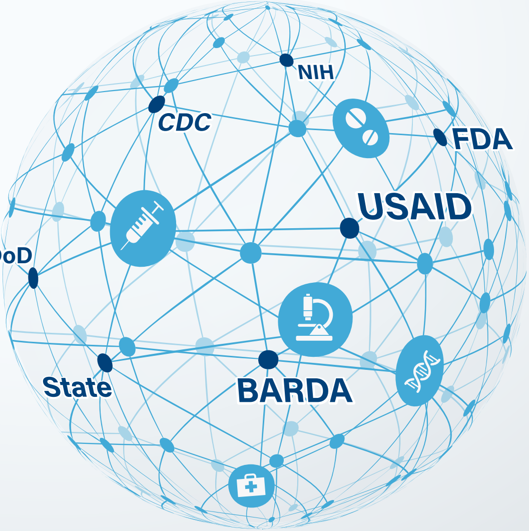
Advancing R&D for Global Health Security

A whole-of-US-government effort



GHTC
global health technologies coalition

An overview of key agencies and programs engaged in R&D for health security

March 2021

We are in the midst of a global pandemic unprecedented in our lifetimes. The rapid emergence and spread of COVID-19 has caused immense human suffering and death, as well as significant economic and societal upheaval.

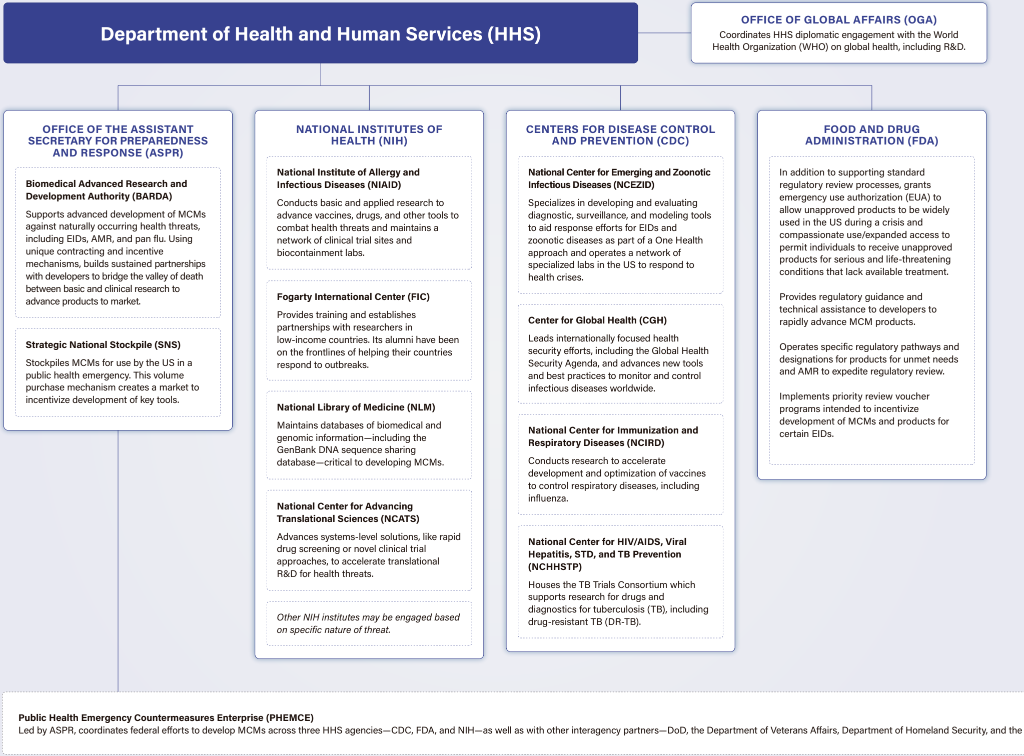
Thankfully, this unparalleled health crisis has spurred an equally unparalleled scientific response. Scientists have raced to develop and deploy new vaccines, therapeutics, and other tools in record time to flatten the curve, shore up overburdened and fragile health systems, and save lives. The US government has been at the forefront of this effort, deploying the full force of our biomedical research and development (R&D) infrastructure across dozens of US agency programs. This resource is designed for policymakers and advocates navigating this infrastructure and considering where additional resources may be put for immediate impact.

