Working Together
to Address the Global Threat of Antimicrobial Resistance

CARB-X
Combating Antibiotic-Resistant Bacteria

ANNUAL REPORT 2021-2022
Beginning with penicillin in 1942, antibiotics have transformed modern medicine and saved millions of lives. Antibiotic resistance—bacteria’s ability to overcome the effects of the drugs designed to kill or disarm them—is one of the world’s greatest public health threats.

Resistance is spurred by the misuse of existing antibiotics, and its public health impacts are worsened by the lack of scientific innovation due to poor economic incentives. 10-15 years of drug development are needed to produce one new antibiotic with little opportunity for commercial returns. Global support for the innovation pipeline is essential to ensure that new antibiotics will be available when patients need them.

1. Why is it so hard to develop new antibiotics?

The CARB-X mission
CARB-X accelerates a diverse portfolio of innovative antibacterial products towards clinical development and regulatory approval with funding, expert support and portfolio acceleration tools. We focus on the most dangerous bacteria identified by the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) priority lists.

Antibiotic resistance is a top global killer

Antimicrobial resistance (AMR) is one of the most urgent global health threats. A 2022 study published in The Lancet estimated that 1.27 million people died due to drug-resistant bacterial infections in 2019, a death toll that exceeded HIV/AIDS (864,000) and malaria (643,000) in that same year. Yet, innovation is lagging. The latest analysis of antibacterial research and development (R&D) from the World Health Organization concluded that “the clinical pipeline and recently approved antibiotics are insufficient to tackle the challenge of increasing emergence and spread of AMR.”

As bacteria evolve to evade our current arsenal of drugs, CARB-X is delivering on its promise to replenish the clinical pipeline with high-impact products to prevent, diagnose and treat the most dangerous drug-resistant infections. Over the year, eight CARB-X product developers advanced their therapeutics and preventatives to first-in-human clinical trials. Additionally, two diagnostics entered the Verification & Validation stage and are being evaluated with patients.

Since 2016, CARB-X has accelerated 18 projects that entered or completed first-in human clinical trials. Among them, two are on the market, seven have advanced development partnerships, and 12 are in active clinical development.

We must continue to forge ahead, and global leaders agree. We are grateful for renewed grants with the U.S. Government and Wellcome, CARB-X’s founding funders. In May 2022, they committed up to an additional US$370 million over the next decade so CARB-X can continue targeting the greatest unmet medical needs with innovative products, managed as an integrated portfolio.

These commitments are in line with the prioritization of AMR during Germany’s G7 Presidency. G7 Leaders declared that they “will spare no efforts” to continue addressing the silent pandemic of drug-resistant infections. G7 Health Ministers highlighted “the importance of accelerating early and late-stage development of urgently-needed antimicrobial drugs, vaccines, alternative therapeutics and diagnostics,” and reiterated that they “value and support initiatives like CARB-X.”

In October 2022, CARB-X launched new funding rounds to support R&D projects and fill critical gaps in the antibacterial pipeline. These include oral therapeutics to replace our workhorse antibiotics that are failing; vaccines for neonatal sepsis, which kills 2.5 million infants annually; and oral therapeutics, vaccines and rapid diagnostics for gonorrhea. Resistant strains of gonorrhea have evaded all but one existing antibiotic.

We thank our global partners for their dedication to addressing AMR. We are in this together.

Kevin Outterson, Esq.
Executive Director, CARB-X

Erin Duffy, Ph.D.
Chief of Research and Development, CARB-X

2. G7 Health Ministers’ Communiqué
http://www.g7utoronto.ca/healthmins/2022-0520-communique.html
CARB-X is an essential link in the antibacterial R&D chain

CARB-X sits at a crucial junction of the innovation journey, ensuring a future to the most promising scientific advances from academia and companies by accelerating early-stage R&D projects. CARB-X maximizes the impact of funding for advanced development by replenishing the clinical pipeline with critical R&D projects. CARB-X coordination with upstream and downstream funders is essential to maintain the integrity of the R&D chain.

“CARB-X is a crucial accelerator, driving innovative AMR programs toward advanced development and regulatory approval. With our recently renewed commitment to this global partnership, we will continue to work together over the next decade to develop products that help save lives and address national health security concerns.”

— Gary Disbrow, Ph.D., Director, BARDA

“We recognise the urgent need to foster innovation and to strengthen the R&D pipeline. We therefore highlight the importance of accelerating the early- and late-stage development of urgently-needed new antimicrobial drugs, vaccines, alternative therapeutics and diagnostics. We value and support initiatives such as CARB-X and GARDP and will continue national and international efforts on AMR R&D for new therapeutics, vaccines and diagnostics.”

