Deloitte.
Insights

# Intelligent post-launch patient support

## Enhancing patient safety with AI

Deloitte Centre *for*
Health Solutions

# About the Deloitte Centre for Health Solutions

The Deloitte Centre for Health Solutions (CfHS) is the research arm of Deloitte's Life Sciences and Health Care practices. We combine creative thinking, robust research and our industry experience to develop evidence-based perspectives on some of the biggest and most challenging issues to help our clients transform themselves and, importantly, benefit the patient. At a pivotal and challenging time for the industry, we use our research to encourage collaboration across all stakeholders, from pharmaceuticals and medical innovation, health care management and reform, to the patient and health care consumer.

## Connect

To learn more about the CfHS and our research, please visit www.deloitte.co.uk/centreforhealthsolutions

## Subscribe

To receive upcoming thought leadership publications, events and blogs from the UK Centre, please visit https://www.deloitte.co.uk/aem/centre-for-health-solutions.cfm

To subscribe to our blog, please visit https://blogs.deloitte.co.uk/health/

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

# Why patient safety strategies need to change

Ensuring the quality and safety of a medicinal product is both a moral and a regulatory requirement across the biopharmaceutical (biopharma) value chain. Pharmacovigilance (PV) is a crucial mechanism for providing evidence to the biopharma industry and regulators of the long-term safety profile of medicines. Meanwhile, patient support programmes (PSPs) help patients manage their medication and disease outcomes more effectively and, in certain circumstances, can improve equitable access and provide early safety signals.

A RISING INCIDENCE OF post-launch adverse event reports (AERs) and increasing expectation of more personalised, preventative, predictive and participatory (4P) medicine has coincided with advances in artificial intelligence (AI) technologies and data analytics. This conjunction increases the potential for post-launch strategies to increase safety, improve equity and enhance patient engagement and experience.

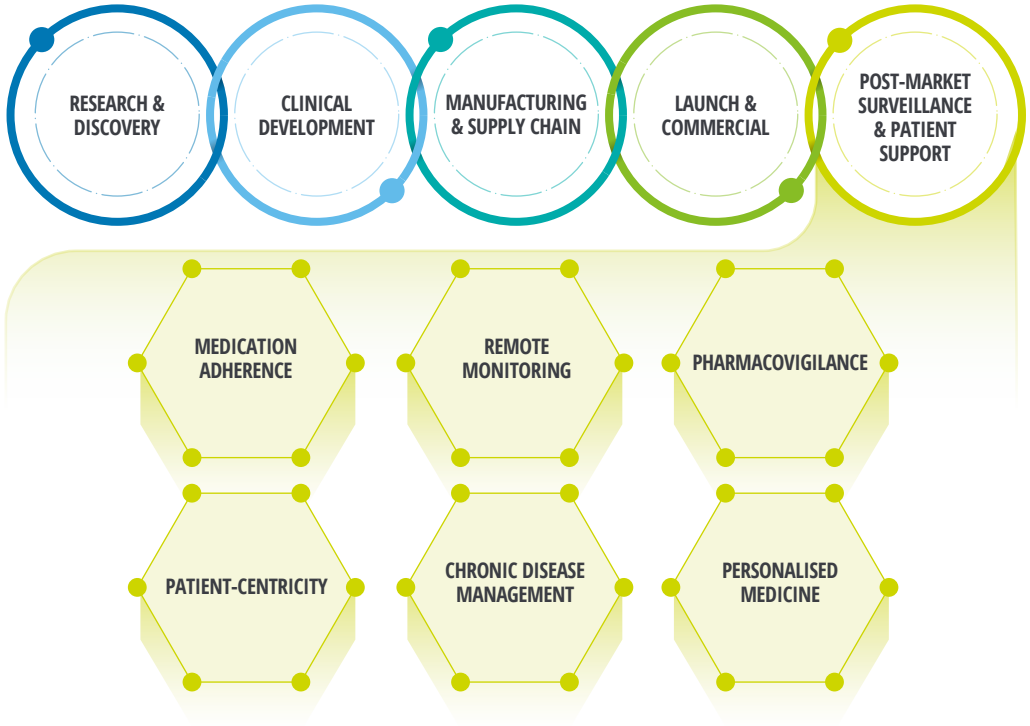
## Improving patient support is a critical step in the biopharma value chain

As we highlighted in our 2019 overview report, Intelligent biopharma: Forging the links across the value chain, the pace and scale of scientific innovation are improving patient engagement and experience, creating new business models and transforming the biopharma industry. We concluded that digital transformation, with advanced technologies such as AI, was the next logical step in the evolution of biopharma. This could enable innovation in new products and services and improve customer engagement and process efficiency.[1]

This is the sixth and final report in our series on the role of AI in driving biopharma's digital transformation. It explores the potential of AI to improve the last step in the value chain – specifically post-market PV and PSPs (figure 1). The overarching aim of the report is to explore how AI can improve patient outcomes by detecting real-time adverse events (AEs) more efficiently and effectively; and how it can be applied to interoperable health data, generated within PSPs to improve the remote monitoring of patients and deliver safer, more personalised and precise treatment options promptly.

FIGURE 1

**The biopharma value chain and its post-market surveillance and patient-support aspects**




Source: Deloitte analysis.

## Why pharmacovigilance needs to transform

PV is fundamental across the biopharma value chain but is particularly relevant in providing the mechanisms needed to monitor the safety and efficacy of medicines post-launch.
PV comprises a set of data-driven and process-orientated activities to detect and identify AEs and report these to regulators to optimise the benefit-risk ratio of health care products.

### DEFINITIONS

An AE (adverse event) is defined as "any response to a drug which is noxious and unintended, and which occurs at doses normally prescribed for the treatment of disease or the modifications of physiological function."[2] A serious AE is a life-threatening side effect that causes hospitalisation or prolongation of existing hospitalisation, results in persistent, significant disability or incapacity or causes the death of a patient.[3]

FIGURE 2

## Global health care trends impacting the pharmacovigilance (PV) landscape

The volume of adverse event cases is growing as disease complexity increases, and the substantial surge of global databases in recent years is causing the industry to be oversaturated with data:

- The growth in new product portfolios and therapy areas are creating more complex challenges for PV teams.
- New sources of information, for example, wearables and social media, are leading to availability of real-time data and potentially new PV obligations, requiring advanced analytics capabilities to drive value.

Increased regulatory scrutiny is continuing to drive the need for new PV capabilities as regulations evolve and are formalised in countries with less mature regulatory environments.

Regulators are ahead of the industry in evaluating and implementing processes and standards to explore real-world evidence sources for signals and safety information.

There are growing top-down organisational pressures to reduce PV costs.

Data science and automation are increasingly being used for signal detection and case management, focusing on risk/benefit analysis that requires advanced safety data analytics tools.

Patient-focused strategies and engagement throughout the health care continuum are leading to greater consumer activation and increased focus on patient centricity.

Stakeholders have raised expectations on how pharma engages with them and are more open to non-traditional channels for interactions.

Source: Deloitte analysis.

Biopharma's PV functions have a legal responsibility to collect, process and report details of AEs and other product safety information to regulators. Over recent decades, increased warnings and awareness about AEs, increasing requirements for better safety documentation and enhanced predrug approval reviews, have made drug safety a top priority for health care professionals (HCPs), patients and regulators.

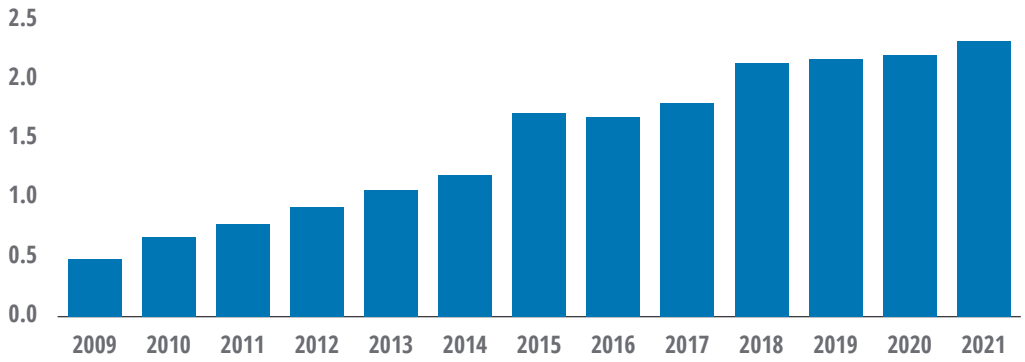
Most AE reports are self-reported by patients and HCPs to biopharma companies, who then pass them to the relevant regulator. Today AEs can be directly reported to regulators by HCPs and patients. However, handling individual case safety reports (ICSRs) requires significant resources across manual workflow models. Consequently, PV spending is predominantly allocated to case processing.[4] A number of global health care trends are affecting the PV landscape and reshaping the PV function (figure 2).

