

consortia-**pedia**

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



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***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.**

Executive Summary

WHEN IT COMES TO THE SEARCH FOR CURES, NO ONE GOES IT ALONE.

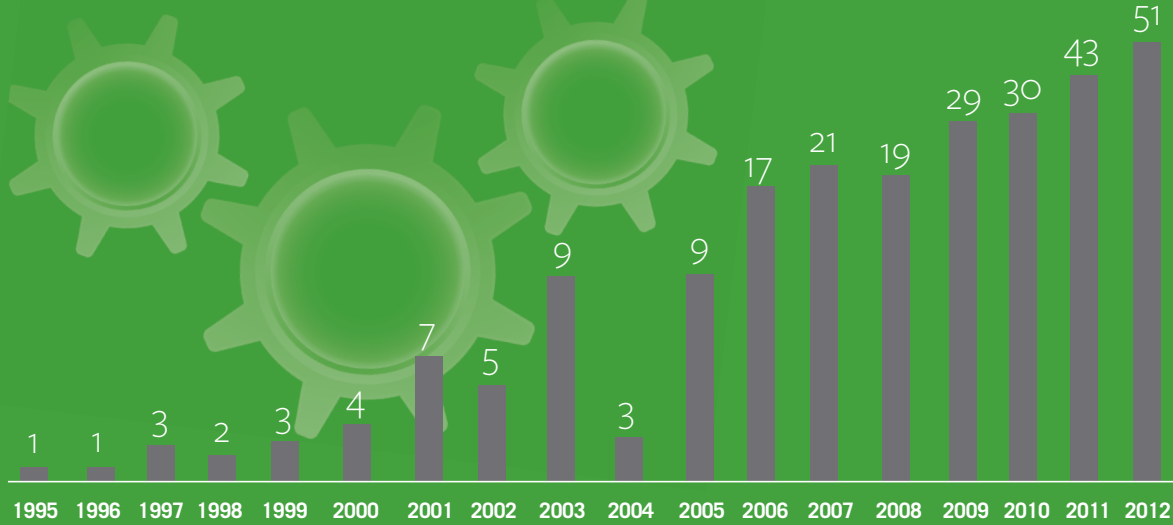
Getting new medical products from discovery to patients requires all sectors—academia, industry, government, clinical care, nonprofits, and philanthropy—to work together throughout the research and development process. **But collaboration is a complex endeavor, and integrating the right partners is far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

We are demanding increased productivity from the R&D enterprise in an environment of decreasing resources. This stress is forcing all stakeholders to innovate their processes, and a growing number are finding creative ways to collaborate within open environments of data- and knowledge-sharing. These partnerships span a range of models and can include interdisciplinary academic initiatives and industry-university alliances, as well as large formalized consortia that encompass researchers from multiple sectors who share resources to generate research results that are broadly needed.

***FASTERCURES* HAS SEEN AN INCREASE IN THE NUMBER OF CONSORTIA SPECIFICALLY CREATED TO ACCELERATE BIOMEDICAL RESEARCH. 2012 WAS A LANDMARK YEAR WITH THE LAUNCH OF 51 NEW CONSORTIA (SEE FIGURE 1).**

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. Efforts to redefine this paradigm by consortia are centered on collaborative approaches that leverage expertise and resources of a wide range of partners to create tools and knowledge that advance the research objectives of all stakeholders (see Figure 2). This model of partnership provides a neutral ground to coordinate the sharing of risks, costs, resources, data, and expertise in the pursuit of a unified research mission, while addressing the differences in culture and expectations that each participant brings to the partnership.

FIGURE 1: Number of New Consortia Launched, by Year



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. This report highlights the key findings of the Consortia-pedia project and:

- Offers a framework to better understand and potentially adopt the consortium approach. We present a series of questions that must be contemplated by those seeking to create a new collaborative effort, expand existing ones, or re-orient early-stage programs.
- Identifies seven partnership components that cut across efforts and define the nature of each consortium. How each component is handled often determines the viability of the partnership, and consideration of each will be key to advancing collaborative efforts. The components are:

- 1) **mission and governance**
- 2) **financing**
- 3) **human capital**
- 4) **intellectual property**
- 5) **data-sharing**
- 6) **patient participation**
- 7) **measurement of value and impact**

- Profiles 21 partnerships with diverse governance and operations strategies that represent the breadth of consortia currently underway (see Appendix). We analyzed more than 250 multi-sector collaborative efforts at different stages of development, with various operational structures and unique areas of focus. As a whole, they provide a broad view of the current landscape and allow a deeper understanding of what it takes to implement multi-sector collaborative efforts. We do not attempt to identify best practices or develop rankings, since most are still in the early stages of implementation with variability in mission and governance.

Framework

Alignment of mission, expectations, and a clear understanding of the nature of the partnership are key to the vitality of any consortium. We present the following questions to better guide conversations and thinking around the structure of this unique model of partnership.

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? Who are the beneficiaries? Is this consortium created to provide data, tools, and resources to benefit all partners and the broader research community?

TERMS OF ENGAGEMENT

- What assets and resources can each partner bring to the effort?
- What resources are needed to augment existing assets? How do you access those external resources?
- What policies and practices can each partner agree to, regarding:
 - > Data-sharing
 - > Intellectual property
 - > Conflict of interest
 - > Material-sharing
 - > Confidentiality
 - > Data Access

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 milestones on consortium progress toward mission
 - > Other strategic measures and mission-driven considerations
 - > Procedures to ensure return-on-investment to participants and sponsors
- How will metrics be used to provide real-time feedback, and how will these impact the 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?



Why a Consortia-pedia?

FasterCures has found that research-by-consortium is becoming an integrated part of the R&D pipeline. And yet, there's a growing sense of "consortia fatigue" and confusion that's stemming from an unmapped landscape and unclear value proposition.¹

We developed the Consortia-pedia to define the parameters of consortia, dissect their characteristics, and categorize existing efforts to bring clarity. Our goal is to ensure that research-by-consortium efforts are at their highest performance and achieving the best possible outcomes. When it comes to medical research, time is short and resources are limited. Done right, these consortia hold great potential to accelerate the way we pursue medical research and development.

WHAT IS A CONSORTIUM?

The word "consortium" is widely used to describe many types of collaborations. To provide focus for our analysis, we limited the definition of a consortium to the following characteristics:

- Integration of researchers from multiple sectors (academia, government, industry, nonprofit, clinical care), particularly those including researchers from the same sector that normally "compete" with each other.
- 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.
- A governance structure that provides each stakeholder with an opportunity to provide input to the partnership's strategic objectives and operations.

- An integrated research plan that leverages the research resources and knowledge from each stakeholder.

While also valuable, we did not include consortia with the following characteristics:

- Researchers sharing their independent results without a strategic plan to integrate their research. This includes government-funded researchers that convene, typically through a principal investigator's meeting, without governance to coordinate their activities toward a primary objective.
- Consortia used to create or evaluate a medical product that will benefit only one stakeholder (for example, a clinical-trial network that integrates trial sites to evaluate a specific medical product). Conversely, we included clinical trial networks with an objective to develop new methods or tools that could be broadly used, such as adaptive-trial designs or research into broadly useful biomarkers.*²

WHO'S ON FIRST?

To provide a framework for analysis and comparison, *FasterCures* categorized each consortium by the sector responsible for initiating the consortium. These groups are the original "champions" for the effort, developing a mission and framework that encouraged participation from other sectors.

For example:

- Critical Path Initiative is a third-party organization that manages several independent consortia. Some of their programs are initiated by government agencies (Predictive Safety Testing Consortium), by patient advocacy groups (Polycystic Kidney Disease

Outcomes Consortium), or are products of their own due-diligence processes (Coalition Against Major Diseases).

