About the FasterCures Consortia-pedia project:

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

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

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

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

UPDATED May 2014
KEY POINTS - HUMAN CAPITAL:

- Obtain **high-level buy-in** of the sponsoring companies and institutions, and find a champion within the organization who ensures that the support is sustained.
- Find project leaders who are **passionate and committed to the effort**, and equipped with project management and scientific expertise as well as people skills.
- Build team cohesiveness among all of the participants through **open dialogue and respect**.
- Provide incentives that aim to **reduce turnover and maintain motivation** for each participant.

Many consortia find it challenging to identify, coordinate, and retain talented individuals within a project team composed of members from multiple organizations. Many of our interviews stressed the importance of assessing the total human capital available to a consortium at the onset of any partnership, and delegate responsibilities that are appropriate to an individual’s commitment of time and expertise. These considerations should not only include members of a research team, but also a consortium’s program staff as well as participants within governance and advisory boards.

In the end, human capital considerations are essential for advancing the collaboration. Aligning participants toward a mission-driven goal where they feel that their contributions advance the objectives of the consortium, while at the same time receiving some sort of value for their participation, are essential components within any operational strategy (see Table 1).

### Table 1: General examples of consortia leadership responsibilities

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Typical role</th>
<th>External stakeholder/consortium staff</th>
<th>Consortium responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business development</td>
<td>Board of directors / Executive committee</td>
<td>Stakeholder</td>
<td>Provide input to overall consortium direction in fiscally responsible and deliverable-directed manner</td>
</tr>
<tr>
<td></td>
<td>CEO</td>
<td>Consortium</td>
<td>Day-to-day management of multi-department operations</td>
</tr>
<tr>
<td>Scientific, managerial</td>
<td>Steering committee/Scientific advisory committee</td>
<td>Stakeholder</td>
<td>Provide technical input to the consortium’s various research efforts</td>
</tr>
<tr>
<td></td>
<td>Project director</td>
<td>Consortium</td>
<td>Manages several projects that might align with subject matter expertise</td>
</tr>
<tr>
<td>Scientific, technical</td>
<td>Working groups</td>
<td>Stakeholder</td>
<td>Provide in-depth technical analysis in support of steering committee</td>
</tr>
<tr>
<td></td>
<td>Project manager</td>
<td>Consortium</td>
<td>Manages specific projects that directly relate to subject-matter expertise</td>
</tr>
<tr>
<td>Project management</td>
<td>Project manager</td>
<td>Consortium</td>
<td>Manages administrative tasks and enforces timelines</td>
</tr>
</tbody>
</table>

**Leadership from sponsoring organizations**
A consortium is often initiated and driven by passionate members who donate their time and expertise to champion these research efforts, often without personal, financial, or professional gain. It’s important that they are allowed by their employer to participate; excitement and sign-off at the highest leadership level of a sponsoring or participating organization has been an essential success factor for many of the consortia that we interviewed.

One strategy for obtaining this level of organizational commitment is to have leadership participate as members of a consortium’s executive committee or board of directors. Engaging leadership in upper governance committees can provide:
- A steady stream of fiscal contribution.
- Access to sufficient resources to succeed, such as in-kind contributions of laboratory resources.
- Access to strategic advice that reflects a leader’s experiences and perspectives.
- Access to networks of prospective participants; these individuals are often well-connected within their sector or disease interest with the credibility to motivate others to participate.

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

Table 2 provides examples of efforts managed by the Foundation for the National Institutes of Health (FNIH) and the Innovative Medicines Initiative (IMI) with the leadership roles that participants held in their sponsoring organizations, and their contributions to the consortium strategy.

