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The impact of artificial intelligence on the transformation and optimization of drug launches: How executives from the health industry perceive the ongoing revolution

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Abstract

This paper explores the growing impact of artificial intelligence (AI) on the transformation of drug launch strategies in the French market. In this strictly regulated environment, where pressure regarding lead times and profitability has increased, AI becomes a lever for operational, organizational and strategic change. Based first on a review of extant literature and trends in the French market, and second on data collected during interviews with ten executives from the pharmaceutical industry, this contribution sheds light on what AI can offer in concrete terms: anticipating medical needs, dynamic targeting, medical and economic simulations, real-time management using key smart performance indicators, adaptive scripting of launch processes. It also highlights emerging new models of integrated governance, as well as a cultural shift towards a "learning launch" form of logic. This article identifies technical, human and regulatory barriers to the adoption of AI, and shows that AI does more than optimize existing processes: it brings about a deep redefinition of value-creating conditions in drug launches. France could be a pioneer in this new reference model, at the intersection of data, ethics and health-related innovation.

Keywords: artificial intelligence, drug launch, pharmaceutical industry, organizational strategy, health innovation management

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Foreword

This work would never have been possible without the availability, kindness and commitment of a number of executives from the French pharmaceutical industry. The authors wish to express their gratitude to each and every one of them for the time they devoted to the interviews, the depth of their thoughts and the sincerity of their answers. What they shared with us nourished, shed light on, and sometimes shook up our initial intuitions. Their analysis of AI's role in drug launches was relevant; in addition, they proved to be remarkably lucid concerning the profound metamorphosis and upcoming changes in the healthcare sector.

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Introduction – A silent revolution in drug launches

It takes a long, costly and complex process to bring a drug to market. Traditionally, this crucial stage is the outcome of a series of successive activities that include analyzing non-addressed medical needs, planning clinical trials, crafting a pricing, reimbursement and communication strategy aimed at healthcare professionals.

A new paradigm is establishing itself as artificial intelligence (AI) emerges. AI is now present at each and every stage of the drug launch process, offering the promise of improved performance, reduced uncertainty and speedier implementation.

Based on the French example and data from interviews with ten executives from the sector, this article explores how AI is generating profound change in the dynamics of drug launches in the pharmaceutical industry.

The French drug market: specific issues

France is one the main European drug markets, within a strongly regulated and constrained environment. To be brought to market, an innovative drug must go through the following steps: obtain a market authorization (*Autorisation de Mise sur le Marché* or AMM), be assessed by the country's top health authority (Haute Autorité de Santé, HAS), go through price negotiations with a specific body (Comité Économique des Produits de Santé, CEPS) then be incorporated into the coverage scheme.

Compared to many other markets, France's case is particular in that it is constrained by strict regulation (*Code de la santé publique*, GDPR, AI Act among others). This strict legal framework means that the deployment these technologies in our country, and more broadly throughout the European Union, comes up against considerable limits. This partly hinders AI's impact on the launch of new drugs: our regulatory framework undeniably offers better protection for health data, yet it also causes us to fall behind other countries such as the US or China, who not only invest more massively in AI but also are way ahead in terms of possible uses and application in the domain of health.

These constraints, along with rising pressure on health expenses, make successful launches more uncertain. In this context, because AI helps better anticipate expectations, customize approaches and enables real-time adjustment, it becomes a strategic tool to secure and optimize drug launches.

AI to optimize launch processes

Our study is based on ten interviews with biopharmaceutical leaders. It sheds light on several operational uses of AI throughout the drug launch process:

- *Market watch and predictive analysis of medical trends*: by treating large volumes of scientific data, publications, posts on social media and anonymized health data, AI helps detect weak signals that herald new medical needs or changes in clinical practices.

- *Dynamic segmentation and targeting:* industrial players may use machine learning algorithms to modelize prescriber types and adjust their medical communication messages according to the behavior of the targets that the laboratory has selected among healthcare professionals.

- *Optimized clinical trials*: AI enables the company to identify higher-performing sites, predict necessary recruitment rates and detect the most relevant patient profiles to shorten trials and improve result quality.

- *Preparation of the medical and economic files*: AI can analyze Real World Evidence care paths to help simulate cost-efficiency scenarios and anticipate health authorities' expectations concerning new drug coverage.

