CARB-X key features

Next CARB-X 2025 funding round: Expression of Interest portal opens on 16 April and close on 30 April.



A global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria, a leading cause of death around the world.

- CARB-X is the only global partnership that integrates solutions for the **prevention**, **diagnosis** and **treatment** of life-threatening bacterial infections, translating innovation from basic research to first-in-human clinical trials.
- CARB-X is funded by <u>a global consortium of</u> <u>governments and foundations</u>.
- CARB-X headquarters are located at Boston University.





Combating Antibiotic-Resistant Bacteria

- A **global approach**, with the world's largest early development antibacterial portfolio
- Entrepreneurial culture, accelerating the most urgently needed innovative products with both funding and expert business, technical and regulatory support
- Focused on the **most dangerous bacterial pathogens**. Making a difference in the fight against drug resistance
- **Investment community and policy makers** gain valuable insight into potential new products, science and technology
- Bias towards more innovative, ground-breaking projects



What CARB-X Funds

- Early development projects that address serious bacterial threats
- antibiotics and therapeutics
- prevention such as vaccines, microbiome, antibodies
- rapid diagnostics (pathogen ID/AST)

Projects must target specific bacteria on the Antibiotic Resistance Threats List issued by the Centers for Disease Control and Prevention (CDC) in 2013 or on the Priority Bacterial Pathogens list published by the World Health Organization (WHO) in 2017



- CARB-X does not fund basic research/drug discovery including screening for novel targets
- CARB-X supports projects in **Early Development** (up to phase 1 for therapeutics and preventatives)
- CARB-X welcomes applications from around the world, companies, academic institutions, research centres, research hospitals
- **Consortium** of 2 or more entities can apply: contributions from the different partners should be specified, and a Principal Investigator should be named



- Projects must be in scope CARB-X and specific round
- Applicants must have a legal entity
- Applicants must be able to contribute at least 20% of the cost of the project/program ('cost-share') base and option stages. At the time of execution of the sub-award (contract), applicants must have secured cost-share funds for the base stage of the project
- Be a going concern or have a viable strategy to achieve/maintain financial sustainability
- At the time of execution of a sub-award (contract), applicants must own or have rights to the IP and reasonable expectation of freedom to operate required to carry out the project
- Applicants must have operations or capabilities in place to support product development, particularly through development stages in scope for CARB-X
- Applicants from noncommercial centers or academic institutions must meet additional requirements (next slide)



Research Compliance Requirements

• CARB-X is committed to the highest ethical standards in all research and business operations.

• CARB-X funded companies must comply with US Government regulatory requirements for animal research and human subjects research, even if the research is conducted outside the United States

• Office of Laboratory Animal Welfare (OLAW) requirements for studies involving any vertebrate species

• USDA Registration requirements for US-based research facilities performing studies involving warm-blooded animals not specifically excluded from the definition of "animal" in the US Animal Welfare Act and Animal Welfare Regulations

- Office of Human Research Protections (OHRP) requirements for human subjects research
- CARB-X funded companies must make every reasonable effort to comply with NC3R guidance for studies involving large animals (primates, cats, dogs, equines)
- These requirements may impact both time and budget; they are critical to consider when building your project plan

CARB-X Welcomes Applications from Academic and Non-commercial Developers Organization must be able to demonstrate R&D/business capabilities:

- Capabilities similar to those expected of a drug development industry partner, particularly through the development stages in scope for CARB-X.
- Access to and use of **relevant experts** (internal and/or external) to advance projects toward clinical investigation within the framework of a major regulatory agency, e.g. FDA, EMA, PMDA
- Active management of IP supporting the project
- Well-developed strategy for advancement to early clinical development
- Capabilities in **commercial (business) development and technology transfer** with options for 'exit strategy' (e.g. spin out, licensure to biotech)
- Financial commitment and stability to cover cost share of at least 20% of the base stage (and any subsequent option stages as these are contracted)



The CARB-X 2025 funding round has two distinct themes

Therapeutics for infections caused by Gramnegative pathogens

The scope is restricted to **direct-acting smallmolecule 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.

Target Product Profiles and minimal entry criteria will be available here in the coming weeks.

Diagnostics for typhoid fever for lowresource settings

We seek a diagnostic 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 will be available here in the coming weeks.

Application process

three-stage process - about 8 months from EOI to decision

Applicants must contribute funding ("cost share") equal to a % of the total cost of the agreed WP

1. Non-confidential Expression of Interest (EOI)

- Fillable template for salient details of proposed project
- Evaluated by CARB-X Research & Development Team for responsiveness

2. Confidential project narrative and budget ("full proposal")

- Fillable template for data-rich proposal, with several required attachments
- Low- and Middle-Income Country-focused programs might qualify for funding through the Official Development Assistance program
- Juried by a multidisciplinary external Advisory Board

3. Focused presentation to Advisory Board

- Short virtual presentation, followed by focused questions and answers
- Juried by a multidisciplinary external Advisory Board
- Recommendations made to CARB-X

Decisions on projects that will advance into negotiations to enter the CARB-X portfolio are made by the CARB-X Investment Committee (CIC).

EOI

Generally, an Expression of Interest (EOI) includes:

- The main features of the proposed product.
- A project description of up to 1,000 words.
- Summarize the background in one or two sentences and use the remaining words to outline the project details.
- While the EOI is non-confidential, it is crucial to include quantitative information and focus on the key requirements outlined in the funding call. This ensures that evaluators can clearly understand the project and its potential impact on global health.



Entering Portfolio

To enter the CARB-X portfolio, successful applicants can expect the following:

Executing your agreement

- Negotiate final workplan and associated budget for initial stage of development
- Complete prequalification and due diligence exercises
- Review and sign a <u>CARB-X Portfolio Company Agreement</u>
- Demonstrate proof of cost share. Successful applicants must contribute cost share equal to a percentage of the total cost of the agreed work package. Please refer to the FAQ document for additional information regarding cost share.



Interested in applying? Contact Innovation Acta for more details!

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