Breakout Group #6
“Effective modes of collaboration between physician-investigators and the biotechnology/pharmaceutical industry”

William Bremner, MD, PhD
Mark Geraci, MD
Framing the Issues

- Where are we now?
- Who “does it well’?
- Common issues / barriers around partnerships
- What might be a path forward?
Sources of Research Funding over Time

Open Access, JAMA
Recent History of NIH Funding Trajectory

“Furthering America’s Research Enterprise”
National Research Council, 2014
# Incentives for Development in Academia, Industry and Society

## Table 1 Incentives in drug development for academia, industry and society

<table>
<thead>
<tr>
<th></th>
<th>Academia Institutions</th>
<th>Academia Faculty</th>
<th>Industry Companies</th>
<th>Industry Executives</th>
<th>Society Government</th>
<th>Society Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>New discovery</td>
<td>++</td>
<td>++</td>
<td>0</td>
<td>+</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Drug target</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Effective drug</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Wide use</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>High profit</td>
<td>±</td>
<td>±</td>
<td>+</td>
<td>++</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Appropriate use</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>++</td>
<td>+</td>
</tr>
</tbody>
</table>

Academia, industry and society share many but not all incentives in the development of new discoveries and in their distribution and use. Incentives: ++, strong; +, weak; ±, possible; 0, no incentive; -, disincentive. Estimates based on the authors’ opinions.

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Enhancing ties between academia and industry to improve health

S Claiborne Johnston1, 2, Stephen L. Hauser1 & Susan Desmond-Hellmann3

[THE ALLIANCE] [Even Better Together]
Framing the Issues

• Where are we now?

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• Common issues / barriers around partnerships

• What might be a path forward?
<table>
<thead>
<tr>
<th>Institution</th>
<th>Partners</th>
<th>Focus</th>
<th>Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvard University (7 deals)</td>
<td>Yale, Columbia, Rockefeller, Biogen Idec, Evotec, Brigham and Women's Hospital, Biogen Idec, UCB, Boehringer Ingelheim, Evotec, Janssen Pharmaceuticals, UCB</td>
<td>Amyotrophic lateral sclerosis, Kidney damage, Human interactome, Autophagy in neurodegeneration, Cancer, cardiometabolic disease, others, Regeneration of insulin-producing cells, Human microbiome</td>
<td>$10 million, 3-year collaboration. Formed CureNephron for biomarker discovery. Financials not disclosed. Biogen provides single-digit millions over 4 years and 200 proteins. UCB to develop small molecules. Harvard eligible for milestones, royalties. Joint research committee awards funds to identify signaling pathways and targets. Janssen granted an exclusive license to products from CureBeta Initiative. UCB will provide up to $4.5 million over 3 years.</td>
</tr>
<tr>
<td>University of Texas system (7 deals)</td>
<td>Southern Research Institute, UTMB, Onyx, MD Anderson, Trovagene, MD Anderson, GloxoSmithKline, MD Anderson, Profectus Biosciences, UTMB, LoneStar Heart, UT Southwestern, University of Washington, Kineta, UTMB</td>
<td>Viruses, Multiple myeloma, lymphoma, Pancreatic cancers with R-Ras mutations, Tumor necrosis factor family member 4, Ebola and Marburg viruses, Diabetes, Viruses.</td>
<td>Co-develop screening platform. Financials not disclosed. Nonexclusive license to Onyx's proteasome inhibitors. Financials not disclosed. Collaboration on urine markers. Financials not disclosed. GSK responsible for development. UT eligible for up to $335 million. $5.4 million, 5-year grant from National Institute of Health's NIAID. Company gains rights to develop isoxazoles. Financials not disclosed. $8.1 million NIAID grant split between parties.</td>
</tr>
<tr>
<td>University College London (6 deals)</td>
<td>Sarepta Therapeutics, Institute of Child Health, UCL's Dubezwitz Neuromuscular Centre, Eli Lilly, Ark Therapeutics, Oxford Pharmascience, Horizon Discovery, Eisai</td>
<td>Duchenne muscular dystrophy, Neurodegeneration, Fetal growth restriction, Safestat drug delivery technology, Huntington's disease, Neurological diseases.</td>
<td>EU Health 2012 Innovation-1 research grant of undisclosed amount. Wellcome Trust Pathfinder Award of up to £100,000 ($162,220) for 18 months. Six-year, £6 million grant from European Commission’s Framework Programme 7. Company exercised licensing option on products. Horizon granted exclusive rights to university-generated cell lines and option on new IP. Target discovery. University receives undisclosed milestones and royalties.</td>
</tr>
</tbody>
</table>

