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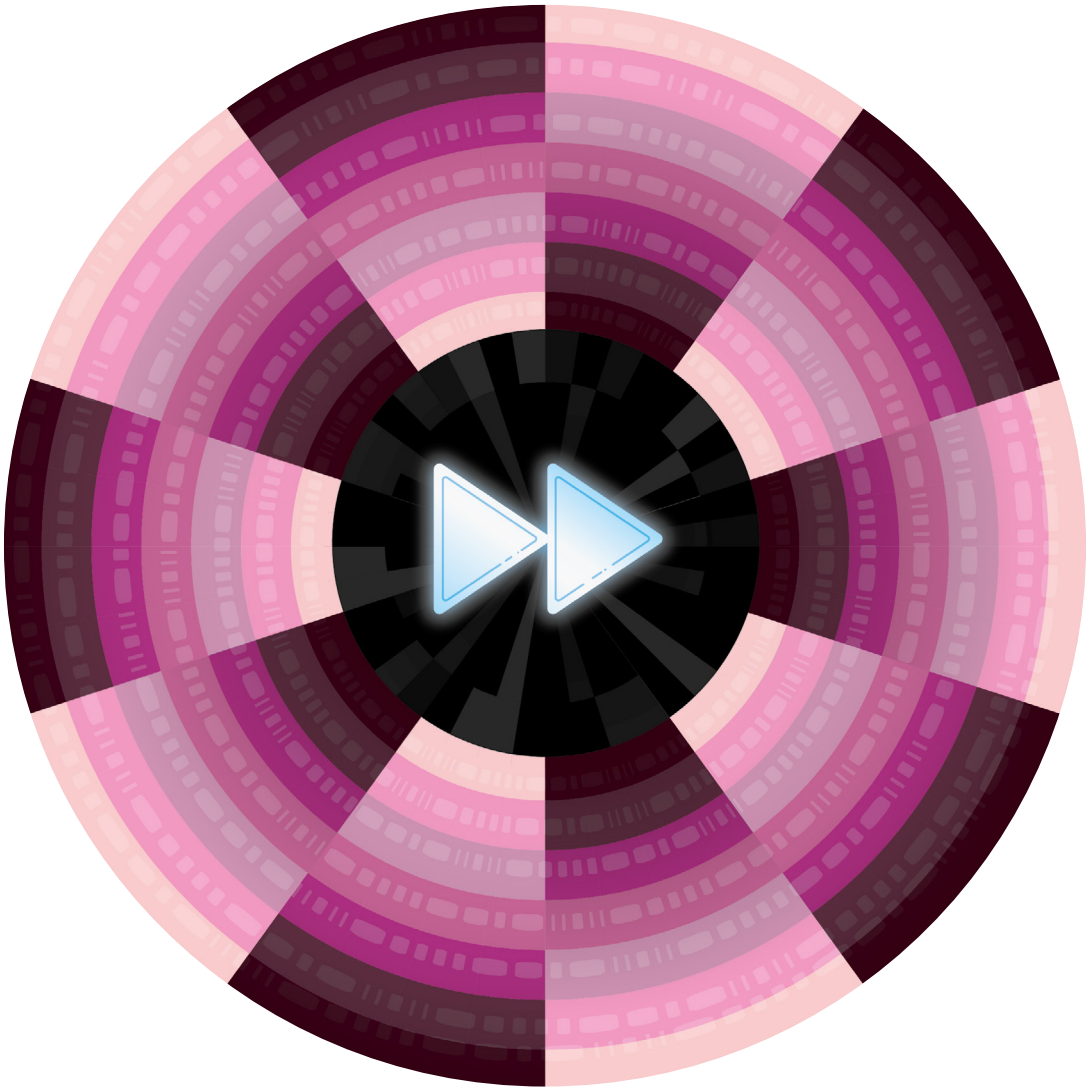

The future unmasked

Predicting the future of healthcare and life sciences in 2025

Prediction Seven

Companies have reversed the decline in the returns from pharma R&D

Deloitte Centre *for* Health Solutions

Foreword

Welcome to our seventh prediction, *Companies have reversed the decline in the returns from pharma R&D*, from our report *The future unmasked: Predicting the future of healthcare and life sciences in 2025*. This is the seventh of ten predictions, all of which have been informed by emerging evidence of the impact of the COVID-19 pandemic on society and the health ecosystem. They have also been shaped by our research insights including our global 2040 Future of Health campaign. This seventh prediction considers what the world in 2025 looks like for biopharma companies who have adopted digital technologies to transform their drug discovery and clinical development activities.

