Boston Biomedical Innovation Center
Funding Programs Guidelines

The Boston Biomedical Innovation Center provides funding to accelerate the development of device, diagnostic, and therapeutic solutions to heart, lung, blood, and sleep disorders. Applications must address unmet clinical needs to improve healthcare outcomes and aim to generate viable technologies for commercial development. Projects that are in the earlier stages of pre-commercial development will be considered as applications to the Pilot funding program. Awards through the DRIVE program are provided as investments in early-stage technologies that have the potential for commercial translation within two years. Awards include resources provided through business development and project management expertise.

Areas of Interest:

B-BIC will select early stage technologies that address unmet medical needs or offer great scientific opportunities with either immediate commercial potential or otherwise present compelling reasons for continued development. B-BIC is currently focused on innovative devices, diagnostics, and therapeutics related to heart, lung, blood, and sleep disorders. Program priority areas include, but are not limited to, the following:

- Cardiovascular Diseases: heart failure, atherothrombosis, myocardial infarction, hypertension, atrial fibrillation along with other atrial and ventricular arrhythmias, sudden cardiac death, adult and pediatric congenital heart disease, cardiovascular complications of diabetes and obesity, acquired valve disease, cardiomyopathies, and peripheral vascular diseases.
- Lung Diseases and Sleep Disorders: asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, sleep-disordered breathing, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis.
- Blood Diseases and Resources: sickle cell disease (SCD), the thalassemias, Fanconi anemia, Diamond-Blackfan anemia and other bone marrow failure syndromes, iron metabolism, fetal hemoglobin production, white blood cell disorders, myeloproliferative and myelodysplastic syndromes, hematopoietic stem cell transplantation and novel cell-based therapies, transfusion medicine (red blood cells, platelets, and plasma) and blood banking including technologies to store and process blood, thrombosis and hemostatic disorders including but not limited to idiopathic thrombocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP), hemophilia, and coagulation factor deficiencies and disorders.

Eligibility:

Faculty from the B-BIC member institutions are eligible to apply.

For-profit entities are eligible to apply as collaborators with Principal Investigators at member institutions.

The proposed work must support the advancement of technology that is owned by a B-BIC member institution.

Funding Considerations:

Applications to the Pilot program may request up to $50,000 direct costs.

Applications to the DRIVE program may request up to $200,000 direct costs.

Indirect costs are provided at the applicant institution's Federally-negotiated rate up to 77% MTDC for awards supported with Federal dollars.

The current NIH salary cap must be applied to personnel costs.

B-BIC supports the advancement of technology towards commercial development. Funds are not awarded for the purchase of equipment, travel, or publication costs except under unusual circumstances.

DRIVE awards will be released in accordance with milestone and tranche plans included with the application.

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. Invited full proposals

 submitted by the first week of the calendar quarter will be given priority review.

Format:

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

All required supporting documents, including the B-BIC budget form, compliance form, NIH biosketches, and institutional authorization should be included in one .pdf file and 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 may be sent to Lesley Watts, B-BIC Operations and Finance Director,
at (857) 307-2440 / lwatts@partners.org

FREQUENTLY ASKED QUESTIONS

These FAQs are broken out into those that address the program overview, proposal requirements, what to expect after proposal submission, supporting documentation that is needed, and expectations for post-award collaborations. If additional information is needed, contact information is provided at the end of this document.

PROGRAM OVERVIEW:

Who can apply for B-BIC grants?
Anyone holding a faculty appointment at a B-BIC member institution may apply for a B-BIC grant.

What are B-BIC's areas of interest?
B-BIC will select early stage technologies that address unmet medical needs or offer great scientific opportunities with either immediate commercial potential or otherwise present compelling reasons for continued development. B-BIC is currently focused on innovative devices, diagnostics, and therapeutics related to heart, lung, blood, and sleep disorders. Program priority areas include, but are not limited to, the following:

- Cardiovascular Diseases: heart failure, atherothrombosis, myocardial infarction, hypertension, atrial fibrillation along with other atrial and ventricular arrhythmias, sudden cardiac death, adult and pediatric congenital heart disease, cardiovascular complications of diabetes and obesity, acquired valve disease, cardiomyopathies, and peripheral vascular diseases.

- Lung Diseases and Sleep Disorders: asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, sleep-disordered breathing, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis.

- Blood Diseases and Resources: sickle cell disease (SCD), the thalassemias, Fanconi anemia, Diamond-Blackfan anemia and other bone marrow failure syndromes, iron metabolism, fetal hemoglobin production, white blood cell disorders, myeloproliferative and myelodysplastic syndromes, hematopoietic stem cell transplantation and novel cell-based therapies, transfusion medicine (red blood cells, platelets, and plasma) and blood banking including technologies to store and process blood, thrombosis and hemostatic disorders including but not limited to idiopathic thrombocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP), hemophilia, and coagulation factor deficiencies and disorders.

