



Commonwealth of Massachusetts
Office of the State Auditor
Suzanne M. Bump

Making government work better

Official Audit Report – Issued February 14, 2018

Massachusetts Life Sciences Center

For the period July 1, 2013 through June 30, 2017





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Making government work better

February 14, 2018

Jay Ash, Secretary
Executive Office of Housing and Economic Development
1 Ashburton Place, Room 2101
Boston, MA 02108

Michael J. Heffernan, Secretary
Executive Office for Administration and Finance
24 Beacon Street, State House, Room 373
Boston, MA 02133

Dear Secretaries Ash and Heffernan:

I am pleased to provide this performance audit of the Massachusetts Life Sciences Center. This report details the audit objectives, scope, and methodology for the audit period, July 1, 2013 through June 30, 2017. My audit staff discussed the contents of this report with management of the agency, whose comments are reflected in this report.

I would also like to express my appreciation to the Massachusetts Life Sciences Center for the cooperation and assistance provided to my staff during the audit.

Sincerely,

A handwritten signature in blue ink, appearing to read "SMB", written over a light blue circular background.

Suzanne M. Bump
Auditor of the Commonwealth

cc: Travis McCready, President and Chief Executive Officer, Massachusetts Life Sciences Center

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LIST OF ABBREVIATIONS

ACL	Audit Command Language
CEO	chief executive officer
CFO	chief financial officer
DOR	Department of Revenue
MLSC	Massachusetts Life Sciences Center
SAB	Scientific Advisory Board

EXECUTIVE SUMMARY

In accordance with Section 12 of Chapter 11 of the Massachusetts General Laws, the Office of the State Auditor has conducted a performance audit of the Massachusetts Life Sciences Center (MLSC) for the period July 1, 2013 through June 30, 2017. According to its website,

The Massachusetts Life Sciences Center (MLSC) is an investment agency that supports life sciences innovation, education, research & development, and commercialization. The MLSC is charged with implementing a \$1-billion, state-funded investment initiative.

In this performance audit, we examined MLSC's administration of its capital and investment programs and its tax incentive program to determine (1) whether MLSC awards and monitors grants, loans, and tax incentives in accordance with applicable laws, contracts, and policies and (2) whether programs related to grants, loans, and tax incentives promote MLSC's mission of encouraging innovation in the life sciences; commercializing health-related products, cures, and treatments; and fostering economic development and job creation.

Our audit revealed no significant instances of noncompliance by MLSC that must be reported under generally accepted government auditing standards.

OVERVIEW OF AUDITED ENTITY

The Massachusetts Life Sciences Center (MLSC) was established by Section 24 of Chapter 123 of the Acts of 2006 and codified as Chapter 23I of the Massachusetts General Laws as an independent quasi-governmental organization to stimulate economic development and job creation through research and development, manufacturing, and commercialization of health-related innovations in the life sciences.¹ MLSC's activities include providing grants, loans, and tax incentives, as described in this report's appendix, to private institutions and grants to public institutions, as well as strengthening bonds across the Massachusetts life science community. Although it was established in 2006, MLSC had no significant activity, and only one employee, through the fiscal year that ended in June 2008. On June 16, 2008, Chapter 130 of the Acts of 2008 (the Life Sciences Act), which committed the Commonwealth to investing \$1 billion in the life science industry over a 10-year period, was signed into law.

The table below summarizes the grants, loans, and tax incentives MLSC awarded from its inception through the end of the audit period, as well as the number and totals awarded only during the audit period.

MLSC Financial Awards

Type of Award	Number of Awards July 31, 2006– June 30, 2017	Amount Awarded July 31, 2006– June 30, 2017	Number of Awards July 1, 2013– June 30, 2017	Amount Awarded July 1, 2013– June 30, 2017
Grants	233	\$513,771,882	119	\$ 141,828,889
Loans	32	22,441,196	7	6,249,696
Tax Incentives	206	181,751,836	95	84,781,596
Total	<u>472</u>	<u>\$717,964,914</u>	<u>221</u>	<u>\$ 232,860,181</u>

Grant award amounts actually disbursed from MLSC's inception through the end of the audit period totaled \$464,611,390. Of this amount, \$237,068,847 was disbursed during the audit period. Loans disbursed totaled \$22,441,196 from inception, of which \$9,234,196 was disbursed during the audit period.

