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Insights

Intelligent clinical trials

Transforming through AI-enabled engagement

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.

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Why clinical trials must transform

The traditional 'linear and sequential' clinical trials process remains the accepted way to ensure the efficacy and safety of new medicines. However, suboptimal patient selection, recruitment and retention together with difficulties managing and monitoring patients effectively, are extending the length of trials and contributing to high trial failure rates. Artificial intelligence (AI) can improve clinical cycle times while reducing the cost and burden of clinical development. This report is the third in our series on the impact of AI on the biopharma value chain.

HEALTH CARE COSTS continue to rise as a percentage of every country's gross domestic product (GDP) causing governments and private payers to scrutinise rigorously the economic value of new treatments. Increasingly, regulators expect clinical trials to demonstrate not only efficacy and safety, but also a meaningful impact on the lives of patients. This is particularly the case for more precise, high-cost therapies that target smaller patient groups. The growing expectations of regulators and payers requires biopharma companies to increase the quality and quantity of evidence generated during clinical trials and, in turn, is increasing the complexity of clinical trial design and development.

Screening patients to identify potentially better responders and linking payments to individual outcomes are among measures that payers are negotiating with sponsors to ensure value for money. Demonstrating value also requires a change in the traditional methods of conducting clinical trials, most notably in the collection of real-world clinical and non-clinical data on costs and outcomes.
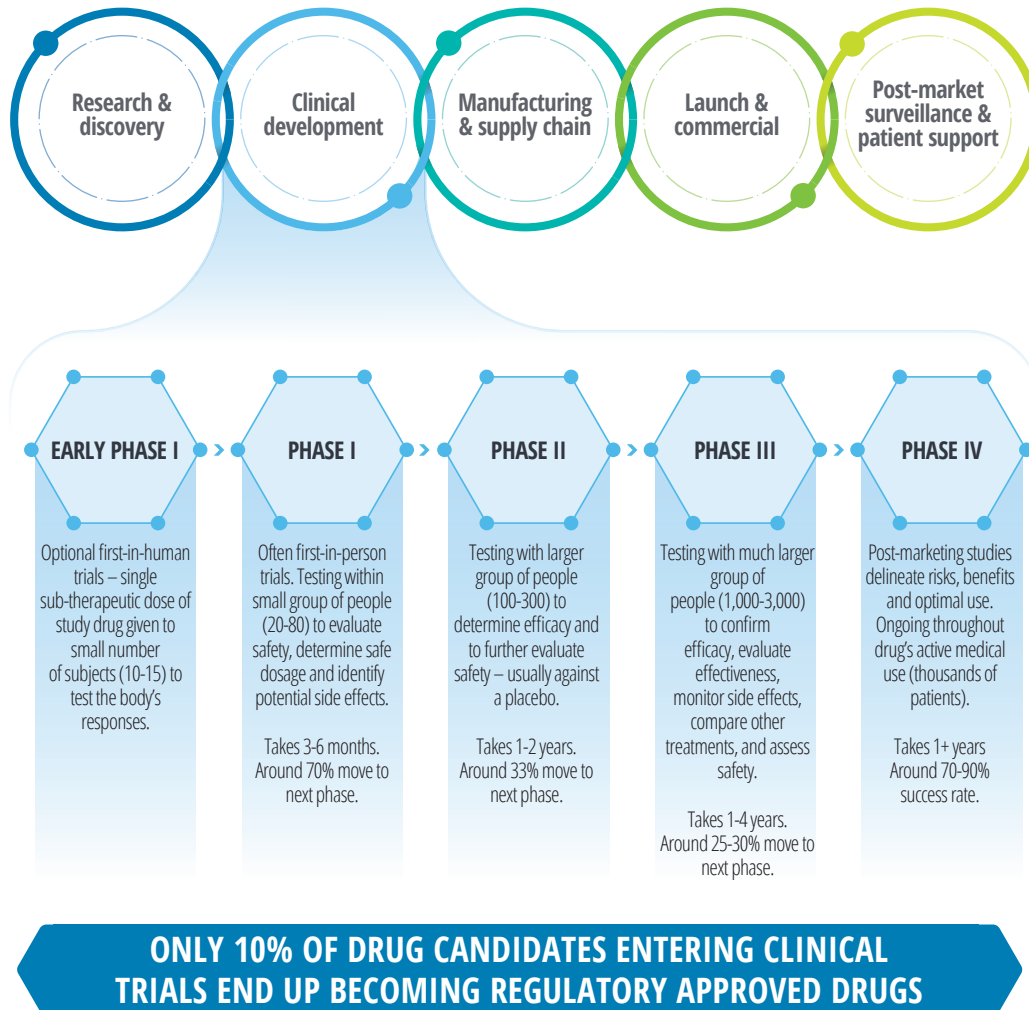
Consequently, the race to collect impactful data to expand biopharma's knowledge of the epidemiology of disease and to satisfy regulators and Health Technology Assessment (HTA) authorities is accelerating. The growth in number and complexity of clinical trials, particularly in oncology, means there is also increasing competition for suitable trial participants and sites. These factors are shaping the highly competitive landscape of the life sciences industry.

The traditional approach to clinical trials

Researchers design clinical trials to answer specific research questions relating to the efficacy and safety of a new intervention by measuring defined endpoints, including diagnostic biomarkers, in trial participants.[1] Clinical trials can only commence after approval by a regulatory authority and an ethics committee review of the pre-clinical regulatory submission.[2] The basic assumption of clinical research is that investigators take data from a relatively small but representative selection

FIGURE 1

The traditional approach to clinical development is a lengthy process with only 10 per cent success rate

Research & discovery

Clinical development

Manufacturing & supply chain

Launch & commercial

Post-market surveillance & patient support

EARLY PHASE I

Optional first-in-human trials – single sub-therapeutic dose of study drug given to small number of subjects (10-15) to test the body's responses.

PHASE I

Often first-in-person trials. Testing within small group of people (20-80) to evaluate safety, determine safe dosage and identify potential side effects.

Takes 3-6 months. Around 70% move to next phase.

PHASE II

Testing with larger group of people (100-300) to determine efficacy and to further evaluate safety – usually against a placebo.

Takes 1-2 years. Around 33% move to next phase.

PHASE III

Testing with much larger group of people (1,000-3,000) to confirm efficacy, evaluate effectiveness, monitor side effects, compare other treatments, and assess safety.

Takes 1-4 years. Around 25-30% move to next phase.

PHASE IV

Post-marketing studies delineate risks, benefits and optimal use. Ongoing throughout drug's active medical use (thousands of patients).

Takes 1+ years Around 70-90% success rate.

ONLY 10% OF DRUG CANDIDATES ENTERING CLINICAL TRIALS END UP BECOMING REGULATORY APPROVED DRUGS

Source: Deloitte analysis.

of subjects and generalise the results to the larger patient population. If the sample is too constrained or poorly selected, it hinders the broad applicability of the results. This is not only a statistical concern, but also an ethical and medical one.[3]

Today it takes 10-12 years on average to bring a new drug to market, with limited change over the past decades in the linear and sequential process used to assess the efficacy and safety of drugs.

Currently, drug discovery, which is the initial phase of R&D takes five to six years, followed by around five to seven years for clinical trials.[4] Of the 10,000 candidate drugs originally screened, only ten make it to clinical trials. On average, of the ten drug candidates that enter clinical trials, only one is approved for use with patients (see figure 1).[5]

The *2018 State of industry-sponsored clinical development* report by Trialtrove (2019) found

that, on average, 25 per cent of completed trials across all therapy areas achieved their primary endpoint in 2018, compared to 31 per cent in 2017. This potentially reflects the growing complexity of the R&D landscape in terms of the number of compounds and diseases being targeted. According to the US Food and Drug Administration (FDA), approximately 33 per cent of drugs move from Phase II to III, while around 25 to 30 per cent move from Phase III to the next phase.[6]

Transforming clinical trials is critical to improve productivity

The tried and tested process of discrete and fixed phases of randomised controlled trials (RCTs) was designed principally for testing mass-market drugs. However, RCTs lack the analytical power, flexibility and speed required to develop the complex new therapies that target smaller and often heterogeneous patient populations. Furthermore, a Deloitte survey of biopharma industry leaders in 2018, conducted for the *Digital R&D: Transforming the future of clinical development* report, found general agreement that the current high-risk, high-cost R&D model is unsustainable. Furthermore, that clinical development is struggling to keep pace with the ever-growing amount of genomic information, real-world evidence (RWE) and other emerging data sources (such as biosensors).[7]

For the past decade, our annual *Measuring the return from pharmaceutical innovation* report series has demonstrated that a new model of R&D is now needed. This research tracks the internal rate of return on investment (IRR) that a cohort of 12 leading global biopharma companies (and for the past five years four smaller, more specialised companies) might expect to achieve from their late-stage pipelines. It shows that the IRR has declined significantly. Specifically, our 2019 report found that the average cost of bringing a drug to market increased from $1.188 billion in 2010 to

$1.981 billion in 2019; the average forecast peak sales per asset declined from $816 million in 2010 to a low of $376 million in 2019. As a result, the expected IRR decreased from 10.1 per cent in 2010 to 1.8 per cent in 2019. These declining returns are the result of internal and external productivity challenges across the discovery and clinical development phases of drug development that call into question big pharma's R&D model.[8]

The main challenges for clinical development in 2019

The main drivers of R&D performance are the increase in clinical development (or cycle) times, changes in drug modalities and sources of innovation. Specifically:

- the growing length of the clinical trial cycle is arguably the most pressing challenge for clinical development

- historically, companies have focused largely on small molecules, but over the past decade, there has been an increase in the proportion of more scientifically complex large biological molecules (known as biologics) in companies' pipelines

- acquisitions and partnerships are an increasing source of innovation.[9]

As most pharma companies have integrated biologics into their pipelines, for the purpose of this report we refer to all pharma companies as biopharma companies.