- Innovative Medicines Initiative is a third-party organization that leverages public and private resources in the management of more than 40 consortia. All of their efforts are considered as industry-initiated in *FasterCures'* analysis because the original vision for the partnership was created by the pharmaceutical industry through the European Federation of Pharmaceutical Industries and Associations, even though it operates within the jurisdiction of the European Commission.

WHY CREATE AND/OR JOIN A CONSORTIUM?

We further categorized these consortia according to research objectives that serve as the central organizing principle of the effort:

- **Advance knowledge**—elucidation of broadly applicable scientific knowledge, such as a biological pathway or mechanism-of-action.
- **Biomarker research**—discovery or validation biomarkers that can be broadly used, such as those that can stratify patient populations or indicate safety or toxicity.
- **Broadly used tools**—creation of tools, such as standards, methods, and technologies, which can be used by all stakeholders to advance their independent research.
- **Product-development**—focused on leveraging the resources of multiple sectors to advance the development of a specific product, such as an informatics platform, or to create a class of products, such as those targeted toward the needs of a specific patient population.

*Biomarkers are any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease.

¹ Papadaki M, Hirsch G., *Sci. Trans. Med.* 2013, 200(5), 1-3.

² WHO International Programme on Chemical Safety Biomarkers in Risk Assessment: Validity and Validation. 2001. Retrieved from <http://www.inchem.org/documents/ehc/ehc/ehc222.htm>.



Seven Partnership Components

1 MISSION AND GOVERNANCE ADDRESSING MISSION AND VISION BY DEFINING TERMS OF ENGAGEMENT

Consortia serve to advance research collaborations that address a shared but unmet need. Successful consortia are able to align the interests and resources across diverse stakeholders through a unifying mission statement. The mission statement is supported by a series of research questions and milestones that provide the foundation for a consortium's activities.

A clear definition of goals and a formalized governance structure that outlines decision-making authorities and management responsibilities build confidence among the participants and funders. This helps to ensure that partners are engaged in well-defined, mutually agreed-upon activities that aim to maximize the return on their investment of time and resources.

A board of directors defines the mission and provides oversight to all of the consortium activities, while the executive and steering committees provide operational leadership. These latter committees also are responsible for identifying the research questions and developing a strategic plan to guide the collaborative effort. The majority of consortia leverage the capabilities of an independent and third-party organization to manage its governance and research activities to ensure transparency and equality across partners.

In addition to boards and committees, many have staff members who are directly employed by the consortium and report to these upper levels of governance. For example, a president or CEO often serves as the public face of the consortium and is responsible for day-to-day functions, with the support of program staff and external advisory committees. Table 1 summarizes the governance of most consortia.

The inception and development of most consortia are typically the result of specific stakeholders coming together to champion a specific solution or idea, and creating enough momentum to sustain the effort. The *FasterCures*

A clear definition of goals and a formalized governance structure that outlines decision-making authorities and management responsibilities build confidence among the participants and funders.

Consortia-pedia categorizes the consortia by the sector that initiates the collaboration (see Table 2):

- a. government**
- b. industry**
- c. patient advocacy group/foundation**
- d. third-party organization**

Table 2 provides a snapshot of each type of consortium according to governance and program management structure.

a. Government-initiated consortia

FasterCures analyzed more than 250 consortia and found that 42 percent of them were initiated by a government agency. These government-initiated consortia often identify a gap in the R&D infrastructure that can only be

TABLE 1: Summary of Consortia Governance

GOVERNANCE RESPONSIBILITIES	OVERSIGHT	RESPONSIBILITIES	REPORTS TO	MEMBERSHIP
BOARD OF DIRECTORS	All Consortia	<ul style="list-style-type: none"> • Ensures organization's mission is the focus of all consortia • Approves new consortia 	Stakeholders	<ul style="list-style-type: none"> • Representatives from all stakeholders • Typically represent highest level of management in their organization • Commonly includes experts in business development
EXECUTIVE COMMITTEE	Individual Consortium	<ul style="list-style-type: none"> • Focuses on policies/procedures and business aspects • Approves consortium project concepts 	Board of Directors	<ul style="list-style-type: none"> • Representatives from all stakeholders • Typically represent middle-level management within organization
STEERING COMMITTEE	Individual Consortium	<ul style="list-style-type: none"> • Focuses on scientific/technical aspects • Proposes project concepts • Tracks technical progress of research projects • Convenes additional advisory groups • May act as Scientific Advisory Committee 	Executive Committee and/or Board of Directors	<ul style="list-style-type: none"> • Representatives from stakeholders, typically subject matter experts • Employed project directors and project management staff, typically as non-voting observers

addressed by combining the needed expertise and resources from multiple sectors, or if there is a need for a neutral broker to mediate collaboration. Stakeholders that do not have a scientific mission may also use the consortium model to promote public interest, such as improving or sustaining the local economy by fostering bioscience startup creation and job growth. **Approximately 40 percent of the government-driven consortia that were reviewed had mission statements that included economic growth as part of their objective.** These types of partnerships are often managed through third-party organizations that help the government avoid conflicts of interest and perform functions that government cannot do, such as fundraising. For example, the Foundation for the National Institutes of Health was created to support the research missions

TABLE 2: Characteristics of Consortia, by Sector

SECTOR INITIATING CONSORTIUM	COMMON MISSION OBJECTIVES	GOVERNANCE STRUCTURE	PROGRAM MANAGEMENT STRUCTURE
GOVERNMENT	Address gap in R&D infrastructure, job/company creation, regulatory and policy changes	<ul style="list-style-type: none"> • Board of directors and topic-specific executive committees ensure transparency • Steering committees ensure equal participation and input from all sectors 	<ul style="list-style-type: none"> • Employed project directors and project management staff
INDUSTRY	Address operational inefficiency in industry, job/company creation, harmonization through standards development, data-sharing	<ul style="list-style-type: none"> • Board of directors ensure transparency and participation • If support includes government funding, steering committees include non-industry representative to ensure public interests are addressed 	<ul style="list-style-type: none"> • Employed project directors and project management staff • Industry sponsors provide in-kind research staff and resources to assist with technical program management
FOUNDATION	Accelerate drug development for specific disease, provide research resources for research community, risk-benefit assessments	<ul style="list-style-type: none"> • Board of directors and advisory boards include scientific and product/business development expertise 	<ul style="list-style-type: none"> • Employed project directors and project management staff with extensive subject-matter expertise, sometimes located at research/clinical sites • Funded researchers assist in governance
THIRD-PARTY ORGANIZATION	Address unmet scientific needs, provide tools that can be broadly used to accelerate innovations	<ul style="list-style-type: none"> • Board of directors and topic-specific executive committees ensure transparency • Steering committees or <i>ad hoc</i> advisory committees are used to identify and evaluate new research concepts 	<ul style="list-style-type: none"> • Employed project directors and project management staff • Appointed project co-director role by sponsor



In-kind contributions have been shown to be beneficial for both the consortium and the sponsor as it helps to ensure that the research activities remain focused on industry needs and provides the sponsor with an insider's look at the research.

of the National Institutes of Health, while the Critical Path Institute and Reagan-Udall Foundation support the mission of the U.S. Food and Drug Administration. Each consortium under these third-party organizations is characterized by a customized governance and management structure, with some initiated by the government and managed by the organization, and others providing only administrative support to government-managed efforts. At the highest level of governance is a board of directors that includes representatives from multiple sectors and is focused on ensuring that all cross-consortia activities are aligned to the overall mission of the organization to enhance government capabilities.

