U.S. Agency for International Development
Report to Congress
Health-Related and Antibiotic-Related Research and Development (R&D) for FY 2024

The U.S. Agency for International Development (USAID) submits this report pursuant to Section 7019(e) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2024 (Division F, Public Law 118-47, Senate Report 118-71 and House Report 118-46, which state:

Senate Report 118-71: *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 detail on USAID's research and development of antibiotics.*

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.*

House Report 118-46*: Antibiotics.—The Committee directs the Administrator of USAID to submit a report not later than 180 days after the date of enactment of this Act detailing research and development of antibiotics to be used in developing countries.*

Introduction

USAID's *Global Health Research and Development (R&D) Strategy (2023 - 2028)* outlines the Agency's approach to ensure 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. With these cross-cutting 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 that took place during FY 2023, and areas of focus during FY 2024. Accompanying appendices report USAID's estimated FY 2023 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 by Program Area

Tuberculosis (TB): The 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. Through the SMART4TB project, USAID identifies, advances, and field tests point-of-care tests for diagnosing TB among adults and children. USAID also supports clinical trials to identify optimal treatment regimens and durations, including for drug resistant (DR) TB according to a patient's baseline risk of treatment failure and relapse (PRISM-TB); a treatment-shortening drug-sensitive (DS) TB trial in children with a stratified medicine approach (SMILE-TB); and Bedaquiline for TB prevention in HIV infected and uninfected adults, children, and pregnant women (BREACH-TB). USAID is also evaluating a new medicine compound (TBAJ-876) as part of a combination regimen to treat DS-TB. Finally, USAID continues to support Phase III clinical trials to evaluate combinations of Bedaquiline, Delamanid, Linezolid, and Clofazimine to treat multidrug-resistant TB in South Africa, as well as the SimpliciTB clinical trial to evaluate the efficacy, safety and tolerability of a pan-treatment regimen (BPaMZ) in adults with DS and DR-pulmonary TB.

Global Health Security*:* USAID global health security partners contributed to R&D to prevent and respond to infectious diseases outbreaks and antimicrobial resistance. USAID continued investing in the Coalition for Epidemic Preparedness Innovations (CEPI), which is developing vaccines against priority pathogens. In November 2023, the U.S. Food and Drug Administration (FDA) approved the first-ever vaccine against Chikungunya, a mosquito-borne viral disease that causes severe joint and muscle pain, developed by Valneva with support from CEPI and the European Union. Furthermore, USAID's TRANSFORM project is partnering with the private sector to support locally-led research on the potential of animal feed additives (including probiotics, postbiotics, phytogenic feed additives, and phages) to reduce zoonotic and foodborne pathogens, minimize the need for antibiotic interventions, improve post-vaccine immune response, and increase farmer return on investment. Since March 2023, TRANSFORM has developed 11 new research trials (22 total ongoing trials have been developed since March 2021) in Vietnam, India and Kenya, across four species (poultry, dairy, swine and shrimp). The STOP Spillover project also helped optimize detection and diagnostic assays for the virus that

causes Lassa fever and is also developing and validating a point-of-care diagnostic assay for integration into clinical care at community health centers.

Neglected Tropical Diseases (NTDs): USAID continues to support the World Health Organization (WHO) Diagnostics Technical Advisory Group (DTAG) for NTDs to establish new Target Product Profiles and technical products for preventive chemotherapeutic NTD diagnostics—notably for Lymphatic Filariasis, Trachoma, Onchocerciasis, Schistosomiasis and Soil Transmitted Helminthiasis. The goal of this work is to diversify products on the market and improve their analytical performance. USAID supported research addressing laboratory and field performance evaluations through the U.S. Centers for Disease Control and Prevention (CDC) and the Task Force for Global Health, which shaped recommendations for filariasis and onchocerciasis surveillance strategies. 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 the integration of female genital schistosomiasis (FGS) care into national health systems. Results from this research could impact global strategies to improve FGS care, thus 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 initiated a clinical study to assess the immunogenicity of a vaccine to reduce malaria disease. MVDP also funded production of a clinical grade anti-infection vaccine candidate for future clinical assessment. Through MVDP, USAID supported several preclinical studies to evaluate malaria antigens and vaccine-delivery platforms to inform malaria vaccine candidate design. 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 developing therapies for under-served populations. Through the Innovative Vector Control Consortium, USAID supports the development of critical new insecticides, for bed nets and indoor residual spraying, to address the growing resistance of mosquitoes to existing insecticides in sub-Saharan Africa. USAID is also investing in novel technologies to address outdoor malaria exposure in addition to the traditional indoor-focused prevention tools.

