

Mass. Eye and Ear Summit Fund Proposal Guidelines

Translating discoveries into treatments that address important unmet medical needs can have a profound impact on the quality of life for children and adults suffering with field of vision, hearing, and balance disorders. Traditionally, despite thousands of breakthrough medical discoveries being made each year, only a handful of new drugs and devices make it to market and the patients who need them.

The Mass. Eye and Ear Summit Fund will help overcome obstacles to commercial translation in a number of ways. It will:

- Fund promising technologies, positioning them to attract venture and industrial partners.
- Support access to expertise to lay the foundation for the handoff to a commercial entity.

Applications must address unmet clinical needs to improve healthcare outcomes and aim to generate viable technologies for commercial development. Awards include financial support in addition to business development, commercialization, and project management expertise.

Eligibility:

Faculty from the Mass. Eye and Ear are eligible to apply.

For-profit entities that have optioned or licensed the technology from Mass. Eye and Ear are eligible to apply as collaborators.

The proposed work must support the advancement of technology that is owned by Mass. Eye and Ear.

Funding Considerations:

Applicants may request up to \$300,000 direct costs. Indirect costs are provided at 15%

The Summit Fund supports the advancement of technology towards commercial development. Funds are not awarded for the purchase of equipment, travel, tuition, or publication costs except under unusual circumstances.

Awards will be released in accordance with milestone and tranche plans determined with assistance from the Project Manager.

Deadlines:

Pre-proposals may be submitted anytime throughout the year. There is no set deadline for pre-proposal submissions. A subset of applicants who submit pre-proposals will be invited to develop full proposals.

Format:

All pre-proposals and full proposals must be submitted using the on-line application system at <https://bic.fluidreview.com>

All full proposals, including all supporting documents must be uploaded into the on-line application system.

All text material must be in a readable font (at least Arial 11 point), and margins must be at least 0.5 inches.

Questions:

Questions may be sent to Lesley Watts, Operations and Finance Director at (857) 307-2440 | lwatts@partners.org or Ojas Mehta, Partners Innovation, Director at (857) 307-2469 | omehta1@partners.org

Mass. Eye and Ear Summit Fund

FAQs

What is B-BIC and how is it related to the Mass. Eye and Ear Summit Fund?

The Boston Biomedical Innovation Center (B-BIC) is a life sciences accelerator designed to translate academic discoveries into the commercial sector. B-BIC provides Commercialization Coaching, Project and Program Management services to the Mass. Eye and Ear Summit Fund.

What support does B-BIC provide to applicants during proposal preparation?

Applicants invited to submit full proposals receive substantial coaching and project management input from B-BIC staff members as they develop their full proposals to submit for funding consideration.

May I submit more than one application?

Applicants may submit more than one application. However, each application must have a distinct set of aims and workplan.

Is there a limit to the number of applications I can submit?

The Summit Fund and B-BIC encourage and support the entrepreneurial personality. Investigators are encouraged to re-apply with proposals for different applications of the same technology as well as new technologies. Early determination of technology failure is part of the process.

How do I know if my technology is at the right stage to be commercialized?

Projects should have already advanced from scientific discovery into the early stages of product development. As a guiding principle, projects should be within one or two steps of a commercial transaction (selling, partnering, licensing, startup, or entry into another commercialization assistance program to continue development). Broad guidelines for different types of projects are as follows:

- *Small molecule therapeutics*: The compound is at the lead optimization or preclinical stage. The target is known, and/or there is some method or assay to determine its effect.
- *Biologics or cell based therapies*: The biologic or cell population has been identified and some reasonable method of development, sourcing, manufacture, or proliferation is proposed. Mechanism of action has been determined to a sufficient level that there is a reasonable understanding of the product to be developed or tested in the project.
- *Interventional medical device*: The proposal includes prototype development and testing, either on the bench or in animals. Physiologic experiments have been conducted or reported in the literature, providing rationale for prototype development.
- *Diagnostic medical device/IVD/MDx*: The proposal includes prototype development and some method of testing.
- *Health IT, software, apps, and algorithms*: The proposal should be beyond the concept stage and already have an existing code base. The idea should be grounded in previous experiments or solid peer reviewed evidence. The proposal should include steps to validate the technology by demonstrating its efficacy versus the standard of care or

utility in pilot studies or user testing, or, if already validated, to refine the technology to make it appropriate for commercialization.