1. According to Section 2 of Chapter 23I of the General Laws, "life sciences" are "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, [ribonucleic acid] interference, stem cell research and veterinary science."

A seven-member board of directors oversees MLSC's operations. The Secretary of Administration and Finance and the Secretary of Housing and Economic Development, or their designees, are the board's co-chairs. Four board members are appointed by the Governor, and in accordance with MLSC's enabling legislation, the remaining board member is the president of the University of Massachusetts or his/her designee. The board appoints a president, who is the chief executive officer of MLSC and oversees 14 staff members.

A certified public accounting firm audits MLSC's annual financial statements in accordance with generally accepted government auditing standards.

AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

In accordance with Section 12 of Chapter 11 of the Massachusetts General Laws, the Office of the State Auditor has conducted a performance audit of certain activities of the Massachusetts Life Sciences Center (MLSC) for the period July 1, 2013 through June 30, 2017.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Below is a list of our audit objectives, indicating each question we intended our audit to answer and the conclusion we reached regarding each objective.

Objective	Conclusion
1. Did MLSC properly administer its Capital and Investment Fund Programs?	Yes
2. Did MLSC properly administer its Life Sciences Tax Incentive Program?	Yes

To achieve our audit objectives, we gained an understanding of the internal controls we determined to be relevant to our audit objectives and tested the controls' operating effectiveness over the awarding, payment, and monitoring of MLSC grants and loans, as well as the awarding and monitoring of MLSC tax incentives. We conducted further audit testing as described below.

Grants and Loans

To gain an understanding of MLSC's practices regarding the awarding and payment of grants and loans, we reviewed pertinent MLSC policies and interviewed management and staff members involved in these functions.

Organizations seeking grant funds must submit an application, which MLSC's staff reviews for completeness. Because of the technical nature of the subject matter, most proposals are reviewed by MLSC's Scientific Advisory Board (SAB), which consists of 20 professionals, including PhD-level scientists,

medical doctors, and life science company executives.² Some grants are also subject to peer review³ and review by the board of directors' investment committee. The SAB makes recommendations to the board of directors, which approves or rejects the proposal. Subsequently, an agreement is signed by the president of MLSC or another designated MLSC official and by the president or chief executive of the recipient entity. Payments are not issued until an agreement is executed. When a grant or loan awardee submits a payment request, the manager of the grant or loan program sends a check request to the finance team for review and processing. Only the president, chief financial officer (CFO), and general counsel are authorized to sign checks, and all checks equal to or greater than \$10,000 must be signed by two of those three people. Supporting documentation, such as invoices, must be provided for each check and available for review at the time of signing. Additionally, awardees are required by the grant agreements to submit quarterly and annual reports to MLSC to remain in good standing. The process is similar for the Life Sciences Accelerator Loan Program.

To determine whether MLSC followed Section 6 of Chapter 23I of the General Laws as well as its own policies regarding the awarding of grants, we selected a nonstatistical judgmental sample of 20 grants from a population of 119 (representing \$44,622,978 of \$141,828,899 awarded during the audit period). We reviewed the selected awards to verify staff review of application information; peer and/or SAB review, if necessary; approval by the board of directors; and award agreements signed by MLSC's CEO, as well as to determine whether the purpose of each award was consistent with MLSC's mission.

We tested all seven (100%) of the loans made during the audit period, totaling \$6,249,696, to determine whether they were reviewed by the SAB, peer reviewers, and the board of directors' investment committee and approved by the board of directors. We also verified that each loan resulted in an executed loan agreement signed by the CEO, or another designated officer of MLSC, and that the purpose of each loan was consistent with MLSC's loan solicitation⁴ and mission.

