

The Fight Against Superbugs

Supporting the development of antibiotics, vaccines, rapid diagnostics and other life-saving products to tackle drug-resistant bacteria

CARB-X
Combating Antibiotic Resistant Bacteria

ANNUAL REPORT 2018-2019

**BOSTON
UNIVERSITY**



CARB-X Mission

Accelerate a diverse portfolio of high-quality antibacterial products into clinical development, focusing on drug-resistant bacteria prioritized by the World Health Organization (WHO) and the United States Centers for Disease Control and Prevention (CDC).

What we do

CARB-X funds and supports innovative therapeutics and preventatives in the early phases of preclinical development through the end of Phase 1, and the development of diagnostics from feasibility through the early phases of product verification and validation. We provide non-dilutive awards and business, regulatory and scientific support through our Global Accelerator Network and Advisory Board. CARB-X is entirely non-profit, with its headquarters at Boston University.

Why we target drug resistance

Bacteria's ability to evolve and escape the effects of antibiotics, called drug resistance, is one of the world's greatest public health and health security threats. Drug-resistant bacteria kill people young and old, rich and poor, in every corner of the earth. CARB-X partners are investing up to \$500 million in 2016-2021 to accelerate antibacterial innovation.

700,000

DEATHS PER YEAR
WORLDWIDE
FROM RESISTANT
BACTERIA¹

57

YEARS SINCE
AN APPROVED ANTIBIOTIC
CLASS WAS DISCOVERED
FOR GRAM-NEGATIVES²

Only 11

ANTIBIOTICS IN CLINICAL
DEVELOPMENT TO TREAT
THE DEADLIEST SUPERBUGS³

¹ World Health Organization

² Pew Charitable Trusts; Deak D, Powers JH, Outterson K, Kesselheim AS. Progress in the Fight Against Multi-drug Resistant Bacteria?: A Review of FDA Approved Antibiotics 2010-2015. *ANNALS OF INTERNAL MED.* 2016 MAY 31

³ Pew Charitable Trusts, March 2019. Antibiotics in development with potential activity against carbapenem-resistant *Enterobacteriaceae*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*

“The clinical pipeline of antibacterial products is fragile and the threat to public health and global health security is already upon us. CARB-X is improving the size and depth of the global clinical pipeline by supporting new approaches and innovative R&D.”



Shaping a new world to fight drug resistance

*Message from Kevin Outterson,
CARB-X Executive Director and Professor of Law at Boston University*

2018-19 has been a year of stable growth for CARB-X. We continued to expand the world's largest portfolio of innovative antibacterial products. As of 31 July 2019, we have 30 projects in our portfolio and have celebrated as 14 projects achieved key milestones and five projects graduated. We announced funding for seven new projects in the fiscal year that ended July 31, 2019. The world needs better antibacterial products, and we are on the task.

Our partnership with funders expanded in 2018-19. Germany (BMBF) joined CARB-X in March 2019, committing €39 million to the development of new products. Germany's Federal Ministry of Education and Research also joins our governance body, the Joint Oversight Committee. Combined with funding from the US government (BARDA and NIAID), Wellcome Trust, the UK government (GAMRIF/DHSC), and the Bill & Melinda Gates Foundation, CARB-X has up to US \$500 million to invest in antibacterial R&D. None of our achievements would be possible without the vision and leadership of our funders.

We established the CARB-X Global Accelerator Network, a network of 10 world-class accelerators from six countries to provide business, regulatory and scientific support to the projects we fund, in addition to support from the Advisory Board and our in-house experts at CARB-X. CARB-X is unique among AMR funders in that we

offer such support, free of charge, which provides critical experienced guidance, especially for the small product developers that make up most of the CARB-X awardees.

We have been building deeper scientific and drug development expertise on the CARB-X team and working to improve our processes. It is essential that we have the best operational and scientific platform for future success. The core of CARB-X is science, and we could not achieve our mission without thousands of hours of effort from experts and scientists around the globe who advise and support the mission.

CARB-X is making tremendous progress after only three years in operation, and only two years since the initial 11 CARB-X-funded product developers were announced. But real success will be measured by the life-saving products that complete clinical development, achieve regulatory approval and ultimately reach patients who need them.

A handwritten signature in black ink that reads "Kevin Outterson".