Given the above trends, the regulatory requirement to monitor AEs to ensure patient safety post-launch is becoming especially challenging, driven by the growing complexity of product portfolios, the higher volume and variety of products, and increased public awareness. For example, in 2021, over 2.2 million AERs were submitted to the US Food and Drug Administration (FDA) Adverse Event Reporting System, up from 500,000 in 2009 (figure 3).[5] Consequently, the global technology-enabled PV market is forecast to grow from $7.8 billion in 2022 to $17.36 billion in 2030, a compound annual growth rate of 10.5 per cent.[6]

FIGURE 3

**FDA adverse events reporting**

Total number of reports (million)




Source: FDA Adverse Events Reporting System Public Dashboard, 2022.

Despite the volume of ICSRs increasing year-on-year, it is estimated that more than 90 per cent of AEs go unreported.[7] As the increased availability of data sources, data and information on AEs continue to rise, new challenges are emerging, for example:

- social media is increasingly used as a platform to share personal health-related insights, however the terms used for medical concepts are often inconsistent and difficult to extract.[8] The heterogeneity adds difficulty to identifying a signal and defining a relationship between the drug and the expressed effect.

- connected medical devices, such as wearables, are increasing the volume of data that can be integrated into PV. This rise in real-time data from such sources requires mature processing systems with the capacity to perform advanced multimodal analysis to derive value.[9]

The obligation for biopharma companies to report AEs that arise from the unique patient insights and increased data being collected means many biopharma companies are adopting automation and advanced analytics to improve transparency across reporting methods and build trust in their PV systems. This includes creating next-generation digital learning systems that can increase the efficiency and cost-effectiveness of generating richer insights on product quality and patient safety.[10]

**As the increased availability of data sources, data and information on AEs continue to rise, new challenges are emerging.**

Over the past decade, many biopharma companies have adopted alternative delivery models to increase their PV capacity and efficiency, from full-scale redesign to outsourcing their PV collection and analytical functions (pharmacovigilance outsourcing – PVO). PVO can address talent shortages and knowledge gaps by providing access to customised automation and advanced tools from subject experts. PVO providers can also help biopharma companies navigate the increasing volume and complexity of regulatory requirements. Biopharma's increasing acceptance and adoption of PVO should stimulate market growth in the coming years and increase the adoption of PV and drug safety software to deliver cost-effective monitoring and reporting workflows, maintain safety data and minimise costs.[11]

## Why patient support programmes need to embrace 4P medicine

A PSP is a data collection system where the marketing authorisation holder (MAH) exchanges information about the use of its medicinal products with HCPs and patients. Traditional examples include post-authorisation patient support and disease management programmes, surveys of patients and HCPs, patient compliance data or compensation/reimbursement schemes.[12]

PSPs involve direct interaction with patients to help manage medication and disease outcomes (such as awareness and education, adherence and disease management). A PSP can also, where relevant, provide or arrange financial assistance for patients unable to afford the prescribed medication.[13]

Patients today have access to more information than ever, which can be empowering but also overwhelming. The volume of data makes it difficult for individuals to identify which sources are relevant and appropriate for their own condition or circumstances. However, PSPs can improve patient outcomes by providing personalised guidance on navigating health care services and an understanding of why treatment is needed. Moreover, emphasising supported self-management can improve disease progression tracking, patient knowledge and treatment adherence.

For many patients managing a chronic disease, the health system appears disjointed and siloed. Pharma companies increasingly see the standardisation and extension of PSPs as a top priority, especially if this can overcome the disjointed components of chronic disease management. PSPs can help to:

- increase the amount of data captured and, therefore, enhance patient safety by detecting AEs that would otherwise be undetected
- offer more personalised and preventative disease management services, especially where chronic conditions involve a wide range of HCPs and interventions (such as medical, lifestyle, social and pharmacological)
- improve therapy and treatment adherence and subsequent efficacy by enabling HCPs to modify disease progression via earlier intervention.[14]

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. A PSP that embraces the tenets of 4P medicine and educates, empowers, involves and reminds each patient, will improve medication adherence and disease prognosis.

The future success of a biopharma company will be dictated by its ability to improve long-term patient outcomes, including providing wrap-around services for innovative therapies. For example:

- 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 be a factor in treatment approvals and 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.[15]

While providing patients with PSPs is not new, the evolution of digital technology can increase equity of access and the potential value of PSPs. Moreover, growing evidence demonstrates the value of PSPs.[16] Digital approaches offer new opportunities to design and deliver PSPs in novel, impactful and cost-effective ways. The advent of automated health devices can reduce the need for patients to manually input data and help patients understand and manage their health more effectively through continuous monitoring. PSPs can be outsourced to access the operational expertise and technology required to continually scale as the amount of data increases.

## COVID-19 has raised the profile of biopharma's approach to and need for better patient support

The COVID-19 pandemic altered the way patients everywhere access and receive care. The use of direct-to-patient channels such as at-home disease monitoring, medicine home delivery services and telehealth grew dramatically, improving health equity by benefitting patients who are less mobile and/or live in more remote areas.

Importantly, the pandemic raised public awareness of the importance of biopharma innovation and drug safety. The roll-out of the vaccines and extensive media reporting of the benefits and side effects increased awareness of the PV monitoring and reporting processes. These advancements in PV have been facilitated through embracing changes in the role of people, processes and technology while maintaining the focus on quality and compliance. For example, the FDA received over one million COVID-19 vaccine AERs in the first year, and the European Medicines Agency (EMA) received a million AERs from the five vaccines used over the past two years (out of some 868 million doses).[17]

This increase in AERs has demanded innovative approaches to AE reporting and analysis. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) enhanced their Yellow Card Scheme using AI to enable the processing of high levels of self-reported AEs, deviating away from the stepwise process via the MAHs.[18] During the pandemic, biopharma companies were inundated with large volumes of reports, and in response, the industry quickly simplified PV reporting processes and widened access to patient reporting.

The industry was able to uphold compliance and safety through rapid implementation of new frameworks and technologies – bringing forward planned technology investments by as much as five years. Improved reporting processes, and more proactive public reporting of AEs have helped provide manufacturers and regulators with increased drug safety data. According to IQVIA, the number of AEs reported to the EMA increased by around 50 per cent in 2021 compared to 2020.[19]

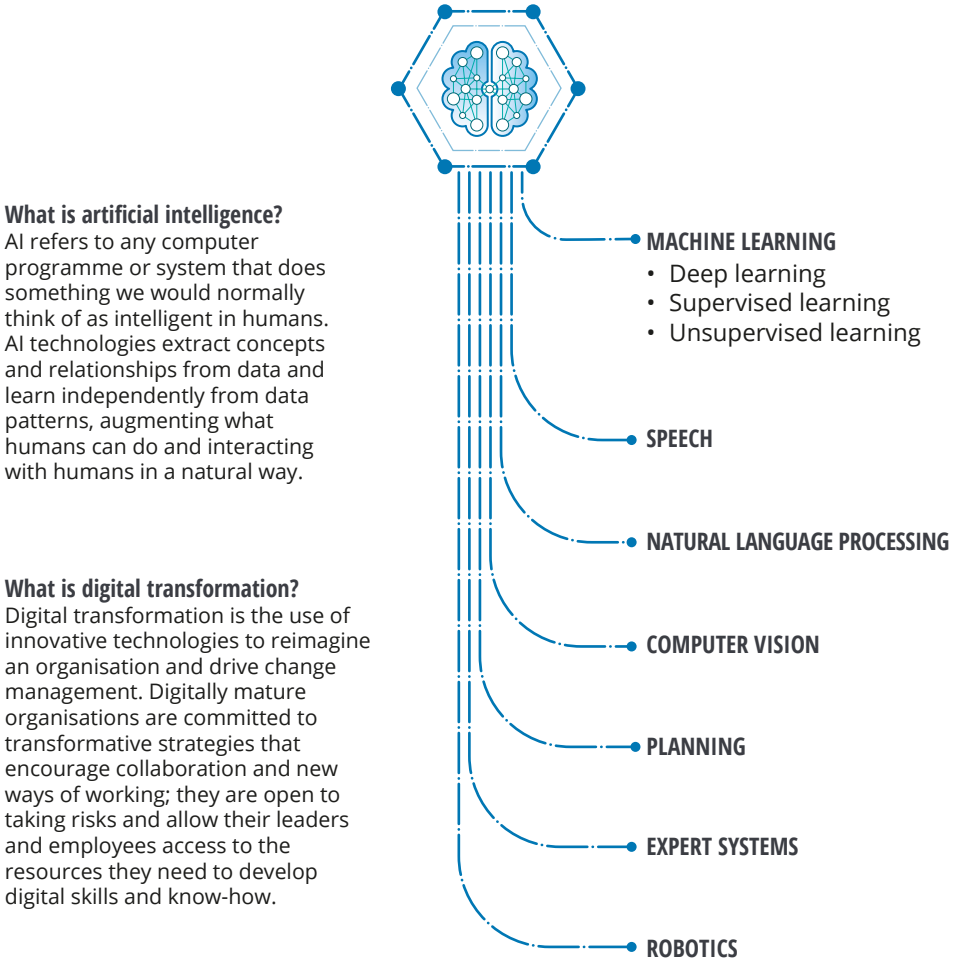
Surveillance, collaboration and standardisation have also been a priority. The WHO manual for COVID-19 vaccine safety surveillance aimed to standardise reporting of both AEs following immunisation (AEFI) and AEs of special interest (AESI).[20] While collaboration is improving the safety of patients across the globe, barriers to data sharing such as siloed infrastructure and interoperability challenges and lack of transparency still need to be addressed to gain the full benefits of these partnerships and collaborations.

