
Innovation indicators for the Pharmaceutical Industry: Patents and Clinical Trial

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Abstract: This study analyzes the use of patents and clinical trials as indicators of innovation in the pharmaceutical industry. Innovation is presented as a complex and non-linear process, based on the interaction between multiple actors and the conversion of knowledge into practical applications. Drug development involves costly and risky steps, especially in clinical trials, which act as bottlenecks but also as collaborative networks and sources of continuous evidence. Patents, in turn, act as technological indicators and economic instruments, allowing for protection, value capture, and competitive advantage. The systematic review identified four main axes: innovation as a complex system, the role of knowledge, the economics of innovation, and the use of data. It concludes that the combination of patents and clinical trials offers a more complete view of the technological trajectory, highlighting gaps and opportunities for future research.

Keywords: Pharmaceutical innovation; Patents; Clinical trials; Innovation management; Technological development

1 Introduction

The innovation capacity of companies shows a growth curve and relevance for the accumulation of intangible factors such as technology and knowledge, since these assets promote constant changes in organizations and assist in adapting to unstable markets (Cohen and Levinthal, 1990). The ability to create new knowledge from the exploration of the diversity of complementary skills that can be used, inside and outside the organization, constitutes an important competitive advantage (Carayannis, 2008; Bolade, 2022). Innovation can therefore be understood as a multidimensional process, associated with the convergence of complementary knowledge, interaction processes and mechanisms to support cooperation in specific contexts (Basso, 2019).

In the pharmaceutical industry, new products begin in the discovery phase. Researchers detect new chemical entities and subject them to various studies to be discarded or improved into a promising substance (Malerba and Orsenigo, 2002; Ornaghi, 2009).

Thousands of components can be potential candidates for drug development, but after preclinical trials, only a small number appear promising for further study (FDA, 2017). The fact that this process is complex and costly demands a strong national ecosystem so that research conducted at universities and research centers can be tested and commercialized by industry (Basso, Pereira and Porto, 2021). To this end, it is necessary that there be alignment between the industry's interest, the novelty and the direction of the research.

In a second phase, there are the stages of clinical trial, a set of investigative procedures carried out to allow safety and efficacy data to be evaluated (Fiori, Basso & Porto, 2022). Among the information that can be evaluated from clinical studies is the interest of organizations in certain therapies and the commercial capacity that these technologies possess.

Because this sector has a high proportion of R&D&I spending relative to sales volume, it is necessary to use mechanisms that guarantee the appropriation of the gains from technological innovation (Horner, 2014). Companies in this sector choose to protect their findings through patents, in order to use the monopoly provided for by law to recover the investments necessary for this entire process (Leten, Kelchtermans, Belderbos, 2022), preventing new chemical entities from being copied, giving the industry time to develop them and place them on the market exclusively for a period of time (Rout, 2016).

It is important to emphasize that organizations are more likely to take greater risks in R&D investment with the guarantee of technology protection, since not all research will result in a product (Gamba, 2017). In this sector, 60% of inventions would not be developed without patent protection (Mansfield, 1986) and approximately 80% of the technical information is contained in these documents (Asche, 2017).

In this context, clinical trial and patents can be considered complementary indicators of innovation in the pharmaceutical industry, as they reflect both the generation of novel knowledge and the progression of technological discoveries toward market application. Analyzing these two sources together may allow the reconstruction of the trajectory of technological development in the sector. Stiller et al (2021) used patent and clinical trial data to assess radical innovation in medicines. Gadiya et al (2023) combined the data to identify drug repurpose. These studies suggest that there are still numerous ways to combine data to assess innovation.

Thus, this study aims to conduct a systematic literature review to examine how patents and clinical trials have been used as indicators of innovation in the pharmaceutical industry. The review seeks to answer the following research questions: (1) How have patents and clinical trials been used as indicators of innovation in the pharmaceutical sector? (2) What methodological approaches have been adopted to analyze these indicators jointly or separately? (3) What gaps remain in the literature regarding the evaluation of innovation from a portfolio perspective?

2 Method

A systematic literature review is justified because the authors previously conducted a search using the following keywords "patent," "clinical trial," and "innovation management" and found only 28 results, some of which only discuss technical aspects of pharmacological discoveries. A new review was conducted based on the PRISMA protocol guidelines to ensure transparency and reproducibility. Searches were performed in the Web of Science database using the following keyword combination as figure 1.

Figure 1 Key words

The search resulted in 305 results, of which 221 are articles. Subsequently, all the abstracts of the articles were evaluated to understand the object of the study. Of these, 168 evaluated clinical studies and patents in a technical context, without addressing the strategic issue of technological asset management. In most of these articles, the term management was used in the process of administering a particular drug intervention. This generates a false understanding that there are many studies addressing patent indicators and clinical studies in innovation management.

