

News

CARB-X LAUNCHES 2025 FUNDING ROUND TARGETING GLOBAL INFECTIOUS DISEASE THREATS

Seeking therapeutics for infections caused by Gram-negative pathogens and diagnostics for Salmonella Typhi

(BOSTON: February 26, 2025) – Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) announced today a funding solicitation with two distinct product themes:

• THERAPEUTICS FOR INFECTIONS CAUSED BY GRAM-NEGATIVE PATHOGENS

The scope is restricted to direct-acting small-molecule therapeutics. Strategies requiring potentiator molecules (including, but not limited to, BLIs, efflux inhibitors, membrane permeators) are not within scope. Molecules with properties that will deliver an IV route with an oral stepdown are preferred. In all cases, activity against both susceptible and multidrug-resistant organisms on priority bacterial threat lists is essential.

DIAGNOSTICS FOR TYPHOID FEVER FOR LOW-RESOURCE SETTINGS

We seek diagnostics to support the portfolio to diagnose acute infection of *Salmonella enterica* serovar Typhi, the causative pathogen in typhoid fever. The primary health care level is the preferred use setting, with ease-of-use, high performance and affordability prioritized.

Target product profiles and minimal entry criteria for each theme will be defined and available on CARB-X.org. Expressions of interest may be submitted from 16 April 2025 at 10:00 ET – 30 April 2025 at 23:59 ET. Two public webinars will be held during the week of 14 April 2025 to discuss the scope of the funding round, application process, and to answer questions. Register for the CARB-X newsletter to receive updates.

"Although progress has been made in the discovery and early development of therapeutics addressing various AMR challenges, there is broad agreement that we still need a new antibiotic, particularly an orally available one, with broad-spectrum activity against Gram-negative pathogens," said Erin Duffy, Ph.D., R&D Chief of CARB-X. "At the same time, fast, affordable, and accessible diagnostics for *S. typhi* are essential to improve early detection and treatment. CARB-X is committed to addressing these pressing challenges by issuing strategic, targeted funding solicitations to accelerate innovative science for antibacterial products."

Recent estimates show that a regular release of new, potent antibiotics targeting Gram-negative bacteria, which is part of CARB-X's mission, could avert 11.1 million cumulative deaths caused by antimicrobial resistance in the coming 25 years, with the largest reductions in low-and-middle-income

countries (LMICs) in regions including South Asia, Southeast Asia, East Asia and Oceania, and sub-Saharan Africa. The economic benefits would also be significant: introducing new Gram-negative antibiotics would reduce health care costs by US\$84 billion, generate improved health outcomes worth US\$174 billion, and add US\$740 billion to global GDP per year by 2050.

Typhoid fever is a severe systemic illness caused by the Gram-negative *Salmonella enterica* serovar Typhi. Each year, there are between 11 and 21 million cases of typhoid fever, with the greatest burden among children and individuals living in LMICs in South Asia, and Southeast Asia and sub-Saharan Africa. The illness is responsible for approximately 128,000 to 161,000 deaths globally, and its symptoms include abdominal pain and fever. Typhoid fever is usually spread through the consumption of contaminated food or water.

Applicants from around the globe are encouraged to apply, particularly from areas where the burden of antimicrobial resistance is the highest. When the sub-award contract is executed, applicants must provide a cost share through the contract performance period. Applications must come from a legal entity, and applicants must adhere to the highest ethical research standards. Applicants must also own, or have secured, the rights to intellectual property and have a reasonable expectation of freedom to operate. Academic centers and non-commercial developers are encouraged to apply, if they can demonstrate similar capabilities expected of a drug development industry partner. Applications will be reviewed by external experts, and final funding decisions are made by CARB-X.

To inform its recent funding calls, CARB-X performed a strategic portfolio review that included a review of the global product pipeline, the CARB-X portfolio, and the reports from the Antimicrobial Resistance Collaborators, highlighting the substantial global burden of bacterial antibiotic resistance, the key syndromes and pathogens contributing to this and the geographies most impacted.

When CARB-X was founded in 2016, the early-stage antibiotic pipeline was stalled. Since its inception, CARB-X has supported 113 R&D projects in 14 countries, and CARB-X product developers have made significant progress: 19 projects have advanced into or completed the first stage of clinical trials; 12 remain active in clinical development, including late-stage clinical trials; 2 diagnostic products have reached the market and 1 antibiotic for which CARB-X supported nonclinical activities has received FDA approval. 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. All CARB-X-funded product developers are contractually obligated to develop a Stewardship and Access Plan for their product, outlining strategies to ensure responsible stewardship and appropriate access in low- and middle-income countries.

