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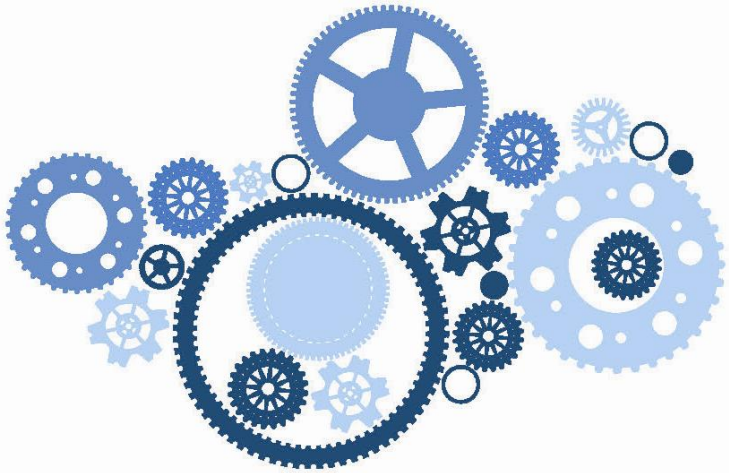

Financing

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 – FINANCING:

- Diversify **sources of financing** to ensure sustainability.
- Leverage **in-kind contributions** that may be invaluable contributions to the strategy and execution of the consortium projects.
- Use a financing model that **matches your partnership mechanism** and research questions.

Multi-sector consortia bring together stakeholders who have different cultures and incentives, but also provide the collaboration with access to finances, expertise, research resources, and patient populations. This section of the Consortia-pedia report discusses several examples of how financial and in-kind support are being leveraged by many consortia to ensure sustainability and growth, while ensuring that the collaboration has the scientific and logistical resources to pursue its research objectives.

Many of the consortia researched by *FasterCures* use a diversified financial model for securing funding, a strategy that has become increasingly important in an atmosphere of across-the-board dwindling resources (see Table 1). Diversification is also important at the early stages of the collaboration when sponsors and participants may be willing to only provide a conservative amount of funding and time commitment until the consortium demonstrates initial proof-of-concept and value. The anticipated costs shouldn't just be focused on operational expenses; many have emphasized the need to have fiscal reserves to mitigate unanticipated delays or costs, such as the additional legal fees and time needed to finalize the negotiation of data sharing or intellectual property agreements.

"In-kind" support often proves to be just as valuable as financial contributions and comes in many forms, such as dedicated full-time staff support, laboratory resources, access to technology, or subject-matter experts. As discussed in the "Human Capital" section of the Consortia-pedia report, when used effectively, this type of contribution has provided unexpected non-financial benefits to the collaboration, such as increased sponsor buy-in as well as access to specialized scientific expertise and resources. There are also several examples of consortia that have found creative ways for extending the value of their finances, such as initiating collaborations that cost-share specific research projects with other organizations.

Examples of funding sources used by consortia researched by *FasterCures*:

- government grants
- industry financing
- membership fees
- contributions from nonprofit foundations
- individual donations
- fundraising events
- philanthropic endowments
- non-financial, in-kind support
- cost-sharing project costs with organizations with similar missions

Table 1: Financing characteristics of consortia

Sector driving consortium	Unique characteristics
Government	• Funds used to de-risk the scientific concept, sometimes through an early government-sponsored and -managed research effort • Efforts with preliminary proof-of-concept transfer to third-party organizations to obtain additional sources of financing
Industry	• Pool funds from multiple industrial partners • Some mix their funding with government support • In-kind contributions from industry sponsors
Patient advocacy / foundations	• Private donations and support from fundraising events • Government funding is usually pursued and leveraged • Some leverage in-kind contributions from industry sponsors
Third-party organizations	• Membership-based funding for broad participation • Additional financing required for participation in specific activities • Fundraising activities target additional non-participating organizations and individuals

Third-Party Organizations

Most neutral and third-party organizations rely on membership fees from industry participants, with the amount of contribution often based on a percentage of the sponsoring organization's internal budget or revenue. Some also require membership fees from public and nonprofit organizations with dues that tend to be smaller than those from the private sector (see Table 2 for examples).

