Intelligent drug launch and commercial

Optimising value through AI

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Life sciences companies continue to respond to a changing global landscape and strive to pursue innovative solutions to address today's challenges. Deloitte understands the complexity of these challenges and works with clients worldwide to drive progress and bring discoveries to life.

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# Why launch and commercial activities need to change

In the biopharma value chain, launch and commercialisation enable patients to get access to new therapies. However, challenges to access have increased, including escalating costs of drug development, growing competition, mounting pressure to reduce time-to-market, new models of care and ability to pay for new, innovative medicines. This report focuses on biopharma commercial operations and the role of digital transformation. Specifically, how companies can use artificial intelligence (AI) to get the right drugs to the right patients and improve launch and sales performance, while gaining a competitive edge.

THIS REPORT IS the fifth in our series on the role of AI technologies in accelerating and driving biopharmaceutical (biopharma) companies' digital transformation across the value chain.[1] All reports acknowledge that the explosion of data in today's digital economy is driving the adoption of advanced technologies, such as AI. The insights highlighted in this report on biopharma's launch and commercial activities are based on our research, including comprehensive literature reviews, interviews with colleagues collaborating globally with clients on drug launches and commercialisation strategies and evidence from other relevant Deloitte research reports. This report also reflects on the impact of the COVID-19 pandemic on launch and commercial activities in 2020.

As in any industry focused on meeting market needs, biopharma has to plan and execute winning launch and commercial strategies, including optimising marketing, pricing, regulatory, compliance and sales approaches (figure 1). Today, biopharma companies are experiencing increasing costs of drug research and development (R&D), growing competition and a reduction in average peak sales; consequently, the right drug launch and commercial strategies have become more important than ever. To optimise returns, companies need to target and engage effectively with all stakeholders (figure 2) matching different channels to the preferences of different stakeholders over the development and launch timeline.

FIGURE 1

The biopharma value chain and launch and commercial operations
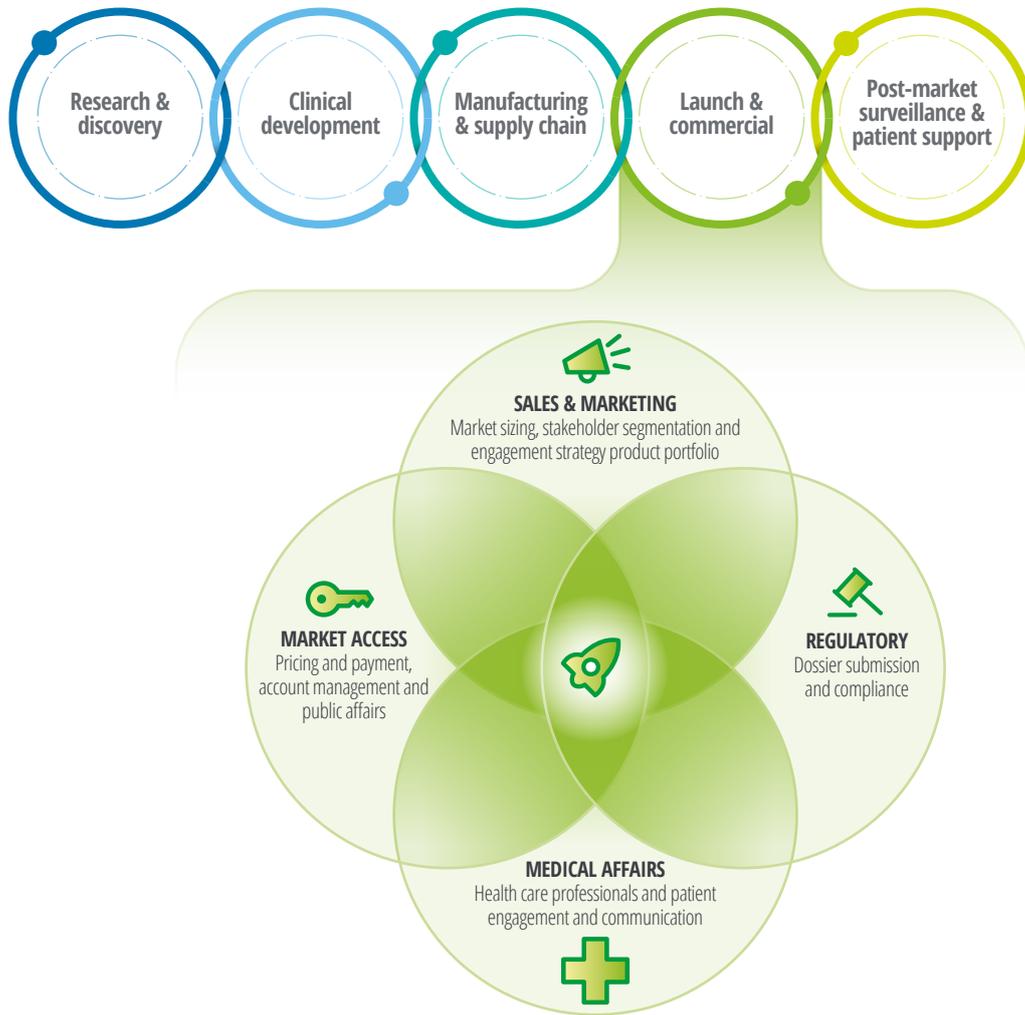
Source: Deloitte analysis.

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FIGURE 2

Stakeholder landscape in biopharma's launch and commercial operations

- National and international regulatory agencies (EMA, FDA, MHRA)
- Local and national governments and international governmental bodies

- Public/government payers (local and central)
- Private payers
- Insurance companies
- Pharmacy benefit managers (PBM)
- Individuals (out of pocket)

- Medical doctors
- Nurses
- Pharmacists
- Key opinion leaders (KOLs)
- Health care organisations (hospitals, clinics and pharmacies)

- Patients
- Patient advocacy groups
- Caregivers
- Families

- Pharma companies and consortia
- MedTech companies
- Digital technologies startups
- Digital health app developers
- CRM providers
- Trade associations (PhRMA, ABPI, EFPIA)

EMA - European Medicines Agency
FDA - US Food and Drug Administration
MHRA - Medicines & Healthcare products Regulatory Agency
CRM - Customer relationship management
PhRMA - Pharmaceutical Research and Manufacturers of America
ABPI – Association of the British Pharmaceutical industry
EFPIA - European Federation of Pharmaceutical Industries and Associations
Source: Deloitte analysis.

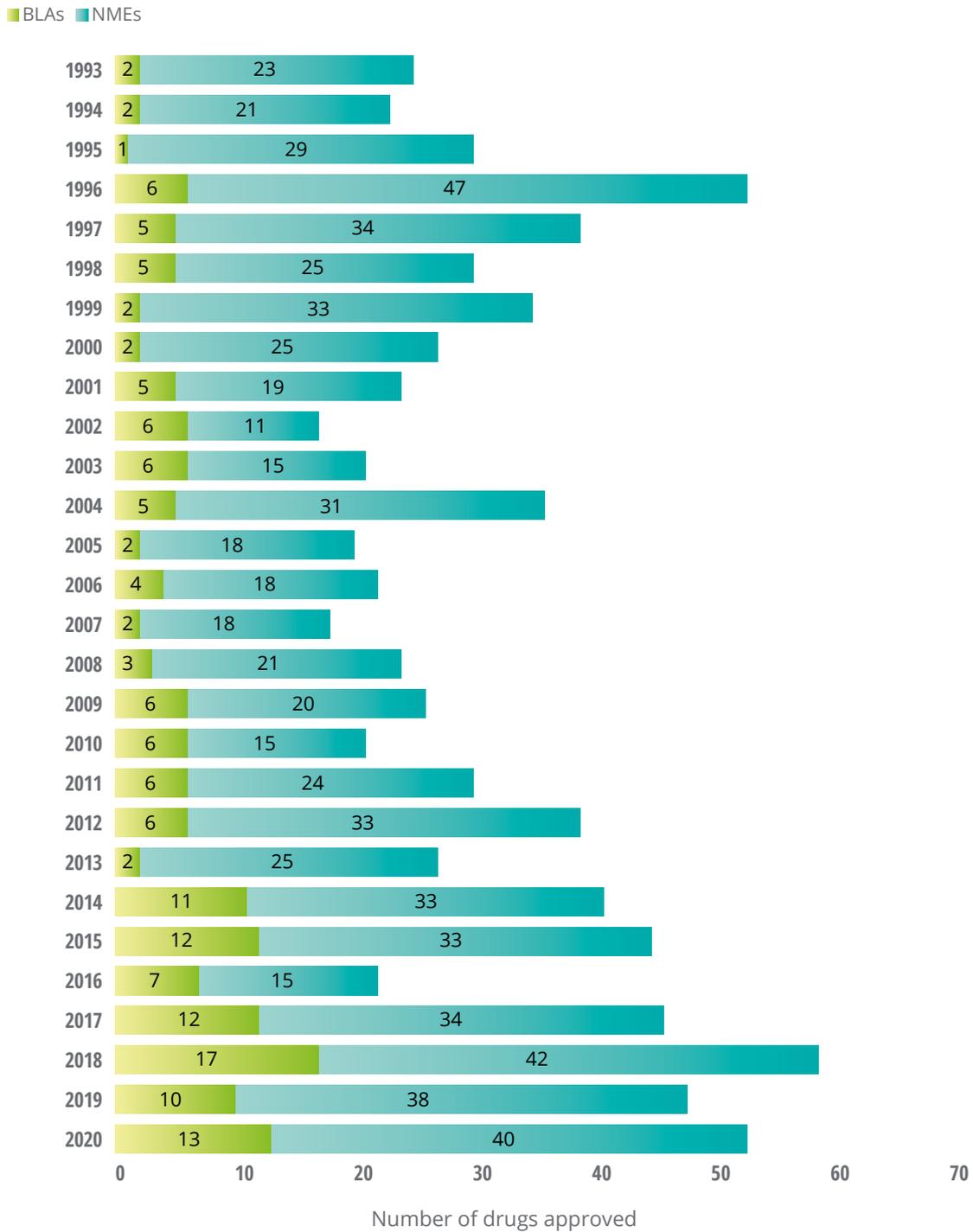## Launch strategies in an increasingly competitive and complex landscape

