GHTC global health technologies coalition

The Supporting Innovative Global Health Technologies (SIGHT) Fund:

A new proposal to drive inclusive innovation at USAID and stock the global health toolbox of the future

January 2022

advancing **innovation** to save lives

Contents

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 35 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.

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Background

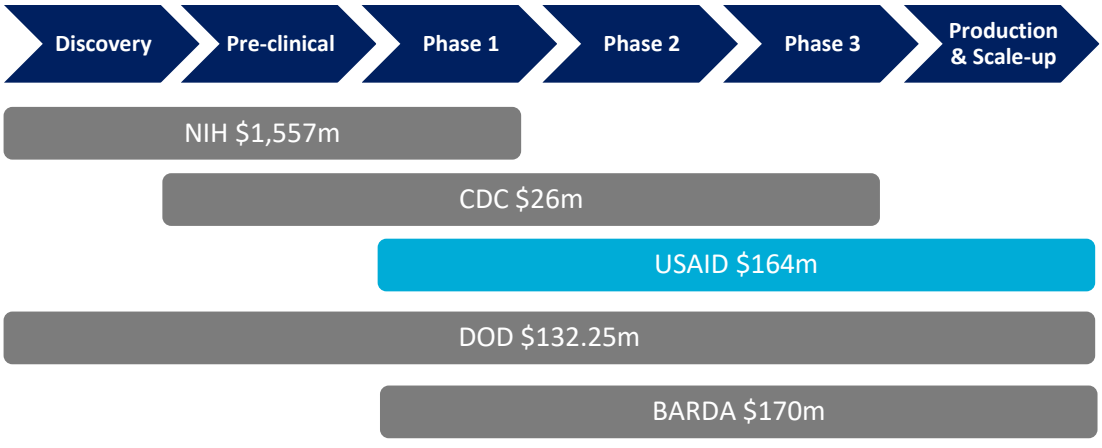
Over the past century, biomedical innovation has transformed the way we diagnose, treat, and prevent diseases—but innovation is not always focused where it is needed most to improve human health. Today's health innovation economy does not prioritize diseases or conditions associated with poverty at the scale their burden demands. Poverty-related and neglected diseases (PRNDs)—including HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases (NTDs), and the leading causes of preventable maternal and child health—account for 14 percent of the global burden of disease,[1] yet just 1 to 2 percent of the roughly $286 billion per year[2] spent on health research and development (R&D) worldwide is focused on these conditions. The private sector, which funds most clinical development of new health products, has little commercial incentive to invest in R&D for diseases that disproportionately affect people living in poverty.

This global innovation disparity extends beyond just PRNDs, however. Most health products for noncommunicable diseases (NCDs) such as diabetes and cancer and emerging infectious diseases such as COVID-19, Zika, and Ebola are designed for use in settings with access to reliable electricity, sanitation, refrigeration, health worker and laboratory expertise, and strong supply chains. For communities without these resources, many health products, such as multidose vaccines requiring ultracold storage or IV therapeutics, are difficult or even impossible to implement effectively at the scale needed.

These challenges are complex, but their impact is clear: today, at a moment of unparalleled scientific progress and opportunity, hundreds of millions of people in low-resource settings around the world are still without the drugs, vaccines, diagnostics, health devices, and other tools they need to live healthy lives.

Public funding for innovation is essential to fill the global health gaps left by the private sector. Government funders provide two of every three dollars spent on neglected disease R&D.[3] Within the US government, primary funding agencies for neglected disease R&D are the US Agency for International Development (USAID), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Department of Defense (DOD), and the Biomedical Advanced Research and Development Authority (BARDA). Each agency contributes to the pipeline of global health R&D; **USAID, however, is the only agency with both a primary mandate to improve global health and development and a focus on late-stage development of health products specifically designed for populations living in low-resource settings (Figure 1). With these unique strengths, USAID has become one of the most impactful public funders of global health innovation worldwide.**

Figure 1. Estimate of average annual neglected disease R&D spending (2016 to 2019) by US agency and primary stages of R&D supported.[4,5]



Note: USAID spending estimate includes both product development and implementation research. Mapping of agencies to stages of R&D is generalized.

A new moment, a new opportunity: Why USAID needs a SIGHT Fund

USAID's primary mission is, as its name makes clear, advancing international development—a purpose distinct from that of science and research agencies like NIH and CDC. USAID, however, has long recognized that research is a catalyst for development—particularly in global health, where the agency's footprint and global impact is largest. R&D not only creates the tools needed to achieve development goals, but can also strengthen in-country scientific capacity, which is itself a development goal.

Within this context, USAID has for decades applied its unique strengths in global health innovation to sponsor the development of dozens of lifesaving technologies, including better treatments for TB and malaria, rapid diagnostics for HIV, insecticide-treated bed nets to prevent mosquito-borne illness, devices that save the lives of newborns and their mothers, and a meningitis A vaccine that has virtually eliminated this disease wherever used.[6]

USAID excels at bringing together partners to achieve innovation goals. For instance, USAID has developed many new products through support of product development partnerships (PDPs), collaborations between academia, nonprofits, and businesses to develop medical products for neglected diseases at affordable prices. USAID has also hosted a series of Grand Challenges, led by the Center for Innovation and Impact, to identify and advance promising health innovations for Ebola, Zika, health supply chains, and maternal, child, and newborn health, sourcing and supporting innovators from around the world to solve global health challenges. USAID's strong track record in global health product development is further detailed in the appendix.

