LUISS

Course of

SUPERVISOR

CO-SUPERVISOR

CANDIDATE

Academic Year

Table of Contents

Introduction

Artificial Intelligence (AI) has emerged as a transformative force across various industries, and the pharmaceutical sector is no exception. With its vast potential to enhance efficiency, improve decision-making, and drive innovation, AI has the power to revolutionise the pharmaceutical industry across the entire value chain. This thesis aims to explore the profound impact of AI on the pharmaceutical sector, providing an in-depth analysis of its current state, challenges, opportunities, and future potential.

The first chapter delves into the rise of artificial intelligence across the pharmaceutical industry, providing an overview of the current state of artificial AI in the pharmaceutical industry. It analyses the multifaceted trends influencing the industry, including the market size of AI in pharma and a glance at key industry players. Additionally, it sheds light on the different AI technologies being leveraged in pharmaceuticals, such as machine learning, robotics, artificial neural networks, and natural language processing. The chapter examines the key drivers fueling the current wave of AI growth, including the growth of big data, increasing computational power, pharma funding trends, and the democratisation of AI through open-source communities. Furthermore, the legal and regulatory challenges, ethical considerations, the talent gap, and organisational hurdles are examined, as they present formidable barriers to AI adoption that need to be overcome to fully realise the revolutionary potential of AI. Lastly, recognizing the competitive landscape in the age of AI is crucial, and the chapter explores this phenomenon extensively. It emphasises the collision and fragmentation within the industry as traditional players and emerging disruptors compete and collaborate simultaneously. The chapter also underscores the shifting nature of competitive advantage, illustrating how organisations must evolve to possess universal capabilities that enable them to thrive in the AI-driven era. Additionally, it explores the concept of co-opetition, where strategic partnerships and collaborations become essential for harnessing the full potential of AI.

The second chapter delves into the transformative applications of AI across the pharmaceutical value chain. It begins with examining AI in research and discovery, highlighting the challenges posed by traditional R&D processes, which are often lengthy, complex, expensive, and inefficient. However, the rise of AI drug discovery disruptors has brought about a paradigm shift, enabling researchers to leverage AI technologies and algorithms to streamline the discovery of new drugs. Moving on to clinical development, the traditional approach to clinical trials is discussed, emphasising the complexities and limitations of the existing system. However, the transformation of clinical trials is underway, driven by the integration of AI. This section explores the drivers behind this transformation and delves into the impact of AI on the clinical trial process.

The study then turns its attention to the role of AI in manufacturing and supply chain management in the pharmaceutical industry. It overviews the critical stages of producing and delivering high-quality drugs and highlights the complexities and risks inherent in the pharmaceutical supply chain. AI's role in enhancing supply chain transformation is examined, focusing on its ability to optimise processes, mitigate risks, and drive efficiency. The challenges and complexities of introducing new drugs to the market are discussed in the context of launch and commercialisation. Factors contributing to the improvement of launch and commercialisation

are examined, with a particular emphasis on the potential applications of AI in optimising these operations. Lastly, the thesis explores the role of AI in post-market surveillance and patient support. It highlights the reasons for the shift in patient safety strategies and examines how AI can enhance pharmacovigilance, enabling more efficient monitoring and identification of adverse events. The potential of AI-enabled patient support programs to improve patient care and engagement is also explored.

Each stage is accompanied by a comprehensive case study illustrating the practical implementation and effectiveness of AI-driven solutions in real-world scenarios.

Finally, the third chapter presents a visionary outlook on the pharmaceutical industry's future in AI. It identifies the five forces of potential disruption that are poised to revolutionise the pharma industry. These forces include prevention, early detection, personalised treatment, curative therapies, digital therapeutics, and precision intervention. Each point represents a distinct area of innovation and has the potential to transform the way healthcare is delivered, and pharmaceutical products are fundamentally developed and utilised. By exploring these forces, we gain valuable insights into the future direction of the pharma industry and the opportunities and challenges that lie ahead. The subsequent section of this chapter delves deeper into the prospects and potential developments in the pharmaceutical value chain. It explores how these disruptive forces will likely impact critical areas such as drug discovery, drug development, manufacturing and supply chain, and commercial operations. By examining each stage of the value chain, we gain a comprehensive understanding of how the future of pharma is set to unfold.

1. The Rise of Artificial Intelligence across the Pharmaceutical Industry

1.1 The State of Artificial Intelligence in the Pharmaceutical Industry

1.1.1 An Analysis of the Multifaced Trends Affecting the Industry

Figure 1

Source: Hillary Dukart, Laurie Lanoue, Mariel Rezende, and Paul Rutten. *Emerging from disruption: The future of pharma operations strategy*. 2022. McKinsey.

The pharmaceutical industry faces numerous challenging trends (see Figure 1). Global demand for pharmaceutical products is increasing rapidly, and the COVID-19 pandemic has created an unprecedented need for vaccines and therapeutics, placing additional pressure on the industry. Although the industry has demonstrated a remarkable ability to develop innovative solutions to this challenge, the sustained growth in demand for pharmaceutical products remains a significant long-term challenge. Moreover, the landscape of pharmaceutical products is changing swiftly, with new modalities such as cell and gene therapy and mRNA vaccine technology accounting for an increasing percentage of the drug development pipeline. This shift will likely lead to increased technology fragmentation, new supply chains, and unique product life cycles.

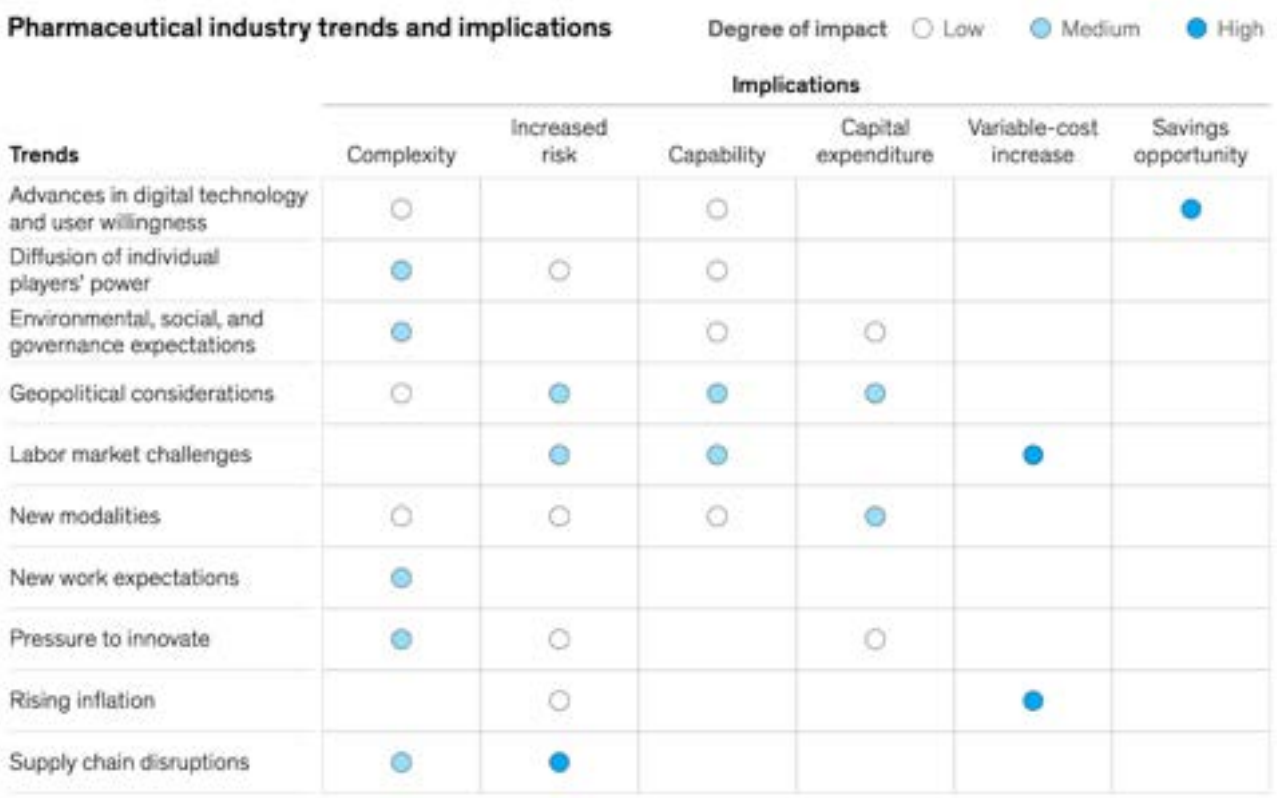
Beyond these industry-specific trends, the pharmaceutical industry is also experiencing broader global trends, such as supply chain pressures, which can lead to potential disruptions and result in the loss of up to 25% of EBITA over ten years. Furthermore, inflation has risen to unprecedented levels, leading to increased labour, raw materials, and transportation costs, further intensifying price pressures. Increased state interventions and protectionist trade policies also create new stresses on manufacturing networks, which may drive increased regionalisation and require significant investment. In addition, the pharmaceutical industry is experiencing talent shortages linked to broader labour market trends and is struggling to recruit technical talent: the current pool of pharma digital talent is at least 14% lower than demand. However, the advancement of digital and analytics tools offers a potential industry tailwind, with digital devices, robots, and sensors becoming cheaper

and more accessible. Combined with edge computing and cloud analytics, these tools can provide real-time optimisation and transparency, enabling pharmaceutical companies to become more agile and resilient.

Each of these global trends represents a significant challenge, and their interactions may compound and strengthen their effects, further complicating the evaluation of an effective strategic response.

These trends have six significant implications for pharma companies: rising operational complexity, increasing risk, shifting capability requirements, higher capital expenditure requirements, variable-cost increases, and opportunities for savings (see Figure 2).

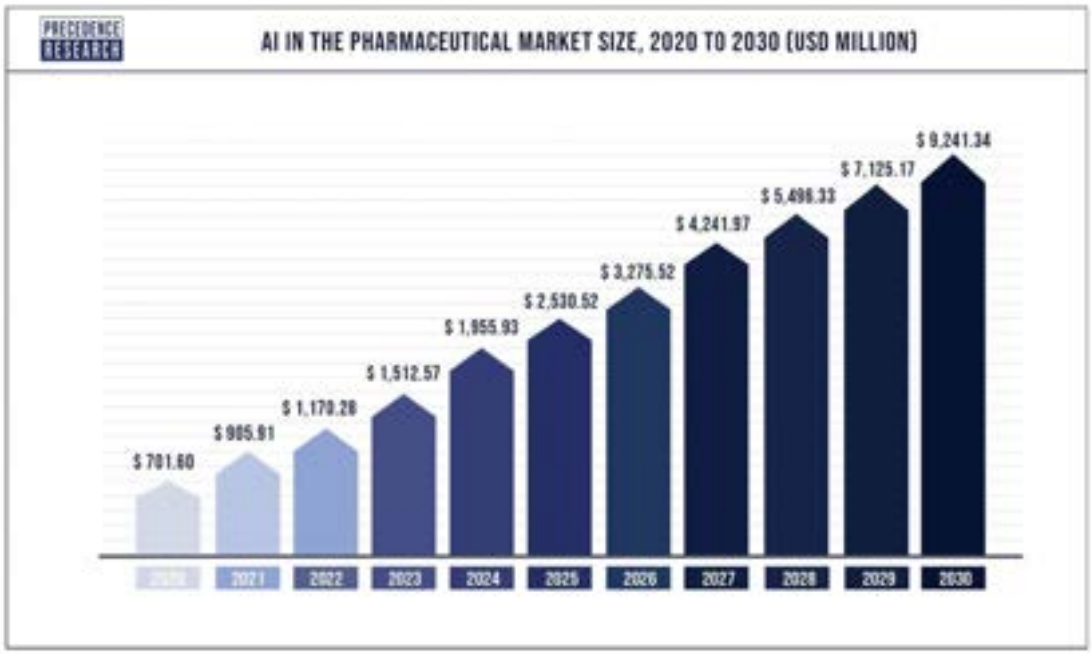
Figure 2



Source: Hillary Dukart, Laurie Lanoue, Mariel Rezende, and Paul Rutten. *Emerging from disruption: The future of pharma operations strategy*. 2022. McKinsey.

1.1.2 Artificial Intelligence Market Size in Pharma

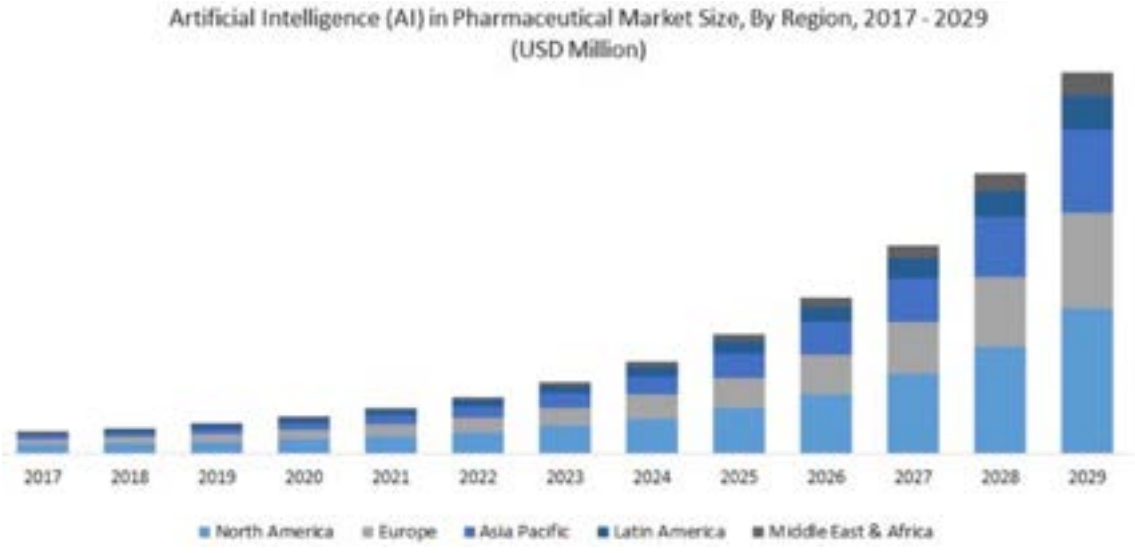
Figure 3



Source: *Precedence Research*.

The global Artificial Intelligence (AI) market in the pharma was valued at $ 1,170.28 million in 2022 and is predicted to exceed $ 9,241.34 million by 2030, growing at a compound annual growth rate (CAGR) of 29.4% from 2022 to 2030 (see figure 3).

Figure 4



Source: *Polaris Market Research Analysis*.

North America is the leading AI industry player: in 2022, the region garnered a market share of around 44%, making it the largest revenue-generating area in the industry (see Figure 4). Its dominance in the global AI in the pharmaceutical market is due to a combination of factors. One of the main reasons for the strong growth in the adoption of AI in the pharmaceutical sector is the clear regulatory framework in the region. The Food

and Drug Administration (FDA) has played a significant role in driving the adoption of AI in the pharmaceutical industry in North America: it has established a program to explore the use of AI in regulatory science that aims to evaluate the potential of AI to enhance its ability to analyse large and complex datasets related to drug development and safety. The FDA has also issued guidance on using AI and machine learning in medical devices and software that provides recommendations on developing and validating AI algorithms for medical purposes and ensuring the safety and effectiveness of AI-enabled medical devices. In addition, it has approved several AI-enabled medical devices and software applications. These efforts to explore and regulate the use of AI in the pharmaceutical industry have helped to increase confidence in AI technologies and encourage their adoption by pharma companies and other stakeholders. The region's large revenue share is also attributed to its accessibility to capital spending: the National Health Expenditure Account (NHEA) reported that healthcare spending in the USA had risen to 9,7% to $4.1 trillion, contributing to 19,7% of the nation's Gross National Product (GDP). North America also leads the rest of the world in AI for companies and funds that invest in drug discovery, with more than half of the world's AI for drug discovery companies headquartered there. This is due to the country's pioneering role and many companies using AI to force R&D, research centres, and investments. Moreover, the presence of numerous market players, several top pharma companies investing heavily in strengthening their position, and a growing number of cross-industry collaborations and partnerships are also contributing to the growth of AI in the pharmaceutical market.

However, Asia Pacific is significantly expanding the use of AI technologies in the pharmaceutical industry: it is aggressively increasing the number of AI for drug discovery companies to the point where the proportion of companies using AI for drug development in the UK and European countries is decreasing in comparison to the Asian Pacific market, and this trend is expected to continue.

Figure 5

Source: *Mordor Intelligence*.

The Asia Pacific region is considered the most opportunistic market for the adoption of AI in the pharmaceutical business (see Figure 5). This area is seeing an increase in investments in the adoption of AI to improve pharmaceutical production, which is supporting market growth. This is due to the presence of multiple prominent contract research organisations (CROs) and contract manufacturing organisations, which are boosting the adoption of AI in the pharmaceutical business. Rising healthcare costs and a rapidly growing senior population in the region also push up demand for pharmaceuticals, which drives up demand for AI in the pharmaceutical business. Furthermore, due to increased healthcare spending, regional economic development, and rising market demand for individualised treatments, the Asia Pacific region witnessed a high CAGR in the global market in 2021. With the introduction of AI technology, the Asia Pacific area is primed for significant growth in the pharmaceutical business. The region's favourable market conditions, rising healthcare spending, and market demand for individualised therapies are pushing AI adoption in the pharmaceutical industry.

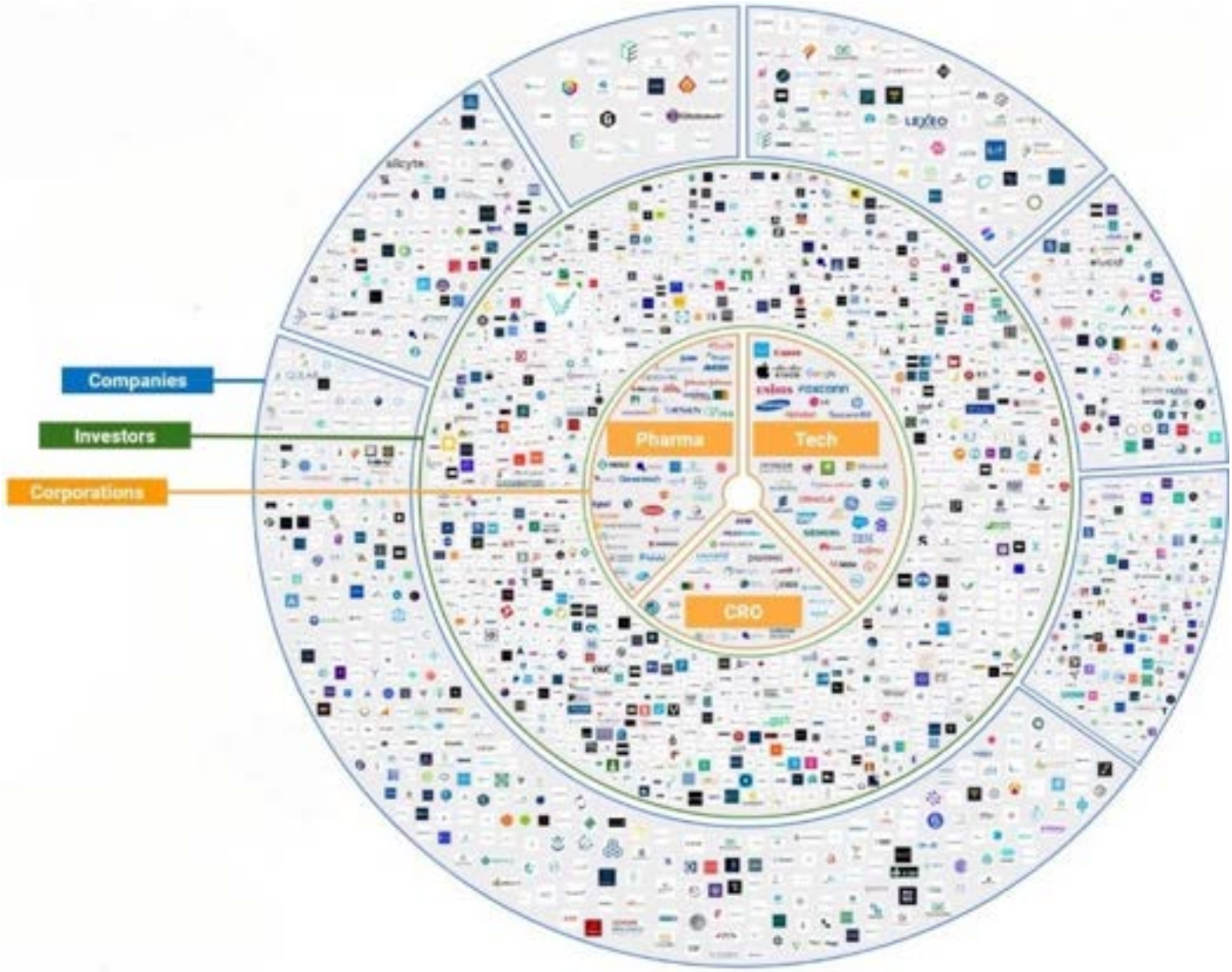
1.1.3 A Glance at the Key Industry Players

The pharmaceutical industry is witnessing a transformational shift with the adoption of AI technology, revolutionising drug discovery and development. The competition is intense, and companies that can provide the most effective and efficient solutions will be the ones that succeed in this rapidly growing industry. As a result, the AI market in pharma is experiencing remarkable growth, with an increasing number of players entering the market to capture the opportunities presented by this emerging field.

The market is characterised by various key players, including big tech companies, big pharma companies, biotech start-ups, academic research institutions, CROs, and other technology providers (see Figure 6). These players are contributing to the growth of the AI market in pharma by developing innovative solutions, strategic partnerships and collaborations, and investments in research and development.

Understanding the roles and contributions of these key players is crucial for comprehending the current state and prospects of the AI market in pharma. Therefore, this paragraph provides an overview of the various players in the AI market in pharma and their roles in driving the growth and development of this industry:

Figure 6



Source: *Deep Pharma Intelligence*.

***Big tech companies*:** Alphabet, Amazon, Apple, and Microsoft, collectively known as Tech Giants, have played a significant role in driving the digital revolution. These companies possess extensive technology portfolios and expertise in exploiting network and lock-in effects, allowing them to experience rapid growth and become influential conglomerates. Conversely, most leading pharmaceutical companies need more broad-based competencies in digital technologies, such as artificial intelligence, essential for developing digital applications. As a result, Tech Giants have recognised the potential value of the healthcare and pharmaceutical industries and are actively penetrating these markets. Several factors drive their interest in the pharmaceutical industry. One such factor is the existence of inefficiencies across various processes and workflows in the drug development value chain, which can be improved by partnering with Big Tech: Pharma is partnering with Big Techs companies to decrease costs by improving drug discovery, enabling faster clinical trials, and offering better distribution models. Additionally, the exponential increase in patient data has enabled Big Tech to identify drug targets, predict real-time medication demand, and build patient monitoring and health record

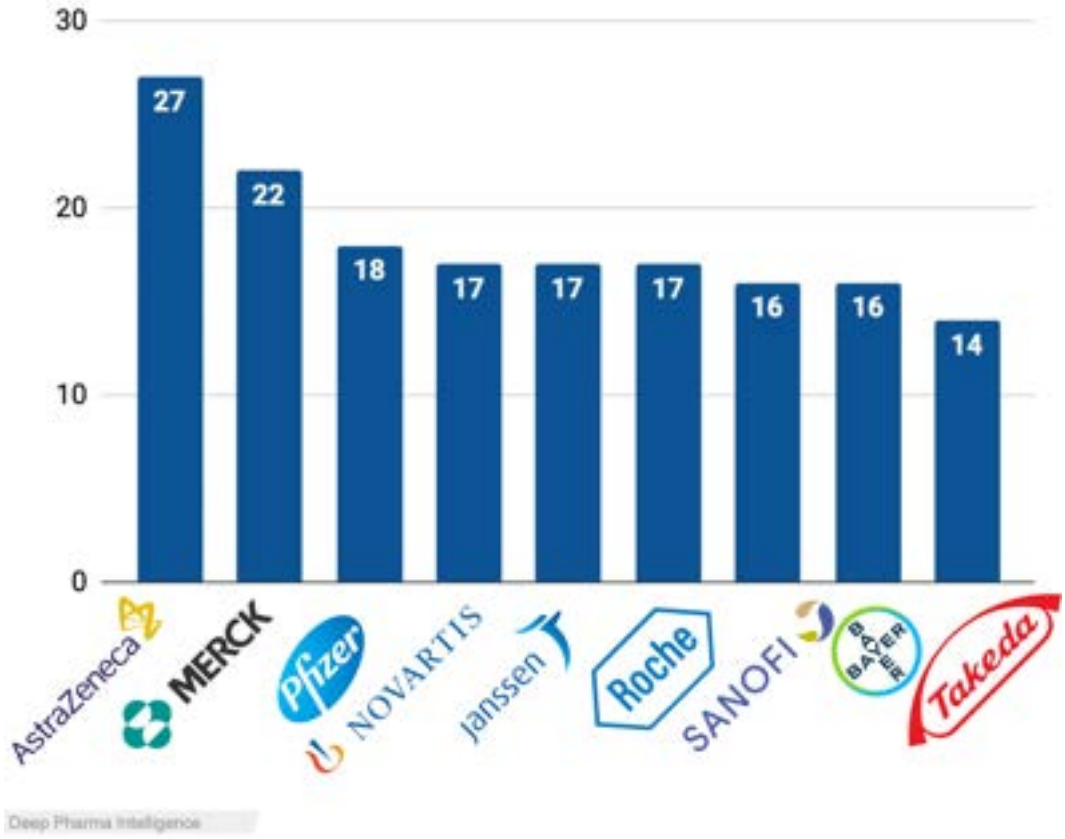
technologies. Moreover, they are capitalising on cloud, AI, and IoT opportunities throughout the pharmaceutical value chain (see Figure 7).

The digital transformation process presents two main hurdles for pharmaceutical companies that could facilitate the success of Tech Giants: hesitancy to adopt agile and technology-driven business models and limited attractiveness for top talent from the tech industry. Furthermore, pharmaceutical companies face significant challenges in managing big data and data analytics, which raises ethical issues such as accountability, transparency, permission, and privacy. Big Tech's experience in an economic environment where data sharing, context transgression, and privacy protection are less regulated than in the biomedical field may give them an edge. In addition, due to Big Tech's financial power to enter the pharmaceutical business and compete, pharmaceutical companies face the potential threat of losing market share to Big Tech, which is venturing into the pharmaceutical market with AI, cloud technology, and sensor-driven wearables to automate drug discovery, clinical trial management, and post-marketing surveillance. Depending on how intellectual property (IP) around data is governed, Big Tech may also be able to profit from data network effects, making pharmaceutical companies more dependent on them: the more biomedical data Big Tech can pull from wearables, electronic health records, and other products or services, the more valuable they become to pharma, and the more pharmaceutical companies become dependent on Tech Giants. In the pharma industry, Tech Giants can be potential partners, competitors, or both an opportunity and a threat as they disrupt specific areas of the industry.

Figure 7

Source: *CBInsights*.

Figure 8



Big Pharma: Large pharmaceutical companies invest heavily in AI technology to streamline drug discovery, clinical trial design, and patient care. They have a wealth of clinical trials, and patient records data, which can be analysed using AI to identify new drug candidates and predict treatment outcomes. Big Pharma is increasingly open to partnerships with AI startups and corporations to get a competitive edge and mitigate the problem of declining R&D efficiency. AstraZeneca and Merck are the leading Pharma players by the number of significant industry AI-focused partnerships till Q41 2023 (see figure 8).

Contract research organisations (CROs): CROs offer outsourced services for the pharmaceutical industry, such as clinical trial management and data analysis. They have also begun incorporating AI technology into their services, as it allows them to process large amounts of data quickly and efficiently. CROs can use AI to optimise clinical trial design, patient recruitment, and data analysis.

Other technology providers: Several other technology providers offer AI-powered solutions for the pharmaceutical industry. These include startups specialising in drug discovery, precision medicine, and clinical trial design. These companies have partnered with big pharma companies and CROs to develop and deploy AI-powered solutions.

Biotech startups: Many new biotech startups are emerging in the AI market for pharma. They are developing AI solutions to tackle specific challenges in drug discovery, such as identifying new drug targets, optimising lead compounds, and predicting drug toxicity. These startups often have close partnerships with academic research institutions and can move quickly and efficiently in developing new AI solutions.

Academic research institutions: Universities and research institutions are also significant players in the AI market for pharma. They have expertise in AI research and development, and many are conducting cutting-edge research in drug discovery and personalised medicine. Academic institutions are also essential partners for big pharma companies and startups, providing them access to expertise and resources.

1.1.4 AI Applications across the Pharma Value Chain *from Molecule to Market*

AI can transform pharmaceutical companies' operations, enabling them to develop more innovative and effective patient treatments, reduce costs, and improve profitability.

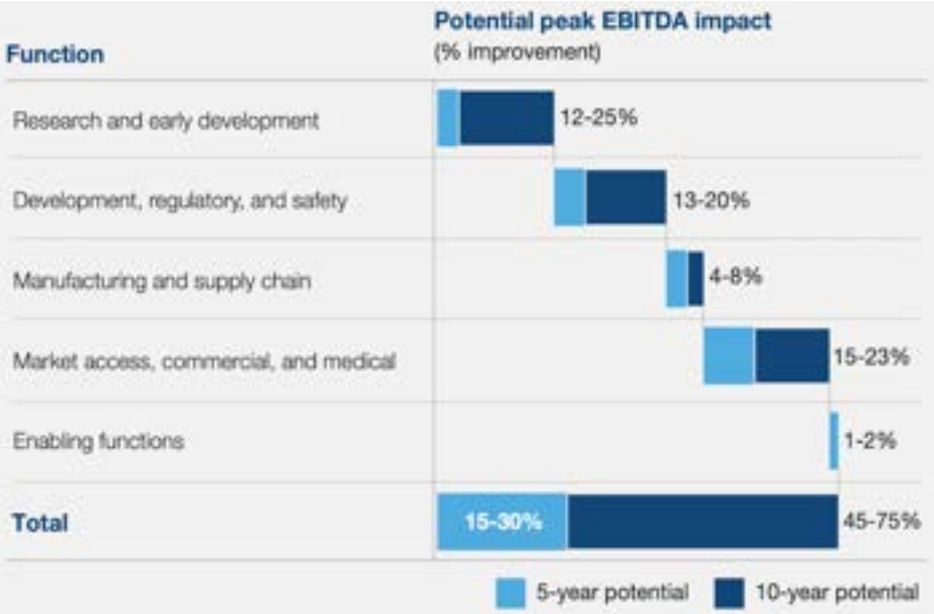
AI is being used across every stage of the pharma value chain, from drug discovery and clinical development to manufacturing and supply chain, launch and commercialisation, and post-market surveillance and patient support (see Figure 9).

Figure 9

Source: *Deloitte analysis*.

The potential of AI in the pharmaceutical industry is immense, and its impact has already started to show significant improvements. According to a McKinsey report (see Figure 10), AI applications can improve pharmaceutical companies' EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortization) by 15% to 30% over the next five years. This improvement is set to accelerate to a staggering 45% to 70% over the next decade as AI continues to enhance efficiency and cost savings across the entire pharma value chain.

Figure 10



Source: *McKinsey*.

The use of AI in pharma is not just a matter of innovation but also a competitive advantage that can benefit companies that adopt it. The potential for AI to transform the pharmaceutical industry is already underway, and the full potential is yet to be realised.

In the following chapters, we will explore the different areas of application of AI across the pharma value chain in more detail, discussing the benefits and challenges associated with each site. We will also discuss the potential future impact of AI on the pharmaceutical industry and how it will shape the future of drug development and patient care.

1.2 AI Technologies in Pharmaceuticals

1.2.1 Machine Learning

Machine learning entails creating new learning algorithms and enhancing current ones so that computers can respond without being explicitly programmed. These algorithms enable computers to evaluate massive amounts of complex data and are used to perform tasks such as classification, regression, grouping, and so on. Machine learning programs learn from existing data and then apply it to new or forecast data. Machine learning is classified into three types:

I. *Supervised Learning:* The main goal of supervised machine learning algorithms is to predict an outcome as accurately as a human expert. A model is the operationalisation of the algorithm that takes the general-purpose statistical technique and provides a context-specific parameterisation of the prediction problem that needs to be solved. This class of machine learning systems' algorithms relies on an expert-labelled dataset containing the result (the Y) and potential characteristics or features (the Xs).

In supervised learning, the initial step is constructing or acquiring a labelled dataset. The data is then divided into training and validation sets. The training dataset is used to calculate the parameters of the model that predicts the outcome. The model makes predictions on the validation dataset, which we can then compare to expert forecasts to gauge the model's quality. The validation dataset is used to test the model's accuracy once trained. These algorithms can predict either a binary or a numerical outcome. We may determine whether we are satisfied with the error rate between model prediction and expert prediction by comparing the algorithmic model's prediction of the product to the validated labelled outcomes. Suppose we are not pleased with the results. In that case, we can try a different statistical approach, collect more data, or focus on discovering other features that may help us develop a more accurate prediction. The major problem is to keep iterating between data, features, and algorithms until the error rate between the model and expert forecasts is acceptable.

II. *Unsupervised Learning:* Unlike supervised learning models, where data inputs are labelled with a specific outcome, unsupervised learning algorithms primarily identify insights in data with minimal preconceptions or assumptions. In this case, the system must be given the correct answer and should learn independently. It accomplishes this by studying the data to discover some form of structure or pattern; it seeks to find "natural" groups in the data without labels and reveal structures that may not be visible to the viewer. In other words, the AI system applies its knowledge of one problem to another related. So, the algorithm's job is to identify patterns in data, with humans or other algorithms labelling the patterns or groupings and deciding on appropriate actions. It can be used to extract insights from social media postings, such as identifying customer groups and sentiment patterns that can be used to influence product development and deliver personalised marketing. Once again, an unsupervised learning algorithm does not suggest specific labels but establishes the most robust statistical groups. Humans or other algorithms handle the rest.

It can be classified into three types. The first is about algorithms that group data into groups. The second broad category is association rule mining, in which computers search for the frequency and probability of co-occurrence among any data group and then generate relationships that are likely to occur between different sorts of products. Anomaly detection is the third type of unsupervised learning technique. In this case, the algorithm examines each new incoming observation or datum and determines whether it follows earlier patterns: If it does not fit the way, the algorithm flags it as abnormal. This type of application is frequently used in fraud detection, patient data collection, and system and machine maintenance.

III. *Reinforcement Learning*: Although they are still in their early stages, the potential applications of reinforcement learning may outweigh those of supervised and unsupervised learning. Unlike supervised learning, which begins with data on an expert's opinion on the outcome, or unsupervised learning, which starts with a pattern-and-anomaly recognition system, reinforcement learning requires only a starting point and a performance function. We begin somewhere and investigate the space around us, utilising it to reference whether we have improved or deteriorated our position: the algorithm learns through a trial-and-error process in which actions are either rewarded or punished. It then remembers each encounter and

applies what it has learned to subsequent ones. The fundamental trade-off is whether to spend more time exploring the complex world around us or utilising the model we have built thus far to drive decisions and actions; the more time we spend studying, the more convinced we will be that we have the best way down, but if we spend too much time researching, we will have less time to exploit the information and walk down. Addressing the trade-off between exploration and exploitation is critical as we optimise and increase operational efficiency across processes.

1.2.2 Robotics

The field of robotics is concerned with developing and training robots. Usually, the capabilities of a robot to interact with people and the world follow general rules and are predictable.

However, current efforts also revolve around using deep learning to train robots to manipulate situations and act with a certain degree of self-awareness. Machine learning advances, such as computer vision and tactile perception, will continue to be essential facilitators in developing robots' capabilities.

There are various types of robotics:

- *Soft robotics*: These robots are built out of soft and deformable materials, allowing them to mimic the movements of living beings. These structures can achieve complex movements and are more adaptable than traditional rigid robots;
- *Swarm robotics*: A branch of robotics concerned with deploying mini-robots that frequently replicate insects or animals that work in groups, such as ants or bees. The goal is to operate a large number of basic robots to do complex tasks;
- *Robotics by touch*: Usually employed in surgery, these robots provide the operator with a sensation of touch, feel, and vision. They are typically intended to seem like biologically inspired hands;
- *Humanoid robots*: Robots have the same structure as humans, including a torso, head, arms, and legs. Some robots may merely model a portion of the body, such as the upper body. Android robots have masculine bodies, but Gynoids have feminine bodies;
- *Serpentine robots*: Robots are meant to travel through densely crowded environments by mimicking the movement of snakes.

1.2.3 Artificial Neural Networks

Artificial neural networks (ANNs) are designed to function similarly to the human brain. Connected units (artificial neurons) are grouped in layers to process information. Each team can send a signal to another branch, simulating a human brain. Artificial neurons, on the other hand, are placed in a linear sequence, whereas neurons in the brain are coupled in a complicated and unpredictable fashion. The whole process of transforming input into output relies on each neuron's programming. Artificial neural networks are classified into three types:

- *Deep Learning*: These algorithms use many layers of neural networks to process data at multiple levels. Before the advent of deep learning, ANNs frequently had only three layers, unlike deep learning networks, which typically have more than ten layers. Deep learning is highly beneficial for evaluating complex, rich, and multidimensional data, such as voice, pictures, and video. It is most effective when used to assess massive data sets. This field of machine learning is particularly significant because it is the first algorithm family that does not require human involvement. Instead, it learns from raw data, much like the human brain, using many sensory inputs. The significant distinction between deep learning and other machine learning techniques is that more extensive neural networks continue to improve their performance as they have access to more and more data, whereas other techniques reach a plateau earlier;
- *Convolutional Neural Networks (CNN)*: In terms of the overall operation, these are highly similar to regular neural networks. The only difference is that the neuronal layer connections resemble those seen in the animal visual cortex, the brain region that analyses images. These architectures are set up to interpret each input as an image;
- *Recurrent Neural Network (RNN)*: These neural networks are distinguished from others by their architecture. These neurons are linked, allowing them to send feedback signals to one another. Here, information travels in loops from layer to layer, allowing each bit of data to be kept as memory and the network to behave dynamically. RNNs are hence well-suited for natural language processing applications.

1.2.4 Natural Language Processing

Natural language processing (NLP) is a branch of artificial intelligence that deals with computers' interpretation and manipulation of human language. Although in a more primitive form, the technology gained widespread acceptance as early as the 1950s, when linguistic experts began developing machines to automate language translations. Today, significant advances in NLP are being driven by various deep-learning methods designed to mimic the functioning of neurons in the human brain. Interestingly, deep learning NLP can now continuously learn from examples or their experiences, allowing it to find multiple applications in virtually every industry. NLP's primary uses include:

- Speech to text: Also known as voice recognition, this approach includes converting spoken words into text that other programs can process.
- Text-to-speech: This, sometimes called voice synthesis, entails converting text to relevant speech.
- Text processing: This approach entails making sense of the text and extracting bits of information that may be utilised to generate valuable insights.
- Natural language generation (NLG): This approach varies from text processing in that it does not require significant human participation. In this case, insights are derived straight from a vast dataset.
- Chatbots: NLP-powered bots can grasp a wide range of human speech. While they cannot understand human language's complexities, they may be trained to answer particular inquiries.

- Machine translation: This involves automatic text translation from one language to another. This approach has progressed from relying merely on predetermined rules to employing complicated statistical models and, most recently, neural networks to simulate human-like reasoning.

1.3 Key Drivers Fueling the current wave of AI Growth across the Value Chain

The global AI in the pharma market is experiencing significant growth and is poised for digital transformation due to several influential factors. These factors include the escalation of data volumes, the surge of computing power, the decrease in the cost of computing, significant funding, and the rise of open-source platforms.

1.3.1 Growth of Big Data

The availability of vast amounts of big data is currently fueling the growth of the Artificial Intelligence industry. The abundance of big data is critical to developing AI applications, as AI systems become more intelligent as they consume more data. This is particularly relevant to AI applications, such as deep learning, requiring significant data to generate accurate results. Recent research by the International Data Corporation indicates that the digital economy's enormous data growth rate is currently at 40% annually and is projected to reach 163 trillion gigabytes by 2025. This proliferation of data is primarily driven by the rise of intelligent devices, the Internet of Things (IoT), and social media. It is crucial to the expansion of AI applications across multiple industries. The pharmaceutical industry is also generating increasing amounts of data from various sources within the value chain. This data is obtained from real-world sources, including electronic health records, medical imaging, insurance records, wearable devices, health applications, social media, and clinical trials. As the volume of real-world data (RWD) expands, companies are exploring advanced analytics techniques such as machine learning, deep learning, and natural language processing to extract real-world evidence (RWE). Critical applications of AI in this field include understanding patient behaviour, segmenting patients for clinical trial matching, and enabling data-driven comprehension of disease progression.

This trend is expected to continue, particularly in light of the ongoing digitisation of the global economy and the rapid proliferation of intelligent devices and IoT. Pharmaceutical companies are also contributing to this trend by generating large volumes of real-world data, which can be used to develop and apply advanced analytics tools to extract real-world evidence.

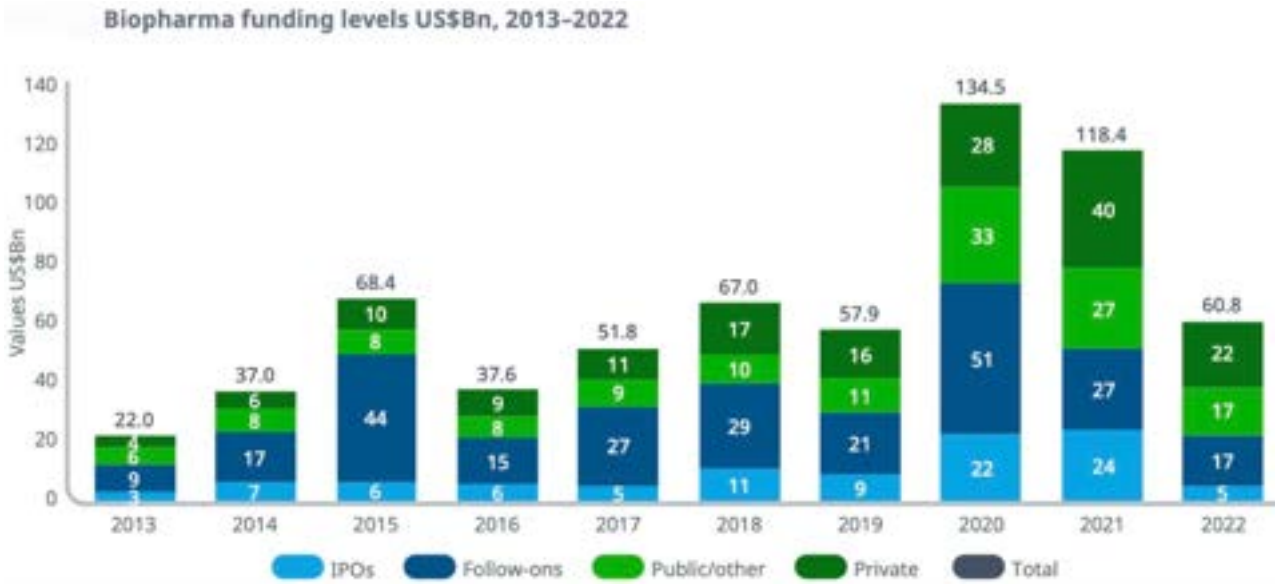
1.3.2 Increasing Computational Power at decreasing costs

With advances in technology and manufacturing, the cost of computing power has decreased significantly while the performance of computing devices has increased exponentially. This has enabled organisations and individuals to access powerful computing resources at a lower cost, allowing them to develop and deploy AI systems. As computational power prices have decreased, collecting and storing large amounts of data has become more feasible, which is essential for training AI algorithms. With more data, AI systems can be trained

to recognise patterns and make more accurate predictions, significantly improving natural language processing, image, and speech recognition. Furthermore, the availability of powerful computing resources has allowed for the development more sophisticated AI algorithms, such as deep learning and reinforcement learning, which require significant computational power to operate. These algorithms have been applied to various applications, including computer vision, speech recognition, natural language processing, and game playing.

1.3.3 Pharma Funding Trends

Figure 11



Source: *Bioworld*.

The pharmaceutical industry saw decreased funding activities in 2022 after two years of increased levels due to the COVID-19 pandemic. However, funding remained higher than that of 2019. Initial public offerings (IPOs) saw a significant drop, and there were changes in the types of funding vehicles used. This shift can be attributed to alterations in the types of companies being invested in, their therapeutic areas of focus, and their geographic location. Start-up companies focusing on COVID-19 experienced slower funding expansion in recent months. Interestingly, funding deals slowed down more for pharma companies based in China and Europe than those in the United States.

1.3.4 Rising Open-Source Community Facilitates Democratisation of AI

Rising open-source platforms have played a significant role in driving the growth of artificial intelligence. Open-source software refers to computer software whose source code is available for users to view, modify, and distribute; these give rise to a collaborative environment where developers can freely access and use AI software tools and libraries to build and train their machine-learning models.

The potential for a community to lead in solving new generations of problems is enormous: communities can be tremendous assets in the push to master the challenges created by digital operating models. Despite competing as individual businesses, each will benefit or suffer from collective accomplishments, such as improving privacy, removing news bias and manipulation, or creating effective systems to encourage and retrain displaced labour. New kinds of organisations modelled after the open-source community, but with an even broader and more powerful mandate, could play a critical role in solving many problems confronting our digital economy and society, from algorithmic bias to fake news.

The availability of open-source AI platforms has promoted and enabled *AI democratisation*, making it accessible to individuals and organisations with limited resources. The polarization and diversity combined with a distributed process in which anyone can participate helped higher quality content. Open-source platforms have also facilitated collaboration among developers and researchers, accelerating innovation and advancing AI's state-of-the-art. As a result, the development and deployment of AI solutions have become faster, more efficient, and more cost-effective.

Furthermore, open-source platforms have enabled the customisation of AI solutions to meet specific business needs: developers can modify the source code of open-source AI software to create bespoke solutions tailored to their organisations' requirements. This level of flexibility and customisation has resulted in more diverse and specialised AI applications.

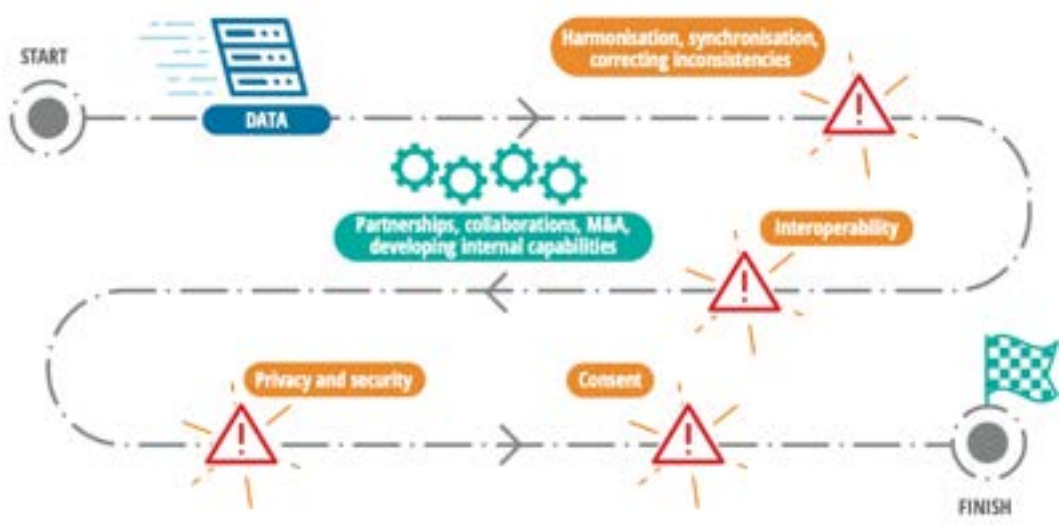
Finally, open-source communities have also contributed to developing AI talent: developers and researchers can collaborate and learn from each other, creating a vibrant AI community. This community has nurtured the growth of AI expertise and skills, which have led to the creation of new AI applications and businesses.

1.4 Barriers to AI Adoption

A recent survey conducted by McKinsey in November 2022 among 100 digital and analytics leaders in life science functional areas revealed that the primary impediments to the utilisation of digital and analytics in healthcare had undergone a shift. In contrast to the challenges of strategic misalignment and a lack of executive leadership support identified in 2020, the critical challenges in 2022 are the need for integrated data sources and talent acquisition. In this context, it is pertinent to explore in detail the principal obstacles encountered by pharmaceutical companies during the implementation of artificial intelligence and how these can be addressed:

1.4.1 The Data Challenge

Figure 12



Source: *Deloitte analysis*.

AI heavily relies on data, and the properties of the data, such as type, quality, and sensitivity, must be meticulously considered. The quality of data is a critical determinant for the practical training of AI algorithms that are unbiased, robust, and safe. In the context of digital transformation, the ability to acquire real-time data for feeding AI technologies is a competitive differentiator that will likely decide the survival and prosperity of pharma companies. Thus, winning the competition for the highest quality data is essential for gaining a competitive edge in the evolving digital landscape of the pharma industry (see Figure 12).

