

The science of collaboration

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It's a long, expensive, risky road to turn a scientific breakthrough into a treatment that can help patients. Fewer organizations are trying to tackle the challenges alone, says a new paper from MIT researchers published August 28 in the journal *Science Translational Medicine*.

An essential new way to move discoveries forward has emerged in the form of multi-stakeholder collaborations involving three or more different types of organizations, such as drug companies, government regulators and <u>patient groups</u>, write Magdalini Papadaki, a research associate, and Gigi Hirsch, a physician-entrepreneur and executive director of the MIT Center for Biomedical Innovation.

The authors are calling for a new "science of collaboration" to learn what works and doesn't work; to improve how leaders can design, manage and evaluate collaborations; and to help educate and train future leaders with the necessary organizational and managerial skills.

"Getting new, better, affordable drugs to the right patients faster involves a series of historically independent decisions made by different players or stakeholders," says Hirsch. The system is uncoordinated, takes too long, and costs too much. In some cases, the drug—such as new antibiotics for life-threatening resistant infections—may never become available.

"One of the interesting paradoxes of biomedical innovation is increasingly going to be that even though we have the <u>scientific</u> <u>knowledge</u> required to provide potentially better treatments for



patients—or even to prevent disease in those who are at high risk—we may be unable to help patients benefit from them anytime soon," she says.

To help change this scenario, in the last decade, thousands of researchers, pharmaceutical and biotechnology companies, government regulators, payers, clinicians and patients have come together in more than 100 multi-stakeholder collaborations to solve some specific shared problem standing in the way of finding a cure or a better diagnostic approach.

"Multi-stakeholder collaborations provide the opportunity to create an environment that allows for new kinds of interactions among the players," Hirsch says. The largest multi-stakeholder effort, the European Union's Innovative Medicines Initiative (IMI) began in 2008 and has established more than 40 consortia with financial and in-kind investments totaling €2 billion. Some projects focus on specific health issues, such as Alzheimer's disease, chronic pain, diabetes and obesity. Others tackle bigger issues, such as drug and vaccine safety and the use of stem cells for drug discovery. The success has led to a proposal to extend the effort for 10 years and €3.5 billion. Last year, the U.S. President's Council of Advisors on Science and Technology (PCAST) recommended the U.S. form something similar.

"The prevalence of multi-stakeholder initiatives reflects a continued optimism about the value of this collaboration approach for addressing biomedical innovation bottlenecks," the authors write in the paper. "Although the need for collaboration is no longer in question, it is worth noting the importance of this development. A willingness to share proprietary data among industry competitors represents a dramatic shift in the culture of the historically highly competitive pharmaceutical industry."



The article reviews the history of collaborations beginning with HIV/AIDS. By the early 2000s, multi-stakeholder collaborations proliferated to address the need for important tools, such as biomarkers, that require preclinical data sharing. Since then, they have reached to encompass later stages in product development, including manufacturing, reimbursement and post-market monitoring.

Some people involved in multi-stakeholder consortia are concerned about redundancy, inefficiency and lack of productivity of some collaborative efforts, all contributing to a sense of "consortium fatigue," the researchers write.

In a newer trend, funders and participants are seeking a smaller number of strategically coordinated initiatives that will reliably address critical gaps, Hirsch and Papadaki write. They cite the example of TransCelerate BioPharma, a group of 10 major pharmaceutical companies that came together to share and direct resources toward selected priorities in order to improve the efficiency of drug development, such as clinical trial site qualification standards.

The authors propose a rigorous evidence-based approach (the science of collaboration) to figure out what works and doesn't work in collaborations. They recommend early steps in this new field and structuring the research to help learn from the past but also to evolve effectively as new innovation challenges emerge.

To launch their new discipline, the Robert Wood Johnson Foundation just awarded Hirsch and her colleagues a start-up grant to lay the foundation. Their research will begin with case studies in biomedical innovation to identify the organization design components, as well as systematic learning from a broad range of collaborative innovation models in other industries.



More information: "Curing Consortium Fatigue," by M. Papadaki, G. Hirsch *Science Translational Medicine*, 2013.

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