



WIPO | Re:Search
Sharing Innovation
in the Fight Against
Neglected Tropical Diseases



WIPO Re:Search

**Advancing Product Development for
Neglected Infectious Diseases through
Global Public-Private Partnerships**



Your partnership will help eliminate the human devastation of neglected tropical diseases, malaria, and tuberculosis

Over one *billion* people currently suffer from neglected tropical diseases (NTDs), malaria, and tuberculosis (TB). Because these diseases disproportionately afflict the poor in low- and middle-income countries, there has historically — and tragically — been a lack of investment in much needed Research and Development (R&D).

In 2011, BIO Ventures for Global Health (BVGH), an industry-engaging non-profit organization, and the World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, joined forces to create a market-based model to foster investments in drug, vaccine, and diagnostic R&D for these disease categories.

We launched the WIPO Re:Search Consortium to unite public and private market forces around an organizing framework that enables the sharing of intellectual property across sectors and geographies, thereby advancing science and scientific networks to address NTDs, malaria, and TB. To date, WIPO Re:Search has catalyzed over 150 R&D collaborations and managed capacity-building fellowships for scientists across sub-Saharan Africa and other low- and middle-income regions. This publication highlights seven exciting collaborations that are advancing solutions to some of the world's most pernicious diseases.

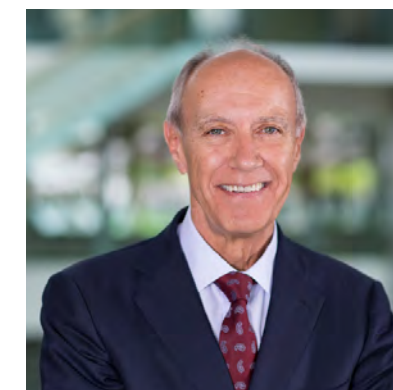
The foundational success and market sustainability of WIPO Re:Search have been made possible by a membership model whereby companies contribute funding annually. This innovative, public-private partnership demonstrates that coupling industry-driven commitments with international scientific expertise efficiently accelerates R&D. Scientists working on critical solutions gain access to industry assets and expertise. Companies, in turn, gain insights into new applications of their existing assets, knowledge about rapidly expanding new markets, and goodwill — both internal and external to the company.

We call on new partners to join WIPO Re:Search to help address the significant unmet needs in the prevention, diagnosis, and treatment of these devastating diseases. Your commitment will support the human ingenuity needed to transform the lives of people and communities throughout the world.

Sincerely,



Jennifer Dent
President & CEO
BIO Ventures for Global Health



Francis Gurry
Director General
World Intellectual Property Organization

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WIPO Re:Search

Overview

WIPO Re:Search is a global public-private consortium that accelerates drug, vaccine, and diagnostic research and development (R&D) to address unmet medical needs for neglected infectious diseases and drive progress toward the United Nations Sustainable Development Goals.

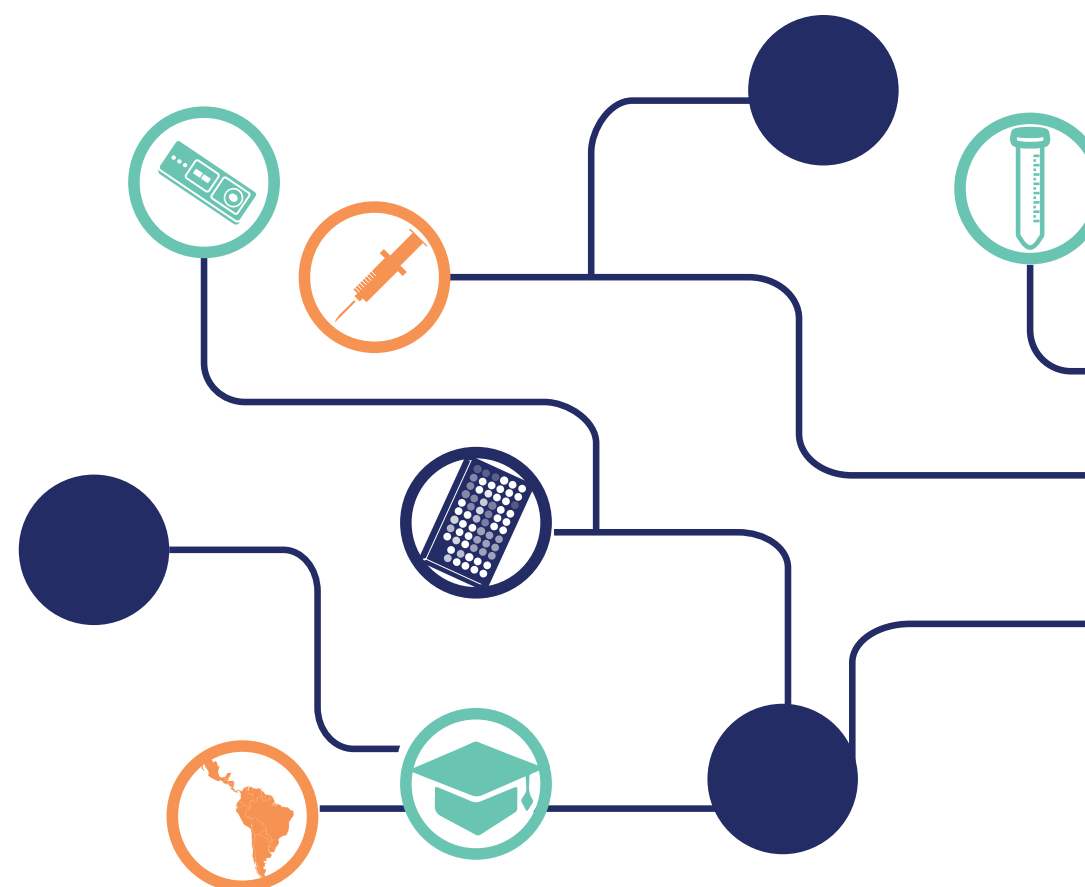
Neglected Infectious Diseases Covered by WIPO Re:Search

Parasitic Diseases	Bacterial Diseases	Viral Diseases	Other Conditions
Chagas disease	Buruli ulcer	Dengue	Podoconiosis
Cysticercosis	Leprosy	Rabies	Snakebite
Dracunculiasis	Trachoma		
Echinococcosis	Tuberculosis		
Foodborne trematodiasis*	Yaws		
Human African trypanosomiasis			
Leishmaniasis			
Lymphatic filariasis			
Malaria			
Onchocerciasis			
Schistosomiasis			
Soil-transmitted helminthiasis			

