

Appendix 1. Project Details

ID: G2026-104

Project Title	Progressing a Fully TPP-Compliant, Field-Validated, and Manufacturable Trachoma RDT to Regulatory Approval and Programmatic Launch.
Collaboration Partners	1. Drugs & Diagnostics for Tropical Diseases (USA) 2. Medical & Biological Laboratories Co., Ltd. (Japan) 3. The Carter Center (USA) 4. Big Eye Diagnostics, Inc. (BEDx/USA)
Disease	Trachoma
Intervention	Diagnostics
Stage	Clinical Validation, Registration
Awarded Amount	JPY 456,338,720 (USD 2.9 million)
Status	Continued project
Summary	<p>[Project objective] The primary objective is to bring the new trachoma dipstick rapid test from an advanced, manufacturable candidate to regulatory acceptance and programmatic launch in 2028. The test is designed for high-throughput laboratory testing of dried blood spots and serum and has already demonstrated the performance, usability, heat stability, and affordability expected by trachoma programs. During this project, the consortium will establish a verification and validation (V&V) plan in consultation with relevant WHO and technical experts, conduct the required V&V studies both in the laboratory and in the field using production-quality pilot lots, compile a complete regulatory dossier, and support a launch decision by global trachoma stakeholders. A second objective is conditional on programmatic demand: the consortium is also evaluating a cassette version that uses the same assay strip but adds a blood filter, enabling testing with fingerstick blood at or near the point of care. Evidence on performance, cost, operational feasibility, and user and community acceptance will guide whether this format should also proceed through verification, validation, regulatory review, and launch. A third, objective is to advance pre-conjugated, freeze-dried Pgp3 multiplex bead assay (MBA) beads which have been shown in the precursor project, G2024-108, to maintain the same diagnostic performance as freshly prepared beads – yet with proven thermal stability for at least two weeks at room temperature. This project will optimize and scale the process, assess reproducibility and thermal stability, obtain independent laboratory validation, and produce pilot lots. Together, these objectives aim to provide trachoma programs with practical diagnostic options spanning centralized laboratories, field settings, and integrated multiplex surveillance. Finally, this project will also continue manufacturing the new Pgp3 dipstick to cover immediate and pressing programmatic needs while waiting for regulatory approval to be secured.</p> <p>[Project design] The project is organized as a staged development program with clear decision points. First, the consortium will prepare a detailed verification and validation plan for the dipstick test in consultation with relevant WHO scientific and diagnostic experts. The plan will define the laboratory studies and, if required, field studies needed to</p>

	demonstrate that independently manufactured lots perform consistently under realistic operating, transport, storage, and use conditions. A separate plan will be prepared for the cassette version only if trachoma programs decide that this format is needed. Second, Medical & Biological Laboratories will supply production-grade Pgp3 antigens, while Big Eye Diagnostics will manufacture tests under an ISO-13485:2016 certified quality system to cover immediate and urgent programmatic needs. The three pilot lots will undergo laboratory verification studies covering performance, repeatability, reproducibility, specimen-related variables, stability, and other parameters. The Carter Center will coordinate any additional field validation studies required by, and included in the V&V plan, in trachoma-endemic countries. Results will be reviewed with stakeholders and incorporated into the manufacturer's quality records. Once all results from the V&V studies are available, the consortium will assemble and submit the regulatory dossier to the appropriate WHO-supported review mechanism, respond to questions, and work with stakeholders on programmatic introduction. The multiplex bead work follows its own go/no-go pathway, whereby the team will optimize conjugation and freeze-drying, demonstrate scale-up and inter-laboratory reproducibility, assess thermal stability, obtain independent validation, and manufacture three pilot lots to lay the ground for future development.
Project Detail	https://www.ghitfund.org/investment/porfoliodetail/detail/281/en

