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Author: Alexander Schuhmacher Paul-Georg Germann Henning Trill Oliver Gassmann

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Models for open innovation in the pharmaceutical industry

Alexander Schuhmacher[1], Paul-Georg Germann[2] Henning Trill[3] and Oliver Gassmann[4]

[1]Reutlingen University, School of Applied Chemistry, Alteburgstrasse 150, 72762 Reutlingen, Germany
[2]Takeda Pharmaceuticals International Inc., Byk-Gulden-Str. 2, 78467 Konstanz, Germany
[3]Bayer Business Services GmbH, Gebäude B151, 51368 Leverkusen, Germany
[4]University of St. Gallen, Institute of Technology Management, Dufourstrasse 40a, 9000 St. Gallen, Switzerland
Corresponding author: Schuhmacher, A. (alexander.schuhmacher@reutlingen-university.de).
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Teaser: As open innovation has proven to be of significant interest for the pharmaceutical industry, the new innovation model '*knowledge leverager*' supports the adaptation to a more open approach of pharmaceutical R&D.

The nature of the pharmaceutical industry is such that the main driver for its growth is innovation. In view of the vast challenges that the industry has been facing for several years and, in particular, how to manage stagnating research and development (R&D) productivity, pharmaceutical companies have opened their R&D organizations to external innovation. Here, we identify and characterize four new types of open innovator, which we call 'knowledge creator', 'knowledge integrator', 'knowledge translator' and 'knowledge leverager', and which describe current open R&D models.

Pharmaceutical companies are among the top investors in R&D worldwide [1,2]. The R&D-based pharmaceutical industry spends annually over US$100 billion on R&D , with top investors, such as Novartis and Roche, investing US$8–9 billion annually [3].

High attrition rates and the long development times translate into high R&D costs per new molecular entity (NME), ranging from US$1.24 billion to US$1.32 billion and might even be higher if adjusted for post-approval costs or inflation [4–7]. It has been reported that increasing costs of funding clinical studies, as well as a trend towards more personnel in R&D functions, are surrogates of the increasing R&D costs [8]. There is also evidence that a focus on chronic diseases, as well as mergers and acquisitions (M&A), might have affected negatively the overall costs and performance of pharmaceutical R&D [9,10].

Over the past few years, the number of NMEs approved by the US Food and Drug Administration (FDA) has been stable, with an average annual approval rate of 21.8 NMEs [9,11,12], which is below the NME rate required to generate sufficient growth for the whole industry. Thus, it has been reported that the innovative capacities of the established R&D model of the pharmaceutical industry are at their limits and that the industry uses non-NME filings as another source for revenues and profits [6,8].

Ways out of this current productivity crisis are being sought and might comprise better understanding of the biology underlying diseases, better validation of drug targets, or the use of biomarkers and companion diagnostics. Although these scientific advances are awaiting a breakthrough, pharmaceutical companies have changed their business models, consolidated via M&A, increased partnerships, outsourced information technology, back-office and R&D functions, or reorganized their entire R&D. To improve their return-on-investment, companies have also re-evaluated their R&D strategies.

Open innovation in the pharmaceutical industry

In 2003, Chesbrough published for the first time a shift in innovation paradigm from primarily inside-driven 'closed innovation' to 'open innovation', a business model that uses internal and external ideas to generate value [13]. With respect to the pharmaceutical industry, increased complexity, new technologies, the availability of highly qualified experts outside the traditional pharmaceutical companies and the increased pressure on time and cost might have advanced the development of open innovation. Today, multinational pharmaceutical companies have started to realize the full potential of open innovation as they have begun to harness external sources of innovation by accessing ideas, technologies and R&D projects [14]. For example, companies are complementing internal project portfolio gaps through licensing and acquisition of drug candidates or acquisition of entire companies (Table 1). Pharmaceutical companies also access external know-how by outsourcing, either to fulfill the demand of reduced development times and costs, or to access external knowledge and know-how that companies do not have or (strategically) do not want to have within their organizations.

At the same time, some pharmaceutical companies have aligned their organizational structures to access external innovation more efficiently. In 2007, GlaxoSmithKline (GSK) launched its Center for Excellence for