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Intelligent drug supply chain

Creating value from AI

Deloitte Centre *for*
Health Solutions

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

Contents

The rationale for transforming the biopharma supply chain

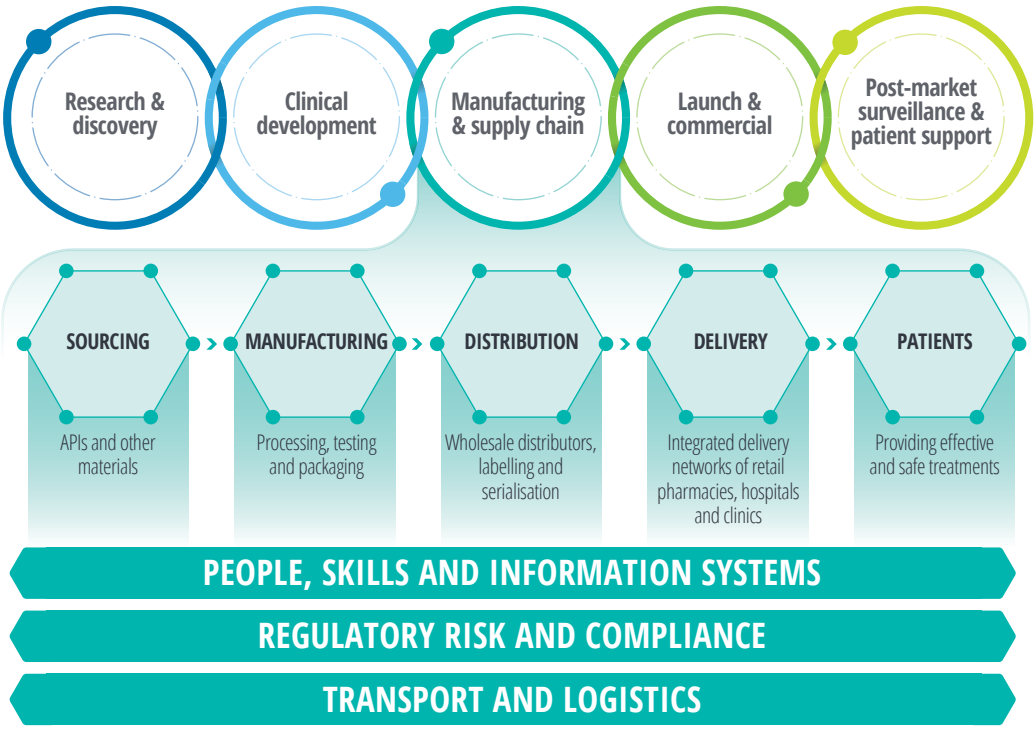
The *Intelligent biopharma* series explores the ways artificial intelligence (AI) can impact the biopharma value chain. The first two reports, *Intelligent drug discovery*[1] and *Intelligent clinical trials*,[2] highlight the potential of AI to accelerate the development of new drugs. This report explores the potential for AI technologies to improve the value of the biopharma supply chain and manage risks more effectively. Evidence shows that the need for digital transformation of the supply chain has never been more pressing.

THE BIOPHARMA SUPPLY chain involves a complex set of steps that are required to produce a drug, from sourcing and supply of materials, through manufacturing and distribution, to delivery to the consumer. This forms a golden thread between the discovery of new therapies and patients receiving them (figure 1).[3]

Protecting biopharma supply chains is a priority not only for companies but also for all governments, given the importance of ensuring access to the lifesaving and life-enhancing products that are vital for the health and well-being of their populations. The COVID-19 pandemic has highlighted the importance of biopharma supply chains in meeting the demand for leading-edge products.[4]

FIGURE 1

The different steps in the biopharma supply chain



Source: Deloitte analysis.

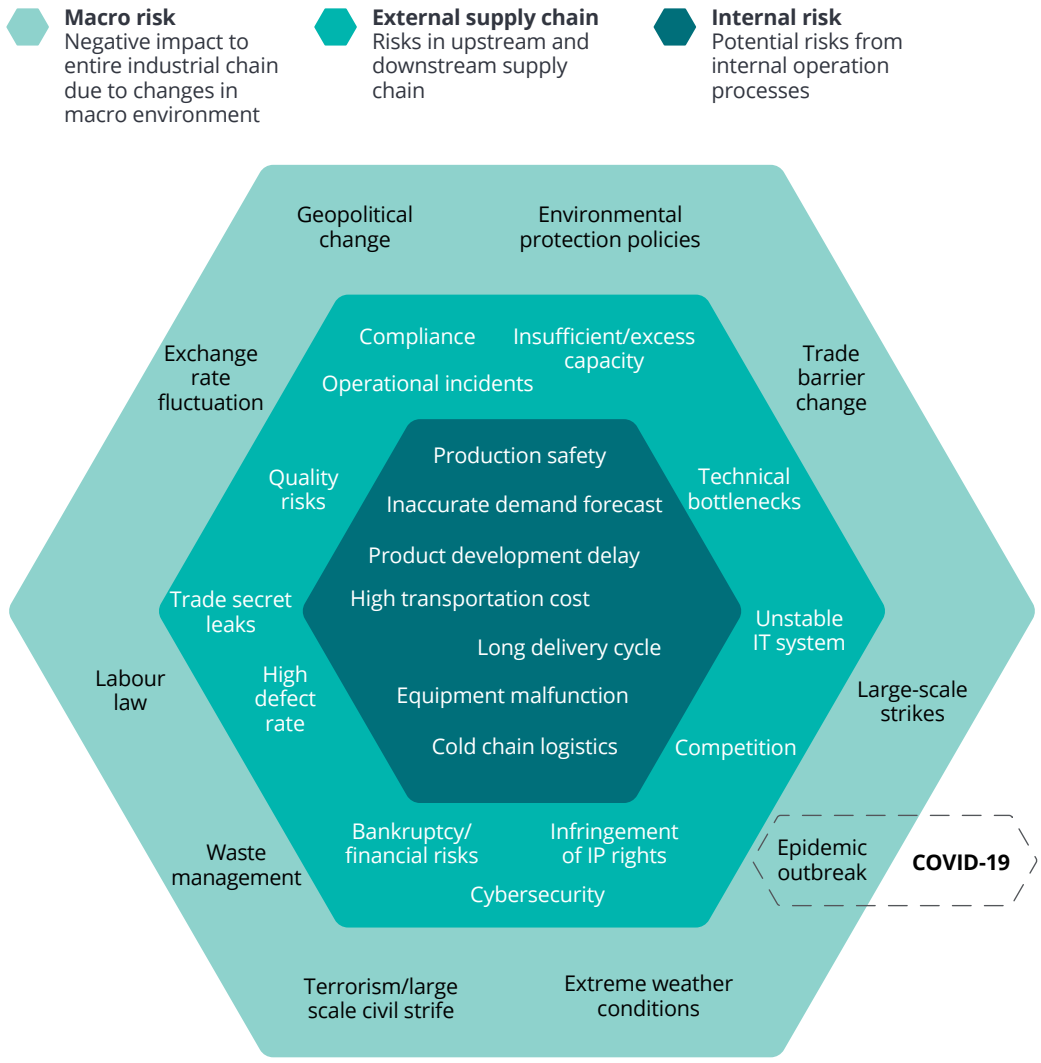
Biopharma supply chains create inherent resilience risks for corporations and governments alike. Supply chains must also meet the expectations of a complex range of stakeholders, comprising multiple payers, health care providers and patients with complex and varied needs, both within and across different countries. Consequently, intelligent and insightful monitoring and management of the supply chain is an imperative.

This report examines the rationale for transforming the supply chain (Part 1) and the role that AI can play in its digital transformation (Part 2). Given the unprecedented challenges to the health care ecosystem resulting from the COVID-19 pandemic, the report also considers the role that AI can play in helping the supply chain to respond, recover and thrive (Part 3). Finally, the report provides a strategic roadmap for implementing an AI-enabled supply chain (Part 4).

The risk landscape for biopharma supply chains comprises internal, external and macro risk factors (figure 2).

FIGURE 2

The complexity and risks affecting the globally distributed biopharma supply chain



Source: Deloitte analysis.

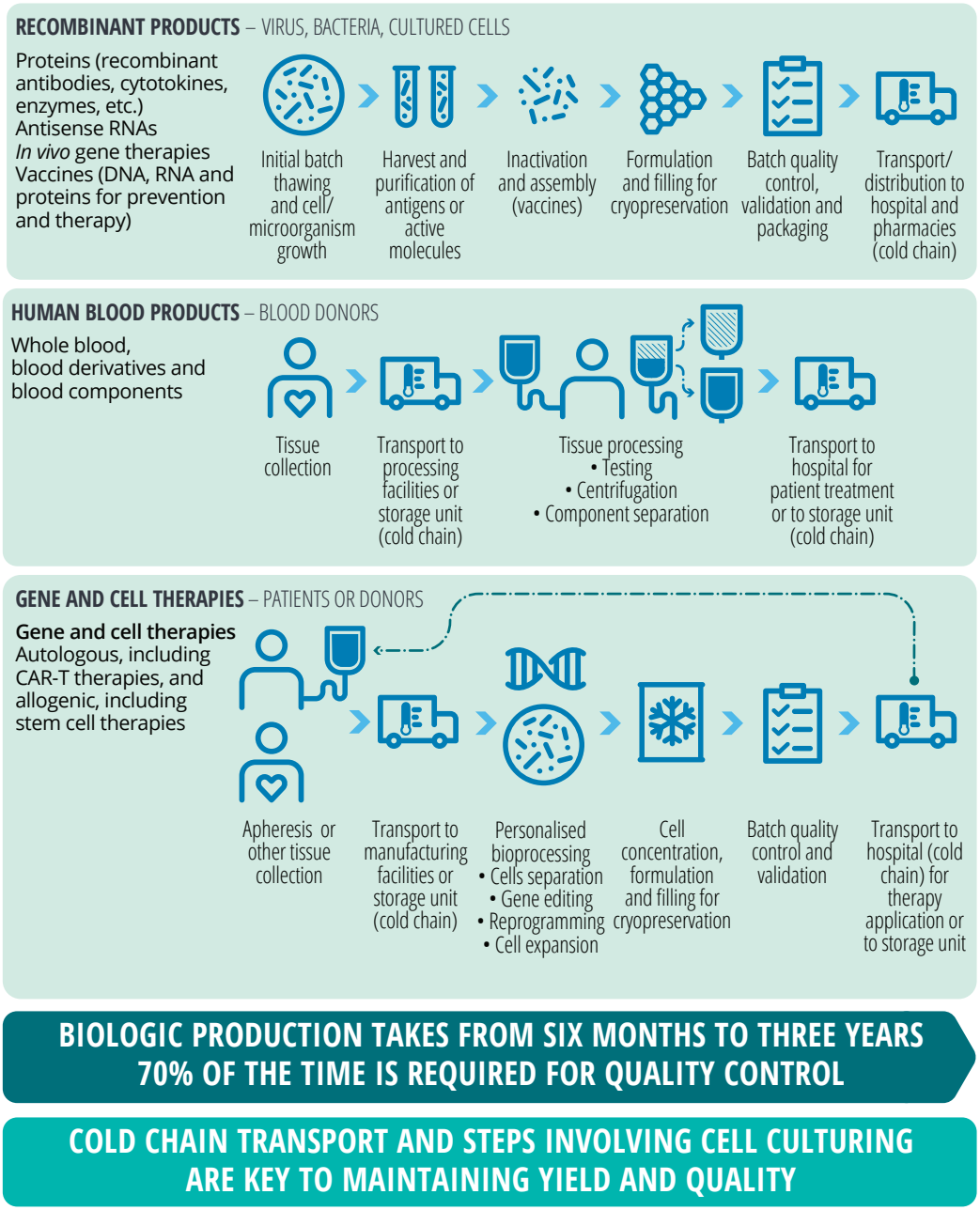
Given the above complexity and risks, governments have established an evolving and complex framework of local, regional and international regulatory bodies. There are also global bodies, such as the World Health Organisation (WHO) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, aimed at improving regulatory collaboration.[5]

