

Executing an open innovation model: Cooperation is key to competition for biopharmaceutical companies

Executive summary

Many biopharmaceutical (biopharma) companies are facing a challenging research and development (R&D) environment and increased competitive pressures. Their heavy reliance on a closed, traditional model of product development might stifle true innovation and may cause biopharma companies to lag behind their more creative peers. Companies in other industries have turned to open innovation (OI) – along a spectrum of openness that ranges from closed/traditional to open/emerging – as one way to successfully overcome many R&D and marketplace challenges by sourcing innovative ideas, knowledge, and new skills/technologies from outside their organization.

Deloitte's analysis of the current state of OI in biopharma reveals a higher success rate for OI pursuits than for closed-model product development. However, companies have sourced around 80 percent of their R&D pipeline via the more closed end of the OI spectrum. Adoption at the most open end is still infrequent and slow, mainly due to concerns about

intellectual property (IP) rights, adopting new OI-based R&D models, and cultural and management style issues. Nonetheless, for biopharma companies, OI seems to be the way forward, as it appears to be a more cost- and time-effective way to bring drugs to market. In fact, several key trends will likely continue to drive the adoption of OI, especially at the most open end of the spectrum.

Biopharma companies looking to initiate or expand an OI effort should consider evaluating its maturity against this paper's openness spectrum framework and taking steps towards aligning the OI operating model with the effort's specific goals and desired outcomes.



Closed development model stifles innovation

Biopharma companies seeking to stimulate product innovation by using a closed, traditional model of product development have not generated optimal results. Drug R&D is a high-risk endeavor in which only 16 percent of candidates entering clinical testing make it to regulatory approval.¹ Further, the long timelines of bringing drugs to market have remained constant over many decades. Although there was a slight uplift in R&D returns in 2014,² biopharma continues to look for strategies to improve gains.

Mounting cost and competitive pressures and proliferation of new technologies (from growing reliance on predictive analysis to using new biological approaches for efficiently identifying drug targets) are raising the stakes in biopharma R&D and compelling many biopharma companies to use external resources to fill in-house capability gaps.³ Other factors spurring a surge in collaboration include increasing disease complexity and a lack of understanding of the molecular pathways and triggers of disease pathophysiology.⁴

Biopharma companies' heavy reliance on a closed, traditional model of product development might stifle true innovation and may cause them to lag behind more creative competitors. In contrast, adopting a focused OI framework such as the one laid out in this paper provides the opportunity to access a large, diverse pool of ideas and experts which, in turn, could spur product innovation, speed time to market, reduce costs, and increase competitiveness.

To establish a transformative OI approach to product development, companies should consider the OI framework's five elements: (1) network characteristics (number and type of partners); (2) talent; (3) IP management and contracting; (4) participant contributions and impacts; and (5) governance.

Other industries' success with open innovation

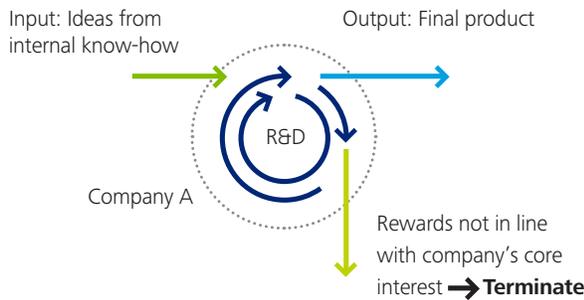
OI's value has been demonstrated at companies in industries ranging from toy to paint manufacturing.⁵ AkzoNobel, a global coatings, decorative paints, and specialty chemicals company, embraced OI as an essential element of its R&D strategy. The company created an OI portal called Open Space to reach out to creative and innovative thinkers. The effort resulted in multiple successful projects, including corrosion-resistant additives, concrete for the building industry, and software that enables a digital camera to match paint colors to home furnishings.⁶ Similarly, many other companies have created new market opportunities using OI by accessing and integrating resources and capabilities beyond their organizational boundaries.

What is open innovation?

Companies use OI to source external knowledge, ideas, resources, and technologies. OI involves liberally sharing information, capabilities, and IP with other organizations, including competitors. And, unlike more traditional collaboration models, it may leave collaborators free to exploit a new technology in other, non-competing areas. In many ways, OI takes a “jobs to be done” approach to identify and outline where real value will likely be created in the longer term.⁷ OI is the opposite of the conventional, vertically integrated R&D model, in which companies rely heavily on internal knowledge and resources (Figure 1).