* Clonorchiasis, fascioliasis, opisthorchiasis, and paragonimiasis

Established in 2011, WIPO Re:Search catalyzes royalty-free sharing of intellectual property—including compounds, data, clinical samples, technology, and expertise—among Consortium Members in targeted, mutually beneficial R&D collaborations that unite the:

- ✓ Scientific know-how and creative thinking of academic, non-profit, and government investigators
- ✓ Firsthand disease knowledge of researchers in endemic countries
- ✓ Material assets and product development experience of global pharmaceutical companies



WIPO Re:Search promotes broad access to resulting products by requiring Members to agree to the Consortium's Guiding Principles, including:

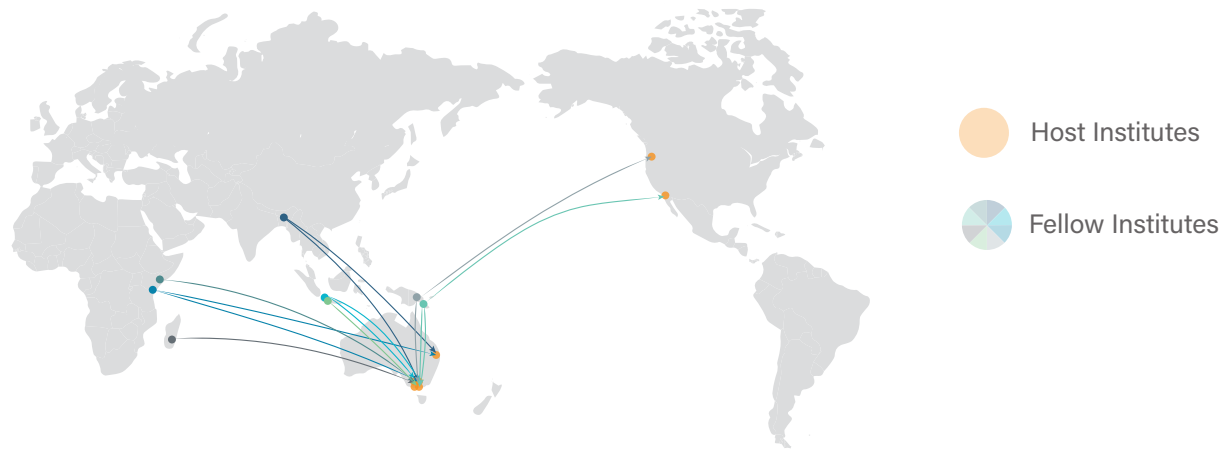
- ✓ Royalty-free licenses for product use and sale in nearly 50 least-developed countries
- ✓ Good-faith consideration of product access for all developing countries

Leadership

BIO Ventures for Global Health (BVGH) is a non-profit organization that connects the for-profit and non-profit sectors to solve global health challenges. BVGH leads Member engagement, partnering, and alliance management for R&D collaborations and fellowships.

World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations and the global forum for intellectual property services, policy, information, and cooperation. As the WIPO Re:Search Secretariat, WIPO manages the WIPO Re:Search Resource Platform, an interactive tool that enables users to visualize and retrieve information about Consortium Members, collaborations, and assets.

The **WIPO Re:Search Fellowship Program**, supported by the Government of Australia through WIPO Funds-in-Trust, organizes training sabbaticals in advanced laboratories to bolster the capacity of low- and middle-income countries to engage in neglected infectious disease R&D. BVGH matches fellows and hosts with complementary research interests and capabilities, with the aim of seeding long-term, mutually beneficial collaborative relationships.



Membership



• Eisai Co., Ltd. • GlaxoSmithKline • Johnson & Johnson • Merck KGaA, Darmstadt, Germany • MSD* • Novartis • Pfizer • Takeda Pharmaceutical Company Limited

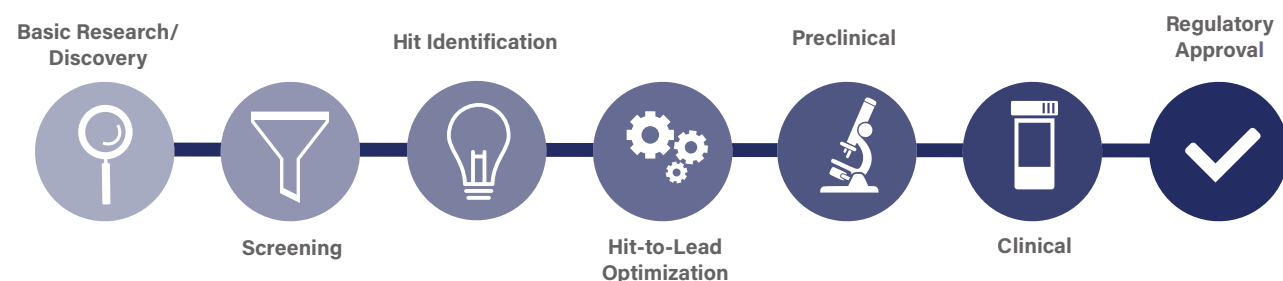
*MSD is a trademark of Merck & Co., Inc., Kenilworth, NJ, USA

BVGH's Unique Partnering Approach Optimizes Collaborative R&D for New Products

BVGH proactively coordinates cross-sector collaborations in alignment with WIPO Re:Search Member priorities. By providing Members with end-to-end alliance management support, BVGH advances and de-risks product development to help ensure successful partnership outcomes.



Since 2011, BVGH has catalyzed **155** innovative WIPO Re:Search R&D collaborations. Of those, **10** ongoing collaborations are advancing critical solutions for neglected infectious diseases along the product development pathway. The pathway for drug products is depicted below; the pathways for diagnostics and vaccines are similar.



Screening: Testing of compounds for desired activity (e.g., inhibition of a specific drug target) in laboratory assays.

Hit: A compound that exhibits the desired activity in a screening assay.

Hit-to-Lead Optimization: Chemical modification of hit compounds to improve their potency, selectivity, and pharmacokinetics (PK; including absorption, distribution, metabolism, excretion, and toxicity), as well as in vitro and in vivo validation studies to identify a small number of compounds (leads) to take forward to preclinical development.