The first clinical research step is the development of a clinical protocol (a document that describes how the trial will be conducted and ensures the safety of participants and integrity of the data collected). The availability of a growing volume and variety of data sources (including genomics, imaging, digital health and patient-reported outcome data)

FIGURE 2

Cost drivers in clinical trials

- ■ Patient recruitment
- ■ Outsourcing costs
- ■ Site recruitment
- ■ Clinical trial management system and other technology
- ■ Site retention
- ■ Data management and validation
- ■ Patient retention
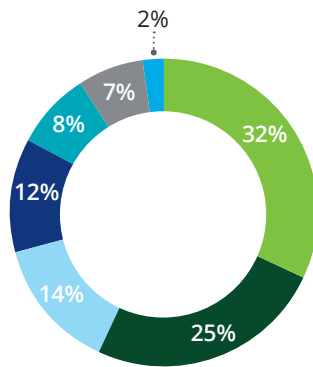
Source: Deloitte analysis.

has led to an expansion in trial protocols in an attempt to meet challenging regulatory require-ments. At the same time, companies have found it increasingly difficult to recruit patients that meet trial selection criteria. Moreover, the shift in drug development efforts to new modalities is increasing the competition for patients, which is adding to recruitment complexity. These factors have increased the average length of clinical trials.[10]

More specifically, as clinical trials progress, more patients are required, but the eligibility and suit-ability requirements also increase. A patient may be ineligible to participate due to their medical history or a mismatch in the stage of their disease compared to the trial protocol. Eligible and suitable patients may find the requirements challenging or the recruitment process complex and cumbersome, or they may not be aware or incentivised to participate.

The burden of frequent clinic visits also limits participation. Recent data suggest that 18 per cent of patients drop out after enrolling, with difficulty

attending clinics cited as a major factor. These challenges often create delays to the point that 86 per cent of all trials do not meet enrolment timelines and 30 per cent of Phase III trials fail due to enrolment challenges.[11] As a result, patient recruitment is the largest cost driver of clinical trials, accounting for 32 per cent of overall costs (see figure 2). Involving patients in developing new therapies and trial design, and engaging them throughout the development and post-market process, helps in both recruitment and retention, and also provides irrefutable evidence of the value of therapies in the real world.

Identifying suitable patients can improve the speed and efficiency of clinical trials and ultimately accelerate the approval of and access to new medicines.

Identifying suitable patients can improve the speed and efficiency of clinical trials and ultimately accelerate the approval of and access to new medicines. However, research shows that a rela-tively small number of eligible patients participate in clinical studies. For example, only two to nine per cent of adult cancer patients participate in clinical trials.[12,13] A 2019 meta-analysis of 13 studies involving 8,883 patients found that only 8.1 per cent of potential patients participated in clinical trials; of those that did not, some 55.6 per cent did not have a trial available where they were being treated, 21.5 per cent were deemed ineligible and 14.8 per cent chose not to enroll in an available trial.[14]

There is also a mismatch between the patient population that a new therapy is expected to treat and participants in the related clinical trial. Despite

numerous initiatives to tackle this, increasing clinical trial diversity in an effective, scalable and sustainable manner remains a challenge for clinical research.[15] Furthermore, patients considering participation in trialling a new medicine have to weigh up the benefits of early access to a potential new therapy against the risks of adverse events, as well as the inconvenience, potential financial burden and time requirements.[16]

The difficulties faced in an increasing proportion of clinical trials include ineffective site selection, poor study design and trial execution, safety issues and dropouts due to practical or financial issues.[17] Although patient recruitment and retention extends the time taken to complete a trial, four-fifths of trials fail because they are unable to demonstrate efficacy or safety.[18] Moreover, the time and funding required to complete a trial increase at each phase. The total cost of a Phase III failure includes the cost of all previous phases plus the time that could have otherwise been used to trial a different drug. Each failed trial contributes to the rising costs of biopharma R&D.[19]

SUCCESS RATES ARE DEPENDENT ON DISEASE TYPES

Clinical trial success rates are highly dependent on disease type. An extensive study that looked at 186,000 unique trials between 2000 and 2015 found an overall probability of success (POS) was 13.8 per cent. However, the POS of oncology trials was much lower at 3.4 per cent.[20] As many biopharma companies are increasingly targeting oncology as their preferred therapy area, this low POS is problematic.[21]

A report from the Tufts Center for the Study of Drug Development found that between 1999 and 2018 the average development timeline for cancer drugs was nine per cent longer than for other disease areas, but the time the FDA took to approve cancer

drugs was 48 per cent shorter.[22] This is because new oncology products are more likely to receive special designations from the FDA to speed up availability of medicines that address unmet medical needs. However, despite an increasing number of oncology drug candidates receiving fast-track designations over the past few years, there has not been a discernible effect on cycle times. This is likely due to increasing complexity of protocol design as well as increased competition to recruit eligible patients.[23]

Innovative solutions to expedite clinical cycle times

In the past few years a number of solutions for innovating clinical trials have emerged that rely on a more efficient use of data from multiple sources. Examples include:

- **Adaptive clinical trials** allow for the continual modification of trial design based on interim data. This can reduce the resources and time needed and improve the likelihood of success.[24] A broader use of adaptive trials could eliminate many unanticipated risks that undermine efficacious drugs and unnecessarily extend development timelines. For example, adaptive approaches can deliver trial dosing information in a single two-year combined Phase II/III, which might otherwise require three or more consecutive conventional trials over several years. In addition to shortening development time, such seamless trials may reduce the total sample size needed by using the same patients in more than one stage. Other advantages include changing allocation rates, early termination and reassessment of the sample size, patient subgroups or specific treatments, all of which improve efficiency. Research conducted by ICON, a global contract research organisation (CRO), suggests that the use of adaptive

trials across portfolios, as encouraged by regulatory agencies in both Europe and the US, could reduce trial costs by 25 per cent.[25]

- **Master protocols** are used to simultaneously evaluate more than one investigational drug within the same overall trial structure.[26] A report from the Deloitte US Center for Health Solutions found that by using master protocols, biopharma companies can de-risk R&D programmes, improve the quality of evidence and enhance their R&D productivity, all while reducing costs and study times. For a Phase II oncology trial, estimated costs could be reduced by 12-15 per cent and study time would be reduced 13-18 per cent (15-21 weeks).[27]

- **Synthetic control arms** use RWE as a more convenient, safe, time-saving and cost-effective way of conducting trials, especially ones with small numbers of potential participants. Currently, fear of being assigned a placebo is one of the top reasons patients choose not to participate in clinical trials. A synthetic control arm collects data from previous clinical trials, electronic health records (EHRs), patient-generated data from fitness trackers or home medical equipment, disease registries and others. These data are then used to model or simulate the expected results comparing them with those on the clinical trial. Eliminating or reducing the need for normal control arms ensures that all participants receive the active treatment, eliminating concerns about treatment assignment. Synthetic control arms can increase efficiency, reduce delays, lower trial costs and accelerate the access of therapies to market. In addition, their use can also eliminate the risk of unblinding, which happens when patients discover which treatment they are being given, harming the integrity of the trial.[28]

- **Pharmacogenetics testing** for patient selection. Over half of all trials (55 per cent) initiated in 2018 included the use of selective pharmacogenetic biomarkers for patient selection to predict individual responses to drugs in terms of efficacy and safety. These trials were four times more likely to succeed as compared to clinical trials where no biomarkers were used.[29]

Using AI to improve efficiency and effectiveness

The excessive cost, delays and failures of clinical trials has a strong impact on patients. Despite numerous innovations, two-thirds of classified diseases still lack an effective drug therapy.[30] Therefore, finding more effective and efficient ways of conducting clinical trials is of critical importance.