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2. Some grants, such as the internship program, legislative earmarks, education grants, and chief executive officer (CEO) discretionary awards, do not require SAB review. (For the internship program, the board authorizes the amount of funds to be spent in a particular year but does not select the individual grantees. Additionally, in 2013, the board of directors voted to allow the CEO to make awards, at his/her discretion, up to a total of \$350,000 per year without prior board approval. The CEO reports annually to the board the awards s/he has approved.)
 3. Peer reviewers are life sciences business and scientific experts selected by the SAB. Peer reviewers perform their review before any SAB review to eliminate projects that have questionable scientific merit or chance of payback.
 4. MLSC issues proposals, referred to as solicitations, to provide loan financing to early-stage life science companies in Massachusetts. Companies must submit applications and other information that meet the requirements in the proposal. The process is competitive, and applicants are not guaranteed to receive loans.
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To determine whether grant and loan payments were adequately reviewed and were consistent with MLSC practices and applicable contract agreements, we used Audit Command Language (ACL) audit software to develop a stratified statistical random sample (95% confidence level) of 62 payments, totaling \$103,411,457, from a population of 2,005 payments, totaling \$246,303,043, made during the audit period. We tested each payment to determine whether there was supporting documentation (e.g., invoices), a completed check request, a check signed in accordance with MLSC requirements, CFO approval, and an annual (or quarterly, if no annual report was due yet) report from each awardee receiving payments.

Tax Incentives

To gain an understanding of MLSC's practices regarding the awarding and monitoring of tax incentives, we reviewed pertinent laws and MLSC policies, and we interviewed management and staff members involved in these operations.

The Life Sciences Tax Incentive Program was established as part of MLSC's enabling legislation (Section 5d of Chapter 23I of the General Laws). Under the program, MLSC, in consultation with the Department of Revenue (DOR), awards tax incentives of no more than \$25,000,000 annually. Tax incentives proposed by MLSC must be reviewed and approved by the Commissioner of Revenue with regard to the tax cost of extending them. They must then be approved by the Secretary of Administration and Finance. Awardees must provide annual and quarterly reports detailing their numbers of full-time employees (headcounts), and tax incentives are subject to revocation if recipients do not meet the headcounts stipulated in their agreements. Most awardees that do not meet 70% of their minimum agreed-upon headcounts are subject to investigation and possible termination of their agreements; awardees that meet less than 40% must have their agreements terminated. Upon termination, MLSC notifies DOR, which, as of the termination's effective date, disallows any future tax benefits allowed under the agreement and recaptures (claws back) the value of any such benefits already provided.

To determine whether MLSC awarded tax incentives in accordance with the General Laws and its own requirements, we tested a nonstatistical judgmental sample of 20 (totaling \$29,634,245) of 95 (totaling \$84,781,596) tax incentives awarded during the audit period to determine whether (1) MLSC verified that each applicant was in good standing with the Secretary of State and DOR and, for awards after fiscal year 2013, had obtained approval from the Department of Unemployment Assistance; (2) the Commissioner of Revenue and the Secretary of Administration and Finance approved the tax incentive

proposed by MLSC; (3) the MLSC board of directors approved the tax incentive; and (4) the tax incentive, if accepted, was documented in a signed agreement.

To determine whether MLSC monitored tax incentive awards to ensure that awardee companies met the terms of their award agreements (e.g., adding the number of jobs specified in the agreements) and took appropriate action when they did not, we reviewed a nonstatistical judgmental sample of 24 (totaling \$50,086,937) of 98 (totaling \$88,698,679) tax incentive awards that were subject to monitoring during the audit period.⁵ We tested each tax incentive to determine whether MLSC (1) received and reviewed certified reports specifying the awardee's headcount and (2) took appropriate action, including termination of the agreement, if the awardee did not meet the agreement terms (e.g., did not add the number of jobs committed to). Except where noted, we used nonstatistical sampling to help us achieve our audit objectives and therefore did not project our results to the various populations.

