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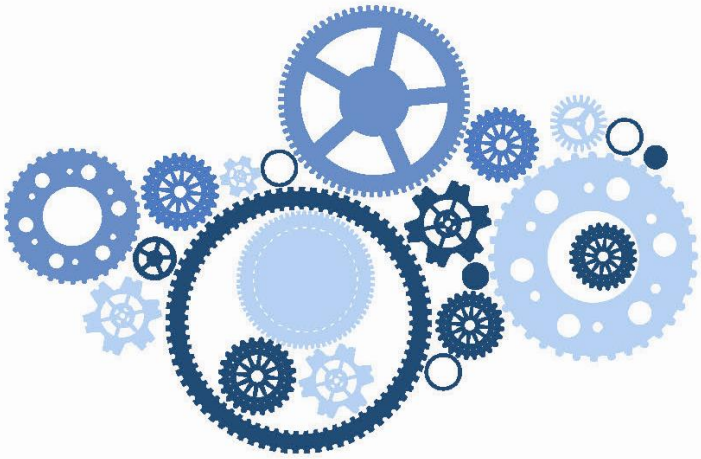

Governance

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.

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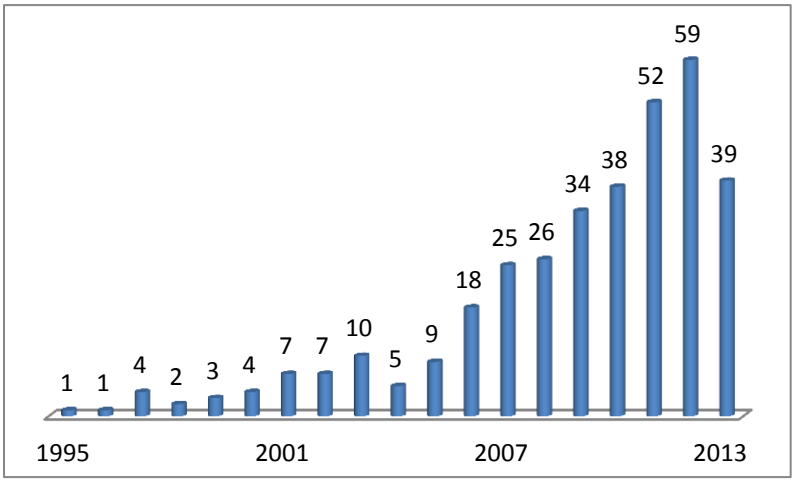
KEY POINTS – GOVERNANCE:

- **Define the mission, vision, and scope** clearly up front.
- **Neutral third-party organizations can be important resources** that help ensure transparency and provide support and leadership.
- Pursue the mission using **clear and concise research questions** defined using milestone-driven projects that drive the collaboration.
- Utilize a governance structure that ensures the appropriate level of decision-making and participation to **create an environment of transparency and accountability**.
- **Ensure a sustainable commitment to the mission** – recruit leadership and support staff with business and scientific acumen.

Consortia serve as an infrastructure for collaborations that strategically address an unmet need that is shared across one or multiple research sectors. Typically, most of the participants would consider each other competitors; but within a consortium, all have agreed to align their interests and resources to collectively create a broadly usable solution. These types of collaborations have only amplified in times of dwindling resources, and the adoption of the consortium model for resource-coordination is evident throughout the biomedical research landscape. For example, *FasterCures* has documented a large increase in multi-sector consortia over the past decade, with nearly 60 new collaborations emerging in 2012 (Figure 1).

Figure 1: Growth of multi-sector consortia



Ensuring the right expertise

A formal and agreed-upon governance structure is important for creating an environment of trust and transparency, but it is equally essential to also have a flexible infrastructure that can address the scientific issues that emerge during the course of a project. Many consortia have found a need to temporarily convene *ad hoc* and technology-specific working groups or advisory committees to conduct 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-science. These groups may also serve the role of outside peer review for proposals submitted to the consortium or address technical topics that are narrow in scope, such as issues related to data standards, clinical aspects of a specific disease, and technology platforms.

