Patenting your invention and linking your project to biotech collaboration/support

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Thomas J McMurry, PhD
Director, Business Development
Office of Technology Development

Today's topics

- OTD overview
- Types of Intellectual Property
- Requirements for a patent
- Types of patents important for commercialization of life sciences inventions
- Advancing life science discoveries

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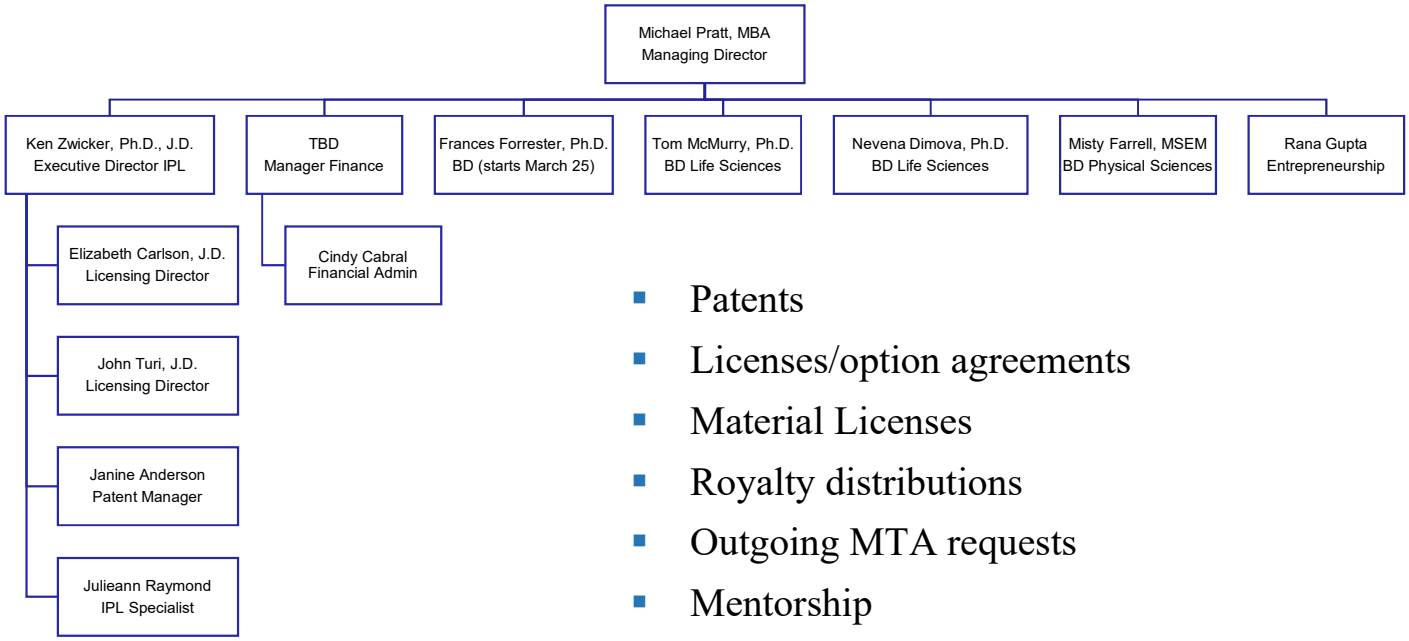
Office of Technology Development



- Patents
- Licenses/option agreements
- Material Licenses
- Royalty distributions
- Outgoing MTA requests
- Mentorship
- Ignition Awards (gap funding)

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Types of Intellectual Property

IP Type		Examples
• Patents	-	Composition of matter, method, design
• Copyright	-	Software, music, photograph, painting
• Trademark	-	Disney, Google, Xerox
• Trade Secret	-	Formula for Coke
• Know-how	-	hard to duplicate process or material
• Name/Likeness	-	your name, image, signature, etc…
• Maskworks	-	Semiconductor design

Patents are critical for commercialization of life sciences technologies due to high R&D cost and risk

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What is a patent?

- Enshrined in the Constitution

  "Congress shall have the Power... to promote the Progress of Science and useful Arts by securing for limited Times to *Authors and Inventors* the exclusive Right to their respective Writings and Discoveries."