Kevin Outterson
Executive Director, CARB-X
Professor of Law, Boston University

CARB-X 2018-2019 Highlights

CARB-X activities in fiscal 2018-2019 focused on expanding our funding base, diversifying our growing portfolio, providing support for antibacterial R&D projects through our Global Accelerator Network, and optimizing our team in Boston as a platform for further success.

In fiscal 2018-19, we expanded our partnership, expanded and diversified the pipeline, strengthened our team, and strengthened our support for projects

Germany joined the CARB-X partnership

Germany's Federal Ministry of Education and Research (BMBF) joined the CARB-X partnership, committing €39 million over four years and boosting CARB-X funds to up to \$500 million to invest in the early development of antibacterial products. Under the partnership agreement announced in March 2019, BMBF is also providing an additional €1 million in direct support to the German Center for Infection Research (DZIF), one of the accelerators in the CARB-X Global Accelerator Network.

“Resistant pathogens spread globally. Thus, combating them takes joint international collaborative actions, such as CARB-X.”

— Anja Karliczek,
German Federal
Minister of Education and Research



Building a robust portfolio

CARB-X's pipeline is the world's most innovative and diverse portfolio of new antibiotics, rapid diagnostics, vaccines and other life-saving products to address drug-resistant bacterial infections, with 30 active projects as of July 31, 2019. Our projects are in the early stages of preclinical development through the end of Phase 1.

In the 2018-19 fiscal year, we announced seven new awards for product developers. In addition, funding for more than 20 new projects has been approved, awaiting finalization of the contracts before a public announcement is made. Other pipeline highlights include:

- Entasis Therapeutics' beta-lactamase inhibitor ETX0282 delivered initial results in 2019 in Phase 1 clinical trials. This oral therapy is in development for the infections caused by multidrug-resistant (MDR) Gram-negative pathogens, including ESBL-producing and carbapenem-resistant Enterobacteriaceae.
- Another Phase 1 project was a new class (LpxC) against Gram-negatives. While this project did not proceed to Phase 2, we applaud the company, Recida, for their efforts. CARB-X funds innovative R&D because that is the best way at hand to significantly improve the quality of the global clinical pipeline.
- Vedanta Biosciences' VE303 microbiome project progressed through Phase 1 studies and graduated from the CARB-X portfolio. This ground-breaking project is currently in Phase 2 testing in patients with recurrent *C. difficile* infection.



- Another CARB-X graduate this year was the sulopenem development program from Iterum Therapeutics, which is now moving into Phase 3 clinical development with oral and IV formulations. It joins graduates SPR741 from Spero Therapeutics, and a next-generation tetracycline from Tetrphase Pharmaceuticals, which are both in Phase 1.
- Significant progress was registered in earlier stage products as well, with key milestones achieved by Debiopharm, Bugworks, Zikani, ContraFect, Forge, Summit, Microbiotix, Integrated Biotherapeutics, Seres, T2 Diagnostics, Talis, Proteus, Specific Diagnostics, and Helixbind.

Up-to-date information about funded projects and portfolio evolution can be found at carb-x.org/portfolio/gallery/

Global Accelerator Network expanded

As CARB-X's portfolio has grown in geographic and scientific diversity, the need for more expertise and support has also grown. In February 2019, CARB-X announced a major expansion of our Global Accelerator Network. Each of the accelerators has areas of highly specialized expertise, supported by experts from our Advisory Board, and tailored to the needs of product developers.



For more on the CARB-X Global Accelerator Networks, please see pages 8-9.

“Antibacterial product development is challenging. We know the failure rate is high in preclinical and clinical development. The only way to score is to take many shots on goal. CARB-X helps product developers take higher quality shots on goal.”

— Kevin Outterson
Executive Director of CARB-X

Investing in innovation

CARB-X initiated four new funding rounds in the 2018-2019 fiscal year, beginning in June 2019. The scope of each is designed to meet the most urgent needs in the global pipeline, as determined by our governing body, the JOC.

- **Vaccines and biotherapeutics:** Vaccines, therapeutic and preventative antibodies/fragments, microbiome prevention, and other large molecule approaches.
- **Diagnostics:** Diagnostics that will rapidly identify either the bacterial species or antibiotic susceptibility, or both.
- **Direct-acting small molecule antibiotics:** New classes of antibiotics and/or new targets for therapeutics.
- **Non-traditional approaches:** Alternatives to antibiotics – including, for example, indirect-acting small molecule therapeutics, direct acting or indirect-acting large molecules, microbiome therapeutics, phage, nucleic acid/antisense, and drug conjugates.

