U.S. Agency for International Development
Report to Congress
Health-Related Research and Development (R&D) for Fiscal Year 2022

The U.S. Agency for International Development (USAID) submits this report pursuant to Section 7019(e) of Division K of Public Law 117-103, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2022, which incorporates by reference the requirements of House Report 117-84 and the FY 2022 Joint Explanatory Statement (JES).

House Report 117-84: The Committee directs the USAID Administrator to continue the annual report on health-related research, which is important for transparency and oversight of the agency's work on global health research, to be submitted not later than 45 days after enactment of this Act and posted on a public website.

USAID's *Global Health R&D Strategy (2017– 2022)* broadly outlines the Agency's global health R&D goals and its approach to the R&D process. USAID, in consultation with Congress, establishes priorities for investment working alongside the global community, including partner countries, non-profit and multilateral organizations, private sector partners, and other U.S. government partners. Collaboration among these partners ranges from informal data sharing and coordination of investments to more formal agreements like co-funding activities or leveraging infrastructure established through other partner investments. USAID is currently drafting its Global Health Research Strategy beyond 2022 and is using this opportunity to reevaluate its approach to global health R&D, including how it works with other U.S. government partners and the international community to fill gaps and achieve goals in a rapidly changing global health landscape. The report below outlines key developments and collaborations with FY 2021 funding and highlights areas of focus for the coming fiscal year.

I. Research and Development into Health Products

Tuberculosis (TB): The development of effective, shorter, and well-tolerated treatment regimens for people with drug-resistant TB (DR-TB) remains a priority for USAID. USAID is supporting Phase III clinical trials to evaluate combinations of Bedaquiline, Delamanid, Linezolid, and Clofazimine for the treatment of extensively drug-resistant TB (XDR-TB) in India and multidrug-resistant TB (MDR-TB) in South Africa. Enrollment in India is complete and over half of enrolled patients have completed the study. Enrollment in South Africa is 75 percent of target sample size. Both teams are working closely with the local National TB Programs to ensure access to studied treatment options and, if successful, the results would influence national protocols and global policy and guidelines. Both studies include a community engagement component to create a beneficial, respectful, sustained, and transparent partnership that ensures community stakeholders are adequately informed and empowered throughout the research, which will foster constructive collaboration for future implementation. In addition, USAID is supporting a

clinical trial evaluating the efficacy, safety, and tolerability of a novel and potentially shorter drug regimen (BPaMZ) for patients with drug-sensitive and MDR pulmonary TB. The BPaMZ regimen is composed of four antimicrobials: bedaquiline, pretomanid, moxifloxacin and pyrazinamide and is being implemented in 26 centers in 10 countries in Africa, Asia, and Europe.

Global Health Security: USAID partners published more than 80 new journal articles, books/chapters, studies, and other publications related to the spillover, amplification, and spread of zoonotic diseases and antimicrobial resistance—information critical to preventing and responding to future infectious disease outbreaks. USAID continued its financial support to the Coalition for Epidemic Preparedness Innovation (CEPI), which goes toward stimulating and accelerating the development of vaccines and other countermeasures against biological threats. CEPI recently launched a study of individuals who have recovered from Nipah in Bangladesh to research the immune response to the Nipah virus, which is categorized as a pathogen with pandemic potential by the World Health Organization (WHO). The results of the study will provide critical data which could guide the development of much-needed tests, treatments, and vaccines.

Neglected Tropical Diseases (NTDs): USAID is supporting the new WHO Diagnostics Technical Advisory Group (WHO DTAG) for NTDs, to establish new Target Product Profiles (TPPs) for preventive chemotherapeutic NTD diagnostics, notably for Lymphatic Filariasis, Onchocerciasis, Schistosomiasis and Soil Transmitted Helminthiasis, to diversify the products on the market and improve field performance. A request for proposals addressing laboratory and field performance evaluations, through the U.S. Centers for Disease Control and Prevention (CDC), will guide final selection and recommendation for uptake in national elimination programs for surveillance of filariasis and onchocerciasis. USAID is continuing to fund a multi-country trial to evaluate the efficacy of a six-week course of doxycycline to improve the clinical outcomes and quality of life of patients with Lymphatic Filariasis (sometimes called elephantiasis). Results from this study could impact or redefine global strategies for the treatment of patients with moderate disease, which would reduce morbidity and improve quality of life.

Malaria: USAID's Malaria Vaccine Development Program (MVDP) supported research activities to develop novel or improved vaccine candidates against malaria. MVDP completed a clinical study to assess the efficacy of a vaccine targeting the infectious stage of the malaria parasite life cycle. Through MVDP, USAID funded several preclinical studies to evaluate malaria antigens and vaccine-delivery platforms to inform the design of malaria vaccine candidates to stop infection or disease. USAID continued to fund the development of antimalarial drugs through the Medicines for Malaria Venture, including research toward novel treatments to address drug resistance and relapsing malaria. USAID continued to fund the development of critical new insecticides for bed nets and indoor residual spraying (IRS) through the Innovative Vector-Control Consortium. These new insecticides are critical to address the growing resistance of mosquitoes to existing insecticides throughout sub-Saharan Africa. USAID is also supporting the development of novel technology for the application of IRS to improve the coverage of insecticides, reduce waste, and maximize efficiency.

