The digital transformation: How could artificial intelligence re-shape drug launch?

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Introduction

Within the pharmaceutical and biotechnology industries, the advent of advanced analytics including artificial intelligence (AI) and machine learning has triggered a fundamental paradigm shift. These new technologies open a world of opportunity including enhanced drug discovery, advanced precision medicine, and optimised clinical trials. With the first drugs discovered and developed by AI entering clinical trials, the focus from key players in the pharmaceutical and biotechnology industry has switched beyond development to exploring the applicability of AI technologies to augment drug launch and market access.

Aim

To conduct a proof-of-concept thematic analysis to identify and characterise ways in which the top-20 pharmaceutical companies are leveraging AI to optimise market access activities.

Objectives

1. Establish if pharmaceutical companies are integrating AI into their market access strategy.
2. Highlight different ways in which AI is being implemented.
3. Outline the potential ways manufacturers could use AI to optimise pricing, reimbursement, and new product launches.

Methods

A targeted grey literature search was conducted to explore whether any potential applications of AI are being developed and publicised by top-20 pharmaceutical companies. Examples of the material investigated include promotional posts on company websites, articles in leading pharmaceutical magazines and newsletters, and social media posts on platforms such as LinkedIn.

A framework was developed to map ongoing priority areas and themes for the use of AI to different "building blocks" of a successful drug launch strategy. These building blocks include identifying the target population with highest unmet need, developing impactful value propositions, engaging with external stakeholders, and submission for reimbursement.

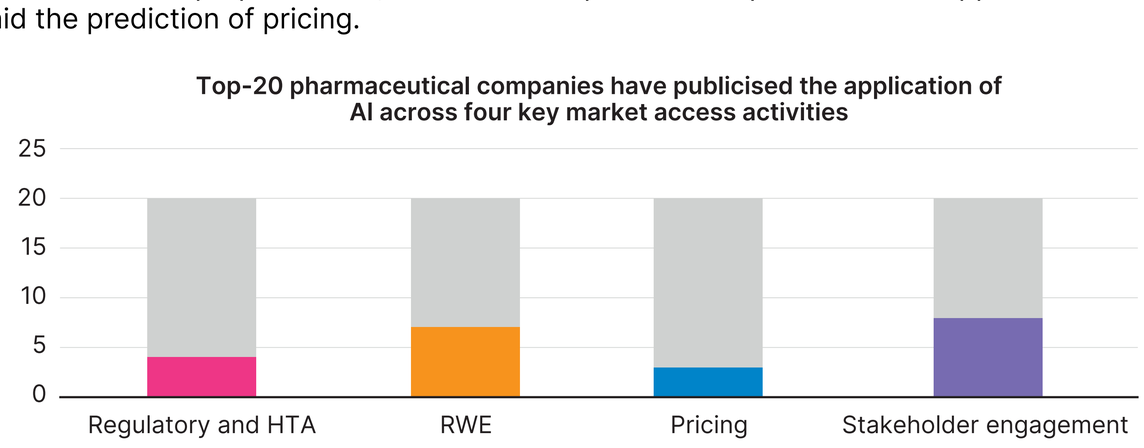
Results

The grey literature search identified four key themes to describe how AI is being used to augment market access strategy: to predict pricing, maximise effective use of real-world evidence (RWE), prepare for regulatory decisions and reimbursement, and manage key stakeholder engagement. Our results showed that the majority of the top-20 pharmaceutical companies have publicised a strategy of their application of AI under at least one of these four key themes (Table 1).

Table 1: Mapping of publicised market access activities using AI across top-20 pharmaceutical companies

Company	Pricing prediction	RWE	Regulatory and reimbursement preparedness	Stakeholder engagement
Pfizer	x	✓	✓	x
AbbVie	x	x	x	✓
Johnson & Johnson	x	✓	x	✓
Novartis	✓	x	x	✓
Merck	x	x	x	x
Roche	x	x	x	x
Bristol Myers Squibb	x	x	x	x
AstraZeneca	✓	✓	x	x
Sanofi	x	✓	x	✓
GSK	x	x	x	x
Takeda	x	x	x	✓
Gilead	x	x	x	x
Eli Lilly	x	x	✓	✓
Novo Nordisk	x	x	x	x
Amgen	x	✓	x	✓
Boehringer Ingelheim	x	✓	x	x
Bayer	x	x	x	x
Moderna	x	x	x	x
Viartis	x	x	✓	x
CSL	✓	✓	✓	✓

Eight of the top-20 pharmaceutical companies have publicised the application of AI to facilitate or support stakeholder engagement, seven companies have publicised the application of AI in RWE, four companies have publicised the application of AI to aid regulatory and reimbursement preparedness, and three companies have publicised the application of AI to aid the prediction of pricing.



From these results, we have identified three interesting case studies that showcase the versatility of AI in terms of its potential to optimise launch strategy.

RWE

Pfizer is using AI in adverse event (AE) processing, a key post-marketing authorisation activity, to work on AE case report intake and processing in anticipation of an annual 20% increase in AE reporting.

Regulatory and reimbursement

Eli Lilly is using Yseops Augmented Analyst automation to improve the efficiency of developing clinical study reports for regulatory approval reducing report-writing times by an average of 40%, expediting the process of submitting new drugs for approval.

