working with developing and least developed countries to enable them to reap benefits from the IP system and to enhance their participation in the global innovation economy.

BIO Ventures for Global Health (BVGH) was established in 2004 by the Biotechnology Innovation Organization (BIO) to engage BIO stakeholders – biopharmaceutical, diagnostic, and life science companies – in meaningful initiatives and programs to impact global health. BVGH focuses its activities on three core areas: establishing collaborations to accelerate product development for diseases of poverty, building biomedical R&D capacity in Sub-Saharan Africa, and enabling access to innovative medicines.

The creation of WIPO Re:Search in 2011, with the initial involvement of 31 Members from the public and private sectors, was based on two interrelated considerations. The first was to demonstrate that the IP system can and does work to stimulate investment in innovation, although at times, such as in the case of NTDs, there is a need to facilitate creative, non-commercial deployment of IP when there is no obvious economic reward. This first consideration largely explains why WIPO, as an organization with no direct mandate for global health, sponsors a global health program. The second is to catalyze more research on NTDs, malaria and tuberculosis (TB). These principles are detailed in the key founding documents, namely:

- the WIPO Re:Search Guiding Principles (see Box 1 and Annex 1); and
- the Memorandum of Understanding (MoU) between WIPO and BVGH (see Annex 2).

Box 1: The IP Policy of WIPO Re:Search

With the ultimate aim of enabling access to medicines, all Members agreed to abide by the WIPO Re:Search Guiding Principles and to incorporate these into their research collaboration agreements. In these Guiding Principles, IP has been defined to include patent and related registered rights, know-how, manufacturing processes, and regulatory data and the corresponding physical materials, such as proprietary compounds and technologies.

These Guiding Principles require that any products resulting from research on licensed IP will be distributed free from IP royalties derived from sales in the 49 least developed countries and that Members will consider, in good faith, access to any products in all other developing countries. Such licenses, issued on a case-by-case basis, are to be negotiated in good faith, taking into consideration the burden of disease and economic development. It is important to note that Providers will not make any claims to rights in new IP, materials or derivatives of materials generated by a User under a license agreement (i.e. no reach-through).

It is timely to prepare a Strategic Plan for four reasons that reflect a changing world:

1. The UN has launched the Sustainable Development Goals (SDGs); they are the framework for the work of the UN and the global health community. SDG 3 is to “Ensure healthy lives and promote well-being for all at all ages” and includes target 3.3, to “end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.” WIPO Re:Search contributes to the achievement of the SDGs, especially target 3.3.
2. Based on the success of the first five years of WIPO Re:Search, WIPO, as a specialized agency of the UN, has made an institutional commitment to maintain and further develop WIPO Re:Search and thus a commitment to contribute to global health efforts. In addition, BVGH, a results-oriented non-profit organization with close ties to the health industry which administers the Partnership Hub of WIPO Re:Search, has greatly expanded its role as an international actor in global health.

¹ www.wipo.int/members/en/

3. The debate on the role of IP in health innovation and access to medicines continues and is accompanied by high-level multi-sectorial discussions with proposals for modifications of how IP is used. WIPO is the global forum for IP services, policy, information and cooperation. As such, it will continue to play a role in these discussions on global health through WIPO Re:Search and other activities. The tangible, results-oriented approach of WIPO Re:Search provides a sound platform for communicating the positive relationship between IP and global health.
4. The global health environment continues to rapidly evolve, including some successes in the control of NTDs, malaria and TB, and emerging priorities such as NCDs, and an aging population. While WIPO Re:Search and its Members will continue to take note of the evolving landscape, the focus remains on NTDs, malaria and TB, and the positive role that IP plays in catalyzing R&D.

1.2 The changing environments of IP and research on NTDs, malaria and TB

Intellectual property

WIPO Re:Search is an innovative initiative to promote R&D partnerships based on voluntary licensing of IP assets.

Despite the broad range of diverse initiatives and some successes, NTDs are still neglected diseases and for several of the diseases, there has been no significant progress, e.g., in terms of new and better treatments or vaccines. Even though there is increased policy awareness for IP, there is a continuing policy debate on new models to overcome traditional gaps in innovation and new ways to make medicines available. This debate has evolved from the 1990s and a focus on patents exemplified by the phrase “patents kill” to a broader assessment of how IP in its many forms – such as patents, trademarks, confidential data and know-how – may affect access to new health technologies by people in developing countries.

As a public sector program concerned with the health of the poor in developing and least developed countries, the key comparative advantage of WIPO Re:Search is its ability to work with private industry on issues of IP, innovation, and access to medicines. WIPO Re:Search will continue to emphasize access by the poor in this work.

Policies on NTDs, malaria and TB research

In 2010, WHO highlighted 17 bacterial, parasitic, and viral tropical diseases it deemed to be “neglected”. These diseases disproportionately affect the poor; cause significant morbidity and mortality; and lack safe, effective, and affordable drugs, vaccines, and diagnostics. In 2012, a number of international organizations, foundations, governments, and pharmaceutical companies met in London, the United Kingdom, and pledged to support the control, elimination, or eradication of at least ten NTDs by the end of the decade. The London Declaration has been endorsed by 80 organizations but, because it focuses especially on product donations, has so far not led to greatly increased funding for product development for NTDs (see Annex 3 for an overview of research and product needs in NTDs, malaria and TB). Priority for research on NTDs was recently further emphasized in the SDGs. Adopted in 2015, the SDGs succeed the already ambitious UN Millennium Development Goals (MDGs). They focus on ending poverty, hunger, inequality, and injustice; taking action on climate change; improving education; and, under SDG 3, ensuring health and well-being for all at every stage of life by 2030. This ambitious goal can only be reached through a global effort that includes further innovation in treatments for those diseases. The SDGs also call for collaborative partnerships and address all countries and stakeholders.

There are several other groups working in this space and WIPO Re:Search seeks to provide strong and unique contributions to this issue. See Annex 4 for a discussion of other IP sharing platforms illustrating the complementary role of WIPO Re:Search with those platforms.

2. Accomplishments

Of most importance, WIPO Re:Search has demonstrated that IP is not a barrier to upstream research on NTDs, malaria and TB.

As of April 2017, 112 collaborations focused across 14 diseases have been established. Of the 107 Provider and/or User Members, 56 from 19 countries have participated in a collaboration. Drugs have been the primary focus and most of the assets shared have been compounds. 34 collaborations are ongoing. A description of the partnerships is provided online.² WIPO Re:Search has grown from 31 Members to the present 126 Members from 35 countries, including 30 from Africa. WIPO and BVGH have issued a variety of publications to disseminate information about WIPO Re:Search and to report on results obtained including from the collaborations. Six capacity-building fellowships were awarded to scientists from Africa.

An External Strategic Review carried out in 2015 summarized a number of important successes of WIPO Re:Search:

- It has attracted the support of several of the world's largest pharmaceutical companies, that have contributed resources for the operation of WIPO Re:Search and have made available proprietary technologies, supportive technical information, research compounds and know-how.
- It has assembled a large database of potentially valuable assets that might be useful in the development of products for NTDs, malaria, and TB.
- The Partnership Hub Administrator, BVGH, is widely recognized as capable, energetic, and productive.
- It has identified a significant number of research centers and university laboratories in both developed and developing countries that are interested in participating in the WIPO Re:Search platform.
- It has fostered the formation of a significant number of partnerships between the pharmaceutical companies and the research centers and university laboratories.
- It has supported capacity-building in developing countries by providing opportunities for developing country scientists to work in laboratories of the pharmaceutical companies and developed country research centers.

In addition, WIPO Re:Search has made value-added contributions to Members in several areas: collaboration and partnership development, communications and advocacy, and access to information (see Annex 5 for the value proposition).

The External Strategic Review pointed to opportunities to expand WIPO Re:Search in two valuable areas: contribution to a pool of funds to support research projects resulting from the collaboration agreements and capacity-building, particularly in developing countries.

The WIPO Re:Search website³ provides more detail on the accomplishments to date; see also "Strategic Review of WIPO Re:Search."⁴ For illustration purposes, Box 2 provides a summary of one of the partnerships.

This Strategic Plan builds on the progress made.

² See www.wipo.int/export/sites/www/research/docs/collaboration_agreements.pdf

³ See www.wipo.int/research/en/

⁴ See www.wipo.int/export/sites/www/research/en/docs/wipo_research_external_review.pdf

Box 2: An example of a partnership

Title: Screening Hsp90 inhibitors against juvenile and adult *Onchocerca* with counter-screen against *Loa loa* microfilariae

Partners: Merck KGaA, Darmstadt, Germany and the University of Buea, Cameroon

Need: Onchocerciasis is the second leading infectious cause of blindness globally; however, there is currently no available treatment that can cure or resolve the disease. The only recommended drug on the market, ivermectin, is only effective against juvenile forms of the parasite, and must be taken for up to 14 years until the adult worm dies, and concomitantly kills *Loa loa* microfilariae, which can cause severe adverse effects in humans. A drug targeting both the juvenile and adult *Onchocerca* that does not affect *Loa loa* is needed.

Collaboration description:

- Heat shock protein 90 (Hsp90) is a molecular chaperone involved in the trafficking of proteins in the cell; it is one of the most highly expressed cellular proteins across all species and is essential in all eukaryotes.
- Previous work has demonstrated that Hsp90 inhibitors are potent against the microfilariae and adult forms of *Brugia pahangi*, a microfilarial nematode similar to *Onchocerca volvulus*.
- Merck KGaA has 2.5 million diverse small molecules in its portfolio, including Hsp90 inhibitors.
- BVGH connected Merck KGaA with Dr. Fidelis Cho-Ngwa at the University of Buea, who had developed a highly efficient, medium-throughput, whole parasite assay to screen small molecule compounds that selectively kill both microfilariae and adult *O. volvulus* without also killing *Loa loa* microfilariae.
- Dr. Cho-Ngwa is currently screening Merck KGaA's subset of Hsp90 inhibitors to identify those that selectively inhibit adult and juvenile *Onchocera* but not *Loa loa* microfilariae.

Current status: University of Buea and Merck KGaA are jointly pursuing the best leads identified from initial screens of two subsets of inhibitors.

Through BVGH FundFinder, the BVGH team supported the collaborators to apply for and secure funding from the Wellcome Trust to advance this research program.

3. Principles underpinning the continued operation and expansion of activities

Based on the first five years of activity, it is possible to define several principles for the continued operation and expansion of WIPO Re:Search. These principles serve as the basis for WIPO Re:Search to plan for success.

The positive value of IP. Innovation in medical technologies is strongly based on the incentives that the IP system provides. First, the system gives investors the confidence to allocate large resources to R&D in the expectation that they can profitably access markets to recoup their investments. Second, IP provides the basis for the formation of R&D partnerships in which organizations can collaborate to develop new products. It is particularly with respect to this second aspect of IP that WIPO Re:Search helps to catalyze research on NTDs, malaria and TB.

The need for a proactive partnering mechanism. The successful formation of collaborations demonstrates the effectiveness and necessity of a proactive partnership broker. The Pool for Open Innovation in Neglected Tropical Diseases (POINT) program, established in 2009 by GSK and managed by BVGH, was a starting point for WIPO Re:Search. POINT had the same goals as WIPO Re:Search, yet it lacked proactive partnering and a collaborative network of pharmaceutical companies. After over a year in existence, POINT had finalized only one collaboration. In WIPO Re:Search, and with the active support of a range of Members, BVGH incorporated a proactive partnership development model and approach to facilitating collaborations among WIPO Re:Search Members. In comparison, through this proactive partnering approach, 12 collaborations were established over the first year of WIPO Re:Search.

