

Life Sciences Milestone Achievement Program (MAP) Solicitation Fiscal Year 2019

1. Summary

The Milestone Achievement Program (MAP) is a program created to address the need of early-stage life sciences companies to reach critical value-creating technical milestones. In addition, the program's goals are to fill a gap in the existing funding environment and to enable companies to attract additional follow on funding.

The MAP will fund grants to Massachusetts companies to support their work toward completion or fulfillment of technical milestones, e.g. prototype development, pre-clinical work and clinical testing. Successful completion of the milestone is expected to contribute to the overall development of the technology, as well as create value for the company. Companies applying to the program must be in the fields of **life sciences**, which include **bioinformatics, biopharmaceuticals, biotechnology, diagnostics, medical devices and digital health**.

Up to \$2 million is available for this round to fund grants of up to \$200,000 to life science companies, selected through an application and review process. Applications to the program are **due no later than Friday, December 14, 2018 at 12:00 p.m. (noon) EST** via an online submission.

2. Who We Are

The Massachusetts Life Sciences Center (Center) is an investment agency that supports life sciences innovation, research, development and commercialization. These investments create jobs and support advances that improve health and wellbeing. The Center offers the nation's most comprehensive set of incentives and collaborative programs targeted to the life sciences ecosystem. These programs propel the growth that has made Massachusetts the global leader in life sciences. The Center creates new models for collaboration and partners with organizations, both public and private, around the world to promote innovation in the life sciences. For more information, visit www.masslifesciences.com

3. MAP Model

A Massachusetts-based life sciences company will submit an application and proposal for a new milestone the company needs to complete. The Center will then conduct and administer a review process in order to select fundable milestones.

- **Milestone Goal:** Early-stage life sciences companies have various needs in regards to their overall development. This program is designed to support the achievement of technical milestones necessary to reach a value inflection point for the company. Ideally, the milestone has been identified and informed by conversations with potential follow on investors.
- **Evaluation:** Upon submission of an online application, the Center will conduct an internal review to ensure that all applicants are eligible for the program. A Scientific Advisory Board (SAB), comprised of scientific and industry experts, will then review eligible applications and recommend high scoring applicants to the Center's Investment Committee. The Investment Committee will then recommend finalists to the Center's Board of Directors, for

discretion of final awards.

4. Eligibility Criteria

- The Applicant company (Applicant) must be a for-profit corporation, limited liability company, sole proprietorship, or partnership located in the Commonwealth of Massachusetts, which is registered to do business in Massachusetts, and in good standing.
 - **Note:** Applicants will be required to provide Certificates of Good Standing from the Department of Revenue and Secretary of State no later than January 4, 2019. Certificates of Good Standing must not be dated prior to July 1, 2018. If an applicant does not have Certificates in this timeframe, an applicant must request one no later than the date of submission and upload proof of this request.
- The Applicant must be a life sciences company as defined by the Center’s authorizing statute (e.g., bioinformatics, biopharmaceuticals, biotechnology, diagnostics, medical devices or digital health).¹
- Subject to the requirements below, Applicants must have raised / received as of the date of application:
 - At least \$50,000 and no more than \$5,000,000
 - No MLSC funding may be included to meet the minimum threshold
 - No more than \$100,000 in non-convertible debt
 - No more than \$1,000,000 in equity or convertible debt
 - No more than \$5,000,000 in grants
- The Applicant must outline and describe a new milestone to be achieved with Center funds.
 - Fundable milestones include:
 - Prototype development
 - Technology assessments
 - Manufacturing scale-up
 - Production of clinical supply
 - Pre-clinical work
 - Clinical trials
 - Filing 510k, IDE, IND
 - Regulatory strategy design
 - Market analyses
 - KOL interviews
 - Competitive assessments
 - Examples of what is not fundable:
 - Paying board members and/or paying scientific advisory board members
 - Paying off debt
 - Paying for ongoing expenses, such as utilities and rent.

