

Global health partners collaborate to accelerate development of a new schistosomiasis test to bring this neglected tropical disease under control

- The Foundation for Innovative New Diagnostics (FIND), the Global Health Innovative Technology (GHIT) Fund, the Nagasaki University Institute of Tropical Medicine (NUITM) and Leiden University Medical Center (LUMC) and Merck are joining forces to accelerate development and access to a rapid diagnostic test (RDT) for schistosomiasis
- RDTs are urgently needed to simplify testing and guide targeted deployment of vital medicines in community settings
- The project is supported by an investment of US\$3.5 million from the GHIT Fund

GENEVA, SWITZERLAND; TOKYO & NAGASAKI, JAPAN & LEIDEN, NETHERLANDS – 12 OCTOBER 2020. The Foundation for Innovative New Diagnostics ([FIND](#)), the Global Health Innovative Technology ([GHIT](#)) Fund, the Nagasaki University Institute of Tropical Medicine ([NUITM](#)), and Leiden University Medical Center ([LUMC](#)) announced today a collaboration in partnership with [Merck](#) to develop a rapid diagnostic test (RDT) for schistosomiasis, supported by an investment of US\$3.5 million from the GHIT Fund. This new collaboration will build on the prototype successfully completed by FIND, Mologic Ltd (Thurleigh, UK), LUMC and Merck,¹ and will accelerate the development and validation of an innovative RDT for Asian and African schistosomiasis. This RDT will enable monitoring of treatment campaigns as well as programmatic monitoring and evaluation surveys.

Schistosomiasis is a neglected tropical disease affecting more than 220 million people.² Caused by infection with parasitic worms due to contact with parasite-infested water, the disease devastates whole communities, leading to organ damage, chronic ill health, and ultimately death, if left untreated. With more than 90% of cases in Africa, it is estimated that a further 700 million people could be at risk of infection.^{2,3}

Current field testing for schistosomiasis relies on microscopic examination of stool or urine samples to detect parasite eggs. This practice is time-consuming, and the detection of eggs in the samples can be difficult in patients with moderate-to-low infection levels. To account for this, sampling must typically be repeated over multiple days by trained microscopists, making it costly

¹ FIND extends neglected tropical diseases portfolio to include schistosomiasis <https://www.finddx.org/newsroom/pr-14mar19/>

² WHO fact sheet. Available online at: <https://www.who.int/en/news-room/fact-sheets/detail/schistosomiasis> (accessed 18 September, 2020)

³ WHO fact sheet. Available online at: <https://www.who.int/schistosomiasis/disease/en/> (accessed 18 September, 2020)

and challenging to deploy. Furthermore, inaccurate diagnosis can lead to treatment being stopped early and to recurrence of infection to original levels soon after.

The RDT being developed by the collaborating partners will be based on a finger prick test to detect circulating levels of an antigen (CAA) that is secreted continuously by living schistosomes from various species. It has been shown to have sensitivity that is comparable with repeated microscopy, but without the drawbacks of complex sample preparation, specialist expertise in microscopy and the need for repeat testing.

The test is urgently needed to guide targeted deployment of medicines to the individuals and areas where they can have the greatest impact. The test is subject to global access terms to ensure that it will be affordable and accessible in communities within endemic countries. It represents a critical asset towards reducing the global public health and economic burden caused by schistosomiasis while paving the way to reach disease elimination by 2030.

Catherine Ohura, CEO and Executive Director of GHIT, said: “Schistosomiasis affects hundreds of millions of people, and lack of diagnostic innovation is preventing treatment from reaching those who need it. We are pleased to support this collaboration to accelerate the development of urgently needed tests that will help to achieve sustainable control of the disease, and allow progress towards its elimination.”

Cornelis Hokke, Research Professor at the Department of Parasitology of LUMC said: “LUMC and its collaborators have worked on schistosome glycan antigens and diagnostic assays for endemic settings for more than two decades. We are excited that this work and the antibodies that we have developed now feed into a schistosomiasis RDT that will have a strong impact on global schistosomiasis control and elimination goals. This has always been among the main goals of our research.”

