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*Published in:*
Drug Discovery Today

*DOI:*
10.1016/j.drudis.2018.01.002

*Publication date:*
2018

*Document version*
Publisher's PDF, also known as Version of record

ELSEVIER

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# Unlocking the full potential of open innovation in the life sciences through a classification system

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**A common understanding of expectations and requirements is critical for boosting research-driven business opportunities in open innovation (OI) settings. Transparent communication requires common definitions and standards for OI to align the expectations of both parties. Here, we suggest a five-level classification system for OI models, reflecting the degree of openness. The aim of this classification system is to reduce contract negotiation complexity and times between two parties looking to engage in OI. Systematizing definitions and contractual terms for OI in the life sciences helps to reduce entry barriers and boosts collaborative value generation. By providing a contractual framework with predefined rules, science will be allowed to move more freely, thus maximizing the potential of OI.**



## Introduction

OI holds much promise as a new business model for collaborative value creation in the life sciences [1]. From a corporate perspective, benefits include faster access to new relevant technology; the opportunity for biotechs and small–medium-sized enterprises (SMEs) to explore new market opportunities; improved identification of relevant licensing partners; and boosted value creation. It is no longer possible to look at innovation as an isolated in-house event. Instead, creating new value by innovation has become an increasingly complex process involving knowledge flows across the entire ecosystem [2]. The need to put such policies into practice is also acknowledged by public–private partnerships, such as the Innovative Medicines Initiative (IMI) exploring new models for collaborations (www.imi.europa.eu).

OI enables more-efficient dialog between early- and late-stage research organizations so that relevant matchmaking can occur more often, faster, and more easily, by sharing needs for innovative solutions and reducing traditional barriers during the exploration phase.

For this to happen, a common understanding of expectations and requirements is critical for truly boosting the identification of research-driven business opportunities. Transparent communication requires a common definition and standard for OI, to align the expectations of both parties.

Here, we suggest a five-level classification system for OI models, reflecting the degree of openness. The aim of this classification system is to reduce contract negotiation complexity and times between two parties looking to engage in OI, to systematize definitions and contractual terms for OI in the life science industry, reducing entry barriers, and boosting explorative collaborations. This classification system is derived from the pharmaceutical industry perspective and the corporations usually responsible for dictating the legal and business framework regarding intellectual property (IP) rights, business terms, conditions, and confidentiality. The need to align the conditions of interacting under the OI banner comes from an increasing, but greatly varying, interpretation in the pharmaceutical industry. The intention is to provide a starting point for clear and transparent conditions when either providing an OI platform for the pharmaceutical industry, or


https://doi.org/10.1016/j.drudis.2018.01.002


**FIGURE 1**

Appearing open for business might be attractive from an outside perspective, but often there are limiting and greatly varying conditions. To align expectations and fully unleash the powers of open innovation, a standardized definition of openness is required.



engaging with such as a private or public research institution.

## The difference OI can make for life science and pharmaceutical research

When implemented broadly in the life science ecosystem, OI allows research knowledge and technology to flow more easily between parties, enabling need-based matchmaking. Standardized OI creates a precompetitive infrastructure that will in turn boost the ability of all parties to explore opportunities [3]. Sourcing external innovation in life sciences often improves the chances of getting a drug or technology to market [4].

However, both the perception and the implementation of OI vary greatly and, to avoid confusion, we suggest a terminology standard for these types of collaboration [5]. For this, we need to first define the framework, the language we use, and the rules of engagement. When the claim 'We do OI in life science' is made, it must be clear what that entails, from both perspectives; inbound (seeker, often a larger pharmaceutical corporation) and outbound (provider, often a biotech company or a university). Contractual negotiation is the single-biggest hurdle when trying to establish a collaboration [6], but by providing transparent and aligned contractual terms for OI, we can spend less time and fewer resources negotiating contracts, instead focusing on the scientific collaboration itself and enabling OI to happen.

Typical questions that might arise in an OI setting are those related to the contractual framework, such as: who owns the data generated (IP rights)? Will a party claim rights to pursue further (business terms)? Are some aspects not disclosed (confidentiality or trade secrets)? Is the proposal subject to scrutiny before being explored (restraints)? The potential answers and, hence, the contractual conditions can vary greatly, as can the expectations when engaging in OI. Although it will be impossible for us to delve deeper into legal details in this short contribution, it is clear that negotiations can be reduced if a quick alignment can be established by pointing out what 'openness' in fact refers to when exploring OI (Fig. 1).

