Cornerstones of Collaboration

Foundation-led partnerships to accelerate R&D
Biomedical R&D through multi-stakeholder collaboration

FasterCures convened a workshop to discuss:

• When is collaboration the right solution?

• How can foundations preserve their mission while accounting for their partners’ differing interests?

• What are the main obstacles to creating collaboration?

• What resources exist or are needed to address legal agreements, data sharing, and intellectual property?
Why are foundations becoming collaboration conveners?

• “Because we have no choice. None of us can do this alone.”

• “Because we have the end in mind”

• Foundations can build a bridge between basic and applied science.

• Foundations are driven by a sense of urgency to streamline processes, reduce redundancies, learn from failures, and enable communication.
Defining collaboration

• “If you’re doing it right, you’re not just a funder, you’re a partner.”

• *FasterCures* defined consortia as initiatives characterized by:
  
  • *Integration of researchers* in a non-competitive space
  • *Agreement on a mission* that addresses a shared need
  • A *governance structure* that values each stakeholder’s input
  • An *integrated research plan* that utilizes each stakeholder’s resources/skills
# Workshop Participants are Experienced Collaborators

Many of the participants in the workshop have already convened and led multi-stakeholder, collaborative R&D initiatives with a wide range of objectives and partners. Here is a small sample of such initiatives.

<table>
<thead>
<tr>
<th>Foundation Conveners</th>
<th>Name of Collaboration</th>
<th>Purpose</th>
<th>Partners</th>
</tr>
</thead>
</table>
| American Heart
  Association (AHA) | AHA Precision Medicine
  Platform | Allows researchers and clinicians to access and analyze vast and diverse data to facilitate collaboration and accelerate breakthroughs in prevention, treatment, and cures for heart disease and stroke. | Amazon Web Services, AstraZeneca, Cedars-Sinai Heart Institute, Dallas Heart Study, Duke Clinical Research Institute, Intermountain Medical Center Heart Institute, International Stroke Genetics Consortium, and Stanford Cardiovascular Institute |
| Amyloidosis
  Foundation | Amyloidosis Research
  Consortium | Works to accelerate the development of advanced diagnostic tools and effective treatments for systemic amyloidosis. | 25 academic research centers |
| Children’s Tumor
  Foundation | NF Preclinical
  Initiative | Works to accelerate proof of concept testing of potential effective repurposed drugs in neurofibromatosis-1 (NF1)-Relevant models, and to frontload the clinical pipeline with new drug candidates for NF1. | Four leading NF academic laboratories with plans in 2017 to expand to partners in the pharmaceutical Industry |
| COPD (Chronic Obstructive Pulmonary Disease) Foundation | COPD Biomarker
  Qualification
  Consortium | Pools existing data from clinical studies evaluating various biomarkers to provide sufficient information to qualify them so that the U.S. Food and Drug Administration (FDA) and the European Medicines Agency can use them to evaluate new treatments. | GlaxoSmithKline; Boehringer-Ingelheim; AstraZeneca; Pfizer; National Heart, Lung, and Blood Institute; and FDA |
| CURE Duchenne | Collaborative Trajectory Analysis Project | Works to unleash the power of collaborative data science on clinical trial design, potentially helping the entire community to bring effective new therapies to patients more quickly. | Pfizer, BioMarin, Shire, Sarepta, PTC Therapeutics, Solid Biosciences, Catabasis Pharmaceuticals, Bristol-Myers Squibb, and Parent Project Muscular Dystrophy |

*FasterCures*

A Center of the Milken Institute
## Workshop Participants Are Experienced Collaborators

Many of the participants in the workshop have already convened and led multi-stakeholder, collaborative R&D initiatives with a wide range of objectives and partners. Here is a small sample of such initiatives.

<table>
<thead>
<tr>
<th>Foundation Convener</th>
<th>Name of Collaboration</th>
<th>Purpose</th>
<th>Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundation for the NIH</td>
<td>Biomarkers Consortium</td>
<td>Identifies, develops, and qualifies biomarkers to advance specific applications for diagnosing disease, predicting therapeutic response, and improving clinical practice using new and existing technologies.</td>
<td>National Institutes of Health (NIH), FDA, Centers for Medicare and Medicaid Services, more than 20 biopharma companies, and five nonprofits</td>
</tr>
<tr>
<td>JDRF</td>
<td>Encapsulation Consortium</td>
<td>Develops a product that will hide implanted beta cells from the immune system and allow people with type 1 diabetes to live life as if they don’t have the disease.</td>
<td>More than 25 research institutions</td>
</tr>
<tr>
<td>One Mind</td>
<td>Track-TBI</td>
<td>Coordinates a national collaboration among Level I Trauma Centers that will enroll 3,000 patients in the largest longitudinal study of TBI (traumatic brain injury) ever undertaken.</td>
<td>11 research universities</td>
</tr>
<tr>
<td>Unitio, Inc.</td>
<td>T1D Exchange</td>
<td>Coordinates a network of clinical care and research centers, combined with a registry, biobank, and social network, offering researchers access to aggregated clinical, biological, patient-reported outcomes, and electronic health record data.</td>
<td>77 clinics, patients, physicians, researchers, and industry representatives</td>
</tr>
</tbody>
</table>
Collaboration life cycle: Start-up

Start-up issues that workshop participants discussed:

1) Mission & Governance
   - Alignment of goals and expectations
   - A formal, transparent governance structure
   - How much control a foundation should have in setting collaboration terms
Collaboration life cycle: Start-up

Start-up issues that workshop participants discussed:

2) Human Capital

• Carefully consider how the initiative will be staffed
• Different partners bring different skill sets
Collaboration life cycle: Start-up

Start-up issues that workshop participants discussed:

3) Anticipating Future Needs

- Consideration given to the needs, or wants, down the road that can be anticipated or planned for up front
- Importance of bringing in industry, regulators, and even payers early on in the planning
Collaboration life cycle: Building relationships

1) Building Trust
   • Ensuring that all milestones in agreements are decided upon together
   • Understanding the incentives that drive each stakeholder in the collaboration
   • Instilling in the group a sense of purpose and pleasure via team-building

2) Data Sharing and Reuse

3) Protection and Management of Intellectual Property

4) Using the Right Tool for the Ask

WORKSHOP WISDOM

“You need a few ‘bell cows,’ a few leaders who say ‘we can do this.’”
Collaboration life cycle: Evaluation and sustainability

1) **Defining Success**: It’s important to define success up front, in the service of transparency and accountability.

2) **Maintaining Focus**: Lengthy and large-scale projects can create mission creep.

3) **Surrogate Markers of Success**: There have to be measures of successful collaboration other than objective achievement.

4) **Sustainability**: Redefining the value proposition to engage the biopharma industry’s interest/support.
### Challenges Cited by Workshop Participants

What are the most significant challenges for partners internally and externally that need to be addressed?

**Start-Up**
- Engaging interest and buy-in from the right partners, including regulators
- Understanding and influencing stakeholder incentives
- Alignment of goals and expectations
- Need for different types of talent, management, and special expertise
- Governance structure
- Managing conflicts of interest for foundations, investigators, and companies
- Length of time to launch

### Solutions, Tools, and Resources Cited by Workshop Participants

What tools and resources would be useful in streamlining the planning and execution of collaborative initiatives by foundations that do not currently exist?

**Start-Up**
- More thinking about role of foundation in management, governance of collaboration
- Sample organizational guiding principles
- Access to common agreements and common infrastructure (IRBs, trial networks) developed by NIH
- Templates for contracts, protocols, etc.
- Mentoring, peer-to-peer network for information and guidance
- Case examples and contacts of organizations that have done specific types of projects (e.g., trial networks, biomarker initiatives, etc.)
- Governance models, including information about international consortia
- Catalogue of resources that could benefit pre-competitive collaborations (e.g., preclinical animal study databases, etc.)
CHALLENGES CITED BY WORKSHOP PARTICIPANTS

What are the most significant challenges for partners internally and externally that need to be addressed?

ESTABLISHING AND MAINTAINING

- Internal resources to manage the initiative
- Due diligence on choosing projects
- Data policies and practices, and allocating resources to support sharing
- IP policies—what is the foundation’s role, what solutions serve objectives
- Maintaining focus, guarding against mission creep
- Quality of science across all partners

SOLUTIONS, TOOLS, AND RESOURCES CITED BY WORKSHOP PARTICIPANTS

What tools and resources would be useful in streamlining the planning and execution of collaborative initiatives by foundations that do not currently exist?

ESTABLISHING AND MAINTAINING

- Good approaches to IP policies and management
- Training in how data sharing works
- Tools for system and stakeholder mapping
- Data and sample sharing policies and agreements
- Model consent language
- Examples of IRB efficiencies (e.g., reliance agreements)
- Antitrust policies for industry in collaborations
- Information about liability insurance for foundations engaged in health research activities
- Toolkit of resources other foundations have developed to address issues
- List of law firms, consultants, etc. who can provide support for tech transfer, statistical analysis, etc.
- Ideas for how to engage more data scientists
- Models for engaging with regulators, e.g. Research Roundtables, drug development tools meetings
CHALLENGES CITED BY WORKSHOP PARTICIPANTS
What are the most significant challenges for partners internally and externally that need to be addressed?

EVALUATING AND SUSTAINING
> Tracking IP and commercialization of funded research
> Getting negative data shared publicly
> Measuring financial and non-financial ROI
> Metrics for organizational success, how you measure your contribution
> Educating and communicating with stakeholders, setting realistic expectations
> Process evaluation in addition to impact evaluation
> Mechanism to sunset large collaborations
> Measuring the impact of the scientific strategy versus the impact of the collaboration—do they need to be separate?
> Demonstrating the value to donors
> Sustainability model with industry

SOLUTIONS, TOOLS, AND RESOURCES CITED BY WORKSHOP PARTICIPANTS
What tools and resources would be useful in streamlining the planning and execution of collaborative initiatives by foundations that do not currently exist?

EVALUATING AND SUSTAINING
> Examples of evaluation, success criteria
> Develop tools to more easily track IP generated from research funding
> Models for sustainability plans for registry operating costs
Key Takeaways

1) Collaboration is necessary

2) Collaboration is not for the faint of heart

3) Foundations are uniquely positioned to be collaboration conveners

4) Investing in a strong framework during the start-up phase is worth it

5) Resources to streamline collaborations exist, but more are needed

WORKSHOP WISDOM

“If you want to go fast, go alone; if you want to go far, go together.’ We’re asking the question, ‘Can we go quickly together?’”