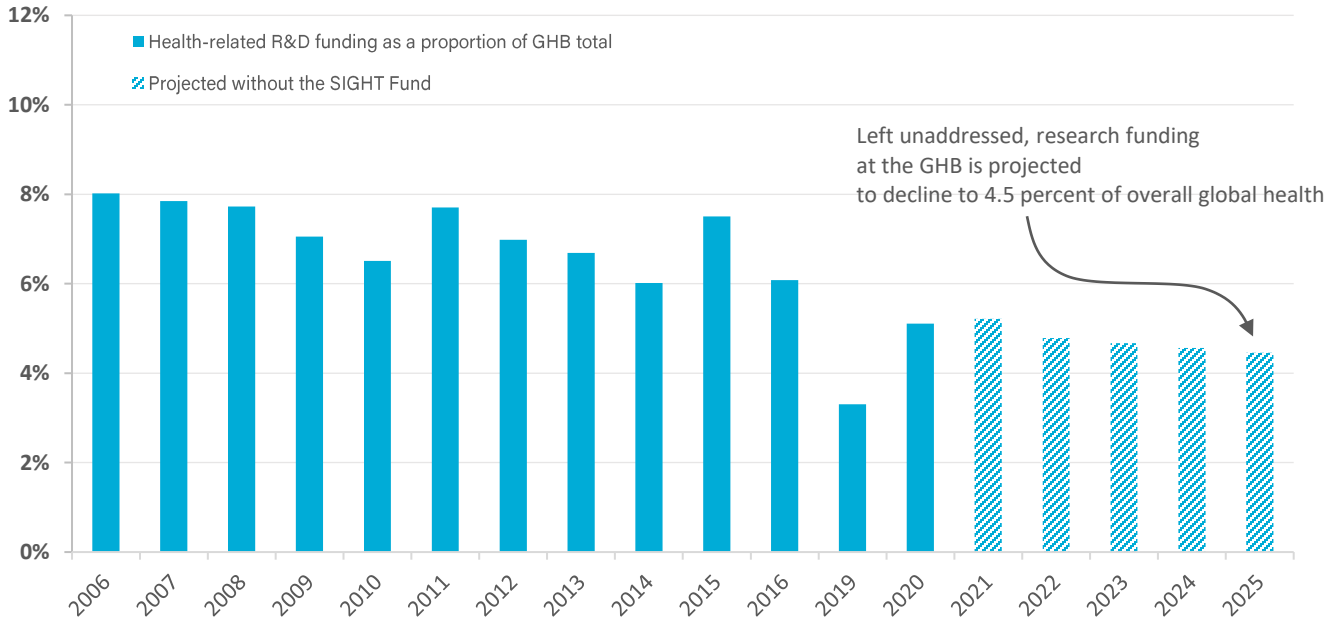
Despite this rich history of impact, USAID's global health innovation mandate has been increasingly constrained by three interrelated challenges:

1. **Funding for health-related R&D has declined as a proportion of overall global health spending (Figure 2).** USAID devotes a small proportion of its total global health funding to R&D. In 2006, this proportion peaked at 8 percent but has steadily declined to around 5 percent as total funding for global health has grown and funding for R&D has slightly declined (Table 1).

2. **Innovation at USAID is siloed by health area, limiting opportunities for multipurpose products and responsive research that can be pivoted and deployed in emergencies like the COVID-19 pandemic.** Funding for innovation today is primarily drawn from disease- and population-specific appropriations accounts, limiting the ability of USAID to fund products that address multiple health issues or explore new R&D areas.

3. **Constrained budgets force leaders in the USAID Global Health Bureau (GHB) to prioritize immediate impact over innovation and long-term progress.** With limited resources, leaders in the GHB must find a balance between funding health programs using today's imperfect tools to drive immediate impact and supporting health innovation—developing new and improved tools to drive transformative and accelerated impact in the future. Understandably, leaders often choose to limit risk and focus on immediate results rather than make bets on R&D that could transform future global health programming, achieve greater impact, and ultimately reduce costs.

Figure 2. Health-related R&D funding as a proportion of USAID GHB appropriations.[7]



Note: Health-related R&D funding data unavailable for 2017 and 2018.

Each of these challenges became clear in March 2020, when in response to COVID-19 USAID put out a call for proposals for innovations specifically designed to mitigate the pandemic in low-resource settings. During previous health crises, including Zika and the West African Ebola outbreak, USAID pursued a similar approach through Grand Challenge programs to identify and successfully fund the development of new tools, such as a battery-powered IV infusion rate monitor for Ebola treatment centers and a low-cost diagnostic for Zika, which improved care in low-resource settings. Within weeks, the agency received several hundred proposals for technologies to aid the global response to COVID-19. Unfortunately, without dedicated funding available for the agency to invest in innovation, USAID was able to support just two promising technologies, despite the clear need for tools designed and adapted to prevent and treat COVID-19 in low-resource settings.[8]

Today, USAID is responding to a diverse array of health threats, from long-standing priorities like AIDS, malaria, and TB to new challenges like climate change, antimicrobial resistance (AMR), and emerging diseases like COVID-19. To solve these challenges and drive a global health innovation agenda at USAID that is more flexible, responsive, and coordinated, we need a new approach that supplements and supercharges ongoing innovation efforts at USAID. Below we describe GHTC's proposal—the Supporting Innovative Global Health Technologies (SIGHT) Fund—and some considerations, informed by interviews with global health innovation experts, to ensure its impact.

Overview of the SIGHT Fund

The Supporting Innovative Global Health Technologies (SIGHT) Fund would function as a new and additive source of flexible, catalytic funding at USAID to conduct *research, development, and deployment* of new global health products, created through a new appropriation to the USAID Global Health Bureau. The SIGHT Fund would be used to advance new global health products through the research pipeline—with an emphasis on clinical development, regulatory approval, and product introduction—prioritizing support for innovators close to affected communities and the engagement of end users