- Grants the holder exclusive right to *prevent others from practicing their invention* for a defined period in return for making their knowledge public
  - 20 year monopoly
  - Not a right to practice

What are the legal requirements for patentability?

- Utility (not frivolous) 35 U.S.C. 101
- Novelty (completely new) 35 U.S.C. 102
- Non-obvious to a person of ordinary skill in the art 35 U.S.C. 103
  - A claimed invention is unpatentable if the differences between it and the prior art “are such that the subject matter as a whole would have been obvious … to a person having ordinary skill in the art”
  - Difficult to determine because it is somewhat subjective.
  - Teachings of references may be combined

Requirements for patent specification and claims

- Written Description
  - Ensures that the claimed invention was envisioned by the applicant at the time of filing.
- Enablement
  - The scope of enablement provided to one of ordinary skill in the art must be commensurate with the scope of claim protection without undue experimentation.
- Best Mode
  - Ensures that the public, in exchange for the exclusive rights under a patent, obtains from the inventor a full disclosure of the preferred embodiment of the invention contemplated by the inventor.

Patent grant

- Term 20 Years from earliest priority application
- Term can be shortened by Terminal Disclaimer or lengthened by Patent Term Adjustment or Patent Term Extension for regulatory delay.

Why are patents valued by companies & investors?

- Used to establish an exclusive market position
- Provide a bargaining position against third parties attempting to enforce patents
- May be licensed to produce substantial sources of income
- Defensive purposes for preventing others from claiming same subject

Types of patent claims for life science inventions and commercial value

Type of Claim	Commercial Value	Rationale	Caveats
Composition of matter	+++++	• Market exclusivity • Control of asset	• High bar for selection of drug development candidate (vs. initial screening “hits”)
Method of use	+++	• Expands use of known drug	• Existing patents may broadly claim many uses
Formulation	++	• Expands use of known drug	• Easy to design around
Biomarker	++	• May accelerate clinical trials • May support reimbursement	• Biomarker alone is not patentable (natural phenomena) • Patent office appears to be approving claims that include biomarker assessment linked to treatment decision
Diagnostic test	++	• Improve patient care • May lower costs	• Challenging commercial space
Drug screening assay	+	• Limited	• Companies are screening experts • Easy to design around • Difficult to identify infringement
Novel drug target	+	• Generic “Reach through claims” for a drug to modulate target are not allowable	• Adds value when linked to activity of a novel compound

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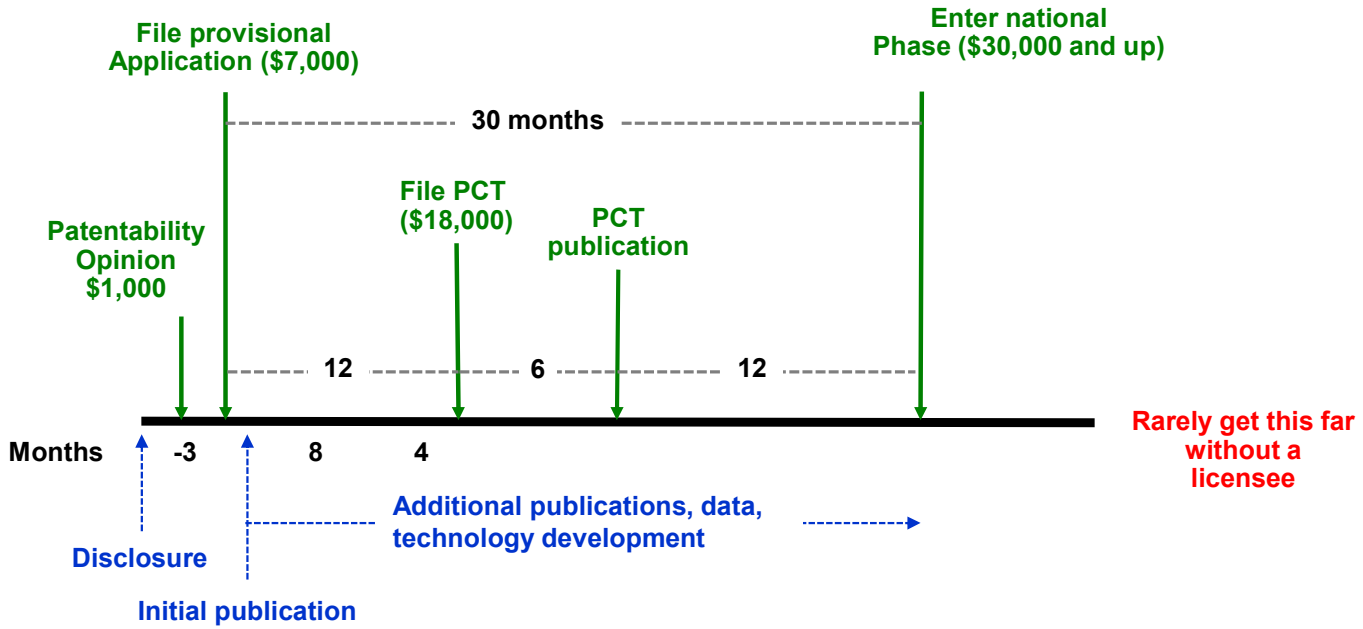
Patent prosecution timeline