Over the past few decades, the number of new drugs launched each year has increased, resulting in a more competitive landscape. Until the 1980s there were on average ten new drug launches per year.[2] Figure 3 shows the number of Food and Drug Administration (FDA) approvals since 1993, including a notable spike in 1996 and the more consistent growth recorded in recent years.[3] In 2020, despite the challenges posed by the COVID-19 pandemic, the FDA approved 53 new drugs, second only to the all-time high of 59 in 2018.[4] Importantly, an increasing proportion of innovation and new drug launches over the past ten years have come from outside big pharma companies, increasing the competitive pressures.[5]

The number of new drugs approved in the EU has also increased. In 2020, 42 products received an EU marketing authorisation, a sharp rise on the 28 products approved in 2019, and just short of the three-year peak of 45 seen in 2018. Notable among the new approvals in 2020 was the first-ever COVID-19 vaccine, Pfizer/BioNTech's Comirnaty®.[6]

FIGURE 3

Annual numbers of new molecular entities (NMEs) and biologics license applications (BLAs) approved by the FDA's Center for Drug Evaluation and Research (CDER) since 1993

■ BLAs ■ NMEs

Year	BLAs	NMEs
1993	2	23
1994	2	21
1995	1	29
1996	6	47
1997	5	34
1998	5	25
1999	2	33
2000	2	25
2001	5	19
2002	6	11
2003	6	15
2004	5	31
2005	2	18
2006	4	18
2007	2	18
2008	3	21
2009	6	20
2010	6	15
2011	6	24
2012	6	33
2013	2	25
2014	11	33
2015	12	33
2016	7	15
2017	12	34
2018	17	42
2019	10	38
2020	13	40

Number of drugs approved

Note: Multiple applications relating to a single new molecular/biologic entity are only counted once.
Source: FDA.

Over the past few years, biopharma companies have worked more closely with governments and regulators to introduce agile, adaptive initiatives to accelerate drug development, approvals and market access.[7] Examples include:

- the creation of the breakthrough therapy designation by the FDA in 2012 for candidates deemed to offer 'substantial improvements' over existing therapies

- the priorities medicines (PRIME) scheme launched by the European Medicines Agency (EMA) in 2016, which provides early and enhanced support for the development of medicines that target unmet clinical need.[8]

Executing a successful launch is increasingly complex

The launch of a new drug is a pivotal moment in a product's life cycle. However, planning and executing a successful launch has become even more complex and challenging. The reasons include:

- growth in competition in key therapeutic areas like oncology

- rising costs of drug research (with the average cost per drug now more than $2 billion), due in part to a move to more personalised treatments, such as biologics[9]

- increasing molecular complexity, changing modality of treatments and a compelling need to demonstrate added value all affect the launch price[10]

- more targeted launch and stakeholder engagement strategies due to decreasing size of target population (for example, using precision therapies)[11]

- shorter commercial time to patent expiry due to longer trial cycle times[12]

- changing market access rules and prescribing behaviours combined with tightening pricing controls and toughening payer stance on pricing and reimbursement, as well as payer pressures on providers to prescribe generics and biosimilars[13]

- enhanced scrutiny from stock markets.

To tackle these challenges, companies are looking to improve the commercial success of drugs once they reach the market. At the same time, health care providers and payers are looking for new, cost-effective life-saving and/or life-extending treatments. In addition, the window for commercial success is becoming smaller while the expectations of stakeholders are growing. As a result, the pressure on companies to get the design and execution of launch and commercial strategies right – and optimise returns from new drug launches – is higher than ever. This requires a rethink in how marketing and commercialisation are planned and executed.[14]

In 2019, Deloitte analysed actual and forecast sales for 149 novel drugs approved in the US between 2012 and 2017. We found wide variability in launch performance: a third of drug launches failed to meet market expectations, and 26 per cent exceeded expectations. Moreover, most new drugs continue the revenue trajectory established at launch: around 70 per cent of products that underperformed at launch continued to do so in the following years. Similarly, around 80 per cent that met or exceeded expectations continued doing so years later. The top three reasons for missing expectations were:

1. limited market access due largely to formulary restrictions (50 per cent)

2. inadequate or incomplete understanding of market and customer needs, including converting stakeholders from existing therapies (46 per cent)

3. poor product differentiation because the product's proposition did not offer compelling enough value to physicians of patients (44 per cent).[15]

New payment models – the industry is shifting from volume-based to innovative agreements
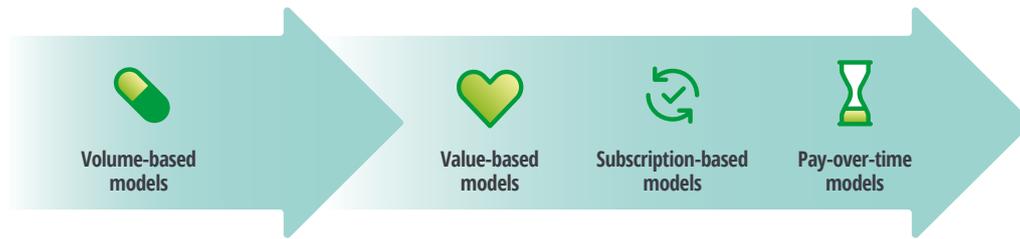
Source: Deloitte analysis.

Balancing timing of marketing authorisation and pre-launch preparations

Before a company can launch a new drug, regulatory authorities in each target market must grant market authorisation based on the company's submission of a detailed dossier. Dossiers include information about pre-clinical studies and clinical trials, as well as manufacturing and packaging details. They are typically submitted following a successful Phase III clinical trial.[16] To expedite authorisation, maximise the product's patent life and avoid unnecessary additional costs, companies are increasingly applying for accelerated approvals and preparing dossiers before reaching Phase III.[17]

In anticipation of marketing authorisation, companies should also plan and coordinate their commercial activities to engage early with stakeholders in each target market.[18] However, companies risk jeopardising their plans and relationships established during pre-launch marketing operations if safety or efficacy concerns delay authorisation, especially if clinical trials are halted or suspended. Biopharma companies, therefore, need to strengthen their cross-functional collaborations, in particular ensuring commercial functions work closely with R&D, and adopt a customer centric approach from development to commercialisation. Underpinning these collaborations is

the need to find ways to extract value from all the data that flows across all pre-launch activities.[19] For example, early alignment (from Phase IIb) between commercial and R&D functions is more likely to ensure that a drug will meet patient needs.[20]

The introduction of social distancing measures in response to the COVID-19 pandemic and the need to reduce infection risks for patients and providers has meant a number of clinical trials have been delayed or even suspended. This disruption has led to delays in some submissions for regulatory approvals and, consequently, drug launches.[21]

Understanding the pricing and reimbursement landscape

Pricing and reimbursement are critical value drivers at the time of launch. Even before COVID-19, one of the most talked-about health system issues has consistently been the rising cost of health care, including the increasing cost of pharmaceuticals.[22] Many governments and payers have adopted aggressive pricing strategies to exert downward pressure on the price they are willing or able to pay for drugs.[23] This requires biopharma companies to find effective ways of gaining deeper insights into how the medicines add value to patients and society, and into payer attitudes and their approach to pricing and reimbursement.

