Innovator’s Commercialization Guide
Table of Contents

On Innovation 4
Introduction 5
Acting on an Invention 9
Intellectual Property 12
Licensing 16
Digital Health 18
Company Creation and Investing 20
Strategy and Alliances 25
Research Collaboration Agreements 27
Faculty Engagement 33
Funding 35
Working with Industry 37
Index 42
Dear Mass General Brigham Innovator,

As a member of the Mass General Brigham community, your inspiration and insights are essential to improving care for our patients and delivery by our colleagues. Your success as an innovator is a system priority and reflects a central element of our strategic plan.

Our goal is to drive innovation in every unit, phase and corner of our large system. This guide supports a key part of that, the translation and commercialization of the innovations of our staff. The guide should help enable industry collaborations and result in new patient benefiting products. From the first steps of disclosing, translating and protecting an idea, to the basics of “who do I contact?” It provides important information for the full distance of your innovation journey.

Whether early in your journey or an experienced veteran, Mass General Brigham Innovation is ready to assist you in achieving a commercial outcome. The path from bench to bedside can be complex. Innovation provides support through each step of the process.

Innovation works closely with colleagues from our hospital research institutes and system-wide research support groups including the Clinical Trials Office, Human Research Affairs, the Office of Interactions with Industry, Research Institutes, Research Management, Supply Chain, Data and Tissue Sharing Committee and others.

Best wishes in your future breakthroughs.

Sincerely,

Anne Klibanski, MD
President and CEO
Mass General Brigham
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 the 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, “Who do I contact,” at any point. Achieving successful commercial outcomes that transcend the boundaries between the academic and industrial sectors, given their different missions and cultures, requires a clear understanding of processes, priorities and challenges.

Expanding the pool of innovators is a priority for the entire Mass General Brigham system. Relatively low participation rates among women, clinicians, underrepresented minorities and early career faculty deprive medicine of innovations that might benefit patients. Innovation runs a set of programs, described later in this guide, designed to increase staff participation in each area. Please note, for narrative brevity, the 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 hospitals.

**Overview**

Innovation is a way of thinking to solve problems and often enables the creation of commercial value. As Thomas Edison famously said, “the value of an idea lies in the using of it.”

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. These can lead to products by addressing a specific problem, demonstrating its importance and establishing that someone is willing to pay for it.

The need and opportunity for health care innovation have never been greater. Health care transformation and digital health have further accelerated due to the pandemic. Life science venture and applied research investments are at historic highs, NIH annual funding is nearly $44 billion and public markets continue to amply 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 to implement them. These might be in a clinical department to drive innovative care paths, an administrative unit looking to create disruptive solutions or a hospital research institute convening faculty to jointly advance disease focused translational research.

Invention Disclosure Form

Find your department’s Licensing Manager

Innovators are a small segment of the 80,000 Mass General Brigham employees yet their impact can be enormous. Their unique insights solve problems, improve care and enhance lives – in New England and around the world. Commercialization almost always starts with their inventive inspiration.

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 Licensing Manager 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 its 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 Licensing Manager.

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

Inventors 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 for the invention.

**Commercialization**

Responsibility for commercialization of Mass General Brigham discoveries and technology-based innovation rests exclusively with Innovation. A business development unit, it serves all employees and hospitals within the system. It 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
**Licensing Manager**

Licensing Managers (LMs) are members of the Innovation Licensing Group. They are the primary point of commercialization interface and act as a partner to the inventor. LMs work collaboratively with other Innovation units including Digital Health, Venture, Market Sectors, Intellectual Property (IP), Operations and the Transactional Affairs Group and draw in other system units such as the Office of Interactions with Industry, as needed.

The LM provides technology assessment, process support, market outreach, deal making, company liaison and knowledge of system capabilities. LM outcomes include licenses, options, sponsored research agreements, invention assessment, technology marketing, IP development and license compliance. Efficiency increases when the inventor and the LM have a strong working relationship.

Productivity is of extra importance for both the active inventor and LMs who are responsible for dozens of investigators and hundreds of agreements.

**Continuing Partnership**

Innovators are encouraged to provide specific performance feedback to their LM and/or the Innovation office. Ongoing input helps to enhance commercialization outcomes as well as innovator service levels and satisfaction. A simple email is a continuous improvement tool and much valued. There is also an annual innovator survey to gain large scale insights which in turn may affect process changes.

Maintaining a strong inventor-LM collaboration is also important given the dynamics of the local labor market. Boston based drug, device, diagnostic, digital and startup companies as well as investment funds continuously search for new, deal making employees. Providing a vibrant workplace where LMs and other team members are valued, engaged, and have an opportunity to grow is key to their retention and helps in the recruitment of new staff.