A long-term perspective of potential contribution to product development. WIPO Re:Search has consistently exceeded annual expectations for forming partnerships, but given that the drug development process is lengthy, expensive and high-risk, it is premature to expect that new drugs, vaccines, or diagnostics would have emerged yet. It is important to take a long-term view of achieving impact and to recognize that contributing toward “filling the pipeline” of new promising compounds or leads is of great value when coupled with a means to hand over promising compounds or leads to product development groups such as product development partnerships (PDPs).

The importance of mobilizing additional resources for partnering. 107 Members are Provider and/or User Members. 47 of these Members have yet to participate in a WIPO Re:Search collaboration. The potential policy support and general involvement in the project of the 19 Supporter-only Members (e.g., professional organizations, national patent offices) have largely been untapped. WIPO Re:Search will establish processes to more fully engage Supporter Members. This is an area that requires additional discussion and planning, particularly in the context of assisting developing country institutions in IP management.

The need for financial support for collaborations. Accessing IP alone is not sufficient to drive innovation; funding support is an essential element in addition to capable scientists and well-equipped laboratories. Members participating in collaborations frequently lack the financial resources to undertake a more substantial development project. WIPO Re:Search was not established with a pool of funding for collaborations. In order to achieve the full potential of WIPO Re:Search, a mechanism to financially support its collaborations is crucial.

The need for broader understanding of IP, research and of WIPO Re:Search itself. Both BVGH and WIPO have invested considerable effort in raising awareness of WIPO Re:Search and its contributions. This work needs to be continued and expanded. In addition, as documented in the External Strategic Review, there is some lack of clarity about the roles and responsibilities of the Secretariat and the Partnership Hub.

Based on these key concepts, the following section describes a strategy for continuing to build upon successes and to address key challenges.

4. Strategic Goals, Implementing Activities and Milestones

WIPO Re:Search has four Strategic Goals with associated Implementing Activities, and Milestones. These are summarized in Table 1.

Strategic Goal No. 1: Use IP assets to advance R&D for NTDs, malaria, and TB through collaborations

Implementing Activity 1.1: Establish and maintain, in collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR) and others, as appropriate, a landscape analysis of technologies (including target product profiles [TPPs]) for each priority disease to help guide priority setting and collaboration formation.

Implementing Activity 1.2: Establish new collaborations that address priority needs and provide assistance and support to ongoing partnerships, as required.

Implementing Activity 1.3: Expand the number of company Providers who can offer assets and support for the operations of WIPO Re:Search and expand the number of Members, especially from developing countries, that contribute needed capabilities. New Members will be recruited to meet needs for addressing particular diseases or technologies and to increase membership from Africa, Asia and Latin America.

Implementing Activity 1.4: Provide comprehensive IP management assistance to partnerships that are moving toward downstream product development.

Context

This Strategic Goal will be achieved through continued partnership formation and a greatly expanded set of activities concerning IP.

Partnership Formation: The Partnership Hub, administered by BVGH, was created to facilitate research collaboration opportunities between Members. BVGH functions are crucial to connecting Members, including Providers of IP, and other assets, with qualified researchers interested in exploring a WIPO Re:Search collaboration. The record number of collaborations facilitated to date demonstrates clear success in this regard. Partnership development will continue to be central to WIPO Re:Search. BVGH will implement a more targeted approach to establishing collaborations in order to address gaps in pipelines and disease burden. There will be more focus on gaps in current research and in needed products.

IP Management: During the first five years of WIPO Re:Search operations, IP matters concerned upstream research and were addressed through adherence to the Guiding Principles; the emphasis was on forming partnerships. This work demonstrated that IP did not inhibit upstream research. In the next five years, WIPO Re:Search will expand its focus on IP, *per se*. WIPO will work with selected partnerships to construct downstream product development IP management strategies. These strategies will address IP questions with respect to a wide range of issues, including clinical trial data ownership; strategies for filing new patents; and licensing to potential downstream developers, manufacturers and distributors. The strategies will be based on licensing principles and practices that have been demonstrated to be in the public sector interest and therefore benefit the populations of developing countries. This work will also be of value to developing country companies that collaborate in WIPO Re:Search projects in that it will offer them opportunities to develop and market products to their population while still obtaining a suitable return on investment. Through this work, WIPO Re:Search will demonstrate that the IP system encourages and facilitates innovation and supports access to health technologies. These strategies will hopefully set a positive precedent for other similar collaborations around the world.

Table 1: Strategic Goals, Supporting Strategies and Milestones

Strategic Goals	Implementing Activities	Milestones
No. 1: Use IP assets to advance R&D for NTDs, malaria, and TB through collaborations	1.1: Establish and maintain, in collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR) and others, as appropriate, a landscape analysis of technologies (including target product profiles [TPPs]) for each priority disease to help guide priority setting and collaboration formation.*	Perform a landscape analysis, followed by annual updates, initially through publicly-available pipelines, including those published by TDR.*
	1.2: Establish new collaborations that address priority needs and provide assistance and support to ongoing partnerships, as required.	Establish at least eight new collaborations annually and support all other ongoing partnerships.
	1.3: Expand the number of company Providers who can offer assets and support for the operations of WIPO Re:Search and expand the number of Members, especially from developing countries, that contribute needed capabilities. New Members will be recruited to meet needs for addressing particular diseases or technologies and to increase membership from Africa, Asia and Latin America.	Add one company annually. Add three to six targeted User Members annually.
	1.4: Provide comprehensive IP management assistance to partnerships that are moving toward downstream product development.	Prepare comprehensive IP management strategies for two or three partnerships per year.
No. 2: Accelerate the advancement of promising compounds or leads	Accelerate progress in a selected group of collaborations by assisting collaborators to obtain grants from donor agencies. The highest priority will be those projects with the potential for the compound or lead to move rapidly to later stages of evaluation.	Connect two to three partnerships or collaborations per year to relevant funding.
No. 3: Enhance global capacity for IP management and biomedical R&D	Support capacity development of Member organizations, from developing countries and academic institutions, by strengthening IP management capabilities. Also provide to them research fellowships for capacity-building at leading research centers.	Provide two to four training sabbaticals annually.**
No. 4: Communicate the beneficial role of IP in innovation for NTDs, malaria, and TB	Increase dissemination of information about the role of IP for R&D in NTDs, malaria, and TB; the potential technologies to combat these diseases; and the specific contributions of WIPO Re:Search. Also leverage the capacity of Members to disseminate information about WIPO Re:Search.	Provide a user-friendly web page of available resources to facilitate the formation of partnerships and update annually based on user feedback. Publish at least four articles in journals and magazines; make at least six presentations in subject-matter meetings. These activities should include IP and NTDs, malaria and TB subject matter.

* Dependent upon receipt of new funding.

** Partial support for this activity has been obtained from the Government of Australia. Full implementation will depend upon receipt of additional funding.

Strategic Goal No. 2: Accelerate the advancement of promising compounds or leads

Implementing Activity: Accelerate progress in a selected group of collaborations by assisting collaborators to obtain grants from donor agencies. The highest priority will be those projects with the potential for the compound or lead to move rapidly to later stages of evaluation.

Context

WIPO Re:Search was created in the belief that more R&D could be stimulated through a trusted intermediary that would ensure, *inter alia*, that valuable IP assets could be made available within a framework of IP protection. On this foundation, 112 collaborations, covering a diverse range of diseases and types of assets shared, have been facilitated since the launch in late 2011.

Of these initial collaborations, approximately one third are still active, and some have advanced beyond initial development milestones. One of the key findings of the External Strategic Review was the need to contribute to a pool of funds to support partnerships. WIPO Re:Search will seek to address this need by assisting Members to access sources of financial support to further develop promising leads. We note that this initiative fits well within WIPO's Medium-Term Strategic Plan, which states that "Institutional arrangements for attracting extra-budgetary funding will be strengthened [...]."⁵

To this end, WIPO Re:Search will prepare applications for grants from donor agencies of Member States. WIPO and BVGH will monitor and respond to opportunities that would add to the available financial resources.

Additional tools to achieve this Strategic Goal include engaging the expertise and networks of the Advisory Committee to identify funding opportunities. In addition, BVGH operates a separate program, BVGH FundFinder, that could be made available to all WIPO Re:Search Members subject to the availability of financial support for this service.

The goal is not to fully finance product development into downstream steps but rather to ensure that partners, in particular those from developing countries, are able to conduct the required upstream research. As products advance, agreements under appropriate licensing arrangements will be facilitated (prepared in collaboration with WIPO under Strategic Goal 1) to downstream developers such as PDPs.

Strategic Goal No. 3: Enhance global capacity for IP management and biomedical R&D

Implementing Activity: Support capacity development of Member organizations, from developing countries and academic institutions, by strengthening IP management capabilities. Also provide to them research fellowships for capacity-building at leading research centers.

Context

The WIPO Medium-Term Strategic Plan Strategic Goal III is "Facilitating the Use of IP for Development" and thereby informs the elaboration of WIPO Re:Search's activities in capacity-building.

From its inception, a part of WIPO Re:Search's value proposition (see Annex 5) has been access to WIPO's other capabilities, within the context of its mandate and mission. Members have benefited from a range of activities, such as IP training workshops.

Additional capacity-building supported through WIPO's Funds-in-Trust program has been specific to WIPO Re:Search. For example, WIPO Re:Search has established a series of research "sabbaticals" for developing country scientists, made possible by Funds-in-Trust from the Government of Australia. Between 2013 and 2016, six scientists from five African countries undertook research sabbaticals at WIPO Re:Search Member facilities in India, Switzerland, and the United States of America.

Building on the success of the WIPO Re:Search capacity-building activities, the Government of Australia in 2015 renewed and increased its support for this activity, with guidance to prioritize countries in the Asia-Pacific region.

WIPO has several other programs that can support Member efforts. These programs include its Access to Research for Development and Innovation (ARDI) program⁶ and its IP training workshops. ARDI is coordinated by WIPO and its partners in the publishing industry, with the aim of increasing the availability of scientific and technical information in developing countries. Other relevant programs include the Hinari Access to Research for Health Program. This program, managed by WHO,⁷ facilitates access to global health and biomedical journals, articles, etc., for developing countries.

⁵ Medium-Term Strategic Plan for WIPO, 2016-2021, A/56/10, August 17, 2016: www.wipo.int/edocs/mdocs/govbody/en/a_56/a_56_10.pdf

⁶ See www.wipo.int/ardi/en/

⁷ See www.who.int/hinari/en/

Strategic Goal No. 4: Communicate the beneficial role of IP in innovation for NTDs, malaria, and TB

Implementing Activity: Increase dissemination of information about the role of IP for R&D in NTDs, malaria, and TB; the potential technologies to combat these diseases; and the specific contributions of WIPO Re:Search. Also leverage the capacity of Members to disseminate information about WIPO Re:Search.

Context

This goal fits well within the framework described in the WIPO Medium-Term Strategic Plan, under Strategic Goal VIII, “A Responsive Communications interface between WIPO its Member States and all Stakeholders.” Specifically, WIPO’s communications strategy recognizes that to illustrate the positive nature of IP, communications material should be based on practical stories. WIPO Re:Search fits exactly into this framework.

WIPO Re:Search will utilize additional and alternative communications methods, such as social media, to ensure that both Members and the greater global health community understand the structure, strategies, activities, objectives, and goals of WIPO Re:Search. WIPO will leverage its media department to develop appropriate media and link them to the WIPO Re:Search website.