Table 2: Financial support for third-party consortia

Organization	Membership dues		Additional financial support
	Private/Industry	Public/nonprofit	
Health and Environmental Sciences Institute	Yes, tiered fees based on annual global sales and committee participation	No	Financial and in-kind from U.S. and international government regulatory and research agencies
Biomarkers Consortium	Yes, tiered fees dependent on organization's R&D budget	Yes, set membership fee	Financial and in-kind support from NIH, FDA, and some nonprofit foundations
Center for Integration of Medicine and Technology	Yes, annual fee based on organization size (greater or fewer than 500 employees)	Yes, private donations are donor-determined amounts	Massachusetts General Hospital, Partners Healthcare system, U.S. Department of Defense, research institutions

For example, Health and Environmental Sciences Institute (HESI), an organization that focuses on issues in global health and environment sciences, has annual private-sector dues that are based upon the sponsor's worldwide sales. By paying their membership dues, industry organizations are allowed to provide a representative to the HESI Assembly and participate in project or technical committees. HESI does not charge members of the public sector for their participation. As another example, the Biomarkers Consortium, an umbrella organization within the Foundation for the National Institutes of Health (FNIH), also has tiered membership divided into public and scientific membership. Scientific members are further tiered by their affiliation with a nonprofit or private sector organization with differential dues; membership allows them to participate in the projects and provides them with the ability to nominate members to the consortium's governance committees. With the exception of patient foundation representatives, public members do not have the ability to participate in the consortium's scientific projects or governance.

Adopting Diverse Funding Models

Critical Path Institute (C-Path) was started with funding from the FDA and contributions from the state of Arizona, the city of Tucson, Pima County, regional municipalities, foundations, organizations, and private individuals. Each consortium within C-Path utilizes a funding model that is dependent on the characteristics of the project. This flexible approach allows C-Path to meet the unique needs of specific programs and capitalize on a diversity of funding sources.

Models include government-funded, fee-for-participation, and single entity sponsorship, or a hybrid of the three sources. Current funding models include:

- **Electronic Patient-Reported Outcomes Consortium** is managed by C-Path in conjunction with firms that provide electronic data collection technologies/services, with membership dues and in-kind support provided by the participating firms.
- **Patient-Reported Outcomes Consortium** is funded by membership dues paid by the pharmaceutical company members.
- **Polycystic Kidney Disease Outcomes Consortium** is funded through a grant from the PKD Foundation and philanthropic donations.
- **Critical Path to TB Drug Regimen Regulatory Science Consortium** is funded by the Bill and Melinda Gates Foundation; governmental agencies such as the FDA, the World Health Organization, and the Centers for Disease Control and Prevention; and participating pharmaceutical companies.
- **Predictive Safety Testing Consortium** is funded by 18 pharmaceutical company members.
- **Coalition Against Major Diseases** is funded by a membership structure, which includes a broad range of industry partners, academic institutions, and nonprofit and governmental agencies.

Government-Driven Initiatives

There are several examples of projects that were developed and pursued by a government agency with an intent to de-risk a concept for the broader research community. For various reasons, government resources often can only take a project to a certain degree of demonstration, and the consortium model is one method for providing the project with additional resources to get to the next stage. Many of these types of efforts are then transferred to third-party organizations that have the capability to obtain finances from other sources and apply their management expertise.

The I-SPY 1 trial was originally funded solely by the National Cancer Institute (NCI) as a pilot project to evaluate neoadjuvant chemotherapy in patients with locally advanced breast cancer. The I-SPY 2 trial follows on to this effort by expanding the number of patients and academic centers in the testing of candidate therapeutics. The project's management was transferred from the NCI to FNIH's Biomarkers Consortium to help manage its growth and increasing complexity. With an expected cost of $26 million over five years, I-SPY 2 was able to use FNIH to diversify its funding sources to include the Food and Drug Administration (FDA), industry, nonprofit organizations, and donations from individual sponsors.

In addition to directly funding a project, government can also set the scientific research agenda of a consortium and provide a financial contribution for its operations. For example, the Alzheimer's Disease Neuroimaging Initiative (ADNI) was initially launched by FNIH as a five-year program with a contribution of $40 million from the National Institutes of Health (NIH) and $20 million from various industry and nonprofit sponsors. The program was re-funded in 2009 by NIH with $24 million for an extension known as ADNI-GO and received another contribution from NIH in 2011 to continue and expand its studies. ADNI also receives funding from the U.S. Department of Defense to use its platform to identify biomarkers correlated to traumatic brain injury and post-traumatic stress disorder in veterans, but this extension study is not managed by FNIH.