Kenji Hirayama, Head of Secretariat at Japan Alliance on Global Neglected Tropical Diseases (JAGNTD), said: “Schistosomiasis has spread to Africa, South America, China and Southeast Asia, and although mass drug administration with praziquantel is in place, there is still a long way to go before it is eliminated. The project is significant in reducing the time it takes to implement a comprehensive public health policy including transmission and morbidity control and surveillance. We are proud to have researchers from Japan, which was the first country in the world to declare an end of endemic schistosomiasis in 1996, participating in this project.”

Béatrice Gréco, Head of R&D and Access at [Merck Global Health Institute](#) said: “Merck remains committed to fight schistosomiasis until its elimination. To achieve this goal, it requires delivering integrated health solutions, including drugs and diagnostics to the communities in need. This international collaboration is an essential element of such a strategy as it addresses the major gap of providing an accessible diagnostic tool to health systems in endemic countries.”

Joseph Ndung’u, Head of FIND Kenya and lead of the Neglected Tropical Diseases programme at FIND, said: “New technology is urgently needed to get testing out of the laboratory and into the community, so that we can ensure targeted use of the effective treatments we have available today. Effective, accessible RDTs are vital not just for patient care, but also for essential

surveillance and disease tracking that can accelerate progress towards the 2030 elimination goals.”

The new test is being developed in collaboration with Mologic Ltd. The project is expected to complete by the end of 2022.

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About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the development of 24 new diagnostic tools used in 150 LMICs. Over 50 million FIND-supported products have been provided to our target markets since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit www.finddx.org

About GHIT

The GHIT Fund is a Japan-based international public-private partnership fund (PPP) between the Government of Japan, multiple pharmaceutical companies, the Bill & Melinda Gates Foundation, the Wellcome, and the United Nations Development Programme (UNDP). The GHIT Fund invests and manages an R&D portfolio of development partnerships aimed at neglected diseases, such as malaria, tuberculosis and neglected tropical diseases that afflict the world's vulnerable and underserved populations. The GHIT Fund mobilizes the Japanese industry, academia, and research institutes to create new drugs, vaccines, and diagnostics for malaria, tuberculosis, and neglected tropical diseases, in collaboration with global partners. For more information, please visit <https://www.ghitfund.org/en>

About LUMC

The LUMC is a modern university medical center for research, education and patient care with a high-quality profile and a strong scientific orientation. LUMC strongly underpins the idea that ‘Science is the driving force behind innovative healthcare’. Its unique research practice, ranging from pure fundamental medical research to applied clinical research, organised in specific themes including academic pharma, cancer, immunity and infection, places LUMC among the world top. The Department of Parasitology at LUMC consists of an interdisciplinary group of basic and clinical scientists conducting pioneering research on parasitic infections of humans, with a focus on understanding host-parasite interactions at the molecular, cellular and population level. In order to participate in the global fight against poverty-related and neglected diseases we are working to develop vaccines against malaria and helminth infections. Moreover, our activities to advance diagnostic methods in parasitology continue to help patient care in and outside the LUMC. Together with our local and international partners we have developed immunodiagnostic assays based on the detection of *Schistosoma* circulating glycan antigens such as CAA and applied those in over 200 published studies supporting global initiatives for schistosomiasis control and elimination. For more information please visit <https://www.lumc.nl/org/parasitologie/research/>

About NUITM

The Institute of Tropical Medicine, Nagasaki University, aims to overcome tropical diseases, particularly infectious diseases, and the various health problems associated with them, in cooperation with related institutions, to strive for excellence in the following areas:

1. Spear-head research in tropical medicine and international health
2. Global contribution through disease control and health promotion in the tropics by applying the fruits of the research
3. Cultivation of the researchers and specialists in the above fields

For more information, please visit <http://www.tm.nagasaki-u.ac.jp/nekken/en/>

About Merck

Merck, a leading science and technology company, operates across healthcare, life science and performance materials. Around 57,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2019, Merck generated sales of € 16.2 billion in 66 countries. Scientific exploration and responsible entrepreneurship have been key to Merck's technological and scientific advances. This is how Merck has thrived since its founding in 1668. The founding family remains the majority owner of the publicly

listed company. Merck holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the business sectors of Merck operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Within the scope of its [schistosomiasis elimination program](#), Merck provides free of charge up to 250 million tablets of praziquantel annually to endemic countries. In addition, the company is implementing a comprehensive approach combining treatment, research and development, health education & WASH (water, sanitation and hygiene) as well as advocacy and partnership to control transmission and eliminate the disease. www.merckgroup.com

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