Global Health Innovation at USAID: Accelerating the Journey to Self-Reliance

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) works to save and improve lives by encouraging the research and development of essential health technologies. We bring together more than 30 nonprofit organizations, academic institutions, and aligned businesses to advance policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people.

About this report

This analysis reflects key findings gathered from a literature review of USAID’s strategies, reports, and publicly available data and interviews with US government and non-US government stakeholders in the global health research and development field. These findings outline challenges in leadership, strategy and reporting, and funding that the agency faces in its global health innovation work. Policy recommendations to address these challenges were then developed in collaboration with GHTC. A more detailed description of the methodology is included at the end of this report.

This report was commissioned by GHTC and prepared by Lindsay A. Gilchrist of Gilchrist & Company.

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Overview

In 2018, the US Agency for International Development (USAID) began a process of realigning and reorienting its policies, strategies, and programs to better support partner countries along the journey to self-reliance. This journey has been defined as supporting partner countries in their ability to plan, finance, and implement solutions to their own development challenges. This approach prioritizes fostering stable, resilient, prosperous, inclusive, and self-reliant countries.\(^1\)

To move countries along the journey to self-reliance within the health sector, USAID has sought first, to reduce disease burden, and second, to strengthen the capacity and health systems of partner countries to enable them to sustainably implement and manage progress toward health goals. Central to achieving these goals are USAID’s contributions to advancing global health innovation, and in particular, the agency’s leadership on the development of new drugs, vaccines, diagnostics, and other tools for global health applications.

New health technologies have catalyzed global health progress, fostering more resilient and prosperous nations. New health innovations resulted in 4.2 million fewer child deaths in 2013, compared to 1990.\(^2\) Antiretroviral therapies have prevented 7.8 million deaths from AIDS globally since 2000.\(^3\) The world is on the verge of eradicating polio due to the development and delivery of polio vaccines.\(^4\) Additionally, 11 percent of economic growth in low- and middle-income countries (LMICs) between 2000 and 2011 is attributable to health improvements.\(^5\) To continue to strengthen the capacity of partner countries to meet their health needs, it is critical to invest in innovation to ensure the most effective health solutions are available.

USAID focuses on developing new tools to meet unmet health needs in LMICs that are both affordable and suitable for low-resource settings. Through funding product developers, the agency has helped advance groundbreaking technologies that have improved the efficiency and effectiveness of USAID’s global health programs while also building local, long-term scientific capacity, enabling partner countries to become closer to self-reliance. USAID support has helped advance 22 new global health technologies approved since 2000—more than one-quarter of all new tools registered globally during that time—and 36 promising technologies now in late stage-development.\(^6\,7\,8\,9\)

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i. This reflects the number of vaccines, drugs, diagnostics, vector control products, and other biomedical products developed or in development with USAID support. It is not inclusive of other health system and service innovations supported by the agency.
advanced by USAID include new child-friendly malaria medicines that have saved more than 750,000 lives globally and a low-cost vaccine against meningitis A that has prevented 673,000 cases of meningitis and 378,000 deaths in seven years.8

In recent years, the agency has also introduced innovative new practices, financing models, and partnerships to catalyze new ideas and funding to support health product development.

Despite significant gains achieved in global health, countries still lack many of the necessary tools to combat both long-standing and emerging health challenges, from shorter and simpler treatments for tuberculosis, to vaccines against diseases like HIV/AIDS and Chagas, to a range of tools to mitigate outbreaks of Ebola and Zika. Without new and improved technologies, USAID partner countries will not have the tools they need to address the health challenges impeding their economic development and will be unlikely to achieve self-reliance.

This report examines how USAID’s global health innovation investments will be the key to accelerating progress in global health to advance countries on the journey to self-reliance and explores the challenges and opportunities the agency faces. It also provides recommendations for policymakers in the Administration and Congress to strengthen the agency’s health research and development (R&D) activities within the Global Health Bureau to maximize the impact of US investment.