Data Reliability

We relied primarily on physical documentation such as contracts, agreements, annual and quarterly reports from awardees receiving funding or tax relief, resolutions by the board of directors, minutes from the board's meetings, advisory board reviews and recommendations, check requests, checks, invoices, and supporting documentation. To ensure the accuracy of payment data from the automated accounting system, we selected a sample of grant account and investment account payments from the general ledger and reconciled the payment data to source documentation (invoices and canceled checks). We used ACL to perform additional validity and integrity tests on the general ledger data, including (1) scanning for duplicate entries; (2) testing for missing data; (3) testing for grant, activity, and transactional codes other than those associated with the Capital and Investment Fund Programs; and (4) determining whether all document dates and effective dates were within the audit period.

MLSC gave us a list of tax incentives awarded since its inception. Each year, MLSC consults with DOR on tax incentives and develops a group of proposed incentives, which must be approved in writing by DOR and the Secretary of Admiralty and Finance. We traced a sample of tax incentives awarded by MLSC to the proposed tax incentive amounts certified by DOR to verify that they were consistent.

We determined that the data were sufficiently reliable for the purposes of this audit.

5. Tax incentive awards can only be claimed in years after the award year and therefore are only subject to monitoring after the award year.

APPENDIX

Massachusetts Life Sciences Center Programs

The Massachusetts Life Sciences Center (MLSC) has various programs that provide loans, grants, and tax incentives to industrial organizations and nonprofit entities to encourage the expansion and vitality of the life science sector in Massachusetts. Except where otherwise indicated, the following program descriptions are excerpted from MLSC's website.

Programs for Academic and Nonprofit Organizations

Capital Program

The Competitive Capital Program is designed to provide grants for capital projects that support the life sciences ecosystem in Massachusetts by enabling and supporting life sciences workforce development and training, research and development, commercialization and/or manufacturing in the Commonwealth. Applicants are academic organizations, research institutions, research hospitals, business incubators and other non-profit organizations. MLSC recognizes that investment in capital projects and infrastructure is required to create and sustain the attributes that make Massachusetts attractive to innovation clusters such as life sciences. This program is designed to help fund high potential economic development projects that promise to make a significant contribution to the state's life sciences ecosystem.

Cooperative Research Matching Grant Program

According to the press release "Massachusetts Life Sciences Center Announces New Round of Cooperative Research Matching Grants," issued June 26, 2015,

The MLSC's Cooperative Research Matching Grants seek to increase industry-sponsored research at academic institutions in Massachusetts in order to accelerate scientific discoveries that lead to commercially viable products and treatments. Under the program, applicants may receive up to \$500,000 over two years. The grants support research that could lead to life-saving therapies and commercialized products, and seek to further the goal of sustaining and growing the state's vital life sciences ecosystem.

STEM Equipment and Supplies Grant Program

The STEM Equipment and Supplies Grant Program enables the purchase of equipment and supplies for high schools and middle schools in the Commonwealth in order to train students in life sciences technology and research, as well as addresses a funding gap in capital dollars for public and not-for-profit workforce training and educational institutions. The program also seeks to increase student achievement and student interest in STEM

(Science, Technology, Engineering, and Math), as well as support the implementation of state STEM standards.

The program also offers funding for teacher professional development to ensure that all recipient schools have teachers that are trained to use the equipment and have access to relevant curricula that deploy the equipment in labs and activities that support learning goals throughout the academic year.

Programs for Industry

Life Sciences Accelerator Loan Program

The Accelerator Loan Program is a funding program intended for early-stage life sciences companies in Massachusetts. Accelerator loans bridge the gap in a company's capital-raising lifecycle, providing the company with time and resources to advance to a point at which it would become a good candidate for private investment. . . .

Applicants are early-stage life sciences companies with a high potential for technology commercialization, rapid growth, and private equity financing. For therapeutics companies, the applicants should not have raised more than \$15 million in total equity financing. For non-therapeutics companies, the applicants are companies that have raised no more than \$7.5 million in total equity financing.

High School Apprenticeship Challenge

The Massachusetts Life Sciences Center (MLSC) High School Apprenticeship Challenge facilitates and funds paid internship opportunities for high school students throughout the Commonwealth. Since the program first launched in 2016, the MLSC has supported 106 internships at 49 life sciences companies and research institutions.

