Easing the pain of partnerships: How can we make cross-sector collaborations in R&D worth the effort?

Thursday, June 15, 12-1 p.m. EDT
10,000 DISEASES.
ONLY 500 TREATMENTS.
WE HAVE WORK TO DO.
An Imperative to Work Together
Megatrends Forcing ‘Horizontal’ R&D

- Foundations not just writing checks for basic research
- Internet makes it possible to mobilize patients, via honest brokers
- Regulators paying attention to new endpoints: PROs, QoL
- Pharma R&D productivity slide forces outsourcing, external R&D
- Payers pushing back, demanding new definition of ‘value’
Oh, but the Pain!

• Find common ground, but don’t kick the can
• Keeping communication clear, focused, timely
• Getting past infatuation phase, making collaboration last
Jodi Black
Deputy Director,
Office of Extramural Research,
National Institutes of Health
Easing the Pain of Partnerships: Lesson Learned From An NIH Proof Of Concept Center Experiment

Jodi B. Black, PhD
Deputy Director of the Office of Extramural Research (OER)
National Institutes of Health

FasterCures Panel Discussion
June 15, 2017
Disclosures: None
Partnerships work

Inventions logged by the University of California system 1990 - 2005

1. **Who funds inventions?**

   - No sponsor information: 3,949
   - Federal: 5,572
   - Other sponsors: 1,527
   - Federal and corporate: 581
   - Corporate: 887

   Total inventions logged: 12,516

   Less than one-fifth of inventions have any corporate funding

2. **How do inventions fare?**

   - Most licences taken by third parties

   - Percentage chart showing patented and licensed inventions, with grey for not licensed by sponsors, red for licensed by inventors, and blue for licensed by sponsors.
The problem and the experiment

NIH Centers for Accelerated Innovations
Research Evaluation and Commercialization Hubs

Innovation

New Company

Licensing

Promising Technology
Private-Public Partnership
Patient and Societal Benefit

Turning discoveries into health

https://ncai.nhlbi.nih.gov/ncai/
How do the NCAI and REACH Work?

The Centers Provide Comprehensive Product Development Support

- Up to $400K in project funding
- Project management and coaching by industry-experienced mentors
- Personalized feedback
  - FDA, CMS, USPTO, Kaiser Permanente
  - Life science industry experts
- Training and Resources
  - Business development, Regulatory planning
  - Financing and partnerships
Things to consider

- Unrestricted matching funds and resources
- On-site project managers
- Application development support
- Reviewer instructions and reorientation
- Access to appropriate expertise

- Agile development
- Academic reward system misalignment
- Time
- Patience
It’s worth the pain: Inputs and outputs

**Inputs**
- Letters of intent and pre-applications: 856
- Full applications: 393
- Funded projects: 144
- Guidance from program partners

**Outputs/Outcomes**
- New companies: 11
- Technology licenses and options: 17
- Follow-on Funding: $45M
- SBIR Awards: 5
Todd Sherer
CEO,
The Michael J. Fox Foundation for Parkinson’s Research
PATIENT ORGANIZATIONS CAN DRIVE UNIQUE COLLABORATIONS

Todd Sherer, PhD
The Michael J. Fox Foundation
Our Mission

The Michael J. Fox Foundation is dedicated to finding a cure for Parkinson’s disease through an aggressively funded research agenda and to ensuring the development of improved therapies for those living with Parkinson’s today.

Vital Stats

» Founded in 2000 by Michael J. Fox
» Public charity
» 4,200 grassroots fundraisers reaching 175,000 supporters worldwide in 2016
» More than $700 million in research programs funded to date (2,600+ projects)

» 600 active grants in current portfolio
» 33% of funded projects led by researchers outside the United States
» Fund academics, biotechs and pharma
» Public policy/advocacy program focused on research, drug development and approvals, and access to care and support
UNITING COMPETITORS TO ANSWER BIG QUESTIONS AROUND DRUG SAFETY

Genentech

MJFF-led LRRK2 Safety Initiative

Merck

Pfizer

The Michael J. Fox Foundation for Parkinson’s Research
UNITING VARIOUS STAKEHOLDERS TO VALIDATE CRITICAL BIOMARKERS

- 33 Clinical Sites
- 1,000+ Volunteers
- 20 Industry Partners

PARKINSON'S PROGRESSION MARKERS INITIATIVE
Play a Part in Parkinson's Research

The Michael J. Fox Foundation for Parkinson's Research
WHAT WE’VE LEARNED:

- Appeal to stakeholders’ goals/needs while aligning on shared mission
- Look for nontraditional partners
- Leverage partners’ expertise and resources
- Patient organizations can serve as neutral convener and offer holistic perspective
Stephen Yates

Head, External Resource Optimization & Innovation

UCB Biosciences, Inc.
Collaborative Patient Engagement

Stephen Yates, PhD
Head, External Resource Optimization & Innovation
UCB Biosciences, Inc.