Our *Intelligent drug discovery: Powered by AI* report, the second in our series on the impact of AI on the biopharma value chain, highlighted the growing importance of disparate data sets in R&D. It found that, in 2019, AI was more widely adopted in drug discovery than in clinical development. This is largely because drug discovery involves the optimisation and validation of potential new drugs through *in vivo* cell assays and animal models, and does not face the regulatory hurdles required in testing potential drug candidates in people.[31]

However, there is an increasing realisation among academic institutions, biopharma companies, CROs and smaller biotech firms of the potential of AI to transform clinical trials. Specifically, AI has the potential to transform many of the key steps in clinical trials, from protocol design to study execution, thereby improving trial success rates and lessening the biopharma R&D burden.[32] The rest of this report explores the use of AI in clinical trials.

The impact of AI on the clinical trial process

Biopharma companies have access to growing amounts of scientific and research data from a variety of sources, known collectively as real-world data (RWD). While applying AI to operational data can drive clinical trial efficiencies, unlocking RWD using predictive AI models and analytics tools can accelerate the understanding of diseases, identify suitable patients and key investigators to inform site selection (including virtual trials), and support novel clinical study designs. Adoption of AI technologies is therefore becoming a critical business imperative.

KEY FACTORS undermining the effectiveness of clinical trials are patient and site selection along with patient recruitment and retention processes; as well as the lack of suitable infrastructure to manage the complexity of running a clinical trial. This is especially problematic in the later phases, including the need for efficient and reliable adherence controls, endpoint detection and patient monitoring systems.[33]

AI, particularly deep learning (DL), machine learning (ML) and natural language processing (NLP), combined with an effective digital infrastructure, has the potential to improve drug approval rates, reduce development costs and deliver medications to patients faster. All large biopharma companies are investing in AI and its applications. Novartis, for example, used AI to combine clinical trial data from a variety of internal sources to predict and monitor trial cost, enrolment and quality. As a result, the company reported a 10-15 per cent reduction in patient enrolment times in pilot trials.[34]

A Deloitte survey of 28 biopharma industry leaders in 2018 identified several use cases for AI and other digital technologies across the clinical trials process (see figure 3).[35] These use cases have continued to escalate.
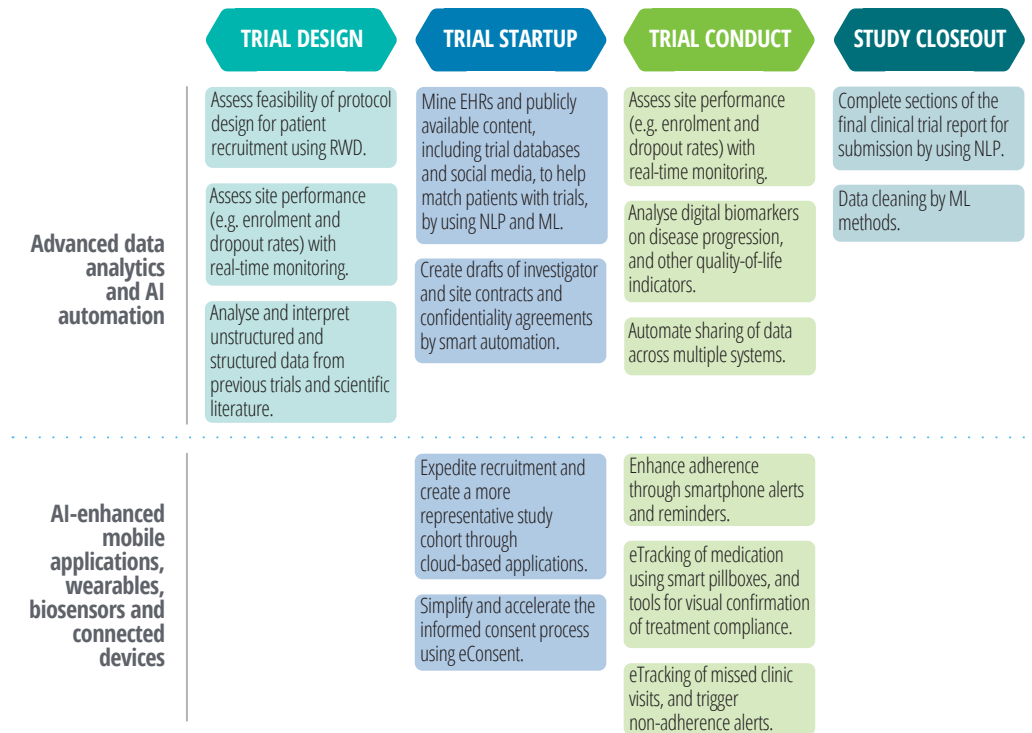
WHAT IS AI?

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, machine learning, natural language processing, robotics, speech, supervised learning and unsupervised learning.[36]

Transforming the design and conduct of clinical trials

As highlighted in the first part of this report, biopharma companies are adopting various strategies for innovating clinical trials. To be effective, these rely on increasing amounts of scientific and research data arising from a variety of disparate data sources,

FIGURE 2

Applications of AI-enabled technology in clinical trials

	TRIAL DESIGN	TRIAL STARTUP	TRIAL CONDUCT	STUDY CLOSEOUT
Advanced data analytics and AI automation	Assess feasibility of protocol design for patient recruitment using RWD.	Mine EHRs and publicly available content, including trial databases and social media, to help match patients with trials, by using NLP and ML.	Assess site performance (e.g. enrolment and dropout rates) with real-time monitoring.	Complete sections of the final clinical trial report for submission by using NLP.
	Assess site performance (e.g. enrolment and dropout rates) with real-time monitoring.	Create drafts of investigator and site contracts and confidentiality agreements by smart automation.	Analyse digital biomarkers on disease progression, and other quality-of-life indicators.	Data cleaning by ML methods.
	Analyse and interpret unstructured and structured data from previous trials and scientific literature.		Automate sharing of data across multiple systems.	
AI-enhanced mobile applications, wearables, biosensors and connected devices		Expedite recruitment and create a more representative study cohort through cloud-based applications.	Enhance adherence through smartphone alerts and reminders.	
		Simplify and accelerate the informed consent process using eConsent.	eTracking of medication using smart pillboxes, and tools for visual confirmation of treatment compliance.	
			eTracking of missed clinic visits, and trigger non-adherence alerts.	

Source: Deloitte analysis.

such as current and past clinical trials, patient support programmes and post-market surveillance. Access to additional data can be obtained by collaborations with academia, hospitals and technology companies. Sources of RWD available include EHRs, insurance records, medical imaging, 'omics' (e.g. genomics, metabolomics and proteomics), wearables and health apps, as well as social media. AI applied to RWD can extract meaningful patterns of information to help improve the design of clinical trials.

AI can optimise the collection and analysis of biomarker data at pre-prescribed time points more reliably and efficiently than current patient-driven self-monitoring methods. In addition, AI-enabled technologies have unparalleled potential to organise and analyse the increasing body of data collected as part of biopharma R&D. For example, the industry can use data from previous trials, including failed ones, to improve future designs.

The use of AI can also enable the continuous stream of RWD to be cleaned, aggregated, coded, stored and managed. This makes data management a quicker, seamless and dynamic process. In addition, improved electronic data capture (EDC) can also reduce the impact of human error in data collection and facilitate seamless integration with other databases.

Patient enrichment, recruitment and enrolment

AI-enabled digital transformation can reduce the challenges in patient selection through clinical trial enrichment strategies (see figure 4). The FDA has published guidance on *Enrichment strategies for clinical trials to support determination of effectiveness of human drugs and biological products* that identifies three strategies to assist the biopharma industry in detecting a drug's effectiveness.[37] The three strategies, together with the specific use of AI, are as follows:

- **Reduced population heterogeneity** includes choosing patients with baseline measurements of a disease or a biomarker characterising the disease in a narrow range, while excluding patients whose disease or symptoms improve spontaneously or whose measurements are highly variable, to increase study power Decreasing variability often uses a process known as electronic phenotyping, which focuses on reducing population heterogeneity. Electronic phenotyping requires mining large databases of EHRs and accounting for heterogeneity between patient records and data types. Applying AI technologies, especially ML and DL, to electronic phenotyping processes can accelerate identification of eligible patients for clinical trials.[38]

- **Prognostic enrichment** includes choosing patients with a greater likelihood of having a disease-related endpoint or a substantial worsening in condition (for continuous measurement endpoints). Prognostic enrichment strategies are ripe for AI applications. Neurological diseases have been the initial targets, as key biomarkers are often expensive or invasive to measure, but non-linear combinations of inexpensive and non-invasive models can approximate the biomarkers.