For biopharma companies, determining drug pricing is increasingly complex and requires consideration of the relative priorities in each target market including:

- the political agenda and economic dynamics

- product-demand analysis and patient segmentation

- regulatory policies

- reimbursement policies and the available health care budget

- treatment regimens, medical need, burden of illness and disease prevalence

- influence of patient advocacy support groups.

The need for companies to create a return on investment from their R&D (including the cost of failure) has led to higher prices and increasing resistance from payers. This, in turn, causes friction with health care professionals (HCPs), patients and patient advocacy groups who would like to see early introduction of medicines to address unmet medical needs.[24]

In trying to balance growing health care costs, payers expect biopharma companies to demonstrate evidence of each new therapy's effectiveness on clinical outcomes and health care budgets as part of a health technology assessment (HTA).[25] This is leading companies to explore new 'win-win' pricing models, moving away from price-per-unit, to volume-based agreements to value-based contracting (VBC) models (financial-, outcome- or service-based) and pay-over-time models. There are also discussions on subscription-based models, in which the payer is offered a flat rate for unlimited access to various products for a set period (figure 4).[26]

The VBC model shifts the balance of risk to the biopharma company's ability to deliver the promised impact. Companies are, therefore, having to think differently about pricing strategies, including VBC and other financing mechanisms.[27] However, payers and manufacturers often struggle to assess the value of a new drug due to the lack of data on long-term clinical outcomes at the time of the launch and other clinical trial data limitations, particularly in orphan drug trials that have small patient cohorts.[28]

Such innovative agreements will require collaborative relationships among companies, HCPs, patients and payers, as well as new regulatory approaches.[29] A deep understanding of local health care systems and the partnerships available is, therefore, crucial, with pricing strategies adapted to meet the requirements of different countries or regions.

Stratifying marketing strategies and customer engagement

Today, biopharma companies seek to identify and direct their commercial activities towards the right market segment at the right time by leveraging different commercial channels based on the needs of each stakeholder. For the past few years, driven by progress in digitalisation, the traditional one-size-fits-all go-to-market strategy, predominantly based on physical channels, has started to shift towards the use of digital channels.[30]

While digital channels were becoming more prevalent before the COVID-19 pandemic, social-distancing measures introduced to mitigate the spread of infection removed most opportunities for salesforce representatives (reps) to engage buyers face to face. In March 2020, as lockdown measures took hold, most companies 'grounded' their field salesforces and pivoted to virtual technology-enabled marketing and HCP engagement strategies.[31]

Companies that had already invested in digital platforms to engage virtually with physicians were well placed to respond, while others had to accelerate their use of digital platforms. Indeed, digitalisation has been crucial to most stakeholders' response during the pandemic. Nevertheless, many companies had to make tough decisions as to whether to delay or continue their planned launches in this uncertain market, particularly as companies plan and time these operations to optimise patent life.[32]

Engaging with HCPs during and after COVID-19

The challenges created by the COVID-19 pandemic have forced commercial teams to ask new business questions, including: which channels are best suited for current stakeholder needs, how to better address the needs of HCPs and patients, and what digital technologies can be leveraged to drive successful launches and market uptake?[33]

According to a survey of life sciences executives conducted in April 2020, 73.5 per cent of respondents expected direct messages via digital channels from commercial teams to HCPs and providers to increase over the following 12 months.[34] In addition, 73.9 per cent anticipated increased difficulties in accessing HCPs face to face post-COVID-19, and 79.7 per cent believed the pandemic would influence priorities around investments in customer experience.[35] Around 47 per cent of respondents said their customer relationship management (CRM) system could not completely support virtual HCP engagement.[36] Moreover, the pandemic has exposed the digital gaps within and between biopharma companies struggling to adapt to these new ways of working and has accelerated the digital transformation needed to meet stakeholders' needs.

The disruptions and challenges caused by COVID-19 are likely to have a long-lasting impact after the pandemic is over. Companies have an opportunity to embrace digital channels while balancing them with customer preferences. They can also reorganise their commercial activities to focus on using the immense amount of more accessible data to create tailored and hyper-personalised customer experiences. Indeed, ongoing market research suggests companies are increasingly adopting more targeted marketing strategies, which combine traditional and remote digital approaches, to manage and execute engagements as efficiently as possible. However, for this to be effective, it will require much more robust data.

In addition, a series of surveys aimed at understanding how HCPs have been affected by the pandemic, including their engagements with pharma sales reps, has found that half of doctors think remote interactions during COVID-19 have been similar to or better than in-person interactions pre-pandemic. However, others consider them to be worse due to challenges associated with scheduling, technology and increased difficulty in establishing a personal connection. Most HCPs prefer remote interactions to be scheduled, but there is also a strong interest in having on-demand access to sales reps.[37] HCPs want biopharma companies to deliver effective remote interactions while increasing the value of engagements through high-quality and differentiated content that is uniquely positioned to meet their needs.[38]

Using online and digital tools for tailored and enhanced customer experiences

All stakeholders, especially clinicians, patients and payers, perceive 'value' differently, requiring companies to tailor the language they use to each stakeholder. For example, while a payer may see value in a competitive price, HCPs or patients will place a higher value on how the treatment is administered and its effects.[39] In addition, given the shift towards more complex therapies, biopharma companies aiming to commercialise next-generation therapeutics should ensure sales reps are confident in leveraging all necessary tools to communicate effectively with their stakeholders.[40] Having strategies that build in the need to communicate the product's value using the right messaging to the right customer group will become as important as the development of the product itself.

To develop patient-centric marketing strategies, companies need to be mindful of how HCPs and patients use online tools, smartphone apps and social media to create more effective lines of engagement. For example, patients can now access a wide range of health-related information before seeing their doctor. The growth of patient portals, including online educational resources, such as PatientsLikeMe, allows patients to share real-world experiences and learn from the health journeys of other patients.[41] Moreover, patients are increasingly accessing services through a digital-first front door, such as virtual clinical consultations.[42] The adoption of digital platforms and clinician decision aids by HCPs has also grown significantly. Resources such as doctors.net.uk, Medscape, epocrates and Sermo enable clinicians to easily access content on their specialty.[43] Even mainstream social media channels, such as Twitter and LinkedIn, are used daily to engage with colleagues and to seek or share advice.[44]

Biopharma companies need to capitalise on these trends by tapping into this information flow and tailoring their approaches based on trust and what each stakeholder needs. Importantly, companies also need to comply with regulatory requirements around the use of digital channels, including the storage and security of patient data.

To effectively deliver value through their marketing and sales operations, companies should improve their understanding of their customers' journeys and be able to tailor engagements by leveraging the right mix of digital and physical channels. When done correctly, personalised interactions with stakeholders can lead to mutually beneficial relationships, including improved customer engagement and enhanced effectiveness of biopharma's business models. This is likely to complement rather than replace face-to-face engagement models.

Using AI to improve launch and commercial activities

As the digital transformation of biopharma's launch and commercial strategies evolves, the resulting explosion of data can power the use of AI technologies to drive digital transformation further still. The AI-enabled transformation of drug discovery, clinical trials and supply chain management is also relevant to launch and commercialisation activities.[45] Advanced data collection and analysis is essential to meet the needs of patients across the globe, and to create tailored customer experiences, anticipate key challenges and deepen the understanding of access issues in key global markets.

With the growing pressure to shorten time-to-market, companies need to understand which components of their sales and marketing operations, as well as other innovative strategies, drive prescribing behaviours and expand patients' access to new treatments. Early and efficient engagement with stakeholders is crucial to ensure companies can communicate their product's value while addressing the needs of HCPs, patients and payers. Moreover, companies are increasingly using data to better understand HCPs' need for education, information and training and are investing in 'next best action' analytical tools, often AI-based, to predict the type of information and commercial channels needed.

Data is at the heart of any successful customer-centric approach. Companies need to capitalise on the growing digital footprints of HCPs and patients, as well as their increased connectivity and willingness to share data in the right circumstances, and to apply AI technologies to this data to derive intelligent insights. Our overview report, *Intelligent biopharma: Forging the links across the value chain*, identified potential applications for AI in launch and commercial activities. These included launch coordination, patients and clinician engagement, and decision support, to more effective marketing and predictive pricing decisions.[46] The rest of this report will explore these and other applications to improve drug launches and the commercialisation of new products.

How AI technologies can improve launch and commercial

The data landscape is evolving quickly. Today, biopharma companies have access to an abundance of data from multiple internal and external sources. AI technologies will enable companies to realise the power of data, particularly real-world data (RWD), to significantly improve their launch and commercial performance, managing tailored engagements with different stakeholders and delivering added value that meets their needs more effectively.