15 June 2017
UCB: creating value for patients

Bringing solutions to people living with neurological or immunological diseases

- Global biopharmaceutical company
- More than 7500 employees globally
- Operations in ~40 countries
- Epilepsy, Parkinson’s Disease, Restless Legs Syndrome, Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Axial Spondyloarthritis, Crohn’s Disease
- Core Products:
  - Cimzia® (certolizumab pegol)
  - Vimpat® (lacosamide)
  - Neupro® (rotigotine)
  - Briviact® (brivaracetam)
What UCB stands for

Everything we do starts with a simple question:

“How will this make a difference to the lives of people living with severe diseases?”

Creating value for patients
If you don't know where you are going, any road will get you there.

~Lewis Carrol
Establishing Collaborative Patient Engagement

- Create a strategic vision
- Establish collaboration(s)
- Set expectations
- Use a common language
- Share findings
Patient Engagement Opportunities Along the Clinical Development Continuum

- **TPVP**
  - Include patient perspective for patient product value and patient population

- **CDP**
  - Support ICF preparation
  - Review schedule of events and visits
  - Serve on study steering committee
  - Support regulatory & HTA activities re protocol and development plan

- **Protocol Design**
  - Support study recruitment strategy
  - Operational Ad Board - benefits and barriers to participation
  - Support trial awareness and recruitment
  - Support preparation of all patient facing study materials

- **Study Start Up**
  - Educate/motivate patient community
  - Peer advocate during informed consent procedure
  - Patient feedback re: sites, investigators, and study experience
  - Serve on a Independent Data Monitoring Committee
  - Support safety signal detection

- **Study Conduct**
  - Data for patients – data sharing
  - Serve on regulatory authority advisory committees
  - Provide testimony at regulatory authority hearings
  - Support regulatory activities (written testimony)

- **Analysis and dissemination**
  - Patient community response to results
  - Sharing study results
    - UCB.com
    - study participants
    - patient community
    - newsletters; blogs; patient advocates

- **Filing**
  - Share product information with patient community and provide feedback from patients
  - Alumni Network
  - Serving on post-approval surveillance initiatives
  - Supporting NIS, pregnancy registries re: expectations of patient community

- **Post approval**
  - Support trial awareness and recruitment
  - Supporting preparation of all patient facing study materials

Adapted from CTTI – PG Engagement Across the Research & Development Continuum
http://www.ctti-clinicaltrials.org/
Inspired by patients. Driven by science.
Past Webinars

03/29/2017

But that's the way we've always done it! Changing organizational culture in medical R&D

Many of the behaviors slowing faster progress in the discovery and development of new medical products are things that organizations everywhere have been confronting for decades, if not centuries – lack of effective communication and collaboration, silo-ization of information and expertise, incentives not aligned with the collective behaviors we want to see. What can the biomedical R&D ecosystem learn from the...

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01/23/2017

Top Medical Research Issues and Trends to Watch in 2017

Peering into the crystal ball, the trajectory for medical R&D over the next year may seem a bit hazy. But never fear – FasterCures has analyzed trends and determined some of the issues critical to the future of medical innovation that we'll be tracking over the coming year and that we think you should as well.

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Coming soon from FasterCures!
New resources for collaboration conveners

train.fastercures.org
Register now to be a part of

P4C Boston on July 12

P4C San Francisco on Nov. 14

partneringforforcures.org
Risk vs. Reward: The Growing Cyberthreat to Interconnected Health Care

by Mark Williams, Associate

As health care has become increasingly digitized, its vulnerability to cyberthreats has also increased. Kim McCleary, managing director, FasterCures, moderated a panel on this topic and noted that, in a recent survey, business leaders whose organizations were victims of cyberattacks compared the disruption to that of suffering a fire, flood, or other natural disaster. When we think of this vulnerability in light of our health-care data, the stakes could not be higher.

“Anything that harms public trust in this technology could

Free Webinar: Easing the pain of partnerships: How can we make cross-sector collaborations in R&D worth the effort?

By Margaret Anderson, Executive Director

Easing the pain of partnerships: How can we make cross-sector collaborations in R&D worth the effort?

Everyone knows that to get a discovery...

Be a Go- Getter: Reflections on My Departure

By Taylor Cushe, Senior Associate

After almost 13 years with FasterCures, I am announcing that I will step down as executive director. I am confident in the leadership team that you will see in place...

Cracking the Code of Addiction and Mental Health

The opioid abuse crisis is the latest challenge the U.S. faces in dealing with the deeply intertwined issues of addiction and mental health. Effective treatments are difficult to develop and are often difficult to access. At the Milken Institute’s 20th Annual Global Conference, a panel of experts discussed the opportunities in prevention and treatment, needed changes in the health-care workforce, and what can be done about the social stigma against these conditions.

“You can’t be your own chief medical officer if you’re suffering.”
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