¹ For purposes of the Program, “life sciences” means advanced and applied sciences that expand the understanding of human physiology and have the potential to lead to medical advances or therapeutic applications including, but not limited to, agricultural biotechnology, biogenetics, bioinformatics, biomedical engineering, biopharmaceuticals, biotechnology, chemical synthesis, chemistry technology, diagnostics, genomics, image analysis, marine biology, marine technology, medical devices, nanotechnology, natural product pharmaceuticals, proteomics, regenerative medicine, RNA interference, stem cell research and veterinary science.

- Paying for legal fees (I.E. IP filing and prosecution, contract negotiation, freedom to operate studies)
- The Applicant must have engaged with potential future investors, in addition to demonstrating an understanding of what milestone or types of milestones may be required to secure follow on investment.
- The Applicant must be able to issue its own equity (stock or units of ownership) if majority owned (50% or more) by a parent company.
- Applicant must have one full time equivalent (FTE) employee.
- The Applicant must be in compliance with all other Center agreements, if any.
- The Applicant must not be a Center Accelerator Loan Awardee.

5. Funding

- Up to \$2,000,000 (USD) in funding is available for this round of the program. The number and amount of awards will be determined by the quality of the proposals.
- The Center will provide awardees a grant of no more than \$200,000.
- Eligible expenses are direct costs related to the milestone and may include: direct labor, clinical trials, consultants and subcontractors, materials, supplies, equipment, and travel (excluding mileage and meals) up to 2.5% of the total Award.

Companies awarded grants of up to \$200,000 will receive the payments using the following structure:

- \$25,000 payment upon execution of the Grant Agreement.
- Subsequent payment requests will be based on a reimbursement basis for costs incurred related to the milestone.
- Grantees will be required to submit an invoice to the MLSC with supporting documentation of the costs incurred (invoices, receipts, etc.) with a detailed description of the goods or services purchased. Expenses relating to direct labor (salaries and fringe) will have to be supported by a payroll register. Note that for the first payment request after the execution of the Agreement, grantees will also be required to report on and submit the backup documentation on how the initial \$25,000 was used.
- Invoices should be submitted to MLSC no more frequently than monthly and for a minimum of \$25,000.
- MLSC will withhold the final payment until all required deliverables and Final Report have been satisfactorily received.
- Failure to submit a Final Report within 60 days of the milestone completion or termination of the grant, whichever is earlier, will result in forfeiture of the final invoice, unless otherwise approved by the MLSC.
- Costs incurred for the proposed milestone must be within the 24-month term of the Grant

6. Deliverables

Awarded companies are required to submit to the Center the following reports:

- **Semi-Annual Reports** – will be submitted within thirty (30) calendar days at the end of June 30th and December 31st of each year beginning with December 31, 2019. This report summarizes progress of the milestone, describes the use of funds relative to the original proposal, and explains, if applicable, any changes to the proposed plan. A **Final Report** will be due at the completion of the milestone or within 60 days after the termination of the Grant Agreement, whichever is earlier.
- **Post-Progress Report** – will be submitted by all awardees, within 90 days of the end of each calendar year for a total of 2 years following submission of the Final Report. This report should describe the financial, clinical and market impact resulting from the grant and number of new FTE employees employed by the company since the completion of the milestone.

7. Program Process

The Center has full discretion and authority to determine (1) which Massachusetts companies, if any, are entitled to receive awards under the program and (2) the amounts of any such awards. Submission of an application does not guarantee the award or receipt of any award or other benefit under the program. The Center reserves the right to close the call for applications at any time.

In Figure 1 we highlight the overall process by which the applications are submitted, evaluated and the decisions are communicated.

Figure 1

The steps in the process are described below:



Application

- Applications will be accepted from October 2, 2018 through 12:00 p.m. (noon) EST on Friday, December 14, 2018 via an [online application](#).
- Applicants are allowed to submit only one application containing one milestone proposal for the FY 2019 Milestone Achievement Program.