Of the remaining 53 articles, it was decided to read the articles that had at least 60 citations, totaling 20 articles. This selection was made considering the median of the sample. However, quantitative data from the entire sample that focuses on innovation management will be presented. The selected literature was searched using qualitative synthesis and thematic categorization.

3 Results

The articles analysed were published from 2012 to 2025 and reflect a demonstration of the sample, since most articles were published in this period, as shown in Figure 2. Another relevant quantitative piece of data is that the largest number of articles in this area were published in the journal Technological Forecasting and Social Change, with 5 in total. There is a great dispersion of knowledge in this area across 45 journals.

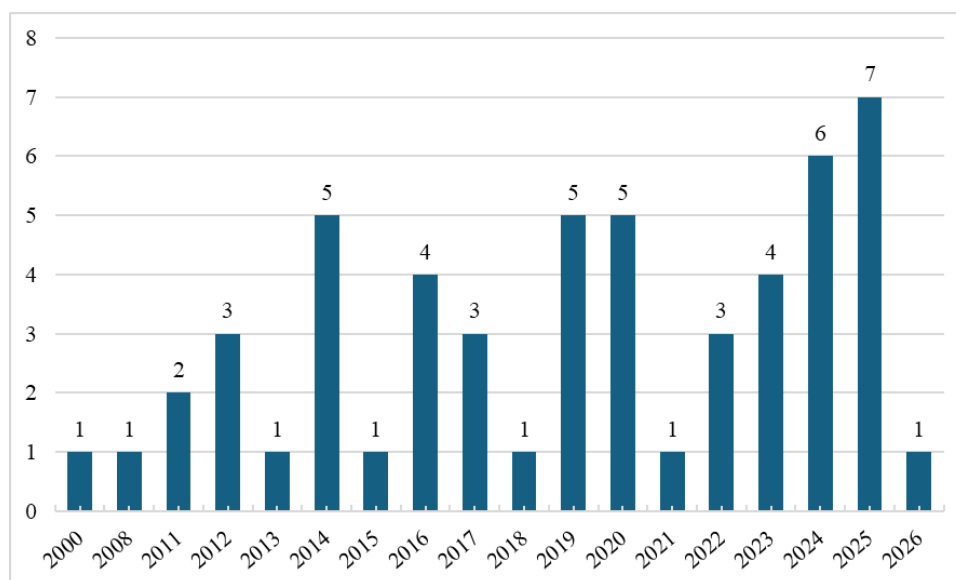


Figure 2 Publication Year

Clinical trials appear indirectly, but they play a crucial role in the dynamics of these articles. They can be understood as a significant bottleneck in the innovation process, as they are generally expensive, time-consuming, and fraught with uncertainty. Given this scenario, many companies tend to avoid investing in long-term projects, which can limit the development of more complex or disruptive innovations (Bai et al., 2014).

In addition, clinical studies can also be understood as part of a broad collaborative network. The literature on cooperation in research and development shows that these trials involve multiple actors, articulated in global research networks. In this sense, clinical trials are not just technical validation steps but constitute a scientific infrastructure that supports the production of biomedical knowledge (Budish, Roin, Williams, 2015; Fiori, Basso, Porto, 2022).

Finally, a relevant transformation in the role of clinical studies is observed when considering the generation of evidence after products enter the market. Studies on Real-World Evidence in medical devices indicate that the production of evidence does not end with traditional clinical trials (Manetti, Guidotti, Vola, Vainieri, 2025).

In turn, patents play a central role as a proxy for innovation, allowing us to observe different dimensions of the technological and economic process. They function as an indicator of technological activity and can be used to identify patterns and anticipate technological trends, offering insight into the direction of scientific and industrial progress (Pereira et al, 2019; Huang et al, 2019).

In addition, patents play a role as an economic instrument. Studies on licensing in biotechnology and on the role of scientists in patenting show that they are not only legal records, but also strategic financial assets. In this context, they serve as a basis for licensing agreements and constitute a value capture mechanism, allowing companies and institutions to monetize their innovations (Ali; Gittelman, 2016)

Another relevant aspect is the link between patents and scientific production. Studies on academic medical centres show that patenting is associated with the interaction between basic science and clinical practice, presenting a continuous articulation between different spheres of knowledge, reinforcing the role of academic institutions in the innovative ecosystem (Shah, Vaughan, Ledley, 2023).

Finally, patents also reflect power structures and competitive strategies. Research on the strategies of pharmaceutical companies in areas such as stem cells demonstrates that controlling patent portfolios allows companies to influence markets, block the entry of competitors, and strengthen their position in partnership negotiations (Avila-Robinson, Islam, Sengoku, 2019).

Based on the reading and organization of the texts using mind mapping techniques, four main themes were identified in the articles, which are summarized in Figure 3.

