Pre-Application Expression of Interest Form (EOI)

Intro:
All applicants for CARB-X Funding Round 1 (Non-traditional approaches) must submit an Expression of Interest Form (EOI). For details on the funding scope, priorities and timing, please visit www.carb-x.org. If your project is in scope, it will be assigned for scientific and business review, and you may be invited to complete a Short-Form Application.

*Please complete one form for each antibacterial product you are proposing.*

1. ABOUT YOU

A. Basic Information (*required fields)

First Name* _______________________________________
Last Name (or surname)* ___________________________
Email address * _________________________________
Address line #1 * __________________________________
Address line #2_____________________________________
City * _______________________ State/Province/Region _______________________
Zip/Postal Code ___________ Country* ___________
Phone Number * _______________
Mobile Number _______________
Organization* ________________________________
Organization’s Website ____________

2. ORGANIZATION

*denotes required field
B. Organizational Information

B1. Specify the legal structure of the organization applying for the CARB-X award:* (Select one)
   - LLC, corporation or other legal entity
     B1.1 What is the size of your business?*
       - Micro (<10 employees)
       - Small (<50 employees)
       - Medium (<250 employees)
       - Large (>250 employees)
     - Academic institutions or other non-commercial drug development center

B1.2 CARB-X can support products under development in academic or non-commercial drug development centers, but such organizations must have a track record of transitioning products from pre-clinical development to clinical research. Please note: CARB-X does not fund basic research (drug discovery) projects, including screening for novel antibacterials. If you are submitting an application from an academic institute or non-commercial drug development center, it is the responsibility of the applicant and host organization to demonstrate to CARB-X reviewers that it has:

   - 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' from organization (e.g. spin out, licensure to biotech)
   - Financial commitment and stability to cover the required cost share of at least 10% of the base stage dependent on stage of development and any subsequent option stages

Does your organization comply with each of the criteria?
   - Yes
   - No

➢ B1.3 Is the University or non commercial drug development center a legal entity?
   - Yes
   - No

- No legal entity established

*denotes required field
B2. Please indicate if you have applied to CARB-X or any of its funders/partner for the same or a substantially similar project.* [choose all that apply]

- CARB-X
- BARDA
- Wellcome Trust
- NIAID Pre-clinical Services
- NIH
- The Bill & Melinda Gates Foundation
- Global AMR Innovation Fund (GAMRIF) (UK)
- Bundesministerium für Bildung und Forschung – BMBF or Federal Ministry of Education and Research (Germany)
- Other US federal funding agencies

B2.1 Please specify previous CARB-X ID(s) (ex. 01CARB-X001):

C. Current Funding Sources

C1. Do you presently receive funding from any CARB-X funder/partner?* [choose all that apply.]

- BARDA
- Wellcome Trust
- NIAID Pre-clinical Services
- NIH
- The Bill & Melinda Gates Foundation
- Global AMR Innovation Fund (GAMRIF) (UK)
- Bundesministerium für Bildung und Forschung – BMBF or Federal Ministry of Education and Research (Germany)
- Other US federal funding agencies
- None of the above

D. CARB-X Project Proposal

D1. What is the name of your antibacterial Product or Project?:* __________________________

*denotes required field
D2. What stage of development is your product?* [choose one]
- Hit-to-Lead
- Lead Optimization
- Pre-Clinical
- Phase 1

D3. Please complete the table below by selecting your **product modality** and **targeted pathogen(s)** indicating for each pathogen, where applicable, whether your approach is **direct** or **indirect acting**. Please note that the scope of this funding round is limited to non-traditional approaches including indirect-acting small molecules (anti-virulence approaches, potentiators, BLI combinations, etc.), direct acting or indirect-acting large molecules (peptides, etc.), microbiome, phage, nucleic acid/antisense, drug conjugates (ADC, other dual acting drug conjugates, etc.) as per the pathogens in the table. If you must select **Other**, please be mindful that host-directed therapies as well as biocides/antiseptics/disinfectants are not in scope.*