The governance structures are designed to balance public taxpayer interests with real-world scientific challenges, while ensuring that each stakeholder has a forum to provide strategic input. Since they operate in the interests of government, almost 10 percent of their consortia actively engage regulatory scientists, providing a real-world perspective in the tools and standards created by the consortium.

b. Industry-initiated consortia

Our analysis of the landscape found that almost 20 percent of consortia are initiated by the biopharmaceutical and device industry. These consortia primarily serve as a method to pool resources to overcome tough translational challenges that companies cannot easily address alone. Of these consortia, 36 percent are focused on creating broadly used and non-competitive tools that can be implemented across their sector, and 27 percent are focused on researching biomarkers that can also be used broadly, such as those for safety and toxicity indications. Such consortia are typically convened by third-party organizations that serve to secure exemption from anti-trust regulation and create an environment of trust by ensuring objectivity and transparency.

Examples of industry-initiated consortia include the Quebec Consortium for Drug Discovery and Europe's Innovative Medicines Initiative that build collaborations particularly across industry and academia, and TransCelerate BioPharma that is exclusively comprised of industry partners. These consortia address key, common challenges in the therapy development process.

For industry consortia obtaining government funding, their governance structure typically resembles those of government-driven consortia with a

greater need to be accountable to the general public. As such, these organizations have both board of director- and executive committee-levels of upper governance that include industry representatives and non-industry participants. Others that are only supported with industry resources rely on a board of directors composed solely of industry executives.

A distinct aspect of many industry-driven consortia is their leverage of in-kind contributions. Under these arrangements, industry scientists remain employed by a sponsoring company and are tasked with managing the technical aspects of a consortium's research activity or serving as scientific mentors to funded researchers as part of their day-to-day responsibilities. This type of in-kind contribution has been shown to be beneficial for both the consortium and the sponsor as it helps to ensure that the research activities remain focused on industry needs and provides the sponsor with an insider's look at the research. In addition to staffing, in-kind contributions can also include access to research resources and facilities.

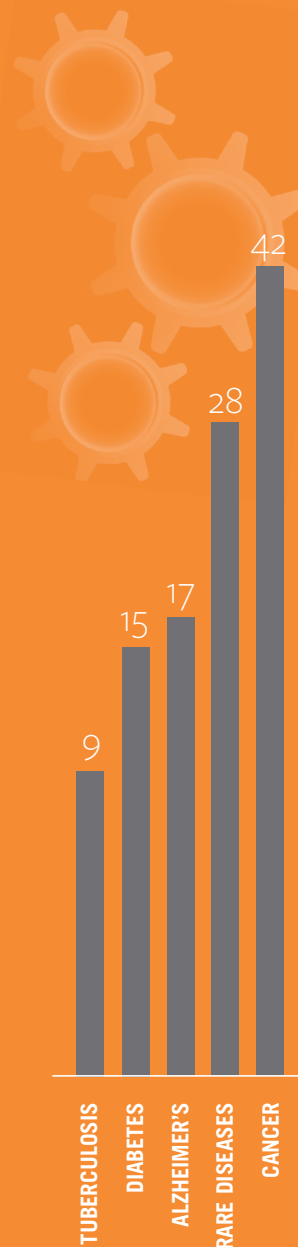
c. Foundation-initiated initiatives

Of the more than 250 consortia we surveyed, almost 10 percent were initiated by patient advocacy groups and nonprofit foundations. These types of consortia typically featured a narrower mission than government- and industry-driven initiatives in that their efforts commonly have the goal of leveraging the resources owned by the various sectors to advance the development of a cure for a specific patient population. Diseased-focused partnerships were also initiated by other sectors, and the patient populations with the most consortia include oncology and rare diseases (in aggregate), followed by Alzheimer's disease and diabetes (Figure 2). Among all consortia, *FasterCures* found that:

- 46 percent focus on developing disease-specific biomedical products such as drugs, devices, or vaccines;
- 27 percent aim to create broadly used tools; and
- 15 percent aim to accelerate biomarker research with data (and sometimes annotated biospecimens) made publicly available to other researchers.

Most of these consortia are led using internal resources, while others use third-party organizations to help coordinate and manage research efforts. Some examples include the Multiple Myeloma Research Consortium and the Parkinson's Progression Markers Initiative, initiated by the Multiple Myeloma Research Foundation and the Michael J. Fox Foundation for Parkinson's

FIGURE 2:
Top Patient Populations Addressed by Consortia



These foundation-driven efforts strategically employ program staff with specific expertise and extensive scientific credentials directly applicable to the funded projects within their portfolio.

Research, respectively. The highest levels of governance for most of these consortia are focused on ensuring that the products of their efforts have a pathway for commercialization or dissemination.

At the program level, most of these consortia employ active program management staff that is centrally located at the foundation office or distributed at the research and clinical sites. These foundation-driven efforts strategically employ program staff with specific expertise and extensive scientific credentials directly applicable to the funded projects within their portfolio. Many have an in-depth understanding of the biology of the disease or experience in the execution of drug development and clinical trials that meet the requirements of their specific patient population. Thus, their staff not only manages and guides the research activities by working on-the-ground with funded investigators, they may also help steer the research strategy by working with the governance committees to identify and develop solicitations. Funded researchers also tend to play a larger role, as they are typically experts in the disease of interest and can contribute to the scientific direction of the consortium's efforts by serving as members of a governance committee.

d. Third-party-initiated initiatives

Third-party organizations play important roles for government-, industry-, and foundation-driven consortia by providing the mutual ground among all of the stakeholders. **These organizations have also played primary roles starting and managing approximately 22 percent of the total consortia reviewed by *FasterCures*.** Since these efforts are initiated within the organization, working groups and steering committees are used to:

- identify broad, unmet needs that are not addressed elsewhere by other consortia;
- validate from the scientific community that they are truly unmet needs;
- ensure the availability of resources; and
- develop a process to pursue the intended output and outcome.

The final decision to pursue the research consortium is made by the board of directors, which is responsible for ensuring that the new concepts are within scope of the overall mission. **A common theme for output is cross-sector utility; more than one-third of these consortia are focused on developing broadly used tools, such as prediction methods or clinical-trial designs, and 20 percent are focused on developing biomarkers that can be used by multiple stakeholders such as those that stratify patient populations or indicate safety.**

2 FINANCING

DEFINING TERMS OF ENGAGEMENT TO ENSURE SUSTAINABILITY

FASTERCURES FOUND THAT THE MAJORITY OF CONSORTIA USE A DIVERSIFIED FINANCIAL MODEL TO ENSURE THEIR SUSTAINABILITY (Table 3). Effective fundraising is necessary, and almost all collaborations have sources of funding that include government grants, industry financing, membership fees, contributions from nonprofit foundations, individual donations, fundraising events, philanthropic endowments, and private sponsorships.

Consortia stakeholders are driven by different cultures, incentives, and resources, and have varying abilities to contribute finances, expertise, or access to specific patient populations. The sources of funding for these multi-stakeholder collaborations are diverse, and securing funding poses a common challenge in terms of amounts and length of commitment. In addition to operational expenses, some consortia 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.

Many third-party organizations that initiate their own consortium 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. Many consortia have also found creative ways for extending the value of their finances, such as initiating collaborations that cost-share specific research projects with other initiatives or by leveraging in-kind support from their sponsors, as mentioned earlier.

3 HUMAN CAPITAL

ACTING ON TERMS OF ENGAGEMENT TO ENSURE SUSTAINABILITY

Recruiting and retaining talented individuals to comprise a multi-sector team is a challenge for many consortia. Although most individuals are passionate about the science and are driven to accelerate innovation, each brings unique experiences and expectations to the collaboration. It's important to assess the total human capital that is available to a consortium and delegate responsibilities that



Ensuring the Right Expertise

A formal governance structure is important for creating an environment of trust and transparency, but it is equally essential to have a flexible framework that can address technical issues that may emerge during the course of a project. Many consortia have found a need to create *ad hoc* and technology-specific working groups or advisory committees that temporarily convene and conduct technical due diligence on behalf of the scientific advisory board or steering committee. These working groups typically are a mix of outside subject matter experts that ensure that the consortium is not using or developing tools that are behind the state-of-the-science. These groups also may serve the role of outside peer review for proposals submitted to the consortium or address technical topics that are narrow in scope.