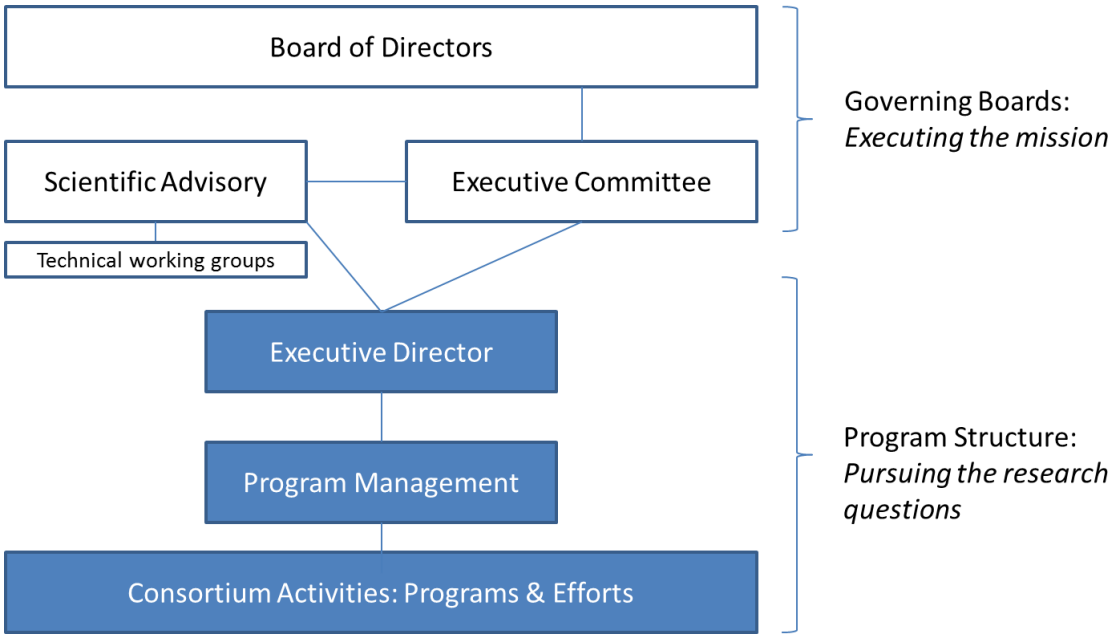
Some consortia have found that the input of these subject matter experts are valuable to the ongoing execution of the consortium and have converted working groups to permanent governing bodies. One example was the Observational Medical Outcomes Project's Health Informatics Advisory Board, which provided input into the consortium's technology efforts as it related to privacy and security, terminology and coding, data, and data models.

Creating a culture of trust among all members is usually the first challenge. Each participant within a consortium is typically invited because he or she has access to expertise and resources necessary for the success of the partnership, but each also brings a unique set of expectations. To establish trust among members, many consortia publish a clear definition of goals and a formalized governance structure. This helps ensure participants and sponsors that they are engaged in well-defined, mutually agreed-upon activities that aim to maximize the return on their investment of time and resources. Both mission and governance are described in a consortium's charter and its negotiated agreements, which define each participant's level of contribution and expected benefits along with the processes for entering

and exiting the collaboration. In addition to providing a legal framework, these documents serve to reassure stakeholders that the execution of the consortium is designed to be objective, democratic, and transparent.

A mission statement provides an overview of the solution being developed through the collaboration and should be supported by a series of research questions and milestones that provide the foundation for a consortium's activities. The governance structure describes the operational framework of the consortium by outlining decision-making and management responsibilities at the organization and project level. Formalizing this structure is extremely important for establishing a culture of trust because it clearly defines where each stakeholder has an opportunity to provide input in the collaboration's strategic direction.