In response to the COVID-19 pandemic, the pharma industry, academia, biotech, and governments, formed an unprecedented level of collaboration and partnerships to develop new treatments and vaccines for the novel coronavirus. In addition, regulators entered into immediate dialogue aimed at supporting the most promising innovations. Developing a widely available and affordable vaccine is considered one of the most effective ways of turning the tide on the pandemic. As a result, there has been an unparalleled acceleration in the pace and scale of R&D, particularly to develop a vaccine to stop or eliminate the virus. In response to concerns about the speed of development, the CEOs of nine leading developers signed a pledge committing to uphold the integrity of the scientific process and provide robust evidence of safety and effectiveness. Vaccine developers and governments are anticipating emergency use authorization (EUA) of some of these vaccine candidates by the end of 2020.

In 2025, pharma R&D processes have been augmented through digital platforms and large-scale access to FAIR data and research partnerships with academia and digital tech companies, driven by leaders with digital skills and a fail-fast mind-set. AI for drug discovery companies have revolutionised biopharma's understanding of biological targets and AI and RWE have helped define new patient-centric digital end-points. Pharma companies now employ data rich visualisation tools across R&D and operate virtual clinical trials, enabling faster recruitment and monitoring of more diverse groups of trial participants.

Our seventh prediction is brought to life through a series of portraits imagining the experience of individuals in 2025, with reference to the evidence today to predict what the future might look like tomorrow.

Stay tuned for the subsequent predictions in our series.

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Companies have reversed the decline in the returns from pharma R&D

Advanced AI-enabled technologies have accelerated drug discovery and clinical trials improving efficiency and reducing costs

Prediction: In 2025, Pharma R&D processes are augmented through digital platforms and large-scale access to FAIR data and research partnerships with academia and digital tech companies, driven by leaders with digital skills and a fail-fast mind-set. This is improving success rates and reducing the time to market. AI for drug discovery companies are using DL to derive crucial insights from multiple datasets, improving the speed and accuracy of drug discovery, and delivering more precise therapeutic candidates. Innovative clinical trials, using digital technologies, AI and RWE have helped define new patient-centric digital end-points, refine indications and improve trial enrichment strategies. Pharma companies now employ data-rich visualisation tools across the study lifecycle and deploy hub-and-spoke command centres to operate virtual clinical trials, enabling faster recruitment, enrolment and monitoring of more diverse groups of patients. Apps, wearables, eConsent platforms and telehealth help reduce the time commitment and financial costs that hindered recruitment and retention. All these changes are reversing the previous upward trend in R&D costs.

The world in 2025

- Pharma companies use DL algorithms in their drug discovery processes, deploying in-house data analysts and partnering with AI for drug discovery start-ups and government-supported genomic teams.
- Novel biomarkers and drugs identified using AI have increased alongside better knowledge on disease mechanisms. As a result, a greater proportion of pipelines comprise candidates for more precise pathologies.
- Increasingly, early-stage research uses *de novo* design and/*or in silico* clinical trials. Many Phase I trials also use quantum computer simulations to accelerate decision making at key milestones.
- Advanced techniques such as DL are embedded in clinical trials improving the diversity of trial participants and the development of precise treatments, such as for rare diseases.
- New platform technologies have changed the development of next gen therapies, such as CRISPR and mRNA, leveraging the experience of cell and gene therapies, to create new treatment paradigms.
- Liquid biopsies, combined with improved use of bio-sample libraries, have accelerated the development of precision medicine.
- An AI-enabled digital infrastructure, has improved approval rates, lowered development costs, and is delivering medications to patients faster.
- An enhanced hybrid clinical trial experience has embedded patient-centricity across R&D, with patient groups and their unique 360-degree perspective, inputting to the design and management of clinical trials.
- Biopharma companies use digital twins to simulate clinical trials including costs, patient selection, and the likelihood of success.

