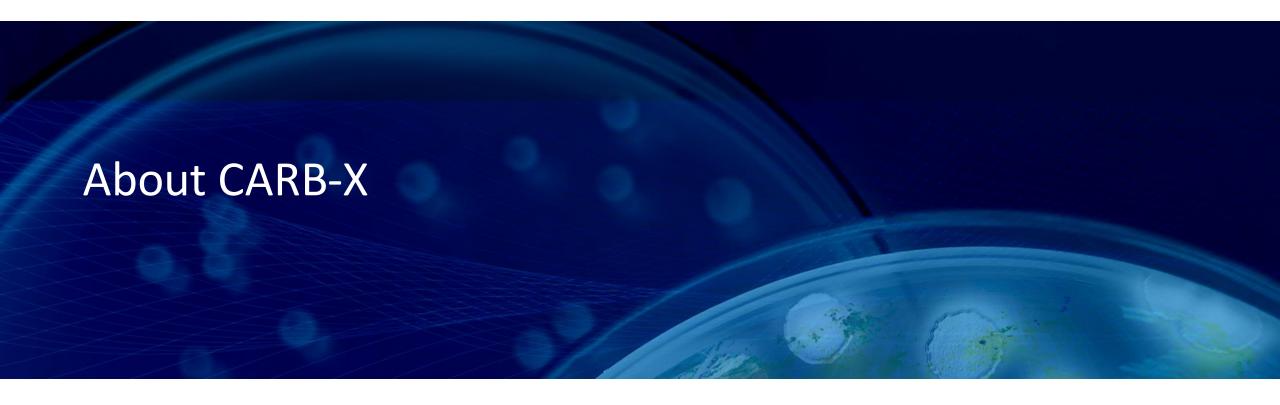






Agenda

- About CARB-X
- Overview of 2025 Funding Call
- How to Apply
- Q&A







A global non-profit partnership replenishing the clinical pipeline of innovative products to prevent, diagnose and treat the most dangerous drug-resistant bacterial infections













BILL & MELINDA
GATES foundation

novo nordisk foundation





CARB-X now operating at global scale









- Accelerates translational R&D projects into human clinical trials
- Support development of therapeutics, preventatives and diagnostics
- Selects R&D projects through public funding calls
- Focus on performance characteristics, pathogens and infectious syndromes with highest morbidity and mortality rates attributable to/associated with AMR globally
- Requires stewardship and access obligations
- Provides non-dilutive funding plus a multi-layered support model
- Requires product developers to cover a cost-share to ensure sustainability

1733 expressions of interest

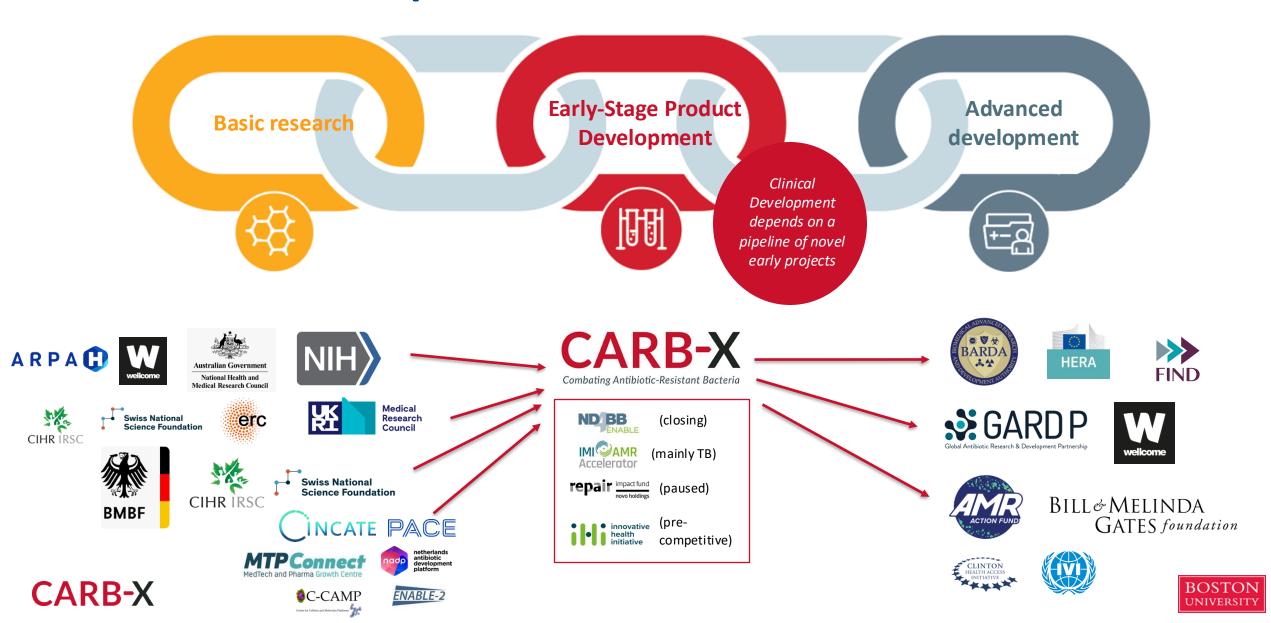
114 projects since 2016 from **13** countries