## Terminology used when referring to openness

Although the idea of working openly with external partners is older, the first attempt to define OI was proposed by Henry Chesbrough in 2003 [7]. The concept of OI is strategic, but the implementation can be considered an operational tool or new business model.

To establish a common standard terminology, a few frequently used terms must be defined, because they are occasionally used with different meaning and expectations. These definitions are based on the perspective that a larger corporation is seeking innovation by engaging in collaboration with external partners in OI. A quick definition of each is provided in Table 1.

So, is it open or not? Here, we suggest that to be labeled OI, the basic requirement is that specific details are revealed to a greater extent than required for traditional outsourcing. This could refer to disclosure of the problem, or sharing both the risks and potential benefits.

The general definition of 'open source' involves public disclosure of underlying protocols, methods, and processes, which are also often jointly developed. For pharmaceutical research and development (R&D), the definition typically refers to full description of the methodology or protocol(s) made available for anyone to reproduce, copy, or develop. The purpose is to reach out and create a potential scientific overlap between two parties, to explore otherwise nonobvious ideas.

**TABLE 1**

**Definitions of terminology related to openness in life science R&D**

| Open terminology in relation to life science R&D | Brief definition from innovation seeker perspective | Brief definition from innovation provider perspective |
|---|---|---|
| OI | Disclosing needs for innovation or problems and sharing risk and benefits | Insight to what solutions will create value with a partner |
| Open source | Methods are openly shared to enable practical use and further development by others | Possibility to develop technology toward tangible value creation |
| Open science | Sharing of scientific rationale of strategic interest for others to explore intellectual overlaps | Identification of relevant science that is of relevance to a partner |
| Open access | Unbiased access to resources allowing external exploration of nonobvious solutions | Opportunity to test assets with potential partner exploring new possibilities |
| Open data | Release of scientific data without restrictions on use, enabling reanalysis | Chance of combining others' data sets to increase relevance with own assets |

**TABLE 2**

**Defining levels of openness in life science research collaborations**

| Degree of openness | Disclosing innovation need | Open access to resources | Open science, open source | No terms or commitment | Open data, waived rights |
|---|---|---|---|---|---|
| Not open | – | – | – | – | – |
| Level 1 | X | – | – | – | – |
| Level 2 | X | X | – | – | – |
| Level 3 | X | X | X | – | – |
| Level 4 | X | X | X | X | – |
| Level 5 | X | X | X | X | X |

'Open science' for pharmaceutical R&D represents the disclosure of theoretical and scientific rationale. The purpose is to share underlying science knowledge and grant external partners access to rationales to facilitate the identification of intellectual overlaps that could be jointly explored.

The ability to freely, without cost, retrieve or use published material, tools, resources, or knowledge is referred to as 'Open access'. In a pharmaceutical R&D setting, 'open access' is proposed to refer to 'unconditional access to otherwise and traditionally restricted resources, tools or knowledge'. The 'unconditional' access should be seen within practical limitations, but importantly, this removes a biased selection of how such resources are used by external parties.

'Open data' means providing access to, and use of, generated data that are stored publicly and are openly available for independent analysis. For pharmaceutical R&D, 'open data' refers to sharing results and data openly without any restrictions on use. External partners are invited to use the results or reanalyze the raw data to explore new and yet unknown possibilities. From a practical perspective, it is usually recommended to apply an open data license even though the intention is for the data to be in the public domain. This is to avoid confusion and make it clear for the user that the data in fact are available and open for any usage. The Creative Commons CC Zero (CC0) license is an example of such an open data license that waives all rights.

## Levels of openness: classification based on contractual framework

The intention of this classification system is to provide a reference point of what to expect from OI, both for seekers and providers of innovation. The classification system is intended as a first step towards a standardization, but might require some modification for broader implementation. The level going from one to five should not be seen as the higher the better, but instead reflects a difference and wider degree of implemented openness. Also, the reason behind the use of OI might not require more than, for example, a third level of openness. A summary of the five different levels of OI is provided in Table 2.