THE BIOPHARMA INDUSTRY wants to meet the needs of patients with new and better medicines, while returning profit to investors who have taken a risk in investing in what is often a lengthy product development cycle. In addition, current market conditions are becoming more challenging, and traditional product launch strategies are increasingly unlikely to achieve the predicted results. To stay competitive, biopharma companies have to break free from inflexible and siloed data management systems and tap into the opportunities offered by AI to unlock the value of data and deliver crucial business insights.[47] By embedding AI capabilities into core business functions, companies can use previously unexplored data sources and optimise marketing strategies. This will greatly improve launch and commercial operations – particularly where traditional methods have failed.

Market conditions are becoming more challenging, and traditional product launch strategies are increasingly unlikely to achieve the predicted results.
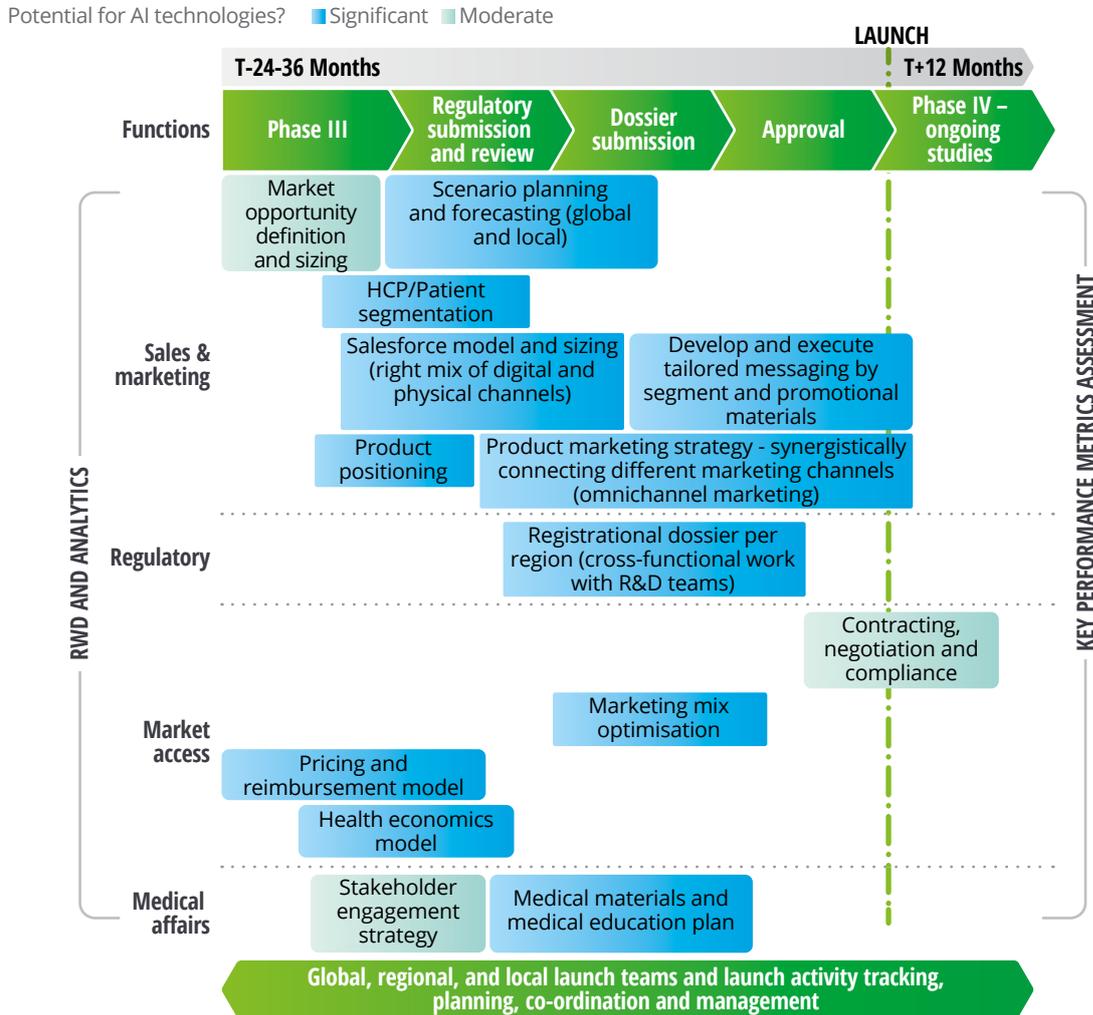
WHAT IS AI?

AI refers to any computer programme or system that does something we would think of as intelligent in humans. AI technologies extract concepts and relationships from data and learn independently from data patterns, augmenting what humans can do. These technologies include computer vision, deep learning (DL), machine learning (ML), natural language processing (NLP), robotics, speech, supervised learning and unsupervised learning.[48]

All pharma-relevant data, both externally and internally sourced, can be accessed and used more effectively using bespoke AI algorithms, which are markedly more advanced than statistical methods used in more traditional analytics. Tools, such as machine learning (ML), deep learning (DL) and natural language processing (NLP), can mine and analyse data in real time to uncover nonlinear, complex interactions in the data and recognise patterns that would otherwise be missed. By effectively implementing these AI technologies, companies can gain access to comprehensive real-world results and obtain valuable strategic insights to support key decision-making (figure 5).

FIGURE 5

AI applications across launch and commercial functions to develop key strategic insights and support decision-making

Potential for AI technologies? ■ Significant ■ Moderate

			LAUNCH	
T-24-36 Months				T+12 Months

Functions: Phase III | Regulatory submission and review | Dossier submission | Approval | Phase IV – ongoing studies

Sales & marketing
- Market opportunity definition and sizing
- Scenario planning and forecasting (global and local)
- HCP/Patient segmentation
- Salesforce model and sizing (right mix of digital and physical channels)
- Develop and execute tailored messaging by segment and promotional materials
- Product positioning
- Product marketing strategy - synergistically connecting different marketing channels (omnichannel marketing)

Regulatory
- Registrational dossier per region (cross-functional work with R&D teams)

Market access
- Contracting, negotiation and compliance
- Marketing mix optimisation
- Pricing and reimbursement model
- Health economics model

Medical affairs
- Stakeholder engagement strategy
- Medical materials and medical education plan

Global, regional, and local launch teams and launch activity tracking, planning, co-ordination and management

(RWD AND ANALYTICS — left axis; KEY PERFORMANCE METRICS ASSESSMENT — right axis)

Source: Deloitte analysis.

Making the most of RWD for commercial success

RWD can provide more representative information about a therapy's impact in a broader patient population, provide an accurate view of the evolving standard of care and more comprehensively reflect routine clinical care in comparison to traditional data sources. The rise in availability of RWD from non-traditional data sources, such as connected devices and health apps, and resultant generation of real-world evidence (RWE) has substantial implica-

tions for launch and commercial activities from the perspective of all stakeholders. Since 2017, Deloitte has undertaken three RWE benchmarking surveys of business executives from global life sciences companies. In 2018, it found that 90 per cent of respondents had established or were investing in building RWE capability across the entire product life cycle. In addition, 95 per cent intended to build or increase their AI capabilities. Visibility and importance of RWE was increasing at the executive level, including supporting commercial goals.[49]

Companies can only fully realise the potential of real-world evidence through using deep learning and machine learning, which enable the continuous flow of real-world data to be collected, cleaned, aggregated and analysed in a seamless and dynamic process.

The most recent survey report in 2020 found that more than 80 per cent of respondents have or are entering into strategic partnerships to access new sources of RWD. Furthermore, almost all companies expect to increase investments in external partnerships, talent and technology to strengthen their in-house RWE capabilities. The report concluded that the industry has yet to realise the full potential of RWE in transforming how medicines are developed, commercialised and reimbursed.[50]

The evidence available suggests that by using RWE effectively, companies can understand and proactively address, in real time, evolving stakeholder needs both pre- and post-launch. RWE utilisation is, therefore, expected to continue to grow across companies and the life sciences industry as its value throughout clinical development, launch and post-marketing phases is realised in terms of cost and time efficiencies.[51] Real-time monitoring and tracking of product performance through RWE also provides companies with opportunities to identify and obtain actionable feedback on differing needs from HCPs, patients and payers.[52] Biopharma commercial teams can capitalise on RWE to widen engagement with their identified target customers and deliver tailored and high-value messages.