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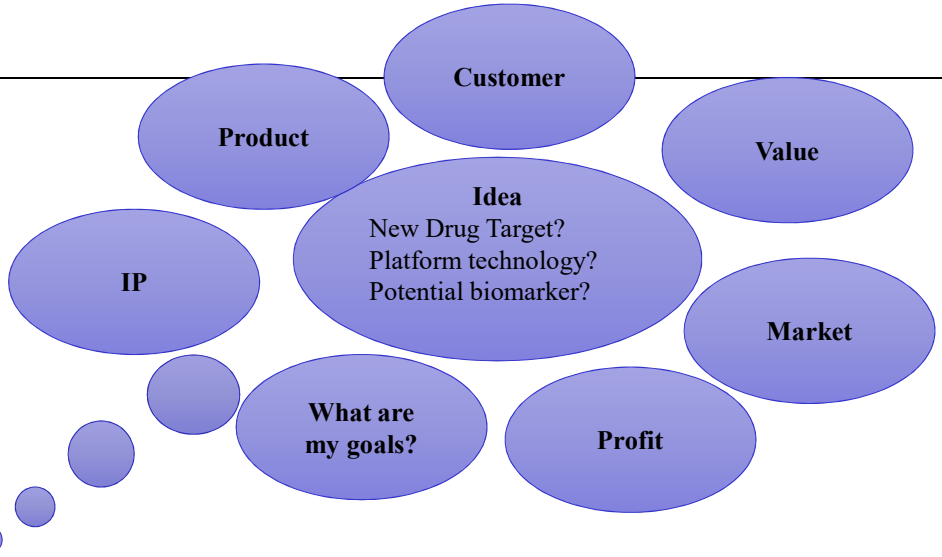
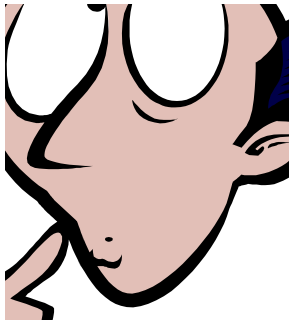
Where do I start?





Is it an invention or a discovery?

Is it novel & non-obvious?

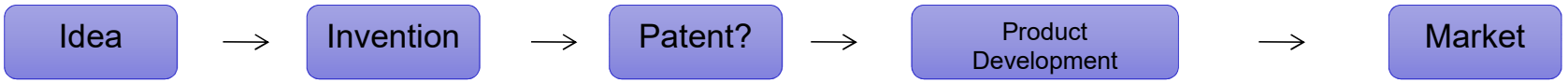
What is the product?

Do customers actually want/need such a product?

Differentiation vs other products?

Addressable market?

Engage with OTD early and often!



Discuss ideas/inventions with OTD

Document invention (TDF)

Technology assessment (OTD)

Understand the market and existing products

Define product differentiation

Patent filing decision (yes/no)

Inventor goals: research funding? Develop product? Collaborate with industry?

Commercialization strategy: License to pharma/biotech? start up company? collaborative R&D?