**USAID’s unique role in catalyzing global health innovation**

USAID plays an essential role in supporting the development, introduction, and scale-up of urgently needed global health technologies. As the only US agency with a mission and vision focused exclusively on global development, it is uniquely positioned to support product development to address the critical shortfall of appropriate tools to advance health in low-resource settings. Its deep international footprint, combined with its in-depth understanding of community needs and culture, enables the agency to develop new health tools that are appropriate, affordable, and accessible for widespread uptake in LMICs.

Through its research investments, USAID also builds scientific capacity and global research networks in countries. These networks strengthen countries’ ability over time to address their own health challenges and support economic growth, in turn creating stronger, more resilient markets for American goods.

The agency is guided by a research-to-use approach to ensure products ultimately reach those in need that includes four interconnected and iterative phases: define, design, develop, and deliver (Figure 1).11 USAID continually uses its...
knowledge of program implementation, including how interventions will be used and which are most needed to influence research priorities.

Within its 2017–2022 Global Health Research and Development Strategy, USAID defines three interrelated goals: (1) To accelerate the development, introduction, scale-up, and sustained use of health technologies, tools, and approaches to address critical unmet needs and emerging challenges; (2) To identify, generate, and apply evidence to influence the adoption, implementation, and health impact at scale of priority life-saving health and development interventions; and (3) To strengthen the capability and resilience of people, systems, and partnerships to conduct research and utilize results to improve health outcomes. Agency staff are trained technical experts both in the science and global development environment in which they work. They have a unique development perspective and, in conjunction with partners, bring an important skill set to advancing product-oriented global health innovation. USAID’s ability to form strong partnerships at every stage of
Grand Challenges for Development

Grand Challenges for Development are a family of initiatives, launched by USAID and partners, to source new solutions and foster innovation to solve key development challenges. The three Grand Challenges highlighted below are focused on advancing innovation in different global health areas.

**Saving Lives at Birth**

Through the Saving Lives at Birth partnership, USAID has worked with a number of other donors to help advance tools that can help save lives of mothers and newborns. USAID has committed up to $20 million in US government funding that successfully leveraged a commitment of more than $150 million from outside donors to fund a pipeline of 120 technology and system innovations.

Two examples of these innovations are the Odon Device to assist during labor and delivery and bubble continuous positive airway pressure devices for neonatal resuscitation.12

**Combating Zika and Future Threats**

In 2016, the World Health Organization declared the spread of Zika an international public health emergency. The virus, spread primarily through mosquito bites, is linked to serious birth defects in babies of mothers who were infected while pregnant. In response, USAID launched Combating Zika and Future Threats to crowdsource and advance innovative approaches to fight the outbreak and prevent other infectious disease outbreaks. For example, BluSense, a Copenhagen-based startup, received funding to develop a multiplex point-of-care diagnostic test that uses Blu-ray technology to diagnose Zika and dengue from a single drop of blood.13

**Fighting Ebola**

In 2014, the world faced the largest Ebola epidemic in history. In response, USAID issued Fighting Ebola with the White House Office of Science and Technology Policy, the Centers for Disease Control and Prevention, and the US Department of Defense to identify innovations to address barriers faced by health care workers in combating the epidemic. International experts reviewed more than 1,500 ideas and rapidly selected 14 promising innovations, identified for their potential to reinforce the response to the Ebola outbreak and future epidemics.14

Despite USAID’s uniquely positioned capacities and the gap it fills in the global health R&D ecosystem, there continues to be low recognition of the agency’s leadership and success in the R&D space by the public and policymakers. More importantly, R&D is often overlooked as an integral part of USAID’s mission and an essential enabler of greater country self-reliance.
Opportunity

New technologies hold tremendous promise to accelerate progress on health goals and the journey to self-reliance. Rapid advances in science and technology and growing interest in global health innovation among stakeholders across sectors and nations has opened new opportunities to advance the health of the world’s poorest people through innovation. Likewise, efforts underway by the agency to reform procurement and private-sector engagement approaches and design innovative financing mechanisms are opening new avenues to fully leverage the comparative advantage of partners in advancing global health innovation.