HIV/AIDS: Under the President's Emergency Plan for AIDS Relief (PEPFAR), USAID

developed and launched a multi-product HIV biomedical prevention platform that continues to target, optimize, and expedite the R&D of novel, high-impact biomedical HIV prevention products and technologies, including subcutaneous implants, locally-acting inserts, vaginal rings, an HIV vaccine, and broadly neutralizing antibodies. USAID supports the introduction and scale-up of newly-approved products to accelerate availability, acceptance, uptake, and impact in PEPFAR programs to ultimately achieve a world where women, especially adolescent girls and young women, can live a life free from HIV. Recognizing that a durable HIV vaccine is critical to ultimately ending the HIV epidemic, USAID is partnering with IAVI, Moderna, the Bill & Melinda Gates Foundation, and the National Institutes of Health to prepare sites for the first HIV vaccine trial in Africa to employ an mRNA platform. Along with strengthening the capacity of local scientists and specific research sites, USAID contributed to building shared systems and partnerships capable of enhanced collaboration and consensus building in pursuit of African-based and African-led projects, which will drive the agenda for future locally-relevant vaccine research.

Voluntary Family Planning/Reproductive Health: USAID continues to invest in expanding the range of affordable contraceptive options available in low resource settings. USAID is supporting the development of a microneedle patch, offering women an innovative, discreet, longer-acting contraceptive with simple, safe self-administration. A human subjects study was conducted with placebo patches to obtain end-user feedback and refine final patch formulation and selection. USAID is supporting the research and development of two biodegradable contraceptive implant formulations, which would remove the need for costly and time-intensive removal procedures. In partnership with a private-sector pharmaceutical company, USAID is supporting a pivotal Phase III trial to obtain regulatory approval for a six-month formulation of depo medroxyprogesterone acetate, which would reduce clients' cost, annual dose, and number of clinic visits.

Open Innovation: USAID supports a broad range of global health innovators by running grand challenges, cultivating innovation communities, and supporting innovators as they scale. These initiatives harness the power of crowdsourcing, competition, and partnerships to identify breakthrough innovations around critical health and development problems. For instance, through the Saving Lives at Birth (SL@B) partnership, USAID has supported several of the innovations forming the NEST360° bundle, a private-public partnership to scale a package of 17 technologies that address the major causes of newborn death in Africa. Leveraging more than $68 million in external funding, NEST360° will work with local professional schools to scale and maintain the package of innovations, as well as to train new innovators. The technology was recently awarded Global Health Technologies Coalition's 2021 Innovating for Impact Partnership Award.

II. Implementation Science Research

TB: To provide progressively drug-resistant TB patients with early access to new drug combinations, USAID supports the Clinical Access Program (CAP) that provides controlled access to medications undergoing regulatory or registration processes. In South Africa, CAPs increased access to the BPaL regimen, whose efficacy was demonstrated by the USAID-supported NIX-TB study. USAID, through BPaL-CAP, is accelerating the rapid uptake of this potential life-saving treatment for patients with limited treatment options while generating evidence on the appropriate process for programmatic delivery in order to maximize access.

Global Health Security: USAID supported the research capacity of partner country universities through small grants to faculty and students for applied research on "One Health" topics—12 of which have been published in peer-reviewed publications. Across multiple countries and regions, USAID partners conducted research to assess laboratory capacity; conducted surveillance and mapping of several zoonotic diseases, including avian influenza, swine influenza, MERS-CoV, SARS-CoV-2, and Nipah virus; carried out situational analyses of regional workforce development programs; documented best practices for risk management and reduction measures for zoonotic diseases; and conducted impact assessments of zoonotic disease outbreaks, including COVID-19. USAID supported completion of mixed-methods baseline data collection efforts to understand the knowledge, attitudes, and practices related to on-farm biosecurity among smallholder farmers in India and Kenya, paired with social behavior change research to understand how best to communicate with and influence farmer behaviors related to farm management, biosecurity, antimicrobial usage, and holistic animal nutrition. USAID also supported a feasibility study to improve access to finance for smallholder farmers, in order to facilitate adoption of improved biosecurity and farm-management practices.

Malaria: Through the President's Malaria Initiative (PMI), USAID supported operational research activities to optimize the delivery of malaria-control interventions, evaluate expanded access to malaria prevention and treatment services, and assess new and effective tools against malaria. Completed studies include an evaluation of topical repellents to address outdoor transmission of malaria; evaluations to better understand the intersection of human and mosquito behaviors; evaluation of a new point of care test to guide the safe treatment of vivax malaria; and novel approaches to measure coverage of malaria interventions through mobile phone surveys. USAID also supported studies on new and effective tools to reduce malaria in low to moderate transmission areas through chemoprevention approaches; the feasibility and effectiveness of extending community case-management to all age groups; evaluation of supportive supervision models to improve malaria case management; and novel vector control to further drive down malaria transmission. Additionally, USAID, through PMI, collaborated with the Bill & Melinda Gates Foundation and the Global Fund to Fight AIDS, Tuberculosis, and Malaria to develop a set of country-driven operational research and program evaluation priorities for Africa, which will serve as a valuable resource for donors to better align investments with country needs, and for national malaria programs and partners to identify areas of alignment with their own individual country priorities to collectively drive more impactful investments and achieve the shared goal of ending malaria faster.