ID: G2026-124

Project Title	Development of a new RT-LAMP / nucleic acid chromatography diagnostic device for the rapid screening of Bundibugyo virus
Collaboration Partners	1. Medical & Biological Laboratories Co., Ltd. (Japan) 2. Nagasaki University (Japan)
Disease	Ebola Disease
Intervention	Diagnostics
Stage	Product design
Awarded Amount	JPY 171,000,000 (USD 1.1 million)
Status	New project
Summary	<p>[Project objective] The objective of this project is to develop a novel diagnostic device for the rapid and, user-friendly detection of Bundibugyo ebolavirus. Given the limited availability of laboratory infrastructure and trained healthcare personnel in outbreak-affected regions, the project aims to establish a diagnostic system that can be used in field settings, including healthcare facilities and community clinics, without requiring sophisticated laboratory equipment. By enabling early identification of infected individuals and timely implementation of infection control measures, the proposed system is expected to contribute to reducing disease transmission and supporting outbreak containment.</p> <p>[Project design] This project aims to develop a novel diagnostic method that combines RT-LAMP with nucleic acid chromatography to enable rapid and accessible visual detection of Bundibugyo ebolavirus. Unlike conventional PCR-based methods, MEMLINE BDBV</p>

	<p>does not require the sophisticated laboratory equipment used for PCR testing, making it suitable for use in healthcare facilities and community clinics. By combining the accuracy of molecular diagnostic tests with the rapid and practical features of antigen tests, this technology can support the rapid detection of infected individuals in outbreak settings.</p> <p>Furthermore, the platform may be adaptable to the detection of other Ebola virus species, providing a valuable tool for preparedness against future outbreaks.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/282/en

ID: T2026-193

Project Title	Development and field investigation of a lateral flow immunoassay for the Ebola hemorrhagic fever Bundibugyo strain in the Republic of Congo
Collaboration Partners	1. Saitama University (Japan)
Disease	Ebola Disease
Intervention	Diagnostics
Stage	Technical Feasibility
Awarded Amount	JPY 20,000,000 (USD 0.1 million)
Status	New project
Summary	<p>[Project objective] The objective of this project is to develop a portable diagnostic kit capable of detecting Ebola virus infection with high sensitivity in less than 15 minutes. The test will be designed for use by frontline healthcare workers without requiring laboratory infrastructure, enabling earlier detection, patient isolation, and treatment. Ultimately, the project aims to support global Ebola control efforts and contribute to improved public health outcomes through faster and more accessible diagnosis.</p> <p>[Project design] The project will first identify Ebola-specific target antigens and high-performance antibody pairs. These components will then be integrated into a highly sensitive diagnostic platform based on proprietary Aggregation-Induced Emission (AIE) fluorescent nanoparticle technology. The prototype will be optimized for analytical performance and evaluated for stability under harsh environmental conditions, such as high temperature and humidity. Usability testing will also be conducted to ensure effective operation in resource-limited settings. In parallel, preparations will be made for future clinical validation and regulatory approval.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/283/en

ID: T2026-194

Project Title	Development of a LAMP-based assay for detection of Bundibugyo virus
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Collaboration Partners	1. Eiken Chemical Co. Ltd. (Japan)
Disease	Ebola Disease
Intervention	Diagnostics
Stage	Technical Feasibility
Awarded Amount	JPY 19,506,586 (USD 0.1 million)
Status	New project
Summary	<p>[Project objective] The project aims to develop a prototype reverse-transcription LAMP reagent that can detect Bundibugyo (BDBV) rapidly and specifically. The target is to achieve a 15-minute result while maintaining sensitivity comparable to existing real-time PCR assays. The project will also evaluate whether the assay can be used with multiple real-time PCR instruments. Ultimately, the prototype developed through this project is intended to undergo external pre-evaluation by WHO or other public health organizations to demonstrate its potential utility for future clinical applications.</p> <p>[Project design] The six-month project consists of three sequential stages. First, Eiken will compare publicly available BDBV genome sequences, select conserved target regions, and design LAMP primers and fluorescence probes. Candidate assays will be screened using non-infectious synthetic RNA or equivalent reference materials, and reaction conditions will be optimized for rapid and specific detection. Second, the selected assay will undergo preliminary analytical evaluation, including sensitivity, interference, and instrument-compatibility studies using contrived whole-blood or plasma samples. Third, the optimized formulation will be transferred to a freeze-dried prototype format. Eiken will manufacture 10,000 prototype tests using existing facilities and conduct performance evaluation.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/284/en

