Innovator's Commercialization Guide

Second Edition

Chris Coburn, Chief Innovation Officer

"We applaud the thousands of Mass General Brigham innovators who work tirelessly every day, exercising new ways of thinking and learning to bring their inventions to market so that patients have the best novel therapies, surgical procedures, and diagnostics available. This guide outlines the commercialization journey and is designed to assist early career and experienced innovators in successfully bringing the bench to the bedside."

Cover: Sabrina Paganoni, MD, PhD, Spaulding Rehabilitation Hospital

All photographs in this document are of Mass General Brigham researchers.

To access Insight and Research Navigator, connect to the MGB network via VPN.

Table of Contents

On Innovation

From President and CEO, Anne Klibanski, MD

Dear Innovator,

Mass General Brigham is built on a legacy of medical discovery. Every day, we strive to provide exceptional patient care and treatments that improve outcomes, expand access, and support quality of life. These goals, central to our mission, depend on the unrelenting curiosity of investigators who pursue new ways of thinking and drive life-changing breakthroughs for the patients we serve.

This Innovator's Guide is a resource for investigators as they move through the discovery process. It includes guidance to help innovation from idea to clinical use, and practical information about protecting an idea, connecting with industry partners and investors, and who to contact for help. New to this edition is an enhanced section on AI and Digital Health which play an increasingly important role in healthcare delivery and patient care.

Our Innovation office collaborates with colleagues across Mass General Brigham—from hospital research institutes to systemwide research support groups, including the Clinical Trials Office, Human Research Affairs, the Office for Interactions with Industry, and the Data and Tissue Sharing Oversight Committee. The team is built to support investigators and I encourage you to reach out and work with them.

Mass General Brigham is a national leader in innovation. Our patient-centered mentality and systemwide collaborative approach enables research breakthroughs that drive medical innovation and improve patient outcomes.

Thank you for the work you are doing to serve our patients and enrich our tradition of innovation.

Sincerely,

Anne Klibanski, MD
President and CEO
Mass General Brigham

Introduction

Mass General Brigham is committed to making breakthroughs widespread across the continuum of care. It collaborates with industry to grow clinical and commercial impact. Innovation, the unit charged with realization of that collaborative vision, has a mission to pair Mass General Brigham scientific excellence with industry to enable patient-benefiting products and generate new revenue.

This document was developed to guide innovators through the commercialization process and to streamline their interactions along the way. It is meant to answer the question of who to contact at any point. Achieving successful commercial outcomes that transcend the boundaries between the academic and industrial sectors requires a clear understanding of processes, priorities and challenges.

Expanding the pool of innovators is a priority for the entire Mass General Brigham system. Increasing participation rates among women and other underrepresented groups provides medicine with countless additional innovations benefiting patients. Innovation runs a set of programs, described later in this guide, designed to increase staff participation in each area.

This guide refers organizationally to the Mass General Brigham system and does not call out individual hospitals or entities. Readers should be aware that many legal rights, such as patent ownership, rest discretely with the system hospitals.

The result of innovative thinking expresses itself in many fashions. From a commercial standpoint, it can be a product (including materials, devices, tools, etc.), a system, a manufacturing process or algorithm.

The need and opportunity for healthcare innovation have never been greater. Healthcare transformation and digital health have further accelerated due to the pandemic as well as life science venture and historic research investments. NIH annual funding is at nearly $50 billion, and public markets continue to reward breakthrough innovation.

Mass General Brigham provides an environment that enables and rewards staff-driven innovation. There are many mechanisms to help staff recognize actionable concepts, nurture innovations and implement them. While its thousands of Harvard Medical School faculty are an unmatched engine of discovery, the system recognizes that valuable innovation can occur anywhere. Identifying, adapting and implementing externally developed innovation is also key to the system's success.

Innovation occurs if someone creates or improves an existing product, process or service. It flows from an invention.

Inventor

The impact of an inventor can be enormous. Their unique insights solve problems, improve care and enhance lives around the world. Commercialization almost always starts with inventive inspiration. And clinicians can be great inventors.

Innovation is a collaboration between Innovation's specialists, including legal, business development, licensing and others, and the innovator.

The inventor also brings depth of knowledge of the field, such as commercial insights, understanding of competitors, product concepts, market observations and industry contacts. Successful commercialization can require a significant time commitment. These activities rest on top of the inventor's core clinical, research or administrative responsibilities and at times can compete with them. Staffing and systems are designed to minimize the total inventor time required for commercialization.

The path to a commercial outcome is always collaborative and involves multiple participants. The inventor and Business Development & Licensing Manager (BD&LM) are at the center of the process. They work as a team, each with their own role. Like any group effort, the greater the teamwork, the better the work product and the quicker and more efficiently a favorable outcome is realized.

The inventor, as the creator of the invention, details it in documents and participates in meetings to explain the invention to patent counsel or industry representatives. The process frequently starts with the inventor sharing the characteristics and potential of the invention with the BD&LM.

The inventor collaborates in developing a patent application and interacting as needed with patent counsel. The inventor seeks BD&LM clarification if patent counsel requests it or other aspects of the patenting process are not entirely clear. The inventor also shares new results, upcoming publications, and any external interactions.

Inventors can contact Innovation even when an idea is not fully fleshed out. This occurs before having discussions with outside individuals, including company representatives, the media or at poster presentations or other public forums. It helps to prevent loss of patentability and damaging the market opportunity for the invention.

Commercialization

Responsibility for commercialization of Mass General Brigham discoveries and technology-based innovation rests exclusively with Innovation. A business development unit focusing on this serves all employees and hospitals within the system and includes scientists, engineers, physicians, business executives and attorneys. It works collaboratively with innovators and industry to rapidly translate research outcomes into patient-benefiting products and services.

Mass General Brigham commercialization priorities include increasing the volume and value of system technologies, expanding the size of its innovation community and accelerating commercial outcomes and revenue. Innovation is organized into units that reflect each of the key elements in the commercialization process – licensing, digital transformation, investing, company creation, strategy, industry alliances, translational research support, innovation management, financial distribution and compliance. It adheres to performance management with regular reporting of outcome and activity measures. Innovation's functions include:

- Assessing, prosecuting and managing intellectual property
- Asset development
- Commercialization strategy
- Company creation, investment and governance
- Connecting technologies to market needs
- Developing system-wide technology strategy
- Digital development and technology support
- Engaging regulatory, reimbursement and other domain experts
- Identifying and securing collaborators
- Investing and accessing translational capital
- Negotiating deals
- Translational research development

Why Commercialize?

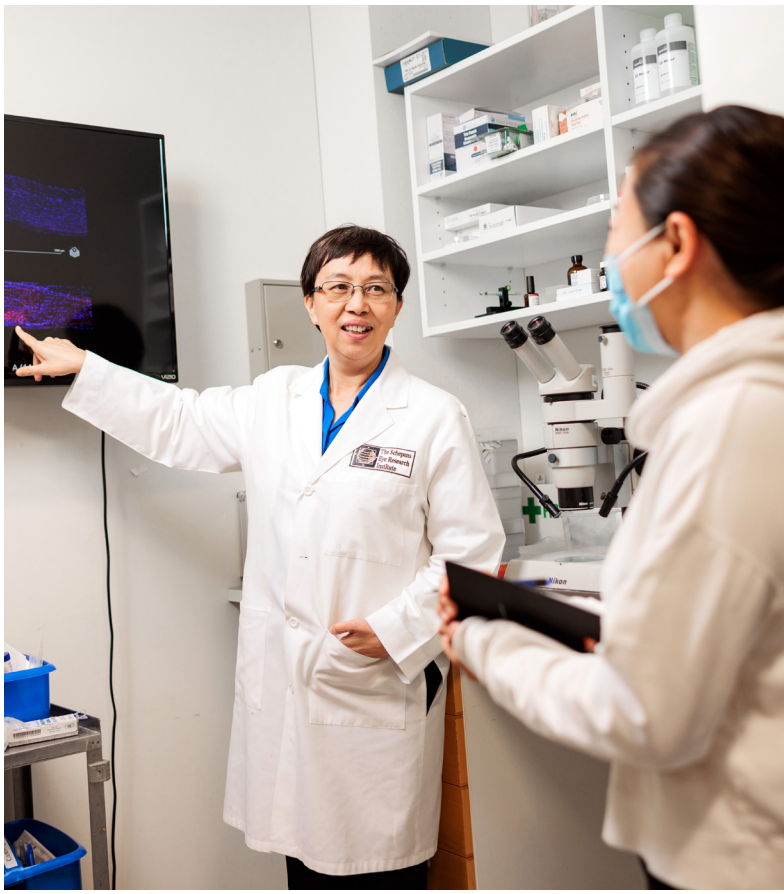
- Advance your ideas into products that help patients
- Generate funds for your lab through sponsored research and/or royalties
- Work with industry
- Build a wider reputation
- Supplement income
- Secure funding

Business Development & Licensing Manager

Business Development & Licensing Managers are members of Innovation's Business Development and Licensing team. They are the primary point of commercialization interface and act as a partner to the inventor.

The BD&LMs provide technology assessment, process support, market outreach, dealmaking, company liaison and knowledge of system capabilities. BD&LMs' outcomes include licenses, options, sponsored research agreements, invention assessment, technology marketing, IP development and license compliance. Efficiency increases when the inventor and the BD&LM have a strong working relationship. Productivity is of extra importance for both the active inventor and BD&LMs who are responsible for dozens of investigators and hundreds of agreements.

There is an assigned BD&LM for every chief code at Mass General Brigham. Complete lists of BD&LMs and other Innovation contacts can be accessed via Insight.