The website will be updated to include more detailed descriptions of each Member organization, the collaborations the Member has participated in, and the outcomes – i.e., publications, presentations, and funding awards – of those collaborations. The database, which provides information on assets available for use by Members, will also be updated. An updated database with a more user-friendly, interactive format should stimulate communication between Members. To update the database, WIPO will encourage each Member to review the assets that it could contribute to the database, as well as identify which assets currently in the database are useful to researchers.

With the global health R&D field becoming more diversified across sectors and organizations, it will be important to ensure that there is minimal overlap in research projects and that research projects are not unnecessarily repeated by different groups. To address this risk, BVGH will develop and curate a database of the methods and results of collaborations. This database will capture both positive and negative data and describe the methods used to obtain those data. In addition to supporting the development of novel and impactful research projects, this updated online platform could be used to communicate the activities and achievements of WIPO Re:Search to the greater global health field.

WIPO will leverage its IP expertise and connections within the IP and policy communities to identify opportunities to publicize how WIPO Re:Search is using IP to stimulate innovation for NTDs, malaria, and TB. This will include preparing reports and distributing them across the IP field and making presentations at key IP and policy meetings.

BVGH will leverage its close links with industry to continue identifying and publishing WIPO Re:Search success stories. It will expand its social media outreach and coordinate with WIPO in order to draw more attention to WIPO Re:Search and the use of industry’s IP to advance R&D for NTDs, malaria and TB. WIPO Re:Search presentations and sessions at key industry and global health events will be pursued by BVGH, such as the BIO International Convention, the American Society of Tropical Medicine and Hygiene (ASTMH) and others. WIPO and BVGH will also encourage Members to communicate about WIPO Re:Search.

Table 2 summarizes the allocation of effort between the Secretariat and the Partnership Hub. See also Section 6.3 on management.

Table 2: Allocation of efforts between the Secretariat and Partnership Hub

Strategic Goals	WIPO Secretariat	BVGH Partnership Hub
Use IP assets to advance R&D for NTDs, malaria, and TB through collaborations	Provide IP management assistance to partnerships that are moving toward downstream product development.	<p>Engage Members in discussions about NTDs, malaria and TB R&D in order to identify and facilitate collaboration opportunities between Members.</p> <p>Present partnership opportunities relevant to individual Member's research and product development programs.</p> <p>Monitor and track WIPO Re:Search collaborations and statuses.</p> <p>Provide alliance management support to collaborators.</p> <p>Recruit new Provider and User Members.</p> <p>Perform a landscape analysis, followed by annual updates, initially through publicly-available pipelines, including those published by TDR.</p>
Accelerate the advancement of promising compounds or leads	<p>Identify grant opportunities and submit proposals.</p> <p>Oversee and administer grant programs in collaboration with BVGH.</p> <p>Collaborate with BVGH in resource mobilization.</p>	<p>Facilitate the provision of grant support to collaborations.</p> <p>Collaborate with WIPO in resource mobilization.</p>
Enhance global capacity for IP management and biomedical R&D	<p>Identify grant opportunities and submit proposals.</p> <p>Manage research sabbatical funds (Funds-In-Trust) for developing country scientists.</p> <p>Provide capacity-building activities in IP management.</p>	Facilitate Funds-In-Trust sponsored sabbatical placements for developing country scientists in collaboration with WIPO.
Communicate the beneficial role of IP in innovation for NTDs, malaria, and TB	<p>Serve as the Secretariat of the Advisory Committee.</p> <p>Organize annual or biennial Member meetings.</p> <p>Provide technical support on IP matters.</p> <p>Produce videos and other materials.</p> <p>Maintain website.</p>	<p>Participate in global health congresses, meetings, etc.</p> <p>Prepare monthly Snapshot newsletter.</p> <p>Publish articles on WIPO Re:Search.</p> <p>Convene meetings of WIPO Re:Search Company Members.</p>

5. System for priority-setting

5.1 Setting priorities for technologies

The original criteria for priority-setting for WIPO Re:Search were burden of disease, the need for new or improved technologies, and shortfalls in resources. Within this context of global health and the needs of developing countries, priority-setting for WIPO Re:Search was further guided by the WHO list of NTDs, plus malaria and TB. Going forward, and based on the experience of the first five years, it may be possible to further sharpen the program's disease priorities. For example, some NTDs, such as guinea worm disease or human African trypanosomiasis, are either on the verge of eradication or the subjects of other large programs. Product development for other diseases, such as malaria, is supported by many organizations, yet the need is so great that WIPO Re:Search can also make useful contributions.

Having selected the diseases, the next step in priority-setting is to prioritize the technologies that companies and other Members make available to WIPO Re:Search. This prioritization is based on assessments of potential to lead to new technologies and the capability of potential partners to conduct further development. BVGH will submit these assessments to Members to solicit their willingness to share their particular asset(s).

5.2 Priorities for programs

The core priorities of WIPO Re:Search are: establishing research collaborations; building research capacity in developing countries; and communicating the activities, objectives, achievements and impact of WIPO Re:Search – as well as the use of IP to stimulate innovation. Subject to the availability of additional financial resources, the contribution of financial support to WIPO Re:Search collaborations will also be a priority.

Capacity-building was not foreseen as a major activity when WIPO Re:Search was created, even though it is a core activity of WIPO overall. Nonetheless, due largely to donor funding being made available, support for research sabbaticals for developing country scientists by WIPO Re:Search has become a significant activity, involving both the Secretariat and the Partnership Hub Administrator.

Secondary to partnering, communications activities are important to cultivating a wide understanding of, and interest in, WIPO Re:Search. This greater awareness of WIPO Re:Search will ensure that its resources can be appreciated and used by a wide audience. It will also contribute to the understanding that IP is not a barrier to research into NTDs, malaria and TB.

During the first five years, it was clear that funding to support research collaboration would enhance Member's participation in collaborations. If there were a pool of bridge funding that could be provided via small grants to WIPO Re:Search collaborations, this would help more Members – including those based in developing countries – to participate in collaborations and contribute to achieving the mission of WIPO Re:Search.

6. Programmatic support

6.1 Governance

WIPO Governance: The WIPO General Assembly (GA) is the governing body of WIPO.⁸ WIPO Re:Search is led and managed by the Director of the Global Challenges Division at WIPO, reporting to the Senior Director, Department for Traditional Knowledge and Global Challenges, reporting to the Assistant Director General, Global Issues Sector, who in turn reports to the Director General of WIPO. The operations of WIPO Re:Search are managed by the Head, Global Health.

BVGH Governance: The President of BVGH is appointed by the BVGH Board of Directors. The BVGH Board of Directors holds four meetings a year and reviews BVGH strategy, programs, including WIPO Re:Search, and finances and operations. The Board provides overall governance of the organization.⁹

WIPO Re:Search Governance: The collaboration between WIPO and BVGH is governed by a Memorandum of Understanding (MoU) (see Annex 2). The participation of the WIPO Re:Search Company Members is governed by an MoU between each company and BVGH. The primary purpose of these MoUs is to ensure that the activities and operations of WIPO Re:Search are in line with the WIPO Re:Search Guiding Principles and mission.

6.2 Technical input

Advisory Committee: The Advisory Committee was established in 2016 following a recommendation of the External Strategic Review consistent with the Guiding Principles, which state that such a committee could be established to provide inputs and strategic advice for the activities and operations of WIPO Re:Search. The Advisory Committee Terms of Reference are provided in Annex 6.

WIPO: It provides technical input on WIPO Re:Search-related IP activities and other IP matters as needed and serves as the Secretariat of WIPO Re:Search.

BVGH: It provides the Partnership Hub function and technical input on WIPO Re:Search IP assets and the potential value of such assets in collaborations. BVGH shares this information with WIPO Re:Search Members in order to engage researchers in collaboration discussions.

WHO: Since the launch of WIPO Re:Search, WHO has committed to provide technical advice on research needs and opportunities to WIPO, as appropriate. Going forward,

as noted earlier, a number of potential synergies with other programs, such as TDR, should be considered and, if appropriate and useful, pursued.

6.3 Management

The Secretariat is responsible for ensuring that WIPO Re:Search is responding to the needs of the WIPO Member States and those of WIPO Re:Search Members. It is also responsible for ensuring that WIPO Re:Search is consistent with the WIPO Medium-Term Strategic Plan. The Secretariat ensures effective communication about WIPO Re:Search with other UN agencies. It is responsible for coordinating the annual or biennial meeting of Members and the quarterly teleconferences. It leads the mobilization of funds from Member States for WIPO Re:Search. Finally, the WIPO Secretariat manages the WIPO Re:Search website, which is a focal point for WIPO Re:Search Members and stakeholders.

BVGH is a results-oriented non-profit organization based in Seattle, Washington. As noted in section 1.1, BVGH was established in 2004 by the Biotechnology Innovation Organization (BIO) to engage BIO stakeholders – biopharmaceutical, diagnostic, and life science companies – in meaningful initiatives and programs to impact global health. BVGH programs fall within three categories: R&D for poverty-related diseases, capacity-building in low- and middle-income countries, and access to medicines.¹⁰

BVGH leverages its industry origins and ties to establish WIPO Re:Search collaborations that support the neglected infectious disease research of academic and non-profit scientists, while also aligning itself with the strategies and needs of participating companies.

BVGH is responsible for engaging WIPO Re:Search Provider and User Members in research partnerships and discussions. BVGH employs a structured and transparent framework for partnering, including the use of a set of standardized documents: a description of BVGH's collaboration guidelines, a collaboration outline document, and a collaboration close-out form. BVGH convenes the annual meetings of the WIPO Re:Search Company Members with BVGH and WIPO. During these meetings, BVGH provides a detailed report on its activities and achievements, and also presents, for approval, its deliverables for the following year. In addition to facilitating and managing collaborations, BVGH plays a key role in WIPO Re:Search communication activities in coordination with WIPO.

⁸ See www.wipo.int/about-wipo/en/activities_by_unit/units/global_challenges/ for information on the Global Challenges program.

⁹ www.bvgh.org/Who-We-Are/BVGH-Board-of-Directors.aspx

¹⁰ More information is available at www.bvgh.org

The success of WIPO Re:Search relies on its continued collaboration with key organizations such as WHO (e.g., through the Department of Essential Medicines and Health Products [EMP], and TDR), the World Trade Organization (WTO), private companies, academic research centers, product development partnerships (e.g., DNDI), and national governments (e.g., Australia).

Many individuals who were interviewed for the External Strategic Review, Members of the Advisory Committee, and others have expressed a need to clarify the management structure of WIPO Re:Search. The concern is that WIPO Re:Search is managed by two separate organizations, WIPO and BVGH, and there is no single entity with overall authority. WIPO and BVGH will work together to better communicate each organization's roles, responsibilities and program deliverables.

The Advisory Committee, WIPO, and BVGH meet regularly via telephone and in at least one face-to-face meeting per year to discuss the operation and priorities of WIPO Re:Search.

WIPO and BVGH staff meet regularly, at least twice per month via telephone and at least twice per year in person to align on strategies, deliverables, and work plans, and to review progress.

6.4 Resource mobilization

During the next five years, WIPO and BVGH will give due attention and increased focus to resource mobilization. These efforts will seek funding for all components of WIPO Re:Search and will focus particularly on identifying funding to support collaborations and fund developing country researcher capacity-building programs. It is expected that both activities will be of interest to bilateral donors and foundations.

In order to obtain funding to support its research collaborations, WIPO Re:Search will need to demonstrate the added value these collaborations contribute to the global effort to develop and introduce new technologies for the prevention and control of NTDs, malaria, and TB. This will be achieved by demonstrating the novelty of the collaborations, the scientific rigor applied to establishing them, and the results of and advancements made by the collaborations, e.g., publications, presentations, and new IP. As time advances and more collaborations generate important results or enter later-stage development, their value will be demonstrated by their advancement by companies and PDPs.