RWE in pricing and commercial compliance activities

Companies are increasingly interested in using RWE for new VBC and pricing models developed around financial and/or health outcomes.[53] VBC arrangements require a strong foundational use of RWD and RWE, as well as robust data-sharing capabilities and strong collaborations between stakeholders, to bolster the evidence supporting the product beyond what is required for regulatory approval. RWE can help identify and maximise value across the health care system, providing critical insights to ensure the design of VBC agreements benefits all stakeholders. In the future, RWE is likely to be at the centre of any effective, innovative pricing and payment arrangement.[54]

From a regulatory perspective, RWE can support informed decisions about the product safety and efficacy and can help monitor and identify adverse events once the drug is being used across appropriate patient populations.[55] Indeed, there has been a concerted effort from regulatory bodies, including the EMA and the FDA, to formulate policy and guidance around the use of RWE, as they recognise its potential benefits and opportunities to support a more holistic view of health care.[56] By December 2019, RWE and non-traditional study designs had been used for a growing number of drug approvals and labelling changes in their regulatory submissions.[57]

Companies can only fully realise the potential of RWE through using DL and ML, which enable the continuous flow of RWD to be collected, cleaned, aggregated and analysed in a seamless and dynamic process. Indeed, to obtain high-quality RWE that can be used for regulatory or other important decision-making purposes, large sets of RWD must be collected and analysed through AI technologies, such as ML and NLP, to ensure the accuracy, reliability and robustness of generated insights (case study 1).[58]

CASE STUDY 1 – HOW ACORN AI'S RWE PLATFORM CAN OPTIMISE COMMERCIAL DECISION-MAKING

Medidata Acorn AI applies data science to accelerate innovative therapies to patients and drive actionable insights and important decision-making. Acorn AI Commercial Data Solutions, including QUANTUM and STRATA, provide commercial-stage companies with the infrastructure and expertise to acquire and analyse the right data to answer vital questions leading up to a launch.

QUANTUM, Acorn AI's RWE platform, is designed to make sense of RWD and help understand the potential patient population through detailed profiles and lines of therapy. This platform can find pockets of untreated or undiagnosed patients by conducting a complex line of therapy analysis and can apply advanced analytical methods to move beyond traditional segmentation to target accounts and HCPs with greater accuracy. In addition, Acorn AI's STRATA data management platform delivers the data and targeted insights needed to execute on launch strategies. By providing the right data at the right time, these targeted insights enable sponsors to find more patients, remove barriers to treatment, and improve treatment adherence.

Through Acorn AI's advanced analytics approach, companies can build a comprehensive understanding of patient access through insights into patient population demographics and payer analytics. Acorn AI provides commercial teams with the insights and RWE needed to improve reimbursement through comparative effectiveness and outcomes research.[59]

Predictive pricing

When determining drug prices, biopharma companies generally conduct extensive market research and analysis around health outcomes, which is becoming increasingly important as the industry moves towards VBC models. Advanced analytics tools will help companies respond to growing scrutiny from payers and other stakeholders when making a case for new drug prices. Having confidence in these data-driven approaches is essential for biopharma to develop better-informed pricing strategies. Innovative analytical models can improve confidence and will be crucial to identify more effective pricing opportunities, which will ultimately translate into profit and revenue.[60]

DL and ML tools can be used to develop predictive models with unmatched statistical power and scale. These models can leverage cognitive learning technologies to provide improved predictive power and a flexible modelling environment that continuously learns and adapts.[61] Such capabilities will be crucial for companies to understand their products' value and efficacy, as well as to justify costs in a competitive landscape (case study 2).

CASE STUDY 2 – MODEL N'S AI-ENABLED SOLUTION OPTIMISES DRUG PRICING STRATEGIES

Model N's Revvy Global Price Management (RGPM) is an enterprise-grade software-as-a-service (SaaS) solution that helps global pricing teams realise better prices throughout a drug's life cycle. It executes a pricing strategy by more effectively surfacing insights and driving better business governance with unified pricing and data processes.[62]

RGPM enables organisations to have visibility and easy access to pricing and market access information in one single, consolidated global repository that is flexible and extensible to fit unique business processes. It helps in collaborating more effectively by operationalising pricing and market access data, as well as governance and management processes – streamlining everything from alerts and notifications to price proposals, approval workflow and regular data verification processes.[63]

RGPM's predictive analytics help optimise launch prices and timing for new products and access the future impact of pending pricing decisions and events like international reference pricing (IRP). Other features of RGPM include:

- in-built IRP simulation and price controls
- launch sequence optimisation and tracking
- price and sales forecasting
- accurate and validated price and reimbursement database.

Using RGPM, one of Model N's customers reduced price erosion by 40 per cent.[64]

AI-enabled omnichannel marketing

AI-based analytics are ideal for marketing strategies that require complex decision-making. Advanced, non-linear AI algorithms that process substantial amounts of structured and unstructured data and recognise behavioural patterns can help companies make sense of marketing interactions and outcomes, thereby improving financial results.[65] AI can be used at scale to filter out 'noise' and identify key metrics and actionable, data-driven insights for important marketing decisions.

As companies embrace the tenets of patient centricity, sales and marketing are crucial to demonstrate that they have a deep understanding of the patient's condition, what the individual values and needs, and what is most likely to result in a positive health care outcome. It also means understanding patients' experience of care and HCPs' experience in caring for those patients. For marketing, this means finding the optimum routes of engagement to get as close to the best patient outcome as possible while aligning with other stakeholders' expectations.

The COVID-19 pandemic has also highlighted the power of omnichannel virtual engagement strategies (telemedicine and digital health). The sudden move to virtual engagement drew sales reps deeper into the world of non-personal promotion and the use of advanced AI-enabled tools for reaching physicians through multiple touchpoints. This has enhanced customer engagement and increased the overall reach of marketing strategies. It will be crucial for sales reps to interconnect and efficiently use online and offline channels to meet each target stakeholder's needs by delivering the right content at the right time, and in a way that works for them.[66]

Synergistically connecting different marketing channels allows companies to develop tailored experiences for different stakeholders. AI-enabled omnichannel marketing solutions, which leverage ML and NLP, enable companies to capitalise on multiple available data sources, including CRM systems, electronic health records and social media platforms, as well as demographic, geographic, socioeconomic and historical sales data (figure 6). The insights from such analyses can be used to predict behaviour and provide recommendations to biopharma marketers on next best actions, the channels to leverage, and how to optimise stakeholder engagement through personalised messaging.[67]

The heavily regulated scrutiny of biopharma communications means that marketing strategies are unlikely to reach the digital engagement levels seen in the entertainment or retail sectors, in which advertising content is based on the consumers' browsing history or purchasing activity. Nevertheless, as engagement compliance evolves in line with regulator guidelines (including data acquisition,

handling and storage) companies can leverage the possibilities and opportunities offered by advanced technologies to create targeted, personalised customer content in a compliant and trusted manner.[68]

As marketing interactions become increasingly digital and part of an omnichannel experience, the balance of rep to HCP interaction will shift dramatically towards knowledge sharing, information distribution, patient support and compliance. Given the time that reps traditionally spent with HCPs and the specific knowledge this gives them, they can help focus and personalise omnichannel approaches, choosing when to bring in medical science liaisons (MSLs) and proactively making decisions on what meetings to have or data to send.

While the human touch will remain an asset, the question is how to best use their time with the customer. This will require companies to upskill their field force to operate in a hybrid in-person/ virtual role and develop the leadership, skills and behaviours needed to thrive in response to these changes. The significant retraining needed to create

FIGURE 6

Omnichannel marketing in biopharma – putting stakeholders at the centre by integrating, combining and interconnecting the right communication channels

Source: Deloitte analysis.

a new mindset, enable reps to use digital tools and platforms, and work with data and data technology will also require a focus on enhancing 'soft' skills (in much the same way as health care providers are upskilling physicians to use virtual consultations).[69]

AI tools have the potential to help reps take more effective actions and assimilate data points to create new experiences for customers. AI capabilities can be integrated into widely used CRM platform services, such as Salesforce cloud-based software, which can be integrated to build other platforms. An example of such integration is Veeva's Crossix (see case study 3).

For those organisations that develop the right blend of 'hard' and 'soft' marketing skills, there is emerging evidence that this can result in a more effective and productive salesforce. For example, by not having to drive miles between engagements,

reps can use their time more efficiently, make more calls and have more touchpoints with customers. This change can also contribute to the achievement of the industry's carbon net-zero goals, as discussed in our report, *The future unmasked: Predicting the future of healthcare and life sciences in 2025*.[75]

For those organisations that develop the right blend of 'hard' and 'soft' marketing skills, there is emerging evidence that this can result in a more effective and productive salesforce.