The complexity of biologics manufacturing and supply chains

In comparison to 'traditional' small molecules, biologics have more complex supply chains (figure 3). A 2019 survey of 151 experts to understand more about manufacturing practices and trends identified that the biggest challenges of biologics

FIGURE 3

The different complexities affecting the three main biologics manufacturing processes



Source: Deloitte analysis.

manufacturing are process robustness (59 per cent of respondents), process reproducibility (56 per cent), product yield optimisation (46 per cent) and product characterisation (42 per cent).[6]

Deloitte research demonstrates a continued growth in biologics and estimates an equal split with small molecules in worldwide sales by 2024.[7] However, large-scale production of biologics is at present seen as one of the main challenges of the biopharma industry, mostly due to the inherent variability of biological systems and the instability of finished products. Ascertaining the yields and quality of these types of drugs is crucial in ensuring that they are reproduced effectively and maintained until they reach patients, with regulatory bodies applying strict inspection and reporting requirements. These need additional analytical methods that measure specific physical and biochemical properties to ensure these therapies remain safe and have not lost their activity during manufacturing.[8]

NEXT-GEN THERAPIES BRING A NEW LEVEL OF COMPLEXITY TO SUPPLY CHAINS

Responses to a 2019 survey indicate that the most commercially important biopharma therapeutic products currently available are monoclonal antibodies (80 per cent), followed by vaccines (51 per cent) and other recombinant proteins (36 per cent). Fewer respondents mentioned cell therapies (18 per cent), gene therapies (18 per cent) and RNA-based therapies (9 per cent). When the same question was asked concerning the next five to ten years, the answers were substantially different. Respondents put gene therapies in first place (66 per cent), followed by monoclonal antibodies (58 per cent) and cell therapies (52 per cent).[9]

The high sensitivity and more precise targeting of biologics requires a direct connection between pharma companies, the health care system and even individual patients; consequently, this requires a more agile supply chain structure. This is particularly the case for cell therapies (known as *ex vivo*); for example, chimeric antigen receptor T-cell (CAR-T) therapies. By the end of 2019, the FDA had approved two CAR-T therapies; however, there were some 600 clinical trials involving CAR-T therapies in the biopharma pipeline.[10]

The need for a new supply chain model is driving the digital transformation of most industries, supply chains

In the past few years, manufacturing companies across all industries have initiated digital transformation of the different steps in the supply chain. Big tech giants such as Amazon, Apple Inc. and Google have led the way in the early adoption of end-to-end digital supply chains. The opportunity was created by the availability of large amounts of reliable and relatively untapped data at the same time as technological breakthroughs were developing, such as advanced analytics and AI, blockchain, digital twins and the Internet of Things (IoT), intelligent automation and virtual and augmented reality.[11]

While many life sciences companies have been exploring the opportunities that digital technologies offer, many are yet to make consistent, sustained and bold moves to take advantage of the new capabilities.[12] Companies able to make the transition could rocket ahead of competitors and fend off intruders from outside the industry trying to enter biopharma's orbit. In 2019, the Deloitte US Center for Health Solutions led a four-day online crowdsourcing simulation with biopharma leaders and found that companies are getting closer to incorporating digital technologies more broadly in everything, from R&D, to supply chain, to patient engagement.[13]

How AI can augment supply chain transformation

A huge amount of internal and external data is generated routinely across the biopharma supply chain, but historically these data have been underutilised. Simply capturing data fails to provide actionable insights. Using AI technologies to process these data will be critical to orchestrating operational efficiency and, ultimately, to creating a cost-effective, near autonomous and thriving biopharma supply chain.

AI TECHNOLOGIES ARE poised to transform supply chain and manufacturing through real-time data processing and decision making to make supply chains truly data-driven, reducing human subjectivity and bias. AI tools have the potential to unlock commercial, regulatory and operational data to find non-linear and complex relationships that would otherwise be missed and to deliver powerful strategic insights. AI algorithms have the potential to deliver significant improvement in productivity and gross margins and contribute to the sustainability of the biopharma industry. In particular, 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.

AI algorithms have the potential to deliver significant improvement in productivity and gross margins and contribute to the sustainability of the biopharma industry.

WHAT IS AI?

AI refers to any computer programme or system that does something we would think of as intelligent in humans. AI technologies extract concepts and relationships from data and learn independently from data patterns, augmenting what humans can do. These technologies include computer vision, deep learning (DL), machine learning (ML), natural language processing (NLP), speech, supervised learning and unsupervised learning.[14]

Deloitte has identified five critical areas and processes of the biopharma supply chain where AI is likely to have the highest impact (figure 4). This is based on our research, including comprehensive literature reviews, interviews and workshops with colleagues working on supply chain projects, analysis of the relevant findings from the US Deloitte Center for Health Solutions' online crowdsourcing simulation with biopharma leaders, and discussions with digital technology companies.

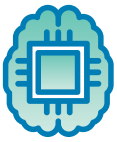
FIGURE 4

Applications of AI-powered technologies in the biopharma supply chain

END-TO-END VISIBILITY
Point-to-point visibility across the whole supply chain will enable companies to become more efficient by rapidly responding to and mitigating disruptions. AI-augmented control towers provide advanced decision-making systems, by efficiently collecting and managing data in real-time and generating actionable insights.

DEMAND FORECASTING, LOGISTICS AND INVENTORY MANAGEMENT
AI tools can mine and analyse data from multiple sources to detect patterns and potential anomalies to generate accurate demand forecasts and help companies efficiently manage their inventory levels.

INTELLIGENT AUTOMATION ENABLING INDUSTRY 4.0 AND THE INTERNET OF THINGS
Adoption of AI tools, such as ML, NLP and computer vision, into an Industry 4.0 and IoT platform will be the key to minimising human error and leveraging operational data to generate strategic insights and improve productivity and accuracy of processes.



OPTIMISING PREDICTIVE MAINTENANCE
AI technologies can find patterns and interdependencies between variables that would otherwise be missed by traditional methods. Leveraging AI through real-time performance monitoring will optimise maintenance, minimise downtime and, ultimately, maximise productivity.

PROTECTING THE INTEGRITY OF THE SUPPLY CHAIN
Combining AI with other advanced technologies, such as blockchain, can create a system that is immutable, transparent, secure, and shielded from counterfeit and substandard drugs.

Source: Deloitte analysis.

End-to-end visibility: the holy grail of supply chain management

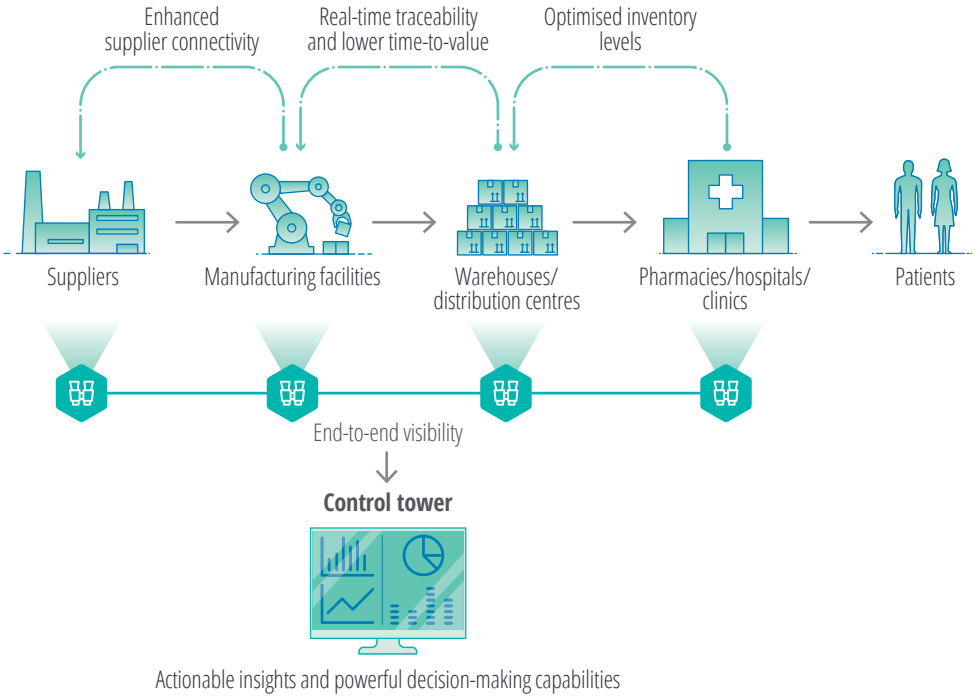
In biopharma's hyper-connected globally complex supply chain, companies need to be able to respond rapidly to any supply chain event that impacts outcomes. End-to-end visibility is the foundation for quickly making the right decisions to mitigate risk and deliver required outcomes. Supply chain visibility means having access to data relating to every transaction and demand trigger, across every step and tier of the supply chain and all the logistics movements in between.

