U.S. Agency for International Development
Report to Congress on
Health-Related Research and Development (R&D) for Fiscal Year 2023

The U.S. Agency for International Development (USAID) submits this report pursuant to Section 7019(e) of Public Law 117-328, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2023, which incorporates by reference the requirements of the FY 2023 Joint Explanatory Statement (JES).

JES: Not later than 60 days after the date of enactment of the act, the USAID Administrator shall update the report required under this heading in Senate Report 116–126 on USAID's health-related research and development strategy. Such report shall include details on USAID's research and development of antibiotics. The Committee recognizes that drug-resistant bacterial infections are increasing globally and that lower-income countries experience the highest rates of antimicrobial resistance related deaths.

***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.*

Introduction

USAID's *Global Health Research and Development (R&D) Strategy (2023 - 2028)* outlines the Agency's approach to ensuring research is translated into timely action to improve health, well-being, and resilience of people around the world. To achieve this vision, USAID focuses on: the development of new technologies, tools, and approaches; and implementation science, knowledge management, and research utilization. Cross-cutting these research areas, USAID continues a long-standing focus on partnerships and collaboration, while aiming to develop ethical, locally-led R&D systems. While USAID's Global Health R&D strategy outlines broad approaches to meeting these objectives, this report highlights key developments and collaborations in FY 2022, and areas of focus for FY 2023. Accompanying appendices report USAID's estimated FY 2022 funding levels for health-related research and development (Appendix I) and a detailed list of USAID-supported product R&D (Appendix II).

I. Research and Development into Health Products

Tuberculosis (TB): The new USAID Global TB Strategy (2023 – 2030) reflects the U.S. Government's response to the global TB epidemic, with a focus on developing new tools and approaches. The newly launched USAID project SMART4TB aims to identify, advance, and field evaluate point-of-care tests for diagnosing TB among adults and children. USAID will support the investigation of: treatment of drug resistant (DR) TB by identifying the right regimen and duration, based on a patient's baseline risk of treatment failure and relapse (PRISM-TB); treatment-shortening drug-sensitive (DS) TB trial in children, with a stratified medicine approach (SMILE-TB); and Bedaquiline for TB prevention in adults, children, and pregnant women (BREAK-TB). USAID continues to support Phase III clinical trials to evaluate combinations of Bedaquiline, Delamanid, Linezolid, and Clofazimine to treat extensively drug-resistant TB in India and multidrug-resistant TB in South Africa, as well as the SimpliciTB clinical trial to evaluate efficacy, safety, and tolerability of a pan-treatment regimen (BPaMZ) in adult patients with DS and DR- pulmonary TB.

Global Health Security: As part of USAID's programming, USAID-supported partners published journal articles, books/chapters, studies, and other materials to USAID's Development Exchange Clearinghouse and other publicly available sources 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 increased its non-supplemental funding contribution to the Coalition for Epidemic Preparedness Innovation (CEPI) from $4M in FY 2021 to $55M in FY 2022 (pending Congressional notification). This contribution supports activities aimed at stimulating and accelerating the development of vaccines and countermeasures against biological threats. CEPI recently announced support for the development of an international antibody standard against Sudan ebolavirus to assess and compare vaccine performance against the deadly virus responsible for a recent outbreak in Uganda, which was declared over on January 11, 2023.

Neglected Tropical Diseases (NTDs): USAID continues to support the WHO Diagnostics Technical Advisory Group (WHO DTAG) for NTDs, to establish new Target Product Profiles and technical products for preventive chemotherapeutic NTD diagnostics—notably for Lymphatic Filariasis, Onchocerciasis, Schistosomiasis and Soil Transmitted Helminthiasis. The goal is to diversify products on the market and improve analytical performance in the field. A USAID supported request for proposals between 2020 and 2022 addressing laboratory and field performance evaluations, through the U.S. Centers for Disease Control and Prevention (CDC) and the Task Force for Global Health, will guide final selection and recommendation for uptake in national elimination programs for surveillance of filariasis and onchocerciasis. USAID continues to fund multi-country field evaluation studies to assess priority NTD diagnostics and is also evaluating new diagnostic algorithms and clinical competencies for ensuring female genital schistosomiasis (FGS) is integrated into national health systems. Results from the FGS study could impact or redefine global strategies for improving the treatment of individuals with this condition, thereby reducing morbidity, and improving quality of life.