The need for robust, reliable, curated data

In AI technologies, robust, reliable, and curated data is paramount to effectively train AI algorithms and instil user confidence in technology performance. The pharmaceutical industry generates significant amounts of data, which must be identified, processed, and stored efficiently to facilitate analysis. However, this data is frequently unstructured, leading to limited value extraction. Moreover, data sources vary in quality and reliability, often as unstructured text, audio, video, and images that current AI technologies can only process with intervention by highly skilled human operators. Such interventions include harmonising data sets, synchronising data types and models, rectifying inconsistencies and inaccuracies, and inputting missing values to enable data to use in analytical contexts. Consequently, data curation has become a critical bottleneck in applying AI technologies in the industry.

Data interoperability

Achieving interoperability presents a significant challenge for all stakeholders in the healthcare ecosystem. In healthcare, interoperability refers to the ability of different systems and devices to exchange and interpret shared data over wired and wireless networks. Pharma companies operate across multiple geographies with

diverse IT systems and require access to data from various IT systems used by healthcare organisations and other partners. Establishing connectivity and communication between devices and IT systems and between data and workflows is essential for enabling secure and transparent data exchange through consensus standards and protocols, which is a complex task. Interoperability is crucial for improving functions across the entire pharma value chain, especially regarding the consented sharing of patient data. It also helps companies engage more effectively with clinicians and patients, improve the track and trace of products in the supply chain, enhance clinical decision support, identify patients, and improve medication adherence, among numerous other applications. Developing interoperable systems is necessary to improve workflow speed and performance and break down siloed behaviours that inhibit efficiency. Therefore, companies must address interoperability challenges to enhance their effectiveness and competitiveness in the healthcare industry.

Data security

The proliferation of data in the pharma industry presents a significant challenge for maintaining data privacy and security. This issue has become more pronounced due to the industry's information-rich nature, which attracts cybercriminals and state-sponsored actors seeking to exploit patients' personal and medical data, research, and product information. Health data is precious as it can be used to orchestrate financial and medical fraud, identity theft, and intelligence gathering, and breaches of personal health information can remain undetected for long periods. These attacks can target the data, the model, or the underlying infrastructure of the AI system, potentially leading to the corruption or alteration of data and system behaviour, resulting in erroneous decisions or even physical harm.

To mitigate these risks, pharma companies must remain vigilant in actively monitoring their data and implementing robust security processes. Given the persistent nature of these threats, a multifaceted approach is necessary, involving various components such as people, governance, organisations, procedures, controls, technology, and intelligence. Moreover, IT and business leaders must work collaboratively to develop and manage a comprehensive cyber risk strategy encompassing security, privacy, integrity, and confidentiality. This strategy must be integrated into the business mindset, process, and policies, rather than solely within the IT architecture and systems design.

Given the severity of these risks, cyber risk strategy must be a key priority for senior management. A comprehensive strategy tailored to the organisation's risk tolerance and focusing on vulnerable gaps, valuable data, and systems could drive a company's market position and provide a competitive advantage.

1.4.2 The Technological Challenge

The pharmaceutical industry faces the challenge of managing legacy systems that often contain heterogeneous and disparate data stored and analysed locally, which limits their sharing across the organisation. Integrating AI hardware and software into existing IT infrastructure is a complex task that requires skilled talent, which

currently needs more supply among many companies. Maintaining or replacing IT infrastructure to an acceptable standard can be costly and time-consuming. Developing a secure and centralised data governance and security system can also be daunting.

Integrating cloud-based architecture is replacing traditionally siloed enterprise software systems. Organisations across industries are moving away from traditional on-premises IT infrastructures to overcome these challenges and opting for cloud computing and data storage for analytics and predictive modelling. The Healthcare Information and Management Systems Society reported that over 83% of pharma companies currently use cloud services, compared to 42% in 2020.

Using a third-party provider for software as a service (SaaS), infrastructure as a service (IaaS), and platform as a service (PaaS) can provide numerous benefits over on-premises data storage and analysis.

These benefits include meeting data security, privacy, and regulatory requirements, increased efficiency, reduced operational costs, advanced processing and transferring speed, increased scalability and flexibility, simple deployment, and improved data connection and collaboration. The cloud enables better collaboration by eliminating data silos and overcoming organisational complexity, which is typical of large pharmaceutical companies often spread across different countries. This allows employees to work together much more effectively across different geographies. Cloud computing can also improve collaboration between pharma companies, smaller biotech companies, research laboratories, and academic institutions worldwide. It can provide smaller and mid-sized pharma companies with access to information and communication technology (ICT) resources, including hardware and software previously unavailable to them. This helps minimise SMEs' strategic disadvantages in leveraging ICT to increase internal operational efficiencies and save costs. Data security is another crucial factor driving the move to the cloud. Encryption, cloud data protection gateways, combination passwords, firewalls, cache patterns, and other cloud security technologies can protect sensitive information.

Cloud computing for biotech and pharma is a game-changer in many areas, from early-stage research to drug development and commercialisation. The cloud's impact on the sector and its numerous benefits make it essential for any pharmaceutical company that intends to grow.

1.4.3 The Legal and Regulatory Challenge

AI is subject to the same legal and regulatory frameworks as other healthcare technologies but poses unique challenges and concerns. The pharmaceutical industry operates in an increasingly complex and constantly evolving regulatory landscape. Over the past few years, the industry has seen many regulatory changes, and many new regulations are still in force. With increased regulatory changes and new rules, the industry must balance protecting patients and enhancing public health while fostering innovation in medicine, science, and technology.

Regulatory compliance is critical to product development and commercialisation, providing a framework for optimising commercial objectives and patient access. Companies that consider regulation merely as a financial burden run the risk of compromising the possibility of innovative medicines gaining regulatory approvals as quickly and safely as possible. Therefore, companies must navigate regulation effectively and collaborate with regulators: navigating regulation well and collaborating with regulators can be a differentiator for pharma companies as both parties embrace AI and other digital technologies to enhance the economy, efficiency, and effectiveness of regulatory operations.

A critical area of regulation is data protection and privacy. The use of AI in healthcare often involves the processing of sensitive personal data, which is subject to strict data protection laws such as the General Data Protection Regulation (GDPR) in the European Union. Healthcare organisations and AI developers must comply with these regulations when collecting, storing, and processing personal data. Another critical area of law is approving and regulating AI-based medical devices and drugs. With the growing use of AI in healthcare, the FDA (Food and Drug Administration) and EMA (European Medicines Agency), the two regulatory bodies responsible for ensuring the safety and efficacy of products in their respective regions, have started to develop guidelines and regulations for the use of AI.

In the United States, FDA has established a regulatory framework for AI in medical devices. This framework categorises AI-based medical devices into three classes based on the level of risk they pose to patients. Class I devices pose the lowest risk and are subject to general controls, while Class II and III devices pose higher risks and are subject to more stringent regulations. It also requires manufacturers to submit premarket approval applications for Class III devices, which undergo a rigorous review process to ensure their safety and efficacy. Similarly, EMA has developed guidelines for using AI in drug development and European approval. The guidelines focus on using AI to analyse clinical trial data and create predictive models for drug safety and efficacy: any AI-based drug development tools must be validated to ensure their accuracy and reliability.

In addition, ethical and social considerations are also crucial in the legal and regulatory landscape for AI in healthcare. There are concerns about the potential bias and discrimination in AI systems and the potential for AI to replace human decision-making in healthcare. These concerns have led to calls for the development of ethical frameworks and guidelines for the development and use of AI in healthcare.

AI technologies can offer significant advantages to pharma companies in optimising their response to the increasingly complex regulatory environment. These advantages include increased efficiency, improved oversight, improved submission quality, improved submission planning, increased capacity, and improved responses. One of the primary benefits of AI technologies is increased efficiency: with automation bots, companies can transition outsourced activities and in-sourced repetitive tasks, freeing up highly skilled resources and reducing overall spending. This not only improves efficiency but also increases productivity.

Another advantage of AI technologies is improved oversight. Robots operate in a controlled manner, and an audit trail is kept of every performed action. Advanced reporting helps control and enables sound decision-making, reducing the likelihood of errors and improving the overall quality of work. AI technologies can also

improve submission quality by enhancing the ability to compile, store, update, and operationalise regulatory intelligence. This improved ability to manage regulatory intelligence can help ensure compliance and reduce non-compliance risk.

Furthermore, automation bots can facilitate improved submission planning through advanced search and contextualising capabilities. This enables faster and improved knowledge management, making it easier for companies to stay up-to-date with the latest regulations. AI technologies can also increase capacity by freeing skilled resources to focus on more value-add work. This can improve staff satisfaction, productivity, and the potential to innovate. Finally, AI technologies can improve query responses, leading to streamlined market submissions. This can enhance a company's reputation and increase its competitiveness in the marketplace.

1.4.4 The Ethical Challenge

The complexities surrounding the ethical considerations of AI systems can be challenging to navigate. As AI technologies progress, the likelihood of unintended or negative consequences also increases. As a result, every industry's responsibility is to take measures to ensure ethical concerns are adequately addressed. The operational facets of AI ethics are intricate and multifaceted, generating five primary matters about the ethics of data and AI technologies: privacy, bias and discrimination, lack of transparency and explainability, lack of governance and accountability, and workforce displacement and transitions.

Privacy

The right to privacy is a crucial aspect of human rights, especially in AI systems, which require robust data governance policies to maintain the quality and integrity of the data used. The relevance of data in the domain of AI systems, access protocols, and the ability to process data in a manner that safeguards privacy are integral aspects of data governance. AI systems, through digital records of human behaviour, have the potential to discern not only individuals' preferences but also their age, gender, sexual orientation, and religious or political views, making privacy a fundamental concern for individuals. To ensure trust in the data-gathering process, data collected about individuals mustn't be used unlawfully or unfairly to discriminate against them.

It is crucial to strike a fair balance between data privacy and the benefits that data-driven insights can generate. Pharmaceutical organisations must be aware of the legal and compliance requirements necessary to protect the increasing volume of data. They must guarantee privacy and data protection throughout the entire lifecycle of AI systems and be transparent about how information is collected and used to protect individual privacy.

Organisations can use data anonymisation techniques to protect privacy to ensure that personal information is not directly identifiable. Additionally, companies should establish data access protocols that outline who has access to the data and for what purpose. This would ensure that data usage is limited to those who require it to perform their job functions and that data security measures are in place to prevent data breaches. Furthermore,

organisations can deploy data privacy impact assessments (DPIAs) to assess potential privacy risks and develop appropriate mitigation strategies.

By prioritising privacy protection and implementing transparent data governance policies, pharma companies can demonstrate their commitment to respecting fundamental human rights and building trust with stakeholders.

Bias and discrimination

AI models rely on data to generate insights and predictions, and the quality and fairness of such models are inherently linked to the quality and right of the data they are trained on. Unfortunately, data sets used by AI systems, whether for training or operation, may need more historical bias, incompleteness, and better governance models, leading to biased and potentially discriminatory outcomes that could exacerbate prejudice and marginalisation. Addressing these biases at the collection phase, where possible, is crucial to prevent further discrimination against certain groups or contexts. Additionally, oversight processes must be implemented to analyse and address any unfair bias inherent in the development of AI systems, including their purpose, constraints, requirements, and decision-making processes.

To mitigate data biases, pharmaceutical companies must adopt a comprehensive strategy to ensure standardisation, equity, and fairness in the underlying data used in AI models. Engaging data scientists to understand the causes of data bias and how best to mitigate the data risk is critical. Organisations must also ensure that end users are trained to interpret and respond to AI outputs while recognising the existence of any biases before taking further action. Furthermore, a diverse team with backgrounds in various disciplines and cultures can ensure a diversity of opinions and mitigate the impact of discrimination. Hiring a diverse team is an essential step toward creating a fair and unbiased AI system that benefits all members of society.

Moreover, to ensure AI models' fairness, companies can utilise techniques like counterfactual analysis to simulate different scenarios and evaluate the impact of other interventions. This approach can help identify areas where the AI system may be biased and help formulate strategies to mitigate these biases. Furthermore, pharma companies must establish clear guidelines and standards for data collection, governance, and transparency to promote responsible and ethical AI development. By incorporating these practices, companies can build more trustworthy and fair AI systems, helping to prevent discrimination and bias and promoting better health outcomes for all.

Lack of transparency and explainability

One of the primary critiques of AI algorithms is their *black-box* nature and need for more transparency, leading to a clearer understanding of the basis for their insights. Explainability addresses this issue by providing the ability to explain the technical processes of an AI system and the associated human decisions. Technical explainability necessitates that the decisions made by an AI system are comprehensible and traceable by humans. The healthcare industry's key stakeholders, including manufacturers, payers, providers, and

regulators, will likely accept machine learning algorithms that need more transparency. Left unchecked, this may lead to machine learning becoming akin to alchemy, with users needing help to discern why some algorithms succeed while others fail or what criteria distinguish between different algorithm structures. Additionally, more transparency is required to limit machine learning's impact. Users need to be made aware of which aspect of the algorithm provided a gain over conventional methods, resulting in the loss of the algorithm's ability to identify novel causes.

Greater attention to explainable artificial intelligence is crucial in overcoming scepticism and establishing trust among healthcare stakeholders. Leading pharmaceutical companies have recognised this issue and are using machine learning to improve their algorithms' transparency by clarifying their components and unique effects on a decision or prediction. This enables stakeholders to interpret, comprehend, and trust the data and reasoning on which decisions are based. Additionally, trade-offs may be necessary between enhancing a system's explainability, which may reduce its accuracy, and increasing its accuracy at the expense of explainability. Whenever an AI system significantly impacts people's lives, stakeholders should be able to demand a suitable explanation of the AI system's decision-making process. Such an explanation should be prompt and tailored to the expertise of the relevant stakeholder. Furthermore, answers should be available for the degree to which an AI system influences and shapes organisational decision-making processes, the design choices of the system, and the rationale for its deployment.

Lack of governance and accountability

Processes and accountability for AI applications need to be better defined, with a need for clarity on roles of responsibility across the algorithms workflow. This lack of governance and accountability in AI deployment in healthcare can lead to various negative consequences, such as patient safety issues, biased decision-making, and compromised privacy and confidentiality.

Auditing can be critical in addressing the need for more governance and accountability in AI deployment in healthcare. Auditing refers to assessing and evaluating the performance and outcomes of AI algorithms and systems to ensure that they align with the intended objectives and do not cause unintended harm. Auditing can help mitigate these risks by independently assessing the AI algorithms and systems to ensure they comply with ethical, legal, and regulatory requirements. Auditing involves several steps, including data collection, algorithm analysis, performance evaluation, and reporting of findings. The audit process should be transparent, objective, and comprehensive, identifying potential risk areas and recommending appropriate remedial actions. Auditing in addressing the concerns of lack of governance and accountability in AI deployment in healthcare is becoming increasingly important as the use of AI technologies in healthcare continues to expand. Auditing can help build trust in AI systems and ensure they are used responsibly and ethically to improve patient outcomes. It can also help healthcare organisations comply with regulatory requirements and avoid potential legal and reputational risks.

Workforce displacement and transitions

AI is expected to cause workforce displacement by automating various routine and repetitive tasks that humans previously did. This displacement is caused by the ability of AI to process vast amounts of data, analyse it, and perform tasks that were once only possible for humans; this includes tasks such as data entry, fundamental analysis, and specific customer service tasks. As AI technology advances, it can increasingly perform more complex tasks, such as decision-making and problem-solving. This means that even highly skilled jobs, such as those in healthcare, are at risk of displacement as AI technology improves.

According to McKinsey's projections around how AI adoption and absorption will affect employment in 2030, the number of displaced workers due to automation will amount to 400 million, while 75 million to 375 million workers (3% to 14% of the global workforce) will need to switch occupational categories. Moreover, all workers will need to adapt as their occupations evolve alongside increasingly capable machines: some of that adaptation will require upgrading their skills.

The workforce displacement caused by AI is expected to have significant social and economic impacts.

Governments and business leaders are therefore taking steps to mitigate the impact of workforce displacement caused by AI. Their priorities include the following:

- Economic growth: ensuring robust demand growth and economic dynamism because economies that are not expanding don't create jobs;
- skills upgrade: investing in training programs to help workers upgrade skills they need to transition to new roles, especially retraining midcareer workers, as people work more with machines;
- fluid labour market: the shifting occupational mix will require more fluid labour markets, greater mobility, and better job matching;
- transition support: implementing policies that adapt income and support transition to help workers displaced by AI and enable them to find new employment.

Artificial intelligence has the potential to revolutionise the pharmaceutical industry by improving drug discovery, optimising clinical trials, and enhancing patient care.

However, the use of AI in pharma also poses significant ethical, legal, and social challenges that must be addressed through AI governance and trustworthy AI.

AI governance refers to the policies, procedures, and controls governing AI systems' development, deployment, and use. In the pharma industry, AI governance is critical to ensure that AI is used ethically, responsibly, and in compliance with legal and regulatory requirements. This includes ensuring that AI systems are designed and developed using transparent and fair algorithms and that data privacy and security are maintained throughout the data life cycle.

Trustworthy AI, on the other hand, refers to AI systems that are reliable, transparent, and ethical. Responsible AI is critical in this industry to ensure that AI systems are safe and effective for patients and do not perpetuate bias or discrimination. Trustworthy AI can be achieved through explainable AI, which allows users to

understand how AI systems arrive at their decisions, and through ethical AI principles, which ensure that AI systems are designed to promote the public good and not harm individuals or communities.

Building a culture of AI governance and trustworthy AI in pharma companies is essential for a few reasons:

- Compliance: AI governance is necessary to ensure compliance with existing regulations, such as the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA).
- Patient safety: Trustworthy AI is essential for ensuring patient safety, as decisions made by AI systems can have significant implications for patient health.
- Reputation: A commitment to AI governance and trustworthy AI can enhance a company's reputation, demonstrating its commitment to responsible AI development and deployment.
- Innovation: Building trustworthy AI can encourage innovation, as stakeholders will be more willing to embrace new technologies they can trust.

By doing so, pharmaceutical organisations can harness the power of AI to accelerate drug discovery, improve clinical trials, and enhance patient care while promoting public trust and confidence in the use of AI in pharma. By ensuring compliance, prioritising patient safety, enhancing reputation, and encouraging innovation, pharma companies can demonstrate their commitment to responsible AI development and deployment.

1.4.5 The Talent Gap Challenge

AI development has significantly increased the importance and prominence of technology in the pharma field, leading to an urgent need to attract and retain skilled personnel who can successfully navigate these technologies. It’s impossible to imagine a business today succeeding without a strong base of tech talent.

Although pharmaceutical organisations are known to offer higher salaries than other industries and possess a compelling mission to enhance the quality of life, the recruitment of tech talent remains a challenge.

Significant skill gaps in seven critical areas are expected to become more severe over time: DevOps, Platforms and products, Automation, Customer Experience, Cybersecurity and privacy, Data management, and Cloud. According to a survey conducted by McKinsey, 87% of senior executives across the globe agree that their companies need to be adequately prepared to address the skill gap, and 61% of HR professionals predict that hiring developers will be their most significant obstacle in the years ahead.

Several macro trends contribute to this hiring challenge. Firstly, digital technology is becoming an increasingly vital catalyst for scientific advancements, particularly in remote clinical trials, biomarker identification, and digital therapeutics. Secondly, tech capabilities are rapidly evolving, and the essential roles and skills for creating differentiating tech solutions, products, and services are quickly changing. Traditional hiring, upskilling, and reskilling approaches have fallen short, as organisations often need to identify the talent they need or fully understand their expectations and requirements. Thirdly, the "Great Resignation" phenomenon is natural. Many employees leave their jobs due to a misalignment between their expectations and employers'

offerings, thus exacerbating the talent supply-demand gap. Finally, competition for tech talent is increasingly industry and location agnostic, with life science firms competing not only with each other but also with other sectors seeking the same talent pool. Remote work has also eliminated regional advantages and intensified competition for these workers.

There are five measures that CEOs, CIOs, CHROs, and functional leaders can employ to improve their technological talent:

I. *Establish skill-based, strategic workforce planning*: Life science companies require different skill sets today than they did three years ago due to changes in technology and business models. With many project and relationship managers, traditional tech delivery models are replaced by more agile models incorporating product roles, designers, and internal engineers. Adopting new cloud-based architecture and innovative open-source tools and languages necessitates updated engineering skills. Organisations can use strategic workforce planning to address these changes and proactively refresh their tech talent bench. This approach aligns talent planning with the tech-business roadmap, allowing for targeted hiring, upskilling, reskilling, and partnerships. Strategic planning is essential as tech talent becomes a crucial strategic differentiator for life science companies.

II. *Have an authentic, digitally focused value proposition*: a well-defined employee value proposition (EVP) can enhance a company's attractiveness to potential employees. In the life science industry, the focus of the value proposition has been primarily on R&D and commercialisation employees, who have traditionally brought significant benefits to the organisation, emphasising patient outcomes. We have identified four dimensions of EVP - exciting work, great employer, personal growth, and energising culture - and suggest ways life science digital can be differentiated to make it more appealing to tech employees. To accentuate exciting work, companies can showcase challenging projects that offer intellectual stimulation and share examples of unique problems that employees will work on, along with the exciting technology behind them. To provide an excellent employer experience, companies can emphasise their meaningful mission and values that align with those of employees and their quest to give treatments, keep vulnerable populations safe, create scientific breakthroughs, bridge disparities, and respond to global crises.

III. Additionally, benefits that resonate with the digital workforce, such as "anytime, anywhere" remote work and generous educational travel budgets, should be highlighted. To offer personal growth opportunities, companies can provide horizontal and vertical paths for career advancement and tailored capacity building. They can communicate varied and relevant career advancement opportunities, such as internal temporary assignments to learn about digital therapies. They underscore how joining the organisation will help develop digital skill sets through external partnering for learning, certifications, and conferences. Finally, an innovative team with a supportive environment encourages employees to be their best selves to create an energising culture. Companies can demonstrate how the science-driven culture underpinning the organisation's success also applies to the digital workforce through labs, research initiatives, engineering

town halls, etc. They can articulate examples of how agile approaches and mindsets have benefited the entire organisation through narratives focusing on non-hierarchical decision-making, rapid and iterative product development, empowered teams, and individual autonomy. However, companies need to back up their EVP with programs and a culture that explicitly delivers on the promise. If employees perceive a disconnect between the stated EVP and the reality on the ground, they are likely to leave and, worse, spread negative reviews. Therefore, companies must ensure that the EVP aligns with reality, as it is a de facto social contract with employees.

IV. *Take a candidate-centric approach to hiring*: According to a McKinsey report, Job seekers in the tech world are impatient: 57% of job seekers are unhappy with the waiting time after an interview, while 23% are willing to wait only one week to hear back. Searching for a job should be simple and manageable for job seekers. Like any other customer experience, the hiring process can be improved using design thinking, which focuses on addressing consumer needs to enhance products and services. To achieve this, companies can start by examining their current hiring process from different perspectives, such as new hires, recruiters, hiring managers, and online reviewers. This helps them identify the strengths and weaknesses of their existing approach. With this baseline information, they can gather stakeholders to work together in designing an optimal hiring experience. One approach can be adopted in developing the personas of both internal and external candidates to understand their motivations, aspirations, and needs. With this understanding, the company can create a streamlined hiring process that eliminates unnecessary steps and efficiently assesses candidates' technical and behavioural skills. By using design thinking to create a more effective hiring process, companies can reduce the stress and frustration of job searching for candidates.

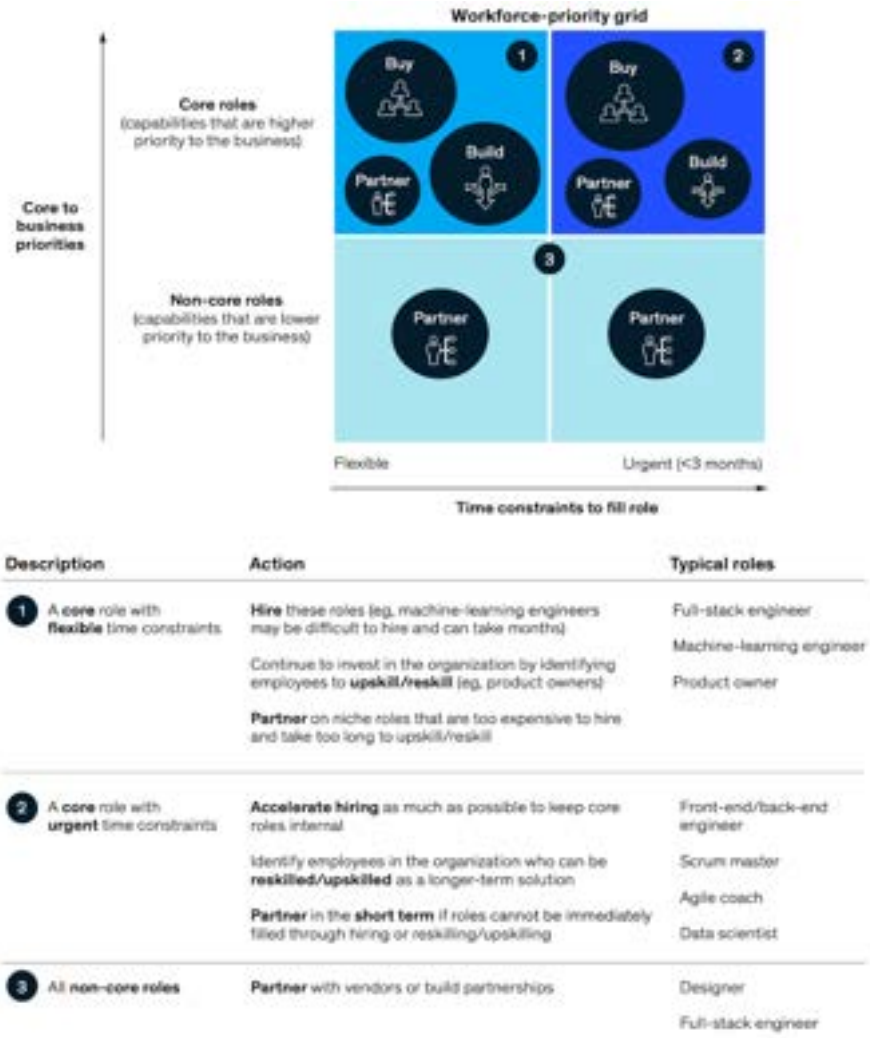
V. *Embrace agile ways of working:* In today's workplace, technology professionals seek to work in small, agile teams operating within a flexible and nimble organisational structure. This agile way of working involves self-selection of tasks, iterative testing and release of products, and continuous refinement of working models and interactions with each sprint. This approach is becoming increasingly prevalent in life sciences research and development (R&D) teams, including clinical trial leads and bench scientists. For technology talent, this approach emphasises minimising command-and-control processes and empowering team leaders to encourage and guide their teams in interpreting roadmaps and facilitating progress toward goals. As a result, this approach often leads to tighter integration among tech teams, business operations, and customers, fostering more outstanding contributions to an organisation's health- and patient-centric mission rather than simply fulfilling abstract tech requirements. The benefits of this approach include improved employee satisfaction, reduced costs for delivery, increased speed, and less non-value-added work. This model also enables a more personalised and dynamic approach to employee development, where teams can gain expertise in multiple areas of the business through lateral career moves, promoting growth and exciting career opportunities. Overall, this approach to workforce management has proven effective in facilitating innovation, fostering collaboration, and promoting employee engagement and development.

VI. *Build growth-oriented career ladders*: Implementing a growth-oriented career ladder can foster career development and job satisfaction among junior staff in the life science industry. A flexible career ladder allows employees to apply their skills and knowledge across various life science use cases, leading to diverse experiences and opportunities for professional growth. Top-performing companies recognise the value of lateral career moves in promoting the advancement and offering exciting career paths. By encouraging staff to move across different products, channels, and roles, individuals are exposed to new challenges and gain expertise in multiple business areas. Lateral career moves can also provide valuable cross-functional experience, which is highly valued in today's dynamic and complex work environment. By providing employees with opportunities for growth and advancement, companies can promote employee retention and reduce the costs associated with turnover. In addition, investing in employee development through lateral career moves can improve organisational performance by providing employees with a breadth of knowledge and skills that can be applied across the business.

Furthermore, companies that offer flexible and growth-oriented career ladders may be better equipped to attract top talent in the industry. By emphasising the importance of professional development and offering diverse career paths, these companies can appeal to individuals seeking a challenging and dynamic work environment that supports their growth and development. Building growth-oriented career ladders can significantly benefit employees and organisations in the life science industry. Employees can gain the skills and expertise necessary to excel and contribute to the business's success through lateral career moves and other development opportunities.

In talent management, the notion of hiring or outsourcing as a panacea for talent-related issues needs to be revised. While hiring external talent can be a valuable strategy for accessing specialised expertise or filling urgent talent gaps, it can sometimes be a quick fix for talent gaps. There is often a lag time before new hires can become productive. Additionally, there may be a need for more qualified talent in the external job market, leading to intense competition for top candidates. On the other hand, outsourcing is often viewed as a cost-effective means of obtaining specialised talent. Still, it can result in losing control over core business functions and intellectual property and a need for agility in responding to rapidly changing market conditions. The solution to these talent challenges is to build and develop skills internally. Moreover, Reskilling is cheaper than hiring: while reskilling an internal employee may cost $20,000 or less, hiring often costs $30,000 for recruitment alone, in addition to onboarding training, and new hires are two to three times more likely to leave then. To achieve this, organisations must strike an appropriate balance between building skills internally, hiring externally, and outsourcing: a workforce-priority grid can aid in identifying which roles should be created, acquired, or partnered within the organisation (see Figure 13).

Figure 13



Source: *McKinsey*.

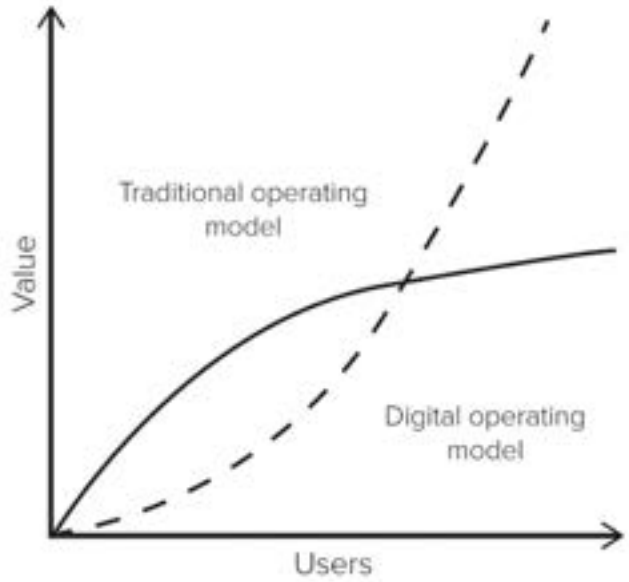
Successful training initiatives provided by leading companies transcend traditional and insufficient programs by offering continuous and personalised learning opportunities that help employees build new skills and keep pace with emerging technologies and industry trends. Rather than solely providing certifications, the emphasis is placed on building experience. Effective reskilling and upskilling require a clear understanding of the skills that best translate into new skills. Developing a comprehensive career development program that identifies career paths and promotes internal mobility can help create a pipeline of skilled talent within the organisation. This approach can increase retention rates, employee engagement, and a more robust internal talent pool. To attract and retain top candidates, companies must ensure that their employer brand is strong and that their hiring process is efficient and effective. Maintaining positive relationships with staffing agencies and third-party vendors is essential to access specialised talent when needed.

Organisations must rely more on hiring or outsourcing to overcome talent challenges. Instead, the most effective approach to talent management requires a multi-faceted strategy that includes developing internal talent, hiring external talent, and outsourcing as appropriate. By building a strong internal talent pipeline and maintaining a robust external talent network, organisations can better position themselves to meet their talent needs and achieve their strategic goals.

1.4.6 The Organisational Challenge

Rearchitecting the Firm: a critical and Difficult Transition

Figure 14



Source: Marco Iansiti, Karim R.. Lakhani. *Competing in the Age of AI*. Harvard Business Review

Digital firms operate differently from traditional enterprises. Instead of relying on specialised and siloed organisational processes, digital firms have an integrated and highly modular digital foundation.

This digital foundation is critical in delivering value to customers and generates increasing returns to scale, scope, and learning (see Figure 14). Rising levels of digitisation, analytics, and AI can dramatically improve a business's scalability, increasing the value curve more rapidly as a function of the number of users or their engagement. A digital operating model can overwhelm the status quo as it collides with a traditional company.

Traditional operating architecture created severe constraints on firm growth and value. Traditional enterprises deploy numerous IT systems, each meeting the demands of a specific function, creating functional silos that hinder collaboration. Aggregating these systems and connecting valuable data is a long and challenging process that requires custom software development, which can become resistant to change over time. Methods, software applications, and data are embedded in individual, largely autonomous, and siloed organisational units: many major enterprises still operate with distributed and inconsistent data and technology, separated by corporate divisions and incompatible legacy systems. Furthermore, the traditional operating architecture of functional structures and operational silos causes firms to hit limits, diminishing scale, scope, and learning returns.

When organisations expand, they become more complex, and it becomes more challenging to manage them: they build bureaucracies and inefficiencies and embed norms, incentives, and rewards that foster inertia. With too much scale, scope, or demand for learning and innovation, the managerial process will eventually stop working well, leading to inefficiency and failure.

To fight these issues and scale a software- and data-driven organisation, firms must break geographical, subfunctional, and technological silos and collaborate across functions and industries. By doing so, they can make information flows and decision-making processes faster and more transparent. This transforms the growth process by removing the traditional operating bottlenecks constraining the firm's scale, scope, and learning potential.

To extend their knowledge and data networks, pharmaceutical companies can break the silos that separate internal functions and enhance collaboration with external partners, including academic researchers, CROs, providers, and payors. However, addressing the challenges of communication, governance, and data sharing requires a shift in mindset away from information boundaries and towards a collaborative culture.

Organisational silos result in data silos, and functions typically have responsibility for their systems and the data they contain. Adopting a data-centric view with a clear owner for each data type across functional silos and through the data life cycle can significantly facilitate using and sharing of data. Furthermore, having a single owner will enhance accountability for data quality.

These organisational changes will be possible only if a company’s leadership understands the potential long-term value that can be unlocked through better use of internal and external data.

When firms set up a new digital core, they should avoid creating deep organisational divisions. Instead, they must be architected differently and built on fundamentally different business and operating foundations. Rather than rest on a traditional corporate model and run through various specialised and siloed organisational processes, digital firms rest on an integrated, highly modular digital foundation. Information technology is no longer merely an enabler and optimiser of traditional techniques and methods; instead, the software makes up the actual operating core of the firm. Software is critical in delivering value to the firm's customers by replacing traditional labour- and asset-intensive organisations fueled by a data pipeline and powered by algorithms. For traditional firms, becoming a software-based, AI-driven company is about becoming a different data-centric organisation supported by an agile organisation that enables ongoing change.

Stages of Operating Model Transformation

In "*Competing in the Age of AI*," Iansiti and Lakhani highlight a natural sequence of four stages in becoming a state-of-the-art AI factory, ranging from siloed data to an AI factory (see Figure 15).

The journey starts at stage 1, characterised by siloed data, where organisations usually begin their analytics-based decision-making processes. The authors note that there are typically few barriers at this stage as vendors and consultants can often demonstrate the value of analytics-based decision-making without significant organisational and cultural shifts.

As companies progress to stage 2, the pilot stage, they test and experiment with AI solutions. At this stage, the authors observe that companies are typically more receptive to change as the value of AI becomes apparent.

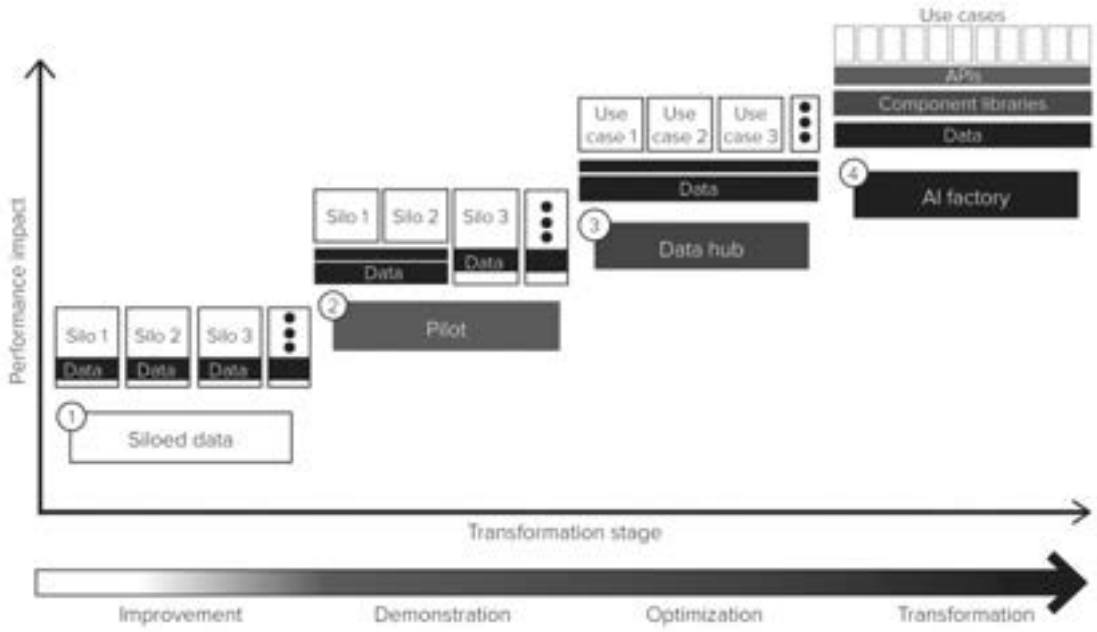
However, as organisations move into stage 3, the data hub stage, they must re-architect to aggregate data from multiple sources and leverage it to identify opportunities that cut across the entire organisation. This stage

requires substantial investment and organisational change and is also when organisational resistance is commonly observed. Organisations' most significant challenge in this stage is adopting a single source of truth to guide decision-making processes, encompassing market opportunity, pricing, planning, and operational optimisation. To achieve this, companies often create a centralised organisation devoted to data sciences and analytics, frequently deployed across applications, products, and strategic business units (SBUs) in a hub-and-spoke fashion. While individual functions and product units may require some flexibility to adopt unique capabilities and approaches, the data sciences team must maintain the ability to connect the organisation's different groups to bring back insights and drive necessary changes. The centrality of the data assets, privacy, and security must remain a top priority.

Moving from the data hub stage to stage 4, the AI factory requires another significant investment. However, much of the architectural shift should have already occurred at this stage. The authors note that this stage involves intense, cross-disciplinary capability-building activities that extend beyond engineering organisations. Companies at this stage have established a standard operating model for AI that includes centralised data, powerful algorithms, reusable software components, and transparent policies and governance to address privacy and bias issues.

The transition from siloed data to an AI factory is a complex and multi-stage process that requires significant investment, restructuring, and capability building. Still, it can provide organisations with significant competitive advantages. Going from a data and analytics company to an authentic AI factory requires an ongoing journey in building AI skills and capabilities across the organisation beyond engineering organisations. This is when everyone should understand what increasingly shapes the critical path to the customer and society.

Figure 15



Source: Marco Iansiti, Karim R. Lakhani. *Competing in the Age of AI*. Harvard Business Review

Five Principles for an Effective Transformation Process

Iansiti and Lakhani have delineated five fundamental principles that underpin a successful organisational transformation process. These guiding principles have been derived from the authors' extensive research and active involvement in transformation initiatives across various organisations. The five guiding principles include a unified strategy, clarity in architectural design, an agile and product-focused approach, and the establishment of capability foundations alongside transparent, multidisciplinary governance.

The first guiding principle for effective transformation is establishing strategic clarity and unwavering commitment. While digital transformation generates significant interest, translating a new strategy into operational reality, especially one that involves change, necessitates a profound and unwavering commitment to the endeavour's seriousness, sustainability, and endpoint clarity. Specifically, the goals of the change should be unambiguously articulated, such as the construction of an integrated data platform or the adoption of an agile team structure. The process of aligning the organisation around a fundamental shift is inherently challenging. A lack of genuine, long-term commitment from leadership is cause for concern, prompting the need to engage a headhunter.

A crucial aspect of transformation is unifying the company while simultaneously transforming it. This process involves more than establishing an autonomous group, spinning off an AI division, or initiating a skunkworks. Instead, it necessitates reengineering the company's operational model by rebuilding it on a new, integrated foundation. A clear and compelling vision, reinforced consistently, is critical for driving alignment throughout the multifaceted and integrated effort involving sales, marketing, engineering, research, IT, HR, operations, and even the legal team. As boundaries between functional areas blur and cross-functional interactions proliferate, coordination becomes increasingly important. Functional limitations do not constrain data, and redirecting the organisation's focus towards analytics and AI necessitates close, multidisciplinary collaboration to improve outcomes while minimising risks. As alignment across functions becomes increasingly cohesive, it unlocks the potential for substantial business model innovation. The convergence of networks, analytics, and AI provides new opportunities for value creation and capture across various learning and network opportunities.

The second fundamental principle in transformation involves bringing clarity to the technical goals of the process. For the change to be successful, all stakeholders must clearly understand the desired future operating architecture. Implementing a data-centric, analytics-driven, and AI-supported approach necessitates a degree of centralisation and standardisation. Integrating data assets across diverse applications to fully leverage the transformation's benefits is essential. Suppose the data is separate from a single centralised repository. In that case, the organisation must maintain an accurate catalogue of data locations, transparent data management and protection guidelines, and consistent data storage standards that facilitate its reuse by multiple parties. Furthermore, fragmented data poses significant challenges to privacy and security, making centralisation even more critical. The importance of standard policies, components, and architecture becomes even more pronounced as the organisation deploys increasingly sophisticated AI to drive its operating model.

Unfortunately, the IT organisation frequently resists transformation efforts, which is one of the biggest obstacles to success. Many enterprise IT organisations were designed to operate a complex IT back office, primarily focusing on ensuring effective and secure operations. Traditional IT charters did not include innovation and transformation, and standard IT skill sets often need more expertise in analytics, let alone AI. Moreover, IT was typically incentivised to work within existing company silos, further exacerbating fragmentation and inconsistency. As a result, a significant shift in the IT organisation's charter, structure, culture, and capabilities is necessary to drive the new data-centric architecture.

In an AI-centered operating model context, fostering a product-focused mentality among the teams deploying AI-centered applications is crucial. The deployment of AI applications necessitates an in-depth comprehension of the specific settings in which they will be utilised, akin to any product-focused endeavour. At its core, developing an AI-centered operating model involves embedding numerous conventional processes within software and algorithms. In essence, the transformed core services organisation, replete with a diverse array of AI-driven processes, represents the actual "product" of such an enterprise. The adoption of agile methods is complementary to the implementation of a transformed, data-centric functional architecture. Gone are the days of lengthy, custom-built applications, each rigidly linked to particular datasets and executed by teams of consultants over the years. Once data, models, and technology components are readily available via the organisation's AI factory, applications can be swiftly developed, especially when teams possess adequate knowledge of downstream settings and operate rapidly and agilely. A significant cultural shift is necessary beyond the architectural and organisational alterations required for transformation. The digitisation of the operating model mandates the development of a software culture and mindset, encompassing everything from dress code and reward systems to recruitment and compensation. It is not a mere pilot or research initiative but a concerted effort to transform the organisation's core.

Developing a deep foundation of capability in software, data sciences, and advanced analytics is the most conspicuous challenge in establishing an AI-centered firm. Although building this foundation may take time, making significant strides with a few motivated, knowledgeable individuals is possible. However, the organisation may need help realising the need to systematically hire a different type of person and establish an appropriate career path and incentive system. If the organisation is serious about transformation, traditional practices must be altered, as the market for this type of talent is highly competitive.

Another crucial skill set to recruit and cultivate is that of the data and analytics product manager, which may take time to become apparent. As enterprise data consolidate in new AI factories, businesses must groom individuals who can identify critical use cases and lead teams in developing innovative applications. Individuals with business backgrounds and experiences may be at an advantage for this role. Furthermore, as leadership challenges become more complex, the part of the data and analytics product manager is likely to expand, requiring the same combination of skills and capabilities. This trend may indicate the emergence of a new generation of business leaders who promote a more deep analytics and software mindset throughout the organisation and are fully aware of the impact of AI, both beneficial and detrimental.

As the importance of artificial intelligence in various firms continues to grow, its broader impact on society poses significant challenges that are expected to increase with time. While the benefits of AI-driven services are evident, the unintended consequences can be severe. Furthermore, privacy and cybersecurity issues have become pressing, driving significant investments, debates, and regulatory measures. These challenges have become the primary bottlenecks for AI-driven firms, exposing them to sudden and catastrophic failures. As a result, it is imperative to implement digital governance that involves the collaboration of various disciplines and functions. This approach revitalises the roles of legal and corporate affairs personnel, enabling them to contribute to product and policy decisions rather than just engaging in lobbying and litigation activities. The deployment of AI requires profound consideration of ethical and legal exposures, which necessitates active staffing and support. Lastly, beyond establishing robust internal governance processes, organisations must engage their partners, customers, and local communities to address AI's extensive and diverse challenges effectively. Given the vast networks that AI connects, it is imperative to adopt a comprehensive and dedicated governance strategy that explicitly considers and engages with the many stakeholders across the economy and society.

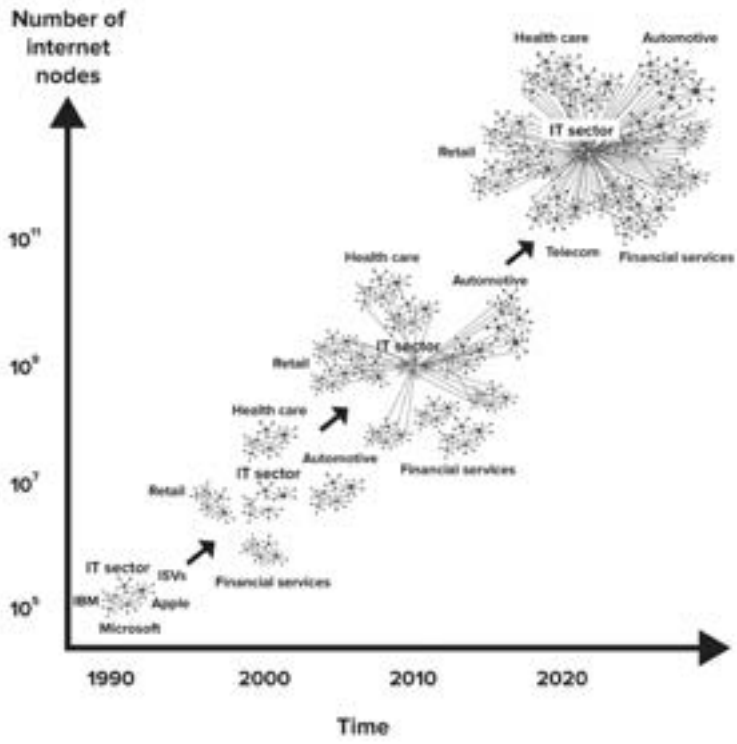
1.5 Competing in the Age of AI

1.5.1 The Collision and Fragmentation Phenomenon

The phenomenon of industries becoming increasingly interconnected and the recombination of capabilities across traditional boundaries is becoming the norm. This convergence is driven by the advent of software, data-centric architectures, and AI, which are removing traditional operational constraints and enabling a new generation of business models that transcend industries allowing operating models to cross old verticals and enter new sectors with innovative, highly connected business models. As collisions multiply across the economy, different sectors become increasingly connected to each other through the new, ubiquitous digital fabric, resembling a vast, highly connected network coalescing around a small number of digital superpowers (see Figure 16).

Firms operating with digital models may easily overwhelm traditional firms: new companies may offer exciting and innovative solutions even on a smaller scale, and as the value delivered by digital operating models increases, the space left for competitors at a lower scale, scope, and learning continues to shrink, making it difficult for a traditional company to sustain a profitable offering.

Figure 16

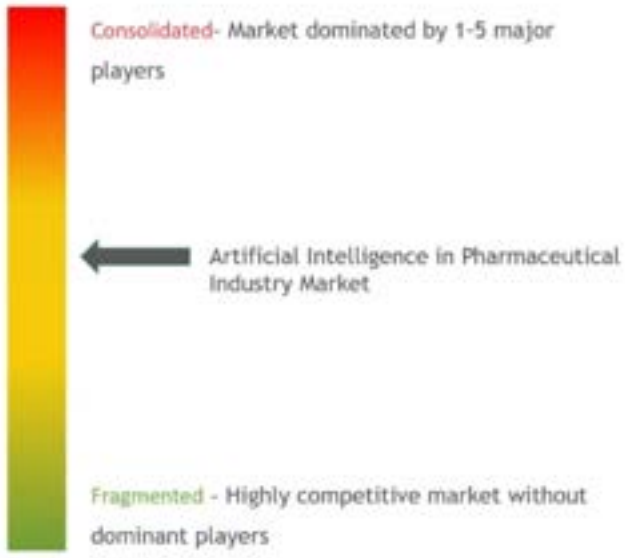


Source: Marco Iansiti, Karim R.. Lakhani. *Competing in the Age of AI*. Harvard Business Review

Consequently, firms are finding themselves competing for the profit pool with other companies from different sectors, using different business models, and integrating bundling, and cross-subsidizing products and services; this results in a more fragmented industry compared with the past and in a middle-level AI in pharma market concentration (see figure 17).

