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Accelerating the future
Convergence of AI technologies and human expertise in pharma R&D

Life sciences and healthcare predictions 2030

Deloitte Centre *for* Health Solutions

Convergence of AI technologies and human expertise in pharma R&D

Accelerating value for companies and quicker access to innovations for patients

Prediction 2030

End-to-end digitalisation, automation and integration of AI technologies have enabled pharma companies to speed up decision-making across the R&D value chain, improving R&D productivity. Biopharma has embraced digital-first, patient-centric technologies, like clinical outcomes assessments (eCOA), sensors and imaging, to generate deeper insights across multiple trials and patient interactions. Clinical trial teams use AI in trial design and in recruiting trial participants and deploy integrated digital platforms that enhance data interoperability and support R&D collaborations. Accelerated R&D timelines mean that innovations reach patients and realise value sooner. Since 2023, the year-on-year return on investment (ROI) in biopharma innovation has improved substantially. Strategic alliances, outsourcing, and earlier and ongoing dialogues with regulators, have improved success rates for curative and preventative therapies for previously untreatable diseases. There has also been a refreshed focus on new blockbuster drugs to treat non-communicable diseases, building on the lessons learned from the success of GLP-1-receptor agonists (GLP-1) drugs in treating obesity. New value-based funding models have encouraged a greater focus on preventative therapies, including mRNA vaccines.

The world in 2030

- De-novo protein design using GenAI models, in-silico research, digital twins, computational science and improved translation capabilities have improved the speed and accuracy of drug discovery.
- Advanced gene editing, multiomics technology, digital platforms, bioengineering, synthetic control arms, and GenAI tools have helped design more cost-effective clinical trials in order to develop more personalised medicines.
- Internal and/or outsourced hub and spoke command centres manage virtual clinical trials employing data-rich visualisation tools and trial enrichment strategies to ensure optimised recruitment, enrolment, monitoring and retention of trial participants.
- Diversity in clinical trials is achieved using real-world evidence (RWE), AI-enabled recruitment tools, and defined enrolment targets, and by raising awareness of and training the R&D workforce on diversity, equity and inclusion.
- Quantum computing's ability to solve complex logistical problems has helped speed up drug discovery and development timelines and reduce costs.
- Clinical research data plus real-world data (RWD) from insurance claims, wearables, patient-reported outcomes and patient histories provide deeper, more refined insights on drug performance.
- Multi-dimensional datasets are used to enhance trial execution, generate evidence of safety and efficacy, and design equitable drug reimbursement strategies.
- AI is applied to pharma's extensive library of documentation to help design the first drafts of clinical trial protocols and standard operating procures and GenAI tools are used to automate the creation of clinical study reports, all of which are then reviewed and developed further by humans.
- Trial design and data management initiatives together with adoption of 'sustainability by design' principles and adoption of science-based carbon reduction targets has dramatically reduced emissions.

Conquered constraints

Skills and talent

An agile and adaptable R&D workforce has emerged by bringing together engineering, computational science and biotechnology and by investing in AI, digital, genomics and medical skills. This together with greater collaborations between R&D, commercial and manufacturing teams, and partnering with academia and digital tech companies has enhanced the R&D talent pool.

Funding and business models

Collaborations between government and private sector investors (including private equity), pharma companies and research institutions, have led to innovative funding models that share the risks and rewards from developing new treatments. Subscription-based models for access to drugs provide a steady revenue stream for ongoing R&D, and value-based care has shifted payments towards effectiveness and value delivered.

Regulation

Pharma have responded to increasingly demanding compliance requirements by incorporating 'quality-by-design', data retrieval and document safeguarding, into their clinical trial dossier submissions. Risk-based monitoring (RBM) and acceptance of RWE have improved transparency and speed of approvals. A plethora of new international regulations, such as the US Inflation Reduction Act and the reform of the EU pharma legislation, aimed at improving drug access and affordability have created new more collaborative ways of working with regulators; but also changed pharma's risk appetite, the allocation of R&D resources and associated portfolio strategies.

Digitalisation and data

Pharma companies have established a dynamic data system that connects cross-functional data and embeds GenAI-generated insights into business workflows. Advanced analytics and a deep culture of cyber vigilance with strengthened technology-enabled resilience and advanced third party risk management practices are integrated across the R&D value chain.