ID: T2025-257

Project Title	Construct and formulation optimization and efficacy evaluation of a bivalent mRNA-lipid nanoparticle vaccine for Lassa virus
Collaboration Partners	1. The University of Osaka (Center for Advanced Modalities and Drug Delivery System, CAMaD) (Japan) 2. The University of Osaka (Research Institute for Microbial Diseases, RIMD) (Japan) 3. The University of Texas Medical Branch at Galveston (UTMB/USA) 4. The University of Osaka (Graduate School of Medicine, UOsaka Med) (Japan)
Disease	Lassa Fever
Intervention	Vaccines
Stage	Vaccine Design
Awarded Amount	JPY 100,000,000 (USD 0.6 million)

Status	New project
Summary	<p>[Project objective] The objective of this project is to advance a safe, effective, and field-deployable bivalent mRNA-LNP vaccine against Lassa virus (LASV) by encoding both LASV GPC and NPL within a single bicistronic mRNA construct. This approach aims to enhance antigenic breadth, improve protective immunity, and streamline manufacturing for future deployment in resource-limited settings. During the project period, we will evaluate vaccine efficacy and immunogenicity in multiple animal models, including a bona fide LASV infection model, and optimize LNP formulations for improved thermal stability. These efforts will accelerate the transition toward clinical development of a thermostable, accessible LASV mRNA vaccine.</p> <p>[Project design] We will develop and validate a bicistronic mRNA encoding LASV GPC and NP, supported by analytical assays to ensure its quality and manufacturability. Bicistronic mRNA-LNPs will be tested in the BSL-2 infection model to assess immunogenicity and protection, and promising candidates will be evaluated in a lethal guinea pig model of authentic LASV infection under BSL-4 conditions. Thermostable LNP formulations will be optimized through lyophilization and compositional adjustments, and their stability will be assessed at elevated temperatures. A scalable manufacturing process will be established to produce preclinical-grade vaccine lots using a controlled mixing method suitable for future clinical production. Finally, protective efficacy will be evaluated in a lethal BSL-4 guinea pig model to support the progression toward clinical development.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/285/en

ID: T2026-152

Project Title	Strategic High-Performance Immunoglobulins for Epidemic and Lethal Diseases (SHIELD)
Collaboration Partners	1. PATH (US) 2. iBody Inc. (Japan)
Disease	Nipah and Hendra virus Infection
Intervention	Diagnostics
Stage	Technical Feasibility
Awarded Amount	JPY 99,900,000 (USD 0.6 million)
Status	New project
Summary	<p>[Project objective] Our goal is to deliver an affordable, robust, easy-to-use, and highly accurate RAT that detects and discriminates between Nipah virus (NiV) and Hendra virus (HeV) infections. This tool will enable early outbreak detection in rural and LRSs, reducing transmission and saving lives.</p>

	<p>[Project design]</p> <p>The project combines the identification of appropriate immunogens, innovative antigen design, and memory B cell antibody screening with iBody's Ecobody technology for very rapid, high-throughput identification of highly specific recombinant Fabs. These will be sequenced and used to develop recombinant forms of IgG that will be assessed by PATH for performance and suitability for use in immunoassays.</p>
Project Detail	https://www.ghitfund.org/investment/porfoliodetail/detail/286/en

ID: S2025-211

Project Title	Improving antimalarial potency of antisense oligonucleotides through bioinformatics and machine-learning
Collaboration Partners	1. Eisai Co., Ltd. (Japan) 2. Medicines for Malaria Venture (MMV/Switzerland)
Disease	Malaria
Intervention	Drug
Stage	Screening
Awarded Amount	JPY 24,031,200 (USD 0.1 million)
Status	New project
Summary	<p>[Project objective]</p> <p>The primary objective of this project is to use bioinformatic approaches and machine learning algorithms to further expand on our previous findings and identify ASOs against Plasmodial genes with improved potency and broader target coverage that are active across multiple parasite species.</p> <p>[Project design]</p> <p>In this project, we will design ASOs that target conserved regions of <i>P. falciparum</i> and <i>P. berghei</i> genes using bioinformatic approaches. These ASOs will be screened against <i>P. falciparum</i> blood-stages and against <i>P. berghei</i> liver-stages using standard assays. The results will be integrated in machine-learning algorithms to further optimize ASO design. We expect that this screening will identify ASOs with improved potency and broader target coverage, which can then be validated for on-target activity using existing genetic tools.</p>
Project Detail	https://www.ghitfund.org/investment/porfoliodetail/detail/287/en