Industry-Driven Initiatives

The industry-driven consortia that we interviewed were unique in their leverage of in-kind contributions from their company sponsors. The Innovative Medicines Initiative (IMI), a European Union (EU) initiative to accelerate drug discovery, receives industry support through the European Federation of Pharmaceutical Industries and Associations (EFPIA), which acts as a third-party representative to the pharmaceutical industry in Europe. The European Commission provides fiscal support that is matched by EFPIA's mostly in-kind contribution, which includes project management and research resources. The Quebec Consortium for Drug Discovery (CQDM) is another consortium focused on supporting technology development projects that can accelerate drug discovery. CQDM uses a pooled resource model with equal financial and in-kind contributions directly from their pharmaceutical partners. The in-kind contributions include a unique mentorship program that involves industry scientists who provide ongoing advice to the funded research teams. These mentors not only give industry sponsors a window into the progress of the research activities, but also ensure that project teams have the necessary resources and expertise to develop a technology that has relevance to the pharmaceutical sector. CQDM has also leveraged its funding through collaborations with the Ontario province, two provinces in France, and the Massachusetts Life Sciences Center. Collaborative projects that are selected for funding under these latter programs must still involve Quebec-based researchers to satisfy their mission requirements, and the costs for their efforts are split by CQDM and another funding organization.

TransCelerate BioPharma, a consortium that is limited to industrial sponsors, pools funds from 18 pharmaceutical companies in an effort to improve the efficiency of clinical trials. In addition to financial contributions, the sponsoring companies also provide in-kind scientists and laboratory resources. The additional staff serve as project and operations managers for the individual research efforts, while other in-kind contributions are used to support the research activities and develop the consortium's data-sharing portal and communication materials. See Table 3 for more information on these examples.

Table 3: Financial support for industry-driven initiatives

Consortium	Industry sponsorship		Other sources of financing
	Financial	In-kind contributions	
Innovative Medicines Initiative	Yes, via EFPIA	Approximately €1 billion in value • Laboratory resources and research activities • Project management	Government (€1 billion) from EU's Seventh Framework Programme
Quebec Consortium for Drug Discovery	Yes, direct from sponsors	Approximately $250,000/year • Strategic input on board and committees • Industry mentors on funded projects	Quebec and Canadian governments
TransCelerate BioPharma	Yes, direct from sponsors	• Laboratory resources and research activities • Project and operational managers • Communications	None

Foundation-Driven Initiatives

Patient foundations traditionally secure donations from individual patients and family members, but many of those leading consortia tend to have a more diverse funding structure. The Michael J. Fox Foundation for Parkinson's Research (MJFF) Parkinson's Progressive Markers Initiative (PPMI) has an anticipated cost of $55 million. This effort obtains its financial support partially from MJFF and through a consortium composed of 13 industry partners, nonprofit organizations, and private individuals. In addition to financial contributions from industry, the effort also receives in-kind support in terms of expertise from its Industry Scientific Advisory Board as well as access to resources such as imaging tools from its industry partners.

The Multiple Myeloma Research Foundation (MMRF) manages the Multiple Myeloma Research Consortium and depends on direct donations and partnered or matched funding from industry to support its projects. Some of its collaborations, such as the eight-year Personalized Medicine Initiative, depend directly on the scientific and fiscal support of several companies. They have also piloted different approaches for diversifying their funding, such as cost-sharing with industry on a specific initiative, or provided venture philanthropy opportunities to create a small revenue stream for the organization. According to MMRF's 2011 annual report, 27 percent of their funding comes from private foundations, 28 percent comes from sponsored events, 33 percent comes from healthcare corporations, 8 percent from individual donors, and the remainder includes individuals and other sources.

Other groups require their clinical trial sites and clinical care sites to pay a participation fee to cover organization costs and data management. The Chronic Collaborative Care Network, an effort to demonstrate that a clinical care system can be improved through a continuous learning platform, is one example. In addition to the grants it receives from the NIH and the Agency for Healthcare Research and Quality, it also requires a membership fee from its participating clinical centers with the belief that membership dues help to increase the participation and retention of its networked clinical sites. These membership fees cover approximately 80 percent of to the total $1.2 million necessary for operating costs.

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