CASE STUDY 3 – VEEVA'S CROSSIX USES AI TO OPTIMISE MARKETING CAMPAIGNS

Veeva's Crossix data platform is built for the development and delivery of large-scale patient data and analytics. Crossix's SafeMine™, a patented distributed data network and technology, connects health and non-health data for more than 300 million US patients. This includes Rx, over the counter (OTC), clinical, claims, consumer, hospital and media data and more – all of which are protected by privacy-by-design safeguards. Crossix collaborates with pharmaceutical companies to leverage massive amounts of data to better plan, target, measure and optimise their marketing campaigns.[71]

Crossix's cloud-based platform DIFA™ allows real-time measurement and optimisation of complex, cross-channel media campaigns aimed at patients and health care professionals.[72] The industry's most comprehensive data set, connected by Crossix's unique technology, enables DIFA to tie advertising campaigns to enhance brand impact.[73]

For one of its clients, DIFA drove efficiencies that reduced cost-per-target-list-HCP by 56 per cent year on year, increased website visitation rates five times compared to the previous year and saw site engagement rates spike by 54 per cent.[74]

Digital marketing strategies and social media analytics

Payer cost-containment strategies and regulations have driven structural changes in the approach to marketing for more than a decade, making marketing and selling direct to HCPs more challenging. The rise of specialty and more personalised medicines has also added to the difficulties. Analytics has, therefore, become an increasingly crucial part of the salesforce strategies of many pharma companies, based on mining data to get direction on salesforce size, structure and activity planning, as well as sales targets. Today, advanced analytical tools applied to social media are becoming part of the solution aimed at 'knowing your customer(s)' with ML applications helping unleash a new wave of customer engagement in a meaningful, outcome-oriented manner.

Market sensing through social media analytics can help companies detect consumer trends, market changes and mitigate risks by staying ahead of competitors. Though companies have been cautious about using social media content for targeted marketing strategies, social media analytics tools can help guide their engagement efforts with greater certainty.[76] Social media analytics and insights assist to better understand patients' journeys and their needs, as well as how to best engage with them.

Social media platforms can be used to exchange health care information with HCPs, such as symptoms, possible diagnosis, treatment options, potential adverse side effects and personal experiences. Biopharma marketers can use social media to enrich communications and interactions with stakeholders, including HCPs, patient groups and payers. Advanced analytics with AI capabilities, such as NLP, together with sentiment analysis, can be applied to social media platforms to obtain real-time customer engagement insights, aligned with regulatory guidelines (case study 4).[77] Other examples include:

- **Liquid Grids** is a health care–focused social media health intelligence and marketing platform that aggregates health care dialogue across the digital landscape and applies deep, patented, persona analytics. Liquid Grids' combination of advanced NLP analytics and focus on specific health care dialogue enables brands to effectively follow all conversations about a particular condition, disease, procedure or treatment, while providing valuable insight into the target audience's personas and their subjects of focus in these disease conversations. Liquid Grids' Direct to Persona marketing strategies drive highly targeted contextual ads and content to the exact target audience, helping them make the right health care decisions.[78]

- **Voxx Analytics** provides solutions for converting big data into specialised and integrated data products by applying social network analytics. Using AI, NLP and other tools, it enables companies to develop effective engagement strategies. Its Voxx.Engage integrated data platform supports medical affairs and commercial engagement planning, helping with HCP mapping and Key Opinion Leader (KOL) identification. Meanwhile, Voxx.Gateway supports early-stage product teams to establish relationships with KOLs and other stakeholders, and Voxx.RWD adds HCP and patient journey insights from claims data. Voxx.Social brings the online discussion of disease areas into one portal, allowing users to efficiently identify knowledge gaps, trends, and KOLs and digital opinion leaders (DOLs) who are shaping the online conversation.[79]

Biopharma marketers can use social media to enrich communications and interactions with stakeholders, including HCPs, patient groups and payers.

CASE STUDY 4 – SYNTHESIO'S AI-POWERED TOOLS HELP TO IMPROVE CONSUMER ENGAGEMENT

Synthesio, an Ipsos company, offers a 'Social Intelligence Suite' consisting of social listening tools and audience insights that help to measure the impact of social and mainstream media conversations. The Synthesio Social Intelligence Suite provides biopharma organisations with robust, transportable data about doctors and patients.[80]

Synthesio's social listening tool tracks real-time conversations over social media. Its AI-powered trend detection unites the speed of social listening with market research to identify statistically relevant shifts in conversation, co-mentions of topics, daily posting patterns, trending images, etc. Moreover, the solution provides customisable business intelligence (BI) styled reporting to gain insight from the data.[81]

Synthesio's audience insights tool, called Profiler, provides clients with the information needed to choose the right promotion opportunities for their products.[82] Using Profiler, one of Synthesio's clients decreased its ad spend by 30 per cent in a year, while increasing consumer engagement by 200 per cent and profit margins by 15 per cent.[83]

In addition, the use of autonomous ML chatbots that engage in two-way communications across social messaging provides valuable data to help improve efficiency and elevate the customer experiences. These insights can be leveraged to promote an innovative and agile approach to deliver the right products, services and experiences through improved engagement models. It can also improve the strategies, communications and product development of biopharma companies.[84]

AI-driven market segmentation

Market segmentation is essential for effective targeting and customisation of marketing strategies. However, one of the most common reasons for missing launch expectations is not understanding customers.[85] For biopharma, it is crucial that they understand unmet needs and identify relevant HCP/patient segments. Computational learning algorithms can be critical in helping these types of applications as they can be constantly updated to capture changes in the behaviours and attitudes of HCPs and patients over time, providing a much-needed robustness to sales strategic decision-making and tactics.[86] AI-driven market segmentation solutions can identify methods to improve commercial performance and optimise product value proposition specific to different geographies and health care systems. Axtria, a cloud software and advanced data analytics provider to the life sciences industry, is using ML methods to improve customer engagement strategies through segmentation and targeting (case study 5).

CASE STUDY 5 – HOW AXTRIA HELPED A CONSUMER HEALTH COMPANY OPTIMISE HCP TARGETING

OTC drugs save the health care system more than $145 billion annually, while reducing an unnecessary burden on the system. The market for OTC drugs is vastly different from those of prescription drugs, as decision-making power lies directly in the patient's hands. However, pharma companies must invest in targeting high-value HCPs as their verbal recommendation could affect the patient's buying behaviour.

Axtria helped a consumer health company with HCP-targeted list creation and management for the marketing of their OTC drugs. This resulted in efficient targeting, increased reach, maximised brand awareness and cost savings.[87]

Scenario planning and intelligent forecasting

Increasingly, biopharma companies are leveraging the abundance of available (internal and external) data to build accurate forecasts and develop effective planning and long-term strategies that enable them to respond to the growing complexity and rapid changes in the market. Detailed and comprehensive scenario planning (figure 7) can be a crucial element to drive evidence-based decision-making about future marketing strategies.

ML can be used for effective scenario planning to help companies refine the variables that provide insight into existing and future market landscapes.[88] This enables companies to determine how to optimise resource allocation and understand the key performance indicators at play. Importantly, intelligent forecasting and scenario planning can be a vital tool to use in a 'what-if' forward-thinking framework to understand the potential actions and behaviours of stakeholders and competitors and how they should respond (case studies 6 and 7).[89]

FIGURE 7

Scenario planning and intelligent forecasting
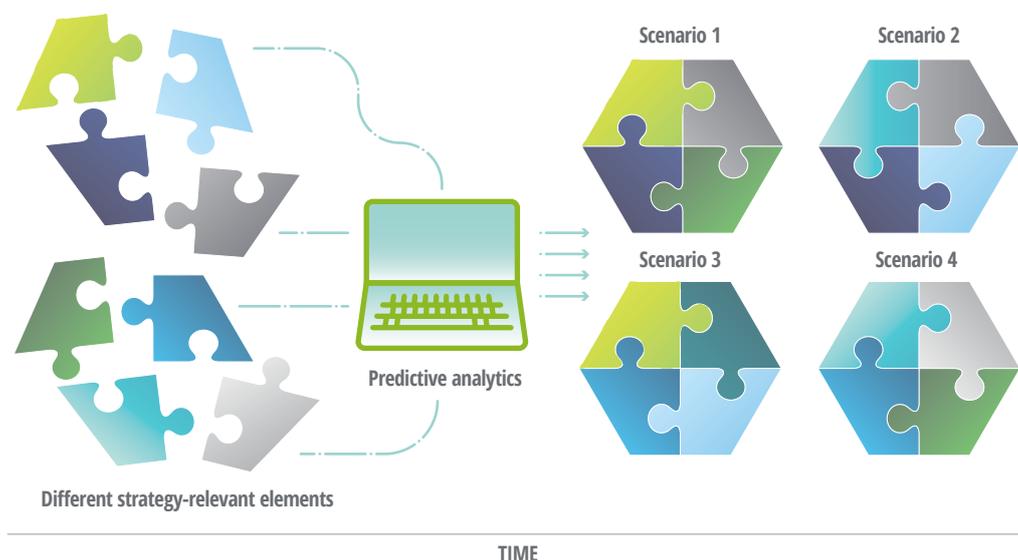
Source: Deloitte analysis.