Digital technologies that improve visibility across the supply chain, such as AI and blockchain, can create a dynamic, interoperable system where transactions are transparent and traceable.[15] Disruptions in specific parts of the supply chain can impact subsequent steps, creating a cascade of inefficiencies. End-to-end visibility across the interconnected supply chain will allow data to be safely extracted in real-time using AI tools to generate actionable insights, consequently improving decision-making. This can help companies mitigate disruptions and become more agile, efficient and responsive (figure 5).

The concept of end-to-end visibility can be realised through supply chain control towers, which provide a holistic view across all supply chain functions. Control towers function as centralised hubs that collect information from disparate systems to be used for monitoring, auditing and generating insights.[16] For control towers to be successful in supply chain management, companies need to incorporate AI capabilities, such as ML, to help orchestrate operations and, ultimately, have a near autonomous and self-learning supply chain. In October 2019, IBM launched Sterling Supply Chain Insights, an AI-enabled control tower that allows for comprehensive, real-time visibility of the supply chain by providing rapid integration and interpretation of structured and unstructured data at scale (case study 1).[17,18]

FIGURE 5

End-to-end visibility of the supply chain



Source: Deloitte analysis.

CASE STUDY 1 – IBM STERLING WANTS TO UNTANGLE COMPLEXITY WITH SMARTER SUPPLY CHAINS

Tech giant IBM created Sterling Supply Chain Insights with Watson to help companies achieve end-to-end visibility with a control tower that leverages AI to connect data across siloed systems. Watson AI correlates data from both internal and external sources, enabling analysis of 80 per cent of unstructured data, including digital media and weather reports. These capabilities allow companies to better understand and assess how these data impact their entire supply chain.

When disruptions occur, Sterling Supply Chain Insights aids with faster decision-making to align issue resolution with business objectives, optimising management while responding to unplanned events. Sterling Supply Chain Insights is a critical part of the IBM Sterling Supply Chain Suite, an integrated suite that enables companies to connect crucial data and supply chain processes, while leveraging AI, blockchain and IoT. Sterling Supply Chain Insights powers the IBM Sterling Supply Chain Suite's Intelligence Services and Control Tower capabilities.[19]

Lenovo, a global technology and manufacturing company, wanted to establish greater visibility across its complex supply chain systems and data sources to minimise disruptions and improve customer order management. Lenovo implemented IBM Watson Supply Chain Insights to optimise the orchestration and gain end-to-end visibility of its supply chain. With this tool, Lenovo adopted an AI-powered approach to risk management, reducing its average response time to supply chain disruptions from days to minutes (up to 90 per cent faster than before) and gaining opportunities to reduce costs and drive revenues. Ultimately, these innovations could enable Lenovo to generate more precise delivery estimates for its clients in real-time, adding value to its offering.[20]

Demand forecasting, inventory management and logistics

Demand forecasting plays a critical role in logistics and supply chain management. Accurately adjusted inventory levels are needed if the value of the supply chain is to be unlocked and, importantly, patients are to obtain timely, reliable access to their therapies.[21] Forecasting uses a combination of decision variables, including historical shipment and sales data, market intelligence and other external data inputs that can affect inventory levels, such as weather and epidemiological developments (including infectious diseases outbreaks).[22] The use of AI tools, specifically DL and ML, is particularly important in demand forecasting. Predictive analytics techniques can mine, analyse and interpret data aggregated from various sources to detect patterns and certain anomalies and generate more accurate demand forecasts compared to traditional methods (case study 2).[23]

CASE STUDY 2 – MERCK KGaA USES ML TO OPTIMISE DEMAND FORECASTING

Merck KGaA, also known as the Merck Group, a large German multinational pharmaceutical, chemical and life sciences company headquartered in Darmstadt, has embarked on a data-driven supply chain operation to optimise demand forecasting.[24]

Merck is using Aera Technology, formerly FusionOps, an ML and cloud-based software solution that enables a holistic and actionable view of a company's supply network to increase efficiency across its supply chain, including demand forecasting. Aera continuously combs through enterprise systems to collect, harmonise and refine data, and to consequently provide real-time analytics and end-to-end visibility of the company's supply chain operation and performance.[25]

By using this technology at scale, Merck improved the forecast accuracy of 90 per cent of its products. Aera's AI algorithms use data collected from Merck's enterprise resource planning software to quickly and accurately forecast the demand for its products in terms of both quantity and location.[26]

Having robust data on the significant macro, external and internal risks affecting the biopharma supply chain is critical for forecasting demand. For example, weather prediction technologies using algorithms are now fairly reliable when forecasting up to two weeks ahead.[27] Still, in 2017 and 2018, extreme weather conditions, such as droughts, floods and heatwaves, resulted in economic losses of $215 billion.[28] In 2016, IBM announced the launch of Deep Thunder, a research project that combines big data and AI algorithms and a global forecasting model built from The Weather Company's vast wealth of data, to provide accurate predictions to weather-dependent business operations, including supply chains.[29,30]

In addition, as seen in the COVID-19 pandemic (Part 3), infectious diseases that spread directly or indirectly from one individual to another can cause serious disruption to supply chains.[31] Today, vast amounts of public health surveillance data are available from multiple sources, such as academic institutions, climate databases, digital media, global transportation, genome databases, human demographics, official public health organisations, livestock reports and social media.[32,33] AI tools can make sense of these data sets by generating accurate analyses and projections of potential infectious diseases outbreaks. For example, the severe acute respiratory syndrome (SARS) outbreak in 2003 led to the founding of BlueDot, a company that uses advanced analytics and AI tools for automated, real-time infectious disease surveillance.[34,35] Such information can then be used by companies to adjust their operations accordingly. This can be vital for biopharma to optimise the manufacturing and distribution of specific drugs to affected areas.

TRANSPORTATION LOGISTICS CAN BE SUPPORTED BY AI

A particular challenge of biologics production and supply is their large size and structure, which is difficult to keep stable. Temperature fluctuations and contamination can impact batch quality and yield, especially during transportation. Therefore, maintaining biologic APIs and finished products at a constant low temperature is a key requirement, which has led to stricter regulations that mandate rigorous, end-to-end temperature control. Cold chain transportation technology needs to be integrated with tracking software to ensure the effectiveness and safety of therapeutics when they reach patients. By 2022, an estimated 30 of the 50 top global biopharma products will require cold chain handling and specialised, temperature-controlled logistics.[36]

In addition, research has shown that temperature control is not sufficient to deliver efficacious and safe biological medicines, as other physicochemical parameters, such as humidity, light and vibration, also affect the integrity of these compounds.[37] To thrive, biopharma companies can leverage advanced, intelligent technologies that allow for real-time, end-to-end visibility. This enables biopharma and logistics companies to track the state of the drugs and take proactive and timely interventions when any issue arises.

As seen in the COVID-19 pandemic, infectious diseases that spread directly or indirectly from one individual to another can cause serious disruption to supply chains.

Intelligent automation enabling Industry 4.0 and the Internet of Things

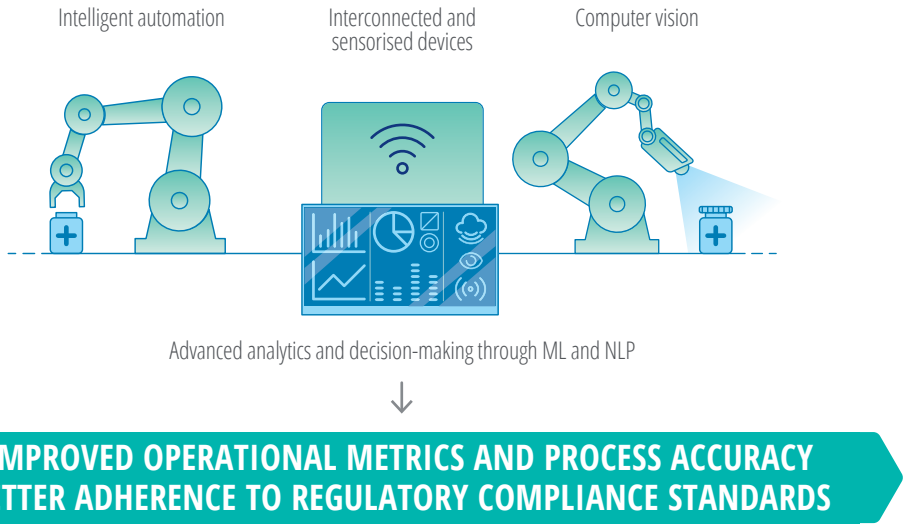
Industry 4.0 aims to encourage the digitalisation and automation of manufacturing processes (figure 6). This is increasingly being adopted in the biopharma sector to help overcome the multiple obstacles that the industry is facing, such as strict regulatory and production demands.[38,39] In addition, embracing Industry 4.0 will enable companies to move towards Quality by Design (QbD), a data- and risk-based approach for the development and manufacturing of drugs that the US FDA and European Medicine Agency (EMA) are actively encouraging.[40,41]

Digitalisation and automation of operations can help biopharma companies establish cost-effective, reliable and robust processes that are coordinated across the supply chain.[42] This can be optimised through the implementation of an IoT platform, which interconnects 'digital' and 'physical' assets through the use of chips, sensors and networks.[43] IoT connections, therefore, generate a vast amount of monitoring data, which can then be unlocked and optimised by using advanced analytics with AI capabilities.

Robotic process automation (RPA) is increasingly deployed to reduce manual effort in repetitive and time-consuming tasks, minimising human errors, and enabling operators to focus on higher-value and more motivating work. Today, the convergence of AI, automation and customer data has resulted in the emergence of a new class of tools, known as intelligent process automation (IPA). IPA combines 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.[44,45] This will be key to minimising human intervention and leveraging operational data to generate strategic insights and improve performance metrics.[46,47] Recent research by the Everest Group estimated that the 2019 intelligent automation market was worth $80 million–$85 million and is expected to reach $450 million–$490 million by 2023, highlighting the strong focus biopharma companies are placing on their digital and automation journeys.[48]

FIGURE 6

Benefits from intelligent automation, Industry 4.0 and the Internet of Things



Source: Deloitte analysis.