This evolution poses significant challenges to traditional firms facing a "*prisoners' dilemma*": preserve the existing profitable model and disrupt it by investing in considerable transformation or a hybrid scenario sustaining the current model while preparing for the future through the out-sourcing of innovative compounds.

Figure 17



Source: *Mordor Intelligence.*

1.5.2 Shifting Towards Universal Capabilities: The Changing Landscape of Competitive Advantage

The business landscape is transitioning towards horizontal and universal capabilities driven by AI and network-centric organisations. In this context, traditional industry specialisation is becoming less critical while a universal set of capabilities is gaining significance. The competitive advantage is no longer rooted in vertical capabilities but is shifting towards versatile capabilities in data sourcing, processing, analytics, and algorithm development. Consequently, organisations are investing in AI factories and implementing operating models that can make automated decisions. This transition has led to a marked erosion of traditional differentiation strategies and the emergence of a new breed of universal competitors. The universality of capability is reshaping operational tasks, strategy, business design, and leadership. Digital and networked settings now exhibit similar systems, drivers of operating performance, and market characteristics that respond more to new drivers, such as network and learning effects, rather than traditional industry-specific knowledge and expertise. We are moving from an era of core competencies to an age shaped by data and analytics, powered by algorithms and hosted in the computing cloud for anyone to use. Each sector now requires a similar technological foundation, standard methods, and tools, all powered by massive computing capacity available on demand. The emphasis on primary differentiation based on cost, quality, and brand equity is shifting from specialised, vertical expertise to the firm's position in the network, its accumulation of differentiated data, and its deployment of a new generation of analytics.

1.5.3 Coopetition

As digital networks and AI increasingly capture our world, we see a fundamental transformation in firms. This removes historical constraints on scale, scope, and learning, creating enormous opportunity and extraordinary turbulence. The new kinds of operating models characterising firms in the age of AI are binding us together across industries, countries, markets, and political affiliations. The many resulting interdependencies have become too important to ignore, motivating the need for a new kind of collective wisdom. The challenges could be better, more complex, and more amorphous to solve alone.

Coopetition, the simultaneous pursuit of competition and cooperation between firms, has gained attention as an essential strategy for organisations in the pharmaceutical industry looking for ways to grow their competitive advantages through collaboration. It is becoming increasingly popular due to potential individual and collective benefits, including resource access, research and development costs reduction, and innovation. By collaborating with other firms, pharmaceutical companies can pool their expertise, knowledge, and resources to achieve common goals they may need help to succeed. This can lead to faster development of new products, technologies, and services, enhancing firms' competitive advantage and performance.

Cooperation is desirable due to the high costs associated with innovation. In the pharmaceutical industry, research and development are costly and time-consuming, taking several years to bring a new product to market. By cooperating with other firms, companies can share the costs associated with R&D, which can help reduce their financial burden and speed up bringing new products to market.

Moreover, it allows companies to limit duplication of efforts and increase access to a broader range of resources. For example, one company may be good at developing a specific technology, while another may have expertise in marketing and distribution. Consequently, both companies can leverage each other's strengths and resources to achieve a common goal. Coopetition can also enable firms to shape industry standards and advance technologies. By working together, firms can create new measures to benefit the industry and contribute to developing new technologies to help all participants in the collaboration.

Coopetition can be achieved through strategic alliances, joint ventures, and consortia that aim to improve individual firms' market positions while supporting the collective success of combined activities (see Figure 18).

Figure 18

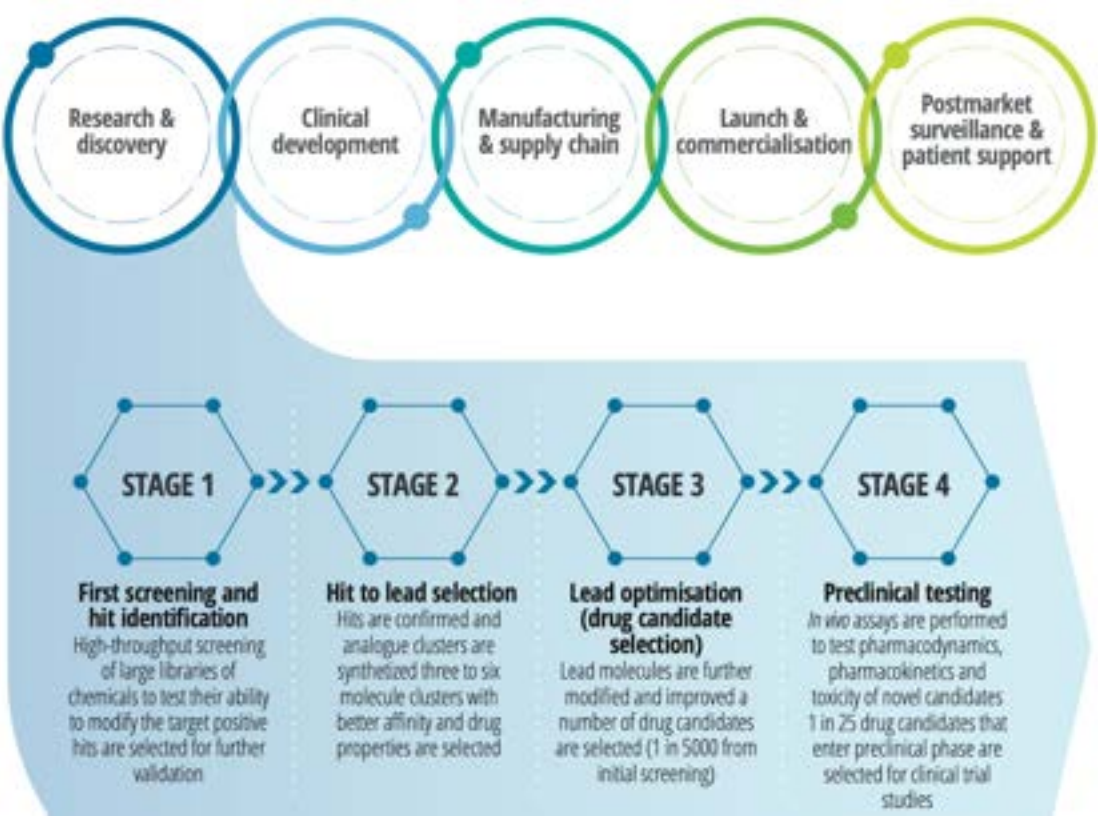
Source: *Deep Pharma Intelligence*

2. Transforming the Pharma Industry with AI: Applications Across the Value Chain

2.1. AI in Research & Discovery

2.1.1 Traditional R&D: a long, complex, expensive, and inefficient process

Figure 19



Source: *Deloitte analysis*.

The research phase in drug R&D aims to generate as many quality drug candidates as possible, as quickly as possible, with the highest probability of a successful transition to clinical development. Ideally, this process should only promote compounds for testing that are relevant for targets that would lead to effective drugs for patients. In reality, R&D is a long, complex, expensive, and inefficient process, given the number of compounds initially tested, structured in 4 stages (see Figure 19):

- **First screening and hit identification**: The first stage of drug discovery involves screening large libraries of chemical compounds to identify those that can modify the target. This initial screening is typically done using high-throughput screening (HTS) techniques, which quickly test thousands or even millions of compounds. The compounds are usually screened *in vitro*, using cell-based or biochemical assays that can detect changes in the activity of the target molecule. This stage aims to identify "hits," compounds that show some level of action against the target. The hits are then subjected to further validation to confirm their activity and specificity. This validation process involves a more detailed analysis of the chemical and biological properties of the hits, such as their binding affinity, selectivity, and mechanism of action. Only the most promising impacts with a high affinity for the target are taken to the next stage.

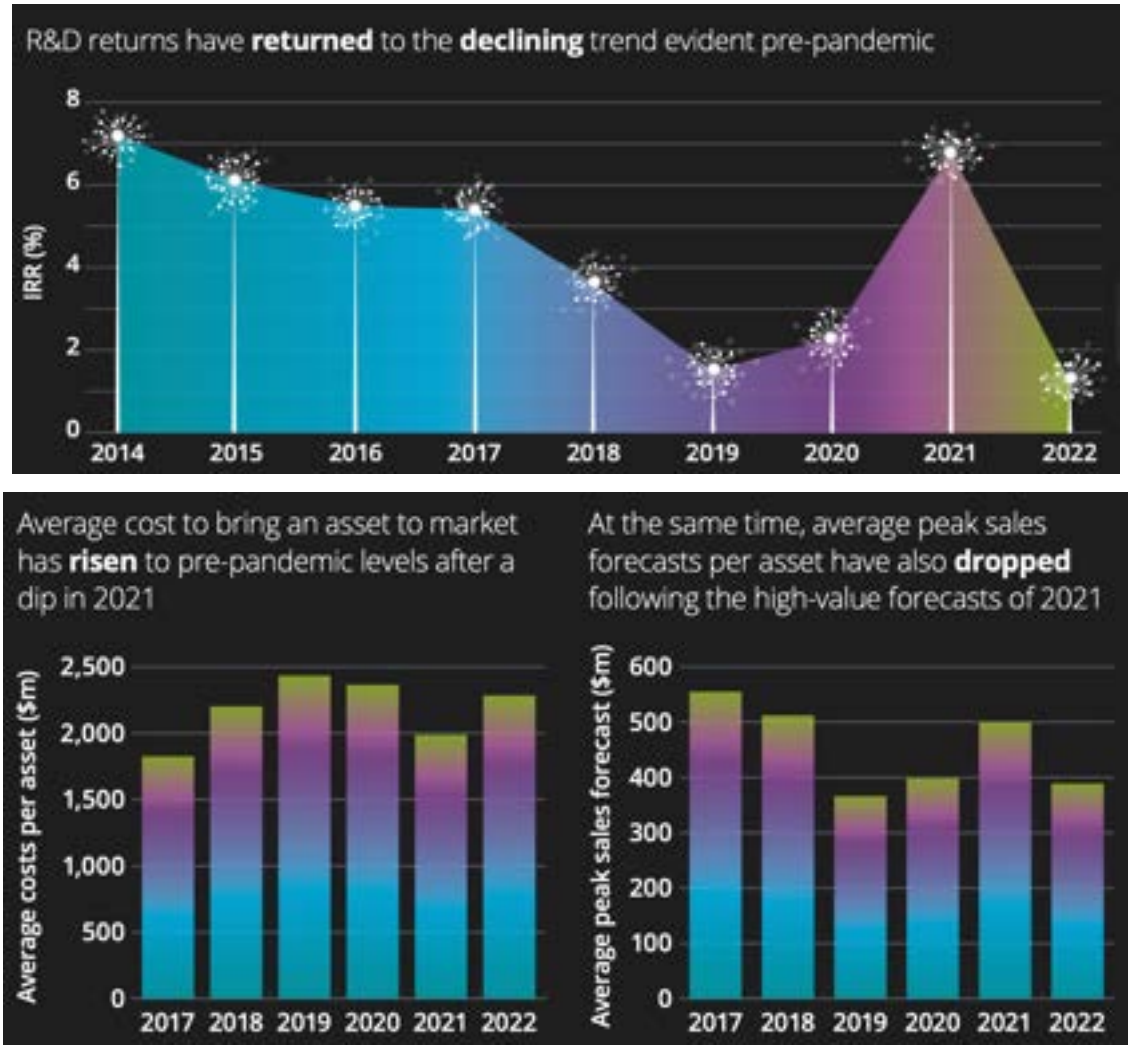
- **Hit-to-lead selection**: The second stage of drug discovery involves optimising hits to improve their potency, selectivity, and drug-like properties. The goal of this stage is to identify a small number of lead compounds that have the potential to become viable drug candidates. The lead optimisation process typically involves the synthesis of analogue clusters, which are groups of three to six molecules that are structurally similar to the hit compound but have different modifications. These analogues are tested for their activity against the target and pharmacokinetic and toxicological properties. The most promising analogues are selected for further optimisation, while the others are discarded. The lead optimisation process can take several rounds of synthesis and testing; only the most promising compounds go to the next stage.
- **Lead optimisation (drug candidate selection):** The third stage of drug discovery involves the further optimisation of lead compounds to increase their potency, selectivity, and drug-like properties. Only a tiny percentage of the initial compounds, usually 1 in 5000, will advance to this stage. The lead optimisation process involves the iterative modification of lead compounds to improve their pharmacological properties, such as their bioavailability, half-life, and target selectivity. The goal is to create a small number of drug candidates that have the potential to become viable drugs. The drug candidates are then tested *in vitro* and *in vivo* to assess their pharmacological properties, such as their efficacy, toxicity, and pharmacokinetics. Only the drug candidates that show a high degree of effectiveness, specificity, and safety move on to phase four.
- **Preclinical testing:** the fourth stage of drug discovery involves testing drug candidates in preclinical studies to assess their safety and efficacy. Preclinical testing typically consists of animal models to determine the pharmacological properties of the drug candidates, such as their efficacy, toxicity, and pharmacokinetics. *In vivo* tests identify potential safety issues or toxicities that may arise in human trials. If the drug candidates pass preclinical testing, they can proceed to clinical trials involving testing the drugs in humans. Approximately 1 in 25 drug candidates that enter the preclinical phase are selected for clinical trial studies.

The drug discovery process usually takes 5-6 years from the start of Stage I to the conclusion of Preclinical Testing. Only a tiny fraction of the initially screened 10,000 molecules are allowed to progress to clinical trials: the likelihood of success for a compound entering Phase I trials is less than 10%, a rate that has remained unchanged over the past decade.

Despite the rigour and extensive efforts involved in drug discovery, several factors can reduce its accuracy and success. One of the significant challenges in drug discovery is the need for precise knowledge of the three-dimensional structure of drug compounds and targets, as well as their binding affinity and kinetics, which are essential for determining the efficacy of action and efficient drug delivery. In addition to the challenges posed by the complexity of drug compounds and targets, preclinical testing and animal models also contribute to the high failure rate of drug candidates in clinical trials. For over a hundred years, animal testing has been used as a 'clinical prediction' method to identify which drugs are clinically safe and efficacious and merit entry to

clinical trials. Unfortunately, animal testing is an extremely poor predictor of clinical safety and efficacy, leading to discrepancies in preclinical findings and human tests that result in inaccurate pharmacokinetics/pharmacodynamics (PK/PD) and toxicity predictions: a stunning 89% of drug candidates successfully pass animal testing fail in clinical trials.

Figure 20



Source: *Measuring the return from pharmaceutical innovation 2022. Deloitte.*

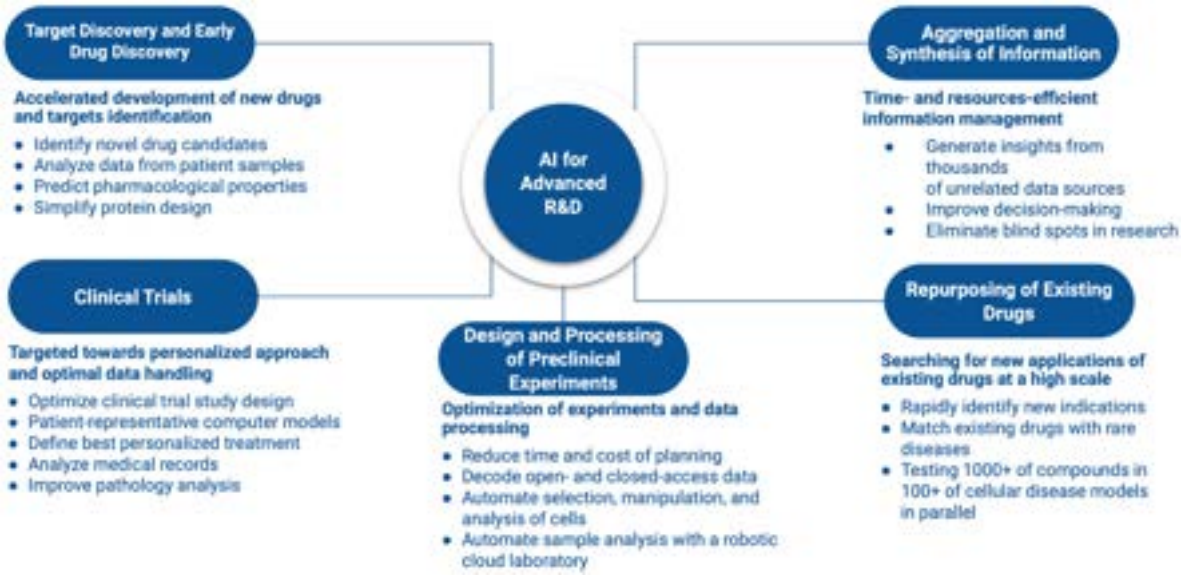
In addition, according to Deloitte's *Measuring the Return from pharmaceutical innovation 2022* report, the average cost to develop an asset from discovery to launch has risen to $2,284 million, with an increase of $298 million from 2021 while the average forecast peak sales per pipeline asset have declined from $500 million in 2021 to $389 million in 2022. As a result, the expected return on investment from drug development has reduced significantly from 7% in 2021 to 1,2% in 2022, returning to the declining trend evident pre-pandemic (see figure 20).

2.1.2 The Rise of AI drug discovery disruptors

Pharmaceutical companies must find new approaches to improve productivity and increase their output of original drugs, not only to satisfy the demands of the healthcare sector to increase the life expectancy and

quality of life of billions of people but also to ensure their business survival in terms of return on R&D investment. Consequently, finding ways of improving the efficiency and cost-effectiveness of bringing new drugs to the market is imperative for the industry. Today, R&D organisations must strive to achieve drug innovation to address critical issues such as the substantial decrease in the number of new chemical entities launched yearly and the eroding patent estate. Their main objective is to deliver hits, leads, and, finally, drug candidates of the highest possible quality to decrease the risk of failure in clinical phases at the end of the development process.

Figure 21



Source: *Deep Pharma Intelligence*.

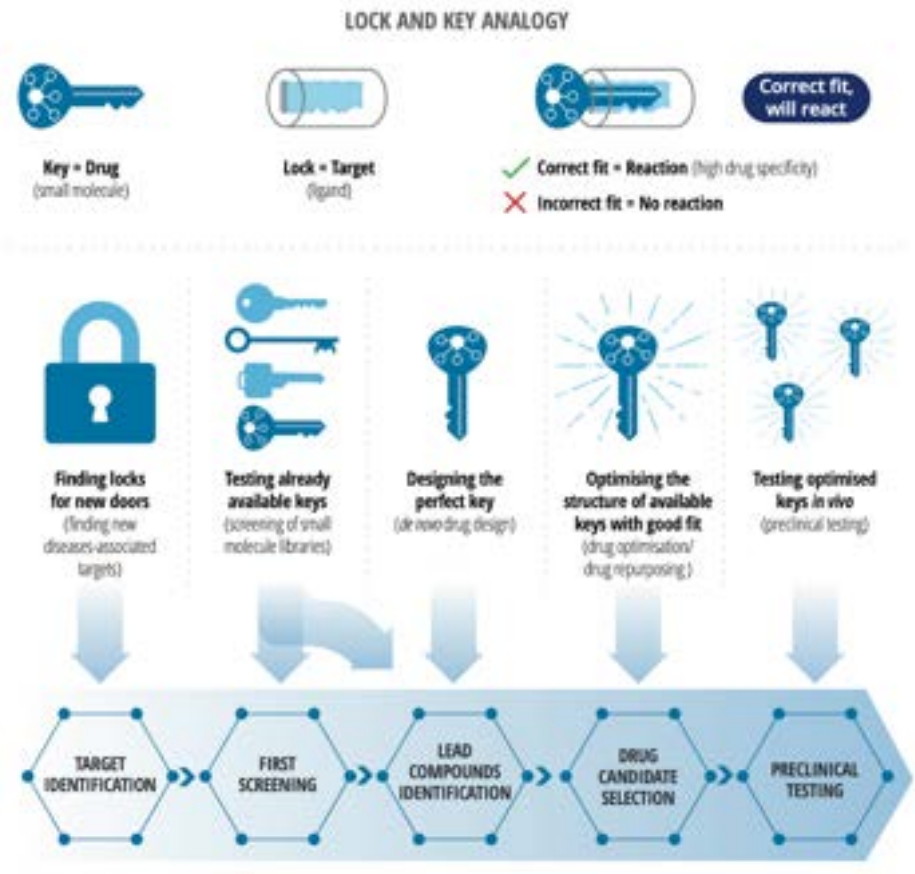
AI-enabled solutions are emerging as a crucial tool for researching disease mechanisms of action and revolutionising the understanding of how drugs bind to targets, improving specificity and safety prediction, drastically cutting the time and cost of developing drugs, and tailoring them to individual patients (see figure 21). AI has the potential to:

• *Reduce timelines for drug discovery and improve the agility of the research process*: the successful application of innovative technologies could speed up the discovery and preclinical stages by a factor of 15.

• *Increase the accuracy of predictions on the efficacy and safety of drugs*: currently, only 1 of 10 drugs are approved after clinical trials. Most fail due to efficacy and safety issues. Given the growing cost of bringing a drug to market, a 10% improvement in the accuracy of predictions could save billions of dollars spent on drug development.

• *Improve the opportunity to diversify drug pipelines*: AI-enabled prediction tools could improve the speed and precision of discovery and preclinical testing, opening new research lines and enabling more competitive R&D strategies. Finding new niches of competitive advantage could reduce withdrawals and improve asset sales. Failure to demonstrate value compared to available therapies is a crucial factor undermining clinical trial progression.

Figure 22



Source: *Deloitte analysis*.

Discovering novel pharmaceutical agents for disease targets can be compared to a detailed search for an optimal key that can precisely unlock a complex lock. This lock and key analogy show the five main challenges for AI employment to expedite drug discovery efforts (see Figure 22):

- **Finding new diseases-associated targets**

  AI algorithms are gaining traction in disease research. By leveraging large amounts of primary research data from public and private sources, AI algorithms can facilitate a more profound comprehension of disease mechanisms. This, in turn, can make it easier to identify new pathways associated with diseases and identify new targets for drug development. AI algorithms employ methods similar to those of a systematic literature review but with a significant reduction in time, allowing for tailored approaches to improve the accuracy of pathological understanding at the cellular and molecular levels. The ML algorithm can learn which underlying compound structures are most effective against a target and suggest other molecules in the library to prioritise for testing. As the ML algorithm gathers more data, its predictions rapidly become more accurate, and a disproportionately large number of "hits" are identified for the relative amount of the library screened. This iterative screening loop reduces overall costs, has a higher probability of success, and accelerates R&D processes compared to the existing approach of randomised selection of compounds. Research systems harness synergies when AI technologies are embedded into the *wet-lab* scientific process.

- **Screening of small molecule libraries**

The selection of new compounds is being driven by data obtained from libraries of small molecules, aided by deep learning (DL) technologies that allow for the creation of exact predictions of binding profiles for targets. An alternative approach, network-driven drug discovery, focuses on assessing a potential drug's impact on disease networks rather than specific targets. This approach employs large-scale proprietary databases and customised computational tools and has demonstrated efficacy in at least 12 biological pathways. DL technology is transforming small molecule research and showing potential in identifying new biologics, such as therapeutic antibodies against cancer, fibrosis, and other diseases. This approach has reduced the time required for antibody therapeutic discovery by three to 18 months. Furthermore, researchers use ML algorithms for new antibiotics and novel antisense drugs for a subset of genetic diseases.

- **De novo drug design**

  Recent advancements in AI technology have enabled the *de novo* design of new compounds with precision for specific target binding, representing significant progress from the AI-enabled screening of small molecule libraries. Unlike traditional methods of small molecule screening, de novo design only requires the target's structural information, eliminating the associated bias. DL solutions are central to this innovative approach, which allows for the creation of drugs with great speed and accuracy, avoiding unwanted offset interactions. In a matter of months, preliminary hit-to-lead results can be delivered. At least nine AI technology providers offer tailored *de novo* drug design services and have established collaborations with major bio-pharmaceutical companies in different areas, such as cardiovascular diseases and fibrosis. Additionally, the *de novo* design of biologicals, including antibodies, DNA, and peptides, is an emerging trend that most AI drug discovery companies are pursuing. Insilico Medicine, an AI drug discovery company, has successfully used *de novo* AI to design a new molecule in just 21 days and validate it in 25 days, which is 15 times faster than the traditional bio-pharmaceutical process.

- **Drug optimisation/repurposing**

  A deeper understanding of the polypharmacology of drugs can enhance drug development success rates by identifying undesired off-target effects, toxicities, and opportunities for drug use repurposing. A drug's interaction with a biological target is not limited to that specific target alone but can involve numerous proteins, with up to 300 proteins potentially contributing to adverse side effects. Several AI companies focused on polypharmacology have already developed a proteome-wide, drug-centric approach to identify all the proteins a small molecule could interact with and provide information on unintended targets or prioritisation for other diseases. These collaborate with various big pharma companies, biotech start-ups, and research institutions to create novel multitargeted drug-like molecules with favourable properties, explore new applications for their small molecule repositories, and determine the mechanism of action and safety profiles of their drugs in discovery and early development.

- **Preclinical testing**

Inaccurate prediction of human physiological responses is a common issue with animal models, leading to suboptimal returns on research and development efforts. Although efforts are being made to improve preclinical technologies, such as organs-on-a-chip or 3D cell cultures, AI algorithms can potentially improve the accuracy of animal models for certain diseases. The statistical method 'Found in Translation' leverages ML algorithms to identify matches in gene expression profiles between humans and mice, enabling better prediction of cross-species differences. This approach can identify critical information that may be missed, preventing false leads and reducing experimental costs.

2.1.3 Case Study – Atomwise: Revolutionizing Drug Discovery with Deep Learning for Difficult Targets

Company Overview:

Atomwise, a US-based company established in 2012, is at the forefront of AI technology in drug discovery. Leveraging its expertise in artificial intelligence, Atomwise focuses on predicting the binding affinities between small molecules and proteins, aiming to identify potential therapeutics for a wide range of disease targets. Atomwise's innovative application of deep learning in drug discovery has the potential to revolutionise the field by accelerating the identification of promising compounds and streamlining the drug development process. With a team of 46 employees, Atomwise has established more than 300 partnerships with leading pharmaceutical companies and academic research centres worldwide. With their impressive track record and extensive collaborations, Atomwise continues to make significant contributions toward advancing therapeutics for a wide range of challenging diseases.

The AI Solution for Drug Discovery:

At the core of Atomwise's innovative approach is their patented AI platform called AtomNet. This platform utilises deep learning Convolutional Neural Networks to understand the three-dimensional characteristics of drug-to-target molecular binding. By identifying key discriminators, AtomNet enables the selection of promising hit compounds for further exploration. The platform's exceptional capability to rapidly generate new lead compounds, even capable of crossing the blood-brain barrier, eliminates the need for time-consuming and expensive high-throughput screening experiments.

Main Projects and Achievements:

Atomwise is a pioneering pharmaceutical company combining cutting-edge technology with AI to transform the small molecule drug discovery field. At the core of Atomwise's innovative approach is their invention of using deep learning for structure-based drug design, a breakthrough that has revolutionised their AI discovery engine. The AI discovery engine Atomwise developed is exceptional in identifying and optimising novel chemical compounds. This sets it apart as a best-in-class solution for accelerating drug discovery. The machine has undergone extensive validation, consistently showcasing its effectiveness by identifying compounds with therapeutic potential in 90% of internal programs and over 70% of the company's 270 academic collaborations. Notably, Atomwise's AI technology has targeted various proteins, including those considered challenging or complex to develop drugs for.

In addition to their collaborations, Atomwise is building a pipeline of small-molecule drug candidates. The company is committed to developing innovative medicines that address unmet medical needs, with three programs currently in the lead optimisation stage and over 30 programs in the discovery phase.

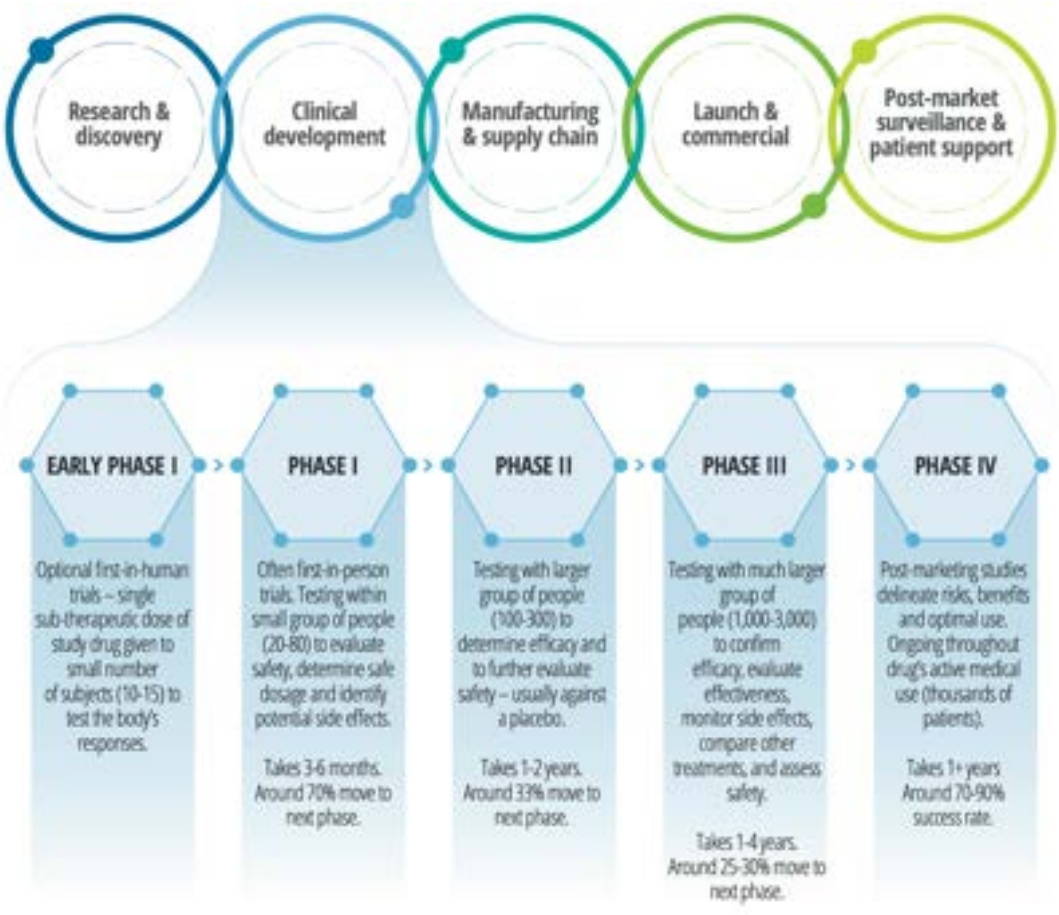
To support its mission of accelerating drug discovery, Atomwise has secured significant funding, raising over $194 million from leading venture capital firms and establishing strategic collaborations. These resources enable Atomwise to continue advancing its groundbreaking work and drive the development of better medicines at an accelerated pace. Atomwise's dedication to harnessing AI and its extensive expertise in small molecule drug discovery positions them at the forefront of the industry. Their innovative approach holds great promise for improving the speed and efficiency of drug development, ultimately benefiting patients worldwide.

2.2. AI in Clinical Development

2.2.1 The traditional approach to Clinical Trials

The traditional approach to clinical development is a lengthy process structured in a sequence of phases (see Figure 23):

Figure 23



Source: *Deloitte analysis*.

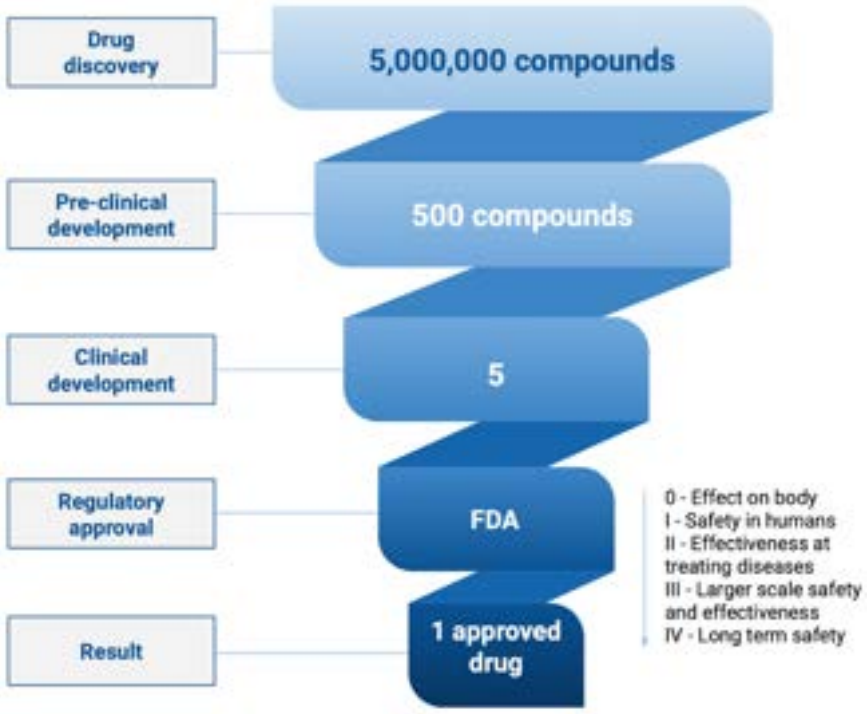
- **Early Phase I**: in the early phase of clinical development, the first step is conducting a first-in-human (FIH) trial, which involves administering a single sub-therapeutic dose of the study drug to a small group of healthy volunteers (usually 10-15). The purpose of an FIH trial is to test the safety and tolerability of the drug, as well as to assess the body's response to the drug, including its pharmacokinetics (PK) and pharmacodynamics (PD). During an FIH trial, the study drug is typically administered at a low dose unlikely to cause any significant pharmacological effect or adverse events. The study participants are closely monitored for any signs of toxicity or adverse reactions to the drug, and blood samples are collected to measure the drug's PK and PD properties. Suppose the FIH trial results show that the drug is safe and well-tolerated. In that case, the next step is to conduct a Phase I clinical trial to evaluate different dosing regimens or administration routes. Overall, the early clinical development phase is a critical step in the drug development process. It helps establish the safety and tolerability of a new drug or therapy in humans and lays the groundwork for further testing and evaluation.
- **Phase I**: Phase I takes 3-6 months and is usually conducted with a small group of healthy volunteers, typically ranging from 20 to 80 participants. The main objective of this phase is to assess the drug's safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD). It can provide initial data on potential side effects, the drug's metabolism and elimination, and human biological activity. It may also explore different formulations, routes of administration, and drug-drug interactions. The dose-escalation design is commonly used to identify the maximum tolerated dose (MTD), the highest drug dose that can be given without causing severe side effects.
- **Phase II**: Phase II clinical trials take 1-2 years and are usually conducted with a larger group of patients (100-300 participants). The main objective of this phase is to determine the efficacy and safety of the drug in patients with the targeted condition or disease. This phase may involve multiple arms with different dosages or treatment regimens to identify the optimal therapeutic dose and schedule. It may also include biomarker assessments to evaluate the drug's mechanism of action and patient stratification. The results of Phase II trials inform the design of Phase III tests.
- **Phase III**: Phase III clinical trials that take 1-4 years are usually conducted with a much larger group of patients, usually from 1,000 to 3,000 participants. The main objective of this phase is to confirm the efficacy and safety of the drug in a large, diverse population and to generate enough data to support the drug's approval by regulatory authorities. Phase III trials are typically randomised, double-anonymized, and placebo-controlled to minimise bias and ensure the validity of the results. It may also involve comparative effectiveness research, where the drug is compared to existing treatments or standards of care. The results of this phase form the basis for regulatory submissions and approval decisions.
- **Phase IV**: Phase 4 clinical trials, also known as post-marketing surveillance or pharmacovigilance, begin after regulatory authorities have approved the drug, are available for public use, and last more than one year. The main objective of this phase is to monitor the long-term safety, effectiveness, and potential side effects of the drug in a larger population, including patients with co-morbidities or other conditions. It may

also explore new indications, dosages, and treatment regimens to expand the drug's use. Depending on the research question and population of interest, it may also involve observational studies, registries, or randomised controlled trials. The results of Phase IV trials inform the drug's ongoing evaluation and risk management.

2.2.2 Understanding the Drivers Behind the Transformation of Clinical Trials

Clinical trials are essential in the development of new medicines and therapies. However, the success of clinical trials is often hampered by several factors contributing to their failure.

Figure 24



Source: *Conflict of Interest in Medical Research, Education, and Practice, medinicenet.com.*

The growing length of the clinical trial cycle is a significant challenge in clinical development, as it takes ten years on average to complete. Furthermore, the success rate is only 10%, with just one drug approved for use and reaching the market out of every 5,000,000 candidate drugs initially screened (see Figure 24). The increasing length of the clinical trial cycle has contributed to the rising costs of pharma R&D, with each failed trial leading to wasted time and funding.

Pharma companies are expected to demonstrate efficacy, safety, and meaningful impact on patients' lives during clinical trials. Moreover, as healthcare costs continue to increase as a percentage of every country's GDP, governments and private payers are scrutinising the economic value of new treatments more rigorously. This increased expectation of regulators and payers requires the pharma industry to raise the quality and quantity of evidence generated during clinical trials, which adds to the complexity of clinical trial development.

Two of the critical factors causing a clinical trial to be unsuccessful are suboptimal patient cohort selection and recruiting mechanisms, which fail to bring the best-suited patients to a problem in time, as well as a lack of technical infrastructure to cope with the complexity of running a trial in the absence of reliable and efficient adherence control, patient monitoring, and clinical endpoint detection systems. As clinical trials progress, more patients are required, but the eligibility and suitability requirements also increase, making it challenging to find and enrol suitable patients. A patient may be ineligible to participate due to their medical history or a mismatch in the stage of their disease compared to the trial protocol.

Patients considering participation in clinical trials must weigh the benefits of early access to a potential new therapy against the risks of adverse events, potential financial burden, and time requirements. Eligible and suitable patients may find the criteria challenging or the recruitment process complex and cumbersome, or they may need to be incentivised to participate. The responsibility of regular clinic visits also limits participation, with difficulty attending clinics cited as a significant factor in the dropout of patients. These challenges often create delays to the point that most trials do not meet enrollment timelines, leading to high financial costs; as a result, patient recruitment is the most effective cost driver of clinical trials, accounting for 32% of overall costs (see Figure 25). Consequently, identifying suitable patients can improve the speed and efficiency of clinical trials and ultimately accelerate the approval of and access to new medicines. Other factors contributing to clinical trial failure include ineffective site selection, poor study design and trial execution, safety issues, and dropouts due to practical or financial matters.

Each failed trial contributes to the rising costs of pharma R&D. Moreover, the time and funding required to complete a trial increase at each phase. The total price of a Phase III failure includes the cost of all previous stages plus the time that could have otherwise been used to trial a different drug. Therefore, addressing these challenges is essential to improve the efficiency and effectiveness of clinical trials and ultimately bring new therapies to patients more quickly and efficiently.

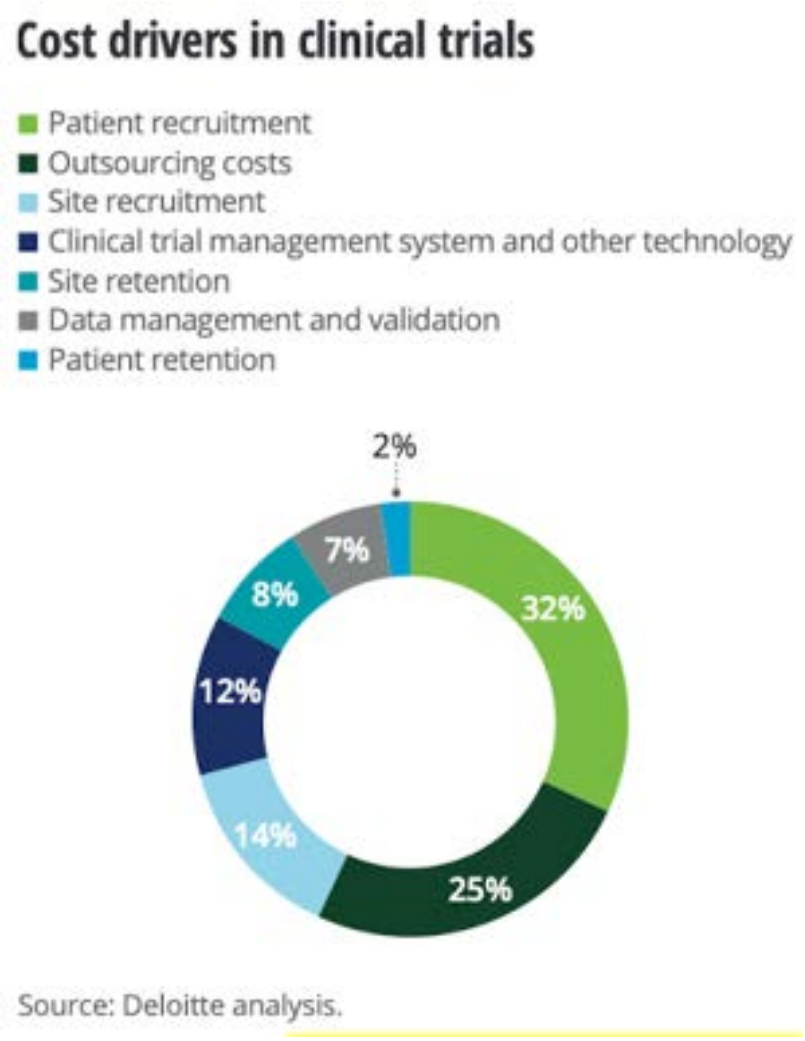
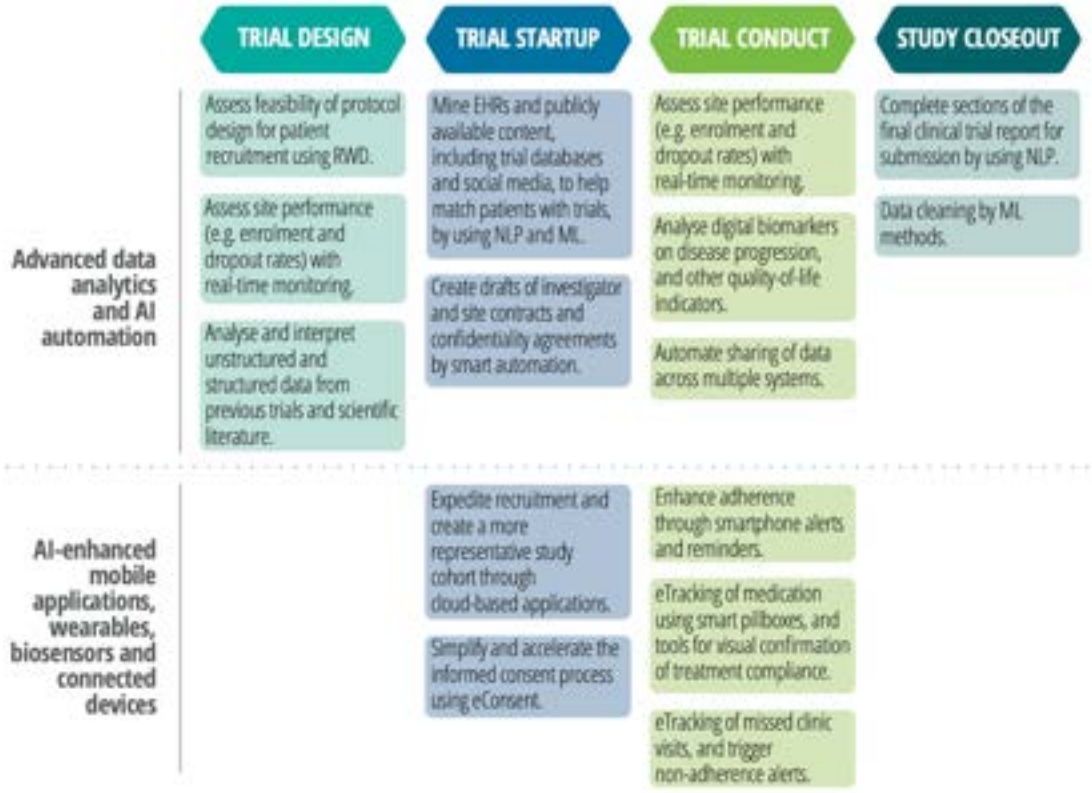


Figure 25

2.2.3 Revolutionising Clinical Trials: Exploring the Impact of AI on the Process

Figure 26



Source: *Deloitte analysis*.

Figure 27

Source: *Mordor Intelligence*.

Pharmaceutical companies are presently investigating the use of AI technology applications to enhance the effectiveness of their clinical trials (see figure 26 and 27). The potential benefits of such an approach include optimising trial design, facilitating patient recruitment, and analysing both trial outcomes and real-world data. Automation could also be employed to increase the speed and efficiency of results publication. The successful integration of AI technology could lead to decreased development costs, greater adherence to trial protocols, and improved clinical outcomes. Furthermore, the availability of vast data sets and AI-driven analytics could also pave the way for developing highly effective personalised therapies without the need for extensive clinical

trials. This development could revolutionise the pharmaceutical industry, allowing for more targeted and efficient patient treatments. These advancements could significantly reduce traditional clinical trial processes' financial and logistical challenges while improving patient outcomes. The benefits of AI in clinical development include the following:

- **Improving study design**

  ML algorithms have the potential to significantly improve the design of clinical trials by leveraging data from past studies, including both successful and failed ones. This can be achieved by identifying variables most relevant to the outcome and recommending changes to the study design, such as the number of participants, the inclusion and exclusion criteria, the study duration, the choice of endpoints, or the optimal dosing regimen. By analysing past study protocols and their results, ML algorithms can provide study teams with suggested enhancements to protocol design, thus improving the efficiency and likelihood of trial success. In addition, ML algorithms can be used to analyse real-world data (RWD) to match patients to trials based on disease and socioeconomic and behavioural characteristics. The recruitment process can be made more efficient and effective by identifying patients who meet the inclusion criteria for a particular trial and have a higher likelihood of adherence and lower dropout rates. This can lead to a more diverse patient population and faster enrolment, ultimately reducing the time and cost required for clinical trials.

  Moreover, ML algorithms can help identify subgroups of patients most likely to benefit from a specific treatment or intervention. By analysing data from past studies and RWD, ML algorithms can identify patient characteristics predictive of treatment response, enabling study teams to design more targeted and effective clinical trials. This can be achieved by using ML algorithms to identify biomarkers or other indicators of treatment response, such as genetic profiles or clinical measurements, and using this information to design clinical trials more likely to produce positive outcomes. Furthermore, ML algorithms can also help identify potential safety issues early in the study design phase. By analysing RWD and other relevant data sources, ML algorithms can identify possible safety signals that may not have been previously detected, enabling the study team to adjust the trial design and protocol accordingly. This can help reduce the risk of adverse events and ensure patient safety throughout the trial.

- **Reducing trials error with AI-driven Digital Data Flow**

  The volume of data associated with clinical trials is substantial. However, the traditional flow of data across the clinical trial lifecycle is often hampered by manual effort and inefficiency, leaving researchers feeling like they are working in the past rather than the present: today, indeed, creating trial artefacts such as case report forms and study reports requires manually inputting data into multiple systems, and this leads to inconsistencies and errors and the need for rework, slowing down trial execution.

  In this context, using AI-based cognitive automation offers a promising solution to streamline data management and enhance the efficiency of clinical trials. By creating structured, standardised digital data elements and automating data management across the lifecycle, AI can help to streamline data gathering and artefact creation tasks, enabling clinical site investigators to focus on value-added services such as

patient engagement. Furthermore, AI can intelligently interpret data elements, feeding downstream systems and auto-populating required reports and analyses, resulting in a more efficient and less error-prone clinical trial process. Moreover, AI can be used to establish an interoperable, intelligent, single source of truth, accelerating clinical trials and improving decision-making. Insights generated from past and current practices can be utilised to foster continuous improvement, thereby informing and enhancing future problems.

The adoption of AI-enabled data management offers several potential benefits, including faster trials at lower cost, avoidance of the need to rebuild databases across trials through intelligent reuse of existing data based on standardised data elements, and acceleration of the drug approval process, leading to more rapid market entry for new drugs. These developments can transform the efficiency and effectiveness of clinical trial design and execution, resulting in improved patient outcomes.