To obtain funding for the developing country researcher capacity-building sabbaticals, WIPO Re:Search must demonstrate to potential funders that the past and current sabbaticals have had measurable impacts on the capability of the participants to undertake research that could lead to the advancement of further R&D and use of the participants exposure for the benefit of their institutions and communities.

6.5 Financial management

WIPO has institutional oversight mechanisms for due diligence on planning and budgeting, which include legal and auditing procedures. It follows International Public Sector Accounting Standards. BVGH is a non-profit organization incorporated in the USA under section 501(c)(3) of Title 26 of the Code of Laws of the USA and complies with US government laws, regulations, and statutes. WIPO and BVGH have well-established and well-governed management systems.

7. Evaluation and impact

The performance of WIPO Re:Search will be assessed by comparing achievements with the Milestones described within this Strategic Plan. At annual/biennial meetings of Members, progress reports will be presented to all Members for information, feedback and advice. The Advisory Committee will also provide its report to the Members.

The Secretariat will submit its program strategy to all 189 WIPO Member States for approval on a two-year cycle (as part of the WIPO Program and Budget). Through the Program and Budget Committee, Member States review annually the progress of each WIPO program against its goals as part of the WIPO Program Performance Report submission. The Organization's Internal Oversight Division evaluates several programs every year and reports to Member States.

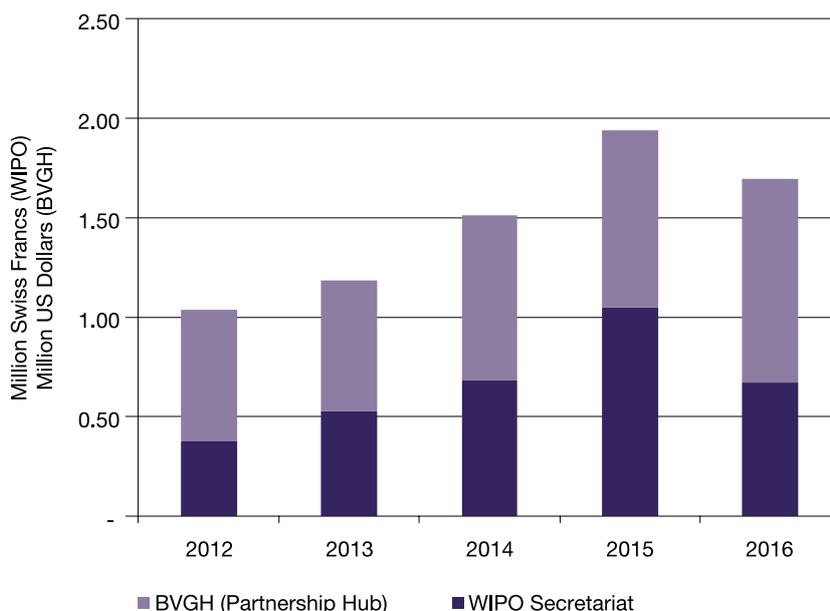
BVGH will provide WIPO Re:Search Company Members with verbal and written reports describing the companies' contributions and participation in WIPO Re:Search for their review and continuous feedback.

8. Expenditures to-date and allocation of resources

The WIPO Re:Search expenditures have grown since its launch in late 2011, as illustrated in Figure 1. In 2016, WIPO Re:Search had a direct program expenditure of 1.7 million Swiss Francs. These expenditures are composed of:

- a) the allocation from WIPO’s regular budget (where WIPO Re:Search forms part of Program 18);
- b) contributions from Member States through the Funds-in-Trust program, for the WIPO Re:Search fellowship program funded by the Government of Australia, and the production of communication materials funded by the Government of Japan;
- c) sub-contracts by WIPO to BVGH for work deliverables related to WIPO Re:Search; and
- d) the critical and substantial contributions from the funding Members of WIPO Re:Search (currently Eisai, GlaxoSmithKline, Johnson & Johnson, Merck KGaA, MSD, Novartis, Pfizer, Sanofi and Takeda) to the Partnership Hub at BVGH.

Figure 1: Actual WIPO and BVGH expenditures, 2012-2016

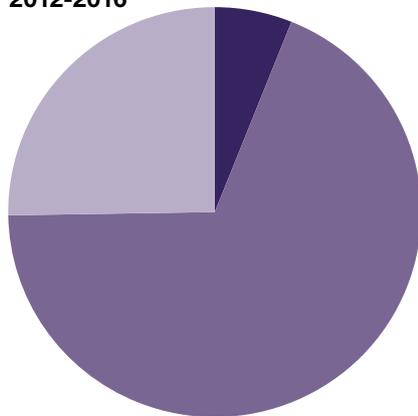


Notes:

1. At the time of publication, the US Dollar-Swiss Francs exchange rate was essentially at parity.
2. WIPO expenditure comprises direct expenditure for WIPO Re:Search related activities in the Global Challenges Division (i.e. items a), b) and c) above) for a total of 3.3 million Swiss Francs over the period 2012-2016. Included are funds transferred by the WIPO Secretariat to BVGH in support of specific deliverables by the Partnership Hub (110,000 Swiss Francs), and contributions from the Government of Australia through the WIPO Funds-in-Trust program transferred by the WIPO Secretariat to BVGH in support of hosting arrangements (92,000 Swiss Francs).
3. The expenditure figures do not include: a) IP training and capacity-building financed by WIPO Funds-in-Trust through other WIPO Divisions and Programs; b) the costs of inputs provided by the Office of the Director General, Office of the Assistant Director General of the Global Issues Sector, Communications Division, Regional Bureaus (for example, funding was provided for the participation of developing country WIPO Re:Search members to WIPO Re:Search events that were implemented in collaboration with COHRED and ANDI), Department for Transition and Developed Countries, Division for Least-Developed Countries and IP Office Business Solutions Division; c) the cost of indirect support from the Administration and Management Sector (such as information technology, premises and infrastructure, finance, budget, travel services, etc.).
4. For BVGH, the total expenditure over the 2012-2016 period is 4.1 million US dollars. Figures do not include BVGH’s overhead of 20% and funds transferred by WIPO to BVGH.

The allocation of the WIPO Secretariat expenditures is shown in Figure 2 and those of BVGH in Figure 3.

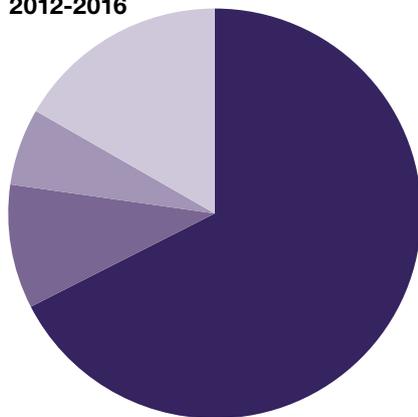
Figure 2: Estimated allocations of WIPO expenditure, 2012-2016



- Partnerships (6%)
- Communications (68%)
- Capacity building (26%)

Note: Allocation of direct Program 18 expenditures and Funds-in-Trust contributions only (WIPO). Excludes administration and management and other indirect expenditures (for details, see Notes, Figure 1).

Figure 3: Estimated allocations of BVGH expenditure, 2012-2016



- Personnel (65%)
- Travel and meetings (9%)
- Program expenses (6%)
- Overhead (20%)

Annexes

1. WIPO Re:Search Guiding Principles (as of June 8, 2011)

Overview

WIPO Re:Search is a Consortium sponsored by the World Intellectual Property Organization (WIPO) in collaboration with BIO Ventures for Global Health (BVGH). The Consortium aims to accelerate the discovery and product development of medicines, vaccines, and diagnostics to create new solutions for people affected by neglected tropical diseases (NTDs),¹ malaria, and TB by making intellectual property and know-how available to the global health research community. These diseases affect more than one billion people across the globe.

The Consortium will comprise institutions from all relevant sectors, including public, private, academic, and civil society.

The Consortium is a voluntary endeavor open to all *bona fide* private and public entities, including intergovernmental institutions, that endorse these Guiding Principles for the purpose of developing new medicines, diagnostics or vaccines (hereinafter “Products”) in the field of NTDs.

The objective of the Consortium is to encourage and support research and development of Products for NTDs. In particular, *WIPO Re:Search* will benefit patients in the Least Developed Countries (LDCs as defined in Annex 1 [of these Guiding Principles]) by creating an open innovation platform through which public and private sector entities can share, for this purpose, Intellectual Property.² The Consortium has three major components:

1. A **Database**, hosted by WIPO, providing details of Intellectual Property available for licensing from a Provider (as defined below), as well as services and other technology or materials not necessarily protected by intellectual property rights which can be accessed by Users (as defined below).
2. A **Partnership Hub**, managed by a Partnership Hub Administrator, which shall be BVGH or any subsequent competent entity, in cooperation with WIPO, where Members (defined below) and other interested parties that support or are considering sup-

porting these Guiding Principles can learn about the Consortium, available licensing and research collaboration opportunities, networking possibilities, and funding options.

3. A range of specific **Supporting Activities**, led by WIPO in cooperation with BVGH, to facilitate negotiation of licensing agreements and to address technical matters such as identifying research needs and opportunities, among others, with technical advice from the World Health Organization (WHO).

WIPO’s sponsorship of this Consortium supports WIPO’s mandate from its Member States as expressed in the “Development Agenda”³ recommendations. These aim to ensure, *inter alia*, that development considerations form an integral part of WIPO’s work, specifically:

- facilitating access to knowledge and technology for developing countries including LDCs,
- promoting the transfer and dissemination of technology to the benefit of developing countries, including LDCs,
- encouraging Member States, especially developed countries, to urge their research and scientific institutions to enhance cooperation and exchange with research and development institutions in developing countries, especially LDCs, and
- cooperating with other intergovernmental organizations to provide developing countries, including LDCs, upon request, advice on how to gain access to and make use of intellectual property-related information on technology.

WHO draws its rationale for collaboration with WIPO and for providing technical advice on research needs and opportunities from elements of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA-PHI), which is being implemented by WHO and its Member States in collaboration with other stakeholders, including WIPO. Moreover, a World Health Assembly Resolution⁴ specifically requests WHO to implement the GSPA-PHI in collaboration with other IGOs, including WIPO. Specific provisions of the GSPA-PHI that are relevant to the objectives of the Consortium include:

- prioritizing research and development needs,
- promoting research and development,
- building and improving innovative capacity,
- improving transfer of technology, and
- improving delivery and access.

1 The term “NTD” herein means the NTDs listed in Annex 2 [of the Guiding Principles] which include malaria and tuberculosis.

2 The term “Intellectual Property” as used herein includes, patent and related registered rights, know-how, manufacturing processes, and regulatory data and the corresponding physical materials such as proprietary compounds and technologies.

3 WIPO, 2007. The 45 Adopted Recommendations under the WIPO Development Agenda. www.wipo.int/ip-development/en/agenda/

4 WHA 61.21, May 24, 2008.

WHO is committed to provide technical advice on research needs and opportunities to WIPO as appropriate.

WIPO Re:Search is a cooperative, voluntary arrangement among groups and institutions collaborating towards a common set of principles and objectives but each acting on its own. No legal structure is hereby created.

Principles and Objectives

The Members believe that public health challenges in developing countries are complex and require multiple approaches, and that:

- there are opportunities to use Intellectual Property innovatively and to encourage both public and private sector research and development of health solutions that are particularly needed by the world’s poorest populations, and
- an open innovation framework for the sharing of Intellectual Property, and technology and research materials not protected by intellectual property rights, can facilitate such research and development into new Products for NTDs.