42 active projects*

15 Phase 1 (Tx & Pv) **5** Verification & Validation (Dx) >10 advanced development partnerships

3 on the market

A central and indispensable link of the R&D chain



What CARB-X funds in our link of the chain

Therapeutics

Hit-to-Lead through
 First-in-Human*

Preventatives

 Antigen/composition discovery through First-in-Human*

Diagnostics

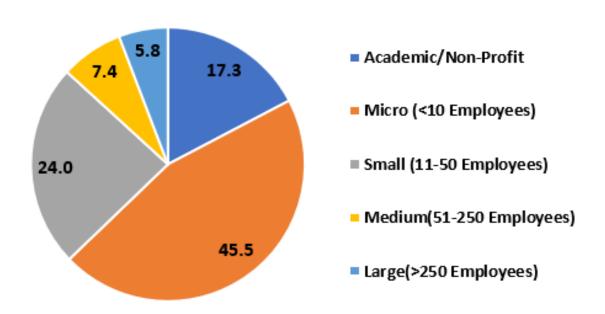
 Feasibility through alpha-prototype development**



^{*}in specific cases, may extend into a proof-of-mechanism study to best prepare for Ph2

^{**}for diagnostics targeting the lowest levels of the healthcare system, later stages of development may be supported

CARB-X is supporting a fragile AMR ecosystem



Source: CARB-X EOI applications (2016 – 2024) (n = 1733)

- Almost 1 in 2 applications are from companies with <10 employees
 - 85.6% companies are private
 - Large companies not solely AMR focused
- Significant attrition observed
 - Typically have single asset/small portfolios
 - Many (37.1%) of early company applicants (2016-2019) no longer exist
- Small groups carry risk around less breadth of discipline expertise
 - Company support teams include technical expertise









CARB-X funding rounds

- Multiple research themes announced simultaneously
 - Address unmet medical needs identified by CARB-X strategic review
 - Prioritized to balance investment portfolio
 - Scope and budget are approved by CARB-X funders
- Planning two separate intake dates with same funding themes

www.carb-x.org



2025 Funding Themes



Therapeutics for infections caused by Gram-negative pathogens

- Direct-acting small molecules
- IV/oral preferred
- Eligible TPPs: LRTI, UTI, diarrheal diseases



Diagnostics for typhoid fever for low-resource settings

- To support diagnosis of acute typhoid fever
- Primary healthcare level setting preferred
- Ease of use, high performance, and affordability prioritized

Key dates for 2025 cycle 1

- EOI portal live: 16 April 2025 @ 10:00 ET
- EOI submission deadline: 30 April 2025 by 23:59:59 ET

