2024 CARB-X Funding Rounds

What You Need to Know
Agenda

• About CARB-X
• Overview of 2024 Funding Call Design
• How to Apply
• Q&A
About CARB-X
The global partnership accelerating early-stage antibacterial R&D

- Three pillars: therapeutics, preventatives and diagnostics
- Non-dilutive funding and comprehensive support model
- Programs enter through active funding calls
- Focused on performance characteristics, pathogens + infectious syndromes with highest morbidity and mortality rates attributable to/associated with AMR
- Created the world’s most scientifically-diverse discovery & early-development portfolio, with significant progress:

1,400 Expressions of Interest
100 funded projects
36 active projects
14 | 4 FIH | V&V Tx/Pv | Dx
4 | 2 adv dev | CE marks all | Dx
Portfolio built and refined to respond to global burden of disease

Source: Antimicrobial Resistance Collaborators, The Lancet, published online January 20, 2022

* = mostly targeted secondary indication;
dark grey = global deaths attributable to AMR in 2019;
light grey = global deaths associated with AMR in 2019

CARB-X = first 92 projects
= omnibus
CARB-X is a crucial link in the antibacterial innovation chain

**Basic research**

**Early-Stage Product Development***

**Advanced development**

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**IMPORTANT:** Most organizations are placed where the majority of their activities take place. Some organizations may conduct activities in other links of the chain.

**CARB-X**

Combating Antibiotic-Resistant Bacteria

- (closing)
- (mainly TB)
- (pausing)
- (pre-competitive)
- (no AMR focus)

*HTL, lead opt., preclinical development, FIH

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(Coordination via jpiamr/OH AMR)
What CARB-X funds in our link of the chain

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<th>Tx</th>
<th>Pv</th>
<th>Dx</th>
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<tr>
<td>• Hit-to-Lead through FIH</td>
<td>• Antigen/composition discovery through FIH</td>
<td>• Feasibility through alpha-prototype development</td>
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How programs enter portfolio: active funding calls

- 8 funding calls (2016-2020)
  - First 4 “all-comer” calls, predicated on a product focused on one or more priority pathogens
  - Last 4 thematic (non-traditional products; vaccines & biotherapeutics; rapid diagnostics and Gram-negative-targeting therapeutics)

- 1 omnibus solicitation (2022-2023)
  - 3 funding themes (oral therapeutics; vaccines against top etiologies for neonatal sepsis; cross-pillar gonorrhea products)
  - 3 sequential intakes to allow for package-building or resubmission

- New funding themes shaped by 2023 Strategic Review
Stages and evaluation of applications

• non-confidential **Expression of Interest (EOI)**
  – reviewed by CARB-X R&D for responsiveness

• confidential written proposal/project narrative + high-level budget
  – juried by sub-teams of external Advisory Board

• presentation to virtual advisory board (invitation only)
  – juried by full external Advisory Board

• negotiations to enter CARB-X portfolio
  – recommended by Advisory Board and CARB-X R&D
  – decided by CARB-X Investment Committee
Application outcomes

2016 - 2020

- 1,163 Expressions of Interest
- 401 Short Forms
- 169 Long Forms + Program Pitches
- 92 Initial Subaward Contracts

2022 - 2023

- 237 Expressions of Interest
- 101 Project Narratives
- 37 Program Pitches
- 13 CIC Approved for Negotiations
A unique and layered support model

- Help teams to secure funding and partners for advanced development; includes annual Investor Day

- NIAID – recently expanded to Dx services

- Regulatory strategy to build best package for intended label

- R&D Core Team with decades of antibacterial R&D from both large and small companies

- Utilizes extensive, global SME pool across all disciplines

- Studies that unblock paths to benefit multiple product developers and ecosystem

- Pilot project under development

- Business Development Council

- Market-Shaping Support

- Preclinical Services

- Portfolio Acceleration Tools

- Clinical Advisory Board

- Company Support Teams

- R&D Core
A look at portfolio acceleration tools

**Many programs experience the same hurdles – let’s lower them**

- **early-evaluation of pre-existing resistance**
- **early-evaluation of antigenic variability risk**
- **consistent assessment of key safety risk**
- **models of efficacy with back-translation**
- **access to optimal adjuvants**
- **sample collection optimization**
- **clinical-trial design**