Malaria: USAID's Malaria Vaccine Development Program (MVDP) supports research on 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 supported several preclinical studies to evaluate malaria antigens and vaccine-delivery platforms to inform the design of malaria vaccine candidates. USAID continues to support the development of antimalarial drugs through the Medicines for Malaria Venture, including research toward novel treatments to address drug resistance and relapsing malaria. USAID supports the development of new insecticides for bed nets and indoor residual spraying 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 a novel technology for the application of indoor residual spraying to improve the coverage of insecticides, reduce waste, and maximize efficiency.

HIV/AIDS: Under the President's Emergency Plan for AIDS Relief (PEPFAR), USAID supports R&D of novel, high-impact HIV prevention products and technologies, including subcutaneous implants, long-acting injectables, locally-acting inserts, vaginal rings, broadly neutralizing antibodies, multipurpose prevention technologies, and a durable and effective HIV vaccine. USAID supports the introduction and scale-up of newly-approved products to accelerate availability, acceptance, uptake, and impact in PEPFAR programs to help women, especially adolescent girls and young women, achieve lives free from HIV.

Voluntary Family Planning/Reproductive Health: USAID continues to invest in expanding the range of affordable contraceptive options. Through enabling couples and individuals to determine whether, when and how often to have children, access to safe, effective, and affordable family planning leads to healthy families and communities and contributes to reductions in maternal and child mortality. USAID supported completion of a clinical trial confirming Sayana Press® is a highly effective contraceptive method when administered every four months, a month longer than the currently labeled three-month interval. In partnership with a private-sector pharmaceutical company, USAID is supporting a pivotal Phase III trial, which began enrollment in FY 2022, to obtain regulatory approval for a six-month formulation of depo medroxyprogesterone acetate. To better inform contraceptive development and counseling, USAID is supporting a clinical trial to evaluate the effect of commonly used contraceptive methods on cervicovaginal structure and function. USAID-supported publication of a Contraceptive-Induced Menstrual Changes (CIMC) research and learning agenda, which encourages better research and implementation around beneficial and negative effects of CIMCs.

Open Innovation: USAID supports a broad range of global health innovators through grand challenges and cultivating innovation communities and 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 example, through the Saving Lives at Birth (SL@B) partnership, USAID 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° works with local professional schools to scale and maintain the package of innovations, as well as to train new innovators. NEST360° has developed a country roadmap tool that USAID is supporting the rollout of in Ghana and Ethiopia.

II. Implementation Science Research

Tuberculosis: To accelerate the rapid programmatic uptake of the WHO recommended BPaL (Bedaquiline, Pretomanid, Linezolid) treatment for patients with DR-TB, USAID continues to support the Clinical Access Program in South Africa. USAID also supports operations research on feasibility and acceptability of the BPaL regimen in Nigeria, Ukraine, Bangladesh, and the Democratic Republic of the Congo. USAID is prioritizing localization efforts for several activities within SMART4TB, including country-led TB research optimizing delivery and uptake of TB transformative diagnostics, prevention, and treatment.