- **Predictive enrichment** includes choosing patients who are more likely to respond to the drug treatment than other patients with the condition. Such selection can lead to a larger effect size (both absolute and relative) and can permit use of a smaller study population. Selection of patients can be based on a specific patient physiology, a biomarker or a disease characteristic that is related to the study drug's mechanism. Patient selection could also be empiric (e.g., the patient has previously appeared to respond to a drug in the same class).[39] Predictive enrichments require complex ML models that characterise and assess disease progression. Current efforts are focused on numerous diseases, particularly mild cognitive impairment (MCI) and Alzheimer's disease, where disease-modifying drugs are largely unavailable.[40]
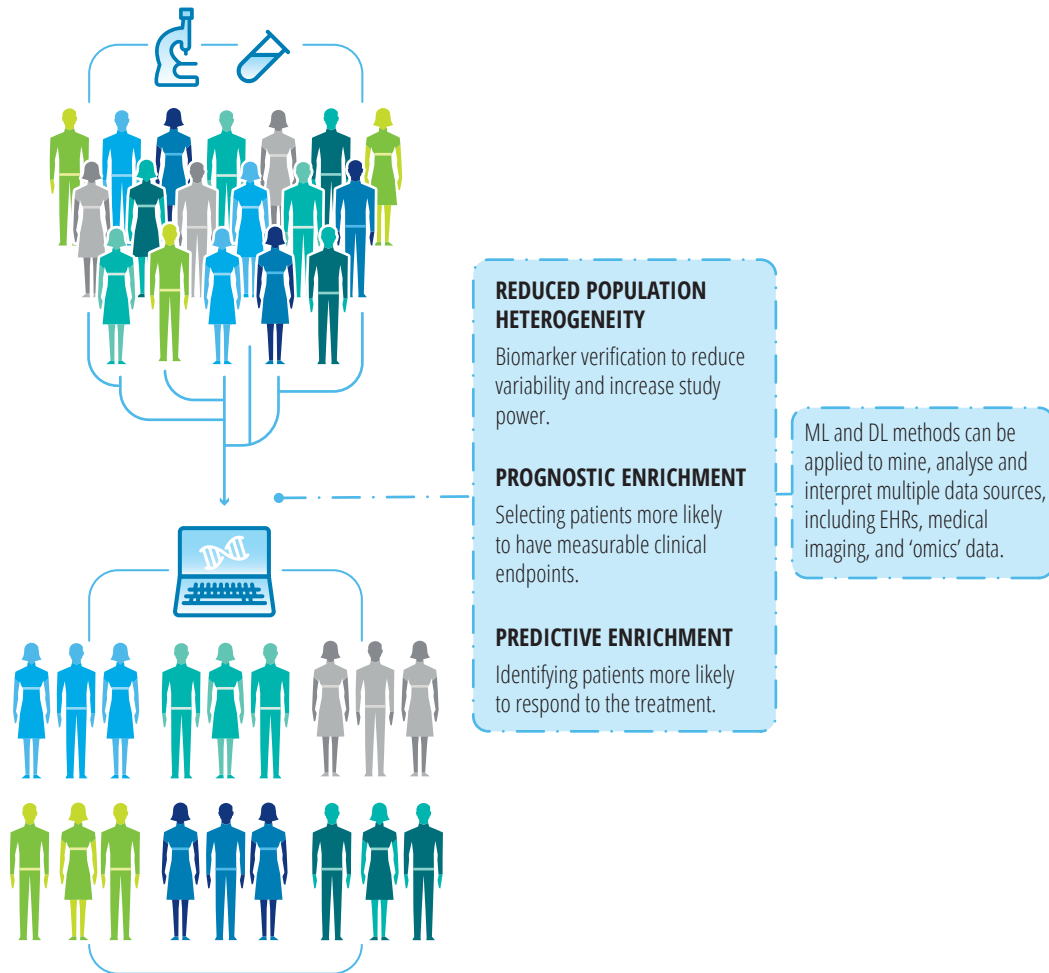
The European Medicines Agency (EMA) also recommends in its Regulatory Science to 2025 strategy to work with stakeholders to design collaborative clinical trials, particularly with international partners on the Clinical Trial Transformation Initiative (CTTI) and similar initiatives to innovate and expedite patient identification.[41]

MINING OF PUBLICLY AVAILABLE DATA

ML and NLP can proactively mine publicly available web content, including digital trial announcements, trial databases and social media, to help match patients with relevant trials. AI-based clinical trial matching systems, such as IBM Watson for Clinical Trial Matching, are helping to reduce the burden of recruitment and enrolment (see case study 1).

FIGURE 3

How AI technologies can help deliver clinical trial enrichment strategies highlighted in FDA guidance

Trial enrichment strategies

REDUCED POPULATION HETEROGENEITY

Biomarker verification to reduce variability and increase study power.

PROGNOSTIC ENRICHMENT

Selecting patients more likely to have measurable clinical endpoints.

PREDICTIVE ENRICHMENT

Identifying patients more likely to respond to the treatment.

ML and DL methods can be applied to mine, analyse and interpret multiple data sources, including EHRs, medical imaging, and 'omics' data.

Source: Deloitte analysis.

It is difficult for both patients and clinicians to understand and assess eligibility for a specific trial, largely due to the complexity of clinical terminology used. For example, ClinicalTrials.gov was designed for researchers, not patients, so patients usually rely on other patients with similar conditions or doctors to identify a potential trial. However, doctors rarely have time to discuss trial options. Several AI technologies can offer vital assistance by automatically extracting meaningful information from EHRs and other unstructured data sources to identify participants with matching criteria (see case studies 2 and 3).

CASE STUDY 1. IBM WATSON FOR CLINICAL TRIAL MATCHING USES NLP TO BOOST ENROLMENT AND REDUCES TIME TO PROCESS PATIENTS AGAINST PROTOCOLS

IBM Watson Health's Watson for Clinical Trial Matching (CTM) can collect and link structured and unstructured data from EHRs, medical literature, trial information and eligibility criteria from public databases like ClinicalTrials.gov. NLP enables Watson for CTM to analyse collected data, which helps increase the accuracy and efficiency of the clinical trial matching process by reading and identifying trial inclusion and exclusion criteria that limit enrolment, determining viable patient populations at trial sites and matching the subsequent data to structured and unstructured data from EHRs.

Early use of Watson for CTM by Mayo Clinic resulted in an 80 per cent increase in enrolment to systemic therapy clinical trials for breast cancer in the 11 months after implementation. Further training for additional cancer types is under way following on from the current targets of breast, gastrointestinal and lung cancers. Mayo and IBM Watson Health also plan to develop the system further for other applications, including for radiation, surgery and supportive care.[42]

In another collaboration during a 16-week pilot, IBM Watson Health, Highlands Oncology Group and Novartis used the CTM system to process 90 patients against three breast cancer protocols in 24 minutes compared to a clinical trial coordinator who took one hour and 50 minutes – a 78 per cent decrease.[43]

CASE STUDY 2. ANTIDOTE USES ML TO CONNECT PATIENTS TO CLINICAL TRIALS

Surveys show that 75 per cent of patients in the US are interested in participating in research, but finding a clinical trial can be challenging. The Antidote platform uses ML to seamlessly connect patients with clinical trials, creating a simple process for both drug sponsors and the patients they need to reach. The system uses ML to structure and organise trial listings from ClinicalTrials.gov into a patient-friendly, searchable format. Patients use the search tool, Antidote Match, to answer a few questions about their health, and the system automatically identifies clinical trials for which they may qualify. For sponsors with multiple trials in their programs, Antidote offers multi-trial matching as a recruitment tool. This approach allows patients to match against several clinical trials from the same sponsor, increasing their chances of finding a trial and accelerating research for the sponsor. And if none of those trials are right for them, the platform automatically reveals a list of additional, sponsor-agnostic trials that may be a fit.[44]

CASE STUDY 3. MENDEL.AI IS IMPROVING IDENTIFICATION OF SUITABLE CANCER PATIENTS AND MATCHING TO CLINICAL TRIALS

Mendel.ai, a US-based company founded in 2016, uses AI tools to analyse clinical data, including medical history and genetic analysis, from cancer patients. Its goal is to facilitate clinical trials in oncology research by organising and analysing RWD, and matching patients to the right clinical trials.[45] They take medical data from many structured and unstructured data sets and turn these into *data digitised patient journeys* aligned to specific treatments. Having collected data on over 1 million journeys, its algorithm can segment patient populations by their demographic, such as how African American women with breast cancer respond to a particular drug. In essence creating *in silico* or patient-less trials. The AI algorithm built on these data helps trial recruitment by finding eligible patients.

