The race against superbugs

Investing to develop new antibiotics and other life-saving products to treat drug-resistant bacteria.

CARB-X

Xccelerating global antibacterial innovation

Annual Report 2016-2017

Vision

Protect humanity from the most serious threats from drug-resistant bacterial infections.

Mission

Accelerate a diverse portfolio of at least 20 high-quality antibacterial products towards clinical development focusing on the priority bacterial pathogens identified by the WHO and CDC.

Boston University, home of CARB-X

CARB-X was created in response to the US government's 2015 Combating Antibiotic Resistant Bacteria (CARB) initiative and the UK government's call in 2016 for a concerted global effort to tackle antibiotic resistance.

A non-profit partnership headquartered at Boston University, CARB-X was launched July 28, 2016, by two divisions of the US Department of Health and Human Services: the Biomedical Advanced Research and Development Authority, a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR/BARDA) and the National Institute of Allergy and infectious Diseases, part of the National Institutes of Health (NIAID/NIH). Current funders are Wellcome Trust and BARDA. NIAID provides preclinical services.

Other partners include the Broad Institute of MIT and Harvard, the Massachusetts Biotechnology Council (MassBio), the California Life Sciences Institute (CLSI), and RTI International.

CARB-X projects are selected through a global competitive process. Applications are vetted by the CARB-X Science Advisory Board, comprised of leading antibiotic and diagnostic professionals as well as experts in other modalities including vaccines, microbiome, phage and immunology. To be considered, projects must target one of resistant bacteria on the Serious or Urgent Threat List issued by the CDC or on the Priority Pathogens list published by the WHO.

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Photo credits: U.S. Centers for Disease Control and Prevention

2016-17

A first year of achievement

CARB-X is investing $455 million over five years into the research and development of new antibiotics, rapid diagnostics and other life-saving products to tackle the global threat of drug-resistant bacteria. CARB-X is a non-profit public-private partnership established in July 2016 at Boston University.

2016-2017 Highlights

- **$41.6 million announced** to help fund antibacterial pre-clinical research projects plus an **additional $52.6** if project milestones are met
- Targeting the **most urgent drug-resistant Gram-negative bacteria**, as prioritized by the WHO and CDC
- **18 innovative projects funded**, all potential game-changers in fight against drug-resistant bacteria. More projects to come in late 2017
- **8 new classes of antibiotics** in the pipeline
- Projects selected through highly competitive process by independent panel of more than **60 world-renowned** scientific advisors
- **368 applications** received from researchers around the world
- Providing fully non-dilutive funding, with wrap around business support services from **from world leading life-science accelerators**
- Efficient low-cost structure with more than **96% of budget** in first year injected directly into research funding
- Global reach expanding with funded projects in **6 different countries** and no geographic restrictions on funding

"R&D initiatives such as CARB-X are absolutely critical in addressing antimicrobial resistance as a global health challenge. GARDP is pleased to collaborate with CARB-X as part of a global effort to ensure the development of new antibiotics and diagnostics, as well as to ensure access to and stewardship of new drugs."

— Dr. Manica Balasegaram
Director, Global Antibiotic Research and Development Partnership (GARDP),
a Joint DNDi / WHO initiative

A Year of Progress and Hope

For antibiotics, "business as usual" isn't working. CARB-X breaks the mold, because we need radical innovation to defeat drug-resistant infections.

CARB-X makes portfolio investments like a venture capital fund, but we are non-dilutive and non-profit. Many investors want to see a return on investment in a few years; we take the long view, prioritizing sustainable health security for everyone against the threat of drug-resistant infections.

For our core executive team, this isn't just a job, but a mission. We've seen first-hand how infections can ravage good health, even for the young. One of my grandchildren needed powerful antibiotics in the first week of life in the NICU at Boston Children's Hospital. Some of us lost jobs as big pharma retreated from antibiotics, or have struggled to treat patients when nothing was left that still worked. The CARB-X team knows from history what life was like before antibiotics and we work hard so the next generations don't learn about the post-antibiotic era from personal experience.

