

All together: Consortia boom as scientific complexity grows

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Biomedical competitors, fierce as ever, are finding complementary aid in mission-driven collaborations, according to a new survey of the largely unmapped consortia landscape. Consortia-pedia, a new project of the nonprofit Fastercures, is documenting more than a decade of progress in the fast-growing space.

By November, the group expects to launch an open-source database of global consortia, with an eye toward facilitating more efficient and coordinated efforts in the space. But before then it will publish a quantitative analysis of the regional, therapeutic and other trends driving the boom in a June issue of *Science Translational Medicine*.

Fastercures, part of the Milken Institute, found that even as partners realize big wins from sharing risks, costs and resources, they often face substantial challenges integrating diverse teams and measuring progress.

"Science has gotten more complex, so it's hard for people developing

medical products to answer all the questions they have," Mark Lim, associate director of medical research innovation at Fastercures, told BioWorld Today. However, he said, there's still a lot of confusion about what a consortium is.

To clear things up, Fastercures identified 387 consortia launched between 1995 and 2014 to date, with 62 new consortia emerging in 2012 alone. Half the total are focused on specific disease areas, with Alzheimer's disease, oncology, rare diseases and diabetes at the top of the list. The group defined consortia as groupings of people who don't usually work together but have a shared pain point, coming together temporarily to share resources and effort for a common objective.

Most consortia cataloged by Fastercures are dedicated to advancing drug development. It found 208 active groups in Europe, 144 in the U.S. and just 10 in Asia, with nearly 44 percent started by government as compared to just 17 percent created by industry.

The European Union's €2 billion (US\$2.4 billion) Innovative Medicines Initiative (IMI) and its €3.45 billion follow-on, called IMI 2, have generated especially brisk consortia-creation, where companies are working to accelerate drug discovery with a combination of government and matching industry funding. (See BioWorld Today, Aug. 8, 2012, and July 16, 2013.)

Though on a smaller scale, U.S. consortia have been active, too. The National Institutes of Health launched Accelerating Medicines Partnership in February. Dubbed "IMI lite" by some, the program committed \$230 million to precompetitive drug discovery, half of which came from industry. (See BioWorld Today, Feb. 5, 2014.)

Projects, such as the industry-driven nonprofit Transcelerate Biopharma Inc. launched in 2012, are working to modernize and streamline the way clinical trials are conducted and monitored. It released the first update to its methodology for risk-based site

monitoring in January. (See BioWorld Today, Sept. 26, 2012.)

A newer project, Project Data Sphere, driven in part by Sanofi SA, Quintiles and Sage Bionetworks, is making patient-level, comparator-arm, phase III cancer data available to all comers in an effort to build a clearer picture of disease progression and endpoints, aid efficient trial design and reduced duplication of efforts.

Patient foundations, such as the Michael J. Fox Foundation for Parkinson's Research, have undertaken new collaborative projects, too. The group's Parkinson's Progressive Markers Initiative, for instance, is funded in part by Roche AG, Pfizer Inc. and Merck & Co. Inc., companies more often at odds with each other than not. It's looking to identify biomarkers of Parkinson's disease progression, a critical step in the development of new and better treatments for the disease.

ShaAvhrée Buckman-Garner, director of the FDA's Office of Translational Sciences, told participants in a FasterCures webinar Wednesday that consortia are not easy to build. She said groups need to find common denominators and identify small, discrete, manageable deliverables, then find ways to disseminate that information publicly.

"We have to be able to communicate wins early and often," she said. "We often hear about consortia fatigue, and part of that challenge is because these are overwhelming and very challenging efforts."

The FDA measures success by many yardsticks, said Buckman-Garner, including publications, workshops to discuss emerging science with stakeholders, the creation of data repositories to share knowledge, and the creation of qualified tools, such as diagnostics identifying key biomarkers. The FDA has even begun working to validate such consortia-created biomarkers through the work of its Drug Development Tool Qualification Program.

Given the enormous amount of research needed to lay the foundations for revolutionary advances in drug development, Fastercures originally thought it might create a guidebook for how to form new consortia, said Fastercures' Lim, who in addition to his work at the Milken Institute advises CQDM, a pharma-based consortium in Quebec. The initial result of his group's efforts, a report published Wednesday, came out as a mix, cataloging both existing efforts and best practices.

"It's so early in this consortium world," he said. "We field a lot of calls from patient groups that want to start their own consortium. We usually try to discourage people from doing that. There's room for more collaboration."