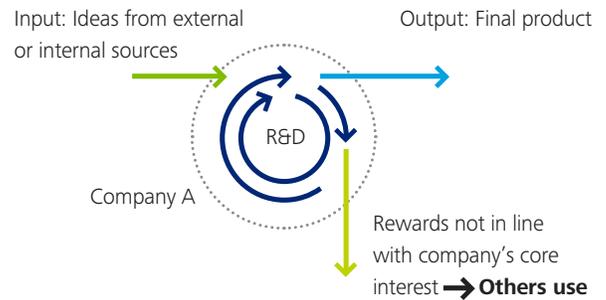
Figure 1. Closed, traditional product development model versus open innovation

Closed/traditional innovation

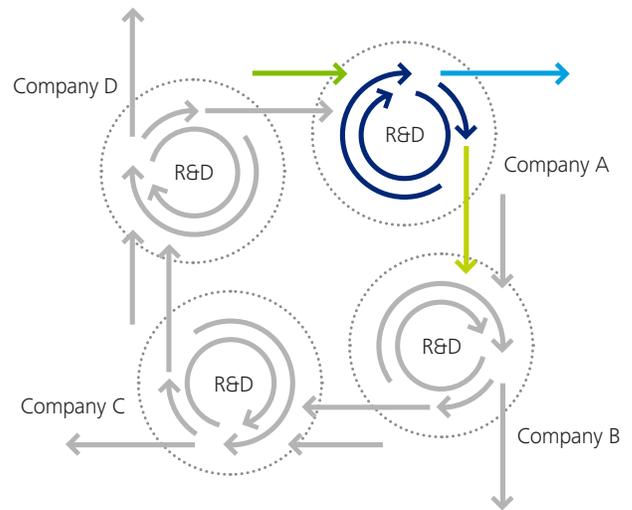


- Companies rely heavily on internal know-how and existing technology base for new ideas
- Products strictly developed internally using in-house R&D
- Internal products preferred over those developed externally
- Products marketed by the same company or by a licensee
- Product ideas for which the company has no experience or which are not in line with company's core interest are terminated

Open innovation



Open innovation network



- Companies look beyond the confines of their own organizations for new ideas and technologies
- R&D resources outside the organization are leveraged. Companies tap skills and experience of external collaborators
- Proactive innovation management
- Companies share technology and ideas with other organizations
- Collaborator free to exploit the technology in non-competing areas
- Companies can expand their current offerings with products from other organizations

Source: Henry Chesbrough, Wim Vanhaverbeke, and Joel West, eds. "Open Innovation: Researching a New Paradigm," 2006, Figs.1.1, 1.2 (By permission of Oxford University Press); Deloitte Consulting LLP and Deloitte Services LP analysis

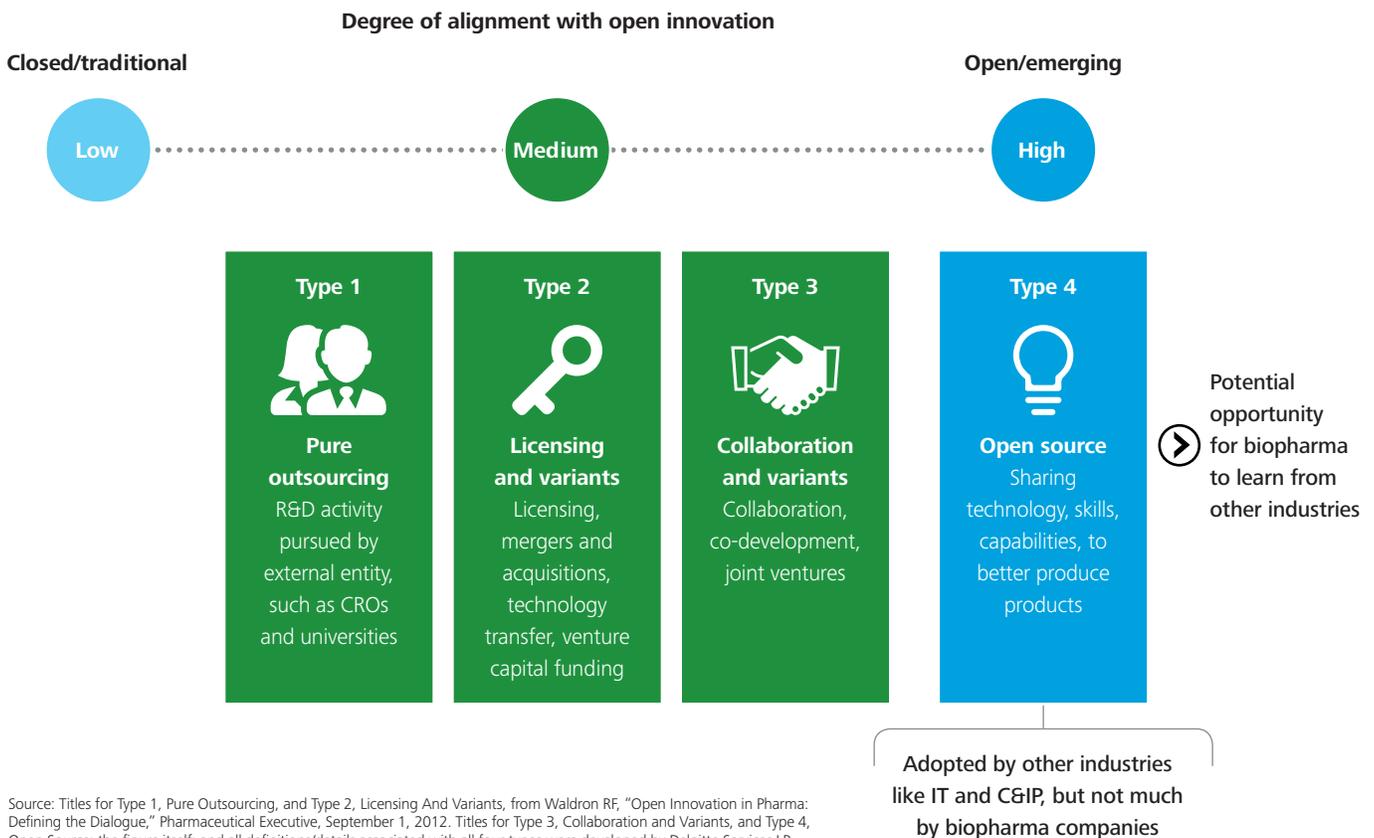
OI for biopharma can be categorized into four major types, arrayed along the spectrum of openness (Figure 2):