Preclinical: Critical in vitro and in vivo (animal) studies of lead compound toxicity, efficacy, dosing, and PK, conducted to demonstrate to regulatory bodies (such as the US Food and Drug Administration [FDA]) that the compound is ready to proceed to clinical testing.

Clinical: Testing of drug candidates in human volunteers to determine safety, tolerability, dosing, and efficacy prior to regulatory approval. Sometimes classified as Phases 0 through III.

Regulatory Approval: Determination by a government authority (e.g., US FDA) that a drug candidate has met certain standards (defined by each authority) for therapeutic use and may be sold within the relevant jurisdiction.

Advancing Collaborations

The seven promising drug development collaborations featured in this publication have achieved key R&D milestones and have been advanced and de-risked through WIPO Re:Search.

MSD* and Walter and Eliza Hall Institute of Medical Research Malaria

Disrupting malaria parasite replication via a novel target

The Disease

In 2017, an estimated 219 million cases of malaria occurred worldwide.

Fifteen countries in sub-Saharan Africa and India bear almost 80% of the global malaria burden.

The Challenge

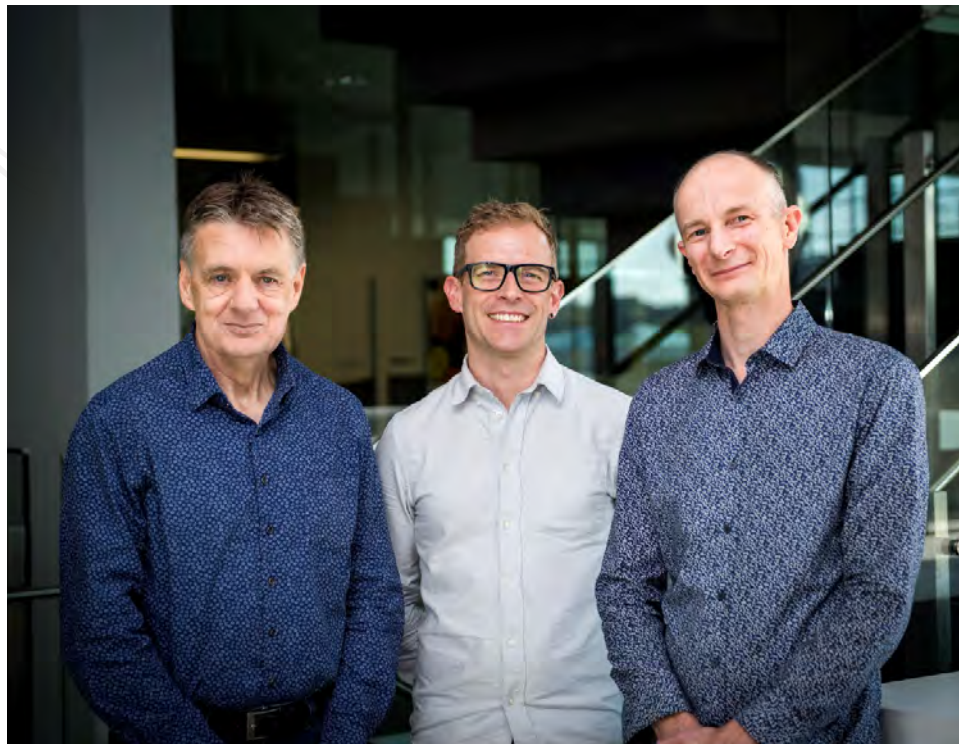
The World Health Organization sounded an alarm in 2018, noting that progress against malaria has stalled after years of unprecedented successes.

Resistance to current medicines is a major threat to malaria control.

The Solution

Change the narrative by developing new drugs with novel modes of action that bypass resistance mechanisms.

Target an aspartyl protease enzyme required for malaria parasite replication.

