CARB-X

Combating Antibiotic-Resistant Bacteria

ACCELERATING INNOVATION *to* PROTECT LIVES *from* BACTERIAL INFECTIONS

ANNUAL REPORT | 2024

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BUILDING *on* 2024: ACCELERATING *the* FIGHT AGAINST ANTIMICROBIAL RESISTANCE

This year has been pivotal in re-energizing global, regional and national efforts to address antimicrobial resistance (AMR). The United Nations General Assembly's High-Level Meeting on AMR in September, the G7 Health and Finance Ministers' Meeting in early October, the G20 Health Ministers' Meeting in late October, and the 4th Global High-Level Ministerial Conference on AMR in November all underscored the urgency of addressing AMR and highlighted the crucial role that innovation plays in ensuring sustainable access to effective antibiotics as well as improving how health systems prevent and diagnose drug-resistant infections. These meetings also reinforced the importance of investing in public-private partnerships and "push" incentives such as CARB-X to replenish a global pipeline which needs to be larger and more innovative. The CARB-X track record of success has proven the return on funder investments. In 2024, we proudly announced support for our 100th R&D project and our portfolio is stronger than ever. CARB-X has supported 67% of the current Phase 1 clinical pipeline of non-traditional antibacterial therapeutics targeting WHO critical priority pathogens. As the global demand for new antibacterial therapeutics, diagnostics, and preventatives grows, we accelerate progress and continue driving innovation.

Looking ahead, our vision remains clear: to reduce deaths from bacterial infections by advancing life-saving products toward the market. Global leaders committed to reducing the estimated 4.95 million human deaths associated with AMR annually by 10% by 2030 at the UN High-Level Meeting on AMR.

We are playing our part in achieving this goal and working closely with our funders and partners around the world. According to new estimates of the global burden of AMR until 2050, more than 11 million deaths could be averted through the development of a Gram-negative drug pipeline. In the end, sustainable access to effective antibiotics depends on the continued release of innovative products responding to the natural evolution of dangerous bacteria. With ongoing global support and commitment to long-term R&D investment, we are confident that we can address the antibacterial pipeline and access crisis by accelerating the development of much-needed innovation poised for global impact.

Together, we can build on this momentum and forge a future where millions of lives are saved from preventable bacterial infections.

Global leaders committed to reducing the estimated 4.95 MILLION human deaths associated with AMR annually by 10% by 2030

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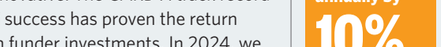

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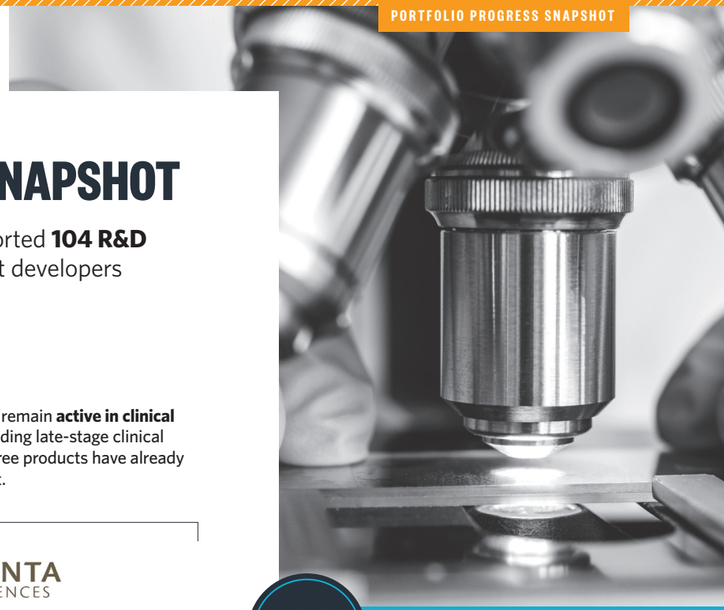


PORTFOLIO PROGRESS SNAPSHOT

Since its founding in 2016, CARB-X has supported **104 R&D projects** in **13 countries**, and CARB-X product developers have made significant progress:

20
projects have advanced into or completed **clinical trials**.

13
graduated projects remain **active in clinical development**, including late-stage clinical trials; moreover, three products have already reached the market.

