



Advice for university scientists applying for CARB-X funding

CARB-X supports the best science around the world, from companies of all sizes, and academic groups to advance the development of antibacterial products. Basic research must be completed before applying for CARB-X funding.

Below are resources and key elements that university scientists should consider to ensure their projects are competitive

Which project stages does CARB-X support?

CARB-X awards funding to projects from hit-to-lead through Phase 1 clinical trials for preventatives and therapeutics, and from feasibility through development and validation of an alpha prototype for diagnostics.

Minimal entry criteria and development stages for the following programs are available on carb-x.org:



When applying for CARB-X funding, data should be presented to justify the project's current stage of development, according to the criteria provided in the relevant **CARB-X Development Stages in Scope guidance document** found under the Apply section on CARB-X.org.

In addition, applicants must provide partial funding for their project. Non-profit applicants must provide 15% of the project's funding, known as a cost share, to be eligible for an award from CARB-X.

When does CARB-X announce funding calls?

- To receive information about an upcoming funding call, register for the CARB-X newsletter on the Sign Up page of carb-x.org, and follow us on X and LinkedIn.
- Details about each funding call will be available under the Apply section on CARB-X.org.
- Each funding call with have more than one intake period when applications will be accepted.

What should be included in the project application?

Each funding call has a different scope, themes, and minimal entry criteria that projects must meet.

Use those guidelines to describe **how the project will** address an unmet medical need to prevent, diagnose or treat drug-resistant bacterial infections, including those caused by antibiotic-resistant bacteria.

Develop a **Target Product Profile** (TPP) with key performance characteristics to differentiate the project from competitive products and to guide both the preclinical and clinical development of the resultant product. Examples of TPPs for therapeutics and other products can be viewed on the websites of CARB-X, WHO and NIH. Projects that do not meet all the minimal entry criteria required during the first intake period are encouraged to develop these criteria and apply during the next intake period. NIAID preclinical services offer free resources that can help build a robust application.

How should the expression of interest (EOI) be framed?

An expression of interest (EOI) submission typically includes:

- Key attributes of your proposed product
- Up to a 1,000-word description of your project. In one or two sentences, summarize the background. Use the rest of the word count to outline project details.

While the EOI is non-confidential, it is critical to include data-rich information which is quantitative, focusing on key requirements in the funding call, so reviewers can understand the project and its potential to make a meaningful impact on global health.

How to foster a product development mindset as you move forward.

Strategize how the final product will be positioned in the market and understand how your product is differentiated from competitors. Speak with stakeholders and consultants who are experts in their fields, particularly those who understand how the product will be used in the clinic. This will show the reviewers that there is a plan in place, even though it might change during the development stages.



For diagnostic developers, we recommend viewing *In Vitro Diagnostics (IVD) Product Development*, a free, 11-part video series on carb-x.org. The series covers the fundamentals of moving an IVD product from concept through development. It was created by CARB-X, FIND and C-CAMP to help developers make the transition from academic and grant-based research to quality compliant product development.

How does an intellectual property (IP) strategy impact the application process?

As your program progresses it is important to have an IP strategy. There is no requirement to have filed patents or patent applications before applying to CARB-X. Likewise, a formal freedom to operate (FTO) opinion is not needed at the time of application. However, it is expected that FTO will exist.

FTO demonstrates the ability of your institution to develop, make and market products without legal liabilities to third parties. It is important to describe your thoughts on both FTO and patent exclusivity and their effect on the successful execution of the program.

If there is existing project IP, ensure that all inventors are listed and all appropriate licensing agreements are referenced. Ensure that all contracts properly assign the IP to the applicant (i.e. university policies, employment contracts, manufacturing agreements, collaboration agreements, etc.) We recommend that your institution's tech transfer office review the status of existing IP prior to application submission.

Why is it important to collaborate with experts and create a business strategy?

As your program develops, it's **crucial to partner with experts who can help you understand the translational aspects and what it will take for the project to be successful**. Gaps in essential technical, clinical, and regulatory expertise should

be filled by engaging consultants or collaborators with appropriate product development expertise. Incorporating the advice from drug or diagnostic development experts will result in a more product-focused program and a better application.



Create a **clear project management structure** to ensure essential collaborators engage and disengage

appropriately. If students are involved in deliverables, ensure that the work package is clearly defined and the research team has enough redundancy to allow for student flux as the university-led project progresses through different disciplines.

Outline a **business strategy** about how the project would progress into later stages of preclinical development and into clinical evaluation.

Understand the risks early, so there is time to adjust the experimental focus and mitigate pitfalls. Consideration of IP ownership, regulatory pathway requirements, and the reimbursement potential of the final product needs to inform the initial product design and be reviewed periodically.

Resources:

Federal Ministry

of Education

and Research

The Omnibus Outcomes page explores the 2022-2023 funding rounds, including themes, trends, and applicant demographics from the most recent call cycle, which has completed.

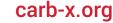
Contact carbxpr@bu.edu with questions.

Canada



Combating Antibiotic-Resistant Bacteria

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