The primary objective of *WIPO Re:Search* is to catalyze new research and development for NTDs, with a particular focus on the needs of patients in LDCs, by making Intellectual Property available on concessionary terms to researchers everywhere. The commitment to sharing Intellectual Property, however, goes beyond research. Members also commit to the licensing of Intellectual Property contributed to the Consortium under the following terms, subject to individually negotiated licensing agreements:

1. Providers agree to grant Users royalty-free licenses to this Intellectual Property for research and development, anywhere in the world, of products, technologies or services, for the sole purpose of addressing public health needs for any or all NTDs in LDCs.
2. Providers agree to grant Users royalty-free licenses to this Intellectual Property anywhere in the world to make or have made such products, technologies or services, and to import and export, for the sole purpose, to sell or have sold, these products in LDCs.
3. Users shall be allowed to retain ownership of and apply for registration of intellectual property rights generated as they deem fit, but shall be encouraged to license to third parties through *WIPO Re:Search* new intellectual property rights generated under an agreement made pursuant to membership in the Consortium under terms consistent with these Guiding Principles.
4. For the avoidance of doubt, Providers will not make any claims to rights in new intellectual property, materials or derivatives of materials generated by a User under a license agreement made pursuant

to membership in this Consortium, but may require such User not to assert such new intellectual property rights against the Provider.

5. The provision of physical supplies of active pharmaceutical ingredients (API) is encouraged subject to resource availability, but such provision is not required.
6. In the event of the need for arbitration and/or dispute resolution, Users and Providers are encouraged, but not required, to use the services of WIPO’s Arbitration and Mediation Center which shall develop mediation procedures specific to the needs of WIPO Re:Search.

For products resulting from licenses through the Consortium, all Providers of Intellectual Property agree to:

- Provide licenses for these products on a royalty-free basis for use and sale in all LDCs.
- Consider in good faith the issue of access to these products for all developing countries, including those which do not qualify as LDCs. This includes considering in good faith the granting of a license under any relevant Intellectual Property on a case-by-case basis, taking into account the economic development of the countries and the need to facilitate access to disadvantaged populations.

Structure and Governance

Membership in the Consortium is open to those that agree in writing to these Guiding Principles. The Consortium shall comprise a Membership, a Secretariat, and a Governance Committee.

Membership shall include Providers, Users and Supporters, and each may define themselves as Members by indicating their commitment to these Guiding Principles via the relevant facility on the *WIPO Re:Search* website or in writing to the Secretariat (Global Challenges Division, WIPO, 34 chemin des Colombettes, 1211 Geneva 20, Switzerland; re_search@wipo.int) providing suitable personal or corporate identification and contact details. Specifically:

- “Providers” are Members that contribute Intellectual Property, materials or services to *WIPO Re:Search* for license or use. Certain further understandings in relation to Providers are set out in Annex 3 [of these Guiding Principles].
- “Users” are Members that have entered into license agreements with Providers to use Intellectual Property and/or materials and/or services made available through *WIPO Re:Search* in accordance with, and in furtherance of, the Principles and Objectives.
- “Supporters” are Members that encourage the facilitation of research and development of Products for NTDs. Supporters may voluntarily offer to provide support, services or assistance of any kind to the Consortium

or its members in order to facilitate achievement of the Principles and Objectives. WIPO and the Partnership Hub shall, if requested by a Supporter, consider publishing on the website of the Consortium details of the availability of such support, services and assistance.

Any Member may withdraw from the Consortium by giving notice via the relevant facility on the Consortium’s website or in writing to the Secretariat. Any withdrawals shall not lead to the termination of licensing agreements executed as a result of participation in the Consortium unless so provided in such agreement.

The Secretariat will be financed and administered by WIPO and shall provide the following services, among others, in coordination with the Partnership Hub Administrator:

- Promote the sharing of information on available Intellectual Property, materials or services for licensing through the creation, development and operations of a database and website.
- Liaise with WHO, which provides technical advice to WIPO on NTD research challenges and opportunities.
- Organize an Annual or Biennial Meeting of Members.
- Develop, with Members and others, a range of specific supporting activities to facilitate licensing, including offering model licensing clauses, and support capacity building activities, in particular by building on and expanding WIPO’s existing and numerous activities in these areas.
- Encourage policy dialogue among Members and other interested parties, with a particular focus on supporting the Partnership Hub.
- Facilitate the establishment of a Partnership Hub for the Consortium, administered by the Partnership Hub Administrator, to provide the following services, among others, as mutually agreed by those Providers participating in the Partnership Hub, in coordination with WIPO:
 - i. create opportunities for Members and other interested parties, such as potential Users, to learn about available licensing and research collaboration opportunities, networking possibilities, and funding options,
 - ii. recruit Users to the Consortium by identifying potential research and product development organizations and introducing them to the assets of WIPO Re:Search, and
 - iii. facilitate the discussions between Providers and potential licensees leading to research projects.

The Governance Committee is comprised of the Members. In addition to the Annual or Biennial Meeting, the Secretariat shall, as required organize meetings of the Governance Committee by teleconference. Over time, should a consensus of the Providers and Users deem it necessary, a Steering Committee may be established to ensure the efficient oversight of the Consortium’s activities. WIPO, WHO and/or the Partnership Hub Administrator may participate as observers in the meetings of the Governance Committee and the Steering Committee and provide technical advice within their respective areas of expertise.

The principal duties and responsibilities of the Governance Committee shall include inputs on and guidance of the general activities and operations of WIPO Re:Search, including its effectiveness at realizing its stated aims.

The Governance Committee has no powers in regard to financing of WIPO Re:Search.

Changes to the Guiding Principles and Annexes 1, 2 and 3 [of these Guiding Principles] shall only be possible by unanimous vote of those Members who cast a vote.

Where proposed changes to the Principles and Objectives significantly affect WIPO’s or the Partnership Hub Administrator’s interests, the respective Organization’s approval will be required prior to their adoption.

All decisions on individual collaborative and supporting activities will be made solely by the parties involved in the transactional activity and any resulting agreements are the sole responsibility of the licensing partners. Any changes to the Consortium’s Guiding Principles will not affect already executed licensing agreements unless so provided in such agreements.

Financing Consortium Activities: In addition to WIPO’s financing of the Secretariat function as set out above, it is recognized that the activities of the Consortium may require direct disbursement of funds to support the Partnership Hub Administrator or for other matters.

ANNEX 1 [of the Guiding Principles]

Least Developed Countries (LDCs)

LDCs, as defined by the United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and the Small Island Developing States (UN-OHRLLS), as of November 29, 2010:

Africa (33)

Angola	Madagascar
Benin	Malawi
Burkina Faso	Mali
Burundi	Mauritania
Central African Republic	Mozambique
Chad	Niger
Comoros	Rwanda
Democratic Republic of the Congo	São Tomé and Príncipe
Djibouti	Senegal
Equatorial Guinea	Sierra Leone
Eritrea	Somalia
Ethiopia	Sudan
Gambia	Togo
Guinea	Uganda
Guinea-Bissau	United Republic of Tanzania
Lesotho	Zambia
Liberia	

Asia (15)

Afghanistan	Nepal
Bangladesh	Samoa
Bhutan	Solomon Islands
Cambodia	Timor-Leste
Kiribati	Tuvalu
Lao People's Democratic Republic	Vanuatu
Maldives	Yemen
Myanmar	

Latin America and the Caribbean (1)

Haiti

ANNEX 2 [of the Guiding Principles]

The neglected tropical diseases and conditions covered by *WIPO Re:Search* are:

1. Buruli Ulcer
2. Chagas disease (American trypanosomiasis)
3. Cysticercosis
4. Dengue/dengue hemorrhagic fever
5. Dracunculiasis (guinea-worm disease)
6. Echinococcosis
7. Endemic treponematoses (Yaws)
8. Foodborne trematode infections
 - Clonorchiasis
 - Opisthorchiasis
 - Fascioliasis
 - Paragonimiasis
9. Human African trypanosomiasis
10. Leishmaniasis
11. Leprosy
12. Lymphatic filariasis
13. Onchocerciasis
14. Podoconiosis
15. Rabies
16. Schistosomiasis
17. Soil transmitted helminthiasis
18. Trachoma
19. Snakebite

As previously defined, the scope of the Consortium and the term NTD as used herein also includes the following:

20. Malaria
21. Tuberculosis

ANNEX 3 [of the Guiding Principles]

Providers of Intellectual Property or services agree to the following common understandings relating to their participation in WIPO Re:Search, whether in relation to research and development, manufacture and/or sale of products:

1. Providers' contributions to the Consortium are made entirely at their own discretion. Access by Users to Providers' contributions will occur under individually negotiated agreements, in accordance with the Consortium Principles and Objectives, and be consistent with any obligations any Provider may have under existing agreements, as well as international agreements related to trade, intellectual property, and proprietary regulatory data.
2. Providers will clearly identify a contact point for potential Users seeking information about the contributions to the Consortium made by the Provider and about such matters as terms of license to Intellectual Property, materials and/or services.
3. The following information regarding Intellectual Property may be made publicly available on the Consortium website/database:
 - (a) Patents and, published patent applications.
 - (b) Chemical structures.
 - (c) Additional information, if the provider chooses to make such information available, in the form of a plain language summary, of the compound's known characteristics/mode of action for which utility against one or more NTDs is suspected.
 - (d) Whether or not physical materials, regulatory data or know-how, including information relevant to manufacturing, is available for licensing. The provision of physical supplies of active pharmaceutical ingredient (API) or supplies is encouraged, subject to availability, but not required.
 - (e) Scientific or other literature relating to contributed Intellectual Property
 - (f) Any caveats or exclusions required by existing Provider's activities, obligations or licenses.
4. Subject to considerations of business confidentiality, Providers and Users agree to inform WIPO and BVGH of concluded agreements and to provide regular and simple reports of the progress of collaborations made pursuant to the licenses, and will consider making public disclosure of general aspects of any collaboration(s) for the purposes of tracking the use and impact of the Consortium.

2. MoU between WIPO and BVGH



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MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND BIOVENTURES FOR GLOBAL HEALTH (BVGH)

Preamble

The World Intellectual Property Organization (WIPO), having its Headquarters at 34, chemin des Colombettes, 1211, Geneva 20, Switzerland, and BIO Ventures for Global Health (BVGH), a non-profit organization having its Headquarters at 221 Main Street, Suite 1600, San Francisco, California 94105, United States of America, hereinafter referred to as “the Parties”;

Considering that WIPO is a specialized agency of the United Nations whose objective is to promote the protection of intellectual property (IP) throughout the world through cooperation among its Member States, and, where appropriate, in collaboration with any other intergovernmental organization;

Considering that BVGH is a non-profit organization whose mission is to save lives by accelerating the development of novel biotechnology-based drugs, vaccines, and diagnostics to address the unmet medical needs of the developing world;

Supporting WIPO's mandate as expressed by its Member States in the “Development Agenda” recommendations, including:

- Facilitating access to knowledge and technology for developing countries, including Least Developed Countries (LDCs),
- Promoting the transfer and dissemination of technology, to the benefit of developing countries, including LDCs,
- Encouraging Member States, especially developed countries, to urge their research and scientific institutions to enhance cooperation and exchange with research and development institutions in developing countries, especially LDCs, and
- Cooperating with other intergovernmental organizations to provide to developing countries, including LDCs, upon request, advice on how to gain access to and make use of IP-related information on technology;

Recognizing the paramount importance of patent and licensing information in the research and development of new and essential medicines and medical treatments;

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND BIOVENTURES FOR GLOBAL HEALTH (BVGH)

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Considering that in consultation with a number of pharmaceutical companies and other parties, WIPO is planning the formation of *WIPO Re:Search*, a Consortium as defined below, to facilitate license agreements for research and development of drugs, diagnostics and vaccines for Neglected Tropical Diseases (NTDs), to benefit those in need, and particularly those in the LDCs. The structure and key attributes of the Consortium will be established by a set of Guiding Principles.