TABLE 3: Funding Characteristics of Consortia

SECTOR DRIVING CONSORTIUM	FUNDING CHARACTERISTICS
GOVERNMENT	<ul style="list-style-type: none"> • Continuation or expansion of a pilot, government-sponsored and -managed research effort • Efforts with preliminary proof-of-concept transfer to third-party organizations to obtain additional sources of finance and collaboration
INDUSTRY	<ul style="list-style-type: none"> • Pool funds from multiple industrial partners • Government funding is sometimes included, typically for regional/national economic growth • In-kind contributions from industry sponsors
PATIENT ADVOCACY / FOUNDATIONS	<ul style="list-style-type: none"> • Private donations and support from fundraising events • Government funding is usually pursued and leveraged • Leverage of in-kind contributions from industry sponsors
THIRD-PARTY ORGANIZATIONS	<ul style="list-style-type: none"> • Membership-based funding for broad participation • Additional financing required for direct participation in specific activities • Fundraising activities target additional non-participating organizations and individuals

are appropriate to an individual’s commitment of time and expertise, matching these with incentives that motivate their participation. This includes members of a consortium’s program staff, governance and advisory boards, and project teams, as well as those provided as part of a sponsor’s in-kind contribution.

Leadership from sponsoring organizations

We found that often collaborations are driven by passionate leaders who donate their time and energy to these efforts without personal, financial, or professional gain. **Enthusiasm and sign-off at the highest leadership level of a sponsoring or participating organization have been an essential determinant for many of the collaborations that we interviewed.** These leaders typically serve as members of a consortium’s executive committee or board of directors, and it is important that they stay engaged and focused on the best interests of the collaboration. Leadership buy-in has multiplying power and validation that can motivate other passionate leaders to participate.

Additionally, it is just as important to involve mid-level leadership in the collaboration. Compared to upper management, these leaders often have more technical expertise and time to assess the progress of a consortium, often serving as members of a steering committee. This layer of participation reinforces the motivation within a sponsoring organization and also ensures that the decisions made by the leadership are followed through. In addition to time and strategic input, this two-level approach is also important for retaining sponsorship in the event of turnover within the organization.



Consortium leadership

The leadership teams of most consortia, particularly those managed by a third-party organization, are typically full-time employees that report to the board of directors and steering committees. Since these individuals also serve as the public face of the consortium, many groups employ a CEO or president with credentials that include prior upper-leadership roles within the sector that is driving the consortium. To be effective, these leaders need to understand and appreciate the real-world challenges addressed by the collaboration, as well as have credibility to the external communities, since they also play a pivotal role in sustaining sponsorships and gaining new participants.

Program staff

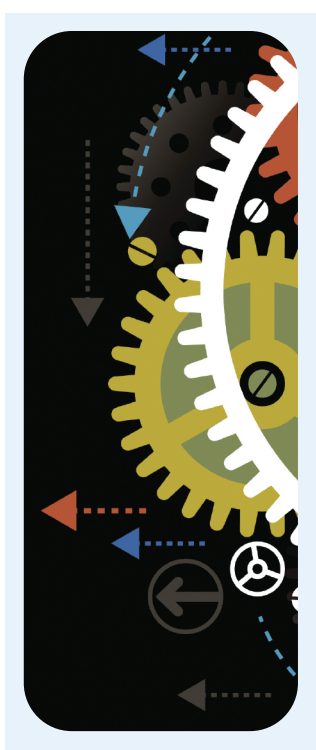
Consortia managed by third-party organizations often use two different types of project managers to coordinate the collaboration and ensure the momentum of the research efforts. One is a subject matter expert who can communicate with both the participants and the leadership on the technical aspects of the project. These individuals are usually paid members of the consortia staff or are dedicated industry representatives who are provided to the consortium as an in-kind contribution. The other project manager is one who is not necessarily a subject matter expert but whose full-time responsibilities are to enforce project milestones, ensure team communication, and maintain a focus on the project goals.

FasterCures also found that in addition to scientific and programmatic expertise, many of the consortia that we interviewed stressed the requirement that the program managers also have “people skills.” The multi-stakeholder nature of these consortia brings together a diversity of cultures and opinions, many of which may not naturally agree with each other. Program managers who have the diplomatic skills for negotiation and driving consensus have been essential for maintaining the pace and direction of many of the efforts that we reviewed.

Volunteer army

Many consortia rely on people who volunteer their time and intellectual capacity to the effort. As talented and dedicated as these participants may be, it is a challenge to propel the project forward with a purely volunteer project team. Under these circumstances, participants do not get paid to work on the collaboration, and most make their contributions to the consortium in addition to their “day jobs.” This can challenge the ability of a project manager

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Staff Turnover

Staff turnover within a sponsoring or participating organization creates unique challenges within many consortia. When this happens, the consortium can lose historical context that justified a sponsor's partnership and may also lose a subject matter expert who champions its efforts. As mentioned earlier, engaging multiple leaders within one organization may help mitigate turnover; several consortia use this strategy to ensure the consortium's sustainability.

to maintain forward momentum on any given task and can make it difficult to retain talent and expertise.

Most consortium leaders agree that incentives for team science should be defined early in the process. Creating team cohesiveness among the diverse and talented volunteer participants can be achieved in many ways using both formal and informal mechanisms, where the reward and incentive include professional development and networking. Many consortia also use “mini-teams” or working groups that can address a consortium's need with the incentive for networking around a specific subject of mutual interest. Formal mentoring programs also have proven effective in focusing members toward a common goal.

4 INTELLECTUAL PROPERTY DEFINING TERMS OF ENGAGEMENT

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 during the course of the projects would require additional negotiation by all participants, potentially causing a delay in momentum. It is also important to anticipate the resources needed for these agreements—sorting out questions about IP among partners can be a significant drain on financial and human resources in addition to ongoing resources needed to manage and enforce IP protection. Licensing may also be complicated, as sponsors may want to have the privilege of the first right-to-refusal for any non-exclusive licensing agreements. There is no universal method that works for all multi-stakeholder collaborations, but these agreements and policies help to ensure transparency and set expectations.

Many consortia stressed the importance of defining the precompetitive and competitive boundaries at the very beginning, and as the consortium evolves, continually monitoring if the line between precompetitive and competitive activities changes over time. 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 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 as long as it can be broadly used or 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.

FasterCures has found that only 16 percent of the more than 250 consortia we reviewed are focused on directly developing specific products, such as drugs, devices, or informatics platforms (Figure 3). The remainder could potentially be classified as pre-competitive as the focus is to advance scientific knowledge, develop broadly used biomarkers, or create research tools such as standards and frameworks. Research objectives that are commonly included within the pre-competitive space include:

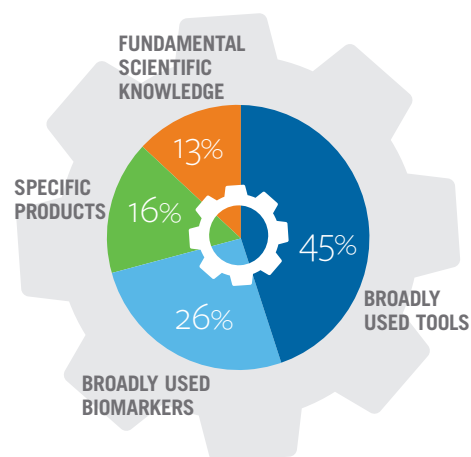
- disease pathway knowledge
- biomarker research efforts (where data are openly shared)
- toxicity and safety information (technologies that broadly improve drug discovery and development)
- data standards (clinical trial data, clinical trial endpoints, and data-sharing vocabularies)
- clinical care methods

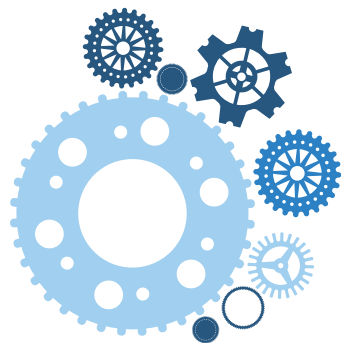
FasterCures found that approximately one in four consortia focuses on developing broadly used biomarkers. Biomarkers are any substance, structure, or process that can be measured in the body or its products and can influence or predict the incidence of outcome of disease. These types of biomarkers could be used by the research community to accelerate the discovery and development of more potent diagnostics and therapeutics, particularly if their use was recognized by a regulatory authority that participated in a consortium. But even if these biomarkers are intended for broad use, some consortia protect these inventions as intellectual property to ensure that participants who sponsored and conducted the research are able to recover their investments by licensing to outside researchers.