Mendel.ai is compliant with Health Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GDPR) requirements and has helped research clinicians to increase the number of eligible patients. The company applied its platform retroactively to three oncology studies that had recently completed enrolment. This allowed a direct comparison between the results that can be achieved through Mendel.ai's augmentation tools and conventional practices. Mendel.ai showed that the use of its service can deliver a 20-50 per cent increase in patient enrolment and drastically reduce the time needed to screen through large data sets during patient identification process.[46]

Investigator and site selection

One of the most important aspects of a clinical trial is selecting high-functioning investigator sites. Site qualities such as administrative requirements procedures, resource availability, team dynamics and experience ultimately impact both study timelines and data quality and integrity. Site selection has the potential to dramatically affect product approval, study costs and timelines. However, it is an often underrated and poorly understood discipline. Moreover, investigators and sites need to sign a formal agreement to conduct the trial in compliance with regulators' Good Clinical Practice and approved protocol requirements. This includes complying with auditing, data recording and reporting procedures, permit monitoring and inspection timetables, and retaining essential documents in accordance with sponsor requirements.[47]

AI technologies can help optimise the way in which target locations, qualified investigators, and priority candidates are identified accurately, as well as help analyse the data that is collected more effectively.[48] AI can also help to automate workflows by creating drafts of standardised contracts such as confidentiality, investigator and site agreements to shorten study startup time.

Patient monitoring, medication adherence and retention

Algorithms can also help monitor and manage patients by automating data capture, digitalising standard clinical assessments and sharing data across multiple systems.

In addition, nurses and physicians can use AI solutions to identify relevant actions according to protocol requirements, such as specific clinical tests and procedures to monitor diagnostic biomarkers; assist in scheduling patient visits; and pre-populate patient data into EDC systems. For example, NLP can complete sections of the dossier for submission to pre-populate standard information into the final clinical study report. This saves costs and effort and reduces compliance risk and overall time to market.

Trials require enough patients to create enough statistical power to assess the effectiveness of a drug. Once patients are recruited and enrolled, it is important to avoid dropout and non-adherence as recruiting additional patients leads to trial delays and additional costs. Patients who leave the trial cannot be replaced one-for-one due to the required statistical power of the trial protocol. For example, a 20 per cent decrease in patient adherence requires a 50 per cent increase in sample size to maintain an equivalent statistical power.[49] However, the average dropout rate across clinical trials is 30 per cent, and only 15 per cent of clinical trials do not experience patient dropout.[50]

During most clinical trials, researchers' understanding of patients' health is limited to site visits. Patient compliance to the treatment protocol is, therefore, difficult to ascertain accurately. This can create a mismatch between the efficacy of treatments during clinical trials and the effect of the drug in the real world. Clinical trials based on advanced AI algorithms, using data collected from trial participants via wearables, apps and sensors, can provide real-time insights into the safety and effectiveness of the treatment. AI can also integrate multiple digital biomarkers to understand how the patient is responding to the drug and whether there is need for dose adjustments. Importantly, these connected apps and devices allow patients to stay informed and supported in real time, which can

enhance engagement and retention. Currently, a number of AI-augmented platforms for remote patient monitoring, which can be used both in health care and in clinical trials, have been approved by the FDA.[51,52] Other technologies developed to improve adherence include smart pillboxes or pill bottles, virtual pillboxes and behavioural economics-based incentives.[53] DL and ML algorithms can analyse patient data from wearables and video monitoring in real time and predict the risk of dropout for an individual patient by detecting the onset of behaviour that led to non-adherence previously.

Using operational data to drive AI-enabled clinical trial analytics

Clinical trials generate immense operational data, but functional data silos and numerous applications often hinder biopharma executives who need a comprehensive view of their clinical trials portfolio over multiple global sites to make informed decisions. As a result, many hours are lost collecting and analysing diverse data sets to optimise trial operations, as well as to improve cost and resource efficiencies. By consolidating operational data on a clinical trial analytics platform with predictive capabilities, biopharma companies can improve their ability to discern whether a data anomaly is a true risk, which helps stage more efficient and productive visits.

CASE STUDY 4. MEDIDATA'S ACORN AI

Medidata, a global CRO, established Acorn AI in early 2019 to develop new insights across all phases of drug development. Its aim is to make data 'liquid' across the end-to-end life cycle of a biopharma company: from research all the way to development and into post-market surveillance to build linkages between clinical trials, genomics, RWE, translational health and other data sets.[54] Its aim is to help biopharma make quick 'go/no go' decisions, accelerate clinical trials and demonstrate value. Acorn AI is built on the Medidata platform, which comprises more than 17,000 clinical trials with structured, standardised clinical data repositories from over 4.8 million patients.

Acorn AI is focusing on addressing two big trends. The first is precision medicine with CAR-T therapy, tissue engineering, and gene and cell therapy. The second is the advancement of AI and new sources of data to give researchers a 360-degree view of the patient, including clinical, genomic, molecular, as well as socio-economic, behavioural and environmental data. It aims to help sponsors make critical decisions on which drugs to progress from discovery to clinical trials; how to accelerate clinical trials to speed the treatment to market; and how to create better-integrated evidence, including both clinical and RWE, to demonstrate the value of products to regulators, patients, payers and providers.

There are also serious IT infrastructure and data interoperability challenges with a lack of standards for data sharing across multiple EDC systems and sites, for example, providing access to EHRs. Some biopharma companies deal with interoperability across their studies by dictating data management rules, specifying which data platforms to use and how the data should be delivered.[55] An important solution to this is the adoption of open data standards, which can improve interoperability and allow seamless integration. An open platform solution allows easy integration of sensors, user applications and wearables data via standard application programming interfaces (APIs).[56]

Consolidating all data – whatever the source – on a company's shared analytics platform can foster collaboration and integration, and provide insights across vital metrics ranging from enrolment rate and screening failure rates, to protocol deviations. An effective integrated platform incorporates advanced analytics, including predictive analytics, at every stage of the process to uncover actionable insights that were previously difficult or even impossible to attain. Incorporating a self-learning system, designed

to improve predictions and prescriptions over time, as well as data visualisation tools, can proactively deliver reliable analytic insights to users.[57] One CRO has established an AI-driven platform to develop new insights across all phases of drug development (see case study 4).

Game changers supporting the use of AI for clinical trials

OUTSOURCING AND STRATEGIC RELATIONSHIPS TO OBTAIN NECESSARY AI SKILLS AND TALENT

Biopharma companies are looking to strategic and operational relationships based on outsourcing models. A number of companies increasingly see CROs that have invested in data science skills and talent as strategic partners as they provide access not only to specialised expertise, but also to a wide range of potential trial participants.[58]

In 2016, Deloitte research identified that, by outsourcing clinical trials to external partners with expectations set around outcomes, biopharma companies can leverage their knowledge and

expertise gained from repeatedly providing the service.[59] Further research in 2018 suggested more companies will use outsourcing to obtain the necessary expertise, especially in advanced technologies, such as AI, cloud computing and robotics. Sector growth will be driven by strategic partnerships with academia, analytics companies and big tech, as well as CROs, as biopharma companies focus on strengthening their R&D capabilities.[60]

CROs provide a range of expertise to bring understanding and solutions to the highly technical challenges of transforming clinical trials. In 2015, Research and Markets estimated that by 2020 over 70 per cent of all clinical trials will be outsourced to CROs.[61] As AI generates increasing momentum and interest across the biopharma industry, CROs will be in great demand due to their ability to combine AI knowledge with expertise in specific therapeutic areas, including indications and regulatory requirements, and by offering pharmacovigilance specialists.[62]

The 2018 report from Research and Markets predicts the global CRO market will grow with a compound annual growth rate (CAGR) of 7.62 per cent, from $36.27 billion in 2017 to $56.34 billion in 2023.[63] This is due to the expected increase in outsourcing of R&D activities, in R&D expenditures and the number of clinical trials. Globally more than 1,100 CRO companies were active in 2017, with the top ten generating a collective total revenue of $34.514 billion.[64]

As we mentioned in our *Intelligent drug discovery: Powered by AI* report, the vast majority of AI startups working on biopharma R&D are currently focused on the drug discovery stage of the process.[65] However, an increasing number of startups (around 30) are now working in the clinical trials space, including partnering or contracting with biopharma.[66] Examples include:

