

Partnering for progress

How collaborations are fueling biomedical advances

Abridged version

Introduction

In today's era of rapid scientific progress, public and private-sector researchers are seeking to leverage their strengths in collaborative ways to accelerate innovation in patient treatment and care. Biopharmaceutical companies increasingly are partnering with a diverse set of health care stakeholders to address scientific and technological challenges, create greater efficiencies in research and development (R&D), and accelerate the discovery, production, and delivery of critical new treatments for patients in need. Forward-thinking biopharmaceutical companies serve not just as partners, but often also act as integrators in this ecosystem, bringing together diverse players and providing scientific, regulatory, and delivery system insights; operational capabilities; and financial resources.

Deloitte was contracted by the Pharmaceutical Research and Manufacturers of America (PhRMA) to analyze the various types and number of biopharmaceutical partnerships created over the past several decades, which resulted in a comprehensive database of partnerships formed between 1980 and 2014. From this effort, we found that R&D-focused partnerships—most notably, non-asset-based, pre-competitive models (those whose primary objectives do not necessarily center on a specific drug candidate) have grown substantially over the last decade and highlight the growing role and importance of more open, collaborative approaches to R&D innovation.

Keeping pace with the science

Recent decades have seen tremendous progress against some of the most complex and difficult-to-treat disease areas, with scientific breakthroughs in novel diagnostics technology, genomics, and molecular medicine reshaping drug development. Yet even as researchers learn more about the molecular underpinnings of complex diseases, traditional methods for assessing the clinical safety and efficacy of a medicine in development create myriad scientific, regulatory, payment, operational, and financial hurdles that complicate the R&D process and can increase the cost, time, and risk of drug development.



“It would be hard to imagine five years ago that the industry would be sharing resources and information about drug targets as openly as it does now. Many companies are essentially working on the same targets; we all share the need to achieve a better understanding of what underlies them.”

David Wholley, MPhil, Director, Research Partnerships at Foundation for the National Institutes of Health¹

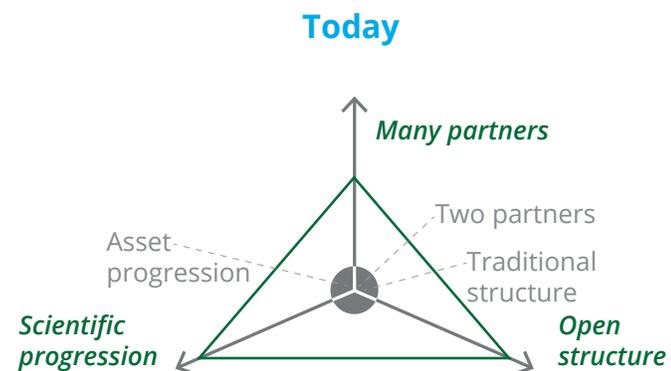
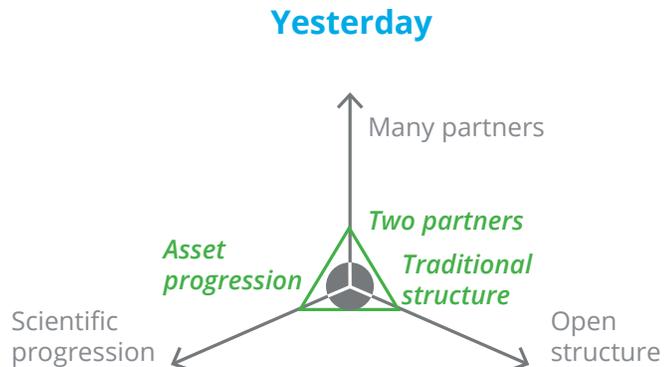
Overcoming scientific obstacles with collaboration

Collaborating across the R&D ecosystem enables partners to better navigate increasingly complex scientific, technological, and regulatory hurdles in a more efficient and timely manner, and bring new innovations to patients faster. Stakeholders each bring differentiated, complementary capabilities to the table, such as deep insights into patient needs and close relationships with patients through hospital systems and patient groups, unique basic research insights, innovative clinical development/technology capabilities, and more. Biopharmaceutical companies serve as both contributors to and integrators of the R&D ecosystem, bringing together participating players with a common goal of improving patient health outcomes. As such, patients are positioned at the ecosystem’s hub as both key participants in driving patient-centered innovation and as the recipients of the value the ecosystem collaboratively creates.

Partnership models and trends

There is a major shift underway as stakeholders move from traditional asset-based partnerships, typically involving two parties which are focused on advancing a particular asset (i.e., investigational medicine), to collaborative, non-asset-based alliances. These new models may include three or more parties, often a mix of ecosystem stakeholders including biopharmaceutical companies, academia, non-profits, and government entities. Non-asset-based partnerships, such as consortia, often aim to expand knowledge and understanding within and across one or more indications, therapeutic areas, or even operational capabilities. Importantly, these partnerships feature shared control and decision-making, thus spreading both the potential risks and rewards.