On the other hand, USAID’s 2019 report, Unleashing Private Capital for Global Health Innovation includes a needs assessment, which highlights an absence of investors and innovators in the global south driving drug and vaccine product development for low-income and low-resource settings where these innovations are needed most. This gap stresses the need for USAID to continue advancing product development while simultaneously supporting research/life sciences–oriented capacity-building of countries on the journey to self-reliance to cultivate their own product innovators to tackle global health challenges.

In 2016, an analysis was conducted by PATH in partnership with Johns Hopkins University to examine the contribution innovation can make to achieving coverage-level targets set by USAID’s Acting on the Call report. The report estimated that more than 6 million mother and child lives could be saved by 2030 if just 11 emerging innovations are advanced and scaled up in 24 countries. These results are further evidence of the power of innovation to help reach global targets to end preventable mother and child deaths. Health interventions are among the most cost-effective approaches to reducing poverty and building more resilient societies. This is a clear example of why USAID’s investment in health innovation is so critical to achieving its mission and vision.

To capitalize on these opportunities, the Administration and Congress need to ensure USAID has the leadership structure, strategic framework, and financing needed to most effectively harness the potential of innovation to tackle our greatest global health challenges.
Key findings

Leadership: Global health R&D at USAID lacks high-level leadership and a clear focal point for external stakeholder engagement.

Decision-making on global health R&D is decentralized, without a focal point to elevate the work within the agency and provide leadership and oversight across all agency R&D activities.

Several different entities and offices at USAID play a role in setting and advancing the agency’s global health R&D priorities and activities. Congress appropriates funding for global health to USAID by disease and health area, which the agency in turn uses to support product development within that health area. Therefore, decisions on where to invest and how much to invest in R&D are made within each of the Global Health Bureau’s technical offices (e.g., Office of HIV/AIDS, Office of Maternal and Child Health and Nutrition, etc.), with the exception of earmarked funding for microbicides and HIV vaccine research within the Office of HIV/AIDS.

Situating product development decision-making at the technical office level has some advantages. It allows for experts in each health area to think critically about the highest-priority unmet technology needs and how resulting tools will best fit into overall health programming for that area. However, this structure also creates challenges. Since R&D decision-making is decentralized across offices, so too is accountability, responsibility, and learning. There is no identified leadership role with authority and line of sight over all the agency’s health R&D activities and clear mandate to champion this work internally. This decentralized structure also reduces opportunities for interagency coordination across teams, shared learning, and identification and dissemination of best practices. It also creates confusion for product developers working across health areas who find it challenging to identify a clear point of contact to discuss potential collaborations with USAID. Decision-making can also be impacted by the specific expertise of office leads, resulting in product development being inconsistently invested across health areas.

In addition to its technical, health-area offices, USAID established the Center for Innovation and Impact (CII), which sits within the Global Health Bureau, to serve as a center for excellence for global health innovation at USAID. CII applies business-minded approaches to the development, introduction, and scale-up of health interventions and can help design innovative programs. Although CII has introduced new approaches to complement efforts already being supported across the Global Health Bureau, its work is significantly demand driven. Outside of overhead funding the program receives, which is taken as a small percentage from all health-area offices, CII receives the remainder of its funding from health area offices that choose to engage the Center’s expertise on specific initiatives. Therefore, many approaches or best practices incubated at CII remain at the pilot scale and are not utilized or integrated across health portfolios, and CII’s work specifically on product development remains limited. In addition, USAID has not selected a permanent Director for CII, leaving the position under temporary leadership since the start of the current Administration. Lack of higher-level leadership and internal champions creates uncertainty about how the agency values R&D within its broader portfolio of global health activities. Some stakeholders perceive that product development is not a high-priority agency activity, a notion possibly reinforced by the quiet release of the agency’s 2017–2022 Global Health Research and Development Strategy with limited exposure and without a forward by the Administrator, as is typically included in many other USAID strategies.
USAID has achieved important gains in improving intra-bureau and implementing partner coordination, but decentralization still creates confusion and complexity for external stakeholders working across health program areas.

