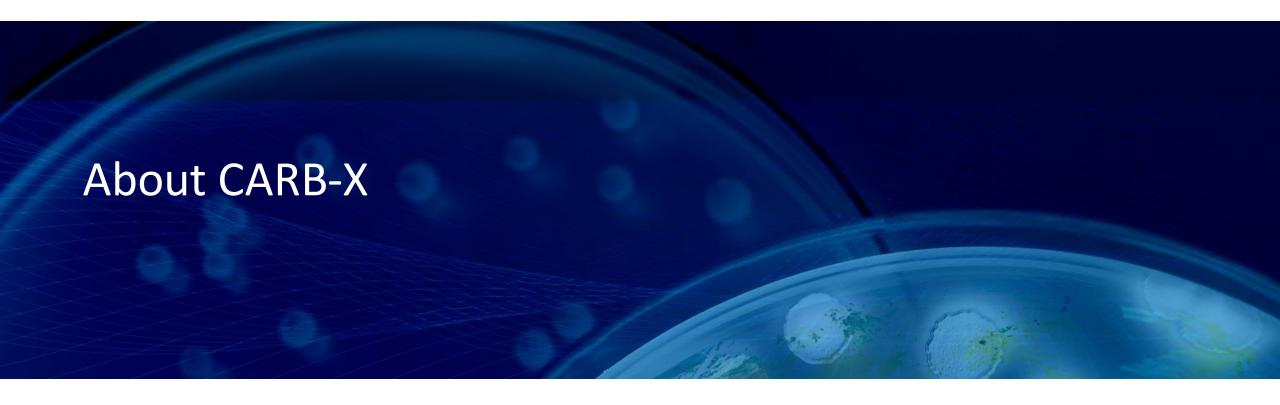






Agenda

- About CARB-X
- Overview of 2024 Funding Call Design
- How to Apply
- Q&A





The global partnership accelerating early-stage antibacterial R&D















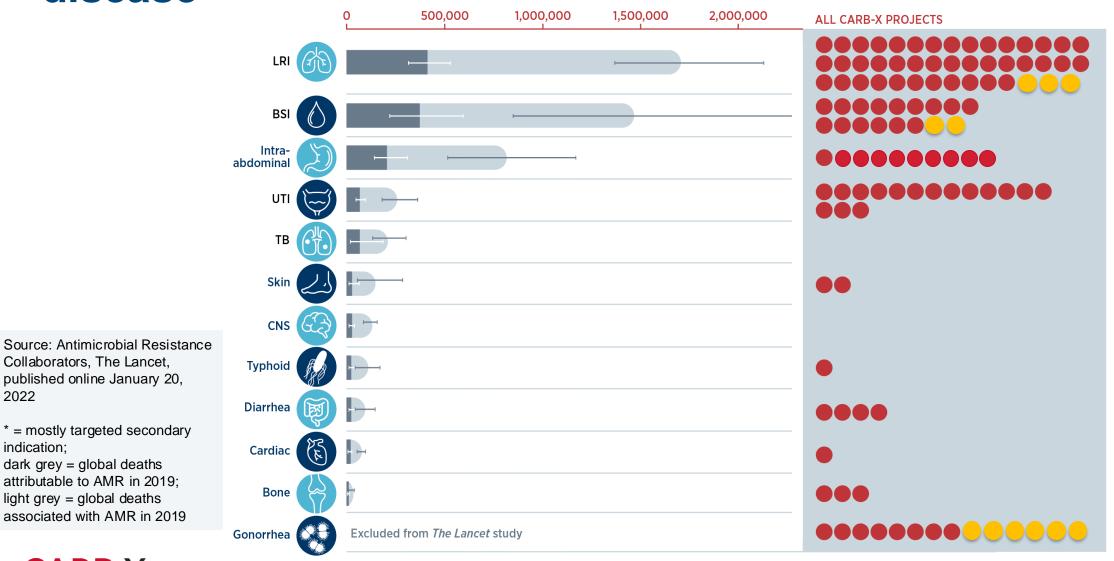




- Three pillars: therapeutics, preventatives and diagnostics
- Non-dilutive funding <u>and</u> comprehensive support model
- Programs enter through active funding calls
- Focused on performance characteristics, pathogens + infectious syndromes with highest morbidity and mortality rates attributable to/associated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