### Open innovation Level 1: disclosure of needs with shared risk and benefits

This is the entry level of implementing OI by allowing external partners insight into an innovation need or goals, sometimes in the form of a challenge or a request. Note that more-traditional external collaborations, such as contract research, are not classified as OI because they lack the 'openness' from the external perspective (the solution providers). The difference, and a critical parameter, for the OI definition is that some parts or details are openly disclosed, asking for a solution from an unspecified party.

Opportunity for innovation seekers include the identification of new solutions to old problems, or new theoretical ideas and concepts that are not restricted or biased to the tradition, mind-set, culture, capabilities, or history of a corporation. By contrast, opportunities for innovation providers include the possibility to identify and provide new partners with solutions that they otherwise would not ask for.

Limitations or risks to this approach include the isolation of a specific problem or detail limiting the scope of innovation, or that disclosure of details and aims reveals strategic interest or direction.

An example of OI Level 1 is the challenger from Novo Nordisk to discover a small-molecule glucose binder on a third party crowdsourcing platform (https://www.innocentive.com/ar/challenge/9933823). The request is for an external party to submit a molecule with documented effects. The openness is based on the disclosure of the need for such a solution together with an invitation to unknown external parties to participate. The use of third-party innovation brokers can increase the chances for an organization to identify novel solution opportunities, which is one of the great benefits of OI for both parties and highlights the difference from traditional outsourcing.

### Open innovation Level 2: open access to tools, resources, or competencies

In Level 2, the specific OI platform offers something more to engage with external partners and explore new opportunities. A typical example is a pharmaceutical company offering external parties access to specific resources or assets, such as a collection of molecules. This effectively creates a (one-way) extension of the research of the company by allowing others to explore novel science and opportunities. This level of openness is regularly accompanied by an agreement from the external innovation provider to waive any rights to novel IP. Hence the provider of the Level 2 OI platform claims the right to explore possible outcome, often in the form of first right of refusal.

Opportunities for innovation seekers include the fact that shelved projects can create value for someone else, more science and additional data sets can be generated externally, and new future collaborations can be seeded. By contrast, opportunities for innovation providers include access to unique tools and resources, possibility to find collaboration opportunities with a new partner and widen the scope of scientific involvement.

Limitations or risks involve the fact that avoiding potential disclosure to competitors is sometimes accomplished by limiting the offered resources to nonbusiness critical tools. However, this will also more likely result in new inbound opportunities that are not relevant. This becomes a problem if the external party expects mutual interest.

An example of an OI Level 2 is Eli Lilly's OI platform for compound screening (https://openinnovation.lilly.com/dd/what-we-offer/screening.html). This resource is freely available

and anyone can submit molecules to be tested in undisclosed biological models.

### Open innovation Level 3: open science and open source

The methodology and underlying science is disclosed so that external parties can suggest new and relevant opportunities. In addition to disclosing a request openly (Level 1) and supplying open access to tools for external partners (Level 2), the third level of OI involves the detailed disclosure of the science or methodology, allowing external partners to fully understand the underlying rationale of the innovation seeker. This is critical if the full potential of OI is to be achieved. Offering collaborative research tools (Level 2) without disclosing the science behind can result in novel opportunities, but only by chance, whereas Level 3 open science/source ensures that external parties can contribute with rational ideas. By being more transparent and providing open science, potential partners can participate in 'sense making', which is becoming increasingly difficult as the amount of external data and information grows exponentially.

The opportunities for innovation seekers include the increased chance of unexplored ideas suggested by independent external parties, whereas those for innovation providers include the fact that it will be easier to create a relevant outreach to a potential partner by understanding the science behind value creation.

Limitations or risks involve the fact that scientific information and methodology is often considered 'business critical' and it is thought that disclosing such information could benefit competitors. However, by doing so, the potential gain can be larger in the form of opportunities that otherwise would not be identified.

An example of an OI Level 3 is AstraZeneca OI offering access to their clinical compound bank (https://openinnovation.astrazeneca.com/preclinical-toolbox.html). Available resources that are also described in detail add open science to this OI model, although there are business terms with limiting conditions.

### Open innovation Level 4: no business terms or commitment

To encourage participation and reduce the hurdle of exploring scientific overlaps, it is important not to impose premature restrictions or business constraints. Such terms are suited for work with a predictable outcome, but not to explore completely novel opportunities. However, given that being able to patent is often a critical aspect of the pharma business model, giving up business terms is hard because one effectively relinquishes control. Nevertheless, it is equally important to realize that, after an initial and open exploration phase has been achieved, the continuation can be more traditional, with confidentiality and patentability.