USAID has taken important steps at an operational level to mitigate some of the challenges resulting from the decentralization of R&D programming. The agency has a Senior Medical and Scientific Officer role in the Office of the Administrator for Global Health, who has informally served in a coordination capacity to help establish connections between research leads in each technical office and the Administrator's office. This position has provided a valued and critical coordination function, but the role has certain limitations. As currently defined, the role has no specific authority over R&D programs, limiting the position's ability to elevate and champion this work. In addition, the role currently is inward-facing, so it does not serve as a focal point for outside stakeholder engagement nor does it serve in a spokesperson capacity to address questions or bring visibility to the agency's R&D successes. The mandate for this role is also informally defined, so there is a risk that the responsibilities of the role could shift or be eliminated under future administrations or leadership.

In addition to the Senior Medical and Scientific Officer position, the agency has also established a cross-bureau global health research group, composed of staff involved in research in each technical office, a CII representative, and the Senior Medical and Scientific Officer. This group meets regularly to help coordinate crosscutting tasks such as reporting and provides a forum for staff to share and learn from each other. Together, these are important functions to improve coordination. However, they have not been sufficient in elevating the role of global health R&D at the agency or establishing a clear focal point for external stakeholder engagement. Agency stakeholders, particularly the private sector, described confusion in navigating the R&D structures at USAID and identifying which staff to engage with to discuss opportunities outside formal solicitations. The decentralization of R&D decision-making creates a complex labyrinth to navigate for external stakeholders seeking to better understand USAID's R&D work or pursue opportunities for partnership and engagement.
Strategy and reporting: USAID’s strategy and progress reports for global health R&D need further clarification.

Though USAID has a documented strategy for global health R&D, there is a need for greater clarity on the agency’s target outcomes and desired impact.

USAID has articulated its continued strategic commitment to global health R&D through the release of its 2017–2022 Global Health Research and Development Strategy. The strategy articulates the agency’s approach to global health R&D and its unique value add in this space. However, it provides limited details on product development targets the agency hopes to achieve in R&D within the five-year time period or how the agency plans to prioritize product development investments within and across health areas. Several stakeholders cited a lack of transparency or clarity on how the agency is making investment decisions.

USAID’s annual Health-Related Research and Development Progress Report provides limited information on investment to impact.

The agency produces an annual report to Congress on progress achieved under its R&D strategy. USAID’s annual report provides valuable examples of the agency’s achievements each year in global health innovation. However, the current reporting structure provides limited information on the agency’s investments in R&D. It is not clear on how the agency is allocating resources across its three strategic goals—accelerating product development, advancing implementation research, and strengthening country research capacity—or how much the agency is specifically spending on product development within each disease or health area. Reports from FY2008 through FY2016 included a funding table that provided some limited detail on how the agency obligated funds on certain activities in each health area, but for the most recent report for FY2017, this table was removed entirely.18, 7

Greater clarity is needed to understand how the agency is investing in R&D and whether the agency has appropriate and sufficient resources to execute on its global health R&D strategy and goals. The passage of the Global Health Innovation Act (GHIA), which requires USAID to report annually for five years on its R&D progress and impact and how its work with other partners and agencies to advance health innovation, creates a new opportunity for USAID to tell its global health product development impact story with greater clarity and draw direct connections between investment and impact.19
Funding: Resource constraints challenge USAID’s continued leadership in global health R&D.

Funding levels for global health innovation have historically been low and are eroding USAID’s catalytic leadership.

USAID investments in global health R&D often have outsized impact, but the need for new tools eclipses current resourcing. While USAID’s research investments are small relative to other scientific agencies like the National Institutes of Health and to the substantial resources required for drug and vaccine development, they have important “catalytic” or “signaling” power, which multiply their impact. Investment by USAID can influence the willingness of other donors or the private sector to invest in an area and “de-risk” an investment with little prospect for commercial return.