We also approach this project with humility. Experts are often wrong, so we invest in a broad range of technologies and teams, even if opinions differ. Drug development is fraught with failure, so we want many, many shots on goal. And we listen carefully: to the companies we fund; to the experts on our Science Advisory Board; to external stakeholders and critics; to our funders, partners and medical professionals; and especially to the patients around the world who desperately need safe and effective treatments. Listening helps us to learn, and therefore improve how we support the innovative projects that could potentially become life-saving treatments for the future.

CARB-X is a rare opportunity to actually achieve tangible progress in global health. We're not throwing away our shot. We have achieved solid progress in our first year and we will continue to work closely with our partners to build our pipeline and our global reach to accelerate the delivery of new products.

Kevin Outterson
Executive Director, CARB-X

Solving the Superbug threat

Drug resistant bacteria is a global public health threat that is getting worse. An estimated 700,000 people die each year around the world from drug-resistant bacteria, according to the World Health Organization (WHO). In the US alone, the Centers for Disease Control and Prevention (CDC) estimates that 23,000 people die each year, and the European Centre for Disease Prevention and Control (ECDC) estimates that 25,000 people die annually in Europe.

Many advances of modern medicine — joint replacements, organ transplants, cancer therapy, and treatment of chronic diseases such as diabetes, asthma, rheumatoid arthritis — are dependent on the ability to fight infections with antibiotics. If that ability is lost, the ability to safely offer people many life-saving and life-improving modern medical advantages will also be lost.

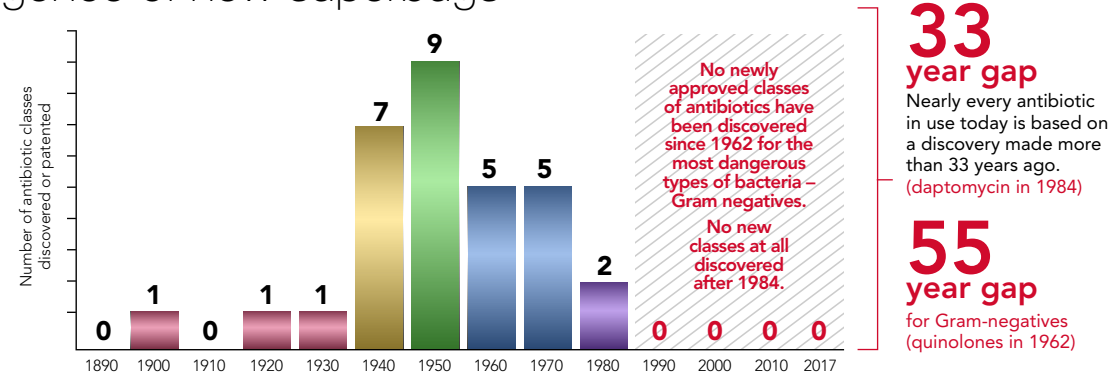
Part of the solution is to accelerate the development of new drugs to treat drug-resistant infection. No newly approved classes of antibiotics have been discovered since 1962 for the most dangerous types of bacteria – Gram negatives, and innovations to improve the diagnosis and prevention of drug-resistant infections have been slow.

Most large drug companies have reduced or abandoned infection research due to scientific challenges, and because it has become impossible for them to recoup the cost of research.

The economic model that once meant we could rely on industry for a steady supply of new antibiotics simply no longer works. At the same time, the deadliest superbugs have been rapidly developing resistance to existing antibiotics, hastened by overuse and misuse in humans and animals. It takes on average 10 years and hundreds of millions of dollars to develop a new drug. Superbugs can develop resistance much faster.

Patients urgently need new treatments, particularly for hard-to-treat infections such as those caused by Gram-negative bacteria, as well as C*lostridium difficile* (*C.difficile*), carbapenem-resistant Enterobacteriaceae, and drug-resistant gonorrhea. CARB-X is a new model that represents part of the solution. CARB-X supports the development of therapeutics, diagnostics, vaccines and other products to reduce the threat from drug-resistant infections.

Discovery of novel antibiotics* is not keeping pace with the emergence of new superbugs



*This chart excludes bedaquiline, which is the first drug in a new class to treat tuberculosis.

Source: Pew Charitable Trusts; Deak D, Powers JH, Outterson K, Kesselheim AS. Progress in the Fight Against Multidrug Resistant Bacteria?: A Review of FDA Approved Antibiotics 2010-2015. ANNALS OF INTERNAL MED. 2016 MAY 31. DOI: 10.7326/M16-0291.

