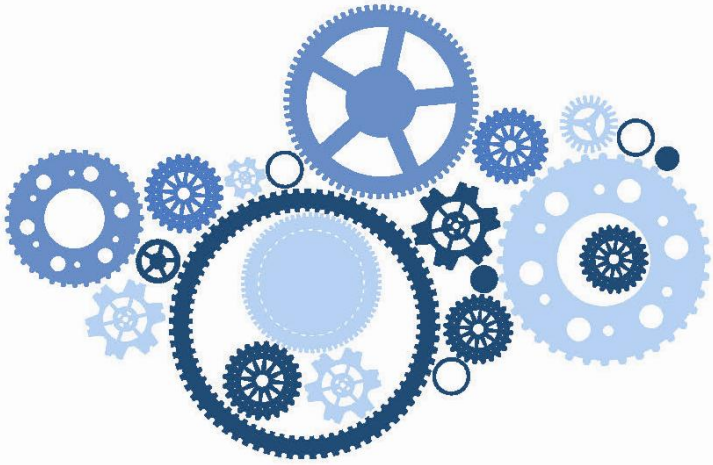
FasterCures
A CENTER OF THE MILKEN INSTITUTE



Intellectual Property

THE *FASTERCURES* CONSORTIA-PEDIA REPORT

About the *FasterCures* Consortia-pedia project:

FasterCures initiated the Consortia-pedia project to better understand the breadth and scope of approaches that a wide range of consortia have adopted to bring together non-traditional partners with a shared R&D goal. Since 2012, our analysis of more than 350 biomedical research consortia has been aimed to better understand how different stakeholders are using this model of partnership to address shared unmet needs.

To better understand consortia models, *FasterCures* analyzed 21 efforts that represent the diversity of models used to bring together non-traditional partners to accelerate biomedical research. We present our analysis under seven partnership components.

1. Governance
2. Financing
3. Human Capital
4. Intellectual Property
5. Data Sharing
6. Patient Participation
7. Measurement of Impact

Each component is a chapter in the Consortia-pedia report and can be downloaded at: www.fastercures.org/consortiapedia.

UPDATED May 2014

KEY POINTS – INTELLECTUAL PROPERTY

- Define the **precompetitive and competitive space** and identify potential opportunities for projects to transition between the two at the beginning of the collaboration.
- Establish pre-negotiated **intellectual property, licensing, and commercialization agreements** early in the process.
- Allow sponsors the ability to **opt-out, opt-in, or exercise their option** at any time.

Early agreement on intellectual property (IP), licensing, and commercialization principles is important for creating a culture of trust and properly setting expectations within any consortium. These agreements should be negotiated and finalized prior to any research activity, as any changes that occur after the launch of the projects would require additional negotiation by all participants, potentially causing a delay in momentum. It's also important to anticipate the resources needed for these agreements – negotiations among partners can be a significant drain on financial and human capital, in addition to ongoing and future resources needed to manage and enforce IP protection. Licensing may also be complicated; for example, sponsors may want to have the privilege of the first right-to-refusal for any non-exclusive licensing agreements.

Many of the consortia interviewed by *FasterCures* stressed the importance of defining the precompetitive and competitive boundaries at the very beginning of the establishment of the consortium and as the consortium evolves, monitoring if the line between precompetitive and competitive activities changes. These proactive exercises should aim to identify and track the deliverables that have IP implications as well as mitigate any ownership issues as they emerge. Some consortia that anticipate potential complications with the IP generated from its efforts use specialized committees to develop agreements and advise the executive committee on an ongoing basis. For example, the agreements for the Critical Path Institute's (C-Path) Predictive Safety Testing Consortium designate an independent advisory committee composed of representatives from each member organization to provide continuous guidance on any IP generated from the consortium.

Some consortia define the pre-competitive space as one in which a specific product is not created as a result of the collaboration, while others may still consider product development as pre-competitive if it can be broadly used or made available through a non-exclusive license. Determining the dividing line between pre-competitive and competitive activities may also depend on the perspective of any given sector, complicating the negotiation of a multi-sector agreement.