- **Improving patient enrichment, recruitment, and enrollment**

The Food and Drug Administration (FDA) has published guidance on clinical trial enrichment strategies that aim to assist the pharma industry in overcoming challenges in patient selection and improving drug development effectiveness and efficiency. Three main methods are identified, which can be combined with the use of AI technologies to facilitate clinical trial enrichment (see Figure 28):

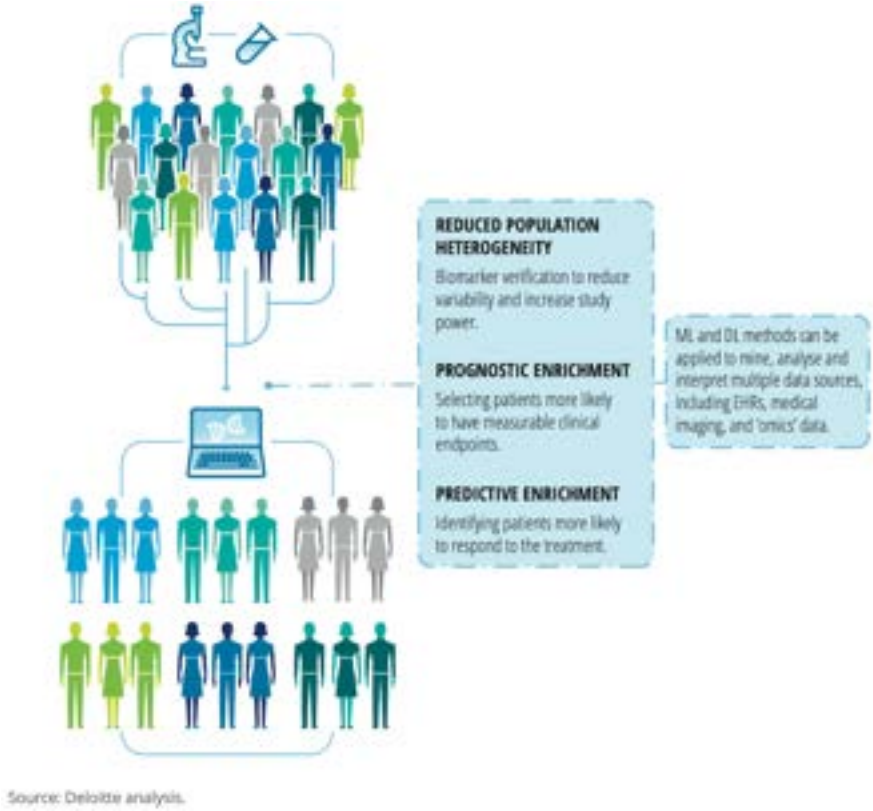
I. *Reduced Population Heterogeneity* involves selecting patients with a narrow range of disease baseline measurements or biomarker characteristics while excluding patients whose symptoms improve spontaneously or have highly variable sizes. Electronic phenotyping is a well-established discipline within health informatics that focuses on reducing population heterogeneity, namely identifying patients with specific characteristics of interest. Electronic phenotyping is far more challenging than a simple code search. It requires sophisticated methods to account for heterogeneity among patient records across multiple data types and leverage complex clinical domain knowledge representations. In recent years there have been increasing efforts to design a diverse range of ML methods, ranging from NLP to association rule mining to DL, that have shown significant progress toward identifying eligible patients for clinical trials.

II. *Prognostic Enrichment* involves selecting patients with a higher likelihood of experiencing a disease-related endpoint or substantial worsening in condition. AI is beneficial for predictive enrichment in neurological diseases, as key biomarkers are often invasive or expensive to measure. AI models can approximate biomarkers by combining inexpensive and non-invasive models. ML and DL can help develop complex models that characterise and assess disease progression, particularly for mild cognitive impairment (MCI) and Alzheimer's disease, where disease-modifying drugs are largely unavailable. These methods for disease progression modelling are being developed to provide an increasingly accurate and nuanced understanding and characterisation of the complexity and heterogeneity of many diseases.

III. *Predictive Enrichment* involves selecting patients more likely to respond to treatment than patients with the same condition. ML models are required to characterise and assess disease progression, and current

efforts are focused on numerous diseases. AI models can identify patients based on specific physiology, biomarkers, or disease characteristics related to the study drug's mechanism. Empirical patient selection, where the patient has previously responded to a medication in the same class, is also an option.

Figure 28



- **Predicting optimal site and country selections**

  In clinical trials, selecting high-performing investigator sites is crucial for ensuring the study's success in terms of timelines and data quality. Site selection is a complex process that involves evaluating site qualities such as administrative requirements, resource availability, team dynamics, and experience. These factors can ultimately have a significant impact on study costs and timelines, as well as product approval. Compliance with auditing, data recording, reporting procedures, permit monitoring and inspection timetables, and retention of essential documents by sponsor requirements is also necessary.

  Despite its importance, site selection is often underrated and needs to be better understood, leading to suboptimal site choices and ultimately impacting study outcomes.

  AI technologies can optimise the selection process and accurately identify qualified investigators, target locations, and priority candidates to address this issue. For example, AI can analyse large datasets and identify the most suitable sites based on previous experience, patient population, and infrastructure. In addition, AI can help automate the creation of standardised contracts such as confidentiality, investigator, and site agreements to reduce study startup time.

  AI can also facilitate monitoring compliance with regulatory requirements and approved protocol procedures. By automating workflows and identifying potential issues early on, AI can help to streamline the site selection process, reduce the time and cost associated with trial initiation, and ultimately improve

the likelihood of obtaining high-quality data. Furthermore, AI can help monitor the performance of investigator sites in real time, allowing sponsors to take corrective action as needed.

Overall, using AI technologies in site selection can help streamline the process and improve the quality and efficiency of clinical trials. However, careful consideration must be given to regulatory compliance and ethical concerns, particularly data privacy and confidentiality.

- **Improving patient monitoring, medication Adherence, Endpoint Detection, and Retention**

  Recruiting suitable patients into a clinical trial is a massive investment of time and funding. The return on this investment can only be realised through successful trial completion. Hence, it is imperative that patients stay in the trial, adhere to trial procedures and rules throughout- the go, and that all data points for monitoring the impact of the tested drug are collected ef- efficiently and reliably. Only 15% of clinical trials do not experience a patient dropout, and the average dropout rate across clinical trials is 30%. Dropouts caused by a lack of adherence to trial protocols require additional recruiting efforts, which lead to trial delays and substantial additional costs, as patients cannot be replaced on a one-to-one basis. A linear increase in the non-adherence rate in a trial leads to an exponential rise in additional patients required to maintain the statistical power of the outcomes. This creates a mismatch between clinical trial efficacy and the drug's real-world effects.

  Improved patient monitoring and coaching methods during ongoing trials can lower the adherence burden, make endpoint detection more efficient, and thus reduce dropout and non-adherence rates. Consequently, AI algorithms have become an increasingly valuable tool for managing and monitoring patients in clinical trials. They can automate data capture, digitise clinical assessments, and facilitate data sharing across multiple systems. Healthcare professionals can leverage AI solutions to identify relevant actions by protocol requirements, such as specific clinical tests and procedures to monitor diagnostic biomarkers, schedule patient visits, and pre-populate patient data into Electronic Data Capture (EDC) systems. This can help reduce costs, effort, compliance risks, and overall time to market.

  Using advanced AI algorithms, clinical trials can leverage data collected from participants via wearables, apps, and sensors to gain real-time insights into treatment safety and effectiveness. AI can integrate multiple digital biomarkers to assess the patient's response to the drug and detect the need for dose adjustments. FDA-approved AI-augmented platforms for remote patient monitoring can be used in healthcare and clinical trial settings. These connected devices allow patients to stay informed and supported in real time, enhancing engagement and retention. Other technologies, such as intelligent pillboxes, virtual pillboxes, and behavioural economics-based incentives, have been developed to improve adherence. DL and ML algorithms can analyse patient data from wearables and video monitoring in real-time and predict an individual patient's risk of dropout by detecting the onset of behaviour that led to non-adherence previously.

2.2.4 Case Study - Wearables in Clinical Trials: Johnson & Johnson and Apple

As technology evolves and wearables become increasingly sophisticated, their role in research will expand, leading to more inclusive, patient-centric, and data-driven approaches to advancing medical knowledge and improving patient outcomes. The integration of wearable devices in clinical trials has opened up new avenues for enhancing participant engagement and expanding the reach of research studies. Wearables can revolutionise clinical trials by enabling remote monitoring and eliminating barriers such as travel and time constraints.

AFib research study:

Johnson & Johnson and Apple have partnered to launch the Heartline Study, a virtual research initiative. The study aims to explore how the Heartline™ Study app on iPhone and the heart health features on Apple Watch can improve health outcomes and reduce the risk of stroke by detecting atrial fibrillation (AFib) at an earlier stage. The collaboration between Johnson & Johnson's Janssen Pharmaceutical Companies and Apple seeks to utilise digital health tools, such as the ECG app and irregular rhythm notification feature on Apple Watch, to enable the early detection of AFib and encourage proactive engagement in heart health.

AFib is often challenging to diagnose due to the lack of noticeable symptoms. Consequently, many individuals with AFib go undiagnosed until they experience a severe cardiovascular event like a stroke. By integrating the Heartline™ Study app and Apple Watch features, the researchers aim to address this issue and enhance stroke prevention by facilitating timely detection and intervention.

The ECG app on Apple Watch can analyse electrocardiograms to determine if they exhibit a normal sinus rhythm or indicate AFib. The irregular rhythm notification feature will also alert users to irregular heart rhythms that may indicate AFib. The Heartline™ Study provides participants with a heart health engagement program through the app, offering educational resources, tips, surveys, and questionnaires about overall heart health.

The study's remote and app-based approach allows participants to conveniently engage in the study using their iPhone or, in some cases, an Apple Watch, eliminating the need to travel to a physical trial site. This innovative approach has the potential to save time and reduce costs associated with traditional clinical trials.

Wearables 'advantages:

- Improved Convenience and Accessibility: One of the significant advantages of wearables in clinical trials is their convenience to participants. Traditionally, individuals interested in participating in research studies faced various challenges, such as taking time off work, arranging childcare, or travelling long distances to attend study visits. Wearables alleviate these burdens by enabling participants to monitor their health status and provide data from the comfort of their own homes. This ease of participation not only enhances recruitment efforts but also increases the diversity and representation of the study population.
- Familiarity and Comfort: Unlike traditional medical equipment that can be cumbersome and unfamiliar, wearables offer a user-friendly and familiar experience. Many individuals already own smartwatches or fitness trackers and are accustomed to using these devices for personal health tracking. This familiarity

reduces the learning curve and potential intimidation of using new medical equipment, leading to higher compliance rates and more accurate data collection. Researchers can leverage this familiarity by incorporating wearable technology into clinical trials, making the integration seamless for participants.

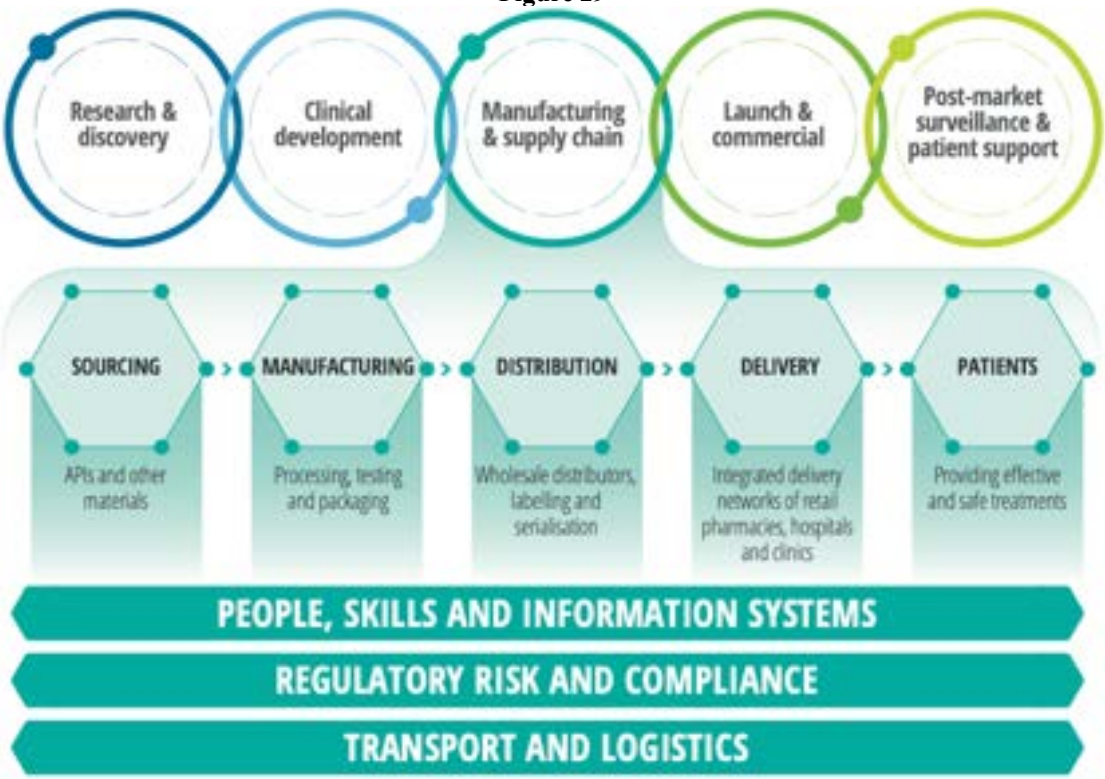
- Unlocking Valuable Health Insights: Although the medical community may not formally endorse some data collected by smartwatches and fitness trackers, it provides a wealth of information about an individual's health status. Wearables can track heart rate, sleep patterns, physical activity, and stress levels. While these measurements may not be diagnostic independently, they serve as valuable indicators and alert individuals to potential health issues. Integrating wearables into clinical trials enables researchers to tap into this wealth of data and comprehensively understand participants' health profiles, contributing to more nuanced and holistic research outcomes.
- Ensuring Data Accuracy and Quality: To maintain the integrity and accuracy of data collected in research studies, sponsors often provide participants with precisely calibrated and validated wearable devices for analysis. These devices offer higher accuracy and consistency, ensuring the collected data meet rigorous scientific standards. By leveraging validated wearables, researchers can have confidence in the data quality collected and draw robust conclusions from their analyses.
- Expanding the Frontiers of Research: The adoption of wearables in clinical trials benefits participants and opens up new possibilities for researchers. The continuous and real-time data collection of wearables allows for more dynamic and comprehensive monitoring of participants' health. Researchers can gain insights into trends, patterns, and fluctuations in health parameters over extended periods, leading to a deeper understanding of disease progression, treatment efficacy, and personalised interventions. Wearables also facilitate remote patient monitoring, enabling researchers to monitor participants' health in real-time, intervene promptly when necessary, and make timely adjustments to treatment plans.

2.3. AI in Manufacturing & Supply Chain

2.3.1 The Pharma Supply Chain: An Overview of the Critical Stages Involved in Producing and Delivering High-Quality Drugs

The pharma supply chain is a series of interconnected steps that start with sourcing and supplying raw materials and end with delivering the finished drug product to the consumer. The process involves various stages, and each stage is critical in ensuring the safety, efficacy, and quality of the final product (see Figure 29):

Figure 29



Source: *Deloitte analysis*.

- **Sourcing**: The sourcing and supply of materials stage are crucial in the pharma supply chain, as it sets the foundation for the entire manufacturing process. These materials may include active pharmaceutical ingredients (APIs), excipients, and other raw materials. The quality and consistency of the raw materials used in drug production can significantly impact the final product's safety, efficacy, and quality; Therefore, pharmaceutical companies must ensure that they source high-quality materials from reliable suppliers who adhere to strict quality standards. The sourcing process involves assessing potential suppliers based on their quality standards, reliability, and compliance with regulatory requirements. Once the suppliers are selected, the contracts are negotiated, and the raw materials are ordered. Ensuring the materials are correctly stored, handled, and transported to the manufacturing facility is essential to avoid contamination and ensure their quality.
- **Manufacturing:** The manufacturing stage is the most critical in the pharma supply chain, as it involves converting the raw materials into the final product. It is highly regulated and involves several locations, including formulation, filling packaging, and labelling. The formulation is the first step, where raw materials are mixed in specific quantities to create the drug product; this process must be carefully controlled to ensure the correct dosage and consistency of the drug. The filling stage involves transferring the drug product into its final container, including vials, syringes, or bottles. The packaging and labelling stage is also critical, as it must meet regulatory requirements and communicate essential information, such as dosing instructions, side effects, and storage requirements.
- **Distribution:** Once the product is manufactured and passes the quality control tests, it is ready for distribution. This stage involves coordinating the logistics of transporting the product from the

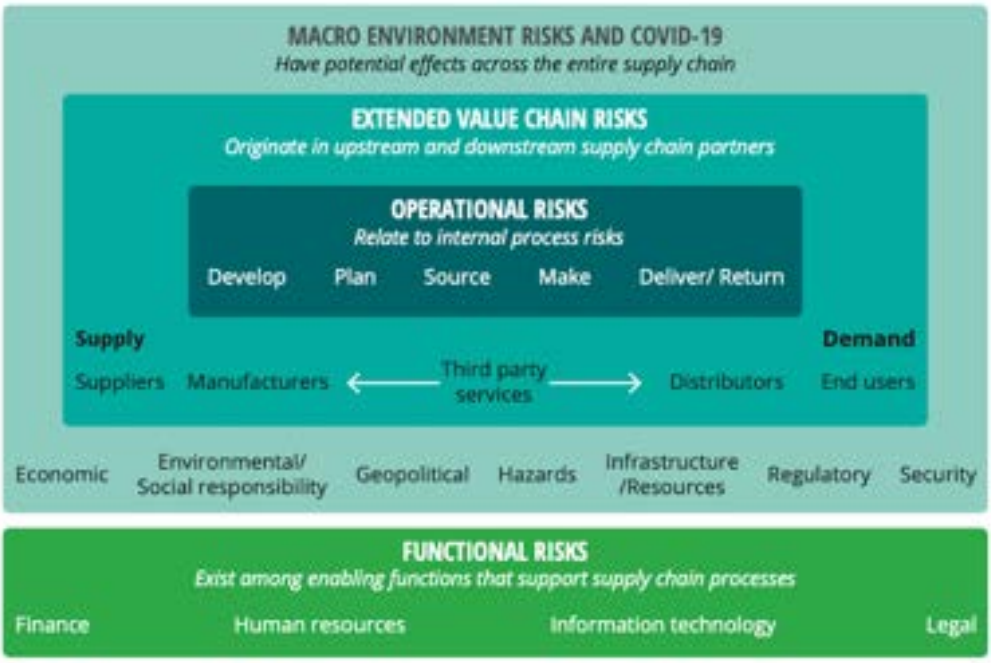
manufacturing facility to various distribution points, such as warehouses and distribution centres. The distribution process may involve multiple modes of transportation, such as air, sea, or land, depending on the product's destination and urgency. This stage involves several challenges, such as ensuring that the product is transported under the appropriate conditions to maintain its quality and safety: For example, some drugs may require cold-chain management, which involves maintaining specific temperature ranges during transportation.

- **Delivery to the Consumer**: The final step in the pharma supply chain involves delivering the product. This may include providing the product to retail pharmacies, hospitals, clinics, or directly to the patient. The delivery process may involve additional logistical challenges, such as cold-chain management, to ensure the product's quality and safety during transportation. The delivery process must ensure that the product is delivered to the correct location, at the right time, and in compliance with regulatory requirements.

2.3.2 Exploring the Rationale for Transformation: The Complexities and Risks Impacting the Pharmaceutical Supply Chain

The risk landscape for pharma supply chains comprises four distinct categories of supply chain risk that need to be considered and addressed with a more holistic approach (see Figure 30):

Figure 30



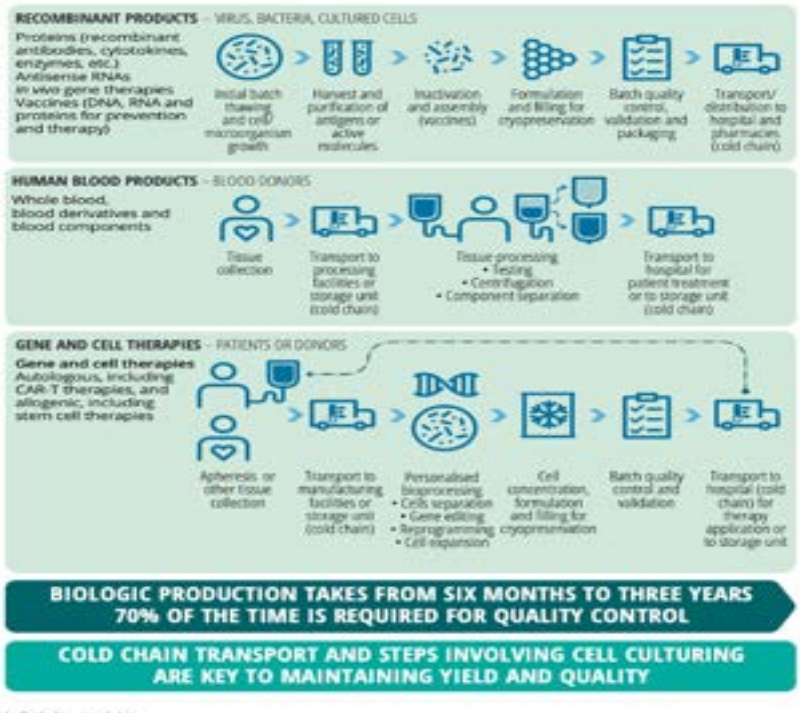
Source: *Deloitte analysis*.

- The *macro-environment* presents various external *risks* that affect businesses and their supply chains. While globalisation has granted companies access to more cost-effective labour and materials and opened up new markets, it also has complicated supply chain operations and magnified the impact of disruptions that were once geographically isolated. These disruptions can range from natural disasters to political

turmoil, piracy, and regional economic crises and are increasingly common. Specifically, the emergence of the global public health emergency due to the COVID-19 pandemic that started in early 2020 could serve as a pivot point to drive changes and updates to existing processes, as pharmaceutical manufacturers have faced additional pressure to adapt to a fast-paced, unpredictable landscape. Throughout the pandemic, ongoing drug shortages have highlighted critical limitations in current manufacturing and supply chain paradigms.

- *Extended value chain risks* concern a company's upstream and downstream supply chain partners. Recent events have demonstrated that a quality issue or disruption in a critical supplier's operations can have far-reaching consequences for a company's global supply chain; supplier consolidation can create economies of scale but also increase the potential for supply chain disruptions by relying on fewer suppliers. Outsourcing has improved efficiency and allowed businesses to concentrate on their core competencies, but it has also added complexity to operations and increased third-party risk.
- *Operational risks* are tied to a company's internal product development, manufacturing, and distribution operations. Lean manufacturing, just-in-time inventory, and capacity rationalisation have improved supply chain efficiency and agility but have also decreased the margin for error and amplified the impact of any issues that may arise.
- *Functional risks* pertain to the business functions that support supply chain activities, such as Finance, Human Resources, Legal, and Information Technology. Today's supply chains rely heavily on various applications and systems, and any disruption or breach in these critical systems can immediately impact the customer experience. Moreover, the increasing complexity of regulatory requirements and the more significant repercussions of non-compliance have made supply chains more reliant than ever on legal and regulatory functions.

Figure 31



Source: Deloitte analysis.

Over the past five years, the pharmaceutical industry has made significant progress by moving beyond producing small molecule drug products and towards developing complex protein therapeutics with the recent acceleration in bispecific, multispecific, cell, and gene therapies. These new modalities are bringing a new level of complexity to the supply chain (see Figure 31).

Across product types and therapeutic areas, manufacturers face increased cost and timeline-related pressures to bring new medicines to patients, adapt to local manufacturing requirements, and manage manufacturing equipment and processes throughout the entire supplier chain.

2.3.3 The Role of Artificial Intelligence in Enhancing Supply Chain Transformation

Due to the abovementioned factors, the pharma industry must operate efficiently while recovering quickly from unforeseen or unexpected challenges. However, these two goals often conflict: simply increasing production levels can lead to bottlenecks. If failures worsen those bottlenecks, the entire network can slow down and become less resilient.

AI technologies can help companies improve their value chain's resilience-efficiency balance. Achieving this balance entails addressing challenges such as local decision-making in silos without considering downstream implications and diverse expectations of stakeholders regarding digital technologies' deliverables. These technologies can transform supply chains and manufacturing through real-time data processing and decision-making, making supply chains truly data-driven and reducing human subjectivity and bias. AI tools can unlock commercial, regulatory, and operational data to identify non-linear and complex relationships that may be missed and deliver powerful strategic insights. AI algorithms can also significantly improve productivity and gross margins, contributing to the pharma industry's sustainability. Specifically, AI algorithms can improve end-to-end visibility, leading to more efficient demand forecasting, inventory management, logistics optimisation, procurement, supply chain planning, and workforce planning.

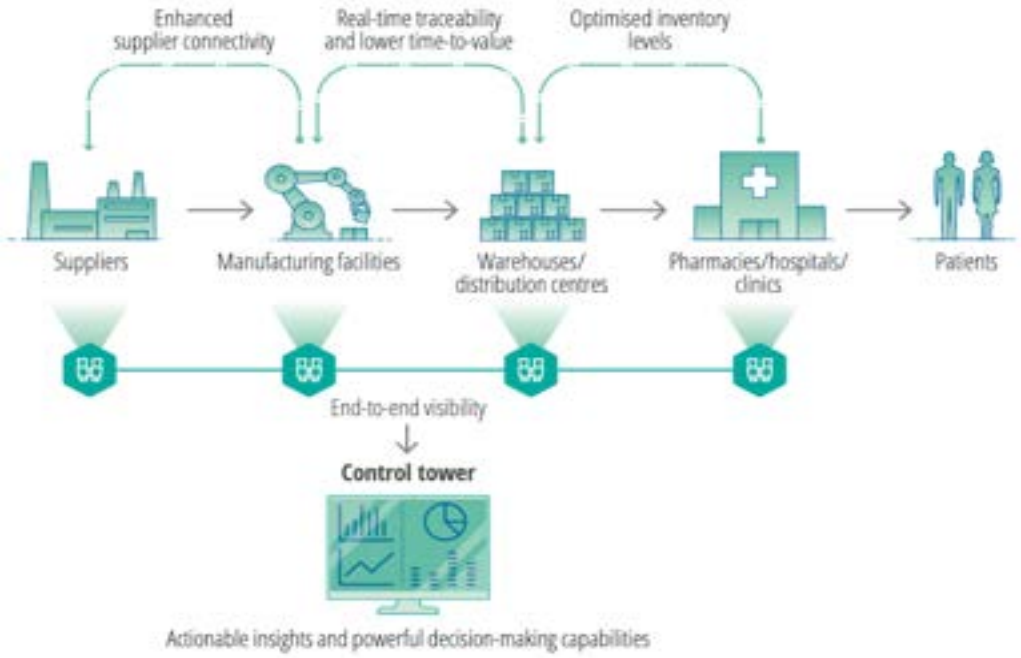
There are five critical areas and processes of the pharma supply chain where AI is likely to have the highest impact:

- ***End-to-end visibility***

In the pharmaceutical industry, where the supply chain is globally complex and hyper-connected, the ability to respond quickly to any supply chain event that impacts outcomes is critical. To achieve this, end-to-end visibility is essential for making informed decisions to mitigate risks and deliver the required results. This requires access to data at every step and tier of the supply chain, including logistics movements, and an interoperable, transparent, and traceable system. AI can improve supply chain visibility and enable a dynamic, interconnected system that generates real-time actionable insights, enhancing decision-making and improving agility, efficiency, and responsiveness (see Figure 32). Digital end-to-end control towers represent a promising strategy for increasing supply chain resilience. One way to achieve end-to-end visibility is through supply chain control towers that provide a holistic view across all supply chain functions. Control towers function as centralised hubs that collect information from disparate systems and use it for monitoring, auditing, and

generating insights. By leveraging AI technologies, these control towers can monitor the entire supply chain in real time, which can help anticipate and respond to potential disruptions. Such comprehensive monitoring can also facilitate end-to-end planning by providing transparency to historically isolated functions. Additionally, AI can foster improved communication between partners across the value chain, leading to more informed decision-making and earlier detection and response to disruptions. Notably, this transparency underscores the importance of elastic demand, as greater flexibility can increase the range of options available to the value chain in responding to challenges.

Figure 32

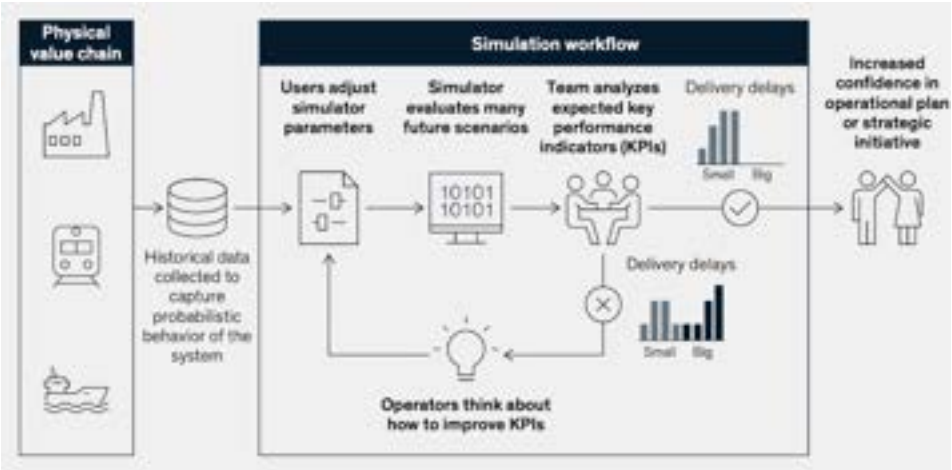


Source: *Deloitte analysis*.

- ***Demand forecasting, inventory management, and logistics***

Accurately forecasting demand is essential to logistics and supply chain management in the pharma industry. It enables companies to maintain appropriate inventory levels and ensure patients' timely access to therapies. AI tools have emerged as critical aids in accurate forecasting: they can reduce errors by 30% to 50%.

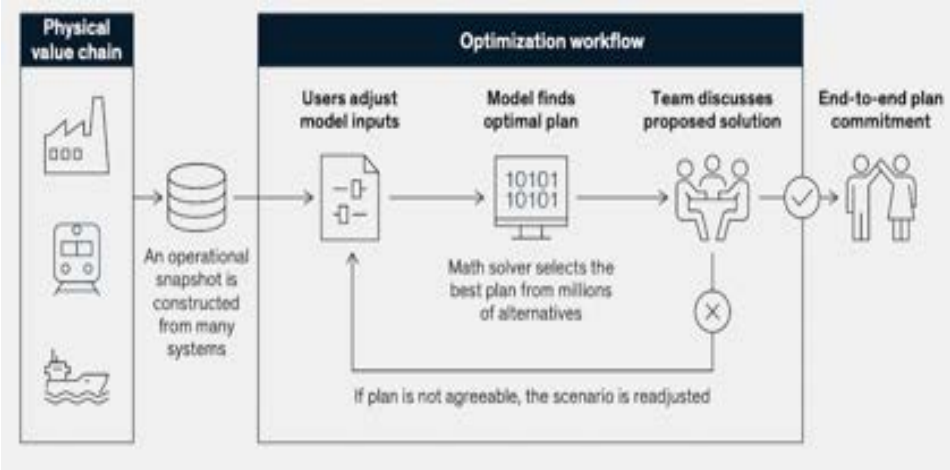
Figure 33



Source: *McKinsey*.

AI can help balance efficiency and resilience by incorporating uncertainty into realistic simulations of reality to help organisations evaluate scenarios and identify risks (see Figure 33). Simulations are descriptive analytics tools that can help identify and analyse the root causes of bottlenecks and evaluate different 'what if' scenarios. In a simulation, a digital twin is constructed with uncertainty measures and operational inputs. A digital twin is a digital replica of a physical process, such as an operation, machine, or activity used to understand better, evaluate, predict, and optimise performance. Digital twins can be based on empirical data (data-driven models) or integrate both empirical and mechanistic simulations to provide high-resolution models with real-time or near-real-time data to assess process performance. The result, a set of key performance indicators (KPIs) describing current challenges, helps companies better understand how deviations or disruptions may impact performance and how related risks can be mitigated. Manufacturers can use real-time AI-based insights to evolve beyond simplistic rules like "frozen periods," rhythm wheels, or minimum order quantities. Companies can run multiple simulations simultaneously, allowing them to plan across multiple dimensions simultaneously, moving to multi-echelon planning. All this saves time and reduces the need for inventory buffers so that companies can plan and sequence runs more effectively while staying focused on customer requirements. It is essential when responding to choke points in the system that vary over time, including changing operating conditions, maintenance downtime, weather conditions, or third-party dependencies. Simulations can also analyse the impact of strategic decisions across the value chain, such as closing or opening a location, building new storage buffers, or making capital expenditures. Such models outperform traditional process models in terms of resolution and real-time feedback.

Figure 34



Source: *McKinsey*.

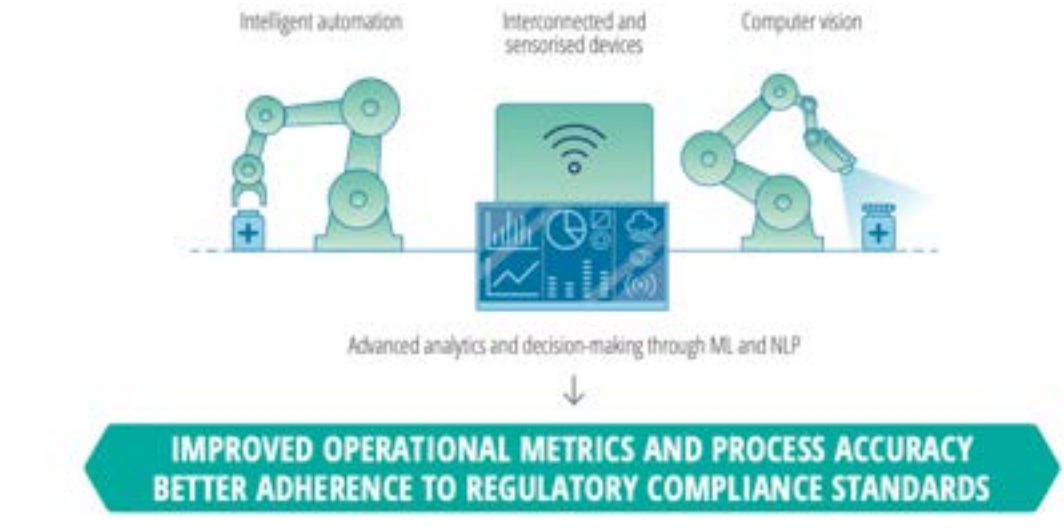
AI can also find optimal plans for current operational set-ups: optimisation models are a type of prescriptive analytics tool that generates an optimal method of execution for a given environment, considering the end-to-end impact of decisions (see Figure 34). These models consider operational considerations such as the current conditions of the supply network and possible uncertainties about the future. Such models are effective in improving operational and commercial decisions. An example of the application of optimisation models is a

company's deployment of an optimisation AI to enhance throughput across the entire value chain. The user creates a snapshot of the current value chain, adjusting live data on demand, production capacity, and price information. The optimisation model determines an optimal solution once the inputs match the planner's requirements. This way, the company can optimise production parameters for highly complex systems accurately and proactively without risk. Organisations implementing these systems can generate and discuss more than ten scenarios in a live one-hour call with multiple stakeholders. The optimisation AI eliminates millions of suboptimal plans that perform worse on efficiency or resilience key performance indicators, selecting an optimal plan in each cycle iteration.

- ***Enabling Industry 4.0 and the Internet of Things through Intelligent Automation***

Industry 4.0 technologies can transform pharmaceutical manufacturing and logistics platforms through digitisation, autonomous systems, robotics, and computing advancements. This adoption seeks to tackle the industry's challenges, such as stringent regulatory and production demands: by adopting Industry 4.0, pharmaceutical companies can progress towards Quality by Design (QbD), a data- and risk-based approach for drug development and manufacturing that FDA and EMA actively encourage. In particular, the pharmaceutical supply chain, production processes, distribution, and inventory frameworks could significantly improve. Digitalisation and operations automation can help these companies establish cost-effective, reliable, and coordinated processes across the supply chain. This can be optimised by implementing an IoT platform, which interconnects digital and physical assets using chips, sensors, and networks, generating a vast amount of monitoring data that can be unlocked and optimised through advanced analytics with AI capabilities. The convergence of AI, automation, and customer data has led to the emergence of intelligent process automation (IPA), combining RPA and machine learning to deliver powerful tools that can mimic human interaction and make advanced decisions based on the outputs of those robotic inputs. Integrating IPA, IoT, and Industry 4.0 in the manufacturing step of the biological supply chain is one of the most promising approaches towards reducing variability and ensuring the safe and reliable large-scale production of drugs derived from living organisms (see figure).

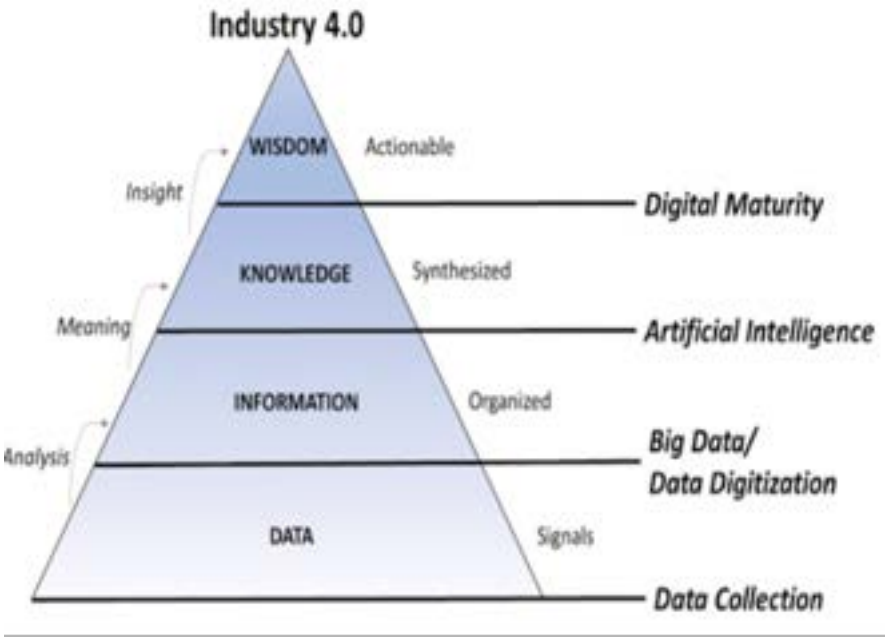
Figure 35



Source: Deloitte analysis.

The fourth industrial revolution brings together advanced manufacturing technologies to enable integrated, autonomous, and self-organising manufacturing systems that operate independently of human involvement: in such an environment, performance data can be analysed by AI algorithms and used for critical real-time business and operational decisions that directly impact production outputs enabling unprecedented real-time responsiveness, monitoring, control, and prediction. This transition from simple data collection to digital maturity empowers autonomous systems and cyber-physical machines capable of self-optimizing, judgment/decision-making, a slight movement, and adaptive control (see Figure 36). Digitisation, automation, and real-time data integration will enable pharma manufacturers to establish a well-controlled, hyper-connected, digitised ecosystem in the pharmaceutical value chain.

Figure 36



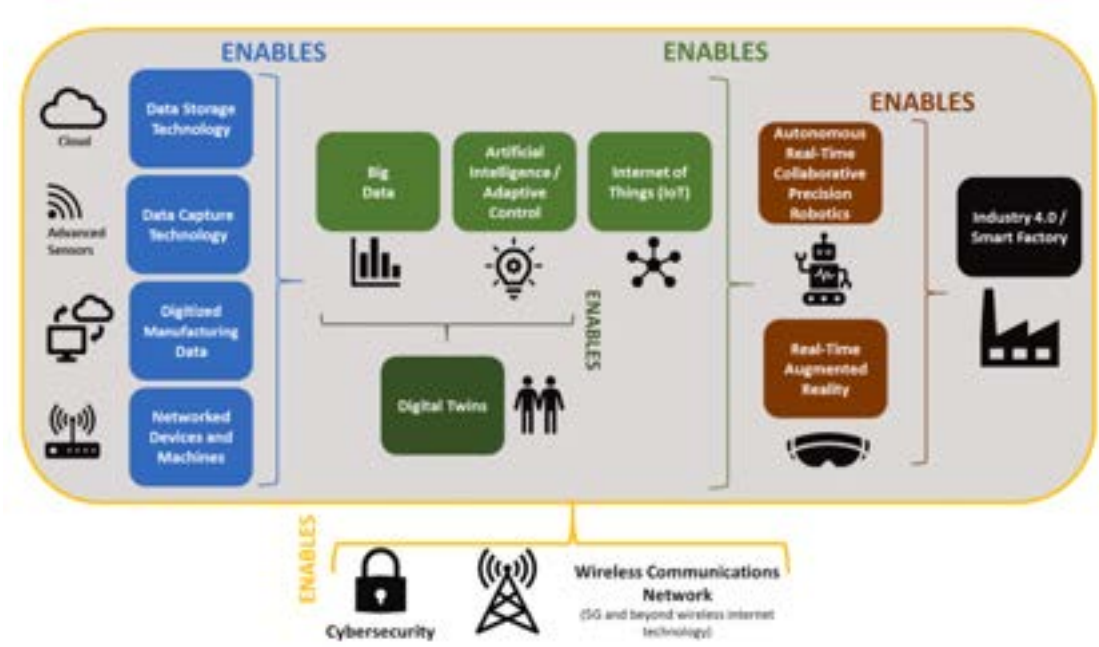
Source: *International Journal of Pharmaceutics*.

Industry 4.0 has revolutionised manufacturing by introducing intelligent factories that leverage advanced technologies to enable efficient, precise, and autonomous production processes (see Figure 37). At the heart of these intelligent factories are two key technologies: data storage and data capture. Data storage technology, such as cloud-based systems, facilitates the long-term storage of digitised data captured from advanced sensors used in manufacturing operations. This creates a data-rich environment that enables advanced analytics, simulations, artificial intelligence, adaptive control, digital twins, and cyber-physical systems like the IoT. By harnessing the power of these technologies, intelligent factories can achieve real-time, data-driven decision-making, improved process optimisation, and increased operational efficiency.
On the other hand, data capture technology involves using advanced sensors integrated into manufacturing operations to capture real-time data from various sources. These sensors can detect changes in temperature, pressure, humidity, and other critical parameters that impact the manufacturing process. By capturing and analysing this data, intelligent factories can identify and address issues before they cause delays, defects, or

downtime, enhancing overall product quality and reducing costs. The integration of these technologies enables intelligent, precision, real-time, collaborative robotics, and augmented or virtual reality technologies to operate and manipulate the manufacturing process. This allows for seamless interaction between machines, processes, and people, creating a highly efficient and flexible production system that can adapt to changing demands and requirements. Furthermore, wireless internet networks and appropriate cybersecurity measures are crucial for the effective functioning of an intelligent factory. These enable the secure transmission and storage of data and protect against cyber threats that could compromise the integrity and safety of the production process.

The potential impact of Supply Chain 4.0 is enormous: according to a McKinsey report, up to 30% lower operational costs and a reduction of 75% in lost sales while decreasing inventories by up to 75% is expected, at the same time increasing the agility of the supply chains significantly.

Figure 37



Source: *International Journal of Pharmaceutics*.

- ***Optimising predictive maintenance***

Traditional maintenance approaches in manufacturing facilities have been characterised by preventive maintenance or run-to-failure modes. Preventative maintenance involves regularly scheduled procedures, such as visual inspections and asset monitoring, to obtain information on system components' condition. Conversely, run-to-failure care allows machines to operate until they break down before being repaired. However, these methods can lead to inefficiencies, permanent equipment failure, and production line downtime, resulting in serious financial consequences.

According to a 2016 Deloitte survey, the life sciences sector had a higher incidence of business disruption resulting from product compliance, quality, or safety-related issues, with 35.6% of companies affected, compared to 19.2% across other industries. Slow responses to such problems can have a threefold negative impact, including negative market perception, regulatory agency response delays, and significant investments to compensate for the lack of controls.

Predictive maintenance has gained significant momentum in this industry, as it can improve operational effectiveness and machine uptime, which is a top priority for supply chain leaders.

Predictive maintenance is a proactive maintenance strategy that involves predicting equipment failures before they occur. It can be used in all stages of the pharmaceutical supply chain, starting with R&D and carrying on to product design, manufacturing, and distribution services. It is enabled by advanced technological tools, such as AI and ML, that transform vast amounts of manufacturing data, unused or unanalysed (estimated to be around 60%-73%), into valuable insights about equipment performance and maintenance needs. By analysing data from various sources, such as equipment sensors, maintenance records, and manufacturing data, AI algorithms can allow equipment units to be interconnected, identify patterns and complex relationships between variables, and forecast equipment failures and other issues before they happen. This enables maintenance teams to schedule repairs before a failure occurs, minimising unplanned downtime and reducing maintenance costs, thus improving operational effectiveness. By reducing the risk of product compliance, quality, or safety-related issues, predictive maintenance can also improve market perception and minimise the risk of financial consequences associated with unnecessary downtime.

This approach has gained significant momentum in the pharma industry, with a predicted CAGR of 39% and an estimated market value of $23.5 billion by 2024.

- ***Protecting the integrity of the supply chain***

The issue of counterfeit medicines, as the dark side of networked markets and globalisation, has become increasingly pressing regarding the economic cost of this global black market and the risk to human life that comes from taking counterfeit drugs. The manufacturing and distribution of counterfeit or substandard drugs, which may include the incorrect quantity of APIs or none, is today one of the most significant risks facing the world pharma sector and worldwide health organisations and society. These fake drugs include everything from cancer medication to birth control pills and are frequently infected with harmful microorganisms and contain contaminants; these can be dangerous when consumed by patients seeking cheap alternatives for already expensive medical treatments. According to the WHO, 1 in 10 medical products in low- and middle-income countries must be revised or corrected. In many developing countries in Asia, Africa, and South America, counterfeit drugs comprise 10% and 30% of the total medicines on sale. This issue, however, is not limited to developing countries but touches all: with the exponential increase in internet connectivity, those engaged in the manufacture, distribution, and supply of substandard and falsified medical products have gained access to a global marketplace. In addition, millions worldwide need more means to access original medications due to their high price points and sometimes supply shortages; their only option appears to be cheaper black-market products with unknown ingredients.

The importance of supply chain integrity in pharma goes beyond counterfeit medications since major product categories require a chain of identification and custody, especially in personalised medicines and gene therapies. To address this, pharma businesses are investing in modern technologies, such as blockchain and AI, to maintain the integrity of the end-to-end supply chain. There are in-built vulnerabilities in the drug supply

chain at the many points where drugs transfer ownership to patients. Pharma manufacturers and other stakeholders need more visibility to track the authenticity of products. Using AI in the supply chain allows for real-time monitoring of products from manufacturing to distribution, effectively preventing counterfeit drugs from entering the legitimate supply chain; it can also use forensic security technologies, such as product authentication and security systems, to ensure that the supply chain is free of counterfeit drugs.

AI anti-counterfeit technology has the potential to improve security, transparency, and traceability throughout the pharma supply chain, allowing drug tracking at every step: AI algorithms can be trained to detect markers that are unique to certain types of drugs or packaging materials as well as size changes as are familiar with counterfeit drug packages which would not necessarily show up as anything suspicious to a human but would for AI tech. It is also a proven cost-saver since it assists healthcare firms in more effective identification of fake pharmaceuticals, allowing pharmaceutical to screen out fakes and quickly plug possible income loss routes. Consequently, pharmaceutical businesses must begin actively deploying AI-based solutions that can match the current speed of counterfeiters.

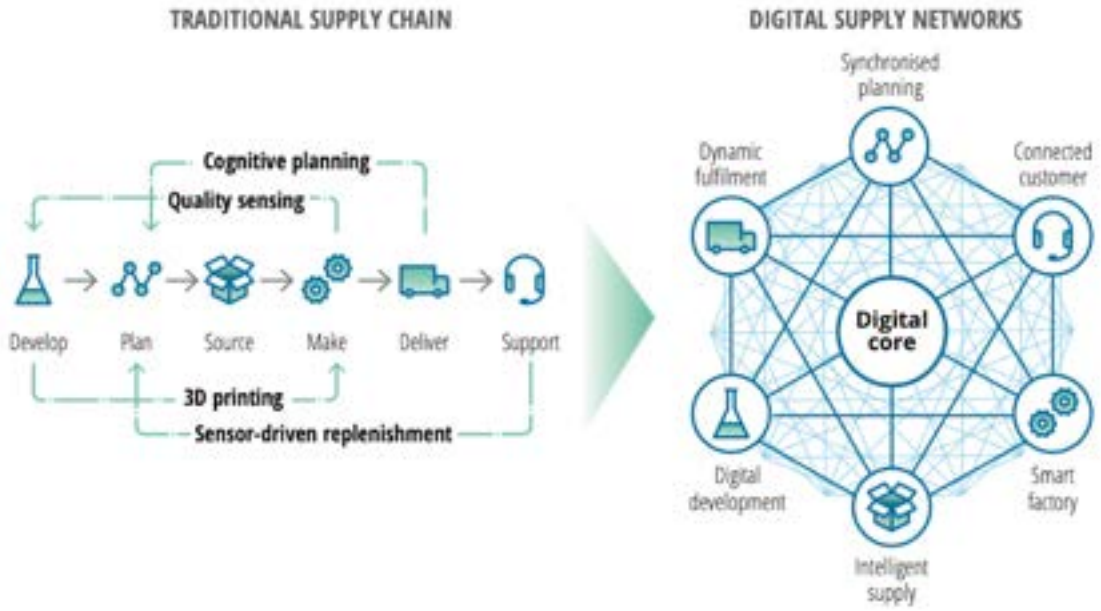
2.3.4 Enabling the Transition from Traditional Supply Chains to Digital Supply Networks (DSNs) through AI-Driven Innovations

The adoption of AI tools at various stages of the supply chain is poised to revolutionise the operating models of the pharmaceutical industry, producing a fundamental shift from linear supply chains to dynamic, interconnected, and open digital supply networks (DSNs).

