

University-Foundation Relations: From Transactional to Transformative Partnerships

A SUMMARY FROM THE SEPT. 8, 2014 **FASTERCURES** WORKSHOP

In biomedical research, both nonprofit disease foundations and academic research institutions are committed to translating research into effective therapies for patients. Despite this key area of alignment, universities and foundations have expressed different views about what mechanisms can best foster innovation and development. As just one example, many nonprofit disease foundations have incorporated provisions allowing them to exercise rights to foundation-supported inventions if the grantee fails to meet certain development milestones. These provisions, also known as "march-in rights," are included in an effort to ensure that research continues to move forward toward commercialization. However, many academic institutions have pushed back against such provisions, cautioning that this approach can actually hinder development by discouraging critical third-party investment.

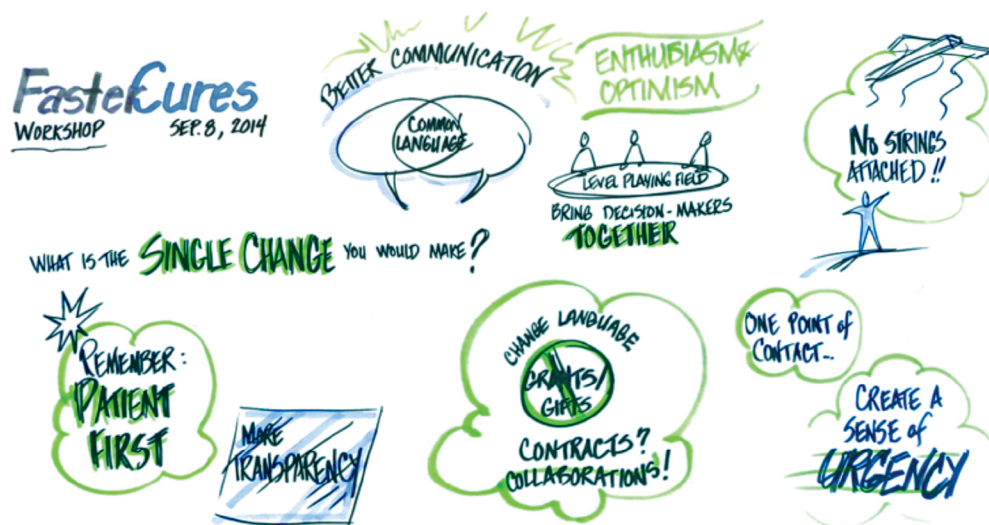
In recent years, the nonprofit and academic communities have each produced thoughtful work product and participated in group discussions directed at addressing these disagreements and identifying ways to maintain fruitful partnerships. On Sept. 8, 2014, *FasterCures* convened a group of more than 60 stakeholders representing academic research institutions, nonprofit disease foundations, industry, investors, and the legal community to explore these issues and identify actionable solutions. Led by facilitator Robert Mittman, the interactive workshop, "University-Foundation Relations: From

Transactional to Transformative Partnerships," consisted of dynamic, candid discussions designed to identify strategies to overcome barriers to successful university-foundation partnerships.

What *single* change would you make to university-foundation partnerships?

To kick things off, each participant was asked to identify the one change he or she would make to the existing framework of university-foundation partnerships that would most speed the translation of research into life-saving therapies. Common themes emerged from the dozens of answers.

Many participants suggested changes aimed at **enhancing transparency and improving communication**. One participant said he would "bring decision makers together early" to ensure productive communication. Another participant reasoned that "maintaining one point of contact" throughout negotiations would help build stronger relationships and improve communication.