The integration of IPA, IoT and Industry 4.0 in the manufacturing step of the biologic supply chain is one the most promising approaches towards reducing variability and ensuring safe and reliable large-scale production of drugs derived from living organisms. Case study 3 describes how one of the most disruptive companies in this sector, Moderna Therapeutics, has digitalisation as a core part of its business strategy and is applying these types of technologies for large-scale production of RNA-based therapeutics.

CASE STUDY 3 – MODERNA THERAPEUTICS

Moderna Therapeutics is a clinical stage biotechnology company based in Cambridge, Massachusetts (MA), in the United States. It is pioneering the development of messenger RNA (mRNA) therapeutics and vaccines. Their mRNA medicines are designed to instruct the body's cells to produce proteins that have a therapeutic or preventive effect on a broad spectrum of diseases, including cancer and cardiovascular, infectious and rare diseases.[49]

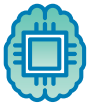
Moderna is a fully digital company that has digitisation as a core attribute of its business strategy. Their landscape has been built on the following six key building blocks:

- **AI** – To enable key breakthroughs in analytics and predictive modelling that will help provide critical insights into production and research data.[50]
- **Cloud** – Built on Amazon Web Services (AWS) Cloud to provide computational power, agility to operate, cost-effectiveness and efficient organisation and processing of data.[51]
- **Integration** – To bring data and processes together in a consistent manner, avoiding silos of information and manual interventions.
- **IoT** – Based on smart, interconnected devices to generate information about their environments and operations. This provides real-time guidance in compliance and traceability in supply chain and manufacturing, including controlling inventory, optimising energy consumption and tracking material.
- **Automation and robotics** – Use of robotics to reach an unprecedented level of automation to increase operation accuracy, repeatability and throughput, while reducing human errors and improving quality and compliance.
- **Analytics** – Use of the latest tools and analytical methods to generate scientific and business insights for informed decision-making.

In July 2018, Moderna opened their state-of-the-art, digitally enabled Moderna Technology Center (MTC) manufacturing facility in Norwood, MA, which was designed to Current Good Manufacturing Practices (cGMP) specifications. The facility has three core functions:

- **Pre-clinical production** – To develop materials for pre-toxicology studies using integrated robotics to produce around 1,000 mRNA per month at research scale.
- **Clinical production** – To run Phase I and II clinical development programs driven by real-time data and a fully integrated manufacturing execution system.
- **Personalised cancer vaccine (PCV) unit** – For the fast manufacturing and supply of individualised batches.[52]

Moderna's digital strategy enables continuous exchange of data, while reducing response time and error proofing, to integrate compliance and provide information on all the manufacturing activities.[53]



Optimising predictive maintenance

Traditionally, manufacturing facilities have operated in preventive maintenance or run-to-failure modes. Preventive maintenance normally consists of scheduled procedures, such as routine asset monitoring and visual inspection, to obtain regular information on the condition of the different system components.[54] In contrast, run-to-failure maintenance lets machinery run until it breaks down before being repaired.[55] These approaches can make operations inefficient, lead to permanent equipment failure and, ultimately, may result in unnecessary downtime of entire production lines with serious financial consequences.

A 2016 Deloitte survey found that more than a third (35.6 per cent) of companies in the life sciences sector experienced a business disruption because of a product compliance, quality or safety-related issue within the previous 12 months, compared with one-fifth (19.2 per cent) of respondents across a range of industries.

A slow response to a compliance- or quality-based disruption can have a threefold negative impact:

- negative market perception because of product recall or investigation,
- delays in terms of responding to the regulatory agency,
- an enormous investment to compensate for the lack of having controls in place.

This can be rectified through integrating a digitised quality management system into a digital supply network (DSN), starting with R&D and carrying on through to product design, manufacturing and distribution services.[56]

A digitised and integrated quality and compliance function can be a competitive advantage in terms of innovation, pricing and quality. However, manufacturers still commonly face the challenge of reducing maintenance costs and duration of time-sensitive repairs, while ensuring that operating units work efficiently. Estimates suggest that between 60 to 73 per cent of all manufacturing data is not utilised or analysed.[57,58] By using advanced technological tools, such as AI, these data can be transformed into vital insights about operations and equipment performance, by identifying patterns and complex relationships between variables, as well as forecasting failures, faults or other issues before they happen. ML can help manufacturing assets to be ready when needed by preventing unplanned downtime. This technology can supply information not only to pinpoint and address the problem causing current downtime, but also to avoid future stoppages. This is known as predictive maintenance.[59]

Predictive maintenance can improve operational effectiveness, including machine uptime, which is the top problem that supply chain leaders are looking to solve with digital technologies.[60] This approach has gained significant momentum in the biopharma industry.[61] Research by IoT Analytics estimated that the global predictive maintenance market reached $3.3 billion in 2018 and is expected to reach $23.5 billion by 2024, reflecting a compound annual growth rate (CAGR) of 39 per cent.[62] A significant contributor to the rapid growth of predictive maintenance is the emergence of sensor technologies that record vast amounts of performance data and allow equipment units to be interconnected.[63]

Protecting the integrity of the supply chain

The production of counterfeit or substandard drugs, which may contain the wrong amount of APIs or none of the correct APIs, has been a longstanding and widespread supply chain problem for the biopharma industry, as well as for international health organisations and society in general.[64] Counterfeit medicines often contain impurities and can be contaminated with pathogenic microorganisms, posing a serious threat to public health.[65] According to the WHO, "an estimated one in 10 medical products in low- and middle-income countries is substandard or counterfeit".[66] However, this problem is not exclusive to developing countries. The exponential increase in internet use to access countless products online has created multiple ways to sell counterfeit drugs.

The European Union Intellectual Property Office (EUIPO) report in 2016 estimated that counterfeit medicines cost the European pharma sector around €10.2 billion, 37,700 jobs and 4.4 per cent of sales each year.[67] Pfizer shared that, as of June 2018, 42 different counterfeit versions of their medicines had entered the legitimate supply chain in at least 62 countries, including Canada, the UK and the US.[68]

For biopharma, the importance of supply chain integrity goes beyond counterfeit products, as key product types need chain of identity and chain of custody, particularly in personalised medicines and gene therapies. To tackle this, biopharma companies are investing in a combination of advanced technologies, like blockchain and AI, to ensure the integrity of the end-to-end supply chain.

Indeed, blockchain technology can be instrumental in providing assurance over transactions across the entire biopharma supply chain, including improving security, transparency and traceability, to enable medication tracking at every step.[69,70]

In January 2020, the PharmaLedger project, a public-private partnership sponsored by the Innovative Medicines Initiative (IMI), was launched to connect the health care value chain using blockchain technology.[71] This three-year project aims to strengthen IMI's efforts to accelerate innovation in health care through the creation of a trusted blockchain-based framework across supply chain, clinical trials and health data management.[72]

The PharmaLedger project brings together 12 global pharma companies and 17 public and private entities to support the design and adoption of a blockchain-based platform in the life sciences and health care spaces.[73] This consortium aims to leverage blockchain to enhance compliance with standards and regulations and to achieve end-to-end connectivity and interoperability, which will help with product tracking for combating counterfeit medicines and medical supplies and ensure supply chain integrity.[74,75]

AI algorithms, based on DL or ML, can be designed to accurately distinguish between genuine and counterfeit versions of the same drug.[76,77] Case study 4 shows how the start-up RxAll is using big data and artificial intelligence for real-time drug authentication.

CASE STUDY 4 – RxAll IS USING DL TO FIGHT FAKE MEDICINES AROUND THE WORLD

RxAll, a US-based start-up, has developed an AI-based technology to assure that patients across the world have access to authentic, high-quality drugs. Their platform combines a proprietary molecular sensor (a spectrometer) and a cloud-based DL algorithm, which uses a database of spectral signatures of drugs, to perform non-destructive verification of drugs authenticity.[78]

Their newest device, the RxScanner II, can identify the authenticity and quality of prescription drugs – in tablet, powder or liquid forms – in 20 seconds and with an accuracy of 99.9 per cent.[79] A customised database of drug spectral signatures is built on the RxScanner platform and real-time information about drug quality and locations of where brand counterfeiting is taking place can be seen. This technology can be used by different stakeholders, including hospitals, pharmaceutical companies, pharmacies and regulatory bodies around the world. Their AI system continuously learns from the spectral reads and can rapidly inform pharmaceutical manufacturers about counterfeiting.[80]

In 2017, RxAll was selected to participate within the Merck Accelerator Program in Nairobi, Kenya, and, in 2018, was selected to join the Norwegian Katapult Accelerator to help expand their operations.[81,82] They are currently operating in Canada, China, Ethiopia, Gambia, Ghana, Kenya, Myanmar, Nigeria, Uganda and the US, and plan to expand in Africa, the Americas and Southeast Asia.[83]

More recently, RxAll started working with a leading global pharma company with sales operations across 120 countries to enable faster identification of brand counterfeits across problematic spots around the world. RxAll developed a spectral library for the client for a significant brand and the RxScanner was deployed with the client's drug security team to quickly test suspect brand copies in trouble spots. Importantly, they allowed test results to be connected in real-time to the drug security control centres in the US and the UK. Over a six-month period, RxScanner's deployment and real-time test reporting to the two control centres reduced reaction time for removing counterfeit copies of this brand off the market from six weeks to two weeks. RxAll is now expanding the library to include more brands facing serious counterfeiting problems.

Another example is FarmaTrust, a company that offers digital solutions that combine AI tools and blockchain to create a system that is immutable, secure and transparent, to provide data-driven decisions.[84] FarmaTrust's solution provides an end-to-end traceability of biopharma products to safeguard the supply chain from being corrupted with falsified or substandard medicines. In addition, their clients can use their Consumer Confidence App for authentication of medicinal products.[85] The FarmaTrust platform ensures data integrity and can automate processes such as purchase ordering, automated payments and regulatory compliance. Its solutions are operational and installed in a variety of clients.

