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Breakout Group #6

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

William Bremner, MD, PhD

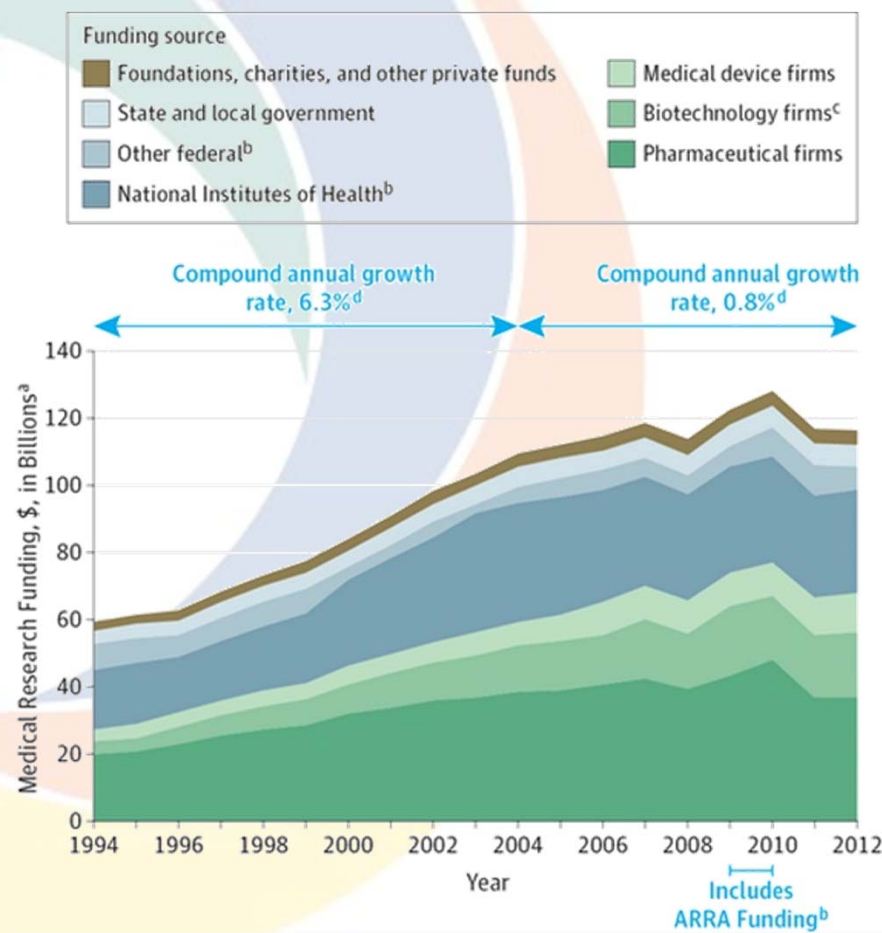
Mark Geraci, MD

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



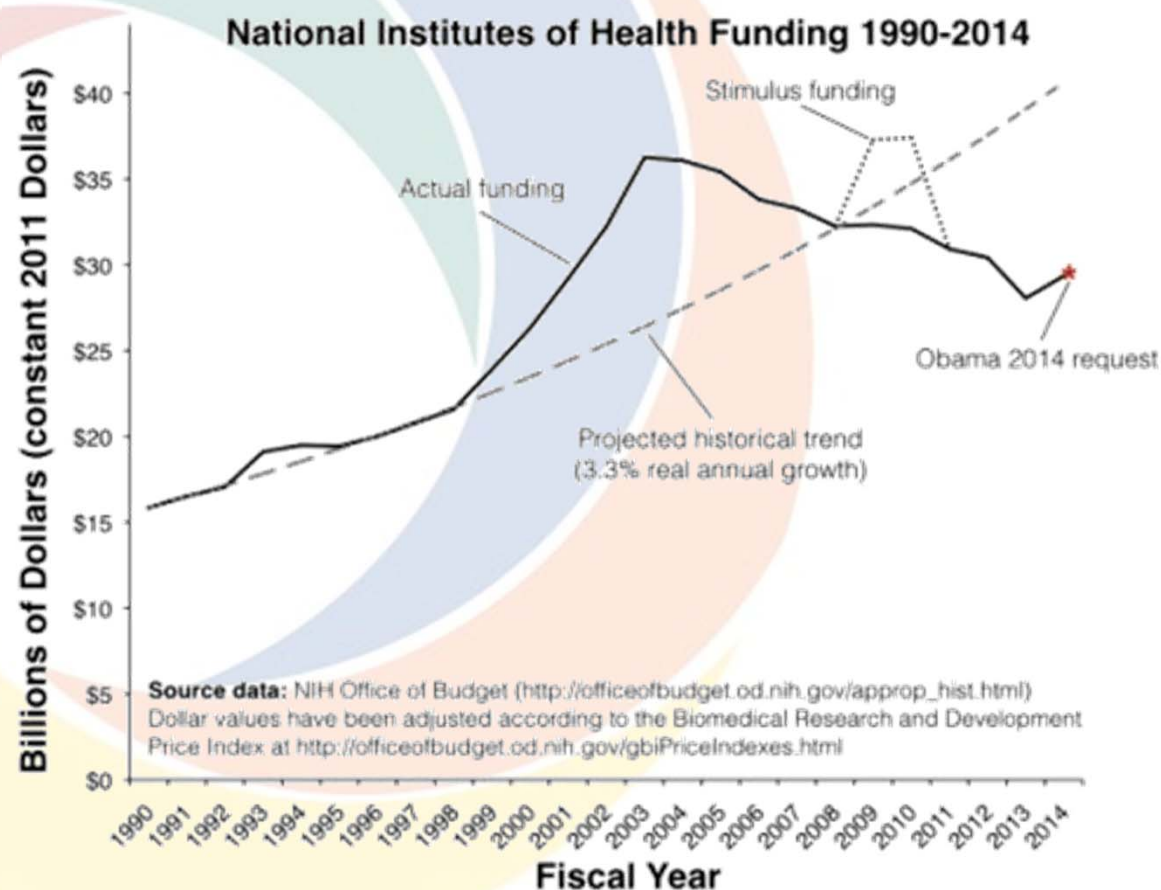
Open Access, JAMA

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Recent History of NIH Funding Trajectory



“Furthering America’s Research Enterprise”