HIV/AIDS*:* Under the President's Emergency Plan for AIDS Relief (PEPFAR), USAID prioritizes multiple novel and promising products and delivery mechanisms through collaborative R&D platforms for HIV microbicides and vaccines. For example, Accelerate the Development of Vaccines and New Technologies to Combat the AIDS Epidemic (ADVANCE) prioritizes novel products and delivery mechanisms, such as broadly neutralizing antibodies (bNAbs) for postnatal prophylaxis, through collaborative clinical research centers. USAID also optimizes products to meet the needs of country programs and improve program impact and success. For example, Microbicide Research and Development to Advance HIV Prevention Technologies through Responsive Innovation and Excellence (MATRIX) conducts discrete choice experiments and engages key stakeholders throughout the product development process to prioritize product attributes that enhance end-user acceptability, improve adherence, increase feasibility and ease of delivery, and consider health system integration. USAID primes enabling environments to accelerate and scale-up product introduction through health system integration and end-user community engagement in PEPFAR programs, especially those serving

adolescent girls and young women. For example, Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) harnesses multilateral, USG, and country partnerships to effectively coordinate with national and global stakeholders to adapt and develop policies so that newly available products and technologies such as the dapivirine ring, injectable cabotegravir, and lenacapavir, are poised for successful rollout.

***Voluntary Family Planning/Reproductive Health**:* USAID continues to invest in expanding the range of affordable contraceptive options. By enabling couples and individuals to determine whether, when and how often to have children, access to safe, effective, and affordable family planning contributes to reductions in both maternal and child mortality. 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 depot 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 molecular and physiological markers of health. Through collection of samples before, during, and after contraceptive use, researchers will gain valuable information on the effect of contraceptive method use on markers associated with HIV/STI acquisition, reproductive tract health, anemia, fertility, and other key health outcomes. USAID also provided co-funding with the U.S. National Institutes of Health for a clinical study evaluating the impact of the hormonal intrauterine system on anemia. Finally, the USAID-supported Contraceptive-Induced Menstrual Changes (CIMC) research and learning agenda was published, which encourages better research and implementation around beneficial and negative effects of CIMCs.

II. Implementation Science Research by Program Area and Health Systems

Tuberculosis: To accelerate the rapid programmatic uptake of the WHO recommended Bedaquiline, Pretomanid, Linezolid (BPaL) treatment for patients with DR-TB, USAID continues to support the Clinical Access Program in South Africa. USAID is prioritizing localization under the SMART4TB project, including country-led TB research optimizing delivery and uptake of TB transformative diagnostics, prevention, and treatment.

Global Health Security: USAID's Infectious Disease Detection and Surveillance (IDDS) project applied implementation research to adapt interventions and ensure evidence-informed technical approaches in specimen referral systems (SRS) and diagnostic workflows across 25 countries in Africa and Asia. In addition, the STOP Spillover project implemented wastewater surveillance strategies in three countries to proactively detect high priority pathogens as a form of early warning biosurveillance: influenza virus in Bangladesh; influenza virus and SARS-CoV-2 in Cote d'Ivoire; and SARS-CoV-2 and Lassa virus in Liberia. Through USAID's partnership with the Food and Agriculture Organization of the United Nations (FAO), the Emergency Centre for Transboundary Animal Diseases (ECTAD) helped 49 countries approach the goal of operating effective surveillance, early warning, and response systems for priority animal and zoonotic disease threats, including antimicrobial resistance. For example, with USAID support, FAO developed the Rift Valley Fever Early Warning Decision Support Tool (RVF DST), which successfully forecasted RVF outbreaks in Africa in 2023, providing regular updates and disease alerts to national and international counterparts. After the piloting of the RVF DST in Kenya,

Uganda, and the United Republic of Tanzania, the tool was extended to eight new countries in Africa in 2023–2024, including Libya, Madagascar, Mali, Mozambique, Niger, Rwanda, Senegal, and South Sudan. Finally, through support for the One Health Workforce Academy, USAID helped strengthen the multisectoral research capacity of universities in 15 countries in Southeast Asia and Africa.