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 intended for use as part of the consortium’s research activities. It may be necessary for the consortium to license the background IP from a researcher or their institution before it can be used for the consortium’s research activities, or to narrow the use of

**FIGURE 3:
Products created
by consortia**





Listing background inventions within an agreement serves many purposes: protecting a participant's own invention rights, ensuring that a consortium can legally perform its research, and serving as a safeguard that the IP generated from the partnership is free from legal entanglements.

the IP by all participants under a limited agreement. Listing these inventions within an agreement serves many purposes: protecting a participant's own invention rights, ensuring that a consortium can legally perform its research, and serving as a safeguard that the IP generated from the partnership is free from legal entanglements.

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. The IP agreements shared among partners of a consortium are typically more complex than those used in smaller 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 that IP agreements took more time to complete than anticipated as they need to consider organizational self-protection and legal detail, which may differ among sponsors. 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.

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 broadly provide all of 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. In addition to IP rights, licensing rights are also 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.

Data as IP

The data generated by some consortia are considered as protectable IP, and a common mechanism is to allow a short patent-free period 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 being released to the public. For other pre-competitive collaborative efforts, all data are immediately placed into the public domain and intellectual property is a relative non-issue.

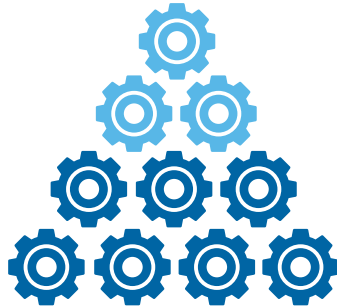
5 DATA-SHARING ENABLING TERMS OF ENGAGEMENT

There seems to be consensus that sharing data for the common good is the right thing to do, but putting this agreement into operation has been challenging for many of the data-focused consortia. **We found that one of the key issues for consortia focused on creating an environment of data exchange is complying with promises to contribute data.** Even when data are equally contributed, the transactional costs and resource intensity of these efforts are generally exponentially more than anticipated. The methods used to share data and other information within a consortium range from informal and infrequent, to standardized, systematic, and timely. The type and format of the shared data also widely vary, from raw data from a clinical trial to summaries of data provided as a publication or presentation.

The challenges are not limited to developing an effective informatics infrastructure. There are other complexities that require additional fiscal and human capital to address standards and interoperability while ensuring that the sharing of data addresses patient privacy and current policy, as well as ethical and legal concerns. The issues of standards and interoperability are widespread among all biomedical stakeholders; more than 16 percent of the total consortia reviewed by *FasterCures* are focused on enabling more efficient data-sharing.

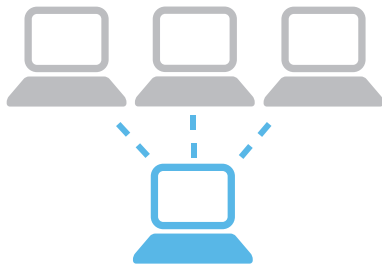
There is also a need to determine where the data will be stored and rules for access. The level of data that a particular participant can access is

Some consortia provide participating researchers the opportunity to analyze data and patent any discoveries or inventions prior to being released to the public. For other pre-competitive collaborative efforts, all data are immediately placed into the public domain and intellectual property is a relative non-issue.



3 in 10

**TOOL-DEVELOPING
CONSORTIA ARE FOCUSED
ON METHODS OR STANDARDS
FOR DATA-SHARING**



1 in 4

**PRODUCT DEVELOPMENT
CONSORTIA ARE CREATING
DATA-SHARING PLATFORMS**

sometimes governed by the amount of data that is contributed to the consortium; or, if it is released to the public, may be based on the external researcher's qualifications and objectives. It is important to establish data-sharing guidelines that describe a participant's level of contribution and access, as well as provide timelines for contributing data prior to launching a consortium. Many of these policies are included in intellectual property and data-sharing agreements, which detail the requirements, restrictions, and timelines for sharing data resulting from the collaboration, as well as mechanisms for releasing the data to the public.

Interoperability and data-sharing standards

Pre-negotiated agreements on data-sharing should include requirements for common data languages and interoperable platforms. The shared data could range from historical data that have already been collected independently to data that are actively collected as part of the collaboration by researchers at different sites. Both sources require that the data are formatted in a manner that permits sharing across platforms, as having all data within one system is important for bringing together researchers from multiple institutions, each of whom may have their own computational and analytical systems.

Regardless of the source or application, the varying methods used to pool, standardize, and contribute data create a challenge for many of these consortia as datasets often differ in structure, quality, and content—and can also include summaries derived from different methods of analysis and interpretation. In addition to technical infrastructure, participants should also agree upon a set of data ontologies, which is needed to create a shared vocabulary and define relationships among datasets. This helps to reduce variability in interpretation by ensuring that the collection and analysis are conducted uniformly across participants.

Data quality

Even if the data are collected, annotated, and pooled following standardized procedures, their value to the broader community is directly related to the quality of the original data. Quality is dependent on multiple factors that can include implementation of proper quality assurance/quality control measures at different stages of collection and analysis, quality of resources, institutional infrastructure, and investigator expertise. One example of a source for variability is related to the quality of the original biospecimens that are analyzed, particularly if they were not collected or handled uniformly. Some consortia address data quality issues by

adopting principles of good laboratory practices (GLP), which standardize the procedures used to collect, handle, and analyze biospecimens, and also include a requirement to track and trace the data back to the original analytical source. Some consortia also utilize a third party to perform quality control and standardization of data before they are shared within the collaboration.

Public dissemination of data

Most consortia have a mission to share their research findings with the public. The timing and manner in which this information is disseminated vary among the consortia that we interviewed. Very few groups have a completely open-access policy and many have different levels of control for data dissemination. These are described in the intellectual property and data-sharing agreements, and enforced through rules that are established to limit the level access of data to the participants and the public.

Examples of methods for public release of data:

- Unconditional and immediate release of data and tools
- Immediate release of data to external researchers with proper qualifications and objectives
- Release of data after sponsor-exclusive time period
- Release of summarized results
- Publications and presentations

A major concern regarding the uncontrolled release of data to the public is the potential for the irresponsible or inappropriate use that could result in statistically weak correlations among treatment, diagnosis, and patient condition. To mitigate these concerns, the majority of consortia that provide clinical research data to outside researchers require an application and qualification step prior to access, and some may also request a research proposal as part of their application process. Additional groups require an agreement that limits the use of the data and the venues where results can be published. Some consortia have their own data access and publications committee to manage and enforce their policies.

The datasets themselves may also require additional work by the consortium to address patient privacy concerns, which can be particularly time consuming if the data come from multiple sources. There are also ethical concerns to be addressed if patients did not provide consent to the re-analysis of their previously collected data, particularly if their data are going to be analyzed for a purpose that is different from the specifications of the original informed consent.