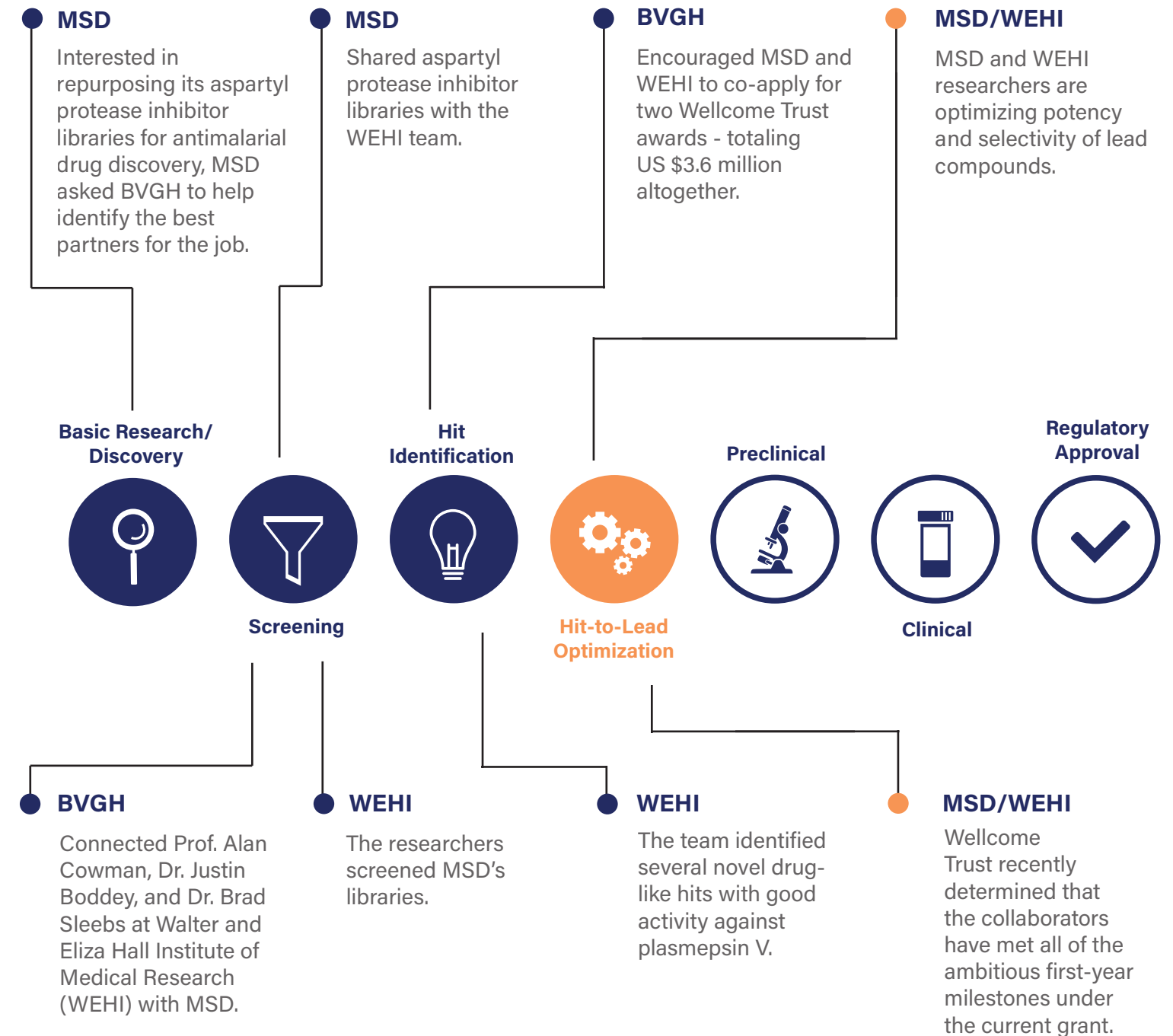


Prof. Alan Cowman, Dr. Justin Boddey, and Dr. Brad Sleebs, Walter and Eliza Hall Institute of Medical Research

The MSD/WEHI collaboration has made some great progress identifying potent chemical matter that has also provided useful tools to decipher some important malaria biology. We are hopeful that our research will lead to a drug that will benefit those who suffer from the deadly effects of this horrible parasite.

— Prof. Alan Cowman, Walter and Eliza Hall Institute of Medical Research

WIPO Re:Search Advances Solutions Along the Product Development Pathway



*MSD is a trademark of Merck & Co., Inc., Kenilworth, NJ, USA

Merck KGaA, Darmstadt, Germany and University of Buea Onchocerciasis (river blindness)

Fighting onchocerciasis, a leading cause of infectious blindness, through Global North/South collaborations

The Disease

Onchocerciasis (river blindness) is the second-leading cause of blindness due to infection globally.

Caused by worms transmitted near rivers by the bite of the blackfly.

The Challenge

The current drug treatment kills young onchocerciasis worms but not adult worms.

Patients must take the drug for 15 years – the lifespan of adult worms.

Fatal side effects of the drug may occur in patients co-infected with *Loa loa* worms.

The Solution

Develop a medication with activity against onchocerciasis adult and juvenile worms but not *Loa loa* worms.

Prevent patients with *Loa loa* from experiencing the devastating side effects associated with the current treatment.



Dr. Frédérique Santerre, Merck KGaA, Darmstadt, Germany

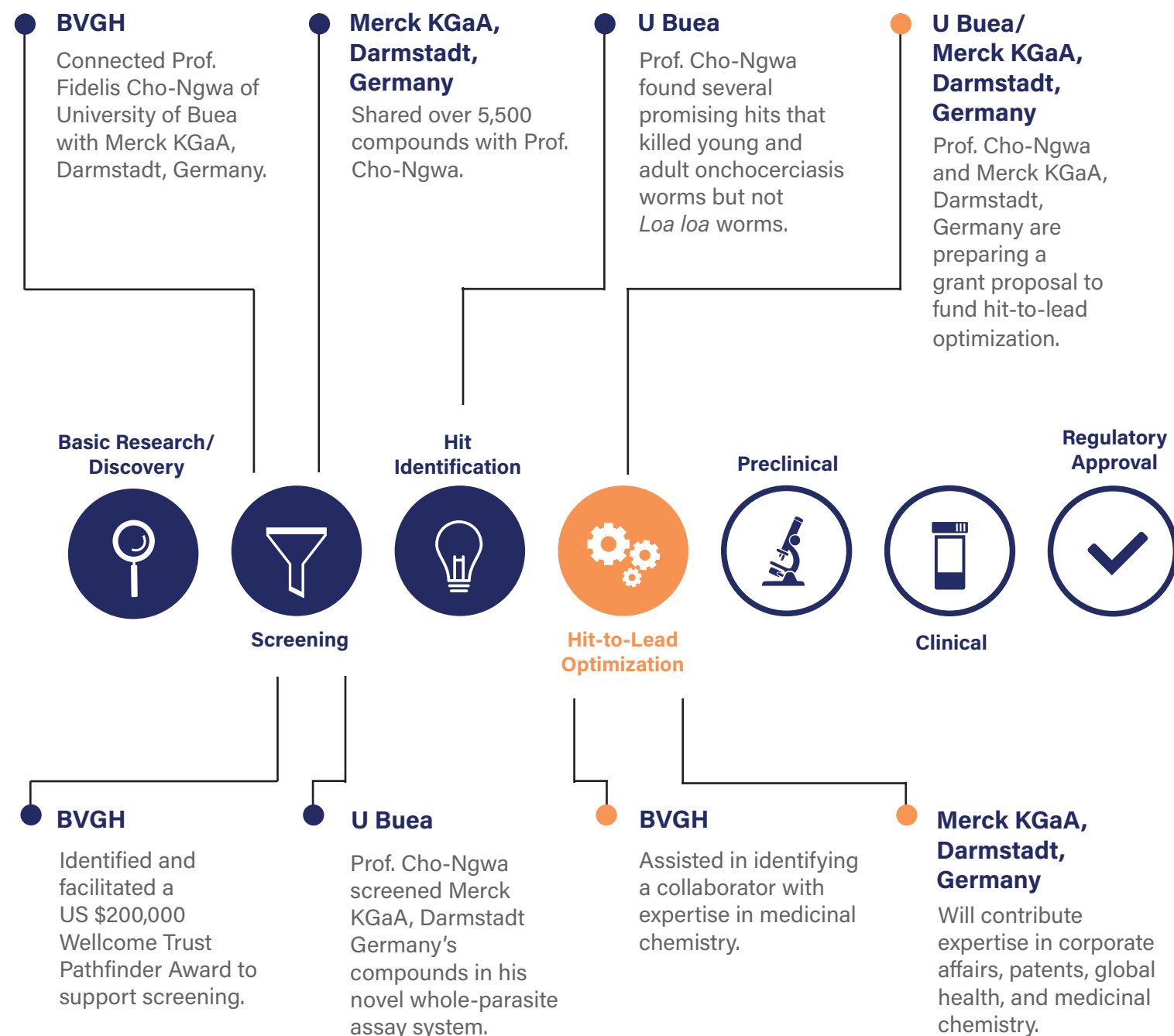


Prof. Fidelis Cho-Ngwa, University of Buea

“Through our Open Innovation Initiative, Merck KGaA, Darmstadt, Germany is committed to addressing access challenges around affordability by sharing our proprietary knowledge to accelerate early discovery for disease areas where we do not have competencies or expertise, such as onchocerciasis or Buruli ulcer. Our aim is to contribute to a vibrant pipeline for these diseases as well as capacity building and health system strengthening in the countries where many of these diseases are endemic.”