***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 tools against malaria. Key studies include the evaluation of housing modifications in Uganda to assess a promising vector control intervention that prevents mosquitoes from entering the house, an assessment of the efficacy of the RTS,S/AS01 vaccine co-delivered with perennial malaria chemoprevention, and assessment of proactive approaches to enhance community case management in Zambia. USAID is also supporting an evaluation of supportive supervision models to improve case management; peer supervision of community health workers in Madagascar; and the deployment of an AI-based rapid diagnostic test (RDT) reader to assess healthcare workers' adherence to the RDT results. Through PMI, and in collaboration with Gavi, the Vaccine Alliance, and WHO, USAID supported the development of an operational research prioritization agenda for malaria vaccines. In addition, PMI and the Roll Back Malaria (RBM) Partnership to End Malaria Vector Control Working Group led the development of an *Anopheles stephensi* mosquito research agenda. Both research agendas are driven by country priorities and will enable donors to better align investments with country needs, and for national malaria programs and partners to identify areas of alignment with global 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. USAID supported the WHO to update and launch health facility guidance to strengthen program managers' capacity to monitor, analyze, and use routine maternal, newborn, child, and adolescent health data. Using statistical modeling techniques, USAID is conducting research to better understand predictors of child mortality in more than 40 countries receiving USAID support. Researchers are utilizing machine-learning techniques to help donors and countries identify key factors in child mortality and useful insights that build upon Demographic and Health Survey (DHS) data to identify areas for programmatic improvements. (Results are forthcoming.) Using data from Bangladesh and Nepal, USAID supported research to avert neonatal deaths with low-cost, effective interventions. Within the next year, the study will yield a policy brief and publication to support countries as they scale up life-saving newborn umbilical cord care. In Madagascar and Malawi, USAID tested virtual mentoring models for improved management of postpartum hemorrhage, a leading cause of death among 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 areas of relevance for integrated models of care to USAID-supported programs using evidence-based mental health and psychosocial support. This research 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 to support refinement of indicators of micronutrient deficiencies, including reliable assessment of hemoglobin concentration to determine anemia prevalence in individuals and populations. In the first phase of this work, USAID completed an inter-country study that concluded venous blood is the preferred sampling method, although collection through pools of capillary blood may be useful. In collaboration with the United Nations Children's Fund (UNICEF) and research centers, USAID-supported advances in the measurement and interpretation of biomarkers associated with iodine status are ongoing alongside simplified 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 disseminated evidence about the appropriate use and interpretation of stunting data and complementary indicators to assess the quality or impact of nutrition interventions.

Water, Sanitation, and Hygiene (WASH): USAID-supported desk reviews, in-depth key informant interviews, and field-based implementation research in area-wide sanitation (AWS), drinking-water quality, market-based sanitation, WASH in health care facilities (HCF), and hygiene environments for infants and young children. 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 of how to increase market penetration and reach marginalized populations with commercial sanitation products; understand the costs of providing on-premises drinking water services; 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 service delivery across 31 priority countries. USAID-supported research on digital interventions showed significant impact on improved knowledge, attitudes, and behavior for adolescent girls in India; and significant impact on contraceptive use, young people's attitudes towards family planning, and self-efficacy to access services for adolescent boys and girls in Rwanda. USAID has also funded four regional learning collaboratives of local researchers and implementing partners in Africa and South Asia to improve behavioral science research utilization and evidence generation on gender norms.