Applications are reviewed by panels of experts on the CARB-X Advisory Board, and decisions on funding are made by the JOC. We expect to announce awards in 2020, as contracts are finalized.

Building the CARB-X team in Boston

With rapid growth comes the need to adapt and respond to changing needs. Over the fiscal year, CARB-X has matured its processes and expanded its resources.

We have strengthened our in-house capabilities in science and drug development with the addition of four Alliance Directors led by the Chief of R&D. All have outstanding backgrounds in science and drug development, and are supported by a team of Alliance Managers. We have redesigned our organizational approach such that each product developer engages with the same CARB-X team from the application process through graduation.

In 2018-19, CARB-X announced new awards to 7 product developers, and another 20+ awards have been approved by the JOC and are being finalized



Inside our pipeline

Projects in the CARB-X portfolio are in the early stages of development for the prevention, diagnosis or treatment of the most serious drug-resistant bacterial infections. A few examples of the exciting research in the pipeline are highlighted on the next four pages.

Full portfolio details can be found at carb-x.org/portfolio/



Vedanta Senior Research Associate Tony Volpini checks on liquid-handling robotics used to automate experiments with bacteria.

Fighting fire with fire: Boosting the Microbiome to fight *C. difficile*

Vedanta Biosciences is developing a new therapy based on bacteria from the human microbiome—the community of good bacteria that live in the body. The new therapy, VE303, consists of eight types of clonal human commensal bacteria strains that colonize the gut and safely outcompete *C. difficile* bacteria, and then rebuild the damaged gut microbiome to protect against recurring infection. VE303 graduated from the CARB-X portfolio in early 2019 and has progressed into Phase 2 clinical trials.

C. difficile infections are one of the most urgent bacterial threats, accounting for an estimated 14,000 deaths each year in the US alone. Current antibiotics can damage the body's microbiome and leave patients vulnerable to serious re-infection.

"We need alternatives to antibiotics to treat infection. Two key issues with antibiotics are: resistance and loss of colonization resistance. VE303 is a microbiome-based therapy based on a defined bacterial consortium which has the potential to address both issues. The support of CARB-X has allowed us to rapidly advance VE303 through Phase 1, demonstrate favorable safety, PK, and PD, and select dosing regimens for our ongoing Phase 2 study."

— Bernat Olle, Ph.D., Chief Executive Officer
Vedanta Biosciences, Cambridge, MA, USA

An ounce of prevention.....

Powered by CARB-X since 2017, **Integrated Biotherapeutics** is developing a vaccine to prevent *Staphylococcus aureus* infections, including those caused by Methicillin-resistant strains (MRSA), which can lead to sepsis and death. The project is a new approach to MRSA, which secretes toxins that cause tissue destruction, disable the patient's immune system, and help bacteria spread in the body. IBT-V02 is the first multivalent *S. aureus* vaccine entirely based on rationally designed toxoids. They include seven toxoids that collectively provide protection against three large families of toxins secreted by the *S. aureus* pathogen.



MRSA bacteria
(Photo: CDC)

"MRSA infections are leading causes of morbidity and mortality. In partnership with CARB-X, we are developing a multivalent toxoid vaccine (IBT-V02) for prevention of S. aureus / MRSA recurrent skin infections. IBT has now completed the pre-clinical efficacy studies as well as process and analytical development for IBT-V02 and plans to initiate cGMP manufacturing in Fall 2019. IBT anticipates starting a first-in-man clinical trial of IBT-V02 in 2021."

— Javad Aman, Ph.D., President and CSO
Integrated BioTherapeutics, Rockville, MD, USA

Llamas produce antibodies that kill superbugs without harming other parts of the body

There are many chemicals that can kill bacteria, but developing substances that are not also toxic to humans is a tough scientific challenge. Many antibiotics in use today can have limiting side effects.

InhibiRx scientists are developing a new drug with a novel mechanism of action that uses the unique qualities of llama antibodies to kill the *Pseudomonas* pathogen without causing harmful side effects. Llamas, like alpacas and other members of the Camelidae mammal family, have an immune system which produces single domain antibodies (sdAbs). These can be made smaller to reach places that normal antibodies—including human—cannot reach and can be adapted to precisely target pathogens without causing toxicities.