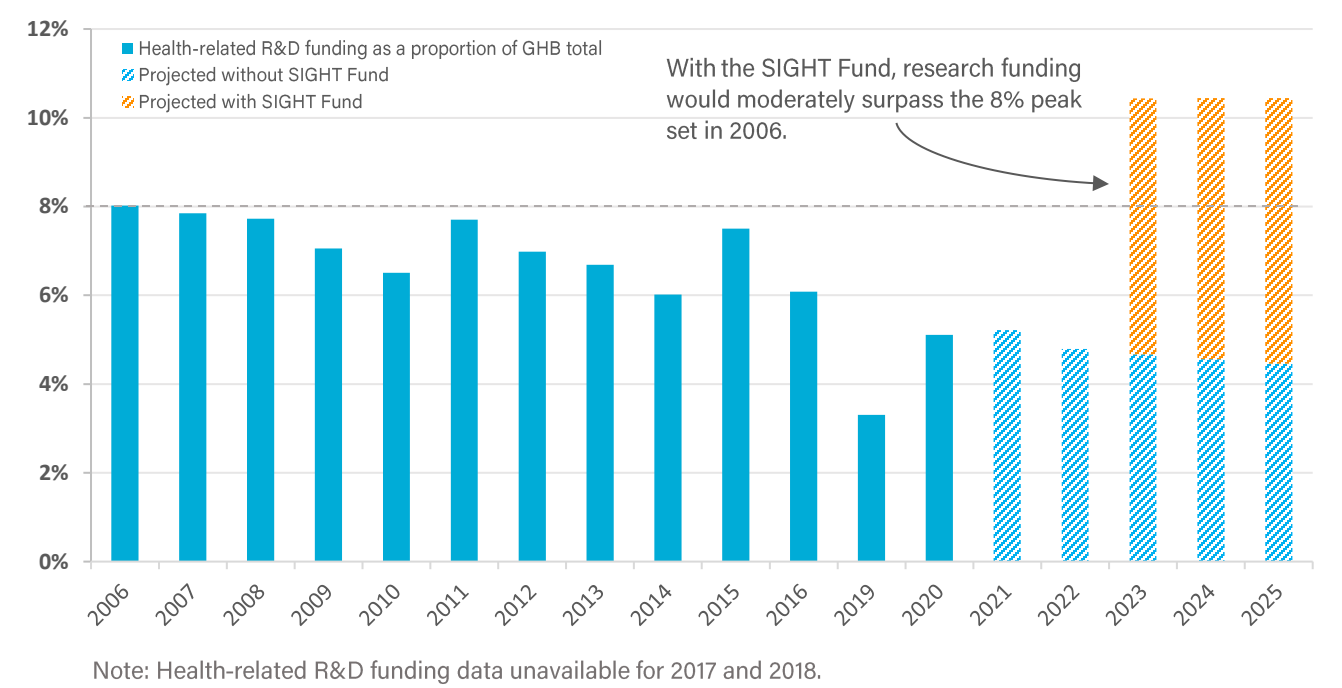
in the research process. In alignment with USAID's goals to foster inclusive development, the SIGHT Fund should be engineered to drive *inclusive innovation*: centering the perspectives and priorities of people in affected communities—the end users of innovations—in every stage of product development.

To address the first challenge identified above—proportionately declining funding for health R&D—the SIGHT Fund would be launched through an **initial appropriation of $250 million to the USAID Global Health Bureau.** This level of dedicated innovation funding would raise total annual USAID investments in global health innovation to a healthy target of approximately 10 percent of overall GHB funding (Figure 3). Once launched and institutionalized at USAID, appropriating multi-year funding for the SIGHT Fund would allow the agency to progressively grow innovation investments as it creates the structure and human resources needed to deploy such resources most effectively.

To address the second challenge—that USAID's approach to innovation is currently siloed by health area—the SIGHT Fund would be based within the GHB but independent of any health-area technical offices. The SIGHT Fund would be disease agnostic and could be tapped for different health challenges as R&D needs evolve and opportunities emerge. As a centralized, additive source of innovation funding, the SIGHT Fund would improve research coordination across the agency, and its independence would foster investments in multipurpose products, or products that address more than one disease or condition.

The SIGHT Fund would address the third challenge—of leaders being forced to choose between near-term programming and long-term innovation potential—by creating an additional pot of resources dedicated only to innovation. Several GHB offices have long and rich partnerships with innovators funded directly from their appropriation lines, and the SIGHT Fund would *supplement, not supplant,* these existing programs and partnerships. By expanding the global health pie rather than slicing it further, the Fund would enable USAID to make bolder investments in game-changing innovations by lifting some of the risk inherent in R&D from the shoulders of GHB office leaders and removing the perceived trade-off between either investing in global health delivery or global health innovation.

Figure 3. Health-related R&D funding as a proportion of GHB appropriations with the SIGHT Fund.



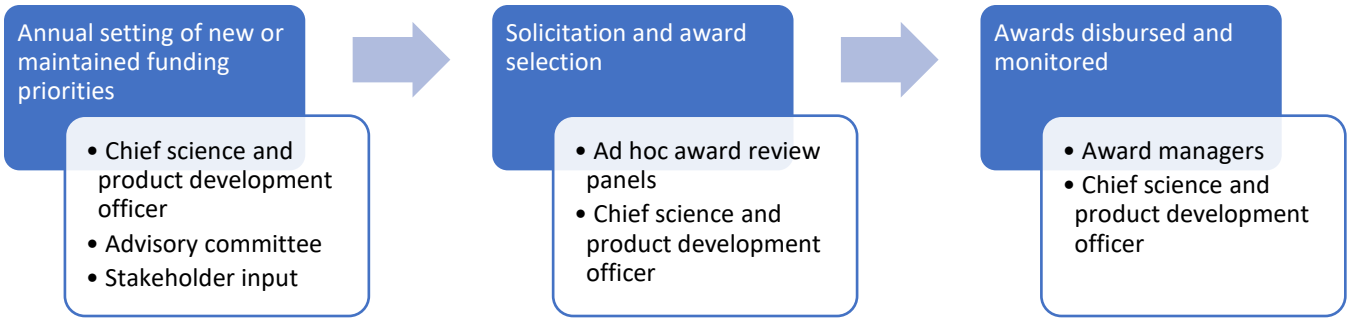
Operational considerations

Deployed effectively, the SIGHT Fund could produce new tools that accelerate progress against long-standing global health challenges—saving US tax dollars, maximizing impact, and ultimately improving and saving lives around the world. GHTC consulted a range of global health research, development, and innovation experts—from product developers to former agency officials—about how USAID could best use the SIGHT Fund to achieve this goal. From those conversations we created a broad outline of operational considerations for the SIGHT Fund, described below, focused on efficiently driving inclusive development of health products that serve as global public goods. These considerations build upon past precedents for global health innovation and existing USAID mechanisms to support such work and are oriented by three core principles:

1. ***Inclusive product development*:** Incorporating input from affected communities and end users into every stage of product development, beginning with the justification of need and study design.
2. ***Product introduction and access*:** Emphasis on sponsoring technologies that can be introduced to new markets and made accessible to end users; making awards with regulatory approval, manufacturing, and product introduction considerations in mind to ensure they are affordable and accessible to end users and able to be scaled.
3. ***Flexibility and failing forward*:** Supporting USAID to better embrace the risk inherent to innovation—which is essential to long-term progress—while also providing much-needed flexibility to innovators to readjust programs as needed, cut losses quickly, and maximize the impact of every dollar.

The process for determining SIGHT Fund investment priorities and making awards could draw from successful approaches pioneered by several other US government innovation programs, including USAID Development Innovation Ventures (DIV), the DOD Congressionally Directed Medical Research Programs, and NIH.[9–11] Figure 4 provides an overview of a potential award process approach and is followed by a description of each component.