The above solutions solve different aspects of risk across the biopharma supply chain. By enabling transactions data to be stored across a distributed supply chain, blockchain technology can then feed these data into AI tools to obtain an additional level of automation and decision-making in real-time. The combination of AI and blockchain have the potential to generate accurate insights, as well as efficient and secure updates of data throughout the whole supply chain.

AI's role in helping supply chains respond, recover and thrive after COVID-19

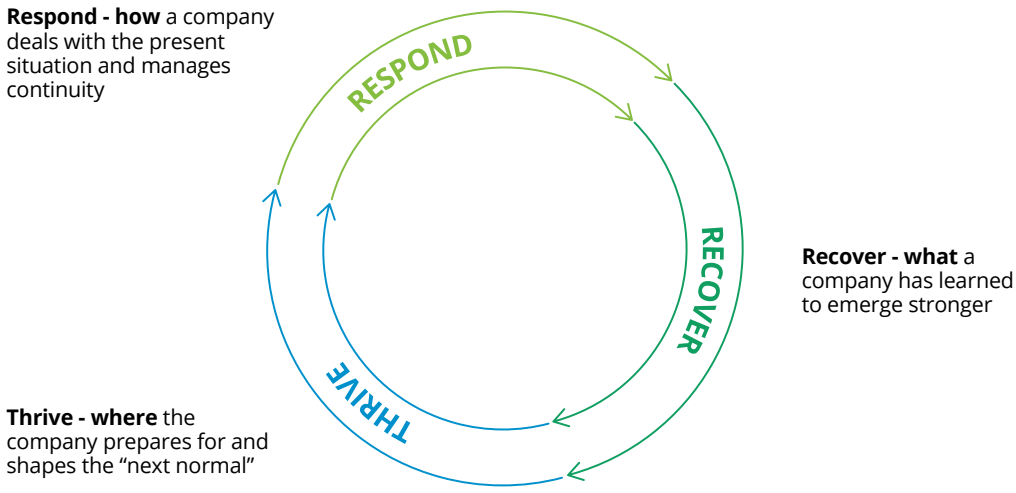
Alongside its human impact and the economic downturn caused by its spread, the COVID-19 pandemic is affecting all biopharma supply chains. Indeed, COVID-19 is increasingly acknowledged as the black swan event that has acted as a catalyst to force many biopharma companies to recognise their vulnerabilities and transform their global supply chain models, including the use of AI.

DELOITTE CONSIDERS THAT the recovery from COVID-19 has three phases – respond, recover and thrive (figure 7). AI technologies can help biopharma respond and manage continuity; recover and emerge stronger; and thrive by preparing for what comes next.

A decades-long focus on supply chain optimisation to minimise costs, reduce inventories, and drive up asset utilisation has exposed biopharma's vulnerability to global shocks through their supply chain relationships. Supply chain risks involve numerous potential points of failure and few margins of error for absorbing delays and disruptions. One of the most crucial areas of risk is human resources, with workforce absenteeism due to sickness absence and lockdown, likely to cause much of the disruption across the supply chain. Understanding the supply chain requires stringent processes and capabilities for supply chain data analytics.[86] Figure 8 illustrates how the COVID-19 risk aligns with the other macro environment risks which can impact any and all aspects of the supply chain.[87]

FIGURE 7

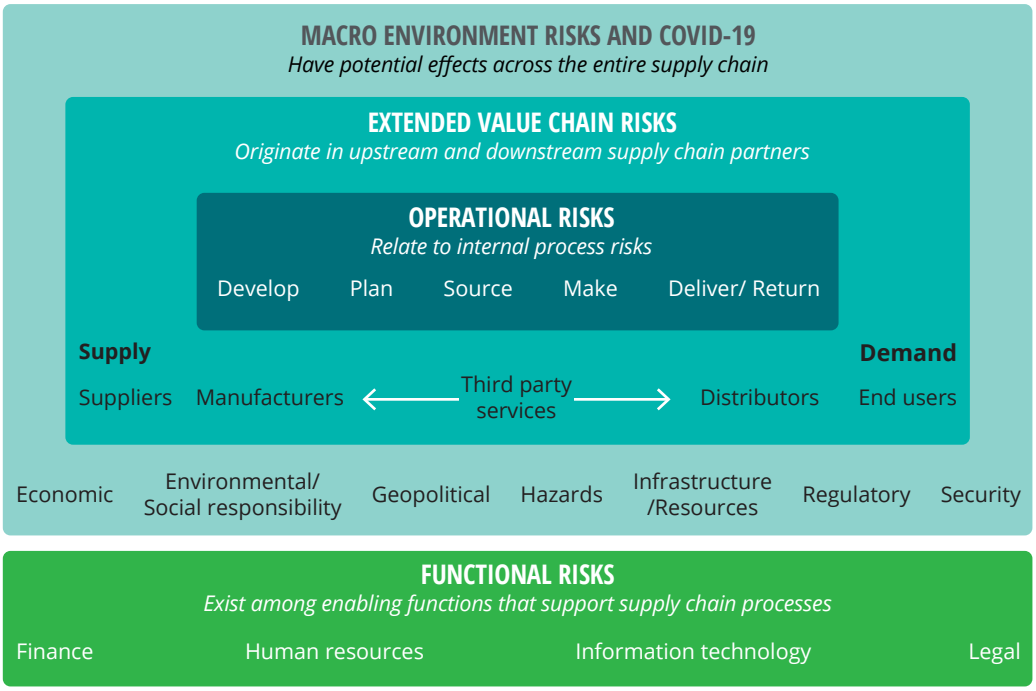
Managing biopharma's supply chain risk disruption due to COVID-19



Source: Deloitte analysis.

FIGURE 8

Supply chain risks



Source: Deloitte LLP.

The impact of COVID-19 on the biopharma supply chain

COVID-19 has had unprecedented global health, social and economic ramifications, which are affecting the supply chains of all industries, including the global supply chains of biopharma, from raw materials to finished products. China, the first affected country, has a strategically important role in biopharma, given it is a primary producer of APIs, as well as a large customer of global commodities and industrial products.[88] India, with its large generic drug industry, plays a vital role in the global supply chain. However, India relies on China for a large percentage of the APIs used to manufacture these drugs. Generic drug manufacturers are already paying more for APIs in India, and prices may still rise if Chinese manufacturing continues to lag or business closures are extended. Consequently, it is likely that the cost of generic drugs manufactured in India could rise in the future.[89]

With much of the global population in quarantine, plant closures and supply shortages across the extended supply network are leading to significant global supply chain disruption.[90] Companies affected the most by the impact of COVID-19 are those that:

- are primarily reliant on a single geography or a single supplier for key products
- do not have enough visibility across the extended supply network to see their risks
- do not have the systems to monitor their inventory status; to project stock-outs of direct materials and optimise production; to project stock-outs of finished goods to optimise customer allocation
- do not have flexible logistics networks to ensure the flow of goods in a profitable manner.[91]

Distribution of biopharma products is becoming increasingly complex, due largely to population movement restrictions. At the beginning of April, at least 12 countries across the world, including a number of European countries, had used export bans, price caps and supply chain diversions to shore up supplies and marshal support for COVID-19 patients within their own borders.[92]

Many of our biopharma clients tell us they are now considering whether to compensate for market disruptions by relocating their biopharma manufacturing facilities. However, the process to establish facilities is lengthy due to tight regulations and the need for precise capabilities. Consequently, in the short-term, expanding production at existing facilities in less-affected markets is a more likely option. However, in the longer term, companies expect to have to diversify their manufacturing capacity across markets and determine whether it makes sense to rely on a small numbers of locations or if they should be attempting to diversify factory locations.[93] Biopharma companies are also seeing sustainability as a reason for biopharma companies to rethink the sourcing of APIs and location of manufacturing facilities.

Distribution of biopharma products is becoming increasingly complex, due largely to population movement restrictions.

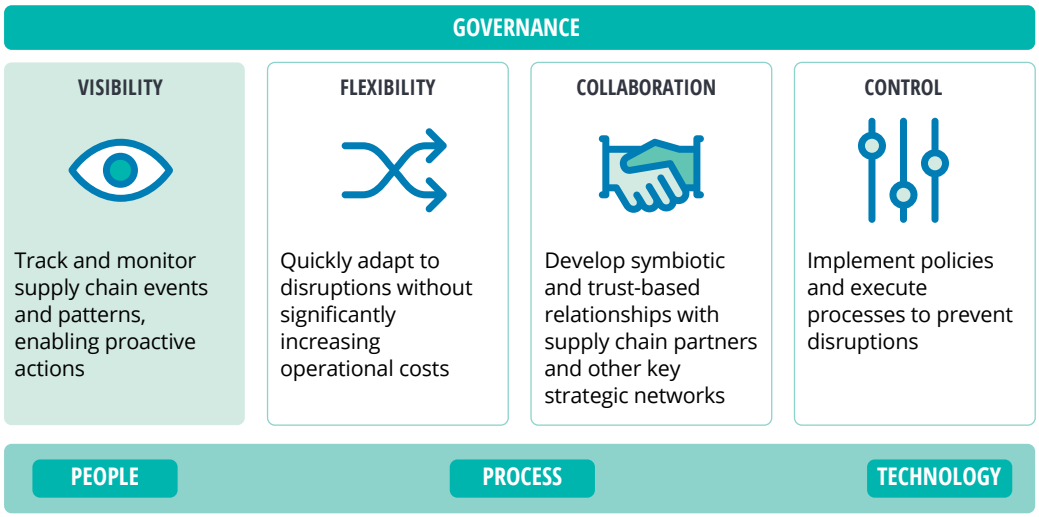
Supply chain resilience requires an intelligent risk-based approach to help biopharma 'Respond' to COVID-19

Managing risks has always been an important part of supply chain management. Having alternate supply arrangements reduces potential disruption, while ensuring adequate stockpiles provides a buffer against temporary turbulence.[94] However, the increasing complexity and hyper-connectedness of today's global business environment has taken the challenge to a whole new level. While eliminating all risk is impossible, a resilient supply chain using an AI-powered risk management strategy can help biopharma companies identify and sidestep risks that are avoidable – and bounce back quickly from those that are not.