Conquered constraints

- **Skills and talent:** recruiters target data science, bioinformatics, computational biology and biochemical specialists. R&D scientists are increasingly a blend of clinician, natural scientist and computer data scientist. Companies are also partnering with academia, AI for drug discovery companies and tech giants to bring people with proficiency in data science and data ethics into the R&D team. Skilled interdisciplinary leaders with AI-friendly, tech-savvy boards create new businesses and operating models.
- **Funding:** biopharma companies have increased investment in data, analytics, technologies and research collaborations. Faster drug discovery, use of synthetic control arms and improved recruitment and retention of patients in clinical trials have reduced R&D costs and helped reverse the previous decline in ROI, attracting high levels of investment. Reimbursement discussions with payers begin at Phase I, with new funding models, for example for cell and gene therapies.
- **Regulations:** rapid changes to regulatory requirements in response to the growing use of technologies (including experience during COVID-19) have created new relationship paradigms. Regulators readily accept RWE in support of new drug applications, label expansions and revisions. New regulatory pathways have increased flexibility, transparency and speed of approval. Regulators have also collaborated globally to develop new evidence frameworks and enhance their own skill-sets to use the vast data stored on cloud platforms.
- **Data and interoperability:** HIPAA and GDPR compliant cloud, quantum computing, blockchain and AI-enabled services and tools facilitate global FAIR data management and sharing. Blockchain technology is also used to verify the origin and veracity of dossier submissions.

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Imagine the world in 2025

Using AI algorithms to match patients to clinical trials

Susan has been diagnosed with a rare cancer for which there is no available treatment. Her doctor, Dr Nemo, used her clinical data (including EHRs and genomic data) to find a suitable clinical trial through an AI-enabled search tool. By mining numerous datasets, the AI algorithm matched Susan with a Phase II study and Dr Nemo helped Susan enrol. The pharma company provided Susan with comprehensive information about the study and addressed her anxieties, so that she was happy to sign the eConsent form. Susan received a smart watch, digital diagnostic tools and an app, all of which fit seamlessly into her daily routines providing real-world remote two-way communication while continually monitoring her health. AI algorithms capture and analyse data to provide insights, including precise digital biomarkers that monitor Susan's response to her treatment and whether there is need for dose adjustments or any indications of adverse reactions. Susan receives automated reminders throughout the study to ensure that she follows the treatment and personalised messages that keep her informed about the progress of the trial. Home monitoring means that Susan visits the trial site much less frequently than she would otherwise have done. When she does visit, she uses her app to arrange her appointments and transportations. Susan adheres to the trial protocol throughout and responds so well that she is invited to join the next stages of the study providing her with continued access to the treatment.

The regulatory function of a biopharma company is fully integrated across clinical development

Luis is the regulatory affairs director of MJ Biopharma (MJBP) and is accountable directly to the Board for ensuring that the use of next generation technologies helps drive regulatory compliance. Luis has automated the company's dossier compilation to reduce the time and cost of the marketing authorisation application process. He also uses AI to identify any anomalies in dossier compilation and rectify them before submission, with NLP used to translate dossiers for multiple applications. Automation has been implemented across the clinical development process to improve regulatory compliance with enriched recruitment and retention strategies. The custody and serialisation of blockchain capabilities are used for real-time tracking of the control, transfer and distribution of medicines to trial participants. Automation has also made it easier to create an audit trail to review compliance and decision-making. Overall, Luis has transformed pre-authorisation information management by leveraging AI and BI capabilities, based on his understanding of the regulators own use of advanced analytics to detect patterns and trends to ensure products' safety and efficacy.