## How AI can enable digital transformation of patient support services

The building blocks needed to successfully transform the digitalisation of PV and PSPs include supportive leadership and a culture of collaboration and experimentation. However, the main driver is the application of emerging technologies, including AI, blockchain and cloud computing, to improve workflow efficiencies and the capacity of insights derived from this data (figure 4).

FIGURE 4

**Artificial intelligence (AI) technologies can expedite digital transformation and help enhance the efficiency and effectiveness of pharmacovigilance and patient support programmes**




Source: Deloitte analysis.

When we published our overview report in November 2019, machine learning (ML) and deep learning (DL) were already at the core of most AI technologies used by biopharma. However, we concluded that for biopharma to thrive in a digitally transformed industry, companies would need to:

- increase the rate at which they can leverage their data
- modernise their IT infrastructure
- navigate the evolving regulatory landscape
- adopt a rules-based approach to data ethics
- respond to the impact of AI on the future of work.[21]

Over two years later, and with the hindsight of biopharma's response to COVID-19, companies that made significant digital investments before the pandemic are benefitting from their bold vision as digital transformation has accelerated every part of the life sciences value chain. The rest of this report examines how AI is transforming PV and PSPs and what the future might look like.

# How AI is improving pharmacovigilance

Biopharma companies can improve health outcomes by applying AI to health data to identify AEs. Applying advanced analytics to the ever-growing flow of real-world data (RWD) from various sources such as AERs, social media, PSPs and wearable apps can automate end-to-end post-launch PV and drive improvements in patient outcomes. This can also support the move towards increasingly personalised treatments, which will be crucial in improving patient safety, particularly detecting AEs or signalling potential AEs in real-time.

## Advanced digital technology will enable the end-to-end transformation of PV

The moment a new therapy enters the marketplace, its impact becomes more complex, requiring effective post-market surveillance. AE reporting is a critical and time-consuming part of ensuring the safe and effective use of medicines within the biopharma industry and is also a regulatory requirement. PV involves the collection, assessment and reporting of AEs, or single case processing and the continuous communication, interpretation and monitoring of product benefit-risk profiles to enable signal detection and benefit-risk management.

AI can help address both areas, including providing new opportunities for PV. For example, ML algorithms can be trained to extract and classify information from incoming AERs, using structured, semi-structured and unstructured data (figure 5). AI-extracted and classified information is then submitted to a drug safety specialist for review and confirmation or correction. This 'augmented intelligence' of AER processing serves as input for subsequent ML rounds, improving the algorithms over time, increasing consistency and reducing errors. These advancements have the potential to deliver a significant efficiency boost to the current PV operating model.[22]

FIGURE 5

## Integrating data from multiple formats


Source: Deloitte analysis.

AI provides a scalable and adaptable solution for handling the growing case volume and diverse types of incoming data formats effectively. NLP supports the end-to-end transformation of PV by enabling the analysis of multi-formatted AERs, including mass unstructured data littered with colloquialisms and non-technical terminology. The improved effectiveness and consistency of automated AE reporting allow better regulatory compliance by ensuring the timeliness and accuracy of submissions (case study 1).[23]

The increasing amount of data social media is generating can also be used to detect safety signals. However, colloquial terminology, including emoticons and duplicate reporting, such as parallel posting on multiple platforms, makes it challenging to mine social media data and extract meaningful health-related information.[24] AI tools can address this challenge (case study 2).

Another value-adding use case is applying NLP to datasets such as free text in social media, news articles and literature to detect unexpected benefits of a pharma product. This approach provides an opportunity for PV to improve patient care while contributing to the top-line revenues of a company.[25]

### CASE STUDY 1 – LINGUAMATICS NLP-BASED AI PLATFORM SUPPORTS MEDICAL CODING IN AE REPORT PROCESSING

PV workflows deliver vast volumes of reports from many sources, including call centre feeds, emails and regulatory AE reports. These generally require coding into a standardised format for processing using the Medical Dictionary for Regulatory Activities (MedDRA). Most of this coding is manual and time-consuming as only when the verbatim is an exact match with a MedDRA term is coding automatic.

A Linguamatics NLP-based AI platform delivers high-value knowledge discovery and decision support from free text reducing the burden of manual coding by traditional methods. The NLP platform offers flexibility, scalability and data transformation power to analyse unstructured data. The NLP solutions read the required documents to understand the many ways a single concept can be represented linguistically and then extracts the required information.

Linguamatics worked with CSL Behring to develop an NLP workflow that doubled the level of auto-coding of AEs from 30 per cent to over 60 per cent. The use of NLP reduced the manual time needed by 50 per cent, improved coding consistency and reduced risk for case processing and medical evaluation.[26]

### CASE STUDY 2 – SOCIAL MEDIA MONITORING FOR ADVERSE EVENT REPORTING THROUGH AI

In PV, monitoring social media as a source for potential AEs is challenging and costly due to the high volume of data and the need to extract meaningful, timely insights from text containing non-traditional written communication like acronyms, emojis, hashtags, images and slang. To counter these challenges, Novartis created an NLP model using Amazon SageMaker to analyse social media posts automatically and, based on the content and context, predict whether they contain reports of AEs.

AE Brain monitors social media channels for mentions of potential AEs, assesses them using sentiment analysis and flags messages of interest to human researchers for review. Sixty per cent of AEs are processed by AE Brain directly as a triage mechanism, enabling humans to focus on a smaller number of significant events of interest. Currently, AE Brain processes around 15,000 messages per week, capturing far more data than a human team could review, and increasing the overall quality of Novartis' drug monitoring.[27]

## Outsourcing provides an opportunity to improve safety reporting by using innovative, AI-enabled platforms

As the number of reports and varied data sources increases exponentially, the infrastructure to cope with the growth in large and diverse datasets will need to improve. Likewise, as health care providers continue to evolve from reactive to more proactive-preventive care, they are looking to digital transformation to provide actionable data.

The rising cost of PV tasks has led many companies to outsource these to specialist companies. This is especially important given the steady rise in PV cases. Regulators also require HCPs to report more incidents and encourage patients to share their AE stories via chat groups and social media. The intention is to provide industry bodies with more in-depth trends across treatment categories and patient populations.

Intelligent automation and predictive analytics can be deployed to capture and translate AE data from multiple channels. Using these integrated data sets to conduct deep analysis and identify critical signals will enable biopharma to transform their entire PV workflow to become more efficient and effective. The current generation of PV platforms augments the best data analytics tools with human science expertise. They also offer a variety of automation features, including front-end automation and NLP, making it possible to integrate data into safety databases with minimal human intervention required.

NLP and automation tools can identify relevant information to build clinically robust auto-narratives, eliminating-labour intensive data entry. AI and ML can increasingly identify patterns within structured and unstructured narratives, negating the need for routine reviews of single cases and manual identification and validation of signals.[28] Benefits include reducing errors related to manual data entry and anonymised data, reducing time and labour costs and increasing speed in delivering information. Consequently, several companies have developed innovative platforms, for example:

- EVERSANA™ pioneers the use of next-generation commercial services in the life sciences industry. In 2020, EVERSANA™ and ArisGlobal, a leading provider of life sciences software that automates drug development functions, announced a strategic partnership to digitally transform end-to-end PV services. This digital transformation of integrated compliance services utilises ArisGlobal's end-to-end, cloud-based LifeSphere® Safety Platform for clinical and commercial product safety management. It deploys intelligent automation and ML-enhanced AE case processing to provide real-time predictive intelligence to EVERSANA's PV services. This includes the ability to process and analyse safety data to predict key signals and risk factors confidently, identify safety issues and make recommendations for appropriate product utilisation that optimises patient outcomes.[29]

- Pfizer processed approximately 1.4 million AEs globally in 2019 alone and expects the volume of AEs across the industry to increase by 20 per cent. In order to keep up with the growing volume of cases, experts at Pfizer's Worldwide Safety programme partnered with industry experts to develop an innovative AI platform that can handle the more repetitive tasks of AE case report intake and processing and augment humans' decision making. This means PV professionals are able to focus on activities requiring more critical thinking and interventions. The tool currently focuses on the first part of AE case processing — the "intake" phase, where information is received from patients, doctors and others and sorting and identifying safety signals. In coming years, Pfizer hopes to implement an end-to-end tool that can help with case processing, following up with patients and regulatory reporting.[30]

## Optimising the use of voice data

Voice data is becoming ubiquitous and expanding the avenues for detecting previously unidentified AEs and safety insights. PV teams who utilise voice data effectively arm safety teams with the tools to secure patient well-being and increase compliance and product prospects. Biopharma companies can harness safety technology to remove as much as 60 per cent of the 'noise' from their safety risk identification workflow. Virtual agents can also enable coverage in multiple languages and monitor AE reports around-the-clock (case study 3).