— Dr. Frédérique Santerre, Global Head, Access to Health, Merck KGaA, Darmstadt, Germany

WIPO Re:Search Advances Solutions Along the Product Development Pathway



“WIPO Re:Search is a game changer for neglected infectious disease drug development. Thanks to the Consortium and the partnerships that BVGH has facilitated over the last few years, my team at the University of Buea has been able to achieve what some of our predecessors could not accomplish in a decade.”

— Prof. Fidelis Cho-Ngwa, University of Buea

Johnson & Johnson and National Institutes of Health Tuberculosis

Helping the human immune system win the battle against tuberculosis

The Disease

Tuberculosis is the leading infectious disease killer, taking more lives than HIV and malaria combined.

Mycobacterium tuberculosis has been successfully co-evolving with *Homo sapiens* almost as long as humans have walked the earth.

The Challenge

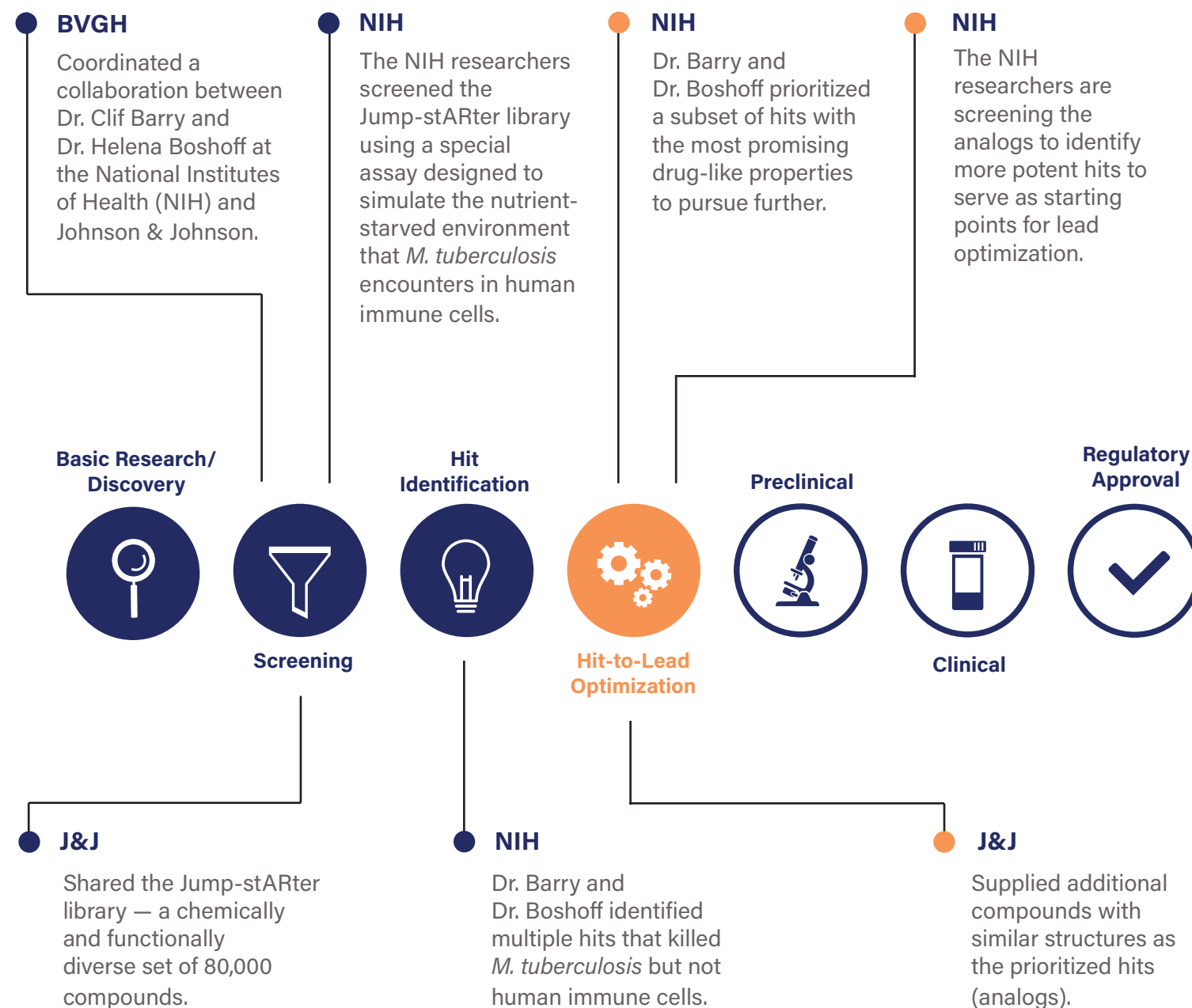
M. tuberculosis has become adept at surviving and reproducing inside human macrophages (immune cells), killing the cells and impairing the body's ability to fight the disease.

A trademark feature of *M. tuberculosis* is its ability to survive nutrient-starved conditions within immune cells.

The Solution

Defeat tuberculosis by developing a drug that is active against the pathogen residing inside immune cells, but not toxic to the cells.

WIPO Re:Search Advances Solutions Along the Product Development Pathway



Takeda Pharmaceutical Company Limited and University of British Columbia
Tuberculosis
Protecting human immune cells from the ravages of tuberculosis

The Disease

Tuberculosis is the world's deadliest infectious disease.

In 2017, approximately 500,000 people developed tuberculosis that was resistant to rifampicin, the most effective first-line drug.

The Challenge

Current treatment regimens are lengthy and complicated, often involving multiple drugs taken on varying schedules, for up to two years.