What is a DRIVE grant?
A DRIVE grant is an investment in which the B-BIC will be significantly involved to help demonstrate proof of value. In addition to financial support, DRIVE projects receive active mentoring during proposal development from a team with significant entrpreneurial, product development, technology, and business development expertise and project management support during the award.

What are the differences between DRIVE grants and Pilot grants?
DRIVE grants offer up to $200,000 to support direct costs for milestone-driven projects that are expected to be completed within 18 – 24 months. A B-BIC project manager will be assigned to the project in addition to the award.
Pilot grants offer up to $50,000 to support direct costs for completion of tasks that help demonstrate proof of concept, such as prototype development or reproducibility experiments in different model systems. Pilot grants are expected to be completed within one year.

May I submit more than one application?
Applicants may submit more than one application to both the Pilot and DRIVE programs. However, each application must have a distinct set of aims and workplan.

Is there a limit to the number of applications I can submit?
B-BIC encourages and supports 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.

PROPOSAL REQUIREMENTS:

When are applications due?
B-BIC accepts pre-proposals for DRIVE and Pilot grants at any time throughout the year in accordance with the priority areas noted above. Invited full proposals received by the first week of the calendar quarter will be given priority review.

Where and how do I submit my pre-proposal and full proposal?
All pre-proposals and full proposals must be submitted through the online submission system at
https://b-bic.fluidreview.com/

What needs to be included in my pre-proposal to the DRIVE program?
Pre-proposals submitted to the DRIVE program need to include a brief description or elevator pitch and answer the required sections of the on-line the web document. To begin submitting a pre-proposal, enter the fields requested on the initial submission page and your elevator pitch, and click the continue button to register the pre-proposal. You will automatically be sent to the next web-based submission page to complete the required sections. You may return to the initial page to edit your elevator pitch by clicking on the overview tab. Once you are ready to submit your DRIVE pre-proposal, click the green button to submit it to the next stage within the on-line submission system.

What needs to be included in my pre-proposal to the Pilot program?
Pre-proposals submitted to the Pilot program must be no more than two pages. To begin submitting a Pilot pre-proposal, enter the fields requested on the web-based submission page and click the continue button to register the pre-proposal. You will automatically be sent to the next web-based submission page to complete the required sections. Once you are ready to submit your Pilot pre-proposal, click the green button to submit it to the next stage within the on-line submission system.

 Are there format requirements for pre-proposals and full proposals?
 All text material must be in a readable font (at least Arial 11 point), and margins must be at least 0.5 inches.

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 center providing expertise and supporting the development of commercial outcomes.

What support does B-BIC provide to applicants during proposal preparation?
Site miners, domain experts, and staff are available to answer questions throughout the year. Pre-proposals accepted into the DRIVE process will also receive substantial input and mentoring to develop the full DRIVE plan proposal.

SUPPORTING DOCUMENTATION (BUDGETS, BIOS, COMPLIANCE & AUTHORIZATIONS):

What is the "institutional sign off page?"
The institutional signature page is the official form or letter provided by your research administration office indicating that your full proposal is approved by your institution. All full proposal submissions must include institutional authorization. Signature from an authorized business official on the budget page is sufficient for institutional authorization.

Are there any requirements for the budget?
Each performance site must submit a separate budget using the Center Budget Form that is modeled on the NIH 398 format. 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 personnel responsibilities and effort commitments as well as descriptions of all project costs. DRIVE grant applications must include a breakdown of the budget request in accordance with the proposed milestones and deliverables.

Are there any budget restrictions or limitations?
Personnel costs are subject to the NIH salary cap. Equipment must be well justified to the purpose and exclusive need of the project. Alterations and renovations will not be supported. DRIVE grants offer up to $200,000 to support direct costs that are expected to be completed within 18 – 24 months. Pilot grants offer up to $50,000 to support direct costs and are expected to be completed within one year.

Are biosketches needed?
Standard NIH Biosketches with Parts A-D for all key personnel must be combined into a single file and uploaded to the on-line submission system.

What information is needed regarding the use of human or animal subjects?
Full proposals must include information about the use of human and/or live vertebrates in compliance with standard NIH application requirements. In addition, each performance site must submit separate compliance information using the Center Compliance Form. The form must be uploaded to the on-line submission system.

Where can I find the supporting document forms?
If you are invited to submit a full proposal, budget and compliance forms are available within the on-line submission system from within the full application stage at https://b-bic.fluidreview.com/ . Please contact the B-BIC office if you have any difficulty acquiring the forms. There is no standard form for institutional authorization; each institution may use their individual format.

What is the earliest possible start date?
Awards can begin once all administrative documents have been received, should any additional materials be needed. Applicants selected for funding can expect to receive funding notification within four months. Awards can begin once all administrative documents have been received, should any additional materials be needed.