Figure 4. Potential award process for the SIGHT Fund.



Leadership and oversight

Chief Science and Product Development Officer

To lead the SIGHT Fund, GHTC recommends that USAID establish a Chief Science and Product Development Officer (CSO) for global health at the deputy assistant administrator level. This position should bear responsibility for ensuring USAID is delivering on the agency's vision and strategy for R&D and serve as a clear focal point for inter- and intra-agency collaboration and external stakeholder engagement—prioritizing input from affected communities—to inform the annual setting of new or maintained innovation priorities. The CSO should be guided by the advisory committee and would be responsible for overseeing or coordinating with the award managers of Fund investments.

Advisory committee

GHTC recommends the SIGHT Fund be guided by an advisory committee with the purpose of assisting the CSO in setting annual funding priorities, convening the ad hoc award review panels, ensuring the SIGHT Fund operates with the input of end users, coordinating with other US government agencies, and ensuring access and implementation are prioritized. This advisory committee should include:

- Representatives of affected communities (geographic or disease specific).
- Representatives of other US government agencies advancing product development, such as the Fogarty International Center at NIH, CDC, DOD, BARDA, and others.
- Scientists or experts from PDPs, the US government, academia, or the private sector, particularly individuals with robust experience in health product development, introduction, and scale-up.
- Representatives from USAID country missions.
- Experts in access to and implementation of medical products.

Ad hoc award review panels

GHTC recommends ad hoc award review panels (AHARPs) be used to review SIGHT Fund award proposals through a scoring process and provide recommendations to the CSO on which to fund. The process should evaluate proposals' justification of community need, plans to continue to incorporate community input, scientific merits, and plans for introduction and equitable access. AHARPs could be convened by the CSO and advisory committee on an annual basis for each priority area with an emphasis on gender parity and the participation of end users. AHARPs should include:

- Representatives of potential end users and affected communities.
- Scientists and experts from PDPs, academia, government, and industry with subject matter expertise of the area under review.
- Representatives from USAID country missions or health-area technical offices.

Awards

SIGHT Fund awards could support any activities related to research, development, and deployment of new or improved global health products. Awards should be flexible and enable awardees to pivot quickly in reaction to project failures, emergencies, or new opportunities. Depending on the priorities set by the CSO and advisory committee with stakeholder input, awards should also be open to technologies that fall between or outside the specific remits of existing GHB offices, such as multipurpose products, platform technologies, or innovations for challenges like AMR without a clear footprint in the GHB. Applications for awards should align with the AHARP scoring process described above by providing a clear justification of community need, a description of how project leaders will continue to consult with community representatives, a plan for product introduction and equitable access, and scientific rationale.

Nearly every global health innovation expert we consulted said the greatest barrier to successful innovation partnerships with USAID was its default award mechanisms. For most of its partnerships, including health R&D programs, USAID deploys standard **cooperative agreements and contracts**, which work well for most global health programming awards and give USAID substantial control and oversight. R&D, however, requires flexible and diverse types of funding, and the **SIGHT Fund CSO should be equipped with a toolbox of diverse award options to meet a variety of R&D funding needs.** With such flexibility, the SIGHT Fund could provide a multi-year, milestone-based grant for a vaccine R&D portfolio in one instance, and in another could provide a grant to an intermediary institution that would administer sub-awards to local innovators working to solve community-specific health challenges.

Different innovation partnerships require different financial arrangements to succeed. Fortunately, USAID has more than 30 mechanisms through which it can financially engage with other institutions,[12] many of which are types of **grants** with

greater flexibility and less burdensome reporting requirements than cooperative agreements and contracts and would be ideal for many types of R&D. The SIGHT Fund could leverage these grant mechanisms to provide partners the flexibility needed to best pursue high-impact innovation. Some examples of financial arrangements that USAID might pursue with SIGHT Fund resources include the following:

- **Seed funding, flexible grant capital, and milestone-based payments:** Funding can be used like venture capital to de-risk development of new technologies that might be then scaled by partners.[13,14] USAID is also able to provide **milestone-based payments, or Fixed Amount Awards,** an instrument pioneered by DIV and Grand Challenges to create a payment structure based on predetermined outcomes and with reduced reporting requirements.[15,16] Milestone-based payment structures are preferred by many innovators and are often used by private-sector medical product developers when managing their own product portfolios.
- **Broad Agency Announcements (BAAs):** A mechanism in which USAID poses a specific health challenge and innovators submit expressions of interest through a simplified process. BAAs enable the agency to convene multiple stakeholders, which could and should include representatives from affected communities, to co-define problems and co-design solutions.
- **Blended finance, loan guarantees, pooled investments, and other de-risking mechanisms:** USAID has several options available for de-risking the development of health products and attracting private or philanthropic capital investors to projects that otherwise might not be attractive investments.[17] For instance, the SIGHT Fund could contribute to an R&D financing pool or de-risk R&D investments by guaranteeing a proportion of loan repayment in case of a failed project.[18]
- **Internal matched funding arrangements:** The SIGHT Fund could provide matching funding to GHB offices or country missions pursuing their own product development efforts or which have identified a product development need.
- **Recoverable grants:** Like a private equity investment, the SIGHT Fund could provide grant funding that acts like an interest-free loan to profit-seeking partners to de-risk research programs.

Interagency collaborations

USAID is a key US agency funding the development of new health products for global health, but its unique strengths are complemented by different capacities at a variety of other health, science, and R&D agencies. The GHB CSO could leverage the SIGHT Fund to build upon and strengthen USAID's ongoing collaborations and coordination with other agencies sponsoring health research.