Should I disclose any unprotected proprietary information in the submission?

Do not disclose any unprotected proprietary information. Protecting proprietary information is the responsibility of the applicant and the applicant institution. Pharma and device companies are actively involved in the program providing expertise and supporting the development of commercial outcomes.

Are there any requirements for the budget?

Each performance site must submit a separate budget using the Budget Form template. Budgets must be signed by an authorized institution official and uploaded into the web-based submission system along with the other supporting documents.

A separate budget narrative must be provided that includes a description of personnel responsibilities and effort commitments as well as justification of all project costs. Applications must include a breakdown of the budget request in accordance with the proposed milestones and deliverables.

When will I be notified if my pre-proposal has been selected to submit a full proposal?

You can expect to receive an answer within four to six weeks. Every attempt will be made to return an answer as quickly as possible, but heavy volume and reviewer availability will determine the actual turn-around time.

My pre-proposal was accepted and I have been invited to submit a full proposal. Now what?

If you are invited to submit a full proposal to the program, you can download the proposal application form from the MEE Summit Fund website or from within the electronic system at <https://b-bic.fluidreview.com/>

Who retains the rights to any intellectual property generated by a proposal?

Management of intellectual property will be determined by the policies of the institution(s) responsible for the proposal. Investigators shall seek to establish IP via disclosures and patent filings with their institution's technology transfer office, with an indication that MEE Summit Fund support has been used to develop the technology.

When will I receive my funding?

Projects selected for funding will receive initial funds once all administrative materials have been received, should any additional materials be needed. Awardees will be required to work with their B-BIC Project Managers in order to trigger the release of additional funds.

How will I receive my funding?

Separate funds will be established at Mass. Eye and Ear to support research projects costs.

What if I need to re-budget?

Requests to re-budget more than 25% of the total award should be submitted to Lesley Watts, B-BIC Operations and Finance Director, for prior approval. Re-budgeting any amount into subcontracts, patient care, or equipment, if such costs were not approved as part of the initial budget, must be submitted for prior approval.

Will no-cost-extensions be allowed?

No-cost-extensions may be requested by completing the Request for No-cost-Extension Form that is available from the B-BIC program office. Please send your requests, with current IRB/IACUC approvals as applicable to the

B-BIC Operations and Finance Director. All reports must be up to date before a no-cost-extension request will be reviewed.

What if I need to change the direction or focus of my project?

Any significant change in your work plan, including a change in the use of animals or humans, must be submitted in writing by email for prior approval. Requests for change of scope should be sent to the B-BIC Operations and Finance Director who will ensure review by the Program Directors.

What are my reporting responsibilities if I receive an award?

All projects must provide final written reports using the MEE Summit Fund program report template. Awardees may be asked to provide additional information on an interim basis to assess the progress of the individual project and effectiveness of the overall program. Additional information may be requested that is related to intellectual property and the start-up and/or licensing opportunities enabled by the Summit Fund investment.

What should I do if I forgot my username and/or password to the on-line submission system at <https://b-bic.fluidreview.com> Your username is the email address that you used to register in the system. If you do not remember your password, just below the password entry box will be a link “Forgot your password?” which will take you to a second page. Once you enter your email address, a message will be sent to your regular email inbox with. The message will contain a link to reset your password

Who do I call for help if I have further questions?

Questions may be sent to

- Lesley Watts, Operations and Finance Director at (857) 307-2440 | lwatts@partners.org or
- Ojas Mehta, Partners Innovation, Director at (857) 307-2469 | omehta1@partners.org