Dong Feng Chen, MD, PhD, Mass Eye and Ear

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Aloysius Domingo, MD, PhD, Massachusetts General Hospital

Acting on an Invention

The first step in the commercialization process is the inventive insight that may occur anywhere and made by any Mass General Brigham employee. Disclosing an invention is the first formal action in the commercialization process. Commercialization proceeds more smoothly when initial disclosures are thorough. The path forward from an invention is well-established. It can be long, complex, and iterative. It takes many steps to successfully develop new treatments, therapeutics, diagnostics and digital solutions.

Disclosing an Invention

An invention disclosure is a description of the invention and submitted online to the Innovation team. In addition to the details of the invention, it lists all contributors, funding sources and labs involved. It sets the initial path for IP protection, marketing and commercialization. An Invention Disclosure Form (IDF) should be completed when an idea is sufficiently developed. It is helpful to contact Innovation prior to preparing it. The IDF is confidential and not a public disclosure.

All contributors to the invention should be listed in the Invention Disclosure, including affiliated labs. With respect to inventorship, Innovation teams will work with inventors to determine who should be listed in the patent application.

The Invention Disclosure Form

A fully completed Invention Disclosure Form – with citations, prior art references, market descriptions, co-inventors, and related documents — is required to allow the commercialization process to proceed. A disclosure typically takes two to three hours to complete. It includes:

- Overview of invention in lay terms
- The fundamental problem the invention seeks to address and why it is significant
- What is new about the invention compared to existing solutions or the standard of care
- Scientific basis of the invention
- Stage of development (e.g., conceptual, tested in animal models, etc.)
- Whether the invention is a platform technology that can be the basis for multiple products
- Invention demographics – i.e., funding sources, contributors, labs involved

Inventor review of prior art helps to identify technologies that might compete with or even block the issuance of a patent. The U.S. Patent and Trademark Office website can be used to sometimes quickly spot blocking IP.

Questions to consider in addressing the novel features of the invention are:

- Scope — whether the invention applies to specific cases or generally to a broad class of cases
- Advantages of the invention
- Whether an incremental improvement to existing technology or an entirely new technology
- Key technological differences between the invention and the current standard of care and similar technologies on the market

The disclosure should also describe the commercial products or processes that may be enabled by the invention, i.e., what applications might a company develop if they had rights to the invention, what products might be based on the invention or what products might be blocked by it. For a platform technology, the multiple products or processes that could be developed should be included.

Any previous or upcoming public disclosures of the invention, i.e., if any aspects of the invention have been or will be published in papers, presented at conferences or discussed with outside collaborators or company contacts, needs to be part of the submission.

Invention Disclosure Form

Confidentiality

Public disclosure of an invention may limit, or even forfeit, the right to obtain a patent. A public disclosure is any communication of the invention to individuals who are not Mass General Brigham employees or not covered by a confidentiality agreement or policies. Some common examples include journal or book publications, published meeting abstracts, interviews, posters and oral presentations, dissertations and theses, and online publications, including laboratory webpages or social media.

Common situations that may not be public disclosures include internal presentations not open to the public. Grant proposals are often confidential and may not initially be a public disclosure until the granting organization publishes elements of the proposal such as the abstract or progress report publications. Discussions with external parties under a confidentiality agreement are also protected and not considered public disclosures.

It can sometimes be difficult to know what a public disclosure is. Innovation can help address questions. Notifying the assigned BD&LM in advance of any potential public disclosure is recommended to assure protection.

Insight is the system of record for submitting, tracking and managing research requests for Clinical Trials Office, Innovation, Institutional Animal Care and Use Committee, Institutional Review Board, Research Management and more. Please check Research Navigator for further information.

Even if an IDF has been submitted, the invention needs to be confidential until a patent application is filed. The inventor must keep their BD&LM apprised of any potential public disclosures, even after submitting an IDF, to ensure that a patent application is filed prior to any public disclosure, if appropriate. Important areas of inventions are often pursued competitively by multiple groups. Sometimes, in a highly competitive field, a difference of even a day in filing can determine who is ultimately awarded the patent. See page 10 for more background on patenting.

Contact(s):

Find your department's Business Development and Licensing Manager: Complete lists of BD&LMs and other Innovation contacts can be accessed via Insight.

Invention Assessment

Shortly after submission, the invention disclosure is assessed for both patentability and commercial opportunity. This structured evaluation considers IP approach, prior art, competitive advantage, market potential and commercialization strategy, including potential partners, next steps in development, investment requirements, speed to market and advancement plans. In the case of digital technologies, additional platform and timing questions are evaluated. The timeline varies for assessments.

Following the initial assessment, Innovation may revisit its decision to file a patent for an invention at any time based on changing market conditions, patentability challenges, or lack of commercial interest.

Technologies not pursued by Innovation are eligible for the inventor to obtain the right to pursue on their own. BD&LMs can provide guidance.

Intellectual Property

Nearly all commercialization of life science discoveries relies on Intellectual Property (IP). As such, IP creates an asset that can be the basis of investment, product development and companies. The protection of ideas and their unique competitive attributes enables them to become commercially viable.

There are four main types of Intellectual Property:

- Patents for inventions
- Copyrights for software, artistic or literary works
- Trademarks for logos and brand names
- Trade secrets that cover expertise and know-how

Commercialization relies primarily on patents and copyrights. Licensing for trademarks or trade secrets is not typically pursued. Occasionally a license related to know-how is negotiated. The U.S. Patent and Trademark Office website provides extensive background of patents and the patenting process.

Common Definitions

Claims define the scope of the protection, i.e., which disclosed subject matter is protected. Careful review of the wording of claims is crucial.

Copyright is a legal right that protects an original work of authorship. It provides the right to determine how a work of authorship can be used, re-printed or sold. It does not protect ideas — it protects the specific expression of an idea. For example, others may adapt a process described if the text and illustrations describing the system are not republished.

Patent is a legal grant that gives the holder the right, for a limited term, to exclude others from making, using, or selling the patented invention. Patents incentivize inventors to publish their inventions (in the patent itself) in exchange for a limited-term monopoly. They are core to the commercialization process, creating an asset that the institution may license to others to enable others to make, use, and sell the invention. In the U.S., the term of a patent is in most cases 20 years from the non-provisional or patent filing date. Patents go through several stages before an official patent is granted, which can take several years from the time it is initially filed. Any patent that is not yet granted can be referred to as “patent pending.” Patents do not guarantee the right to practice the invention.

Strategy

Mass General Brigham has a large and active patent estate investing up to $15 million per year to secure and maintain patent protection for the inventions of its staff. Innovation filed patent applications on roughly 50% of the disclosures it received during the five years 2018-2022.

A set of domain expert patent law firms draft, file and prosecute patents and maintain dockets. About half of patent expenditures are ultimately reimbursed by licensees.

IP creates an asset that can be the basis of investment, product development and companies. The protection of ideas and their unique competitive attributes enables them to become commercially viable.

Patentability

Essential to securing a patent is determining if an invention is truly novel, i.e., has not been patented or published before nor is in the public domain, and is non-obvious. Lack of novelty and/or non-obviousness are common reasons for initial rejections. BD&LMs work with inventors to evaluate ideas within the context of what is publicly known about the subject. It is often possible to uncover prior art in an hour or two of investigation. The USPTO and Google are among the many services an innovator can access.

Obtaining patent protection requires meeting four key requirements:

Novelty The invention must not form part of the state of the art (also known as prior art), i.e., all knowledge that has been made publicly available anywhere in the world from a single source prior to applying for a patent. This includes printed and online publications as well as public

Natalie Artzi, PhD, Brigham and Women's Hospital

lectures and exhibitions. As a rule, anything the inventor makes publicly known about the invention before a patent is filed is considered prior art and, therefore, invention is no longer considered new.

Inventive The invention must be inventive or Non-obvious to a person of skill in the art. The standard for Non-obviousness is similar to Novelty except that to satisfy Non-obviousness for an invention no combination of publicly available knowledge sources should be available to assure or teach a person of skill in the art to practice the invention with a reasonable expectation of success.

Utility, Enablement, Written Description and Best Mode The invention must have some utility, describes the invention in such a way that it allows one of skill in the art to practice the invention, demonstrates that the inventor had possession of the invention being claimed at the time in which the patent application was filed and discloses the best practice mode or version of the invention.

Patentable Subject Matter Laws of nature, natural phenomena and abstract ideas are not patentable. Discoveries such as a new genes or algorithmic formulas, as examples, are not considered inventions and, therefore, are not patentable.

Provisional vs. Non-Provisional Applications

The first patent application filed is often a "provisional" and lasts for one year. Its less formal format is useful to quickly establish an initial filing date to protect an invention while providing additional time to conduct research and add supporting data. Provisional patents are not reviewed by the USPTO and are not made publicly available.

Within one year, the provisional application must be converted to a "non-provisional" application or else abandoned. Non-provisional patent applications are highly structured with a detailed description of the invention and a set of claims. Each country has its own laws relating to patent applications, and each requires a separate non-provisional patent application to review for patentability. The Patent Cooperation Treaty (PCT) provides a convenient way to file a single non-provisional application that will be acceptable for further patentability review by any of the current 153 countries and regions that have signed the PCT. At the non-provisional conversion stage, a PCT non-provisional patent application is usually filed as it provides more future flexibility.

Inventorship Determination

Inventorship must be correct for patent validity. If there are inventorship questions, Innovation should be promptly alerted. After an initial assessment, the BD&LM may engage in-house patent counsel to work with the inventor to assess the contributions made by the multiple individuals to determine whether they meet the required level of inventorship.

The criteria for a contributor to be listed as an inventor on a patent application is defined under U.S. patent law. An inventor must have contributed to the conception of the invention. Someone who did not contribute to the conception of an invention is not considered an inventor, even if they were a valuable contributor to the development of the invention. For example, someone who contributes to the invention solely by following prescribed steps to build the invention or by conducting experiments to show that the invention works (but who did not contribute to the conception of the invention itself) would not be considered an inventor.

