A NEW CHAPTER IN INNOVATION

A growing appreciation that cooperation and competition can coexist is transforming the life-sciences innovation landscape. Development was once shrouded in secrecy, but now organizations are coming together. By David Holmes; illustration by Mohamed Ashour.

STRAIGHT PATHS OF OLD

Historically, life-sciences partnerships were linear and closed in nature. The conception, development and delivery of therapies was handled separately — the involvement of one partner ending as that of another began.

This arrangement had its advantages. Risk and reward increased as the drug moved down the chain. But the lack of dialogue with the wider community could often result in costly duplications of effort.

US\$2.6 billion

Average pre-tax cost per approved drug, including cost of failures¹

MOORE PROBLEMS

The number of drugs approved by the US Food and Drug Administration (FDA) per billion US dollars spent on research and development (R&D) has halved roughly every 9 years since 1950 — seemingly the opposite of Moore's law (Gordon Moore, co-founder of technology company Intel, observed that the number of transistors that can be placed, inexpensively, on an integrated circuit doubles every 18–24 months)². In an effort to defy 'Eroom's law', organizations have been forced to search for ways to boost returns on investment.

SQUEEZED MARGINS

Increasing R&D costs and competition from drugs that are no longer covered by patents have squeezed the margins of the conventional linear innovation model.

INCREASING INFORMATION

As researchers better understand the biological complexity of targeted diseases, and the technological complexity of drug discovery and the size of data sets increase, organizations are becoming more reliant on outside expertise.

UNMET NEEDS

A conventional closed model of innovation is unsuitable for some medical needs, such as the development of antimalarials or Ebola vaccines.

A GROWING MOVEMENT

In response to the limitations of the closed model of innovation, a growing number of organizations have come together over the past two decades to share ideas, data and tools with each other, and often with the wider community.

OPEN TO INTERPRETATION

According to Google's Ngram Viewer, which shows the relative frequency with which certain words and phrases are published, the phrase 'open innovation' gained prominence in the English language in 2003 — the year that business specialist Henry Chesbrough, now at the University of California, Berkeley, used it to describe the concept that companies should use external ideas as well as internal ones to advance their technology. But open innovation is just one of the terms that seeks to capture different, but overlapping, themes of openness in the broader innovation ecosystem.

OPEN SOURCE

Pioneered by the software-development industry, open-source projects make the fruits of open collaboration free to everyone, with little or no direct profit for the collaborators.

OPEN DATA

The Open Data Institute in London describes open data as data that anyone can access, use and share.

OPEN ACCESS

Open access was a major shake up to the conventional publishing model. Literature is digital, online, free at the point of use and usually free to reproduce in some form.

OPEN SCIENCE

Open science is the practice of science such that others can contribute. Lab notes are freely available, and the research and its underlying methods can be shared.

DEGREES OF OPENNESS

Whether or not a collaboration qualifies as an example of open innovation can be subjective, but criteria (**pictured**)³ devised by the Wellcome Trust in London can be used to categorize collaborations. It is generally agreed that the ideal open initiative would be a broad collaboration with public participation through all stages of innovative development, resulting in an output that is free to all.

Whom a collaboration is open to can vary, from an internal collaboration within an organization to a project fully open to anyone.

PARTICIPATION

- Open to the public 5
- International collaborations with multiple partner types 4
- Multiple partner types in a similar geography or limited number of international partners 3
- Limited number of partners (<10) within a similar geography 2
- Internal collaboration within a single organization 1

- Narrow focus within a single R&D stage (usually very early stage) 1
- Focus on early conceptualization (proof of mechanisms) 2
- Pre-clinical or clinical studies (not both) 3
- Pre-clinical and some clinical studies 4
- Pre-clinical, clinical and commercial development 5

SCOPE

Openness can vary depending on the stage of the development process. Some projects are open until clinical studies begin, at which point access to data becomes tightly controlled. Open collaboration in other projects may persist through to final release.

CASE STUDIES

DIVISION OF SIGNAL TRANSDUCTION THERAPY

Industry researchers work with academics at the University of Dundee, UK, to understand the fundamentals of protein phosphorylation and ubiquitylation. The six participating pharmaceutical companies have access to unpublished results, technology and first rights to license intellectual property.

OPEN SOURCE MALARIA

The project takes promising public domain compounds and refines them for clinical trials. Anyone can contribute and all experimental data are shared in near-real time. E-mails are discouraged, with contributors instead urged to communicate on public discussion boards.

STRUCTURAL GENOMICS CONSORTIUM

The consortium is a public-private partnership that aims to catalyse drug-discovery efforts by determining the structure of potential drug targets. The structures are then released to the public, but no data are made available before then.

Individual partner retains their intellectual property

Intellectual property is shared and retained within the partnership

Intellectual property generated before and as a result of the partnership is shared within the partnership only

Some of the resulting intellectual property is protected and made available to the public

A completely open approach is adopted in the partnership

ACCESS

For many, the right to access the fruits of a collaboration is central to whether it can be considered open. In some cases, individual partners retain intellectual-property rights, whereas in others results are made available to all.

Sources: 1. Tufts Center for the Study of Drug Development; 2. J. W. Scannell *et al.* *Nature Rev. Drug Discov.* **11**, 191–200 (2012); 3. R. Pigott *et al.* Shaping the Future of Open Innovation (Wellcome Trust, CASMI & Kinapse, 2014).