Pseudomonas bacteria—found widely in the environment—can cause blood, pneumonia, urinary tract, and post-surgical infections that can lead to severe illness and death.

“Novel funding mechanisms are needed now more than ever to advance the most innovative R&D that will create the therapies of the future. Partnering with CARB-X allowed us to progress our pseudomonas program toward clinical development.”

— Mark Lappe, CEO, InhibiRx, LaJolla, CA, USA



Llama antibodies might help in preventing and treating infections caused by drug-resistant *Pseudomonas aeruginosa* (photo: CDC)



Members of the Bugworks team take a break from a recent meeting with FDA representatives

Destroying dangerous bacteria while avoiding resistance

Bugworks Research India is developing a novel first-in-class broad-spectrum antibiotic to kill multi-drug resistant Gram-negative bacteria, such as *A. baumannii*, *P. aeruginosa* & Enterobacteriaceae (CRE & ESBLs). The project, BWCO977, is being developed as an intravenous and oral treatment, with a low risk of developing resistance because it inhibits two essential targets in the replication machinery of the bacteria and has been designed to bypass the efflux resistance mechanism.

“With the support of CARB-X, BWCO977 is progressing towards Phase 1 studies in early 2020. CARB-X has invited several antibacterial drug development experts to critically review the progress and provide key inputs to steer the project. This has helped us tremendously, and CARB-X funding and support have helped endorse our research, resulting in private investment.”

— Bala Subramanian, Co-Founder and Chief Operating Officer, Bugworks Research India, Bangalore, India

Powered by **CARB-X**

New treatment in development for drug-resistant gonorrhea

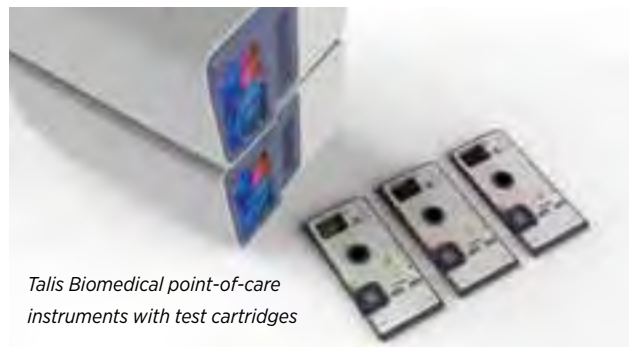
Summit Therapeutics researchers use bacterial genetics-based technology to develop a new class of antibiotics with the potential to be the new standard of care in the treatment of gonorrhoea.

Gonorrhea is an urgent and growing public health problem. The World Health Organization estimates there are 78 million new cases of gonorrhoea globally per year. The *Neisseria gonorrhoeae* superbug has consistently developed resistance, and today, only one antibiotic recommended by the US Centers for Disease Control and Prevention remains effective.

Using its Discuva platform, Summit has discovered two novel targets to kill the *N. gonorrhoeae* bacteria and a new series of antibiotic compounds against each of these targets. In early testing, the antibiotics have been shown to have high potency against gonorrhoea, including drug resistant strains.

“Gonorrhea has continually developed resistance mechanisms. New classes of antibiotics are urgently needed to avoid a future epidemic. With our CARB-X award, we have advanced SMT-571, a new class antibiotic targeted to Neisseria gonorrhoeae, to IND-enabling studies. Early research has shown SMT-571 to be potent against globally diverse and clinically-relevant strains of N. gonorrhoeae, including several extensively- and multi-drug resistant strains.”

— Dr. David Roblin, President of R&D Summit Therapeutics, Oxford, UK; Cambridge, MA, USA



Talis Biomedical point-of-care instruments with test cartridges

Rapid diagnostics needed to speed up treatment of drug-resistant bacteria

Rapid diagnostics enable physicians to know quickly what bacteria are causing an infection and prescribe appropriate treatment, minimizing unnecessary antibiotic usage. CARB-X supports five diagnostics in the portfolio and plans to increase the number in the coming year.

Talis Biomedical is developing a high-performance, low-cost point-of-care molecular diagnostic system that will enable health professionals to rapidly identify pathogens causing a chlamydia or gonorrhea infection and, through antibiotic susceptibility testing (AST), refine treatment.