The standards for inventorship are different from and usually more stringent than for scientific authorship. Although an invention comprises both a complete performance of the creative part of the invention ("conception") and the carrying out of the creative part ("reduction to practice"), inventorship is limited to conception. Research records (e.g., lab notebooks, emails, grants, published papers, etc.) can be used in this determination. If needed, outside counsel may be consulted.

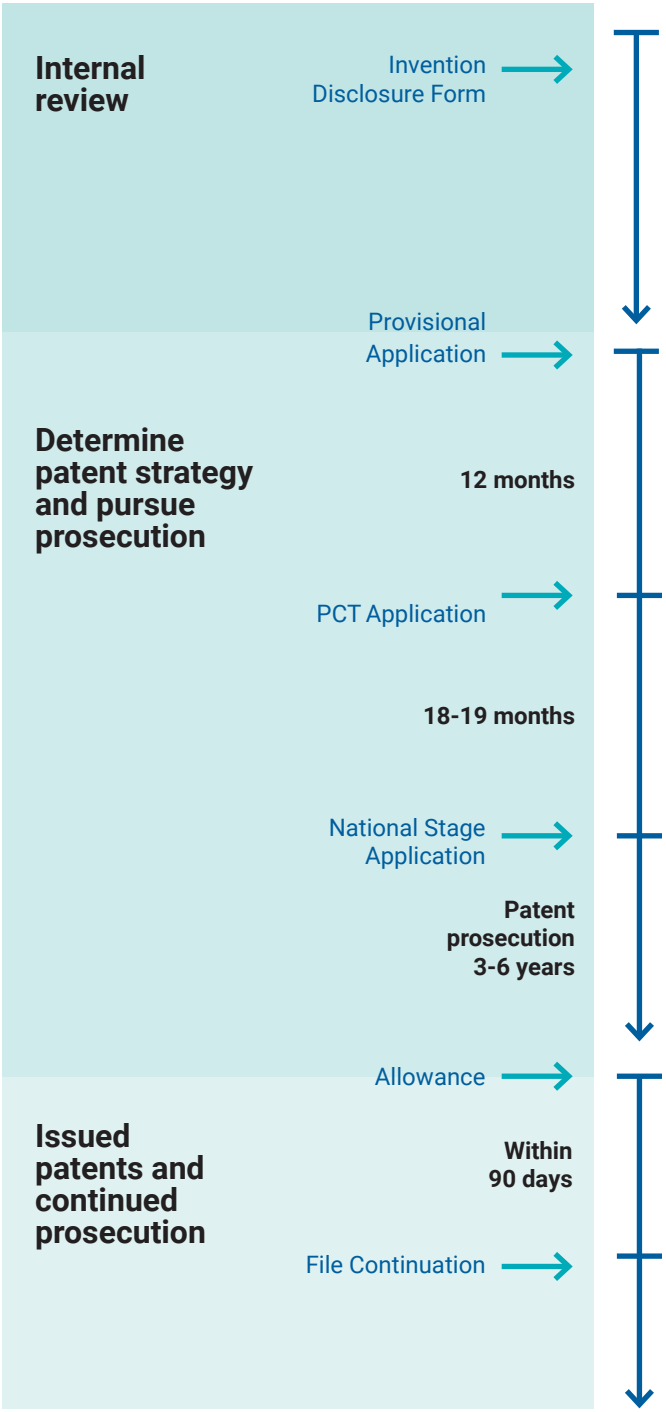
Ownership

IP discovered during employment and activities supported by Mass General Brigham and all its entities is owned by Mass General Brigham or its entities. Joint appointments should be disclosed to properly determine IP ownership.

Inventor Compensation

U.S. academic institutions distribute a portion of the net proceeds from a commercialization to the inventor(s). The Mass General Brigham IP policy defines the applicable distribution policy based on specific criteria. A typical Mass General Brigham distribution policy for revenue from IP includes 45% total to the inventor(s) and the inventor's lab or unit, 20% to the department or service and 35% to the institution. If there are multiple inventors, the inventors' shares are allocated following a process in the Mass General Brigham IP policy.

Patent Timeline for U.S.



Cost

Securing and maintaining a patent often costs tens of thousands of dollars for U.S. patents and more for international patents. Mass General Brigham pays for patent expenses. Reimbursement is a standard element of a license or option. Unreimbursed patent expenses are recouped before any distribution occurs.

Contact: phspatents@mgb.org

Milica Margeta, MD, PhD, Mass Eye and Ear, with Research Fellow Anthony Mukwaya, Mass Eye and Ear

Licensing

Licensing intellectual property to a commercial entity is the principal commercialization route for Mass General Brigham inventions. Licenses are agreements where the licensor, the owner of an invention, gives the licensee the right to the technology allowing them to produce, use or sell products protected by the licensed patent(s).

License terms define the rights, responsibilities, and exclusivity of the parties. Key terms include the specific items being licensed, field of use, duration of the license, right to sublicense and financial or other considerations to be paid to Mass General Brigham by the licensee.

Financial and other terms in a license can vary in structure (e.g., royalties on products sold, milestone, upfront and change of control payments, annual fees, equity in the licensee, etc.). Such terms also require the licensee to diligently develop the technology (so it doesn't "sit on the shelf") and mandate that the hospital retain the right to continue to research on the licensed invention. In almost every case, reimbursing the system's back patent costs and payments for continuing patent expenses are part of the license. An option agreement, often a prelude to a license, gives the company a limited exclusive period to explore or validate the business potential enabled by the patents.

The process can vary in length but at a minimum executing a license generally takes several months.

Business Development and Licensing

The BD&LM team covers every clinical and research chief code at Brigham and Women's, Mass General, Mass Eye and Ear, McLean and Spaulding and selectively at the community hospitals. BD&LMs evaluate new inventions, market technologies, negotiate industry-sponsored research agreements and option/license agreements, support the maintenance of IP portfolios and maintain relationships with licensees. All have graduate training as scientists, engineers, physicians, attorneys and business executives. Each BD&LM is responsible for several dozen investigators. Mass General Brigham IP policy

Contact:

Nimra Taqi
Vice President, Business Development & Licensing
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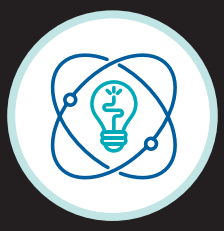
Innovation Pathway



Ideation

Turn creativity, experimentation and dreams into reality

Collaboration

Foster partnerships and identify pathways to commercialization

Implementation

Match innovations with motivated industry partners

Value Creation

Nurture innovations to drive patient and commercial benefits

Digital Health

As an early leader in digital health development, starting with medical informatics pioneer Octo Barnett, MD, who came to Mass General Hospital in 1964 to head the pathbreaking Hospital Computer Project, Mass General Brigham continues its legacy of prioritizing digital transformation by advancing efforts to enhance patient access to life-saving care through investments and innovation in digital technologies.

Today Mass General Brigham seeks to infuse the patient journey and internal operations with digital innovation. Our Digital Health teams seek to implement and support future-facing digital capabilities that will play a fundamental role in bringing all levels of care onto shared technology to best serve our system's patients, researchers and community – locally and globally. This effort prioritizes a platform-based approach to enable better cross-functionality across our system, which aims to make hospital visits better for all stakeholders, including providers, patients and their families.

Achieving our system's digital health goals includes both supporting and leveraging our core technology while exploring and implementing new digital capabilities. This could be achieved through partnerships with some of the best technology companies in the world, through embracing new emerging technologies in healthcare, and through investing in and scaling proven home-grown capabilities. Exemplative partnerships and innovations include:

- Enhancing our researcher experience through improved computer and data management with a number of key industry partners
- Working with Venture Capital and Private Equity to license our Intellectual Property into New Companies focused on market "white space"
- Spinning out companies from Mass General Brigham, like Codametrix, an automatic coding company first developed in the Mass General Physicians Organization

Digital Health Commercialization

The Business Development (BD) team supports a diverse portfolio of projects focused on expanding the impact and reach of Mass General Brigham-developed digital health capabilities via strategic engagements between industry partners and MGB innovators, entrepreneurs, and executives.

The BD team's expertise includes bringing Mass General Brigham digital health solutions to market through new business ventures, co-developments and out-licensing arrangements, in addition to cultivating system relationships with innovative, external stakeholders. Success is defined by our ability to accelerate promising internal and external digital tools through partnership models that ensure the system is a partner-of-choice for collaborative and strategic relationships in virtual/digital based care initiatives.

Key support offerings include:

- Creating and structuring strategic deals with industry partners including alliances, co-developments and collaborations
- Facilitating connections between MGB stakeholders and strategic partners such as industry leaders, new market entrants and investors
- Commercial assessment of early-stage digital health inventions
- Out-licensing of digital assets, including software
- Providing business planning and strategic support to home-grown digital capabilities
- Supporting new company creation when indicated

Additionally, the Business Development team works closely with the $30 million AI and Digital Innovation Fund (AIDIF) founded in 2020 that invests in external digital companies with active commercial relationships with Mass General Brigham.

Contact:

Mike Freni
Vice President, Business Development
mfreni@mgb.org

Company Creation and Investing

Mass General Brigham Ventures

Mass General Brigham Ventures (MGBV) is the venture capital arm of Innovation. MGBV invests in next-generation life science companies based on intellectual property created within the Mass General Brigham research community. Established in 2008, the team manages half a billion dollars in internal and external capital. Since inception, MGBV has created over 55 portfolio companies, which collectively have raised over $4 billion in outside capital.

The Ventures team seeks strong co-investor syndicates to develop products across a range of categories including drugs, devices, diagnostics, and digital health. Initial investments are directed at the seed and Series A stages; however, the team supports each portfolio company through its entire financing lifecycle.