What is the indirect cost rate?
B-BIC is jointly funded by the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI), its supporting partner institutions, and industry partners. As a result, B-BIC will reimburse Pilot

and DRIVE recipient institutions for indirect costs in accordance with the funding source providing support for the individual project award. Pilot and DRIVE grants will primarily be supported by Federal funds and will receive reimbursement for indirect costs in accordance with the recipient institutions' federally negotiated indirect cost rate, MTDC, up to the rate that is received by B-BIC. B-BIC will endeavor to support grants using Federal funds to the extent possible within the overall budget but reserves the right to fund grants through non-federal funding sources in order to best manage the flow of funds into the Center and accommodate its open solicitation process.

** MTDC includes all directs costs with the exception of capital equipment, patient care costs, alterations and renovations, animal care, and sub-contract costs over $25,000 per sub-contract aggregated over the grant project period.

What is the Institutional Support requirement?
Awards to investigators at Beth Israel Deaconess Medical Center, Boston Children's Hospital, Boston University, Boston Medical Center, Draper Laboratories, Massachusetts Institute of Technology, Northeastern University, Forsyth Institute, and Tufts University include an institutional support requirement per the agreements reached with these institutions as affiliate members of B-BIC. The institutional support requirement is equal to half of the direct costs of the project and must be transferred to B-BIC. A commitment to this support will be needed prior to award; the commitment is not needed at the time of proposal submission.

Institutional support is used to support the project and the investment of our coaches, project managers, and skills development center. Awards are granted with full Federal overhead on top of the total direct costs. B-BIC does not take royalties or IP ownership, because we know what it takes to get a technology to the point where accelerators enter the picture. Institutional support enables our member institutions to support B-BIC infrastructure while still being able to tie their support back to specific gains at their institutions. Questions regarding institutional support should be addressed to Lesley Watts, Operations and Finance Director | lwatts@partners.org.

WHAT TO EXPECT AFTER PROPOSAL SUBMISSION:

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 B-BIC.org website or from within the electronic system at https://b-bic.fluidreview.com/

When will I be notified if my full proposal for a DRIVE grant has been selected for funding?
Once a full proposal is received, external review may take up to four months to allow for sponsor input.

Who reviews the applications?
B-BIC reviewers include practicing clinical specialists and domain experts, engineers and scientists with broad experience in medical innovation, and business development and commercialization experts.

Will I receive a copy of the reviewers' comments?
Reviewer comments will be anonymized and returned to applicants to the extent that it is practicable.

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 responsible for the proposal. Investigators funded by B-BIC shall seek to establish IP via disclosures and patent filings with their institution's technology transfer office, with an indication that B-BIC funding has been used to support the work. Copies of such communications should be submitted to the B-BIC program office in parallel.

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. DRIVE grant awardees will be required to submit milestone reports in order to trigger the release of additional funds.

How will I receive my funding?
Awards will be released via cost-reimbursement subcontract with the exception of projects that will be conducted at Brigham and Women's Hospital, which serves as the prime institution and fiscal agent for B-BIC. Separate funds will be established within the B-BIC chief code to support research projects conducted at the prime institution.

Once the necessary compliance and administrative approvals are received, Pilot projects will be awarded in full at the outset of the project period.

DRIVE award will be released in accordance with the approved milestones.

POST AWARD COLLABORATION:

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 to the B-BIC Administrative Director.

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.

How do I acknowledge B-BIC funding in publications?
Publications resulting from work supported by B-BIC should include a statement such as "Research reported in this publication was supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health award number U54HL119145." Please send a copy of all publications to the B-BIC program office.

What are my reporting responsibilities if I receive a B-BIC DRIVE or Pilot award?
All projects must provide final written reports to the B-BIC program office. Awardees and their home institutions may be asked to provide additional information on an interim basis to assess the progress of the individual project and effectiveness of the overall B-BIC program. Additional information may be related to intellectual property and the start-up and/or licensing opportunities enabled by the B-BIC investment.

What is expected for collaborations and how can I contribute to B-BIC sustainability?
Opportunities to share research and technology development may arise for which investigators may be invited to participate. It is anticipated that investigators are motivated to showcase and enhance their work and promote the B-BIC program.

Further, there is an expectation that investigators are motivated to see their research have an impact on patient care and the healthcare marketplace through start-up and/or licensing opportunities. B-BIC provides guidance, support, and connections with the tech transfer and entrpreneurial communities. Grantees understand that if funded by B-BIC, they will be asked to assess these opportunities with their home institutions and participate to the extent that opportunities are practicable.

ADDITIONAL HELP:

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?
The B-BIC main office number is 857-307-2440. Email may also be sent to Lesley Watts, B-BIC Operations and Finance Director, at lwatts@partners.org.