Global Health Security: USAID supported the launch of the One Health Workforce Academy online learning platform building on insights from stakeholder surveys and an eDelphi Panel, which reviewed and updated essential One Health competencies to guide the implementation of training activities. USAID also supported the research capacity of universities in Indonesia, Malaysia, Myanmar, Thailand, Vietnam, and Cambodia with small grants to faculty and students for applied research on "One Health" topics, including emerging infectious diseases, One Health education, food security, antimicrobial resistance, and medical waste management. With the intention of reducing antimicrobial use (AMU) and prevalence of zoonoses and transboundary animal diseases, USAID supported the establishment of research activities with universities and government research institutions in Kenya and India to study the impact of immunity-supporting holistic animal nutrition on the health of poultry and dairy cows. USAID also supported the development of research protocols to expand holistic nutrition research on mitigation of AMU and zoonosis in India, Kenya and Vietnam. USAID is supporting qualitative research in the form of a 'needs and capabilities' assessment of key poultry sector stakeholders in Indonesia and Vietnam to design data-based products to improve animal health surveillance. This activity serves as the first step in establishing a market-supported data and analytics system: understanding the stakeholders and their needs regarding production management, disease surveillance, and AU. USAID also supported a behavioral risk assessment to characterize risk associated with the captive wildlife farming value chain in Dong Nai province, Vietnam.

Malaria: Through the President's Malaria Initiative (PMI), USAID supported operational research 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. Key studies include the evaluation of time-limited mass drug administration in Senegal to support malaria elimination acceleration; housing modification in Uganda to evaluate a promising vector control intervention that prevents mosquitoes from entering the house; malaria community case management expansion in Madagascar; and the role of antenatal care surveillance as a monitoring tool. USAID is supporting studies on new and effective tools to reduce malaria in low-to-moderate transmission areas through chemoprevention approaches; evaluation of supportive supervision models to improve case management; novel vector control to further drive down transmission; and assessment of the efficacy of the RTS,S/AS01 vaccine co-delivered with perennial malaria chemoprevention. Through PMI, and in collaboration with the Bill & Melinda Gates Foundation and the Global Fund to Fight AIDS, Tuberculosis, and Malaria, USAID supported development 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 country priorities to collectively drive more impactful investments, and achieve the shared goal of ending malaria faster. USAID is planning to support a similar country-driven operational research prioritization exercise for malaria vaccine(s) in collaboration with Gavi, the Vaccine Alliance and WHO.

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. 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 adversely affect the urban poor. Kampala health authorities sustained a novel partnership with private sector providers 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 providers. In Ghana, USAID-supported implementation research contributed to strengthening the primary healthcare system with a focus on emergency obstetric and newborn care services using a package of rapid delivery and results-oriented interventions; referral transport and emergency dispatch centers; and quality improvement enhancing provider capacity and use. In Madagascar and Malawi, USAID tested virtual mentoring models for improved management of postpartum hemorrhage, a leading cause of death of women. Along with learning on improving blood supply management, this research 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, USAID-supported research identified where more integrated models of care, using evidence-based mental health and psychosocial support, may be relevant to programs supported by USAID. This leverages previous learning supported by USAID in community mental health and the impact of mistreatment of women and children.

Nutrition: USAID continues to support a study on breastfeeding counseling, focused on mentoring and training health workers. USAID continues work to refine indicators of micronutrient deficiencies, including reliable assessment of hemoglobin concentration to determine anemia prevalence in individuals and populations. The first phase of this included the completion of an inter-country study that concluded venous blood is the preferred sample, but pools of capillary blood may be useful. The second phase of the inter-country study is ongoing and aims to establish procedures for the reliable use of capillary blood. In collaboration with UNICEF and research centers, USAID-supported advances in the measurement and interpretation of biomarkers associated with iodine status are ongoing alongside simplifying monitoring of iodized salt. Results will inform new WHO recommendations. As part of USAID's Demographic and Health Surveys Program's efforts to collect and disseminate high-quality data, the program undertook cognitive testing on nutrition indicators and assessed the association between anemia and early childhood development outcomes. USAID continues to support studies on dietary data collection methods, which will inform how dietary data are collected in large population-based surveys. In addition, USAID-led efforts are underway 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 the technical themes of area-wide sanitation (AWS), market-based sanitation, WASH in health care facilities (HCF), and hygiene environments for infants and young children are being undertaken. Research has been launched to: develop a consensus monitoring system for AWS that will be piloted or expanded; examine the integration of targeted sanitation subsidies in combination with other approaches; develop an understanding how to increase market penetration and reach marginalized populations with commercial sanitation products; promote innovative artificial intelligence handwashing aid in HCF; an assessment of WASH in HCF operation and maintenance management models; and study the impacts of improved handwashing stations and food hygiene behavior change on infants and young children.