Portfolio built and refined to respond to global burden of disease



indication; dark grey = global deaths attributable to AMR in 2019; light grey = global deaths associated with AMR in 2019

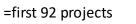
* = mostly targeted secondary

Collaborators, The Lancet,

2022

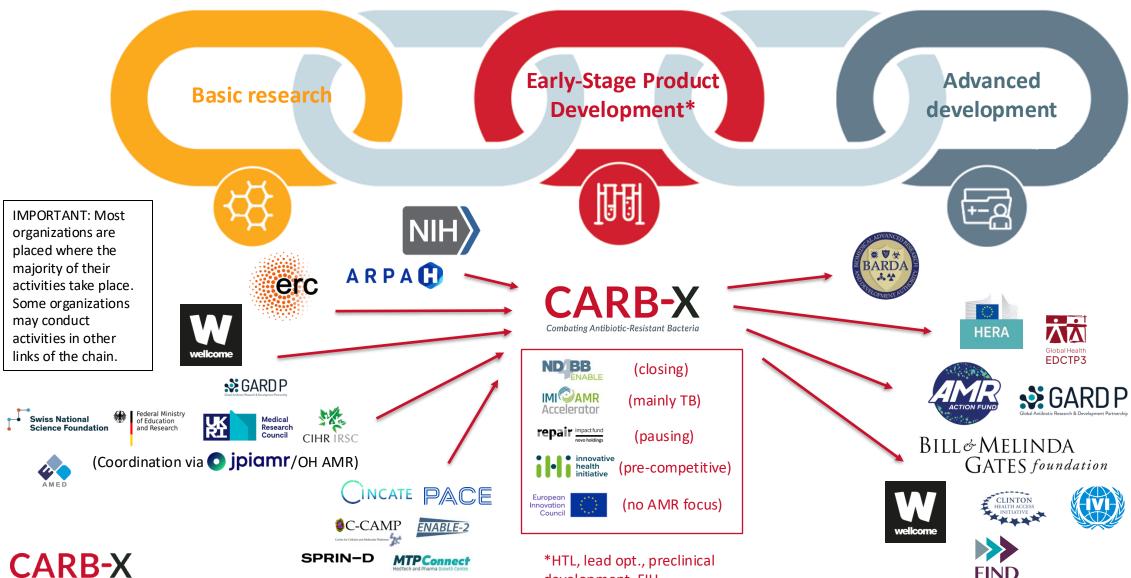
published online January 20,







CARB-X is a crucial link in the antibacterial innovation chain



development, FIH

What CARB-X funds in our link of the chain

Tx

Hit-to-Lead through
 FIH

Pv

 Antigen/composition discovery through FIH Dx

 Feasibility through alpha-prototype development

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

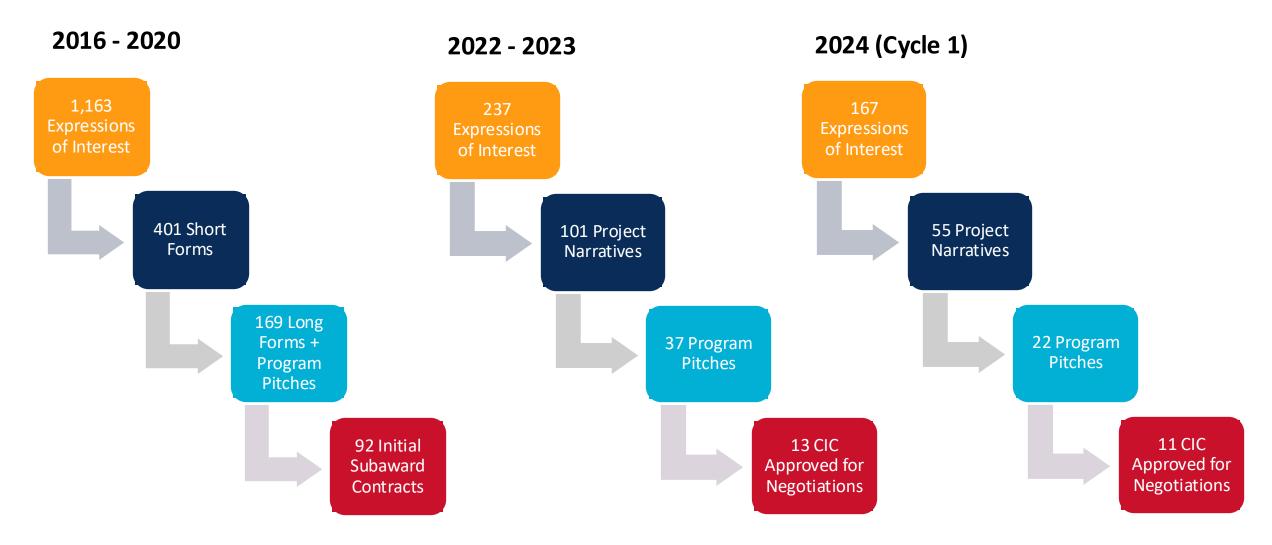


Stages and evaluation of applications

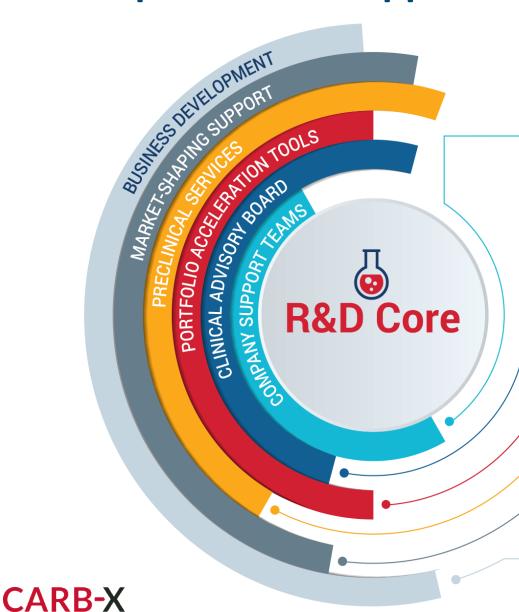
- non-confidential <u>Expression of Interest</u> (EOI)
 - reviewed by CARB-X R&D for responsiveness
- confidential written proposal/project narrative + high-level budget
 - juried by sub-teams of external Advisory Board
- presentation to virtual advisory board (invitation only)
 - juried by full external 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



A Comprehensive 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



Market-Shaping Support

Efficient deployment of new antibacterial products



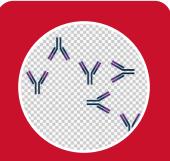
Business Development Pitch prepareties

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

A look at portfolio acceleration tools



earlyevaluation of
pre-existing
resistance



earlyevaluation 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