- **Trials.ai:** Uses AI to analyse large sets of genomic data, journal articles, past clinical studies and other forms of research to improve study design. Using its proprietary codified clinical trials database, the system is able to unlock information, derive insights and make recommendations to trial sponsors on how to best design and optimise their trial protocols, as well-designed protocol limits improves recruitment and retention and reduces burden on patients and trial sites by bringing in cost and time efficiency.[67] For one of its clients, Trials.ai shortened study timelines by 33 per cent and reduced data errors by 20 per cent.[68]

- **Concerto HealthAI:** Uses its RWD capabilities and eurekaHealth AI platform to design robust clinical trials and generate precision treatment insights. In March 2019, Concert HealthAI announced a strategic agreement with Bristol-Myers Squibb (BMS), and in April 2019, announced a partnership with Pfizer.[69]

- **GNS Healthcare:** Uses its Reverse Engineering & Forward Simulation (REFS) causal AI and simulation platform to analyse RWD and clinical trial data to model patient responses to treatments *in silico* and has worked with biopharma companies, including Amgen, BMS, Celgene, Johnson & Johnson and Novartis.[70]

TECH GIANTS DISRUPTING THE STATUS QUO

The size and growth of the health care market and the potential for technology to impact the life sciences industry in the same way as other customer-facing industries, such as banking, retail and travel, has attracted the attention of the tech giants. This is disrupting the status quo and threatening biopharma's legacy culture. In 2019, initiatives converging advanced data science, medical knowledge and technology included the following:

- Verily Life Sciences, a subsidiary of Google's Alphabet Inc., teamed up with Novartis, Otsuka, Pfizer and Sanofi on a project to improve patient recruitment and retention and speed up clinical trials. This project, collectively known as Project Baseline, is using Verily's AI-powered research tools, including wearable devices and sensors as well as analytical tools that can bring together EHRs, biometrics and patient-reported data. It plans to launch studies across multiple therapeutic areas, including cardiovascular disease, dermatology, diabetes, mental health and oncology.[71]

- Apple announced the launch of three clinical studies in partnership with leading academic and research institutions that will use its new ResearchKit app. These are: Apple Women's Health Study, in partnership with Harvard T.H. Chan School of Public Health and National Institute of Environmental Health Sciences; Apple Heart and Movement Study, in partnership with Brigham and Women's Hospital and American Heart Association; and Apple Hearing Study, in partnership with University of Michigan. Apple previously completed the Apple Heart Study using Apple Watch and its ResearchKit app.[72] In addition, large biopharma companies have launched apps that were developed through ResearchKit platform to improve RWD collection and patient monitoring in clinical studies (see case study 5).

- Amazon launched Comprehend Medical, an AWS Cloud NLP service that decodes and mines structured and unstructured data to extract information such as medical condition and medication regimen from clinical trial reports, doctors' notes and EHRs.[73] AWS Cloud AI-enabled services and tools are HIPAA and GDPR compliant and can be used to streamline clinical trials by facilitating, among others, global data management and patient recruitment and monitoring.[74] Roche Diagnostics is using Comprehend Medical to enable its NAVIFY Clinical Trial Match platform to extract and structure information from medical documents to match patients to available independent clinical trials.[75]

CASE STUDY 5. HOW BIOPHARMA COMPANIES ARE WORKING WITH APPLE'S RESEARCHKIT TO MONITOR PATIENTS IN CLINICAL TRIALS

In 2016, GSK launched the PARADE (Patient Rheumatoid Arthritis Data from the Real World) study for which it developed an app using Apple's ResearchKit framework. This app was downloaded over 200 times within 48 hours of launch. Having patients using this app allowed research clinicians to obtain more realistic symptomatic reports, including morning stiffness, one of the key symptoms of rheumatoid arthritis, which might have dissipated by the time patients reached the clinic.[76]

More recently, in 2018, Novartis announced the launching of FocalView, an app developed through Apple's ResearchKit to be used as an ophthalmic digital research platform. FocalView aims to make ophthalmology clinical trials more accessible and flexible by allowing clinical researchers to monitor disease progression by collecting self-reported data in real time directly from consenting patients. This app was launched in the App Store in the US to be tested in a prospective, non-interventional study to assess its ease of use and ability to collect important clinical data and other documentation, including informed consent. In the future, Novartis aims to validate the app by comparing it with traditional visual testing methods in clinical settings.[77]

- Microsoft has entered a five-year collaboration with Novartis to explore how to combine Microsoft's advanced AI technology with Novartis' deep life sciences expertise. The aim is to find new ways to address challenges, such as drug discovery, clinical trials, manufacturing, operations and finance. As part of Microsoft's work with Novartis, data scientists from Microsoft Research and research teams from Novartis will work together to investigate how AI can help unlock transformational new approaches in three specific areas: personalised treatment for macular degeneration; use of AI to make manufacturing new gene and cell therapies more efficient; and use of AI to shorten the time required to design and develop new medicines.[78]

Pharma sponsors are partnering with large tech companies to leverage their core expertise in digital science. They are also looking to the burgeoning ecosystem of smaller tech companies to develop potentially disruptive data innovation and new methods of obtaining and tracking relevant clinical and socioeconomic data to improve patient interfaces. For life sciences, tech giants can be:

- potential partners

- competitors

- and both an opportunity and a threat as they disrupt specific areas of the industry.[79]

Today, we are seeing a growing number of examples of how the end-to-end utilisation of AI is also impacting how biopharma companies interact with patients (see case study 6).

CASE STUDY 6. TAKEDA IS USING AN AI-ENABLED PLATFORM TO CREATE PATIENT-CENTRED TREATMENTS

In 2016, Takeda Pharmaceuticals established the R&D Data Science Institute, including a R&D data hub that integrates data sets such as clinical trials, observational studies, population-level biobanks and RWD, aimed at generating insights using advanced ML techniques.

Takeda chose two complex therapeutic areas, non-alcoholic steatohepatitis (NASH) and treatment-resistant depression (TRD), to evaluate the capabilities of its ML algorithms and platform. The aim is to improve the treatment journey for patients as well as helping to guide decisions on the cost-effectiveness of treatments, drug development investments and planning protocols for clinical trials.

To create better testing models and prove its hypotheses, Takeda used Deloitte's ConvergeHEALTH Deep Miner™ platform to analyse massive amounts of RWD. The platform is designed to accelerate predictive modelling by utilising ML and neural network algorithms with real-world health care data. The AWS Cloud-enabled Deep Miner™ platform used DL and ML techniques to improve the predictive accuracy of Takeda's earlier results from 53.4 per cent to 92 per cent.[80]

Clinical trials of the future

Biopharma has traditionally been slow to adopt innovative technologies in the recruitment and management of clinical trials. However, the convergence of medical knowledge, exponential increases in the amounts of RWE and advances in technology and data management present a transformational opportunity. Harnessing data by applying AI technologies has the potential to enhance clinical trial productivity, improve the patient experience and accelerate regulatory decision-making.

Clinical development and the future of health

The life sciences and health care industries are on the brink of large-scale disruption driven by interoperable data, open and secure platforms and consumer-driven care. The next 20 years will see a fundamental shift from 'health care' to 'health'. While diseases will never be fully eradicated, our understanding of data and science, as well as the use of AI and other digital technologies, will enable the identification of pathological conditions earlier. This will facilitate more proactive interventions and provide a better understanding of disease progression to sustain patient well-being more actively and effectively.

Advanced early intervention and enhanced adherence will help ensure the effectiveness of these new therapies.[81] AI-enabled digital transformation is

Biopharma companies are set to develop tailored therapies that cure disease rather than treat symptoms.

becoming a strategic imperative, and biopharma companies need to decide what role they will play in the transformed health ecosystem.[82]

As discussed in our report *Intelligent drug discovery*, AI will accelerate the identification of new, more precise and targeted therapeutics. These new drugs will be designed to be highly specific, linked to genetics and to avoid side effects. Clinical trials will need to accommodate the increased number of more targeted approaches required.

In the future, AI, together with enhanced computer simulations and advances in personalised medicine, will lead to *in silico* trials, which use advanced computer modelling and simulations in the development or regulatory evaluation of a drug. While *in silico* trials will potentially reduce, refine and partially replace *in vivo* experimentation, completely simulated clinical trials are not feasible with current technology and understanding of biology. Nevertheless, their development will have major benefits over current *in vivo* clinical trials. Indeed, the FDA is already planning for a future in which more than half of all clinical trial data will come from computer simulations.[83]

In silico trials can eliminate the need for Phase I, in which the safety of compounds in healthy subjects is tested.