Primary research indicates that the most significant challenges faced by the global supply chain sector across industries remain the coordination of operations across multiple silos, inventory management, and increasing visibility. DSNs are well-positioned to address these challenges by integrating data and information from various sources and locations using advanced digital technologies; they also provide greater product visibility, traceability, and inventory control. DSNs ensure that the market receives the appropriate products manufactured to high standards, in targeted volumes and delivered at the proper time to the right customers. A critical operational objective of DSNs is to enhance transparency and trust in the security of valuable production and financial data. However, companies must tailor DSNs to meet their specific needs by managing numerous moving parts, people, and processes and establishing an enabling IT infrastructure. By doing so, they can optimise inventories and operations and improve cost-effectiveness. DSNs can also help fulfil regulatory requirements, enhance customer satisfaction, and accelerate innovation. Nonetheless, digital transformation is a complex and resource-intensive undertaking that fundamentally alters business operations. Traditional supply chains operate in a linear fashion where each step is dependent on the one before it. This structured chain of events - develop, plan, source, make, deliver, support - is susceptible to inefficiencies, leading to delays and increased costs. The lack of visibility into other processes further limits stakeholders' ability to react or adjust activities, resulting in the bullwhip effect. In contrast, DSNs create a dynamic, integrated supply network that employs real-time data to inform decisions, provide transparency, and enhance

collaboration across the entire supply network. With digital at the core, the interconnected lattice of the DSN model enables interactions between each node and every other point of the network, allowing for more excellent connectivity among areas that previously did not exist. This multidirectional communication fosters connectivity in traditionally disconnected links in the supply chain, ultimately improving the efficiency and effectiveness of supply chain management (see Figure 38).

Figure 38



Source: *Deloitte analysis*.

The DSN is characterised by five main attributes that are critical in enabling organisations to make more informed decisions and address key strategic questions related to achieving competitive advantage (see Figure 39). The DSN's *always-on* attribute serves to facilitate well-informed decision-making and address strategic questions that may arise in the context of business operations. It implies that location-based tools and sensors continually transmit data with minimal latency, allowing for an integrated network view. Furthermore, the DSN's characteristics extend beyond resolving latency issues and provide a more comprehensive understanding of the supply network, leading to more informed strategic decisions. The *connected community* feature facilitates direct communication and data sharing among various stakeholders, including suppliers, partners, customers, products, and assets. This enables more significant data synchronicity and machine-driven decision-making.

On the other hand, intelligent optimisation involves leveraging data to optimise decision-making, with machines and humans working together to achieve this goal. *End-to-end transparency* enables instant visibility across multiple aspects of the supply chain, providing insights into critical areas, including material flow, schedule synchronisation, supply-demand balancing, and financials. This allows companies to view the supply network holistically and better understand how all components interact and relate. Finally, the *holistic decision-making* attribute enables information transparency across all areas of the supply network and all functions, leading to better decision-making related to supply-demand balancing and strategic planning. This

holistic thinking allows for broader strategic transformations, which can fuel growth across the entire business rather than focusing solely on incremental improvements within the supply chain.

Figure 39

Source: *Deloitte analysis*.

To mitigate the potential risks associated with integrating new digital technologies and platforms, manufacturers across industries have adopted a phased approach, beginning with pilot projects to evaluate data use and achieve measurable outcomes before scaling up. This approach is comprised of three stages:

- *Start small*: first, to quickly demonstrate the value of AI-enabled solutions, companies should identify and prioritise small proof of value pilot projects, which can yield quick wins and help build confidence and buy-in. Prioritise areas that can unlock several waves of potential value and build on those successes to establish DSNs where they make strategic sense. At the same time, it is essential to act with growth in mind: Focus on areas that unlock several waves of potential value, creating a ripple effect that leads to exponential growth. However, executive-level commitments are also necessary to adopt the selected technology, establish success criteria for the proof of value, and agree on an approach for future expansion.
- *Act fast*: secondly, once a technology implementation has proven to deliver a sufficient return on investment, companies should scale the project across relevant parts of the supply chain, leveraging agile methodologies to progress prioritised use cases. Small successes can serve as proof points, leading to a greater willingness to take a chance on more substantive investments. By starting small and moving quickly, organisations can generate success stories that prove the value and importance of the DSN. Success creates success: sharing examples of successful DSNs can evangelise sceptics within the organisation. It can also demonstrate to customers that the or- organisation is at the forefront of technology and is focused on their needs. Concurrently, companies should develop an agile supply culture and promote

a more strategic approach to meeting customers' needs while developing strategies to identify, train and retain skilled talent to manage and nurture rapidly evolving digital transformation solutions.

- *Think big*: Third, successful technology deployment must be focused on a value-driven approach for innovation and applied throughout the supply chain. With a firm grasp on how and why one wants to differentiate, organisations can examine real supply chain applications that suit their business objectives. End-to-end implementations can yield significant benefits, both upstream and downstream, by providing immediate access to data and information across all parts of the manufacturing network. A "Digital Foundry" approach, which uses a controlled environment to minimise risk and reduce barriers to DSN implementation, can enhance decision-making, generate momentum in converting ideas into actionable plans, increase efficiency, and deliver measurable value.

2.3.5 Case Study – Merck's AI Utilisation to improve demand forecasting

Company Overview:

Merck KGaA, also known as the Merck Group, is a leading German multinational pharmaceutical, chemical, and life sciences company headquartered in Darmstadt. With an expanding product portfolio and a commitment to operational excellence, Merck recognised the need to optimise its supply chain management processes, particularly in demand forecasting.

The challenge of enhancing Supply Chain efficiency:

Merck faced the challenge of ensuring increased efficiency in its supply chain processes to become a top customer-supplier. The company needed to leverage intelligent technologies and solutions that could provide actionable insights and a comprehensive view of its supply network to achieve this.

Aera Technology as the Foundation of a Self-Driving Supply Chain:

Merck turned to Aera Technology, a cloud-based software solution empowered by machine learning capabilities, to address these challenges. Formerly known as FusionOps, Aera provides Merck with a holistic and real-time understanding of its supply chain operations, specifically on demand forecasting. By continuously analysing data from various enterprise systems, Aera collects, harmonises, and refines information, offering valuable analytics and end-to-end visibility into the supply chain. Aera's solution supports Merck in streamlining and accelerating its supply chain processes, encompassing demand, inventory, replenishment, and life cycle planning. Leveraging machine learning techniques, Aera's algorithms analyse internal data and incorporate external factors such as weather conditions, natural disasters, trends in patient health, and expansion plans of pharmacies. These insights enable Merck to generate accurate demand forecasts, reducing waste in the supply chain and optimising resource allocation. By integrating Aera into its operations, Merck has established a self-driving supply chain that operates in real-time and makes intelligent decisions at scale. The software's capabilities significantly enhance the speed, quality, and impact of decision-making processes within Merck's supply chain operations.

Remarkable Achievements:

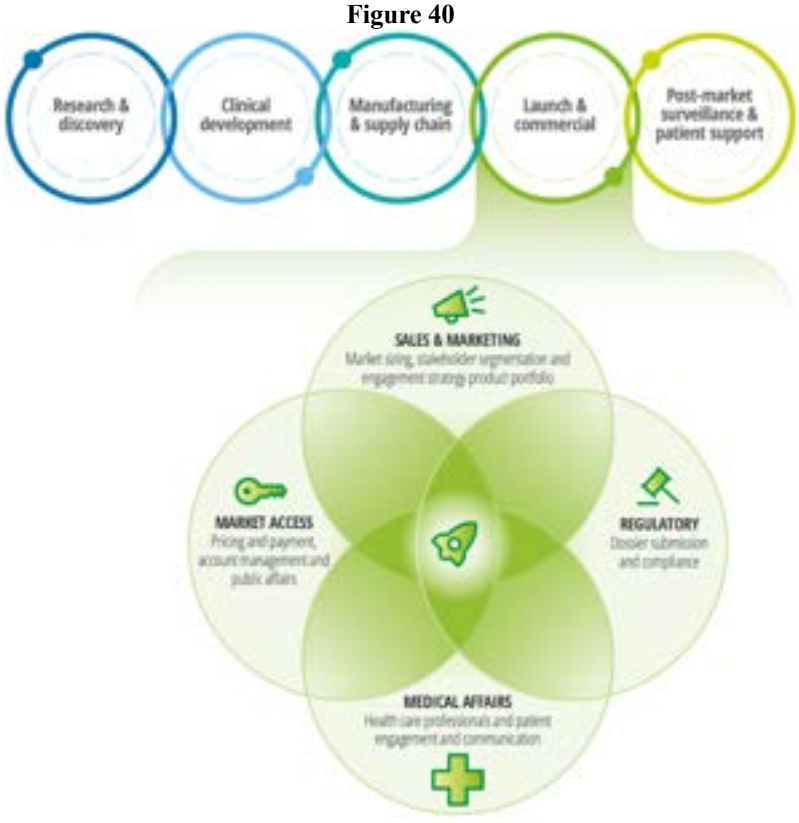
- Improved Forecast Accuracy: Merck has successfully enhanced the forecast accuracy for 90% of its products. Aera's AI algorithms leverage data from the company's enterprise resource planning software, enabling quick and accurate demand predictions regarding quantity and location.
- Increased Customer Service Level: Merck has elevated its customer service level for pharmaceutical products delivered to hospitals from approximately 97% to 99.9%. This improvement ensures that hospitals receive the right products at the right time, enhancing patient care and satisfaction.
- Real-Time Performance Monitoring: Aera's integration allows Merck to monitor supply chain performance in real-time, down to the individual stock-keeping unit (SKU). This level of granular visibility is made possible by leveraging data from sensors installed on factory machines and information collected from the company's enterprise resource planning system.

2.4. AI in Launch & Commercial

2.4.1 Challenges and Complexity of Launching New Drugs in the Pharma Industry

In the competitive pharmaceutical industry, the success of a new product launch is contingent on effective planning and execution of commercialisation strategies. Critical components of this process include developing a pricing strategy, ensuring regulatory compliance, implementing effective marketing tactics, and establishing successful sales strategies (see Figure 40). These elements are essential for creating a positive outcome in the launch and commercialisation phase:

Figure 40



Source: *Deloitte analysis*.

- **Pricing strategy**

  Pricing strategy is an integral part of the launch and commercialisation phase. Pharmaceutical companies must adopt appropriate pricing strategies to ensure their products are priced competitively while generating revenue. The two primary pricing strategies pharmaceutical companies adopt include price skimming and market penetration. Price skimming involves setting high prices for new products to maximise revenue in the early stages of the product lifecycle. On the other hand, market penetration involves setting lower prices to attract a more extensive customer base and gain market share.

- **Marketing Strategy**

  The marketing strategy plays a critical role in launching and commercialising pharmaceutical products. A comprehensive marketing strategy should involve an in-depth understanding of target markets and efficient promotion of product benefits to healthcare providers and patients. This involves identifying the target audience, developing messaging that resonates with the audience, and leveraging various marketing channels to reach the target audience.

- **Regulatory Compliance**

  Regulatory compliance is a crucial consideration during the launch and commercialisation phase. Pharmaceutical companies must adhere to strict regulations while ensuring patient safety remains paramount. Companies must ensure that their products meet regulatory requirements, including clinical trial requirements, product labelling, and marketing authorisation. Failure to comply with regulatory requirements can result in severe consequences, including product recalls and financial penalties.

- **Sales Strategies**

  The sales approach is another critical aspect of the launch and commercialisation phase. This approach involves identifying the most effective distribution channels to reach the target audience and developing relationships with stakeholders to drive sales. Pharmaceutical companies often collaborate with key stakeholders to build distribution networks that enable them to access desired markets.

Pharma companies must focus on these critical aspects during the launch and commercialisation phase to achieve sustainable growth and success. Achieving this requires a rigorous academic approach that maximises opportunities for growth and expansion over the long term. Therefore, companies must adopt effective planning and execution strategies that incorporate these factors to succeed in the industry.

However, the process of planning and executing a successful product launch in the pharmaceutical industry has become increasingly complex and challenging due to several reasons:

- *Intensified Competition*: The pharmaceutical industry has become increasingly competitive due to the many new drugs launched yearly. With an increasing number of companies entering the market, the competition has intensified, making it more challenging for firms to launch a successful product. This has increased the pressure on pharma companies to differentiate themselves and find new ways to attract and retain customers.

- *Rising Costs of Drug Research and Development*: The cost of developing a new drug has increased over the years, costing over $2 billion per drug. This makes it more challenging for pharmaceutical companies to recoup their investments and generate profits from new drug launches. A reduction in the average peak sales of drugs has also contributed to the challenges associated with successfully launching new drugs.
- *Increasing Molecular Complexity and Changing Modality of Treatments*: With advances in medical technology and the increasing complexity of diseases, the molecular complexity of drugs has also increased, making it more challenging to demonstrate their efficacy and safety. Furthermore, the changing modality of treatments, such as gene therapies and immunotherapies, has added to the complexity of launching and commercialising new drugs.
- *More Targeted Launch and Stakeholder Engagement Strategies*: As the target population for many drugs has decreased, launching a successful product has become more challenging. To address this, pharmaceutical companies must develop more targeted launch and stakeholder engagement strategies, which can be costly and time-consuming.
- *Shorter Commercial Time to Patent Expiry*: Due to longer trial cycle times, the commercial time to patent expiry has decreased, making it more challenging for companies to recoup their investments and generate profits from new drug launches.
- *Changing Market Access Rules and Prescribing Behaviors:* The changing market access rules and prescribing behaviours of physicians, coupled with tightening pricing controls and toughening payer stance on pricing and reimbursement, have added to the challenges of launching new drugs. Payer pressures on providers to prescribe generics and biosimilars have also contributed to the difficulties associated with new drug launches.
- *Enhanced Scrutiny from Stock Markets*: The stock market's increased scrutiny of pharmaceutical companies has created additional pressure on these firms to get the design and execution of launch and commercial strategies right and optimise returns from new drug launches. This has made it more challenging for firms to launch successful products while meeting shareholders' expectations.

Therefore, the proper drug launch and commercial strategies have become more crucial than ever to optimise returns and meet the growing expectations of stakeholders. To achieve success, companies must effectively target and engage with all stakeholders, matching different channels to the preferences of various stakeholders over the development and launch timeline (see Figure 41).

Figure 41

Source: *Deloitte analysis*.

2.4.2 Factors Contributing to the Improvement of Launch and Commercialisation

The Importance of Balancing the Timing of Marketing Authorization and Pre-Launch Preparations

Regulatory authorities in each target market must grant market authorisation in the pharma industry before launching a new drug. This authorisation is based on the company submitting a detailed dossier, including pre-clinical studies, clinical trials, and manufacturing and packaging details. Typically, dossiers are presented following a successful Phase III clinical trial. However, companies are increasingly applying for accelerated approvals and preparing dossiers before reaching Phase III to expedite authorisation and maximise the product's patent life while avoiding additional costs.

In addition to obtaining market authorisation, companies must plan and coordinate their commercial activities to engage with stakeholders in each target market early. This is to avoid jeopardising their plans and relationships established during pre-launch marketing operations if safety or efficacy concerns delay authorisation, significantly if clinical trials are halted or suspended. To address this challenge, the companies must strengthen their cross-functional collaborations by ensuring that commercial functions work closely with R&D and adopt a customer-centric approach from development to commercialisation.

Underpinning these collaborations requires extracting value from all the data flowing across all pre-launch activities. Early alignment between commercial and R&D functions is necessary to achieve this, which is more likely to ensure that a drug will meet patient needs. By doing so, companies can optimise their launch and commercialisation strategies and maximise returns on their investment.

Understanding the Pricing and Reimbursement Landscape

Pricing and reimbursement are significant drivers of value during the launch of a drug, as governments and payers aim to exert downward pressure on the cost of healthcare, including pharmaceuticals. Pharma companies must gain deeper insights into their medicines' value to patients and society and payer attitudes towards pricing and reimbursement. Determining drug pricing requires considering the political agenda, economic dynamics, regulatory policies, reimbursement policies, available healthcare budgets, treatment regimens, and patient advocacy support groups. Creating a return on investment from R&D has led to higher prices and increased resistance from payers, causing friction with HCPs, patients, and patient advocacy groups. Payers expect Big Pharma companies to demonstrate evidence of new therapies' effectiveness on clinical outcomes and healthcare budgets, leading to the exploration of new pricing models such as volume-based agreements, value-based contracting (VBC) models, pay-over-time models, and subscription-based models (see Figure 42). VBC shifts the risk to the company's ability to deliver the promised impact, requiring new pricing strategies, financing mechanisms, and collaborations among companies, HCPs, patients, and payers. However, assessing the value of a new drug is challenging due to limited data on long-term clinical outcomes at the launch, especially in orphan drug trials with small patient cohorts. Innovative agreements require new regulatory approaches, collaborative relationships, and a deep understanding of local healthcare systems and partnerships adapted to meet different countries' or regions' requirements.

Figure 42

Source: *Deloitte analysis*.

Stratifying Marketing Strategies and Enhancing Customer Engagement

In the current landscape, pharma companies aim to tailor their commercial activities to specific market segments and utilise various retail channels according to stakeholder needs. Digitalization has played a vital role in the response of most stakeholders during the pandemic. Traditional approaches to go-to-market strategies, predominantly based on physical channels, have been transitioning to digital media due to advancements in digitalisation over the past few years. Although adopting digital channels was gaining momentum before the COVID-19 pandemic, implementing social-distancing measures in response to the outbreak made face-to-face engagement by salesforce representatives impossible. Consequently, in March 2020, most companies suspended their field salesforces and switched to virtual technology-enabled marketing and healthcare professional (HCP) engagement strategies. Companies that had already invested in digital platforms for virtual physician engagement were better equipped to respond, while others had to hasten their

implementation of digital media. Nevertheless, in this uncertain market, companies have faced difficult decisions regarding delaying or continuing planned launches, particularly as these operations are timed and designed to optimise patent life.

Engaging with Healthcare Professionals (HCPs)

The COVID-19 pandemic has presented new challenges for commercial teams, prompting them to re-evaluate the most suitable channels to meet the needs of stakeholders, including healthcare professionals (HCPs) and patients, and to explore how digital technologies can facilitate successful launches and market uptake. It is expected that the disruptions and challenges caused by COVID-19 will have a lasting impact even after the pandemic subsides. This provides an opportunity for companies to embrace digital channels and tailor customer experiences through the use of readily available data. Recent market research indicates that companies are increasingly adopting targeted marketing strategies that combine traditional and remote digital approaches to manage and execute engagements as efficiently as possible. However, the success of these strategies depends on the availability of robust data.

Furthermore, a series of surveys aimed at understanding how HCPs have been affected by the pandemic and their interactions with pharma sales reps revealed that remote interactions during COVID-19 have been viewed positively by some doctors. In contrast, others have experienced scheduling, technology, and personal connection challenges. Many HCPs prefer scheduled remote interactions but also express interest in having on-demand access to sales reps. Pharma companies need to deliver effective remote interactions that increase the value of engagements through high-quality and unique content tailored to meet the specific needs of HCPs.

Leveraging Online and Digital Tools to Deliver Tailored Customer Experiences

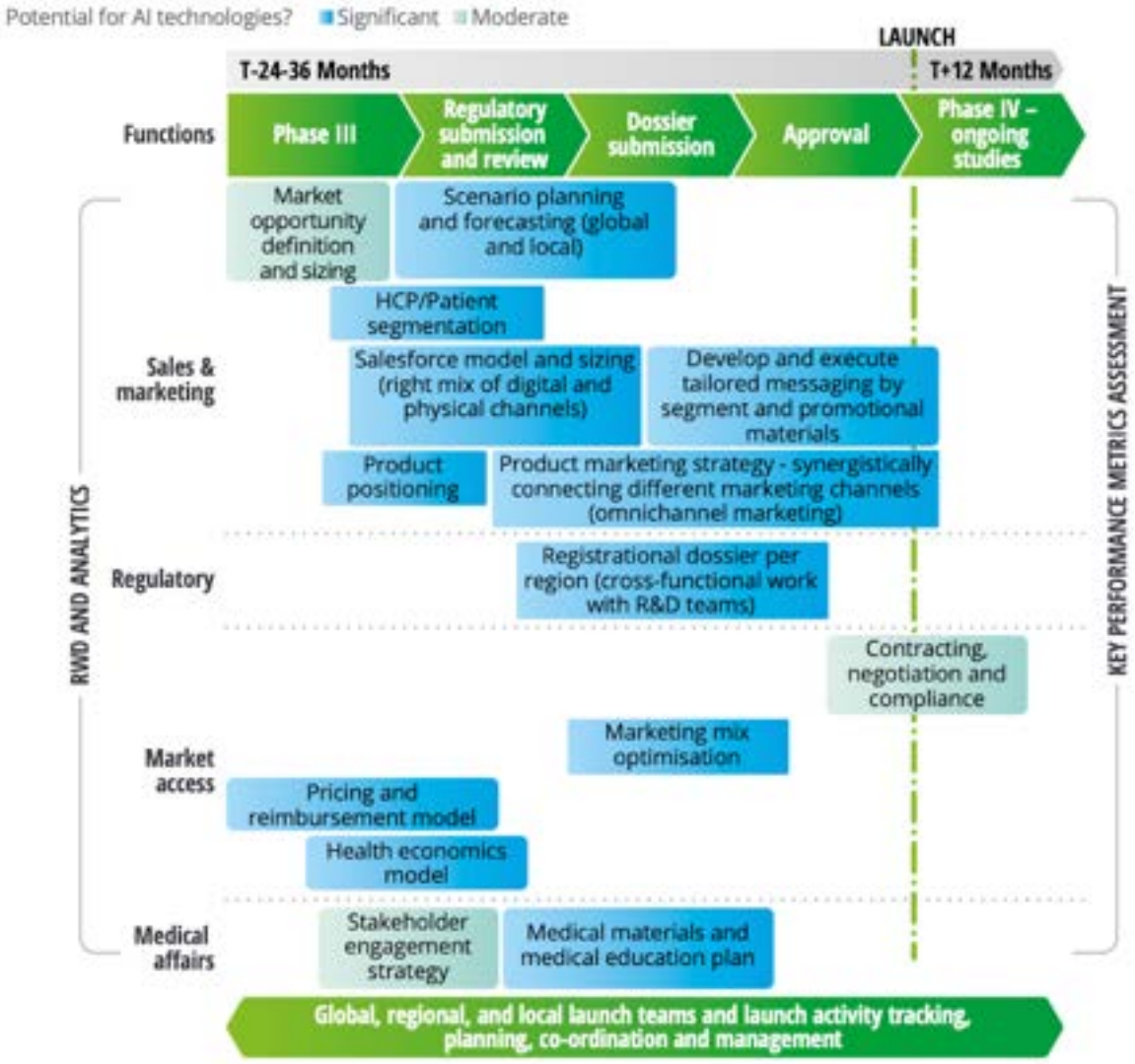
In this industry, companies need to target the appropriate market segment at the optimal time by utilising various commercial channels that cater to the needs of each stakeholder. To effectively market and sell new therapies, pharma companies must understand that different stakeholders, such as clinicians, patients, and payers, perceive value differently. Thus, it is essential to tailor messaging to each stakeholder, highlighting the aspects of the treatment they value most. For example, payers prioritise competitive pricing, while HCPs and patients place more excellent value on the mode of treatment administration and its impact. Developing marketing strategies that communicate the product's worth with the appropriate messaging to the right customer group is becoming increasingly essential, as critical as developing the product itself. Pharma companies can capitalise on these trends by tapping into this information flow, tailoring their approaches based on trust and the needs of each stakeholder. Developing patient-centric marketing strategies requires an understanding of how HCPs and patients use online tools, smartphone apps, and social media, enabling more effective engagement: companies should take advantage of the growing use of digital tools by both HCPs and patients, such as patient portals and virtual consultations, to improve concentration and develop patient-centric marketing strategies.

Moreover, it is essential to comply with regulatory requirements around the use of digital channels and to tailor approaches based on trust and the needs of each stakeholder.

By leveraging the right mix of digital and physical channels, pharma companies can improve customer engagement and enhance their business models, complementing face-to-face engagement rather than replacing it.

The Role of Artificial Intelligence in Enhancing Launch and Commercial Activities

Figure 43



Source: Deloitte analysis.

As pharmaceutical companies continue to undergo digital transformations in their launch and commercial strategies, the subsequent increase in data can facilitate using AI technologies to enhance this transformation further (see Figure 43). Data is a critical component of a successful customer-centric approach. Companies must take advantage of the increased digital footprints of healthcare providers and patients and their growing connectivity and willingness to share data under the right conditions.

Effective data collection and analysis are crucial in meeting the needs of patients worldwide, providing tailored customer experiences, predicting potential challenges, and deepening the understanding of access issues in critical global markets. The time pressure to accelerate the drug development process necessitates a comprehensive knowledge of the sales and marketing operations and innovative strategies influencing prescribing behaviours and increasing patient access to new treatments. Timely and efficient engagement with stakeholders is essential to ensure that the company can effectively communicate the product's value while addressing the needs of healthcare providers, patients, and payers. In addition, companies are increasingly using data to comprehend better healthcare providers' requirements for education, information, and training. They are investing in analytical tools, frequently based on AI, to predict the type of information and commercial channels required for optimal outcomes.

The following paragraph details potential AI applications across launch and commercial functions to develop critical strategic insights and support decision-making.

2.4.3 Exploring the Possible Applications of Artificial Intelligence in Launch and Commercial Operations in Pharma

Maximising the Value of Real-World Data (RWD) for Successful Commercialization

RWD has the potential to offer more representative and comprehensive information on the impact of therapies in a broader patient population, accurately reflect the evolving standard of care, and provide a more comprehensive view of routine clinical care compared to traditional data sources. The increasing availability of RWD from non-traditional sources such as health apps and connected devices has led to the generation of real-world evidence (RWE), which has significant implications for launch and commercial activities from the perspective of all stakeholders. The importance of RWE is now being recognised at the executive level, as it can support commercial goals. Evidence suggests that RWE can help companies understand and proactively address evolving stakeholder needs in real-time pre- and post-launch. Real-time monitoring and tracking of product performance through RWE also allow companies to obtain actionable feedback on differing needs from HCPs, patients, and payers. Pharma commercial teams can leverage RWE to broaden engagement with their target customers and deliver tailored high-value messages. As a result, RWE utilisation is expected to continue to grow across the life sciences industry as its value in terms of cost and time efficiencies throughout clinical development, launch and post-marketing phases is realised.

Potential Role of Real-World Evidence (RWE) in Pricing and Commercial Compliance Strategies

Pharmaceutical companies are increasingly interested in leveraging RWE to develop new VBC and pricing models focused on financial and health outcomes. Such arrangements require a strong foundation of RWD and RWE, robust data-sharing capabilities and collaborations between stakeholders to bolster the evidence supporting the product beyond what is necessary for regulatory approval. RWE can provide critical insights to identify and maximise value across the healthcare system and ensure that VBC agreements are designed to

benefit all stakeholders. In the future, RWE is expected to be at the centre of any effective and innovative pricing and payment arrangement. RWE can support informed decisions about product safety and efficacy from a regulatory standpoint and help monitor and identify adverse events once the drug is used across appropriate patient populations. Regulatory bodies, such as the EMA and the FDA, have formulated policies and guidance around using RWE, recognising its potential benefits and opportunities to support a more holistic view of healthcare. Indeed, RWE and non-traditional study designs have been used for many drug approvals and labelling changes in regulatory submissions.

To fully realise the potential of RWE, pharmaceutical companies must leverage DL and ML, which enable the continuous flow of RWD to be collected, cleaned, aggregated, and analysed in a seamless and dynamic process. Large sets of RWD must be collected and analysed through AI technologies, such as ML and NLP, to obtain high-quality RWE that can be used for regulatory or other important decision-making purposes, ensuring the accuracy, reliability, and robustness of generated insights.

Predictive pricing

In this industry, determining drug prices is a complex process involving extensive market research and analysis of health outcomes. This process has become increasingly important as the industry moves towards VBC models. As the scrutiny from payers and other stakeholders grows, pharma companies must rely on advanced analytics tools to make a case for new drug prices. Innovative analytical models can improve morale and are crucial to identify more effective pricing opportunities, which will ultimately translate into profit and revenue. Companies must be confident in these data-driven approaches to develop better-informed pricing strategies.

DL and ML tools can be employed 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. Such capabilities will be crucial for companies to understand their products' value and efficacy and justify costs in a competitive landscape.

Omnichannel Marketing Empowered by AI

AI-based analytics have become increasingly important for marketing strategies that require complex decision-making. Advanced, non-linear AI algorithms can process substantial amounts of structured and unstructured data and recognise behavioural patterns to help companies make sense of marketing interactions and outcomes, thereby improving financial results. By filtering out 'noise' and identifying key metrics and actionable, data-driven insights, AI can be used at scale to support essential marketing decisions.

As pharmaceutical companies embrace patient-centricity, sales and marketing become crucial in demonstrating a deep understanding of the patient's condition, values, and needs. For marketing, this means finding the best routes of engagement to achieve the best patient outcome possible while aligning with other stakeholders' expectations. Additionally, understanding patients' experiences of care and healthcare providers' experiences in caring for those patients is crucial. The COVID-19 pandemic has also highlighted the power of

omnichannel virtual engagement strategies, such as telemedicine and digital health. The sudden move to virtual engagement has drawn sales reps deeper into 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. AI enables the alignment of timely personalised marketing messages and behavioural nudges across the customer journey. Companies must synergistically connect different marketing channels to meet each target stakeholder's needs by delivering the right content at the right time (see Figure 44).

AI-enabled omnichannel marketing solutions leveraging ML and NLP would allow companies to capitalise on multiple available data sources, including CRM systems, electronic health records, social media platforms, and demographic, geographic, socioeconomic, and historical sales data. The insights from such analyses can be used to predict behaviour and provide recommendations to biopharma marketers on the following best actions, the channels to leverage, and how to optimise stakeholder engagement through personalised messaging. The heavily regulated scrutiny of pharma communications means that marketing strategies are unlikely to reach digital engagement levels in the entertainment or retail sectors. Still, companies can leverage the possibilities and opportunities offered by advanced technologies to create targeted, personalised customer content in a compliant and trusted manner. AI tools can help reps take more effective actions and assimilate data points to create new customer experiences. Companies that develop the right blend of 'hard' and 'soft' marketing skills can have a more effective and productive salesforce. AI technologies can increase the efficiency and effectiveness of a company's marketing spend, improve customer engagement, and increase customer conversion rates.

Figure 44

Source: *Deloitte analysis*.

Digital marketing strategies and social media analytics

For over a decade, payer cost-containment strategies and regulations have brought about structural changes in the marketing approach, posing challenges for marketing and direct selling to HCPs. The emergence of

speciality and personalised medicines has further compounded these challenges. Consequently, many pharmaceutical companies have incorporated analytics as an essential component of their salesforce strategies, utilising data mining to determine the appropriate salesforce size, structure, activity planning, and sales targets. Advanced analytics, able to intelligently extract information, is being applied to social media, providing a deeper understanding of customer needs and concerns and a solution to engage customers in a meaningful, outcome-oriented manner. By utilising social media analytics, companies can sense market changes, detect consumer trends, and mitigate risks, thus keeping them ahead of competitors. Although cautious in using social media content for targeted marketing strategies, social media analytics tools offer companies greater certainty in their engagement efforts. These tools also provide insights to better understand patients' journeys and needs and how to engage with them most effectively. Pharma can leverage the proliferation of social media and online forums to gain valuable insights into patients' and HCPs' feedback, complaints, and adverse events. This can inform product development, packaging, and educational materials, ultimately improving patient care. By gathering and analysing data from multiple sources, companies can capture the Voice of the Patient and the Voice of the HCP, generating actionable recommendations and insights that can augment decision-making across the value chain. Thus, AI can also facilitate the creation of actionable insights that improve product design and engineering, fundamentally changing how the next iteration of products is developed.

Using AI in analysing social media feedback, complaints, and adverse events can yield significant benefits, such as increased customer satisfaction with fewer complaints, as companies better understand customer needs and concerns.

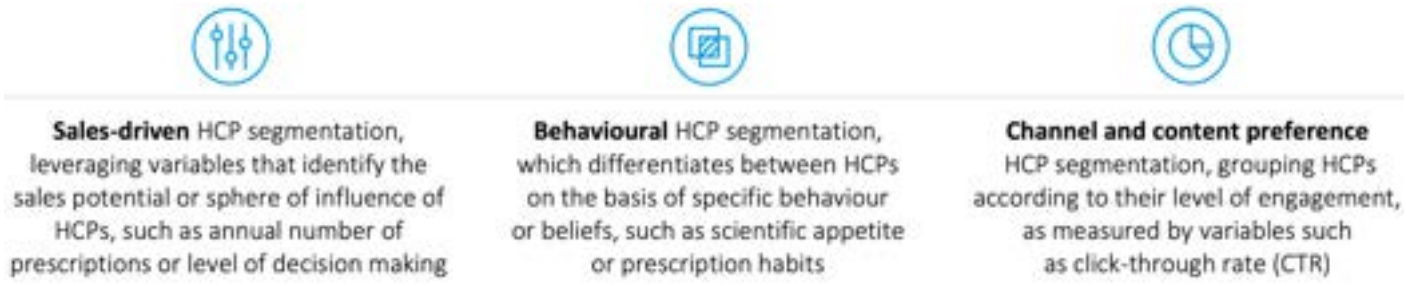
AI-based Segmentation Strategies for Effective Market Targeting

Market segmentation is a crucial aspect of effective targeting and customisation of marketing strategies. It involves dividing a market into distinct consumer groups with similar characteristics, such as demographics, psychographics, behaviours, and needs. However, even with the best segmentation efforts, one of the most common reasons for missing launch expectations is needing to understand customers fully. In the pharmaceutical industry, this understanding is crucial because it can help companies identify unmet needs and relevant HCP/patient segments. Therefore, it is essential to constantly update computational learning algorithms to capture changes in the behaviours and attitudes of HCPs and patients over time, providing much-needed robustness to sales strategic decision-making and tactics.

Traditionally, customer segmentation tended to follow a qualitative and hypothesis-driven approach. The definitions of HCP segments were based primarily on subjective evaluation by the field force and, therefore, potentially biased reasoning. In today's fast-paced and competitive environment, companies need to make the segmentation process more objective and robust by leveraging the growing amount of data: AI-driven market segmentation solutions can identify methods to improve commercial performance and optimise product value propositions specific to different geographies and healthcare systems. This approach relies on identifying

hidden patterns from historical data to group customers into segments based on homogenous behaviours that can be detected along different dimensions depending on the primary segmentation focus (see Figure 45).
Once AI-driven HCP segmentation has established an understanding of whom to engage and their channel preferences, companies need to revisit their segment-specific channel mix and frequency of interactions.
It can enable companies to tailor their marketing messages and tactics to particular customer segments and drive sales performance. By leveraging AI-driven market segmentation, companies can better understand their target audiences, develop more effective marketing strategies and achieve better commercial outcomes.

Figure 45



Source: *Deloitte analysis*.

Intelligent Forecasting and Scenario Planning

The pharmaceutical industry has an increasing trend towards utilising internal and external data sources to construct accurate forecasts and develop robust planning and long-term strategies to respond to the ever-evolving market complexities. Scenario planning, which involves the analysis of potential future events and outcomes, has become a crucial element for pharma companies to make informed decisions about their future marketing strategies. This approach enables companies to identify critical variables that provide insights into current and future market trends, optimise resource allocation, and understand key performance indicators.
Intelligent forecasting and scenario planning can be essential tools for companies to explore potential scenarios and identify the actions and behaviours of stakeholders and competitors they may face. To achieve this, ML can be implemented for effective scenario planning by refining the variables that offer insight into the market landscape. In turn, this helps companies to determine the best approach to optimise resource allocation and understand the key performance indicators that impact their operations. This forward-thinking approach allows companies to respond effectively to challenges that may arise in the market.
Case studies have demonstrated the effectiveness of intelligent forecasting and scenario planning in this industry. Through data analytics, companies have generated insights that enable them to anticipate and respond to market changes more effectively. Pharma companies can better understand market dynamics, optimise resource allocation, and achieve a competitive advantage by leveraging ML and other analytical tools.

2.4.4 Case study - Augmenting Sales Representatives' Interactions with Physicians: Biogen's NLP-Powered Internal Search Engine

Biogen, a leading biotechnology company, has taken a transformative step by developing a custom internal search engine that leverages the power of NLP technology to enhance the effectiveness of sales representatives' interactions with physicians. This innovative solution has revolutionised how information is accessed and shared and empowered sales representatives to swiftly find accurate and relevant answers to physicians' questions about Biogen's products.

Traditionally, sales representatives had to rely on frequently asked questions (FAQs), text-heavy documents, and educational materials assembled over the years. This approach often resulted in time-consuming searches and information gaps. Biogen developed a solution to streamline this process, recognising the need for a more efficient and precise method to address physicians' queries.

Implementing NLP technology in Biogen's internal search engine has profoundly transformed how sales representatives access information. Instead of sifting through vast amounts of text, sales representatives can now enter the exact words or phrases physicians use. The search engine employs advanced algorithms that analyse the context and meaning of the queries, providing quick and accurate answers tailored to the specific needs of physicians. This breakthrough allows sales representatives to deliver accurate and up-to-date information to healthcare professionals, fostering more meaningful and productive interactions.

The benefits of Biogen's NLP-powered solution extend beyond time savings and improved information retrieval. With the implementation of the search engine, sales representatives now have access to a centralised and reliable knowledge base that ensures consistency in messaging and eliminates potential information gaps. This fosters greater confidence in their interactions with physicians and strengthens the overall sales process, as they can rely on a trusted source of information to provide accurate and comprehensive responses.

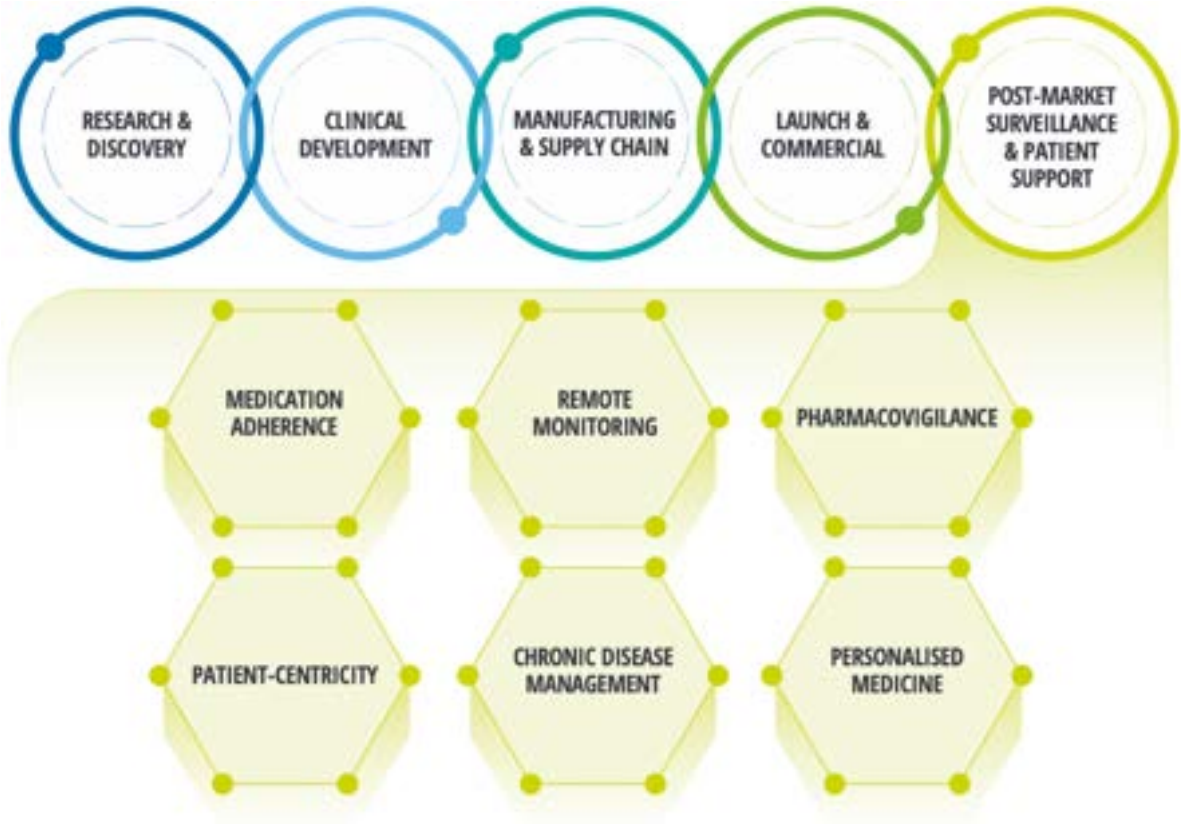
Furthermore, the NLP-powered search engine significantly enhances the efficiency of sales representatives by reducing the time and effort required to find relevant information. Instead of combing through lengthy documents, sales representatives can swiftly retrieve specific answers to physicians' queries, allowing them to dedicate more time to engaging with healthcare professionals, understanding their needs, and tailoring their discussions to provide valuable insights and support. This newfound efficiency allows sales representatives to have more focused and productive conversations, ultimately strengthening physician relationships.

Another notable advantage of the NLP-powered search engine is its ability to adapt to the ever-changing landscape of physician-patient interactions. By leveraging NLP technology, the search engine can quickly adjust to new terminologies, medical jargon, and emerging trends in healthcare. This ensures that sales representatives have access to the most up-to-date information, enabling them to effectively address physicians' concerns and provide accurate guidance on Biogen's products. The dynamic nature of the search engine enables sales representatives to stay informed and knowledgeable, instilling confidence in their abilities to address evolving healthcare challenges.

2.5. AI in Post-market Surveillance & Patient Support

2.5.1 Reasons for Change in Patient Safety Strategies

Figure 46



Source: *Deloitte analysis*.

Pharmacovigilance

Pharmacovigilance (PV) in pharma refers to the science and activities of detecting, assessing, understanding, and preventing adverse effects or other drug-related problems (see Figure 46). It involves monitoring the safety profile of medicinal products before, during, and after their authorisation and evaluating the risk-benefit balance of these products in the real world.

PV aims to ensure patient safety and minimise the risk of using medicinal products. It is an essential component of drug development and regulatory decision-making, as it enables the continuous evaluation of the safety profile of drugs and the identification of potential safety concerns that were not observed during clinical trials. PV activities include collecting, evaluating, and reporting adverse drug reactions (ADRs) and other drug-related problems from various sources, such as spontaneous reporting, clinical trials, literature, and electronic health records. The data collected from these sources are analysed and evaluated to detect potential safety signals, which are then investigated further to determine the cause and extent of the problem.

Pharma companies are responsible for implementing and maintaining effective PV systems to ensure the safety of their products: they are legally responsible for collecting, processing, and reporting details of ADRs and other safety information to regulatory agencies.

Several global healthcare trends are affecting the PV landscape and reshaping the PV function:

- *Increased Volume of ADRs*: As the disease's complexity increases and the number of new product portfolios and therapy areas grows, PV teams face more complex challenges. Drug safety has become a critical concern for healthcare professionals, patients, and regulators due to increasing warnings, awareness of ADRs, enhanced pre-drug approval reviews, and requirements for better safety documentation. While pharmaceutical companies typically receive most ADR reports from patients and healthcare professionals, there is a growing trend of direct reporting of ADRs to regulatory bodies. Despite this, processing individual case safety reports (ICSRs) remains time- and resource-intensive, often using manual workflow models. As a result, a significant proportion of PV spending is allocated to case processing. It is estimated that more than 90% of ADRs remain unreported as the volume of ICSRs increases yearly.
- *Availability of Real-time Data*: New sources of information, such as wearables and social media, are creating real-time data and potentially new PV obligations.
- *Increased Regulatory Scrutiny*: Regulations are evolving and formalised in countries with less mature regulatory environments.
- *Use of Real-World Evidence*: Regulators explore real-world evidence sources for signals and safety information.
- *Pressure to Reduce PV Costs*: There is growing top-down organisational pressure to reduce PV costs.
- *Patient-Focused Strategies*: Patient-focused strategies and engagement throughout the healthcare continuum lead to greater consumer activation and increased focus on patient centricity.
- *Increased Stakeholder Expectations*: Stakeholders have raised expectations on how pharma engages with them and are more open to non-traditional interaction channels.

These emerging challenges drive the need for more sophisticated data analytics tools to help drive value from the data and manage the risk associated with adverse event cases.

Pharmaceutical companies are adopting automation and advanced analytics to improve transparency across reporting methods, build trust in their PV systems, and generate richer insights on product quality and patient safety.

Patient Support Program

A patient support program (PSP) is service pharmaceutical companies offer patients using their medicines (see figure). The program is designed to provide additional support and education to patients to improve treatment outcomes and quality of life. PSPs involve direct interaction with patients to help manage medication and disease outcomes. The program may offer personalised guidance on navigating healthcare services and understanding why treatment is needed. Additionally, PSPs may provide or arrange financial assistance for patients unable to afford the prescribed medication. They may include post-authorization patient support and disease management programs, surveys of patients and healthcare providers, patient compliance data, or compensation/reimbursement schemes.

PSPs are becoming increasingly important as patients have access to more information than ever, which can be overwhelming. The volume of data makes it difficult for individuals to identify which sources are relevant and appropriate for their conditions or circumstances. PSPs can improve patient outcomes by providing personalised guidance on navigating healthcare services and understanding why treatment is needed. Moreover, emphasising supported self-management can improve ADR identification, disease progression tracking, patient knowledge, and treatment adherence. Successful PSPs integrate and harmonise treatment timing, in-person care, and complicated schedules while providing continued support and education to enable patients to self-manage more effectively.

The future success of a pharma will be dictated by its ability to improve long-term patient outcomes, including providing wrap-around services for innovative therapies. PSPs that help improve overall patient outcomes will be a critical success factor in the move to outcomes-based reimbursement models. A good PSP can also factor in treatment approvals, market authorisation, and improved patient retention. Implementing and scaling PSPs can help meet the increasing demand for patient-centric strategies and plays a significant role in a company's overall acquisition strategies.

While providing patients with PSPs is not new, the evolution of AI technologies can increase equity of access and the potential value of PSPs.

2.5.2 Enhancing Pharmacovigilance through AI

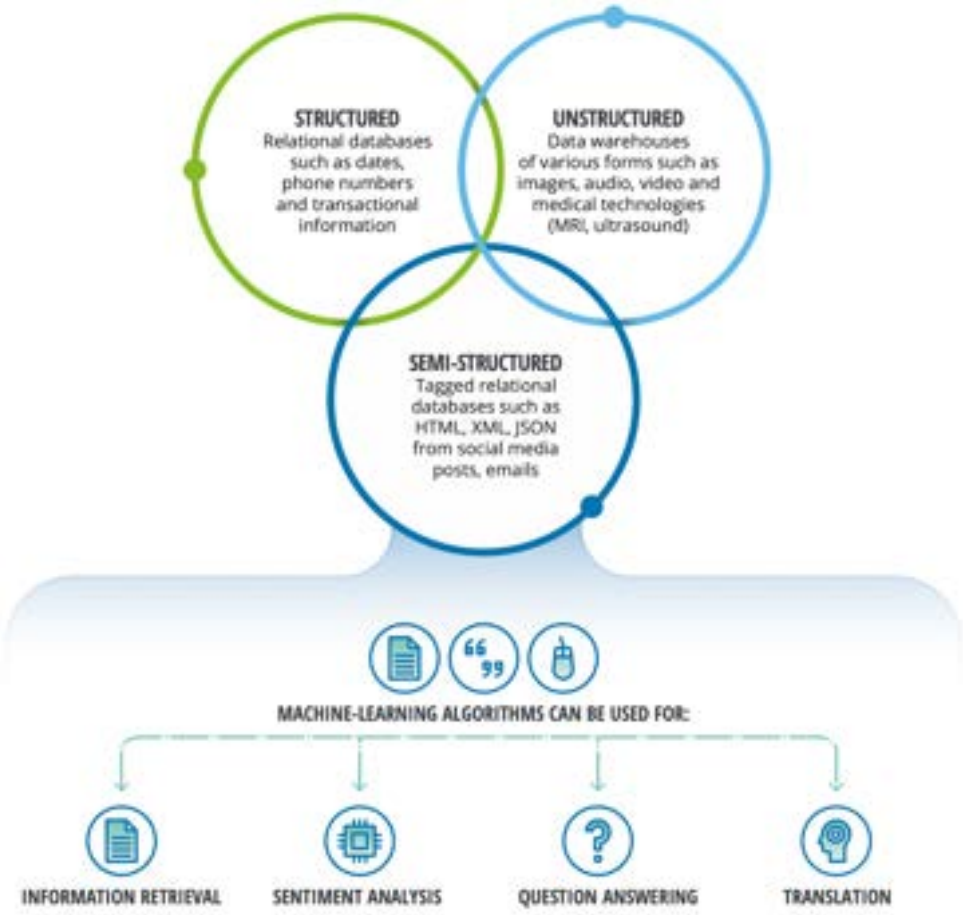
The application of AI to health data is a promising avenue for pharma companies to improve health outcomes by identifying ADRs. Advanced analytics to process the exponentially growing volume of RWD from diverse sources, including ADRs, social media, PSPs, and wearable apps, can enable end-to-end post-launch PV automation and drive improvements in patient outcomes. Integrating AI-powered analytics can further facilitate personalised treatment strategies, a critical element in enhancing patient safety, particularly in detecting or signalling potential ADRs in real time. By leveraging the power of AI, pharma companies can drive significant improvements in the quality of care and treatment outcomes.