IHMA program cuts across all pillars
- 23 Tx (susceptibility); 7 Pv (antigenic conservation); 6 Dx (challenge panels) refresh underway
- Queensland nephrotoxicity studies transitioning to NIAID Preclinical Services
- Lung model standardization (IMI Combine/iiCON) and validation (CARB-X/Hartford Hospital)
- Discussions with NIAID to aid both vaccine developers and adjuvant innovators
- Urine, sputum challenging samples – better methods unlock interest in Dx development
- Superiority-design workshops; decolonization systematic review consortium
This is your CARB-X team
Overview of 2024 Funding Call Design
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<th><strong>GRAM-NEGATIVE PATHOGENS</strong></th>
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<td><strong>Required:</strong> direct-acting, small-molecule antibiotic (or small molecules that can be used in combination with an existing drug that can restore the potency of that drug to clinically useful levels in an in vitro MIC assay by inhibition of a specific resistance mechanism); MW &lt; 1500</td>
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<td><strong>Preferred:</strong> properties to deliver both intravenous and oral forms</td>
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<td><strong>Target Indications:</strong> hospital-associated and ventilator-associated bacterial pneumonia, complicated urinary-tract infection (and associated bacteremias)</td>
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<th><strong>PREVENTION OF INVASIVE DISEASE</strong></th>
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<td><strong>Required:</strong> novel approaches, with supportive preliminary data</td>
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<td><strong>Preferred:</strong> non-vaccine and non-monoclonal-antibody-based, unless novelty can be underscored with supporting preclinical data</td>
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<td><strong>Target Pathogens:</strong> <em>Staphylococcus aureus</em> and <em>Escherichia coli</em></td>
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<th><strong>DIAGNOSTICS FOR NEONATAL SEPSIS</strong></th>
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<td><strong>Key criteria:</strong> small sample volumes, rapid time-to-result, low cost-of-goods, POC data on clinical or contrived samples</td>
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<td><strong>Target Tests:</strong> (1) rapid triage (bacterial vs other; host response); (2) bacterial identification; (3) genotypic or phenotypic susceptibility tests</td>
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<th><strong>ALTERNATIVE SAMPLE TYPES FOR DIAGNOSING LOWER RESPIRATORY TRACT INFECTIONS</strong></th>
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<td><strong>Required:</strong> sample types other than bronchoalveolar lavage, endotracheal aspirate or sputum</td>
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<td><strong>Preferred:</strong> demonstration of detection of at least one bacterial pathogen in contrived or clinical samples at a clinically-relevant threshold</td>
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*Development stages in scope, minimal entry criteria and TPPs will be available on www.carb-x.org*
2024 solicitation

- There will be two funding intake cycles
- Applications for any of the four themes welcomed for each intake cycle

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<th>Cycle</th>
<th>EOI portal opens</th>
<th>EOI submission date</th>
<th>EOI disposition</th>
<th>Narrative submission date</th>
<th>Advisory review period</th>
<th>Narrative disposition</th>
<th>Advisory presentation &amp; review</th>
<th>CIC decisional meeting</th>
<th>Enter-into-negotiation notice</th>
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Key dates for first cycle

• EOI portal live: 18 March 2024 @ 10:00 ET
• EOI submission deadline: 29 March 2024 by 23:59:59 ET
How to apply
CARB-X Portal: Registration

- Beginning on 18 March 10:00 ET, applicants can register in the CARB-X Portal and complete the Expression of Interest for any of the four funding themes.

- You will find the link to the CARB-X Portal on our website: [https://carb-x.org/apply/apply-here/](https://carb-x.org/apply/apply-here/)

- Your login name will be the email address you registered with appended with `.carbx`

- Note: if you have already registered, you will receive an email with your username.
CARB-X Portal: Completing the EOI

Templates for every EOI are available on our website: https://carb-x.org/apply/apply-here/

2024 EOI Template for Therapeutics
2024 EOI Template for Preventatives
2024 EOI Template for Diagnostics for Neonatal Sepsis
2024 EOI Template for Alternative Sample Types

The EOI contains several sections with questions about your organization, your project, your product and/or proof-of-concept.

You may pause and save your draft EOI at any time by clicking the 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 object types:

  - **Project**
  - **Product**
  - **Product Characteristics**
  - **Product Pathogens**