

The Art of Managing Complex Collaborations

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[COLLABORATION]

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BY ERIC KNIGHT, JOEL CUTCHER-GERSHENFELD, AND BARBARA MITTLEMAN

Society's biggest challenges are also its most complex. From shared economic growth to personalized medicine to global climate change, few of our most pressing problems are likely to have simple solutions. Perhaps the only way to make progress on these and other challenges is by bringing together the important stakeholders on a given issue to pursue common interests and resolve points of conflict.

However, it is not easy to assemble such groups or to keep them together. Many initiatives have stumbled and disbanded. The Biomarkers Consortium might have been

one of them, but this consortium beat the odds, in large part due to the founding parties' determination to make it work. Nine years after it was founded, this public-private partnership, which is managed by the Foundation for the National Institutes of Health and based in Bethesda, Maryland, is still working to advance the availability of biomarkers (biological indicators for disease states) as tools for drug development, including applications at the frontiers of personalized medicine.

The Biomarkers Consortium's mandate — to bring together, in the group's

words, “the expertise and resources of various partners to rapidly identify, develop, and qualify potential high-impact biomarkers particularly to enable improvements in drug development, clinical care, and regulatory decision-making” — may look simple. However, the reality has been quite complex. The negotiations that led to the consortium's formation in 2006 were complicated, and the subsequent balancing of common and competing interests remains challenging.

Bringing the Group Together

Many in the biomedical sector had seen the need to tackle drug discovery costs for a long time, with multiple companies concurrently spending millions, sometimes billions, of dollars only to hit common dead ends in the drug development process. In 2004 and 2005, then National Institutes of Health director Elias Zerhouni convened key people from the U.S. Food and Drug Administration, the NIH, and the Pharmaceutical Research and Manufacturers of America to create a multistakeholder forum.

Every member knew from the outset that their fellow stakeholders represented



many divergent and sometimes opposing interests: large pharmaceutical companies, smaller entrepreneurial biotechnology companies, FDA regulators, NIH science and policy experts, university researchers and nonprofit patient advocacy organizations. Each organization represented in the room had a different starting position and its own internal structure and operating rules, decision-making structure, processes and metrics — and sometimes even multiple, distinct internal subcultures. The only thing shared by all was a conviction that this research constituted lifesaving work and that a means to reduce duplication and mitigate the cost of failure was needed, now. Fortunately, despite the many obstacles, the group's sense of determination and a common mission provided enough momentum to launch a new organization, the Biomarkers Consortium, in 2006.

How did this happen, and how is it working? To find out, we conducted 36 interviews with senior consortium leaders about the group's history. Our research points to five lessons for anyone trying to build consensus to address

broad societal challenges among multiple stakeholders with both common and divergent interests:

LESSON ONE: Agree on what you can't achieve alone and create a permanent, well-defined space to advance collaborative projects. Pharmaceutical companies compete with each other for market share of drugs and therapeutics but regard biomarkers as tools that lie outside their core business. By defining biomarkers as an explicitly precompetitive space, these companies are able to engage in activities that are mutually beneficial, cheaper to each if funded jointly, and unlikely to erode the respective competitive advantages of their core businesses.

Government agencies also liked the idea of a precompetitive space. The precompetitive character of the Biomarkers Consortium ensures that the public interest will be served in all the group's activities, keeping them consistent with the missions of both the FDA and NIH. Finally, academic researchers gain an opportunity to translate their discoveries to biomarker development and qualification, to develop contacts and relationships that may facilitate future technology transfer and to provide complementary expertise to other participating organizations.

The implication for managers is that even in contested and complex marketplaces, stakeholders can still carve out neutral precompetitive territory through consortia that enable ongoing, collaborative initiatives.

LESSON TWO: Negotiate creative and flexible time frames for sharing risks and developing opportunities. A dual functional requirement of any organization and any multistakeholder consortium is to create value and mitigate harm. Stakeholders will usually agree on the importance of these two functional requirements — but to different degrees and with differing ideas of what constitutes both value and harm. Industry tilts more

toward economic value creation, though it does have to pay some attention to mitigating harm (reducing liability, protecting reputation and preserving core values). Participants from the nonprofit sector (such as patient advocacy organizations and academics) and government science agencies such as the NIH are committed to providing scientific and clinical value and doing so in a safe manner. Government regulatory agencies like the FDA lean more toward mitigating harm, but they do have to worry about value creation in the context of their specific agency missions.

The Biomarkers Consortium model requires mixed teams with representation by all founding partners to both evaluate and execute project proposals. This sounds like a structural challenge — and it often is — but consortium participants said that in practice this mix is part of what makes the consortium useful. As one government regulator said, “The fact that you have different groups with disparate interests being put toward a common goal is an advantage.” For example, through the consortium, big pharmaceutical companies gained greater insight into regulators' thinking. At the same time, the FDA valued having advance understanding of new scientific developments, enabling faster and more informed regulatory review.

The Biomarkers Consortium also has enabled greater planning and deal-making possibilities as stakeholders gain better understanding of others' motivations and long-term interests. Being part of a consortium makes it possible to negotiate deals for mutual interest not only at this point in time but over a long period. The consortium did not and could not fundamentally change the priorities of the stakeholders, but it has been able to bring them together in constructive ways that expanded the proverbial pie.

LESSON THREE: Establish an independent, fair process for stage-gating

decision making, with continuous process improvement. Government agencies are often seen as excessively cautious, prioritizing consistency and process over responsiveness and invention. On the other hand, industry tends to be characterized as guilty of a “ready-shoot-aim” mentality that lets pressure from high burn rates force hasty decisions. The Biomarkers Consortium, by being located outside both government and industry and by having the FNIH as a managing partner, creates systems and processes that lend added agility to government and augment industry deliberativeness.