Another recurrent theme was implementing a **“common language”** to foster better understanding and more efficient negotiations. Many nodded in agreement when one participant acknowledged that “if you’ve seen one agreement, you’ve seen one agreement.” However, there appeared to be some consensus that common tools, templates, and guidelines could reduce or even eliminate some of the negotiation friction. One participant proposed the concrete example of **changing words like “gifts and grants” to “contracts.”**

Multiple participants focused on **modifying the approach to research in the pre-competitive space**. In particular, rather than expend resources negotiating details of a technology transfer that has a low probability of success, why not develop tools to defer negotiation until the intellectual property (IP) is further developed? As one participant put it, if she could make one change, she would mandate that research in the pre-competitive space has **“no strings attached.”**

Other opening proposals to facilitate more effective partnerships included: involving investigators in the technology transfer process, keeping the patient first, maintaining collaborations after the money changes hands, and acknowledging up front the unique strengths and limitations of both sides.

Success stories—It can be done!

Many participants were careful to note that for every failed negotiation, countless others are resolved successfully. Indeed, many universities and patient foundations have developed sustained partnerships. What has made these relationships work where others have failed? To help uncover the basis of these effective relationships, the facilitator asked three participants to share their success stories.

- Lou DeGennaro, president and CEO of the Leukemia and Lymphoma Society (LLS), described a successful partnership between LLS and the University of Michigan. Both LLS and the University of Michigan recognized that research that began with an LLS grant was showing promising development potential. In an effort to move the research forward more efficiently, these groups transformed their

relationship into what DeGennaro characterized as a **“business alliance.”** Under this arrangement, LLS serves as the project manager, providing resources and support to ensure that the downstream needs of commercialization are addressed, while the academic researchers are able to focus on developing the IP. This arrangement allows each entity to employ its strengths while moving toward the shared goal of translating research into therapies.

- Robert Beall, president and CEO of the Cystic Fibrosis Foundation (CFF), spoke about a successful consortium of seven experts from different institutions focused on a specific area of research in the field of cystic fibrosis. To participate, member institutions committed to share reagents, models, and other IP developed in the process. Importantly, while individual researchers agreed to give up rights to products based on consortium-related research with applications in the field of cystic fibrosis, the CFF agreed to give up any rights to products based on consortium-related research with applications in another disease field. Beall emphasized that successful partnerships must contain such **“give and take.”**
- Ken Schaner, an attorney with the law firm Schaner & Lubitz, described an agreement between his client, the Bluefield Project, a nonprofit foundation, and five academic partners to further research in the field of frontotemporal dementia (FTD). Under the arrangement, Bluefield provided substantial funding for the consortium of academic partners to conduct FTD research. Each of the five academic partners agreed to share its FTD research results with other consortium members and Bluefield. The parties also agreed to share revenues earned from the license of any invention with each academic partner's share based on its scientific contribution to a particular invention. The Bluefield Project was given the initial authority to negotiate financial licensing terms on behalf of itself and the participating institutions, allowing the researchers to focus on the research. This arrangement enables each party to benefit from the consortium's scientific input and the Bluefield Project's experience with the disease, relevant companies, and investor community.

In the discussion that followed, there was recognition that factors that lead to success in some situations may not be universally present. For example, both the size of the grant and the size of the organizations can shift leverage, and organizations need to fairly value their contributions and manage expectations accordingly. Moreover, efforts to promote “a culture of sharing” may be met with resistance or fail to come to fruition. One participant suggested that to foster a culture of sharing, the directive needs to come from the top-level entities at the institution and that without buy-in from academic deans and presidents, the “right people might not be in the room.” Despite the many challenges, these examples demonstrate that flexibility and creativity can lead to partnerships that play to the strengths of each entity.

Mapping out interests and priorities—What does each side bring to the table?

To empower each group to speak freely about concerns, challenges, interests, priorities, and paths forward, the facilitator divided the groups in two: one consisting of representatives from academia and the other from nonprofit foundations. The handful of participants who did not plainly fit into either group were distributed between the two.

UNIVERSITY SESSION

In the breakout session of representatives from academic institutions, participants had a frank discussion about the concrete challenges facing the research community and the misperceptions that can compound these challenges. This includes the very real problem of **stagnant federal funding**. Participants acknowledged that when the decreased availability of federal funding is coupled with increasing costs, budget considerations infiltrate nearly every decision.