Duke University, University of Oxford: 4 deals apiece; Yale, Stanford, University of Pennsylvania, University of Edinburgh: 3 deals apiece

Source: SciBX; Science-Business eXchange UTMB=University of Texas Medical Branch
Distribution of 387 “P/P” Deals 2012 by Category

Source: SciBX: Science-Business eXchange UTMB=University of Texas Medical Branch

Figure 1  Number of deals by business area 2012

Source: SciBX: Science-Business eXchange

Academic-industry partnerships 2012

Brady Huggett

THE ALLIANCE  Even Better Together

NATURE BIOTECHNOLOGY  VOLUME 31  NUMBER 5  MAY 2013
Most Active Pharma Companies with Academic-Industry Partnerships

Figure 2 Most active pharma

- GlaxoSmithKline: 14 deals
- Pfizer: 11 deals
- Sanofi: 10 deals
- AstraZeneca: 9 deals
- Johnson & Johnson: 9 deals
- Bristol-Myers Squibb: 7 deals
- Astellas Pharma: 6 deals
- Eli Lilly: 5 deals
- Horizon Discovery: 5 deals
- Bayer: 4 deals
- Biogen Idec: 4 deals
- Boehringer Ingelheim: 4 deals
- General Electric: 4 deals
- Merck & Co.: 4 deals
- Novo Nordisk: 4 deals
- Roche: 4 deals

Source: SciBX: Science-Business eXchange
Examples of “How It Has Worked”

• Many examples are “institution-driven” or “thematic / project” driven.

• Example of “Institution-Driven” model - Indiana Physician Scientist Initiative and Eli Lilly

• Example of “Project-Driven” model – Academia, CFF and Vertex
Indiana Physician Scientist Initiative

• $60 Million grant from the Lilly endowment (designed to be “matched” from IU)
• Recruitment of physician researchers (1:1 match)
• $10M endowment to strengthen MSTP program
• $8M for Indiana Biobank
• $2M for international programs
• $2M for ITRAC – Trans Research Acceleration
Recent University of Washington Examples

- Novo-Nordisk – Michael Schwartz CNS control of blood sugar and body weight
- Glaxo – Altius Institute. John Stamatoyannopoulos. Roles of “non-coding” DNA
- Celgene – Nora Disis. Immune therapy for cancer
- Vertex – Bonnie Ramsey. CF drug development
Complementary Strengths: Academia and Industry

**FIGURE 1**
Complementary strengths between academia and pharmaceutical companies. *Abbreviation: POC, proof of concept.*

Racing to define pharmaceutical R&D external innovation models

Liangsu Wang¹, Andrew Plump² and Michael Ringel³

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Drug Development and FDA Registration Program Roles (Courtesy Bonnie Ramsey, MD U. of Washington)

<table>
<thead>
<tr>
<th>Academic* (Ramsey/TDN)</th>
<th>CFF*</th>
<th>Vertex*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defining patient population</td>
<td>“De-risked” program with initial funding</td>
<td>Pre-clinical development</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Drug Screening</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Formulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Animal Toxicology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Manufacturing</td>
</tr>
<tr>
<td>Identifying biomarkers and clinical endpoints</td>
<td>Formed development committee</td>
<td>Regulatory FDA documents</td>
</tr>
<tr>
<td>Designing studies</td>
<td>Found experts and developed teams</td>
<td>Funding for clinical trials</td>
</tr>
<tr>
<td>Conducting studies</td>
<td>Supported TDN</td>
<td>Conducted clinical program</td>
</tr>
<tr>
<td>Data analysis</td>
<td></td>
<td>Data analysis</td>
</tr>
</tbody>
</table>

*Joint Development Committee oversaw program.
Framing the Issues

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Issues and Barriers to Partnerships

• Promotion and Tenure recognition
  – 25% do not consider Intellectual property in P&T
    • Bayh-Dole Act of 1980
  – What is the “value” of funding from alternative sources?

• Conflict of Interest (COI) management
  – Physician Payment Sunshine Act (of Affordable Care Act, 2010)
Framing the Issues

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Questions for Consideration

• What are other examples of successful partnerships?
• Are there continued issues with Promotion and Tenure recognition?
• Are COI Management issues impeding interactions?
• Can we define / endorse “Best Practices”?
• Should there be more federal mechanisms to leverage partnership funding?