There is an assigned Licensing Manager (LM) for every chief code at Mass General Brigham. Complete lists of LM and other Innovation contacts can be accessed via Insight.

---

**Clinicians**

Clinicians have a unique ability to perceive unmet needs and improve patient outcomes. While satisfying to develop a new method or technique to help one or a few patients, through commercialization, it is possible to extend benefits to hundreds, thousands or more patients. By creating more convenient, more effective, and less expensive treatments patients can be served at scale.

Mass General Brigham combines discovery research and world class care. That allows practitioners to be innovators in the truest sense – to invent and to inform conversion to practice. Even without prior experience, practitioners learn to speak the language that allows them to better communicate effectively with grant agencies, funders, colleagues, and other clinician and research leaders and with potential commercial partners.

---

**Bayh-Dole Act**

The U.S. Bayh-Dole Act of 1980 allows institutions to own the rights to discoveries resulting from federally funded research, provided they work to actively commercialize the technology.

---

**Additional information**

innovation_partners.org
phsinnovationsupport@partners.org
LM Chief Code
The first step is the inventive insight which may occur anywhere and be made by any Mass General Brigham employee. Disclosing an invention is the first formal action in the commercialization process. The more thorough the initial disclosure the more rapidly the commercialization can proceed. 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.

**Invention Disclosure**

An invention disclosure is a description of the invention and is submitted online. 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 to allow the person to contact Innovation prior to preparing. The IDF is confidential and not a public disclosure.

**The IDF**

A fully completed Invention Disclosure Form
- with citations, prior art references, market descriptions, co-inventors and related – helps the commercialization process proceed quickly. 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, as 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 USPTO search engine is a helpful tool and 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 (IDF)**

**Inventorship**

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 criteria for a contributor to be listed as an inventor on a patent application are 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 the invention is not considered an inventor, even if they were a valuable contributor to the development of the invention. For example, someone who contributed 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.

**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, meeting reviews, posters and oral presentations, dissertations and theses, and online publications including laboratory webpages or social media.

Common situations which 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 Licensing Manager in advance of any potential public disclosure is recommended to assure protection.

Even if an IDF has been submitted, the invention needs to be confidential until a patent application is filed. This is often initially via a “provisional filing”, a temporary 12-month protection that becomes public information if it is converted into a “non-provisional” (i.e. full) patent. 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 13 for more background on patenting.

**Contact(s)**

Find your department’s Licensing Manager
phspatents@partners.org

**Post Disclosure**

As the technology advances, the inventor should plan on devoting time for interactions with licensing staff, patent counsel and industry representatives, including make themselves available to the Licensing Manager and IP staff for follow-up information as required; execute documents required for completion of the patent application filings in a timely fashion; provide perspectives on commercial application of the technologies.

**Timing**

Following the submission of a completed Invention Disclosure Form, Invention Record numbers and Licensing Managers are assigned within 24 hours of receipt. Assessing the disclosure may take. The Licensing Manager provides guidance regarding timelines.

**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 advantages, market potential, 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.

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

**Status Updates**

LMs provide updates and be contacted directly with any questions. New electronic tools are being implemented to automate status updates.
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:

1. Patents for inventions
2. Copyrights for software, artistic or literary works
3. Trademarks for logos and brand names
4. Trade secrets, which cover expertise and know-how

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

Common Definitions

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

**Copyright.** A legal right which 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.

**Inventor.** The U.S. Patent and Trademark Office describes an inventor as “one who contributes to the conception of an invention.” The invention is defined by the novel claims that it gives rise to, so an inventor must have contributed to what is claimed by the disclosure.

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

**Inventor’s Commercialization Guide | Mass General Brigham**

In 2011 the America Invents Act (AIA) was passed into law converting the U.S. patent system from intellectual property protection based on “first to invent” to “first to file”.

**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. The approach to protecting an invention considers patentability, markets, opportunity for an innovation and freedom to operate. These are used to prioritize the expenditure of limited resources and increases the likelihood of a return. A set of domain expert patent law firms prosecute patents and maintain dockets. About half of patent expenditures are ultimately reimbursed by licensees. Targeted patent strategies are used to enhance the value of breakthrough technologies or portfolios. This asset development is used in active fields with substantial commercial opportunity and competition. Tactics can include “picket fences” and “patent estates”. A picket fence is used to block competitors from designing around the claims of an original patent by filing a series of patent applications that vary in claim scope around the original core invention. A patent estate is the complete patent rights in an area owned by a person or entity.
Patentability

Essential to securing a patent is determining if an invention is truly novel, i.e. has not been patented before nor is in the public realm. Lack of novelty is the most common reason for initial rejections. Licensing Managers 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 U.S. Patent and Trademark Office and Google are among the many services an innovator can access.

