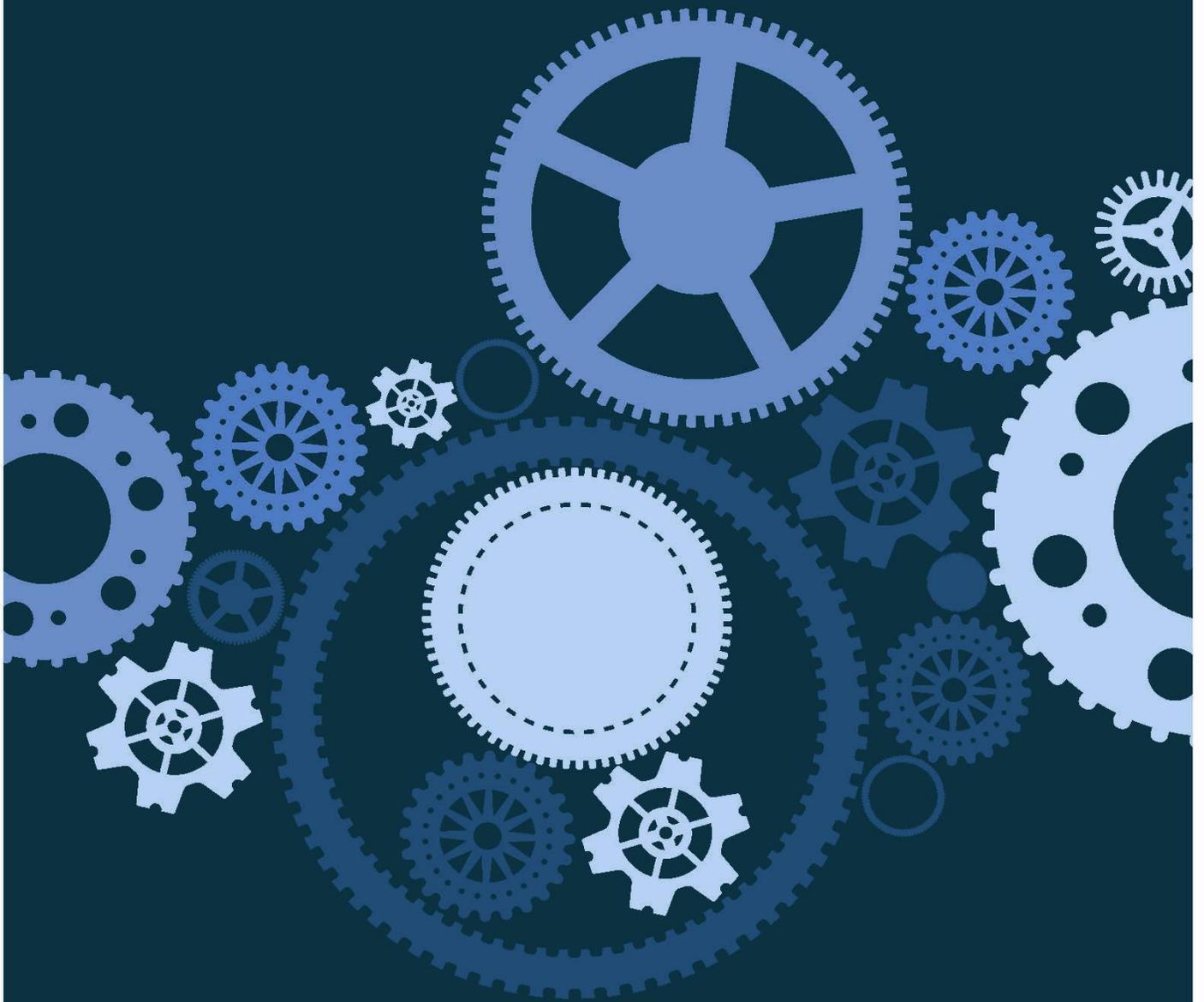




FasterCures
A CENTER OF THE MILKEN INSTITUTE



consortia-**pedia**

An In-Depth Look at the Research-by-Consortium Trend
in Medical Research and Development



Introduction

Getting new medical products from discovery to patients requires all sectors — academia, industry, government, clinical care, nonprofits, finance, and philanthropy — to work together throughout the research and development process. But collaboration is a complex endeavor, and integrating the right partners is far from easy.