<table>
<thead>
<tr>
<th></th>
<th>Small molecule</th>
<th>Phage</th>
<th>Microbiome</th>
<th>Peptid</th>
<th>Nucleic Acid/antisense</th>
<th>Drug Conjugates (ADC, other dual acting drug conjugates)</th>
<th>Other</th>
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<tbody>
<tr>
<td><em>Acinetobacter baumannii, carbapenem-R</em></td>
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<td><em>Pseudomonas aeruginosa, carbapenem-R</em></td>
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<td><em>Enterobacteriaceae, carbapenem-R, 3rd-gen ceph-R (ESBL)</em></td>
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<td><em>Salmonella spp, fluoroquinolone-R</em></td>
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<td><em>Neisseria gonorrhoeae, 3rd-gen ceph-R, fluoroquinolone-R</em></td>
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<td><em>Shigella spp, fluoroquinolone-R</em></td>
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<td><em>Enterococcus faecium, vancomycin-R</em></td>
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<td><em>Staphylococcus aureus, methicillin-R, vancomycin-IR</em></td>
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<td><em>Streptococcus pneumoniae, penicillin-NS</em></td>
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<td><em>Campylobacter spp, fluoroquinolone-R</em></td>
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<td><em>Group A Streptococcus</em></td>
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<td><em>Group B Streptococcus</em></td>
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*denotes required field
D3.1 [If indirect acting small molecule is selected] is your small molecule a new class?
  D 3.1.1 [if yes is selected] Please explain why your molecule is considered a new class. (limit to 100 words)
  D 3.2 [If Microbiome is selected] Please describe in 10 words or less: __________________________
  D 3.3 [if Other is selected] Please describe in 50 words or less: __________________________

D4. What is your intended mode of delivery?
  - IV
  - PO
  - Inhalation
  - Intramuscular
  - Subcutaneous
  - Other
    - D4.1 Describe in 100 words or less the mode of delivery and the rationale for the targeted pathogen(s). Topical delivery (other than inhalation) is not in-scope.

D5. Please describe your product in 1000 words or less. Your application will be judged on the merits of its scientific content; describe your science with as much data as possible. Please do provide sufficient data to allow a knowledgeable scientist to get a reasonable sense of the product. Do not provide other manuscripts, references, citations or similar. Note that the form can only accept text; you may not enter tables or graphics. Do not include foundational information regarding the significance of antibiotic resistance; this is not necessary, as the reviewers understand this.

4. FUNDING

*denotes required field
D6. For estimation purposes only, what is the likely funding request for Total Project and the duration of funding? CARB-X’s scope of funding extends to Phase I. If you do not request support up to and including Phase 1 in this funding round, you will need to submit a new application in a future funding round to support that work.

Note: you will have the opportunity to update these sections if progressed to the Short Form application.

Please use a start date of May 1, 2020 or later. This is an indicative date for start of funding at the earliest for this round and this date may be refined as the process develops.

- Total CARB-X Funding: ___________ (must be in US Dollars)
- Total Project Company cost: ___________ (must be in US Dollars)
- Total Project Cost Share (%): ___________
- Project start date: _____________
- Project end date: _____________
- Total Project Duration (months): __________

D7. For estimation purposes only, what is the likely funding request for the Base Stage of the project and the duration of the Base Stage?

- Base Stage Funding request from CARB-X: ___________ (must be in US Dollars)
- Base Stage Company cost: ___________ (must be in US Dollars)
- Base Stage Company Cost share (%): ___________
- Base Stage start date: _____________
- Base Stage end date: _____________
- Base Stage Duration (months): __________

D8. Describe the impact this funding will have on the advancement of the program: [free text field – limit to 100 words]

To submit your application, please enter the month and day of your birth. If you are invited to complete a Short-Form Application, this identification code will be used to establish access to our secure application system. This information will not otherwise be retained.

Once you submit your application, it will be moved to a secure server where it will be reviewed by a CARB-X team member. Once submitted, you will no longer be able to access your application. Please ensure all fields are filled before you click on submit. Duplicate applications will not be accepted.

*denotes required field