The Ventures team works closely with innovators across the system to identify investment opportunities, leveraging our extensive network of scientific and business talent to build great companies. The group has first access to disclosed inventions from the Mass General Brigham community.

Spin-Offs

Most inventions are commercialized via licensing to an established pharma, biotech, medtech, digital or diagnostic company. An invention occasionally may be the basis for a new company (newco). Deciding to create a company typically follows a detailed consideration of the technology, its competitive position and market dynamics. MGBV investments are initially directed at the seed and Series A stages.

A key consideration is whether a novel technology can be a “platform”, i.e., the basis for or contribution to multiple marketable products or combinations of technologies that can serve the same purpose. Such newcos (new companies) may ultimately be sold to an established company or, alternatively, they may become publicly traded. The potential for a new company often reflects the overall commercial marketplace. Currently, digital and therapeutic technologies are investment community priorities.

Investment

Venture-backed companies are funded and organized to manage the high risk associated with early-stage programs. Solid intellectual property is almost always a requirement for funding. A thorough due diligence process is conducted prior to an investment decision to consider market potential, freedom to operate and patent landscape, among other topics.

Stage of technology and the attributes of the product category are also assessed. For example, new biology defining novel drug targets can be of great interest with only mouse data, especially if it addresses a disease with high unmet need. In contrast, digital technologies carry a burden of commercial proof – investors expect to see pilot implementations that demonstrate benefits in a real-world setting with the ability to access meaningful markets. The more advanced the program, the more value and attention will be paid by the venture community, regardless of the product category.

For an asset to merit investment it must have some level of competitive advantage. This typically includes intellectual property in the form of patents and know-how. If this derives from biology, the recognition of its commercial potential may come from the pending patents and/or the inventor’s knowledge of the field.

Articulating a specific unmet need is a standard framework. Value creation occurs if the need is met. A development plan is often prepared by the inventor. It focuses on addressing the need and includes a realistic budget that can lead to a substantial investor return relative to the level of risk taken.

Freedom to operate is an additional consideration. It is established by analysis of the patent landscape to ensure that prior filings do not impinge on the inventor’s IP in a way that diminishes its market viability. For example, it is possible to have the rights to a valid patent but to market a product would be impossible without licensing additional patents held by other parties.

Company Leadership

From an investor perspective, securing the right leadership for the newco is critically important. Seasoned entrepreneurs with deep domain experience are expected. Investors are wary of proposed company leaders who have a family relationship with the scientific founder or those with limited experience in the targeted field. MGBV selectively uses experienced corporate executives as Entrepreneurs in Residence to shape and lead new company creation.

Scientific Founder

Inventors participate in new company formation and operations as a scientific founder. In doing so they add their expertise, know-how judgment, name and reputation to the new enterprise. They may also serve on the company's scientific or medical advisory board. As a scientific founder, they receive an ownership stake in the company through the founder's equity. Advisory board members typically receive options to purchase shares in the future at a set price. Scientific founders also receive compensation from commercialization revenue that Mass General Brigham receives for the license of the technology.

These roles can create conflicts of interest, or the appearance of conflict, due to the simultaneous responsibilities of a system employee and those related to the operation of a company. Mass General Brigham and Harvard Medical School adhere to a comprehensive set of conflict management policies. As described, they restrict scientific founders from holding executive management positions in the company but permit them to hold equity, accept consulting contracts and participate as scientific advisory board members. All require prior, written approval from Mass General Brigham's Office for Interactions with Industry.

Artificial Intelligence and Innovation Fund

In addition to the early-stage investment opportunities in spinouts described above, when Mass General Brigham decides to adopt a digital solution, it can provide an important validation proof point that the 'fit' between product and market need has been de-risked. The Artificial Intelligence and Digital Innovation Venture Fund (AIDIF) is a $30 million venture fund investing in commercial stage digital health companies that are working with the Mass General Brigham system. Established in 2020, AIDIF works closely with Innovation's Business Development Digital Health group and system clinical, operations, research and digital leadership to identify key areas for investment with an emphasis on technology that increases efficiency, utilization and margin.

Translational Investments

The Innovation Discovery Grants (IDG) are an ongoing awards program focused on providing targeted support for promising pre-commercial technology of any Mass General Brigham appointed staff. IDG is meant to accelerate commercial outcomes and has returned nearly 20 times in new system revenue from the funds expended.

Brigham Ignite is an early-stage innovation acceleration program specifically for Brigham and Women's Hospital innovators. It is focused on advancing discoveries with commercial potential by guiding researchers through the development process with not only funding but also experts in licensing, product development, intellectual property and commercialization.

The Summit Fund was launched with the goal of raising philanthropic support from friends of Mass Eye and Ear to help fast-track the translation of laboratory discoveries into approved medical devices and pharmaceutical treatments to improve the lives of patients. These philanthropic gifts are augmented by additional funding from MEE long-term investment pool. The Fund focuses on unmet medical needs in the fields of hearing and vision disorders.

Amplify addresses the later stage translational funding gap between basic research and clinical proof-of-concept. Amplify's focus is to make investments to advance very high commercial potential technologies emerging from Mass General Brigham investigators. Amplify enhances the value of these select pre-commercial projects prior to commercialization. The team strengthens the value of these technologies both by creating new intellectual property starting from an existing tool or prototype molecule, device, or diagnostic and by de-risking their further development. These investments are operated by an experienced team of product developers in close collaboration with both the innovator and the Venture team.

https://www.massgeneralbrigham.org/ventures

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Innovation Discovery Grants
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Strategy and Alliances

Senior Strategists

Senior executives with decades of industry experience, known as Strategic Innovation Leaders, provide guidance on technology marketability, asset development, industry trends, as well as large or complex transactions and deal structures. SILs also work with entity research institutes to advance emerging areas of opportunity and unmet need. They work in partnership with other Innovation units, including Business Development & Licensing, Digital Health Innovation and Ventures.

The SIL team drives the development of strategic and operational plans to grow commercial outcomes in areas of system priority. The system-wide Gene and Cell Therapy Institute (GCTI) is an example of an SIL-facilitated strategic initiative that was developed to increase industry linkages, enhance internal capabilities and identify potential investments to enhance high-value GCT assets.

Commercialization Council The Council is a system-wide group of senior investigators and research leaders who provide input to Innovation on system matters, including program priorities, investigator engagement, electronic tools, innovator support, process improvement and general operational feedback. It meets throughout the year.

Alliances

Large-scale alliances to develop and translate cutting-edge technology are a commercialization priority and long-standing Mass General Brigham competency. Focused on specific therapeutic and diagnostic opportunities, these collaborative alliances pair faculty and system capabilities with market-facing corporate teams and resources. Examples are typically global healthcare and pharma companies.

Alliances are part of an open innovation strategy that integrates faculty from one or more of the hospitals with companies to cross-leverage unique capabilities and create breakthrough technologies. Open innovation has become an industry priority to secure disruptive innovation from all possible sources. Mass General Brigham participates in a wide range of collaborative structures. These are tailored to match the nature of the technology being developed and the market to be served. They are staffed by dedicated units within Innovation actively collaborating with entity clinical, research and institute staff.

Madeline Grucci, Technical Research Assistant, Brigham and Women's Hospital

Technology co-development consortia Mass General Brigham works with industry partners to co-develop core technology and capabilities that are integral to academic medical center operations. Examples include Health Catalyst, General Electric, American Heart Association, Best Buy and Codametrix.

Research collaborations Long-term strategic collaborations with individual industry partners are designed to co-develop drugs and devices. These partnerships have committed executive sponsorship, an active oversight board, measurable objectives, shared outcomes and a strong collaborative culture. Examples include Canon and Pfizer Centers for Therapeutic Innovation.

Funding programs Several large companies provide a collaboration framework using an annual award cycle and access to company expertise in areas such as medicinal chemistry, prototyping or regulatory affairs. These typically include a call for proposal from industry with a brief pre-proposal followed by a more extensive full proposal for selected projects. Examples include Sanofi iAwards, Simcere, and Novartis Institute for Biomedical Research (NIBR) Global Scholars Program.

Educational programs Innovation also manages dedicated programs to build industry skills among system faculty and nurture translational collaboration. The Innovation Fellows Program provides part-time opportunities for Mass General Brigham MD and PhD staff to embed on a team in industry to perform short-term, co-mentored Fellow Projects for 6 to 24 months. Fellows receive education and training from industry experts to enhance knowledge and capabilities, and industry gains access to scientific/clinical insight from world-class health care faculty. Hosting a Fellow includes a Master Agreement between the industry host and Mass General Brigham. It also, in limited circumstances, arranges for company employees to be posted within system labs.

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Innovation Team

- Clinicians
- CPAs
- Deal makers
- Digital BD
- Diversity and Equity
- Drug developers
- Engineers
- Entrepreneurs
- Inventors
- Investors
- Marketers
- Patent attorneys
- Product developers
- Scientists
- Strategists
- Transaction lawyers

Innovation Functions

Corporate and Business Development and Licensing

- Asset identification
- Corporate development, strategy, analysis
- Deal shaping and execution
- Relationship management

Company Creation and Investment

- Company establishment and opportunity development
- Governance
- Investing
- Recruitment

Translation and Faculty Support

- Collaboration enablement – e.g., SRA, MTA, CDA, SBIR/STTR
- Enterprise partnering and alliance management
- Translational funding and asset development
- Patent strategy and prosecution
- Faculty engagement and service
- Unmet needs assessment and systemwide coordination

Market Research, Research Analysis, Asset Management and Finance

- Distribution, billing, and compliance
- Market research, modeling and forecasting
- Research applications and analytics


Kerry Ressler, MD, PhD, McLean Hospital
invitrogen
FALCON
ACD

Research Collaboration Agreements

Sponsored Research Agreements

Sponsored Research Agreements (SRAs) enable industry-funded, pre-clinical research. SRAs rely on hypothesis-driven research to further the hospital's medical and educational mission.