National Research Council, 2014

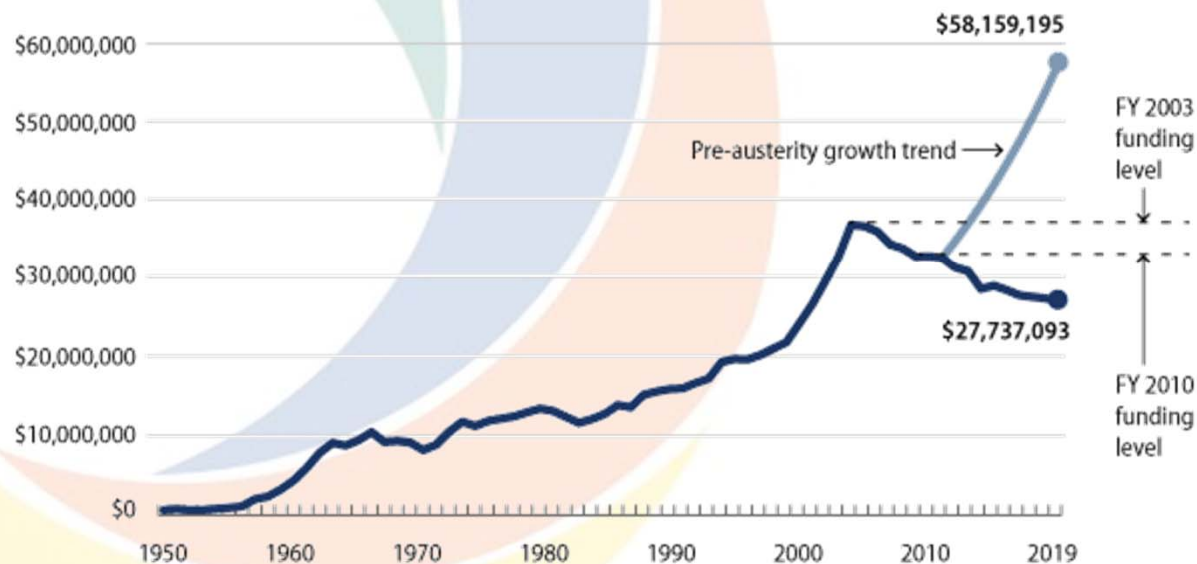
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Projected Future NIH Funding (Congressional Budget Office)

FIGURE 2
NIH funding, FY 1950–2019
in thousands of constant 2013 BRDPI adjusted dollars



Source: NIH funding figures through FY 2014 are based on total budget authority. Projected NIH funding figures for FY 2015 through FY 2019 are based on data from the Congressional Budget Office.

