CARB-X 2019 Funding Rounds – FAQ

Q: I need clarification regarding the exact scope of CARB-X's 2019 Funding Rounds, and which round is most appropriate for my technology. What is the best way to get detailed guidance?

A: Please review the 2019 Funding Rounds description in the Apply > What CARB-X Funds section of the CARB-X website at tps://carb-x.org/apply/what-carb-x-funds/. Additional questions regarding scope and eligibility can be submitted to carbxapp@bu.edu. We encourage you please first to review the information in the Apply section of the CARB-X website and to frame your questions as precisely as possible. This will enable us to answer your questions most effectively.

Q: In the sample EOI, phage therapy is limited to the 6 pathogens for which direct-acting therapeutics are eligible in Round 1. Does this mean that phage approaches are out of scope unless they address these 6 pathogens?

A: The sample EOI was designed on the assumption that phage are always direct-acting. To be in scope as a direct-acting agent, a phage technology needs to address at least one of the 6 pathogens (coverage of all 6 is not necessary). However, if a phage technology is to be used in a preventative approach, it would be in scope for Round 1 if it addresses any of an expanded list of pathogens, as outlined in the detailed guidance for Round 1. If you have a preventative phage technology and the EOI form does not have an appropriate checkbox for your targeted pathogen, please check the "indirect/other" box and provide an explanation in the relevant text field. Please keep in mind that you will need to have a clear rationale for why your approach is prevention instead of therapy (e.g., decolonization of carrier individuals who do not have active disease), how your product would be used clinically, and a plan for demonstrating clinical benefit.

Q: May I submit more than one application?

A: Yes. However, please carefully consider how much effort you will be able to invest in supporting each application.

Q: Can a university or health or research partnership apply for funding, or does the company need to be a start-up?

A: As long as the entity that is applying for funding is a legal entity, it does not need to be a start-up.

Q: What types of funding can be used towards cost share? For applicants at academic/research institutions, could cost share be met using research grants from local institutions or research agencies?

A: Funds raised from public or private investors, foundations, or other sources may be used to meet your cost share requirement, provided that those funding sources agree to do so according to the CARB-X terms of award, which is flowed down from the company to the third party entity providing the cost share. Please note, CARB-X requires documentation of the approval when applying cost share from a third-party source. U.S. federal or U.S. state/local governments funds (including NIH and SBIR grants) cannot be used towards cost share. In general, funding provided by non-U.S. governments may be considered to fulfill the cost share requirement, if the government consents to the CARB-X terms of award.

Q: How would an applicant demonstrate that cost share has been secured if it comes from internal (company) R&D funding?

A: During financial due diligence, we will need clarity on the source of the funds pledged for cost share. If the cost share does not appear on the audited financial statements, the applicant could be asked to provide additional verification such as a bank statement and a letter from the CEO.

Q: Does the applicant need to have all established intellectual property for the proposed project in place before applying?

A: No, but the applicant must have an Option or Letter of Intent for the transfer of any already established Intellectual property at the point of Long Form submission.]

Q: What kinds of activity will CARB-X fund in Phase 1?

A: CARB-X will fund programs through the end of Phase 1 SAD/MAD. To help companies prepare for post-Phase 1 work, CARB-X may (in parallel) fund CMC and other activities needed to support Phase 2 studies.

Q: Are there any restrictions on applicant size/structure?

A: The size of the applicant organization is not restricted. Please visit the Apply > Before You Apply section of the CARB-X website, in the Who Can Apply for CARB-X Funding? section for detailed guidance on applicant eligibility.

Q: Can two companies partner to submit a single application, if they have complementary technologies (e.g. unique therapeutic with a companion/complementary diagnostic)? Can a startup company co-apply with a well-established development partner as a subawardee under our grant?

A: Yes, but only one company can be the lead applicant organization. The relationship between the two partners will need to be described fully and meet all administrative and

corporate diligence requirements. The IP should be owned or controlled by the lead applicant organization.

Q: Can you apply across different bands (i.e., late preclinical and Phase 1)?