The approximately 200 SRAs and 230 SRA amendments transacted annually are each based on a scope of work and budget determined by the innovators and agreed to by the industry sponsor. The scope of work and budget must have departmental approval and include appropriate fringe/indirect charges, which is the same as used in NIH-funded, non-clinical projects. In all cases, the Research Management budget template is required to create the initial budget.

SRAs are not used to cover the provision of rote services or individual/institutional consulting arrangements. Typically, these arrangements are covered by Institutional Service and individual consulting agreements, which are supported by the Office of General Counsel and the Office for Interactions with Industry (**PHSOII@mgb.org**), respectively.

After the SRA scope of work and budget are agreed to by the industry sponsor and the PIs, the SRA request is reviewed by Innovation to confirm the following requirements are met:

- Investigator and MGB system have rights to use any third-party material in the performance of the research
- Any proposed patient tissue/data use complies with Data and Tissue Sharing Oversight Committee guidelines
- If any use of human material or patient data is contemplated, the PI has provided an Institutional Review Board (IRB) protocol and IRB determination letter confirming that any use of human material/data is not Human Subjects Research or protocol and approval letter for non-clinical research use of human material/data, or confirmation that protocol has been submitted to the IRB for any use of human material/data
- Budget has full overhead, or hospital Senior Vice President approval that appropriate overhead was used
- There are no conflicts of interest per MGB conflict of interest policies

Once conditions are met, Innovation negotiates SRA terms to comply with MGB and federal policies. While turnaround time is a key performance measure, it can take up to several months to complete an industry agreement. Any changes to the statement of work during negotiation can further delay the completion of the agreement. Processing time can be minimized by an upfront conformance with organizational requirements.

Contract terms for sponsors to be aware of include: protecting the investigator's ability to publish, hospital ownership of any intellectual property created by the investigator during the project, sponsor's scheduled payment of budgeted expenses, no unauthorized use of the investigator, hospital or system name, and sponsor's use of patient materials/data, if any, falls within the Data and Tissue Sharing Committee guidelines and scope of IRB review. Sponsors are typically given an exclusive option to license any IP created under the SRA. If the sponsor elects to license the IP, the license terms are separately negotiated. Like all academic transactions, the license must provide for fair market value of the IP. If the IP is licensed, the system retains the right to continue using the IP for research and educational purposes.

SRAs are not used to cover the provision of rote services or individual/institutional consulting arrangements. Typically, these arrangements are covered by Institutional Service and individual consulting agreements, which are supported by the Office of General Counsel and the Office for Interactions with Industry (PHSOII@mgb.org), respectively.

Material Transfer Agreements

A Material Transfer Agreement (MTA) allows investigators to receive or share material or human specimens for pre-clinical research. These agreements are required by nonprofits, the federal government and industry alike and are also used to help track activities that might affect ownership or licensing of results. The Innovation Transactional Affairs Group (TAG) negotiates several thousand MTAs per year covering research materials provided by or sent to another academic researcher or company.

The external transfer of material or human specimens to a company, academic institution or other external entity should be done as part of a scientific collaboration between the providing investigator and the receiving party. Such transfers to for-profit entities are allowed if:

- Part of a genuine research collaboration
- Intended to maintain active, ongoing involvement in the company's work with the specimens in an area of science that is of interest to the principal investigator
- Results of the study will be made readily available to the investigator; if it is reasonably likely that a publication may result, the investigator is free to publish

Mass General Brigham does not accept compensation for these human specimen transfers (except for documented preparation costs and shipping fees) or patient data.

MTA process Members of the TAG group negotiate and execute agreements on behalf of Mass General Brigham's member hospitals. In addition, MTAs often contain encumbering language related to intellectual property rights. TAG is staffed by attorneys to manage rapid agreement execution.

If the material sought is commercially available, it may be purchased. Supply Chain is the required path for purchasing. Contact Supply Chain at **mmcontracts@mgb.org**. If the material is to be received at no cost (or for a nominal transfer fee), an MTA is required. Note that even if the material does not involve a direct cost, the terms of the MTA will specify limitations on use of the material and, in some cases, IP constraints.

Timeline Most MTAs are executed in days. A small number take longer. Timing is almost always a function of the nature of the collaborating organization. Agreements with academic or other nonprofit entities generally follow a standard template and are quickly executed. Many companies and some academic and non-profit entities require nonstandard terms that must be aligned with system and federal tax-exempt requirements. Fully completing the questionnaire in Insight is a requirement to initiate an MTA and it accelerates the process. This includes contact information and details such as protocol numbers for IRB approval, plus any draft agreements that may have been prepared. It also helps for companies to be aware at the outset of system requirements.

The Mass General Brigham Human Research Committee (MGBHRC) is the Institutional Review Board (IRB) of Mass General Brigham. The MGBHRC reviews all human-subject research conducted by a Mass General Brigham-affiliated investigator. For further guidance, please refer to the IRB website.

MTA Review by IRB The transfer of any human specimen in or out, i.e., clinical specimens, research specimens and/or patient data, always requires Institutional Review Board review.

For additional information, please contact **phsinnovationsupport@mgb.org** or TAG **PHSMTA@mgb.org**

Confidentiality Agreements

Confidentiality agreements are ubiquitous in the life sciences business sector and key to protecting intellectual property rights and business opportunity. They cover meetings and other information exchanges with external entities, including companies, nonprofit and academic organizations. Key focus areas are discussions about inventions or intellectual property, business strategy and sessions that could reveal undisclosed information, research outcomes, etc.

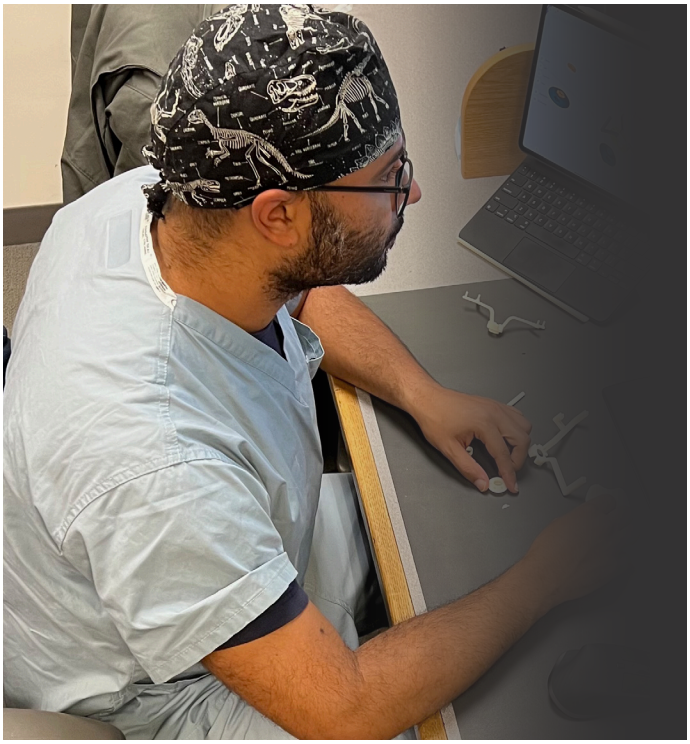
Data Use Agreements

Patient data entering or leaving Mass General Brigham must be accompanied by an agreement outlining how the data will be used, protected and maintained through a Data Use Agreement (DUA). The Innovation Transactional Affairs Group is responsible for developing, negotiating and executing data-sharing agreements with industry for research or human data the IRB has determined to be de-identified. DUAs with for-profit entities should be submitted to Innovation through the Insight Agreement module for TAG to review.

TAG ensures use is limited to the scope of the project and the industry sponsor will not sell the data or use it for marketing purposes. The investigator confirms the data are accurate and complete, have been de-identified in compliance with HIPAA, the data are limited to the minimum necessary to meet project scope, appropriate subject consent has been obtained for data sharing (with IRB confirmation) and if there are any other agreements related to the research under the proposed DUA.

Mass General Brigham Data and Tissue Sharing Oversight Committee

Nonstandard requests for SRAs, MTAs and/or DUAs may be referred to the MGB Data and Tissue Sharing Oversight Committee (DTSOC). The committee becomes involved if the human specimen and/or clinical data recipient intends to leverage such materials or data solely as part of a product development or commercial validation; the project involves whole genome or exome sequencing; the scope of use includes secondary use to leverage data or derived data as part of product development, validation, study or other commercial activities; the request is to



Walid Ibn Essayed, MD, Brigham and Women's Hospital

share de-identified data fields beyond disease status or basic demographic information; the costs to collect and transmit data are not part of a payment or financial considerations; insights or results from the study are not being shared back with the system; the data request is outside the original scope of work or the request is for a significant volume of human specimens and/or data.

Innovation Operations and Analytics

Innovation Operations consists of five groups, Intellectual Property, Transactional Affairs, Finance, Contract Compliance, and Research Applications and Analytics, charged with supporting the innovator's pathway to commercialization. Their range of services include processing Invention Disclosures, working with Business Development & Licensing Managers to protect intellectual property through patent filings, prosecution management, agreement data entry, licensee compliance, and managing hundreds of millions of dollars of revenue invoicing, collections and internal distributions.

Intellectual Property Group collaborates with innovators and Business Development & Licensing Managers on disclosures to ensure they are ready for review and patent protection. They set IP strategy, file worldwide patents on behalf of the innovators, manage the system's up to $15 million annual patent investments and ensure that the necessary documentation is in place to support patent filings and timelines.

Transactional Affairs Group (TAG) executes Material Transfer, Confidentiality and industry Data Use Agreements. TAG associates process thousands of contracts annually under specified turnaround times.

Finance is responsible for ensuring that the financial obligations of licensees are compliant. It makes thousands of disbursements annually and also handles invoicing and collections.