Marketing/Licensing

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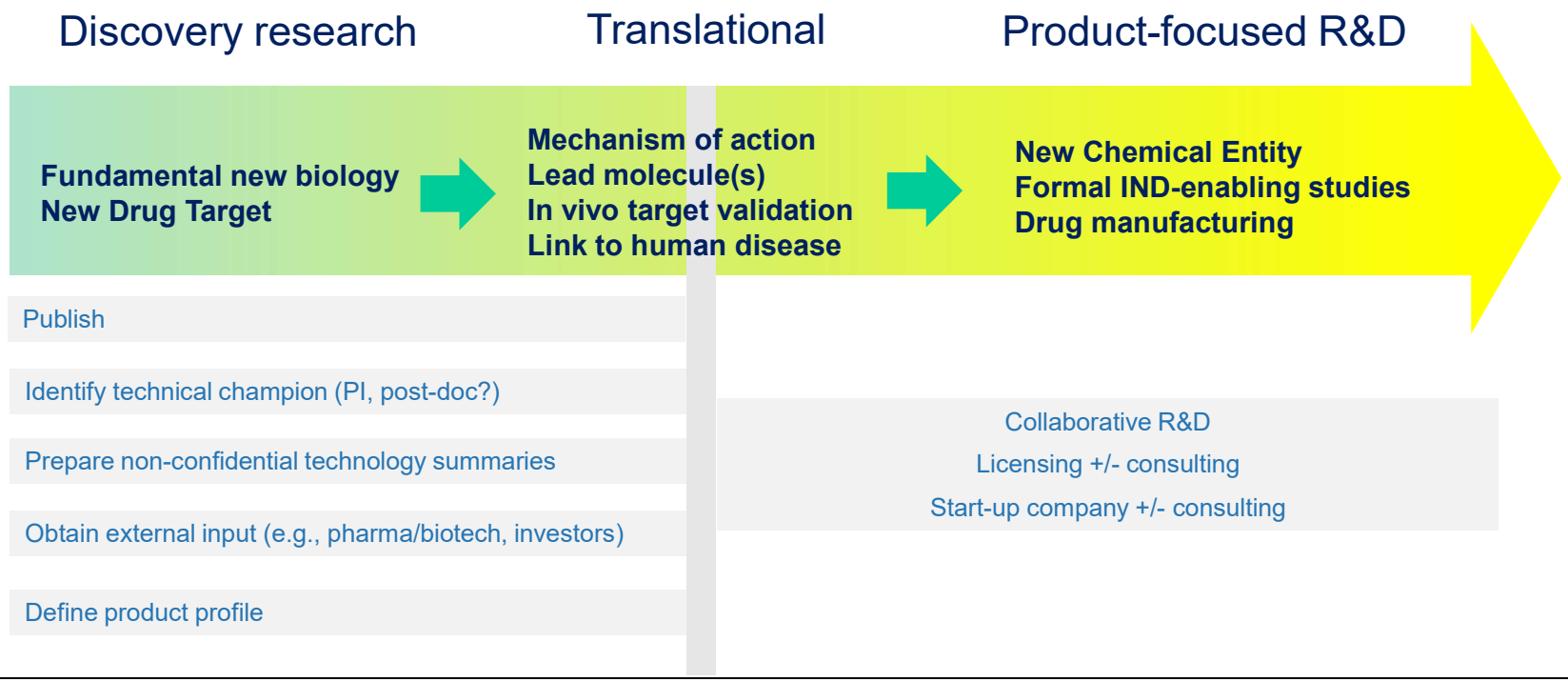
Commercializing new drug target discoveries



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Potential options for advancing life science target biology discoveries

- **In house: University drug discovery with traditional funding**
  - For example, grant in collaboration with Center for Molecular Discovery (CMD) to identify small molecules
- **Collaborative Target Development With External Organizations, Investors or CRO's**
  - Celdara (Hanover, NH), Amorchem (Montreal)
  - NCATS
  - Evotec (Germany)
  - Start-up company to advance technology
- **Research Collaborations With Industry**
  - Sponsored Research Agreements
  - Funded R&D Collaborations (e.g., Pfizer CTI)

Examples of pharma/biotech collaborations

- Pfizer CTI: requires validated target, validated human clinical biomarkers and clear understanding of clinical trial, potent and selective antibody
- J&J LCI: novel approaches to interrogating or modulating early stage lung cancer
- Lilly Open Innovation Drug Discovery (OIDD): seeks novel biology and assays
- Atomwise: requires novel target, well characterized; delivers set of predicted hits

Industry Engagement Overview

March 2019

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Task Force on University Collaboration with Industry

Boston University's *Task Force on University Collaboration with Industry* was charged with creating a shared vision for how the University should connect its research programs to industry to better serve the institution's core missions in discovery, innovation, and promotion of societal good.