Moreover, while **universities strive to produce science of the highest quality**, several internal challenges make this more difficult. In addition to budgetary constraints, those in the room acknowledged that the **pipeline of qualified scientists is shrinking**, and it is increasingly difficult to entice the scientists they do have to stay. The **stiff competition among universities for individual faculty** only adds to the retention challenges.

When asked to articulate what foundations “don’t know about us,” the university representatives pointed out that at many institutions, foundation grants do not carry the same prestige as a National Institutes of Health grant when making tenure decisions. Although there was acknowledgement that this may not have direct impact on the deal-making process, it can affect how such grants are prioritized and perceived by both researchers and the institution. In addition, many academics argued that **indirect costs are misunderstood**. Although there are well-defined procedures in place to calculate indirect costs, misperceptions exist about what is covered by these costs, and participants acknowledged that institutions could and should do a better job of clearly articulating what expenses must be addressed to **cover the “full cost of research.”**

As the discussion shifted to identifying ways to better engage with research institutions, representatives from technology transfer offices were quick to point out that interacting with technology transfer offices is wholly appropriate as **“we do represent the deans.”** Other participants indicated that it would be helpful if foundations more readily acknowledged their shifting role from that of a traditional grant-maker to that of a venture investor by **proposing models beyond gifts and grants**.

Finally, many participants explained that they **really do care about patients** and raised concerns that many foundations seemingly don’t believe this to be true. One representative from a tech transfer office explained that unrestricted royalty money can benefit patients in many ways, even if it is not the particular patient group a foundation seeks to benefit. Many participants felt that universities are unfairly maligned for prioritizing budgetary concerns over patients, when in reality **institutions face many competing priorities** and must make difficult decisions about how to **allocate scarce resources** in a way that will best fulfill their academic mission and commitment to the broader community.

PATIENT FOUNDATION SESSION

Representatives of nonprofit disease foundations engaged in a similarly open discussion.

As participants listed key interests and priorities, many identified the important goal of achieving **high-quality**,

relevant science. Specifically, foundations cited the need to perform experiments efficiently, openly, and in a manner that can be replicated and shared.

Foundations also identified the need to **manage overhead costs** as a critical priority. This goes hand in hand with a widespread desire to ensure that the limited money that is available is being invested effectively. Another participant stressed the need to **encourage “fast failure”** so that unsuccessful projects can be wound down and resources reallocated quickly.

Foundations cited numerous challenges, including **justifying overhead costs to donors**, competing for donations, and obtaining sufficient funding to support the high costs of later-stage research. Participants also raised concerns about **managing patient expectations** and ensuring that patients understand the processes and timelines for basic, clinical, and translational science that lead to commercially available tests and treatments.

Participants conveyed widespread frustration that **research institutions don't appreciate or understand the non-financial contributions** patient groups bring to the research process. Specifically, foundations have access to patients, depth of knowledge about a disease area, and contacts with key researchers and companies in relevant fields. They may also be aware of unpublished studies or existing datasets and commercial partners with an interest in the disease or technologies related to it. All of these attributes can streamline the research process, which in turn can have a positive impact on an institution's bottom line.

Finally, participants identified several behaviors universities could employ to more effectively engage with foundations. **Bringing the decision-makers to the table at the beginning of the negotiation and ensuring that a dedicated contact person is present throughout** were two suggestions that surfaced as a way to improve partnerships.

During these brainstorming sessions, comments from each group were mapped out on poster boards and, when groups were brought back together, each participant had the opportunity to view the board developed by the other group. This generated a lively

discussion about the perceptions, impressions, and realities that impact negotiations.

Viewing the posters together revealed some areas of alignment. For example, both groups prioritize not only creating high-impact, high-quality, and relevant science, but also ensuring that the research is reproducible. This is a concrete area where both sides could work together to improve outcomes. Moreover, there is widespread recognition that translation must happen faster and improved training, funding, and focus can facilitate this. Participants agreed that an improved understanding of the downstream goals of translation, including compliance with regulatory requirements, will help bring drugs to market more efficiently.