Maternal and Child Health: USAID is accelerating learning in real world settings to improve quality of care and survival of mothers and children. Research in Kenya demonstrated how a digital two-way communication system with critical personalized health messages and referrals guided by machine learning, can increase utilization of health services for poor, urban, and often adolescent mothers. This research responds to the expressed needs of mothers and has the potential to address needs in similar sub-Saharan Africa settings. In Uganda, research documented that the poor quality and higher cost of maternal and newborn care in private clinics, weak referral linkages, and limited access to emergency referral transport can adversely affect the urban poor. Kampala health authorities developed a novel partnership with private sector midwives through an accreditation model and a new collaborative approach. Linked to a model emergency transportation network accompanied by a 24/7 call and dispatch center, this approach has

allowed the public and private sectors to work together for the first time to manage at-risk pregnant women and guide lower risk women to seek care from private midwives. In Madagascar and Malawi, USAID tested virtual mentoring models for better provider management of postpartum hemorrhage, a leading cause of death of women. Along with learning on how to improve blood supply management, this research also provided compelling data on the importance of provider mental health and the impact of mental health on respectful care, quality, and health outcomes. Coupled with an analysis of common perinatal mental health disorders in low- and middle-income countries, research identified where more integrated models of care using evidence-based mental health and psychosocial supports may be relevant. This leverages learning supported by USAID non-Global Health Programs funding in community mental health and the mistreatment of women and children. Finally, a developmental evaluation in Tanzania used embedded evaluators to support real-time evidence generation, continuous stakeholder engagement, co-creation and methodological flexibility to identify barriers to integrated service delivery. Advocacy and engagement with health management teams led to high-quality integrated services across antenatal care, postnatal care, and HIV. Recommendations on system and policy-level constraints were shared with national health authorities.

Nutrition: USAID continues to support two studies assessing infants and young child (IYC) feeding counseling, focused on training health providers in lactation counseling and nutrition and community health workers in pneumonia counseling. USAID continues work to refine indicators of micronutrient deficiencies including reliable assessment of anemia prevalence through an inter-country study and simplifying monitoring of iodized salt and urinary iodine concentration to measure intake with UNICEF and other partners. Results will inform new WHO recommendations. Together with UNICEF and the Bill & Melinda Gates Foundation, USAID supports a field study in Tanzania to determine the dietary need, acceptance, and impact of the use of multiple-micronutrient supplements or iron and folic acid during pregnancy. This study uses results from household consumption and expenditure surveys for making dietary inferences for the whole country. As part of the Demographic and Health Surveys Program's efforts to collect and disseminate high-quality data, the program developed a composite anthropometry data quality index to rank the quality of surveys while performing simulation models assessing the impact of measurement error on anthropometric estimates. USAID led efforts to analyze and disseminate evidence about the appropriate use and interpretation of stunting data and complementary indicators suitable for assessing quality or impact of nutrition interventions.

Water, Sanitation, and Hygiene: USAID supported desk reviews, in-depth key informant interviews, and field-based implementation research across Community Led Total Sanitation (CLTS), Market Based Sanitation (MBS), and promoting safe hygiene environments for IYC. CLTS research conducted an examination of whether subsidies targeted at the poorest and most vulnerable households improves use and sustainability of sanitation and a study to better understand the range of conditions in which CLTS is most effective. MBS research focused on understanding the factors that impact viability of sanitation enterprises while Hygienic Environment multi-year research sought to understand whether a protective play space (playmat or play pen) significantly reduces exposure of IYC to harmful enteric pathogens.

Voluntary Family Planning/Reproductive Health: USAID continues to fund implementation and behavioral science research to improve voluntary family planning (FP) and reproductive health (RH) service delivery across 31 priority countries. USAID supported activities that aimed to shift, measure, and evaluate social and gender norms to better support gender equality and positive RH outcomes were completed. USAID supported a critical analysis on impacts of COVID-19 on FP services across African and South Asian countries and conducted a mapping of digital tools and solutions for FP. USAID also supported completion of six country-owned research and learning agendas with local Ministries of Health and civil society partners to advance locally-led research on FP/RH in Nepal, Côte d'Ivoire, Malawi, Mozambique, Niger, and Uganda.

NTDs: For the fourth year, the African Research Network for Neglected Tropical Diseases (ARNTD), with support from USAID and UK Aid, provided small grants to address operational and implementation research on "Emerging Challenges facing NTD program implementation in Africa.'' This year, the grant was awarded to 16 African researchers to undertake operational or implementation research aligned with the goals established in the London Declaration on Neglected Tropical Diseases.

HIV/AIDS: Through PEPFAR, USAID has invested in implementation science to further optimize programmatic responses to tackle 'last mile' challenges for sustained HIV impact. In anticipation of new HIV prevention products and technologies receiving regulatory approval and entering low- and middle-income countries (LMIC) markets, USAID is launching and evaluating a multi-product service-delivery platform to assess the feasibility, product uptake and impact of real world implementation in sub-Saharan Africa. USAID is leading the launch of this implementation science research in five sub-Saharan African countries over the next two years.

Health Systems: USAID conducted health systems strengthening (HSS) research and published HSS evidence across multiple topics. In Guinea, USAID and the Maferinyah Research Center are conducting implementation research on the National Community Health Policy's effectiveness in delivering the essential package of services and meeting population needs among decentralized governmental actors. In Ghana, USAID collaborated with the Ghana Health Service Research Development Directorate to conduct implementation research on the role Primary Care Provider (PCP) Networks can play in advancing equity in service coverage. The study highlighted practices enabling PCP Networks to promote equity for PHC services and elevated demand and supply-side factors that impede the successful implementation of these practices. A Phase II study is underway to guide the design of implementation during a nationwide roll-out of provider networks. USAID additionally co-authored three HSS publications on: integrating the community into primary health care to advance Universal Health Care, country-led institutionalization of community health, and performance-enhancing health worker supervision approaches in LMICs. USAID supported completion of two case studies on digital financial services (DFS) for health, providing evidence on why, how, and under what circumstances DFS investments contribute to achievement of health system outcomes.