At the beginning of 2020, *in silico* medicine is still in its infancy, but there are many promising examples that show the potential to replace traditional clinical trials within a few years.[84,85] In the meantime, improving the efficacy of the entire process is more likely to depend on AI and other technologies to improve efficiency and POS.[86] Indeed, AI-enabled applications are likely to become standard in the biopharma operating model over the next five to ten years (see figure 5).

Deloitte's *Digital R&D: Transforming the future of clinical development* report highlighted the steps needed for biopharma to succeed in clinical trials:

- **engage** effectively with patients and stakeholders through targeted, omnichannel interactions to meet their needs and foster trusted relationships

- **innovate** patient care by catalysing the development of products and services that deliver measurable value for health care providers, payers and patients

- **execute** efficiently by digitalising and rationalising processes to drive efficiencies, reduce cycle times and deliver cost savings.[87]

In the future, AI will ensure that all these steps are done more cost-effectively and efficiently. The quicker the clinical development process the more lives that can be saved.

FIGURE 5

Expected timeline for the adoption of AI-enhanced digital technologies at scale

STILL BEING EXPLORED
- Blockchain • Virtual/augmented reality • Digital assistants and voice recognition

READY FOR NEAR-TERM ADOPTION
- eConsent
- Patient-reported endpoints using mobile applications and wearables
- Risk-based site monitoring
- Assessment of protocol design feasibility using data from multiple sources

NEXT IN LINE
- Automated data capturing, integration and sharing
- Mine EHRs and patient records to assess feasibility and expedite recruitment
- Workflow automation of repetitive activities
- Partially virtual trials
- Digital biomarkers as secondary endpoints

MORE ADVANCED TECHNOLOGIES
- Synthetic control arms and *in silico* trials
- AI tools to analyse and interpret unstructured data
- ML to clean data
- Completely virtual trials
- Digital biomarkers as primary endpoints
- NLP to perform more complex medical writing activities

NOW → 3 YEARS → 5 YEARS → 10 YEARS

Source: Deloitte US Center.

The future of clinical trial regulation

Regulators around the globe have released guidance to encourage biopharma companies to use RWE strategies. In the US, the FDA is leading the way with guidance on *Submitting documents using real-world data and real-world evidence to FDA for drugs and biologics guidance for industry*[88] and on *Use of real-world evidence to support regulatory decision-making for medical devices.*[89] In addition, the 21st Century Cures Act, passed in 2016, was designed to help bring new innovations and advances to patients more efficiently and faster.[90]

Accordingly, the FDA is working with the clinical trial community and patient groups to develop scientific and technical standards for incorporating new digital technologies into clinical trials to make them more agile and accessible to patients and regulators. For example, remote and risk-based monitoring can lower development costs, improve patient care and provide better regulatory oversight.[91]

The FDA also sees immense potential in using digital technologies to bring clinical trials to the patient. It believes that more accessible clinical trials can foster participation by a more diverse patient population and communities where patient care is delivered. This will generate information that is more representative and help providers and patients make better informed treatment decisions. These decentralised clinical trials can help move data collection outside the boundaries of traditional clinical research facilities.[92]

As the variety, velocity and volume of RWD submitted to the FDA increases, the FDA will also increase its use of DL and NLP tools in its regulatory processes. For biopharma, early engagement with regulatory authorities to align on objectives, study design and use of digital biomarkers or surrogate endpoints will be of critical importance. In recognition that AI skills are highly sought after and that there are difficulties recruiting and retaining the necessary talent, the FDA is taking several steps, including:

- developing an FDA curriculum on AI in partnership with external academic partners. The aim is to improve the ability of FDA reviewers and managers to evaluate products that incorporate advanced algorithms and facilitate the FDA's capacity to develop novel regulatory science tools.

- piloting a competitive fellowship programme that enables postdoctoral students from leading academic centres to join the FDA for two-year fellowships to develop high-impact AI-based regulatory science tools.

- the FDA's Oncology Center of Excellence (OCE) is exploring the use of real-world endpoints, like time-to-treatment discontinuation, for pragmatic randomised clinical trials for FDA approved therapies in the post-market setting.[93]

In addition, regulatory agencies will remain focused on leveraging technology and translational data to improve the overall efficiencies and cost control of conducting trials, to speed delivery of benefit to patients and to support shorter development timelines and approvals.

PATIENT CENTRICITY AND AN IMPROVED CLINICAL TRIAL EXPERIENCE

In the future, all stakeholders involved in the clinical trial process will have aligned their decisions with the patient's wants, needs and preferences. Sponsors channel information about the trial, the process, the people involved, through the patient. Sponsors not only incorporate patient perspectives throughout study design, but also deploy open communication channels during study execution. This has improved success in attracting, engaging, and retaining committed patients throughout study

duration and after study termination. Initiatives include the use of digital therapeutics (clinically validated interventions, either stand-alone or in combination with medical products); and using AI-enabled digital health technologies and patient support platforms during the whole trial process, for example: leveraging compliance apps, clinical endpoint and data capture tools, and remote trial delivery systems (see figure 4).

What next for biopharma?

For the next few years, RCTs are likely to remain the gold standard for validating the efficacy and safety of new compounds in large populations. However, for initial registration, innovative trials using RWD are likely to play a more relevant role in defining new, patient-centred endpoints and in expanding and refining indications. One of the most prominent activities that will change clinical trials the most over the next ten years will be moving patient medical information into electronic format and enabling the utilisation of RWD in powerful ways.

The next decade will also see an increase in the implementation of virtual clinical trials. These leverage the capabilities of innovative digital technologies, including apps, eConsent platforms and telemedicine, to lessen the financial and time burdens that patients incur. Virtual trials enable faster enrolment of more representative groups in real time and in their normal environment (as opposed to strictly controlled clinical environments) and monitor these patients remotely. Deloitte research suggests as many as half of all trials could be done virtually. The convenience of virtual trials should improve patient retention and accelerate clinical development timelines, addressing one the biggest challenges

in biopharma R&D.[94] Indeed, the move to virtual clinical trials means that any qualifying patient who wants to participate in clinical research and who meets the selection criteria will be able to do so.

The use of virtual trials is only just beginning. For example, in December 2019, Europe's Innovative Medicines Initiative launched a new project, Trials@ Home. This evaluates how remote decentralised clinical trials (RDCTs), which use AI-enabled technologies to allow bigger, more diverse and remote populations to take part in clinical trials, could become the gold standard for clinical research.[95] The expectation is that within the next five to ten years this should entirely transform clinical trials.
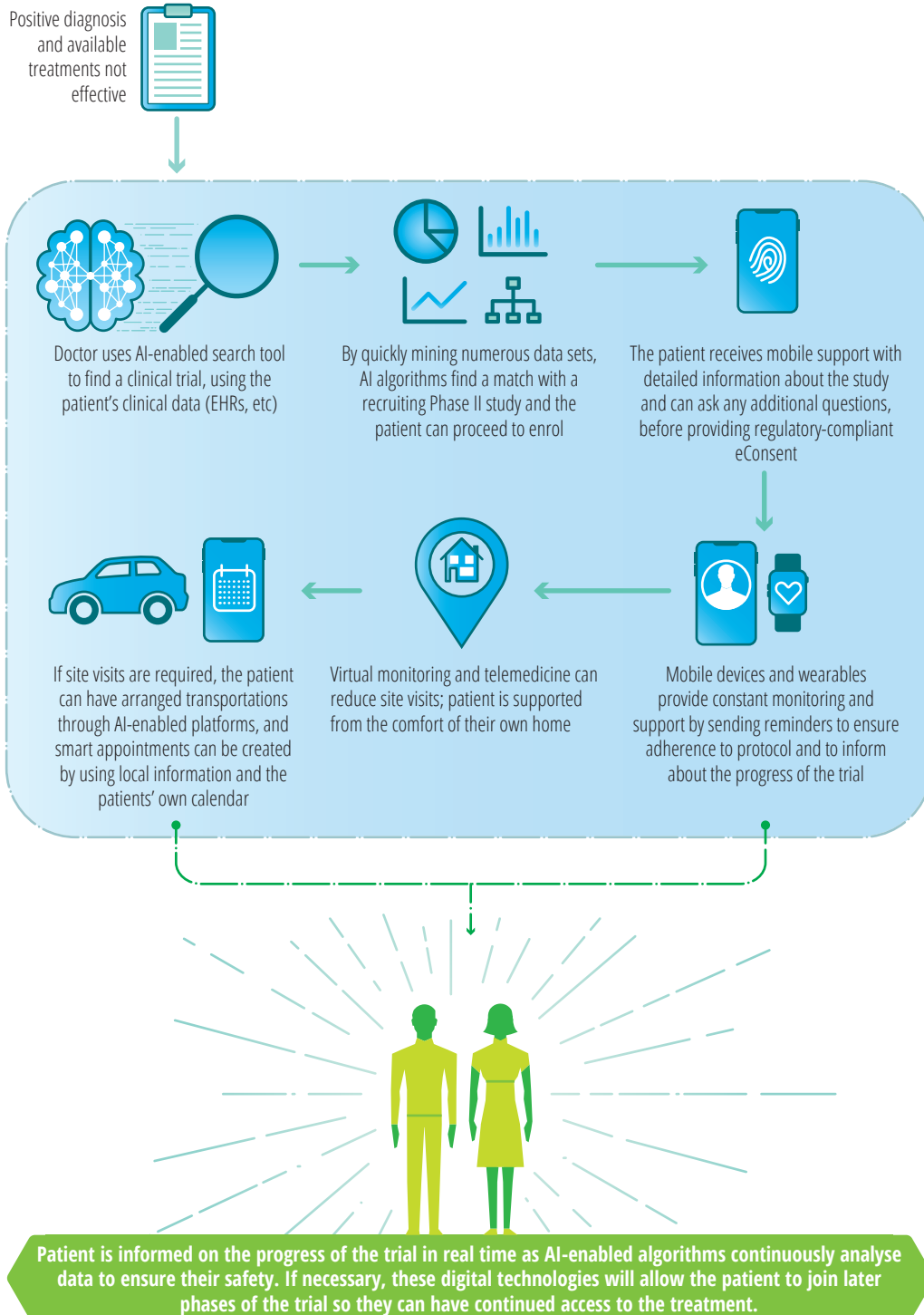
In the future, biopharma companies will capitalise on the digitalisation of health care to manage clinical trials remotely. One such example is the creation of a hub-and-spoke command centre. Novartis is already tackling its R&D costs by creating a single 'control tower' to digitally monitor and troubleshoot clinical trials taking place across the globe in real time, known as Nerve Live. This platform uses ML with predictive algorithms allowing Novartis to identify future potential logjams in its clinical trials 12, 18 or even 24 months down the road, enabling the company to take action to prevent the delay occurring.[96]

