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The clinical landscape for 2025

Introduction

As we enter 2025, the global clinical landscape is continually evolving, driven by a range of factors, including emerging therapies, technological advances, and logistical challenges. The industry is characterised by both opportunities for innovation and challenges that require strategic solutions to deliver clinical success.

Use of technology continues to gain momentum, enhancing patient engagement and streamlining data collection in decentralised and hybrid trials. Integration of advanced technologies such as AI and machine learning (ML) also gathers pace, reshaping clinical trials by reducing trial timelines and improving efficiency.

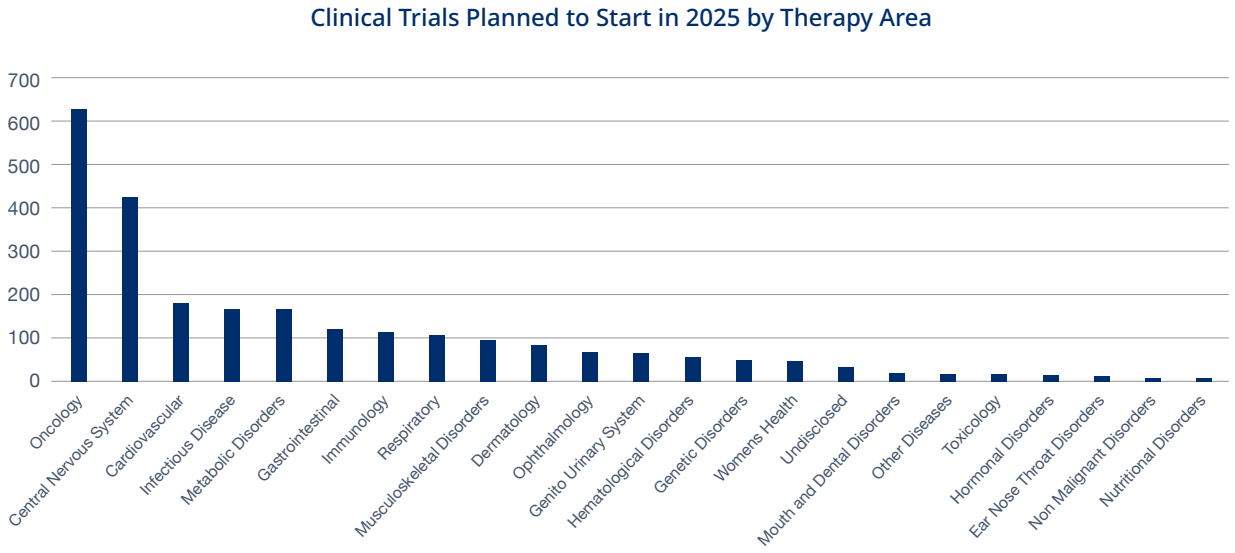
Yet the proportion of terminated trials has increased, reflecting financial pressures and geopolitical factors. In 2025, the focus will likely remain on enhancing efficiency, ensuring patient engagement, and navigating the complexities of a globalised clinical research environment.

This report will provide an overview of key trends shaping clinical trials in 2025 using data and analysis from GlobalData's Intelligence Center. We will also discuss emerging markets, new tech, the burgeoning field of medicinal cannabis, and underline the importance of logistics.

The main therapy areas for 2025

Clinical trials are rapidly evolving, marked by advances in vaccine technology, regulatory reforms, the integration of innovative technologies, and logistics solutions such as the use of AI, blockchain, and drones. Stakeholders in the pharmaceutical industry must remain agile and responsive to these trends to successfully navigate the complexities of clinical research. Other trends to keep track of in 2025 include the growth of cell and gene therapies, and the expansion of medicinal cannabis products gaining regulatory approval.

GlobalData's Intelligence Center Clinical Trials Database recorded 2,174 clinical trials due to start from 1 January 2025 to 31 December 2025, as of 10 December 2024. Oncology, CNS disorders, and cardiovascular diseases (CVDs) comprise the top three therapy areas, continuing the trend from recent years. This number of trials planned for 2025 is certain to increase.



Trends and challenges in oncology trials

The oncology clinical trial landscape comes with considerable challenges. Issues such as patient recruitment difficulties, political instability and economic volatility are significant hurdles. For instance, it has been reported that one in five oncology trials is terminated early due to poor recruitment.[i] Additionally, while the introduction of new technologies can be hugely beneficial, it also presents issues in terms of complexity and cost.

Despite these challenges, the oncology sector continues to expand, with a focus on innovative therapies that address various types of cancers, including both solid tumours and haematological malignancies. The industry is also seeing a shift toward more complex studies, which may require a more nuanced approach to patient engagement and trial design.

A significant aspect of the ongoing innovation in cancer treatment is the focus on cell and gene therapies. Chimeric antigen receptor T-cell (CAR-T) therapies are primarily aimed at haematological cancers and have seen substantial growth, with a reported 32% of the pipeline targeting these malignancies. The increasing investment and research in CAR-T therapies underscore their potential effectiveness and the industry's commitment to finding novel cancer treatments. According to GlobalData's research of marketed and experimental CGTs, cancer remains the primary therapeutic area for CGTs, accounting for about 45% of all pipeline and marketed CGTs, with the market projected to reach $37bn by 2030.[ii]

Oncology's dominance in the CGT pipeline is likely to continue. However, CGTs are also showing real promise for central nervous system conditions, metabolic abnormalities, immunological issues, and certain rare diseases.

Central nervous system (CNS) treatments

CNS disorders maintain a strong presence in clinical trials, with a significant proportion of Phase III trials focusing on various CNS indications.[iii] In 2024, 21% of clinical trials on the GlobalData database were CNS based, with 20% allocated for 2025. This emphasis highlighted the urgent need for effective treatments, as many CNS disorders and neurodegenerative diseases, continue to pose challenges for patients and healthcare providers alike.