USAID already partners regularly with several research agencies, including NIH, the National Science Foundation, the National Aeronautics and Space Administration (NASA), and CDC. According to USAID, it maintains a "strong level of informal communication, information sharing, and collaboration through staff exchanges, regular meetings, and planning for joint activities" with NIH in particular.[19] USAID and the NIH Fogarty International Center have in place a memorandum of understanding and work collaboratively on health research projects, including the Partnerships for Enhanced Engagement in Research health program, in which USAID directly supports scientists in low- or middle-income countries who are partnering with scientists funded by NIH on global health research topics.[20] USAID partners with NASA and the National Science Foundation on specific technology development efforts and collaborative research grant programs. USAID and CDC have worked closely together for decades, most notably via the US President's Emergency Plan for AIDS Relief, but also through other initiatives such as an interagency program to strengthen health systems.[21]

The GHB CSO could also facilitate new interagency partnerships, such as with DOD and BARDA, both of which lead important work on neglected disease R&D (Figure 1). Greater coordination via the SIGHT Fund between NIH and USAID could strengthen the pipeline of projects moving from early-stage research sponsored by NIH to later-stage research

sponsored by USAID. USAID, with SIGHT Fund resources, could further pave the way for market introduction of these products if they are demonstrated as safe and effective.[22]

The global health toolbox of the future

The SIGHT Fund is needed to stock the global health toolbox of the future and accelerate progress in global health. Below is a table of examples of specific health tools—some of which USAID already supports in some capacity, others which would be new investments—that the SIGHT Fund could advance. Since the SIGHT Fund would be based outside of a specific GHB disease- or population-specific office, it would be especially well positioned to advance crosscutting innovations.

Table 1. Products that could be advanced by the SIGHT Fund.

Challenge area	Product	Description
Antimicrobial resistance	Tools to combat, monitor, and prevent AMR in low-resource settings	AMR is a potentially catastrophic health challenge that could affect all health systems. New antibiotics, surveillance technologies, and tools to promote stewardship are needed to combat, monitor, and prevent AMR in low-resource settings.
Emerging infectious diseases and pandemic preparedness	Diagnostics and other devices	Medical countermeasures to prevent or respond to pandemic in low-resource settings, which can have limited electricity, running water, staff capacity, and access to labs.
Emerging infectious diseases and pandemic preparedness	Treatments and therapeutics	Like vaccines, few treatments exist for emerging infectious diseases. USAID should work with BARDA and NIAID to ensure that heat-stable and oral treatments and therapeutics are developed that can be readily deployed in low-resource settings.
Emerging infectious diseases and pandemic preparedness	Vaccines	USAID could use SIGHT Fund resources to complement the work of global partners like the Coalition for Epidemic Preparedness Innovations (CEPI) and US agencies developing vaccines for emerging infectious diseases such as BARDA and NIAID to ensure these vaccines are suitable for distribution in low-resource settings, where inconsistent access to refrigeration, trained health care workers, electricity, sanitation, and other resources can make it challenging to administer cold-chain dependent, multi-dose, intramuscular vaccines. USAID could also use the SIGHT Fund to invest in the development and application of vaccine platforms and adjuvants with multi-disease potential.
HIV/AIDS	HIV/AIDS cure	Cellular and genetic strategies that can be scaled to either control (i.e., induce remission that prevents the need for daily oral antiretroviral medications) or altogether eliminate infection.
HIV/AIDS	HIV/AIDS vaccines	Research that USAID has long sponsored but could be boosted with SIGHT Fund resources. mRNA-based HIV vaccines—leveraging the success of mRNA technologies in the production of vaccines for COVID-19 and other conditions—are a promising area of investment.
HIV/AIDS	Improved HIV therapies for children	Children are an underserved population and could benefit from HIV treatments that are safe, palatable, shorter course, and easier to administer.
Malaria	Next-generation malaria vaccines	RTS,S, the first and only available vaccine for malaria approved by the World Health Organization in 2021, is a triumph of science. Building on this

		milestone through continued R&D might produce a more effective vaccine or one requiring fewer doses, which could further transform the fight against this ancient scourge.
Malaria	Rapid diagnostic tests for malaria	Rapid diagnostic tests for malaria that can be used in low-resource settings to detect all species of malaria.
Malaria	Simplified treatments, ideally single-dose cure, for malaria	In particular, a single-dose therapeutic for *Plasmodium falciparum*, the most severe form of malaria, to ease administration and prevent emergence of drug resistance.
Malnutrition	Multiple tools	Innovations are needed to tackle malnutrition, which still contributes to more than 40 percent of preventable childhood deaths and myriad other health effects, including impaired immune systems and cognitive development. Evidence-based food technology solutions such as micronutrient supplements, fortified foods, and biofortified, nutrient-rich staple food crops, as well as simple, durable diagnostics to detect nutrient deficiencies, are critically needed.
Maternal, child, and newborn health	Context-appropriate, standard of care neonatal CPAP	Continuous positive airway pressure (CPAP) is a technology that has been available for over 50 years as a treatment for neonatal respiratory distress syndrome, the major cause of infant mortality for premature babies. New CPAP design based on user inputs is needed to address common causes for device failures in global hospitals: access to oxygen; power outages; and lack of access to proprietary consumable, servicing, and spare parts.
Maternal, child, and newborn health	New vaccine delivery platforms	Vaccines that are heat stable and can be delivered orally or by a vaccine microneedle patch could improve immunization coverage, especially in hard-to-reach geographies.
Maternal, child, and newborn health	Products designed for use in pediatric populations and pregnant and lactating women	The development of diagnostics, treatments, and vaccines designed or adapted for pediatric populations and pregnant and lactating women is a particularly neglected area of R&D, as product development for these populations is more expensive and requires more resources due to the additional layers of clinical trials and precautionary measures involved. USAID investments in platform trials and the expansion of research capacity in low- and middle-income countries could dramatically improve the speed and efficiency with which new products are investigated and introduced to meet the unique needs of children and pregnant and lactating women.
Maternal, child, and newborn health	Tools to detect preeclampsia	Preeclampsia is a dangerous pregnancy complication. Rapid point-of-care diagnostics and handheld blood pressure monitoring devices could improve outcomes.
Maternal, child, and newborn health	Tools to manage respiratory disorders and pneumonia	Especially in facilities that lack access to high-tech equipment. Examples include low-cost, durable, easy-to-use neonatal resuscitators to help babies breathe and affordable, easy-to-operate tools to monitor respiratory rates and oxygen levels in children.
Maternal, child, and newborn health	Tools to prevent postpartum hemorrhage	Postpartum hemorrhage is a leading cause of maternal death. Examples of new tools needed include new easier-to-administer, heat-stable formulations of the drug oxytocin for use in low-resource settings, blood loss estimation devices, and simple uterine balloon and suction devices to control bleeding after childbirth.
Multipurpose	Combination HIV prevention-contraceptive pills and injectables	Multipurpose short-acting (pills) and long-acting (injectables) products for both preventing pregnancy and HIV, as tools for both family planning and HIV prevention.

