Pre-Application Expression of Interest Form (EOI)

Intro:
All applicants for CARB-X Funding Round 4 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.

☐ Your application is on a public form until transmitted to a secure site. Click here to continue to the application.

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

Version 2, October 7, 2019
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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 organizations with a track record of transitioning products from pre-clinical development to clinical research are of particular interest. 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 cost share are required dependent on the development stage.

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

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

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

C. Current Funding Sources

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

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

3. PROGRAM

D. CARB-X Project Proposal

D1. What is the name of your antibacterial Product or Project?:* [limit to 100 characters]

D2. What stage of development is your product? [choose one]
D3. What is your product’s targeted pathogen? (Check all that apply)

Please complete the table below by selecting your **product modality** and **targeted pathogen(s)** where applicable. Please note that the scope of this funding round is limited to Direct-acting small molecules (restricted to new class and/or new target).

- The spectrum of direct acting products can include Gram-positive pathogens however the program must prioritize the Gram-negative pathogens included in the product’s spectrum, as evidenced by the data developed at time of application and the workplan/TPP presented to CARB-X.
- New class is defined as: a core chemical structure (or scaffold) that does not have an antibiotic approved for human use by the FDA, EMA as of May 1, 2019.
- If program is an LpxC inhibitor program, applicants should access information available on the PEW Spark database, particularly, if the program is hydroxymate based to ensure proposals have considered the learnings appropriately and have these addressed upfront in these application submitted to CARB-X.

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>New Class</th>
<th>New Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acinetobacter baumannii, carbapenem-R</td>
<td>□</td>
<td>○</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa, carbapenem-R</td>
<td>□</td>
<td>○</td>
</tr>
<tr>
<td>Enterobacteriaceae, carbapenem-R, 3rd-gen ceph-R (ESBL+)</td>
<td>□</td>
<td>○</td>
</tr>
<tr>
<td>Salmonellae spp., fluoroquinolone-R</td>
<td>□</td>
<td>○</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae, 3rd-gen ceph-R, fluoroquinolone-R</td>
<td>□</td>
<td>○</td>
</tr>
<tr>
<td>Shigella spp., fluoroquinolone-R</td>
<td>□</td>
<td>○</td>
</tr>
</tbody>
</table>
D3.1 is your small molecule a new class or new target?
- Yes
- No

D 3.1.1 [if yes is selected] Please explain why your molecule is considered a new class or new target. (limit to 100 words)

D4. What is your intended mode of delivery?
- IV
- PO
- Inhalation
- Intramuscular
- Subcutaneous
- Other
  - [if other is selected] 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

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 1. 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.

- Total CARB-X Funding: ___________ (must be in US Dollars)
- Total Company cost: ___________ (must be in US Dollars)
- Cost Share (%): ___________
- Total Project Cost: ___________
- Project Start Date: ___________
- Project End Date: ___________
- Total Project Duration (months): ________

Please use a start date of September 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.

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 CARB-X Funding: ___________ (must be in US Dollars)
- Base Stage Company cost: ___________ (must be in US Dollars)
- Cost share (%): ___________
- Base Stage Total Cost: ___________
- Base Stage Start Date: ___________
- Base Stage End Date: ___________
- Base Stage Duration (months): ________

Please use a Base Stage start date of September 1, 2020 or later. This is an indicative date for start of Base Stage funding at the earliest for this round and this date may be refined as the process develops. Additionally, the start and end dates of the Base Stage must be within the start and end dates of the Total project.
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.

5. SUBMIT