“The relationship with CARB-X is pivotal in the development of a rapid CLIA-waived molecular diagnostic test to detect chlamydia and gonorrhea directly from a patient sample in approximately 20 minutes. With CARB-X support, Talis developed the first lot of test cartridges using our production tools, and the first set of functioning instruments to run them.”

— Marc Valer,
Vice President of Product
Talis Biomedical, Menlo Park, CA, USA



Summit Therapeutics researchers use bacterial genetics-based technology to develop a new class of antibiotics



In the pipeline as of July 31, 2019

- 12 NEW CLASSES OF ANTIBIOTICS
- 14 NEW MOLECULAR TARGETS
- 10 NON-TRADITIONAL APPROACHES
- 5 DIAGNOSTICS
- 3 VACCINES
- 1 PROJECT IN PHASE 1

A breath of new hope for treating Cystic Fibrosis

Cystic fibrosis (CF) is a life-threatening genetic disease, affecting thousands world-wide. Many CF patients have acute chronic *Pseudomonas aeruginosa* lung infections, causing progressive lung damage. *Pseudomonas* is highly resistant to antibiotics.

Antabio's PEi program seeks to develop an inhaled drug which can be used with existing antibiotic therapy to reduce the frequency and severity of *Pseudomonas* exacerbations.

"Pseudomonas elastase is an enzyme that attacks lung tissues and contributes to inflammation in Pseudomonas aeruginosa lung infections in Cystic Fibrosis sufferers. Antabio has discovered several novel elastase inhibitors with specific and potent activity. With funding and access to key development expertise provided by CARB-X, Antabio intends to develop a new inhaled therapy to be used alongside standard-of-care antibiotics to enhance eradication of infections in CF patients."

— Marc Lemonnier, Founding CEO,
Antabio, Labège, France

Next-generation antibiotics offer promise to modern medicine

Existing antibiotics classes are used in modern medical procedures including cancer treatments and routine surgeries like hip replacements. Some CARB-X-funded companies are developing the next-generation of existing therapies. **Iterm Therapeutics**, which graduated from the portfolio in early 2019, is developing sulopenem, a novel oral and IV penem.

"The assistance Iterm received from CARB-X has played a crucial role in the ongoing development of sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with oral and IV formulations. Our organizations are firmly aligned in seeking new compounds to combat the global crisis of antibacterial resistance."

— Judy Matthews
Chief Financial Officer, Iterm Therapeutics
Dublin, Ireland, and Chicago, IL, USA



New classes of antibiotics urgently needed

Forge Therapeutic's lead program is focused on LpxC, a zinc metalloenzyme found only in Gram-negative bacteria and which is essential for the bacteria to multiply. CARB-X supports two separate efforts in this program, FG-LpxC UTI and FG-LpxC LUNG. Both are pursuing novel classes of antibiotics. FG-LpxC UTI is being developed to be administered intravenously and orally for the treatment of urinary tract infections caused by *E. coli*, *K. pneumoniae*, and *P. mirabilis* including multi-drug resistant strains. FG-LpxC LUNG is a new class of LpxC inhibitor being developed to treat serious lung infections attributed to Gram-negative bacteria including multi-drug resistant *P. aeruginosa*.

"CARB-X not only provides funding and support for our FG-LpxC antibiotic program but adds significant value in the form of peer-review validation for our BLACKSMITH chemistry platform and innovative approach toward developing new classes of antibiotics. We have been able to raise additional investment from venture capitalists in the form of a \$17.5 M Series A financing."

— Zachary A. Zimmerman, Ph.D., CEO,
Forge Therapeutics, San Diego, CA, USA

Powered by **CARB-X**

Expert support around the world

CARB-X partners with accelerators around the world to provide scientific, technical and business support to the growing number of CARB-X-funded projects. Services are provided at no cost to the product developer. The Global Accelerator Network is a unique source of specialized expertise and know-how in antibacterial drug development, diagnostics, vaccines, business and legal strategy, regulatory affairs and other areas essential to accelerating CARB-X's growing portfolio.

CARB-X

Global Accelerator Network



“The path to market is challenging with numerous obstacles, especially for the small companies. But by providing business and technical support alongside funding, and working with partners from the public, private and philanthropic sectors, it is our aim that more companies can get their products to the patients who need them the most.”