Technological advances that herald a renaissance in peptide drug discovery

Nina is currently working as a Chief Business Officer at an AI-enabled, peptide-focused drug discovery company founded in 2019 by a renowned scientist who has received numerous awards for her business leadership and scientific work in AI. Her team includes some 60 employees, composed of 'drug hunters' working in partnership with a number of major pharma companies. Last month Nina was part of the team that identified and accelerated clinical development to launch a novel anti-inflammatory product identified by the AI platform and developed in the record time of 420 days. The company has since entered into seven further corporate partnerships and a joint venture and are actively deploying the AI platform in developing new therapeutics that target novel pathways in oncology and cardio-metabolic diseases. Nina and her team have published over 20 peer-reviewed papers, applied for a dozen patents and received a number of industry awards for their innovative drug discovery work.

Note: All elements on this page are from a perspective of 2025 and are fictional

Evidence in 2020

Medidata's Acorn AI gives researchers a 360-degree view of the patient

Medidata, a Dassault Systèmes company, is helping drive the digital transformation of the life sciences industry through its world leading platform for clinical development, commercial, and real-world data. Medidata established Acorn AI in early 2019 to develop new insights across all phases of drug development and make data 'liquid' across the end-to-end lifecycle of a biopharma company (from research to development and into post-market surveillance). In building linkages between clinical trials, genomics, RWE, translational health and other datasets, it aims 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 20,000 clinical trials with structured, standardised clinical data repositories from over 6.3 million patients. Acorn AI is focusing on addressing precision medicine with CAR-T therapy, tissue engineering, gene and cell therapy, while leveraging 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. They help sponsors make critical decisions on how to create better-integrated evidence, including clinical as well as RWE to demonstrate the products' value to regulators, patients, payers and providers.[79,80]

Japan's National Cancer Center Hospital East using circulating tumour DNA analysis for trial selection

Japan's National Cancer Center Hospital East compared circulating tumour DNA (ctDNA) analysis to tissue genotyping for enrolling gastrointestinal patients into two large trials. One trial, SCRUM-Japan GOZILA, used the Guardant360 liquid biopsy to identify patients, while the other one, GI-SCREEN, relied on tissue genotyping. Researchers more quickly enrolled a higher number of patients into a trial using the ctDNA approach. They further noted that liquid biopsy-based profiling uncovered a greater number of actionable mutations demonstrating that genomic profiling by ctDNA analysis using the Guardant360 liquid biopsy has the advantage of shorter turnaround times and improved patient enrolment compared to tissue biopsy for clinical trials, without compromising treatment efficacy.[81]

Flatiron Health uses machine learning (ML) to identify patients eligible for oncology clinical trials and to generate important RWE from the experiences of the 95% of cancer patients who aren't represented in trials

The complexities of identifying and screening patients for trials are consistently cited as causing study delays, unexpected costs and study failure. EHRs are a valuable source of the real-world data key to a solution. Leveraging data from the EHRs of cancer patients, Flatiron has developed an approach that employs ML to provide real-time notifications of potential patient-trial matches to site staff and research coordinators at the point of care, integrated into their daily workflows. The functionality is one feature of Flatiron's OncoTrials® software, which continuously runs ML models trained on tens of thousands of structured and unstructured real-world data points to infer key trial eligibility criteria such as metastatic status and biomarker results.[82,83]

Exscientia and the use of AI for drug discovery

Exscientia is a leading global pharmatech company and was the originator of the first AI-designed molecule to enter clinical trials. Exscientia has developed a full-stack AI-driven drug discovery platform from target identification to drug design and optimisation of novel drug candidates. Fusing the power of the original AI-design with the experience of seasoned drug hunters, Exscientia's Centaur Chemist™ platform enables the discovery of exquisitely optimised molecules with breakthrough productivity. In tandem, Exscientia's Centaur Biologist™ platform drives the flexible analysis and prioritisation of discovery targets across all pharmaceutically relevant disease space. Five assets have been delivered in around 8 to 14 months (compared to the five-year industry benchmark), with drug discovery cost savings of more than 80% (30% achieved for the entire drug development process). Over 20 AI-Driven drug discovery projects are currently active with further growth scheduled throughout 2021. The company plans to develop its own portfolio as well as continue to partner with pharma and biotech companies.[84,85]

Trials.ai uses its proprietary database to derive insights and recommendations for trial sponsors