Biopharmaceutical R&D ecosystem partnering trend



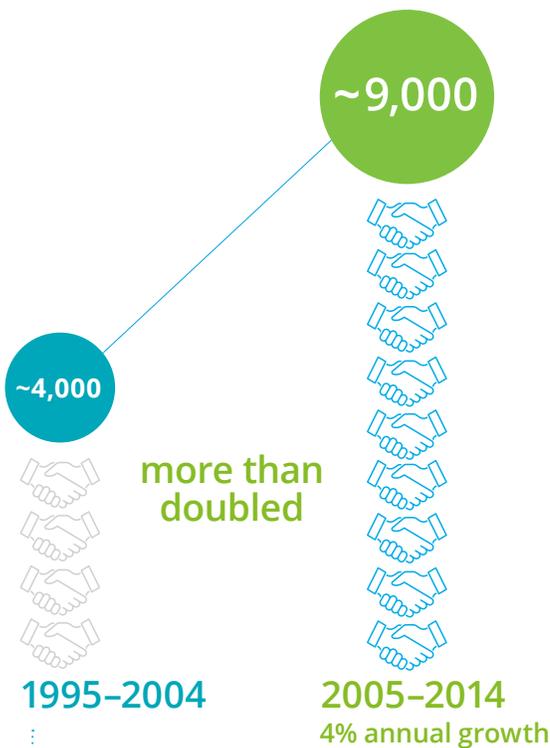
An example, TransCelerate BioPharma Inc., which was formed in 2012, now includes leaders from 18 biopharmaceutical organizations, other industry groups focused on clinical standards, and global regulatory agencies. This non-profit consortium has developed methodologies, processes, and systems to, for example, improve risk-based monitoring, clinical data standards, comparator drug supply, and to create a centralized investigator platform. In February 2016, TransCelerate launched BioCelerate, a subsidiary that aims to improve efficiency in pre-clinical research. Its first initiative, Toxicology Data Sharing, is focused on “enabling access to a broader cross-company set of toxicology data... to modernize toxicology to enhance product safety.”²



Substantial partnership growth among ecosystem stakeholders

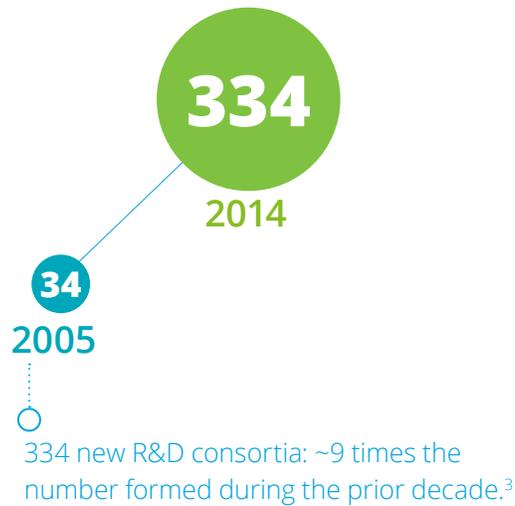
Examining partnership trends in the biopharmaceutical R&D ecosystem from 1980 through 2014 revealed that the number of new biopharmaceutical partnerships have grown substantially in recent years. In fact, in the last 10 years (2005-2014), the number of consortia grew by a factor of nine.³ Over the same period, the number of new partnerships formed annually of the more traditional types, such as in-licensing and acquisition, declined somewhat but still remain a common way to partner.

New R&D partnerships

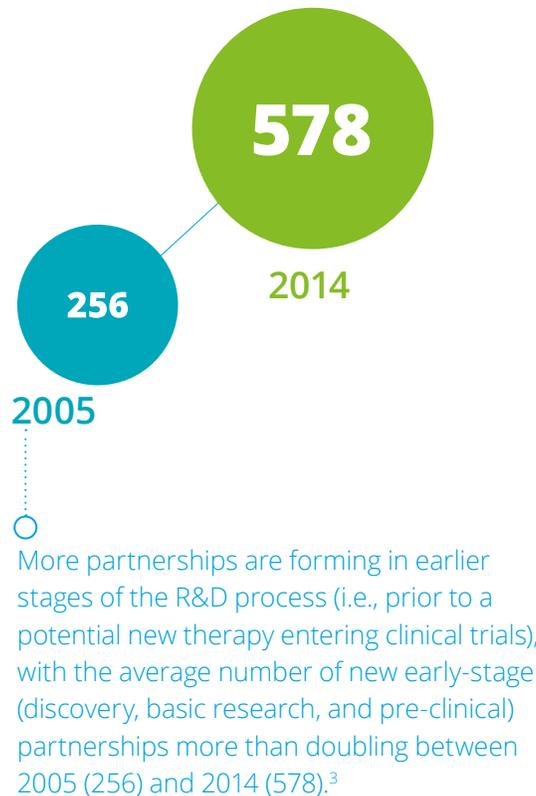


Approximately 9,000 new biopharmaceutical R&D partnerships were formed between 2005 and 2014 at an annual growth rate of four percent during that 10-year period. The 9,000 new biopharmaceutical R&D partnerships formed between 2005 and 2014 are more than double the number formed (approximately 4,000) in the preceding decade (1995-2004).³