In the future, biopharma companies will capitalise on the digitalisation of health care to manage clinical trials remotely.

FIGURE 4

Patient's journey through an AI-enabled digital trial

Connected AI-enhanced digital technologies will transform clinical trials by making them safer, more efficient and effective, and, above all, truly patient-centric

Positive diagnosis and available treatments not effective

Doctor uses AI-enabled search tool to find a clinical trial, using the patient's clinical data (EHRs, etc)

By quickly mining numerous data sets, AI algorithms find a match with a recruiting Phase II study and the patient can proceed to enrol

The patient receives mobile support with detailed information about the study and can ask any additional questions, before providing regulatory-compliant eConsent

If site visits are required, the patient can have arranged transportations through AI-enabled platforms, and smart appointments can be created by using local information and the patients' own calendar

Virtual monitoring and telemedicine can reduce site visits; patient is supported from the comfort of their own home

Mobile devices and wearables provide constant monitoring and support by sending reminders to ensure adherence to protocol and to inform about the progress of the trial

Patient is informed on the progress of the trial in real time as AI-enabled algorithms continuously analyse data to ensure their safety. If necessary, these digital technologies will allow the patient to join later phases of the trial so they can have continued access to the treatment.

Source: Deloitte analysis.

Given the fragmented and highly regulated nature of the industry, biopharma companies will need to establish effective AI strategies for clinical development, including the following:

- **partnerships with AI companies:** The scarcity of skills and talent needed to develop AI algorithms and to understand the complexity of biological systems means biopharma strategies should include partnerships with leading AI for drug discovery and development companies. Biopharma companies benefit from having AI solutions that are specific to their own proprietary data, and the AI firm has the opportunity to develop its skills by accessing vast amounts of longitudinal data sets.

- **data sharing:** Fierce competition between biopharma companies means traditionally there has been limited information sharing, exacerbated by challenging regulatory and compliance requirements. While data-sharing partnerships between biopharma companies can optimise the use of AI, this will only be effective if there is a change to a more collaborative mindset both within and between companies.

- **algorithm transparency:** Regulators expect transparency regarding the algorithms used for drug development to understand AI-based conclusions. The risks of regulators seeing AI as a 'black box' could lead to problems obtaining approval particularly when the submissions use biomarkers developed using AI. Our *A bold future for life sciences regulation: Predictions 2025* report highlights the importance of biopharma companies working proactively with regulators to agree to acceptable regulatory pathways to improve the effectiveness of the regulatory process.[97]

- **data privacy:** The relative ease of working with non-patient data during drug discovery means AI is currently more widely adopted in drug

discovery than in clinical development.[98] The use of patient data is highly sensitive and, as AI capabilities develop, companies need to understand the appropriate legal and compliance requirements needed to protect the increasing volume of data. GDPR compliance in Europe and similar requirements being developed in the US and elsewhere will be important, especially as failure to comply could have significant financial and reputational consequences. Moreover, biopharma companies will need to ensure that any patient data used has specific consent for the specified purpose and that it remains private and secure.[99]

While AI is yet to be widely adopted and applied to clinical trials in a meaningful way, it is clear that AI has the potential to transform clinical development. The applications of AI as outlined in this report could lead to faster, safer and significantly less expensive clinical trials.

The industry is at a tipping point where the adoption of AI technologies can enable less costly and more productive drug development. The potential of AI to improve the patient experience will also help deliver the ambition of biopharma to embed patient-centricity more fully across the whole R&D process. Ultimately, transforming clinical trials will require companies to work entirely differently, drawing on change management skills, as well as partnerships and collaborations. As highlighted in our *Intelligent drug discovery report*, the success for biopharma companies using AI for clinical trials will depend on having highly skilled interdisciplinary leadership and skilled interdisciplinary AI experts who can innovate, organise and guide others, as well as AI-friendly CEOs and board members to drive the adoption of AI.

If biopharma succeeds in capitalising on AI's potential, the internal and external productivity challenges that have driven the decline in the rate of return on investment in biopharma innovation will be reversed and the industry will thrive.

Five key questions for biopharma's adoption of AI in clinical trials

As highlighted throughout the report, we consider that the use of AI tools in clinical development is now a critical business imperative. AI technologies are creating an opportunity for improving the clinical trials process by reducing clinical cycle times and costs and improving patient experience. However, before adopting AI solutions, there are a number of key questions that biopharma companies need to consider carefully.

WHAT ARE YOUR MAIN INTERNAL COST DRIVERS OF YOUR CLINICAL TRIAL PROCESS, AND HOW MIGHT AVAILABLE AI SOLUTIONS HAVE THE MOST IMPACT?

Patient recruitment and data management are among the largest cost drivers of clinical trials and are currently where AI shows the most promise.

DO YOU HAVE THE NECESSARY SKILLS AND TALENT TO INTEGRATE AI TECHNOLOGIES INTO YOUR CLINICAL DEVELOPMENT?

The adoption of AI innovation requires an internal team of experts, comprising biologists, chemists, engineers, data scientists and bioinformaticians, working in cross-functional teams. The aim should be to promote an 'intrapreneurship culture', providing these teams with the freedom and resources to create innovative solutions.

CAN EXTERNAL PARTNERSHIPS PROVIDE A SOLUTION TO THE EXPERTISE NEEDED FOR AI ADOPTION IN YOUR CLINICAL TRIALS?

Biopharma companies can benefit from selecting reliable partners to leverage their extensive knowledge and expertise gained from repeated experience.
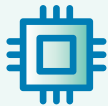
WHAT IS YOUR STRATEGY FOR RESPONDING TO THE DISRUPTION THAT TECH GIANTS ARE BRINGING TO CLINICAL DEVELOPMENT?

Tech giants are the leading experts in the use of big data and in developing new AI solutions. They are increasingly disrupting the health care industry and investing in the development of AI tools for drug discovery and development. For biopharma companies, tech giants can be an opportunity as potential partners; a threat as competitors; or both an opportunity and a threat, for which they need to have a clear strategy for how to respond to this changing landscape.

HOW ITERATIVE IS YOUR APPROACH TO THE REGULATION OF AI-ENABLED PROCESSES, AND IS YOUR REGULATORY FUNCTION SEEN AS A STRATEGIC ASSET?

Regulators accept the potential of leveraging RWD to make clinical trials more accessible and participatory. However, data-driven approaches will only enable faster regulatory approvals, improved patient experience and early access to treatments, if there is early engagement and increased transparency of operations. Regulatory relationships need to be based on a win-win approach.

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