Research objectives that are commonly included within the pre-competitive space include:

- disease pathway knowledge
- biomarker research efforts where the data are openly shared
- toxicity and safety information
- technologies that broadly improve drug discovery and development
- data standards
- clinical trial control data
- clinical trial endpoints and methodology
- clinical care methods

There are examples of consortia that fall entirely within the precompetitive space and have an open sharing policy. As one example, all of the IP generated by the Observational Medical Outcomes Partnership (OMOP) was put into the public domain when it concluded in 2013. The infrastructure and data assets developed by OMOP were transferred to the Reagan-Udall Foundation for the Food and Drug Administration, serving as the foundation for the data methods advanced within their Innovation in Medical Evidence Development and Surveillance program.

Background IP

Agreements should include "background" intellectual property – these are pre-existing inventions or data that are owned by one of the participants and are planned to be used as part of the consortium's research activities. It is important to consider these implications within a research strategy, as a consortium may need to license the background IP from a researcher or his or her institution, or negotiate a limited agreement permitting a narrow use of the IP by all consortium participants.

Listing these inventions within an agreement serves many purposes, including:

- protecting a participant's own invention rights
- ensuring that a consortium can legally perform its research
- safeguarding the IP generated from the partnership by ensuring its freedom from legal entanglements

As one example, the Biomarkers Consortium requires that project team participants declare their background IP and grant all participants a limited, non-exclusive, royalty-free and remuneration-free license to use the pre-existing IP for research purposes only, and only in connection with the consortium's research project.

Consortium-generated IP

Intellectual property might be generated over the course of a collaboration – even for pre-competitive consortia – and it is important to identify what these could be during the early-stage negotiations to minimize unrealistic expectations. For example, the Innovative Medicines Initiative outlined the following examples as potential types of IP that could be generated as a product of their efforts: knowledge, data, know-how, material, compounds, methods, tests, experimental procedures, samples, cell lines, or transgenic models.

The IP agreements shared among partners of a consortium are typically more complex than those used in smaller, non-consortium based partnerships. Some of the additional details include:

- processes that ensure proper IP management, which may include unique benefits in licensing or commercialization
- processes for the addition of a new partner or exit of a partner before the completion of a project
- processes and resources to maintain and enforce IP after the conclusion of the consortium
- mitigation steps if the partnership terminates prior to the completion of a project

FasterCures heard from almost all consortia we interviewed that IP agreements took more time to complete than anticipated, as they need to consider organizational self-protection and legal details that may differ among sponsors (see Table 1 for examples). Many consortia publish general principles for their IP policy on their Web sites since it may be difficult to encourage participation when a formal agreement has not been drafted. Another alternative is to use an agreement that has already been accepted by multiple organizations as a non-negotiable document for new sponsors. Since IP rights can incur extensive legal costs and responsibilities, it is also important to consider that some participants may be interested in re-assigning IP to another party or abandoning their rights completely.

For C-Path, each program has pre-established legal IP agreements that are project-specific and must be agreed to by all partners at the beginning of the collaboration. These agreements become non-negotiable once established, and C-Path serves as the primary owner of the IP. This organization also schedules periodic reviews during the course of a consortium to ensure that agreements reflect current industry practices and IP landscape. This helps to assure their sponsors that the consortium's practices remain current, but these processes can be resource-intensive as any modification of their agreements would require consensus and sign-off from all participating organizations.