CARB-X is funded in part with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under agreement number 75A50122C00028 and by awards from Wellcome (WT224842), Germany's Federal Ministry of Education and Research (BMBF), the UK Department of Health and Social Care's Global Antimicrobial Resistance Innovation Fund (GAMRIF), the Public Health Agency of Canada (PHAC), the Gates Foundation, and the Novo Nordisk Foundation. The U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health

(NIH) in HHS, provides support in the form of in-kind services through access to a suite of preclinical services for product development. The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of any CARB-X funders.

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About CARB-X

CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) is a global non-profit partnership dedicated to supporting early-stage antibacterial research and development to address the rising threat of drug-resistant bacteria. CARB-X supports innovative therapeutics, preventatives and rapid diagnostics. CARB-X is led by Boston University and funded by a consortium of governments and foundations. CARB-X funds only projects that target the most serious, resistant bacteria identified on global priority lists, syndromes with the greatest global morbidity and mortality, and performance characteristics necessary for patients. https://carb-x.org/ | X (formerly Twitter) @CARB_X

About BARDA and NIAID

The U.S. Department of Health and Human Services works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The Administration for Strategic Preparedness and Response (ASPR) leads the nation's medical and public health preparedness for, response to and recovery from disaster and other public health emergencies. Within ASPR, the Biomedical Advanced Research and Development Authority (BARDA) invests in innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures needed to combat health security threats. BARDA is one of the leading public sector funders of advanced development of antimicrobial therapeutics and diagnostics worldwide, having invested more than \$2.4 billion in antimicrobial products since 2010. This investment has supported the development of over 160 antimicrobial products and led to the U.S. Food and Drug Administration (FDA) approval of four new antibiotics and FDA 510(k) clearance of eight diagnostics.

About Wellcome

Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we're taking on three worldwide health challenges: mental health, infectious disease and climate and health.

About the German Federal Ministry of Education and Research (BMBF)

Education and research are crucial foundations for our future. Thus, the promotion of education, science and research is a policy priority of the German Federal Government. The German Federal Ministry of Education and Research (BMBF) strengthens education at all stages of life and provides support for scientific research and innovation.

About the Global AMR Innovation Fund (GAMRIF)

The Global AMR Innovation Fund (GAMRIF) is a One Health aid fund that supports research and development around the world to reduce the threat of antimicrobial resistance (AMR) in humans, animals and the environment for the benefit of people in low- and middle-income countries (LMICs). GAMRIF core objectives are to develop innovative One Health solutions to tackle AMR; increase availability of context-specific, accessible, and affordable innovations for LMICs; establish international research partnerships with industry, academia, and governments; and collaborate with and leverage additional funding from other global donors.

About the Public Health Agency of Canada

The Public Health Agency of Canada (PHAC), established in 2004, is responsible for public health, emergency preparedness and response, and infectious and chronic disease control and prevention. Its mission is to improve the health of all people and communities in Canada by addressing public health priorities through science, innovation, service delivery, and collaborative action. The Agency collaborates closely with all levels of government, non-government organizations, and international partners to build an effective public health system. PHAC has a strong history of addressing health threats, including collaboration on a One Health approach to antimicrobial resistance (AMR). As part of the recently launched Pan-Canadian Action Plan on AMR 2023-2027, PHAC is piloting an economic pull-incentive project to increase access to essential antimicrobial drugs not yet authorized in Canada to address priority unmet public health needs.

About the Novo Nordisk Foundation

Established in Denmark in 1924, the Novo Nordisk Foundation is an enterprise foundation with philanthropic objectives. The vision of the Foundation is to improve people's health and the sustainability of society and the planet. The Foundation's mission is to progress research and innovation in the prevention and treatment of cardiometabolic and infectious diseases as well as to advance knowledge and solutions to support a green transformation of society.

www.novonordiskfonden.dk/en

About Boston University

Founded in 1839, Boston University is an internationally recognized institution of higher education and research. With nearly 37,000 students, it is one of the largest private residential universities in the United States. BU consists of 17 schools and colleges, along with the Faculty of Computing & Data Sciences and a number of multi-disciplinary centers and institutes integral to the University's research and teaching mission. In 2012, BU joined the Association of American Universities (AAU), a consortium of leading research universities in the United States and Canada. For further information, please contact Kim Miragliuolo at kmira@bu.edu. www.bu.edu

Led by Boston University

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