CLARAMETYX biosciences
Product: CMTX-001—Monoclonal Antibody

GSK
Product: GSK3882347—FiMH Antagonist
Product: GVGH iNTS-TCV—Vaccine Against Invasive Nontyphoidal Salmonella and Typhoid Fever

HELIXBIND
Product: Rapid Blood Stream Infection, Direct-From-Specimen Diagnostic

ITERUM therapeutics
Product: Sulopenem—Penem β-Lactam Antibiotic
FDA Cleared & On the Market

pattern
Product: Diagnostic for Rapid ID/AST

Peptilogics
Product: PLG0206—Direct-Acting Engineered Peptides

VEDANTA BIOSCIENCES
Product: VE303—Direct-Acting Microbiome-based Therapeutic

PROTEUS
Product: Rapid Point-of-Care Diagnostic—Optical Bacterial Imaging

SERES THERAPEUTICS
Product: SER-155—Direct-Acting Microbiome-Based Therapeutic

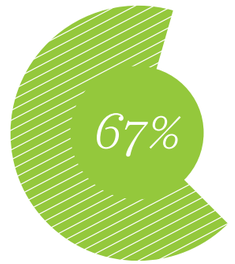
trellis BIOSCIENCE
Product: TRL1068—Indirect-Acting Large Molecule Antibacterial

T2Biosystems
Product: T2 Resistance Panel On the Market

BIOMÉRIEUX
Product: VITEK REVEAL
FDA Cleared & On the Market
Product formerly developed by Specific Diagnostics, which has now been acquired by bioMérieux

10+ Additionally, more than **10 product developers** with active R&D projects have secured advanced development partnerships to support their clinical development after leaving the CARB-X portfolio.

"Our project started but may not have continued without the support of CARB-X."
—CARB-X Product Developer



CARB-X has supported **67%** of the current Phase 1 clinical pipeline of non-traditional antibacterial therapeutics targeting WHO critical priority pathogens.

2024: A DEFINING YEAR *for* GLOBAL ACTION *against* ANTIMICROBIAL RESISTANCE *and* WIDESPREAD RECOGNITION *of* THE IMPORTANCE OF CARB-X

2024 saw the adoption of multiple ministerial declarations and the publication of numerous policy reports which emphasized the urgency of addressing AMR and supporting public-private partnerships and push incentives such as CARB-X.

Leaving the Lab: Tracking the Decline in AMR R&D Professionals, February 2024
"Incentives are required not just to support the R&D pipeline, but to ensure that we can slow down and halt the outflow of key talent in this space. There are organizations like **CARB-X** that are currently supporting several dozen small companies, giving them and their researchers a lifeline. These efforts should be further encouraged. If we are to meet the need for new antimicrobials, then we must invest in the people who are responsible for their discovery."

G7 Finance Ministers and Central Bank Governors Communiqué, Stresa, Italy, May 2024
"[We will] continue discussing instruments to … promote research, including into new antimicrobials as well as alternatives to their use, through **push and pull incentives**."

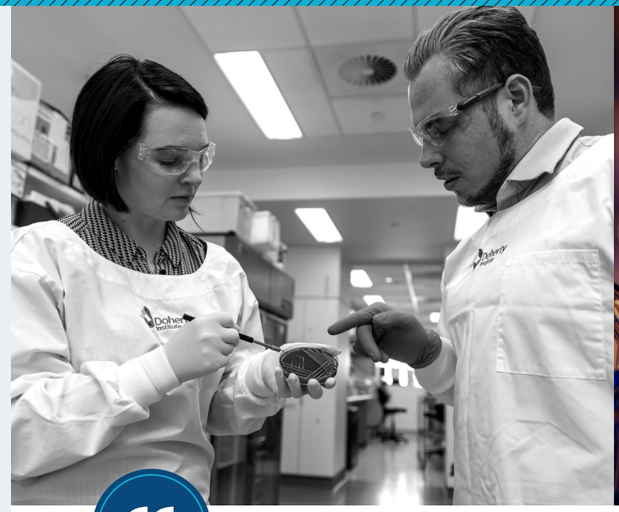
G7 Leaders' Communique, Apulia, Italy, June 2024
"[We will] implement push and pull incentives, support **public-private partnerships** and explore innovative instruments to accelerate research and development on new antimicrobials, their alternatives, and diagnostics."