As this crisis is underscoring, **in our increasingly interconnected world, naturally occurring health threats—including emerging infectious diseases (EIDs), antimicrobial resistance (AMR), and pandemic influenza (pan flu)—pose a growing threat to the safety and security of Americans and people around the world.** As we are experiencing in real time, a disease outbreak in a remote corner of the world can quickly become a global crisis with devastating human and economic costs.

Vaccines, treatments, diagnostics, vector control tools, and other medical countermeasures (MCMs) are vital to enhance our capacity to prevent and combat threats as they emerge. However, R&D for naturally occurring health threats is particularly challenging. The market potential for these tools is too uncertain to drive proactive commercial investment, and testing these products before or during an outbreak is especially difficult.

Strong US government support and smart collaboration with international partners is vital to overcome these barriers and deliver the tools needed to prevent, detect, and respond to threats when we need them most—for the pandemic at hand and those that science and history indicate will follow.

For the most up-to-date snapshot of **each US agency's COVID-19 R&D efforts**, please visit GHTC's tracker at bit.ly/38Lqi3l.



Department of Health and Human Services (HHS)

OFFICE OF GLOBAL AFFAIRS (OGA)

Coordinates HHS diplomatic engagement with the World Health Organization (WHO) on global health, including R&D.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR)

Biomedical Advanced Research and Development Authority (BARDA)

Supports advanced development of MCMs against naturally occurring health threats, including EIDs, AMR, and pan flu. Using unique contracting and incentive mechanisms, builds sustained partnerships with developers to bridge the valley of death between basic and clinical research to advance products to market.

Strategic National Stockpile (SNS)

Stockpiles MCMs for use by the US in a public health emergency. This volume purchase mechanism creates a market to incentivize development of key tools.

NATIONAL INSTITUTES OF HEALTH (NIH)

National Institute of Allergy and Infectious Diseases (NIAID)

Conducts basic and applied research to advance vaccines, drugs, and other tools to combat health threats and maintains a network of clinical trial sites and biocontainment labs.

Fogarty International Center (FIC)

Provides training and establishes partnerships with researchers in low-income countries. Its alumni have been on the frontlines of helping their countries respond to outbreaks.

National Library of Medicine (NLM)

Maintains databases of biomedical and genomic information—including the GenBank DNA sequence sharing database—critical to developing MCMs.

National Center for Advancing Translational Sciences (NCATS)

Advances systems-level solutions, like rapid drug screening or novel clinical trial approaches, to accelerate translational R&D for health threats.

Other NIH institutes may be engaged based on specific nature of threat.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Specializes in developing and evaluating diagnostic, surveillance, and modeling tools to aid response efforts for EIDs and zoonotic diseases as part of a One Health approach and operates a network of specialized labs in the US to respond to health crises.

Center for Global Health (CGH)

Leads internationally focused health security efforts, including the Global Health Security Agenda, and advances new tools and best practices to monitor and control infectious diseases worldwide.

National Center for Immunization and Respiratory Diseases (NCIRD)

Conducts research to accelerate development and optimization of vaccines to control respiratory diseases, including influenza.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Houses the TB Trials Consortium which supports research for drugs and diagnostics for tuberculosis (TB), including drug-resistant TB (DR-TB).

FOOD AND DRUG ADMINISTRATION (FDA)

In addition to supporting standard regulatory review processes, grants emergency use authorization (EUA) to allow unapproved products to be widely used in the US during a crisis and compassionate use/expanded access to permit individuals to receive unapproved products for serious and life-threatening conditions that lack available treatment.