Figure 2: Generic model of consortium governance structure



The governance structure of many consortia resemble that used by a corporation and nonprofit organization (Figure 2), with a board of directors that defines the mission and provides oversight to all of the consortium activities and is supported by executive and steering committees for operational and scientific insight at the project level. The executive committee is typically composed of management-level individuals whose role is to approve project concepts with a focus on policies and procedures. The steering committee is more technical in nature, often serving a dual role as a scientific advisory board. This latter committee is typically composed of subject-matter experts who propose project concepts and, if necessary, convene additional advisory groups to ensure that the consortium has the technical resources to address their research questions. In addition to boards and committees, many consortia have dedicated staff members who 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.

The inception and development of most consortia are typically the result of specific stakeholders championing an idea, with a hope that the momentum eventually becomes sustainable as a collaborative activity. To simplify categorization, the *FasterCures* Consortia-pedia project groups the consortia by the sector that was the initial driver of the collaboration: government, industry, patient advocacy/foundation, and third-party organization. Academia was also responsible for initiating nearly 10 percent of all consortia, but their models were too variable to offer any informative cross-analysis. Table 1 provides more information about each type of consortium.

Figure 3: Sectors that initiate consortia, by percentage (n=345 consortia)

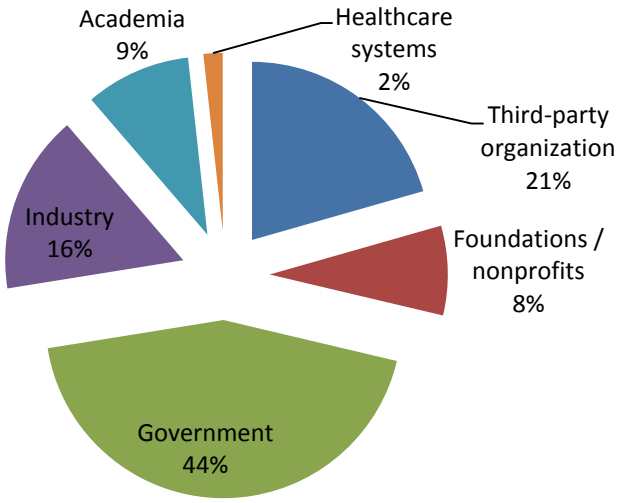


Table 1: Characteristics of different types of consortia

Sector driving consortium	Examples	Common mission objectives	Governance structure	Program management structure
Government	Alzheimer's Disease Neuroimaging Initiative (ADNI), Predictive Safety Testing Consortium (PSTC)	Address gap in R&D infrastructure, job/company creation, regulatory and policy changes	• Board of directors and topic-specific executive committees ensure transparency • Steering committees ensure equal participation and input from all sectors	Employed project directors and project management staff
Industry	Innovative Medicines Initiative (IMI), TransCelerate BioPharma	Address operational inefficiency in industry, job/company creation, harmonization issues, data sharing issues	• Board of directors ensures transparency and participation • If support includes government funding, steering committees ensure public interests are addressed	• Employed project directors and project management staff • Industry sponsors provide in-kind research staff to assist with technical program management
Patient Advocacy / Foundation	Myelin Repair Foundation, Polycystic Kidney Disease Outcomes Consortium	Accelerate drug development for specific disease, risk-benefit assessments	Board of directors and advisory boards include scientific and product/business development expertise	• Employed project directors and project management staff, sometimes located at research/clinical sites • Funded researchers assist in governance
Third-party organization	Biomarker's Consortium (BC), Coalition Against Major Diseases	Address unmet scientific needs	• Board of directors and topic-specific executive committees ensure transparency • Steering committees or *ad hoc* advisory committees are used to identify and evaluate new research concepts	• Employed project directors and project management staff • Appointed project co-director role by sponsor

Government-initiated consortia

Government agencies often initiate a consortium if there is a gap in research infrastructure that can only be addressed by combining the expertise and resources from multiple sectors, or if there is a need for a neutral broker to mediate collaboration. Many of these gaps are due to the high-level of risk or resources required, a hurdle that is often beyond the capabilities of any single organization. For example, *FasterCures'* analysis of 151 government-initiated consortia revealed that nearly half aim to create broadly usable tools whose adoption would accelerate the translation of an innovation to the commercial sector, such as data standards. We considered biomarker research as separate from tools development and found that approximately one-quarter of government-initiated consortia are focused on advancing these resources. *FasterCures* also found that approximately one-third of these consortia have secondary objectives of advancing economic growth. Some of these consortia were created by agencies that do not have a scientific mission but are focused on broader public interests, such as improving or sustaining the local economy by fostering bioscience start-up creation and job growth.