Research Applications and Analytics provides in-depth support across the entire Mass General Brigham research enterprise, including performance analytics, reporting and forecasting. It also develops software solutions to enhance outcomes and productivity in support of all research support offices (see below). Its commercialization duties include driving the use of new electronic tools to enhance the innovator experience. These tools are being continuously designed, assessed and implemented.

Contract Compliance Team drives operational initiatives that enhance the Innovation office's business performance and grow revenue through dedicated stewardship of the Innovation licensing deal portfolio. Team members manage IP agreement lifecycles to ensure integrity of agreement data for robust analytics and reporting, monitor licensee compliance with diligence requirements to develop the technology, update milestone revenue expectations, and generate revenue forecasts for hospital leadership.

For more information, please contact Operational Support at **phsinnovationsupport@mgb.org**

Research Support Offices

Several Mass General Brigham units support research, discovery and invention. Functions are described in the Research Agreement Quick Reference in this document.

Clinical Trials Office (CTO) develops, negotiates and executes agreements and budgets for industry-sponsored clinical research. The CTO also manages clinical electronic support systems, including OnCore and Advarra. Contact **CTOmailbox@mgb.org**

Data and Tissue Sharing Oversight Committee reviews requests to disclose or provide access to clinical and research data and tissue to external parties. It ensures that clinical data and tissue sharing with external parties advances Mass General Brigham's mission.

Hospital Administration Each hospital oversees research activity through its Senior Vice President for Research and related functions. Some exceptions to policy and standard terms require approval from the Senior Vice President.

Human Research Affairs (also known as the Institutional Review Board) reviews and oversees human-subjects research that is conducted by staff in connection with their institutional responsibilities, regardless of the location of the research or source of funding. Contact **irb@mgb.org**

Insight is the system of record for submitting, tracking and managing research requests for the Clinical Trials Office, Innovation, Institutional Animal Care and Use Committee, Institutional Review Board, Research Management and more. Please check Research Navigator for further information.

Office for Interactions with Industry (OII) is part of the Office of General Counsel and manages a system to protect patients, faculty and the institution when there is collaborative research, consulting or other joint activity with the commercial sector. OII reviews all personal consulting agreements.

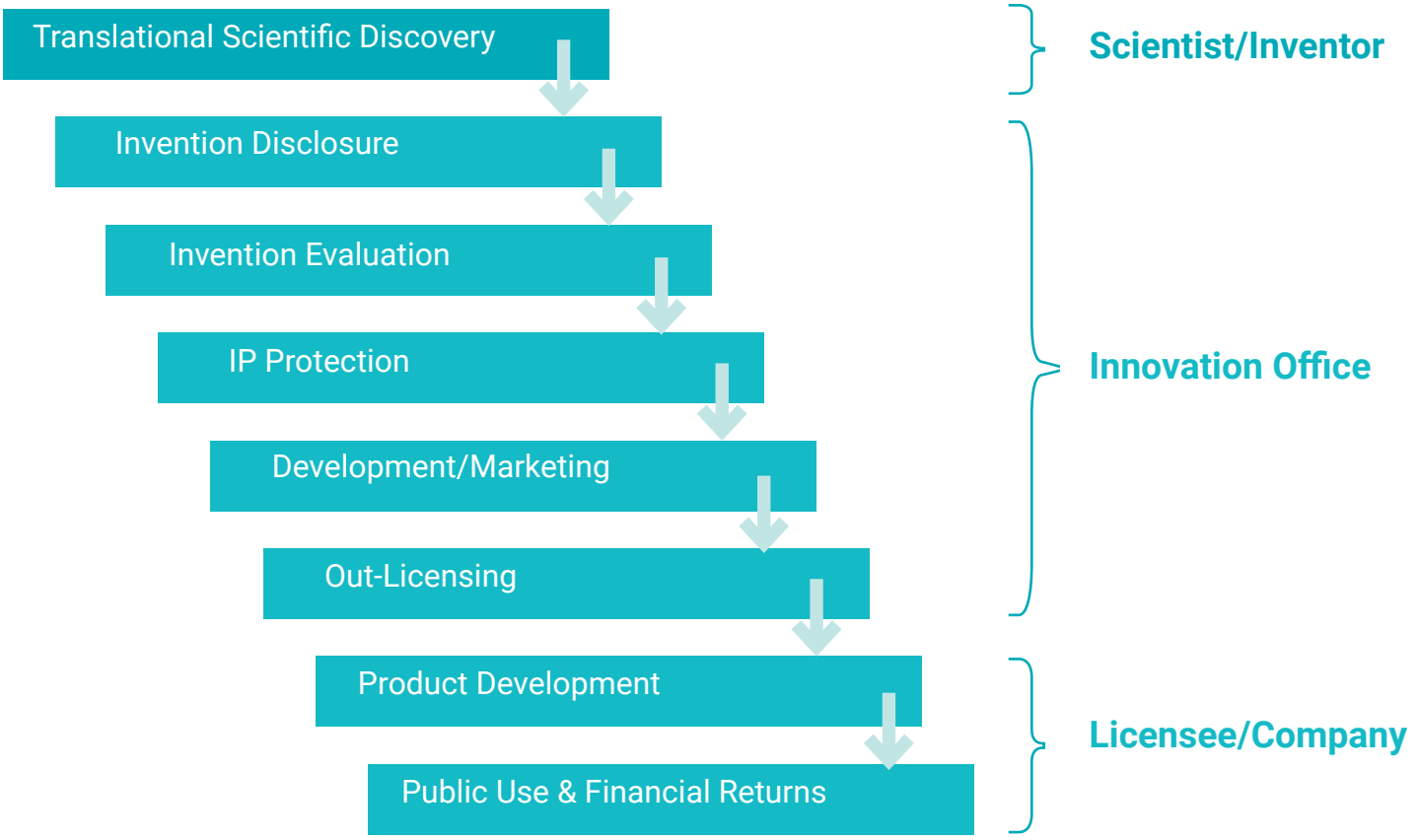
Research Institutes Brigham and Women's and Mass General have research institutes that work with investigators to organize, educate and assist them in their interactions with industry and in obtaining research support. McLean, Mass Eye and Ear, and Spaulding Rehabilitation Hospital have similar activities.

Research Management (RM) supports researchers and hospital departments with grants, contracts, finance, systems, core facilities, analytics and non-profit-sponsored clinical and non-clinical research agreements. Contact **phsresearchmanagement@mgb.org**

Research Navigator is the intranet for all of Research and Innovation. It houses institutional policies, templates, business process flows and announcements.

Supply Chain (SC) makes routine purchase order-based acquisition of goods and services and is also responsible for purchase agreements covering more complex acquisitions of materials, devices, capital equipment or services related to the conduct of research. Research-related transactions typically follow the workflow initiated within the PeopleSoft system. Contact **mmcontracts@mgb.org**

Commercialization process



Faculty Engagement

Increasing the commercial output of Mass General Brigham staff is a continuing system priority. Achieving that goal requires recognition that an academic medical center has a distinct culture and organizational structure that contrasts the structure and culture of potential industry partners.

Engaging potential innovators requires an active, ongoing effort that overcomes the dissonance between the two cultures. Academic innovators have many responsibilities and performance measures. Being an inventor is rarely one of them. Transitioning an idea from an academic setting into the commercial realm can be challenging. Innovation assists and shares information to help optimize the effort and time commitments of innovators. Ensuring the highest level of service is a key Innovation goal.

This support occurs in many ways. The most direct is through Innovation staff – BD&LMs, TAG and others working collaboratively with faculty to get to an outcome. Additionally, most departments have a designated internal point of contact to provide support to potential innovators. There is an ever-expanding number of electronic tools delivered through Insight and MicroStrategy. Innovation also manages several broad educational programs, including annual department briefings plus tailored sessions around key commercialization topics.

The MESH Incubator at Mass General Brigham is Mass General Brigham's system-wide innovation and entrepreneurship incubator for early-stage medical solutions. The first incubator of its kind integrated into a hospital system, and with a physical location onsite, MESH has actively created and supported more than 2,500 clinicians and researchers since 2016 through product development, patents, new company-formation, innovation education, and much more.

MESH has five key programs to help MGB innovators:

- **MGB Innovation MESH Core Healthcare Innovation Bootcamp** is the official innovation course of Mass General Brigham. This award-winning, inventor-built course is designed for the beginner innovator - just the right amount a new clinician or researcher needs to know to participate in the innovation process, network intelligently at conferences, and leverage the resources of a world-class health system. In this course, one systematically learns foundational knowledge, such as the process of creating a new company, landscape digital health, building real artificial intelligence demos, basics of the invention process, patents and much more - all of which are relevant to a vast number of healthcare innovations today. A proven innovation bootcamp curriculum with documented published effectiveness and run at international conferences, this curriculum for all Mass General Brigham employees is free, on demand, at any pace they want. Participants are guided through an 18-hour online course and upon completion are awarded a signed certificate.
- **MESH Innovation Teams Academic Biodesign** A year-long biodesign program transforms ideas submitted by any system clinician, researcher, or health professional to a viable early stage newco, by following the biodesign process and creating multidisciplinary teams across Mass General Brigham, Harvard, MIT, and industry. The healthcare professional can maintain their full clinical or research schedule and does not need to commit more than four hours per week to this program. Clinical champions submit their idea, maintain ownership, and receive assistance from their team and MESH staff to form a company ready for funding. Multiple workshops and design reviews help develop the companies and pitch decks throughout the year. Since 2019, MESH Innovation Teams has produced 12 startups, achieved 22x follow-on funding, won companies' numerous grants, and acquired multiple companies. Any employee may take part. Call for applications is yearly. Learn more.
- **The Innovation MESH Network** An expansive MGB-Harvard-MIT private Innovator's LinkedIn, the Innovation MESH Network is the defacto community for innovators at the health system. Find mentors via structured search across all institutions, investors, co-founders, and more. Learn by taking part in numerous innovation courses and seminars hosted on the platform. https://innovationmeshnetwork.org/register/
- **MESH Innovation & Operations Research Center (MESH IO)** MESH IO is a unique inter-disciplinary research center sitting within the MESH Incubator. IO spans Mass General Brigham, Harvard Medical and Harvard Business School and is comprised of specialty leaders, including physicians and executives in innovation and operations in healthcare. This creative marriage of both innovation and operations researchers is dedicated to investigating key aspects of business in healthcare through original research and thought-leading papers for the medical community. The group is comprised of faculty and executives from

different specialties, including medicine, radiology, emergency medicine, surgery and more.