A dedicated and independent consortium staff, funded within the FNIH, ensures well-specified guidelines and administra-

stakeholders may close out the discussion prematurely. Other times, they may slow down a process that really is ready to move forward. It is crucial to ask — and understand — why there is a sudden push for more action or more deliberation. The protocols or standards for decision making and action are an essential ingredient of the secret sauce for successful multi-stakeholder consortia.

LESSON FOUR: Establish routines to change routines. Institutions always face a conundrum: If they don’t use established tools and methods, they invite chaos. However, if they slavishly follow only known tools and methods, they won’t be able to innovate.

Structured decision-making processes must be adjustable over time, so a continuous improvement capability is essential.

tive process integrity. This was crucial to maintaining momentum, structure and continuity through discussions regarding which projects to pursue and where to deploy further resources. Many consortia focus on the vision but don’t set up this more detailed stage-gating process — often a fatal error. Further, the fact that every party has a veto means that none of them can be forced to do something they do not want to do, so any project that is approved has the support of all the founding partners.

Structured decision-making processes must be adjustable over time, so a continuous improvement capability is essential. Deliberative processes need to be sufficiently detailed to match the issues being addressed (but not more), with defined gateways for action and mechanisms that are adaptable over time.

But beware of hidden agendas. Sometimes, one stakeholder or a coalition of

Obviously, the ability to compromise is essential, but compromise is only possible when you develop a mechanism to achieve it. In this case, the solution is a “metaroutine” — a routine for changing routines.

The Biomarkers Consortium has an executive committee that can change consortium policies — which helps enable agility. For example, a limitation of the consortium’s initial policy for confidentiality was exposed in an early project when team members from both the FDA and industry asked whether they were able to return to their home organization for guidance on a particular project. As the value of the consortium comes from shared institutional knowledge as well as individual expertise, the executive committee moved quickly to craft a new organization-wide confidentiality agreement that made it possible to apply the full

force of member organization strengths to tackle these common problems.

But to create stability as well, consortium founders also put a metaroutine (in this case, a veto) in place from inception so that deal-breaking issues could be dealt with fairly simply. Any founding member had the right to veto any project for any reason. Government, rather than industry, would have been particularly vulnerable without this power. The NIH and FDA could not actually — or even apparently — act in a manner counter to either agency mission or federally determined agency priorities, so they needed an “out.” In practice, the veto has never been used, but it is crucial in allowing the parties to work together.

The lesson for other multistakeholder groups? Managers need to build in periodic “check-and-adjust” mechanisms to enable a consortium to deal with ebbs and flows over time. Being explicit about underlying assumptions regarding where the consortium needs to head so it is responsive to the needs of all stakeholders is crucial.

LESSON FIVE: Strive for alignment both within member organizations and across the consortium membership. The ultimate test of a consortium is whether its stakeholders can take collective action to advance both their separate and shared strategic goals. Achieving this feat requires alignment in two distinct, yet complementary, dimensions: *internal* and *lateral* alignment.

Internal alignment is the extent to which all of the key players in a single organization have “bought into” a specific project idea. *Lateral alignment* is the extent to which the key players across a diverse set of organizations are committed to a specific project idea. In order for the consortium to succeed, both internal and lateral alignment must be strong and resilient. This challenge is compounded by the fact that the internal structure and operation of each consortium member is optimized for its primary mission (competition or regulation), not for collaboration. Internal alignment for

collaboration requires building new internal competencies and “nodes for collaboration,” in addition to existing policies and procedures.

The Biomarkers Consortium has helped create an environment where internal alignment tensions can be aired and addressed. For example, there is little that the consortium can do to remove the pressure of people’s “day jobs” in their respective organizations. However, where organizations have multiple representatives inside the consortium (for example, on steering committees, the executive committee, project teams, etc.), achieving internal alignment may be easier. Internal alignment is most difficult when a stakeholder’s involvement in the consortium is ad hoc, the representative is at a low level within the home organization and cannot be an effective champion, and/or the representative can speak for his or her organization on only one level (for example, *only* on the steering committees). This makes it difficult for that organization to “speak with one voice” as projects come up for investment.

Over time, consortium member organizations have developed internal mechanisms to manage this tension. As one industry member noted in discussing an internal forum established in his organization to support public-private partnerships, “We all get together — there is a champion, an application process, and we decide if it is good for [the company], and finance has carved out a protected budget. [Another company] has done the same thing. In the absence [of this mechanism] the ad hoc process would be a real pain.”

Lateral alignment is faster and more robust when a clear, shared vision for success is outlined at formation and updated regularly. This should be reflected in tools such as key protocols, publications, project documents and data plans, as well as in governance mechanisms. Furthermore, frequent independent and external reviews by participating organizations of

how the Biomarkers Consortium is working bring important tensions to the surface and enable constructive dialogue about changes. This lateral alignment builds trust with individual stakeholders and makes it easier to sell the benefits of the consortium to their respective organizations. Different interests at stake must be accounted for and clearly articulated. Where these interests are opaque or poorly defined, it creates delay or partial engagement by consortium partners.

Critical Mechanisms

Once a precompetitive or collaborative space has been defined, building mechanisms for collaboration, shared risk and opportunity, decision making and action are critical. Less obvious but no less critical are the routines to change routines and the integration of internal alignment and lateral alignment.

There is no panacea for managing collaborative complexity. These five lessons don’t automatically resolve all the difficulties. However, following them can greatly improve the chances that a multistakeholder consortium on a complex topic will succeed.

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