Appendix I: Current Estimated Fiscal Year (FY) 2021 Funding from the U.S. Agency for International Development for Health-Related Research and Development

Program Area	Applied Research	Development Research	Total
	FY 2021 Budgeted	FY 2021 Budgeted	FY 2021 Budgeted
HIV/AIDS	-	73,710,000	73,710,000
Tuberculosis	9,520,000	12,600,000	22,120,000
Malaria	10,204,000	10,100,000	20,304,000
Global Health Security in Development	4,120,000	58,000,000	62,120,000
Other Public Health Threats	4,500,000	-	4,500,000
Maternal and Child Health	4,175,000	435,000	4,610,000
Family Planning and Reproductive Health	13,490,000	9,810,000	23,300,000
Nutrition	4,284,000	62,000	4,346,000

Notes: The HIV/AIDS funding for development research reflects the FY 2021 vaccines and microbicides Congressional directives. The table does not include HIV/AIDS research funding programmed through USAID Missions as part of Country Operational Plans for the President's Emergency Plan for AIDS Relief. The Global Health Security funding for development research includes $50 million from the American Rescue Plan Act, P.L. 117-2.

Appendix II: Global Health - Related Product Development, Collaboration and Gap Analysis - FY 2022 Update

FY 2022 JES (incorporated by Sec. 7019(e) of PL 117-103): Not later than 60 days after enactment of the Act, the USAID Administrator shall update the report required under this heading in Senate Report 116- 126.

Senate Report 116-126: The Committee recognizes USAID's role in health-related research and supports continued investments in new global health technologies across each of USAID's health-related programs to address longstanding and emerging global health challenges. Not later than 60 days after enactment of the act, the USAID Administrator shall submit the annual report to the appropriate congressional committees on USAID's health-related research and development strategy, which shall include: (1) specific health product development goals, including timelines for product development; (2) details about ongoing and planned investments in drugs, vaccines, diagnostics, and devices, including collaboration with other Federal agencies as well as private sector partners; (3) a detailed description of the mechanisms for collaboration and coordination in support of global health product development between Federal agencies; (4) an assessment of any critical gaps in product development for global health; and (5) recommendations for filling such gaps to ensure that U.S. investments in global health research are efficient, coordinated, and effective.

The U.S. Agency for International Development (USAID) invests in health technologies and products that support the Agency's goal to prevent maternal and child deaths, control the HIV/AIDS epidemic, and combat infectious disease threats. USAID recognizes that access to safe, effective, affordable, and context-appropriate technologies is critical to addressing the most pressing health care challenges. While critical gaps and product-related goals vary by health area, *USAID's Global Health R&D Strategy (2017– 2022)* provides a broad set of actions intended to harmonize decision making and ensure investments are coordinated, evidence-based, and have potential for impact.

The table in Appendix III below provides a list of USAID-supported R&D in diagnostics, vaccines, drugs, and devices, as well as other contextual information about the investments. This information includes:

Products and Timelines
Timelines for product development are dynamic with a multitude of factors influencing progress along the research-to-use continuum. For example, progress may be catalyzed by an influx of resources such as from another donor or delayed by slow clinical trial recruitment or regulatory barriers. USAID evaluates progress at milestones appropriate to each product's phase in development. USAID works closely with its partners to establish strong monitoring and evaluation frameworks to ensure decisions around ongoing investments in products are made based on feasibility, strong evidence, and the continuing potential for impact at scale. The table in Appendix III provides the current stage of development for each product and the next anticipated milestone where evidence will guide decisions around future investments.

Federal and Private Sector Coordination/Collaboration

Advancing technologies from discovery to implementation at scale requires considerable time and resources, often more than can be provided by a single organization. USAID approaches product development with an understanding that strong global coordination and collaboration provides the greatest potential for efficient and effective return on investments. Coordination with federal and private-sector partners occurs throughout the R&D process, including co-funding of specific research activities, leveraging other donor investments, or exchanging technical assistance and staff capacity to enhance design and implementation. While the table provides descriptions of current product-related partnerships and details on formal collaborative processes, USAID staff maintain strong professional relationships with a diverse set of partners and informal technical discussions regularly occur.

Critical Gaps

USAID maintains strong relationships with a range of international organizations, partner governments, local partners, and community organizations. Evidence and feedback generated by these groups enables USAID, in partnership with other public and private-sector organizations, to identify gaps and pursue solutions. While *USAID's Global Health R&D Strategy* provides an overarching list of goals and approaches for R&D programming, specific health-related gaps are identified in close collaboration with partners and subject matter experts, including a thorough landscape review of technologies and interventions. Each product in the table in Appendix III includes a description of a specific health gap where USAID support may improve programmatic implementation and enhance access, uptake, and use of health care products and technologies. Alongside direct support to product development, USAID is focused on strengthening systems for health care R&D that attract new and diverse partnerships, and empower local partners to conduct research to address country-level health care needs. USAID is engaging with pharmaceutical manufacturers and academic researchers located in low- and middle-income countries, which will strengthen global capacity for product development and ensure diverse and locally-led voices are driving innovation within USAID priority regions and countries. USAID must also continue to focus on providing resources for the procurement and introduction of new products and commodities. USAID appreciates continued flexibility to determine how best to allocate resources across product R&D, service delivery, and the critical implementation science and operations research programming which guides programmatic decision making around introduction and rollout.

USAID is currently conducting a global stakeholder engagement process to inform design of its updated Global Health Research and Development Strategy, which will be made available to the committees upon completion. This strategy will provide further gaps, goals, and processes to advance R&D goals.