In other ways, it was clear that many areas of conflict and misaligned priorities exist. For example, some disease foundations bristled at the notion that foundations are a small percentage of the overall budget and therefore a lower priority. However, institutions pointed out that while it's not a problem at current levels, if foundation contributions grow but the indirect cost rate does not, research institutions would not be sustainable. Viewing the posters prompted another participant to suggest that industry be involved earlier in the discussion. Both universities and foundations have real limitations and, in the right circumstances, industry can facilitate drug development and accelerate the goals of both foundations and research institutions.

This exercise enabled each side to openly voice concerns and identify challenges while acknowledging areas of alignment. Although there are real sources of tension, participants demonstrated a sincere willingness to work together to find solutions.

What does success look like and what is preventing us from achieving that success?

With a more honest picture of the challenges and competing priorities facing each entity, participants were able to approach the next task—identifying characteristics of successful partnerships—with a better understanding of realistic solutions. Participants identi-

fied numerous and wide-ranging components to successful partnerships. While difficult to distill the range of elements identified during the brainstorming session into one summary vision, recurring themes emerged, three of which are highlighted below.

First, there was broad recognition that successful partnerships would embrace a culture of sharing and openness. For example, participants envisioned relationships where pre-competitive data and information are disseminated with no strings attached. In addition, early and honest assessment of the value of assets, particularly in the pre-competitive space, was flagged as another characteristic of a successful partnership.

Second, participants repeatedly signaled that successful relationships would involve efficient and effective negotiations. Concrete ways to achieve this goal include developing a common lexicon for use in negotiations as well as template provisions to facilitate negotiations. In addition, following shared principles of engagement would help achieve successful and sustainable interactions.

Third, there was universal acknowledgement that a successful partnership must be based on mutual trust and respect. Such values can be fostered through a better understanding of the priorities and processes of each side, acknowledging the contributions of each party, and maintaining an open dialogue. Moreover, ensuring an equitable sharing of rewards based on relative contributions, financial and non-financial, of each side is another concrete sign reflective of a successful partnership.

Having explored what participants see as the elements essential to successful partnerships, participants were asked to evaluate what stands in the way of achieving that success. To that end, participants brainstormed obstacles to success and identified 20 barriers standing in the way of successful partnerships (see p. 6).