1. **Pure outsourcing:** Alliance with single and multifunctional service providers such as contract research organizations (CROs), biotechnology start-ups, or universities. Alliances are formed for functions deemed to be non-core or requiring substantial investment in terms of money, time, or internal R&D resources (e.g., discovery and preclinical testing, clinical trial monitoring, study site management, patient recruitment, and clinical data management). Companies share and implement proprietary governance, methodology, and operating procedures with the collaborator which, in turn, assumes the operating risk for the program.
2. **Licensing and variants:** Allows for majority control of assets; potentially less ability to fully shape development. Risks and rewards are generally in proportion to the amount invested and rights

of operating control (e.g., licensing, mergers and acquisitions, technology transfer, and venture capital funding).

3. **Collaboration and variants:** Collaborating (even with competitors) to exploit complementary resources, share knowledge and experience, leverage capabilities, and spread development risk (e.g., collaboration, co-development, and joint ventures).
4. **Open source:** Participating in a highly-collaborative networked environment, leveraging cutting-edge technology to share the use of data, governance, operating procedures, and manage risk. This arrangement is more common in industries such as information technology (IT) and consumer and industrial products (C&IP). Although biopharma companies have a more stringent regulatory process for new product development, they may look to these industry examples while planning to accelerate their adoption across an industry which deals almost exclusively in innovation.

Figure 2. Mapping the major types of open innovation along the spectrum of openness



The open innovation framework

The characteristics representing each of the five elements of OI can be mapped along the openness spectrum, forming a framework (Figure 3). Each of these elements – network characteristics (number and type of partners), talent, IP management and contracting, participant contributions and impacts, and governance – are explained later in more detail.