### CASE STUDY 3 – IQVIA VIGILANCE DETECT, AN AI-POWERED VIRTUAL AGENT (CHATBOT), DETECTS AES BY MONITORING UNSTRUCTURED DATA

IQVIA seized the opportunity presented by the pandemic to implement AI technologies to support automated AE report intake and retrieval and used Robotic Processing Automation (RPA) bots to support automated case processing. IQVIA's Vigilance Detect (powered by AE Tracker®) uses cloud-based technology combined with advanced analytics, including AI and ML. It processes global regulatory intelligence, legal/ethical guidance, product quality information and safety data on an integrated platform to increase visibility across the compliance landscape.[31]

**Situation** – A biopharma client needed to monitor AEs generated through pharmaceutical sales representative call notes in its customer relationship management system to address the challenges faced by global drug safety professionals detecting AEs in user-entered notes.

**Solution** – Detect was used in a global system of an oncology brand to detect AEs for 12 months of sales representative call data. PV analysts validated the triggered AEs to identify client drug safety issues. The client employed the FDA-recommended random sample audit methodology to ensure the system was error-free.

**Outcome** – Of the 23,000 call notes, 109 records with AEs were identified, and the systems and processes deployed passed the quality audit with 100 per cent accuracy, successfully detecting all potential AEs.[32]

# How AI can transform PSPs

While biopharma companies have been providing PSPs for many years, the evolution of analytics, data and technology has increased the potential for these programmes to increase equitable access and improve patient engagement, experience and outcomes. AI can be used as part of a PSP to track and engage with patients remotely and intervene with personalised treatment options in a timely manner. Reliable, interactive and personalised PSPs can improve adherence to medication prescriptions and help manage complex and long-term conditions more effectively.

## How AI-enabled PSPs can aid self-management, optimise adherence, transform the patient experience and improve health outcomes

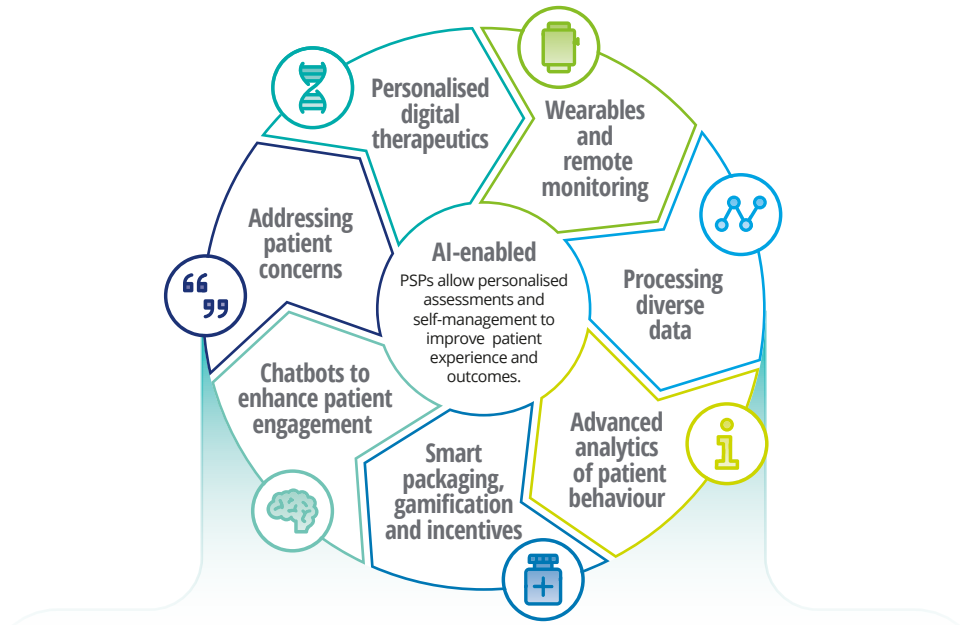
Pharma companies increasingly need to demonstrate value to payers beyond clinical efficacy. This is particularly true for next-generation cancer therapies involving a complex care regime emphasising quality of life and patient experience. Chronic diseases often have a long-term burden of care, and patients require information to self-manage. A well-designed PSP, enabled by digital technologies, can address these challenges and should include the criteria outlined in figure 6.

AI can help across many of the elements outlined, especially if underpinned by a cloud-based platform based on open data approaches that standardise core data to improve interoperability and allow seamless integration of sensor data and user applications. Moreover, as the industry pivots towards outcome-based reimbursement models, the importance of PSPs will continue to grow requiring flexible solutions that are scalable and adaptable with fast roll-out capabilities (case study 4). We have identified seven post-launch activities where AI-enabled PSPs can significantly influence patient outcomes (figure 6).

**AI can be used as part of a PSP to track and engage with patients remotely and intervene with personalised treatment options in a timely manner.**


FIGURE 6

## How AI can improve patient-support programmes and the key criteria for success




### Key criteria for success

**PERSONALISE**
the PSP to individual patient needs by agreeing on the needs and desired outcomes at the outset.

**COMMUNICATE**
using multiple channels to provide 24/7 support so patients receive relevant and easy to understand information in a convenient, simple and targeted way.

**OPTIMISE**
use of data from multiple channels by consolidating into a single patient record that is compliant across geographies.

**COMPLY**
with the regulations, regulatory standards and legal frameworks in each country.

**ENGAGE**
HCPs and other stakeholders in the value of the PSP and maintain enthusiasm through regular communications.

**CONNECT**
patients and their support network with providers and HCPs who will all need to be trained within the PSP.

Source: Anita Osborn, "10 steps to a successful patient support programme," Pharmaphorum, 25 February 2016; Deloitte analysis.

### CASE STUDY 4 – CONVERGEHEALTH CONNECT: REGIONAL PATIENT SUPPORT PROGRAMME

ConvergeHEALTH aims to help provide solutions to many challenges faced across the health care ecosystem by delivering personalised experiences at scale. It is a flexible platform that offers consistent engagement with patients across multiple channels and the care continuum, helping strengthen HCP-patient partnerships. It also enables adherence by educating, engaging and supporting patients and supports care coordination for each patient's care network.

**Situation** – A top global pharmaceutical company's digital health organisation wanted to provide a holistic solution based on patient-centric engagement to deliver an online platform for patients and HCPs to self-manage the services of access programmes.

**Solution** – The PSP core is used as a base for a multi-country roll-out (six countries), allowing for a flexible, scalable and extendable solution that delivers a rapid, agile delivery – from blueprint workshops to all functionality within seven months.

**Outcome** – The solution roll-out lead to many positive changes and results, including:

1. An elevated experience for patients and HCPs: Provided coordinated patient engagement across multiple channels to both patients and HCPs, enabling a 360-degree view to provide the experience of personalised care across the patient journey.
2. Enhanced patient engagement: Enabled a 50 per cent increase in patient interactions, helping educators and agents build sustained relationships with patients.
3. An optimised care team: Helped substantially decrease the care team's workload by enabling community portals where they could quickly access prioritised tasks and use automated workflows to replace manual processing.
4. Increased care network collaboration: Enabled an effective support care coordination across HCPs, providers, nurses and other care team members.[33]

## Wearables, apps and remote patient monitoring empower patients to self-manage

Remote patient monitoring (RPM) using wearables is crucial in empowering patients to self-manage their condition. The COVID-19 pandemic necessitated a shift in care delivery, rapidly accelerating the adoption of RPM solutions. While in-person visits provide a valuable touch point for patients, they are often episodic. In contrast, RPM continuously collects data and information on the progress of an individual's condition. This is particularly important when treating complex conditions sensitive to changes in medication.

Wearables are increasingly more patient orientated with improved battery life and capacity to remotely monitor health measures for extended periods, such as vital signs (oxygen saturation, blood pressure and blood glucose) and physical characteristics (activity levels, walking speed, step length and asymmetry).[34] Pharma's adoption of AI-enabled digital technologies alongside PSPs, means the wealth of objective and longitudinal data collected can be analysed quickly and processed to provide personalised health insights, facilitate increased patient engagement, anticipate deteriorating health and decrease the costs of care for patients and HCPs.[35]

### PROCESSING LARGE AND DIVERSE AMOUNTS OF HEALTH DATA

The application of AI to PSP-generated health data can be used to:

- detect and identify potential AEs proactively in real-time
- anticipate declines in health status and alert the HCP and patient, including identifying red flags early and prioritising those who may require emergency interventions, including hospitalisation
- monitor adherence to medication and predict risk ratios for non-adherence events to occur
- conduct remote interventions and rehabilitation, to enable patients to self-manage their conditions while reassuring them that their condition is being monitored continuously.

As the digital infrastructure and competencies mature, and RPM is used more widely in clinical trials, biopharma companies are uniquely positioned to increase RPM in the post-marketing space. The more data available to the AI algorithm, the more it can learn and improve its pattern recognition capabilities, generating more accurate predictions and improved analysis.