Provides regulatory guidance and technical assistance to developers to rapidly advance MCM products.

Operates specific regulatory pathways and designations for products for unmet needs and AMR to expedite regulatory review.

Implements priority review voucher programs intended to incentivize development of MCMs and products for certain EIDs.

Public Health Emergency Countermeasures Enterprise (PHEMCE)

Led by ASPR, coordinates federal efforts to develop MCMs across three HHS agencies—CDC, FDA, and NIH—as well as with other interagency partners—DoD, the Department of Veterans Affairs, Department of Homeland Security, and the

Department of Defense (DoD)

DEFENSE AGENCIES

Defense Advanced Research Projects Agency (DARPA)

Supports a range of high-risk, cutting-edge research projects to combat infectious diseases, such as developing field-portable, rapid molecular platforms to detect pathogens and diagnose disease and novel vaccine platforms and innovative approaches to significantly speed vaccine and therapeutic development and manufacturing.

Defense Threat Reduction Agency (DTRA)

Serves as lead entity on DoD efforts to combat biological threats and supports the development of tools and platforms to advance disease surveillance.

DEPARTMENT OF THE ARMY

US Army Medical Research and Material Command (USAMRMC)

Through the joint Military Infectious Disease Research Program (MIDRP) and other Army programs like the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Walter Reed Army Institute of Research (WRAIR), supports R&D—from basic to clinical research—of vaccines, drugs, diagnostics, and vector control tools to protect American warfighters against EIDs.

Operates network of overseas military laboratories and clinical trial sites in partner countries which is leveraged to advance R&D for health threats.

Congressionally Directed Medical Research Programs (CDMRP)

Congressionally directed fund, implemented by the Army, that provides grants to support R&D for a range of eligible diseases including EIDs, TB, and AMR.

DEPARTMENT OF THE NAVY

Naval Medical Research Center (NMRC)

Supports R&D, from basic to clinical research, to advance vaccines and other MCMs against infectious disease threats to Naval and other military personnel.

Operates three overseas research centers that conduct medical research and disease surveillance on EIDs.

Defense Health Agency (DHA)

Joint program across military branches that includes programs that conduct epidemiological and surveillance research on EIDs.

Department of Agriculture.

US Agency for International Development (USAID)

Bureau for Global Health (GH)

Through its funding for R&D programs across diseases and health areas, builds critical scientific capacity and relationships to help partner countries respond to health crises.

Has supported development of select tools to combat EIDs and DR-TB designed specifically for low-resource settings.

The Center for Innovation and Impact, in conjunction with the Global Development Lab, has operated two Grand Challenges supporting R&D for health security: 1) *Fighting Ebola*, with CDC, DoD, and the White House Office of Science and Technology Policy, to advance innovations to protect health workers; and 2) *Combating Zika and Future Threats*, to advance tools to fight Zika and other infectious disease outbreaks.

Provides funding to Gavi, the Vaccine Alliance, a multilateral partnership to expand access to vaccines in the world's poorest countries, which serves as a key mechanism for global scale-up of vaccine countermeasures.

Through the President's Malaria Initiative (PMI) and malaria programs, finances R&D for vector control tools that can combat mosquito-borne EIDs.

State Department

Contributions to International Organizations (IO)

Provides funding to WHO, which plays a vital role in coordinating global actors around an R&D blueprint for disease threats, supporting clinical trials, and issuing EUA for unapproved products and other technical and regulatory guidance for member states, which is essential to low-income countries with more nascent regulatory systems or limited capacity nationally.

Global Health Programs (GHP)

- *President's Emergency Plan for AIDS Relief (PEPFAR):* Through support of HIV/AIDS R&D, builds vital scientific capacity and research infrastructure in partner countries that is leveraged during health emergencies. Has also supported R&D for novel vaccine platforms and antibody-based therapies that are being adapted to fight EIDs.
- *Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria:* Supports this multilateral partnership to scale up affordable treatments for these diseases, including DR-TB, globally, which could also serve as a key mechanism for scaling up treatments for EIDs in low-income countries.