Although COVID-19 is putting biopharma's complicated global supply chain under strain, the impact remains unclear. One reason is a difficulty in acquiring information. As the pandemic continues to evolve, companies are attempting to respond and create agile, resilient businesses capable of maintaining ethical, trustworthy and compliant operations. In addition, the role of governance, risk and compliance is increasingly important. The need for transparency and end-to-end visibility is particularly important, as highlighted in Deloitte's risk management framework based around the pillars of a resilient supply chain (figure 9).[95]

FIGURE 9

Risk management and the four pillars of a resilient supply chain



Source: Deloitte LLP.

Moving a product from supplier to customer requires a chain of extensive coordination and collaboration.[96] Therefore, companies should critically evaluate their risks using the above pillars in order to extract value and create or maintain a competitive advantage in the marketplace.[97] A crucial change arising as a result of the current pandemic has been an increase in collaboration and cooperation between biopharma companies.

Deloitte's April 2020 report, *COVID-19: Orchestrating the recovery of organisations and supply chains*, emphasises that recovery from the COVID-19 pandemic will require unprecedented coordination and collaboration across organisations, markets and the economy at large. It identifies three time frames: 'Respond' – dealing with the present situation and managing continuity; 'Recover' – in which companies learn and emerge stronger; and 'Thrive' – where the company prepares for and shapes the 'next normal'. Leaders must be agile, consider all three time frames concurrently and allocate resources accordingly. Given the complexity of the pandemic, there is every reason to expect that the recovery phase for COVID-19 will involve what is likely to be a challenging and protracted period. Planning for this recovery now will pay dividends as the business environment rebounds. This will in turn set the foundation for companies to thrive after the pandemic is over.[98]

AI and digital technologies can play a critical role in helping biopharma to 'Recover' and 'Thrive'

The outbreak of COVID-19 has accelerated interest in innovation as part of the recovery plans of many companies, including a growing interest in the role of AI technologies to mitigate risks across the supply chain. Furthermore, across the world, robots and drones are being repurposed and deployed as part of the COVID-19 response. Robotics have a major role to play across the supply chain, from manufacturing to distribution, to delivering medical supplies to the most vulnerable.[99]

Robotics have a major role to play across the supply chain from manufacturing to distribution.

Intelligent risk sensing can help enhance the resiliency of a recovery programme. Digital risk-sensing solutions can provide locational intelligence on emerging risks (such as a secondary wave of outbreaks) in real-time. As supply chains restart and gradually work their way back to the 'new normal', there will be challenges. Proactive planning of potential risks, developing mitigation plans and making well-informed risk/reward trade-offs will help successful execution during the recovery period. When alarms are triggered indicating possible upsets to the plan, there is a need for a process to identify alternative actions. This process is most efficient when it uses scenario planning to compare, analyse and select the best alternative and present recommendations to decision-makers.[100]

Companies that have developed and implemented supply chain risk management digital transformation strategies alongside business continuity strategies will likely be better prepared to mitigate the impact of disruptions like COVID-19 and continue to thrive. One likely approach is supply chain diversification, from a geographic perspective, to:

- reduce the supply-side risks from any one country or region
- reduce reliance on individual suppliers
- have an inventory strategy to buffer against supply chain disruption.

Vetting potential third-party relationships is also important to mitigate risk. In addition, investing in supply chain planning and control tower solutions can help better sense and respond to – and even predict – risk. As discussed in Part 2, control towers enabled by AI, ML and advanced analytics can provide real-time data visibility, proactive alerts, prescriptive insight and self-driving execution.[101]

Good practices are emerging, including new innovative approaches to business continuity, using advances in IT, advanced analytics and digital technologies. Capturing, sharing and learning from these good practices will be crucial in consolidating the recovery and ensuring the industry can thrive. By working together across the business, stakeholders can design a strategy to increase value across the supply chain. Companies that succeed can both protect their brands and drive business growth. AI-enabled business processes can help companies respond, recover and thrive more effectively to current and future disruptions.

A roadmap for implementing an intelligent supply chain

Over the next few years, AI tools applied to the different steps in the supply chain will transform the operating models of the bio-pharma industry with significant potential for improving business outcomes. However, full digitalisation takes time and strategic thinking and involves a fundamental shift from linear supply chains to dynamic, interconnected and open digital supply networks.

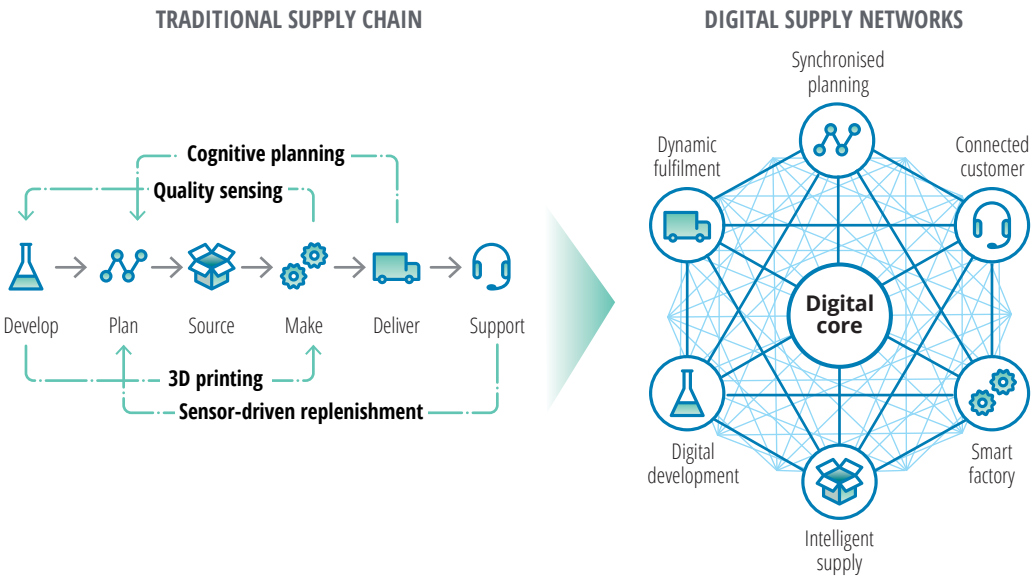
NEW SUPPLY CHAIN technologies are emerging that dramatically improve supply chain management. Leveraging advanced technologies, such as AI, cloud computing, intelligent automation, predictive analytics and sensors, can enable biopharma companies to anticipate risks and mitigate disruptions.[102] As companies continue to respond to the COVID-19 pandemic, we expect to see an acceleration in the adoption of these advanced technologies.

Primary research shows that three of the biggest challenges facing the global supply chain sector across industries remain: coordinating operations across multiple silos, managing inventory, and increasing visibility.[103] DSNs are well placed to address these challenges. A DSN integrates data and information from different sources and locations by leveraging advanced digital technologies, and enables greater product visibility, traceability and inventory control. In addition, a DSN can ensure the market receives the right products, manufactured to a high quality and in target volumes, and delivered at the right time to the right customers.[104] An important operational goal of a DSN is to improve transparency and trust in the security of valuable production and financial data.[105]

Companies need to tailor DSNs to meet their own specific needs by managing numerous moving parts, people, processes and creating an enabling IT infrastructure. A DSN can help optimise inventories and operations and improve cost-effectiveness. Such networks can also help fulfil regulators' requests, improve customer satisfaction and speed up innovation. However, digital transformation can be a complex and resource-intensive undertaking that fundamentally changes the way business is done. While a traditional supply chain resembles a relatively inflexible, linear path that moves information along with raw products and finished goods from one end of the production system to the other, a DSN is a flexible, interconnected matrix that allows data and information to move non-linearly to maximise efficiency to meet changing consumer and market demands (figure 10).[106]

FIGURE 10

The evolution towards the Digital Supply Network: from linear to network thinking

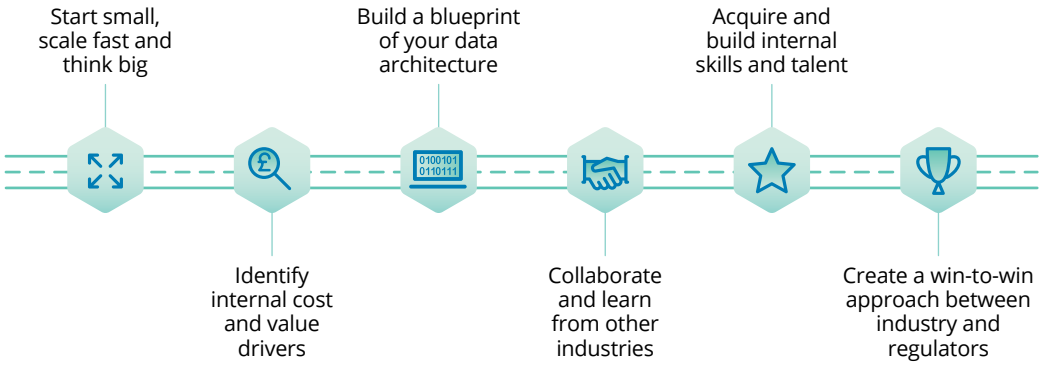


Source: Deloitte LLP.

Creating a DSN requires an understanding of the current inefficiencies, risks and silos of the supply chain; understanding the benefits of improving them with a DSN; and implementing a change management process. A DSN also needs to be part of a well-thought-out, long-term digital transformation strategy, aligned to the business strategy, together with a flexible organisational structure capable of adapting quickly to changes. The following AI technology roadmap can support biopharma in successfully developing a digital transformation strategy (figure 11).

FIGURE 11

A roadmap to support digital transformation of the biopharma supply chain



Source: Deloitte analysis.

A biopharma roadmap for AI implementation across the DSN

START SMALL, SCALE FAST AND THINK BIG

To reduce the risks associated with integrating new digital technologies and platforms, the approach of manufacturers across industries is to start with pilot projects and evaluate the use of data and achievements before scaling up. This involves three stages:

- **Start small** – In order to quickly demonstrate the value of AI-enabled solutions, companies should identify and prioritise small proof of value pilot projects to achieve quick wins that help build confidence and buy-in. However, there is also a need for executive level commitments to: adopt the selected technology; identify success criteria for the proof of value; and agree on an approach for future expansion.