NTDs: For the sixth year, the African Research Network for Neglected Tropical Diseases, based at the Kwame Nkrumah University of Science and Technology, Ghana, 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. USAID and the Gates Foundation co-funded six studies aimed at addressing operational challenges with persistent trachoma infection in key USAID partner countries, including Ethiopia, Nigeria, and Tanzania.

HIV/AIDS: USAID prioritizes data driven programming, fostering innovation and integration, and country-focused collaboration. Through PEPFAR, USAID supports implementation science to rapidly and rigorously answer priority 'last mile' questions to optimize programmatic responses for sustained HIV impact. 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 of multiple HIV pre-exposure prophylaxis products among women, especially adolescent girls and young women, in five sub-Saharan African countries. CATALYST also aims to evaluate facilitators and barriers of the implementation process, and assesses patterns of use and effectiveness.

Health Systems: USAID conducted health systems strengthening (HSS) research across multiple topics. USAID continued research on the effectiveness of behavioral interventions in reducing inappropriate antibiotic prescriptions and strengthening antimicrobial stewardship. USAID also continued research on the system-level challenges and opportunities impacting health worker burnout to develop actionable policy recommendations for countries to prevent and mitigate health worker burnout, thus improving work environments and enhancing quality of health services. USAID continues to invest in implementation research to improve equity in HSS efforts, including using funding from the Leahy War Victims Fund to conduct implementation research to assess the introduction of financing for rehabilitation services in Georgia's Universal Health Coverage (UHC) program. USAID also published research from Kenya and Rwanda on digital financial services for health in support of broad access to health care. With health and adaptation funds, USAID developed four case studies highlighting how the use of climate information was integrated into early warning or surveillance systems and used to adaptively manage programs and strengthen health outcomes, and exploring the potential of climate information services to support climate adaptation within HSS initiatives.

III. Antibiotics and Antimicrobial Resistance

USAID advances a One Health ecosystem approach, recognizing the interconnection between people, animals, plants, and their shared environment, to address the emergence and spread of antimicrobial resistance (AMR). USAID's R&D efforts enable this approach, and include applied research and product development of vaccines and therapeutics, 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 and control, WASH, on-farm biosecurity and management, and vaccine development and distribution; new therapeutics paired with stewardship initiatives that incentivize access to and optimal use of antimicrobials; improved availability of quality-assured diagnostics; strengthened case management and improved treatment regimens, including technologies to improve delayed

diagnosis and inappropriate treatment; and social and behavior change.

As an example, in partnership with USAID's Global Health Security Program, FAO ECTAD has collaborated with national counterparts across Africa, Asia, Europe/Eurasia, Latin America, and the Middle East for over 15 years to establish sustainable One Health platforms. FAO enables countries to review their existing One Health-related policy frameworks, formulate contingency and response plans against priority animal diseases, AMR national action plans, and One Health-related policies and legislation. In the Asia and the Pacific Region, this work has included regional consultations and the engagement of experts through AMR Technical Advisory Groups and in collaboration with the South Asian Association for Regional Cooperation. FAO continues to implement the FAO Assessment Tool for Laboratories and AMR Surveillance Systems (FAO-ATLASS) across the Member Nations supported by FAO ECTAD activities. The tool helps countries systematically describe and assess their AMR surveillance and monitoring in food and agriculture sectors and includes modules for surveillance and laboratory assessment. In 2023, with USAID support, FAO ECTAD supported 62 laboratories globally, increasing their capacities to conduct testing related to AMR.

Additionally, in January 2024, USAID announced the establishment of The Antimicrobial Resistance Access and Stewardship Initiative (AMRASI), in collaboration with Global Environment & Technology Foundation (GETF) and the Clinton Health Access Initiative (CHAI). AMRASI is a public-private partnership under USAID's Project Last Mile mechanism, to address critical gaps in access to antibiotics and diagnostics. AMRASI is assembling a multi-sectoral coalition of industry, policy, donor, and in-country stakeholders to design and implement a "proof of concept" pilot, launched in Ghana. This pilot will utilize a market-based approach to develop, produce, and distribute diagnostics and antibiotics, while incentivizing their appropriate use. The goal is to utilize sustainable means to ensure these products are available, affordable, and used properly, making the solution sustainable without relying solely on external funding. Information derived through AMRASI will further inform Agency R&D priorities for critical antibiotics and diagnostics.