These types of partnerships are often managed through neutral and 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 (FNIH) is a non-government and nonprofit third-party organization that was created by the U.S. Congress to support the research missions of the National Institutes of Health (NIH). FNIH has the capability to convene a diversity of biomedical researchers, manage large research initiatives, issue research grants, fundraise, incubate research concepts, and provide educational programs. This organization uses different models of management for its various programs – some are initiated by NIH and completely managed by FNIH, such as the Biomarkers Consortium's I-SPY 2 effort. Other programs, such as the Alzheimer's Disease Neuroimaging Initiative (ADNI), are initiated and managed by NIH, with support provided by FNIH to secure funding and handle administrative tasks. FNIH also supports NIH's management of ADNI by convening the Steering Committee and a Private Partner Scientific Board.

The Critical Path Institute (C-Path) is an independent third-party organization that supports the U.S. Food and Drug Administration's (FDA) Critical Path Initiative. Similar to FNIH, C-Path manages several consortia that are initiated by different sectors including government, with each effort having its own governance and management structure that is customized to the needs of the individual consortium. For example, the Predictive Safety Testing Consortium (PSTC) is an FDA-initiated effort that is focused on validating biomarkers associated with drug toxicity though collaboration between multiple pharmaceutical companies and international regulatory agencies. C-Path also has efforts that are driven by other sectors, such as the Polycystic Kidney Disease (PKD) Outcomes Consortium, which was initiated by the PKD Foundation to convene four academic medical centers to develop treatments. Other examples of government-driven consortia are described in Table 2.

These types of consortia utilize a diversity of governance structures that are designed to balance public taxpayer interests with real-world challenges, while ensuring that each stakeholder has a forum to provide strategic input (see Table 3). C-Path and FNIH often engage the active participation of regulatory scientists at all levels of the consortium, providing a real-world perspective in the tools and standards created by the collaboration. In regards to governance, both organizations have a board of directors that are focused on ensuring that the cross-consortia activities are aligned to the overall mission of the organization, which for C-Path and FNIH is gauged by the interests of FDA and NIH, respectively. Membership in their boards typically includes various stakeholders representing the upper management from a sponsor's organization with the addition of business experts who bring their product development expertise. To avoid any conflicts of interest between representing the public's interests and those of the consortium participants, government members involved in these boards often do not have the ability to vote and are only present as observers to the deliberations.

Table 2: Government-initiated management structure

Consortium examples	Type*	Agency that initiated	Third-party manager	Mission	Participants
Alzheimer's Disease Neuroimaging Initiative	A	National Institutes of Health /National Institute on Aging	Foundation for the National Institutes of Health	Validate brain imaging and biomarkers for clinical trials in Alzheimer's disease	NIH, FDA, multiple pharmaceutical companies, patient advocacy groups
Observational Medical Outcomes Project (OMOP)	B	FDA	FNIH	Evaluate methods that can be applied to analyze existing healthcare databases to better understand the safety and effectiveness of approved medical products	FDA, Pharmaceutical Research and Manufacturers of America (PhRMA), multiple pharmaceutical companies
Biomarkers Consortium	B	NIH	FNIH	Identify, develop, and qualify potential high-impact biomarkers particularly to enable improvements in drug development, clinical care, and regulatory decision-making	NIH, FDA, PhRMA, Centers for Medicare & Medicaid Services (CMS), Biotechnology Industry Organization, multiple pharmaceutical and biotechnology companies
Predictive Safety Testing Consortium	B	FDA	Critical Path Institute	Validate safety testing methods	FDA, European Medicines Agency, Pharmaceutical and Medical Devices Agency, pharmaceutical companies, contract research organizations