Obtaining patent protection requires meeting four key requirements:

1. **New.** 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 prior to applying for a patent. This includes printed and online publications, as well as public 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.

2. **Inventive.** The invention must not be obvious to a person skilled in the art. In patent law, a “person skilled in the art” is a hypothetical individual who knows the prior art in their specialist field. If the inventor describes the purpose of the invention to this person, and she or he readily comes up with the same solution, then the solution is probably not inventive.

3. **Industrially applicable.** The invention must be industrially applicable and practicable, and it must demonstrate that it is implementable and be possible for others skilled in the art to replicate its implementation. In other words, it must be able to be produced and used in the settings for which it is intended.

4. **Non-patentable.** Laws of nature, natural phenomena, and abstract ideas are not patentable. While discoveries such as a new gene, biomarkers, molecular targets or algorithmic formulas are not considered inventions, and therefore are not patentable, they can lead to patentable inventions.

**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 the solution is probably not inventive.

**Inventorship Determination**

Inventorship must be correct for patent validity. It is a requirement of invention that the invention before a patent is filed is considered prior art and therefore invention is no longer considered new.

**Inventive.** The invention must not be obvious to a person skilled in the art. In patent law, a “person skilled in the art” is a hypothetical individual who knows the prior art in their specialist field. If the inventor describes the purpose of the invention to this person, and she or he readily comes up with the same solution, then the solution is probably not inventive.

**Industrially applicable.** The invention must be industrially applicable and practicable, and it must demonstrate that it is implementable and be possible for others skilled in the art to replicate its implementation. In other words, it must be able to be produced and used in the settings for which it is intended.

**Non-patentable.** Laws of nature, natural phenomena, and abstract ideas are not patentable. While discoveries such as a new gene, biomarkers, molecular targets or algorithmic formulas are not considered inventions, and therefore are not patentable, they can lead to patentable inventions.

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 distribution policy 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. The 45% to the inventor(s) and the inventor’s lab is allocated between inventor and the lab or unit, by the Principal Investigator with 30% maximum going to the inventors or the lab.

**Inventor Shares**

The principal investigator specifies the relative contributions of the multiple inventors at the initial disclosure. That designation becomes the basis for potential financial distribution if the technology generates commercialization revenue. Hospital leadership resolves disputes among inventors regarding their relative contribution following a process in the Mass General Brigham IP policy.

**Former Employees**

IP ownership is retained by the institution. Distributions to individuals continue to be paid to the inventor or to their estate if deceased. Unless the lab continues past resignation, the inventor’s lab share is split between the hospital and the home department.

**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 retired before any distribution occurs.

**Contact**

phspatents@partners.org

---

**Patent Timeline for U.S.**

<table>
<thead>
<tr>
<th>Step</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal review</td>
<td>3-6 months</td>
</tr>
<tr>
<td>Provisional Application</td>
<td>12 months</td>
</tr>
<tr>
<td>PCT Application</td>
<td>18-19 months</td>
</tr>
<tr>
<td>National Stage Application</td>
<td>90 days</td>
</tr>
<tr>
<td>Patent</td>
<td>3-6 years</td>
</tr>
<tr>
<td>Allowance</td>
<td>Within 90 days</td>
</tr>
<tr>
<td>File Continuation</td>
<td>3-6 years</td>
</tr>
<tr>
<td>Issued patents and continued prosecution</td>
<td>3-6 years</td>
</tr>
</tbody>
</table>

---

**Figure 1 | Patent timeline for U.S.**
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 the institution by the licensee. Established precedents generally guide license negotiations. If a technology represents an entirely new category, comparable technologies or products are used to form the basis of an agreement.

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 a executing a license generally takes several months. Early stage technologies that require significant investments can take longer.

Licensing Group

The Licensing team covers every clinical and research chief code at Brigham Health, Mass General, Mass Eye and Ear, McLean and Spaulding and selectively at the community hospitals. Licensing Managers and other licensing staff evaluate new inventions, market technologies, negotiate 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 LM is responsible for several dozen investigators.

Contact

Rebecca Listfield, PhD
Managing Director, Licensing
rlistfield@partners.org
Mass General Brigham was an early leader in digital health starting with medical informatics pioneer Octo Barnett, MD who came to MGH in 1964 to head the pathbreaking Hospital Computer Project. More recently, in 2019, a system-wide initiative was launched to substantially increase the use of data and digital capabilities in the delivery and management of care.

System strategy is to drive care and margin enhancements through the targeted use, collection and analysis of large data sets and implementation of the breakthrough digital solutions. Mass General Brigham seeks to increase digital innovation in every phase of care and every element of its own operations.