Many programs experience the same hurdles – let's lower them

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

































































THERAPEUTICS FOR INFECTIONS CAUSED BY GRAM-NEGATIVE PATHOGENS

Required: 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 < 1500

Preferred: properties to deliver both intravenous and oral forms

Target Indications: hospital-associated and ventilator-associated bacterial pneumonia, complicated urinary-tract infection (and associated bacteremias), bacterial enteric infections (diarrheal diseases)

PREVENTION OF INVASIVE DISEASE

Required: novel approaches, with supportive preliminary data

Preferred: non-vaccine and non-monoclonal-antibody-based, unless

novelty can be underscored with supporting preclinical data

Target Pathogens: Staphylococcus aureus and Escherichia coli

2024 Funding Call Themes

DIAGNOSTICS FOR NEONATAL SEPSIS

Key criteria: small sample volumes, rapid time-to-result, low cost-of-goods, POC data on clinical or contrived samples

Target Tests: (1) rapid triage (bacterial vs other; host response); (2) bacterial identification; (3) genotypic or phenotypic susceptibility tests

ALTERNATIVE SAMPLE TYPES FOR DIAGNOSING LOWER RESPIRATORY TRACT INFECTIONS

Required: sample types other than bronchoalveolar lavage, endotracheal aspirate or sputum

Preferred: demonstration of detection of at least one bacterial pathogen in contrived or clinical samples at a clinically-relevant threshold





2024 solicitation

- There are two funding intake cycles
- Applications for <u>any</u> of the four themes welcomed for <u>each</u> intake cycle