Other Agencies and Programs

Several other agencies and programs play a supportive role

National Security Council (NSC)

Plays a cross-government coordination role on biodefense activities.

National Science Foundation (NSF)

Supports molecular, cellular, physiological, and ecological research to understand certain EIDs and how they act and spread.

National Institute of Standards and Technology (NIST), Commerce Department

Advances research and best practices to support the pharmaceutical industry in developing and manufacturing MCMs.

White House Office of Science and Technology Policy (OSTP)

Advises the President and White House on the scientific, engineering, and technical aspects of health and national security.

Department of Agriculture (USDA)

Regulates veterinary vaccines and treatments that play a role in preventing animal to human transmission of EIDs.

Environmental Protection Agency (EPA)

Regulates pesticide vector control tools needed to combat mosquito- and vector-borne EIDs.

A coordinated, whole-of-government approach at work

A game-changing Ebola vaccine

In December 2019, FDA approved the world's first Ebola vaccine, Merck's Ervebo, marking a major milestone in the fight against this devastating disease. Several US agencies played a critical role in advancing this breakthrough.

DoD's DTRA supported preclinical development of the vaccine in the early 2010s. When the West African Ebola outbreak began in 2014, the US government worked swiftly with international partners including WHO to advance the vaccine. Within the next year, NIH NIAID and Army's WRAIR supported phase 1 safety and dosing trials of the vaccine in the US, and then NIAID, WRAIR, and CDC supported large-scale phase 2 and 3 efficacy trials on the African continent in the midst of the ongoing outbreak. BARDA provided critical funding to support these trials and continue to advance the product's development.

Given the promising trial results, which showed the vaccine was highly effective, Gavi, which receives funding through USAID, issued an advance purchase commitment in 2016 to continue to support the vaccine's development and stockpile it for use in low-income countries. SNS also provided funding to stockpile it for the US market.

Beginning in 2018, there was a second significant Ebola outbreak in the Democratic Republic of Congo, during which the vaccine was widely administered on an emergency basis with WHO and Gavi support. Following approval of the vaccine by European regulators in November 2019, WHO prequalified it, paving the way for its approval and introduction worldwide.

DTRA **NIAID** **Army** **CDC** **State/IO**
BARDA **USAID** **FDA** **SNS**

A breakthrough treatment for extensively drug-resistant TB

In August 2019, FDA approved pretomanid, a new drug for extensively drug-resistant TB (XDR-TB), as part of a combination regimen with the drugs bedaquiline and linezolid. The regimen reduces treatment time for XDR-TB from up to two years to just six months while significantly improving treatment outcomes.

The regimen was developed by the nonprofit TB Alliance, with financial support from NIH NIAID and USAID GHP. This treatment is now being introduced worldwide with WHO providing guidance for countries on its use.

NIAID **USAID** **FDA** **State/IO**

Diagnostics for Zika

When Zika struck the Americas in 2016, reliable diagnostic tests were vital to identifying women infected with the mosquito-borne virus who were pregnant or hoping to become pregnant and were at risk of delivering a baby with health complications.

CDC developed the first available test for Zika shortly after the crisis began, which FDA approved for emergency use. CDC later developed a second EUA-approved test that could distinguish between chikungunya, dengue, or Zika infection in a single test, which is important since patients with these related viruses have similar symptoms.

NIAID and BARDA provided funding to support development of additional diagnostics while USAID provided funding to UNICEF for an advance purchase commitment to support a point-of care test designed for low-resource settings. CDC, BARDA, and FDA also provided blood, plasma, virus samples, and other resources for developers to validate tests. Today, thanks to these efforts, there are three Zika diagnostics with full FDA market authorization, all of which received BARDA support, and 16 additional tests that are EUA-approved, including the USAID-supported test.

CDC **FDA** **NIAID** **USAID** **BARDA**

GHTC

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 25 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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