Multidrug-resistant and extensively drug-resistant tuberculosis are on the rise.

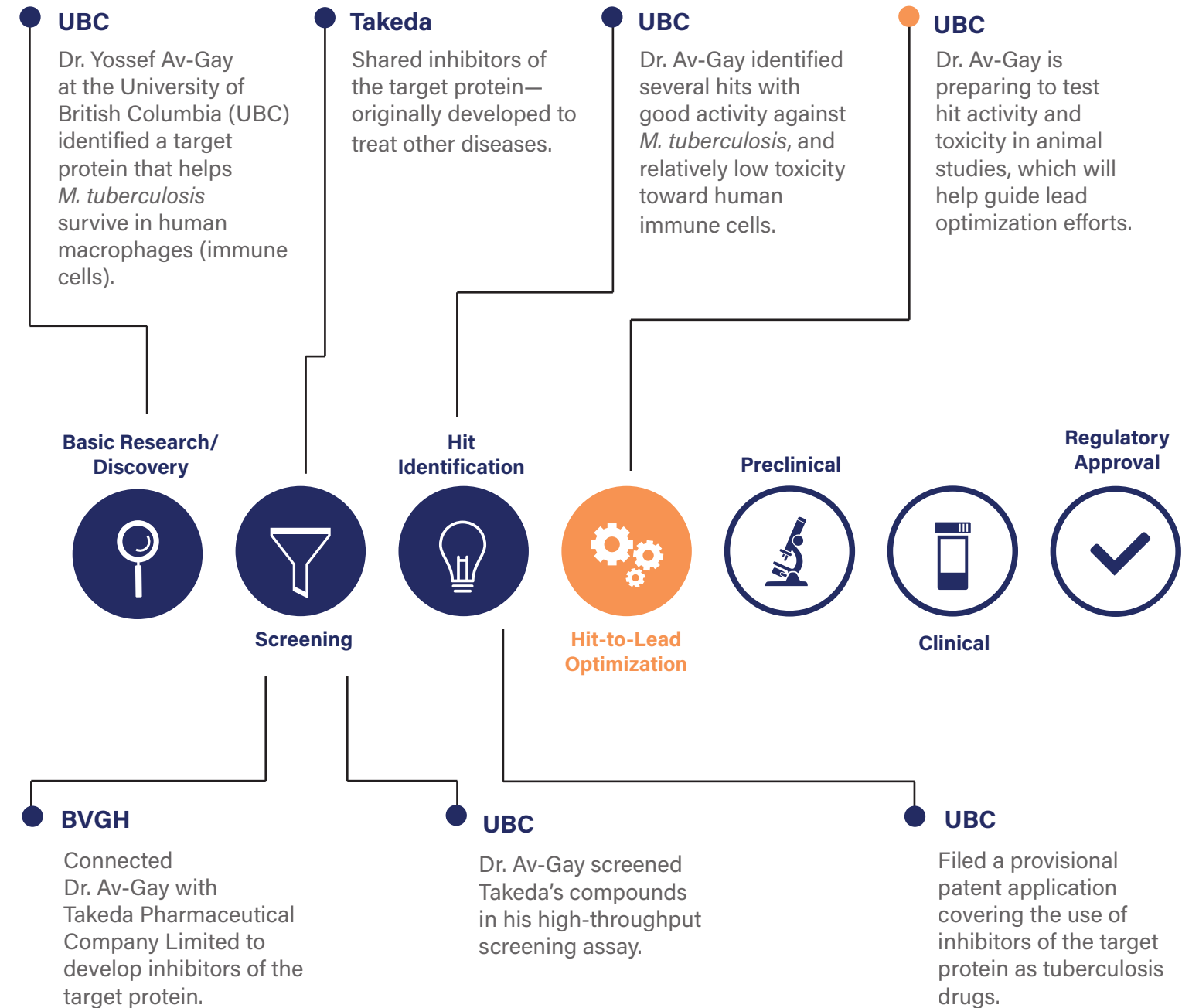
The Solution

Develop new medications with different mechanisms of action (to outpace resistance) and shorter periods of administration.



Dr. Yossef Av-Gay, University of British Columbia

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Johnson & Johnson and Walter and Eliza Hall Institute of Medical Research Malaria

Developing an antimalarial drug with a novel mode of action to circumvent growing resistance

The Disease

Malaria is one of the world's most devastating diseases, causing over 430,000 deaths in 2017 alone.

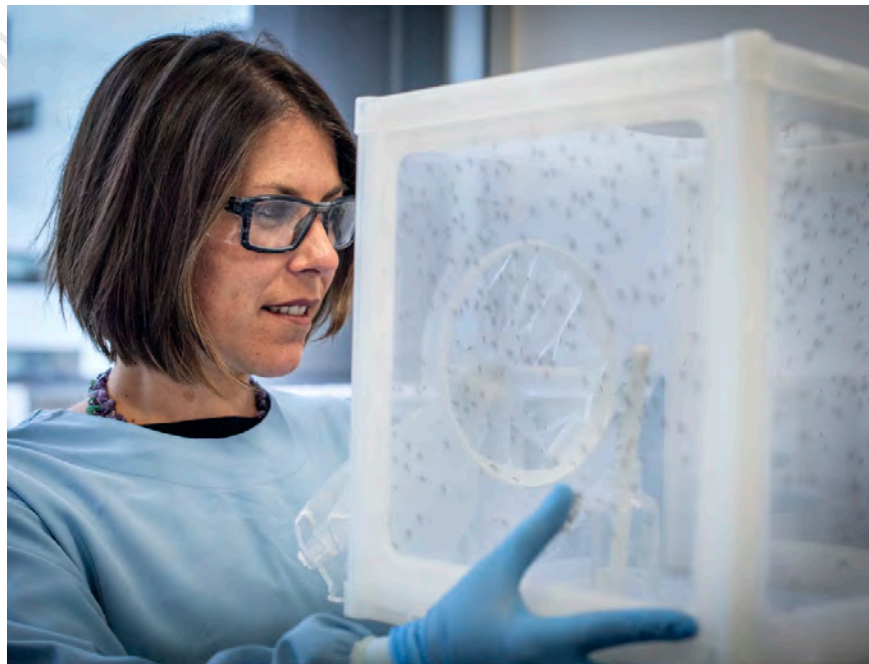
Children under five years old are the most vulnerable — in 2017, they accounted for over 60% of malaria deaths worldwide.