2024 AMR Preparedness Index Progress Report, February 2024

*"Experts widely agree that a combination of push and pull incentives will be a critical component of encouraging the research and development of novel antimicrobial products moving forward. …Governments must continue to tackle AMR via support for global efforts and push mechanisms such as **CARB-X**."*

Global Leaders' Group on AMR's Recommendations to Address the Antibiotic Pipeline and Access Crisis in Human Health, February 2024

*"Several initiatives including **CARB-X** … are fueling innovation of antibiotic and diagnostic development with financial scientific, regulatory and technical support to the early stages of discovery into preclinical and clinical trial phases. … Public and private funders/ donors should increase funding for **push incentives** that support the development of antibiotics and diagnostics. To achieve a sustainable flow of new antibiotic drug candidates into and through the clinical pipeline, drug discovery and clinical development need to be strengthened and expanded. … Some studies have proposed that additional financing of $250–400 million per year is needed for antibiotics alone."*



Black and white photos provided by McDevitt Laboratory.

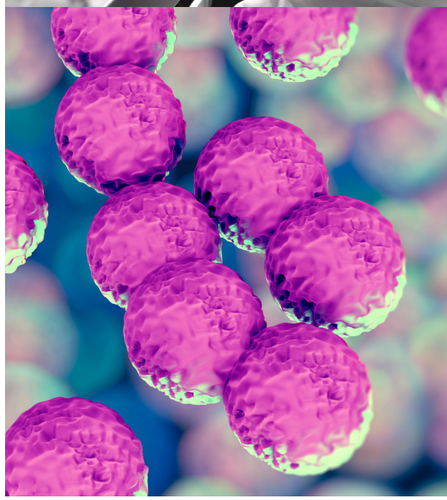
Political Declaration of the United Nations High-Level Meeting on Antimicrobial Resistance (AMR), New York, September 2024

*"[We] recognize the benefits of public-private partnerships in the development of and access to antimicrobials, vaccines, diagnostics and alternatives to antimicrobials and in contributing to supply chain sustainability, and take note of the work of **CARB-X** and GARDP."*

Global Burden of Bacterial Antimicrobial Resistance 1990-2021: A Systematic Analysis with Forecasts to 2050, September 2024
"The development of new antimicrobials for Gram-negative bacteria should be prioritised … We estimated that the potential effect of new Gram-negative antibiotics in reducing mortality is profound, with a forecasted 11.08 million cumulative AMR deaths prevented between 2025 and 2050."

G7 Health Minsters' Communiqué, Ancona, Italy, October 2024
"We reiterate our support for sustainable markets for existing as well as new antimicrobials that promote equitable access and stewardship. We will support funding for push incentives, including contributing to existing global pooled efforts to accelerate R&D of novel antimicrobials, vaccines and diagnostics and alternative therapeutics, through such efforts as the **CARB-X** and the GARDP."

G20 Health Ministerial Declaration on Climate Change, Health and Equity, and on One Health, Rio de Janeiro, October 2024
"[We will] continue to support initiatives such as the Global AMR R&D Hub, **CARB-X**, GARDP and ICARS, as well as regional organizations that guide research, development and strategies to accelerate new AMR health technologies, alternatives to the use of antimicrobials, promote equitable access, global stewardship, and maximize public investment returns."



2024 FUNDING CALL *in* REVIEW

In 2024, CARB-X launched a targeted funding solicitation designed to address critical gaps in the global antimicrobial resistance (AMR) pipeline, as identified by its 2023 strategic portfolio review. This initiative was structured to align the CARB-X portfolio more closely with unmet medical needs and to enhance the diversity and quality of applications through a refined solicitation process.