* Type A – consortium initiated and managed by government; administrative tasks handled by third party
Type B – consortium initiated by government; technical and administrative management handled by third party

Table 3: Governance structures for government-initiated consortia

Consortium examples	Governance Structure	Functions	Composition
ADNI	Steering Committee	• Supports the NIH management • Convened by FNIH	Representatives from all funding sources as well as principal investigators and core leaders of the ADNI sites
	Private Partner Scientific Board	• Reports to steering committee, convened by FNIH • Forum for industry perspective on drug development • Evaluates needs/gaps to recommend projects • Convenes working groups • Funds ancillary projects	Industry sponsors
OMOP	Executive Board	• Reports to FNIH board • Oversees overall partnership	FDA, PhRMA, nonprofit organizations, industry, and academia
	Scientific Advisory Board	• Reports to executive board • Independent expert review and input for science	Qualified scientists from industry, patient groups, academia, FDA
	Health Informatics Advisory Board	• Reports to executive board • Independent expert review and input for data	Clinicians, FDA, academia
Biomarkers Consortium	Executive Committee	• Reports to FNIH Board • Identification and oversight of all BC projects	Senior representatives from FNIH, NIH, FDA, CMS, industry, patient advocacy
	Steering Committees	• Report to executive committee • Four committees identify and monitor individual, disease-specific projects	• Academia, government, industry, and nonprofit/advocacy organizations • Led by two co-chairs representing two of the following three sectors: academia, government, or industry
PSTC	Advisory Committee	• Reports to C-Path board of directors • Oversight of all PSTC projects	Government (observers), member companies (each has one vote)

At the individual consortium-level of governance, both C-Path and FNIH utilize different committee and advisory groups to support their research efforts. All of these organizations employ staff members who are dedicated to the management of the consortium (see Table 4). For example, C-Path's president reports to its board of directors and is supported by an advisory committee, a chief scientist, and a chief operations officer. The chief operations officer is responsible for consortia management as well as administrative functions such as financial and grants management. C-Path's efforts are each led by a dedicated executive director and a co-director who is a member from one of the sponsoring organizations, both of whom collectively report to the chief operations officer.

Table 4: Governance structure of program-level committees and staff

Consortium examples	Project-level structure	Functions	Composition
ADNI	Executive Committee	Responsible for day-to-day operations	Principal investigator, core leaders, NIH, FDA, chair of Private Partner Scientific Board, FNIH representatives
	Administrative Core	Coordinates the activities of the scientific cores	Principal investigator, administrative staff, statistical support, and the Data and Publications Committee
	Data and Publications Committee	• Develops and proposes policy to the executive and steering committees regarding data access and publication • Screens all applications for access to ADNI data • Reviews all publications for adherence to ADNI publication policy guidelines	Experts from participating academic research centers
OMOP	Program Management Office	• Led by OMOP executive director • Responsible for day-to-day management • Ensures compliance with OMOP Executive Board	Dedicated program staff
	Research Core	Designs, develops, and manages research	5 research investigators from industry, academia, and government
Biomarkers Consortium	Project Teams	• Individual teams design, solicit, and manage individual projects • Report to the consortium director • Consortium director reports to disease-specific steering committee	Dedicated program staff with subject matter experts from academia, industry, and government
PSTC	Executive Office	• Executes strategic plan as dictated by advisory committee • Executive director (C-Path) and co-director (sponsoring organization) for each consortium reports to advisory committee and chief operations officer • C-Path project manager supports directors by providing project management, financial, administrative, and scientific support	Dedicated C-Path staff (executive director and project manager), industry members
	Working Groups	• Provides guidance on topic-specific areas • Acts as a forum for sample/data sharing	Industry sponsors, government as observers

Industry-driven consortia

The biopharmaceutical industry sometimes needs to pool its resources to overcome tough translational challenges that each company cannot easily address alone. The Innovative Medicines Initiative (IMI) and the Quebec Consortium for Drug Discovery (CQDM) are examples of public-private partnerships that aim to improve the drug development process and increase competitiveness of the pharmaceutical industry within their areas. Another example is TransCelerate BioPharma, which operates under a different model because it limits its participation solely to industry partners with a focus on simplifying methods used to conduct clinical studies.