Unpredictable funding presents challenges to advancing product development and undermines USAID’s ability to work with partners, including the private sector. Annualized funding and the uncertainty of the Congressional appropriations process leaves USAID-supported product developers in a difficult position with unstable funding streams year to year that can delay or jeopardize research progress. There is a perception that if Congress cuts funding levels for global health, investments in product development, which are drawn from health area–specific budget lines, could be deprioritized. Private-sector stakeholders in particular cited this lack of assurance of funding as a risk factor or significant barrier to engaging with the agency.

Finally, R&D is by nature iterative with unexpected obstacles encountered along the way and evolving areas of scientific opportunity. USAID has traditionally managed the risks and opportunities this presents by utilizing a portfolio approach to investment. Providing this and other continued flexibility is paramount.
Recommendations

Leadership

USAID should establish a Chief Science and Product Development Officer for global health: USAID’s Global Health Bureau should establish a Chief Science and Product Development Officer (CSO) role that will function at the level of a Deputy Assistant Administrator. This position should have direct oversight over CII and responsibility for ensuring USAID is delivering on the agency’s vision and strategy for R&D—as part of broader agency priorities and the journey to self-reliance—and serve as a clear focal point for inter- and intra-agency collaboration and external stakeholder and public engagement.

The CSO should chair USAID’s Global Health Research Working Group, ensuring it meets regularly, and work in close concert with research leads in technical offices and collaborate on cross-sector initiatives with USAID’s Chief Innovation Officer, who provides technical assistance to agency staff looking to bring innovation broadly to their work. As part of its leadership over CII, this role should support the genesis of best practices on structuring R&D projects and contracting mechanisms and ensure innovative financing approaches designed to catalyze innovation and mobilize resources from the private sector and other external sources are incubated at CII and are more broadly adopted across the agency’s health portfolios.

To bring both greater transparency and visibility to the agency’s global health innovation work, the CSO should pursue new opportunities to engage stakeholders and the public. The CSO should consider convening an annual public portfolio review to highlight the diverse range of products USAID and its partners are developing including drugs, vaccines, diagnostics, and other medical devices. The review could note the research stage of each product as well as the estimated timeline to product launch to highlight USAID’s end-to-end product innovation to impact efforts. The CSO should also explore opportunities to present examples of the agency’s product development work in agency-wide townhalls and public meetings or through communications platforms such as the USAID Leads podcast, other agency-wide content or reporting, and in letters or remarks by USAID leadership. Wherever possible, the CSO should also articulate the linkages of global health R&D to the journey to self-reliance and associated country road maps.

USAID should ensure the individual selected for this role has industry experience and a deep understanding of end-to-end product development and health finance.

USAID should fill vacant leadership positions within the Global Health Bureau: The Director for CII and Assistant Administrator for Global Health positions have been vacant since the start of the current Administration. The Administration should prioritize filling these roles to put in place strong leadership over these critical functions.

Strategy and reporting

USAID should strengthen reporting on its global health R&D investments and impact: The passage of GHIA requires USAID to report on global health R&D progress and formally authorizes USAID’s annual report to Congress on health-related research activities. USAID should build on the passage of the GHIA—and the positive support from
Congress that drove its passage—as an opportunity to articulate clearly its investments in global health innovation and anticipated impact on health outcomes. Specifically, USAID should list its health product development targets and provide detailed information about how much USAID is investing in drugs, vaccines, diagnostics, and devices across each of its health areas. The agency should also include an appendix in future annual reports, listing the technologies the agency is currently advancing in its portfolio.

USAID should also include comprehensive information about the agency’s collaboration and coordination in support of global health product development with other departments and agencies including the Department of Defense, the National Institutes of Health, the Food and Drug Administration, and the Office of the Global AIDS Coordinator, in addition to the Centers for Disease Control and Prevention, the one agency specified in the bill. The agency should describe how critical gaps in product development for global health are being filled, to ensure that US investments in global health research are efficient, coordinated, and streamlined.