Strategic Product Themes

Building upon insights from the 2023 portfolio analysis, CARB-X concentrated its 2024 funding efforts on four product themes:

1. **Therapeutics for Gram-Negative Infections**
2. **Prevention of Invasive Disease caused by *Staphylococcus aureus* or *Escherichia coli***
3. **Diagnostics for Neonatal Sepsis**
4. **Proof-of-Concept for Novel Sample Types in Diagnosing Lower-Respiratory-Tract Infections**

Enhanced Solicitation Process

To foster a more equitable and effective application environment, CARB-X introduced a dual-cycle solicitation process in 2024. This approach provided applicants with two distinct windows to submit their Expressions of Interest (EOIs):

First Cycle:
Mar. 18 – Mar. 29, 2024

Second Cycle:
Sept. 23 – Oct. 4, 2024

This bifurcated timeline allowed applicants additional time to gather necessary data, thereby enhancing the competitiveness of their submissions and promoting fairness in the selection process.

Application Overview

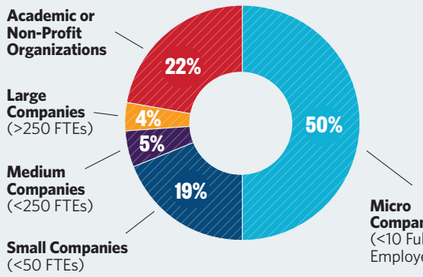
The 2024 funding round attracted a robust response, with a total of **333 EOIs** submitted across the specified themes:

129 Diagnostics

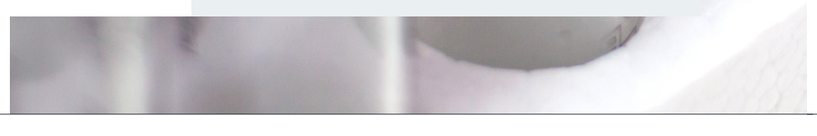
109 Therapeutics

95 Preventatives

The distribution of applicants is as follows:



The strong response underscores the continued global urgency in developing products to address AMR and the effectiveness of CARB-X's refined solicitation strategy. Notably, nearly **70% of applicants were from micro or small companies**, reinforcing the important role of early-stage biotech in innovation. Additionally, applications spanned **34 countries**, signaling increasing international engagement. While previous broad calls yielded larger applicant pools, the high volume of proposals within this more targeted scope suggests a maturing ecosystem that remains dynamic and responsive to AMR challenges. The geographic shift, with growing interest from Australia, India, and Europe, reflects a more globally distributed innovation landscape. These trends affirm CARB-X's role in fostering a robust, diverse, and increasingly international research pipeline.



DRIVING SOLUTIONS *to* ADDRESS GLOBAL ANTIBIOTIC RESISTANCE *by* INVESTING *in* RESEARCH, DEVELOPMENT *and* ACCESS

Significant progress has been made in strengthening the global infrastructure to combat antibiotic resistance. Global and national pathogen lists help prioritize research and development efforts. Push funding is increasing, with critical support from organizations such as CARB-X, the Biomedical Advanced Research and Development Authority (BARDA), the AMR Action Fund and the Global Antibiotic Research and Development Partnership (GARDP). Two G7 governments have introduced substantial pull incentives, with pilots and commitments from the rest of the group. A clinical trial network has been established in high-burden environments, enabling research in the regions most affected. However, critical gaps remain—particularly in ensuring that these innovations translate into sustainable access globally.

Access to innovative antibiotic solutions is essential in regions with the highest need, where the burden of drug-resistant infections is greatest. CARB-X is committed to facilitating that investment in research and development (R&D) translates into sustainable access, bringing life-saving diagnostics, preventatives, and therapeutics to patients who are disproportionately affected by antibiotic resistance.

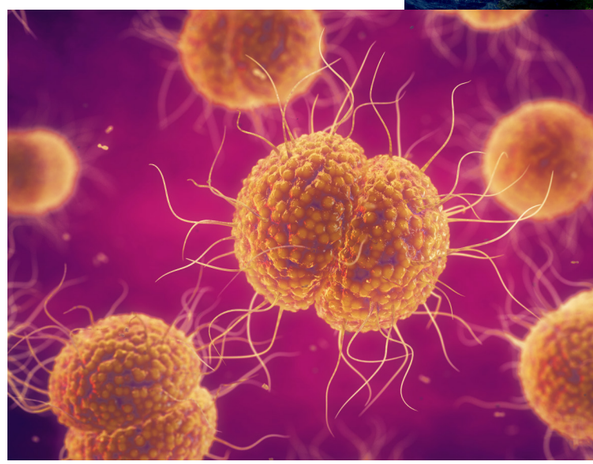
Sustainable access is not just about delivering new products—it requires a holistic approach, including stewardship through continued investment in innovation. Effective antibiotic stewardship begins with the development of novel interventions that address resistance while ensuring that these tools remain effective for future generations.