Facilitating the Complete Transformation of Pharmacovigilance through Advanced Digital Technology

AI has the potential to revolutionise PV by offering new opportunities to handle the growing case volume and diverse types of incoming data formats effectively. ML algorithms can be trained to extract and classify information from incoming ADRs using structured, semi-structured, and unstructured data (see Figure 47). A drug safety specialist then reviews the AI-extracted and classified information for confirmation or correction, increasing consistency and reducing errors. NLP also supports the end-to-end transformation of PV by enabling the analysis of multi-formatted ADRs, including unstructured mass data with colloquialisms and non-technical terminology. The application of NLP to free text in social media, news articles, and literature can also be used to detect unexpected benefits of a pharma product, contributing to the top-line revenues of a company. AI tools in PV also allow for better regulatory compliance by ensuring the timeliness and accuracy

of ADR submissions. Additionally, AI tools can mine social media data to detect safety signals, despite the challenge posed by colloquial terminology, emoticons, and duplicate reporting.

Figure 47



Source: *Deloitte analysis*.

Leveraging AI-Enabled Platforms Through Outsourcing to Enhance Safety Reporting

Outsourcing presents an opportunity to enhance safety reporting by utilising innovative, AI-powered platforms. As the volume and variety of reports and data sources continue to rise, there is a need for improved infrastructure to manage the growth of diverse and large datasets.

To address the escalating cost of PV activities, many companies are outsourcing such tasks to specialised organisations; this is particularly crucial due to the steady increase in PV cases. Regulators require healthcare providers to report more incidents and encourage patients to share their negative event stories through chat groups and social media to provide industry bodies with more comprehensive trends across treatment categories and patient populations.

Intelligent automation and predictive analytics can capture and translate ADR data from multiple sources, enabling deep analysis of integrated datasets to identify critical signals and transform the entire PV workflow to become more efficient and effective. The current generation of PV platforms blends the best data analytics tools with human scientific expertise. It offers various automation features, such as front-end automation and NLP, to integrate data into safety databases with minimal human intervention.

NLP and automation tools can identify pertinent information to create clinically robust auto-narratives, reducing the need for labour-intensive data entry. Furthermore, AI and ML can increasingly identify patterns within structured and unstructured narratives, obviating the need for systematic single-case reviews and manual signal identification and validation. Benefits include minimising errors related to manual and anonymised data entry, reducing time and labour costs, and accelerating information delivery.

Maximising the Potential of Voice Data for Pharmacovigilance Applications

The increasing use of voice data in various settings presents an opportunity for PV teams to gather new insights and improve their detection of previously unidentified ADRs. Effective utilisation of voice data by PV teams provides them with the necessary tools to ensure patient well-being, improve compliance, and increase the prospects of their products. Furthermore, adopting safety technology enables pharmaceutical companies to streamline their safety risk identification workflow by removing up to 60% of the extraneous data, which may otherwise hinder signal detection.

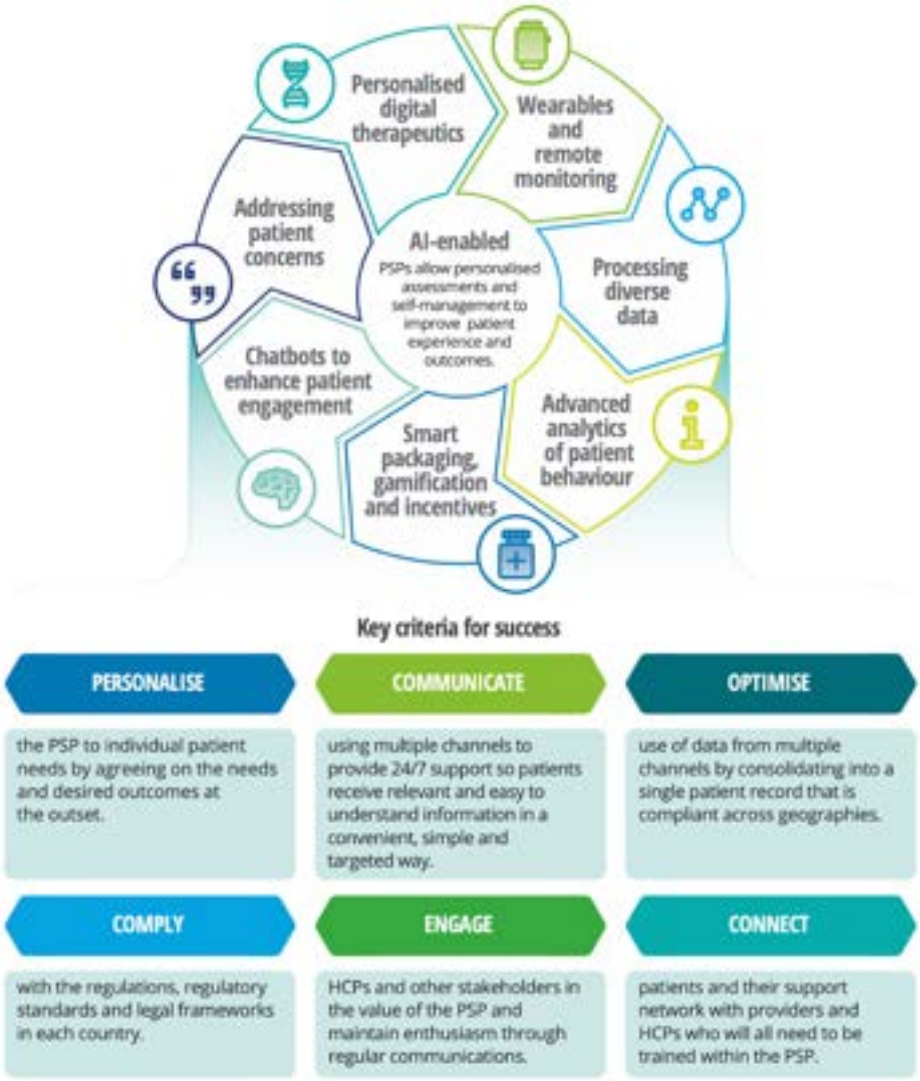
Virtual agents, which pharmaceutical companies are increasingly deploying, can monitor and analyse ADR reports around the clock. This is particularly beneficial for global-operational companies, as virtual agents can provide coverage in multiple languages, ensuring that potential ADRs are timely identified and evaluated. Additionally, using virtual agents allows for the efficient and scalable analysis of large amounts of voice data, which can be processed using AI and ML algorithms.

Integrating voice data into PV workflows can also help overcome challenges associated with traditional methods of ADR reporting, such as data privacy concerns and low patient compliance. By using anonymised voice data, patients can share their experiences without fear of retribution or loss of privacy. This can result in a more accurate and complete understanding of the safety profiles of products, which can lead to better-informed decisions regarding their use.

2.5.3 AI-enabled Patient Support Programs

AI has the potential to revolutionise healthcare, and patient support programs (PSPs) are no exception. Through AI-enabled PSPs, patients can benefit from personalised care plans, real-time monitoring of symptoms and medication adherence, and automated communication with healthcare providers. This has the potential to significantly improve self-management and optimise commitment, which can lead to better health outcomes and a more positive patient experience. There are seven post-launch initiatives identified where AI-enabled PSPs can have a significant impact on patient outcomes (see Figure 48):

Figure 48



Source: *Deloitte analysis*.

The Role of Remote Patient Monitoring in Empowering Patients to Self-Manage Their Conditions and Improving Healthcare Delivery

The COVID-19 pandemic has rapidly accelerated the adoption of remote patient monitoring (RPM) solutions, particularly wearables, in empowering patients to self-manage their conditions. In-person visits are valuable but often episodic, whereas RPM provides a continuous collection of data and information on the progress of an individual's condition, which is especially important when treating complex conditions sensitive to changes in medication. The increasing patient orientation of wearables, with improved battery life and the capacity to remotely monitor health measures for extended periods, such as vital signs and physical characteristics, has made them an attractive tool for RPM. The wealth of objective and longitudinal data collected by wearables can be quickly analysed and processed with AI-enabled digital technologies to provide personalised health insights, increase patient engagement, anticipate deteriorating health, and decrease care costs for patients and healthcare providers. AI processing large and diverse amounts of health data generated by PSPs can offer numerous benefits. AI can detect and identify potential ADRs in real-time, anticipate health status declines, monitor medication adherence, and facilitate remote interventions and rehabilitation. The availability of more

data to the AI algorithm can reduce improved pattern recognition capabilities, generating more accurate predictions and analyses.

Additionally, AI can identify red flags early and prioritise patients requiring emergency interventions, including hospitalisation. This technology can enable patients to self-manage their conditions while providing continuous monitoring and personalised health insights. Furthermore, pharma companies are uniquely positioned to increase RPM in post-marketing as the digital infrastructure and competencies continue to evolve, and RPM is increasingly used in clinical trials.

Utilising Advanced Analytics to Interpret, Predict, and Optimize Patient Adherence Behavior

Adherence to medication regimens is crucial for effective disease management, especially in chronic ones. Increasing adherence rates can improve patient outcomes, reduce waste, and increase medication usage. However, ensuring patients remain engaged and compliant with their medication regimen over time can be challenging: almost half of all patients fail to take medication as prescribed. A review by the British Medical Journal has suggested that 4% of hospital admissions are due to medication non-adherence, and most of these could have been prevented. Tailored solutions are needed to address these complex and varied barriers to medication adherence. Pharmaceutical companies can use AI to predict patients at higher risk of non-adherence by analysing PSP patient data, such as age, cost, employment status, ethnicity, gender, medical history, prognosis, postcode, and complexity of the dosage regimen. This information can help identify patients at high risk of non-adherence and provide them with proactive, tailored prophylactic interventions to improve adherence rates.

Innovative packaging, gamification, and incentives to promote better adherence Promoting Medication Adherence through Smart Packaging, Gamification, and Incentives

AI can enhance the effectiveness of various interventions to improve medication adherence, including intelligent packaging, gamification, and incentives. AI-powered tools can provide personalised interventions and support, identify patient-specific barriers to compliance, and tailor interventions to individual patient needs and preferences. One of the ways AI can improve medication adherence is by analysing patient data to identify personalised strategies to enhance it. By analysing medication use patterns, treatment outcomes, and lifestyle factors, AI algorithms can identify factors contributing to non-adherence and provide targeted interventions to address these issues. For instance, if a patient has a history of missing doses or not adhering to their medication regimen, the AI can provide personalised reminders or interventions to support adherence. AI can also be used to personalise gamification and incentive strategies. AI algorithms can analyse patient data and provide targeted interventions to address specific barriers to adherence. By analysing patient data such as activity levels, medication adherence history, and social engagement, AI algorithms can design customised gamification and incentive programs that are more engaging and motivating for individual patients. This personalised approach can help patients feel more motivated and invested in their medication regimen, leading

to better adherence. Moreover, AI can enable the development of more sophisticated, innovative packaging. For instance, if a patient has a history of forgetting to take their medication, AI-powered innovative packaging can provide personalised reminders to improve compliance.

In conclusion, AI has the potential to improve medication adherence by providing personalised interventions and support, identifying patient-specific barriers to compliance, and tailoring interventions to individual patient needs and preferences. By leveraging the power of AI, healthcare providers can develop more effective interventions to improve medication adherence and ultimately improve patient outcomes.

Improving Patient Engagement with the Help of Chatbots

Chatbots are becoming increasingly popular as part of PSPs due to the COVID-19 pandemic. With the shift towards telemedicine, virtual assistants and chatbots have emerged as essential tools to provide patients with round-the-clock support and information. These chatbots can be programmed to answer questions about medication, dosages, side effects, and interactions, providing patients with 24/7 support and information without needing a healthcare provider's intervention. Furthermore, patients can develop a personalised profile, including information such as age, gender, medical history, and medication regimen. This information enables chatbots to offer a tailored experience, providing reminders and support specific to the patient's needs. For instance, a chatbot may provide reminders to take medication at specific times or suggest ways to manage side effects based on the patient's medical history. Research indicates that AI-powered technological interventions can enhance medication adherence, particularly in vulnerable and marginalised patient populations. For instance, individuals with low health literacy or limited healthcare access may need help following medication regimens consistently. AI-enabled chatbots can deliver customised information and support to these patients, from answering medication-related questions to addressing the underlying reasons for non-adherence. These chatbots can use NLP and ML algorithms to understand patients' needs and provide personalised support.

Effectively Addressing Patient Concerns and Building Trust in Healthcare

A lack of trust or understanding of prescribed medications can significantly impact patient outcomes. PSPs should, therefore, be designed to address a wide range of issues, including emotional concerns such as anxiety related to pharmaceuticals and the fear of side effects. Effective PSPs should include multiple components that involve attitudinal, educational, and technical features to change and improve patient medication-taking behaviour, which can be integrated across AI-enabled PSPs to maintain long-term medication adherence.

AI-powered PSPs have shown promising results in maintaining long-term medication adherence, and they offer an excellent opportunity to increase patient trust in the pharmaceutical industry. Research suggests that AI-enabled PSPs provide a significant opportunity to increase patient trust and motivation to adhere to therapy, ultimately leading to improved health outcomes. Moreover, they can incorporate educational and technical features that aim to improve patient understanding of their medication regimen and address concerns related to adherence. For example, AI-powered reminders can be sent to patients to help them stay on track with their

medication schedules. In contrast, AI-powered analytics can identify patterns of non-adherence and target interventions to address these issues proactively. By leveraging AI-powered PSPs, pharmaceutical companies can build stronger relationships with patients and improve medication adherence rates, ultimately leading to improved health outcomes.

2.5.4 Case Study - Leveraging AI for Efficient Social Media Monitoring in Pharmacovigilance: Novartis' AE Brain

Challenges in social media monitoring in PV:

In the field of PV, social media platforms have emerged as a valuable source of information for adverse event reporting. However, effectively monitoring social media for potential AEs presents several significant challenges that need to be addressed to extract meaningful insights. These challenges include the sparseness of adverse drug events, data features with high dimensionality, and the diversity of tweet terms. Fortunately, advancements in AI offer promising solutions to overcome these obstacles and enhance the process of AE reporting. The first challenge lies in the sparseness of adverse drug events within the vast realm of social media. Due to the diverse nature of social content, most posts are unrelated to adverse drug events. This poses a severe data imbalance problem, resulting in a skewed class distribution between AEs and non-AEs. This imbalance makes it challenging to train predictive models that effectively identify and classify AEs. However, innovative machine learning algorithms and techniques, such as oversampling and undersampling methods, can help address this issue and improve the performance of AE detection models. The second challenge concerns the high dimensionality of data features extracted from social media posts. The unstructured nature of tweet texts, which incorporate elements such as acronyms, emojis, hashtags, images, and slang, contributes to the complexity of the data. The abundance of features extracted from tweets can be overwhelming, making it laborious and challenging to select valuable features and develop appropriate encoding schemes for predictive modelling. Fortunately, advancements in NLP techniques, combined with feature selection algorithms and dimensionality reduction methods, enable the identification of relevant features and the effective representation of data for predictive modelling. By leveraging these AI-driven approaches, the challenge of high-dimensional data can be mitigated, leading to more accurate and efficient AE detection. The third challenge arises from the diversity of terms used in posts discussing adverse events. Social media users can use expressions and language to describe their experiences or opinions on AEs, resulting in various phrases and sentence variations. This diversity poses challenges for NLP, as traditional language processing methods need help to handle the intricacies and nuances of different words and expressions. However, machine learning methods, including deep learning models and contextual embeddings, have demonstrated their ability to address this challenge effectively. These models can learn and adapt to the diverse language used in social media posts, enabling more accurate sentiment analysis and classification of AEs.

Novartis'AE Brain:

To address these challenges, Novartis has developed an innovative solution that leverages AI and NLP to enable efficient social media monitoring for AE reporting. It has created an NLP model using Amazon SageMaker, a powerful AI platform, to automatically analyse social media posts and predict whether they contain reports of AEs based on their content and context. This model allows for the rapid processing of social media data, overcoming the limitations of traditional manual methods and enabling the timely identification of potential AEs.The centrepiece of Novartis' approach is AE Brain, an AI-powered system that monitors various social media channels for mentions of potential AEs. It employs sentiment analysis techniques to assess the sentiment expressed in social media posts and flags messages of interest for further review by human researchers. By triaging the vast amount of social media data, AE Brain directly processes approximately 60% of the identified AEs, enabling human researchers to focus on a smaller yet significant number of events. Currently, it efficiently processes around 15,000 messages per week, surpassing the capacity of a human team to review such a large volume of data. This increased data capture enhances the overall quality of Novartis' drug monitoring efforts, ensuring a more comprehensive understanding of potential AEs associated with their products. By automating the initial triage process and prioritising significant events, Novartis optimises its resources and improves the efficiency and effectiveness of AE reporting.

Advantages:

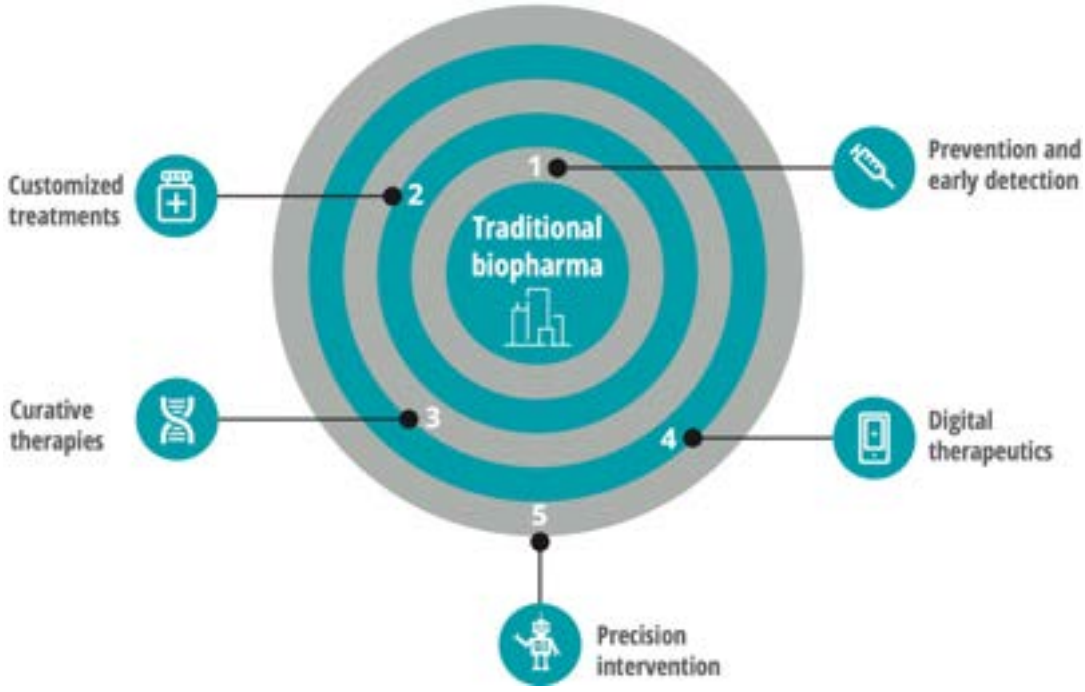
Integrating AI and NLP technologies in social media monitoring for AE reporting brings significant advantages to Novartis. Social media platforms generate an enormous volume of user-generated content, making it a rich source of information for PV. However, manually sifting through this vast amount of data would require more time and effort for human researchers. One of the key advantages lies in the ability to analyse social media data at scale. AI and NLP techniques enable to process and analyse of large volumes of social media posts efficiently. This scalability allows for comprehensive monitoring and a more comprehensive understanding of potential AEs associated with their products.

Furthermore, these technologies' automated processing and sentiment analysis capabilities significantly expedite identifying and assessing potential AEs. Traditional manual methods of reviewing social media data would require extensive human resources and time to analyse each post individually. AI algorithms, trained on vast datasets, can quickly and accurately detect relevant posts and assess their sentiment towards adverse events. This accelerated process reduces response times and enhances patient safety by enabling prompt actions based on potential AEs identified through social media monitoring. While AI technology is crucial in expediting the detection and assessment of potential AEs, it is equally important to emphasise the value of human expertise and judgment: human expertise is indispensable in interpreting complex nuances, validating the findings, and making informed decisions based on the insights derived from social media monitoring. AI technologies can swiftly process and flag posts requiring further investigation, allowing human researchers to focus on the most critical cases. Integrating AI and human review ensures a balanced approach to AE reporting.

3. The Future of Pharma

3.1.The Five Forces of potential disruption to the Pharma Industry

Figure 49

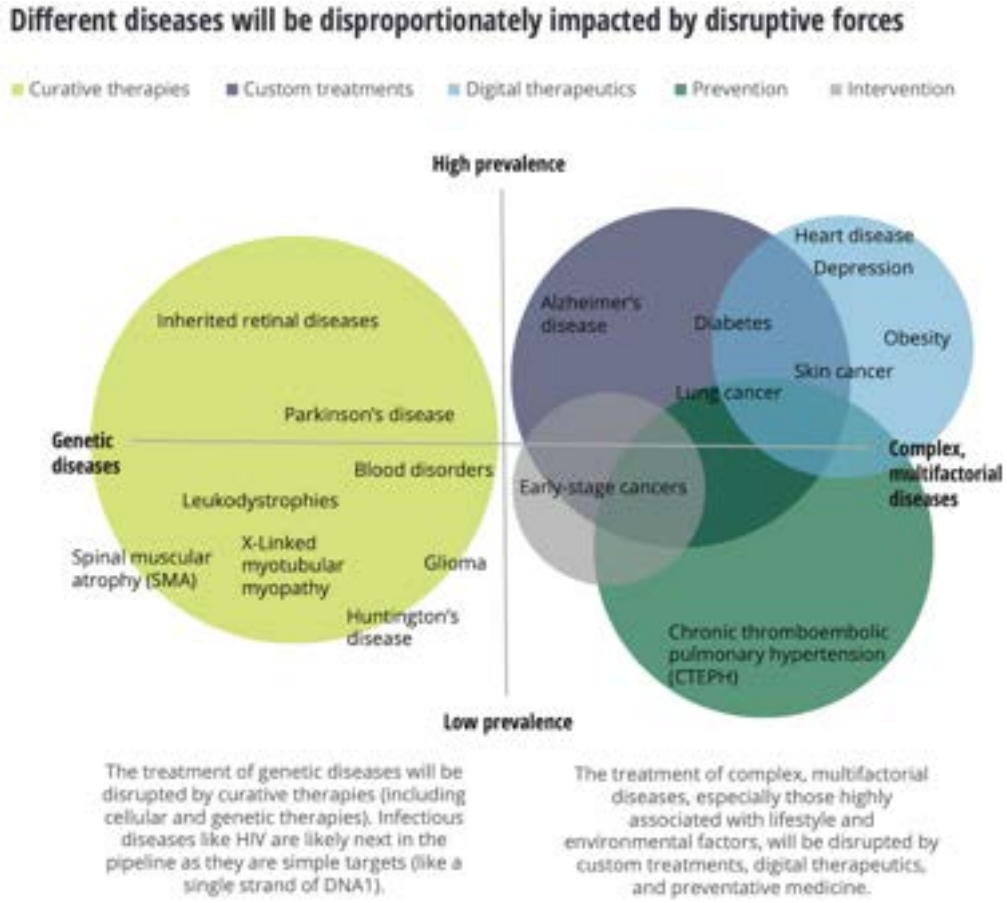


Source: *Deloitte Analysis.*

According to research conducted by Deloitte Centre for Health Solutions, the pharmaceutical industry is poised for significant transformation over the next two decades, driven by five powerful forces within and outside the sector (see Figure 49). These forces present opportunities and threats to established players, profoundly reshaping the pharma product market. To thrive in this evolving landscape, pharma companies must anticipate and embrace these disruptive forces, reimagining their product offerings, market presence, and required capabilities. Company leaders must proactively devise strategies to counter potential threats and capitalise on emerging short- and long-term opportunities. As we navigate towards the future of health, incumbents must proactively explore new strategic investments to position themselves for success. The anticipated changes necessitate a fresh outlook on market dynamics, alternative business models, and even a fundamental redefinition of the industry's purpose. By embracing innovation and evolution, pharmaceutical companies can ensure relevance and thrive in this dynamic environment.

The five forces, listed in order of their potential to disrupt the traditional scope of the pharma industry (see Figure 50), are as follows: Prevention and early detection, Customized treatments, Curative therapies, Digital therapeutics and Precision intervention.

Figure 50



Source: *Deloitte Analysis.*

3.1.1 Prevention and Early Detection

The future of health is built upon a foundation of disease prevention and early detection and its significance in shaping the pharma landscape. Over the next 20 years, there is a promising outlook for detecting diseases and intervening before symptoms manifest, potentially preventing their progression. Advancements in early detection techniques, breakthrough vaccines, and wellness innovations will transform healthcare. This force offers immense potential to reduce the need for specific treatments and improve patient outcomes.

For instance, early-stage melanoma can be detected much earlier than before, allowing for complete eradication of the disease with early treatment. Delaying intervention until it metastasises leads to complications and costly therapies. The same principle applies to chronic diseases like Alzheimer's, diabetes, and rheumatoid arthritis, where early detection could enhance treatment effectiveness. Moreover, knowing that conditions can be avoided or managed better with early intervention can motivate individuals to adopt healthier lifestyles.

Several factors contribute to the prevention and early detection landscape:

- Vaccines: Beyond childhood immunisation and common infectious diseases, vaccines are being developed to address various forms of cancer. For instance, using a patient's immunity against self-antigens expressed in tumour cells opens new possibilities for cancer prevention. The delivery of vaccines may also evolve, with innovations such as painless microneedle patches replacing traditional syringes. This could enhance accessibility and empower patients to self-administer vaccines.

- Genetic testing: Whole-genome sequencing is a game-changing tool that enables early detection and identification of genetic predispositions to diseases and is expected to reach a market value of $17.6 billion by 2025. As gene sequencing, data interpretation, and gene-editing tools advance, we anticipate an upsurge in early detection and preventative or curative interventions. The companies can seize opportunities by utilising genetic information to identify at-risk patients, although caution is necessary to avoid over- or under-treatment based on evolving knowledge.
- Early detection technologies: Emerging technologies enhance our ability to detect diseases in their earliest stages. For instance, intelligent toilets with sensors can analyse urine composition for signs of infection or illness. At the same time, artificial intelligence algorithms can identify biomarkers indicating changes in health status before symptoms manifest. Liquid biopsies are also proving to be valuable tools, allowing the identification of cancer cells through a blood sample. These advancements in diagnostics, coupled with advanced analytics and integration of patient health records, hold the potential to uncover patterns related to disease causes and early markers, empowering pharmaceutical companies to develop interventions for early treatment.
- Nutrition and microbiome: The human microbiome, consisting of trillions of microorganisms within our bodies, plays a significant role in physical and mental health. Understanding the relationship between the microbiome and overall well-being opens up new avenues for disease prevention. Research suggests that the microbiome influences the development of diseases such as Type 1 diabetes in children and may impact susceptibility to certain types of cancer or response to immunotherapy. Analysing microbiome data and leveraging this knowledge can lead to more effective preventive measures and personalised treatments.

Considering the evolving nature of disease causation and the absence of clear underlying causes for certain conditions, it is crucial to lay the groundwork for enhanced disease detection and prevention. Diagnostic technologies and the data they generate will become powerful tools for identifying disease causes and early markers. Leveraging advanced analytics and patient health records can help uncover patterns and pave the way for early interventions and targeted treatments. Pharma companies should actively embrace these technological advancements and leverage their insights to develop effective pathways and interventions for early detection and disease management. By embracing the force of prediction and early detection, they can play a pivotal role in shaping the future of healthcare.

3.1.2 Personalised Treatment

The convergence of medicine and data-driven insights is set to revolutionise patient care through personalised or customised treatment approaches. This paradigm shift empowers patients with tailored drug cocktails or therapies specifically designed for their unique needs, improving outcomes and transforming the healthcare landscape. The variability in disease expression and treatment response among individuals necessitates a move towards personalised treatment. Many patients do not receive the full potential benefit of drugs because patient populations need to be effectively stratified. What may be an effective therapy for one patient might be

metabolised differently by another, resulting in suboptimal concentrations. We can significantly improve treatment outcomes by personalising dosages and identifying the optimal combination of drugs for each patient. Customised treatment involves selecting, tailoring, or developing therapies specifically for individuals. This requires leveraging data to identify the most suitable drug treatment option, determine the proper dosing, and potentially customise treatment plans for each patient. Achieving this level of customisation will require extensive data, either through RWE to inform the targeting or repurposing of existing treatments or through new clinical trial paradigms that identify high responders and optimal dosing. Initially, personalised treatments are likely to be seen with generic and late-life cycle medications with abundant RWE available for stratification, dosing, and regimen tailoring.

Critical aspects of personalised treatment include:

- Disease Stratification: Advances in biomarker and genetic marker research enable the identification of subpopulations within broader disease categories. For instance, Parkinson's disease exhibits various genetic subsets and mutations, representing distinct diseases with different characteristics. The ability to identify smaller patient subsets based on genetic lesions, protein expression differences, and microbiome variations allows companies to develop or target therapies tailored to the unique characteristics of each subpopulation.
- Tailored Dosing: Predictive analytics and longitudinal data analysis for diverse patient populations enable pharma companies to determine optimal dosing levels, identify patients most likely to respond, and understand the conditions influencing treatment effectiveness. This data-driven approach facilitates the development of customised treatment regimens for specific patient types. Evaluating how patients metabolise drugs, considering factors such as liver enzyme expression or kidney function, can help optimise dosing to achieve therapeutic ranges. Pharmacogenomic data will play an integral role and become part of electronic medical records.
- Tailored Drug Regimens: Future clinicians may rely on a comprehensive assessment of biomarkers, genetic information, clinical data, and behavioural digital health data to determine the most suitable combinations of drugs for individual patients. This personalised approach mirrors the current sequencing of tumours, identifying mutations, and matching appropriate therapies in cancer patients. Combining active pharmaceutical ingredients (APIs) at the point of care enables the creation of customised treatments, potentially consolidating multiple medications into one pill and addressing patient convenience and compliance. Additive manufacturing, such as 3D printing, holds promise for new drug delivery methods.

The availability of real-world data sources will enhance understanding of which drugs work best for specific patients and circumstances. However, realising the potential of personalised treatment requires substantial investments in data and analytics capabilities. Pharma companies should explore new drug development paradigms, such as master protocols, to evaluate drugs alone or combined within defined patient subpopulations. Embracing increasingly customised treatments will impact the pharma supply chain,

necessitating new manufacturing capabilities for smaller-volume therapies across branded and generic medications.

The future of healthcare lies in personalised treatment, where data-driven insights and tailored therapies empower patients to receive the most effective and targeted care available. By embracing this transformative approach, companies can usher in a new era of precision medicine and optimise patient outcomes.

3.1.3 Curative Therapies

The emergence of curative therapies has the potential to significantly impact the demand for certain prescription drugs, leading to a reduction or even elimination of the need for ongoing treatment. Pharma companies must adapt to this transformative trend by embracing new capabilities and innovative strategies.

Curative therapies offer time-limited treatments that address diseases by permanently or semi-permanently correcting the underlying condition, thereby eliminating symptoms. These therapies can potentially decrease the occurrence and prevalence of numerous diseases. According to our interviews, infections caused by single genetic mutations, such as certain cancers, sickle cell anaemia, and rare diseases, are expected to be among the first targeted by curative therapies. The global clinical trial landscape reflects this trend, with over 1,000 ongoing trials for cell and gene therapies spanning various disease areas such as cancer, musculoskeletal disorders, and neurodegenerative diseases. To keep pace with this rapidly evolving environment, pharma companies must adopt new business models.

Critical aspects of curative therapies include:

- Gene Therapies: The approval of the first gene therapy in the United States in 2019 marked a significant milestone, and numerous gene therapies are developing. Most of these therapies focus on diseases driven by a single or a few genetic mutations. Diseases like cystic fibrosis, sickle cell disease, fragile X syndrome, muscular dystrophy, and Huntington's disease are potential targets for curative gene therapies. Some researchers even anticipate the possibility of curing specific cancer subtypes caused by inherited oncogenes, such as BRCA. However, challenges remain, including safety concerns and the difficulty of replacing genes in all cancer-causing cells. For multifactorial diseases, gene editing may only address a portion of the problem, with drug therapy still necessary to manage other contributing factors.
- Cell Therapies: Adoptive cell transfer (ACT) therapy, particularly CAR-T therapy, drives significant research and development in pharma companies. CAR-T therapy utilises the patient's immune system to target and eliminate cancer cells. Several CAR-T therapies have gained approval in the United States, demonstrating high remission rates, especially in late-stage cancers that were previously difficult to treat. As the cost of manufacturing and delivering these therapies decreases and toxicities are better managed, they may become standard treatments even in earlier stages of cancer. Moreover, the application of cell therapies could expand beyond oncology to autoimmune diseases, enabling the modulation of the immune system. Stem cells also hold potential as the raw materials for cellular therapies, offering possibilities for treating various conditions. In the future, bone marrow extraction from a young patient could be stored

and used to cure an autoimmune illness that may develop later in life. Companies like Magenta Therapeutics are actively exploring this field.

The advent of curative therapies necessitates the development of new business models that account for the shift from chronic treatment to one-time interventions. While the long-term economic value of cures can be substantial, data demonstrating their value must be generated for widespread adoption. Robust post-treatment patient monitoring methods will be crucial in shaping the value narrative. Questions regarding allocating costs and benefits associated with one-time curative treatments must be addressed. Additionally, innovative financing mechanisms may be required to ensure access and affordability, considering the potential lifetime benefits of short-duration curative therapies.

3.1.4 Digital Therapeutics

The effectiveness and scalability of nonpharmaceutical interventions, particularly digital solutions, are rapidly transforming the healthcare landscape. Digital therapeutics, including behaviour modification programs, can reduce or eliminate the reliance on traditional medications. Pharma companies must adapt to this shift by integrating digital therapeutics.

Digital therapeutics deliver evidence-based interventions to patients through software programs to prevent, manage, or treat medical disorders or diseases. These interventions can be standalone or used alongside medications, devices, or other therapies to optimise patient care and improve health outcomes. By leveraging technology, digital therapeutics offer a promising alternative for various chronic conditions such as diabetes, depression, anxiety, and heart disease.

There are two critical categories of digital therapeutics to consider:

- Digital Therapeutics Enhancing Drug Treatment: Some digital therapeutics focus on enhancing the effectiveness of drug treatments by taking a holistic approach to disease management. For example, diabetes digital programs combine a blood glucose monitor with actionable insights and personalised coaching. Real-time tracking of drug therapy and symptoms allows healthcare professionals to intervene and modify treatment before symptoms worsen. Several digital interventions have received FDA approval, and health plans and pharmacy benefit managers (PBMs) are now covering them. Express Scripts, for instance, has established a digital formulary that evaluates digital interventions based on clinical research, usability, and financial value. Livongo's digital therapeutics for diabetes, prediabetes, and hypertension have even received preferred formulary status, showcasing the recognition of their efficacy and value.
- Digital Therapeutics Reducing the Need for Pharmaceutical Intervention: Digital therapeutics also play a role in reducing the dependence on pharmaceutical interventions. By increasing access to medical providers, these solutions offer alternatives to drug treatments. Cognitive-behavioural therapy (CBT), a psychological treatment known to improve outcomes in mental health diseases, is a common approach employed in digital therapeutics. Virtual coaches, for instance, assist patients in modifying their behaviour in real-time to alleviate symptoms of anxiety, depression, and insomnia. Sleepio, a digital treatment for

insomnia that does not involve drug therapy, is one example covered by a PBM instead of pharmaceutical sleep agents. In addition, digital therapeutics empower patients to take control of their symptoms for complex chronic diseases, including autoimmune conditions.

The future success of digital therapeutics hinges on user adoption, the ability to demonstrate impact and the optimisation of pricing and reimbursement models. Scepticism exists regarding the long-term adoption, or "stickiness," of these digital interventions, as some patients may lose interest after a short period. Moreover, there are concerns about potential health disparities, as higher socioeconomic classes are more likely to embrace these technologies, potentially widening the gap in healthcare access. However, adoption is expected to grow if digital therapeutics offer user-friendly experiences, incorporate human support when needed, use storytelling approaches, and genuinely understand patients' motivations. Crucially, these technologies must demonstrate tangible results. Some experts believe the tipping point for widespread adoption of healthcare apps and digital therapeutics will come when major health systems, health plans, and large pharmacies prioritise these solutions over traditional prescriptions and cover their costs.

3.1.5 Precision Intervention

Advancements in cutting-edge medical technologies, including robotics, nanotechnology, and tissue engineering, pave the way for increasingly precise medical interventions. These breakthroughs have the potential to significantly reduce the reliance on pharmaceutical interventions, presenting both challenges and opportunities for pharmaceutical companies.

The progress in medical technology allows for earlier and more effective interventions that may minimise or eliminate the need for pharmaceutical management. Here are some key developments in precision intervention:

- Robotic Surgery: Robotic surgery has revolutionised medical procedures by surpassing the limitations of human hands. This progression enables surgeons to access previously inaccessible areas, improving outcomes. For example, tumours located around the spinal cord, historically challenging to remove, can now be safely excised through robotic surgery, potentially reducing the reliance on chemotherapy or radiation. Medtech companies are investing in enhancing automated surgery capabilities by integrating augmented/virtual reality, artificial intelligence (AI), advanced analytics, and other emerging technologies.
- Nanotechnology: Microscopic particles in nanotechnology can penetrate diseased tissues, allowing for targeted and precise medical interventions. For instance, nanosponges have been developed to remove toxins from bacterial pathogens and alleviate inflammatory conditions. Moreover, researchers have explored the concept of organic robots using stem cells, envisioning a future where bots derived from a person's cells could be injected into the bloodstream to remove arterial plaque. This innovative approach could replace damaged tissues and cell types within the body.
- 3D Printing and Tissue Engineering: 3D printing enables the creation of highly customised, cost-effective medical technology products tailored to individual patients' unique physiology. This technology has wide-

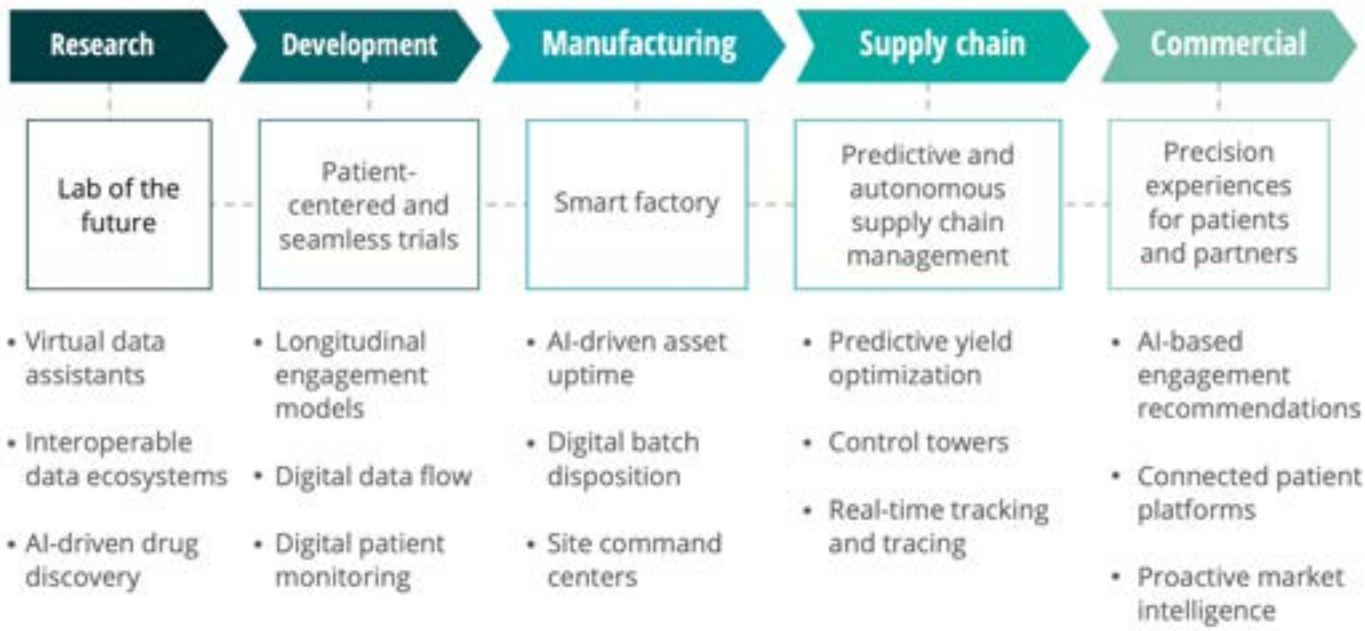
ranging applications, including prosthetics, skin for burn victims, organs, and dental and orthopaedic implants. It offers solutions where conventional approaches fall short, such as creating airway splints for infants with tracheobronchomalacia. Tissue engineering, combined with additive manufacturing, can restore damaged tissues. The ability to fix chronic diseases and regenerate tissues or organs through xenotransplantation could eliminate the need for ongoing drug therapy.

These advancements in precision intervention could disrupt the pharmaceutical industry by reducing the demand for drug therapy. Major drugs like chemotherapy, insulin, and medications for inflammatory conditions could be affected. Pharma companies operating in impacted disease areas should consider embracing these technologies to stay relevant and avoid acting in a diminished market in the future. It is crucial to closely monitor these technological developments and proactively adapt their strategies and offerings. Embracing precision intervention technologies can position them as pioneers in the field, enabling them to provide innovative solutions that align with the evolving medical landscape. Additionally, exploring partnerships and collaborations with technology companies and research institutions can foster advancements and create new opportunities for growth in the precision intervention space.

3.2. Unveiling the Future Prospects: Exploring Potential Developments in the Pharmaceutical Value Chain

This paragraph embarks on a journey to explore the transformative possibilities and emerging trends that hold the potential to revolutionise the entire landscape of the pharmaceutical industry. From the early stages of drug discovery and development to the manufacturing, marketing, and distribution of pharmaceutical products, significant advancements and innovative approaches are reshaping every aspect of the value chain (see Figure 51).

Figure 51



Source: *Deloitte Consulting LLC.*

3.2.1 Drug Discovery

Five Elements of New R&D: Signals and Enablers

The convergence of breakthroughs in biological sciences and advancements in data utilisation, automation, computing power, and AI fuels the progress we are witnessing in the biomedical field. This combination of factors is already propelling advances at every R&D value chain stage, from initial discoveries to clinical testing and real-world applications. However, the genuinely transformative potential lies in taking the next step of integrating automation and AI to connect the data and insights generated throughout the entire process, ushering in a new era of R&D. The intersection of novel technologies and biology breakthroughs fosters progressive changes across all aspects of the biomedical R&D value chain. Industry leaders already embrace some of these innovative approaches, while others are still emerging as potential use cases within academia and biotech start-ups. It's worth noting that only some of these ideas may come to fruition or be superseded by alternative solutions that have yet to come into view.

This paragraph presents a selection of signals and enablers that, when fully realised, have the potential to revolutionise the biomedical industry and reshape the R&D value chain. These and other innovations could pave the way for a more interconnected and technology-driven biomedical R&D paradigm comprising five key elements: disease understanding, therapeutic-hypothesis generation, therapeutic-modality creation, in silico and in vitro validation methods, and clinical and real-world evidence feedback. These elements collectively demonstrate the extent of progress being made. While some are firmly established, others have yet to gain widespread adoption or full validation, and it remains uncertain which will have the most significant impact. Nonetheless, their combined potential is undeniable.

- **Disease understanding**: Advancing therapies and disease prevention requires a deeper understanding of health and diseases' complex mechanisms. While the human genome provided a foundation, it's crucial to acknowledge that genes alone are insufficient. Recent breakthroughs offer promising avenues for disease understanding:
  - Omics-driven insights: Utilizing multi-omic data sets and large genomic databases, we can uncover comprehensive gene-disease relationships and identify reliable biomarkers. Mapping organ structures and functions contributes to innovative disease models.
  - High-throughput data collection: Advanced techniques like patient-derived induced pluripotent stem cells, high-throughput assays, and cutting-edge microscopy enable rapid comparative analysis of healthy and diseased states.
  - Improved disease taxonomies: Shifting focus from symptoms to root causes allows for a more nuanced understanding of diseases, facilitating targeted interventions.
  - In silico system biology modelling: By leveraging technology, we can simulate pathways, cells, organs, and even entire organisms, gaining valuable insights into complex biological systems.

- **Therapeutic hypothesis generation**: its process is undergoing a transformative shift driven by three key factors:
  - Improved access to diverse and abundant data: Open-access databases and larger volumes of disease data, including genomic, biomolecular, and screening data, have revolutionised the field. Scientists can now test hypotheses more effectively by leveraging these datasets, including repurposing existing drugs and designing novel ones.
  - Technological enablers: Advancements in computing power, machine learning, and automation have empowered researchers to tackle complex analytical tasks in biomedicine. These tools facilitate the exploration of correlations between diseases and factors such as genes, nutrition, and behaviour, generating high throughput in silico hypotheses.
  - Enhanced underlying data and methodologies: The availability of actual or predicted structural biology data, improved knowledge graphs, and traditional computational power support hypothesis refinement. Novel algorithms and approaches, including quantum computing, enable exploring a broader range of conformational options and molecule-molecule interactions.

  By utilising these advancements, scientists can comprehensively explore data, uncover novel connections, and generate hypotheses at an unprecedented pace. This data-driven approach holds tremendous promise for accelerating the discovery and development of effective therapies, transforming the biomedical research landscape, and improving patient care.
- **Therapeutic-modality innovation** is continuously advancing, revolutionising the landscape of medical treatments. Here are some key developments shaping this field:
  - Regenerative therapies: Scientists are making strides in identifying the most suitable stem cells for each patient, organ, or tissue, allowing for targeted differentiation and optimal outcomes. Additionally, bioactive scaffolds stimulate extracellular repair mechanisms, enhancing the regenerative process.
  - Cell and tissue engineering: Gene-modified cell therapies and engineered immune cells are becoming increasingly common in therapeutics and diagnostics. The ability to 3D-print tissues, organs, and cartilage opens up new possibilities in transplantation and regenerative medicine.
  - Genetic code design platforms: Innovative gene therapy and gene-editing platforms expand the toolbox for therapeutic interventions and research.
  - Improved delivery, durability, and immunogenicity: Next-generation gene therapies offer enhanced delivery mechanisms, durability, and regulatory control. Predicting and adapting immunogenicity increases versatility in antibody, cell, and gene therapies.
  - Targeted and multifunctional modalities: Novel approaches to known molecular targets broaden the therapeutic repertoire. Next-generation antibodies, including multispecific, minimised, and conjugated antibodies, improve the targeting and safety of biological therapies.
  - Better combinations: Utilizing in silico predictions based on literature and multi-omic data, synergistic drug combinations can be identified. New varieties of traditional treatments, such as surgery, radiation,

psycho- and physiotherapy, and emerging therapies like electrical stimulation, virtual reality, and novel therapeutics improve patient outcomes.

- Microorganism engineering and synthetic biology: Biological manufacturing techniques enable sustainable and versatile production methods. Exploring lesser-known cellular phenomena, such as biomolecular condensates, introduces novel avenues for therapeutic interventions. Synthetic microorganisms offer precise modulation of microbiomes to counteract or prevent diseases. Self-amplifying or reprogrammable molecules contribute to long-lasting immunity through mRNA vaccination.

- **In silico and in vitro validation methods are crucial** in advancing scientific research and development. Here are some critical aspects of these methods:
  - In-silico-first optimisation: Predictive in-silico modelling provides valuable insights into molecular properties and biological activity. Researchers can derisk development processes and prioritise the most relevant experiments by leveraging computational models, saving time and resources.
  - Improved human-biology-based validation models: Innovative testing models, such as cell on-chip, organ-on-chip, or patient on-chip, offer rapid and accurate replication of a patient's genetic or proteomic makeup or the cellular environment of a specific disease. Organoids, which can recreate the 3-D environment of human organs, provide a more comprehensive understanding of biological processes compared to traditional animal models or standardised cell lines.
  - Biomarkers, biosensors, and assays: The availability of these tools the speed and precision of in vitro validation and enable scientists to gather valuable data and insights from experiments conducted outside of living organisms.
  - End-to-end automation: Integrating AI-guided robotics facilitates seamless ultrahigh-throughput screening and experiment chaining automation. This automation streamlines the validation process, allowing efficient and rapid data collection and analysis.
- **Clinical and real-world evidence feedback:** Clinical and real-world evidence feedback plays a vital role in advancing medical knowledge and improving patient outcomes. Through its feedback, the healthcare community can harness the power of data to drive medical advancements, make informed decisions, improve treatment outcomes, and deliver more precise and personalised care to patients. Here are some critical aspects of this feedback process:
  - Tech-enabled data generation: Modern technology enables the accumulation and collection of vast data. Through clinical trials of drug candidates, an increasing volume of data is gathered about diseases, which in turn enhances future hypothesis generation and validation. Similarly, electronic health records and RWD, including biomarkers and wearable devices, provide continuous and comprehensive measurements, enabling robust patient characterisation and more nuanced disease models. Advancements in computational methods, such as natural language processing, also allow for the mining of unstructured patient data from the literature, further enriching our understanding.