IMI's strategic research agenda is developed as a collaboration between the European Commission, through its Seventh Framework Programme (FP7), and the pharmaceutical industry through its trade organization, European Federation of Pharmaceutical Industries and Associations. The FP7 is a seven-year effort to create a European research network that aims to advance economic growth and competitiveness through team-based science initiatives. The Joint Technology Initiatives, which operate under the jurisdiction of FP7, is specifically concentrated on enabling large-scale public-private partnerships that advance industry needs; IMI represents all activities under the health focus. CQDM has a similar mission to advance drug discovery and, as a public-private partnership between the pharmaceutical industry and the government, it has a secondary mission of economic growth in Quebec. IMI, CQDM, and TransCelerate function as neutral third-party organizations necessary for securing exemption from anti-trust regulation, as well as increasing trust by ensuring objectivity and transparency.

For most of these efforts, industry sponsors obtain leadership roles and the right to participate, while some also benefit by having access to the consortium's findings before they are made public. As described in Table 5, the governance structure helps to ensure accountability with a level of complexity that is dependent on their model of sponsorship and participation. For those obtaining government funding, such as IMI and CQDM, there is a greater need to be accountable to the general public. Their governance structure typically resembles those of government-driven consortia with board of director and committee-levels of upper governance that include industry representatives and participants from outside of industry. For example, as a European Commission-supported initiative, IMI governance committees include members of the European Commission as well as representatives from the different European Union states. TransCelerate BioPharma, on the other hand, is only sponsored by the biopharmaceutical industry and has a board of directors composed solely of industry executives.

Table 5: Governance structures for industry-initiated consortia

Consortium examples	Governance structure	Functions	Composition
Quebec Consortium for Drug Discovery	Board of Directors	Provides oversight to all consortium activities	Representatives from founding industry sponsors and other academic, financial, and government stakeholders
	Strategic Orientation Committee	• Reports to board of directors • Acts as both a scientific board and steering committee • Establishes strategic and scientific objectives	Representatives from founding industry sponsors, other scientific experts from industry and government
	Explore Advisory Committee	• Reports to strategic orientation committee • Establishes scientific objectives for CQDM's high-risk/high-reward programs	Sponsoring industry organizations
IMI	Governing Board	Oversees overall partnership, makes recommendation to the FNIH board	5 members from European Federation of Pharmaceutical Industries and Associations, 5 members from European Commission
	Scientific Committee	• Reports to the governing board • Provides recommendations on scientific priorities • Advises ongoing programs • Assists with development of new programs	15 qualified academic/nonprofit scientists from different EU member states
	States Representatives Group	• Reports to the governing board • Ensures equal participation and benefits across member states	• Representatives of EU member states and other countries associated with Seventh Framework Programme
TransCelerate BioPharma	Board of Directors	Provides oversight to all consortium activities	Senior R&D leadership from industry

These organizations also manage their programs differently than other types of consortia, where employed program managers are supported by industry scientists provided to the partnership as part of an in-kind contribution (see Table 6). For example, CQDM has a program office composed of a president and staff who are responsible for managing the individual research projects. They are supported in-kind by industry scientists who serve as subject-matter experts and mentor the funded researchers. IMI has an executive office that is led by an executive director and supported by dedicated IMI staff who serve as central program management. Each program is also supported by two subject-matter experts who play dedicated roles as on-the-ground program managers and are typically provided as part of industry's in-kind contribution. TransCelerate BioPharma has a smaller program office composed of a CEO who depends on an operating committee for the day-to-day management of each effort. This committee is composed of in-kind subject matter experts who are provided by two of the sponsoring companies and serve as technical project and operations managers, with support from an outsourced third-party project manager who tracks and enforces the administrative responsibilities of each effort.