Open Access, Center for American Progress

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Incentives for Development in Academia, Industry and Society

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

	Academia		Industry		Society	
	Institutions	Faculty	Companies	Executives	Government	Individuals
New discovery	++	++	0	+	+	0
Drug target	+	+	++	++	0	0
Effective drug	+	++	++	++	+	++
Wide use	+	++	++	++	+	0
High profit	±	±	++	++	–	–
Appropriate use	0	+	0	0	++	+

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.

Enhancing ties between academia and industry to improve health

S Claiborne Johnston^{1, 2}, Stephen L Hauser¹ & Susan Desmond-Hellmann³

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Table 1 Academic-private partnerships 2012

Institution	Partners	Focus	Terms
Harvard University (7 deals)	Yale, Columbia, Rockefeller, Biogen Idec Evotec, Brigham and Women's Hospital Biogen Idec UCB Boehringer Ingelheim Evotec, Janssen Pharmaceuticals UCB	Amyotrophic lateral sclerosis Kidney damage Human interactome Autophagy in neurodegeneration Cancer, cardiometabolic disease, others Regeneration of insulin-producing cells Human microbiome	\$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
University of Texas system (7 deals)	Southern Research Institute, UTMB Onyx, MD Anderson Trovagene, MD Anderson GlaxoSmithKline, MD Anderson Profectus Biosciences, UTMB LoneStar Heart, UT Southwestern University of Washington, Kineta, UTMB	Viruses Multiple myeloma, lymphoma Pancreatic cancers with K-Ras mutations Tumor necrosis factor family member 4 Ebola and Marburg viruses Diabetes Viruses	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
University College London (6 deals)	Sarepta Therapeutics, Institute of Child Health, UCL's Dubowitz Neuromuscular Centre Eli Lilly Ark Therapeutics Oxford Pharmascience Horizon Discovery Eisai	Duchenne muscular dystrophy Neurodegeneration Fetal growth restriction Safestat drug delivery technology Huntington's disease Neurological diseases	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
University of California system (6 deals)	International Serious Adverse Events Consortium, UC San Diego Sanofi, UC San Francisco NexDx, UC San Diego Intellect Neurosciences, UC Irvine Gilead, UC San Francisco Islet Science, UCLA	Drug-induced renal injury Type 1 and type 2 diabetes Rheumatoid arthritis Alzheimer's disease HIV/AIDS Type 1 diabetes	2,000 patients with drug-induced renal injury examined for genetic variation database Target discovery. University receives \$3.1 million NexDx gets exclusive rights to commercialize research from Gary Firestein's lab Partnership fully funded by company to develop its drug RV03 University funds \$11.2 million to evaluate Truvada as prophylaxis. Gilead supplies drug Islet Science gets small molecules for islet expansion technology. UCLA receives royalties
Broad Institute of MIT and Harvard (4 deals)	Affymetrix Fluidigm AstraZeneca Roche	Cancer Single-cell genomics Antibacterials, antivirals Repurposing compounds	Partnership focuses on Cancer Genome Atlas. Financials not disclosed Launched the Single-Cell Genomics Center. Financials not disclosed Two-year deal. Institute identifies drug candidates. Company develops. Financials not disclosed Collaboration will span 2 years to identify new therapies from Roche's 300 undisclosed compounds

