Research Collaboration & Sponsorship

Sponsored Projects
- Government Agencies
- Foundations
- Industry

Technology Management
- Commercialization

Development
- Foundation Giving
- Corporate Giving
- Grateful Patients
- ...

"...advance the quality of human life by enhancing the diagnosis, treatment, and prevention of disease and injury..."

OSII Mission: Support initiatives that build and communicate our research portfolio and capabilities to collaborate with industry partners to advance our mission.
Research Collaboration & Sponsorship

Education, Research and Patient Care

Supporting Missions

Varies, generally ROI for stakeholders

Benefits through Transactions
- Research and program funding
- Equipment/facility donation
- Commercial perspective in labs
- Expanding faculty knowledge through consulting
- Real world opportunity for students
- Curriculum development

Benefits through Transactions
- Industrial focused research that will positively impact market/patient care
- Objective testing ground for new technology – particularly relevant to new or unique assets at University
- Access to university resources
- New technology licensing for commercial purposes
- Support education of future workforce; employment of trained students

Value Needs:
Industry needs/wants?


Office of Strategic Industry Initiatives
Office of Strategic Industry Initiatives

The Value that we provide

What do we have and where are we going?

Our value proposition

The Wants or Needs of industry

Avoid

Our Value: Research Assets

Our Assets:

• $220M in research expenditures annually producing new discoveries and methods
• >1,000 faculty clinicians with diverse expertise
• Clinical -- 1.6M patient encounters, diversity
  • Sources of data and specimens for clinical research/discovery
  • Patients for clinical trials (Investigator-initiated or Industry-initiated)

Our Needs:

• Funding for research – discovery, validation, translation
• Resources for technology development
  • Prototyping
  • Compound Screening
  • Preclinical/clinical drugs
  • Software coding
  • …
• Business/Technical Expertise
  • Regulatory affairs
  • Engineering
  • …
Research Collaboration & Sponsorship

Industry is increasingly tapping into university discovery to feed their pipelines:

- “Boehringer Ingelheim boasts numerous university partnerships…”
- “Takeda’s university partnerships a key part of retooled R&D strategy…”
- “Pfizer’s open innovation partnerships a key part of R&D strategy…”

-From Industry-Sponsored Research Management newsletter, 2017

Academic institutions are reorganizing to capitalize on industry’s shift in focus:

- “U Penn ramps up industry sponsorships as percent of funding jumps from 6% to 15%…”
- “To match industry needs, university applies ‘lean’ principles to labs and faculty…”

-From Industry-Sponsored Research Management newsletter, 2017

And these are just the pharma examples…

Championing UTHealth:Industry Collaboration

UT Faculty  \hspace{1cm} \downarrow \hspace{1cm} \text{Collaboration}  \hspace{1cm} \uparrow \hspace{1cm} \text{OSII (Champion)}

Industry Research

“Trust Formation”

\hspace{3cm} (e.g. Sponsored Research, Clinical Trials, etc.)

Champion:  
- \textit{Intensely engages} with the objectives and goals of the project and plays a driving role in many of the research-engineering interactions, overcoming technical/organizational obstacles, and propelling the effort through to its final achievement
- \textit{Promotes} ideas to firms and generates interest to obtain commitment and financial support, acting as a firefighter as needed
- \textit{Facilitates} relationships and provide a basis for communication on other issues, thereby improving outcomes
- \textit{Persuades} collaboration partners to adapt and redefine their working goals and plans over the course of a project as needs and environments change.

Adapted from Bloger, and Barczak, Trust formation in University-Industry Collaborations in the US Biotechnology Industry: IP Policies, J Prom Inov Manag 2015;30(1):111-121
Common Industry Interests

- Possible additions to their pipeline
  - New ideas for new products or drugs, such as validated targets for drug generation
  - New uses for existing drugs
  - Enhancements or improvements to their current products
- Novel models to help their pipeline development (discovery & validation)
  - Unique animal models
  - Clinical data/samples
  - New applications/software to help diagnosis and treatment

Finding a Potential Industry Partner

OSII can help!