Why are Gram-negative bacteria so tough to treat?

Bacteria have evolved ways to prevent the entry of unwanted or toxic compounds such as antibiotics. Gram-negative bacteria have a double membrane along with a variety of efflux pumps that expel drugs out of the cell, making it difficult to design new antibiotics that target Gram-negative pathogens. Gram-positive bacteria have a single membrane barrier that is relatively easy to penetrate, so many types of antibiotics get into the cell.

Combating antibiotic resistant bacteria

Better stewardship for existing antibiotics

Eliminate inappropriate use of these lifesaving drugs in both humans and animals.

Reduce the need for antibiotics by using **alternative** and **nontraditional approaches** to disease treatment and prevention.

Ensure that antibiotics are **accessible and available** to the people who need them.

Innovation to find new types of antibiotics

Support **targeted research** initiatives to overcome scientific challenges impeding the discovery of new antibiotics.

Address the complex barriers hindering the development of **new treatment options** for patients.

"Antibiotics transformed modern medicine but overuse and inappropriate use have led to dangerous bacteria developing deadly resistance. Drug discovery must go hand-in-hand with concerted action to ensure antibiotics of last resort are reserved for patients where first-line treatments will not work. And we must ensure these treatments are available in all countries for those who need them. That is why stewardship and fair access are integral to CARB-X support."

— Tim Jinks
Head of Drug Resistant Infections, Wellcome Trust

"The companies funded by CARB-X represent some of the best and most innovative science in the fight against drug-resistant bacteria. The *Powered by CARB-X* portfolio is the first-ever early stage R&D pipeline of this size to be supported as part of a global effort against drug-resistant bacteria."

— Karen Gallant
Global Project Director, CARB-X

"Antibiotic resistance is growing, and we are fast running out of treatment options. If we leave it to market forces alone, the new antibiotics we most urgently need are not going to be developed in time."

— Dr Marie-Paule Kieny
Assistant Director-General for Health Systems and Innovation, WHO

"Revitalizing the antibacterial pipeline is vital in enhancing national security, biodefense, and global preparedness. CARB-X represents the type of novel public-private partnerships that are necessary to promote and accelerate medical countermeasure innovation."

— Rick Bright
BARDA Director

"As it funds innovative research on desperately needed new candidate antibacterial agents & diagnostics, CARB-X is fundamentally shaping our global approach to treatment of drug-resistant Superbugs via its portfolio of both higher risk novel-mechanism products and lower risk known-mechanism products."

— John Rex
Chief Strategy Officer, CARB-X

How CARB-X works

CARB-X provides financial and scientific support to accelerate the most promising drug-resistant bacterial infection research projects from around the world through the early stages of product development so they can attract additional private or public investment for clinical-stage development.

FUNDING

BARDA, Wellcome Trust and NIAID provide $455 million over five years in funding and preclinical services

ASPR Assistant Secretary for Preparedness and Response · BARDA · wellcome · NIH National Institute of Allergy and Infectious Diseases

BEST SCIENCE

The Science Advisory Board reviews applications using rigorous scientific criteria and recommends which projects should receive funding. The SAB is made up of world-renowned scientists and experts

GOVERNANCE

Joint Oversight Committee (JOC) provides oversight, develops strategy and makes investment decisions

BOSTON UNIVERSITY ADMINISTRATION

Hosted by a leading research university, with world-class research administrative support

EXPERT SUPPORT

Partners provide scientific and business expertise to accelerate the research projects

Broad Institute · CLSI California Life Sciences Institute · MassBio Massachusetts Biotechnology Council · RTI International · ASPR Assistant Secretary for Preparedness and Response · BARDA · wellcome · NIH National Institute of Allergy and Infectious Diseases

Companies and research teams from around the world apply for funding to support research against drug-resistant infections.

368 applications
were reviewed in 2016-2017

CARB-X

CARB-X core team ensures the efficient leadership of the application and funding process and works closely with partners, funded companies and global networks to accelerate global antibacterial innovation.

Powered by CARB-X

Only the most promising research is selected for non-dilutive funding. Projects must target priority bacteria.