Voluntary Family Planning/Reproductive Health: USAID continues to support implementation and behavioral science research to improve family planning (FP) and reproductive health (RH) service delivery across 31 priority countries. Partnering with local research institutes, USAID launched a new global project focused on increasing women's empowerment and gender equity through community-led implementation research. USAID supported a comprehensive analysis of digital platforms that provide FP information to clients, and the development of an open-access checklist to assess content quality of FP digital platforms. Based on this analysis, three digital platforms have revised the content of their tools and five organizations are beta-testing the checklist.

NTDs: For the fifth year, the African Research Network for Neglected Tropical Diseases, based at the University of Kumasi, with support from USAID and the Bill & Melinda Gates Foundation, provided small grants to address operational and implementation research on "Emerging Challenges facing NTD program implementation in Africa.'' This year, grants were awarded to ten African researchers to undertake operational or implementation research aligned with WHO 2030 NTD Roadmap goals.

HIV/AIDS: Through PEPFAR, USAID supports implementation science to rapidly and rigorously answer priority 'last mile' questions through "non-routine" data (e.g., data collected through population surveys, demonstration projects, clinical studies, etc.) to further optimize programmatic responses for sustained HIV impact. USAID prioritizes leading with data, fostering innovation and integration, and country-focused collaboration to respond to the new phase of PEPFAR – where epidemic control is a reality or within reach for many countries. For example, USAID generates and applies evidence to rapidly scale innovations in biomedical prevention. The USAID Catalyzing Access to New Prevention Products to Stop HIV (CATALYST) study aims to characterize and assess the implementation of an enhanced service delivery package providing informed choice of HIV pre-exposure prophylaxis products among women, especially adolescent girls and young women, in five sub-Saharan African countries. USAID CATALYST will look specifically at facilitators and barriers of the implementation process and assess patterns of use and effectiveness.

Health Systems: USAID conducted health systems strengthening (HSS) research and published HSS evidence across multiple topics. USAID is conducting research on behavioral strategies and approaches to reduce demand for poor quality medical products, and to investigate the effectiveness of behavioral interventions in reducing inappropriate antibiotic prescriptions and strengthening antimicrobial stewardship. In Guinea, USAID and the Maferinyah Research Center completed 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 and provided recommendations to strengthen policy design and country-wide roll-out. In Ghana, USAID collaborated with the Ghana Health Service Research Development Directorate to conduct a Phase II study, building on past support to guide implementation design during a nationwide roll-out of Primary Care Provider Networks. USAID also published a research brief to help drive global agreement on core Social Determinants of Health-related competencies for pre-service health workforce education, in-service training, and continued professional development, as well as a publication providing strategies through HSS to build health systems resilience and improve global health security at the subnational level.

III. Antimicrobial Resistance

USAID advances a health ecosystem approach to addressing the emergence and spread of antimicrobial resistance. USAID's research and development efforts are consistent with, and enable this approach, and include applied research and product development in vaccine and therapeutics development, treatment regimens, best practices in infection prevention and antimicrobial stewardship practices in human and animal health and the agri-food value chain. The efforts are captured in previous sections, and listed in Appendix II, and are illustrative of investments across infection prevention, like WASH and vaccine development; new therapeutics to combat resistance; appropriate use practices, including availability, quality use, and disposal; case management and improved treatment regimens, including technologies to improve delayed diagnosis and inappropriate treatment; and social and behavior change.