Multipurpose	Combination microbicide-contraceptive vaginal ring	USAID has long supported the development of a microbicide vaginal ring to reduce the risk of HIV infection. With R&D support from the SIGHT Fund, this ring could be combined with contraceptives to create a multipurpose product with incredible global impact.
Multipurpose	NCD-infectious disease products	R&D to address the growing overlap between NCDs and infectious diseases, such as products designed to manage HIV/AIDS in aging populations with additional health challenges like diabetes or hypertension, and long-term complications after recovery from COVID-19.
Multipurpose	New vector and biological control tools	As insecticide resistance grows, new vector control tools are important for preventing the transmission of malaria, NTDs, and other vector-borne diseases. Examples of such tools include new spray insecticides, next-generation bed nets, ingested insecticides such as attractive target sugar baits, and innovative approaches like gene drives to reduce mosquito populations or block transmission.
Neglected tropical diseases	New and improved diagnostics	Diagnostics are needed to rapidly detect infection at point of care in low-resource settings, and in some cases, to distinguish between different strains or stages of a disease.
Neglected tropical diseases	New and improved treatments and cures	Including therapies designed for children and shorter, simplified regimens with fewer side effects. Only seven NTDs are considered "tool-ready"—meaning we have low-cost, effective interventions to combat them—but in many cases these available treatments are still lengthy and burdensome to take with significant side effects.
Neglected tropical diseases	Vaccines	No vaccines exist for 20 of the 21 NTDs prioritized by the World Health Organization, and the existing vaccine for dengue is recommended for use only in select populations.
Neglected tropical diseases—snakebites	Antivenoms	Antivenoms are still produced by injecting venom into domesticated animals, limiting the scale of production and access, even though snakebites take the lives of at least 81,000 people per year.[23]
Non-communicable diseases	Products for addressing NCDs in low-resource settings	NCDs, such as cancer, diabetes, and heart disease, are a rapidly growing global health challenge. Unfortunately, many tools designed to treat NCDs in high-resource health systems are extremely difficult to implement in low-resource settings. Heat-stable or oral formulations of existing products could accelerate global accessibility.
Tuberculosis	More effective vaccines	The TB vaccine currently in use, BCG, was developed in 1921. Though effective at preventing some types of TB in infants, it offers inconsistent protection in adults against pulmonary TB, which affects the lungs. Eliminating TB will require developing new safe, effective, and affordable TB vaccines that improve on the safety and efficacy of BCG in infants or prevent TB infection or disease among adults and adolescents. USAID funding could help support late-stage clinical trials of new TB vaccines.
Tuberculosis	Rapid, non-sputum-based diagnostics	Diagnosis is the weakest link in the TB cascade of care. Closing the TB diagnostic gap and improving linkage to care will require affordable and scalable rapid diagnostics suitable for all populations in low-resource settings and primary health care facilities. This includes tests for predicting the risk of progression from latent to active TB disease to better target and direct scale-up of TB preventive treatment; rapid tests to detect drug-resistant TB and tailor treatment to individuals more quickly and help safeguard against AMR; and rapid tests for monitoring the effectiveness of TB treatments to cure.

Tuberculosis	Shorter, safer, simplified treatment regimens	Recent advances have shown that drug-sensitive TB can be treated in four months, drug-resistant TB in six months, and TB infection in one month. Further reducing treatment duration for all forms of TB—infection, drug-sensitive disease, and drug-resistant disease—would improve patient experience and provide savings to health systems. Research to improve the safety, tolerability, and acceptability of new TB regimens remains important alongside efforts to reduce treatment duration.

Conclusion

Over the past several decades, significant progress in global health has been made through innovation, collaboration, and persistence. But continued progress is never guaranteed: in many health areas, our gains are slowing,[24] and as demonstrated by COVID-19, AMR, and climate change, new crises can set us back. Without new innovations, it is unlikely we will achieve our still distant global health goals—both the universal aspirations enshrined in the United Nations' Sustainable Development Goals and the specific global health goals the US government has committed itself to over the past two decades. USAID, as the only agency with a primary mandate to improve global health and development, has a successful record of developing health innovations that have transformed global health programming and affected millions of lives. Despite this history of progress, USAID's global health innovation mandate is impeded by multiple challenges and risks further backsliding without a new approach. The SIGHT Fund, a proposal endorsed by leading global health innovation stakeholders, is an opportunity to supercharge health innovation at USAID, to build the global health toolbox of the future, and to make global health programming in the long term more efficient, effective, and inclusive.

MenAfriVac, a USAID-supported technology. Photo credit: PATH

Appendix

History of USAID product innovations for global health

USAID has funded health R&D for decades, supporting the development, regulatory approval, and introduction of affordable health products that save lives and lower health treatment costs in low- and middle-income countries. USAID's contributions to advancing global health innovation have been central to better supporting partner countries and achieving its goals.

USAID has supported more than a quarter of all new global health technologies registered since 2000 and more than a quarter of all global health products in late-stage development as of 2017.[25] A sample of the range of tools that USAID has helped advance include:

- HIV/AIDS prevention tools like pre-exposure prophylaxis and microbicide vaginal rings and gels.[26–28]
- TB medicines including the drugs bedaquiline, delamanid, and pretomanid and all-oral regimens for treating multidrug-resistant and extremely drug-resistant TB.[29]
- RTS,S, the world's first vaccine for malaria specifically and for a parasitic disease generally.[30]
- A child-friendly malaria drug, Coartem® Dispersible, which has been distributed in more than 50 countries and has saved an estimated 980,000 child lives since its introduction in 2009.[31]
- A low-cost vaccine against meningitis A that has prevented 673,000 cases of meningitis and 378,000 deaths in seven years.[32]
- Highlight, a powdered bleach additive which enables health care workers to identify areas that have been disinfected.[33]
- Multiple novel classes of malaria drugs, including potential single-exposure radical cures and drugs to combat drug-resistant malaria strains.[34]
- An oxytocin formulation, to prevent and treat postpartum hemorrhage, which does not require refrigeration.[35]
- Bilistick, a low-cost test to diagnose jaundice in newborns without the need for a lab.[36]
- A simple-to-use, rapid point-of-care diagnostic test for COVID-19 designed for low-resource settings.[37]