Identify a potential partner:
- How does the research fit within the company’s product portfolio and/or business strategy?
- Is the company interested in academic collaborations?
- Do we already have a relationship with the company?
Developing an Industry Relationship

Identify a potential partner:
- How does your research fit within the company’s product portfolio and/or business strategy?
- Is the company interested in academic collaborations?
- Do we already have a relationship with the company?

Start a conversation:
- Find a contact (Scientist vs Business Development)
- Share a non-confidential, concise pitch of the collaboration to start a conversation

Keep the relationship alive:
- Follow-up on questions and feedback
- Engage internally to on-board projects

Who? Scientist vs BD&L Representative

- Scientist –
  - Industry champion – can provide leverage to do a deal
  - Can find through publications/conferences
  - Great scientific resources

- BD&L Representative

<table>
<thead>
<tr>
<th>Search and Evaluation</th>
<th>Transactions Manager</th>
<th>Alliance Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine the need for a search</td>
<td>Contract negotiations</td>
<td>Joint Steering Committee</td>
</tr>
<tr>
<td>Aligns search/evaluation with needs of the business</td>
<td>Lead representative on company deal team</td>
<td>Oversight of Project Managers</td>
</tr>
<tr>
<td>Works closely with TA leads</td>
<td>Accountable for company interest in agreements</td>
<td>Integration role</td>
</tr>
<tr>
<td>Coordinates with Transaction Manager for deal execution</td>
<td>Coordinates with Legal, Patent, Safety, Regulatory, Research, Clinical, etc.</td>
<td>Reporting line to management</td>
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<td>Insures goals of company are met</td>
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<td>Facilitates good communication and documentation</td>
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</table>
Non-Disclosure Agreements (NDAs)

Share information while protecting it at the same time!
- Who are the parties? (and who’s authorized to sign!!)
- What is being shared/what is the topic?
- One way vs Mutual
- Requires that information shared is only to evaluate a research or business relationship and NOT for any commercial purposes
- Shared on a need to know basis
- Marked or ID’d as confidential

Elements of an Industry Relationship

Scope of Work:
- Are materials being shared?
  - Data?
  - Clinical?
  - Benchtop?
  - Research materials?
  - Other?
- What are the deliverables?
  - Them?
  - Us?

Research Agreement:
- Material Transfer
- Data Transfer and Use
- Sponsored Research
- Collaborative Research
- Others (Consulting, Service)
**Checks and Balances: Can we use our assets?**

Any data, materials, or other proprietary information:

- **No**  
- **Yes**

- Did we receive it or any of its parts from outside UTH?  
  - **No**  
  - **Yes**

- Does the MTA/DUA allow it to be used for commercial purposes?  
  - **No**  
  - **Yes**

- Does any of it involve patient data or materials?  
  - **No**  
  - **Yes**

- Does the informed consent allow us to use it commercially?  
  - **No**  
  - **Yes**

- Was it obtained under an agreement?  
  - **No**  
  - **Yes**

  - (i.e. SRA, DUA, CTA, NDA)

- Under the terms, do we own it? Are we allowed to use it outside of that agreement with third parties and/or for commercial use?  
  - **No**  
  - **Yes**

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**OSII & Early-stage Collaboration**

<table>
<thead>
<tr>
<th>Idea</th>
<th>Business Discovery</th>
<th>Concept Research</th>
<th>Product Development (Prototyping, Drug Screens, etc.)</th>
<th>Testing and Validation</th>
<th>Biz Dev</th>
<th>Market</th>
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**Industry Collaborations (OSII)**

- Confidential Disclosure Agreements
- Proposal Development
- Research Agreements
- Opportunity Mining: Funding Opportunities
- Local Opportunities for Idea Development (i.e. iCorps, VMS)

**IP Protection and Commercialization (OTM)**

- Patents, Copyrights, Trademarks
- Inter-institutional Agreements
- Technology Marketing
- License Agreements
- Start-up formation assistance
Neurosurgery

Select Examples:

New targets for therapeutics
New diagnostics (Biomarkers!)
New disease models (animal or clinical data)
New platforms for discovery and/or delivery