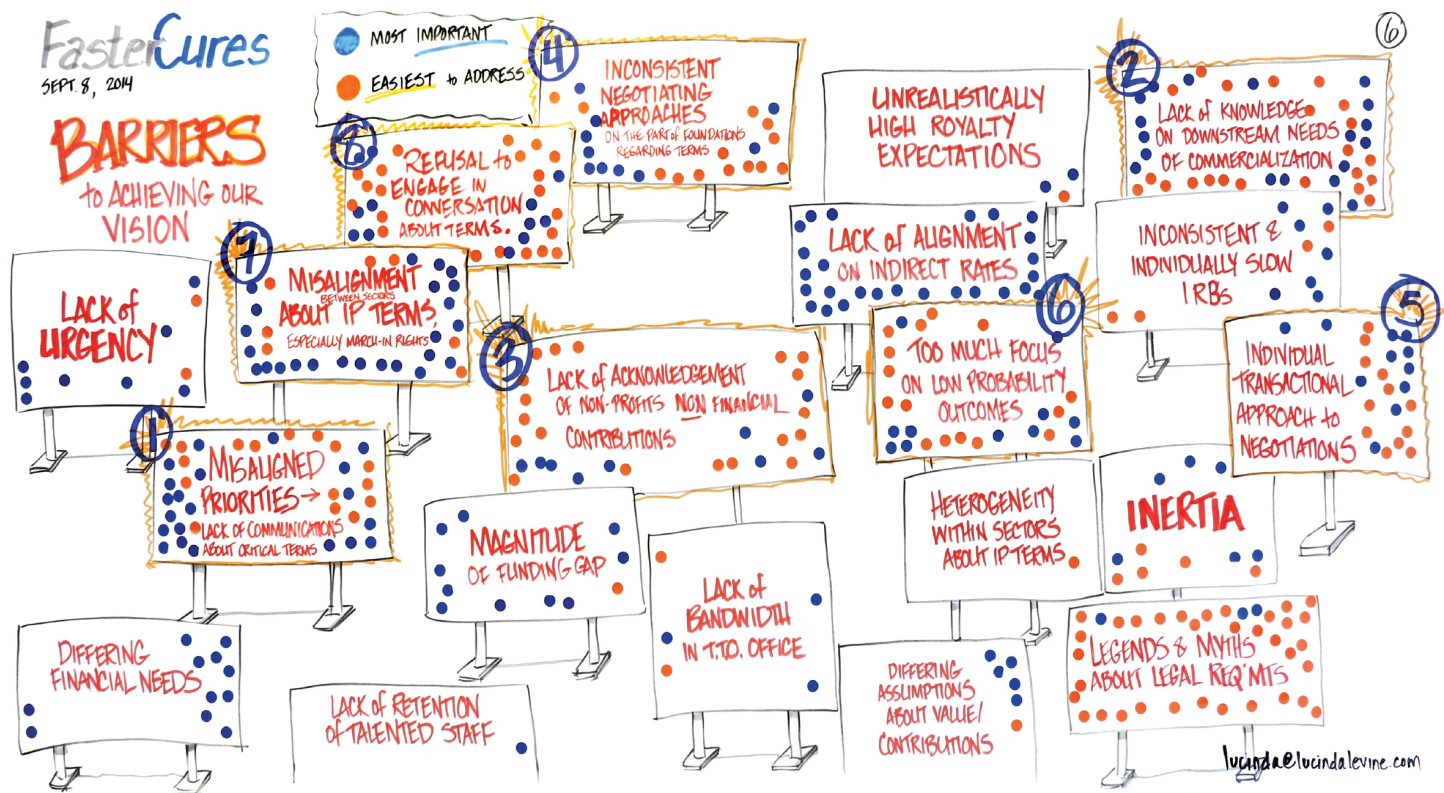
Participants were then asked to vote using two different criteria: assigning blue dots to those barriers that, if mitigated or removed, would have the most significant impact on partnerships, and assigning orange dots to those barriers that appear to be the easiest to address. Eight barriers were identified as being both a top priority and also relatively easy to address.

Recommendations for Moving Forward

So, where do we go from here? Are there avenues these entities—each having different views of what an ideal agreement looks like—can pursue to achieve elements of this successful vision?

The optimistic answer is yes. The participants were divided into eight groups, and each group spent the remainder of the afternoon developing proposed solutions to overcome one of the top priority barriers that was also identified as easy to address. Eight different work streams were proposed, many having overlapping elements. *FasterCures* has evaluated these proposed work streams and synthesized them into the following recommended steps to move forward.

- 1 **Develop a common language.** Develop and disseminate model agreements and/or specific provisions directed at the prime areas of discontent, such as interruption licenses, rights to research in pre-competitive space, and revenue sharing provisions. To ensure that these models are successful and useful, they will need to be developed with buy-in from stakeholders.
- 2 **Improve existing resources and develop new resources to enhance negotiation process.** Such resources could include sample agreements, templates, and anonymized case studies of models of success and failure. A number of these resources are available on *FasterCures*' TRAIN Web site (<http://train.fastercures.org>), but we will continue to work to augment and enhance these tools.
- 3 **Develop a platform where interested parties can connect to privately share best practices and negotiating tips.** *FasterCures* will explore the feasibility of developing a platform that allows stakeholders to privately connect with other stakeholders on issues common to both entities.
- 4 **Develop content to educate key participants in this field through workshops and/or white papers.** Develop educational resources and programs aimed at further enhancing university-foundation partnerships. Potential topics could include:
 - Educating stakeholders about the downstream needs of commercialization to ensure that research is positioned to satisfy regulatory requirements.