Appendix III: USAID-Supported Diagnostic, Vaccine, Drug, and Device Research and Development

Product Name	Health Area	Critical Gap Filled	Development Stage	Next Milestone	USG Partners	Private Sector Partners	Mechanism for Donor Coordination
Diagnostics							
Filarial Test Strip	Lymphatic filariasis	The FTS is currently the only WHO approved diagnostic for community wide implementation for determining prevalence of filarial antigen; however it's performance is mediocre and improvements are greatly needed to this product	Field evaluation/ implementation	QMS negotiations with manufacturer ongoing, no current plan to completely redesign product to address inadequacies, ongoing 2022	CDC	Bill and Melinda Gates Foundation, FHI360, RTI, Task Force for Global Health	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Q-Filarial Antigen Test	Lymphatic filariasis	This newly marketed filariasis diagnostic is more sensitive, and higher reproducibility than the WHO-approved FTS, and will improve program monitoring and save costs	Lab evaluation/ Field evaluation	Field evaluations 2022 and 2023	CDC	SD Biosensor	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Onchocerciasis ELISA	Onchocerciasis	The OV16 ELISA is currently the only WHO approved diagnostic for stopping treatment for onchocerciasis; however it's performance is mediocre and improvements are greatly needed to this product	Field evaluation/ implementation	Field evaluations 2022 and 2023	CDC	Bill and Melinda Gates Foundation	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Onchocerciasis RDT	Onchocerciasis	The OV16 RDT 1.0 is currently the only WHO approved diagnostic for disease mapping and monitoring prevalence of onchocerciasis; however it's performance is mediocre and improvements are greatly needed to this product	Field evaluation	Field evaluations 2022 and 2023	CDC	Bill and Melinda Gates Foundation	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

Onchocerciasis Qualitative PCR (qPCR)	Onchocerciasis	The qPCR is a new platform and method compared to the WHO approved standard PCR; this work will improve cross-lab standardization and sensitivity	Field evaluation/ implementation	Laboratory evaluations 2022	NIAID/NIH	University of Bonn, Smith College, University of S. FL, NY Blood Center	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Lymphatic Filariasis ELISA	Lymphatic filariasis	This new diagnostic is more sensitive than the current, marketed 1.0 product and will improve program monitoring	Pre-Clinical	Prototype design 2022 and 2023	CDC	Drug and Diagnostics for Tropical Diseases	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Onchocerciasis RDT	Onchocerciasis	This new diagnostic is more sensitive than the current, marketed OV16 product and will improve program monitoring	Pre-Clinical	Prototype design 2022 and 2023	NIAID/NIH	Drug and Diagnostics for Tropical Diseases	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Onchocerciasis Diagnostic	Onchocerciasis	This new diagnostic is more sensitive than the current, marketed OV16 product and will improve program monitoring	Field evaluation/ implementation	Field evaluations 2022 and 2023	None	University of Bonn, University of Buea (Cameroon), New England Biolabs	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Schistosomiasis Point of Care Assay	Schistosomiasis	This new diagnostic is more sensitive and user friendly than the current method involving fecal and urine examination by microscopy	Pre-Clinical	Prototype design 2022 and 2023	None	Mondial, Uganda MOH, University of Glasgow	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

Proprietary Schistosomiasis Diagnostic	Schistosomiasis	This new diagnostic is more sensitive and user friendly than the current method involving fecal and urine examination by microscopy	Pre-Clinical	Lab evaluations 2022 and 2023	None	London Natural History Museum, Swiss Tropical Research Institute, FIOCRUZ	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Proprietary Onchocerciasis Urine Validation Test	Onchocerciasis	This new diagnostic is more sensitive than the current, marketed OV16 product and will improve program monitoring	Pre-Clinical	Field evaluations 2022	None	African Research Network for NTDs	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Environmental DNA (eDNA) Snail Schistosomiasis Diagnostic	Schistosomiasis	This new platform is exceedingly less invasive by virtue of it sampling the water environment and not humans for diagnosis	Pre-Clinical	Field evaluations 2022 and 2023	None	African Research Network for NTDs	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Validation of vector traps for onchocerciasis programs	Onchocerciasis	This new method of fly vector trapping will improve mapping and monitoring of onchocerciasis programs	Field evaluation	Field evaluations 2022 and 2023	CDC	African Research Network for NTDs	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Urine Dipstick for Urinary Detection of Onchocerciasis	Onchocerciasis	This new diagnostic is more sensitive than the current, marketed OV16 product and will improve program monitoring	Phase I/Field evaluation	Lab evaluations 2022	None	African Research Network for NTDs	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

Three dimensional paper based aptamer multiplex of malaria and schistosomiasis	Malaria and Schistosomiasis	This new diagnostic is more sensitive and user friendly than the current method involving fecal and urine examination by microscopy (schisto) and increased sensitivity over microscopy (malaria)	Phase I/Lab evaluation	Lab evaluations 2022 and 2023	None	African Research Network for NTDs	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Repurposing urinary hematuria dipsticks for measuring elimination of urinary schistosomiasis	Schistosomiasis	This repurposed rapid diagnostic test for hematuria is hypothesized to be as sensitive, more cost effective, and more scalable than urine filtration diagnosis with microscopes in the field	Phase I/ Field evaluation	Field evaluations 2022	CDC	Safe Water and AIDS Project Kenya	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Chlamydia trachomatis PCR	Trachoma	This new platform is much more cost effective and sensitive at detecting clinical trachoma infection	Phase I/ Field evaluation	Field evaluations 2022 and 2023	CDC	MOH: Ghana, Tanzania, Nepal, Niger, Kiribati, Solomon Islands	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Chlamydia trachomatis Serological Multiplex	Trachoma	This new platform is hypothesized to be much more cost effective and sensitive measuring declining antibody prevalence of blinding trachoma with and with and without other infectious diseases from the same sample	Phase I/ Field evaluation	Field evaluations 2022 and 2023	CDC	MOH: Tanzania, Nepal, Niger, Kiribati, Solomon Islands	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Chlamydia trachomatis lateral flow assay	Trachoma	This new platform is hypothesized to be much more cost effective and sensitive in mapping and measuring declining prevalence of blinding trachoma	Phase I/ Field evaluation	Field evaluations 2022	CDC	MOH: Tanzania, Nepal, Niger, Kiribati, Solomon Islands	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