Trials.ai uses AI to analyse large sets of data including past clinical studies, medical journals, regulatory guidance, standards of care, trial complexity information, amendment information and other forms of trial-related documentation 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, retention, and reduces burden on patients and trial sites by bringing in cost and time efficiency. For one of its clients Trials.ai shortened study timelines by 33% and reduced data errors by 20%.[86]

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The COVID-19 impact

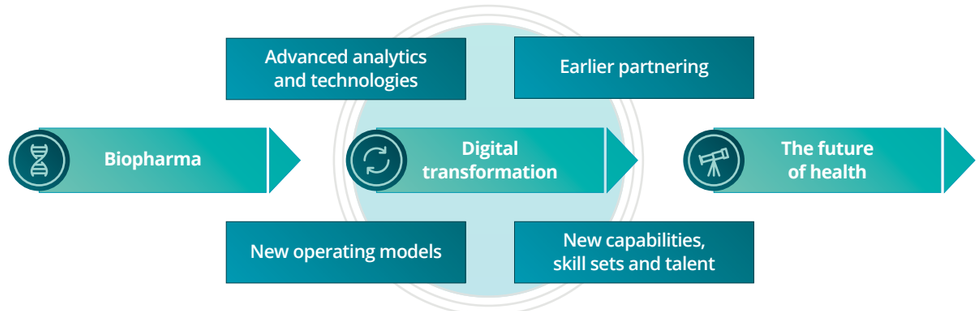
Deloitte view on the impact of COVID-19

In response to the COVID-19 pandemic, the pharma industry, academia, biotech, and hospitals, embarked on unprecedented scientific endeavours funded by governments, multilateral agencies, not-for-profit institutions, and the private sector. Trade secrets and intellectual property have been more widely shared than ever before as collaborations and partnerships formed to expedite the search for new treatments and vaccines. Regulators entered into immediate dialogue aimed at supporting the most promising innovations, discussing cost-plus pricing strategies and improving the diversity of participants in clinical trials. However, pivoting R&D activities towards COVID-19, while necessary, has impacted the progress of other clinical trials. By the beginning of November, ten vaccine candidates were in Phase III trials and developers of three of these vaccines are hoping to obtain regulatory approval before the end of 2020. This is faster than any other vaccine in history. In response to concerns about the speed of development, the CEOs of nine leading developers signed a pledge committing to uphold the integrity of the scientific process and provide robust evidence of safety and effectiveness. While initially any approved vaccines are expected to be targeted at healthcare staff and more vulnerable populations, their ultimate impact globally will depend on the disease's epidemiology and transmission and the duration of immunity from infection. Nevertheless, vaccines will play a crucial role in most response scenarios and will serve as an insurance policy against continued health societal and economic impacts of the pandemic.

23andMe: from genetic testing, to discovery, to drug development

23andMe is a direct-to-consumer online genetic-testing company providing users with insights into their health, genealogy and ancestry, while furthering research into the genetic basis of diseases and leveraging genetic data to help develop new treatments. Since 2007, 23andMe customers have submitted saliva samples, self-reported information and, for those who opt-in to the 23andMe research program, separate consent documents for biobanking and research. 23andMe has sold more than 12 million kits and over 80% of its customers elect to participate in research. In 2018, GSK took a $300 million stake in 23andMe signing a four-year collaboration agreement to work together to discover new drugs. To date around 30 therapeutic targets have been identified with majority of pre-clinical programmes in the target validation phase, and the remainder are in early drug discovery programs. In January 2020, 23andMe licensed the rights to a drug targeting multiple inflammatory diseases (including various dermatological conditions) it developed in-house to a Spanish pharma company, Almirall, who plans to take the drug through clinical trials. During the COVID-19 pandemic, 23andMe has used its research platform to identify a number of genetic and non-genetic associations for susceptibility and severity to COVID-19. In under four months, more than a million 23andMe customers consented to participate in the research, more than 15,000 had tested positive for COVID-19, with 1,100 of them requiring hospitalisation. Through their participation, 23andMe has been able to make new findings, replicate others, and contribute to the larger effort by other researchers who are searching for treatments.[87, 88, 89,90]

Biopharma companies need to pursue a fundamental shift in their R&D model



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