Figure 3. Open innovation framework

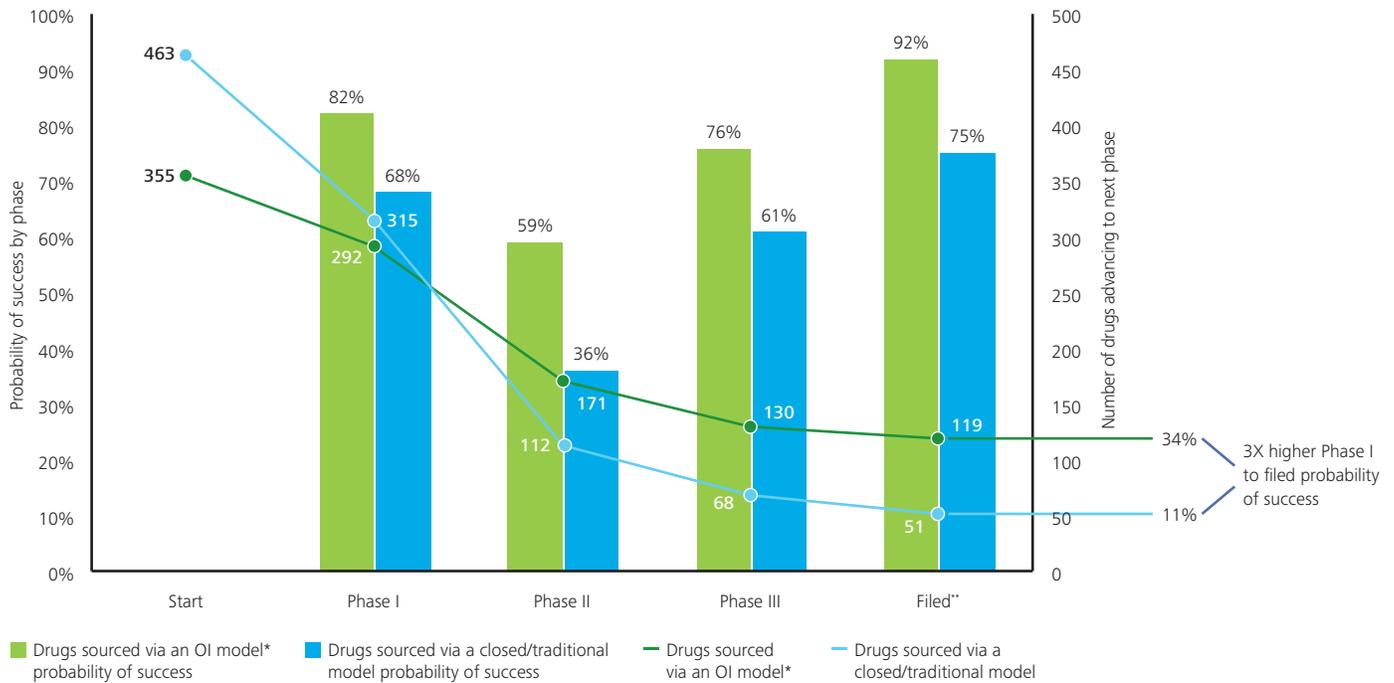
Elements of successful open innovation	Spectrum of openness		
	Closed/traditional		Open/emerging
1 Network characteristics	1 to 5 participants	5 to 20 participants	20+ participants
	Localized to 1 country	1 to 5 countries	5+ countries
2 Talent	High degree of specialization and innovative capabilities only	Innovative and experimental capabilities with moderate specialization	Mixed skill sets with a blend of innovative, experimental and commoditized capabilities
	Narrow acceptance criteria for participants	Flexible acceptance criteria for participants	Broad acceptance criteria for participants
3 IP management/contracting	Understood and defined outcome and contract; participants design participant roles around an explicit agreement; contractual language explicit in protecting IP, preventing use without legal agreement	Agreement between participants is well-defined in some innovation activities and not in others; contract language protects IP but allows use across multiple parties	Participants engage without a clear deal; no formal contract initially, contract based on trust in the platform, mutual interest; contract language enables use, study, distribution, and derivation
	Network's agenda is set by core group or institution	Participants can influence some of the innovation activities (e.g., the extent to which they can influence solution design/development)	Participants can influence most/all of the innovation activities
5 Governance	Predefined and restrictive rules for network participants with reviews and approvals during solution development	Some rules governing network participants with reviews and approvals during solution development	Reviews and approvals are elicited only when absolutely necessary

Source: Deloitte Consulting LLP analysis

Benefits of open innovation

According to a Deloitte analysis, there is a three-fold probability of success when drugs are sourced via OI (Figure 4).

Figure 4. Drugs sourced via open innovation have a higher chance of later-phase clinical success, among 281 biopharma companies, 1988-2012



*Does not include pure outsourcing (type 1 OI)

**New drug application (NDA) submission

Recap Bioportfolio Index (RBI) companies are chosen based on their size, diversity, revenue and scientific innovation. Broadly defined, these companies all self-identified as biotechnology firms from their inception, were largely financed through venture capital and public equity in their early years, and tended to focus on the pursuit of new, untested technologies and unmet medical needs to a greater degree than “traditional” pharmaceutical companies.