**Funding**

**Congress should ensure robust investment in global health R&D:** Congress should provide sustainable and reliable funding for global health programs with a specific call for robust investment in R&D as a critical part of USAID’s mission. This funding enables USAID to develop technologies that are directly employed to make health programs more efficient, sustainable, and cost-effective, thereby enabling them to scale up more rapidly, reach more people, and save more lives more quickly. A sustainable funding stream for R&D is essential to accomplishing the agency’s long-term goals and ensuring countries make progress on the journey to self-reliance.

**USAID should support funding opportunities that are catalytic and provide flexibility:** The agency should continue to support and expand financing and partnership models to drive innovation through co-investment. These models must be flexible and responsive to partners in order to be successful. Mechanisms like Development Impact Bonds, Development Innovation Ventures, and improved models of Broad Agency Announcements should continue to be explored through the lens of the Global Health Bureau’s R&D work. The agency should explore collaborations with the new US International Development Finance Corporation to support partnerships focused on global health innovation.
Conclusion

USAID’s work in global health innovation is an essential enabler of partner countries’ journey to self-reliance. Without new tools to address health challenges, the agency will not achieve its vision and mission of saving lives, reducing poverty, strengthening democratic governance, and helping people emerge from humanitarian crises and progress beyond assistance.21 USAID’s innovation work has tremendous potential to accelerate US development programs around the world, and the agency is uniquely positioned to conduct global health R&D that will result in solutions best suited for low-resource settings. Despite this potential, USAID’s global health R&D initiatives struggle with the challenges outlined in this report. In order to maintain the investment in health innovation and build on the catalytic work of the agency, strong leadership is required, clarity on vision and reporting is necessary, and robust and consistent funding is critical. USAID’s investment in global health R&D has a multiplier effect. It not only saves and improves lives, but it also creates cost savings, drives economic growth, and enhances global security.22 It must remain an essential piece of our development programs and is paramount to achieving a more stable and prosperous world.
Project background and methodology

The objective of this project was to understand current processes and structure for global health product development within USAID's Bureau of Global Health and provide recommendations to help drive efficiencies and strengthen the impact of this programming.

The scope of the project included data gathered on global health R&D work conducted through USAID’s Global Health Bureau. The documents reviewed included USAID’s Global Health Research and Development Strategies, USAID’s annual Health-Related Research and Development Progress Reports, USAID’s 2019 Policy Framework on Ending the Need for Foreign Assistance, Unleashing Private Capital for Global Health Innovation, other related agency strategies and reports, the Global Health Innovation Act, and previous publications from GHTC. A full list of documents reviewed is included in the literature review list that follows.

Interviews were conducted with 15 stakeholders including representatives from USAID, other US government agencies, nonprofit product developers, and the private sector. USAID’s Global Health Bureau also provided written responses to questions with a follow-up group interview with staff from across the Bureau. These consultations were used to supplement the literature review and develop key findings and recommendations.

An analysis was conducted from the data gathered in the literature review and the findings from the interviews. This analysis was used to determine key themes regarding USAID’s engagement in global health R&D. These themes were developed in consultation with members of GHTC. Based on the analysis, several policy recommendations were developed for US government actions to improve global health R&D programs at USAID.
Literature review list

1. Acting on the Call Report 2018

2. From idea to impact: How the US government can improve coordination of global health research and development

3. FY18 Q2 USAID Global Health Users’ Guide

4. Global Health Innovation Act

5. Innovating Foreign Assistance: Harnessing the Power of the Private Sector to Achieve US Global Health and Development Goals

6. The Journey to Self-Reliance, USAID

7. Harnessing the power of innovation to save mothers and children: How 11 emerging innovations could save more than 6 million lives

8. Return on innovation: Why global health R&D is a smart investment for the United States


10. Unleashing Private Capital for Global Health Innovation: Innovator and Investor Support Opportunities


12. USAID’s Health-Related Research and Development Progress Reports 2008–2017

13. USAID Policy Framework: Ending the Need for Foreign Assistance
References