CARB-X is actively engaged in advancing this effort through collaborations with the Clinton Health Access Initiative (CHAI) to evaluate the clinical needs and address market barriers for diagnostic, preventative and therapeutic interventions targeting gonorrhea inflections in eight countries. By conducting market assessments and engaging with key stakeholders, CARB-X and CHAI aim to shape strategies that enable new products to reach the patients living in areas highly impacted by infections and drug resistance.

A significant obstacle in antibiotic development is demonstrating the clinical value of new products, especially when traditional clinical trials are challenging. Funded by Wellcome, ADVANCE-ID is a clinical trial network with sites in Southeast Asia that is working to address this gap by exploring ways to conduct trials in settings where infections and the presence of drug-resistant pathogens have the greatest prevalence. CARB-X participated in the first ADVANCE-ID meeting in June 2024 and continues to contribute to this critical dialogue.

Through strategic collaborations and targeted investments, CARB-X is driving a future where innovation translates into impact, ensuring that the fight against antibiotic resistance is both sustainable and effective in regions with the greatest need.

Read more about CARB-X's collaboration with CHAI.



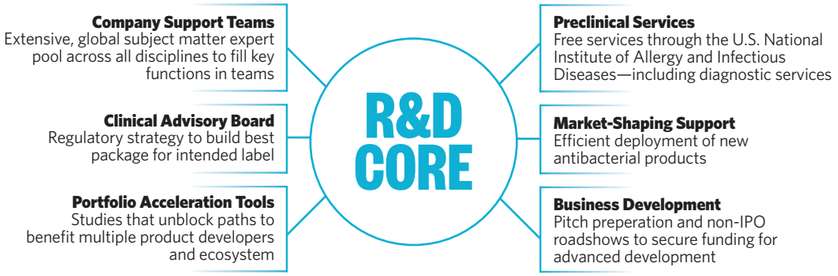
COMPREHENSIVE SUPPORT MODEL

The majority of antibacterial product developers are small and micro teams, with their size making them vulnerable to costly mistakes. Taking the lead on key R&D challenges, CARB-X created its support model to prepare developers with adequate scientific, business, and regulatory advice as they navigate the drug development pipeline. This model saves product developers time and money while advancing products more quickly to patients.

This unique, comprehensive support model accelerates individual projects as well as the entire CARB-X portfolio by connecting experts with innovators, bridging science and knowhow, and creating an ecosystem where progress meets possibility to address the global threat of dangerous drug-resistant bacteria.

With decades of diverse antibacterial R&D at its core, the CARB-X support model includes the following resources that support the evolving needs of projects as they mature.

"We got great feedback on how to present data and tell a compelling story. It was instrumental in succeeding through that milestone."



R&D Core

The backbone of the CARB-X support model is the R&D Core, a unique team of specialized scientists and subject matter experts with decades of experience from both large and small companies. The R&D Core takes a proactive role in supporting product developers by capturing key questions of each project and its risks. Then, the R&D Core matches product developers with their Company Support Teams, comprised of expert advisors, funders, and global subject matter experts across a variety of disciplines. In addition, the R&D Core matches product developers with accelerators to maximize learning within the network. This support is essential to helping product developers reach milestones and advance their product toward the market.

"There is value to have the expertise to bounce ideas off of and to maneuver through a technically challenging program. [You] need people who understand the science, but also get small biotech, infectious disease, and risk."

Company Support Teams

CARB-X product developers are appointed dedicated Company Support Teams (CST) comprised of subject matter experts who regularly meet with developers to deliver support and oversight. CSTs are paired with developers based on their experience with preventatives, therapeutics, or diagnostics, as well as the product phase, scientific area of expertise, familiarity with the project, and geographic alignment with the product developer. Each CST collaborates with product developers to provide tailored guidance based on developers' unique proposals, project challenges, and business structures. Examples of CST support include reviewing regulatory submission documents, providing insight into toxicology reports, and assisting with identifying and working with other research organizations.