The program also offers an after-school laboratory training program for select school districts during the spring that aims to better prepare students for summer internships.

Internship Challenge

The Massachusetts Life Sciences Center's Internship Challenge is a workforce development program focused on enhancing the talent pipeline for Massachusetts companies engaged in life sciences. The program facilitates the placement of college students and recent graduates who are considering career opportunities in the life sciences in paid internships across the state. Consistent with the MLSC's role as a catalyst in growing the talent needed by the life sciences industry, the program is designed to create hundreds of new internship opportunities each year by enabling small businesses to hire paid interns.

Objectives of the Internship Challenge include expanding the pool of prospective employees who have practical experience, enhancing opportunities for mentoring, enabling more students to explore career opportunities despite the challenging economic

environment, and providing to students interested in working in the life sciences a peer network through educational and informational networking events.

Life Sciences Tax Incentive Program

In order to expand life sciences–related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences, the Massachusetts Life Sciences Center [offers] tax incentives to companies engaged in life sciences research and development, commercialization and manufacturing in Massachusetts. The primary goal of the program is to incentivize life sciences companies to create new long-term jobs in Massachusetts.

According to MLSC's Life Sciences Tax Incentive Program Solicitation No. 2017 TAX-01, issued December 14, 2017,

The Life Sciences Tax Incentive Program is a set of ten different tax incentives which address the significant expenditures associated with the life sciences [research and development] cycle and the high costs of translating research into commercially viable products. Several of these tax incentives are refundable, enabling an awardee to receive cash from the Commonwealth, even if no income tax is paid. The incentives offered under this Solicitation may only be claimed after July 1, 2018 (including, without limitation, the calculation of estimated taxes).

The Program consists of the following incentives:

- *Life sciences investment tax credit (pursuant to 62 MGL 6[m] and 63 MGL 38U)*
- *FDA user fees credit (pursuant to 62 MGL 6[n] and 63 MGL 31M)*
- *Extension of net operating losses from 5 to 15 years (pursuant to 63 MGL 30, section 17)*
- *Elimination of throwback provision in calculation of sales tax (pursuant to 63 MGL 38[f], section 6)*
- *90% refund of already-available excess §38M research credits (pursuant to 63 MGL 38M[j])*
- *§38W life sciences research credit (pursuant to 63 MGL 38W)*
- *Deduction for qualified orphan drug expenses (pursuant to 63 MGL 38V)*
- *Designation as [a research and development] company for sales tax purposes (pursuant to 63 MGL 42B, section 3)*
- *Sales tax exemption for certain property (pursuant to 64H MGL 6[xx]) [sic]*
- *Life sciences jobs incentive refundable credit (pursuant to Chapter 68 of the Acts of 2011, outside sections 63, 65, 70, and 211)*

Massachusetts Ramp-Up Program

The Massachusetts Ramp-Up Program (MassRamp) promotes excellence in innovative solutions in the life sciences ecosystem and aims to bridge the funding gaps associated with the long-life sciences [research and development] cycle and the high cost of translating research into commercially viable products.

*MassRamp leverages federal resources by providing supplemental funding for companies who have been awarded **Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Phase I Federal Grants / Contracts** to:*

- support activities that **cannot be covered** by a federal grant (such as [intellectual property] protection);*
- provide **additional resources** when federal funds are insufficient to complete an approved federal project;*
- **expand the scope** of the federal grant provided that the proposal to MLSC is based on the **same technology** approved in the federal award.*

Massachusetts Transition and Growth Program

The Massachusetts Transition and Growth Program ("MassTAG") will provide grant funding to encourage companies to establish operations in the Commonwealth of Massachusetts, the world's leading ecosystem for life sciences innovation and growth.

Critical objectives for this program are job creation, scientific advancement that will benefit patients and further growth of the Massachusetts life sciences ecosystem. The program will focus on companies that do not initially qualify for the MLSC's tax incentive program due to a lack of existing operations in the Commonwealth.