18 projects
were awarded $41.6M in CARB-X's first year, with up to $52.6M more in milestone-based options.

Great science knows no boundaries

CARB-X supports the best science and most promising early stage R&D projects anywhere in the world. We are aggressively expanding our global outreach to ensure that no opportunity is lost in the battle against drug-resistant bacterial infections. In 2016-17, the Powered by CARB-X portfolio has 18 innovative projects in 6 countries targeting the most drug-resistant forms of Gram-negative bacteria.

NORTH AMERICA

Forge Therapeutics
San Diego, CA

Cidara Therapeutics Inc.
San Diego, CA

Achaogen Inc.
South San Francisco, CA

Contrafect Corporation
Yonkers, NY

VenatoRx Pharmaceuticals
Malvern, PA

Spero Therapeutics LLC
Cambridge, MA

Visterra Inc.
Cambridge, MA

Tetraphase
Pharmaceuticals Inc.
Watertown, MA

Entasis Therapeutics Inc.
Waltham, MA

Microbiotix Inc.
Worcester, MA

EUROPE

Iterum Therapeutics Ltd.
Dublin, Ireland

Proteus IRC
Edinburgh, Scotland

Redx Pharma Plc
Alderley Park, UK

Oppilotech Ltd.
London, UK

Eligochem Ltd.
Sandwich, UK

Antabio
Labège, France

Debiopharm International S.A.
Lausanne, Switzerland

ASIA

Bugworks Research
India Pvt Ltd.
Bangalore, India

Powered by CARB-X

The CARB-X portfolio comprises 18 early stage R&D projects investigating 8 new classes of antibiotics, 5 non-traditional antibiotics, 10 new molecular targets and a rapid diagnostic to determine the type of drug-resistant bacteria that is causing an infection.

Company/ Research Team	Project	Novelty*			Project description	Urgency/ Priority**	Bacteria Targeted / Stage of Early Development			
		New Class	Non-traditional	New Target			Hit to Lead	Lead Optimization	Pre-Clinical	Phase 1
Achaogen	AKAO-LpxC	✔		✔	LpxC Inhibitor	✔	*Pseudomonas aeruginosa*			
Antabio	PEI		✔	✔	Pseudomonas Elastase inhibitor	✔	*Pseudomonas aeruginosa*			
Bugworks Research	Gyrox	✔			Gyrase-topoisomerase inhibitor	✔	Gram-negative activity			
Cidara Therapeutics	CD201		✔	✔	Bifunctional immunotherapy	✔	Acinetobacter + *P. aeruginosa* + Enterobacteriaceae			
ContraFect	Gram-negative lysins		✔	✔	Recombinant lysin protein	✔	*P. aeruginosa*			
Debiopharm	Debio 1453	✔		✔	Narrow-spectrum inhibitors of FabI	✔	*Neisseria Gonorrhoeae*			
Eligochem	Helical AMP	✔			Helical Antimicrobial Peptide	✔	Gram-negative activity			
Entasis Therapeutics	ETX0282 CPDP				Oral Gram-negative combination	✔	Gram-negative activity			
Forge Therapeutics	FG-LpxC	✔		✔	LpxC Inhibitor	✔	Gram-negative activity			
Iterum	Sulopenem				Oral and IV penem	✔	Gram-negative activity			
Microbiotix	T3SS Inhibitor		✔	✔	Virulence modifier	✔	*Pseudomonas aeruginosa*			
Oppilotech	LPS	✔		✔	Targets synthesis of LPS	✔	Gram-negative activity			
Redx Pharma	NBTI	✔			Dual-acting topoisomerase inhibitor	✔	Acin. + *P. aerug* + Enterobacteriaceae			
Spero Therapeutics	SPR741			✔	Potentiator	✔	Gram-negative activity			
Tetraphase Pharm	TP-6076				Next-generation tetracycline	✔	Acinetobacter + Enterobacteriaceae			
VenatoRx	VNRX-PBP	✔			ß-lactamase Resistant PBP Inhibitor	✔	Entero-bacteriaceae			
Visterra	VIS705		✔	✔	Antibody-drug conjugate	✔	*Pseudomonas aeruginosa*			

Company/ Research Team	Project	Project description	Development Stage			
			Feasability Demonstration	Optimization and Preparation for Development	Product Development	System Integration and Testing
Proteus	Rapid POC Diagnostic	Optical bacterial imaging	POC Diagnostic			

*Novelty characterizations of new class and new target are established by CARB-X following the Pew Charitable Trusts pipeline analysis model. Pew defines a novel chemical class as a group of antibiotics that share a new common core molecular structure. Non-traditional products include lysins and monoclonal antibodies.