"As a tiny company, we cannot afford expensive consultants. CARB-X does a good job of bringing in expertise (scientific, medical, business) ... Simply the availability of experts in various fields from places is absolutely wonderful."

Clinical Advisory Board

The Clinical Advisory Board (CAB), comprised of experts with deep experience in the global clinical development of infectious disease products, monitors and advises product developers with the goal of streamlining the clinical trial process. The CAB intervenes early, working with product developers to identify what they want their label to look like, whether they have the proper documents for approval, and how to design a Phase 1 study that is informative and attracts downstream investors. In addition, the CAB helps product developers create a regulatory strategy to build the best package for their intended drug label and identify regulatory hurdles and solutions for progressing products in the U.S. market for Federal Drug Administration approval as well as other markets across the globe.

Portfolio Acceleration Tools

Common roadblocks face many product developers, including those in the CARB-X portfolio. To alleviate these challenges, CARB-X developed an economical series of Portfolio Acceleration Tools (PATs) that are designed to save time, energy, and money across the entire ecosystem. Each PAT is a standardized and validated model that helps members of the portfolio optimize their products and advance them more quickly to patients. By utilizing PATs, product developers gain a deeper understanding of toxicity risks, standardized animal models, antibiotic susceptibility, and the antigenic variability of global bacterial strains, among other topics. CARB-X regularly seeks new PATs to add to the portfolio by engaging product developers to learn which tools would help them the most based on their shared experiences.

"I initially thought that NIAID access would be lengthy and difficult. We had several collaborations with NIAID, which in fact very rapidly and efficiently solved key questions. High quality work."

Preclinical Services

CARB-X works with the U.S. National Institute of Allergy and Infectious Diseases (NIAID) to give product developers access to free preclinical services to support the development of therapeutics, preventatives, and diagnostics, at no cost to developers. These preclinical services include synthesis and manufacturing support, efficacy assessment, diagnostic services such as reagent production, assay development, and pathogen sequencing, as well as nonclinical profiling including toxicology profiling and immunogenicity studies, among other services. These preclinical services streamline the development of each project toward the market.

Market-Shaping Support

This tool improves the ability of new products to be readily accessible by patients who need them, including those living in low- and middle-income countries (LMICs). CARB-X offers market-shaping support to coordinate with stakeholders to ensure the efficient deployment of new antibiotics and diagnostics, creating more opportunities for new products to effectively reach their target markets.

"Overall, we're very grateful for the support. It's difficult to work on a program like this with a small company without the support from CARB-X."

Business Development

CARB-X's business development support prepares product developer leadership for the fundraising required for advanced development, connecting developers with the knowhow and investors they need as they mature through the drug development pipeline. Highlights include annual events such as the CARB-X Product Developer Conference and CARB-X Investor Day. The Product Developer Conference invites all of CARB-X's active developers to collaborate and meet with CARB-X staff and leadership, funders, and other developers within their product pillar. During CARB-X Investor Day, developers in more advanced product stages are invited to present their projects to downstream investors that are interested in investing in antimicrobial products. These conferences forge opportunities across the CARB-X portfolio, creating meaningful opportunities for product developers to gain hands-on business development experience and expand their networks.

"CARB-X has helped us to start building a network ... and has been very helpful in identifying new partners."

CARB-X PORTFOLIO ACCELERATION TOOLS BENEFIT *the* AMR ECOSYSTEM

CARB-X created Portfolio Acceleration Tools (PAT) upon observing multiple programs in the portfolio asking the same scientific question or facing a similar logistical or programmatic challenge. The resulting diversity of the PAT portfolio has not only benefited product developers across all three pillars but also supports the foundational understanding of the antibacterial development ecosystem.

Animal Lung Model PAT

(Erin Duffy, PhD, Chief of R&D)

Pre-clinical animal models of infection are essential in building the required Pharmacokinetic-Pharmacodynamic (PKPD) understanding between drug exposure and pharmacological benefit. Lung infections have the largest global mortality burden, with 2.4 million deaths estimated in 2019. Although the murine lung infection model is widely used to demonstrate drug efficacy, the lack of methodological standardization combined with the varying behavior of different bacterial strains can lead to challenges translating observed drug effect to clinical efficacy. CARB-X joined a consortium of drug accelerators to develop and validate a standardized lung infection model. This included establishing consistent experimental methods using panels of bacterial strains that will be made widely available to researchers and supporting the validation of the model using control compounds whose clinical efficacy in the treatment of lung infections is understood. The results have been published and plans to deposit the strains in globally accessible repositories are in progress.