Imagine the world in 2030*

A day in the life of a clinical trial team

Katja manages a clinical trial team and uses GenAI co-pilots to generate ideas and to translate and simplify technical jargon to enable more effective communication with colleagues in regulatory affairs and commercial operations. This enables quicker decision-making and a fail-fast mind-set. In collaboration with colleagues in the commercial team they have agreed metrics to measure the speed, quality, productivity and sustainability of product development. AI chatbots are used to improve the patient experience during trial recruitment and participation, by enabling real-time interactive discussions, e-consent, electronic appointment bookings and reminders. Performance metrics are captured throughout the trial duration. End-to-end digitalisation and the use of AI are having a positive impact on R&D costs and time to market. Katja in launching her latest phase III clinical trial utilising machine learning (ML) algorithms to identify a diverse set of potential participants who are likely to respond to the treatment. She has also used digital twins to create a synthetic set of data and predict how the same patients would progress in the control group. By comparing outcomes, she has significantly reduced the number of control patients needed. Once the clinical trial is under way, clinicians optimise dosing regimens and monitor patient outcomes in real time. Katja uses historical data on efficacy and safety to predict likely risks and identify mitigation strategies to optimise patient outcomes. As the trial progresses, she uses a digital platform to manage the many necessary protocol amendments and adopts the company's risk management framework to ensure protocol and regulatory compliance. The performance metrics show that the trial is progressing 25% quicker than a similar trial in 2025 and, importantly, the research team's understanding of the trial population is much deeper.

How 'AI for drug discovery' companies tackle their search

A wealth of data on ligand properties, therapeutic target binding and 3D structures, coupled with quantum computing capacity and on-demand libraries of billions of small molecules, has continued to drive the shift towards computational drug discovery. Jacob is the founder of a small company, Vridia Pharmaceuticals, which specialises in computational drug discovery using an AI software suite. Jacob's company survived the 'financial hype' and major consolidation of the AI-powered drug discovery (AIDD) industry in the mid-2020s, and he aims to take their discoveries through to commercialisation. He partners with major pharma companies across the globe and collaborates with academia to access clinical data and obtain patients for the subsequent development cycles. His employees have varied academic and career experiences, with AI and data skillsets combined with extensive biological and chemical expertise that provide crucial advantages in the search for drugs. Last month, Jacob's company received regulatory approval for its fourth drug, discovered through AI-enabled computational drug discovery. Due to greater insights, data and modelling capabilities, the failure rate in clinical trials has been reduced by over 15% and more effective and safer drugs are being developed at lower costs and in a shorter time. Vridia's latest small drug to achieve regulatory approval for a novel molecule progressed from discovery to launch in under six years.

Contract research organisations (CROs) help navigate cell and gene therapy (CGT) R&D

PairC is a specialist CRO, with expertise in late-stage clinical trials for precision CGTs. CGTs present unique regulatory, manufacturing and market access challenges. Early engagement by a sponsor pharma company (sponsor) with PairC's expertise and resources enables flexible and scalable development. The sponsor is able to focus on its core competencies by choosing which services to outsource. Martha, PairC's Clinical Director, is currently overseeing the platform trial for a gene therapy targeting six rare diseases under a single, durable master protocol. Its adaptive nature allows real-time modifications based on accumulated data, enabling the clinical team to respond to emerging insights and add or drop treatment arms or adjust patient populations as needed. The trial design is based on information sharing between PairC and the sponsor, leveraging a common infrastructure for multiple gene therapies. Point-of-care manufacturing at the trial site minimises contamination risks and the need for transportation and storage. This reduces the likelihood of temperature fluctuations, ensuring that the CAGT remains viable. The sponsor has a regulatory affairs team overseeing the entire development process for the gene therapy, and Martha is working closely with this team, using appropriate surrogate endpoints and RWD in trials and submissions. Patient quality of life is prioritised with clinical endpoints such as 'life satisfaction' and 'subject well-being' critical criteria for the regulator.

* Note: All elements on this page are from a perspective of 2030 and are fictional

Evidence in 2024

Tech titans are working with life sciences companies on advanced GenAI in many areas

Tech titans are working with life sciences companies on advanced GenAI in many areas. For example **NVIDIA** provides a GenAI drug discovery cloud service, **BioNeMo**, to biopharma companies that want to create or customise their own generative models for offering a Software-as-a-Service (SaaS) model to others via cloud APIs. In January 2024, Deloitte announced Atlas AI TM the latest addition to its **Quartz AI™** suite of cross-industry solutions built on the **NVIDIA AI** and **NVIDIA Omniverse™** platforms. As the first life sciences and health care (LSHC) offering under Quartz, Atlas AI includes a novel drug discovery accelerator that helps expedite research and bring new drugs to market faster. By using GenAI models made accessible with BioNeMo, knowledge representation and reasoning, and custom protein Large Language Models (LLMs) and chemoinformatics LLMs, **Atlas AI** advances digital biology and transforms drug discovery with the latest AI technologies. The launch of Atlas AI aims to unlock the value of GenAI across enterprise software platforms and complies fully with Deloitte's safe and responsible use of GenAI, guided by its **Trustworthy AI™ framework**, which helps users create necessary safeguards and mitigate risks during product development and operation.[1]