The Challenge

Novel drugs with different mechanisms of action are urgently needed, as current therapeutics are becoming less effective due to emerging resistance.

The Solution

Develop a new drug that attacks malaria parasites in a different way than existing therapies, in order to bypass resistance mechanisms.



Dr. Paola Favuzza, Walter and Eliza Hall Institute of Medical Research

WIPO Re:Search Advances Solutions Along the Product Development Pathway



MSD*, UC San Diego, SCRI, and SSGCID Schistosomiasis (snail fever)

Cholesterol-lowering medications prime pump as schistosomiasis treatment leads

The Disease

Schistosomiasis is an acute and chronic water-borne parasitic-worm disease, with 100 million people treated annually.

Infection occurs when larvae, having been released by freshwater snails, breach the skin during contact with infested water.

The Challenge

Praziquantel is the only available treatment.

Reliance on a single drug increases the risk that resistance will develop.

The Solution

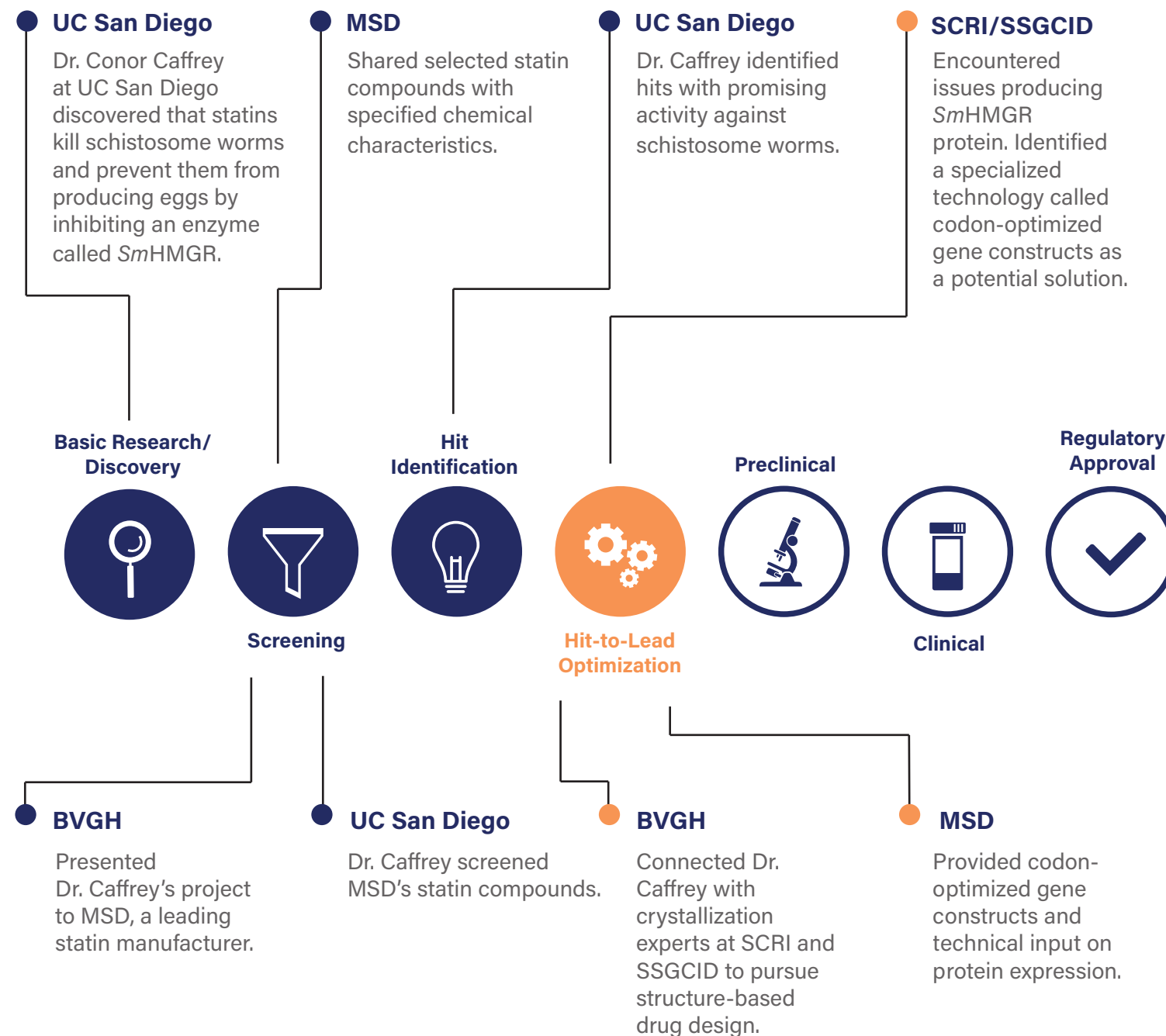
Develop a new drug with a novel mechanism of action.

Repurpose medicines used for other conditions as starting points, to bypass the many time-consuming and risky stages of early drug discovery.



Dr. Conor Caffrey, University of California, San Diego

WIPO Re:Search Advances Solutions Along the Product Development Pathway



SCRI Seattle Children's Research Institute
SSGCID Seattle Structural Genomics Center for Infectious Disease
SmHMGR *Schistosoma* HMG-CoA reductase
UC University of California

*MSD is a trademark of Merck & Co., Inc., Kenilworth, NJ, USA

Johnson & Johnson and Washington University in St. Louis Tuberculosis

Targeting an unexploited vulnerability in *M. tuberculosis* to combat drug-resistant infections

The Disease

In 2018, tuberculosis caused an estimated 1.5 million deaths around the world.

Globally, approximately 500,000 new cases of multidrug-resistant and extensively drug-resistant tuberculosis were reported in 2018.