The Parties:

Further recognizing the ravaging effects of NTDs, as more particularly defined in the Guiding Principles of the Consortium, in the developing world,

Observing that BVGH is the independent administrator of the Pool for Open Innovation against Neglected Tropical Diseases (POINT), an IP pool with contributors representing industry, academia, product development partnerships, and government agencies from both the developed and developing world, and

Taking into account the discussions between the Parties regarding their common purpose in facilitating NTDs research and that such a common purpose would be better served by working together in a combined effort to facilitate research for NTDs;

have entered into the following Memorandum of Understanding (MOU):

Article 1: Formation of *WIPO Re:Search* and Guiding Principles

- A. The Parties intend to establish a Consortium to be known as *WIPO Re:Search*, aimed at encouraging and supporting research and development of medicines, vaccines and diagnostics for NTDs in particular to benefit the LDCs.
- B. The Consortium will be formed with a structure and key attributes set out in the Guiding Principles, consistent with this MOU. These Guiding Principles will be established by the Parties, in partnership with collaborating companies and other institutions, as appropriate. Nothing in this MOU is intended to contradict or vary the terms of the Guiding Principles.

Article 2: Main Operations and Activities

- A. In support of the Consortium's mandate to promote the sharing of information to encourage innovation in the treatment and prevention of NTDs, the operations of the Consortium will include the development and maintenance of a Database, a Partnership Hub, and Supporting Services.
- B. These elements of the Consortium are defined in the Guiding Principles (Annex 1).

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MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND BIOVENTURES FOR GLOBAL HEALTH (BVGH)

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Article 3: Responsibilities of the Parties

- A. WIPO will serve as the Secretariat of the Consortium and will be financed and administered by WIPO and shall provide services, in coordination with the Partnership Hub Administrator, as detailed in the Guiding Principles.
- B. BVGH will administer the Partnership Hub for the Consortium. The outline for this responsibility is summarized in the Guiding Principles.

Article 4: Funding and Resources

- A. WIPO intends to finance from its own budget the operations and activities which are required for:
 - (i) The development and maintenance of the database referred to in Article 2.A above; and
 - (ii) The Secretariat, as referred to in Article 3.A above.
- B. BVGH intends to provide the necessary financial resources which are required for its role in the formation and operations of the Consortium, primarily focused on the Partnership Hub. BVGH intends to obtain that funding by seeking contributions from the for-profit providers to the Consortium, in a manner to be discussed and agreed with WIPO's participation and support. The MOU between BVGH and the funders of their activities, once signed by the companies and BVGH, will be attached as Annex 2.

Article 5: Communications and Cooperation between the Parties

- A. The Parties have agreed on respective roles and responsibilities, as provided in Annex 3, based on the following general principles: mutual respect, shared decision-making, open and frequent communication, and acknowledgement of their respective strengths.
- B. The Parties will frequently and regularly communicate with each other on matters related to the development and operation of the components of the Consortium. In particular, the Parties intend to discuss recommendations on any change in the Guiding Principles consistent with the process identified in the Guiding Principles.
- C. Consistent with the foregoing, both Parties intend that each will be represented in the Consortium's governance structure and process.
- D. The Parties shall work together to create a strategy, approach and mechanisms for communicating the formation and ongoing operation of the Consortium, including primary points of contact for external communications consistent with the roles and responsibilities of the Parties. The Parties also agree that no press release or other public communication shall be made about the Consortium on matters not already

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND BIOVENTURES FOR GLOBAL HEALTH (BVGH)

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publicly known without the prior agreement of either Party, such agreement not to be unreasonably withheld or delayed.

- E. The principal point of contact for WIPO shall be Mr. Anatole Krattiger, Director, Global Challenges Division, WIPO. The principal point of contact for BVGH shall be Mr. Donald Joseph, Chief Operating Officer, BVGH.

Article 6: Amendment

- A. This MOU may be amended only with the mutual written consent of the Parties, formalized through an exchange of letters specifying the date on which the amendment concerned is effective. Organizations represented in the Consortium's governance bodies will be given as much advance written notice as is practical of any proposed amendments to this MOU.

Article 7: Termination

- A. Either Party may terminate this MOU at any time, for any reason, with or without cause, provided that the proposed terminating Party has consulted with the funding Provider companies and discussed their positions in good faith. The terminating Party shall provide as much notice to the other Party as is practical under the circumstances, and in any event not less than one hundred eighty days written notice to the address shown in the Preamble, above.
- B. Upon termination of this MOU by either Party, the Parties shall cooperate reasonably with a wind-down or transition as is appropriate, including, for example, a coordinated notice to users, contributors and other members of the Consortium, and any public announcement that may be desirable.

Article 8: Dispute Settlement; Other Provisions

- A. Any dispute between the Parties regarding this MOU shall be discussed in good faith and settled amicably through negotiations between the Parties.
- B. This MOU is intended to be a statement of the understanding and intentions of the Parties regarding the Consortium, and is not intended to constitute a legally binding agreement.
- C. The Parties will work together to carry out the intent of this MOU and will dedicate reasonable efforts to doing so.
- D. Each Party has the authority to enter into and perform its role under this MOU and no further approvals are required in order to do so.

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND BIOVENTURES FOR GLOBAL HEALTH (BVGH)

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- E. BVGH will undertake to seek to obtain agreement by each of the current users and contributors to POINT to enter into the Consortium prior to the official launch of the Consortium, currently set for October 26, 2011.
- F. The Parties are independent organizations acting together under this MOU. Neither shall have authority to act on behalf of the other.

In witness whereof the undersigned, duly authorized thereto, have signed the agreement. Done in duplicate, in English, in Geneva, Switzerland, and San Francisco, California, United States of America, on September 23, 2011.

For BIO Ventures for Global Health
Organization (BVGH)

For the World Intellectual Property
Organization (WIPO)

Name 
DONALD R. JOSEPH
Title CHIEF OPERATING OFFICER

Name 
Title Deputy Director General

3. Overview of research and product needs in NTDs, malaria, and TB

3.1 Burden and global distribution

The 21 diseases encompassed in the scope of WIPO Re:Search can be divided into three categories: low, medium, or high global prevalence and/or incidence. The low prevalence category (<100 to 200,000 cases globally) includes diseases nearing elimination – dracunculiasis and human African trypanosomiasis (HAT) – as well as Buruli ulcer, rabies, leprosy, and yaws. The medium prevalence group (1 million to 10 million cases globally) includes echinococcosis, Chagas disease, tuberculosis, trachoma, snakebite, leishmaniasis, and podoconiosis. The high prevalence category (25 million to 2 billion cases globally) includes onchocerciasis, dengue, soil-transmitted helminthiases, taeniasis, schistosomiasis, foodborne trematodiases, lymphatic filariasis, and malaria. At least one NTD is endemic to every continent, with the exception of Antarctica. Africa is the most heavily affected continent with 19 of the WIPO Re:Search diseases endemic to the continent. Asia is the next most affected (17 diseases) followed by the Americas (16 diseases). Europe is the least affected, with only three diseases (tuberculosis, leishmaniasis and echinococcosis) endemic to the continent. In addition to having the highest number of endemic diseases, Africa also has endemic diseases not found elsewhere, specifically dracunculiasis, HAT, and onchocerciasis (the latter having been recently eliminated from South America). Table 3 summarizes the global incidence/prevalence and burden of disease and lists the currently available products and control efforts.

3.2 Existing Products

Drugs are available to treat the majority of these diseases. However, most of these are dated treatments marred by significant toxicity or a lack of substantial efficacy. Both yaws and trachoma are treated by commonly-used antibiotics. Buruli ulcer and leprosy are treated with antibiotics developed to treat tuberculosis and other common antibiotics. The treatment for leprosy includes an antibiotic specifically developed to treat leprosy. The two viral NTDs lack effective drugs; however, both have vaccines commercially available. The vaccine against dengue was first licensed in 2015 and uptake has been slow because of a variety of concerns, including safety and price. Several drugs are available to treat helminth infections; however, concerns over resistance, contraindications, and imperfect efficacy against all helminthic pathogens highlight the need for newer drugs. Similar to the helminths, the kinetoplastids have drugs available, but there are concerns about safety and efficacy. No products are available to prevent or treat dracunculiasis and podoconiosis. Both of these diseases rely on mechanical means for treatment, i.e. worm extraction for dracunculiasis and lymphedema control for podoconiosis. Beyond biopharmaceutical products, treatments for many of these diseases also rely on other management activities, including vector control, food safety and encouraging animal health.

Table 3: Research and product needs in NTDs, Malaria and TB

Disease	Global incidence/prevalence	Geographic distribution	Burden of disease by region (DALYs)¹	Products available	Current control efforts
Buruli ulcer ²	2,000 new cases reported in 2015	33 countries in Africa, the Americas, Asia, and Western Pacific	Americas: ND ³ Europe: ND Africa: ND Asia: ND	Drug: rifampicin + streptomycin; rifampicin + clarithromycin; rifampicin + moxifloxacin Vaccine: none Diagnostic: PCR, direct microscopy, histopathology, and culture	Minimize suffering, disabilities, and socioeconomic burden; Early detection; Antibiotic treatment
Chagas disease ⁴	6 - 7 million currently infected	Mainly endemic in 21 Latin American countries	Americas: 235,000 Europe: 700 Africa: ND Asia: 100	Drug: benznidazole; nifurtimox Vaccine: none Diagnostic: numerous molecular and serologic tests (e.g. ELISA, PCR, IFA) ⁵	Vector control; Blood donor screening; Newborn screens
Cysticercosis/Taeniasis ⁶	3-8.3 million currently infected	Africa, Asia, and Latin America	Americas: 31,000 Europe: 2,000 Africa: 154,000 Asia: 117,000	Drug: praziquantel; niclosamide; albendazole Vaccine: none Diagnostic: stool samples ⁷	Food safety; Preventive chemotherapy; Improved sanitation; Anthelmintic treatment and vaccination of pigs; Surveillance
Dengue and Severe dengue ⁸	390 million infections per year	Endemic in >100 countries: Africa, Americas, Eastern Mediterranean, Southeast Asia, and Western Pacific	Americas: 116,000 Europe: ND Africa: 54,000 Asia: 1.7 million	Drug: none Vaccine: Dengvaxia; CYD-TDV Diagnostic: virus isolation; serological testing; PCR; antigen detection ⁹	Surveillance; Vector control
Dracunculiasis (guinea-worm disease) ¹⁰	25 cases detected in 2016	Africa: Chad, South Sudan, and Ethiopia	Americas: ND Europe: ND Africa: ND Asia: ND	Drug: none Vaccine: none Diagnostic: Visual diagnosis ¹¹	Surveillance; Vector control
Echinococcosis ¹²	>1 million affected at any one time	Cystic echinococcosis – globally distributed (minus Antarctica); Alveolar echinococcosis – northern hemisphere	Americas: 11,000 Europe: 33,000 Africa: 37,000 Asia: 92,000	Drug: anti-infective prophylaxis post-surgery Vaccine: none Diagnostic: ultrasonography imaging; radiography; biopsies; serological tests	Surveillance; Prevention and control (slaughter-house hygiene and deworming of domestic carnivores and wild animals)

1. Total number of DALYs in both sexes, all ages. Statistics from 2015. See <http://ghdx.healthdata.org/gbd-results-tool>

2. Buruli ulcer Fact Sheet, February 2017. World Health Organization (WHO). Accessed March 30, 2017.

3. ND = No Data
4. Chagas disease Fact Sheet, March 2017. World Health Organization (WHO). Accessed March 30, 2017.

5. American Trypanosomiasis. Centers for Disease Control and Prevention (CDC). Accessed April 26, 2017.

6. Taeniasis/cysticercosis Fact Sheet, March 2017. World Health Organization (WHO). Accessed April 26, 2017.

7. Parasites – Taeniasis. Centers for Disease Control and Prevention. Accessed April 26, 2017.

8. Dengue and severe dengue Fact Sheet, July 2016. World Health Organization (WHO). Accessed March 30, 2017.

9. Dengue laboratory guidance and diagnostic testing. Centers for Disease Control and Prevention (CDC). Accessed April 26, 2017.