The first area is innovation in health as a complex system, marked by interdependencies and multiple actors. The articles in this axis show that innovation does not follow a linear trajectory and emerges from the interaction between universities, companies, government, regulatory structures, and funding mechanisms. It is an articulated system, in which changes in one component affect the others, reinforcing the idea that innovating in health is a collective and dynamic process, not an isolated activity.

The other area explores the issue of knowledge and intellectual capital as a central position. The studies address the depth and breadth of knowledge, skills gaps in

translational research, and learning from failures in R&D, where the main challenge is not generating knowledge, but converting it into concrete applications.

Another area is the economics of innovation, especially regarding incentives and contracts. Studies on licensing in biotechnology, dissemination of R&D activities, impacts of legislation on startups, and the role of public funding show that innovation is impacted by economic and institutional structures. Financial incentives, intellectual property regimes, and public policies directly influence the behaviour of organizations and the direction of research investments.

Finally, the last area is that of data to guide innovation. Studies that use patent forecasting, text mining in patent databases, bibliometric analyses, and real-world evidence demonstrate a more quantitative approach to the phenomenon. These studies allow for mapping trends, identifying patterns, and evaluating results more systematically, contributing to evidence of the dynamics of innovation in health.

Based on these studies, a future research agenda in health innovation involves greater integration between different data sources throughout the innovation cycle. Moving in this direction would allow for a better understanding of how knowledge is generated, validated, and applied, creating a more complete view of the innovation process.

Another central axis concerns the development of new models to incentivize innovation. The literature points to recurring difficulties in stimulating long-term investments and in directing efforts to neglected areas. Thus, future research can explore institutional and financial mechanisms capable of aligning private and public interests, reducing risks and expanding the social reach of innovation.

The role of artificial intelligence and big data also tends to expand significantly. The use of these tools in patent mining and in predicting technological trajectories opens new analytical possibilities, allowing for the anticipation of trends and guiding strategic decisions with greater precision. This movement reinforces the importance of quantitative and data-driven approaches in the study of innovation.

Governance and regulation also emerge as critical issues, especially in the face of the advancement of complex therapies and sophisticated medical devices. Future research may contribute to the design of more adaptive regulatory models, capable of balancing safety, effectiveness, and speed of access to innovation.

Main Research Focus Areas	Article Title
Innovation Economy	Timing, modifications, and tenor of firms' mandatory R&D disclosures: The role of competition
	Deciphering the therapeutic stem cell strategies of large and midsize pharmaceutical firms
	Comparing the economic terms of biotechnology licenses from academic institutions with those between commercial firms
	Deregulating Innovation Capital: The Effects of the JOBS Act on Biotech Startups
	Does Targeted, Disease-Specific Public Research Funding Influence Pharmaceutical Innovation?
Innovation in Healthcare as a Complex System	A systematic literature review of real-world evidence (RWE) on post-market assessment of medical devices
	Co-evolutionary and systemic study on the evolution of emerging stem cell-based therapies
	The institutional work of life science innovation leadership: the case of a bio venture hub
	Research paradigms and useful inventions in medicine: Patents and licensing by teams of clinical and basic scientists in Academic Medical Centers
	Cooperation in R&D in the pharmaceutical industry: Technological and clinical trial networks in oncology
Knowledge And Intellectual Capital	From depth and breadth of knowledge to technological capability: a journey inside a firm's intellectual capital
	Competency gaps and institutional challenges for translational research in medical devices: insights from Brazilian researchers
	Learning from Failures or Failing to Learn? Lessons from Pharmaceutical R&D
Using Data To Understand Innovation	Changes in PBM Business Practices in 2019: True Innovation or More of the Same?
	Forecasting of emerging therapeutic monoclonal antibodies patents based on a decision model
	Global quantitative analysis and visualization of big data and medical devices based on bibliometrics
	Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials
	Similarities and differences in the discovery and use of biopharmaceuticals and small-molecule chemotherapeutics
	Technological Innovations in Disease Management: Text Mining US Patent Data From 1995 to 2017

Figure 3 Summary of the articles

4 Conclusions

The steps to conduct this research included evaluating existing work and identifying gaps that indicate new avenues for developing studies that assess technological development and disruptive capacity in the pharmaceutical industry. In addition, evidence was sought

from other studies that separately present patents and clinical trials as indicators of innovation to justify the relevance of using both in the same study.

In a society driven by organizational efficiency, whether through waste reduction or time management to achieve results, the evaluation of innovation indicators from a portfolio perspective becomes relevant as a marker of the ability to achieve results. Furthermore, other perceptions, such as companies seeking patents to block competitors, will be highlighted.

By mapping the existing literature, this study sought to contribute to the debate on measuring innovation in regulated industries, highlighting the potential of combining multiple indicators to assess technological development. One limitation is that the study only addressed the ability to assess radical innovation in products, leaving aside other aspects of the approach.

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