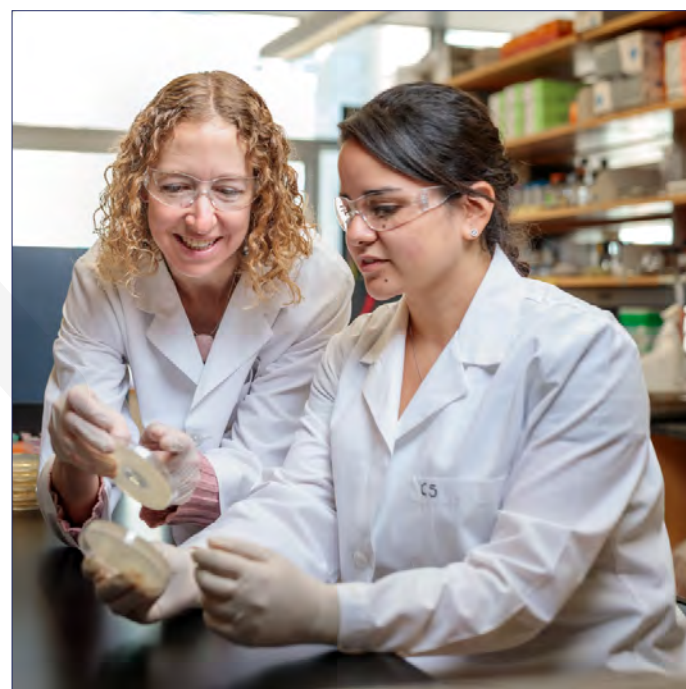
The Challenge

Multidrug resistance is on the rise. Only one in three people with drug-resistant tuberculosis were enrolled in treatment in 2018, with an infected person able to transmit their infection to 15 more people.

Nearly half of patients with drug-resistant tuberculosis are treated unsuccessfully with existing drugs, potentially leaving them both ill and able to transmit the disease.

The Solution

Develop medicines targeting proteins that are not found in humans (reducing the risk of serious side effects) and are not affected by current tuberculosis drugs (decreasing the likelihood that resistance has already developed).

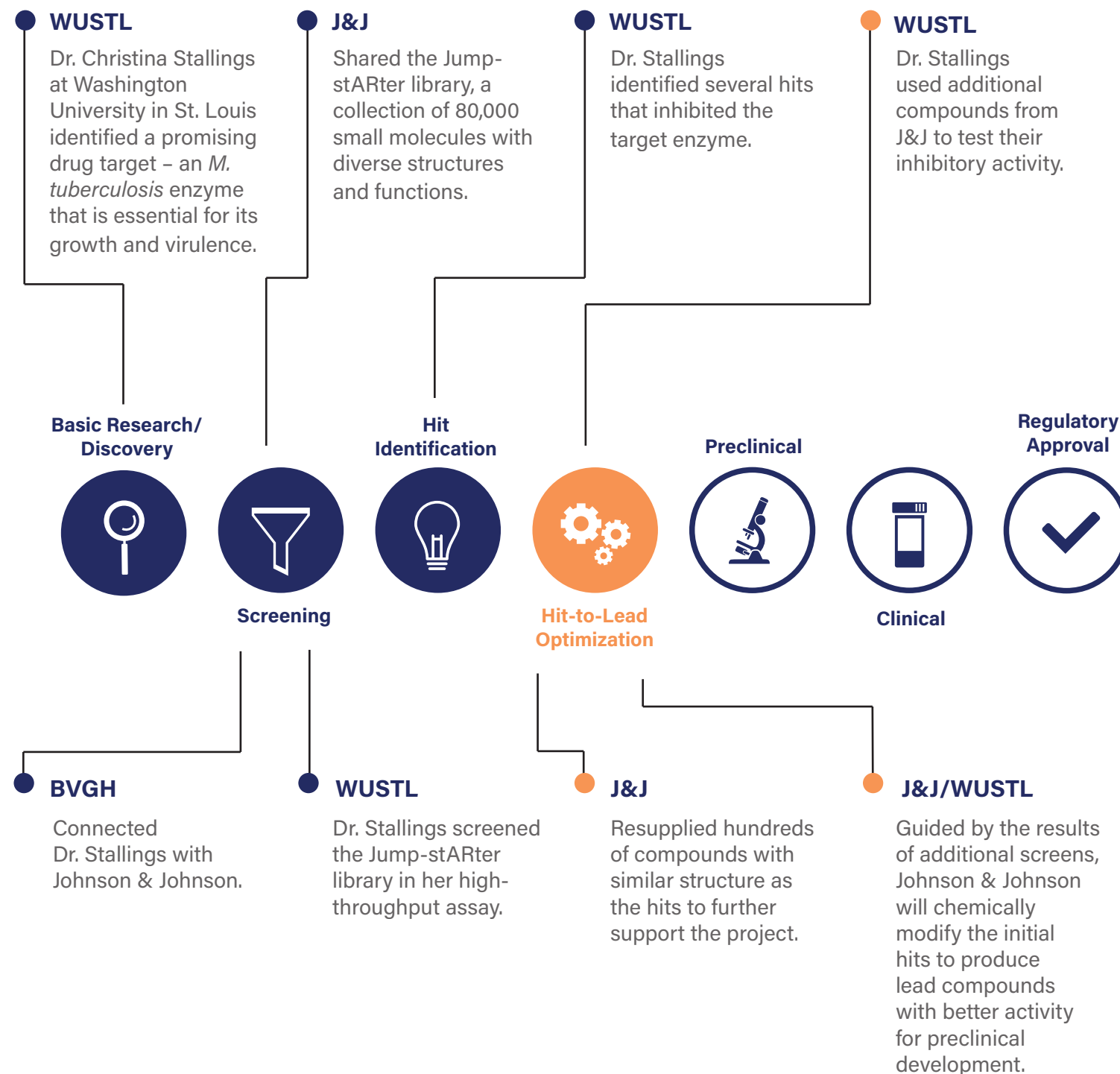


Dr. Christina Stallings and research scientist Sthefany Chavez, Washington University in St. Louis

I am grateful to BVGH for introducing me to Johnson & Johnson— who might not otherwise have returned my calls! — to take my tuberculosis drug discovery research to the next level. We have received not only high-quality compound libraries for screening, but also scientific expertise and logistical support for our ongoing development of the most promising compounds. I am energized by our successes to date and by the prospect of improving tuberculosis treatment for millions of people worldwide.

— Dr. Christina Stallings, Washington University in St. Louis

WIPO Re:Search Advances Solutions Along the Product Development Pathway







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Sharing Innovation
in the Fight Against
Neglected Tropical Diseases

Developed in cooperation with our funding Members:



Johnson & Johnson

Merck KGaA^{*}
Darmstadt, Germany



*Known as EMD in the USA and Canada | **MSD is a trademark of Merck & Co., Inc.,
Kenilworth, NJ, USA



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