## Advanced analytics can help interpret, predict and optimise patient adherence behaviour

Medication adherence is critical in effective disease management, especially for chronic conditions. However, engaging patients to self-track their medication is challenging and often wanes over time, with approximately half of all patients not taking medication as prescribed.[36] A *British Medical Journal* review into the nature and prevalence of non-adherence reported that four per cent of hospital admissions were caused by medication non-adherence. Almost all of those were considered preventable.[37] Higher adherence rates may also aid biopharma by reducing waste and increasing the percentage of medication used.

**DEFINITION**

There are many causes of non-adherence, but they fall into two overlapping categories, intentional and unintentional.

**Intentional non-adherence** occurs when the patient decides not to follow the treatment recommendations.

**Unintentional non-adherence** occurs when the patient wants to comply but is prevented from doing so by barriers beyond their control, including financial and physical constraints, and difficulties in understanding instructions.

Tailored solutions are needed to overcome the complex and varied barriers to medication adherence. The role of the HCP and PSPs is critical in providing equitable access to information to help patients make decisions in accordance with legal and professional codes of conduct.[38]

Pharma can deploy AI across a population of PSP participants to predict patients at higher risk of non-adherence. Factors such as age, costs, employment status, ethnicity, gender, medical history and prognosis, postcode and the complexity of the dosage regimen all influence the likelihood of a patient's adherence to their prescribed regimen.[39] If a patient is identified as having a high risk of non-adherence, they can be targeted for proactive, tailored prophylactic interventions (case study 5).

### CASE STUDY 5 – ALLAZOHEALTH'S AI-OPTIMISED PSP DRIVES MEDICATION ADHERENCE

New York based AllazoHealth is a health care technology company that uses the power of AI to optimise patient outcomes. AllazoHealth's AI platform can predict a patient's adherence risk at a given time for multiple behaviours and accurately forecast how much a specific intervention would change the risk of non-adherence.

One pharma client faced the challenge that an estimated 50 per cent of patients stopped taking their medication within the first 30 days of treatment. AllazoHealth helped patients within the first 30 days of treatment through a customised, multi-channel programme designed to increase patients' days on therapy and help them stay on track with their medication. These patients adhered to the treatment for 4.6 times longer than patients that had not been supported by the AI platform. Additionally, emails powered by AI were 4.5 times more effective than randomly assigned targeting, resulting in increased engagement in the PSP.[40]

## Smart packaging, gamification and incentives for improved adherence

Digital technologies provide an opportunity to build more equitable PSPs that reach new patient demographics and provide clinically relevant interventions. To optimise this opportunity, the design process needs to build on data and patient profiles from the target population and apply behavioural design concepts, processes and techniques, including:

- BEHAVIOURAL ECONOMICS: People do not always make decisions in their best interest. Yet, traditional interventions for influencing behaviour often fail because they assume people make rational decisions. Applying behavioural economic theory provides tools to understand and influence behaviours.

- GAMIFICATION: Often chronic disease treatments lack instant results. Consequently, an immediate gamified reward can encourage patients to take their medication as prescribed and improve the management of their condition. The positive reinforcement of using gamification can help adherence to medication become a habit.[41] Although there is a growing body of evidence that demonstrates gamification can have a positive impact on adherence and health, several studies also report a mixed or neutral effect.[42]

- MOTIVATIONAL DESIGN: Builds on gamification techniques to enable the design of experiences that support the user's psychological needs. The user-centred design process seeks to understand the motivational dimensions of a user's personality and aims to make positive changes to these characteristics. For example, AI can recognise patterns that indicate the patient's gaming style and preferred reward types. It can also identify when patients begin to disengage and can recalibrate the person's gaming style or change the challenge to reignite their interest.[43]

Some of the digital technologies that biopharma can use to support patients remotely include:

- smart packaging such as pill dispensers giving the required dosage at a predefined time with corresponding audio and/or visual cues. To ensure accuracy, smart bottles can detect the opening of the cap with a sensor or measure the weight to monitor when a pill is removed[44]

- a wrist band sensor that can track the unique motion of removing a drug from packaging and consuming it[45]

- an ingestible biosensor embedded into medication that, when consumed, sends a signal to the patient's smartphone and HCP or family member.[46]

## Enhancing patient engagement through chatbots

Accelerated by the pandemic, chatbots are increasingly used as part of a PSP to answer questions relating to medication and side effects or simply for reassurance. Patients can create a personalised profile to enable chatbots to deliver a bespoke experience to help patients stay on track. Research shows that simplistic AI-powered technology interventions can be crucial in low medication adherence among more vulnerable and marginalised patient populations.[47] From answering questions relating to medication to addressing reasons for non-adherence, AI-enabled chatbots can provide personalised information to benefit the patient.[48] Examples include:

- the web and smartphone app, Clinikly.ai, which offers remote patient support through a virtual nurse, focusing on improving the adherence to the treatment of chronic conditions ranging from type 2 diabetes to HIV.[49] The 'Ask the Nurse' section employs NLP and advanced data analytics to instantly retrieve and interpret information, improving health management[50]

- the Sensley website and app enables RPM through an interactive nurse avatar, which can be enhanced with voice and text that is empath-driven and conversational in a language suited to the patient. The app can also link to internet-enabled devices to measure metrics such as weight or vital signs such as blood pressure.[51]

## Responding effectively to patient concerns and building trust

Patient outcomes can be impacted by a lack of trust or understanding of prescribed medications. PSPs should therefore be designed to cover a multitude of concerns, including emotional issues such as fear surrounding medications and the concern of side effects. Multicomponent interventions that include attitudinal, educational and technical aspects to modify and enhance patient medication-taking behaviour, integrated across PSPs, display the most promising results in maintaining long-term medication adherence.[52]

The Deloitte report in 2021, Overcoming biopharma's trust deficit, found that trust in biopharma companies is critical if companies are to gain and retain patients and improve health outcomes. Consumer trust also gives biopharma the incentive to innovate and invest in new life-saving therapies.[53] Deloitte found that participants in the research trusted HCPs (doctors' offices and physician groups) the most. In contrast, biopharma companies ranked near the bottom of the list of eight options.[54] Deloitte identified four trust-building signals:

1. humanity – addressing the perception that biopharma genuinely cares for patients' experience and wellbeing

2. transparency – through openly sharing information, motives and choices in plain, straightforward language

3. capability – creating high-quality products and service to meet expectations effectively

4. reliability – can consistently and dependably deliver high-quality products, services and experiences.[55]

AI-enabled PSPs provide a strong opportunity to improve patient trust in biopharma across these four signals and give patients an amplified desire to maintain compliance with their treatment if the benefits are properly articulated and understood by patients, caregivers, payers and HCPs. Moreover, the digital technologies that allow biopharma companies to design and build a tailored patient engagement experience are the same technologies that can drive better HCP engagement and education. Pharma companies need to involve HCPs in developing programmes and supporting assets to drive awareness and ensure that the solution meets the needs and expectations of all stakeholders.

# Delivering an AI-powered, safe, patient-centric future

The need for better patient engagement and experience is generating new business models. Over the next few years, patient-centric, co-created support services will make patients equal partners in decision-making and help biopharma companies deliver safer, more personalised health outcomes. An AI-supported PV system that enables patients to identify and report AEs directly and the rise of AI-powered patient-centred PSPs will transform biopharma's relationship with patients and deliver improved patient outcomes.