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

Academic-industry partnerships 2012

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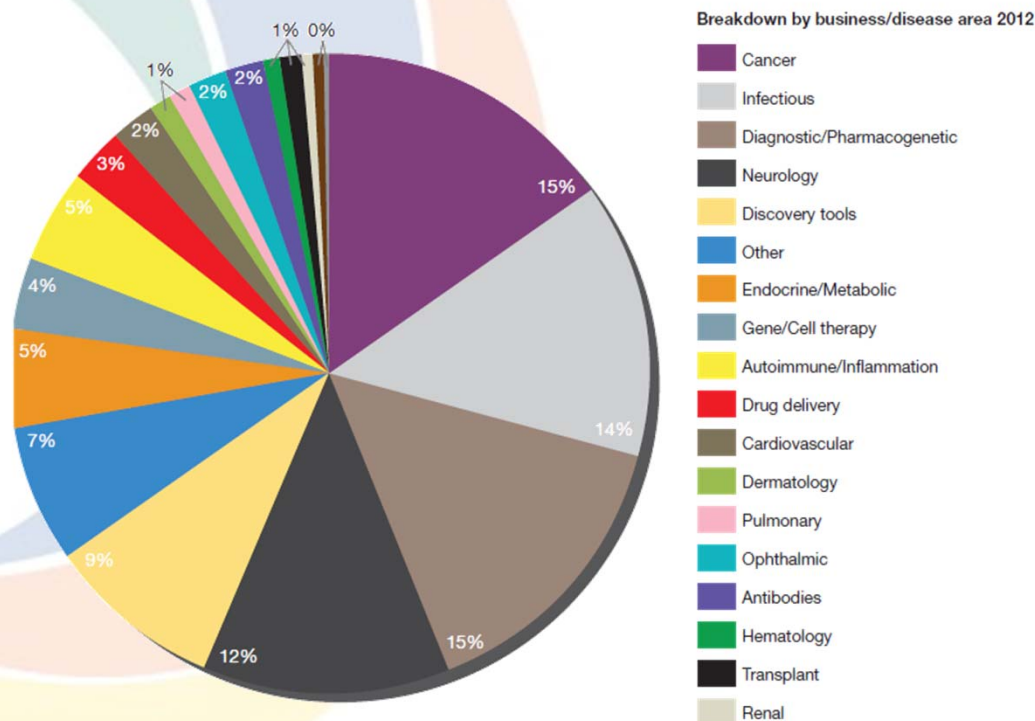
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Distribution of 387 “P/P” Deals 2012 by Category

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

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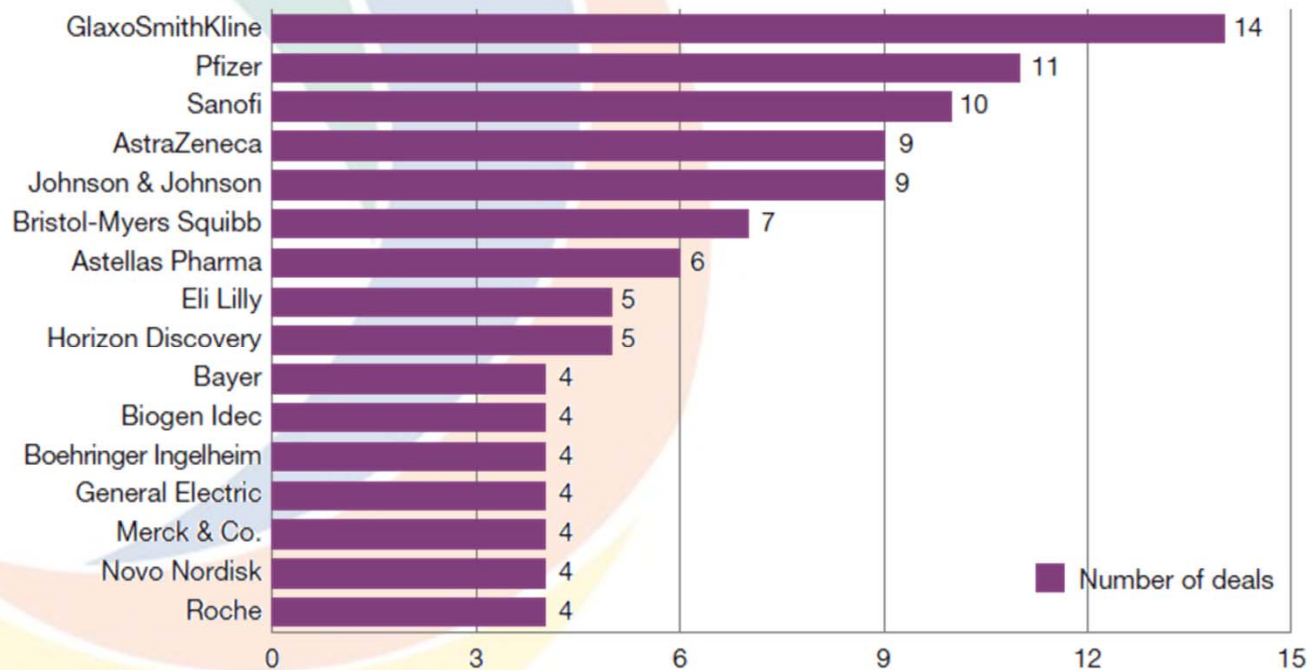
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Most Active Pharma Companies with Academic-Industry Partnerships