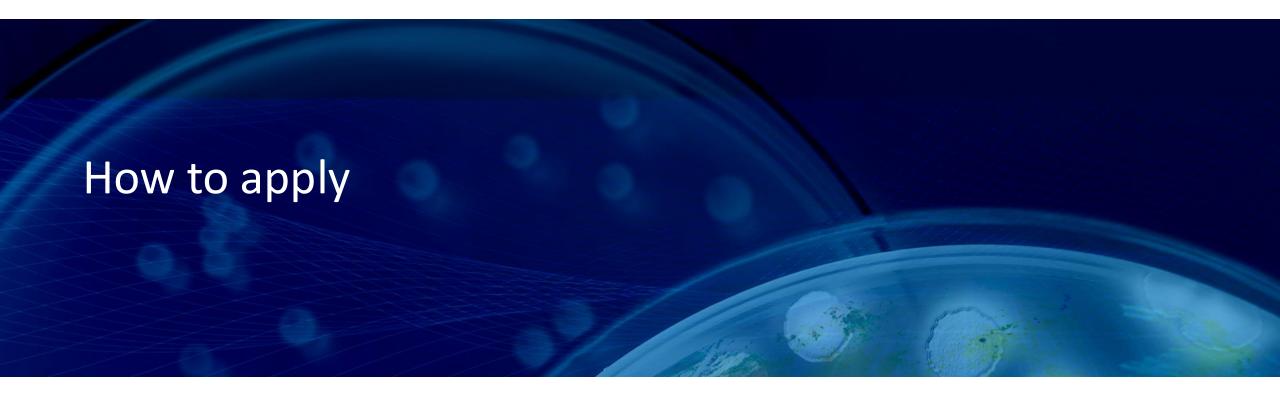
Cycle	EOI portal opens	EOI submission date	EOI disposition	Narrative submission date	Advisory review period	Narrative disposition	Advisory presentation & review	CIC decisional meeting	Enter-into- negotiation notice
1	18-Mar-24	29-Mar-24	5-Apr-24	6-May-24	23-May-24 to 7-Jun-24	14-Jun-24	2-Jul-24 to 1-Aug-24	26-Aug-24	3-Sep-24
2	23-Sep-24	4-Oct-24	11-Oct-24	12-Nov-24	3-Dec-24 to 17-Dec-24	6-Jan-25	22-Jan-25 to 21-Feb-25	10-Mar-25	19-Mar-25



Key dates for second cycle

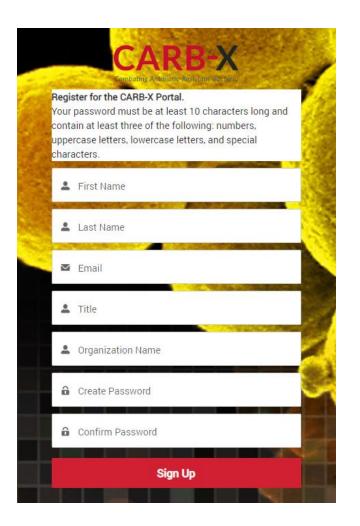
- EOI portal live: 23 Sept 2024 @ 10:00 ET
- EOI submission deadline: 4 Oct 2024 by 23:59:59 ET





CARB-X Portal: Registration

- Beginning on 23 Sept 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/
- 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

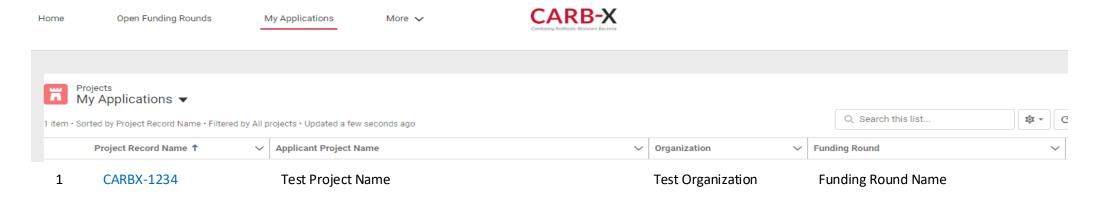
The EOI contains several sections with questions about your organization, your project, your product and/or proof-of-concept.

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