## The necessary steps to realise an AI-powered, patient-centric future

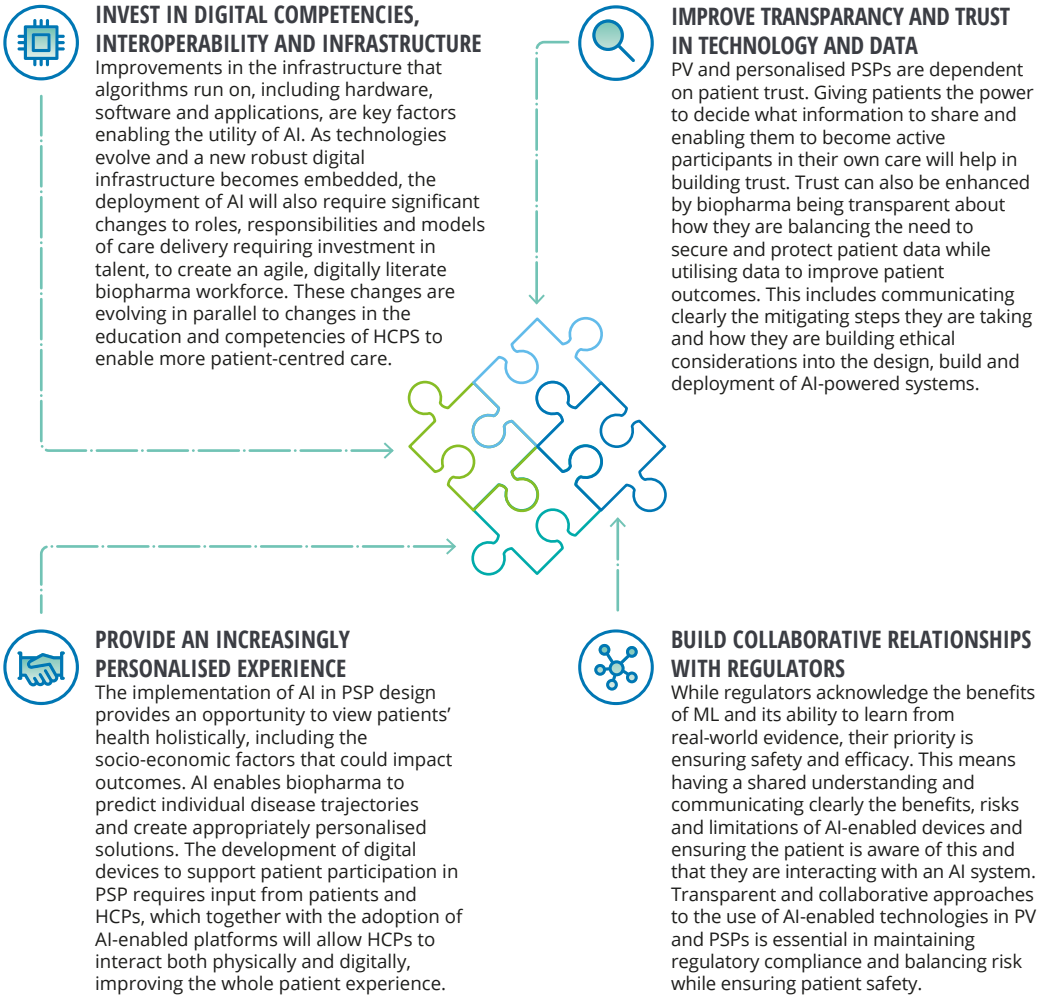
There are several challenges to realising the patient-centric future enabled by adopting AI-enabled PV and PSPs. Several steps must be taken to turn these challenges into opportunities (figure 7).

## Investing in digital competencies, infrastructure and interoperability

While AI models rely on data to train and learn, improvements in the infrastructure that algorithms run on, including applications, hardware and software, are key factors enabling the utility of AI.[56] In the future, data collected, processed and used in real-time by innovative medical devices will be biopharma's new 'currency.' As such, a key differentiator for companies will be how they can spend and earn this currency by generating insights and evidence from multiple, reliable data sources.

FIGURE 7

## Necessary steps to delivering an AI-powered future




Source: Deloitte analysis.

However, this will depend on investment in a robust digital infrastructure as AI cannot be imprinted onto an existing siloed digital system. Biopharma companies should prioritise developing the right technology assets to establish a cohesive and interconnected infrastructure with a high level of connectivity and interoperability that supports secure and transparent data exchange. Digital transformation will also impact business models, the development of new products and services, and transform how companies engage with HCPs, patients and other customers.

AI-powered post-market PV and PSPs have the potential to increase the connectivity, effectiveness, efficiency and resilience of the system.[57] The combination of predictive data analytics, improved infrastructure (such as 5G connectivity) and novel diagnostics will increasingly become more embedded and support a more preventative model with a focus on value (quality of care and outcomes), not the volume of care delivered. These changes will enable HCPs to offer more patient-centred care and spend more time communicating and providing compassionate care.[58]

The deployment of AI will also require significant changes to roles and responsibilities across the post-market PV value chain. Biopharma employees will need to develop new skills and talent and take into account the increasing volume of remote work. Many biopharma companies are consequently re-evaluating their workforce model. This trend could cause talent redistribution and create a need for up-skilling and capacity-building while helping employees stay responsive to changes. The next generation of biopharma PV and PSP talent will need to be agile, digitally literate and open to continuous learning as part of their career development.[59]

Moreover, to realise the benefits of AI, the skills and talent required by biopharma companies will need to include advanced analytical cognitive and digital skills, data scientists and software engineers who understand how to design a digital product and solution that meets patient needs. Therefore, there is a need for skilled interdisciplinary leaders to share learnings and support new business and operating models. The talent shortage needed to support digital transformation initiatives is one of the most significant barriers, so expanding and upskilling talent should be a top priority for the C-suite.

## Improving transparency and trust in technology and data

PV and personalised PSPs are dependent on trust. As patients become increasingly comfortable with virtual care and RPM through wearables and apps, their service expectations will increase. The ability to connect with their HCP on their terms and continuously share the information they choose will be increasingly important in empowering patients to become more active participants in their own care and support the shift to preventative approaches.

Biopharma's increasing access to personal data generated through PSPs comes with a greater responsibility to strike a balance between protecting individual privacy and utilising the data to improve patients' health and quality of life.[60] Companies who demonstrate active steps to protect patient data will gain a competitive advantage while empowering individuals to understand their own data. They are also likely to continue to build greater trust with patients. While a PSP alone cannot drive differentiation and increase trust and engagement, programmes that are well-designed, interactive and tailored to personal preferences, can.[61]

As biopharma embraces AI-powered digital transformation across the post-market ecosystem, the amount of patient data in the hands of these companies will exponentially increase. This data needs to be responsibly and securely handled across an integrated data network. This requires biopharma to include ethical considerations into the design, build and deployment of AI-powered systems. This also includes testing and remediating systems that unintentionally introduce bias and treat users unfairly.

**The combination of predictive data analytics, improved infrastructure (such as 5G connectivity) and novel diagnostics will become more embedded and support a more preventative model.**

## An increasingly personalised patient experience

Over the next few years, patient-centric, co-created experiences will evolve to make patients more equal partners in decision-making throughout their care pathway, helping biopharma deliver better, more personalised outcomes. However, genuine patient centricity means understanding the patient's lived experience of their condition – what the individual patient values and needs, and what is most likely to result in a positive health care outcome.[62] Implementing AI in PSP design provides an opportunity to view patients' health holistically. As biopharma companies capture each patient's unique clinical history, socioeconomic factors and previous experiences, they can create increasingly personalised solutions, providing a seamless delivery of 'what customers want, where they want it, and when they want it.'

AI provides the opportunity to predict, at a personal level, a patient's disease trajectory and recommend treatment or highlight the need for potential intervention while improving patient engagement. Research shows there is an expectation from society for this kind of approach, with 83 per cent of patients saying it is important that providers know them personally, beyond their health record.[63] This increased level of personalisation has been shown to improve patient engagement and outcomes and increase the level of trust between providers and patients.[64] Examples include Orion Health's AI Engage platform which provides personalised, relevant educational information for patients, encouraging them to actively contribute to their health management by sharing their health information and improving ease of access to their HCPs.[65]

Many aspects of drug delivery can be personalised in biopharma, from the tailoring of dose to its administration, including frequency. This can lead to better therapeutic outcomes and decreased AEs.[66] When combined with AI, a personalised drug delivery regimen can create an interactive open feedback loop between the patients' needs and the treatments. Twin Health has created a Whole-Body Digital Twin, a dynamic, digital, AI-enhanced representation of metabolic function derived from personal health data points. It monitors daily activities and personal adaptation.[67] Their Twin Service provides each user with personalised and precise activity, medication and sleep management guidance.[68]

The development of digital devices to support patient participation in a PSP should include input from end-users to assure ease of operability and their engagement in the shift from data entry to data quality assessment. Selecting outcomes that provide meaningful business values and achieving them in a specific timeframe will drive PSP professionals, HCPs and patients to adopt these AI capabilities. AI-enabled platforms allow HCPs to interact physically and digitally concurrently. Importantly empowering patients includes explaining how AI is used in jargon-free language and providing use-cases.

### CO-CREATION OF PATIENT SUPPORT PROGRAMMES

Engaging with patients from the beginning of the PSP development process can significantly improve outcomes. The National Institute for Health Research (NIHR) aims to bring patients and life science companies together earlier in the research and development processes to instil a culture of partnership between the biopharma industry organisations and patients, which can be expanded to the development of PSPs.[69] With greater transparency, biopharma has scope to go beyond co-design to co-creation, where patients are involved throughout development, testing and roll-out. Creating solutions that patients are invested in helps to build advocates for the PSP and ultimately scales a biopharma company's ability to make an impact through patient partnerships.[70]

**AI provides the opportunity to predict, at a personal level, a patient's disease trajectory and recommend treatment or highlight the need for potential intervention.**

## A more collaborative relationship with regulators

By collecting information on AEs and acting in response, regulators aim to protect the public from emerging safety issues throughout a treatment's life cycle. In January 2021, the FDA released the AI-based SAMD Action Plan.[71] The FDA acknowledges that one of the most significant benefits of AI/ML is its ability to learn from real-world use and experience to improve its performance. The FDA has declared its commitment to support a patient-centred approach and emphasised the need to be transparent about the functioning of AI-based devices to ensure users understand the device's benefits, limitations and risks.