Predicting the health trajectory of patients

Kings College London's Foresight is an AI tool trained on NHS electronic health record (EHR) data, using a deep learning approach to recognise complex patterns in both the structured and unstructured data of EHRs to produce insights and predictions. It can forecast the next new biomedical concept in a patient's timeline (disorder, symptom, relapse or medication), in three patient groups with 80%, 90% and 91% accuracy depending on the patient pool. The technology supports virtual trials to find new possible treatments, assess possible complications and evaluate outcomes. It can also find unexpected complications or adverse events not detected through traditional methods.[2]

Success rates are higher for AI-discovered drugs

As of December 2023, 24 **AI-discovered molecules** have completed phase I trials, of which 21 were successful. This suggests a success rate for phase I trial AI discovered molecules of 80-90%, substantially better than historical industry averages (40-65%).[3]

Digital twins are improving ROI

Digital twins can reduce the need for clinical trial enrolment by between 25% and 50%, reducing clinical development time and costs.[4] **Unlearn**'s TwinRCT PROCOVA utilises digital twins (or a comprehensive forecast of individual trial participants' future clinical outcomes) to develop prognostic scores for use in phase II and III trials, making estimates of treatment effects more nuanced and precise. Prognostic scores closely correlate with actual outcomes, enhancing the reliability of estimates of treatment effect. PROCOVA's AI model has been qualified by the European Medicines Agency, providing a regulatory framework for the application of TwinRCT in phase II and III trials with continuous outcomes, and fully aligns with FDA guidance for either reducing trial size or enhancing its power. For example, reanalysing a completed clinical trial in Alzheimer's disease shows that using TwinRCT could have reduced required participants by 23%, resulting in an estimated reduction of five months in the enrolment process.[5]

The potential of decentralised clinical trials (DCTs)

Tufts Center for the Study of Drug Development found that DCTs are associated with reduced clinical trial timelines and substantial extra value to sponsors developing new drugs. If DCT methods are applied to both phase II and phase III trials, the value increases by US$20mn per drug that enters phase II, with a seven-fold ROI. They also have lower screening failure rates and fewer protocol amendments.[6, 7]

Cloud labs and remote research are enabling 24-hour laboratory activity 365 days a year

Emerald Cloud Labs is a software controlled, highly automated life science laboratory that allows scientists to design, execute and analyse experiments remotely. Its ultracapacity model can process 155,400 analytical samples per year (compared to 22,200 in-house or with a CRO), at considerably reduced costs.[8]

Advanced clinical trial platforms enable end-to-end monitoring

The **Medidata Platform** does this by connecting patients, sites, sponsors and CRO partners in a secure, scalable cloud environment that manages a study from start to finish.[9] The Medidata Diversity Program builds diversity into every step of the clinical trial strategy through data-driven site selection, pre – and post-trial patient engagement tools, insights from patient advocates, and a patient-accessible site network.[10] Organisations using Medidata Professional Services build studies one month faster than those that don't and conduct studies five months faster when using multiple Medidata solutions. Medidata Clinical Data Studio is a data management and quality experience that provides seamless access to integrated data from Medidata and non-Medidata sources. It leverages AI to streamline data aggregation, standardization, and management workflows so that multiple users can review real-time data to shorten timelines, reduce risk, and ensure safety. Data managers can shorten review cycle times by up to 80% per cycle.[11]

Algorithms can expedite patient screening and recruitment for clinical trials

Precision research platform **Deep 6 AI** uses AI algorithms and natural language processing to sift through vast amounts of structured and unstructured patient data, such as clinical notes and radiology reports. The platform matches patients and sites to actual trial protocols in real time, within a secure Health Insurance Portability and Accountability Act (HIPPA)-compliant collaborative environment. Deep 6 AI sites recruit patients three times faster than other sites and find 25% more patients than traditional recruitment with 50% less time spent searching for them.[12]

Artificial intelligence and the transformative power of GenAI

The impact on R&D

Deloitte research shows that a top 10 biopharma company with an average revenue of $65-75bn could obtain between $5-7bn of value by scaling the use of AI over five years. R&D represents the leading area of value opportunity for pharma companies at 30-45%, by applying AI to novel drug identification and accelerating drug development could provide both cost savings and revenue uplift.[13] For example:

- GenAI can be used to model the structure and function of proteins and biomolecules, accelerating the identification and validation of molecules and new drug candidates.
- GenAI, by analysing vast amounts of scientific data, helps optimise the exploration of novel drug targets and uncover emerging disease links, which are then validated through experiments, fostering collaborative synergy between AI-driven analysis and human expertise.
- AI and ML algorithms enhance the identification and likely success of potential drug targets, identify drugs that can be repurposed for other applications and enable personalised treatment options tailored to an individual's genetic profile.
- GenAI can control costs and transform clinical development by speeding up tasks across the clinical lifecycle.
- GenAI can be used to draft and refine the documentation required to establish test sites by analysing previous protocols, site contracting agreements and clinical report forms, and design adaptive trials with flexible master protocols.
- GenAI can also identify more diverse trial participants based on specific criteria, enhance the segmentation of disease and patient populations and optimise locations of trial sites to reflect more accurately the target population for the drugs being tested.