ID: T2025-261

Project Title	Innovative approaches to improve success-rate in Chagas disease drug discovery
Collaboration Partners	1. Nagasaki University (Japan) 2. Eisai Co., Ltd. (Japan) 3. Drugs for Neglected Diseases initiative (Switzerland) 4. University of Dundee (UK)
Disease	Chagas disease

Intervention	Drug
Stage	Drug Discovery
Awarded Amount	JPY 99,910,714 (USD 0.6 million)
Status	New project
Summary	<p>[Project objective] The main objective of this project is to increase the success rate of Chagas disease drug discovery by identifying promising drug candidates more reliably at an earlier stage.</p> <p>Specifically, the project aims to:</p> <ol style="list-style-type: none"> 1- Develop and validate new laboratory tests that can detect whether a drug candidate has the potential to fully eliminate the parasite. 2- Use these tests to identify new starting points for future drug development. 3- Understand why certain drug candidate combinations are especially effective, to design safer and more effective treatments. <p>By achieving these goals, the project will help ensure that only the most promising compounds move forward in the drug development pipeline. This reduces the risk of late-stage failure and supports the development of treatments that are more likely to prove effective for patients.</p> <p>[Project design] The project is organized into three coordinated research components.</p> <p>First, a high-throughput laboratory test is used to rapidly measure how quickly compounds kill the parasites that cause Chagas disease inside human cells. This allows thousands of compounds to be screened efficiently and identifies those with strong anti-parasitic activity.</p> <p>Second, a complementary imaging-based test examines whether parasites return after treatment is stopped. This step is critical for identifying compounds that truly eliminate all parasites.</p> <p>Third, the project investigates why certain drug combinations work better than single drugs. By understanding the biological mechanisms behind these effects, researchers can design more effective combination therapies.</p> <p>Together, these steps form a screening ‘pipeline’ that moves from fast testing to deeper biological understanding, ensuring robust and reliable results.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/288/en

ID: T2025-283

Project Title	Rapid Whole-Blood Multiplex Antigen Test for Serotype-Specific Dengue and Chikungunya Detection
Collaboration Partners	<ol style="list-style-type: none"> 1. VisGene, Ltd. (Japan) 2. University of Miyazaki (Japan) 3. Mahidol University (Thailand) 4. Universidad Nacional Mayor de San Marcos (UNMSM/Peru)

	5. Centro de Investigaciones Tecnológicas, Biomedicas y Medioambientales (CITBM/Peru)
Disease	Dengue, Chikungunya
Intervention	Diagnostics
Stage	Technical Feasibility
Awarded Amount	JPY 77,790,558 (USD 0.4 million)
Status	New project
Summary	<p>[Project objective] The objective of this project is to develop and validate a rapid antigen test capable of simultaneously detecting and differentiating dengue virus serotypes 1–4 and chikungunya virus directly from whole blood within 15 minutes. Differences among dengue virus serotypes are known to influence clinical outcomes and the risk of severe disease. This test is intended to support early diagnosis, appropriate patient management, and effective outbreak response.</p> <p>[Project design] The project integrates serotype-specific detection technology targeting the dengue virus NS1 antigen with monoclonal antibodies against the chikungunya virus E1 antigen into a rapid immunochromatographic device. Clinical evaluations will be conducted in Thailand and Peru, followed by regulatory submissions and development activities with the aim of supporting future regulatory approval and potential WHO prequalification.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/289/en

*All amounts are listed at an exchange rate of USD 1 = JPY 157.31, the approximate exchange rate on September 30, 2026.