Table 6: Program-level staffing for industry-initiated consortia

Consortium examples	Project-level structure	Functions	Composition
CQDM	Program Office	• CEO reports to board of directors and strategic orientation committee • Program staff manages efforts	Dedicated staff who are subject matter experts
IMI	Executive Office	• Executive director reports to governing board and scientific committee • Centralized program management works with effort-specific program managers (provided in-kind by industry sponsors)	Dedicated staff who are subject matter experts
TransCelerate BioPharma	Operations Committee	• Reports to CEO and board of directors • Designs, develops, and manages execution of research • Program management provided by in-kind contribution of sponsor and outsourced staff • Operations manager provided by in-kind contribution from a sponsor that is different than the one who provided the program manager	Subject matter experts from industry sponsors, outsourced project management

Foundation-driven initiatives

Several patient advocacy groups and foundations manage their own consortia, typically with a narrower mission than government- and industry-driven initiatives. Their efforts commonly have the goal of creating a broadly usable resource for the scientific community, as a way to direct research toward their disease or conditions of interest. For instance, some aim to propel the development of drugs for their disease of interest by expanding the clinical trials of exploratory therapeutics and diagnostics, while others 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, such as the PKD Foundation, use third-party organizations like C-Path to coordinate and manage their research efforts. See Table 7 for two more examples.

The highest levels of governance for most of these consortia focus on ensuring that the products of their efforts have a pathway for commercialization or dissemination, and program management tends to be much more hands-on with their funded researchers. At the program level, most of these consortia employ program management staff that is centrally located at the foundation office or distributed at the research and clinical sites. Unlike other large consortia that might have staff with management responsibilities spread over several disconnected efforts, these foundation-driven efforts 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 funded research activities by working on-the-ground with the funded investigators, but the staff also

may play an important role steering the research and working with the leadership to identify and develop new solicitations. Funded researchers also tend to play a larger role, as they are typically experts in the disease of interest and contribute to the scientific direction of the consortium's efforts by serving as members of a governance committee (see Table 8).

Table 7: Governance structure for foundation-initiated consortia

Consortium / sponsor examples	Governance Structure	Functions	Composition
Multiple Myeloma Research Consortium (MMRC)/ Multiple Myeloma Research Foundation (MMRF)	Board of Directors	Guides the consortium's research efforts	Business leaders, academic medical researchers, MMRF founder
	Steering Committee	• Provides strategic direction and scientific oversight • Reports to board of directors	Researchers from MMRC member institutions
Parkinson's Progression Markers Initiative (PPMI)/ Michael J. Fox Foundation for Parkinson's Research (MJFF)	Steering Committee	• Guides the initiative's research efforts • Reports to MJFF senior vice president, Research Partnerships	Parkinson's disease biomarker experts, study core leaders, foundation leadership, industry scientists
	Industry Scientific Advisory Board	• Reports to steering committee • Provides input to task forces/working groups on study parameters and goals • Suggests ancillary studies	Representatives from partner companies
	Working Groups	Addresses scientific aspects of various parts of the study	Scientific experts from industry and academia • Cognitive/Behavioral • Sleep • Statistics • Imaging • Biologics • Genetics • Recruitment/Retention • Web site
	Study Committees	Provides operational oversight of study	Scientific experts from nonprofits and academic research centers • Clinical study oversight • Data use and publications • Ancillary studies • Biospecimen review • Patient advisory

Table 8: Project-level governance structure for two foundation-driven initiatives

Consortium	Project-level structure	Functions	Composition
MMRC	Executive Committee	• Provides oversight of MMRC projects • Reports to steering committee	Dedicated MMRF subject matter experts
	Project Review Committee	• Reports to steering committee • Guides pre-clinical and clinical research efforts	One representative from each MMRC member institution
	Operations Team	• Focuses on initiating and managing trials • Reports to MMRC executive committee	Dedicated MMRF subject matter experts
PPMI	Study Cores	• Led by a single principal investigator (PI) who reports to MJFF steering committee • Composed of nine core groups with different expertise	Study core PI
	Project management	Manage all initiative activities	MJFF dedicated staff and funded PI