Machine learning tool for trachomatous trichiasis diagnosis	Trachoma	This new platform is hypothesized to be much more cost effective and sensitive in identifying clinical symptoms and measuring prevalence of blinding trachoma	Phase I/ Field evaluation	Field evaluations 2022 and 2023	None	UNC, Task Force for Global Health	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Vaccines							
FMP013/ALFQ CSP-based malaria vaccine #1 (recombinant protein/adjuvant)	Malaria	Need for highly effective, affordable malaria vaccine	Phase I with controlled human malaria infection challenge (often called Phase IIa)	Trial completed in FY22; No plan for continued development	WRAIR	None	Monthly DoD-USAID meetings, annual USAID Malaria Vaccine Development Program Scientific Consultants Group meeting
CSP-based malaria vaccine #2 (Tobacco-mosaic virus-based virus-like particle (TMV-VLP))	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Phase I trial expected in FY 2023-24	WRAIR	None	Monthly DoD-USAID meetings, annual USAID Malaria Vaccine Development Program Scientific Consultants Group meeting
CSP-based malaria vaccine #3 (mRNA-based)	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Phase I trial expected in FY 24, if milestones are met	WRAIR	None	Monthly DoD-USAID meetings, annual USAID Malaria Vaccine Development Program Scientific Consultants Group meeting
CSP-based malaria vaccine #4	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Pre-clinical testing will continue for selection of formulation	None	PATH, Johns Hopkins University, Scripps Research Institute, Statens Serum Institut (Denmark)	Monthly USAID-PATH management meetings, monthly vaccine team meetings, annual USAID MVDP SCG meeting
E140-based malaria vaccine	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Phase I trial of one or more formulations in FY24 if milestones are met	NMRC	None	Monthly DoD-USAID meetings, annual USAID Malaria Vaccine Development Program Scientific Consultants Group meeting

RH5-based recombinant protein/VLP malaria vaccine	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Phase II clinical trial in Africa	NIAID	PATH, University of Oxford	Monthly USAID-PATH management meetings, monthly vaccine team meetings, annual USAID MVDP SCG meeting
Artesunate pyronaridine	Malaria	Need for highly effective, affordable malaria vaccine	Introduction	Phase IV trials completed and introduction/market shaping underway	None	Medicines for Malaria Venture	Regular meetings with Global Fund and BMGF as well as MMV and other stakeholders
RH5-based mRNA-based malaria vaccine	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Pre-clinical testing will continue for selection of formulation	NIAID	PATH, University of Oxford	Monthly USAID-PATH management meetings, monthly vaccine team meetings, annual USAID MVDP SCG meeting
HIV Vaccine	HIV Prevention	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Pre-clinical	Evaluation of pre-clinical formulation candidates.	State (S/GAC)	IAVI	Collaboration with other donors through Product Development Partnership (PDP) meetings; Standing calls with IAVI to discuss the prioritization of vaccine and monoclonal antibody products that will be funded by USAID through 2026.
Vaccines against priority emerging infectious diseases	Emerging Infectious Diseases	Need for vaccines against priority pathogens including MERS, Lassa, Nipah, Rift Valley fever, Chikungunya, Ebola, and Disease X.	Various stages, including: Lassa - Phase 1a/b Clinical Trials, Nipah - Phase 1 Clinical Trials, Disease X Platform technologies - Preclinical	Various	None	Coalition for Epidemic Preparedness Innovations (CEPI) and a range of product development partners	Monthly interagency calls, participation in CEPI Investors Council and Board meetings.

COVID-19 Vaccines	Emerging Infectious Diseases	Need for improved COVID-19 vaccines.	Various - pre-clinical through clinical trials	Various	None	Coalition for Epidemic Preparedness Innovations (CEPI) and a range of product development partners	Monthly interagency calls, participation in CEPI Investors Council and Board meetings.
Insecticides							
Vectron T500	Malaria vector control	Need for long lasting, non-pyrethroid insecticide for indoor residual spraying (IRS) to mitigate insecticide resistance	Community trials	Plan to submit dossier for WHO PQ listing in Sept 2022. If/when listed, product will be available for use for IRS.	None	BMGF, Unitaid, UKAid, AustralianAid, Global Fund, SDC	Bi-annual Expert Scientific Advisory Committee meetings, IVCC Board meetings, and via agreement deliverables
Confidential - IRS products	Malaria vector control	Need for long lasting, non-pyrethroid insecticide for indoor residual spraying (IRS) to mitigate insecticide resistance	Laboratory/hut trials	Multiple products, therefore various milestones	None	BMGF, Unitaid, UKAid, AustralianAid, Global Fund, SDC	Bi-annual Expert Scientific Advisory Committee meetings, IVCC Board meetings, and via agreement deliverables
Confidential - ITN products	Malaria vector control	Need for long lasting, non-pyrethroid insecticide for indoor residual spraying (IRS) to mitigate insecticide resistance	Laboratory/hut trials	Multiple products, therefore various milestones	None	BMGF, Unitaid, UKAid, AustralianAid, Global Fund, SDC	Bi-annual Expert Scientific Advisory Committee meetings, IVCC Board meetings, and via agreement deliverables
Confidential - attractive toxic sugar baits (ATSB) products; IRS application technology	Malaria vector control	Need for innovative insecticide based tools to mitigate insecticide resistance and address outdoor biting	Laboratory/hut trials	Multiple products, therefore various milestones	None	BMGF, Unitaid, UKAid, AustralianAid, Global Fund, SDC	Bi-annual Expert Scientific Advisory Committee meetings, IVCC Board meetings, and via agreement deliverables
Confidential - surveillance products	Malaria vector control	Need for innovative tools to monitor mosquitoes and resistance	Laboratory/hut trials	Multiple products, therefore various milestones	None	BMGF, Unitaid, UKAid, AustralianAid, Global Fund, SDC	Bi-annual Expert Scientific Advisory Committee meetings, IVCC Board meetings, and via agreement deliverables
Drugs/Devices							
Ganaplacide (KAF156)/lumefantrine	Malaria	Need for alternatives to artemisinin-based combination therapies	Phase II Clinical Trial	Phase II studies underway and planning in place for Phase III	None	Medicines for Malaria Venture	Periodic meetings with MMV to discuss progress