**Table 2: Examples of leadership roles and responsibilities, by sponsoring organization**

<table>
<thead>
<tr>
<th>Consortium</th>
<th>Sponsor/participant</th>
<th>Leadership role in their company</th>
<th>Consortium responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observational Medical Outcomes Partnership (OMOP), managed by FNIH</td>
<td>Pfizer</td>
<td>Chief medical officer</td>
<td>Board of directors, FNIH</td>
</tr>
<tr>
<td>Food and Drug Administration</td>
<td>Commissioner</td>
<td>Board of directors, FNIH</td>
<td></td>
</tr>
<tr>
<td>Center director</td>
<td>Executive board, OMOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chief scientist</td>
<td>Executive board, OMOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associate office director</td>
<td>Scientific advisory board, OMOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associate office director</td>
<td>Health informatics advisory board, OMOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>eTOX, managed by IMI</td>
<td>Novartis</td>
<td>Deputy head translational services – Europe</td>
<td>Governing Board, IMI</td>
</tr>
<tr>
<td>Executive director - Biochemical &amp; translational safety</td>
<td>Project coordinator, eTOX</td>
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<td></td>
</tr>
<tr>
<td>Pathologist</td>
<td>Chair, eTOX steering and executive committee</td>
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<td></td>
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<tr>
<td>Toxicologist</td>
<td>Project team, eTOX</td>
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</tbody>
</table>

**Consortium leadership**

Many consortia have the resources to employ leadership teams after the mission and potential partners have been identified. These teams are responsible for the execution and management of the strategic research agenda, and in some cases, also have the authority to create new consortia. Reporting to the board of directors and steering committees, these individuals also serve as a public face of the consortium. With this consideration, many groups employ a CEO or president with credentials that include prior upper-leadership roles within the sector that is driving the consortium, bringing with him or her an understanding and appreciation of the real-world challenges addressed by the collaboration. Past experiences also provide a level of credibility to the external communities, which is essential for sustaining sponsorships and gaining new participants.

For example, TransCelerate BioPharma, an industry-initiated consortium aimed at improving clinical trial methodology, currently has a CEO with previous experience as a president of a large contract research organization. Another example is the Coalition Against Major Diseases, which aims to accelerate the development of medical products for neurodegenerative diseases. This effort is currently led by an executive director with academic and industry experience in neuroscience and drug discovery, credentials that align with the consortium’s mission.
Project management

Many consortia 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 maintain their primary employment with the sponsoring company and are provided to the consortium as an in-kind contribution. The other type of 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.

For example, IMI provides central program management from its executive offices, using program managers who are responsible for several initiatives. The day-to-day oversight of the individual research projects are performed by industry representatives who are part of industry’s in-kind contribution to the collaboration. See the sidebar for an example of project management roles and the leverage of in-kind contributions by IMI’s eTOX initiative. Other initiatives, such as TransCelerate BioPharma, outsource project management responsibilities and use in-kind support from industry sponsors for the scientific management of projects.

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

Volunteer army

There are many consortia that 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 completely volunteer program team. Under these circumstances, participants do not get paid or recognized for their 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 to maintain forward momentum on any given task and make it difficult to retain talent and expertise. Most consortium leaders agree that incentives for team science should be defined early in the process if they do not have the resources to employ support staff.

Examples of rewards/incentives include:
- Professional networking
- Exposure to other experts and creating new ways to tackle problems
- Certificates of participation
- Authorship in publications
- Recognition by upper management
- Career advancement tied to their participation
- Access to additional sources of funding

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**eTOX Project Strategy for Effective Project Management**

To address the challenges of dealing with a volunteer army, as well as the critical need for skilled project management, IMI’s eTOX Project has a full-time project manager provided as an in-kind contribution from one of its industry sponsors. This project manager has subject matter expertise in safety and pharmacology, which align to the mission of eTOX. Employed by Sanofi, the project manager’s routine performance evaluations are tied to the eTOX Project, in addition to his or her contributions to the research organization.

Sanofi leadership view the output of this initiative as important for their own internal research operations. This high-level commitment is evident as Sanofi has hired and restructured its own organization to increase its participation in this collaboration during the course of this initiative.
Staff turnover
Staff turnover within a partnering organization is an additional and often unpredictable challenge for 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 their efforts to their scientific colleagues within an organization. As mentioned earlier, several consortia routinely involve multiple participants from the same organization to help mitigate the effects of turnover. In addition to having multiple levels of involvement from a single organization, a horizontal approach that ensures cross-sector participation has also been essential in mitigating changes that may broadly affect one sector.

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