Some consortia address data quality issues by adopting principles of good laboratory practices (GLP), which standardize the procedures used to collect, handle, and analyze biospecimens, and also include a requirement to track and trace the data back to the original analytical source. Some consortia also utilize a third party to perform quality control and standardization of data before they are shared within the collaboration.



Utility of Accessible Data

Consortia may still encounter additional challenges for collecting and disseminating their data. One challenge is to ensure that the collaboration's data have utility to the outside community. The format of data, for example, raw data, may not appeal to outside researchers, and some consortia went through significant effort to curate their datasets for the public. Some of the data-intensive consortia recommended the inclusion of potential users as part of a steering committee to provide an understanding on the external research community's data needs.

6 PATIENT PARTICIPATION THE FOCUS OF THE MISSION AND VISION

Patients, as individual advocates or as part of a larger organization, are increasingly expanding their roles in multi-stakeholder consortia. They participate as research subjects and contribute to a consortium's strategy, governance, and operations. Many consortia involve patient advocates as members of their standing governance committees or have a separate patient advisory committee that provides input on all research efforts. In addition to participating, many patient groups actively manage their own consortium, a model of collaboration that appeals to them because of the ability to focus the resources and expertise of the whole product development spectrum.

Patient advocates participating in consortia

Many patient advocacy groups leverage their ability to convene scientific experts and patient cohorts to catalyze biomedical research. These groups serve essential roles in communicating the value proposition of the consortia to patients to encourage participation and support. These groups also help with a consortium's internal processes, such as ensuring that a consortium's informed consent policies reflect a patient and their family's concerns, and by participating as members of a safety and monitoring board to ensure that the ongoing research activities minimize risk to its participants. Many consortia have also benefitted by having advocates develop their legal participation documents in a format that is patient-friendly, complemented with supplemental educational materials. Their broad participation and enthusiasm often serve as an assurance to potential patient-participants.

In addition to communicating with their patient communities, some consortia have taken advantage of the intellectual capital that advocates can contribute to help with the design and pursuit of research questions. These groups often become the experts of their specific diseases, garnering a wealth of basic knowledge of the biological processes underpinning the disease, an understanding of the landscape of therapeutic or diagnostic approaches, and an ability to identify the clinical trial methods that meet the requirements and needs of their patient population. Some also collaborate with each other, even outside of their disease-focus, and can bring to researchers new R&D methods and tools that were effective for other diseases but have yet to be applied to their patient population.

Patient advocates leading consortia

Several patient advocacy groups are involved in the most innovative and cutting-edge academic and industry research programs that impact their disease—as funders, partners, or both—serving as the primary scientific authority for the research community. Instead of depending on others to establish a research infrastructure, many of these groups have set up their own clinical trial and biorepository networks to collect, annotate, and distribute data and biospecimens, using the consortium model to ensure that these resources are useful to the academic and industry communities.

Many groups also play a more proactive role in the development of specific therapeutics with functions similar to a virtual pharmaceutical company. These efforts are characterized by a research infrastructure in which coordination of activities is provided by the foundation at a much more hands-on level, with research results scrutinized by program managers and scientists who are employed by the foundation and an external steering committee.

Continuous and broad-reaching communication

In addition to directly involving patients in the design and implementation process, many consortia have included plans to communicate the mission and outcomes of the consortium to the patient population and public. Each audience brings with it different expectations for impact, and the broader public includes family members and future patients who may have a perspective that is also influenced by media, as well as their socio-economic and cultural backgrounds. The Web sites for many consortia are often designed to separately address the patient, clinician, researcher, and public sectors. Each of these components describes the research progress and presents results in a language and format that is appropriate for those audiences. Many groups are also actively involved in creating dialogue directly within their disease and regional communities, either as physical town-hall style forums or through social media tools like blogs, Facebook, and Twitter.

Many groups also play a more proactive role in the development of specific therapeutics with functions similar to a virtual pharmaceutical company.



65%

**OF CONSORTIA-BASED
BIOMARKER RESEARCH IS
FOCUSED ON GENOMIC OR
GENETIC BIOMARKERS**



MORE than HALF

**OF ALL CONSORTIA CONDUCT RESEARCH
FOCUSED ON A SPECIFIC PATIENT
POPULATION**



Educating Patients in Biomedical Research

Most patient advocacy groups do not have the resources to employ a scientific staff to keep abreast of the latest discoveries or run their own consortium. To address this disparity, some groups have taken on the effort to increase the numbers of advocates that are well-versed in the processes of biomedical research and at least one of these efforts is part of a multi-sector consortium.

The Innovative Medicines Initiative (IMI) is a public-private partnership between the EU government and the European pharmaceutical industry that was set up to accelerate drug R&D. It has several research-oriented efforts in which patients are directly involved in governance and operations.

IMI also manages an independent five-year effort known as the “European Patients’ Academy on Therapeutic Innovation.” The goal of this initiative is to develop education materials, training courses, and an online library to serve as resources to educate the public on the drug development process and create informed patient advocacy groups using material written in seven languages and targeting 12 European countries.

7 MEASURING IMPACT ASSESSING COMPLIANCE TO TERMS OF ENGAGEMENT

FasterCures has seen in the past 10 years a large growth in the number of multi-sector consortia, many of which depend on the same pool of resources, intellectual capital, and patient populations. While most stakeholders agree that collaboration is important for advancing biomedical research, the time and resources that any participant or sponsor can contribute has a finite limit. Their investment varies—from industry that might contribute finances and in-kind resources, to the patient who contributes his or her time, biospecimens, and hope—but all seek to maximize the return from their participation.

We found that only a few of the consortia we interviewed have implemented assessment methods. This can become challenging as sponsors and participants seek some level of validation that their contribution of time and resources have been used efficiently and effectively, often asking for this evidence mid-way through a consortium’s expected lifetime.

The pharmaceutical industry is one stakeholder that is becoming increasingly cautious in committing to new consortia. Many employ “alliance managers” who serve as liaisons between the company’s leadership and all of their external partnerships, including consortia. These teams are responsible for continually monitoring the value that each partnership provides to their company’s strategic plan, basing their assessments on data provided by the consortium and surveys of employees directly involved in the partnership activities.

For those consortia that are making strategic efforts to demonstrate and communicate the value that their partnership model adds to the biomedical research ecosystem, many have employed phase-based metrics implemented at the beginning of the collaboration. To further differentiate from each other, many use metrics that take into account the specific phase of their effort, starting these measurements shortly after the launch of the partnership.

There are some commonalities in their approaches:

- Impact or value statements look beyond the consortium leadership’s expectations and are customized to the unique interests of sponsors, participants, and beneficiaries.
- The anticipated impact of the partnership is clearly described as part of

a consortium's mission statement, supported by milestone-driven research questions that map the pathway.

- Metrics that represent the anticipated impact of the collaboration are defined at the onset of the effort and represent all of the research activities as they relate to the overall mission statement, not just the achievements of a single project.
- Metrics are periodically measured and evaluated to track the progress toward consortium goals throughout its lifespan and reflect the mission, level of risk, and timeline.

Impact is phase-specific, not project-specific

A consortium's timeline should include periods of assessment that aim to measure the effectiveness of its collaboration model. If progress is made, these data points can be used to attract additional sponsors and participants. Alternatively, these measurements can also be used to identify inefficiencies at the earlier stages and determine if there is room for strategic improvement. These metrics reflect all projects and are different from the milestones used for a specific project.

The lifespan of a consortium is typically divided into three phases of development: start-up, steady-state, and wind-down.