— G7 Health Ministers’ Communiqué

20 May 2022, Berlin

February 2022
AMR Action Fund Scientific Advisory Board
AMRAF appointed CARB-X to help evaluate the scientific merit, patient benefit and public health impact of the Fund’s US$1B investments in new antibiotics.

February 2022
Novo REPAIR invests in Centauri
The new investment means that 8 out of 10 REPAIR Impact Fund projects are also supported by CARB-X.

April 2022
AMR Action Fund announces first investments
AMRAF will invest in Venatorx Pharmaceuticals, a CARB-X-supported product developer, as well as Adaptive Phage Therapeutics.

May 2022
US$370M from BARDA and Wellcome
CARB-X will receive up to US$370 million over the next decade from its founding funders, BARDA and Wellcome, and renewed in-kind support from NIAID.

May 2022
G7 Health Ministers’ Communiqué
G7 governments recognized AMR as an urgent global health threat and communicated that they “value and support initiatives such as CARB-X.”

June 2022
World’s first subscription deal
UK National Health Service planned to purchase ceftazidime-avibactam and cefiderocol, antibiotics produced by Pfizer and Shionogi, for £10 million per year up to 10 years.

October 2022
CARB-X new funding rounds
CARB-X funding will support the development of oral antibiotics, vaccines for neonatal sepsis, and gonorrhea products.

October 2022
G20 Call to Action on Antimicrobial Resistance
G20 governments called for strengthened engagement among antimicrobial R&D organizations, including CARB-X.
Over the past year, CARB-X product developers have made tremendous progress to move their projects along the development pipeline.

CARB-X projects in First-in-Human trials

**Bugworks’ BWC0977** is a novel class, broad-spectrum antibiotic that targets infections caused by multidrug-resistant Gram-negative bacteria. BWC0977 is designed in intravenous and oral forms, so patients can be treated within and outside hospitals to lower healthcare costs and infection risks.

**SNIPR Biome’s SNIPR001** is a CRISPR-engineered bacteriophage that selectively targets E.coli, including fluoroquinolone-resistant strains. The goal is to prevent bloodstream infections in cancer patients, while leaving their microbiomes intact. Cancer patients often have leaky guts and weakened immune systems, making them susceptible to infections.

**Seres Therapeutics’ SER-155** is an oral live biotherapeutic product (LBIP) designed to disrupt antibiotic-resistant pathogens from the gut. By restructuring the microbiome and improving the integrity of the GI lining, SER-155 aims to reduce breakthrough bloodstream infections in patients undergoing chemotherapy, organ and stem cell transplants. These patients often have leaky guts and weakened immune systems, making them susceptible to infections.

**GSK’s GSK3882347** is an oral, small molecule drug that binds FimH, an adhesive protein found on the surface of E. coli. When FimH is bound, E. coli cannot stick to the bladder wall, thereby preventing infection. Urinary tract infections (UTIs) are among the most frequent bacterial infections. While most UTIs are easy to treat, if drug-resistant bacteria travel from the bladder to the bloodstream, they can cause sepsis and death.

Hundreds of projects must make it to the early R&D stages that CARB-X supports to result in the few life-saving products that we need every decade.
CARB-X projects align with 2022 GRAM study findings
Since 2017, CARB-X has supported projects that target the most burdensome syndromes.

0 500,000 1,000,000 1,500,000 2,000,000

ALL CARB-X PROJECTS

CARB-X projects advance closer to patients
Since exiting the CARB-X portfolio, three product developers have made it to Phase 3 clinical trials and the verification and validation stage. Two CARB-X diagnostics are now on the market.

**T2 Biosystems’ T2Resistance Panel** identifies 13 antibiotic-resistance genes associated with sepsis-causing bacteria. T2 Biosystems completed product development and the verification and validation stage. Through 2022, T2 Biosystems contracted with BARDA to further advance its technology. The T2Resistance Panel is now commercially available in Europe, and a U.S. clinical trial is underway.

**Specific Diagnostics’ REVEAL® Rapid AST system** identifies antibiotic susceptibility directly from a positive blood sample in four hours. Specific completed product development and the verification and validation stage, and the REVEAL® is now available in Europe. In 2022, Specific was acquired by bioMérieux.