10. Dracunculiasis Fact Sheet, January 2017. World Health Organization (WHO). Accessed March 30, 2017.

11. Dracunculiasis. Centers for Disease Control and Prevention (CDC). Accessed April 26, 2017.

12. Echinococcosis Fact Sheet, March 2017. World Health Organization (WHO). Accessed March 30, 2017.

Disease	Global incidence/prevalence	Geographic distribution	Burden of disease by region (DALYs) ¹	Products available	Current control efforts
Endemic treponematoses (Yaws) ²	46,000 reported cases in 2015 (only 8 countries reported)	13 endemic countries in Africa, Asia, Latin America and the Pacific	Americas: ND Europe: ND Africa: ND Asia: ND	Drug: azithromycin; benzathine penicillin Vaccine: none Diagnostic: serological test; rapid point-of-care tests; PCR	Preventative early diagnosis; Mass or targeted treatment of populations
Foodborne trematodiasis ³	56 million currently infected	>70 countries worldwide – mainly endemic in East Asia and South America	Americas: 9,000 Europe: 49,000 Africa: 6,600 Asia: 1.6 million	Drug: praziquantel; triclabendazole Vaccine: none Diagnostic: detection of eggs in stool ⁴	Food safety practices; Improved access to treatment; Veterinary public health practices; Population-based preventative chemotherapy
Human African trypanosomiasis (sleeping sickness) ⁵	2,804 new cases in 2015	36 sub-Saharan Africa countries	Americas: ND Europe: ND Africa: 202,000 Asia: ND	Drug: pentamidine; suramin; melarsoprol; eflornithine; eflornithine + nifurtimox Vaccine: none Diagnostic: serological tests; cerebrospinal fluid examination	Surveillance; Vector control
Leishmaniasis ⁶	700,000 - 1 million new cases annually	Visceral Leishmaniasis: mainly 7 countries – Brazil, Ethiopia, India, Kenya, Somalia, South Sudan, and Sudan Cutaneous Leishmaniasis: Americas, Mediterranean basin, Middle East, Central Asia	Americas: 25,000 Europe: 5,000 Africa: 274,000 Asia: 1.1 million	Drug: sodium stibogluconate; meglumine antimoniate; amphotericin B; miltefosine; paromomycin ⁷ Vaccine: none Diagnostic: parasitological or serological tests	Surveillance; Vector control; Early diagnosis; Animal reservoir control
Leprosy ⁸	212,000 new cases in 2015	Global distribution with the majority of cases reported in Africa, Southeast Asia, and Western Pacific ⁹	Americas: 4,000 Europe: 2 Africa: 8,000 Asia: 19,000	Drug: rifampicin; clofazimine; dapsone Vaccine: no widely-used vaccine Diagnostic: skin smear or clinical signs ¹⁰	Surveillance; Early case detection
Lymphatic filariasis ¹¹	36 million currently infected	Asia, Africa, Western Pacific, parts of Latin America ¹²	Americas: 19,000 Europe: ND Africa: 921,000 Asia: 1.1 million	Drug: albendazole + ivermectin; albendazole + diethylcarbamazine citrate (DEC) Vaccine: none Diagnostic: blood smears ¹³	Preventative chemotherapy; Vector control

- Total number of DALYs in both sexes, all ages. Statistics from 2015. See <http://ghdx.healthdata.org/gbd-results-tool>
- Yaws Fact Sheet, March 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs316/en/
- Foodborne trematodiasis Fact Sheet, March 2017. World Health Organization (WHO). Accessed March 30, 2017. www.who.int/mediacentre/factsheets/fs368/en/
- Foodborne trematode infections. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs259/en/
- Trypanosomiasis, human Africa (sleeping sickness) Fact Sheet, January 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs259/en/
- Leishmaniasis Fact Sheet, April 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs375/en/
- WHO Model List of Essential Medicines, 19th List, April 2015. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1

- Leprosy Fact Sheet, February 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs101/en/
- Hansen's Disease (Leprosy). Centers for Disease Control and Prevention. Accessed April 26, 2017. www.cdc.gov/leprosy/transmission/index.html
- Diagnosis of leprosy. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/lep/diagnosis/en/
- Lymphatic filariasis Fact Sheet, March 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs102/en/
- Parasites – Lymphatic Filariasis. Centers for Disease Control and Prevention. Accessed April 26, 2017. www.cdc.gov/parasites/lymphaticfilariasis/epi.html
- Parasites – Lymphatic Filariasis. Centers for Disease Control and Prevention. Accessed April 26, 2017. www.cdc.gov/parasites/lymphaticfilariasis/diagnosis.html

Table 3 continued: Research and product needs in NTDs, Malaria and TB

Disease	Global incidence/prevalence	Geographic distribution	Burden of disease by region (DALYs)¹	Products available	Current control efforts
Malaria ²	212 million new cases in 2015	91 countries in Africa, Southeast Asia, Latin America, and Middle East have ongoing transmission, with most cases occurring in Africa	Americas: 27,000 Europe: 400 Africa: 50 million Asia: 5.7 million	Drug: artemisinin combination therapies (ACTs) Vaccine: none Diagnostic: Rapid diagnostic tests; microscopy	Protective drugs; Vector control
Onchocerciasis ³	26 million currently infected ⁴	31 countries in sub-Saharan Africa and some foci in Latin America and Yemen	Americas: ND Europe: ND Africa: 1.1 million Asia: ND	Drug: ivermectin Vaccine: none Diagnostic: skin biopsy; serological tests ⁵	Vector control
Podoconiosis ⁶	4 million currently affected ⁷	Highland areas in tropical Africa, Central America, and India	Americas: ND Europe: ND Africa: ND Asia: ND	Drug: none Vaccine: none Diagnostic: clinical findings	Wearing shoes and covering floor surfaces inside homes
Rabies ⁸	15 million require post-exposure prophylaxis each year	Mainly Asia and Africa	Americas: 500 Europe: 500 Africa: 463,000 Asia: 467,000	Drug: post-exposure prophylaxis (PEP) (vaccine and immunoglobulin) Vaccine: pre-exposure vaccine Diagnostic: no test before onset of clinical symptoms	Canine vaccinations; Immunization; Animal education
Schistosomiasis ⁹	67 million cases treated in 2015	78 countries – mainly in Africa but present in Middle East, Latin America, and Asia	Americas: 23,000 Europe: ND Africa: 2.5 million Asia: 54,000	Drug: praziquantel Vaccine: none Diagnostic: stool or urine samples using Kato-Katz technique; serological tests	Preventative chemotherapy; Vector control; Water, sanitation, and hygiene (WASH)
Snakebite ¹⁰	5 million bitten each year, with 2.5 million envenomations	Mainly Africa, Asia, Latin America	Americas: ND Europe: ND Africa: ND Asia: ND	Drug: antivenom (snake species dependent) Vaccine: none Diagnostic: none	
Soil transmitted helminthiasis ¹¹	1.5 billion currently infected	Sub-Saharan Africa, the Americas, China, and East Asia	Americas: 321,000 Europe: 1,000 Africa: 930,000 Asia: 2,122,305	Drug: albendazole; mebendazole; ivermectin; pyrantel pamoate ¹² Vaccine: none Diagnostic: Kato-Katz technique	Preventative mass drug administration; Adequate sanitation
Trachoma ¹³	56 million treated in 2015	42 endemic countries in Africa, Central and South America, Asia, Australia, and the Middle East	Americas: 9,000 Europe: ND Africa: 67,000 Asia: 203,000	Drug: azithromycin; tetracycline ¹⁴ Vaccine: none Diagnostic: clinical diagnosis ¹⁵	SAFE strategy (surgery, antibiotics, facial cleanliness, environmental improvement)
Tuberculosis ¹⁶	10.4 million people fell ill in 2015; 480,000 developed MDR-TB in 2015	Global distribution with Asia and Africa accounting for the most new cases in 2015	Americas: 619,000 Europe: 824,000 Africa: 11 million Asia: 28 million	Drug: fixed-dose combinations of ethambutol, isoniazid, pyrazinamide, rifampicin, rifabutin, rifapentine, and/or streptomycin ^{17, 18} Vaccine: bacillus Calmette Guerin (BCG) Diagnostic: sputum smear microscopy; rapid diagnostic test; liquid culture; molecular assays ¹⁹	Integrated patient-centered care and prevention; Sustainable capacity (e.g. sufficient drug supply)

1. Total number of DALYs in both sexes, all ages. Statistics from 2015. See <http://ghdx.healthdata.org/gbd-results-tool>
2. Malaria Fact Sheet, December 2016. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs094/en/
3. Onchocerciasis Fact Sheet, January 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs374/en/
4. Onchocerciasis. Global Network for Neglected Tropical Diseases. Accessed April 26, 2017. www.globalnetwork.org/onchocerciasis
5. Parasites – Onchocerciasis. Centers for Disease Control and Prevention. Accessed April 26, 2017. www.cdc.gov/parasites/onchocerciasis/diagnosis.html
6. Podoconiosis: endemic non-filarial elephantiasis. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/lymphatic_filariasis/epidemiology/podoconiosis/en/
7. Deribe, K., et al. Epidemiology and Individual, Household and Geographical Risk Factors of Podoconiosis in Ethiopia: Results from the First Nationwide Mapping. *Am. J. Trop. Med. Hyg.* 2014.
8. Rabies Fact Sheet, March 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs099/en/
9. Schistosomiasis Fact Sheet, March 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs115/en/
10. Snakebite antivenom Fact Sheet, February 2015. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs337/en/
11. Soil-transmitted helminth infections Fact Sheet, January 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs366/en/
12. Parasites - Soil-transmitted Helminths. Centers for Disease Control and Prevention. Accessed April 26, 2017. www.cdc.gov/parasites/sth/
13. Trachoma Fact Sheet, July 2016. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs382/en/
14. WHO Model List of Essential Medicines, 19th List, April 2015. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1
15. Trachoma. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/trachoma/disease/en/
16. Tuberculosis Fact Sheet, March 2017. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/mediacentre/factsheets/fs104/en/
17. Second line tuberculosis drugs include: amikacin, bedaquiline, capreomycin, cycloserine, delamanid, ethionamide, kanamycin, levofloxacin, linezolid, p-aminosalicylic acid, and streptomycin
18. WHO Model List of Essential Medicines, 19th List, April 2015. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1
19. Tuberculosis Diagnostics. World Health Organization (WHO). Accessed April 26, 2017. www.who.int/tb/publications/tbDiagnostics_factsheet1.pdf?ua=1

4. WIPO Re:Search and other IP sharing platforms

Various platforms and initiatives focused on contributing IP to address gaps in certain research and development fields, such as NTDs, have been established over the past decade. In order to provide context to this Strategic Plan, the following IP sharing initiatives were reviewed and compared with WIPO Re:Search:

- the Global Health Innovative Technology Fund (GHIT)
- TransCelerate
- the Innovative Medicines Initiative (IMI)
- the National Center for Advancing Translational Sciences (NIH-NCATS-NTU)

Overall, while certain aspects of the initiatives overlap, each program is unique. Of these initiatives, only WIPO Re:Search and GHIT focus entirely on malaria, TB, and NTDs. TransCelerate is disease-agnostic, whereas IMI and NIH-NCATS-NTU focus predominantly on NCDs. Pharmaceutical companies are key participants in all the initiatives. IMI has the highest number of companies participating (43) while NIH-NCATS-NTU has the lowest (4). The list of companies participating in each initiative overlap – many companies are participating in more than one initiative. All of the WIPO Re:Search company members are participating in at least one other initiative. Johnson & Johnson, Pfizer, and Sanofi are participating in all the initiatives, except in GHIT, which consists mainly of Japanese companies.