Appendix I: Estimated Fiscal Year 2023 Funding from the U.S. Agency for International Development for Health-Related Research and Development

Program Area	FY 2023 Budgeted
HIV/AIDS	73,710,000
Tuberculosis	33,420,000
Malaria	14,800,000
Global Health Security in Development	103,250,000
Other Public Health Threats	11,000,000
Maternal and Child Health	4,030,000
Family Planning and Reproductive Health	8,020,000
Nutrition	3,980,000
Total	**$252,210,000**

Note: The HIV/AIDS funding for development research reflects the FY 2023 vaccines and microbicides Congressional directives. The table does not include HIV/AIDS research funding programmed through USAID Missions as part of Country and Regional Operational Plans for the President's Emergency Plan for AIDS Relief.

Appendix II: USAID Health - Related Product Development, Collaboration and Gap Analysis

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 updated Global Health R&D Strategy (2023– 2028) provides a broad set of actions intended to harmonize decision making and ensure investments are coordinated, evidence-based, and have potential for impact.

The Appendix II table below provides a list of USAID-supported R&D in diagnostics, vaccines, drugs, and devices, as well as other contextual information about the investments. While R&D is not USAID's primary mandate, the agency invests in health products that can support its broader development goals. USAID invests in products with a focus on improving affordability, accessibility, and the experience of end-users. The products included in this table range from pre-clinical stages to post-marketing surveillance and are the result of multi-stakeholder collaborations to both identify programming gaps and possible solutions.

For each product in the table, the column entitled 'critical gap filled' outlines the primary need that may be addressed through the development and introduction of a new or improved product. While USAID would like to provide exact dates when a product may become available, timelines for product development are dynamic with a multitude of factors influencing regulatory approval, introduction, and scale-up. Due to the inherent uncertainty with R&D timelines, USAID has provided the development stage and next milestone in the table, which will provide stakeholders with a better idea of the product's advancement to the next critical funding decision.

Decisions to continue or discontinue investment in a product are critical to ensuring resources are being allocated to the most promising interventions. 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. These relationships are outlined in the columns USG Partners, Private Sector Partners, and Mechanism of Coordination. 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.

While USAID sees R&D as one critical tool in advancing its development goals, the agency must continue to focus resources on the core development work that ensures these products are accessible to those in need. 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.

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 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 higher reproducibility than the WHO-approved FTS, and will improve program monitoring and save costs	Field trials successfully completed and product approved through WHO Expert Review Panel for Diagnostics. Product procurement anticipated in FY25.	Product procurement anticipated in late FY24	CDC	SD Biosensor, Task Force for Global Health	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	Field evaluation/implementation	Additional field evaluations 2024 and potential contract manufacture in FY25.	CDC	Bill and Melinda Gates Foundation	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

		this product					
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 laboratory testing required to complete field evaluations. WHO ERPD submission anticipated in FY25.	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	WHO Diagnostics Technical Advisory Group (DTAG) review in 2024 in conjunction with expanded lab training	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	Additional laboratory testing required to complete field evaluations. ERPD submission anticipated in FY25.	NIAID/ NIH	Drug and Diagnostics for Tropical Diseases	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	Prototype design	Additional field testing required in FY25	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	Prototype design	Additional field testing required in FY25	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	Laboratory evaluations 2024	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	Laboratory Evaluations 2024	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	Field Evaluations 2024	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 2024	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	Phase I/Field Evaluation	WHO DTAG recommendation anticipated in 2024.	CDC	Safe Water and AIDS Project Kenya	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

		the field					
Chlamydia trachomatis PCR	Trachoma	This new platform is much more cost effective and sensitive at detecting clinical trachoma infection	Phase I Field Evaluation	WHO data review meeting 2025	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 2024	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	Data Review Meeting 2024	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 2024	None	UNC, Task Force for Global Health	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Lassa Fever Virus Assay (compatible with Sherlock Bio device)	Lassa Fever Virus (ETD/GHS)	Design of an initial proof of concept demonstration of the bench-developed workflow for Lassa fever virus (pre-device stage) in 9 months; uses CRISPR and nucleic acid based lateral flow technology and will have a colorimetric readout; assay is designed for human samples, but could use others if interested (e.g., urine from rodents)	Pre-Clinical	Laboratory evaluations (2024)	None	Sherlock Biosciences	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting

Mpox/Alternative EID Assay Development (compatible with CXL device)	Mpox/Swine Pox	SOW to include development and field validation of assays for 2 EIDs: mpox and swinepox LAMP and DNA barcode technology; current device is a 5 - plez; variety of samples makes it a good One Health platform Digital readout and data transfer built-in)	Pre-Clinical	Development and field validation of assays for 2 EIDs: mpox and swinepox; using LAMP and DNA barcode technology, current device is a 5 plex; a variety of samples makes it a good One Health platform; digital readout and data transfer built-in	None	Conservation X Labs (CXL)	Monthly portfolio review calls, annual scientific strategic agenda meeting, biannual technical donors' coordination meeting
Vaccines							
CSP-based malaria vaccine #1 (Tobacco-mosaic virus-based	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Complete GMP manufacture in 2024-25	WRAIR	None	Monthly DoD-USAID meetings, annual USAID Malaria Vaccine Development Program Scientific

virus-like particle (TMV-VLP))							Advisory Committee (SAC) meeting
CSP-based malaria vaccine #2 (mRNA-based)	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Phase I trial expected in FY 26, if milestones are met	WRAIR	None	Monthly DoD-USAID meetings, annual USAID Malaria Vaccine Development Program SAC meeting
CSP-based malaria vaccine #3	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 SAC meeting
RH5-based recombinant protein/VLP malaria vaccine	Malaria	Need for highly effective, affordable malaria vaccine	Phase I clinical trial	Phase I clinical trial will be completed in FY25	NIAID	PATH, University of Oxford	Monthly USAID-PATH management meetings, monthly vaccine team meetings, annual USAID MVDP SAC meeting
RH5-based mRNA-based malaria vaccine	Malaria	Need for highly effective, affordable malaria vaccine	Pre-clinical	Pre-clinical testing will continue for	NIAID	PATH, University of Oxford	Monthly USAID-PATH management meetings, monthly vaccine team

				selection of formulation			meetings, annual USAID MVDP SAC 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 1 Clinical Trial	Manuscript to be submitted in Q3, 2024	State (GHSD); NIH	IAVI, Moderna, BMGF	Standing calls and regular meetings with IAVI, Moderna, and BMGF 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 1 Clinical Trial	First Participant Screened in Q3, 2024	State (GHSD)	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 infants (perinatal and postnatal prevention of HIV). A long-acting bnAb product will aid in elimination of	Pre-clinical	Phase I clinical trial	State (GHSD), NIH	IAVI	Standing calls and regular meetings with IAVI, NIH/NIAID, and the HVTN, HPTN and IMPAACT networks to discuss progress and expected challenges

		mother to child transmission of HIV which accounts for 10% of new cases of HIV annually.					
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 - Pre-Clinical & Phase 2 Clinical Trials, Nipah - Phase 1 & 2 Clinical Trials, Disease X Platform technologies - Preclinical, Chikungunya - FDA approval	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.
- BG505 GT1.1 immunogen - 426c.Mod.Core-C4b immunogen - 3M-052-AF adjuvant - Alum adjuvant - Saline Placebo	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Pre-clinical	Phase-1	None	BRILLIANT Consortium	Bi-weekly Executive Committee calls
- CAP 255 and CAP256 HIV envelope immunogens	HIV	A durable HIV vaccine is critical to ultimately ending the HIV epidemic.	Planning pre-clinical	Pre-clinical	None	BRILLIANT Consortium	Bi-weekly Executive Committee calls
Insecticides							
Confidential - IRS products	Malaria vector control	Need for long lasting, non-pyrethroid insecticide for indoor residual	Laboratory/Hut trials	Multiple products, therefore various milestone	None	BMGF, Unitaid, UKAid, AustralianAid, Global	Bi-annual Expert Scientific Advisory Committee meetings, IVCC Board meetings, and via