USAID has fostered impressive innovations for critical health needs largely through partnerships with nonprofit and private-sector organizations. For example, in partnership with the Medicines for Malaria Venture, USAID supported clinical trials for three novel classes of malaria drugs in combination with partner drugs.[38] The agency supported the development of tafenoquine—the first new treatment for relapsing malaria in more than 60 years—and rectal artesunate, a pre-referral treatment for severe malaria in children.[39] Similarly, a partnership between USAID, PATH, and the World Health Organization for the Meningitis Vaccine Project developed the MenAfriVac® vaccine for Africa at a low price of 50 cents per dose, an essential factor in its uptake by developing countries.[40] Since the release of MenAfriVac in 2010, no cases of meningitis A have occurred among the 200 million+ Africans vaccinated.[41]

USAID also has had a critical role in developing and deploying breakthrough innovations to combat emerging infectious diseases. For example, USAID's Fighting Ebola Grand Challenge—led by the Center for Innovation and Impact—identified 1,500 innovative technologies to advance the fight against Ebola and advanced 14. One of these technologies is a low-cost, battery-powered tool used during both the Ebola and COVID-19 responses that manages the flow rate of IV treatments with a simple gravity system, replacing the need for expensive, difficult-to-use infusion pumps.[42]

Despite this history of successful innovation during global health emergencies, USAID has made limited investments in COVID-19 innovations due to a lack of readily available R&D funding—a shortfall the SIGHT Fund could help prevent for future health crises.

Endorsements

ASTMH
AMERICAN SOCIETY OF TROPICAL MEDICINE & HYGIENE
ADVANCING GLOBAL HEALTH SINCE 1903

AVAC
25 Years and Counting

BU Institute for Health System Innovation & Policy

bugworks

CEPI

CHReaD
Fast-tracking health R&D, innovation, and access.

DNDi
Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation
Fighting for an AIDS-free generation

Equalize Health

FIND
Diagnosis for all

GARDP
North America

Global Health Council

HarvestPlus
Better Crops • Better Nutrition

iavi
Translating **science** into **global** health impact


INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES


IVCC
Building Partnerships
Creating Solutions
Saving Lives


International
Vaccine
Institute


MMV
Medicines for Malaria Venture


PATH


POLICY CURES RESEARCH.


SABIN
VACCINE INSTITUTE


SAHTAC
catalysing health R&D, innovation and access


SpeakUpAfrica.


TB Alliance


TAG
Treatment Action Group


Washington
Global Health
ALLIANCE

References

1. Von Philipsborn P, Steinbeis F, Bender ME, Regmi S, Tinnemann P. Poverty-related and neglected diseases - an economic and epidemiological analysis of poverty relatedness and neglect in research and development. *Global Health Action.* 2015;8(1):25818. https://doi.org/10.3402/gha.v8.25818.
2. Røttingen, J-E, Regmi, S, Eide, M et al. Mapping of available health research and development data: what's there, what's missing and what role is there for a global observatory. *The Lancet*. 2013;382(9900):1286–1307. https://doi.org/10.1016/S0140-6736(13)61046-6.
3. Chapman N. Doubell A. Tuttle A. Barnsley P. Goldstein M. Oversteegan L. Chowdhary V. Borri J. Hynen A. Kearney M. *G-Finder 2020: Neglected Disease Research and Development: Where to Now?* Sydney: Policy Cures Research; 2021. https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2021/04/15055816/G-FINDER-2020_Final-Report.pdf.
4. NIH, CDC, DOD, and BARDA estimates are from the G-Finder database. Policy Cures Research (PCR). G-FINDER in Sydney, Australia: PCR; 2020. https://gfinderdata.policycuresresearch.org/pages/datavisualisations. Accessed January 18, 2022.
The USAID estimate is based on USAID's global health related R&D annual reports.
5. USAID estimate is based on USAID's global health related R&D annual reports. USAID website. Health-Related Research and Development Progress Report page. https://www.usaid.gov/global-health/health-relatedresearch-and-development-progress-report. Accessed January 18, 2022.
6. GHTC. *Global Health R&D at USAID.* Washington, DC: GHTC; 2021. https://www.ghtcoalition.org/resources-item/us-agency-series-global-health-r-d-across-the-us-government.
7. GHTC analysis based on data from annual USAID Global Health Program appropriations report language (see https://crsreports.congress.gov/AppropriationsStatusTable) and USAID global health-related R&D annual reports (see reference 5).
8. USAID Center for Innovation and Impact. *2020 Impact Brief.* Washington, DC: USAID; 2020. https://www.usaid.gov/sites/default/files/documents/USAID_2020_CII_ImpactBrief.pdf.
9. USAID website. Understanding USAID Awards: "How to Work with USAID" Training Series page. https://www.usaid.gov/sites/default/files/documents/Module6_UnderstandingUSAIDAwards_final.pdf. Accessed January 18, 2022.
10. Department of Defense – Congressionally Directed Medical Research Programs website. Funding Process page. https://cdmrp.army.mil/about/fundingprocess. Accessed January 18, 2022.
11. Development Innovation Ventures. *A Decade of Turning Bright Ideas Into Global Solutions.* Washington, DC: USAID; 2021. https://www.usaid.gov/sites/default/files/documents/DIV_Lookback_Final_1.pdf.
12. National Institutes of Health Fogarty International Center website. September 6, 2019 Advisory Board Meeting Summary Minutes page. https://www.fic.nih.gov/About/Advisory/Pages/2019-september-minutes.aspx. Accessed January 18, 2022.
13. USAID Center for Innovation and Impact. *Investing for Impact: Capitalizing on the emerging landscape for global health financing.* Washington, DC: USAID; 2021. https://www.usaid.gov/cii/investing-impact.
14. USAID website. Grand Challenges for Development page. https://www.usaid.gov/grandchallenges. Accessed January 18, 2022.
15. Development Innovation Ventures. *A Decade of Turning Bright Ideas Into Global Solutions.* Washington, DC: USAID; 2021. https://www.usaid.gov/sites/default/files/documents/DIV_Lookback_Final_1.pdf.
16. USAID Center for Innovation and Impact. *Investing for Impact: Capitalizing on the emerging landscape for global health financing.* Washington, DC: USAID; 2021. https://www.usaid.gov/cii/investing-impact.
17. USAID Center for Innovation and Impact. Greater than the Sum of its Parts: Blended Finance Roadmap for Global Health. Washington, DC: USAID; 2019. https://www.usaid.gov/cii/blended-finance.
18. USAID Center for Innovation and Impact. *Investing for Impact: Capitalizing on the emerging landscape for global health financing.* Washington, DC: USAID; 2021. https://www.usaid.gov/cii/investing-impact.
19. USAID website. Federal Science Agencies page. https://www.usaid.gov/what-we-do/science-technolog-and-innovation/international-research-science-programs/federal-science. Accessed January 18, 2022.
20. National Institutes of Health Fogarty International Center. USAID, NIH announce global health research collaboration awards [blog post]. *Global Health Matters*. July / August 2013. https://www.fic.nih.gov/News/GlobalHealthMatters/july-august-2013/Pages/usaid-peer-health-grant-awards.aspx.
21. USAID. *US Agency for International Development (USAID) Report to Congress on an Interagency Plan to Strengthen the Capacity of Health Systems in Developing Countries.* Washington, DC: USAID; 2018. https://www.usaid.gov/sites/default/files/documents/1869/Strengthening_the_Capacity_of_Developing_Country_Health_Systems_Web.pdf.

