Industry/Academic Partnerships: Academic Perspective

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October 28, 2012
Overview

- Why should we develop industry partnerships?
- How do we address academic values?
- What are the challenges to partnering?
- What can we expect in the future?
Why develop A/I partnerships?

- The overwhelming reason is the potential to get effective therapies to patients.
- Of 252 new drugs/biologics approved by the US FDA from 1998 to 2007, 25% of the discovery effort came from academia.*

<table>
<thead>
<tr>
<th>Drug/Biologic</th>
<th>Indication</th>
<th>Academic</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vorinostat</td>
<td>Cancer</td>
<td>Columbia/MSKCC</td>
<td>Merck</td>
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<tr>
<td>Darunavir</td>
<td>HIV</td>
<td>U of Ill at Chicago</td>
<td>Janssen</td>
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<tr>
<td>Alemtuzumab</td>
<td>CLL</td>
<td>Cambridge Univ</td>
<td>Genzyme</td>
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Why develop A/I partnerships?

- Synergies to advance basic research to effective translational research
- Support for research that can lead to other discoveries
- Window into another way of thinking about translational research
How do we address academic values?

- Academic freedom: research not subject to economic/political pressure
- Common ownership of academic discoveries
- Disinterestedness, with science not influenced by financial stake
- Skepticism: science open to critical scrutiny
- Obligation to serve the common good
How do we address academic values?

- Finding a balance
- Managing the process
Finding a balance

Public Good

ACADEMIC VALUES

Financial Effect
Drug Life Cycle: consider the balance at each point

1. Drug Repurposing
2. Understanding Biology
3. Drug Discovery
4. Post-Approval Marketing
5. Drug Development
6. Drug Repurposing
Where is the balance?

Understanding Biology

• Example 1:
• Using novel imaging tools from an academic lab to explore a novel drug company target

Academic Values

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Where is the balance?

Drug Discovery

• Example 2:
• Using a novel target, identified in the academic lab to screen the drug company’s proprietary library for potential drug candidates

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Where is the balance?

Post-Marketing Approval

• Example 3:
• Enrolling patients in a company-sponsored open-label trial to get practical evidence

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Managing the process

- Bayh Dole Act
- Contracts and licensing agreements
- Conflicts of interest
Managing the process

- Bayh-Dole Act, 1981
  - Enabled small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs
  - Encouraged universities to collaborate with companies to use this research
  - Required universities to actively promote and commercialize the inventions they chose to protect
  - Ensured transfer of research tools to other academic research institutions (1999)
Managing the process

Disclosures and IP

- Report discovery to technology transfer office
  - Cornell Center for Technology Enterprise & Commercialization (CCTEC)
- Describe the discovery in a formal disclosure filed with CCTEC
- CCTEC decides whether or not to protect the intellectual property (IP) related to the discovery, usually by submitting a patent application
- If CCTEC protects it, it must try to commercialize the discovery: licensing and start-up companies
Managing the process

- Sponsored research agreements (SRA)
  - Many of our discoveries are early and not ready or not appropriate for licensing
  - So we can partner with industry to further develop them
  - SRA outlines the terms of the agreement between academia and industry on these relationships
SRA: Key terms

- WCMC believes that scholarly publication is the fundamental right and responsibility of researchers and WCMC. Sponsors may review manuscripts prior to publication, but WCMC will not accept terms that require “approval” by the Sponsor.
SRA: Key terms

- Institution is free to publish or disseminate the results of the research
- Usually provide the sponsor with a certain period for review prior to submission
  - Usually 30 days, but somewhat negotiable
  - Sponsor can identify patentable subject matter and/or disclosure of the Sponsor's proprietary information
  - If patentable, then may delay submission, usually another 60 days, to file a patent
Managing the Process

- Conflict of interest (COI)
  - A financial COI (fCOI) arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research.
Managing the process

- Key goal: identify and manage fCOI
  - Address the risk of bias or the appearance of bias in research, teaching, clinical practice
  - Protect research subjects
  - Maintain public trust in the institution’s research and its personnel

- Process elements
  - Complete annual disclosure form
  - Administrators to manage process
  - Conflicts Advisory Panel addresses real/apparent conflicts through individual management plans
What are the challenges to partnering?

- Match interests
- Contract
- Expectation
- Culture
- Science
- Terms
- Timing
- Outcome
Addressing these challenges

- Outreach at all levels
- Champions on both sides
- Liaisons
- Communication, scheduled and unscheduled
- Transparency
- Explicit goal setting and timeline management
What can we expect in the future?

➢ More collaborations
  – Address untenable costs and time to achieve new therapies
  – Leverage complementary strengths
    • Deep understanding of biology and pathways in academia
    • Extensive expertise in designing and developing drugs in industry
Collaborating for Drug Discovery

ACADEMIC STRENGTHS

Biology
Pathways
Targets

Drug Probes

Drug Design

In vitro validation
In vivo validation

INDUSTRY STRENGTHS

Medicinal Chemistry
Toxicology
What can we expect in the future?

- New cooperative models
  - Independent nfp institute for translational research
    - Merck-sponsored with exclusive licensing options
    - Collaborations with academic scientists to translate their research into novel medicines
  - Precompetitive collaborations
    - Industry sponsoring development of imaging tools in Alzheimer’s to support all drug development efforts
    - Biomarkers Consortium of industry, government, academia to rapidly identify, develop and qualify potential biological markers, or “biomarkers
What can we expect in the future?

- New cooperative models
  - Pushing out what is precompetitive
  - Structural Genomics Consortium
    - Based in Canada
    - Supported by several pharmaceutical companies
    - Does pre-competitive protein-based science
    - Goals: Knowledge and reagents for basic research and drug discovery, including 3D protein structures, chemical probes, and antibodies
    - All data and reagents are made publicly available, without restriction on use
Collaborating for Drug Discovery

Pre-competitive

Drug Probes

Biology

Pathways

Targets

Drug Design

Medicinal Chemistry

Toxicology

In vitro validation

In vivo validation

IP-protected
Conclusion

- Academic-industry collaborations have great synergistic potential.
- Academic values must be acknowledged and concerns managed.
- The different cultures create challenges for moving forward, but can be addressed.
- New models keep emerging to find effective ways to address the challenges of drug discovery.