Table 1: Examples of agreements for pre-existing and consortium-generated IP

Consortium	Type of invention	Pre-existing (background) IP	New IP resulting from consortium research
I-SPY 2	Drugs (validation), tools (assays)	Retained by contributing inventor, research-use license provided to research teams	Foundation for the National Institutes of Health holds and manages IP – will license back to company (drugs) and will allow tool-based companies to keep IP if tool is improved
Quebec Consortium for Drug Discovery	Platform technologies, broad-use biomarkers	Retained by contributing inventor, research-use license provided to conduct research freely, if necessary	Retained by inventor(s) and their institution(s), non-exclusive license to consortium's industry sponsor for research-use purposes only
Innovative Medicines Initiative	Platform technologies, methodologies, biomarkers	Retained by contributing inventor	Retained by inventor(s) and their institution(s), either independently or jointly
Project Data Sphere	Clinical trial data for candidate cancer therapeutics	Retained by data provider	Retained by data provider; data user is prohibited from seeking patent protection for any research procedure or design resulting from the use of data

General Principles

As mentioned earlier, several consortia publish the general principles that underlie their IP agreements on their Web sites as a measure of transparency and to attract new participants. These serve as a foundation for all agreements in which specific details are negotiated to accommodate the requirements of individual projects. For example, some consortia provide their funded researchers with the right to retain IP for themselves or their institutions, while others may require that the IP generated by the consortium be held by a third-party organization. This flexibility has been effective for consortia that manage several unique projects, allowing agreements to be customized to match the unpredictable nature of science while meeting the diversity of sponsor expectations.

In addition to IP rights, licensing rights are often described as part of their general principles, particularly if there is a period of exclusivity provided to the participants and sponsors prior to its broader use. For the Quebec Consortium for Drug Discovery (CQDM), projects are funded for the broader benefit of the pharmaceutical sector, and IP generated with the consortium's support belongs to the inventors and their affiliated research entities. As an incentive for its sponsors, CQDM provides an opportunity to execute a non-exclusive licensing option to use the technology for R&D purposes only, with the right to first-refusal. Individual sponsors are also able to execute their licensing option early, prior to the completion of a project, upon the agreement of all the other sponsoring partners.

Master licensing agreement

One approach to managing IP is used by the BioPontis Alliance, an effort to accelerate the development of university-based inventions to the clinical phases. This organization uses a *Master License Agreement* that grants the alliance the authority to license and manage the IP. In turn, BioPontis Alliance works with the academic investigator to further develop his or her research project with advice and resources from industry experts and contract research organizations, with an aim to increase the attractiveness of the technology to the commercial sector. Since the value of the IP is expected to rise with the alliance's efforts, the original agreements with the universities are based on pre-negotiated terms, in which the initial estimated value of the asset is not part of the negotiation in the beginning.

Another group that executes this type of agreement is the Myelin Repair Foundation (MRF). Through its Accelerated Research Collaboration, this foundation focuses its effort to accelerate the development of a therapeutic for multiple sclerosis by supporting the research of four leading academic researchers. The universities affiliated with these researchers waive the individual rights to any inventions emerging from the

collaboration to MRF. This gives the patient foundation the authority to act as the sole executer of any licensing rights, with half of the royalties going to support MRF and the remainder being divided evenly among the four universities.

Data as IP

The data generated by some consortia may be considered as protectable IP, and for many of these instances, consortia offer a short period (often a few months or longer) where study partners are allowed a small window to use the data exclusively. This benefit provides participating researchers the opportunity to analyze data and patent any discoveries or inventions prior to the data release to the public. A consortium may also decide to immediately release all data into the public domain, and intellectual property is a relative non-issue. This is the case for the Alzheimer's Disease Neuroimaging Initiative and Sage Bionetwork's Arch2POCM effort, both of which aim to disseminate biomarker data to the broader research community. Additional details are provided in the "Data-sharing" component of the *FasterCures* Consortia-pedia report.

Tools to help inventors manage IP

Some consortia provide training programs and tools to help their researchers manage and understand the intricacies of dealing with IP. The "Accelerator Program" at the Center for Integration of Medicine and Innovative Technology (CIMIT) provides its researchers with support and specialized expertise in intellectual property protection, patents and licensing, technology implementation, and regulatory issues. The foundation of this program relies on CoLab, a CIMIT-developed cloud-based platform that includes an intellectual property module, which helps an innovator and his or her organization to manage their intellectual property and licensing opportunities.

For more information and the latest updates on the *FasterCures* Consortia-pedia, visit www.fastercures.org.