In the past few years, *FasterCures* has seen a proliferation of larger cross-sector collaborations that use the consortium model to bring together multiple organizations representing a diversity of expertise and resources, but are organizations that may not traditionally work with others within and outside of its sector. **A consortium provides a neutral ground to coordinate the sharing of risks, costs, resources, data, and knowledge in the pursuit of a unified research mission, while addressing the differences in culture and expectations that each participant brings to the partnership.** The best collaborations establish an open and mission-focused environment that promotes data and knowledge sharing, ensuring that all participants have access to the latest information. **But the landscape has gone unmapped, resulting in confusion about the multitude of efforts and mechanisms for participation.**

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. **The biomedical ecosystem continues to experience a surge of multi-stakeholder consortia, with 62 new consortia emerging in 2012 alone. Perhaps this increase can be attributed to the current paradigm for developing medical products — a long, costly, and risky endeavor, especially for a single group to pursue alone. It could also be a sign of increased trust and willingness to partner.**

In this report, we analyze 21 consortia that represent the diversity of models used to bring together non-traditional partners to accelerate biomedical research. Some of the organizations that *FasterCures* studied, such as the Collaborative Chronic Care Network and TransCelerate BioPharma, are outliers to the type of collaborations described in this report but are included because they offer unique models that can be applied to multi-stakeholder consortia. Interviews with consortia leadership and participants, in addition to perspectives from outside experts, provided a broad understanding of how different models of multi-stakeholder collaboration are being leveraged to make a specific impact to the bioscience ecosystem. It is still too early to develop a universal set of best practices that could be applied to all consortia, but there are insights worth highlighting from the various ongoing efforts.

Components

Since most are still in the early stages of implementation with a wide variability in mission and governance, there is no attempt to directly compare or rank consortia. Instead, *FasterCures* aims to highlight some of the consortia by analyzing them from the perspective of seven partnership components:

1. **governance**
2. **financing**
3. **human capital**
4. **intellectual property**
5. **data sharing**
6. **patient participation**
7. **measurement of impact**

Each of these components and their examples are described separately within their respective sections at <http://www.fastercures.org/consortiapedia>.

Success factors

With multiple stakeholders come multiple challenges. From our research, we learned that successful consortia have the following traits:

- **Leadership** that defines a mission that's shared by all stakeholders, with an agreed-upon plan that articulates the outcomes of the effort early in the process.
- **A governance** structure that defines decision-making processes and avenues for participants to provide input to the strategic and research plans.
- A recognition that each partner brings to the collaboration **unique strengths and resources**. The best consortia have an operational plan that leverages these capabilities within an integrated research plan.
- A **straightforward** infrastructure to simplify data and resource sharing across organizations.
- A proactive plan to **manage expectations** and establish an environment of **transparency**. These are essential to building trust among all participating stakeholders. Transparency also curbs potential conflicts of interest and creates a culture that allows for open sharing of data and a responsible approach to intellectual property negotiations.
- A proactive plan to **measure the operational performance** of the collaboration at different stages of the lifespan. These metrics can be used to identify inefficiencies at the early stages and provide another method of ensuring transparency and accountability.

Research-by-consortium efforts were created to find a solution to a shared problem. It's the rising tide that has the potential to advance the distinct goals of all researchers.

Methodology

The term "consortium" is widely used by the biomedical research community to describe a diversity of partnership models. As a first step, *FasterCures* utilized a framework based on a series of inclusion/exclusion criteria and definitions to help with its landscape analysis.

- Consortia whose missions and membership were defined by the following characteristics were **included** as part of the *FasterCures* landscape analysis:
 - Integration and coordination of resources (financial, intellectual, research, patient) from multiple sectors, such as academia, government, industry, nonprofit, clinical care (particularly those that include resources from organizations within a sector that normally "compete" with each other)
 - Governance structure that provides each stakeholder with an opportunity to provide input to the partnership's strategic objectives and operations
 - Agreement on a mission that addresses a shared need with a strategic and milestone-driven plan to achieve output that, in turn, can be broadly used by each stakeholder or the outside research community
 - Defined lifespan that anticipates the timeline when research objectives would be met through the partnership
- While also valuable to the R&D ecosystem, consortia whose missions and membership were defined by one or more of the following characteristics were **excluded** from the *FasterCures* analysis:
 - Network of clinical trial sites with the sole purpose of evaluating specific medical products, without any strategic plan to test/validate broadly applicable clinical trial methodology (such as adaptive trial design)
 - Coordination of research resources to create scientific output that only benefits a single partner
 - Partnerships between a single industry stakeholder with one or more academic/nonprofit/government researchers