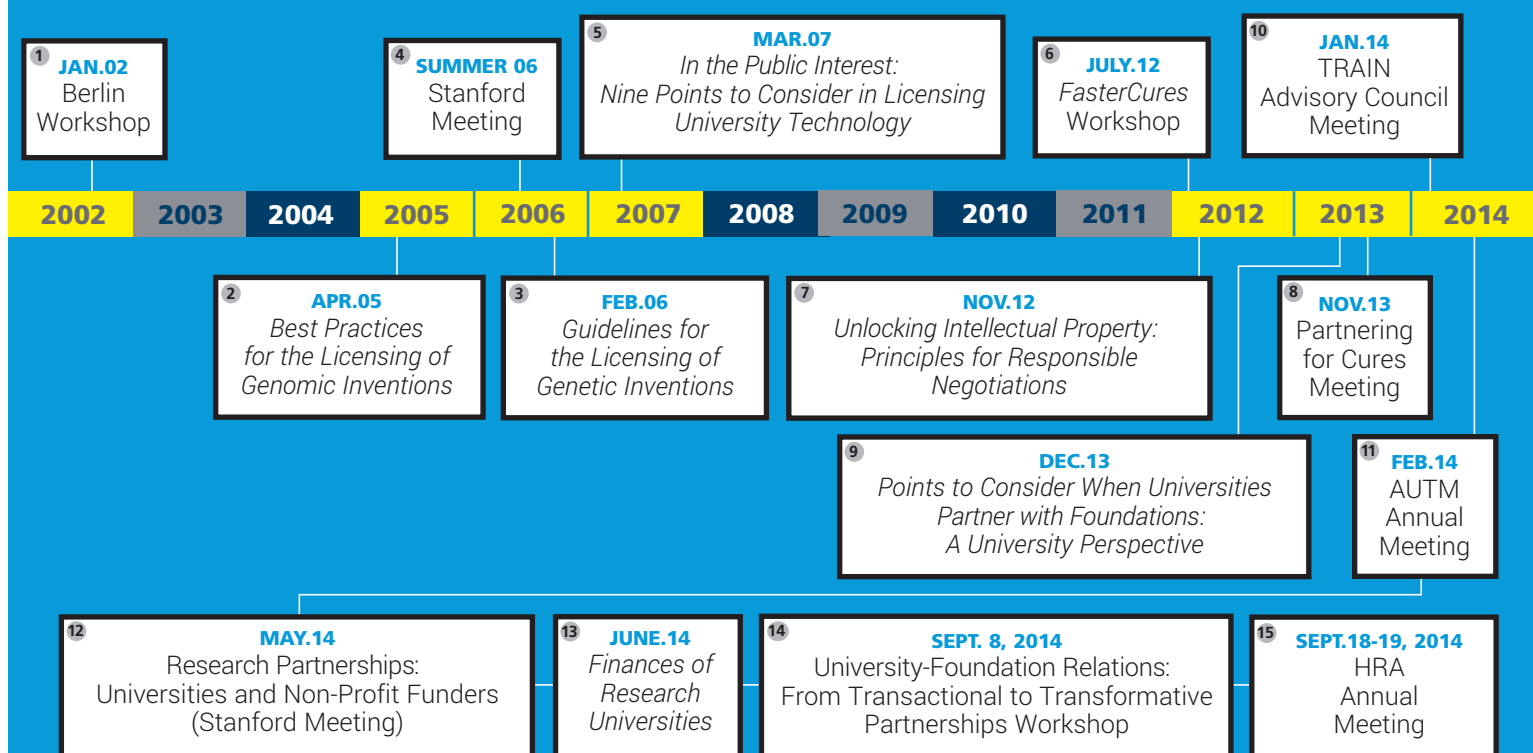
- Ensure that academics are better informed about the types of cure-related, therapy-driven investigations on which foundations are focused.
 - Educate stakeholders about non-monetary ways patient groups can add value and improve the bottom line through access to patients, researchers, and investors in the field. Incorporate case studies showing real value-add to bolster support.
 - Host negotiation workshops where participants can implement common tools and template language while also fostering accountability and an environment of collaboration.
5. Compile data about how frequently and to what extent research funding generates licensable discoveries and consider the implications for IP ownership and negotiation.

indirect rates, and magnitude of the funding gap. While we may not be able to eliminate these barriers in the short term, we can't lose sight of them when entering partnerships and should continue to look for creative ways to mitigate these challenges.