CARB-X application process

Expression of Interest ~4 weeks Project Narrative ~2-6 weeks Advisory Board

- Non-confidential Expression-of-Interest (EOI) 2 week application period
 - Must fit within scope of funding call (modality, pathogen, product characteristics etc.)
 - Important to pay attention to minimal entry criteria and TPPs (on website)
 - If need be, use the time before 2nd entry date to collect appropriate data
 - Relatively short application, a few basic questions and up to ~1000 words
 - No need to describe AMR problem
 - Include as much specific data as possible to showcase your program
 - Data can be shared without release of confidential aspects



CARB-X application process

Expression of Interest ~4 weeks Project Narrative ~2-6 weeks Advisory Board

Written Project Narrative

- Due approximately 4 weeks after notice of successful EOI
- Templated application form <u>follow instructions carefully</u> on content and length
- Written application submitted under confidentiality
 - Supporting background data be data rich and ensure minimal entry criteria are addressed
 - Details of proposed workplan and scientific rationale to be performed with CARB-X funding
 - Information around LMIC plans and enabling access
 - Details around project team and 'business structure'
 - Evidence of clinical development strategy (stage commensurate)
 - Need to include quantitative milestones, TPP that aligns with call, risk register/mitigation strategies, competitive differentiation from related programs, and budget





Scoring Assessment

- Application process is supported by team of external reviewers
 - Across all relevant disciplines, and pillar-specific (Tx, Pv, and Dx)
- Reviewers score across six categories:
 - Severity and Size of Unmet Medical Need
 - Demonstrated Performance Characteristics versus Unmet Medical Need
 - Scientific Assessment and Technical Feasibility
 - Clinical Development Feasibility and Translation of Product to Medical Value
 - Commercial Feasibility
 - Team



CARB-X application process

- Advisory Board presentation
 - Virtual meeting between 2 and 6 weeks after notice of successful Project Narrative
 - Will receive invitation with pertinent details
 - Focused 15-minute presentation to Advisory Board
 - Specifically address the questions provided by reviewers
 - Same experts that have reviewed prior materials no need to repeat information
 - Overview of organization etc. is not required
 - 30 minutes Q&A period
 - May bring additional team members to cover different disciplines and expertise



Other Key Activities During Application

Portfolio Company Agreement (PCA) review

- Engage appropriate person at your organization to review the CARB-X PCA on the website. The terms of this agreement, including Article V which covers Stewardship and Access plus Additional Obligations, are non-negotiable.
 - https://carb-x.org/wp-content/uploads/2024/08/C-X-PCA-Template_July-25-2024_updtd95.pdf
 - The CARB-X and Wellcome Trust webinar on developing a Stewardship & Access Plan is available https://www.youtube.com/watch?v=C5S6oD706-o

Research Compliance

Detailed information about animal, human, or biospecimens experiments

Due Diligence

- High-level details around IP landscape
- Full diligence on business structure, financials, and legal compliance required prior to contract execution

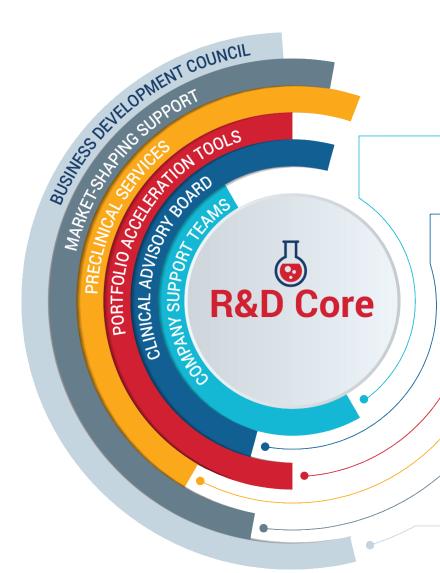


Entering CARB-X Portfolio

- Applications supported by Advisory Board are then recommended to the CARB-X Investment Committee (CIC) for a decision on entering into negotiations.
- Workplans for successfully funded applicants are negotiated with CARB-X Alliance lead, incorporating any feedback or suggestions from the Advisory Board.
- Once contracted, a Company support team is built around each funded group
 - Led by Alliance lead, and contains Compliance and Finance personnel from CARB-X
 - Contains expert consultants in disciplines relevant for stage of project
 - Product Developer may request specific support from Alliance Lead
- Funded groups receive support in additional areas