Read the published research on the Animal Lung Model PAT here.

Antibiotic Susceptibility PAT / IMHA

(Richard Alm, PhD, Chief Scientific Officer)

Evaluating microbiological activity of investigational molecules against real-world bacterial isolates is key to identifying pre-existing resistance risk and providing important data to benchmark against clinically used comparator compounds. In 2024, CARB-X repeated a PAT first performed in 2021 where representative compounds from its product developers were tested against large panels of contemporary bacterial strains alongside numerous clinically approved agents. The strains came from patients with a variety of infection types that had been isolated in 2022 or 2023 from hospitals in 67 countries, including 28 lower-resourced countries, to ensure appropriate global diversity was achieved. This PAT concludes with the ability of product developers to select and acquire a subset of isolates with unique resistance patterns to enable full characterization and support compound optimization and development. Even though direct-acting therapeutics companies test susceptibility against these isolates, the availability of different susceptibility profiles to clinically used comparators from diverse geographical isolates is helpful for diagnostics and preventatives product developers. They can access these isolates to advance their programs by challenging their products against real-world strains. The strain panel composition is being shared externally so that non-CARB-X researchers can access the same IHMA strain panels for their research.

Decolonization PAT

(Trudy Grossman, PhD, Alliance Director)

Many infections, especially those in vulnerable populations, can result from multidrug-resistant (MDR) bacterial pathogens harbored in an individual's gastrointestinal (GI) microbiome. Therefore, decolonization of the GI tract may help prevent the onset of such infections which can be difficult to treat. Several CARB-X-funded products aim at preventing breakthrough infections in colonized patients, and decreasing person-to-person transmission in healthcare settings. However, regulatory and clinical development paths for these products are not well-established, increasing the risk for investment in product development and regulatory approval. CARB-X, in collaboration with researchers from Massachusetts General Hospital, Tufts Medical Center, and Duke University, is undertaking a three-pronged approach to support the development of novel decolonization agents. The first prong is a systematic review to learn what is known about clinical outcomes from colonization by MDR pathogens. The second is conducting an infection control survey to understand how infection control practices vary across healthcare settings. The third is developing microbiological methods to quantify the burden of colonization by MDR pathogens in the background of the host microbiome and support endpoints from decolonization interventions. Together, these efforts are intended to contribute to the design of pivotal studies for the approval of new decolonization agents.

PORTFOLIO MILESTONE HIGHLIGHT

In 2024, product developers in CARB-X's portfolio demonstrated significant progress, with multiple projects reaching critical development milestones. These advancements underscore CARB-X's impact by providing comprehensive support to accelerate innovation toward the ultimate goal of bringing new antibacterial products to patients.

Pattern Bioscience Secures BARDA Contract

Pattern Bioscience was awarded a contract by the BARDA to advance the development of the **Pattern Single-Cell Microbiology System**, its rapid diagnostic that performs phenotypical microbial identification and antimicrobial susceptibility testing for lower respiratory infections. This support will facilitate the progression of their technology toward clinical implementation, aiming to improve the timely diagnosis of life-threatening infections in only four to six hours versus days.

Peptilogics Completes First-in-Human Study

Peptilogics successfully concluded its first-in-human Phase 1b clinical trial for **PLG0206**, an investigational antimicrobial peptide designed to treat periprosthetic joint infections. The study assessed the safety and tolerability of PLG0206 administered to patients in conjunction with the DAIR surgical procedure for the management of periprosthetic joint infections (PJI). This marks a pivotal step toward addressing these challenging infections.

Clarametyx Biosciences Completes First-in-Human Study

Clarametyx Biosciences completed a first-in-human study, funded by the Cystic Fibrosis Foundation, for **CMTX-101**, a novel anti-biofilm therapy targeting pulmonary infections in CF patients. CARB-X supported the nonclinical development of CMTX-101, and this clinical milestone brings the therapy closer to addressing CF-associated infections, and eventually to other difficult-to-treat infections complicated by biofilm formation.