Although this river of activity has been growing and building for several years now, we at *FasterCures* hope that these proposed action items will be the jumping off point for moving quickly toward real, concrete solutions. We will be reaching out to many participants and other stakeholders in the coming months for input, guidance, and feedback as we implement these proposals. Mindful of the challenges that exist, we are optimistic that collaborating to develop a common framework now will streamline the process and foster stronger partnerships in the future.

It's important to remember that several barriers received many blue dots, but few (or no) orange dots. These challenging yet important obstacles to success include: differing financial needs, lack of alignment on

University-Foundations Relations: A Landscape of Events and Publications



1 The Organization for Economic Cooperation and Development (OECD) held the Berlin workshop to investigate the impact of an increase in patent applications filed and patents granted for genetic inventions used in human healthcare on the field of medical research.

2 The Public Health Service (PHS)/National Institutes of Health published *Best Practices for the Licensing of Genomic Inventions*.

3 OECD published *Guidelines for the Licensing of Genetic Inventions*, which arose from the Berlin OECD workshop.

4 Stanford University convened a meeting of research officers, licensing directors from 12 universities, and a representative from the Association of American Medical Colleges to brainstorm about issues in university tech transfer.

5 Arising from the Summer 2006 Stanford meeting, *In the Public Interest: Nine Points to Consider in Licensing University Technology* was published and endorsed by the Association of University Technology Managers' (AUTM) board of trustees and currently has more than 100 signatories.

6 FasterCures convened a small IP expert panel during a workshop to develop a set of guiding principles for use by all parties in biomedical research when negotiating IP agreements.

7 FasterCures published *Unlocking Intellectual Property: Principles for Responsible Negotiations*, the outcome of the July 2012 workshop.

8 At its annual Partnering for Cures conference, FasterCures convened a private session of 25 nonprofit organization representatives and other stakeholders to share their challenges faced regarding IP and tech transfer. Possible action items included convening a workshop with university representatives to address these challenges.

9 University tech transfer and sponsored R&D personnel published *Points to Consider When Universities Partner with Foundations: A University Perspective* to enhance the dialog between universities and foundations and to promote constructive collaboration.

10 FasterCures convened a conference call meeting of The Research Acceleration and Innovation Network (TRAIN) Advisory Council, where nonprofit leaders agreed that IP and tech transfer issues warranted a dedicated workshop convened by FasterCures with participation from venture philanthropy organizations and universities.

11 At AUTM's annual meeting, FasterCures' Margaret Anderson spoke on a panel about "Intellectual Property Rights Granted to Nonprofit Foundations." A small group of university and nonprofit leaders in attendance met privately to discuss the upcoming Stanford meeting.

12 Stanford university tech transfer, sponsored R&D, and nonprofit leaders convened at "Stanford for Research Partnerships: Universities & Nonprofit Founders" to discuss changes to award terms by nonprofit organizations over the last decade and possible steps to improve relations. The meeting summary included action items, and future meetings are possible.

13 The Council on Government Relations, an association of research universities, published *Finances of Research Universities* describing the current financial landscape of research universities and identifying challenges associated with financing research programs.

14 The FasterCures workshop "University-Foundation Relations: From Transactional to Transformative Partnerships" gathered more than 60 leaders representing universities and other research institutions, inventors, companies, investors, government policymakers, and venture philanthropies to discuss evolving relationship among research institutions and foundations.

15 Scheduled to meet during the Health Research Alliance (HRA) annual meeting, HRA has formed a working group to create an action plan around tech transfer issues. The group is conducting research about members' practices related to IP and tech transfer and plans to meet with Stanford in late 2014.



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