Transforming pharma R&D through the strategic application of GenAI

Drug repurposing

Role of AI: Perform metanalysis of clinical trial and research data to generate high-quality hypothesis for drug repurposing

Value levers
- Reduced pre-clinical costs
- Reduced time to market
- Higher new drug applications (NDAs)

AI-driven drug discovery

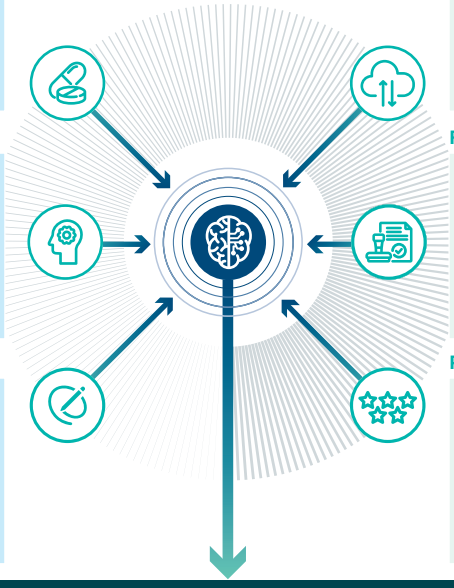
Role of AI: Optimise target and biomarker identification and shortlisting candidates while accessing toxicity and therapeutic efficacy

Value levers
- Improved clinical success rate
- Higher number of NDAs

Rapid design and startup

Role of AI: Automated protocol generation, drafting of study documents (consent form, agreements) and regulatory submissions

Value levers
- Lower average protocol authoring time
- Lower average time to first enrollment



Digital data flow

Role of AI: Collate and standardise trial data elements to create analysis-ready data sets and to auto-populate tables and charts in trial artifacts (e.g., case report forms)

Value levers
- Reduced total time per phase
- On-time database lock
- Faster artifact creation

Regulatory intel and submission excellence

Role of AI: Identify regulatory requirements across geographies, generate drafts of dossiers, and understand competitor regulatory strategy

Value levers
- Higher regulatory success

Participant experiences

Role of AI: Enhancing participant experiences with strategic nudges to revolutionise recruitment and retention strategies

Value levers
- Reduced dropout rate
- Faster recruitment
- Lower terminations for insufficient recruitment

Realising value requires governance to monitor investment and risk, addressing resistance and scepticisms and frequent demonstrations of value

Source: Adapted from Deloitte's 'Unleash AI's potential' report.

- AI and ML can review clinical trial data in real time to detect patterns or potential issues, design digital twins of simulated patient data to reduce placebo groups, amplify patient engagement, and aid the collection and processing of RWE for regulatory approval.[14]

These tools have the potential to improve significantly the efficiency and quality of evidence generated during the conduct of clinical trials, and automate the drafting of study reports, accelerating the drug development process without compromising on scientific rigour. Humans should stay in the loop to actively monitor compliance and integrity.

Examples in 2024

Itkos leverages cutting-edge AI and robotics to transform drug discovery. By integrating the creativity of GenAI with automated synthesis and testing, it is forging a path towards fully autonomous labs, and accelerating the development of new treatments. An AI SaaS platform creates diverse, novel and medchem-like molecules, ensuring that each molecule is synthetically accessible and optimised for success. An AI-driven retrosynthesis platform identifies the most feasible synthetic routes, converting target compounds into commercially available starting materials. An autonomous lab automates the synthesis of compounds to create a seamless workflow.[15]

Mendel.ai employs its deep-learning engine to streamline clinical trial matching. By harnessing natural language processing of clinical records and automated clinical reasoning, Mendel.ai has demonstrated its ability to boost patient enrolment by 24% to 50%, facilitating access to potentially life-saving treatments.[16]

AION Labs is a first-of-its kind Venture Studio built by global pharma, technology leaders and investors coming together to create and promote AI technologies in drug development. They have launched five AI-powered start-ups:

- **PromiseBIO**, a cloud-based platform for precision medicine
- **Omec** to improve the probability of success of drug candidates
- **CombineAble** for reducing reliance on trial-and-error during antibody development
- **TenAces** to discover new molecular glues
- **DenovAI** a platform that designs from scratch high affinity antibodies for targets of choice.[17]

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