Other Programs

Life Sciences Milestone Achievement Program

According to MLSC's Life Sciences Milestone Achievement Program (MAP) Solicitation for fiscal year 2015,

The Life Sciences Milestone Achievement Program (MAP) is a new program created to address the need of early-stage life sciences companies to reach critical value-creating scientific or business related milestones. In addition, the program's goals are to fill a gap in the existing funding environment and to enable companies to attract additional outside funding. The MAP will fund grants to Massachusetts companies to support their work toward completion or fulfillment of scientific and business milestones, e.g. prototype development, clinical testing, legal filings, and business plan development. Successful completion of the milestone is expected to contribute to the overall development of the company or 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, and medical devices**.*

Massachusetts Next Generation Initiative

The Massachusetts Next Generation Initiative (MassNextGen) is a five year, \$1 million commitment to ensure greater gender parity in the next generation of life science entrepreneurs. Increasing the number of successful entrepreneurs is in the best interest of the entire life science industry and as such, this initiative is a public-private partnership between the Massachusetts Life Sciences Center and our initial corporate sponsor Takeda.

Each year, following a competitive program, women-led early-stage life science companies will be awarded a year-long customized package of support, which includes non-dilutive grant funding and access to a network of seasoned Executive Coaches from the life sciences ecosystem to refine their business strategies and effectively raise capital.

National Institute for Innovation in Manufacturing Biopharmaceuticals

In 2016, the Massachusetts Life Sciences Center announced its partnership in the nation's first biomanufacturing innovation institute, known as the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). The Center has committed up to \$20 million for five years as an anchor to the northeastern node for the biopharmaceutical manufacturing project. The NIIMBL project is regionally led by a consortium of small, medium and large biopharmaceutical industry partners from across the supply chain, along with Massachusetts Institute of Technology (MIT), Quincy College, UMass Lowell, UMass Medical School, and the Worcester Polytechnic Institute (WPI). . . .

*The **NIIMBL mission** is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry.*

NIIMBL relies on its members to shape the direction of its research and provide expertise in diverse areas of biopharmaceutical manufacturing. The investment, engagement and collaboration of its members allows NIIMBL to advance biopharmaceutical manufacturing, solve industry challenges and develop a highly-skilled workforce.

Neuroscience Consortium

The Consortium, the formation of which was announced in June of 2012 at the Bio International Convention, will fund pre-clinical neuroscience research at Massachusetts academic and research institutions. . . .

In July of 2013, the MLSC announced the first round awardees under the Consortium including three grants focused on Alzheimer's Disease, two grants focused on

neuropathic pain, and one grant each focused on Multiple Sclerosis and Parkinson's Disease. For this second round, the Consortium has expanded the diseases of interest and is seeking proposals focused on neurodegenerative and neuroinflammatory diseases (such as [Alzheimer's disease], [Parkinson's disease], [multiple sclerosis], Huntington's [disease], [amyotrophic lateral sclerosis]), neuropathic pain and treatment-resistant depression).

Consortium Members have pooled their resources to fund the identification and validation of novel targets for the symptomatic treatment and modification of these chronic and debilitating neurological diseases. All proposals must be anchored in recognized human disease genetics and pathophysiology, or within pathways of known relevance to human disease, and should be translational, rather than exploratory.

According to MLSC's annual audit report for fiscal year 2017,

In June 2012, the Center [MLSC] announced the formation of . . . the Massachusetts Neuroscience Consortium (the "Consortium"), a collaboration between seven global pharmaceutical companies. . . . The Center is not a member of the Consortium and makes no financial contribution to the Consortium. . . . The designated members of the Consortium are responsible for all decisions regarding disbursement of funds. The Center acts solely as a custodian of the Consortium funds.

Universal Partnerships Program

*The UP program will fund grants to Massachusetts companies to support milestone-based [research and development] collaborations with any international organization. Successful completion of the milestone is expected to contribute to the overall development of a new or significantly improved product or process intended for commercialization. Applicable collaborations must be in the fields of **life sciences**, which include **biotechnology, pharmaceuticals, medical devices, diagnostics** and **bioinformatics**.*