- **MGB Innovation Grand Rounds** The marquee Innovation monthly series, open to all system employees and the public, features educational and experiential talks from successful industry and academic innovators. It offers fundamental education and guidance through common barriers in translating ideas and inventions from bench to bedside and builds on successful MESH Core Innovation Curriculum Bootcamp.

Promoting Inclusive Innovation

The Innovator Community Expansion Initiative (ICEI) focuses on cultivating an inclusive community at Mass General Brigham. Its mission is to grow and diversify the pool of innovators and offers developmental opportunities for women and diverse faculty and leaders. The initiative employs a data-driven and unique approach to directly impact its target population by focusing on identifying the barriers to innovation and designing tailored interventions to achieve meaningful outcomes. It includes:

- **The Commercialization and Inclusive Leadership Program** (CILP) A collaboration with Babson College, CILP leverages the expertise of entrepreneurial and leadership trained faculty and technical experts who specialize in addressing key steps in the commercialization process. This unique combination of expertise creates a novel and highly impactful learning experience for CILP participants. The program is offered to new and early career researchers including those who have not initiated an interaction or have had limited interaction with the Innovation office with a focus on women clinicians and those currently under-recognized in innovation.
- **Inclusive Board Advancement Program** (IBAP) This effort provides women and diverse senior faculty and leaders opportunities to learn complementary industry business skills and build relationships with industry leaders. It includes development sessions and a networking platform to learn about board service and build connections.

The World Medical Innovation Forum is an annual educational and business development gathering of leading influencers in healthcare. It seeks to educate and motivate faculty about collaborative innovation by highlighting industry priorities and opportunities. It advances system business development by drawing top-level executives to interact with system faculty around cutting-edge topics and technologies. The Forum is organized around key clinical or technology

Merit Cudkowicz, MD, MSc, Massachusetts General Hospital

topics. Themes have included cancer, AI, neurosciences, cardiovascular diseases, coronavirus and gene and cell therapy.

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World Medical Innovation Forum
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Funding

The following chart illustrates common scenarios and who to contact to get started.

Funding sources

Typical research activities		Supporting units
• Reviewing scientific findings as a foundation for characterizing new technologies • Validating disease targets • Exploring device concepts • Developing therapeutic hypotheses • Identifying hit compounds through screening assays	• Government grants (such NIH, NSF, DoD) • Philanthropic organizations (such as AHA, JDRF) • Innovation Discovery Grant (IDG)	Research Management Inform: Business Development& Licensing Manager/Innovation for: • Initial disclosures • Assess patentability • Identifying potential industry partners • Protecting your IP • Understanding the marketplace **IDG** Lesley Watts **lwatts@mgb.org**
• Developing new matter for further testing • Testing compounds for efficacy • Pursuing pharmacokinetic and pharmacodynamic studies • Identifying markers and endpoints for further studies • Evaluating critical design features and components • Pursuing prototype iterations and bench testing • Demonstrating in vitro efficacy for devices or diagnostics	**Industry** **Amplify** **Brigham Ignite** **The Summit Fund** **MESH Innovation Teams Biodesign**	**Industry** Business Development Licensing Manager/Innovation **Amplify** Dione Kobayashi (Therapeutics) **dkobayashi@mgb.org** Erin McKenna (Devices & Diagnostics) **emckenna4@mgb.org** **Brigham Ignite** Erin McKenna **emckenna4@mgb.org** **The Summit Fund** Erin McKenna **emckenna4@mgb.org** **MESH Innovation Teams Biodesign** Marc Succi **msucci@mgb.org**
Clinical Trials	Industry sponsors	Office of Clinical Trials

Working with Industry

Mass General Brigham has made collaborative innovation a system priority. Working jointly with industry brings a responsibility to actively manage potential conflicts of interest. Policies are in place to ensure that research, educational activities and patient care are not inappropriately influenced by economic stake-holding.

Managing Conflicts

Mass General Brigham and Harvard Medical School have jointly adopted conflict of interest management policies that guide, restrict and, in some situations, prohibit certain outside activities.

Innovators are encouraged to become familiar with the policies and the logic behind them. Typically, the more knowledgeable an innovator is the quicker the COI management process can advance.

Office for Interactions with Industry

The Office for Interactions with Industry (OII) oversees MGB policies on conflicts of interest and assists Mass General Brigham staff in navigating those policies. OII is available to assist all innovators.
Inquiries **PHSOII@mgb.org**

The formal Mass General Brigham conflict of interest policies are contained in the Mass General Brigham Policy on Interactions with Industry and Other Outside Entities full policy document. Policies are organized by topic areas.

Harvard Medical School Rules

Harvard Medical School has adopted conflict of interest policies that apply to all HMS faculty. Mass General Brigham has adopted Harvard's rules and applies them to researchers even if they do not have an HMS faculty appointment. Several of the HMS policies initially prohibit narrow categories of activities; for some of these prohibited activities, there is a process by which an exception may be granted (known as a "rebuttable presumption"). Some of the circumstances that may be considered a potential conflict of interest include:

- Outside financial or other interest that may inappropriately influence how the individual carries out their institutional responsibilities
- Outside interests that may be averse to Mass General Brigham
- Use of Mass General Brigham position for personal financial gain

The Harvard and MGB policies that govern faculty and other MGB researchers' interactions with industry are:

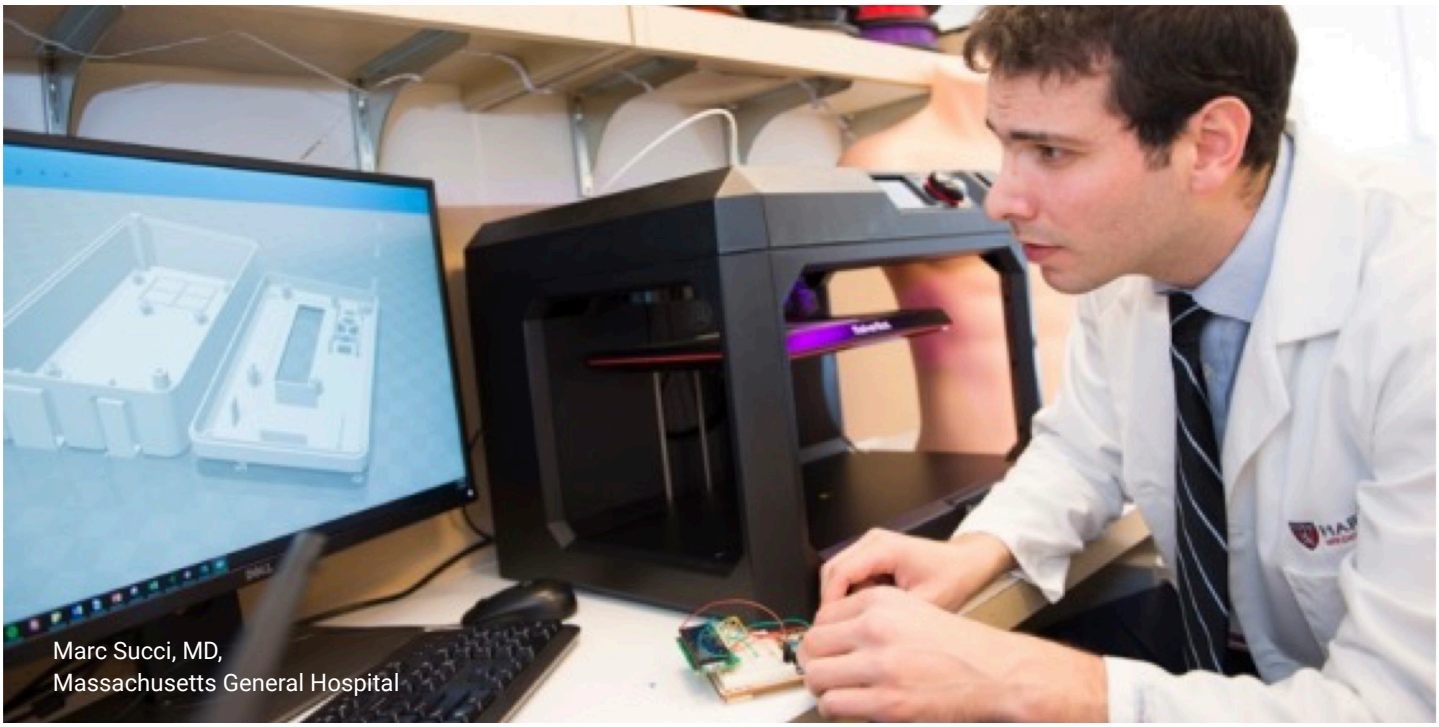
1(a) "Clinical Research Rule" prohibits innovators from participating in clinical research on a technology owned by, or contractually obligated to (e.g., licensed to), a business if the innovator or a member of the innovator's immediate family has any of the following interests in the business:

- Salary, income from consulting or other services, including fees and honoraria, or other financial payments that exceed $25,000 per year
- Stock or similar ownership interest (stock options, member of an LLC) of any amount in a private company
- Stock in a publicly traded company that is valued at greater than $50,000

The policy also defines what it means to "participate" in clinical research (in general having contact with subjects or having access to their personally identifiable information or data) and specifies the duration of "participation" in research for purposes of limiting permissible financial interests to *de minimis* thresholds specified above (generally until first publication). An exception may be granted allowing the innovator to proceed with the research activities even with the financial interest as described above – if a petition is submitted that presents compelling justification for proceeding with the research while holding the financial interest. It requires the approval of the Mass General Brigham and HMS faculty COI committees. Note that exceptions to the Clinical Research Rule are only rarely granted.