Appendix I: Estimated Fiscal Year 2022 Funding from the U.S. Agency for International Development for Health-Related Research and Development

Program Area	Applied Research	Development Research	Total
	FY 2022 Budgeted	FY 2022 Budgeted	FY 2022 Budgeted
HIV/AIDS	54,710,000	19,000,000	73,710,000
Tuberculosis	12,790,000	16,470,000	29,260,000
Malaria	9,550,000	10,450,000	20,000,000
Global Health Security in Development	5,030,000	56,260,000	61,290,000
Other Public Health Threats	5,060,000	80,000	5,140,000
Maternal and Child Health	4,660,000	400,000	5,060,000
Family Planning and Reproductive Health	9,580,000	8,000,000	17,580,000
Nutrition	1,850,000	920,000	2,770,000
Total	**103,230,000**	**111,580,000**	**214,810,000**

Note: The HIV/AIDS funding for development research reflects the FY 2022 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 President's Emergency Plan for AIDS Relief.

Appendix II: Product table

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	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 2023	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 reproducible than the WHO-approved FTS, and will improve program monitoring and save costs	Lab Evaluation/ Field Evaluation	Field Evaluations 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	Additional 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	Additional Field Evaluations 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 2023	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 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 2023, Lab Evaluations 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 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 2023, Lab Evaluations 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	Prototype Design 2023, Lab Evaluations 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 2023	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 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 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 2023	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 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 2023	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	Laboratory and Field Evaluations 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	Laboratory and Field Evaluations 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 2023	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 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 FY25 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	Phase I Clinical Trial with controlled human malaria infection	Phase I Clinical Trial with blood stage challenge being performed in FY23-24	NIAID	PATH, University of Oxford	Monthly USAID-PATH management meetings, monthly vaccine team meetings, annual USAID MVDP SCG meeting
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
CD4 binding site engineered outer domain (eOD)-GT8 mRNA-delivered vaccine	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Phase I Clinical Trial	Preliminary immunogenicity data led by African scientists in Q4, 2023	State (S/GAC); NIH	IAVI, Moderna, BMGF	Standing calls and regular meetings with IAVI, Moderna, and BMGF to discuss progress and expected challenges
HIV Conserved Mosaic vaccine: Chimpanzee Adenovirus (ChAdOx1) and poxvirus modified vaccinia virus Ankara (MVA)	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Phase I Clinical Trial	Manuscript to be submitted in Q3, 2023	State (S/GAC)	Oxford University, European & Developing Countries Clinical Trials Partnership (EDCTP),	Standing calls and regular meetings with IAVI and other partners to discuss progress and expected challenges

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BG505 SOSIP gp140 (native-like HIV envelope trimer), adjuvanted with AS01B	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Phase I Clinical Trial	Last Volunteer Last Study visit in Q2, 2023	State (S/GAC), NIH	IAVI, Glaxo Smith Kline	Standing calls with IAVI and other partners to discuss progress and expected challenges
PrEPvacc: Two HIV vaccine regimens and Descovy oral PrEP (DNA-HIV-PT123, AIDSVAX®B/E; DNA-HIV-PT123, CN54gp140, MVA CMDR,CN54gp140; TAF/FTC; TDF/FTC)	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Phase IIb Clinical Trial	Complete study vaccinations by Q4, 2023	State (S/GAC)	Imperial College, European & Developing Countries Clinical Trials Partnership (EDCTP), IAVI	Standing calls and regular meetings with IAVI and other partners to discuss progress and expected challenges

HIV envelope trimer vaccines (CON-S/CON-M/Mosaic trimers, MPLA adjuvant)	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Phase I Clinical Trial	Study to start in Q4, 2023	State (S/GAC)	IAVI, Polymun, European AIDS Vaccine Initiative (EAVI) consortium	Standing calls and regular meetings with IAVI and other partners to discuss progress and expected challenges
Broadly Neutralizing Antibodies (bNAbs) triple combination	HIV Prevention	Passive immunization of combination broadly neutralizing antibodies to provide broad cross-clade protection in adults, infants, and pregnant women (perinatal prevention)	Pre-Clinical	Phase I Clinical Trial	State (S/GAC), NIH	IAVI, BMGF	Standing calls and regular meetings with IAVI, NIH/NIAID, and BMGF to discuss progress and expected challenges
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