Evaluation

- The Center will conduct an administrative review of each application to check that eligibility criteria have been met.
- An initial screening evaluation of each eligible application will be conducted by the Center's Scientific Advisory Board, and will be assigned to reviewers based on expertise and relevancy. All evaluators will be Center approved.
- Dependant on the evaluator's comments, applicants may be asked to clarify the proposal or to provide further information. Applicants may be expected to present at up to two in-person meetings to discuss the proposal: if selected, the first meeting will be in front of the SAB, and, if advanced, the other in-person meeting will be before the Investment Committee.
- The Investment Committee will make a final recommendation for funding to the Center's Board of Directors.

Awards

- The Center's Board of Directors is expected to review and approve recommended proposals at the May 2019 Board meeting. At the same Board meeting, the Board will certify awardees as certified life sciences companies in accordance with the Center's statute.

Funding

- Grants will be given to the awarded Massachusetts companies upon signing a Grant Agreement with the Center and according to the schedule described in item 5 (Funding).

8. Evaluation Criteria

The purpose of the Milestone Achievement Program is to fill a gap in the funding environment and enable early-stage companies to attract additional follow on funding through completion of value-creating milestones. The primary criteria for assessing the applications include the merit of the technology and opportunity, the necessity of the proposed milestone, and the extent to which the milestone can be completed in a timely and cost-efficient manner. Applications will be evaluated based on how well they meet the following criteria:

Technology	<ul style="list-style-type: none"> • Feasibility of technology execution • Degree to which novelty of technology addresses unmet need and market • Stage of current development • Competitive landscape
Team / Mentorship	<ul style="list-style-type: none"> • Team qualifications and experience • Utilization of existing human resources • Level of support from active mentors, including Board members and their experience
Milestone Importance	<ul style="list-style-type: none"> • Scope and feasibility of proposed milestone • Importance of milestone to company success • Degree to which milestone has been informed by potential investor & advisor engagement
Milestone Budget and Timeline	<ul style="list-style-type: none"> • Proposed use of MLSC funds • Adequacy of funds in relation to milestone cost, and if inadequate, availability of additional resources & partners to fill gap • Quality and cost of service providers involved • Ability to start and complete milestone within proposed timeframe
Leverage on public investment	<ul style="list-style-type: none"> • Potential to create economic, health care or technology transfer impact to Massachusetts

9. Confidentiality

Refer to Appendix A which fully describes the requirements related to confidentiality and handling of public records as set forth in the Massachusetts Public Records Act, M.G.L. c. 66 (the “Public Records Act”), which governs the retention, disposition and archiving of public records. For purposes of the Public Records Act, “public records” include all books, papers, maps, photographs, recorded tapes, financial statements, statistical tabulations, or other documentary materials or data, regardless of physical form or characteristics, made or received by the Center.

10. General Conditions

Contractual Requirements

The Center intends to enter into an Agreement with the Awardees containing certain standard provisions. A copy of

the standard Agreement is available on the Center's website. The Center reserves the right to amend the Agreement without further issuance of another solicitation. Please be advised that this standard Agreement must be executed in substantially the form provided and the terms and conditions therein are non-negotiable.

Waiver Authority

The Center reserves the right, at its sole discretion, to waive minor irregularities in submittal requirements, to request modifications of the application, to accept or reject any or all applications received, and/or to cancel all or part of this solicitation at any time prior to awards.

Disclaimer

This solicitation does not commit the Center to award any funds, pay any costs incurred in preparing an application, or procure or contract for services or supplies. The Center reserves the right to accept or reject any or all applications received, negotiate with all qualified Applicants, cancel or modify the solicitation in part or in its entirety, or change the application guidelines, when it is in its best interests. An application does not constitute an award.

Changes/Amendments to Solicitation

This solicitation has been distributed electronically using the Center's website. It is the responsibility of Applicants to check the Center's website for any addenda or modifications to the Solicitation to which they intend to respond. The Center, the Commonwealth of Massachusetts, and its subdivisions accept no liability and will provide no accommodation to Applicants who submit an application based on an out-of-date solicitation document.

Appendices and Attachments

Appendix A: Confidentiality and Public Records Information

Contact Us

For more information about the Massachusetts Life Sciences Center and this program, please see:

<http://www.masslifesciences.com/programs/map>.

E-mail an industry team member: Map@Masslifesciences.com.