The Enterprise Data and Digital Health (EDDH) initiative incubates innovative digital approaches with the goal of expanding programs that show provider adoption and patient impact. The EDDH is among the multiple system activities to increase the reach and frequency of interactions with patients using novel technologies to deliver cutting-edge programs with proven outcomes to manage chronic conditions such as diabetes and hypertension. Early priorities include hospital operations in bed capacity management, human resources, active asset management, supply chain and revenue cycle operations.

Digital Health Commercialization

To support the rapid acceleration, deployment and commercialization of digital health technologies, Innovation includes a business development team focused exclusively on advancing system digital health solutions to market and accessing external collaborators and technology.

The Digital Health commercialization efforts include the Center for Clinical Data Science (CCDS). It also supports Mass General Brigham’s many digital health departments including EDDH, Data and Digital Health (DDH), AI, big data and analytics, DHI (Digital Health Innovation), and DCT (Digital Care Transformation). The team offers a range of services that support a diverse portfolio of projects. These include new business ventures, co-development with industry and execution of digital-based care delivery initiatives. It also supports and guides the $30 million AI and Digital Innovation Fund (AIDIF) that invests in digital companies partnering with Mass General Brigham (see page 24).

Expertise includes:
- Application development
- Advanced analytics
- Consulting
- Deal structure creation
- Digital frameworks
- Digital integration, deployment and care transformation
- Joint development with industry
- Negotiation
- Piloting and validation

Contact
Trung Do
Vice President, Business Development
tqdo@partners.org

As a clinician scientist you are poised between the science of discovery and the translation to clinical application. You are acutely aware of the unmet clinical needs of your patients, and by problem solving through science and technology, you can arrive at a practical solution for that need. Being a key team member developing new therapies from the laboratory to patients is the most exciting professional experience of my life.

Joan W. Miller, MD
Mass Eye and Ear, Ophthalmology
Mass General Brigham Ventures

Mass General Brigham Ventures (MGBV) is responsible for therapeutic, digital and translational investment funds with half a billion dollars under management. An internal, early stage investment unit of Innovation, established in 2008, it accelerates the commercial application of the system’s research breakthroughs. MGBV has created dozens of portfolio companies. Its financial performance ranks it among the top 25% life science venture funds in the United States. In 2020 it grew to include a $30 million digital early stage investment and a pre-commercial translational investment fund budgeted at $10 million per year. The internal rate of return of the original fund is equivalent with top quartile venture capital funds. It co-invests with the venture industry's leading life science investors. The companies it has backed have raised billions of dollars of follow-on capital.

The Ventures team works closely with innovators across the system and other Innovation units to identify investment opportunities. Fund staff support portfolio companies through their lifecycles from pre-commercial to exit. The Fund 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. 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 contribute to multiple marketable products or combinations of technologies which 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 ability to access meaningful markets. The more advanced the program, the more value and attention will be paid by 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.
### Research agreement quick reference

<table>
<thead>
<tr>
<th>Agreement type</th>
<th>Agreement sub-type</th>
<th>Lead office</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical research</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>CRS Agreement with Regulatory Sponsor as Industry</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>CRS Agreement with Regulatory Sponsor as Non-Profit/Government</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>CTA Agreement with Regulatory Sponsor as Industry</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>CTA Agreement with Regulatory Sponsor as Non-Profit/Government</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Confidential disclosure</strong></td>
<td></td>
<td>Development</td>
</tr>
<tr>
<td></td>
<td>CDA Agreement with Non-Profit/Government</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>CDA Agreement with Industry: Non-Clinical Research and Commercialization</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>CDA Agreement with Clinical Research</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>CDA from/to vendors associated with RFPs</td>
<td>VP/Dept</td>
</tr>
<tr>
<td><strong>Data use</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>DUA Agreement with Non-Profit/Government</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>DUA Agreement with Industry: Non-Clinical Research</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>DUA Agreement with Industry: Clinical Research</td>
<td>VP/Dept</td>
</tr>
<tr>
<td><strong>Educational programs</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Fellowship/Training sponsored by Industry</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>Fellowship/Training sponsored by Non-Profit/Government</td>
<td>VP/Dept</td>
</tr>
<tr>
<td><strong>Epidemiological research</strong></td>
<td></td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>Data Outcomes Research sponsored by Industry</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>Data Outcomes Research sponsored by Non-Profit/Government</td>
<td>VP/Dept</td>
</tr>
<tr>
<td><strong>Equipment/Software</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Equipment/Software Loan from Non-Profit/Government (no funding)</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>Equipment/Software Loan from Industry: Clinical (no funding, not “Try to Buy”)</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>Equipment/Software Loan from Industry: Non-Clinical (no funding, not “Try to Buy”)</td>
<td>VP/Dept</td>
</tr>
<tr>
<td></td>
<td>Equipment/Software purchase and “Try to Buy”</td>
<td>VP/Dept</td>
</tr>
</tbody>
</table>