1(b) "Research Support Rule" initially prohibits receiving sponsored clinical or non-clinical research support from a company if the innovator has:

- Any equity/owner interest in a private company (e.g., stock or options; member of an LLC)
- Equity (including stock options) greater than 1% ownership in a public company



Marc Succi, MD,
Massachusetts General Hospital

This prohibition may be overcome through a petition to the Mass General Brigham and HMS faculty COI committees that demonstrates that the benefits of the proposed research outweigh the risks and the financial interest can be appropriately managed.

Note that "sponsored research support" has a specific, and broad, definition and includes gifts that are made solely for the support of the faculty member's research or laboratory and equipment and materials under many circumstances.

Two additional HMS policies innovators should be aware of:

1(c) "Executive Position Rule" prohibits full- time HMS faculty, and Mass General Brigham researchers who are also institutional officials, from serving in an executive position in a for-profit business engaged in commercial or research activities of a biomedical nature. An "executive position" includes serving as CEO, COO, CFO, scientific or medical director but also has a broader scope and includes any position that is responsible for a material part of the operation or management of a business. The Executive Position Rule applies only to positions held by the faculty member (not family members). There are no exceptions to this rule. The rule prohibits part-time researchers who hold Executive positions from participating in clinical research on the company's technology and from receiving sponsored research support from the company.

1(d) "External Activity Rule" prohibits researchers who serve in a fiduciary role at a for-profit company from participating in clinical research on the company's technology and from receiving sponsored research support from the company. A fiduciary role includes, but is not limited to, members of the board of directors, executive positions or similar posts. Serving on a scientific advisory board is not considered a fiduciary role. The External Activity Rule applies only to financial interests held by the faculty member (not family members). Other than a limited exception for SMIR/STTR-funded research, there are no exceptions to this rule.

Other Mass General Brigham Policies

Outside activity While Mass General Brigham encourages relationships with outside companies, it imposes some requirements on those relationships, including:

- The Policy on Interactions with Industry requires that most consulting or other engagements with a pharmaceutical or medical device company, or any other vendor or potential vendor of Mass General Brigham, be covered by a written agreement.
- All written personal consulting agreements, with limited exceptions, must be reviewed by the Office for Interactions with Industry (OII) before the engagement to ensure compliance with institutional requirements set forth in the Policy on Interactions with Industry.
- Innovators are responsible for ensuring that the terms of any agreement with an outside activity are consistent with the requirements of applicable Mass

General Brigham policies, including but not limited to, the Policy on Interactions with Industry and the Intellectual Property Policy.

Spin-off requirements There are several issues that are unique to spin-offs, whether they are undertaken with the assistance of Innovation or independently. Innovators are advised to contact OII early in the process of forming a startup for assistance in identifying and handling those issues.

An innovator's services under any agreement to engage in outside activities must not:

- Result in engaging in promotional activity on behalf of the outside entity
- Be performed during regular Mass General Brigham hours
- Involve use of students or trainees
- Overlap with employment responsibilities beyond being in the general area of the faculty member's expertise
- Involve the inappropriate use of the institution's name
- Involve the use of institutional funds or substantial use of institutional resources
- Provide for more than fair market value payment for the services rendered
- Special rules for company-paid speaking engagements

Company speaking engagements Innovators may not participate in certain company-paid or company-hosted speaking and training engagements. Many kinds of company-paid or hosted talks are acceptable if the innovator has control over the content of the talk and the content does not promote or endorse the company and will not be used by the company for its promotional purposes.

Financial interest reporting Comprehensive reporting of personal financial interests and outside activities is required on an annual basis with ongoing updates as necessary in connection with certain kinds of activities, particularly research activities. Investigators on research funded by the NIH or other agencies of the US Public Health Service are, in addition, required under federal regulations to report any "new significant financial interest" acquired that relates to any of their Mass General Brigham responsibilities within 30 days of acquiring the financial interest. The regulations contain a complex definition of what constitutes a "new significant financial interest." OII has additional information on its website on this topic; any investigator who has any question about this 30-day reporting requirement is encouraged to consult with OII.

Institutional officials There are requirements for individuals who hold senior Mass General Brigham positions, referred to as "Institutional Officials." Institutional Officials include chiefs of service/departments, vice presidents and above, and others designated by the CEO or entity Presidents. Institutional Officials must receive prior review and approval by the Committee on Outside Activities before taking on any new outside activity.

Board of Director service All Mass General Brigham staff members – even those who are not Institutional officials – must receive prior approval by the Mass General Brigham faculty Committee on Outside Activities before taking on any board of directors or other fiduciary position in a biomedical company. Review is coordinated by OII.

Time commitment Full-time HMS faculty members may spend up to a maximum of 20% of working time, not to exceed one day a week in the aggregate, on outside activities. Supervisors have the discretion to limit the time to less than 20%. Non-full-time employees on the HMS faculty may spend a limited amount of time for outside research, teaching and other activities as determined by the supervisor.

Gifts | Purchasing activity Other provisions in the Mass General Brigham policy for interactions with industry and other outside entities prohibit the acceptance of gifts from vendors or potential vendors and restrict participation in purchasing discussions and decisions if an individual holds financial interests in potential vendors.

Contact:

Office for Interactions with Industry (OII)
PHSOII@mgb.org

Research agreement quick reference

Agreement type	Agreement subtype	Lead office						
		Research Management	Clinical Trials Office	Innovation	Supply Chain	OII	VP/Dept	Development
Clinical research support	CRSA with Regulatory Sponsor as Industry		•					
	CRSA with Regulatory Sponsor as Nonprofit/Government	•						
Clinical research	CTA with Regulatory Sponsor as Industry		•					
	CTA with Regulatory Sponsor as Nonprofit/Government	•						
Confidential disclosure	CDA with Nonprofit/Government	•						
	CDA with Industry: Non-Clinical Research and Commercialization			•				
	CDA with Industry: Clinical Research		•					
	CDA from/to vendors associated with RFPs				•			
Data use	DUA with Nonprofit/Government	•						
	DUA with Industry: Non-Clinical Research			•				
	DUA with Industry: Clinical Research		•					
Educational programs	Fellowship/Training sponsored by Industry					•		
	Fellowship/Training sponsored by Nonprofit/Government	•						
Epidemiological research	Data Outcomes Research sponsored by Industry		•					
	Data Outcomes Research sponsored by Nonprofit/Government	•						
Equipment/software	Equipment/Software Loan from Nonprofit/Government (no funding)	•						
	Equipment/Software Loan from Industry: Clinical (no funding, not "Try to Buy")		•					
	Equipment/Software Loan from Industry: Non-Clinical (no funding, not "Try to Buy")			•				
	Equipment/Software purchase and "Try to Buy"				•			

Research agreement quick reference

Agreement type	Agreement subtype	Lead office						
		Research Management	Clinical Trials Office	Innovation	Supply Chain	OII	VP/Dept	Development
Gifts	Financial gifts for all types of research							•
Institutional services	Mass General Brigham is the vendor						•	
Intellectual property	Licensing of Intellectual Property (Patents/Copyright)			•				
Material transfer	MTA with Industry and Nonprofit/Government (no funding)			•				
Patient registry	Patient Registry sponsored by Nonprofit/Government	•						
	Patient Registry sponsored by Industry		•					
Personal consulting	Mass General Brigham PI is the consultant					•		
	Purchase of external consulting research services				•			
SBIR/STTR	SBIR/STTR with Industry: Non-Clinical Research			•				
	SBIR/STTR with Industry: Clinical Research		•					
	SBIR/STTR Letter of Intent (with proposal)	•						
Sponsored research	SRA with Nonprofit/Government	•						
	SRA with Industry: Clinical		•					
	SRA with Industry: Non-Clinical			•				
Supply chain	Purchase of goods/services from vendors				•			
	“Try to Buy” agreements				•			
	Incoming leases for goods/services				•			

Highest Impact Products from Mass General Brigham Breakthroughs

Innovators at Mass General Brigham are part of a long history of discovery that began more than two centuries ago, involving the operating theater, the lab, the exam room and increasingly, the home. Hundreds of millions of patients around the world have benefited from the inspiration and actions of our caregivers.

Enbrel®
Treatment for autoimmune diseases
Brian Seed, PhD

cobas® EGFR Mutation Test
Diagnostics for non-small cell lung cancer
Daniel Haber, MD, PhD

Victoza®
Treatment for Type 2 diabetes
Joel Habener, MD

INOmax®
Hypoxic respiratory failure treatment in neonates
Warren Zapol, MD

Durasul®, Longevity, E1®, Vivacit-E®
Polyethylene that reduces orthopedic implant wear
William H. Harris, MD, DSc
Orhun Muratoglu, PhD

Visudyne®
Photodynamic therapy of wet AMD
Tayyaba Hassan, PhD
Joan Miller, MD
Evan Gragoudas, MD

Eloctate®, Alprolix®
FcRn fusion technology to extend half-life of coagulation inducing Factor VIII and Factor IX
Richard Blumberg, MD

StarLux™
Laser hair removal
Rox Anderson, MD

Coolsculpting®
Selective freezing of fat for aesthetic fat removal
Rox Anderson, MD
Dieter Manstein, MD, PhD

Entyvio®
Treatment of ulcerative colitis and Crohn's disease
Robert B. Colvin, MD
Andrew Lazarovits, MD

Index

Mass General Brigham

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