** Urgent and priority drug-resistant bacteria are determined by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).
✔ Urgent/Critical priority ✔ Serious/High priority ✔ Serious/Medium priority.
Stage of development is approximate as of July 2017.

2016-2017 in review

In addition to establishing CARB-X and the *Powered by CARB-X* portfolio, we registered progress on several other fronts in our first year.

Partnership that produces results

Among the most significant achievements is the unique working relationship that CARB-X and its partners have forged together to identify, fund and support research projects. CARB-X represents an ambitious new model to drive investment into innovation and by any measure, the new model is working. CARB-X requires that the companies receiving the funding commit significant investment of their own. While CARB-X grants are non-dilutive, we want our partner companies to have significant skin in the game. The result is an innovative pipeline that is growing.

Scientific rigor, efficiency and high standards

Our Science Advisory Board, which includes more than 60 world-renowned scientists and experts in drug and product development in the field of drug-resistant bacteria, has established high scientific and ethical standards for evaluating and selecting applications for funding. Our partners that provide support to funded projects are among the best in the world. These experts drive the high quality of the science in the CARB-X portfolio, working closely with experts in each of the funded companies.

Solutions at a global level

Working closely with partners, CARB-X has been active in raising awareness about the rising global threat of drug-resistance and the solutions that we can help deliver. In July 2017, G20 leaders meeting in Hamburg, Germany, called on nations to support global antibiotic R&D efforts like CARB-X to develop new treatments for drug-resistant bacterial infections. CARB-X is a vital player in the global network of complementary R&D organizations focused on infectious disease, including GARDP, ND4BB, DRIVE-AB, and CEPI.

Raising awareness

Throughout the year, CARB-X has organized and participated in activities to raise awareness about drug resistance and the solutions that are needed at a global level.

Highlights include:

- Articles published in prestigious journals including Lancet Infectious Diseases, Nature Review Drug Discovery and in the New York Times.
- Launch of the *Powered by CARB-X* pipeline at Pew Charitable Trusts in Washington on March 30, 2017. The launch, which drew many government and industry leaders, generated significant coverage by the scientific, business and general media.
- High-profile workshop in Geneva in May 2017, co-sponsored by CARB-X and DRIVE-AB, on global access and stewardship of antibiotics. Presentations, panel discussions and engagement with industry stakeholders at BIO2017 in San Diego in June 2017. In addition, our partners have held workshops with industry and academia.
- Speaking engagements at public and sponsored events including The Atlantic's 'Pulse: On the Front Lines of Health Care' in June 2017.

A solid foundation

In just one year, we have built a solid organization that is a vital part of the global solution to the rising threat of drug-resistant bacteria. We are also lean and efficient; in 2016-2017, more than 96 percent of CARB-X funds went directly into funding pipeline projects.

Building support for CARB-X

Our funders, BARDA, NIAID and Wellcome Trust, have generously supported CARB-X in 2016-2017 and have made commitments for year two that exceed year one – a sure sign that CARB-X represents an exciting model to support development of promising products in the fight against drug-resistance. While our resources are formidable, CARB-X cannot support all applications worthy of funding. We are seeking new partnerships with countries and organizations around the world to expand our global reach.

"Our scientific and business success is driven by strong relationships with partners, investors and advisors. CARB-X's funding and research support is helping us accelerate development of our novel antibiotic to treat Gram-negative bacteria and help fight the global 'superbug' threat."

— **Zachary Zimmerman**
CEO, Forge Therapeutics

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 makes research investment decisions based on recommendations from the Science Advisory Board.

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Supporting great science

Outstanding experts make up CARB-X's Science Advisory Board (SAB). The SAB ensures the highest scientific standards in evaluating applications for CARB-X funding. Every member of the CARB-X SAB and JOC completes a conflicts of interest process and is excluded from participation in the review or approval of any application with which they have a conflict of interest. We thank them sincerely for their work.