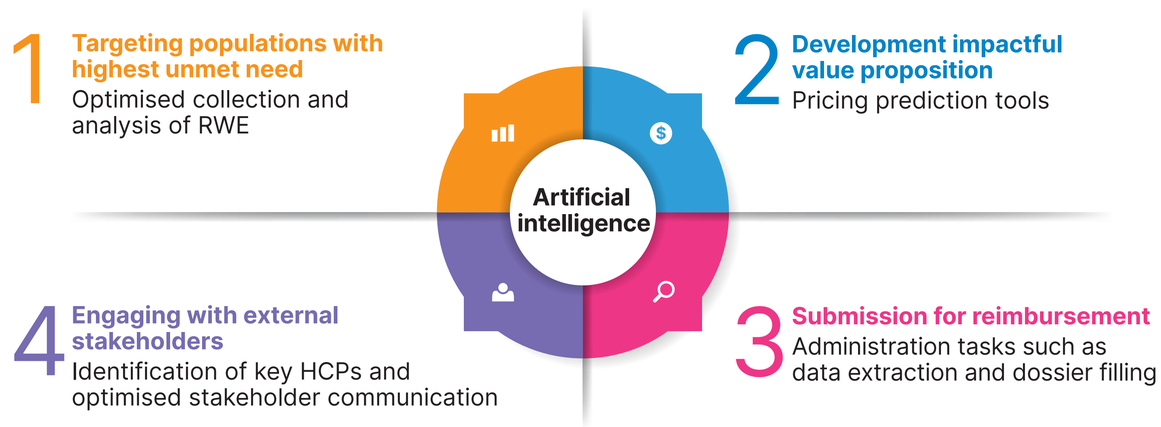
Stakeholder engagement

Sanofi has developed the AI-powered Digital Accelerator to support engagement between pharmaceutical companies and healthcare professionals with the aim of revolutionising omnichannel engagement to effectively reduce the distance between patients and their treatments.

Although Novartis, AstraZeneca, and CSL have publicised activities utilising AI within the theme of pricing, not enough information about the specific uses are provided to develop the findings into a case study. Data were analysed to identify trends such as an increase in the use of AI in market access, and the therapeutic areas of focus; however, no clear trends were identified from this research.

Discussion

Over the past 5 years, pharmaceutical and biotechnology companies have built AI into their everyday processes in efforts to save both time and money, notably in pre-clinical strategy and post-launch supply chain optimisation. As the use of AI becomes standard practice, there is a need for manufacturers to arm themselves with new tools to remain innovative against their competition. Utilising AI to support successful product launch is becoming increasingly common, notably to optimise RWE and stakeholder engagement; however, there is still significant opportunity for further innovation.



AI has the potential to transform the drug pricing and market access landscape by enabling faster, more accurate, and more cost-effective decision-making. AI can help address some of the key challenges faced by pharmaceutical and biotechnology companies in this domain, such as increasing competition, regulatory uncertainty, payer pressure, and patient expectations.

- AI technology can be used to automate regulatory processes such as administrative work, dossier filling, data extraction, auditing, implementation of regulations, and quality management. This will increase time efficiency and reduce expenditure on resources.[1]
- AI can be leveraged to optimise the use of RWE in supporting reimbursement, e.g., improving efficiency and accuracy of data analysis; identifying trends in local market conditions, payer preferences, and patient outcomes; and improving pharmacovigilance monitoring and reporting.[1]
- AI can support optimised stakeholder engagement and communication by generating relevant messages for healthcare professionals, payers, and policy makers, analysing healthcare professional behaviour and patterns; and identifying and connecting with key healthcare professionals.[2]
- There is a potential benefit in utilising AI to demonstrate a product's value for money and to subsequently justify the product's price. Development of tools in this space is underway: the platform ValueScope is able to predict the price of an asset as well as the likely outcome of negotiations with agencies with more than 90% accuracy.[2]

Despite the increase in potential uses of AI in market access, several risks remain. First, if low-quality data are used, the outputs produced will be less reliable and could lead to issues with decision-making. Second, there are potential legal and compliance issues in using data in AI models, especially in the case of RWE. Finally, it is unknown how accepting regulatory and HTA agencies will be of the use of AI. There is no clear consensus among payers on the use of AI in market access. However, the Food and Drug Administration (FDA)[3] and the European Medicines Agency (EMA)[4] have both released guidance relating to best practice use of AI. For example, EMA marketing authorisation applicants and holders must ensure AI is fit for purpose and ethical according to good practice and regulatory standards.

Conclusions

AI is being used by top-20 pharmaceutical companies to augment market access strategy, but there is still vast potential for growth and further innovative application of AI to support successful product launch and streamline patient access to innovative medicines. AI is profoundly impacting market access strategy, will continue to do so, and will be a key tool in developing successful and strategic launch tactics in the next 3-5 years.

Limitations of this research

The findings of this research are limited by the lack of publicised information regarding innovative AI application methods. Innovation is a source of competitive advantage; therefore, companies may be reluctant to share their strategies, outcomes, and challenges with external parties. To address these limitations, primary research engagement should be conducted with key players within the pharmaceutical industry and with payers to understand how AI is being used and where there is opportunity.

Questions companies need to consider before embracing AI

- What are the ethical, legal, and regulatory implications of using AI? How can compliance, transparency, and accountability of the AI systems be ensured?
- How can leading-edge technologies improve and/or empower commercial and strategic aims?
- How can manufacturers use the most relevant digital tools to communicate and demonstrate their value creation to key stakeholders?

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