Similarly, in April 2021, the European Commission published its proposal on AI Regulation, introducing a comprehensive, harmonised regulatory framework for AI with significant turnover-based financial sanctions. For life sciences, the AI Regulation is designed to complement and work alongside several existing legal frameworks, particularly the product safety/CE regime and data protection under GDPR. More specifically, the provider is expected to design the system to ensure:

- the individual is aware they are interacting with an AI system
- that if the AI system involves emotion recognition or biometric categorisation of individuals, the user must be informed that this is happening
- if the AI systems generated content has been artificially created or manipulated, it must be disclosed.[72]

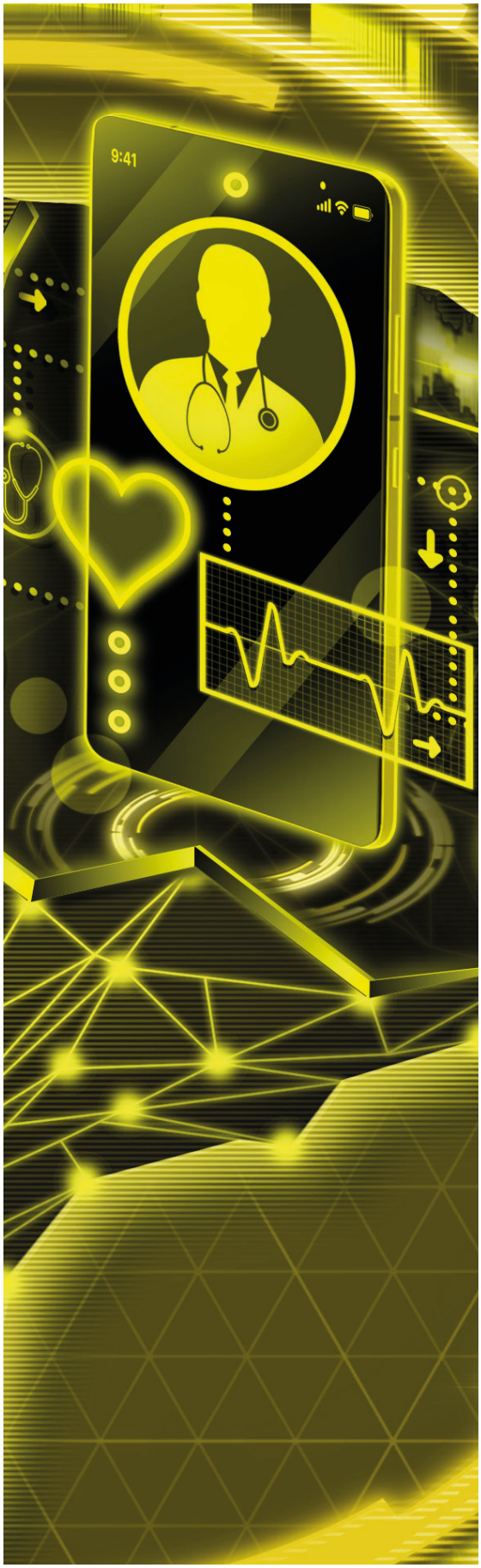
The application of RWD to create adaptive labels brings new opportunities and challenges to the regulatory relationship. Intelligent automation of pharmaceutical labelling can increase the speed and accuracy of labelling compliance as the complexity and expectations of labelling regulations continue to evolve. Between January 2017 and September 2019, 14.9 per cent of drug recalls by the FDA were due to labelling issues.[73]

In the future, AI will compare any number of countries' regulations simultaneously and adjust before noncompliance occurs, helping to ensure resilience against the ever-changing regulatory compliance landscape. This faster updating of new requirements and other label adaptations will enable critical information to be processed and relayed to patients quickly, increasing transparency between the industry and patients.

Transparent and collaborative communications between regulators and biopharma companies about the deployment of AI-enabled technologies in post-market surveillance and PSPs will be essential in maintaining regulatory compliances. Companies will need to report serious incidents and malfunctioning, taking appropriate measures or even withdrawing the AI system when it presents a risk to health, safety, human rights or a public interest. In addition, transparency is essential to ensure that the individual is aware of being exposed to an AI application. Nevertheless, new data-driven approaches will enable biopharma to work more collaboratively with regulators to balance risk and create new evidence frameworks for PV with blockchain-like technology used to verify the origin of data submissions.

## The future of post-launch patient support

Post-launch, biopharma companies will need interoperable health data to track and engage with patients remotely and intervene with personalised treatment options at the right time. This requires integrating and analysing patient data in real-time to determine when an intervention is needed. Applying AI to monitor the safety of patients will be critical, particularly in detecting potential AEs proactively and in real-time. Insights into RPM beyond safety will also be important, and compliance monitoring is an area many biopharma companies and start-ups are targeting. AI-enabled PSPs will transform biopharma's relationship with customers improving enrolment, adherence and retention, delivering improved patient outcomes.



# Endnotes


1. Karen Taylor et al., "Intelligent biopharma: Forging the links across the value chain," Deloitte, 3 October 2019.
2. World Health Organisation (WHO), *International drug monitoring: The role of national centres*, 1971.
3. European Medicines Agency (EMA), *Clinical safety data management: Definitions and standards for expedited reporting*, June 1995.
4. Deloitte, *Transforming pharmacovigilance: Using technology and analytics to enable next-generation patient safety*, 2019.
5. US Food and Drink Administration (FDA), "FDA Adverse Event Reporting System (FAERS) public dashboard," 22 October 2021.
6. Grand View Research, *Pharmacovigilance market size, share & trends analysis report by product life cycle, by service provider, by type, by process flow, by therapeutic area, by end-use, by region, and segment forecasts, 2022-2030*, January 2022.
7. Ruta Mockute et al., "Artificial intelligence within pharmacovigilance: A means to identify cognitive services and the framework for their validation," Pharmaceutical Medicine, 29 March 2019.
8. Azadeh Nikfarjam et al., "Pharmacovigilance from social media: mining adverse drug reaction mentions using sequence labeling with word embedding cluster features," Journal of the American Medical Informatics Association, 9 March 2015.
9. Ramya, "Artificial intelligence and pharmacovigilance," Pharmacovigilance, 12 October 2020.
10. Deloitte, *Transforming pharmacovigilance: Using technology and analytics to enable next-generation patient safety*.
11. Deloitte, *Pharmacovigilance (PV) outsourcing — Emerging PV business models*, 2014; Global Market Insights, *Pharmacovigilance market size by clinical trial phase (Preclinical, Phase I, Phase II, Phase III, Phase IV), by service Provider (in-house, contract outsourcing), COVID-19 impact analysis, regional outlook, competitive market share & forecast, 2021 – 2027*, October 2021.
12. The Association of the British Pharmaceutical Industry, *Guidance notes for patient safety and pharmacovigilance in patient support programmes*, accessed 19 May 2022; European Medicines Agency, *Workshop on Patient Support and Market Research Programmes*, accessed 19 May 2022.
13. Gilles Touraille, *Management of safety data from Patient Support Programmes (PSPs) and Market research Programmes (MRPs)*, European Medicines Agency (EMA), 6 June 2013.
14. Deloitte, *Patient support programmes: Driving competitive advantage and commercial success*, 2020.
15. Ibid.
16. Ibid.
17. Shyreen Kamal and Maria Paula Bautista Acelas, "Pharmacovigilance: Artificial intelligence and global regulatory changes during the pandemic," accessed 19 May 2022.
18. Medicines & Healthcare Products Regulatory (MHRA)," Coronavirus yellow card reporting site," accessed 19 May 2022.
19. Informa Pharma Intelligence, *In Vivo: Outlook 2022*, December 2021.
20. World Health Organization (WHO), "COVID-19 vaccines: safety surveillance manual," 22 December 2020.
21. Ibid.
22. Michael Levy, "How AI is transforming pharmacovigilance," Pharma Boardroom, 28 August 2019.
23. Ramya, "Artificial intelligence and pharmacovigilance."