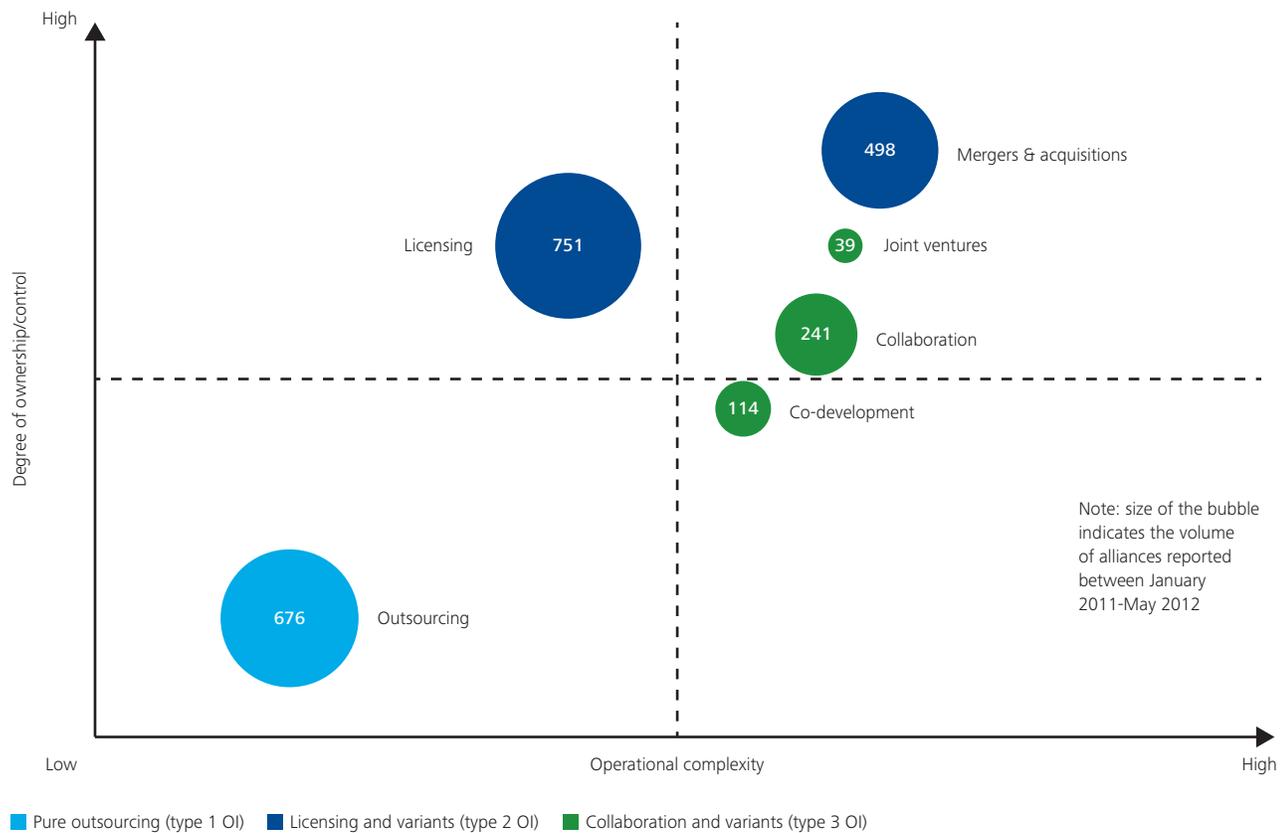
Source: Deloitte Recap DEVELOPMENT optimizer™; Deloitte Consulting LLP analysis

Less frequent adoption of models at the most open end of the spectrum

Among the 12 largest biopharma companies' R&D pipelines in 2014,⁸ 54 percent of all active drugs were sourced through an OI model versus 46 percent that came from a closed/traditional model. However, broader industry analysis indicated that among drugs sourced through an OI model, most (83 percent) were more closed types of OI – pure outsourcing (type 1 OI) and licensing

and variants (type 2 OI). Just under one in five drugs were sourced through collaboration and its variants (type 3 OI), and none were through open source (type 4 OI). Collaboration and variants were pursued three times less often than licensing and variants (type 2 OI), and nearly two times less often than pure outsourcing (type 1 OI) (Figure 5).

Figure 5. Across the major types of open innovation, lower-level pure outsourcing (type 1 OI) and licensing and variants (type 2 OI) were most often used, January 2011-May 2012



Source: Deloitte Recap LLC database; Deloitte Consulting LLP analysis

As seen in Figure 5, biopharma companies appear to be reluctant to shift to the open end of the OI spectrum. Some of the main factors inhibiting biopharma from embracing the open end of the spectrum include:

1. Changing workflows and processes: Adopting a new R&D model based on OI calls for a new way of thinking and the way in which work is usually done. Managing this change is one of the key challenges companies face, as workflows and processes tend to be engrained. Further, adopting an OI-based R&D model involves working closely with different partners and aligning the two organizations' innovation strategies and cultures, which can be extremely difficult.
2. "Not-invented-here" syndrome: A generalized skepticism about ideas "not invented here" is another challenge and may call for an internal culture change so people embrace ideas coming from partners.
3. IP rights: Another factor which may adversely affect the use of OI is the misconception that OI undervalues and undermines the concept of IP protection. Actually, the reverse is true. IP is the currency of OI – value is derived by the ability to use IP for increasing returns.⁹
4. Management styles: Many biopharma companies are used to being managed through a central command center. However, a top-down approach might be new to academic biomedicine or to start-up firms, which may be used to working in a non-commercial environment. To tackle this issue, pharmaceutical companies should consider adopting a more entrepreneurial and collaborative approach.

