Teaser This article provides a framework for evaluating the effectiveness of the Lilly Open Innovation Drug Discovery program and proposes a global leading indicator dashboard incorporating qualitative and quantitative metrics.

Measuring the effectiveness and impact of an open innovation platform

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Today, most pharmaceutical companies complement their traditional R&D models with some variation on the Open Innovation (OI) approach in an effort to better access global scientific talent, ideas and hypotheses. Traditional performance indicators that measure economic returns from R&D through commercialization are often not applicable to the practical assessment of these OI approaches, particularly within the context of early drug discovery. This leaves OI programs focused on early R&D without a standard assessment framework from which to evaluate overall performance. This paper proposes a practical dashboard for such assessment, encompassing quantitative and qualitative elements, to enable decision-making and improvement of future performance. The use of this dashboard is illustrated using real-time data from the Lilly Open Innovation Drug Discovery (OIDD) program.

Introduction

The concept of Open Innovation (OI) was first coined by Henry Chesbrough [1] to describe the paradigm by which enterprises allow free flow of ideas, products and services from the outside to the inside and vice versa in order to remain competitive, particularly in rapidly evolving fields where there is abundant, relevant knowledge outside the traditional walls of the enterprise. Initially, this idea was applied to the emerging realms of computer hardware and software, but since then it has spread to a number of areas in industry, academia and government. According to Chesbrough, there is a continuum from fully open to fully closed enterprises, with the degree of openness depending upon a number of internal and external factors affecting that particular enterprise, including intellectual property (IP) and level of regulation [1]. Today, not only has research and publication into the topic of OI grown exponentially, but typical OI methodologies – including idea competitions, customer immersion and crowdsourcing – are routinely understood and leveraged to seek, refine and spur innovation in a variety of industries [2]. However, given its complexity, highly regulated environment, and reliance on IP concepts [3–7], the Pharmaceutical industry has been relatively slow to adopt OI approaches, particularly in the R&D arena.

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http://dx.doi.org/10.1016/j.drudis.2017.01.009

Notwithstanding the undeniable barriers to implementation of OI methodologies in pharmaceutical R&D, the literature seems to indicate a shift from the debate around the concept of OI to focus instead in the discussion of actual examples of OI approaches. These approaches were developed by different research institutions worldwide with an emphasis on the description of collaborative models that have shown a certain level of success, and the analysis of the best practices underlying such emerging models [8–12]. At its core, this shift accentuates the significant pull for change driven by the well-known shortcomings of the traditional, closed model for pharmaceutical R&D, paired with the actual usefulness of OI models when correctly deployed and implemented. It could be argued that the recent proliferation of OI approaches in pharmaceutical R&D is actually a manifestation of the inherent openness of the scientific discovery process, and that the implementation of OI methods in pharmaceutical R&D is no longer a philosophical problem of '*whether to do it*' but instead becomes a logistical problem of '*how to do it*' [11,12].

One way to understand the apparent paradox between the difference *and* complementarity of traditional closed versus OI models in pharmaceutical R&D is to consider that the long-term objectives of both approaches are actually the same – that is, the successful production of new medicines. The main contrast between the two approaches can then be described in terms of different short-term goals and tactics to achieve this end. Thus, the traditional closed innovation model generates, refines and develops all inputs, ideas and hypotheses inside the organizational walls. In contrast, the OI models seek to enrich the *diversity* of available options by incorporating external inputs, ideas and hypotheses and by possibly refining and developing them internally *and* externally. Secondly, organizations large and small may not have all the expertise they need within their walls to resolve a particular challenge. In this manner, OI programs attempt to leverage external parties to develop a large, broad pool of opportunities and talent *complementary* to those available internally. Likewise, while traditional R&D concentrates on the systematic prioritization of internal opportunities to focus on those options that survive the internal decision-making funnel, open innovation casts a wider net to capture the largest possible library of options *before* the utilization of prioritization and selection mechanisms that help to focus on the most interesting or promising opportunities. Finally, traditional innovation flow tends to be depicted as a linear process, whereby promising opportunities move forward and others get put back on a shelf; open innovation requires an iterative process in which inputs may be continually screened and recycled in future searches [13].

Moreover, the efficiency of the traditional R&D paradigm tends to be measured using long term economic indicators (such as number of IND/launches, or cost per IND/launched medicine) that rely on retrospective historical analyses that incorporate the entire R&D process from idea inception to commercialization [14–16]. In contrast, the evaluation of OI models used in early drug discovery struggles to benefit from such historical analyses given (a) the relative novelty of the models and (b) the difficulty of segregating the contributions of internal versus external inputs with respect to the outcomes of the enterprise at large. More importantly, we argue that macroscopic, retrospective and economic leading indicators traditionally used to measure R&D productivity provide an *inadequate* way of measuring the efficiency of the early phases of drug discovery in general and of OI approaches in particular.

The pharmaceutical R&D process

The pharmaceutical R&D process is generally depicted as a series of sequential stages progressing in linear fashion from hypothesis generation and validation through identification of a clinical candidate, followed by clinical development and finally commercial distribution [15]. While the overall process can be understood as linear, there is a clear inflexion point at Candidate Identification (CI) with a marked differentiation between phases *before and after CI*, with respect to the types of activities implemented and the manner in which progress is achieved [Chart 1].

The R&D process after CI is focused on collecting, understanding and leveraging vast amounts of information about a single molecular entity that is considered competent to test the clinical hypothesis in humans, followed by the careful design and implementation of the clinical experiments required to demonstrate its safety and efficacy in the clinical setting. Thus, development activities *after* CI are indeed linear and sequential, defined by pre-established protocols and subject to high levels of external regulation and therefore data collection. Performance metrics usually chosen to evaluate the pharmaceutical R&D process in its entirety often emphasize the post-CI phase and are focused on clinical success/attrition, overall published costs and dates, and other public domain or retrospectively collected information which more or less aims to describe the progress of a single Candidate Molecule from its identification as such to its approval for distribution as a medicine [14–16].

In contrast, the *R&D process before CI* takes place iteratively through the repetition of a series of 'design-test-analyze' learning cycles fueled by the constant evaluation and prioritization of thousands of distinct molecular entities undergoing biological tests which are carefully designed and selected to provide some sort of indirect indication of future clinical relevance. At this stage, there are massive amounts of information collected on many new molecular entities, but relatively little is known about each one – and rarely does one single chemotype follow a linear path of progression to the end game [17,18]. The process through which diverse chemotypes are evaluated, prioritized and refined – while at the same time probing the biological system of interest – is labyrinthine, fraught with detours and dead ends. The overall goal becomes the generation and incorporation of all information into progressively *better biological understanding and better structural designs* that are capable of regulating the system in a manner that is most consistent with the underlying clinical hypothesis. Thus, the exercise of calculating leading indicators of success or process performance at this time counts with the unavoidable difficulties that (a) the process has an inherently cyclical nature, and (b) the actual chemical entity that may eventually reach clinical development is not yet known, nor are its properties. Meaningful metrics must then be capable of estimating the *efficient transmission of information to enable option prioritization with minimal possible investment*, regardless of the final outcome.

How should OI models be measured?

Open innovation approaches in pharmaceutical R&D are quite varied, based on the details of execution and/or implementation