- **Scale fast** – Once a technology implementation has been proven to deliver a sufficient return on investment, companies should scale the project across the relevant parts of the supply chain. Agile methodologies can be leveraged to progress prioritised use cases. In parallel, companies should put in place strategies to find, train and retain skilled talent to nurture and manage rapidly evolving digital transformation solutions.

- **Think big** – Successful technology deployment needs to be focused on a value-driven approach for innovation and applied throughout the supply chain. There are significant benefits, both upstream and downstream, that companies can realise from end-to-end implementations and having data and information immediately available to all parts of the manufacturing network.[107] A 'Digital Foundry' approach, which uses a controlled environment to minimise the risk and reduce the barriers to DSN implementation can enhance decision-making, inject energy into converting ideas into actionable plans, increase efficiency and deliver measurable value.[108]

IDENTIFY INTERNAL COST AND VALUE DRIVERS

DSNs can help the life sciences sector deliver more value and lead to lower costs, higher efficiencies and better use of capacity across the traditional 'plan – source – make – deliver' supply chain operations framework. DSNs can also foster innovation, delivery and better product yield.[109] For example, research from the logistics provider CargoSense suggests that:

- 30 per cent of discarded pharmaceuticals can be attributed solely to logistics issues

- 25 per cent of vaccines reach their destination degraded due to incorrect shipping

- 20 per cent of temperature-sensitive products are damaged during transport due to a broken cold chain.[110]

As described previously, AI solutions are already available to improve visibility and cold chain transportation and can lead to a quicker and higher productivity gain in the logistics function. Drug manufacturers with a robust knowledge of their supply chain cost drivers in each function are better positioned when deciding which AI technology pilot projects should be prioritised – to mitigate value leakage, and to accelerate incremental value creation.

BUILD A BLUEPRINT OF YOUR DATA ARCHITECTURE

Traditional data architecture is complex and characterised by an inflexible technology stack with data stored across a wide range of dispersed technologies and functions. This makes it hard for organisations to quickly respond to changing market conditions. To accelerate speed to market and reduce costs, each company's data architecture needs to be scalable and agile. A streamlined data architecture allows more applications or new technological enhancements to be added as needed, and makes it easier to cohesively manage data stored in local repositories, cloud, data warehouses, data lakes, and on digital devices. It also enhances organisational ability to access analytical tools or unstructured data within those repositories.[111]

The most important consideration when planning the AI-enabled transformation of the supply chain and moving to an end-to-end digital process is smart and optimised data management (case study 5).

CASE STUDY 5 – HOW LANDING AI IS ACCELERATING QUALITY OF DATA MANAGEMENT IN MANUFACTURING

Founded in 2017, Silicon Valley–based Landing AI is an industrial AI company that provides enterprise-wide transformation programs and deployment-ready AI solutions with a focus on computer vision. They work with companies from cross industries to build AI-driven organisations.

The company currently has three business lines – AI software as a service (SaaS) Solutions, AI Transformation and the Visual Inspection Platform.

- **AI SaaS Solutions**: AI-powered products that automate legacy processes in complex industries and the company will initially focus on the manufacturing industry.[112]
- **AI Transformation**: Through this line of business, Landing AI provides expertise in AI business strategy, AI technologies/applications, and AI talent acquisition and training.[113]
- **The Visual Inspection Platform**: An end-to-end platform that enables organisations to create, deploy and scale automated software solutions that automatically detect and classify defects in objects on a manufacturing line for quality inspection. Landing AI's visual inspection platform is able to reduce the overall AI project development time by up to 67 per cent and speed up the labelling process by as much as 50 per cent.[114]

There are different layers of data produced at every level of the supply process, from planning, sourcing, manufacturing and distribution (figure 12). A three-step approach to enable the use of these data into a DSN includes:

- Liberating the power of data by mapping the sources of each data set throughout the network and identifying at which level the data set produced by the different sources should be stored.
- Enabling data accessibility through open application programming interfaces.
- Improving interoperability to establish connectivity and secure communication of data between multiple and often disparate platforms.

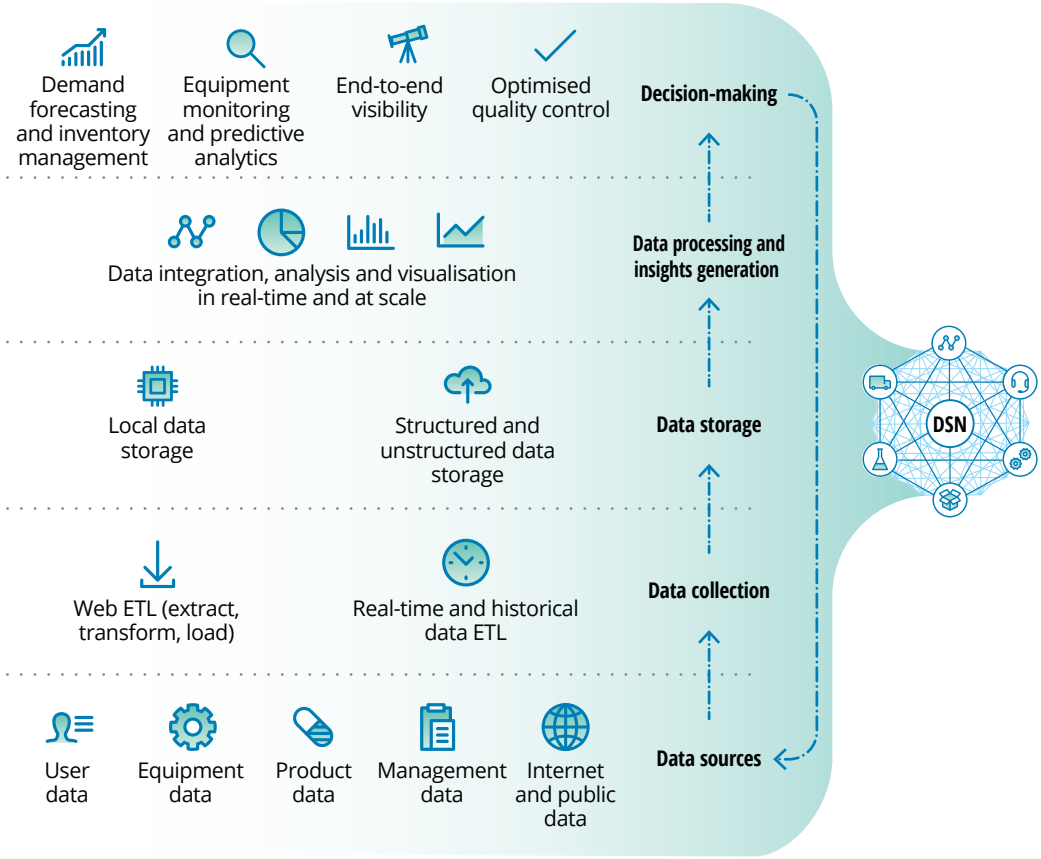
A robust IT infrastructure is crucial. However, currently, inadequate IT infrastructures and a lack of interoperability standards present common and significant barriers to the implementation of biopharma DSNs.[115] More specifically, a significant hurdle in implementing AI-enabled DSNs is ensuring connectivity, interoperability, and stability of legacy assets and new systems. Overcoming these challenges can increase asset connectivity and begin to generate vast amounts of digital information. Such information is often siloed. However, AI tools can help connect these data silos, while ensuring data privacy. An example of a company helping organisations deploying AI to use data from multiple systems is Eder.io. This company is developing solutions that combine federated learning (a distributed ML tool) and confidential computing (a concept that enables encrypted data to be used without exposure risk).[116]

Cloud computing is a key enabler in helping to bridge the whole data ecosystem across multiple parties in a DSN. Tech giants, including Google, Microsoft and Amazon, are leading the way in providing access to cloud computing and AI technologies and platforms, transforming the way companies understand and use software. Their extensive experience with advanced technologies can help companies connect and transform their business operations by developing innovative data and analytics platforms, for example:

- Google Cloud Platform offers different solutions, including ML tools, to make manufacturing processes more efficient and flexible by integrating advanced technologies to collect and analyse data in real-time.[117]
- Microsoft Azure's AI platform technology can be used to develop advanced analytical models with built-in automated ML capabilities that may uncover insights by finding patterns and relationships in the operational datasets and be deployed across the cloud.[118]
- Amazon Web Service (AWS) has developed a customisable cloud-based solution that can help optimise manufacturing processing by harnessing the power of AI and other advanced technologies, while supporting GMP compliance.[119]

FIGURE 12

The different layers underpinning the data architecture



Source: Deloitte analysis.

COLLABORATE AND LEARN FROM OTHER INDUSTRIES

In the past three years, digital technology experts from other industries have established several collaborations focused on developing AI solutions for biopharma manufacturing.

For example, in 2019 Siemens and the National Institute for Bioprocessing Research and Training (NIBRT) started collaborating in a research project for data analytics to support biopharma manufacturing with AI to improve the understanding of manufacturing processes and the efficiency in drug production. The plan is to use the Siemens MindSphere platform to apply data-based analytics solutions to real manufacturing activities in order to identify potential improvements. This enables users to get more value from the wealth of data they generate by using advanced analytics to monitor, predict and control the manufacturing process.[120,121]

CASE STUDY 6 - GSK IS ACCELERATING TECHNOLOGY ADOPTION IN MANUFACTURING

GSK is embracing the fourth industrial revolution with a 'pharmaceutical factory of the future'. In 2016, GSK used the knowledge that other industries gained from using Industry 4.0 technologies and developed their own project in Stevenage, UK: the IIM Digitisation Lab. GSK recognised the immense opportunities presented by the 'world of digital' and built this unit to be used as a proof-of-concept facility to demonstrate what a 'data-based strategy' for manufacturing within the company could look like.[122]

To build the IIM Digitisation Lab, GSK reached out to different partners, including Siemens, as advanced models are still being developed for pharma. As game-changing technological innovations are transforming other industries, it is crucial to have a mechanism to rapidly assess how relevant advanced technologies can benefit the pharma business model. In this partnership, Siemens' role was key to help integrate data acquisition and use, as well as workflow execution, including elimination of paper records.[123]

This state-of-the-art technology-embedded space can be used for training purposes, with a 'learn by doing' approach, where different workers and operators can simulate everyday manufacturing processes in an 'artificial and safe' environment.[124] GSK believes this is a faster and more effective training approach to decrease potential for errors and that it can potentially revolutionise the way the company approaches learning in manufacturing. The work currently being developed in this 'smart space' could eventually lead to an entirely digitised and virtual strategy to design and develop new drugs.