Third-party-driven initiatives

As described in the previous sections, third-party organizations play important roles for government-, industry-, and foundation-driven consortia by serving as the neutral ground among all of the stakeholders. In addition to supporting consortia initiated by other groups, organizations such as C-Path, FNIH, and Health and Environmental Sciences Institute (HESI) have also created their own consortia (see Table 9). Since these efforts are initiated within the organization, working groups and steering committees are used to identify research questions that are not addressed elsewhere, validate from the scientific community that they are truly unmet needs, and develop a process to pursue the research question. The final decision is made by the board of directors, which provides oversight on all of the organization's activities and is responsible for ensuring that the proposed concepts are within scope of the overall mission.

In addition to the consortia mentioned in earlier sections, both C-Path and FNIH have initiated their own consortia, such as the Coalition Against Major Diseases and Biomarkers Consortium, respectively. All consortia must still meet their host organization's overall mission, and this determination is made by the board of directors. For example, C-Path utilizes a checklist to evaluate all proposed concepts to make sure that they address an unmet-need, are a topic within FDA's interest, and have funding accessible or available to execute the collaboration.

As part of the International Life Sciences Institute, HESI has a mission to broadly address global health and environmental issues by convening scientists from multiple sectors. To do this, the organization uses a series of technical project committees that are responsible for defining and addressing the research questions, and eventually making the findings available to the public. Their bylaws require equal representation by the public and private sectors on all of its leadership teams. Industry sponsors obtain a single seat on the HESI Assembly, whose membership makes them eligible to participate on a technical project committee as well as provides them with a vote for electing representatives to the board of trustees. HESI's technical programs are created from input by their emerging issues committee, which uses a survey-based approach of the HESI Assembly and the external scientific community to query and validate emerging scientific issues.

Table 9: Governance structures for some third-party-driven initiatives

Consortium examples	Governance Structure	Functions	Composition
C-Path	Board of Directors	Manages all of the activities, including approving new concepts	Industry, academic research centers, business development, financing, government, patient advocacy
	Consortium-specific activities	Coordinating committee provides strategic direction of consortium	Members of sponsoring companies
		Executive director and co-director provide day-to-day management	C-Path employee and elected member from sponsoring company
		Project management	C-Path employee
HESI	Board of Trustees	• Reports to the HESI Assembly • Approves and manages all project concepts and technical committees	• Chair and vice chair who represent the public interests • President and vice president represent the interests of the sponsoring organizations • Half of membership are from public sector
	Executive Committee	• Reports to board of trustees • Responsible for day-to-day operations	HESI management and officers, the past chair or president, and other members elected by the board of trustees
	Emerging Issues Committee	• Reports to board of trustees • Identifies new scientific issues and guides the overall scientific direction of the organization • Has the authority to nominate subcommittees to further evaluate scientific issues and make recommendations	Elected members from the board of trustees, evenly balanced between public and private-sector representatives
	HESI Assembly	• Participate in technical or project committees • Vote for representatives on the board of trustees	Sponsoring industry companies
	Program Staff	Executive director reports to the president of the board of trustees and an officer of the board and executive committees	HESI staff, nominated by board of trustees
		Project-specific steering committee	Members from HESI Assembly balanced with public-sector representatives
		Project manager	• HESI staff, subject matter expert • Each project may be staffed by one or more project managers • Also supported by non-HESI co-leaders or steering groups
FNIH	Board of Directors	Manages all of the activities, including approving new concepts	• Officers – industry, academic research centers, financing, patient foundation • Elected directors – business development, financing, sponsors, industry, patient foundation, nonprofit research centers, other stakeholders • Ex-officio non-voting directors – NIH and FDA • Honorary directors – academic research institutions
	Consortium-specific activities	Executive committee – overall consortium management, reports to board of directors	Dependent on topic and sponsor
		Steering committee – reports to executive committee	Dependent on topic and sponsor
		Program staff – reports to FNIH president and consortium's steering committee	• Project team director - employed by FNIH with subject matter expertise • Project managers – employed by FNIH with subject matter expertise

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