- Partnerships where one participant acts as the “funder” of other participants, with little/no coordination of research activities or sharing of resources and decision-making among participants
- Aggregation of financing for the sole purpose of establishing a fund similar in function and operation as those used by the venture capital community
- Network of researchers who convene due to a shared interest but lack a plan for research coordination toward a unified objective, data-sharing policies, and/or a governance plan that describes decision-making authorities

In addition to the above-mentioned selection criteria, *FasterCures* developed categories to help with its cross-consortium analysis:

- Sector that conceived of the partnership concept and its initial strategic research agenda (may be different than the sector that provides the principal funding for the collaboration)
 - **Industry** – for-profit organizations focused on the development and commercialization of medical products
 - **Government** – taxpayer-funded agencies responsible for oversight of a nation/state/region’s regulatory, health, research, and economic interests
 - **Academia** – university and nonprofit research institutions that traditionally are focused on the earlier phases of translational research, typically with access to diverse research resources and expertise
 - **Nonprofit organizations** – non-governmental organizations that have objectives to stimulate activities as a way to improve an aspect of society, such as disease-focused patient organizations or organizations focused on regional economic growth
 - **Third-party organizations** – nonprofit organizations that serve as a neutral, third-party convener and manager of multi-stakeholder consortia
 - **Healthcare organizations** – organizations focused on the delivery of healthcare
- Intended research output of the consortium
 - **Advance knowledge** – expand the scientific knowledge base about a specific disease, biological process, or methodology. Primary deliverables are publications for the research community.
 - **Broadly used tools** – create research resources that can be used to advance the research of multiple research organizations, including data ontologies and standards, clinical trial methods, data-sharing frameworks, biobanks, data repositories, regulatory tools, and prediction models.
 - **Biomarker research** – although this type of output can also be considered as a broadly used tool, *FasterCures* separated this subset of tools, defined as objectives to develop and/or validate biomarkers that can be broadly used for purposes such as diagnostic, drug-targeting, and advancement of basic research.
 - **Product development** – advance the development of a specific product, rather than a broad method or approach, including data-sharing platforms or specific classes of products, such as those targeted toward the needs of a specific patient population.

FRAMEWORK

Consortium-based partnerships intend to bring together researchers who can coordinate their assets and expertise to address a specific unmet need, in hopes of creating a tool or a resource that can be broadly shared. The *FasterCures* Consortia-pedia project is designed to provide a framework for participants and sponsors to evaluate the operational models used by ongoing or prospective consortia. The following questions can help with this process:

Mission and vision

- Who are my partners? What incentives drive each of the organizations partaking in this consortium?
- Do we share an unmet need that can advance both a shared goal and our unique individual objectives?
- Can we coalesce around a shared vision for moving forward?
- What are the outputs and outcomes of this effort? Is this consortium created to provide data, tools, and/or resources to benefit all partners and the broader research community?
- Who are the beneficiaries?

Terms of engagement

- What assets and resources can each partner bring to the effort? What is the strategy for leveraging these resources to ensure the highest probability of success?
- What resources are still needed to augment existing assets? How do you access those external resources?
- Is there a formal governance structure that serves as a measure of transparency by describing decision-making roles and methods for providing input to the consortium's scientific and operational strategy?
- Who is responsible for ensuring accountability to all participants and sponsors? Who enforces timelines and deliverables?
- What policies and practices can each partner agree to, regarding:
 - Data-sharing
 - Intellectual property
 - Conflict of interest
 - Materials-sharing
 - Confidentiality
 - Data access to the public

Sustainability

- What accountability measures must be in place to track progress and impact?
 - Equitable and timely contributions of resources and effort from all participants
 - Scientific milestones on research projects
 - Strategic and operational milestones on consortium progress toward mission goals
 - Procedures to ensure return-on-investment to participants and sponsors
 - Other strategic measures and mission-driven considerations
- How will metrics be used to provide real-time feedback, and how will these affect the impact or trajectory of the consortium?
- Are there external factors that must be considered in the near- and long-term that could potentially shift the focus of the consortium, or alter the nature of the partnership?