Figure 2 | Each research agreement type has a responsible office

### Research agreement quick reference

<table>
<thead>
<tr>
<th>Agreement type</th>
<th>Agreement sub-type</th>
<th>Lead office</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gifts</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Financial gifts for all types of research</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Institutional services</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Mass General Brigham is the vendor</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Intellectual Property</strong></td>
<td>Licensing of Intellectual Property (Patents/Copyright)</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Material Transfer</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>MTA with Industry and Non-Profit/Government (no funding)</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Patient Registry</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Patient Registry sponsored by Non-Profit/Government</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Patient Registry sponsored by Industry</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Personal consulting</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Mass General Brigham PI is the consultant</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Purchase of external consulting research services</td>
<td>OII</td>
</tr>
<tr>
<td><strong>SBIR/STTR</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>SBIR/STTR with Industry: Non-Clinical Research</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>SBIR/STTR with Industry: Clinical Research</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>SBIR/STTR Letter of Intent (with proposal)</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Sponsored research</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>SRA with Non-Profit/Government</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>SRA with Industry: Clinical</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>SRA with Industry: Non-Clinical</td>
<td>OII</td>
</tr>
<tr>
<td><strong>Supply chain</strong></td>
<td></td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>Purchase of goods/services from vendors</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>“Try to Buy” agreements</td>
<td>OII</td>
</tr>
<tr>
<td></td>
<td>“Try to Buy” agreements</td>
<td>OII</td>
</tr>
</tbody>
</table>

**Additional information**

[Contact information for other research areas](#)
Company Leadership
From an investor perspective, securing the right leadership for the newco is critically important. Seasoned entrepreneurs with a deep domain experience are expected. Investors are wary of proposed company leaders who have a family relationship with the scientific founder or ones 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 scientific founder they receive an ownership stake in the company through 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 later, 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. Additional considerations must be addressed when patient data or tissue are involved.

Artificial Intelligence
and Digital Innovation Fund
The Artificial Intelligence and Digital Innovation 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 Grant (IDG) program is an annual 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. The Boston Biomedical Innovation Center (B-BIC) is a federally funded translational support and assistance program. Hospital specific translational initiatives help to accelerate promising technology and to assist emerging faculty who aspire to be more commercially active. They seek to identify and ideate around unmet medical needs with a focus on high priority, clinically relevant projects organized via a market pull model. Where appropriate, selected innovations will be deployed into clinical settings to accelerate reduction to practice and commercialization outcomes. Some of the programs provide direct translational funding. Innovation works collaboratively with Brigham Research Institute, Mass General Hospital Research Institute and similar efforts at McLean Hospital, Mass Eye and Ear and Spaulding Rehabilitation Network.

Contacts
Venture
Roger Kitterman
Vice President, Venture
rkitterman@partners.org
AIDIF
Gaye Bok
Partner
gbok@partners.org
TIF
Dione Kobayashi, PhD
Head of Therapeutics and Operating Partner, TIF
dkobayashi@partners.org
innovation.partners.org/partners-innovation-fund-and-company-creation

Strategy
and Alliances
Senior Strategists
Senior executives with decades of high-level industry experience selectively add a market-pull dimension to conventional technology-push commercialization. This group, known as Market Sector Leaders, advises on technology marketability, asset development, industry trends, large transactions, and deal structures. Market Sector Leaders also work with entity research institutes to advance emerging areas of opportunity. It works in partnership with other Innovation units including Licensing, Digital Health Innovation and Ventures.

The Market Sector team drives the development of strategic plans to grow commercial outcomes in areas of system priority. The system-wide gene and cell therapy (GCT) strategy is being developed to increase industry linkages, enhance internal capabilities and identify potential investments to enhance high value GCT assets. The Market Sector team consists of Mass General Brigham employees as well as part time Executives in Residence.

Innovation Growth Board (IGB). The IGB consists of senior leaders from the venture, corporate and entrepreneurial communities and advises Innovation on commercial and technology strategy as well as making priority links. The IGB meets three times a year. It also works through a subcommittee structure to give added support in priority areas such as gene and cell therapy, digital collaborations and human resource development.

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 six times per 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. Alliance partners are global health care 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. The below are staffed by dedicated units within Innovation actively collaborating with entity clinical, research and institute staff.

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. GE, Nvidia, and Nuance participation in the Center for Clinical Data Sciences is a current example.