- Simulated trials: Pretrial simulations leverage computational models to predict the risks of side effects in clinical trials. By simulating trial scenarios, researchers can optimise trial design and increase the likelihood of successful outcomes. These simulations also identify the best responders and help determine the optimal treatment plan for each patient.
- Improved data collection and utilisation: Enhanced utilisation of both traditional and digital biomarkers, including real-time biomarkers, enables disease preemption and strengthens the data on treatment outcomes. AI assists in revisiting medications already in the market to improve the standard of care and explore new potential applications. Additionally, mining unstructured medical data using natural language processing techniques deepens our understanding of the connections among treatments, symptoms, outcomes, and unmet needs.
- Precise treatment design: Precision diagnostics, leveraging novel technologies like rapid sequencing, contribute to refining disease taxonomies and treatment paradigms. In the future, it is possible to tailor individual patient therapeutic plans by assessing them on personalised organoids or chips. This approach holds promise for designing treatments tailored to each patient's unique characteristics, leading to more effective and personalised care.

A new organisational model for a New R&D Paradigm

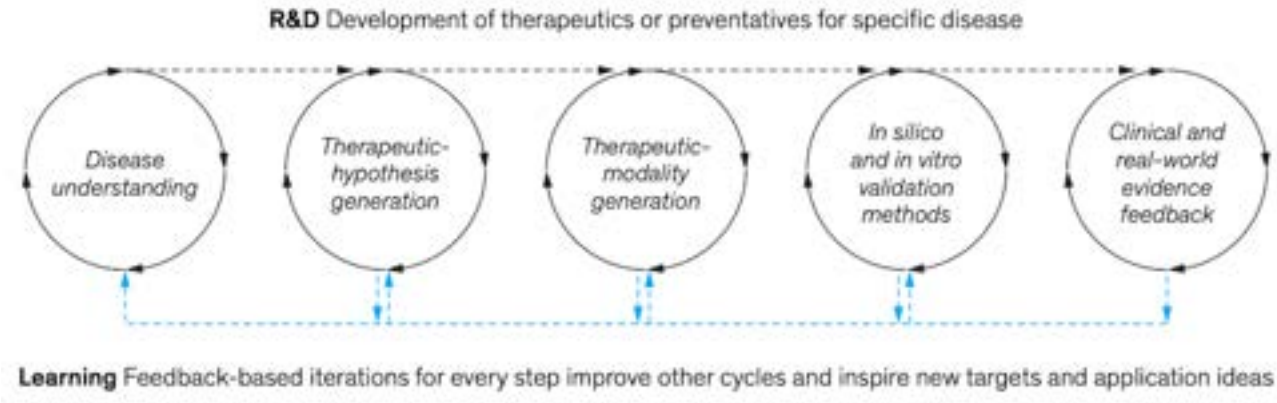
A new paradigm is emerging in R&D, transforming the traditional linear value chain into a highly interconnected and iterative process (see Figure 52). This paradigm harnesses the power of technology, automation, and AI to drive medical breakthroughs and improve the understanding and treatment of various diseases. Here are the critical aspects of this new biomedical R&D paradigm:

- Interconnected value chain: Unlike the linear model, the new paradigm recognises that information and insights flow in both directions throughout the entire R&D process. This interconnectedness ensures that data and insights flow freely and rapidly up and down the value chain, enabling a more iterative and circular approach. It leverages platform technologies like CRISPR, which validate research hypotheses and serve directly as therapeutic modalities.
- Data-driven insights: The new paradigm aims to capture and connect every data point and sense into a centralised data vault. Algorithms can then leverage this vast repository of information to enhance disease understanding and develop highly tailored therapeutic hypotheses. The abundance of data generated from in vitro experiments, real-world data, and in silico analysis feeds into this process, rapidly informing disease understanding and driving the development of new therapeutic platforms.
- Automated experimentation: In silico and in vitro testing significantly influence the new paradigm. Automation and AI facilitate the automatic generation of new rounds of in vitro testing based on AI data evaluation. This iterative process allows for refined experimental parameters and optimised therapeutic candidates. AI can suggest improvements to drug candidates, synthesise them, and test them in simulated clinical trials using real-world data, accelerating drug development.

- Organisational and governance changes: Organizations must undergo structural and management changes to adapt to this new paradigm. The separation between early and late-stage R&D needs to be softened, fostering a more connected approach. Cross-functional teams with deep expertise in multiple disciplines and capabilities spanning the entire value chain become essential. These teams require the authority to make swift decisions, prioritise breakthrough potential, and allocate resources. Collaboration with external expertise and capacity becomes crucial, as success relies on proprietary assets, algorithms, data sets, and digital solutions.
- Open architecture and partnerships: The new biomedical R&D innovation model may involve open-source assets, accessible algorithms, and collaborative partnerships with health-tech and data analytics companies. A flexible and creative innovation model is necessary to incorporate the best methods and solutions at each stage of the R&D process. This open architecture approach allows for the seamless integration of components like data, algorithms, and validation methods as needed.

The new biomedical R&D paradigm embraces interconnectedness, data-driven insights, automation, and collaboration to accelerate medical breakthroughs. By leveraging technology, AI, and cross-functional expertise, this paradigm has the potential to revolutionise the way diseases are understood, therapies are developed, and patient outcomes are improved.

Figure 52

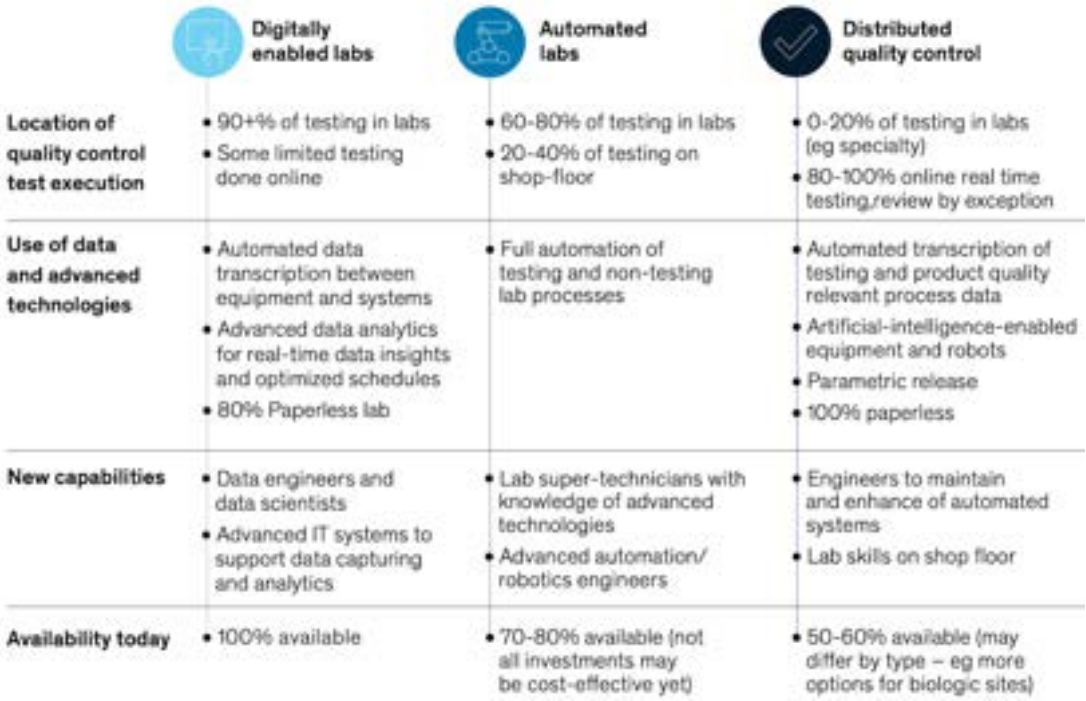


Source: *McKinsey Analysis.*

The Three Horizons of Lab Evolution: Transforming Pharmaceutical Laboratories

Advancements in digital and automation technologies have opened up new possibilities for change in pharmaceutical laboratories, triggering a transformative journey that unfolds across three distinct horizons (see Figure 53). While most pharmaceutical labs have yet to achieve complete technological transformation, they can embark on this evolutionary path by targeting one of the three future horizons of technological advancement. Notably, these horizons are not mutually exclusive and can be implemented non-linearly, with the potential for compounding effects and interdependencies.

Figure 53



	Digitally enabled labs	Automated labs	Distributed quality control
Location of quality control test execution	• 90+% of testing in labs • Some limited testing done online	• 60-80% of testing in labs • 20-40% of testing on shop-floor	• 0-20% of testing in labs (eg specialty) • 80-100% online real time testing,review by exception
Use of data and advanced technologies	• Automated data transcription between equipment and systems • Advanced data analytics for real-time data insights and optimized schedules • 80% Paperless lab	• Full automation of testing and non-testing lab processes	• Automated transcription of testing and product quality relevant process data • Artificial-intelligence-enabled equipment and robots • Parametric release • 100% paperless
New capabilities	• Data engineers and data scientists • Advanced IT systems to support data capturing and analytics	• Lab super-technicians with knowledge of advanced technologies • Advanced automation/ robotics engineers	• Engineers to maintain and enhance of automated systems • Lab skills on shop floor
Availability today	• 100% available	• 70-80% available (not all investments may be cost-effective yet)	• 50-60% available (may differ by type – eg more options for biologic sites)

Source: *McKinsey Analysis.*

Horizon 1: Digitally Enabled Labs

The first horizon focuses on transitioning from manual data transcription and second-person verification to automatic data transcription between the equipment and the laboratory information management system. By embracing digital enablement, labs can integrate quality control systems, automate data transcription, and enhance visibility, thereby reducing risks. Advanced real-time data analytics enable ongoing process verification, trend analysis, and deviation prevention while optimising scheduling and capacity management. Digital tools such as smart glasses provide a step-by-step visual guide for standard operating procedures, and digital twin technology assists in predicting the impact of physical changes on the lab. By becoming digitally enabled, pharmaceutical labs can achieve significant cost reductions, with chemical quality control labs potentially reducing costs by 25% to 45% and microbiology quality control labs by 15% to 35%. Productivity improvements arise from streamlined documentation processes, eliminating redundant tasks, and optimised resource utilisation.

Horizon 2: Automated Labs

The second horizon centres around adopting automation technologies to handle repetitive tasks and improve lab efficiency. Collaborative robots and other advanced automation tools are utilised to perform tasks such as sample delivery, preparation, and high-volume testing. Automation builds upon the digital foundation established in Horizon 1, delivering more excellent value and increased cost savings. Automated microbiology labs can achieve savings of 10% to 25% within the lab, while chemical labs can realise incremental savings of 10-20%. Automation leads to significant productivity gains by automating sample-taking, sample preparation, and equipment maintenance tasks.

Furthermore, automation reduces the burden on operations, minimising sampling and logistics tasks. Automation reduces downtime and reliance on costly equipment by leveraging remote monitoring and failure

prevention. Labs can substantially reduce overall lead time by adopting instantaneous microbial detection and online testing.

Horizon 3: Distributed Quality Control

The third horizon represents a transformative shift in traditional quality control practices, where routine product testing is conducted on the production line, enabling real-time release testing (RTRT). Although complex regulatory requirements have hindered the widespread adoption of process analytical technology and RTRT, the benefits of distributed quality control facilities are becoming increasingly apparent. These facilities leverage equipment and robots with AI capabilities and specialise in speciality and stability testing. Distributed quality control minimises the physical footprint and costs associated with traditional labs while expediting product release. While existing sites with stable or declining volumes may wait to adopt this approach, rapidly growing areas or those under construction can benefit significantly from reducing capital-expenditure investments in traditional quality control labs.

3.2.2 Drug Development

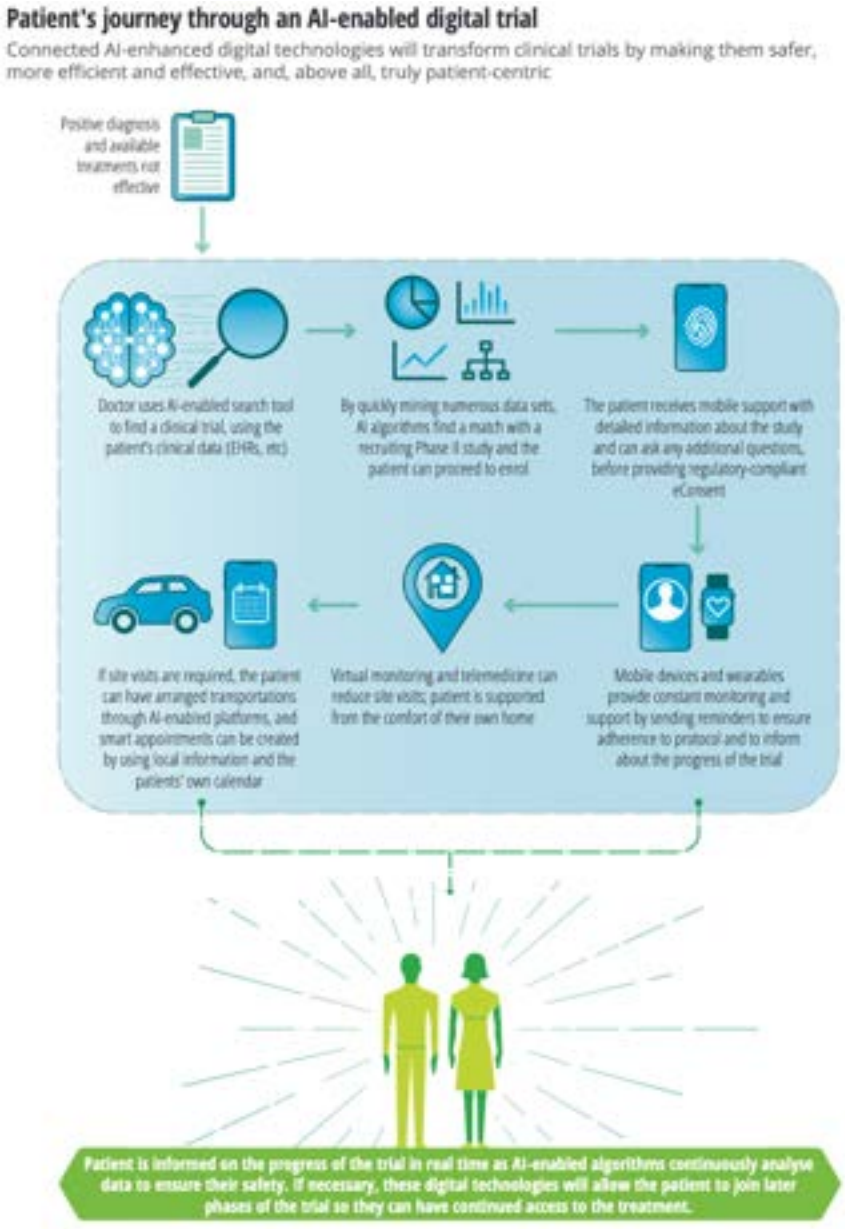
The Clinical Trials of Tomorrow: Patient-centered and Seamless

In the future, patient-centricity will be at the core of the clinical trial process, with all stakeholders aligning their decisions according to patients' wants, needs, and preferences. Patient perspectives will be integrated throughout the study design, and open communication channels will be established during the execution of the trial. Sponsors will actively engage patients by providing comprehensive information about the trial, including its processes and the individuals involved. These patient-centric initiatives have attracted, hired, and retained committed patients throughout the study and even after its termination.

This North Star aspiration aims to address participants' diverse medical and behavioural needs while extending participant engagement beyond the duration of the trial. Achieving this goal requires a comprehensive digital transformation, where every aspect of the trial, from protocol development to clinical observation and dossier creation, is seamlessly executed digitally. Such a North Star approach can accelerate the value-stream processes involved in clinical trials, making attracting and retaining participants easier, reducing development costs, and shortening cycle times.

To enhance the clinical trial experience, various innovative approaches are being explored. This includes the use of digital therapeutics, which are clinically validated interventions that can be used either independently or in combination with medical products. Additionally, AI-enabled digital health technologies and patient support platforms are utilised throughout the trial process. For example, compliance apps, clinical endpoint and data capture tools, and remote trial delivery systems are being leveraged (see Figure 54). These advancements aim to improve patient compliance, data collection, and overall trial efficiency.

Figure 54



Source: *Deloitte Analysis.*

To reach this aspiration, several transformational shifts and targeted digital innovations need to be implemented:

- Cultivating deeper patient relationships: Shifting away from short-term relationships focused solely on trial completion, the goal is to treat patients as longitudinal partners. This approach allows for a better understanding of their disease, long-term safety and efficacy data collection, and improved care outcomes.
- Decentralising trial environments: Redefining the concept of a clinical site, moving from physical medical centres to virtual or preferred local settings such as doctor's offices or alternative sites. This shift aims to ease trial participation for patients. These virtual trials will reduce the environmental impact by decreasing travel, minimising the number of research centres, and mitigating patient non-adherence and dropouts. This transformative approach will revolutionise drug development and significantly reduce the

development timeline and patient burden while generating data-rich results due to high-frequency measurements.

- Infusing digital agility into study deliverables: Rethinking the nature of study deliverables, such as protocols and dossiers, by transforming them from static documents that require rewriting for each trial to living collections of digital elements. This flexibility allows for customisation based on the specific needs of each trial.
- Digitising trial processes: Moving away from inefficient processes that often burden clinical researchers by introducing end-to-end digital workflows across the entire trial life cycle. This includes utilising digital tools, automation, and machine intelligence to streamline processes and improve efficiency.

Over the next decade, integrating electronic medical information and utilising RWD will transform clinical trials. While randomised controlled trials will likely continue to be the gold standard for validating the efficacy and safety of new compounds in large populations, there is a growing recognition of the value of innovative trials using RWD. Such problems can define new patient-centred endpoints and expand and refine indications. Virtual clinical trials are emerging as a significant development in the field. These trials leverage digital technologies such as apps, eConsent platforms, and telemedicine to reduce patients' financial and time burdens. Virtual practices enable real-time remote monitoring by allowing faster enrollment of more diverse populations in their natural environments rather than strictly controlled clinical settings. Deloitte research suggests that up to half of all trials could be conducted virtually. The convenience of virtual practices is expected to improve patient retention and accelerate clinical development timelines, addressing a significant challenge in pharmaceutical research and development. In the future, virtually any eligible patient who desires to participate in clinical research and meets the selection criteria will be able to do so.

The implementation of virtual trials is still in its early stages, with ongoing projects such as Trials@Home aiming to evaluate the effectiveness of remote decentralised clinical trials (RCTs) that employ AI-enabled technologies. These trials could involve more extensive, diverse, and remote populations, potentially becoming the gold standard for clinical research. The transformation of clinical trials is expected to be significant within the next five to ten years.

Big Pharma are embracing the digitalisation of healthcare to manage clinical trials remotely. For instance, Novartis established a centralised control tower called Nerve Live, a hub-and-spoke command centre. Novartis can monitor and troubleshoot clinical problems worldwide in real time using machine learning and predictive algorithms. This proactive approach identifies potential bottlenecks well in advance, allowing the company to take preemptive action and prevent delays.

These innovative digital approaches in clinical trials are poised to revolutionise drug development and significantly reduce development timelines. Here are the key advancements that will drive this transformation (see Figure 55):

Figure 55

Source: *Deloitte Analysis,2022.*

- **Digital patient monitoring:** Through IoT-enabled devices like wearables, patient health indicators can be continuously monitored, providing real-time data on their well-being and capturing important endpoint information. This allows clinicians to promptly detect any signs of risk or adverse events and take necessary actions.
- **Longitudinal patient engagement:** Participants in the clinical trials will benefit from virtual check-ins and behavioural nudges throughout the trial period. By segmenting patients based on behavioural factors, trial designs can be more flexible to accommodate participants' schedules. Mid-trial, personalised behavioural nudges delivered through coaching sessions help improve patient retention and adherence. Post-trial, participants receive relevant information and insights about the treatment's impact on their overall health, fostering engagement and empowerment.
- **Precision patient recruitment:** AI algorithms are crucial in matching patients with trial opportunities by leveraging disease-specific data and patient demographics. By analysing aggregated clinical and real-world data, AI can accurately identify and reach patients based on disease characteristics, health outcomes, socioeconomic factors, and behavioural characteristics. This ensures representative participation and improves the overall quality of trial data.
- **Digital data flow:** To streamline the trial process, standardised digital data elements flow seamlessly across the trial, collating in the cloud. AI technology is employed to reduce manual transcription efforts and automate the creation of trial dossiers. Various structured and unstructured data sources are integrated through AI-driven digital data flow solutions, enabling medical writers, biostatisticians, and clinicians to analyse data efficiently and derive valuable insights.
- **Seamless data sharing and access:** Real-time data exchange and results between peers and multiple regulators accelerate the approval process across different geographies. Collaborative efforts are underway between large pharmaceutical companies and regulatory agencies to build cloud platforms for data

exchange. Cloud platforms facilitate secure and continuous data exchange between trial sponsors and regulatory bodies, expediting new drug applications, submission, and approval.

- **Bilateral data exchange:** Patients own and control their clinical data, giving them the authority to consent to share their data with trial sponsors. In return, trial sponsors provide participants access to their trial data, including test results and lab reports. This empowers patients to share their data with their physicians or donate it for further research studies. In exchange, sponsors gain access to patient digital data, such as EHR and wearable device data, which helps generate long-term RWE on the safety and effectiveness of drugs across different patient cohorts, informing future research and development endeavours.

The Future Clinical Trial Regulation

Regulatory authorities worldwide, including the FDA in the US, have issued guidance to encourage the use of RWE strategies by pharmaceutical companies. The FDA has guided the submission of documents using real-world data and evidence for drugs, biologics, and medical devices and on using real-world evidence in regulatory decision-making. It collaborates with the clinical trial community and patient groups to develop scientific and technical standards for incorporating digital technologies into clinical trials. These technologies, such as remote and risk-based monitoring, can lower development costs, improve patient care, and enhance regulatory oversight. The FDA recognises the potential of digital technologies in making clinical trials more accessible to patients and believes that increased accessibility can foster participation from a diverse patient population, leading to more representative data and better treatment decisions. Decentralised clinical trials conducted outside traditional research facilities are seen as a way to expand data collection.

As the FDA receives a greater variety, velocity, and volume of RWD, it plans to leverage DL and NLP tools in its regulatory processes. Pharmaceutical companies are advised to engage early with regulatory authorities to align on objectives, study design, and the use of digital biomarkers or surrogate endpoints. Recognising the demand for AI expertise and the challenges in recruiting and retaining such talent, the FDA is developing an AI curriculum in collaboration with external academic partners and piloting a fellowship program for postdoctoral students to work on AI-based regulatory science tools.

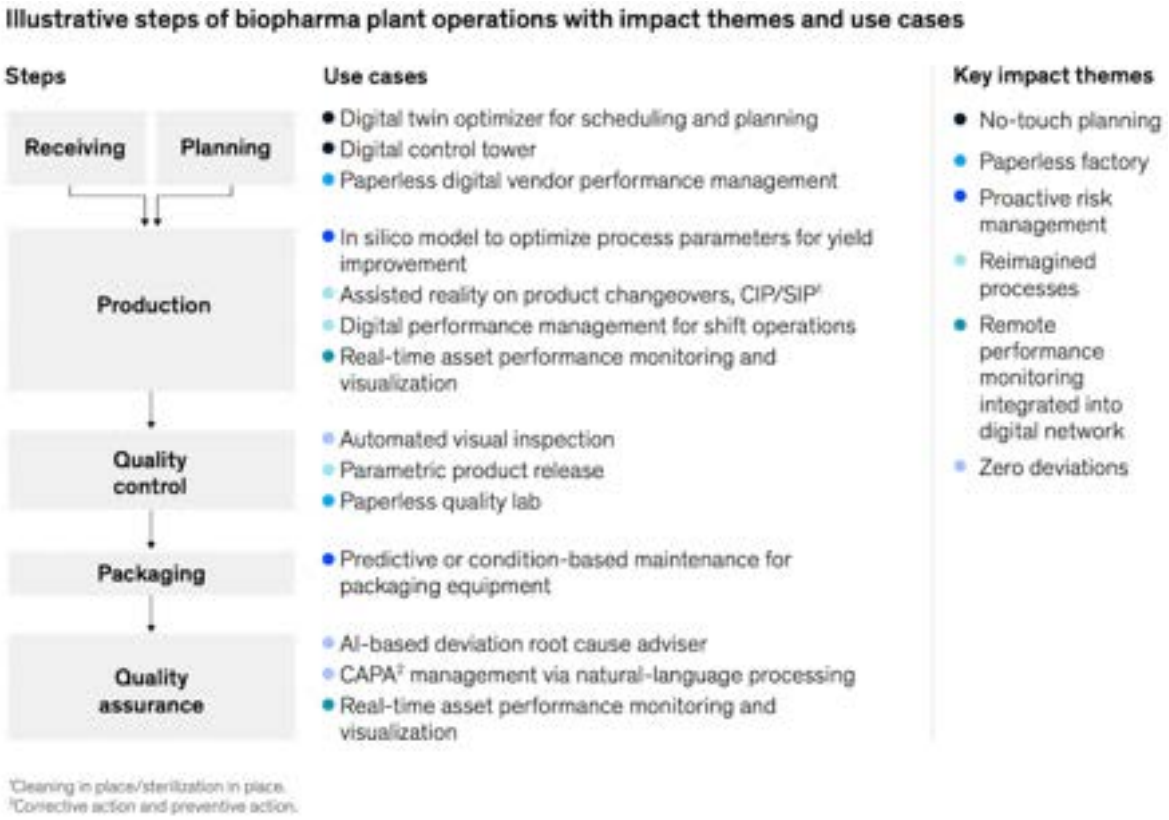
Regulatory agencies are committed to leveraging technology and translational data to improve trial efficiencies, control costs, expedite patient benefits, and support shorter development timelines and approvals. In the future, patient-centricity will be a crucial focus for all stakeholders involved in the clinical trial process. Sponsors will align their decisions with patient preferences and incorporate patient perspectives throughout the study design. They will establish open communication channels with patients to improve recruitment, engagement, and retention throughout the study.

3.2.3 Manufacturing & Supply chain

Smart Factory

The adoption of digital and analytics at scale can potentially revolutionise manufacturing operations in the pharma industry: they can open innovative possibilities and deliver various benefits in pharma manufacturing (see Figure 56).

Figure 56



Source: *McKinsey*.

One of the critical features of the pharma plant of the future is *no-touch planning*. By leveraging digital twins, which are real-time virtual versions of physical objects and processes, companies can optimise the balance between short- and long-term demand and supply of raw materials, equipment capacity, and human assets. This enables more efficient scheduling of production and lab activities.

Reimagined processes through automation and advanced production technologies empower human operators to achieve remarkable gains in productivity. Line sensing, augmented reality tools, assisted-reality tools, and parametric product releases enhance productivity and efficiency.

Advanced analytics models are crucial in predicting and mitigating quality risks, ensuring compliance, and maximising product robustness, resulting in *zero deviations*.

Digitalisation enables *paper-free* factory operations, creating a seamless flow of information from raw-material supply to planning, production, quality, and warehouse management across internal and third-party manufacturing networks.

Proactive risk management through predictive analytics allows real-time monitoring and control of maintenance, environmental, quality, and supply-chain risks, optimising throughput, cost, compliance, and sustainability.

Remote performance monitoring facilitated by interconnected systems enables real-time tracking of site performance, product status, and issue detection, leading to more effective decision-making by management.

These transformative changes in pharma manufacturing can yield significant benefits. Asset utilisation and labour productivity can be doubled, product transfer times can be reduced from months to days, the costs of poor quality can be minimised, and conversion costs can be significantly reduced. These improvements contribute to more agile and resilient operations.

While this vision may seem far-fetched, it is within reach based on research conducted by McKinsey in collaboration with the World Economic Forum. Digital manufacturing can help companies develop new business models, expand capacity, boost productivity, and create lasting business value.

Leading pharma companies have already started capturing some of these benefits, although they have yet to be fully scaled. Digital and advanced analytics use cases have demonstrated substantial reductions in deviations, increased plant capacity, shorter lead times, and improved productivity. Moreover, the transparency inherent in digital systems enables nimble and effective decision-making, freeing up plant leaders' power.

A digitally enabled workplace, led by digital natives not only brings about dramatic performance improvements but also sustains their impact over time. This sets the stage for a transformative and sustainable future in pharma manufacturing.

It is crucial to go beyond enabling digital innovations to build intelligent factories in this industry. Pharma companies can successfully build smart factories that embrace digital innovations and unlock their full potential by addressing these aspects of infrastructure, mindset, innovation culture, and scalability. This holistic approach ensures that the benefits of digitalisation are maximised, driving operational excellence and positioning organisations for long-term success in the pharma manufacturing landscape. The following key factors play a significant role in this transformation:

- Building connectivity: Moving away from siloed manufacturing systems and processes is essential. Instead, organisations should strive to create a connected manufacturing ecosystem that enables the seamless flow of information, data, and actionable insights throughout the value chain.
- Changing innovation mindsets: Adopting a "think-digital-to-be-digital" attitude is crucial. This involves recognising how digital technologies can augment human capabilities and fundamentally transform the execution of processes. Embracing digital innovation becomes a mindset shift that permeates the entire organisation.
- Encouraging the art of the possible: Overcoming the aversion to innovation within the manufacturing organisation is critical. By promoting digital innovation pilots and showcasing tangible value through plant floor innovations, executives can be convinced of the benefits and drive a culture of continuous improvement.

- Productising and scaling digital innovation: Transitioning from fragmented digitalisation efforts is critical. Rather than viewing digital innovation as an in-house engineering problem, organisations should focus on productising or standardising digital solutions across multiple manufacturing sites. Leveraging external capabilities through ecosystems and alliances can facilitate this transition.

Predictive and autonomous supply chain management

To achieve the north star aspiration of predictive and autonomous supply chain management in the pharma industry, it is essential to establish adaptive and flexible supply chain networks. These networks enable real-time visibility into material and product flow, facilitating the prediction of issues and disruptions and autonomous risk mitigation. By embracing predictive and independent supply chain management, pharma companies can optimise processes throughout the value stream, from demand forecasting to product tracking in transit. This transformative approach can reduce lead times and costs associated with oversight and enhance supply chain planning. Targeted investments in digital technologies such as AI and IoT are necessary to realise this vision. Alongside these investments, several transformative shifts are required:

- Championing proactivity: Enabling the free flow of information, data, and insights across supply chain processes is critical. This shift moves from linear and reactive supply chain management to proactive and adaptable supply chain networks.
- Enhancing data usability: Creating an environment where digital tools and solutions ensure data accuracy, latency, and relevancy is essential. This enables the cross-correlation of data, generates valuable insights, and supports effective decision-making.
- Embracing machine intelligence: Leveraging machine intelligence to augment human decision-making and autonomously mitigate risks is critical. By replacing manual efforts with intelligent systems, supply chain operations can be more efficiently managed.
- Building connectivity to other functions: Breaking down silos within supply chain operations by connecting supply chain data with data from different parts fosters synchronised business planning and decision-making. This integration enhances overall business resilience.

During the pandemic, disruptions to logistics and transportation underscored the importance of digitalising supply chain operations. IoT solutions allowed real-time tracking and tracing of product shipments, addressing gaps in visibility. Looking ahead, resilient global supply chain strategies should be developed, leveraging data analytics tools for deeper insights and improved demand prediction (see Figure 57). Digital innovations like AI can further enhance supply chain resilience by predicting and forecasting events such as logistics challenges, geopolitical issues, and supply disruptions. These innovations can autonomously execute or recommend actions for stakeholders, providing a competitive advantage and strengthening overall resilience.

By embracing these transformative shifts and investing in digital technologies, companies can achieve a predictive and autonomous supply chain management approach, ultimately driving the industry's efficiency, agility, and competitive advantage.

Figure 57

Source: *The Semiconductor Chip Shortage Hits MedTech: Strategies to Build Resilient Supply Chains," AdvaMed/Deloitte, 2021.*

Here are some notable advancements shaping the future of supply chain management:

- Control towers: Organizations can establish control towers or data hubs that consolidate internal data, including production and inventory data, with data from intermediaries and partners. This integration provides real-time longitudinal visibility into material and product flow throughout the supply chain.
- Machine-assisted business response: Self-healing AI solutions analyse a wealth of supply chain, manufacturing, and market data to identify potential issues, such as the risk of stockouts due to a raw material shortage. These AI systems delve into the root causes of these issues, such as logistics challenges a vendor's faces, and provide actionable recommendations to supply chain operators. This could involve ordering from an alternative supplier or adjusting production schedules to mitigate disruptions.
- Machine-driven resilience management: AI algorithms leverage predictive capabilities to anticipate and forecast events that can impact the supply chain, such as logistics challenges, geopolitical issues, or supply disruptions. Based on these predictions, AI systems can autonomously execute appropriate actions or recommend response strategies to stakeholders, enabling effective risk management and resilience.
- Market and product tracking:
  - Nontraditional data analysis: Companies incorporate nontraditional data sources, including consumer sentiment, competitor insights, product user data, and experience data, alongside traditional data, such as order patterns and demand signals. This comprehensive analysis helps optimise supply chain planning by holistically understanding market dynamics and customer needs.
  - IoT and blockchain for tracking: As the market sees a rise in next-generation therapies, IoT and blockchain technologies are increasingly deployed to track and trace product movement, monitor

temperature conditions, and coordinate the timely delivery of these therapies to treatment centres. This ensures the integrity and timely availability of critical medicines.

By harnessing these innovations, organisations can transform their supply chains into proactive and autonomous systems that optimise operations, enhance responsiveness, and mitigate risks. Integrating advanced technologies such as AI, IoT, and blockchain enables companies to make data-driven decisions, adapt swiftly to changing market conditions, and ensure the efficient and secure delivery of life-saving treatments.

3.2.4 Commercial

Precision experiences for patients and partners

An AI-powered future holds excellent potential for launch and commercial success for pharmaceutical products. To fully capitalise on this opportunity, companies must embrace a digital commercialisation culture and leverage AI-enabled technologies to address operational challenges and improve efficiencies.

Marketing and commercial teams should align their strategies around achieving launch excellence, integrating advanced digital technologies, and promoting cross-functional collaboration. This approach enhances engagement and maximises the value derived from their products. By connecting clinical development operations with commercial activities, companies can optimise the value of their products throughout the entire lifecycle, starting from the early stages of drug development and continuing through to the product's eventual launch and commercialisation. This interconnected approach ensures that the product's value is maximised from its inception, allowing for seamless transitions and consistent optimisation of its potential impact in the market (see Figure 58). An AI-enabled early launch planning approach, supported by RWD and advanced technological solutions, allows efficient market segmentation and improved engagement with HCPs, patients, and payers. Stakeholder feedback should be incorporated throughout clinical development and commercial strategies, fostering collaboration and differentiation. By breaking down data silos and monitoring performance across the product life cycle, companies can ensure that their activities support product value and lead to commercial success.

This personalised approach enhances the value stream processes from drug launch to post-marketing surveillance, increasing patient conversion, long-term adherence, and care outcomes. To achieve this, pharma companies need to undertake purposeful digital innovation and embrace transformative shifts within the commercial function:

- Tailored engagement: Moving away from high-frequency engagement models and providing customised information based on individual needs, behaviours, and health characteristics.
- Expanding access and affordability: Ensuring that patients who would benefit most from treatment have timely access to value-added information and care when they need it.

- Proactively sensing marketplace dynamics: Shifting from a retrospective understanding of market dynamics to a predictive approach that relies on proactive sensing and continuous learning. This enables companies to stay ahead by anticipating competition, understanding patient sentiment, and assessing the impact of marketing efforts.

Figure 58

Source: *Deloitte Analysis.*

In today's dynamic landscape, innovative solutions revolutionise precision experiences, delivering exceptional outcomes and personalised interactions. Here are some remarkable advancements:

- Comprehensive Insights: Uniting behavioural and socioeconomic patient data with marketing analytics, companies create a panoramic view of patient behaviour across digital and physical touchpoints. By harnessing the power of data lakes or cloud storage, a 360-degree understanding of patient engagement is formed. Moreover, aggregating data on physician interactions with web ads, emails, and social media content offers valuable insights into their engagement across channels, allowing for seamless connections to specific patients.
- AI-Powered Engagement Recommendations: Leveraging the capabilities of AI marketing solutions, patient datasets are thoroughly analysed to generate intelligent recommendations. These recommendations encompass tailored content delivery across various channels and touchpoints along the patient journey, such as personalised ads, customised medication regimens, and adherence programs. Companies can achieve remarkable results by optimising engagement timing, content relevance, and delivery methods.
- Next-Generation HCP Portals: Empowered by natural language processing (NLP) and AI chatbots, next-gen HCP portals provide instant access to information and facilitate peer collaboration, amplifying the quality of care delivery. With these advanced portals, healthcare professionals can seamlessly access on-demand information, seek expert opinions, and enhance their decision-making process. Simultaneously, these platforms create expanded opportunities for companies to engage with healthcare providers effectively.

- Integrated Patient Platforms: Cloud-based connected patient platforms serve as a centralised hub, aggregating data from patient wearables and medical devices. This comprehensive approach allows for real-time tracking, analysis of patient outcomes, and seamless connectivity with physicians and support groups. These platforms deliver holistic care and nurture meaningful patient-physician relationships by fostering continuous engagement.
- Proactive Market Intelligence: AI-driven technologies empower companies to curate and analyse diverse information sources. Organisations gain a competitive edge by continuously monitoring changes in reimbursement practices, regulations, and competitor tactics. This proactive market intelligence enables timely adaptations to launch strategies and competitive dynamics, ensuring sustained success in a rapidly evolving healthcare landscape.

Embracing these innovative solutions unlocks unparalleled precision experiences, driving optimised care delivery, personalised engagement, seamless communication, and informed decision-making. By embracing the power of data-driven insights and AI-enabled technologies, companies can stay at the forefront of innovation and shape the future of precision experiences.

Conclusion

This thesis underscores the imperative for current players in the pharmaceutical industry to recognise and embrace the revolutionary potential of artificial intelligence. The findings leave no room for doubt that AI has the capability to transform the sector, presenting a wealth of untapped opportunities that demand immediate investigation and utilisation. The impact of AI on the pharma industry is nothing short of groundbreaking. From drug discovery to clinical development, manufacturing and supply chain, launch and commercialisation, and post-market surveillance and patient support, AI has the power to revolutionise each stage of the value chain. It offers a paradigm shift in how pharmaceutical companies operate, opening doors to unprecedented efficiency, effectiveness, and innovation.

AI technologies possess the unique capability to unlock new avenues of drug discovery, significantly accelerating the identification of potential drug targets, lead optimisation, and screening processes. By harnessing the power of machine learning algorithms and leveraging vast amounts of data, pharma companies can uncover hidden patterns, correlations, and previously inaccessible insights. This enhanced understanding of disease mechanisms and drug interactions paves the way for developing more effective and targeted therapies.

Moreover, AI holds tremendous promise in optimising the clinical development phase, where traditionally time-consuming and costly processes hinder progress. Through predictive analytics and data-driven insights, AI algorithms can identify patient populations more likely to respond positively to specific treatments. This targeted approach not only enhances patient outcomes but also streamlines clinical trials, reducing overall costs and time to market. It opens up new possibilities for adaptive trial designs, enabling more efficient and personalised approaches to patient care.

AI offers a paradigm shift in efficiency and quality control in manufacturing and supply chain management. AI algorithms can analyse real-time production data, identify bottlenecks, and optimise manufacturing processes. This results in reduced costs, increased productivity, and improved quality assurance. Additionally, AI-powered predictive analytics optimise inventory management, demand forecasting, and distribution, ensuring the timely availability of medications while minimising waste and supply chain disruptions.

The potential for AI to transform launch and commercialisation strategies cannot be overstated. Pharma companies can tailor their marketing strategies to specific target audiences by leveraging AI-based market analysis and customer segmentation. This level of personalised marketing enhances the likelihood of success and market penetration. AI can also assist in pricing strategies, market access decisions, and post-launch surveillance, ensuring that pharmaceutical products reach the right patients at the right time while complying with regulatory requirements.

In post-market surveillance and patient support, AI technologies offer new avenues for enhancing patient care and safety. Through real-world data analysis, AI can proactively identify adverse events and potential safety issues, enabling timely intervention and risk management. AI-powered virtual assistants and chatbots provide

personalised patient support, improving medication adherence and empowering patients with readily accessible information and guidance.

Given AI's immense potential and transformative nature in the pharmaceutical industry, it is imperative for current players to investigate and leverage this technology. The competitive landscape demands proactive engagement with AI to remain at the forefront of innovation. Those who seize the opportunities presented by AI stand to gain a significant advantage, whether in developing more effective drugs, optimising operations, or improving patient outcomes.

In conclusion, the time is now for pharmaceutical companies to embrace AI and explore its full potential. The industry stands on the precipice of a new era where AI-driven innovations have the power to revolutionise drug development, manufacturing processes, commercialisation strategies, and patient care. By investing in and harnessing AI technologies, players can unlock new opportunities, gain a competitive edge, and contribute to advancing healthcare for the betterment of society.

References

2023 Global Life Sciences Outlook. (n.d.). Deloitte Italia. https://www2.deloitte.com/it/it/pages/life-sciences-and-healthcare/articles/2023-global-life-sciences-outlook.html

A bold future for life sciences regulation. (n.d.). Deloitte United Kingdom. https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/life-sciences-predictions-2025.html

A wake-up call for Big Pharma. (2011, December 1). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/a-wake-up-call-for-big-pharma#

Advanced digital health care providers segmentation. (n.d.). Deloitte Switzerland. https://www2.deloitte.com/ch/en/pages/life-sciences-and-healthcare/articles/advanced-digital-healthcare-professionals-segmentation.html

AI for Drug Discovery Q4 2022. (n.d.). Deep Pharma. https://www.deep-pharma.tech/ai-in-dd-q4-2022

AI for medtech commercial growth: Five missteps to avoid. (2022, December 15). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/ai-for-medtech-commercial-growth-five-missteps-to-avoid

AI in biopharma research: A time to focus and scale. (2022, October 10). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/ai-in-biopharma-research-a-time-to-focus-and-scale

AI in Pharmaceutical Market Size, Share, Report 2021-2030. (n.d.). https://www.precedenceresearch.com/ai-in-pharmaceutical-market

Artificial Intelligence (AI) In Pharmaceutical Market Size & Share Analysis - Industry Research Report - Growth Trends. (n.d.). https://www.mordorintelligence.com/industry-reports/artificial-intelligence-in-pharmaceutical-market

Artificial Intelligence (AI) in Pharmaceutical Market Size Global Report, 2022 - 2029. (n.d.). Polaris. https://www.polarismarketresearch.com/industry-analysis/artificial-intelligence-ai-in-pharmaceutical-market

Artificial intelligence: The time to act is now. (2018, January 8). McKinsey & Company. https://www.mckinsey.com/industries/industrials-and-electronics/our-insights/artificial-intelligence-the-time-to-act-is-now

Austin, T., Kishnani, P. K., Mariani, J., Busath, K., & Diehl, A. (2021). Trustworthy open data for trustworthy AI. *Deloitte Insights*. https://www2.deloitte.com/us/en/insights/industry/public-sector/open-data-ai-explainable-trustworthy.html

Bentwich, I. (2023). Pharma's Bio-AI revolution. *Drug Discovery Today*, *28*(5), 103515. https://doi.org/10.1016/j.drudis.2023.103515

Biopharma digital transformation: Gain an edge with leapfrog digital innovation. (n.d.). Deloitte Italia. https://www2.deloitte.com/it/it/pages/life-sciences-and-healthcare/articles/biopharma-digital-transformation---deloitte-italy---lshc.html

Building value-chain resilience with AI. (2021, November 26). McKinsey & Company. https://www.mckinsey.com/industries/metals-and-mining/our-insights/building-value-chain-resilience-with-ai

CB Insights. (2023). The Big Tech in Pharma Report: How Amazon, Microsoft, Apple, and Alphabet are capitalizing on digital transformation. *CB Insights Research*. https://www.cbinsights.com/research/report/famga-big-tech-pharma/

Creating value from next-generation real-world evidence. (2020, July 23). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/creating-value-from-next-generation-real-world-evidence

Data ethics: What it means and what it takes. (2022, September 23). McKinsey & Company. https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/data-ethics-what-it-means-and-what-it-takes

Designing an agile transformation in pharma R&D. (2019, July 22). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/designing-an-agile-transformation-in-pharma-r-and-d

Digitization, automation, and online testing: Embracing smart quality control. (2021, April 14). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/digitization-automation-and-online-testing-embracing-smart-quality-control

Emerging from disruption: The future of pharma operations strategy. (2022, October 10). McKinsey & Company. https://www.mckinsey.com/capabilities/operations/our-insights/emerging-from-disruption-the-future-of-pharma-operations-strategy

Five insights about harnessing data and AI from leaders at the frontier. (2021, March 25). McKinsey & Company. https://www.mckinsey.com/capabilities/quantumblack/our-insights/five-insights-about-harnessing-data-and-ai-from-leaders-at-the-frontier

Five ways that life science companies can build tech talent. (2022, August 3). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/five-ways-that-life-science-companies-can-build-tech-talent

From product to customer experience: The new way to launch in pharma. (2018, August 15). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/from-product-to-customer-experience-the-new-way-to-launch-in-pharma

Future-proofing the supply chain. (2022, June 14). McKinsey & Company. https://www.mckinsey.com/capabilities/operations/our-insights/future-proofing-the-supply-chain

Getting strategic about new-product submissions in the pharma industry. (2021, September 16). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/getting-strategic-about-new-product-submissions-in-the-pharma-industry

Global Trends in R&D 2023. (n.d.). IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d-2023

How AI can accelerate R&D for cell and gene therapies. (2022, November 16). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/how-ai-can-accelerate-r-and-d-for-cell-and-gene-therapies

How big data can revolutionize pharmaceutical R&D. (2013, April 1). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/how-big-data-can-revolutionize-pharmaceutical-r-and-d

How companies can win in the seven tech-talent battlegrounds. (2020, October 19). McKinsey & Company. https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/how-companies-can-win-in-the-seven-tech-talent-battlegrounds

How data is changing the pharma operations world. (2018, August 6). McKinsey & Company. https://www.mckinsey.com/capabilities/operations/our-insights/how-data-is-changing-the-pharma-operations-world

How healthcare services and technology companies can boost productivity with data and analytics. (2021, January 29). McKinsey & Company. https://www.mckinsey.com/industries/healthcare/our-insights/how-healthcare-services-and-technology-companies-can-boost-productivity-with-data-and-analytics

How the European biotech sector can navigate turbulent times. (2022, October 11). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/how-the-european-biotech-sector-can-navigate-turbulent-times

Huang, J., Lee, W., & Lee, K. (2022). Predicting Adverse Drug Reactions from Social Media Posts: Data Balance, Feature Selection and Deep Learning. *Healthcare*, *10*(4), 618. https://doi.org/10.3390/healthcare10040618

Iansiti, M. (2021, January 21). *Competing in the Age of AI*. Harvard Business Review. https://hbr.org/2020/01/competing-in-the-age-of-ai

Innovation sourcing in biopharma: Four practices to maximize success. (2022, May 31). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/innovation-sourcing-in-biopharma-four-practices-to-maximize-success

Integrated evidence generation: A paradigm shift in biopharma. (2021, December 2). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/integrated-evidence-generation-a-paradigm-shift-in-biopharma

Intelligent biopharma Forging the links across the value chain - Google Search. (n.d.). https://www.google.com/search?client=safari&rls=en&q=Intelligent+biopharma+Forging+the+links+across+the+value+chain&ie=UTF-8&oe=UTF-8

Intelligent drug discovery. (n.d.). Deloitte Insights. https://www2.deloitte.com/us/en/insights/industry/life-sciences/artificial-intelligence-biopharma-intelligent-drug-discovery.html

Intelligent drug launch and commercial. (n.d.). Deloitte Switzerland. https://www2.deloitte.com/ch/en/pages/life-sciences-and-healthcare/articles/intelligent-drug-launch-and-commercial.html

Intelligent drug supply chain. (n.d.). Deloitte Switzerland. https://www2.deloitte.com/ch/en/pages/life-sciences-and-healthcare/articles/intelligent-drug-supply-chain.html

Lam, B., Calderon, R. F., & Entrup, C. (2022). Intelligent enterprise fueling the supply chain of the future. *Deloitte Insights*. https://www2.deloitte.com/xe/en/insights/focus/supply-chain/digital-brain-supply-chain-management-with-machine-learning.html