- The first phase includes activities that focus on establishing the governance and research culture with a small subset of pilot projects that can assess their collaboration model.
- The second phase is focused on applying an optimized collaboration model to advance the majority of research objectives.
- The final phase is focused on ensuring that each stakeholder will obtain their expected output or outcome.

As one example, IMI is a 10-year initiative that distributes its assessment milestones into three cross-program stages that reflect assessments of impact at the short-term (approximately 2-3 years after launch of IMI), mid-term (after 4-5 years), and long-term (after 7-8 years).

Communicating impact to a specific audience

While there are some impact metrics that are of interest to all stakeholders, impact summaries should also be tailored to specific audiences. These audiences include funders and sponsors as well as individual participants who want to feel that their time is well-spent, those studying collaborations for models that have and have not worked, and society, which should ultimately benefit from these efforts. This

TOP OUTPUTS OF CONSORTIA

GOVERNMENT

46%

BIOMARKER RESEARCH

INDUSTRY

36%

BROADLY USED TOOLS

THIRD-PARTY

51%

BROADLY USED TOOLS

FOUNDATIONS

46%

PRODUCT DEVELOPMENT

obviously complicates the number and degree of these assessments, but audience-tailored impact measurements have been shown to be important tools that help gain and strengthen support in an era of fiscal conservatism and consortium fatigue. Table 4 lists various stakeholders accompanied by a general description of output and outcomes that may be of interest to them.

Assessing output of collaborations

Most consortia have the secondary goal of demonstrating that a specific model of multi-sector collaboration can improve efficiencies in biomedical research by reporting the specific products created by the consortium, such as new standards, tools, or basic scientific knowledge. Output assessments are not limited to the wind-down phases of a consortium; instead, metrics should be developed to evaluate progress toward the intended output at the earlier stages. The evidence

TABLE 4: Descriptions of Impacts that May be of Interest to Stakeholders

SECTOR	EXAMPLES OF EXPECTATIONS
PUBLIC	<ul style="list-style-type: none"> • Increasing the flow of new therapies reaching patients • Stimulating and sustaining economic vitality • Maintaining productive communities and ensuring tax revenue by supporting local industry • Addressing challenges in translational pathways by spreading the risk of creating broad-based tools and methods • Increasing global competitiveness in the biomedical sector • Supporting and de-risking the pursuit of new research opportunities • Leveraging private funding to maximize taxpayer dollars • Engaging in scientific discourse that can help inform regulatory and reimbursement policies in a forum that is not part of a formal regulatory process • Advancing the general health of society
PRIVATE	<ul style="list-style-type: none"> • Sharing the risk of creating broad-based tools and methods that could be used to increase the speed and/or lower the costs of their own development processes • Cost-sharing the risk for entering new research opportunities • Addressing a technical limitation in infrastructure by supporting pre-competitive initiatives that address translational pathways • Developing partnerships that potentially lead to additional resources from those inside and outside of their sector (academics, patient groups, government)
PATIENTS	<ul style="list-style-type: none"> • Coordinating the expertise and resources in academia and the private sector around their disease of interest • Leveraging funding from the private and public sectors • Enabling data-sharing and collaboration among researchers • Providing opportunities to engage their patient base in biomedical research
ACADEMIC	<ul style="list-style-type: none"> • Translating basic research findings to an application that meets an identified need • Accessing alternative non-government sources of funding • Accessing technology development resources, such as compound libraries, biorepositories, or biostatistics expertise • Accessing research tools that are validated by consensus-through-consortia • Participating in new collaborative efforts that place them at the forefront of state-of-science • Developing partnerships outside of the consortium that could lead to additional resources • Improving their clinical care model



of these achievements should also be delivered in a meaningful way as each stakeholder has his or her own set of expectations. Unfortunately, there are no systematic methods that can be used to compare across consortia, with many organizations relying on those used by academic researchers to assess the impact of interdisciplinary collaborations such as number of patents, number of publications and the quality of journals, or number of citations. There is a need to move beyond these metrics and develop more quantitative measures of output that are meaningful to the audiences interested in the consortium.

Assessing outcomes of collaborations

The greatest opportunity to evaluate the outcomes of collaboration is after the consortium's lifespan as part of a long-term or retrospective assessment. Such long-term data may not be realistic for consortia that are at the earlier stages of maturity, and there are other methods used by some of the consortium for summarizing mid-term value and impact. As with the output, the interest in a specific outcome is dependent on the audience of interest.

Below are some examples of outcomes that may be of interest:

- **Accelerating development of cures**—Some consortia that are driven by patient foundations or government have a mission to accelerate the development of a cure for a specific disease. Various consortia have reported their ability to accelerate clinical trials using starting time or completion of enrollment as metrics. Some consortia focused on improving clinical care evaluate their impact using metrics such as disease remission or hospital readmission rates.
- **Creating broadly used tools and methods**—Some consortia focus on catalyzing the development of new tools and methods that advance biomedical research for all stakeholders. These new tools can include biomarkers and assays, diagnostics, data standards, methods for clinical trials, or clinical decision technologies. Measurements that demonstrate improvements in efficiency or cost for doing research are commonly used. Other examples include improved efficiencies such as reduced patient numbers for clinical trials.
- **Economic growth**—Some consortia are driven by government agencies and nonprofit organizations that view biomedical research as an economic driver and want to leverage collaboration to stimulate and sustain economic growth. The approaches for economic growth can include job creation, creating/maintaining a knowledge base, leveraging taxpayer dollars with private funding, and/or supporting an innovation ecosystem for company creation. Impact measurements for economic growth are based on quantitative analysis, and there are several ways to summarize the data. One metric that is often reported is the leverage effect, in which the pooling of funds and resources by multiple groups results in increased buying power for any individual participant.

The greatest opportunity to evaluate the outcomes of collaboration is after the consortium's lifespan as part of a long-term or retrospective assessment.

Findings

FasterCures found that no two consortia are alike. **The *raison d'être* for each effort, its leadership structure, the resources contributed by the stakeholders, and the implementation strategies in place determine the trajectory of each collaboration and define their method for partnership.**

The Consortia-pedia project aims to provide structure and clarity to the research-by-consortium model. We present both the consortia framework and partnership components in an effort to guide and inform emerging and existing collaborative efforts.

We found that managing expectations and establishing transparency measures are essential to both building trust among all participating stakeholders and the effective implementation of programs that bring the consortia to life.

With multiple stakeholders come multiple challenges. We learned that a consortium will thrive if its leadership and governance structure is able to define a mission that's shared by all stakeholders and articulate the desired outcomes of the effort early in the process. For collaborative efforts to move forward, consortia must recognize and leverage the unique strengths and resources that each partner can contribute and bring to fruition. This requires a clear understanding of each partner organization and the terms of engagement.

Additionally, we found that managing expectations and establishing transparency measures are essential to building trust among all participating stakeholders. Transparency curbs potential conflicts of interest and creates a culture that allows for open sharing of data and a responsible approach to intellectual property negotiations.

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. **We found that for collaborations in the medical research and development ecosystem to be effective and sustainable, they must be driven by the ultimate goal of delivering a medical solution that could improve or save lives.**

Acknowledgments

The Consortia-pedia project came from the work that began at the Milken Institute's 2011 Lake Tahoe Retreat, which brought together a remarkable group of leaders to find new ways of overcoming the barriers that have prevented more progress in medical research.

FasterCures is grateful for the support and guidance provided by Sanofi for the development of this project. We would like to acknowledge the Round Peg Group for its help in scoping the project and conducting interviews. *FasterCures* would also like to thank the following individuals for their time and cooperation in being interviewed about their consortia.