CASE STUDY 6 – EULARIS BRINGS INTELLIGENT BIOPHARMA MARKETING TO LIFE

Eularis provides next-generation advanced marketing analytics for the biopharma industry. It uses AI-based analytics to provide data-driven insights into the revenue impact of sales, marketing and commercial decisions.[90] Eularis applies sophisticated AI algorithms to reduce uncertainty from sales and marketing decisions. Eularis' AI solutions allow biopharma companies to model scenarios to determine the potential impact of decisions affecting marketing or promotional activities, as well as to understand the impact of competitors' actions on their brand.[91]

Eularis' AI powered analytics solution helps biopharma companies to be prepared for a rapid launch and uptake by employing these solutions during pre-launch stages by analysing relevant data from multiple sources, including clinical trial data, overall market landscape, competitor analysis, customer pain points (both patient and physician), pricing and market access landscape, optimal positioning and messaging, and optimal channel allocation. Its precision targeting solutions help identify which physicians will be most likely to switch to the new drug. Eularis' proprietary solutions have been used to launch a drug in the US, which is on track to achieve sales of close to $1 billion by the end of its first year on the market.[92]

CASE STUDY 7 – COMPLEXICA PROVIDES AI SOFTWARE FOR OPTIMISING SALES AND MARKETING DECISIONS

Complexica Pty Ltd is an Australian company providing fully modularised AI software applications for optimising sales and marketing decisions.[93] These applications are available through an integrated, cloud-based platform called Decision Cloud® that addresses the complex challenges inherent within marketing, sales and supply chain functions. Decision Cloud® is powered by Larry, the Digital Analyst®, an AI platform that automates complex analytical tasks and workflows, empowering staff across multiple business functions to make better and faster decisions.[94]

At its core, Larry is made up of a variety of smart algorithms, such as Bayesian networks, artificial neural networks and genetic algorithms, among others. These algorithms perform tasks, such as data collection, augmentation, predictive modelling and trade-off analysis, to provide optimised decision recommendations to marketing, sales and supply chain staff.[95] When applied to sales and marketing activities, Larry can direct sales staff to the best opportunities, along with recommendations on conversations to have, products to offer and prices to quote. Larry can also optimise promotional planning, sales territory mapping, pricing and margins, as well as cross-selling, up-selling and churn prevention.

Pfizer Australia has partnered with Complexica for the deployment of its What-if Simulator & Optimiser, powered by Larry, which can test and optimise a variety of complex what-if scenarios based on large internal and external data sets. Moreover, the AI solution will help to:

· simulate the impact of various sales and marketing strategies

· answer complex what-if questions that contain many variables

· investigate a variety of assumptions and hypotheses that are difficult to test in the real world

· compare the outcome of various what-if scenarios and analyse key drivers behind the differences

· understand the deterministic and non-deterministic factors present in the operations of the business.[96]

An AI-powered future for launch and commercial

As the biopharma industry grows in complexity, companies need to capitalise on widely available data and advanced analytical technologies to successfully launch new products and maximise their commercial value. Indeed, the comprehensive implementation of a robust, AI-enabled commercial strategy will be a vital part of a pharma company's armoury.

Embracing a digital commercialisation culture

AI-enabled technologies are fast becoming a 'must have' for biopharma companies given their potential to improve efficiencies and tackle current commercial operational challenges. Marketing and sales have lagged other parts of the pharma value chain in terms of digitalisation and in the use of AI. However, over the past year, driven largely by the COVID-19 pandemic, companies have accelerated their digital transformation of launch and commercial activities, as virtual engagement became the default position.

In parallel, the pandemic has accelerated health care organisations' digital transformation with most HCPs pivoting to virtual patient consultations. The reluctance of clinicians and patients to adopt digital technologies and change their ways of working was overcome in a matter of weeks, and since then, a digital-first mindset has taken hold.[97] The change in culture and acknowledgement of the value of digital engagement have paved the way for alternative ways of HCPs and patients engaging with pharma; providing an ideal opportunity to optimise the benefits of their own digital transformation.

Moreover, biopharma companies are no longer the sole gatekeepers or providers of information surrounding drug treatments or products. Today, burgeoning web content, mobile apps and online communities provide people with access to a range of pharma-based insights. AI technologies can help create the perfect mix of value-driven content, emotive messaging, eye-grabbing visuals and social media posts.

By creating targeted, value-driven, branded content that offers current and prospective patients insights into relevant information, companies can grow their customer base. By improving transparency and providing answers to common patient pain points in an inspiring and engaging way and helping to improve patients digital and health literacy, companies can also foster trust and position themselves as a crucial part of a more collaborative health ecosystem.[98] Biopharma leaders should create a culture that promotes innovation with a focus on operational excellence while having a clear view of what they can anticipate from investments in data, AI and other advanced technologies.

FIGURE 8

Innovative and successful AI-powered launch and commercial strategies

Source: Deloitte analysis.

Marketing and commercial teams should align their thinking around launch excellence and its execution, and how to integrate advanced digital technologies to foster cross-functional collaboration enhancing engagement and maximising the value from their products (figure 8). In addition, interconnecting clinical development operations with commercial ones will allow companies to optimise their product's value from the beginning of drug development up to its eventual launch and commercialisation.

Marketing and commercial teams should align their thinking around launch excellence and its execution.

AI-enabled early launch planning with an end-to-end market access strategy

Biopharma can use RWD and employ advanced technological solutions to segment their target market efficiently and improve engagement with HCPs, patients and payers in a constructive and collaborative way. Stakeholder feedback can be incorporated into different areas of clinical development and commercial strategies through a cross-functional approach with a clear understanding of customer value and points of differentiation.

By breaking down data silos and interconnecting the right technologies across the product life cycle, performance can be monitored from end to end using key metrics to ensure that business activities support product value and will lead to commercial success. Biopharma can build a robust, end-to-end market access strategy framework, leveraging an effective cross-functional approach to help establish alignment on key strategic decision-making.[99] Such a strategic framework can be instrumental for companies to understand what matters most regarding market access to stakeholders and develop products and approaches that meet their priorities.

Establishing an AI infrastructure and ethical governance framework

As companies embrace and scale up advanced technologies across their launch and commercial activities, they need to ensure that the data acquired, particularly from patients, is managed in an ethical, responsible and secure way, including consent and protecting privacy throughout the entire process. Successful implementation and use of AI are dependent on complying with a company's wider ethics and governance framework.[100] In addition, companies need to be proactive in demonstrating compliance with ethical marketing standards and transparent in their pricing strategies to build and maintain long-term, strong stakeholder relationships based on trust.[101]

Digital infrastructure, interoperability, data privacy and security

A robust digital infrastructure is essential to enable the implementation and upscaling of AI technologies in launch and commercialisation. AI cannot be added simply as an additional module to existing siloed digital systems, including HCP and patient portals; rather, it requires the right technology assets. Therefore, companies should prioritise identifying their needs in terms of computer systems, data architecture and technology capabilities to establish a cohesive and interconnected infrastructure. For some, this may mean investing in new digital architecture and IT capabilities. From a commercial perspective, it is critical for IT teams to support commercial teams to achieve their customer-engagement goals, rather than simply supplying the technology.

Biopharma companies also need to ensure effective interoperability, connectivity and communication between devices and IT systems and between data and workflows to enable secure and transparent data exchange. It is essential to develop interoperable systems that improve workflow speed and performance and that break down siloed behaviours that inhibit efficiency. This includes improving clinician education and decision support, improving patient education and support and tackling consented sharing of patient data.[102]

The exponential increase in the amount and types of data generated through launch and commercial activities increases the importance of maintaining the privacy and security of data, particularly HCP and patient data. AI technologies can help in monitoring the proliferation of laws and regulations in the sphere of data protection and privacy, as almost every government is developing or strengthening its own privacy and security legislation. A key solution to improving the security of data is through cloud computing power and storage ability. A clear understanding of the number and security of HCP and patient portals is important.[103]

Acquisition of the right skills and talent

Digital transformation and deployment of AI technologies require major changes to roles and responsibilities within launch and commercial activities, which requires companies to rethink the workforce experience, adapt to employing a workforce with more diverse skills and transform their approach to leadership development.[104] As the speed of marketing campaigns increases driven by digital AI-enabled messaging, the sales cycles are shifting from month-long campaigns to those of only a few weeks. An AI-powered future will require people with both commercial and advanced data science skills and expertise.[105] Biopharma companies should, therefore, evaluate the skill gaps within their enterprise so they can embrace new ways of working.