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, Bayer and Pfizer Centers for Therapeutic Innovation.

Funding awards. 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 and a facilitated review. Examples include Sanofi iAwards, Boston Scientific and Novartis Institute for Biomedical Research (NIBR) Global Scholars Program.

Educational programs. Innovation also manages dedicated instructional efforts to build industry skills among system faculty and nurture translational collaboration. The Innovation Fellows Program is a short-term, co-mentored industry placement opportunity for Mass General Brigham staff. The program goal is to place junior system faculty in industry experiential settings on a full or part-time basis for between six and twenty-four months. 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.

Contacts
Alliances
Seema Basu, PhD
Market Sector Leader
ssbasu@partners.org

Digital Alliances
Trung Do
Vice President, Business Development
tqdo@partners.org

Market Sectors
Pat Fortune, PhD
Vice President, Market Sectors
pfortune@partners.org

Pharmaceutical Services Strategic Alliances
PHSStrategicAlliances@partners.org
Collaborative innovation is core to advancing healthcare and a long-standing system priority. Successful partnering combines the best of the public and private sectors and is enabled by a set of agreements including Sponsored Research, Material Transfer, Data Use, Confidentiality and Institutional Services.

**Sponsored Research Agreements**

Sponsored Research Agreements (SRA) enable industry-funded, pre-clinical research. SRAs rely on hypothesis-driven research in furtherance of the hospital’s medical and educational mission. The more than 250 Mass General Brigham SRAs transacted annually follow a template with a scope of work determined by the innovators and agreed to by the industry sponsor and a budget. The agreement must have departmental approval and include appropriate overhead, the same as used in NIH funded non-clinical projects. In all cases, it is recommended that the Research Management budget template be used to create the initial budget. It incorporates the appropriate fringe benefit rates for staff along with the required indirect charges. Estimating the correct budget at the beginning of the sponsor negotiation process is essential.

SRAs are not used for packaged services and consulting arrangements – typically they are covered by Institutional Service and individual consulting agreements, both supported by the Office of General Counsel. After the scope of work and budget are agreed to by the industry sponsor and the innovators, the SRA request is triaged by Innovation to confirm the following requirements are met:

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

Once conditions are met, Innovation negotiates SRA terms to comply with system and federal policies. While turnaround time is a key performance measure, it can take up to several months to complete an industry agreement. Processing time can be minimized by an upfront understanding of organizational requirements.

Contract terms for sponsors to be aware of include protecting the investigator’s ability to publish; hospital ownership of any intellectual property (IP) created by the investigator during the project; sponsor’s scheduled payment of budgeted expenses; and no unauthorized use of the investigator, hospital or system name. 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.

**Material Transfer Agreements**

An incoming Material Transfer Agreements (MTA) allows investigators to receive or share material or human tissue for pre-clinical research. These agreements are required by non-profits, 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 tissue 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 and, 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 and,
- 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 tissue 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. 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@partners.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 non-profit entities follow a standard template and are quickly executed. Many companies require nonstandard terms which 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.

**MTA Review by IRB.** The transfer of any human tissue – i.e., clinical specimens, research specimens, or patient data – always requires Institutional Review Board (IRB) review, but not necessarily an MTA. As a matter of course, the transfer of human tissue to an academic institution or academic collaborator will not require an MTA if:
- There is no compensation other than the costs of preparing and shipping the material;
- The specimens or data were not collected in a protocol or study funded by a company;
- The recipient does not plan to use the human tissue in industry-supported research; and
- The human tissue has not been previously transferred to a for-profit company.

Under these circumstances, a letter prepared by IRB is sufficient. If the answer to any of the above questions is yes, an MTA may be necessary. For transfers that do not meet the criteria for use of the investigator template, please submit a Request for a Material Transfer Agreement, via Insight.

For further guidance, please refer to the IRB website.

For additional information, please contact: phsinnovationpartners@partners.org or TAG PHSMTA@partners.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 the 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 (TAG) 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. DUA’s should be submitted to TAG through the Insight Agreement module.

TAG ensures data de-identification and constitute a Limited Data Set (LDS); 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.

TAG refers nonstandard requests to the Data and Tissue Sharing Committee (DTSC). The DTSC becomes involved if the data sharing intends to leverage data solely as part of a product development or commercial validation; 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 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 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 data.

**Consulting Agreements**

Faculty can consult with industry if the engagement follows organizational policies. All agreements for individual consulting are subject to review and approval by the Office for Interactions with Industry (OII). Investigator (the “Consultant”) performs services for a third party. The agreement must not involve Mass General Brigham resources, property, technology, information or other assets. OII reviews agreements for their compliance with institutional policies, not for the faculty personal or business interests.