— Tim Jinks, Head of Wellcome Trust's Drug Resistant Infections Programme

BASEL AREA. SWISS **BaselArea.swiss** promotes innovation and investment for the Basel region, a leading life sciences hub and major center for antibiotics research in Switzerland. BaselArea.swiss is backed by public and private partners and supports entrepreneurs and companies through a network of innovators, researchers and experts.

BII **BioInnovation Institute** **BioInnovation Institute (BII)** is an international initiative for research-based innovation and entrepreneurship, embracing every phase of a life-science start-up. Located in Copenhagen, Denmark, BII offers lab and office facilities, business acceleration programs, business incubation, commercial support, unique funding opportunities and access to high-level mentoring and international networks. BII is an initiative of the Novo Nordisk Foundation.

CLSI **CALIFORNIA LIFE SERVICES INSTITUTE** **California Life Sciences Institute (CLSI)** provides a range of business support and mentoring services to CARB-X companies. Located in one of the world's most innovative biotech hubs, South San Francisco, California, USA, CLSI has extensive experience nurturing start-ups towards Series A financing and beyond.

C-CAMP **Centre for Cellular and Molecular Platforms (C-CAMP)** is India's premier life-science innovation, entrepreneurship and technology hub as well as one of the largest life science incubators in the country. C-CAMP provides funding and mentorship to start-ups. An initiative of the Indian Government's Department of Biotechnology, Ministry of Science and Technology, C-CAMP is located in Bangalore.



Foundation for Innovative New Diagnostics (FIND) is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. FIND is a WHO Collaborating Centre headquartered in Switzerland, and works with more than 200 academic, industry, governmental, and civil society partners worldwide.



German Center for Infection Research (DZIF) With 35 establishments at 7 sites across Germany, DZIF is specialized in translational infection research with the aim of developing new diagnostic, preventative and therapeutic methods for treating infectious diseases. DZIF focuses on AMR funding, project management and regulatory support.



Institute for Life Sciences Entrepreneurship (ILSE) A non-profit located at Kean University in Union, New Jersey, USA, ILSE provides incubator space and accelerator services to life-sciences companies. ILSE's American Type Culture Collection (ATCC) Center for Translational Microbiology focuses on research in microbiome, advanced microbial genomics, clinical multi-drug resistance, and bioinformatics.



Massachusetts Biotechnology Council (MassBio) is a not-for-profit organization that represents and

provides services and support for Massachusetts companies in the life sciences sector. MassBio is based in Boston, a leading life sciences research hub. MassBio was the first biotechnology trade association formed in the US.



RTI International is an independent, non-profit institute based in North Carolina, USA, that provides research, development, and technical services to government and commercial clients worldwide. RTI's product development teams have expertise in toxicology, pharmacology, chemistry manufacturing and controls (CMC), and regulatory affairs. RTI currently supports a portfolio of products from discovery through Phase 3.



Wellcome Trust is an independent global charity and a founding CARB-X partner. During the launch and growth phases of CARB-X, Wellcome Trust provided support as an accelerator to a number of CARB-X funded companies.



The Power of Leadership, Vision & Partnership

CARB-X partners show outstanding leadership and vision in the global effort to stimulate the innovative research and development of products to prevent, diagnose and treat serious drug-resistant bacterial infections. Our goal is to support innovation that will fight drug-resistance and save lives. Through CARB-X, our partners are investing up to \$500 million in 2016-2021 to help accelerate antibacterial product development.



CARB-X's founding US partner, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services, is focused on emergency preparedness and strengthening national health security. BARDA committed up to \$250 million to CARB-X from 2016-2021.



CARB-X's founding UK partner, Wellcome Trust, is one of the world's largest global charitable foundations working to improve health globally. It is a leading funder of biomedical R&D, with significant experience and commitment in antibacterial R&D. The Wellcome Trust has committed up to \$155.5 million to CARB-X.



The US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), is focused on research to better understand, treat, and prevent infectious, immunologic, and allergic diseases. NIAID provides pre-clinical services valued at \$50 million to CARB-X-funded projects.



Federal Ministry
of Education
and Research

Germany's Federal Ministry of Education and Research (BMBF) joined the CARB-X partnership in March 2019 as part of its strategy to support R&D that addresses drug resistance. Germany has committed €39 million to CARB-X over 4 years.