22. Centers for Disease Control and Prevention website. Less Pain, More Gain: Measles Vaccination Using a Microneedle Patch Holds Great Life-Saving Potential page. https://www.cdc.gov/globalhealth/immunization/stories/microneedle-patch.htm. Accessed January 18, 2022.
23. World Health Organization website. Snakebite envenoming page. https://www.who.int/news-room/fact-sheets/detail/snakebite-envenoming. Accessed January 18, 2022.
24. Gates B and French Gates M. 2021 Goalkeepers Report: Innovation and Inequity. Seattle, WA: Bill & Melinda Gates Foundation; 2021. https://www.gatesfoundation.org/goalkeepers/report/2021-report/progress-indicators/.
25. Policy Cures Research, Global Health Technologies Coalition. *Return on innovation: Why global health R&D is a smart investment for the United States*. Sydney: Policy Cures Research; 2017. https://www.ghtcoalition.org/pdf/Return-on-innovation-Why-global-health-R-D-is-a-smart-investment-for-the-United-States.pdf.
26. Impact Blog Team: USAID Commends Major Advance in HIV Prevention Research [blog post]. *Impact Blog.* November 23, 2010. https://blog.usaid.gov/2010/11/usaid-commends-major-advance-in-hiv-prevention-research/.
27. USAID website. Microbicides: New HIV Prevention Products for Women page. https://www.usaid.gov/global-health/health-areas/hiv-and-aids/technical-areas/microbicides-providing-hiv-prevention-options. Accessed January 18, 2022.
28. FHI 360 website. Microbicides page. https://www.fhi360.org/projects/microbicides. Accessed January 18, 2022.
29. US Agency for International Development, National Institutes of Health, Centers for Disease Control and Prevention. *Combating Multidrug-Resistant Tuberculosis: Year Four of the National Action Plan Report.* Washington, DC: USAID; 2020. https://www.usaid.gov/sites/default/files/documents/FINAL_USAID_NAP_2020_Report_DIGITAL_R4_508.pdf.
30. USAID website. Malaria Vaccine Development Program page. https://www.usaid.gov/global-health/health-areas/malaria/research-innovation/malaria-vaccine-development-program-mvdp. Accessed January 19, 2022.
31. USAID website. Medicines for Malaria Venture (MMV) page. https://www.usaid.gov/global-health/health-areas/malaria/research-innovation/medicines-malaria-venture-mmv. Accessed January 19, 2022.
32. PATH. *Hope for less than 50 cents a dose: A revolutionary model for developing low-cost vaccines.* Washington, DC: PATH; 2011. https://path.azureedge.net/media/documents/ER_mvp_fs.pdf.
33. Student team wins USAID Fighting Ebola Grand Challenge [press release]. New York City, NY: Columbia Mailman School of Public Health Center for Infection and Immunity; February 12, 2015. https://www.publichealth.columbia.edu/research/center-infection-and-immunity/student-team-wins-usaid-fighting-ebola-grand-challenge.
34. USAID. *US Agency for International Development (USAID) Report to Congress: Health-Related Research and Development for Fiscal Year (FY) 2016*. Washington, DC: USAID; 2016. https://www.usaid.gov/sites/default/files/documents/1864/USAID-report-on-health-related-research-development-fy2016.pdf.
35. USAID Center for Innovation and Impact. 2018 Impact Brief. Washington, DC: USAID; 2018. https://www.usaid.gov/sites/default/files/documents/1864/impact-brief-2018.pdf.
36. Greco C, Iskander IF, Houchi SZ, Rohsiswatmo R, Rundjan L, Ogala W, Ofakunrin AOD, Moccia L, Thi Xuan Hoi N, Bedogni G, Tiribelli C, Coda Zabetta CD. Diagnostic performance analysis of the point-of-care Bilistick System in identifying severe neonatal hyperbilirubinemia by a multi-country approach. *E Clinical Medicine*. 2018;1:14-20. https://doi.org/10.1016/j.eclinm.2018.06.003.
37. Williams M. Rice awards first COVID-19 research grants [blog post]. *Rice University News and Media Relations*. April 20, 2020. https://news.rice.edu/2020/04/20/rice-awards-first-covid-19-research-grants-2/.
38. USAID. US Agency for International Development (USAID) Report to Congress: Health-Related Research and Development for Fiscal Year (FY) 2016. Washington, DC: USAID; 2016. https://www.usaid.gov/sites/default/files/documents/1864/USAID-report-on-health-related-research-development-fy2016.pdf.
39. USAID. U.S. Agency for International Development (USAID) Report to Congress on Health-Related Research and Development for Fiscal Year (FY) 2017. Washington, DC: USAID; 2017. https://www.usaid.gov/sites/default/files/documents/1864/USAID_Report_to_Congress_Health-Related_Research_and_Development_for_Fiscal_Year_2017_-_508.pdf.
40. PATH. Putting an End to Epidemic Meningitis in Africa. Seattle: PATH; 2019. https://path.azureedge.net/media/documents/Meningitis_fact_sheet_2019.pdf.
41. PATH. USAID and PATH: Working Together to Improve Global Health. Washington, DC: PATH; 2015. https://path.azureedge.net/media/documents/GE_app_path_usaid_fs.pdf.
42. Waite A. How a simple technology can deliver equal access to global health care [blog post]. *Dipnote: International Development*. March 21, 2018. https://2017-2021.state.gov/how-a-simple-technology-can-deliver-equal-access-to-global-health-care/index.html.

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