The potential consultant should send an email, with the proposed agreement, to PHSOII@partners.org to initiate the review process. The Consultant will be asked to complete a Conflict of Interest questionnaire. After completion of the questionnaire, OII reviews the agreement.

**Institutional Service Agreements**

Outside parties (companies, government agencies, foundations, schools, etc.) occasionally ask staff to provide services in exchange for a fee. Examples of requested services include evaluation, feedback, or testing related to devices, software or compounds; retrospective reviews of data or literature associated with research studies; demonstration of clinical techniques; development of training programs focused on specific disease states; and providing other consulting services. The Institutional Service Agreement (ISA) documents the terms and conditions for the services to be provided. An ISA usually must be prepared or reviewed by the Office of the General Counsel prior to finalization.

ISA projects must ensure that system resources and assets are utilized only in projects that support the system’s charitable mission. Indirect cost rates for ISAs are 59% for industry, 44% for academia. The lab or department where the work is to be done is responsible for obtaining required approval. ISA proposals need to include:

- Description of the scope;
- Identification of the company, agency, foundation, etc.;
- Project budget;
- Statement of justification;
- Discussion of any other relevant considerations, including whether any of the system staff who will work on the project have a personal financial interest in the outside party.
Innovation Operations & Analytics

Innovation Operations consists of three groups, Intellectual Property, Transactional Affairs, and Finance, charged with supporting the innovator’s pathway to commercialization. Their range of services include processing Invention Disclosures, working with Licensing Managers to protect intellectual property through patent filings, prosecution management, executing agreements and managing hundreds of millions of dollars of revenue invoicing, collections and internal distributions.

Intellectual Property Group collaborates with innovators and Licensing Managers on disclosures to ensure they are ready for review and patent protection. They set IP strategy, file world-wide patents on behalf of the innovators, manage the system’s up to $15 million annual patent investment, 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.

For more information, please contact Operational Support at: phsinnovationsupport@partners.org

Research Support Offices

Several Mass General Brigham units support research, discovery and invention. Functions are described below and the Research Agreement Quick Reference diagram (Figure 2) describes typical interactions.

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 Forte. Contact: CTOmailbox@partners.org

Data Tissue Sharing Committee (DTSC) approves 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. 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@partners.org

Office of 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.

Research Institutes. Brigham Health and Mass General have research institutes that, among other topics, work with investigators to organize, educate and assist them in their interactions with industry and in obtaining research support. McLean and Mass Eye and Ear have similar activities.

Research Management (RM) supports researchers and hospital departments with grants, contracts, finance, systems, core facilities, analytics and industry-sponsored clinical research. Contact: phsresearchmanagement@partners.org

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.
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 which contrasts the structure and culture of potential industry partners. Engaging potential innovators requires an active, ongoing effort which 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 committed 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 – Licensing Managers, 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 mostly through Insight but also by Innovations Wellspring information management system. Innovation also manages several broad educational programs including annual departmental briefings plus tailored sessions around key commercialization topics.

The Innovator Community Expansion Initiative (ICEI) provides hands on assistance to increase the number of innovators and their actionable output. It includes:

**Clinician and Early Career Outreach.** Spearheaded by the Innovation’s Clinician-in-Residence, this peer-led effort provides tailored, on-line information designed to inform, encourage and demystify the innovation process. It seeks to engage clinicians in their environment and provide the information and encouragement necessary to drive innovative approaches and achieve actionable outcomes. Parallel outreach efforts are designed to reach junior research staff to equip them to work with industry.

**Female and Underrepresented Minorities.** Focused efforts are designed to reach female and minority staff to help overcome a historic pattern where commercialization participation has been 25% or less of male or majority levels. Addressing this underrepresentation will increase the pool of actionable Mass General Brigham commercial innovation. Mentoring, peer modeling and industry mentoring programs are designed to help address the disparity.

**The World Medical Innovation Forum** is an annual educational and business development effort. 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 a key clinical or technology topic. Themes have included cancer, AI, neurosciences, cardiovascular, coronavirus and gene and cell therapy. Contact: worldmedicalinnovation.org

**Funding**

When prepping for the commercialization process, try to think of ‘pathway to platform’ right from the beginning. At some point you may find yourself talking with an investor and you’re going to need to tell the entire story completely and concisely.

Richard Blumberg, MD
BWH, Gastroenterology, Hepatology and Endoscopy
Funding to support the validation, scale up or other translation steps have historically been difficult to secure. A variety of funding opportunities are now available depending on the type and stage of technology development. Licensing Managers can assist in navigating the possibilities while protecting intellectual property throughout this journey.