Although general adoption at the open end of the OI spectrum has been infrequent and slow, some organizations are taking action, with several companies pursuing collaboration and its variants (type 3 OI). For example, regional Johnson & Johnson (J&J) Innovation Centers provide direct access to the J&J group of companies for local and regional scientists, entrepreneurs, and businesses interested in partnerships. The centers are innovation hubs, created to access science and technology sources in the region and to meet the needs of entrepreneurs and scientists developing medical device and diagnostic technologies, consumer health care products, and pharmaceuticals. These centers are located in San Francisco, Boston, London, and Shanghai, regions with life sciences communities that use diverse technologies, and are designed to cut the time and cost of getting potential innovations to patients.¹⁰ Other OI adopters (details in Appendix) include the Eli Lilly (Lilly) Open Innovation Drug Discovery (OIDD) program, Pfizer Centers for Therapeutic Innovation (CTI) program, AstraZeneca (AZ) Open Innovation Platform, and Sanofi Access Platform.

Fewer in number are examples of organizations pursuing open source (type 4 OI) innovation. One example is India's Open Source Drug Discovery (OSDD), a consortium launched in 2007 by India's Council of Scientific and Industrial Research that promotes drug discovery through open source access to underlying information, open licensing practices, and open collaborative methods and platforms to progress projects. As a result of the efforts of OSDD and its partners, there has been a renewed focus on solutions for diseases like tuberculosis and malaria.¹¹ Other examples of this type of approach (details in Appendix) are the transSMART Foundation, Structural Genomic Consortium (SCG), and Asian Cancer Research Group (ACRG).

Different paths for open innovation

Companies should consider tailoring their OI programs along the openness spectrum according to how the five elements of OI help to meet their specific goals and desired outcomes (Figure 6).

Figure 6. Five elements of open innovation

		Element	Description
Operational complexity	1	Network characteristics	<ul style="list-style-type: none"> • Number of network participants (institutions or individuals) • Geographic reach of network (localized or global)
	2	Talent	<ul style="list-style-type: none"> • Relative maturity of capabilities and skills needed (innovative, experimental, and commoditized) • Selection criteria rigor to admit participants into the network
	3	IP management/contracting	<ul style="list-style-type: none"> • Degree of understanding of IP scope and definition • Degree of established rigor around IP management • Formality of the agreement (contractual or trust based) • Flexibility around the outcome of participation (predisposed outcome or adaptive R&D)
Degree of ownership/control	4	Participant impacts	<ul style="list-style-type: none"> • Influence of network participants on innovation activities (setting agenda and direction or providing solutions to pre-defined problems)
	5	Governance	<ul style="list-style-type: none"> • Review and approval of scientific innovation process (flexible or inflexible, bureaucratic or fast, etc.) • IP-related network partner governance processes • Ex-network IP governance

Source: Deloitte Consulting LLP analysis

Network characteristics

An alliance's success at innovating often hinges on network characteristics, including complexity (openness or density and the number of participants) and reach (localized or global).¹² An open network entails loose ties or participants from different sectors/industries whereas a dense network features close relationships among participants (e.g., members within one company or within the same industry sector). Open networks are generally considered more likely to produce radical innovations, while dense networks are more likely to produce incremental innovations. However, an open network is more challenging to manage due to its greater number of participants and their diverse cultural and social backgrounds.

Organizations embracing OI should consider choosing a network structure that aligns with their goals and the type of innovation they wish to drive. Moreover, it is critical to select participating organizations and individuals carefully to assemble complementary skill sets, support cooperation, and make the network attractive to potential future participants.

The Accelerating Medicines Partnership (AMP) is an example of multiple parties coming together for a common goal. The program is a new, \$230 million venture among the National Institutes of Health (NIH), 10 biopharma companies, and several non-profit organizations. It aims to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets of disease.¹³

Talent

Since OI is a multi-disciplinary approach, it requires a variety of talented individuals with a mix of skill sets (e.g., innovative, experimental, and commoditized capabilities) and knowledge. Organizations pursuing OI should consider determining the required number of participants and their level of technical expertise, based on the type of innovation they wish to drive and the anticipated outcome. For example, efforts requiring more subject-specific/knowledge-intensive inputs could be restricted to a small pool of individuals possessing more varied expertise than would typically exist within a single organization. Efforts requiring broader inputs could be open to the whole scientific community or the general public. The input from external contributors should be viewed as opportunities – ways to leverage their knowledge – rather than threats.

IP management/contracting

Moving to OI can create IP-related challenges. For example, which party/parties in a collaborative relationship own the rights to the innovative products that are developed?

OI contracts, similar to other inter-organization contracts, contain a range of clauses that address ownership, field of use, exclusivity, and financial compensation. Reflecting the dynamic nature of OI, the contracts are often valid for a limited time period. For companies adopting OI, it is imperative to define at an early stage how new, jointly created IP will be owned and legal rights maintained. It is equally important to proactively identify exit strategies if goals or milestones are not met. Finally, it is essential to build trust in order to retain existing network participants and attract new ones. Ways to do this include freely sharing information; being transparent about IP management; encouraging the extension of research efforts past the collaboration period by removing restrictions on IP use; and allowing researchers to publish and use results and data.