Case study 6 shows how one company, GlaxoSmith-Kline PLC (GSK), is collaborating with Siemens to use intelligent automation solutions to automate their manufacturing functions.

In addition to collaborating with other industries, biopharma can learn from other sectors by acquiring their expertise and adopting their models. For example, o9 solutions, a company using an AI platform for integrated planning and operations management, has worked with a number of other industries, including health care (case study 7), and is now beginning to apply their proposition to the biopharma industry.[125]

CASE STUDY 7 – o9 IS TRANSFORMING SUPPLY CHAINS WITH AI SOLUTIONS

o9 Solutions is a US-based decision management software company that has built an AI platform to power digital transformations of integrated planning and operations across a variety of global manufacturing and retail companies. o9's AI platform can help transform demand forecasting, commercial and supply chain planning, as well as Integrated Business Planning. It brings together graph modelling, big data analytics, advanced algorithms for demand forecasting, matching supply with demand, and scenario planning. It aligns digital engagement portals and easy-to-use interfaces for customers, suppliers, internal operations and cloud-based delivery on one platform.

The o9 platform is leveraging various ML algorithms to integrate business and operational planning and model the affect of demand and supply challenges across the complex supply chains of various industries. Demand modelling uses advanced forecasting techniques to take account of external demand drivers and events. Supply modelling considers disruptions in raw material, transport or products using ML algorithms that can detect patterns, identify risks and support predictive alerts in planning. o9's planning solution has been recognised by Gartner's Magic Quadrant as "the most visionary planning solution in 2019".[126]

As advanced technologies like AI, cloud computing and IoT convert data into a key asset, biopharma companies will be able to transform their manufacturing plant into smart factories, with as much emphasis given to collection and analysis of data as to the production of therapeutic compounds.[127] In addition, the interactivity between the 'digital' and 'physical' worlds will create an opportunity for companies to create digital twins, which can be used to digitally replicate virtually every product and manufacturing process.[128]

Data streams from supply chains can be aggregated and processed through high-performance analytics, creating digital scenarios to accurately predict outcomes to solve issues much faster. This technology will empower the industry by enabling companies to answer important strategic questions.[129] Consequently, companies will be able to implement digital transformation with a lower capital investment and shorter time to value, before venturing into the 'physical' world (case study 8). By leveraging the right technologies, companies should be able to shift from a reactive to a predictive mode and from fixed to flexible, to optimise dynamically their entire supply chain.

CASE STUDY 8 – SUPPLYCYCLE - USING DIGITAL TWINS TO DRIVE EFFICIENCIES AND REDUCE COSTS FOR MANUFACTURERS

Deloitte's SupplyCycle is an optimisation and simulation engine that helps manufacturers find better ways to balance their production and inventory. In order to understand the best way to meet the demand, SupplyCycle analyses entire product portfolios and builds digital twins of production lines to create a model to minimise the time spent changing between products. It then optimises costs involved in production and storage to determine the right production frequency for every single product.[130] SupplyCycle combines the frequency and sequencing recommendations to create an optimal production pattern. Moreover, it statistically optimises inventory by defining exactly how much stock should be held in each warehouse.[131]

In the final step of the simulation, SupplyCycle tests models against millions of possible permutations to validate findings and arrive at a new operational model. SupplyCycle has shown the potential to cut manufacturers' changeover times by up to 20 per cent and reduce inventories by up to 30 per cent.[132]

When one of the world's largest spirit companies wanted to make their complex production processes more efficient, they became the first to use SupplyCycle. It was implemented across five production lines and in under a year realised a working capital reduction of €1.81 million and additional savings of €210,000. More recent pilots were conducted with a global beer manufacturer and a manufacturer of homecare products. The former identified savings of €2.9 million and a working capital reduction opportunity of €700,000 across 10 production lines; the latter identified €1.1 million savings and a working capital reduction opportunity of €1.4 million across seven production lines.[133]

Technology will empower the industry by enabling companies to answer important strategic questions.

ACQUIRE AND BUILD THE RIGHT SKILLS AND TALENT

The adoption of AI technologies and implementation of DSNs will require major changes to roles and responsibilities within biopharma companies, including employing a more diverse workforce.[134] The next generation of biopharma talent will need to be agile, digitally literate and open to continuous learning as part of their career development. As technology and capabilities evolve, biopharma employees will need to balance the pursuit of new skills with the application of their current skill sets. Deloitte research found that the biggest issue most companies across industries need to overcome to implement DSNs and use AI effectively is finding and training the right employees.[135]

For drug manufacturers that want to move into an end-to-end digital supply chain, hiring experts is a priority given that the lack of dedicated teams with established knowledge on AI design thinking approaches represent a significant weakness. For example, a growing number of biopharma companies are appointing chief digital officers, often hired from other industries, to coordinate their digital transformation programmes.[136] AI experts are also more likely to be able to combine data from the different departments of the supply chain networks, gaining value from the whole process and reducing facility-level data silos and the lack of clear data ownership and structure.[137]

Additionally, as therapeutics become progressively personalised and targeted at smaller patient segments, more expert skills will be required. As a result, contract development and manufacturing organisations (CDMOs) are responding rapidly and effectively to meet the changing needs of biopharma companies.[138] CDMOs represent an interesting opportunity for biopharma companies to access state-of-the-art technologies and skills. This will enable biopharma to integrate AI and digital technologies into the value chain at a lower risk and respond to the changing patient requirements and market needs.

CREATE A WIN-TO-WIN APPROACH BETWEEN INDUSTRY AND REGULATORS

The regulatory environment continues to increase in complexity. These include the emergence of new regulations together with an increase in the pace and scale of changes to existing ones. A failure to comply can damage a company's reputation and have important legal and financial consequences. Today, COVID-19 is proving to be a catalyst for a more facilitative regulatory action, carefully balancing the need for speed to market with the patient safety imperatives.

Regulators are fostering innovation using accelerators (partnerships with academic institutions, industry and other experts) and 'sandboxes' (controlled environments that allow innovators to test products, services or new business models without having to follow all the standard regulations).[139] Meanwhile, biopharma companies see their own regulatory functions as a strategic asset and are streamlining their systems and clinical, quality and regulatory processes to eliminate functional silos and improve compliance efficiency across the product development life cycle and DSN ecosystems. They are also connecting compliance functions and processes across global sites, suppliers, contract manufacturers and other partners, and leveraging cloud technology to drive greater efficiency and visibility across quality processes.[140]

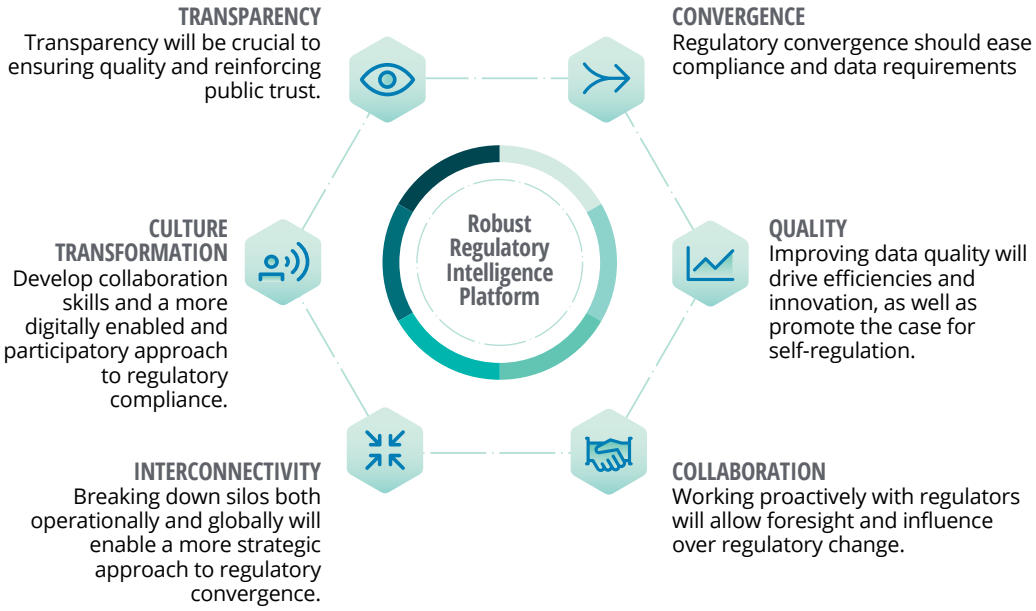
AI and other technologies that enable end-to-end supply chain visibility will ultimately lead to reduced risks in relation to complex biopharma manufacturing compliance. The adopting of automation and data management is also supporting biopharma in developing skills to enable them to collaborate more effectively with regulators to ensure compliance.[141] Figure 13 illustrates how a strong foundation for regulatory compliance can drive efficiencies, quality and improve the reputation of the industry.

The future of AI-enabled supply chains

We believe the life sciences sector is ripe for change and adoption of AI. Early adopters of these advanced technologies to improve their efficiency and visibility across the supply chain will have a competitive advantage over those who wait. The industry needs to move from just producing large amounts of data to generating actionable insights from that data. Biopharma companies should embrace advanced digital solutions and unlock their potential if they want to meet future market demands for more precise, personalised therapeutics. We expect the shift from a traditional linear supply chain to an AI-enabled interconnected DSN, together with radically interoperable data, can provide a foundation for companies to compete in the future. We also expect the biopharma industry's response to COVID-19 to accelerate at an unparalleled rate and scale the digital transformation of the supply chain.

FIGURE 13

How having a robust regulatory intelligence platform can improve the efficiency and cost-effectiveness of compliance



Source: Deloitte LLP.

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Acknowledgements

The authors would like to thank the following Deloitte colleagues who helped with the report: Pratik Avhad, Nishant Sinha, Aakash Deep, Lieven Comeyne, Niraj Dalmia, Shanil Ebrahim, Luciano Lo Tito, Christopher Michael Brooks, Marc Verpaele, and Alex Steinberg.

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