Artesunate pyronaridine	Malaria	Need for newer artemisinin combination therapies to combat drug resistance	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
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 III Trial initiated 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	Downselect candidate formulations occurred in FY22. Laboratory refinement and placebo human studies are ongoing to further downselect a lead for clinical selection.	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	In vivo pharmacokinetic study is ongoing and will be completed in FY23. A go / no-go decision on the product will be made based on these results.	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 in vitro and in vivo studies on first-generation system completed in FY22. Second-generation development and testing are ongoing to finalize candidates for first-in-human studies.	None	None	Monthly update calls with CONRAD/ Eastern Virginia Medical School who is the prime partner for the cooperative agreement under which this work is being funded.
3D-printed copper IUD containing a non-steroidal anti-inflammatory drug	Family Planning/ Reproductive Health	Feasibility of manufacturing a copper IUD containing a non-steroidal anti-inflammatory drug (NSAID) via 3D-printing. NSAID may reduce pain and menstrual bleeding changes that can occur 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	Monthly update calls with CONRAD/ Eastern Virginia Medical School who is the prime partner for the cooperative agreement under which this work is being funded.

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 end of 2023	None	None	None
Novel combination antimicrobial therapy consisting of bedaquiline, delamanid, Linezolid and Cofazimine/Levo floxacin for	Tuberculosis Treatment	This activity evaluates the effectiveness and safety of a 6 to 9 - month treatment combination of Bedaquilibe, Delamanid, Linezolid and Clofazimine/Levofl	Phase III Efficacy Trial	Data analysis shared wth the WHO mid-2022. Ending Sept 2023 for India and mid-2024 for South Africa.	None	None	None

treatment of Drug resistant tuberculosis		oxacin in people with drug resistant TB					
TBI-223 (New oxazolidinone for treatment of Tuberculosis)	Tuberculosis Treatment	Linezolid is an Oxazolidinone that is one of the TB medicines in the new highly efficacious TB treatment regimen combination for DR TB, however Linezolid is associated with serious duration- and dose-dependent side effects which 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 Trial	Finalized multiple ascending dose (MAD) study by Mid-2022 and started enrollment in Phase IIA Clinical Trail	None	None	None

Cabotegravir Hydrogel Depot for HIV Prevention only or a Multipurpose Prevention Technology	HIV Prevention/ Microbicides	USAID's goal is to advance research and development of 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	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 and development of 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 for HIV Prevention only or a Multipurpose Prevention Technology	HIV Prevention/ Microbicides	USAID's goal is to advance research and development of 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	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 for HIV Prevention only or a Multipurpose Prevention Technology	HIV Prevention/ Microbicides	USAID's goal is to advance research and development of 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	Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board

Multipurpose Prevention Technology Intravaginal Ring (IVR) as a Multipurpose Prevention Technology for HIV, HPV and HSV	HIV Prevention/ Microbicides	USAID's goal is to advance research and development of 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 2024	State (S/GAC)	Oak Crest Institute of Science	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) as a Multipurpose Prevention Technology for HIV and HSV	HIV Prevention/ Microbicides	USAID's goal is to advance research and development of-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	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) as a Multipurpose Prevention Technology for HIV, HPV and HSV	HIV Prevention/ Microbicides	USAID's goal is to advance research and development of 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	Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board
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	Scale-up	Scale-up of oral PrEP to AGYW in PEPFAR countries	State (S/GAC)	FHI360	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	Implementation science study to evaluate feasibility of a multi-product platform for HIV prevention launched in 2023	State (S/GAC)	FHI360; Population Council	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. Supporting a multi-product market with informed choice for HIV prevention as new products enter the market	Introduction	Implementation science study to evaluate feasibility of a multi-product platform for HIV prevention launched in 2023	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	Implementation science study to evaluate the acceptability of and adherence to a new oral PrEP regimen among adolescent girls and young women launched 2023	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.