**HelixBind’s RaPID diagnostic system** detects bloodstream infections and their resistance mechanisms directly from whole blood in hours. HelixBind completed product development for the first assay for the system, RaPID/BSI. This assay was designated a Breakthrough Device by the FDA. Currently, HelixBind is leading multiple studies to demonstrate clinical performance in a variety of settings. The company is also expanding its test menu of pathogens and resistance mechanisms for follow-on product offerings.

**Vedanta Biosciences’ VE303** is an oral live biotherapeutic product (LBP) that consists of eight bacterial strains designed to restore gut microbiota to prevent recurrent *C. difficile* infections. In 2022, Vedanta completed Phase 2 studies, and with BARDA support is preparing for Phase 3 and advanced development in 2023. Also in 2022, Vedanta opened a manufacturing facility to supply its clinical and commercial products.

**Proteus’ Lung Imaging Platform technology** uses bacteria-specific Smartprobes and fibre-based imaging to provide real-time visualization of bacteria and host immune cells deep within the lungs. Proteus completed clinical product development, and in 2022 began to evaluate its technology in patients in the verification and validation stage.

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What makes CARB-X unique?

• Non-profit, driven by public health objectives and unmet medical needs
• Public-private partnership, leveraging private sector expertise
• Funded by governments and private foundations committed to global health
• A lean organization: 95% of funding goes to product developers via direct awards or technical and in-kind support
• Runs competitive funding calls to support the best science from product developers around the world
• Employs rigorous application standards with an 8% acceptance rate
• Manages a portfolio with diverse scientific approaches to increase the likelihood of success
• Provides scientific, regulatory, and business support in addition to non-dilutive grants
• Sets strict performance-based milestones for every project
• Leads Portfolio Acceleration Tools to support multiple product developers and create efficiencies
• Awards funding for early R&D when highly-innovative product developers are most vulnerable
• Supports breakthrough scientific advances, including new drug classes, bacteriophages and microbiome-based products
• Accelerates products across three pillars: treatments, preventatives and diagnostics
• Targets the most dangerous drug-resistant bacteria, prioritized by the WHO and CDC
• Focuses on the most burdensome syndromes, confirmed by the 2022 GRAM study
• Internal R&D team, 100+ subject matter experts and a Global Acceleration Network advise product developers on business decisions, legal strategies and regulatory affairs
• Coordinates with upstream and downstream funders, including NIAID, JPIAMR, BARDA, AMR Action Fund and GARDP
• Endorsed by the G7 and G20
• Requires cost-sharing to ensure project sustainability
• Risk-value assessment tool guides investment decisions and portfolio strategies
• Robust SOPs support information security, conflicts of interest, research compliance and financial administration
• Efficient grant management supports product developers
• Stewardship and access requirements for every product are a new global standard that aims to slow resistance and improve health worldwide

In six years, CARB-X has accelerated 92 R&D projects, 18 of which entered or completed first-in-human clinical trials. Among these, 2 are on the market, 7 have advanced development partnerships and 12 are in active clinical development.

95% of funding goes to product developers via direct awards or technical and in-kind support.

“CARB-X is playing a critical role in bringing together partners up and down the research pipeline, helping to ensure that more life-saving, antibacterial products succeed on the road from discovery science to clinics and patients.”

– Timothy Jinks, Ph.D., Head of Infectious Disease Interventions, Wellcome
CARB-X is in a unique position to support a broad portfolio of antibacterial products. From this viewpoint, CARB-X sees common challenges facing many product developers. To save time, energy and money across the entire ecosystem, CARB-X responded with an economical series of Portfolio Acceleration Tools (PATs).

PATs seek to help product developers understand toxicity risks, standardize animal models, and gain a deep understanding about antibiotic susceptibility and antigenic variability of global bacterial strains. The goal of each PAT is to help CARB-X developers optimize their products and advance them more quickly to patients.

What inspired the antibiotic susceptibility PAT? After receiving an invoice for one project’s antibiotic susceptibility testing, we thought rather than supporting every company to do a similar study we could share resources to provide benefits to a wider range of programs. Because it’s expensive to run a susceptibility study against many strains of bacteria, a lot of companies don’t conduct them early on in their programs. They’re missing out on the opportunity to understand if there are pre-existing pools of resistance to their compounds and how well they inhibit real-world clinical isolates.

How was support generated? When we discussed the concept, our R&D Chief Erin Duffy, Ph.D. saw the value. But she wanted to know if product developers would be willing to share their compounds. The therapeutics programs were very interested, because they wanted to evaluate their compounds’ activity against a broad range of contemporary isolates.

