

News

CARB-X LAUNCHES NEW FUNDING ROUND TO FILL MAJOR R&D GAPS IN GLOBAL PIPELINE

Seeking preventatives, diagnostics and therapeutics for critical global health needs

(BOSTON: March 6, 2024) – The Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) announced today a funding solicitation with four distinct product themes:

- **THERAPEUTICS FOR INFECTIONS CAUSED BY GRAM-NEGATIVE PATHOGENS**

The scope is restricted to direct-acting small-molecule therapeutics. 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 the WHO and CDC bacterial threat lists is essential.

- **PREVENTION FOR INVASIVE DISEASE**

Novel approaches to prevention of invasive disease caused by *Staphylococcus aureus* or *Escherichia coli* are sought. Given the history of challenges in drug development in this arena, modalities other than vaccines are preferred; however, if a vaccine is proposed, a novel aspect (e.g. adjuvant strategy or vaccine composition) that makes a compelling case must be underscored.

- **DIAGNOSTICS FOR NEONATAL SEPSIS**

Consistent with our “Aligned by Design” strategy, we seek diagnostics to support the growing portfolio of potential maternal vaccines to prevent neonatal sepsis. Products focused on rapid triage, bacterial identification and/or automated susceptibility testing are sought. Time-to-result and cost-of-goods are key criteria, and small-sample volumes are critical for this patient population. Pathogen ID and AST Products must focus on priority pathogens, including *Klebsiella pneumoniae*, *Escherichia coli*, *Staphylococcus aureus* and *Acinetobacter baumannii*.

- **PROOF-OF-CONCEPT FOR NOVEL SAMPLE TYPES FOR DIAGNOSING LOWER-RESPIRATORY-TRACT INFECTIONS**

Consistent with our “Aligned by Design” strategy, we seek diagnostics to support the many therapeutic projects focused on lower-respiratory-tract infections (LRTI). Owing to the challenges with BAL samples, as a first step, projects that can demonstrate proof-of-concept data with novel sample types are sought.

Target product profiles and minimal acceptable criteria for all funding calls will be defined and available on carb-x.org.

Expressions of interest for all themes may be submitted during these timeframes:

- 18 March 2024 at 10:00 ET – 29 March 2024 at 23:59 ET
- 23 September 2024 at 10:00 ET – 4 October 2024 at 23:59 ET

“For our 2024 funding calls, we continue to seek to fill major gaps in the global pipeline,” said Erin Duffy, Ph.D., R&D Chief of CARB-X. “Some needs have remained the same, as emphasized by our 2023 strategic portfolio review. As such, our call includes new therapeutics for Gram-negative infections and a prevention focus on invasive disease. Rapid diagnostics to support appropriate intervention in low- and middle-income countries with the greatest disease burden are also urgently needed.”

To apply, applicants must be a legal entity. We encourage applicants from around the globe to apply, particularly from areas where the burden of AMR is the highest. When the sub-award contract is executed, applicants must provide at least 30% of the product development cost through the contract performance period. 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. Applicants must adhere to the highest ethical research standards, and the applications will be reviewed by external experts. Final funding decisions are made by CARB-X. For details on the scope of the funding rounds and how to apply, visit CARB-X.org.

“These funding rounds are made possible by continued support from our existing funders, plus two new funders since the last funding rounds: Canada and the Novo Nordisk Foundation. Together, we are able to fill major R&D gaps against superbugs,” said Kevin Outtersen, Executive Director of CARB-X and Professor of Law at Boston University. “The CARB-X model is working, accelerating a diverse portfolio of innovative antibacterial products towards clinical development and regulatory approval with the support of funding, expertise and Portfolio Acceleration Tools.”

In 2019, an estimated 1.27 million people died due to antimicrobial-resistant bacterial infections. Since its founding in 2016, CARB-X has provided US\$452.6M to 100 preclinical candidates to address bacterial infections. These projects include vaccines, rapid diagnostics, antibiotics, and non-traditional therapeutics and preventatives. CARB-X provides funding to projects in the early stages of development, and offers business, clinical and regulatory expertise from its in-house R&D team and worldwide network of subject matter experts. To inform its new funding calls, CARB-X reviewed the global product pipeline, the CARB-X portfolio, and research on unmet medical needs. The highest burden of AMR is in low- and middle-income countries (LMICs). CARB-X provides specific funding to tackle this challenge. Part of the funding available for this call is Official Development Assistance (ODA) from the Global AMR Innovation Fund (GAMRIF) in the UK’s Department of Health and Social Care. ODA is government aid that promotes and targets the development and welfare of low- and middle-income countries.

Two public webinars will be held during the week of 18 March 2024 to discuss the scope of the funding rounds, application process, and to answer questions. Stay tuned and register for the webinars at CARB-X.org.

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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 drug-resistant bacteria highlighted on the CDC's Antibiotic Resistant Threats list, or the Priority Bacterial Pathogens list published by the WHO, with a priority on those pathogens deemed Serious or Urgent on the CDC list or Critical or High on the WHO list. <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 – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products – needed to combat health security threats and is one of the leading public sector funders of advanced development of antimicrobial therapeutics and diagnostics.

As part of HHS, NIH is the primary U.S. federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. NIAID conducts and supports research – at NIH, throughout the United States, and worldwide – to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website.

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