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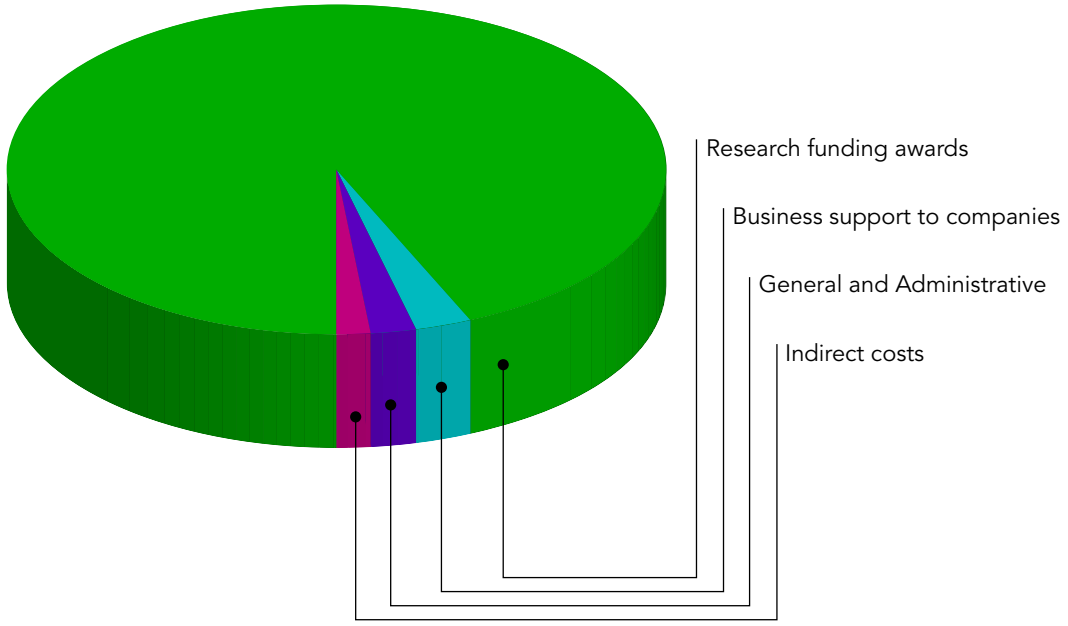
CARB-X Year 2 Budget

Wellcome Trust and BARDA have committed $405 million in funding to CARB-X over five years for investment in preclinical antimicrobial research ($155.5 million from Wellcome Trust and $250 million from BARDA). NIAID has committed pre-clinical services valued at $50 million over five years to support the funded projects. These sums are allocated on a yearly basis.

AWARDS AND EXPENDITURES (Fiscal Year ending 31 July 2018)		(in millions)	
Research funding awards			
Non-dilutive funding awards		**$81.94**	93.5%
Business support to *Powered by CARB-X* companies		**2.42**	2.8%
General and Administrative		**2.04**	2.3%
Salaries and administration	1.09		
IT support	.35		
Consultants	.49		
Advisory Board	.11		
Indirect costs		**1.25**	1.4%
TOTAL		**87.65**	100%

*CARB-X financial year is from August 1 to July 31.

More than 96 percent of CARB-X funds in 2017-2018 will go directly into funding pipeline projects.



Kevin Outterson with journalist Maryn McKenna (left) and Erika Kurt (right) at the Atlantic Pulse discussion on drug-resistant infections. The Atlantic video is available here.

The power of science
and collaboration
will reduce the global threat
of bacterial resistance.

CARB-X

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“Antimicrobial resistance poses a catastrophic threat. If we don’t act now, any one of us could go into hospital in 20 years for minor surgery and die because of an ordinary infection that can’t be treated by antibiotics. And routine operations like hip replacements or organ transplants could be deadly because of the risk of infection. That’s why governments and organisations across the world... need to take this seriously. This is not just about government action. We need to encourage more innovation in the development of antibiotics – over the past two decades there has been a discovery void around antibiotics, meaning diseases have evolved faster than the drugs to treat them.”

— **Dame Sally Davies**
UK Chief Medical Officer

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CARB-X

Xccelerating global antibacterial innovation