LimmaTech Biologics Receives FDA Fast Track Designation

LimmaTech Biologics announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for their vaccine candidate, **LBT-SA7**, targeting *Staphylococcus aureus* infections. This designation facilitates the expedited development and review of vaccines addressing serious conditions with unmet medical needs, potentially accelerating the availability of this critical vaccine.

Trellis Bioscience Completes First-in-Human Study

Trellis Bioscience completed its first-in-human study for **TRL1068 (calpurbatug)**, a monoclonal antibody that targets PJIs caused by biofilm-embedded bacteria. The study aimed to establish the safety and tolerability of calpurbatug in patients with PJIs, with initial efficacy insights guiding future Phase 2 studies. No adverse effects were observed in patients during the study. The published results are available under PMID: 39012102.

SNIPR Biome Secures Funding for Phase 1b Clinical Trial (EB)

SNIPR Biome secured funding for a Phase 1b clinical trial for **SNIPR001**, a CRISPR-based preventative targeting *Escherichia coli* infections in patients with hematological cancers. This innovative approach utilizes CRISPR technology to selectively target and eliminate harmful bacteria using bacteriophages, representing a novel strategy in antimicrobial prevention.

Collectively, these achievements highlight the maturation of CARB-X's portfolio and the successful advancement of innovative solutions to combat antimicrobial resistance. CARB-X remains committed to supporting partners as they progress through critical development stages, bringing us closer to effective interventions against drug-resistant infections.

Vedanta Biosciences Initiates Pivotal Phase 3 Trial

Vedanta Biosciences launched a pivotal Phase 3 clinical trial for **VE303**, an investigational oral microbiome therapeutic for preventing recurrent *Clostridioides difficile* infection. Supported by BARDA and the AMR Action Fund, this trial represents a significant advancement for microbiome-based therapies that combat antibiotic-resistant infections.

Seres Therapeutics Completes First-in- Human Study for Microbiome Therapeutic

Seres Therapeutics, with support from CARB-X, advanced the development of **SER-155**, a microbiome therapeutic candidate designed to prevent infections and graft-versus-host disease in patients undergoing stem cell transplantation. This progress underscores the potential of microbiome-based interventions in preventing life-threatening complications. The FDA also granted Breakthrough Therapy Designation to SER-155 in December 2024.

Iterum Therapeutics Receives FDA Approval of ORLYNVAH™ for Treatment of Uncomplicated Urinary Tract Infections

Iterum Therapeutics announced that the FDA approved the new drug application for **ORLYNVAH™** (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections (uUTIs) caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options.

CARB-X

Combating Antibiotic-Resistant Bacteria

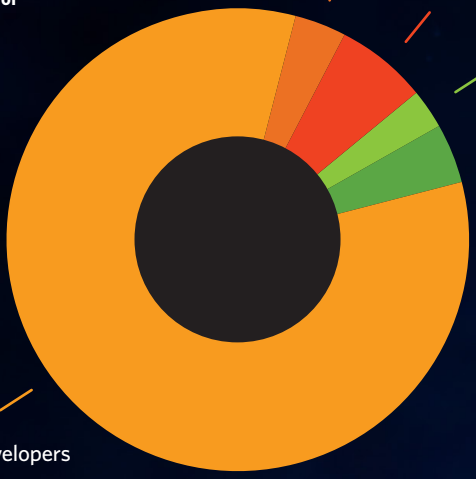
carbxpr@bu.edu | carb-x.org

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.

SUPPORT SINCE 2016

Annual Report Financial Data

Cumulative as of 12/31/2024



In addition to the figures presented above, we estimate NIAID in-kind services provided to Product Developers at **$50M**

93% of funding goes to product developers via direct awards or technical and in-kind support.

*Includes Global Accelerator Network, Portfolio Acceleration Tools, Advisory Boards, and external and in-house R&D technical experts

CARB-X is pleased to support EU-JAMRAI's initiative in promoting antimicrobial resistance awareness with these pins, a global symbol of AMR.
The symbol is formed by three objects: medicine capsules, setting the theme of antibiotics; a heart, telling us to care about AMR; and two bandages, telling us to fix the problem.

"The time to address AMR is now."

EU-JAMRAI
Joint Action
Antimicrobial Resistance and Healthcare-Associated Infections

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