Figure 2 Most active pharma



Source: SciBX: Science-Business eXchange

Academic-industry partnerships 2012

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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

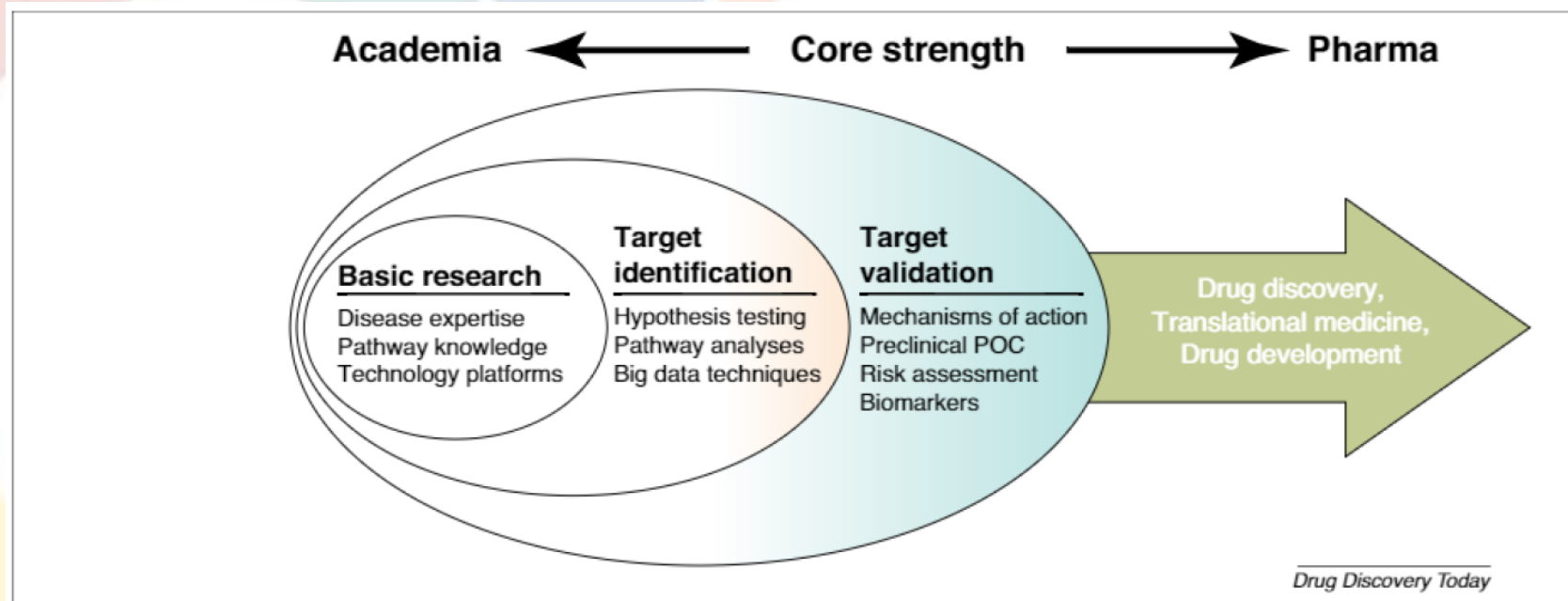


FIGURE 1

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 Rinkel³

Drug Discovery Today • Volume 20, Number 3 • March 2015

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

<u>Academic*</u> <u>(Ramsey/TDN)</u>	<u>CFF*</u>	<u>Vertex*</u>
Defining patient population	“De-risked” program with initial funding	Pre-clinical development <ul style="list-style-type: none"> •Drug Screening •Formulation •Animal Toxicology •Manufacturing
Identifying biomarkers and clinical endpoints	Formed development committee	Regulatory FDA documents
Designing studies	Found experts and developed teams	Funding for clinical trials
Conducting studies	Supported TDN	Conducted clinical program
Data analysis		Data analysis

*Joint Development Committee oversaw program.

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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?