Consortia increased 9x



Early-stage partnerships more than doubled



Already, existing consortia have made progress across the following key challenges and opportunities:

- **Understanding difficult diseases at the molecular level:** The Alzheimer’s Disease Neuroimaging Initiative (ADNI) was formed in 2004 to advance understanding of this devastating disease in order to develop new treatments to *slow or stop Alzheimer’s progression*. The initiative, formed by the National Institutes of Health (NIH), National Institute on Aging (NIA), the Food and Drug Administration (FDA), and numerous industry, academic, and non-profit organizations, has made tremendous strides in Alzheimer’s Disease (AD) detection, helping to elucidate the underlying pathways of AD progression, and improving the efficiency of clinical trials related to addressing AD.⁴
- **Quickly and effectively diagnosing and tracking disease progression:** The non-profit Cure Huntington’s Disease Initiative (CHDI) Foundation was created in 2002 by several biopharmaceutical, academic, and contract research organizations (CROs) to focus on developing therapeutics to track and *slow the progression of Huntington’s Disease (HD)*.⁵ The CHDI Foundation has made significant strides towards understanding and treating HD, including partnering with a biopharmaceutical company to discover and develop an antisense drug for HD (which is the first potential therapy intended to directly target the cause of the disease by reducing the production of the protein responsible for HD)⁶ and developing an assay to measure the build-up of a protein that is known to be harmful for patients with Huntington’s.⁷
- **Evaluating the potential for combination treatments:** Academic centers, biopharmaceutical companies, and nonprofits are collaborating through a partnership called CoNNCT (Collaborative Novel-Novel Combination Therapies) to *accelerate identification of effective drug combinations for cancers*. The goals of this collaboration are to make it easier to test multiple combinations of new drugs, reduce the cost of investigational studies, shorten the time to demonstrate proof of concept and, ultimately, accelerate the development of novel treatments in other diseases and conditions.⁸
- **Accelerating translational research:** The California Institute for Biomedical Research (Calibr) is a not-for-profit collaborative that is bringing partners together to *accelerate translational research* in order to develop new medicines for patients with unmet needs across a broad range of disease areas.⁹ Building on the success of early, open collaboration, Calibr also has a unique structure that enables commercial partnerships later in the development process.



“The knowledge derived from precompetitive collaboration is the source of future competition itself. Well-validated targets are good for the industry. We’ll compete in other ways—over how good our chemists are, how quickly we can generate effective new drugs, and how efficiently we then can bring them to market.”

Adam Keeney, PhD, Global Head, External Innovation Strategy and Business Development, Sanofi¹⁰

Biopharmaceutical R&D partnerships: What lies ahead?

There is a growing recognition of the value and importance of collaboration across the biopharmaceutical R&D ecosystem. In the coming years, we expect to see continued expansion in disease area-focused consortia, including growing emphasis on more “open” agreements with respect to structure, control, risk sharing, and other business arrangements.

Already, active innovators are spawning a variety of open partnership models with diverse objectives and ways to measure progress and success, illustrating the potential for sharing knowledge and capabilities across peers without jeopardizing any participating organization's opportunity to succeed. Lessons learned from these accomplishments can be used to enable more pre-competitive collaboration in additional research areas, increasing the potential for new breakthroughs.

To read the full paper, *Partnering for Progress: How collaborations are fueling biomedical advances*, visit www.deloitte.com/us/biopharma-partners.



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Endnotes

- ¹ Deloitte and PhRMA interview with David Wholley, Director, Research Partnerships at Foundation for the National Institutes of Health (FNIH).
- ² TransCelerate BioPharma Inc.
- ³ EvaluatePharma, FasterCures' Consortiapedia, Deloitte Analysis, 2016.
- ⁴ Alzheimer's Disease Neuroimaging Initiative website; accessed June 30, 2016.
- ⁵ CHDI Foundation website; accessed June 30, 2016.
- ⁶ CHDI news release, "Isis Pharmaceuticals initiates clinical study of ISIS-HTTRx in patients with Huntington's disease", July 21, 2015.
- ⁷ CHDI news release, "New assay measures pathogenic protein in Huntington's disease patients' spinal fluid", April 7, 2015.
- ⁸ "More than 40 Industry Visionaries Meet to Explore New Combination Cancer Drug Development Paradigm", BusinessWire, March 7, 2016.
- ⁹ Calibr website; accessed June 30, 2016.
- ¹⁰ Deloitte and PhRMA interview with Adam Keeney, Global Head, External Innovation Strategy and Business Development, Sanofi.



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