Opportunities for innovation seekers include motivating new partners that normally would not engage. By removing terms, the initial focus is on creating a joint science-based data set without spending time and resources on business and legal conditions. More, novel, and diverse opportunities can enter the OI platform and serendipity can be promoted.

By contrast, opportunities for innovation providers are similar to those for the seekers: removing early business terms is an enabling factor that will allow for exploration of multiple opportunities. Also, a small company can explore several opportunities when not being limited by exclusivity or the first-right-to-negotiate term.

Limitations or risks include the fact that an external party can walk away from an interesting opportunity. The worst-case scenario is that internal resources are spent to create value for a competitor but the alternative is that the external party would still go to the competitor and one would not know about it. If this risk is accepted, the barrier of engagement is significantly lowered.

An example of an OI Level 4 is LEO Pharma OI, where no limiting business terms or acceptance criteria are applied during the initial exploration phase and where scientific resources and rationale are openly disclosed (http://openinnovation.leo-pharma.com).

### Open innovation Level 5: open data

This is the most-advanced model in the degree of openness. First, to be classified as Level 5, an OI platform most also exhibit all the features of Levels 1–4. At this level, the generated data are made publicly available to all through open data. This set-up embraces full participation in the life science ecosystem and can equally benefit someone external to the partnership. Both partners must agree to this level of openness because generated data will be publicly disclosed and made available without any restrictions on usage. The fundamental realization is that completely novel and unpredictable innovation will come your way as you share everything openly. By sharing obstacles, methods, data, and desires willingly, one maximizes the potential and speed of an idea.

Opportunities for innovation seekers include the fact that full openness maximizes the identification of nonobvious opportunities and collaborations to enable orthogonal innovation. Innovation that you did not even know about or to ask for, can find its way to you, potentially creating new value. By contrast, opportunities for innovation providers include the possibility, without risk and commitments, to explore overlapping assets and identify completely new opportunities to create business value.

As limitations or risks, there will be no, or limited options for filing patents because new findings will be public knowledge or obvious. Anyone can use the generated results, including competitors. There is no clear return of investment and no control of IP rights.

Examples of OI Level 5 include the Structural Genomic Center and the Open Source Malaria program, which both openly share protocols and results, inviting others to participate (http://opensourcemalaria.org). The main driver is the progression of science and health, not primarily commercial interests.

### Concluding remarks

It is important to realize that all external innovation does not have to be OI. However, when OI is claimed, it should be clear what it in fact means, for both parties. As collaborations become increasingly important to advance and translate research, as well as staying competitive, we need to facilitate how two parties identify and establish mutual interests. OI is a business model that utilizes transparency to allow exploration and increase engagement by reducing limiting business terms. The degree of openness is herein suggested to be classified and aligned across parties for an upfront recognition of how open an initiative in fact is. With a joint classification system, fewer resources are spent on negotiating contracts and more-collaborative research can performed.

The suggested definitions are intended as a first initiative to standardize expectations and the practical implementation of OI, to boost exploratory and precompetitive collaborations. We realize that there are many individual and specific needs and concerns relating to such definitions. We also recognize that standardization might entail risks and that it is not always the most-feasible way forward where curtailed solutions are required. Moreover, it is clear that other important aspects of the innovation ecosystem, such as business behavior and the legal frameworks pertaining to IP protection and governance, and safety regulations, should be carefully considered and aligned with any standardization and OI initiatives [8,9]. This also includes the potential application of emerging

big data, artificial intelligence technologies, smart contracts and blockchain technology. Hence, we encourage a continued discussion to further improve the implementation of the classification system describing the five levels of openness in life science R&D.

The common classification system for OI in life sciences will provide a contractual framework with predefined rules of engagement that will allow science to move more freely, thus maximizing our joint potential to improve health and lives for all.

**Acknowledgment**

This work was produced in collaboration with the Innovation & Funding Models Work Group of EBE, the European Biopharmaceutical Enterprises. Timo Minssen is Director of the Centre for Advanced Studies in Biomedical Innovation Law at the University of Copenhagen (CeBIL). CeBIL's research is supported by a Novo Nordisk Foundation grant for a Collaborative Research Programme (grant agreement number NNF17SA027784).

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