The UK Government's Global Antimicrobial Resistance Innovation Fund (GAMRIF), part of the Department of Health and Social Care (DHSC), supports innovative R&D to address the threat of antimicrobial resistance, particularly in low- and middle-income countries. GAMRIF has committed up to £20 million to CARB-X.



The Bill & Melinda Gates Foundation joined CARB-X in May 2018 to support the development of new vaccines against drug-resistant bacterial infections, particularly for vulnerable populations in low- and middle-income countries. The Gates Foundation has committed \$25 million.



Boston University leads the CARB-X partnership and CARB-X is headquartered in the Boston University School of Law. Boston University supplies operational and administrative support.

“Revitalizing the antibacterial pipeline is essential to enhancing national health security, biodefense, and global preparedness. CARB-X brings together partners with unique motivation, resources, and perspective. Although our missions are diverse, our goal is the same: to combat antimicrobial resistant infections to save lives. I’m confident that, together, we will make a difference for both global health and national health security.”

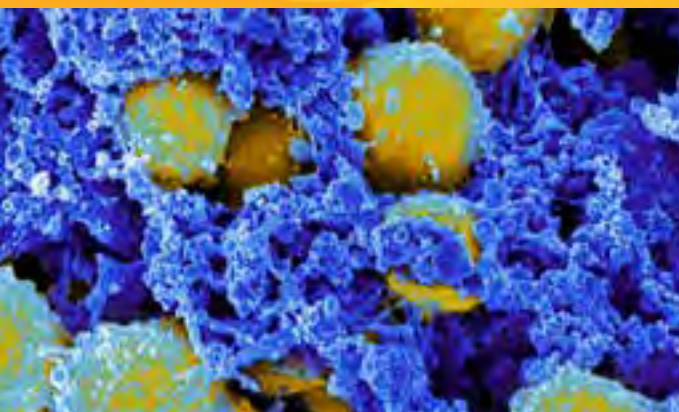
— Rick Bright, Ph.D., BARDA Director

“Drug-resistant infections claim the lives of hundreds of thousands of people annually and more research is needed to develop innovative solutions to this global threat. The CARB-X partnership provides vital funding for early-stage R&D towards potential new life-saving antibiotics, diagnostics and vaccines. Ground-breaking progress has been made so far. These efforts must continue, as they are essential to tackling this critical issue.”

— Dame Sally Davies, UK Chief Medical Officer

“CARB-X is a hugely important part of the R&D ecosystem working to stop super-bugs. We will always need new antibiotics, diagnostics and vaccines, and CARB-X has revitalised the early pipeline for new products.”

— Tim Jinks, Head of Wellcome Trust’s Drug Resistant Infections Programme



“CARB-X is an excellent example of how Boston University puts its expertise to use for the public good. CARB-X represents an efficient and effective new model for funding early development antibacterial research. We are confident that the CARB-X partnership is making progress in the fight against drug resistance.”

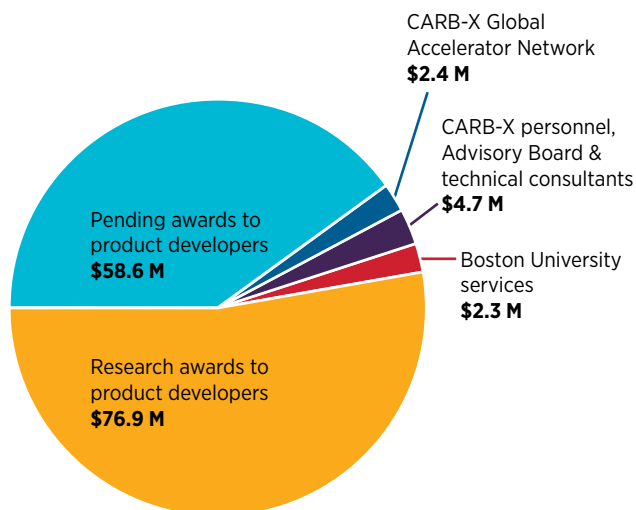
— Gloria S. Waters, Vice President and Associate Provost for Research, Boston University

“The fight against AMR is a priority for the German government. We have to join forces internationally, create synergies and pool expertise. R&D on AMR is a key factor for success. This is why — following the German G20-presidency in 2017 — the Global AMR R&D Hub was established and why Germany supports international research initiatives like CARB-X.”