Participant contributions and impacts

Organizations should consider which potential partners might contribute the most to an OI initiative and what impact each type of partner could have on increasing the chances for successful product development. Participant factors affecting the output of an OI project include partner variety, both in terms of research partners (independent labs, government-run institutions, and academic institutions) and market partners (customers, suppliers, start-ups, strategic alliances, and other value chain participants). Another consideration is which development stages the company wants to collaborate with these partners. For example, Lilly PD2 participants all conduct project research, Lilly tests its assays on the research, and all participants retain autonomy and rights to continued research.¹⁴

Governance

OI network participants may belong to organizations with different structures and goals. Biopharma companies, for instance, are usually managed through a central governance system. Senior management sets individual and organization goals and performance is assessed against each of those goals. In contrast, academic medical organizations may not be used to a top-down management style.

Some OI governance issues that may need to be addressed include ownership and decision rights, issue escalation, organizational structure, resource commitments and potential timing, and termination rights and conditions.

Partners may wish to develop operating procedures that include standards for collecting, storing, and sharing data (including defining standards for data structure and analysis). Establishing clear roles and responsibilities for collaboration team leaders and members for each step of the joint discovery, development, and delivery process are also important.

Essential steps for executing open innovation

Companies looking to start/restart OI projects should consider taking the following steps:



Measure the current state of their existing OI activities against each OI framework element:

- Evaluate the size of the current collaborator network
- Estimate the level of influence that external collaborators have on the R&D process

Develop strategic goals for the future state of OI:

- Analyze trade-offs and select desired OI model configuration
- Align with the company's strategic goals and strategy (e.g., therapeutic area/disease area focus, small vs. large molecule focus, etc.)
- Identify leadership and internal governance model configuration
- Establish culture and incentive structures by which employees are encouraged to innovate by sharing knowledge and resources broadly

Conduct a gap analysis and develop an execution roadmap:

- People and partners – Determine talent requirements (quality and type) and identify internal and external participants
- Process (governance mechanisms to accommodate external collaborators) – Clearly define the selection process, decision rights, and compensation calculations/mechanics
- Technology – Update/implement IT systems to allow secure knowledge-sharing across different sets of collaborators and address international security requirements
- IP – Update systems and draft process guidelines to promote and manage access and equitable sharing of IP with external collaborators

Mitigate execution risks:

- Draft a risk mitigation plan that aligns to the company's strategic goals
- Determine jurisdiction, enforcement, and dispute-resolution mechanisms for existing and/or alleged breaches of IP ownership and/or use
- Pre-configure information security standards and restrictions for internal and external collaborators
- Align internal and external investments around a common outcome that can contribute value to participating parties and help avoid competition within the collaborative environment

Garner leadership support and gain stakeholder alignment to integrate OI with existing R&D initiatives, and strive for consistent success measures:

- Recruit individuals who can build influence, motivation, and trust with leadership to champion OI initiatives
- Identify internal sponsors and external network advocates and establish decision-making authority for OI programs
- Include OI in the official/planned R&D pipeline and company education/communication plans to increase awareness
- Develop performance indicators and success criteria that include recognition of non-financial measures to promote OI activities

The future biopharma landscape: Cooperation becomes key to competition

Several market trends are expected to accelerate biopharma companies' shift to the open end of the OI openness spectrum and usher in an industry landscape with cooperation as the new basis of competition:



Access to ideas becomes central to future innovation

- More companies will likely turn to OI platforms to gain early access to new and diverse ideas. As companies compete for ideas in an open market, the ability to effectively source these ideas, reduce development cycle times, and lower costs may be a distinct advantage.



Funding mechanisms grow more flexible and creative

- Biopharma companies may need to emphasize creative funding criteria and terms to structure innovative deals with investigators and partners. These companies will likely increasingly move away from the existing models used to fund established business units and attempt to keep traditional commercial expectations from being applied to pure OI initiatives.
- The increasing need for certain organizations (start-up firms, academic research centers, and universities) to generate their own funding instead of relying on government grants and public financing sources will likely drive the adoption of OI. Moreover, these organizations might increasingly value the tools, technologies, and experience biopharma companies can bring to a relationship to help partners develop ideas and research for innovative clinical applications.



Leading practices and collaboration tools evolve and gain wider adoption

- OI networks will likely develop new, enhanced tools and standards to share and collaborate on research tasks, lessening the burden of adding new members to networks.

As the life sciences market may shift towards a more cooperative competitive model, biopharma companies that are successfully operating at the open end of the OI spectrum are likely to achieve increased diversity in their R&D asset pool and bring innovative new products to market.