How did you get it off the ground? CARB-X made the case to our funders, as an alternative to strictly awarding grants to product developers. The funders saw the value, and GAMRI funded this study, because they wanted to understand how the entire therapeutics portfolio worked against bacterial isolates from low- and middle-income countries (LMICs).

How did you select the strains? We partnered with International Health Management Associates (IHMA), which collects strains from global medical centers. IHMA sent its 2019 isolates list from which we selected about 5,000 across key bacterial species on the WHO and CDC priority lists. 58.4% were from LMICs, including from Southeast Asia, South America and Africa. We wanted to make the panels as diverse as possible to avoid consecutive isolates.

What are consecutive isolates? If we wanted 6 Klebsiella strains from Thailand, for example, we selected strains from different hospitals. That can greatly reduce the risk of having clonal isolates caused by an outbreak in a single hospital.

How was testing carried out? IHMA performed antibiotic susceptibility tests against the CARB-X compounds and comparator antibiotics available in clinics—such as ceftazidime, ceftazidime/avibactam, levofloxacin and meropenem. After receiving the data, CARB-X performed the population analyses. In September 2021, we gave product developers data on their own compounds, so they could see how they compared against contemporary isolates. Through early 2022, each product developer could also select and obtain key isolates to further study.

How did the CARB-X programs do? We noticed that many CARB-X compounds were far more potent than the clinical comparators at killing the bacterial isolates. In contrast, the activity of the clinical compounds—even a relatively new drug like ceftazidime/avibactam—were already being eroded in LMICs. That underscored the need for us to accelerate new antibiotics.

Did anything surprise you? Now that we had susceptibility data and access to many strains, vaccine and diagnostics developers were also interested in the LMIC strains. This was a pleasant surprise and truly organic. I assumed that the diagnostics companies, for example, would have relationships with hospitals to get clinical isolates whenever they needed them. But a lot of them don’t. Even if they do, they often have access to local hospitals, not worldwide.

In response, CARB-X built four blinded challenge panels with specific bacterial strains for bloodstream, respiratory tract, urinary tract, and sexually transmitted infections. The developers used the panels to evaluate how well their diagnostic platforms could identify the strains.

How did the vaccine developers get involved? When CARB-X started the antigen conservation PAT directed by our prevention leader, Ed Buurman, Ph.D., we provided vaccine developers with custom analyses, so they could examine sequence variations for specific antigens from diverse bacterial strains. But almost without exception, they would see changes in certain antigens and ask, “do you have that strain, so I can test it in my animal models?”

Providing genotypic analyses and access to corresponding strains, especially from LMICs, is really important. If the bacterial pathogens in key geographic locations are better understood, that knowledge should lead to better vaccines that will protect more people. So CARB-X is providing our vaccine developers with genotypic data on global bacterial strains, including where the AMR burden is the greatest. We are also expanding partnerships with other groups to access more strains and the full genomic sequences that we can share with our product developers.

What are key takeaways? There was a strong acknowledgment that CARB-X has an advantage by supporting a portfolio, rather than just a single project. From the portfolio perspective, we learn about common barriers and questions, and can help more programs by sharing resources. And from the funder’s perspective, the PAT leveraged dollars effectively.

“Entering Phase I clinical studies was critical for Bugworks. The PAT data indicated our compound was performing well against multidrug-resistant global isolates and gave us confidence that we were going in the right direction before embarking on costly clinical trials.”

What’s on the horizon for PATs? CARB-X is developing a PAT, led by my colleague Maria Una-Nickelsen, Ph.D. on an animal model for lung infections, the number one infectious disease killer in the world. That’s why this PAT is focused on lung infections, and why CARB-X supports many programs in this area.

The reason to create a pre-clinical animal model is to have confidence that the effect your compound has in the animal model will translate to a human. For example, we plan to test known clinical compounds in a lung animal model with simulated human exposure. So you would know that a certain decrease in bacterial counts in a mouse lung should translate to a clinical result for a human. Then, if you’re testing an unknown compound and the bacterial count didn’t decrease by that same amount, you don’t have much hope in humans. Having a model that is standardized and validated is important. If everyone builds a slightly different model, and you get different results, that makes it harder to develop a consistent understanding.
New CARB-X funding rounds target greatest needs

In October 2022, CARB-X launched new funding rounds soliciting projects to fill major gaps in the global pipeline. The three themes include oral therapeutics, vaccines for neonatal sepsis, and gonorrhea products.