These initiatives are supported by the financial contributions of the participating companies and/or governments. Only TransCelerate is funded solely by its participating companies. Both IMI and NIH-NCATS-NTU rely solely on government funding. WIPO Re:Search and GHIT are supported by participating companies, government, and inter-governmental agencies or programs (WIPO in the case of WIPO Re:Search and the United Nations Development Programme in the case of GHIT). The annual funding for these initiatives varies substantially; WIPO Re:Search relies on the smallest annual funding (<\$2 million US dollars) whereas IMI has the largest (\$330 million US dollars). WIPO Re:Search is the only initiative that has not, to date, provided financial support to its research projects.

Each of these initiatives focus on sharing IP. With the exception of TransCelerate, IP is primarily shared by a participating company with a not-for-profit research organization. WIPO Re:Search has established the most collaborations (112) whereas the NIH-NCATS-NTU program has established the fewest (13). None of the initiatives have resulted, thus far, in a product.

Overall, GHIT and WIPO Re:Search are most similar in scope and strategy, yet there are key differences: (1) GHIT is a fund that provides substantial financial support to IP

sharing projects; and (2) GHIT lacks a group dedicated to proactively engaging eligible research partners in collaboration discussions and subsequently providing alliance management and support upon establishing a collaboration. Both GHIT and WIPO Re:Search focus on cross-sector collaborations; however GHIT is limited to those that engage a Japanese entity. WIPO Re:Search is not limited in this manner. Any Provider and User Member can participate in a WIPO Re:Search partnership, with no geographical restrictions or requirements. This results in more partnership flexibility and a greater variety of research collaborations. Furthermore, because funding accompanies a GHIT project, only a subset of proposed partnerships are accepted and move forward because of limited financial resources. Unlike GHIT, which only supports product development projects, WIPO Re:Search also supports basic research projects whose results could inform product development. The specific research projects accepted by GHIT can vary depending upon the specific requests-for-proposals it has issued. In contrast, any project focused on any NTD, malaria, or TB can be initiated at any time through WIPO Re:Search.

5. Value proposition

Benefits of Membership	For-profit Members	Not-for-profit Members
Facilitated partnering within WIPO Re:Search consortium	✓	✓
Customized collaboration proposals based on research and partnering interests	✓	✓
Establish and develop relationships with emerging and developing world research institutions	✓	✓
Build relationships with other innovators in the field	✓	✓
Personalized introductions to WIPO Re:Search Members	✓	✓
Membership in a UN agency program ¹	✓	✓
Subscription to monthly BVGH Partnership Hub Snapshot newsletter	✓	✓
Communications and Advocacy		
Global organization awareness ²	✓	✓
Resources featured in Snapshot “Highlighted Contributions”	✓	✓
Collaborations highlighted in newsletters, publications and press releases	✓	✓
News of organization’s activities are advertised via BVGH’s social media platforms	✓	✓
Opportunity to represent WIPO Re:Search and organization at high profile global events	✓	✓
Input in Annual Meeting agenda	✓	✓
Advocacy and awareness of organization’s commitment and contributions to global health ³	✓	
Special mention on BVGH website	✓	
Special mention in BVGH Partnership Hub Snapshot	✓	
Access to Information		
Complimentary access to BVGH workshops and symposia	✓	✓
Free access to BVGH FundFinder ⁴	✓	
Customized list of funding opportunities delivered quarterly as requested ⁵	✓	
Access to proprietary BVGH Reports	✓	

1. World Intellectual Property Organization (WIPO)
2. Organization and logo included in marketing materials, media coverage, publications, etc.
3. BVGH will use organizations as examples during discussions with key stakeholders from different sectors.
4. Database of open funding opportunities relevant to NTD, malaria, and TB researchers. More information is available at www.bvgh.org/Current-Programs/BVGH-FundFinder.aspx.
5. Funding opportunities for current or proposed WIPO Re:Search collaborations.

6. Advisory Committee terms of reference and composition

6.1 Terms of reference¹

Preamble: The Advisory Committee is established consistent with the need and evolution of WIPO Re:Search; a similar structure having been foreseen in the Guiding Principles. Its establishment at this juncture was one of the recommendations from the Strategic Review of WIPO Re:Search, and agreed by consensus by the Members during the preparations of the Response from the WIPO Secretariat to the Strategic Review (October 21, 2015). These Terms of Reference were approved at a Quarterly call of Members (June 9, 2016).

Functions: The Committee is an advisory body of WIPO Re:Search with the following functions:

1. Ensure the efficient functioning of WIPO Re:Search's activities;
2. Provide strategic advice relevant to the activities and long-term development of WIPO Re:Search;
3. Review and offer input into the objectives and deliverables, and provide guidance on the development of milestones of WIPO Re:Search;
4. Advise WIPO and BVGH on strategic partnerships and operational models to advance the goals of WIPO Re:Search;
5. Consider other activities, as appropriate, that contribute to the achievement of goals and objectives of WIPO Re:Search, in particular on a fundraising strategy.

Membership: The Committee consists of up to nine members (excluding observers). Committee membership represents the geographical and organizational diversity of WIPO Re:Search Members from the private sector, public sector, product development partnerships, and academia. WIPO Re:Search staff serves as the Secretariat. WHO, as a technical adviser to WIPO, is an observer. WIPO and BVGH may jointly invite other observers.

Appointments and length of term: Upon consultation with Committee members and WIPO Re:Search Members, the WIPO Secretariat and BVGH identify yearly one member of the Committee to serve as Chair and another as Vice-Chair. Three members of the Committee are appointed from among the Funding Company Members. Other members are appointed jointly by the WIPO Secretariat and BVGH. Subsequent to a transition period, the term for Committee members is three years, renewable once.

Frequency and nature of meetings: The Committee meets at least once per year, as well as through teleconferencing, twice per year. Additional meetings to discuss specific or urgent issues may also be arranged, including sub-committees. At the discretion of the Chair, the Committee may meet in executive session.

Minutes and Reports: Minutes of meetings are prepared by the WIPO Secretariat in consultation with BVGH, reviewed by the Chair and approved by the Committee. Committee members and/or observers may be asked by the Chair to prepare written reports for presentation. These reports may be made publicly available upon recommendation of the Committee and approved by the WIPO Secretariat.

Fiduciary responsibility: The Committee is purely advisory, and members assume no personal liability for management of WIPO Re:Search, either programmatically or financially.

Confidentiality: Each member will sign a confidentiality agreement.

Amendments: These Terms of Reference may be amended, as necessary, on the recommendation of WIPO and BVGH, and by a consensus decision of the Members of WIPO Re:Search.

6.2 Composition (as of April, 2017)

Chair	Peter Hotez,* Baylor College of Medicine, USA
Vice-Chair	Roy Waldron,** Pfizer, USA
Funding companies	Jon Pender, GSK, United Kingdom Ken Gustavson, MSD, USA
Public sector	Carlos Morel, Fiocruz, Brazil Kwadwo Koram, Noguchi Memorial Institute for Medical Research, Ghana Patricia Kelly, IP Australia, Australia
TDR	John Reeder
Partnership Hub	BVGH
Observer	Sue Hill, WHO
Secretariat	WIPO (Global Challenges Division)

* Also representing PDPs and academia

** Also representing funding companies

¹ Approved on June 9, 2016 and amended on November 30, 2016.

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Provider and/or (potential) User Members

Papua New Guinea Institute of Medical Research (PNGIMR) – Papua New Guinea
PATH – USA
Research Institute for Tropical Medicine (RITM) – Philippines
Sabin Vaccine Institute – USA
Saint Louis University, Center for World Health & Medicine (CWHM) – USA
Salvensis – UK
Seattle Children’s Research Institute – USA
Social Medicine Institute, Rio de Janeiro State University – Brazil
South African Medical Research Council (SAMRC) – South Africa
Stanford University School of Medicine – USA
Structural Genomics Consortium – Canada
Swiss Tropical and Public Health Institute (Swiss TPH) – Switzerland
Theodor Bilharz Research Institute (TBRI) – Egypt
Tulane University – USA
Université de Yaoundé I – Cameroon
University of Bamako – Mali
University of Bamenda – Cameroon
University of British Columbia (UBC) – Canada
University of Buea – Cameroon
University of Calgary – Canada
University of California, Berkeley – USA
University of California, San Diego (UCSD) – USA
University of California, San Francisco (UCSF) – USA
University of Campinas – Brazil
University of Dundee – UK
University of Edinburgh – UK
University of Georgia (UGA) – USA
University of Ghana – Ghana
University of Ibadan – Nigeria
University of Kansas – USA
University of Lagos, College of Medicine – Nigeria
University of Mauritius – Mauritius
University of Melbourne – Australia
University of New South Wales (UNSW) – Australia
University of South Florida (USF) – USA
University of Toronto – Canada
University of Vermont (UVM) – USA
University of Washington (UW) – USA
Walter & Eliza Hall Institute of Medical Research (WEHI) – Australia

Walter Reed Army Institute of Research (WRAIR) – USA
Washington University School of Medicine in St. Louis – USA

Supporters

Africa Fighting Malaria (AFM) – South Africa and USA
Association of University Technology Managers (AUTM) – USA
Bibliotheca Alexandrina – Egypt
Biotechnology Industry Organization (BIO) – USA
Council on Health Research for Development (COHRED) – Switzerland
Developing World Health – UK
European Commission, Directorate-General for Research and Innovation – Belgium
Indian Council of Medical Research (ICMR) – India
International Federation of Intellectual Property Attorneys (FICPI) – Switzerland
International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) – Switzerland
International Hospital Federation (IHF) – Switzerland
Kenya Medical Research Institute (KEMRI) – Kenya
Licensing Executives Society International (LESI) – USA
Mahidol University – Thailand
National Institute of Industrial Property (INPI) – Brazil
Operation ASHA – India
Public Interest Intellectual Property Advisors (PIIPA) – USA
Tech Transfer Summit, Ltd (TTS) – UK
United States Patent and Trademark Office (USPTO) – USA

Technical Adviser on NTDs to WIPO

World Health Organization (WHO)

Partnership Hub Administrator

BIO Ventures for Global Health (BVGH)

Secretariat

World Intellectual Property Organization (WIPO)

For an up-to-date list of Members, please visit www.wipo.int/research/en/about/members.html

Secretariat:



Partnership Hub Administrator:



World Intellectual Property Organization
34, chemin des Colombettes
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For contact details of WIPO's
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www.wipo.int/about-wipo/en/offices/

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