Leveraging digital and analytics in biopharma operations: Six principles. (2021, May 27). McKinsey & Company. https://www.mckinsey.com/capabilities/operations/our-insights/leveraging-digital-and-analytics-in-biopharma-operations-six-principles

Liu, J., & Wang, G. (2018). Pharmacovigilance from social media: An improved random subspace method for identifying adverse drug events. *International Journal of Medical Informatics*, *117*, 33–43. https://doi.org/10.1016/j.ijmedinf.2018.06.008

Liu, X., & Chen, H. (2015). A research framework for pharmacovigilance in health social media: Identification and evaluation of patient adverse drug event reports. *Journal of Biomedical Informatics*, *58*, 268–279. https://doi.org/10.1016/j.jbi.2015.10.011

McKinsey on Healthcare: Weathering the storm. (2022, September 16). McKinsey & Company. https://www.mckinsey.com/industries/healthcare/our-insights/mckinsey-on-healthcare-weathering-the-storm

McKinsey Technology Trends Outlook 2022. (2022, August 24). McKinsey & Company. https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-top-trends-in-tech

Measuring the return from pharmaceutical innovation 2022. (2023a). *Deloitte*. https://www.deloitte.com/global/en/Industries/life-sciences-health-care/analysis/measuring-the-return-from-pharmaceutical-innovation.html

Measuring the return from pharmaceutical innovation 2022. (2023b). *Deloitte*. https://www.deloitte.com/global/en/Industries/life-sciences-health-care/analysis/measuring-the-return-from-pharmaceutical-innovation.html

Morgan, J., Feghali, K., Chang, C., & Miranda, W. (2022a). Real-world evidence's evolution into a true end-to-end capability. *Deloitte Insights*. https://www2.deloitte.com/us/en/insights/industry/health-care/real-world-evidence-study.html

Morgan, J., Feghali, K., Chang, C., & Miranda, W. (2022b). Real-world evidence's evolution into a true end-to-end capability. *Deloitte Insights*. https://www2.deloitte.com/us/en/insights/industry/health-care/real-world-evidence-study.html

Nguyen, T., Larsen, M. E., O'Dea, B., Phung, D., Venkatesh, S., & Christensen, H. (2017). Estimation of the prevalence of adverse drug reactions from social media. *International Journal of Medical Informatics*, *102*, 130–137. https://doi.org/10.1016/j.ijmedinf.2017.03.013

Notes from the AI frontier: Modeling the impact of AI on the world economy. (2018, September 4). McKinsey & Company. https://www.mckinsey.com/featured-insights/artificial-intelligence/notes-from-the-ai-frontier-modeling-the-impact-of-ai-on-the-world-economy

Out of the shadows: A brighter future for pharma technical development. (2022, September 16). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/out-of-the-shadows-a-brighter-future-for-pharma-technical-development

Pharmacovigilance on twitter? Mining tweets for adverse drug reactions. (2014, November 14). PubMed. https://pubmed.ncbi.nlm.nih.gov/25954400/

Predicting the future of healthcare and life sciences in 2025. (n.d.). Deloitte Switzerland. https://www2.deloitte.com/ch/en/pages/life-sciences-and-healthcare/articles/predicting-the-future-of-healthcare-and-life-sciences-in-2025.html

PricewaterhouseCoopers. (n.d.-a). *Driving the future of health*. PwC. https://www.strategyand.pwc.com/de/en/industries/health/future-of-health.html

PricewaterhouseCoopers. (n.d.-b). *How pharmaceutical firms can shape the future of healthcare*. PwC. https://www.pwc.nl/en/publicaties/precision-medicine.html

Quarterly value releases: Transforming pharma through digital and analytics—fast. (2022, December 9). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/quarterly-value-releases-transforming-pharma-through-digital-and-analytics-fast

Real-world evidence: Driving a new drug-development paradigm in oncology. (2018, July 24). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/real-world-evidence-driving-a-new-drug-development-paradigm-in-oncology

Reimagining the future of biopharma manufacturing. (2022, October 11). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/reimagining-the-future-of-biopharma-manufacturing

Responsible AI: Confronting Risks and Guiding Application. (n.d.). McKinsey & Company. https://www.mckinsey.com/alumni/news-and-events/global-news/firm-news/responsible-ai-confronting-risks-guiding-application

RWE focus is shifting to R&D, early investments begin to pay off. (n.d.). Deloitte Insights. https://www2.deloitte.com/us/en/insights/industry/health-care/real-world-evidence-study-2020.html

Scaling up AI across the life sciences value chain. (n.d.). Deloitte Insights. https://www2.deloitte.com/us/en/insights/industry/life-sciences/ai-and-pharma.html

Schuhmacher, A., Haefner, N., Honsberg, K., Goldhahn, J., & Gassmann, O. (2022). The dominant logic of Big Tech in healthcare and pharma. *Drug Discovery Today*, *28*(2), 103457. https://doi.org/10.1016/j.drudis.2022.103457

Self-learning: The dawn of a new biomedical R&D paradigm. (2022, July 15). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/self-learning-the-dawn-of-a-new-biomedical-r-and-d-paradigm

Stark, D. R., Zweig, O., & Krumbmüller, F. (2022). How do you build future supply chains to best serve patient needs? *EY - Global*. https://www.ey.com/en_gl/life-sciences/how-can-greater-localization-increase-supply-chain-resilience

Supply chain resilience. (n.d.). Deloitte South Africa. https://www2.deloitte.com/za/en/pages/governance-risk-and-compliance/articles/risk-intelligent-approach-managing-supply-chains.html

Taylor, K., May, E., Powell, D., & Ronte, H. (2022). Intelligent post-launch patient support. *Deloitte Insights*. https://www2.deloitte.com/xe/en/insights/industry/life-sciences/artificial-intelligence-in-healthcare-pharmacoviligance.html

Tech talent tectonics: Ten new realities for finding, keeping, and developing talent. (2022, April 14). McKinsey & Company. https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/tech-talent-tectonics-ten-new-realities-for-finding-keeping-and-developing-talent

Tech Trends 2022. (n.d.). Deloitte Italia. https://www2.deloitte.com/it/it/pages/technology-media-and-telecommunications/articles/tech-trend-2022.html

The age of analytics: Competing in a data-driven world. (2016, December 7). McKinsey & Company. https://www.mckinsey.com/capabilities/quantumblack/our-insights/the-age-of-analytics-competing-in-a-data-driven-world

The AI Dossier. (n.d.). Deloitte United States. https://www2.deloitte.com/us/en/pages/consulting/articles/ai-dossier.html

The biopharma smart factory of the future. (n.d.). Deloitte United States. https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/biopharma-smart-factory-of-the-future.html

The future is now: Unlocking the promise of AI in industrials. (2022, December 6). McKinsey & Company. https://www.mckinsey.com/industries/automotive-and-assembly/our-insights/the-future-is-now-unlocking-the-promise-of-ai-in-industrials

The future of biopharma. (n.d.-a). Deloitte China. https://www2.deloitte.com/cn/en/pages/life-sciences-and-healthcare/articles/the-future-of-biopharma.html

The future of biopharma. (n.d.-b). Deloitte Insights. https://www2.deloitte.com/us/en/insights/industry/health-care/future-of-pharmaceutical-industry.html

The promise and challenge of the age of artificial intelligence. (2018, October 15). McKinsey & Company. https://www.mckinsey.com/featured-insights/artificial-intelligence/the-promise-and-challenge-of-the-age-of-artificial-intelligence

The pursuit of excellence in new-drug development. (2019, November 1). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/the-pursuit-of-excellence-in-new-drug-development

The socio-economic impact of AI on European health systems. (n.d.). Deloitte Belgium. https://www2.deloitte.com/be/en/pages/life-sciences-and-healthcare/articles/the-socio-economic-impact-of-AI-on-healthcare.html

Top ten observations from 2022 in life sciences digital and analytics. (2023, January 31). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/top-ten-observations-from-2022-in-life-sciences-digital-and-analytics

Topic: Artificial Intelligence (AI) worldwide. (2023, April 27). Statista. https://www.statista.com/topics/3104/artificial-intelligence-ai-worldwide/#topicOverview

Transforming biopharma R&D at scale. (2022, May 6). McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/transforming-biopharma-r-and-d-at-scale

Why businesses need explainable AI—and how to deliver it. (2022, September 29). McKinsey & Company. https://www.mckinsey.com/capabilities/quantumblack/our-insights/why-businesses-need-explainable-ai-and-how-to-deliver-it

Zhang, Y., Cui, S., & Gao, H. (2020). Adverse drug reaction detection on social media with deep linguistic features. *Journal of Biomedical Informatics*, *106*, 103437. https://doi.org/10.1016/j.jbi.2020.103437

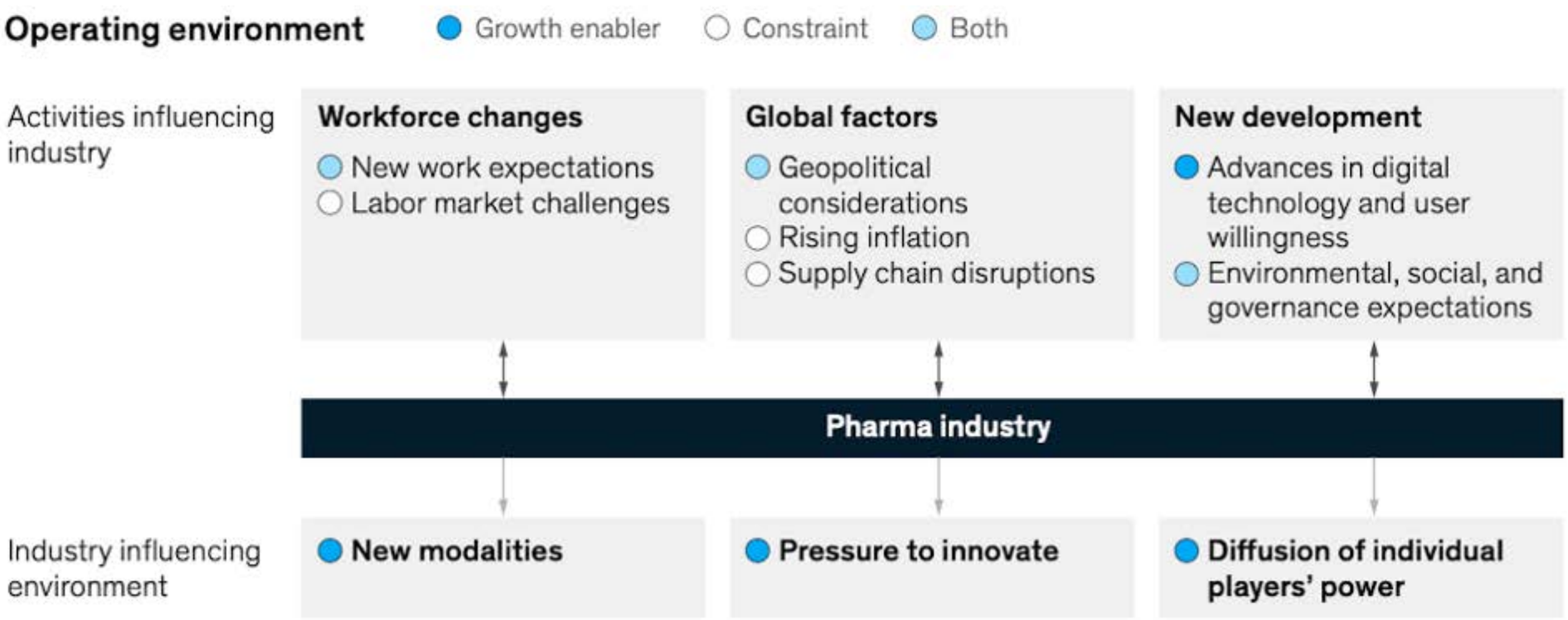
LUISS GUIDO CARLI UNIVERSITY

THE IMPACT OF ARTIFICIAL INTELLIGENCE ON THE PHARMACEUTICAL INDUSTRY ACROSS THE VALUE CHAIN

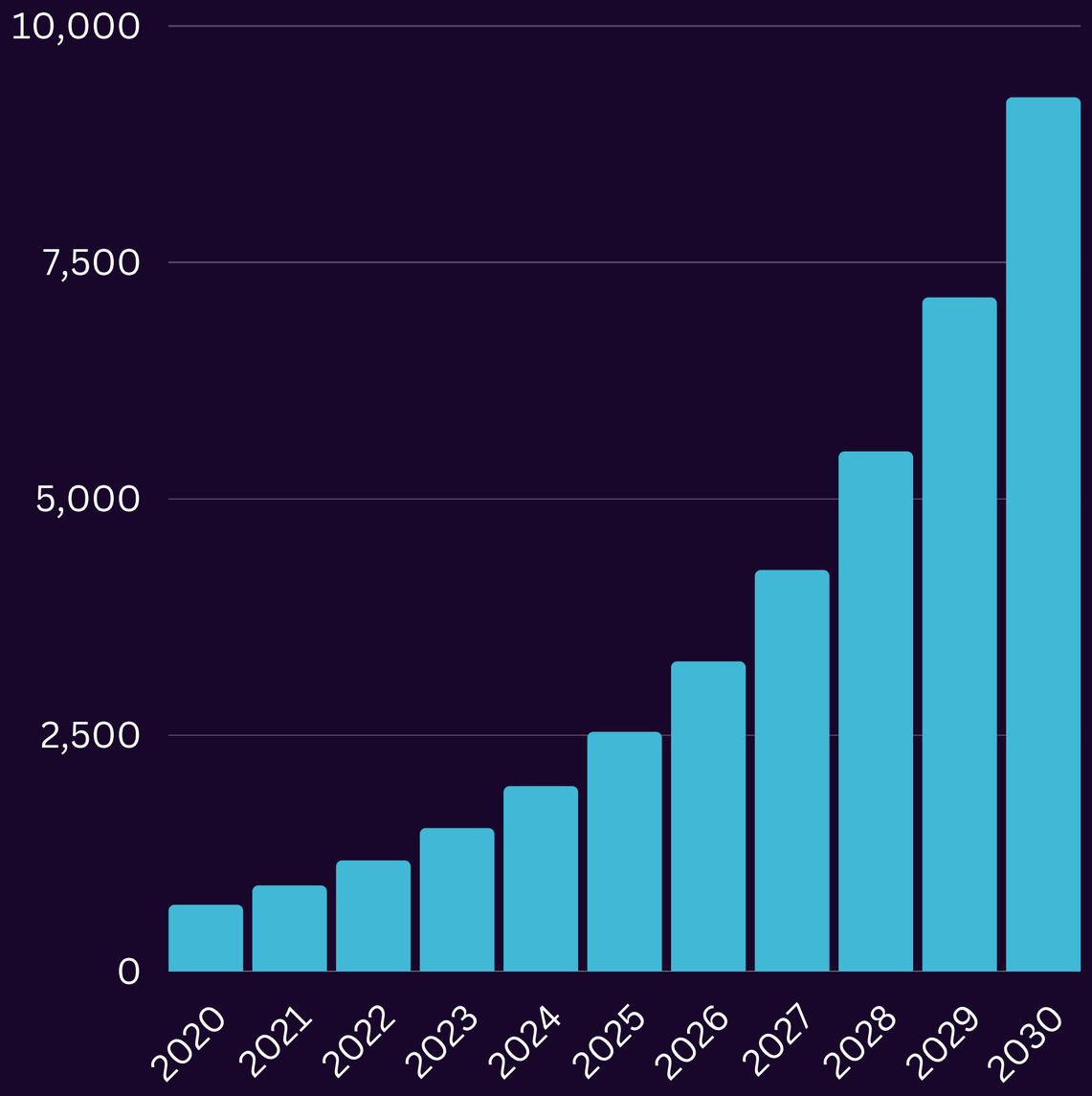
Degree Program in International Management
Course of Managerial Decision Making
ID. 730321 Monica Feliziani

ACADEMIC YEAR 2022/2023

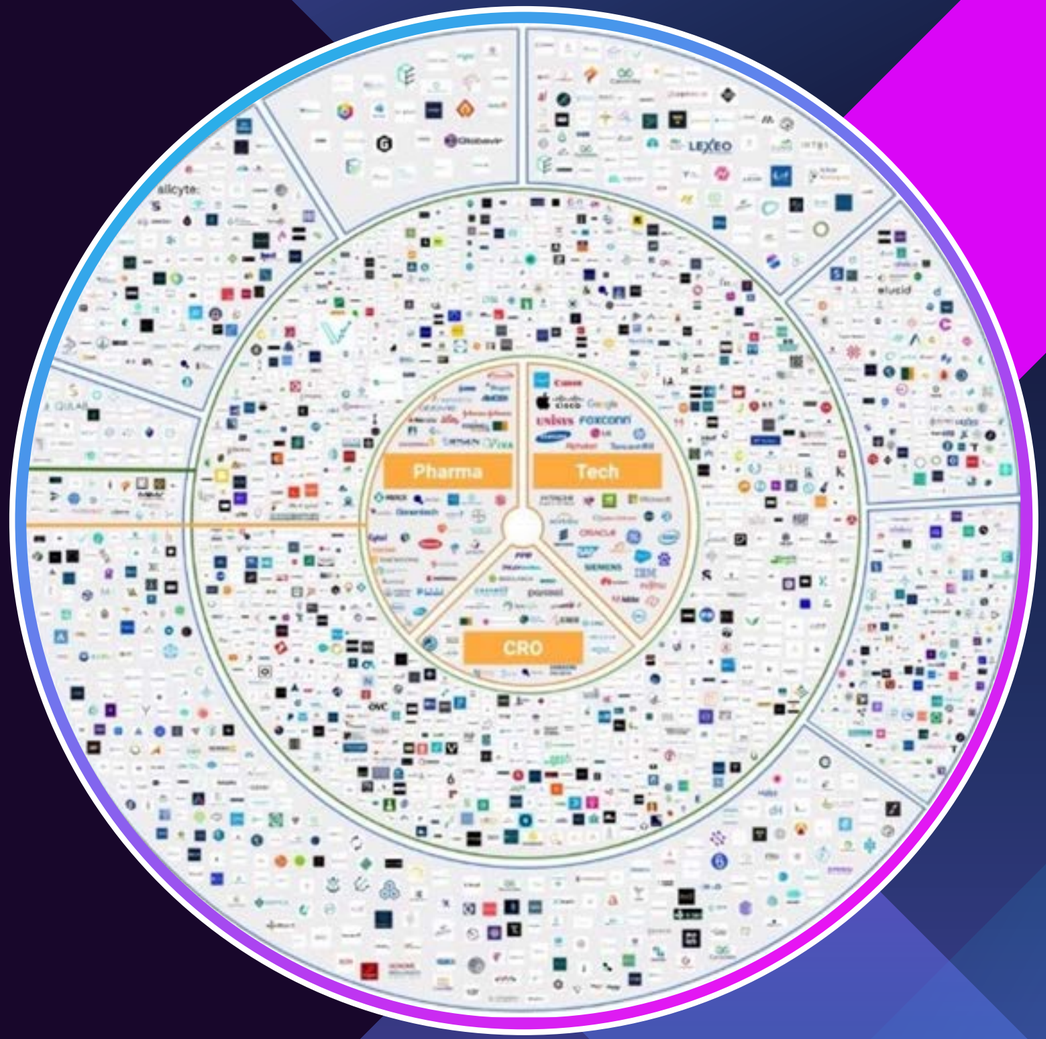
MULTIFACED TRENDS AFFECTING THE INDUSTRY



AI IN PHARMACEUTICAL MARKET SIZE



INDUSTRY PLAYERS



1. **Big tech companies**
2. **Big Pharma**
3. **Contract research organisations (CROs)**
4. **Other technology providers**
5. **Biotech startups**
6. **Academic research institutions**

AI KEY DRIVERS

BIG DATA GROWTH

Big data availability drives AI industry growth, fueled by the exponential increase in digital data from diverse sources, including intelligent devices, IoT, social media, and the pharmaceutical industry, leading to advanced analytics and real-world evidence extraction for improved healthcare outcomes.

GREATER COMPUTING POWER, LOWER COSTS

Affordable, high-performance computing fuels AI development and deployment by enabling data collection, training of algorithms, and application of advanced techniques like deep learning, revolutionising industries through enhanced prediction, recognition, and processing capabilities.

FUNDING TRENDS

Funding played a crucial role in driving AI growth within the pharma industry, particularly in COVID-19, as it accelerated R&D efforts, fostered innovation, and facilitated the application of AI technologies for improved drug discovery and healthcare solutions.

OPEN-SOURCE COMMUNITY

Open-source platforms drive AI growth by promoting democratisation, enabling customisation, fostering collaboration, and nurturing AI talent, resulting in faster, more efficient, cost-effective development and deployment of diverse and specialised AI applications.

BARRIERS TO AI ADOPTION

01

Data Challenge

The need for robust, reliable, curated data
Data interoperability
Data security

02

Technological Challenge

- integration of AI hardware and software into existing IT infrastructure
- legacy systems management
- secure and centralised data governance system (Cloud)

03

Legal & Regulatory Challenge

- Data protection and privacy regulations
- approval of AI-based devices and drugs
- regulatory compliance

04

Ethical Challenge

Privacy
Bias and discrimination
Lack of transparency and explainability
Lack of governance and accountability
Workforce displacement and transitions

05

Talent Gap Challenge

- Digital technology as a catalyst for scientific advancements
- essential roles and skills quickly changing
- Shortcomings of traditional hiring, upskilling, and reskilling methods
- Great Resignation
- industry and location agnostic competition for talent

06

Organisational Challenge

Rearchitecting the Firm: a critical and Difficult Transition
Stages of Operating Model Transformation
Five Principles for an Effective Transformation Process

COMPETING IN THE AGE OF AI

Collision & Fragmentation

Industries are converging, driven by software, data-centric architectures, and AI, creating interconnected business models that transcend traditional boundaries, posing challenges for traditional firms to compete with innovative digital models and disrupting the pharma industry's landscape.

New Competitive adv: universal capabilities

The business landscape is shifting towards universal capabilities driven by AI and network-centric organizations, where traditional industry specialization is less important and versatile capabilities in data sourcing, processing, analytics, and algorithm development are gaining significance, leading to the emergence of universal competitors and reshaping operational tasks, strategy, business design, and leadership.

Coopetition

The growing significance of digital networks and AI is driving a fundamental transformation in firms, leading to the need for coopetition as an essential strategy in the pharma industry to leverage collaboration for competitive advantage, resource access, cost reduction, and innovation, enabling firms to achieve common goals, accelerate product development, and shape industry standards through strategic alliances, JVs, and consortia.

AI APPLICATIONS
FROM MOLECULE TO MARKET

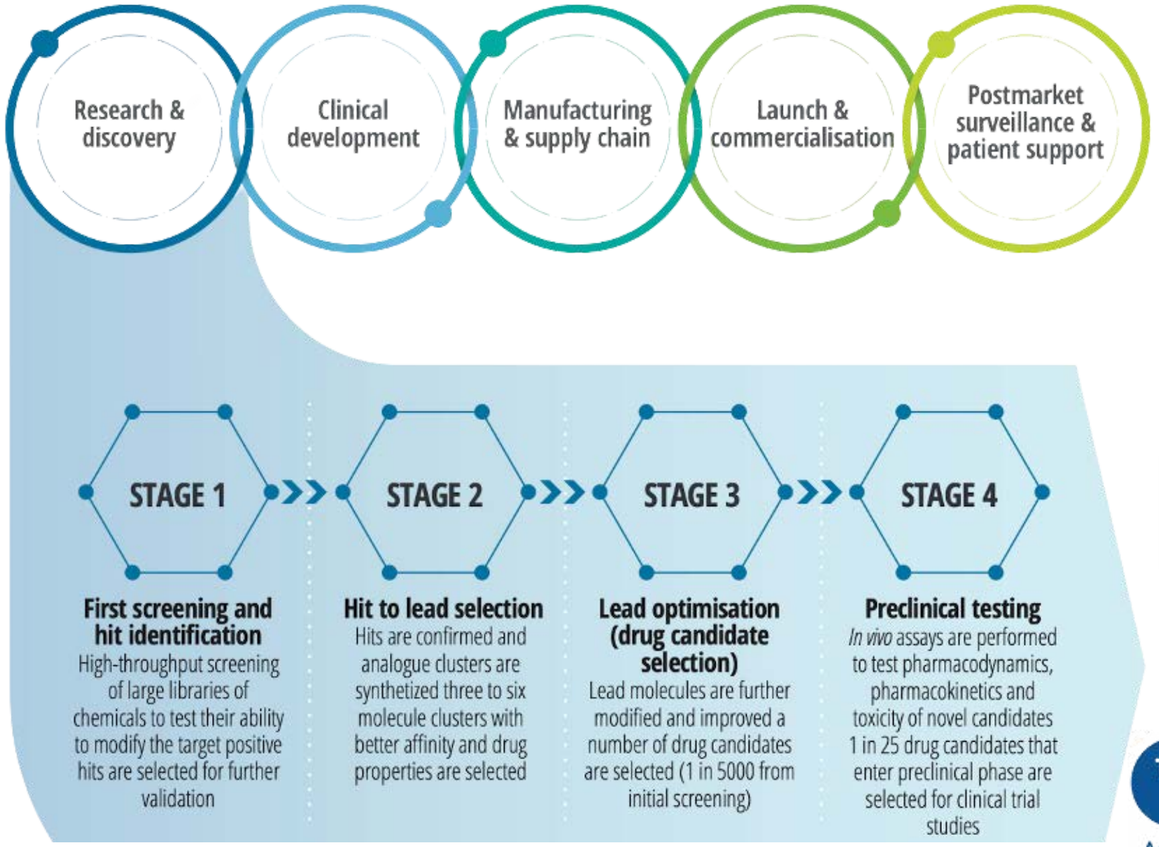
- Aggregating and synthesising information
- Mining data to identify drug targets and molecule interactions
- Understanding disease mechanisms
- Drug candidate generation and selection

- Trial design
- Site selection
- Recruitment optimisation
- Process optimisation
- Predictive toxicity and risk monitoring
- Monitoring drug adherence

- Supply chain planning
- Predictive maintenance
- Inventory management
- Demand forecasting
- Logistics optimisation
- Workforce planning
- Procurement
- Medication tracking, safety and security
- End-to-end visibility

- Launch coordination
- Patient engagement
- Physician decision support
- Marketing operations
- Predictive pricing

- Medication adherence
- Adverse event recognition
- Patient monitoring
- Compliance monitoring
- Patient support programmes/ platforms



AI IN RESEARCH & DISCOVERY

$2,284 M

AVERAGE COST ASSET DEVELOPMENT

$389 M

AVERAGE FORECAST PEAK SALES PER PIPELINE ASSET

1,2%

EXPECTED RETURN ON INVESTMENT FROM DRUG DEVELOPMENT

AI for Advanced R&D

Target Discovery and Early Drug Discovery

Accelerated development of new drugs and targets identification

- Identify novel drug candidates
- Analyze data from patient samples
- Predict pharmacological properties
- Simplify protein design

Clinical Trials

Targeted towards personalized approach and optimal data handling

- Optimize clinical trial study design
- Patient-representative computer models
- Define best personalized treatment
- Analyze medical records
- Improve pathology analysis

Design and Processing of Preclinical Experiments

Optimization of experiments and data processing

- Reduce time and cost of planning
- Decode open- and closed-access data
- Automate selection, manipulation, and analysis of cells
- Automate sample analysis with a robotic cloud laboratory

Aggregation and Synthesis of Information

Time- and resources-efficient information management

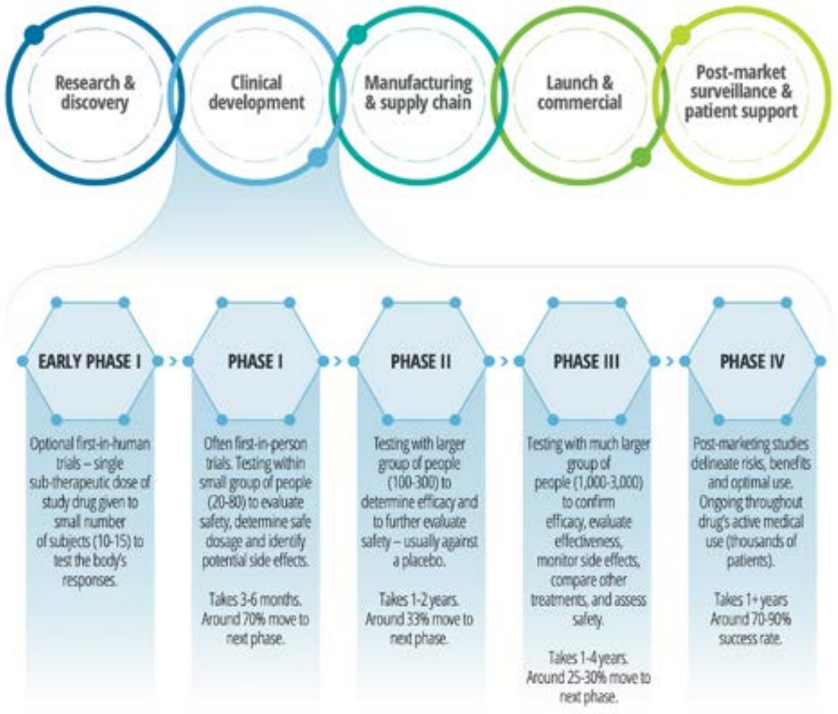
- Generate insights from thousands of unrelated data sources
- Improve decision-making
- Eliminate blind spots in research

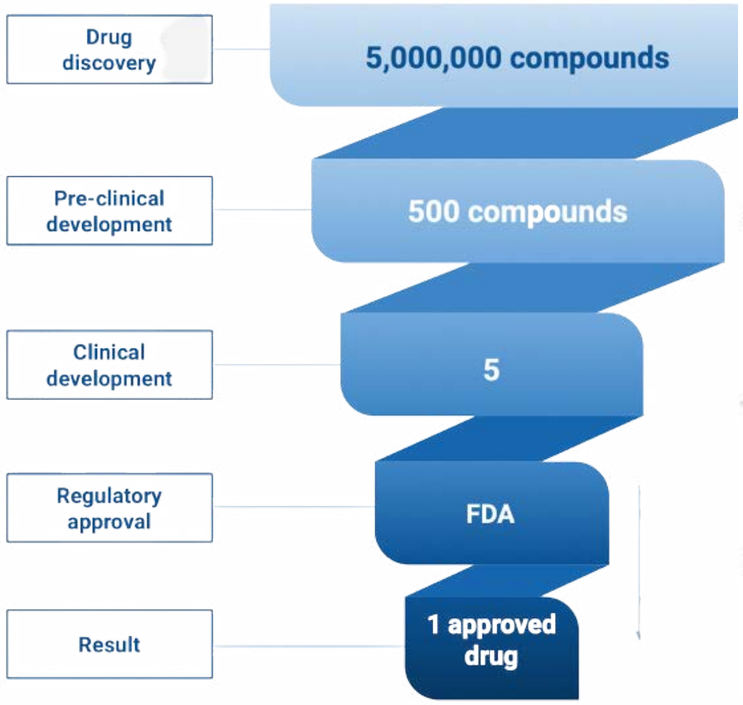
Repurposing of Existing Drugs

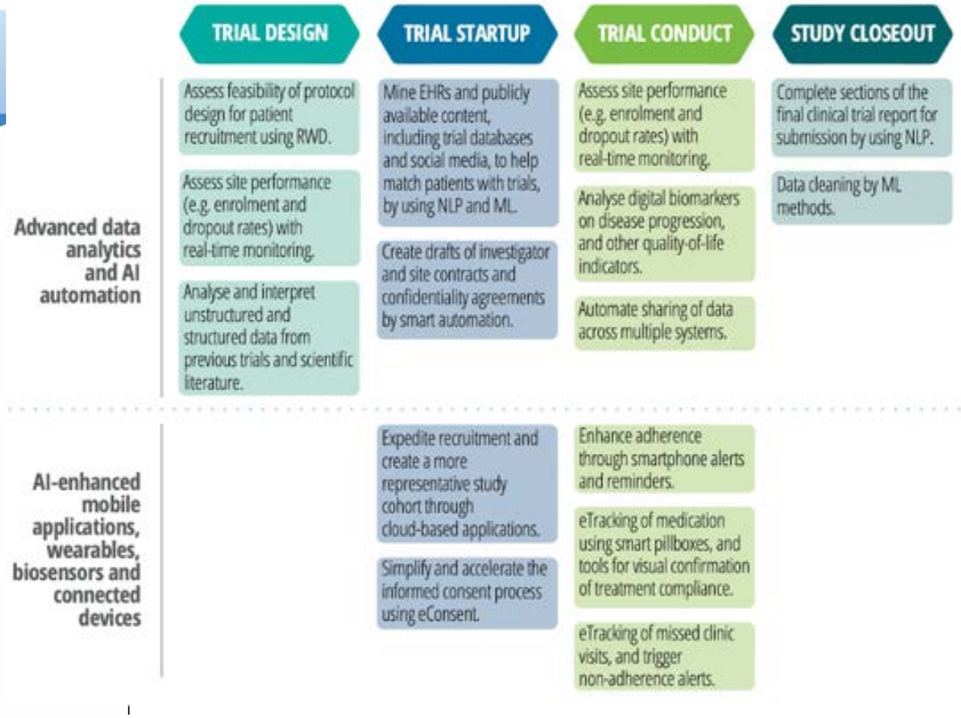
Searching for new applications of existing drugs at a high scale

- Rapidly identify new indications
- Match existing drugs with rare diseases
- Testing 1000+ of compounds in 100+ of cellular disease models in parallel

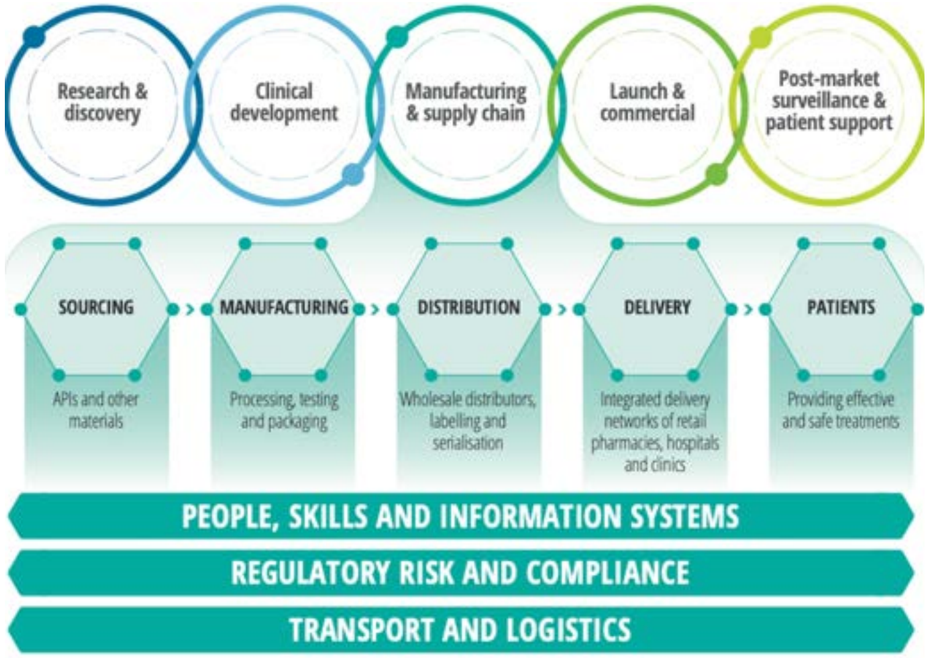
AI IN CLINICAL DEVELOPMENT

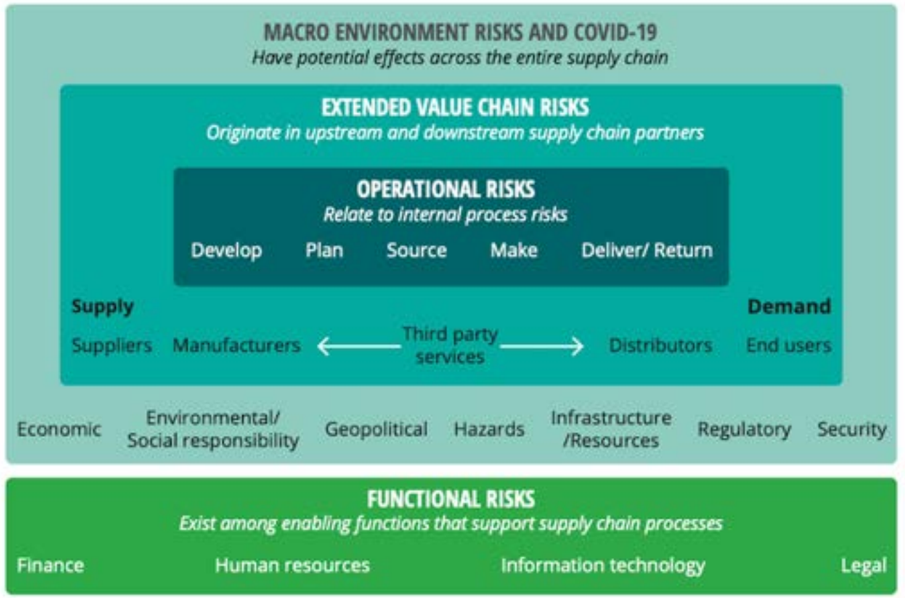




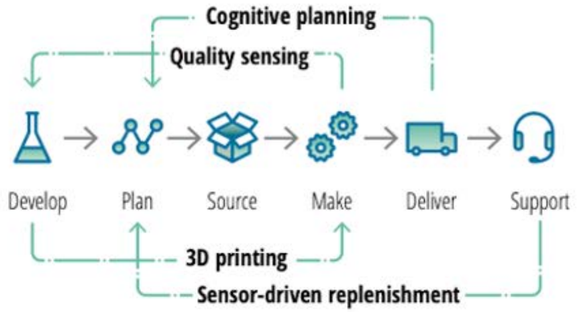


AI IN MANUFACTURING & SUPPLY CHAIN

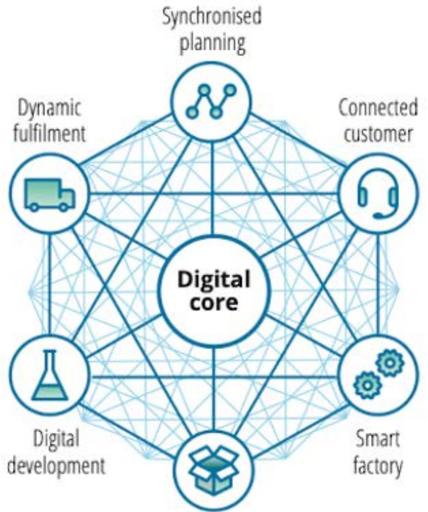




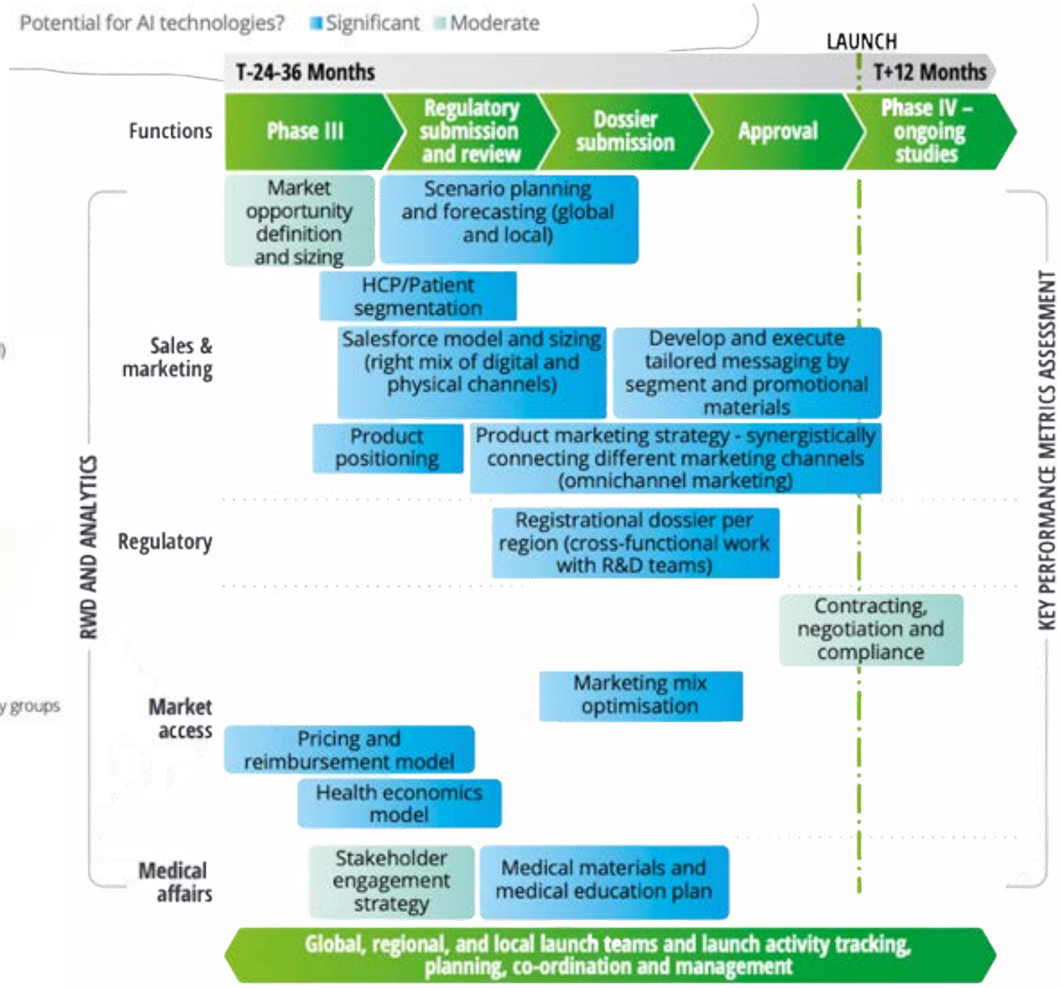
TRADITIONAL SUPPLY CHAIN



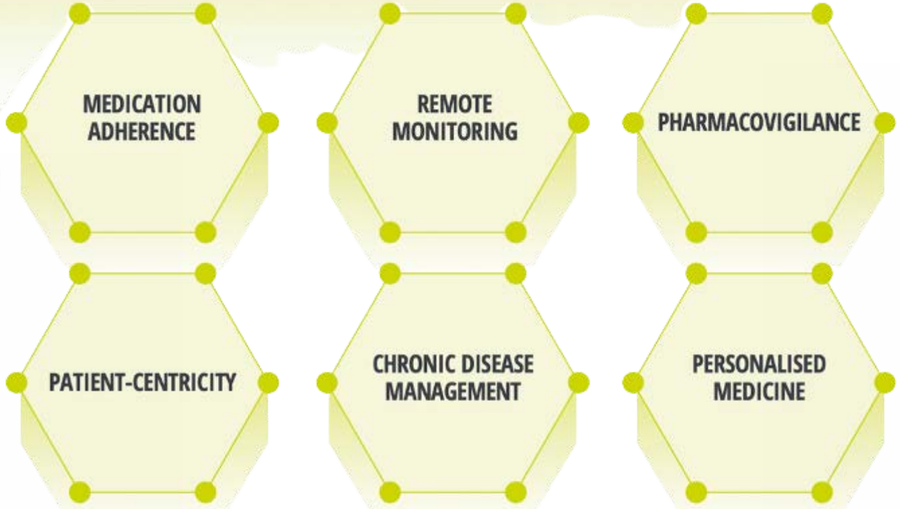
DIGITAL SUPPLY NETWORKS

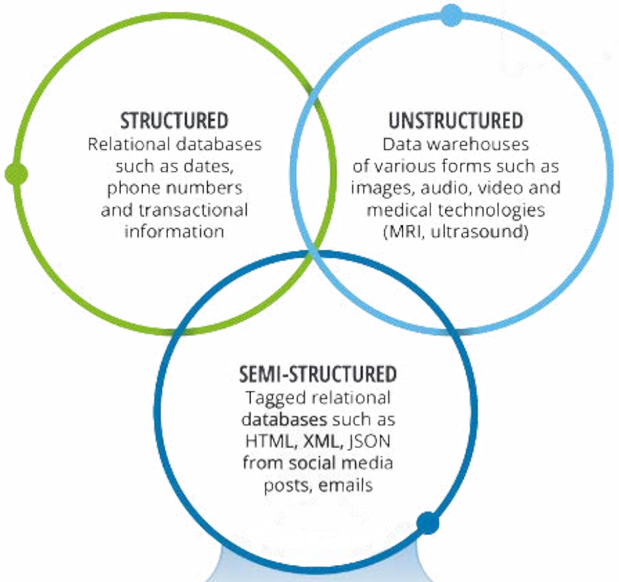


AI IN LAUNCH & COMMERCIAL



AI IN POST-MARKET SURVEILLANCE & PATIENT SUPPORT



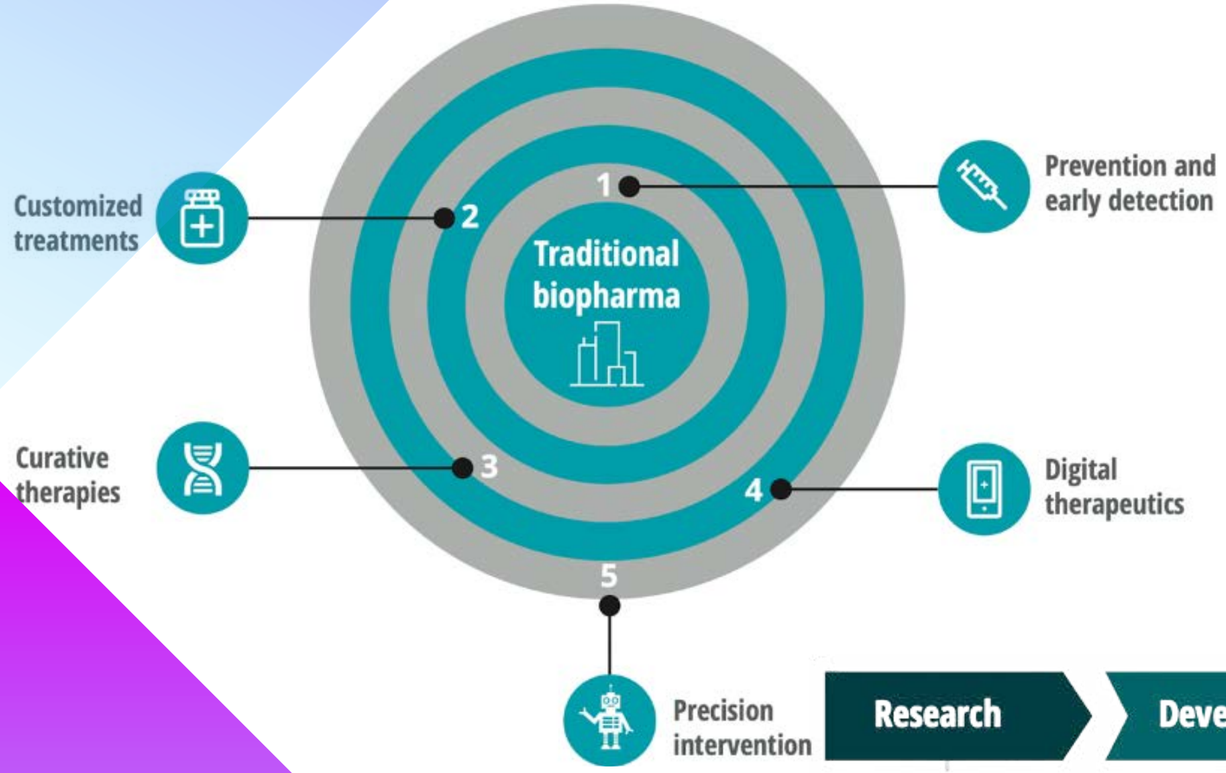


MACHINE-LEARNING ALGORITHMS CAN BE USED FOR:

Key criteria for success

PERSONALISE	COMMUNICATE	OPTIMISE
the PSP to individual patient needs by agreeing on the needs and desired outcomes at the outset.	using multiple channels to provide 24/7 support so patients receive relevant and easy to understand information in a convenient, simple and targeted way.	use of data from multiple channels by consolidating into a single patient record that is compliant across geographies.
COMPLY	**ENGAGE**	**CONNECT**
with the regulations, regulatory standards and legal frameworks in each country.	HCPs and other stakeholders in the value of the PSP and maintain enthusiasm through regular communications.	patients and their support network with providers and HCPs who will all need to be trained within the PSP.

PHARMA FUTURE



Research	Development	Manufacturing	Supply chain	Commercial
Lab of the future	Patient-centered and seamless trials	Smart factory	Predictive and autonomous supply chain management	Precision experiences for patients and partners
• Virtual data assistants • Interoperable data ecosystems • AI-driven drug discovery	• Longitudinal engagement models • Digital data flow • Digital patient monitoring	• AI-driven asset uptime • Digital batch disposition • Site command centers	• Predictive yield optimization • Control towers • Real-time tracking and tracing	• AI-based engagement recommendations • Connected patient platforms • Proactive market intelligence

Thank you for the attention

sanofi