1. Helping University researchers identify, initiate, and conduct collaborative research projects with industry partners, while helping industry partners identify and connect with University researchers
2. Providing researchers with efficient processes for protecting intellectual property arising from research and for licensing it to companies that can translate it into successful products
3. Supporting researcher-led creation of entrepreneurial enterprises and startups

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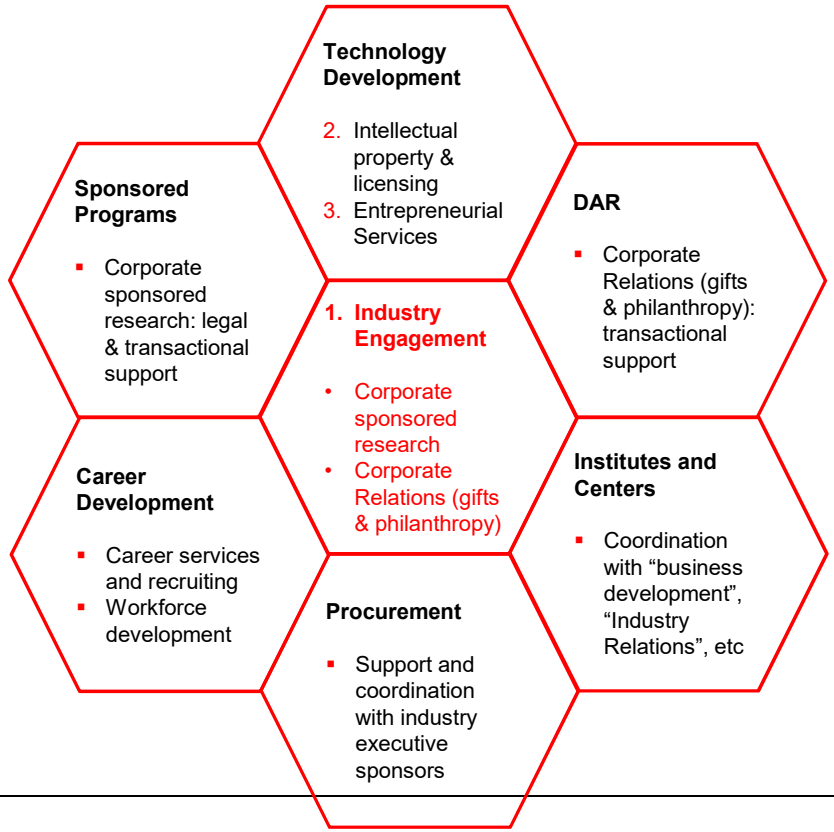
Industry Engagement in Context

1. Helping University researchers identify, initiate, and conduct collaborative research projects with industry partners, while helping industry partners identify and connect with University researchers
2. Providing researchers with efficient processes for protecting intellectual property arising from research and for licensing it to companies that can translate it into successful products
3. Supporting researcher-led creation of entrepreneurial enterprises and startups