— Anja Karliczek, German Federal Minister of Education and Research

“We’re proud to fund CARB-X to support research on vaccines and novel biologics that could play a key role in reducing drug-resistant infections and help save the lives of newborns living in low- and middle-income countries. CARB-X demonstrates the commitment, coordination, and global partnership we need to accelerate the development and delivery of tools that can overcome the global challenge of antimicrobial resistance.”

— Trevor Mundel, President, Global Health, Bill & Melinda Gates Foundation



CARB-X Year 3 Financials

At the end of fiscal year 2018-19, CARB-X had \$76.9 million committed to active research projects, with an additional \$58.6 million approved for new projects awaiting final contract agreement. To support the companies engaged in product development, CARB-X provided \$2.4 million for services delivered by the CARB-X Global Accelerator Network, \$4.7 million for operational support from CARB-X core personnel, Advisory Board and technical consultants, and \$2.3 million to Boston University for oversight and administrative services.



CARB-X Governance

JOC members and colleagues at the June 2019 JOC meeting in Boston. (standing l-r) Nick Adkin, Tina Guina, Andrea Spelberg, Ann Eakin, Mark Albrecht, Kevin Outterson, Karen Gallant, Dennis Dixon, Barry Eisenstein (seated l-r) Christopher Houchens, Tim Jinks, Claudia Baumann

Joint Oversight Committee

CARB-X is governed by the Joint Oversight Committee (JOC), which acts as the board of directors with full oversight for CARB-X operational and financial activities, ensuring the highest scientific and ethical standards. The JOC is made up of representatives of CARB-X's funding organizations and management team.

The JOC makes research investment decisions based on recommendations from the Advisory Board, comprised of leading experts from around the world, which reviews applications for funding in a global competitive process. We thank them profoundly for their dedication and commitment to excellence.

Marit Ackermann
Policy Officer, Global Health Research, Federal Ministry of Education and Research, Germany

Nick Adkin
Deputy Director, Global Health Security, Dept. of Health & Social Care, UK

Mark Albrecht
Chief, Antibacterials Branch, Division of CBRN Medical Countermeasures, BARDA

Dennis M. Dixon
Chief, Bacteriology and Mycology Branch, NIAID

Ann Eakin
Senior Scientific Officer, NIAID

Barry Eisenstein
Chair of the Scientific Advisory Board, CARB-X

Alyson Fox
Lead Sponsor for the Drug-Resistant Infection programme, Wellcome Trust

Karen Gallant
Acting R&D Chief/Deputy Director, CARB-X

Tina Guina
CARB-X Program Manager, BARDA

Christopher Houchens
Acting Director, Division of CBRN Medical Countermeasures, BARDA

Tim Jinks
Head of Drug-resistant Infections Programme, Wellcome Trust

Kevin Outterson
Executive Director, CARB-X

Target: drug-resistant bacteria

CARB-X funds projects that target drug-resistant bacteria, highlighted on the Centers for Disease Control and Prevention (CDC)'s 2013 Antibiotic Resistant Threats list, or the Priority Bacterial Pathogens list published by the WHO in 2017—with a priority on those pathogens deemed Serious or Urgent on the CDC list or Critical or High on the WHO list. Projects are supported from the hit-to-lead phases of development through Phase 1, so that they will attract additional private or public support for further clinical development and approval for use in patients.



Acinetobacter baumannii



Clostridioides difficile



Enterobacteriaceae (CRE)



Neisseria gonorrhoeae



Pseudomonas aeruginosa



Campylobacter



Enterococcus faecium



Salmonella



Shigella



Staphylococcus aureus



Helicobacter pylori



Streptococcus pneumoniae



Haemophilus influenzae

“WHO commends CARB-X and its supporters for building a strong early R&D pipeline of antibacterial products and calls on governments to follow through with their G20 commitments and invest into antibiotic R&D and innovative reimbursement and procurement models paying for services rather than volume.”

— Dr. Hanan Balkhy
Assistant Director-General for Antimicrobial Resistance at the World Health Organization

CARB-X

Combating Antibiotic Resistant Bacteria

CARB-X

Boston University School of Law

765 Commonwealth Ave., Boston, MA, USA 02215

carbx@bu.edu

carb-x.org



Federal Ministry
of Education
and Research

BILL &
MELINDA
GATES
foundation