Results from the field study: tangible benefits and increasing adoption

The verbatim accounts from the experts we interviewed point to a common observation: when AI is properly integrated into the laboratory's internal processes, it significantly improves the quality of decisions made during launches.

They mentioned several benefits: reduced launch times, better preparation of teams in the field, increased customization of promotional tools and greater agility in adapting plans after feedback from the field.

Yet some barriers remain: data quality, interoperability of information systems, team training, and at a national level, the ethical and regulatory framework for the use of AI in the domain of health.

Our study also shows that organizational environments are more or less mature in terms of AI integration, suggesting that launch performance could become a marker of digital maturity for the laboratories involved.

Challenges and limits of AI in launch strategies

AI may provide new levers, yet it also raises crucial strategic and ethical questions. First, the transparency of predictive models is often limited, meaning it is a complex task for regulators to assess their use. Complying with the GDPR (*General Data Protection Regulation*) also translates into strict constraints when exploiting health data, in the very case of previous anonymization. Finally, it is tempting to rely on predictive tools, but doing so systematically and excessively may result in the loss of clinical sensitivity or in a detrimental standardization of the relationship between physicians and health industries.

In light of these three considerations (at the very least), we believe it is essential to promote a reasonable, complementary use of AI, incorporated into a comprehensive vision of laboratories' launch strategies.

Towards a new data-driven launch model

With AI, a new launch model emerges, one that is more iterative, better centered on true uses and able to adapt almost in real time. It challenges the linear, step-by-step model, instead promoting a "learning launch" logic in which feedback from the field feeds into the laboratory's market engagement and access strategy.

This model demands robust ethical data governance, a strategic alignment between medical, sales and market access departments, and a culture of agility and inclusion of various sensibilities within project teams.

In the long run, it is likely that a launch will no longer be deemed successful depending solely on sales results over 6 or 12 months, but also on the quality of continuous adjustments, the level of integration of feedback from the field and the ability to supply and reassure health authorities with relevant data.

To provide a snapshot view of the results of our study and make our managerial recommendations easier to read, the table below summarizes the main opportunities and issues identified by the executives we interviewed concerning AI integration into drug launch strategies.

Table 1: Opportunities and issues around AI integration

Opportunities opened by AI	Issues and implementation challenges
Anticipate medical needs via algorithmic monitoring	Data quality, availability and governance
Dynamic segmentation of prescribers, optimized targeting	Interoperability of information system
Shorter lead times, improved clinical trial results	Team training, AI acculturation
Medical and economic optimization of files (RWE, predictive scenarios)	Algorithm transparency, explainability of models
Real-time, adaptive management of field strategies	Regulatory constrains, GDPR compliance
Emergence of more agile organizational models) ("learning launch")	Risk of excess standardization, loss of clinical sense if usage not reasoned
Value creation via coordination between data science, market access and medical department	Need for ethical and interdisciplinary governance of AI projects

Conclusion and recommendations

Professional skills and expertise remain at the very heart of a launch strategy, and AI cannot replace them. But AI changes the shape of strategies, as it helps better anticipate, allocate resources more efficiently and interact in a more individualized manner with the stakeholders involved.

The study presented here demonstrates that conditions are right to accelerate the adoption of AI in drug launches, as long as certain technical, human and regulatory hurdles are cleared.

As such, the data collected from executives as part of this study may be presented in the form of ten main recommendations. They aim to answer operational and strategic needs, which have already been identified, while taking into account the specific features of the French market, so as to facilitate the optimal integration of AI in the pharmaceutical industry in the coming years:

1. Structure a specific governance for AI
2. Develop training and acculturation between data scientists and medical teams
3. Optimize data quality and access to data

4. Automate regulatory processes
5. Encourage the creation of dedicated AI unit, to support teams in charge of drug development
6. Reinforce the exploitation of data from real life
7. Encourage the development of external partnerships between actors
8. Adopt tools to optimize medical visits
9. Set up predictive indicators along with all the stakeholders involved
10. Encourage measures in favor of ethical, responsible AI

Because France is characterized by a mixed system combining clinical excellence, a culture of data and strict regulation, is well placed to become the perfect testing ground to experiment a new launch model based on augmented AI.

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