Six-month subcutaneous depot medroxyprogesterone acetate injection	Family Planning/ Reproductive Health	Re-purpose an existing three month intramuscular depot medroxyprogesterone acetate formulation for subcutaneous delivery. Data shows this will extend the duration of efficacy to six months, which will result in lower annual cost and require two fewer injections per year, reducing client and provider burden.	Phase III Efficacy Trial	Phase three trial will begin in 2022 and could have regulatory approval by 2026.	None	A confidential private-sector pharmaceutical company is co-funding the trial. Prior investment from Bill and Melinda Gates Foundation	Monthly update calls with FHI360 who is managing the cooperative agreement under which this trial is being funded.
Contraceptive microneedle patch	Family Planning/ Reproductive Health	Develop a 3-6 month contraceptive product with a potential for self-administration outside of clinical settings. The patch is biodegradable, which will eliminate sharps waste.	Pre-clinical	Human studies with placebo patches are ongoing which will inform selection of lead candidate formulations for future studies.	Prior funding from Eunice Kennedy Shriver National Institute of Child Health and Development	Bill and Melinda Gates Foundation	Biannual portfolio-wide donor coordination meetings and quarterly product-specific update calls.
Biodegradable contraceptive implant	Family Planning/ Reproductive Health	Develop an 18-24 month contraceptive implant that will not require costly and invasive removal procedures.	Pre-clinical	Pre-clinical toxicology, formulation and dosing studies are ongoing with a goal of a go/no-go decision by 2024.	None	Bill and Melinda Gates Foundation	Biannual portfolio-wide donor coordination meetings and quarterly product-specific update calls.
Biodegradable contraceptive pellet system	Family Planning/ Reproductive Health	Develop an 18-24 month biodegradable progestin and estrogen pellet system. The product may be provided with or without the estrogen pellet, allowing clients and providers to personalize the system based on medical needs and preferences. Product will not require costly and invasive removal procedures.	Pre-clinical	Pre-clinical formulation studies are ongoing with goal of lead candidate identification in 2022.	None	None	Biannual portfolio-wide donor coordination meetings and quarterly product-specific update calls.
3D-printed copper IUD containing a non-steroidal anti-inflammatory drug	Family Planning/ Reproductive Health	Determine the feasibility of manufacturing a copper IUD containing a non-steroidal anti-inflammatory drug (NSAID) via 3D-printing. Inclusion of the NSAID may reduce pain and changes to menstrual bleeding that can occur immediately after IUD insertion.	Pre-clinical/ Proof of Concept	Pre-clinical formulation studies are ongoing with goal of establishing proof-of-concept data by 2024.	None	None	Biannual portfolio-wide donor coordination meetings and quarterly product-specific update calls.

Low-cost universal implant inserter	Family Planning/ Reproductive Health	Develop a universal low-cost inserter for contraceptive implants, including candidate biodegradable implant products. This device would reduce the burden of provider training for multiple implant inserters.	Pre-clinical	Human-centered design and provider testing ongoing through 2023.	None	Bill and Melinda Gates Foundation	Bi-annual portfolio-wide donor coordination meetings.
Six-week course of Doxycycline with and without Limb Washing Regimen for Moderate Elephantiasis	Lymphatic Filariasis	The double-blind, placebo-controlled study was designed to investigate the impact of six weeks treatment with doxycycline added to standard limb hygiene on early stage filarial lymphoedema in five sites in Africa and the Indian subcontinent as an inexpensive, scalable adjunct treatment	Phase III Efficacy Trial	Phase III trial ending 2022	NIAID/NIH	Lymphatech, University of Bonn, FHI360, University of Bamako, University of Galle, Task Force for Global Health	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Novel combination antimicrobial therapy consisting of bedaquiline, pretomanid, moxifloxacin and pyrazinamide (BPaMZ) for treatment of Drug susceptible and Drug resistant tuberculosis	Tuberculosis Treatment	Current treatment regimen for DS TB requires the combination of 4 antimicrobial drugs given over a period of 6 months. The treatment for DR includes even more TB medicines for 9 to 18 months. This activity evaluates the effectiveness of a four-month BPaMZ regimen compared to the standard six-month regimen, in people with DS-TB and to the standard 9 to 18-month regimen in people with DR-TB	Phase III Efficacy Trial	Data analysis and publication by mid-2022	None	None	None
Novel combination antimicrobial therapy consisting of bedaquiline, delamanid, Linezolid and Cofazimine/Levofloxacin for treatment of Drug resistant tuberculosis	Tuberculosis Treatment	This activity evaluates the effectiveness and safety of a 6 to 9 - month treatment combination of Bedaquilibe, Delamanid, Linezolid and Clofazimine/Levofloxacin in people with drug resistant TB	Phase III Efficacy Trial	Data analysis and publication by mid-2022. Ending 2022 for India and 2023 for South Africa.	None	None	None