The next generation of talent will need to be agile, digitally literate and open to continuous learning. As technology and capabilities evolve rapidly, the race for talent will stretch across industries with biopharma companies competing with both traditional competitors and consumer technology companies, as well as most other industries for data and analytical talent.

Companies might invest in reskilling and/or upskilling their current workforce, or they might opt for acquiring new talent, such as AI researchers, data scientists and software developers. Regardless, realising advanced digital skill sets and expertise will allow companies to better define the strategic and technical steps they should take to ensure value is delivered across the life cycle of their products.

Collaborations and partnerships

Biopharma companies could benefit from forming new collaborations and partnerships, particularly with AI startups and platform providers. This will enable them to access advanced analytics and technical expertise and the right AI technology platforms and services for their business intelligence needs. Collaborative strategies, which lead to the formation of AI ecosystems for biopharma's commercial activities, could be instrumental in enabling companies to enjoy the full benefits from AI. Partnering with technology companies will give access to marketing and analytics expertise and provide opportunities to acquire new knowledge, which can be transferred into internal teams, further helping the development of innovative future business operations.

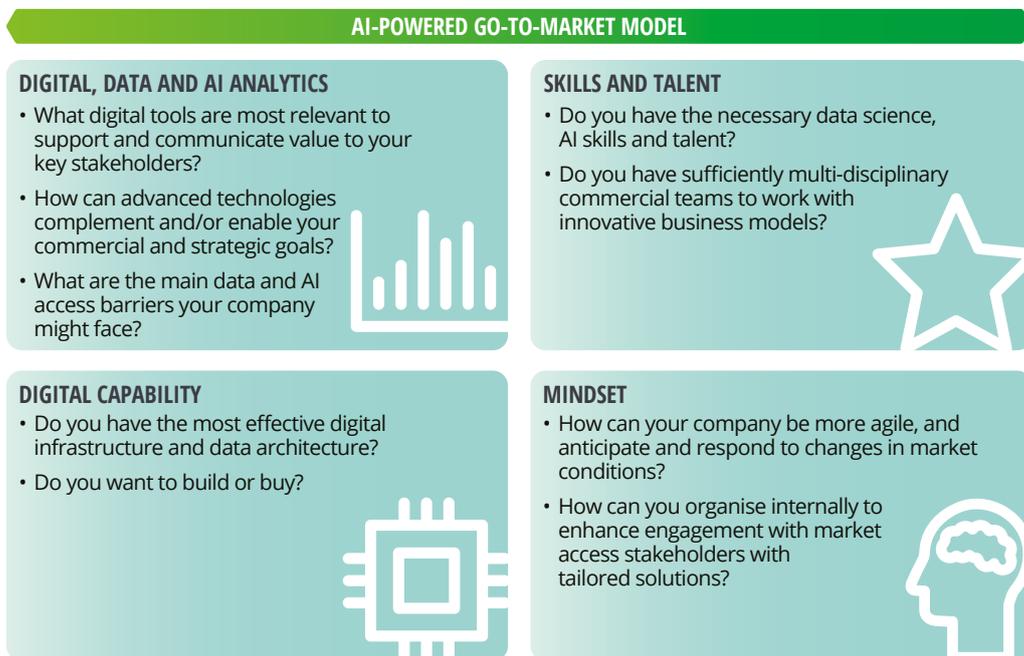## Key questions for biopharma's adoption of AI in launch and commercial strategies

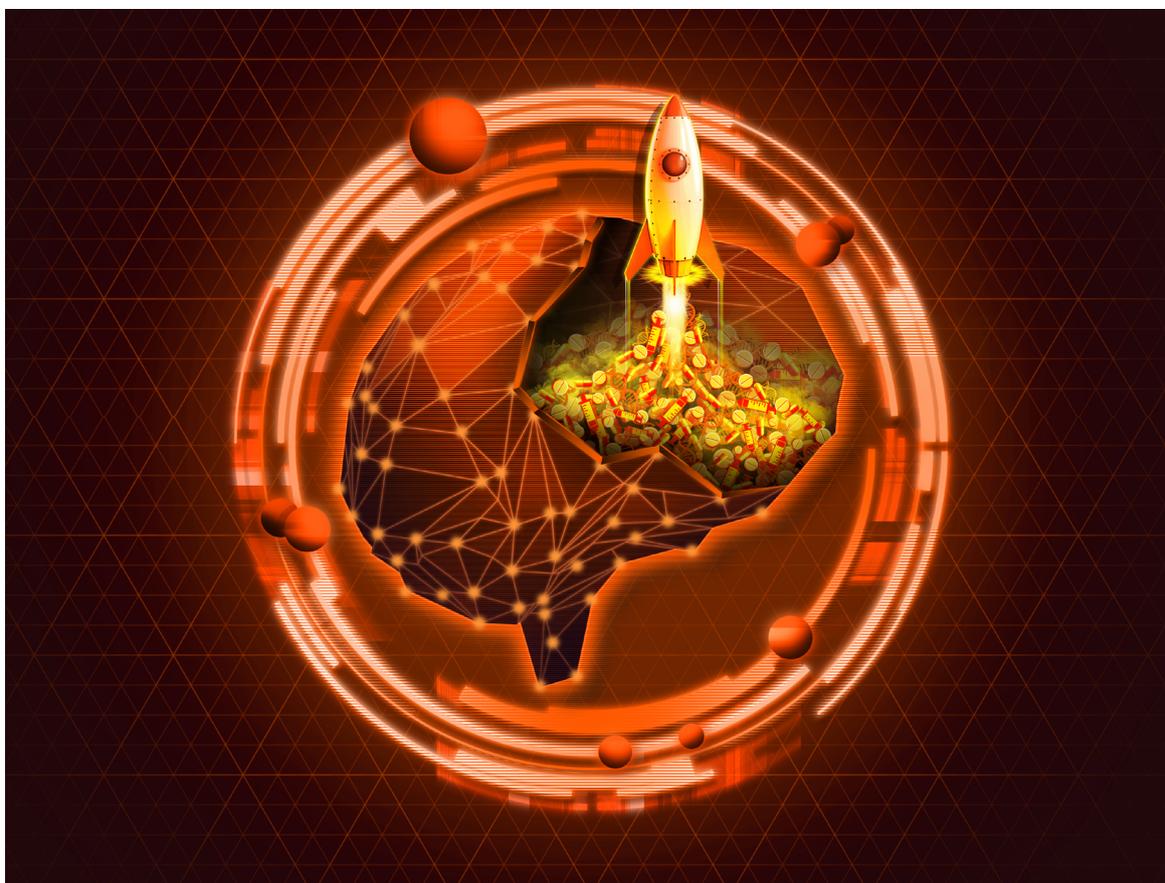End-to-end visibility across commercialisation will provide significant benefits to biopharma companies. By utilising AI technologies, companies can coordinate product launches better, establish proof of value to support reimbursement models for new curative therapies and services, and improve patient engagement. Further, AI technologies can help with physician decision support and marketing operations, and predict market access and pricing decisions. Moreover, AI is already used for precision engagement to tailor behavioural nudges to an individual's personality, motivations, care journeys and engagement challenges. Customised engagement will ensure that the right HCPs get the right content at the right time and patients have access to personalised support programmes. Using AI to stratify HCPs into various 'personas' based on their habits, preferences and receptivity to marketing messages will improve commercial productivity.[106]

As explored in this report, we consider how the use of AI tools in launch and commercial is now a crucial business imperative. However, before adopting and upscaling AI solutions across their commercial operations, there are questions companies need to consider (figure 9). These questions are aimed at addressing the crucial changes that are required to support a new model that is underpinned by data and advanced analytics.

By utilising AI technologies, companies can coordinate product launches better, establish proof of value to support reimbursement models for new curative therapies and services, and improve patient engagement.

FIGURE 9

The questions companies should consider before moving towards an AI go-to-market model

AI-POWERED GO-TO-MARKET MODEL	
DIGITAL, DATA AND AI ANALYTICS • What digital tools are most relevant to support and communicate value to your key stakeholders? • How can advanced technologies complement and/or enable your commercial and strategic goals? • What are the main data and AI access barriers your company might face?	**SKILLS AND TALENT** • Do you have the necessary data science, AI skills and talent? • Do you have sufficiently multi-disciplinary commercial teams to work with innovative business models?
DIGITAL CAPABILITY • Do you have the most effective digital infrastructure and data architecture? • Do you want to build or buy?	**MINDSET** • How can your company be more agile, and anticipate and respond to changes in market conditions? • How can you organise internally to enhance engagement with market access stakeholders with tailored solutions?

Source: Deloitte analysis.

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Acknowledgements

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Our insights can help you take advantage of change. If you're looking for fresh ideas to address your challenges, we should talk.

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