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

<table>
<thead>
<tr>
<th>Funding sources</th>
<th>Typical research activities</th>
<th>Supporting units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government grants (such NIH, NSF, DoD)</td>
<td>• Reviewing scientific findings as a foundation for characterizing new technologies</td>
<td>Primary responsibility: Government grants (such NIH, NSF, DoD) Inform: Licensing Manager/Innovation for • initial disclosures • assess patentability • identifying potential industry partners • protecting your IP • understanding the marketplace</td>
</tr>
<tr>
<td>Philanthropic organizations (such as AHA, JDRF)</td>
<td>• Validating disease targets • Exploring device concepts • Developing therapeutic hypotheses • Identifying hit compounds through screening assays</td>
<td>IDG Team Lead: Lesley Watts, <a href="mailto:lwatts@partners.org">lwatts@partners.org</a></td>
</tr>
<tr>
<td>Innovation Discovery Grant (IDG)</td>
<td>• Exploring device concepts</td>
<td></td>
</tr>
<tr>
<td>Industry sponsors (Translational Innovation Fund (TIF))</td>
<td>• 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</td>
<td>Industry primary responsibility: Licensing Manager/Innovation • sponsor negotiations • protect your IP • understanding the marketplace TIF responsibility • Dione Kobayashi (Therapeutics), <a href="mailto:dkobayashi@partners.org">dkobayashi@partners.org</a> • Erin McKenna (Devices &amp; Diagnostics), <a href="mailto:emckenna4@partners.org">emckenna4@partners.org</a></td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>• Identifying markers and endpoints for further studies</td>
<td>Responsibility: Office of Clinical Trials Primary</td>
</tr>
<tr>
<td>Digital Health Technologies</td>
<td>• Clinical Trials</td>
<td>AIDIF Responsibility: Mass General Brigham AIDIF Fund: Gaye Bok <a href="mailto:gbok@partners.org">gbok@partners.org</a></td>
</tr>
</tbody>
</table>

Figure 5 | Selected translational funding sources
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 more quickly the COI management process can advance.

Office for Interactions with Industry

The Office for Interactions with Industry (OII) assists Mass General Brigham staff navigate policies and to oversee the processes. OII is available to assist all innovators. Inquiries: PHSOI@partners.org

The full policy document provides more detail. Policies are organized by topic areas.

Harvard Medical School Rules

Mass General Brigham has adopted Harvard's rules and applies them to researchers even if they do not have an HMS faculty appointment. The HMS policies initially prohibit narrow categories of activities with the possibility of an exception being 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 responsibilities, or
- Outside interests that may be averse to Mass General Brigham, or
- Use of Mass General Brigham position for personal financial gain.

The Harvard policies that govern faculty interactions with industry are:

1(a), or the "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, or
- Stock or similar ownership interest (stock options) of any amount in a private company, or
- 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) 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.

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

- Any equity in a private company, or
- Equity greater than 1% ownership in a public company.

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.

1(d) The "External Activity Rule," prohibits researchers who serve in a fiduciary company role from participating in clinical research on the company's technology nor receive 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). 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 Consulting Policy 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 Consulting Policy.

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 Consulting Policy 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 start-up 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;
- Be performed during regular Mass General Brigham hours;
- Involve use of students or trainees;
- Overlap with employment responsibilities beyond being in the general area faculty member expertise;
- Involve the inappropriate use of the institution's name;
- Involve the use of institutional funds or substantial use of institutional resources; and
- 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, in particular research activities.

Institutional Officials. There are requirements for individuals who hold senior Mass General Brigham positions, referred to as "Institutional Officials." Institutional Officials” including Chiefs of Service/Departments, VPs 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 Service. All Mass General Brigham staff members – even those who are not Institutional Officials – must receive prior approval by the Mass General Brigham 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.

Chase the problem wherever it takes you. See if you can then exert influence on making the world better by the solutions that you develop.

William Harris, MD, D.Sc
MGH Orthopedics

Contact
Office for Interactions with Industry (OII)
PHSOII@partners.org
OII Policy for Interactions with Industry
Innovators at Mass General Brigham are part of a march of discovery that began more than two centuries ago – in the operating theater, the lab, the exam room and increasingly the home. Hundreds of millions of patients in every nation have benefited from the inspiration and action of our Boston caregivers.

The highest impact products based on Mass General Brigham breakthroughs.

**Enbrel®**
Treatment for autoimmune diseases
Brian Seed, PhD

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

**StarLux™**
Laser hair removal
Rox Anderson, MD

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

**Visudyne®**
Use of Green Porphyrins in Ocular Diagnosis and Therapy
Evangelos Gragoudas, MD
Tayyaba Hasan, PhD
Joan Miller, MD

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

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

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