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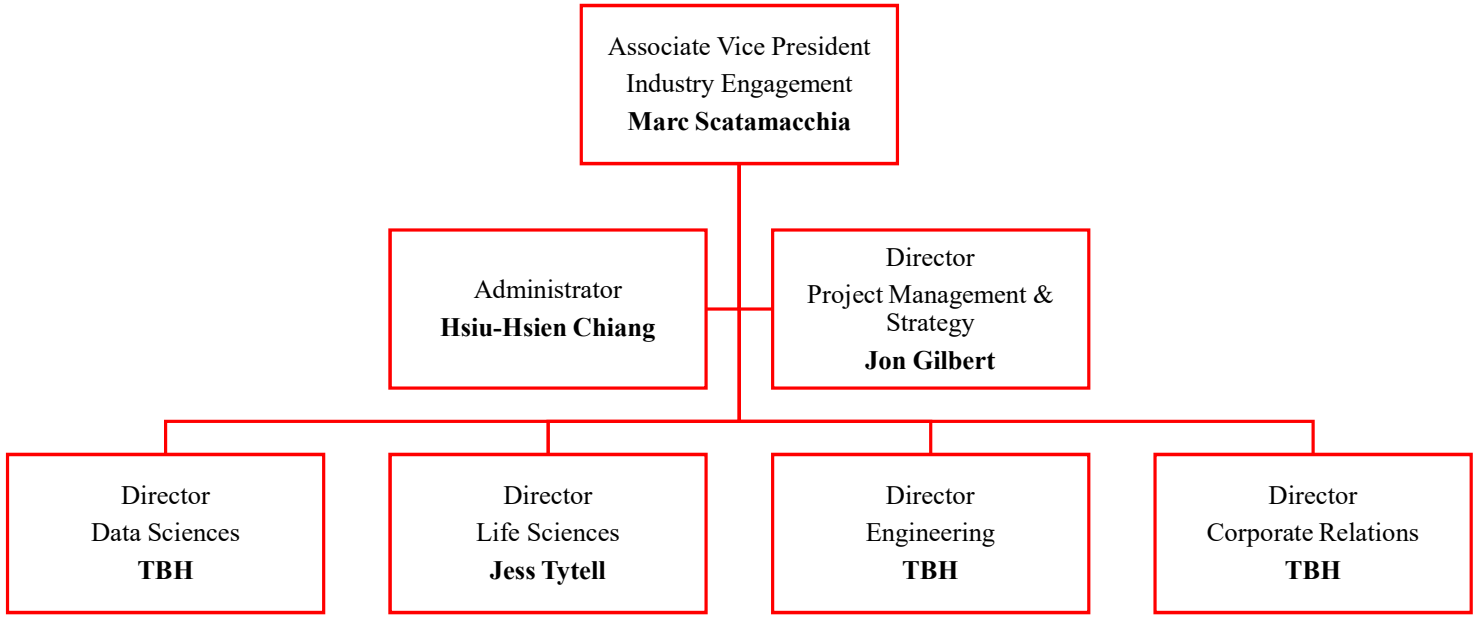
Boston University Industry Engagement



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Roles and Responsibilities

Role	Responsibilities
Administrator	• Administrative management and team support • Project management support • Financial management • Pre-award Grant and Gift administration • Transactional administration of all gifts and grants in coordination with DAR and OSP • Event participation and planning management

Director – Project Management & Strategy	• Large research grant project management
	  • Alliance management
	  • Compliance
	• Industry Engagement strategy development and implementation (policies and processes)
	• Faculty outreach and support
	• Coordination with OTD and Sponsored Programs

Director – Corporate Relations	• Corporate philanthropy
	  • Unrestricted corporate foundation/CSR Gifts
	  • Workforce development in coordination with Career Services
	  • Board and subscription memberships
	• Research grants not associated with defined verticals
	• Primary DAR liaison

Directors – Verticals	

Data Sciences	• Strategic corporate research account management along vertical
	• Implementation of proactive vertical and Researcher-led sponsored research strategy
	  • Research Identification
	  • Commercialization potential and timing
	  • Commercial market and competitive analysis
	  • Target identification and outreach
	• Strategic research grant development along defined verticals

Life Sciences & Healthcare	
Engineering (Initial Focus on BME and Photonics)	

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Governance: Industry Engagement Steering Committee

- Industry Engagement Steering Committee to provide guidance, oversight, and evaluation of developing industry engagement organization, scale, scope, and mission aligned with task force report

- Broader perspective, guidance, and oversight over IE initiatives such as advisory boards, “Research Forward”, and other sponsorship opportunities, prioritization of proactive outreach pilots, and connections to OTD, OSP, DAR, Career Services, Procurement, etc

Contact information

- OTD
  - Tom McMurry (tmcmurry@bu.edu)
  - Nevena Dimova (ndimova@bu.edu)
- Industry Engagement
  - Marc Scatamacchia (marcs1@bu.edu)
  - Jess Tytell (tytell@bu.edu)

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