		spraying (IRS) to mitigate insecticide resistance		s		Fund, SDC	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							
Pyronardine + piperaquine	Malaria	Prevention of malaria during pregnancy is a significant unmet	Phase II	Planning Phase II	None	Medicines for Malaria Venture	Regular meetings with BMGF and Global Fund as well as MMV and other

		medical need.					stakeholders, and via grant deliverables
Six-month subcutaneous depot medroxyprogesterone acetate injection	Family Planning/ Reproductive Health	Repurpose 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 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	Downselection of 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 monthly 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 is 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	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	Pre-clinical/ Proof of Concept	Pre-clinical in vivo studies conducted in 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.

		changes to menstrual bleeding that can occur immediately after IUD insertion.					
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 2024.	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	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

		and the Indian subcontinent as an inexpensive, scalable adjunct treatment					
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	None: Study is completed	None	None	None

Novel combination antimicrobial therapy consisting of bedaquiline, delamanid, Linezolid and Clofazimine/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 Bedaquiline, Delamanid, Linezolid and Clofazimine/Levofloxacin in people with drug resistant TB	Phase III Efficacy Trial	Data analysis and dissemination by end of 2024. Data to be used to inform the next WHO guidelines on the management of drug resistant tuberculosis	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	Finalized multiple ascending dose (MAD) study by Mid-2022 and started enrollment in Phase IIA clinical trial	None	None	None

TBAJ-876	Tuberculosis Treatment	This study is evaluating the safety and efficacy of several doses of TBAJ-876 in treatment combination with other TB medicines such as pretomanid, and linezolid for the treatment of drug susceptible and drug resistant tuberculosis.	Phase II	Complete enrollment by mid 2025 and conduct analysis to inform the phase III	None	None	None
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/clinical	Phase 0 Clinical trial launched in Q1 2024	CDC; State (GHSD)	University of Pittsburgh; 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 0 clinical trial underway; Planning 1 clinical trial	State (GHSD)	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).	Clinical Phase 1	Complete Phase I clinical trial in 2024; Initiate confirmatory Phase 1 in 2025	State (GHSD)	CONRAD; Gilead	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 / 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	Scale-up	Scale-up of oral PrEP to AGYW in PEPFAR countries	State (GHSD)	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	Introduction research	Complete implementation science study to evaluate feasibility of a multi-product platform for HIV prevention by 2026;	State (GHSD)	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

		for HIV prevention as new products enter the market		dissemina te research findings.			
Long-acting injectable cabotegravir (CAB-LA)	HIV Preventio n/ Microbic ides	USAID supports evidence-informe d 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	Introduct ion research	Complete implemen tation science study to evaluate feasibility of a multi-pro duct platform for HIV preventio n by 2026; dissemina te research findings.	State (GHSD)	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 Preventio n/ Microbic ides	Implementation science study to evaluate acceptability of, and adherence to, a new oral PrEP regimen among adolescent girls and young women; critical evidence to	Introduct ion	Analyze and dissemina te findings by early 2025, concurren t with anticipate d Gilead	State (GHSD)	CONRAD; Gilead Sciences	Monthly meetings with CONRAD to discuss trial progress; Quarterly meeting with full consortia and industry to monitor progress and findings.

		complement pending Gilead trial results		trial results			
CAB-LA	HIV Prevention/ Microbicides	A pregnancy registry study to bolster the evidence base on safety of CAB LA exposure during pregnancy and breastfeeding among pregnant women and exposed offspring; findings to support global guidelines	Introduction	Launch pregnancy registry study by 2024	State (GHSD)	Consortium managed by Magee Women's Health Research; ViiV	Quarterly review meetings to discuss progress in-detail; bi-annual review of milestones and benchmark progress by a Scientific Advisory Board