Appendix

Details of companies pursuing collaboration and its variants (type 3 OI):

The **Eli Lilly (Lilly) Open Innovation Drug Discovery (OIDD) program** was conceived to lower the barrier for collaborations between investigators working inside and outside an organization. The program offers participants access to state-of-the-art Lilly science, through two complementary scientific platforms for the identification of novel therapeutics: Phenotypic Drug Discovery (PD2) and Target Drug Discovery (TargetD2). Lilly makes available both TargetD2 and PD2 assays and data at no cost to investigators or institutions to help further research. All generated data and IP rights remain with the investigator or institution. Lilly maintains an exclusive right to negotiate with the investigator for access to the molecules or partner to further advance promising discoveries. If there is no resulting agreement, the investigator is free to use the data to refine a hypothesis, publish, or use in a grant application.^{15, 16}

The **Pfizer Centers for Therapeutic Innovation (CTI) program**, with local centers at each partner site, enables Pfizer and academic teams to work side by side. The focus is discovering and developing biologic therapeutic candidates from research through proof-of-mechanism. CTI funds pre-clinical and clinical development programs and offers equitable IP and ownership rights, as well as access to antibody libraries, screening tools and other proprietary technologies, and provides assistance with pre-clinical regulatory steps. When programs are successful and advance, according to the terms determined by a joint steering committee, Pfizer grants milestone payments and royalties.¹⁷

The **AstraZeneca (AZ) Open Innovation Platform** provides a simple but robust process for AZ to link its own staff's expertise, experience, resources, and technology with those of external experts and to explore prospective partnerships. For collaborators, AZ offers a chance to "access optimized compounds, compound libraries, technologies, multi-disciplinary science, services, and know-how, with the prospect of joint publications in high profile journals and, most importantly, the opportunity to see their ideas develop into treatments for patients," thus building a win-win partnership.¹⁸

The **Sanofi Access Platform** allows the company to collaborate with partners from academic and private organizations to translate innovative compounds/biologics

into leads/tools compounds with clear therapeutic tracks. It provides partners with access to its expertise in drug discovery and development (assay development, screening, hit identification/optimization) and Access Platform sites (Strasbourg FR, Tucson US, and Asia). Sanofi aims to capture early innovation and lower the risk in opportunities over a short timeline; it assesses ideas based on the probability of their success. Joint inventions are co-owned. Promising results can lead to options or license agreements; if Sanofi does not take the option, the collaborator can partner with another party.¹⁹

Details of organizations pursuing open source (type 4 OI):

The **transSMART Foundation** is a public-private partnership (PPP) that spans the United States and the European Union, including talent from biopharma companies, and non-profit, academic, patient advocacy, and government organizations.²⁰ The open source transSMART platform provides researchers with a single self-service portal combining diverse types of data from internal and external sources with flexible search capabilities and analysis tools. The organization and access to clinical and research data within the transSMART platform permits users to explore data efficiently to formulate new research strategies.²¹

The **Structural Genomic Consortium (SCG)** provides open source access, public-private partnership comprising 20 research groups with a primary focus on pre-competitive structural biology research (determining 3D protein structures) and an emerging secondary focus on chemical probes and antibodies, and epigenetics research. All research outputs are openly available to the scientific community. The open collaborative network includes scientists in hundreds of universities around the world as well as nine global pharmaceutical companies.²²

The **Asian Cancer Research Group (ACRG)** is an independent, not-for-profit company established jointly by Eli Lilly, Merck, and Pfizer to accelerate pre-competitive, collaborative research on the cancers prevalent in Asia. ACRG provides open source, comprehensive genomic data sets with the scientific community to accelerate drug discovery efforts.²³

Endnotes

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Authors

Ralph Marcello

Principal
Life Sciences & Health Care
Deloitte Consulting LLP
rmarcello@deloitte.com

Glenn Carroll

Senior Manager
Life Sciences & Health Care
Deloitte Consulting LLP
gcarroll@deloitte.com

Gaurav Vadnerkar

Assistant Manager
Deloitte Center for Health Solutions
Deloitte Support Services India Pvt. Ltd.
gvadnerkar@deloitte.com

Adam Volini

Senior Consultant
Life Sciences & Health Care
Deloitte Consulting LLP
avolini@deloitte.com



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Harry Greenspun, MD
Director
Deloitte Center for Health Solutions
Deloitte Services LP

Sarah Thomas, MS
Research Director
Deloitte Center for Health Solutions
Deloitte Services LP

555 12th St. NW
Washington, DC 20004
Phone: 202-220-2177
Fax: 202-220-2178
Toll free: 888-233-6169
Email: healthsolutions@deloitte.com
Web: www.deloitte.com/centerforhealthsolutions

Deloitte Center for Health Solutions

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