TBI-223 (New oxazolidinone for treatment of Tuberculosis)	Tuberculosis Treatment	Linezolid is an Oxazolidinone that is one the important TB medicines in the new highly efficacious TB treatment regimen combination for DR TB, however Linezolid is associated with serious toxic side effects that are duration- and dose-dependent. These serious adverse events can complicate the use of the regimen. TBI-223 is an oxazolidinone that is being evaluated to determine that it is safer and at least as efficacious as Linezolid.	Phase II	Finalize multiple ascending dose (MAD) study by Mid-2022 and start Phase IIA clinical trail by end 2022	None	None	None
Cabotegravir Hydrogel Depot	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical	Formulation work to increase loading and dosing for the appropriate duration completed by Q3 2022	State (S/GAC)	CONRAD; Viiv Healthcare	Monthly standing call to discuss progress towards broad workplan; Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board
Micro Array Patch (MAP)	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical	Identification and characterization of a suitable API for Microarray Patch use by February 2023	State (S/GAC)	PATH	Monthly standing call to discuss progress towards workplan in detail
Cabotegravir pellets	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical	Formulation work to increase loading and dosing for the appropriate duration completed by Q3 2022	State (S/GAC)	CONRAD; Viiv Healthcare	Monthly standing call to discuss progress towards broad workplan; Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board

Dapivirine Long-acting Film	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical	Non-human primate work assessing efficacy (against multiple SHIVs) starting in Q1 2023	CDC; State (S/GAC)	University of Pittsburg; Janssen; MERCK	Monthly standing call to discuss progress towards broad workplan; Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board
Multipurpose Technology (MPT) Intravaginal Ring (IVR)	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical/clinical	Phase I clinical trial expected in 2023	State (S/GAC)	Oak Crest Institute of Science	Monthly standing call to discuss progress towards broad workplan; Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board
TAF/EVG Fast dissolving insert (FDI)	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical/clinical	Phase I clinical trial starting by end of 2022	State (S/GAC)	CONRAD; Gilead	Monthly standing call to discuss progress towards broad workplan; Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board

Griffithsin Fast dissolving insert (FDI)	HIV Prevention/ Microbicides	USAID's goal is to advance research into a range of products that include, topicals, improved injectables, and on-demand products each of which meet distinct HIV prevention needs of adolescent girls and young women (AGYW).	Pre-clinical/clinical	Phase I clinical trial expected in 2023	State (S/GAC)	Population Council	Monthly standing call to discuss progress towards broad workplan; Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board
Broadly Neutralizing Antibodies (bNAbs)	HIV Prevention	USAID's goal is to advance research into a range of products that include improved injectables and on-demand products each of which meet HIV prevention needs of end users.	Pre-clinical	Phase I clinical trial of a subcutaneous injectable expected in 2023	MHRP; NIH; State (S/GAC)	IAVI; BMGF; Wellcome Trust	Establishing the product profile in collaboration with WHO; Coordinating with other donors including Gates Foundation, MHRP, NIH, Wellcome Trust; Standing calls with IAVI to discuss progress and expected challenges.
Oral PrEP	HIV Prevention	USAID supports evidence-informed and user-centered product introduction, research, research utilization, and capacity development, particularly supporting a multi-product market with informed choice for HIV prevention as new products enter the market	Introduction	Introduction of oral PrEP to AGYW in PEPFAR countries	State (S/GAC)	FHI360, WITS, PZAT, JHPIEGO, AVAC, LVCT	Weekly meetings with prime partner, coordination with larger prevention field including donors and implementing partners to identify gaps within oral PrEP reach and expand oral PrEP availability to women, especially AGYW

Dapivirine Vaginal Ring	HIV Prevention/ Microbicides	USAID supports evidence-informed and user-centered product introduction, research, research utilization, and capacity development, particularly supporting a multi-product market with informed choice for HIV prevention as new products enter the market	Introduction	Q1 2023 expected launch of study to evaluate feasibility of a multi-produce platform for HIV prevention	State (S/GAC)	FHI360; IPM,	Weekly meetings with prime partner; monthly meetings with full consortium members including local partners; Monthly coordination with local MoHs and USAID Missions, Monthly donor calls with key Introduction donor partners BMGF,UNITAID, Global Fund
Long-acting injectable cabotegravir (CAB-LA)	HIV Prevention/ Microbicides	USAID supports evidence-informed and user-centered product introduction, research, research utilization, and capacity development, particularly supporting a multi-product market with informed choice for HIV prevention as new products enter the market	Introduction	Q1 2023 expected launch of study to evaluate feasibility of a multi-produce platform for HIV prevention	State (S/GAC)	FHI360 / ViiV	Routine calls with FHI360, and agreement underway to conduct implementation science on CAB LA introduction as part of multi-product platform for HIV prevention.
Oral F/TAF	HIV Prevention/ Microbicides	USAID supports evidence-informed and user-centered product introduction, research, research utilization, and capacity development, particularly supporting a multi-product market with informed choice for HIV prevention as new products enter the market	Introduction	N/A	State (S/GAC)	CONRAD; Gilead Sciences	Monthly meetings with CONRAD to discuss trial progress; Quarterly meeting with full consortia and industry to monitor progress and findings.