A Comprehensive and Layered Support Model





Company Support Teams

Extensive, global subject matter expert pool across all disciplines to fill key functions in teams



Clinical Advisory Board

Regulatory strategy to build best package for intended label



Portfolio Acceleration Tools

Studies that unblock paths to benefit multiple product developers and ecosystem



Preclinical Services

Free services through the U.S. National Institute of Allergy and Infectious Diseases – including diagnostic services





Business Development Council

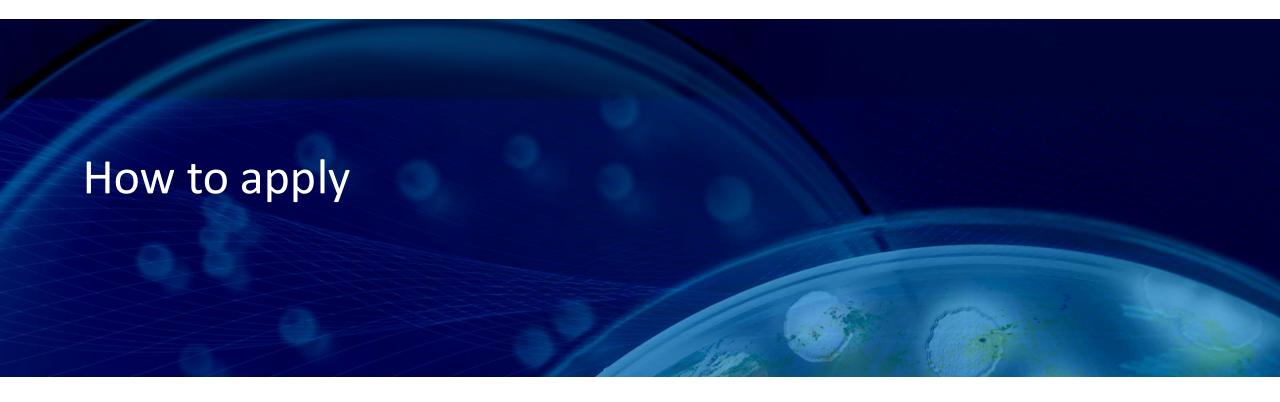
Pitch preparation and non-IPO roadshows to secure funding for advanced development



Final thoughts

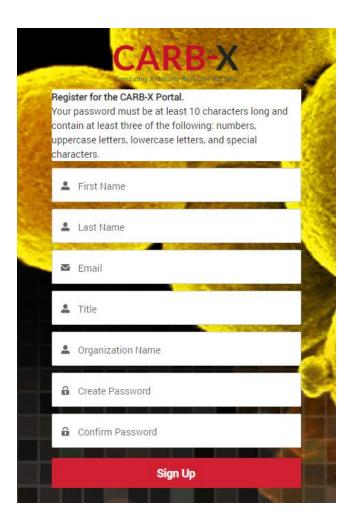
- Never too early to think how your product will be used in the patient journey
 - What TPP will bring meaningful differentiation to clinicians?
 - What experiments will emphasize/demonstrate key product characteristics?
 - How will you perform your clinical development (patient populations, etc.)?
- Data, Data, Data
 - If key data are missing/not included, it is impossible to assess the proposal
 - Pay particular attention to minimal entry criteria
- "Extraordinary claims require extraordinary evidence"
 - Be scientifically critical and transparent/realistic about program challenges
 - Important to work alongside CARB-X as a collaborator to solve problems





CARB-X Portal: Registration

- Beginning on 16 April 10:00 ET, applicants can register in the CARB-X Portal and complete an Expression of Interest for either funding theme.
- You will find the link to the CARB-X Portal on our website: https://carb-x.org/apply/apply-here/
- Your login name will be the email address you registered with appended with .carbx
 - If you have already registered, you will receive an email with your username.
- IMPORTANT: the Portal can only support one Application Contact per EOI. Please ensure that the registrant is the person responsible for submitting your EOI. Any collaboration on content should be done outside the Portal.