Clariivate Search: Spinal Cord Injury

<table>
<thead>
<tr>
<th>Drug Count</th>
<th>Highest Development Status</th>
<th>Parent Company</th>
<th>Indication</th>
<th>Development History</th>
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<tr>
<td></td>
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<td>Acorda Therapeutics Inc</td>
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<td></td>
<td>BioAxove Biosciences Inc</td>
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<td>University of California</td>
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<td>Alere Pharmaceuticals Inc</td>
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<td>Pfizer Inc</td>
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<td>Spinal Cord Therapeutics GmbH</td>
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<td>AM Therapeutics Inc</td>
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<td>Aquia Pharmaceuticals GmbH</td>
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<td>BioMarin Pharmaceutical Inc</td>
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<td>CytoRx Corp</td>
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<td>Eisai Co Ltd</td>
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<td>Ferrer International SA</td>
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<td>Invivo Therapeutics Holdings Corp</td>
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<td>Kringle Pharma Inc</td>
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<td>Neurolabs Inc</td>
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<td>Proncurox Biotechnologies Inc</td>
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<td></td>
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<td>Rutgers University</td>
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</table>

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Select “Successes”:

✓ Discovery program on novel pathway for breast cancer (GlaxoSmithKline)
✓ Collaborative device development for new dental product (Zirc)
✓ Three iAwards granted through sponsored research program (Sanofi)
✓ New product testing in clinical efficacy (Kiss Industries)
Office of Strategic Industry Initiatives

Select Current Projects:

- Imaging Research Initiative – Platforms for handling imaging data and developing new algorithms (AI) – Flywheel
  - Enables more collaborative research with GE, Samsung, Philips and Canon (alliance?)
- Material Acquisition – donation of expensive biomaterial to use in new use (Cook Biotech)
- Development of Digital Strategy – aligning interested faculty to harness available tools
  - Novartis, Merck, AT&T, IBM Watson, Start-ups, etc.
- Aligning Clinical Strategies with AstraZeneca for more effective clinical trial selection and execution
- New indication for a drug current under development (Akebia Therapeutics)
- Compound selection against a new target (HitGen)

Teamwork makes the dream work!

Academia
- Researchers
- Designers/Engineers
- Collaborators/Validators
- Funding Agency(s)
- Administrators
  - SPA
  - IRB
  - IT (data)
  - OTM/OSII

Industry
- Scientific/medical champions
- Business Development Managers
- Regulatory Consultants
- Preclinical Development Specialists
- Clinical Trialists, Clinicians

Intermediary Collaborators
- Design Kitchens
- CROs

External Approvals
- FDA
- PTO
- Market/Customers
Office of Strategic Industry Initiatives

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Newsletter

UTHealth Office of Strategic Industry Initiatives
UTH_OSII

Teamwork makes the dream work!

It's not what you know but who you know?
**Many Stages on the Licensing Path**

1. **Research & Discovery**
   - Commercially Viable?
     - Yes: Distribute Revenue
     - No: Re-market to different companies

2. Market to Potential Licensees (non-confidentially)
   - Is there Interest?
     - Yes: Negotiate & Execute License Agreement
     - No: Execute NDA

3. **Negotiate & Execute License Agreement**
   - Still Interest?
     - Yes: Manage Agreement
     - No: Amend

4. **Manage Agreement**
   - Amendments

5. **Distribute Revenue**

**Common Issues that Arise in Negotiation**

**Basis of Negotiation:**
- Scope of the Research Project
- Overall Cost and Timing, if funding provided
- Who is providing resources to the project?

**Commonly Negotiated Terms:**
- Use of Results
- Confidential Information
- Publication, Review
- Intellectual Property
- Liability and Indemnification
Finding pieces to the puzzle...

What is the need?
- Prototyping
- Idea development
- Compound Generation/HTS
- Animal Models
- App Development

Resources
- Company Partners (pharma, IT, etc.)
- I-Corps/Venture Mentoring
- Design Kitchens, i.e. UT BME
- Start-up company validations
- Services