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Neuroimaging Initiative

Marc Bonnefoi, Innovative Medicines Initiative/eTOX Project

Steve Broadbent, Critical Path Institute

Walter Capone, Multiple Myeloma Research Foundation

Jennifer Chang, Myelin Repair Foundation

Sohini Chowdhury, Michael J. Fox Foundation for Parkinson's Research

Richard Colletti, Chronic Collaborative Care Network

John Collins, Center for Integration of Medicine and Innovative Technology

Sue Dubman, Foundation for the National Institutes of Health/I-SPY2

Stephen Friend, Sage Bionetworks

Dalvir Gill, TransCelerate BioPharma

Diane Gosselin, Quebec Consortium for Drug Discovery

Barbara Handelin, BioPontis Alliance

Lynn Hudson, Critical Path Institute

Charles Hugh-Jones, CEO Roundtable on Cancer/Project Data Sphere

Peter Loupos, Project Data Sphere

Peter Margolis, Collaborative Chronic Care Network

Thea Norman, Sage Bionetworks

Reagan O'Lone, Health and Environmental Sciences Institute

Syriil Pettit, Health and Environmental Sciences Institute

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Steve Schachter, Center for Integration of Medicine and Innovative Technology

Diane Stephenson, Critical Path Institute /Coalition Against Major Diseases

David Tharp, KNODE, Inc.

David Wholley, Foundation for the National Institutes of Health/Biomarkers Consortium

FasterCures would also like to thank the many key opinion leaders who provided their perspectives and insight in the development of this report.

Appendix: Consortia Profiled

These consortia were examined for the Consortia-pedia project, and profiles can be found in the full version of the Consortia-pedia online.

You can also view online a full list of the hundreds of consortia that participated in this project.

Alzheimer's Disease Neuroimaging Initiative

Biomarkers Consortium

Chronic Collaborative Care Network

Coalition Against Major Diseases

Coalition For Accelerating Standards and Therapies

Center for Integration of Medicine and Innovative Technology

CoMMpass (Relating Clinical Outcomes in Multiple Myeloma to Personal Assessment of Genetic Profile)

Quebec Consortium for Drug Discovery

eTOX

Foundation for the National Institutes of Health

Health and Environmental Sciences Institute

Innovative Medicines Initiative

I-SPY2 (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2)

Myelin Repair Foundation

Observational Medical Outcomes Partnership

Polycystic Kidney Disease Outcomes Consortium

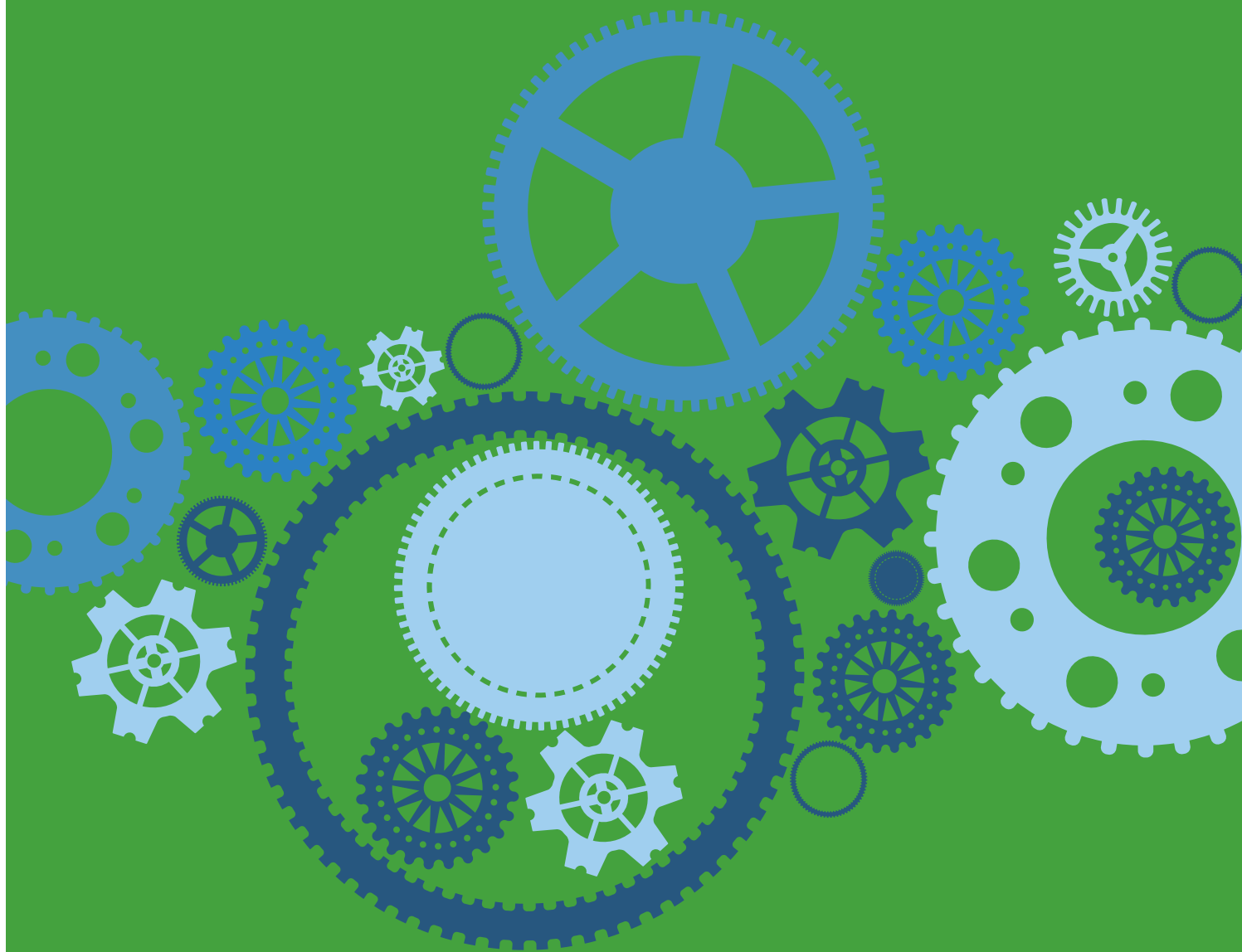
Parkinson's Progression Markers Initiative

Project Data Sphere

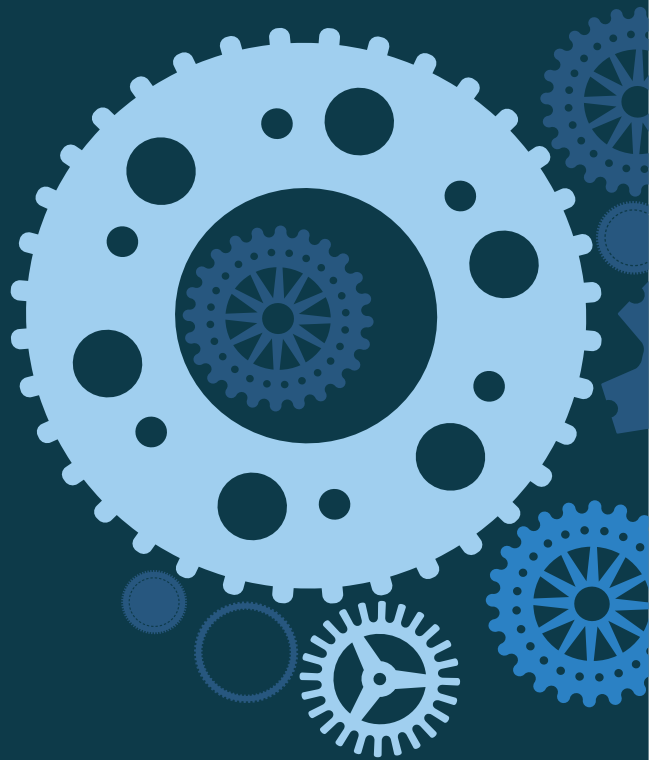
Predictive Safety Testing Consortium

Sage Bionetworks

TransCelerate BioPharma



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