A: Yes. An application can span multiple development stages, with the work plan separated into (and contracted as) a Base and one or more Option stages as appropriate.

Q: When providing budget estimates, should all stages (including Phase 1) be included in the total number?

A: Yes.

Q: Do we need FDA meeting minutes to support applications for funding IND-enabling work?

A: It is not required, but if you have met with the FDA, we encourage you to include relevant information from those meetings in your application, subject to the page limit.

Q: Are ODA applications submitted or reviewed separately?

A: There is no separate application for ODA funding. Applicants whose proposed programs are eligible for ODA funding will be asked to complete a short document ("ODA justification") in addition to the CARB-X application.

Q: Given the restrictions of UK ODA funding, does this mean ODA is not available for 2019 Round 4, and therefore LMIC applicability is not part of Round 4 applications?

A: Applications in 2019 Funding Round 4 (direct-acting small molecules) are not within scope for ODA funding. However, this does not mean that programs with relevance to LMICs cannot apply to Round 4. Successful applicants in Round 4 will be supported by CARB-X using funds from non-ODA sources.

Q: Can UK companies apply with a non-ODA proposal?

A: Yes.

Q: Do overseas companies need to register in U.S.?

A: Applicants do not need to establish a business presence in the U.S. to be eligible for CARB-X funding. However, there are administrative registrations (e.g., DUNS, SAM) that need to be completed during contracting.

Q: Are proposals in the field of animal health relevant for the upcoming funding rounds?

A: No. CARB-X funds only programs with direct application to human health.

Q: If an applicant is a publicly traded company, can your corporate due diligence be limited to publicly available financial (SEC) documents?

A: Our corporate due diligence may not be fully satisfied by publicly available documents, even for public companies.

Q: How long does it take to get an answer from CARB-X on the EOI round?

A: Approximately 6 working weeks.

Q: If EOI to a Joint Oversite Committee decision takes about 8 months, when are the short form and long form submissions due?

A: Please refer to the detailed chart on **Apply > Before You Apply** in the How the CARB-X Application Process Works section. As an example, for the 2019 Funding Round 1 for Non-traditional approaches, EOIs must be submitted the first week of June, Short Forms will be due the first week of August and Long Forms due the first week of November.

Q: Where can I find information regarding CARB-X's indirect rate accounting policies?

A: Indirect costs (IDC) are costs incurred for common or joint objectives (e.g. overhead). If a company has an existing U.S. federally-negotiated indirect costs rate agreement, the applicable rate may be applied and CARB-X will reimburse for indirect costs. U.S. companies without an existing federally-negotiated rate are eligible for the *de minimus* rate of 10%. Non-U.S. companies are ineligible for indirect costs. CARB-X cannot sponsor an application for a federally-negotiated rate agreement.

Q: Is there a CARB-X policy on the purchase of equipment and investment in facility/infrastructure to enable a project (e.g., creation of a GMP production capability)?

A: Guidance is provided below regarding the allowable uses of CARB-X funding for equipment and infrastructure.

EQUIPMENT: Equipment is defined as tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more. Equipment must be allocated appropriately. CARB-X will only reimburse for its fair share of the equipment use. If the equipment will be used exclusively on the CARB-X project, and no other projects, it may be allocated at 100%. If the equipment will be shared amongst other projects, then decrease the use allocation commensurate to its use on the CARB-X project only (e.g., if the

company has 3 projects all using the same piece of requested equipment, determine a use allocation method, such as 50% project 1, 25% project 2, & 25% CARB-X project; or if equal use, 33.33% project 1, 33.33% project 2, & 33.33% CARB-X project, etc.).

INFRASTRUCTURE/CAPITAL EQUIPMENT: Capital Expenditures for general purpose or improvements to equipment, buildings & land are typically unallowable as direct charges except with prior written approval. Such costs would need to be vital to the success of the CARB-X project and be allocated and justified appropriately in the budget for consideration. It should be noted that Rental Costs of property and equipment are allowable if reasonable, allocable, and necessary for the CARB-X project.