Oral therapeutics

The need for oral drugs is critical. In contrast to IV delivery, oral drugs enable patients to be treated at home which increases access to care, particularly for those located in remote settings. Since hospital stays are reduced, oral drugs can help lower health care costs and infection risks.

The CARB-X funding scope is restricted to oral products with several syndromes and causative agents, including respiratory tract infections, urinary tract infections and syndromes caused primarily by Gram-positive pathogens.

Vaccines for neonatal sepsis

The BARNARDS study (2021) estimates that 2.5 million neonates or infants die annually of sepsis, with the greatest burden in low- and middle-income countries (LMICs). A maternal vaccine targeting the pathogens accounting for the highest number of deaths would have a major impact on preventing neonatal sepsis.

The CARB-X funding scope is restricted to vaccines focused on preventing neonatal sepsis, targeting several possible bacterial species, including Klebsiella pneuomiae, Escherichia coli (ETEC or urinary), Acinetobacter baumannii and Staphylococcus aureus.

Gonorrhea products

Only one antibiotic, ceftriaxone, remains effective against resistant strains of Neisseria gonorrhoeae.

The CARB-X funding scope is open to products that address Neisseria gonorrhoeae, including oral therapeutics, low-cost vaccines and rapid, point-of-care diagnostics. Products must address both drug-sensitive and drug-resistant scenarios.

“Premature infants in poor countries who survive long enough to reach hospital then need to endure exposure to multi-resistant bacteria in settings with limited infection control. Vaccines against multi-resistant bacteria such as Klebsiella may be life-saving.”

— Keith Klugman, MD, Ph.D.
Director, Pneumonia and Pandemic Preparedness
Bill & Melinda Gates Foundation

“As England’s Chief Medical Officer, I raised the alarm of gonorrhoea becoming an untreatable disease. As UK Special Envoy for AMR, I am thrilled that the UK is partnering with CARB-X to deliver crucial innovations towards combatting drug-resistant gonorrhoea. This will protect everyone, including the world’s most vulnerable.”

— Professor Dame Sally Davies, CBE DBE FRS FMedSci
UK Special Envoy on Antimicrobial Resistance

Thank you to our partners

CARB-X’s global mission to accelerate the early development of innovative products to address antibiotic-resistant bacteria would not be possible without our partners. They are vital to our success, the success of our product developers, and to protect the future health of humanity.

The Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness & Response (ASPR) in the U.S. Department of Health and Human Services, invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures—vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats.

To date, BARDA has supported 70 FDA approvals of products that cut across our threat space and include vaccines, therapeutics, diagnostics and devices. BARDA co-founded the Combating Antibiotic-Resistant Bacteria Accelerator, currently managed as CARB-X by Boston University, and has committed up to US$541 million since 2016.

Wellcome supports science to solve the urgent health challenges facing everyone. Wellcome supports discovery research into life, health and wellbeing, and are taking on three worldwide health challenges: mental health, infectious disease and climate and health. Wellcome was CARB-X’s first international partner and has committed over US$225 million since 2016.

The US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID provides in-kind services such as preclinical services to CARB-X.

Education and research are crucial foundations for our future. Thus, the promotion of education, science and research is a policy priority of the German Federal Government. The German Federal Ministry of Education and Research (BMBF) is providing up to €500 million over ten years towards research to combat antimicrobial resistance. In 2019, BMBF committed €39 million to CARB-X over four years plus an additional €1 million to DZIF directly for one of the accelerators in the CARB-X Global Accelerator Network.

This research is co-funded by the UK Department of Health and Social Care as part of the Global AMR Innovation Fund (GAMRIF). This is a UK aid programme that supports early-stage innovative research in underfunded areas of antimicrobial resistance (AMR) research and development for the benefit of those in low- and middle-income countries (LMICs), who bear the greatest burden of AMR. GAMRIF committed £213 million to CARB-X through 2022.

The Bill & Melinda Gates Foundation is a major funder of global health research and development. The foundation supports the development of new vaccines and novel biologies against antibiotic-resistant bacterial infections, particularly for vulnerable populations in low- and middle-income countries. They have committed US$25 million to CARB-X.

Boston University supports CARB-X with operational and administrative resources. CARB-X headquarters are located at the Boston University School of Law.
CARB-X is a global non-profit partnership that accelerates antibacterial research and development. CARB-X awards non-dilutive funding and provides scientific, regulatory and business expertise to support early-stage development of products that aim to prevent, diagnose and treat the most dangerous drug-resistant bacterial infections.