24. Linguamatics, "About us," accessed 20 May 2022; Jane Reed, "Supporting non-clinical toxicology, clinical drug safety, and pharmacovigilance with text analytics," Linguamatics, 06 October 2021.
25. Nikfarjam et al., "Pharmacovigilance from social media: mining adverse drug reaction mentions using sequence labeling with word embedding cluster features"; Dimitra Pappa and Lampros Stergioulas, "Harnessing social media data for pharmacovigilance: a review of current state of the art, challenges and future directions," International Journal of Data Science and Analytics, 12 February 2019.
26. AWS and Fierce Biotech, *Rapid response to adverse event reports with cloud technology*, February 2021.
27. Ibid.
28. IQVIA, *Forget (almost) everything you know about pharmacovigilance: Are you ready for next-generation PV technology?*, 08 July 2019.
29. ArisGlobal, *Life science CIOs reduce runaway costs with innovative safety vigilance technology*, accessed 20 May 2022.
30. Pfizer, *"AI in drug safety: Building the elusive 'Loch Ness monster' of reporting tools," accessed 20 May 2022.*
31. Informa Pharma Intelligence, *In Vivo: Outlook 2022*.
32. IQVIA, *Vigilance detect case study brochure*, 22 June 2021.
33. Deloitte, "ConvergeHEALTH Connect—A patient engagement solution suite," accessed 20 June 2022.
34. Duarte Dias and João Paulo Silva Cunha, "Wearable health devices—Vital sign monitoring, systems and technologies," Sensors, 25 July 2018.
35. Benjamin Noah et al., "Impact of remote patient monitoring on clinical outcomes: an updated meta-analysis of randomized controlled trials," npj Digital Medicine, 15 January 2018.
36. Marie Brown and Jennifer Bussell, "Medication adherence: WHO cares?" Mayo Clinic Proceedings, April 2011.
37. Pajaree Mongkhon et al., *Hospital admissions associated with medication non-adherence: a systematic review of prospective observational studies*, BMJ Quality & Safety, 17 April 2018.
38. National Institute for Health and Care Excellence, "Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence," 28 January 2009.
39. Axtria, "The role AI is playing in healthcare patient adherence," accessed 23 May 2022.
40. AllazoHealth, "About AllazoHealth," accessed 23 May 2022; AllazoHealth, "AI-optimized pharma patient support program drives adherence," 03 March 2020.
41. Deloitte, *Boosting patient empowerment and motivational pull: Achieving the next level in a gamified health environment*, February 2016.
42. Daniel Johnson et al., "Gamification for health and wellbeing: A systematic review of the literature," National Library of Medicine, November 2016.
43. Rey Villar, "One-size-fits-all gamification is not enough to improve patient outcomes," Med-Tech News, 21 February 2020.
44. Juergen Morak et al., *Feasibility of mHealth and Near Field Communication technology based medication adherence monitoring*, National Library of Medicine, November 2012.
45. Taksa-on Putthaprasart et al., *Medicine Intake Detection Using a Wearable Wrist Device Accelerometer*, IPCSIT, accessed May 23, 2022.
46. Kourosh Kalantar-zadeh et al., *Ingestible Sensors*, ACS Publications, 01 March 2017; Wismer P, "Smart pill dispenser – a new tool for improving patient adherence," ONdrugDelivery, 20 June 2016.
47. Ahmed Fadhil, *A conversational interface to improve medication adherence: Towards AI support in patient's treatment*, arXiv, accessed 23 May 2022.
48. Ibid.

49. Clinickly.ai, "The ideal patient treatment companion," accessed 20 June 2022.
50. Ibid.
51. Sensely, "Solutions," accessed 23 May 2022.
52. Elyssa Wiecek et al., "Temporal effectiveness of interventions to improve medication adherence: A network meta-analysis," PLOS ONE, 12 March 2019.
53. Greg Reh et al., "Overcoming biopharma's trust deficit: Why people mistrust the biopharma industry—and what to do about it," Deloitte, 06 May 2021.
54. Ibid.
55. Ibid.
56. Karen Taylor et al., "Intelligent biopharma: Forging the links across the value chain."
57. Karolina Danysz et al., "Artificial intelligence and the future of the drug safety professional," Drug Safety – Springer Nature, 20 October 2018.
58. Eric Topol, *Preparing the healthcare workforce to deliver the digital future*, Health Education England, February 2019.
59. Karen Taylor et al., "Intelligent biopharma: Forging the links across the value chain."
60. S Denford et al., "Individualisation of drug treatments for patients with long-term conditions: a review of concepts," BMJ Journals, March 2014.
61. Peter Wallace et al., *Patient support programmes: Driving competitive advantage and commercial success*, Deloitte, 2020.
62. Karen Taylor, Mark Steedman and Amen Sanghera, *Pharma and the connected patient: How digital technology is enabling patient centricity*, Deloitte, accessed 23 May 2022.
63. Salesforce, *Connected healthcare consumer*, accessed 23 May 2022.
64. NHS England, "Making the case for a more personalised care approach," accessed 23 May 2022; Gov UK, *Information: To share or not to share? – The Information Governance Review*, March 2013.
65. Orion Health, "Orion Health: Engage," accessed 23 May 2022.
66. Abhishek Soni, Kuppusamy Gowthamarajan and Arun Radhakrishnan, *Personalized medicine and customized drug delivery systems: The new trend of drug delivery and disease management*, Int J Pharm Compd., April 2018.
67. Twin Health, "Cutting-edge technology. Advanced medical science. Compassionate care.," accessed 23 May 2022.
68. Ibid.
69. National Institute for Health and Care Research (NIHR), "Engage patients to help shape your clinical research," accessed 23 May 2022.
70. Emma Bishop, *Co-creating content with patients: a best practice guide for the life sciences industry*, Cognitant, September 2021.
71. US Food and Drug Administration (FDA), *Artificial intelligence/machine learning (AI/ML)-based software as a medical device (SaMD) action plan*, January 2021.
72. European Medicines Agency (EMA), *Pharmacovigilance*, accessed 23 May 2022.
73. Alex Livingston and T. Joseph Mattingly, "Drug and medical device product failures and the stability of the pharmaceutical supply chain," National Library of Medicine, January 2021.

# About the authors

**Karen Taylor | kartaylor@deloitte.co.uk**

Karen Taylor is the research director of the Deloitte UK Centre for Health Solutions. She supports the Life Sciences and Health Care and Public Sector Health practices by driving independent and objective business research and analysis into key industry challenges and associated solutions, generating evidence-based insights and points of view on issues from pharmaceuticals and technology innovation to health care management and reform. Karen also produces a weekly blog on topical issues facing the life sciences and health care industries.

**Emily May | elmay@deloitte.co.uk**

Emily May is an assistant manager in the Centre for Health Solutions, where she applies her background in both scientific research and pharmaceutical analytics to produce supported insights for the Life Sciences and Health Care practice. Emily leads the research and publication of the life sciences insights, performing thorough analysis to find solutions for the challenges impacting the industry and generating predictions for the future. Prior to joining the centre, Emily worked as an analytical scientist conducting physical chemistry analysis on early stage drug compounds and previously lived in Antwerp, Belgium, where she researched and developed water-based adhesive films.

**Dylan Powell | dspowell@deloitte.co.uk**

Dylan Powell is a research analyst at the Centre for Health Solutions. Prior to joining the centre, Dylan's professional background as a physiotherapist has spanned the NHS, professional sport and the armed forces. His doctoral work in computer science explores the use of wearables in remote monitoring and objective health care assessment with collaborators across the US and Australia. Dylan holds a Bachelor of Science degree in Human Biosciences from University of Exeter and a Master of Science degree in Physiotherapy.

**Hanno Ronte | hronte@deloitte.co.uk**

Hanno Ronte is a partner at Monitor Deloitte, our strategy consultancy business. He has more than 20 years of consulting experience primarily in the health care and life sciences sector. Hanno leads the Life Sciences and Health Care team in Monitor Deloitte and is responsible for building the 'Real World Evidence Capability' within that. His projects have focused on corporate and business unit strategy, competitive response, marketing strategy and capability building.

# Acknowledgements

The authors would like to thank the following Deloitte colleagues who helped with the report: **Pratik Avhad**, **Maria João Cruz**, **Pavithra Rallapalli**, **Sebastien Burnett**, **Ryan Hoffmeister**, **Andrew Gvozdanovic** and **Prateek Natani**.

# Contact us

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

**Hanno Ronte**
Partner | Life Sciences and Health Care | Deloitte North & South Europe
+44 (0) 20 7007 2540 | hronte@deloitte.co.uk

**James Gregson**
Partner | Head of Sourcing & Procurement UK | Deloitte North & South Europe
+44 (0) 20 7007 8866 | jgregson@deloitte.co.uk

**John Haughey**
Partner | Global LSHC Consulting Lead and UK LSHC Industry Lead | Deloitte North & South Europe
+44 (0) 20 7303 7472 | jhaughey@deloitte.co.uk

**Vicky Levy**
Partner | LSHC Industry Lead for Deloitte North & South Europe | Deloitte North & South Europe
+41 (0) 58 279 7877 | vilevy@deloitte.ch

Deloitte.
Insights

Sign up for Deloitte Insights updates at www.deloitte.com/insights.

Follow @DeloitteInsight

**Deloitte Insights contributors**
**Editorial:** Sara Sikora, Prodyut Ranjan Borah and Aditi Gupta
**Creative:** Mark Milward and Sapan Giri
**Promotion:** Maria Martin Cirujano
**Cover artwork:** Taylor Callery

**About Deloitte Insights**

Deloitte Insights publishes original articles, reports and periodicals that provide insights for businesses, the public sector and NGOs. Our goal is to draw upon research and experience from throughout our professional services organization, and that of coauthors in academia and business, to advance the conversation on a broad spectrum of topics of interest to executives and government leaders.

Deloitte Insights is an imprint of Deloitte Development LLC.

**About this publication**



**About Deloitte**

Deloitte provides audit, consulting, financial advisory, risk management, tax and related services to public and private clients spanning multiple industries. With a globally connected network of member firms in more than 150 countries and territories, Deloitte brings world class capabilities and high-quality service to clients, delivering the insights they need to address their most complex business challenges.



Responsible publisher: Deloitte University EMEA CVBA, with registered office at B-1831 Diegem, Berkenlaan 8b