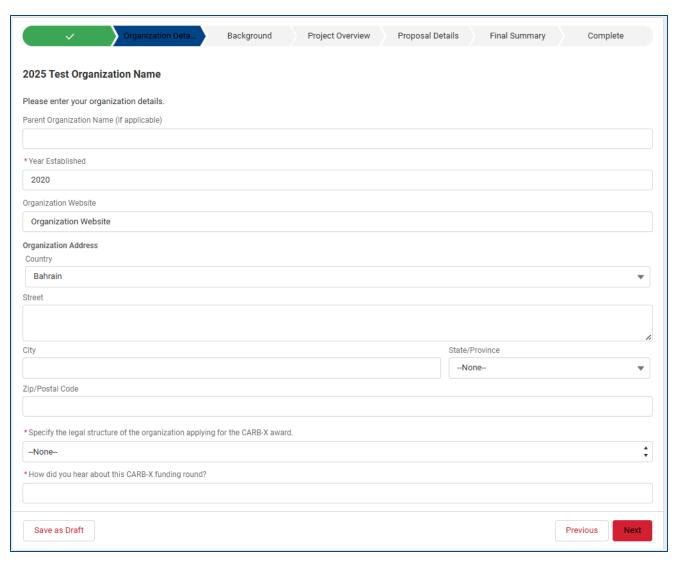




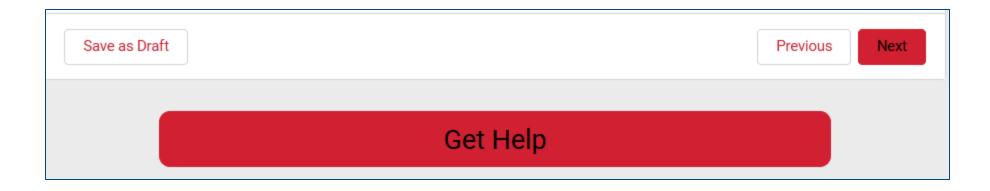
CARB-X Portal: Completing the EOI

Guides for every EOI will be available on our website: https://carb-x.org/apply/apply-here/

The EOI contains several screens with questions about your organization, your project, and your product.



CARB-X Portal: Completing the EOI

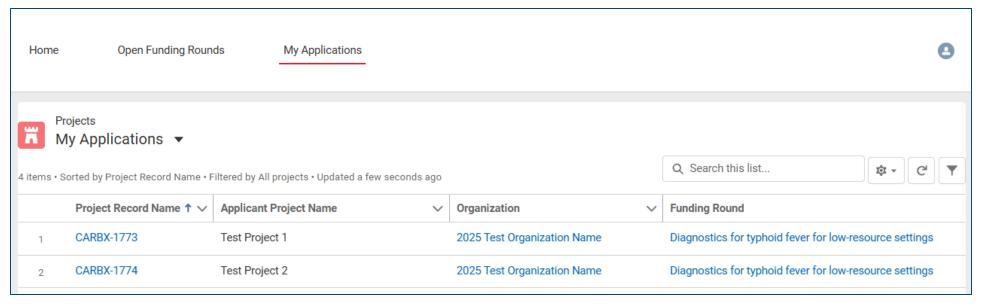


You may pause and save your draft EOI at any time by clicking the Save as Draft button and entering a pause reason. You can then resume your EOI at any time under "My Applications."

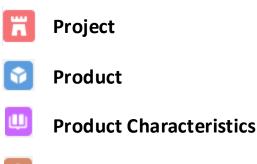
Please note: Once you resume a paused EOI, you must select Save Draft again before exiting – even if you make no changes. Otherwise, the EOI you resumed will be lost.

CARB-X Portal: Reviewing Your Submitted EOI

Submitted EOIs are displayed on the My Applications tab



• Click the **Project Record Name** to review your submitted responses, which are organized under four headings:



Product Pathogens