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Gaining traction in the CNS space is the exploration of novel treatment options – such as targeting the gut-brain axis or utilising personalised medicine approaches. The gut microbiome plays a crucial role in CNS disorders through its influence on neurotransmitter production, immune responses, and overall brain health.

Ongoing research continues to explore the therapeutic potential of microbiome modulation as a treatment strategy for various neurological and psychological conditions, including Parkinson's disease (PD).[iv] Nearly a million people in the US[v] have PD. While current treatments can provide symptomatic relief, the disease is currently incurable, highlighting the ongoing need for clinical trials and drug development.

Recruiting suitable patients for clinical trials is also a challenge in this therapy area. The need for patients to discontinue pain medications for trial participation can also pose ethical concerns, making it difficult to recruit participants already managing their conditions and so complicates the ethical landscape of using placebo controls in trials.

Cardiovascular diseases (CVDs)

CVDs remain a leading cause of morbidity and mortality worldwide. Clinical trials in this are critical for developing new treatments, understanding disease mechanisms, and improving patient outcomes. Yet according to the GlobalData Clinical Trials Database, only 8.5% of all clinical trials were based on CVD – rising slightly to 8.9% in 2025. Although this is still the third highest grouping, this may seem surprising.

> **GlobalData predicts the heart failure (HF) market will grow at a strong compound annual growth rate (CAGR) of 9.6%, reaching sales of $33.7bn by the end of 2032.**

Despite the high burden of CVDs, research funding has not kept pace with demand. According to the British Heart Foundation, CVDs accounted for over 13% of years lived with disability or premature death in 2019 – but only received only about 7% of public and charity research funding in the UK during 2022. This amounts to £208m, with a funding shortfall projected to exceed £259m over the next decade due to inflation.[vi]

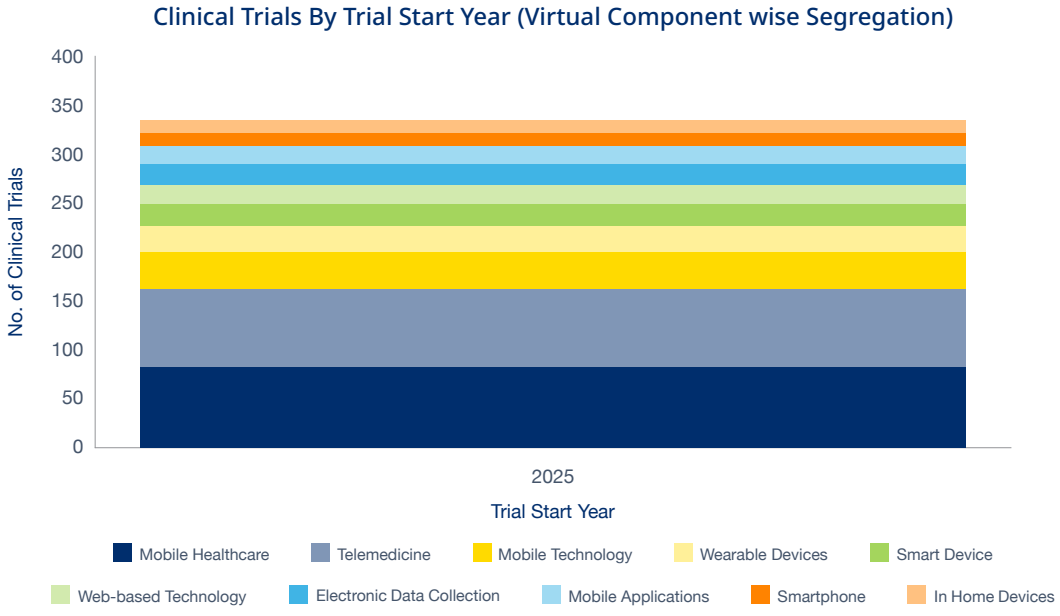
Nevertheless, GlobalData predicts the heart failure (HF) market will grow at a strong compound annual growth rate (CAGR) of 9.6%, reaching sales of $33.7bn by the end of 2032.[vii]

Innovations such as artificial intelligence (AI), gene editing and regenerative medicine are becoming integral to cardiovascular research, potentially enhancing prevention, treatment and survival rates for patients. The integration of mobile health technologies into clinical trials can enhance patient engagement and data collection, particularly for populations that may face barriers to traditional clinical trial participation.

Emerging markets

According to the GlobalData Clinical Trials for 2025, North America has the most unique clinical trials planned with 508. Perhaps unsurprisingly, more than 90% are planned for the US. The next biggest region is Asia-Pacific, with 309 trials planned and around 25% of these in China. Europe is the next highest region with 236, with France having the most unique planned clinical trials at just over 18% with Germany, Spain, and the UK not far behind.

For 2025, mobile healthcare and telemedicine are the leading tech components predicted for clinical trials, according to GlobalData.



The growth of cell and gene therapies

Cell and gene therapies are projected to see substantial growth in the next few years, with oncology the primary focus. There is an ongoing effort to convert the effectiveness of cell treatments in oncology to other diseases and clinical trials are underway in areas such as metabolic, genetic, and central nervous system conditions. The majority of studies conducted outside oncology are in the pre-clinical or early preclinical stages.

GlobalData estimates that the global CGT market is projected to reach sales of $80bn by 2029, with oncology accounting for 44% of the market.[viii] The majority of revenue is expected to come from cell therapies in oncology. GlobalData expects CGTs to become a well-established therapeutic modality in the next decade. Rising development and production costs, the potential of clinical trial failures and increased pricing and reimbursement demands will continue to put a strain on these breakthroughs.

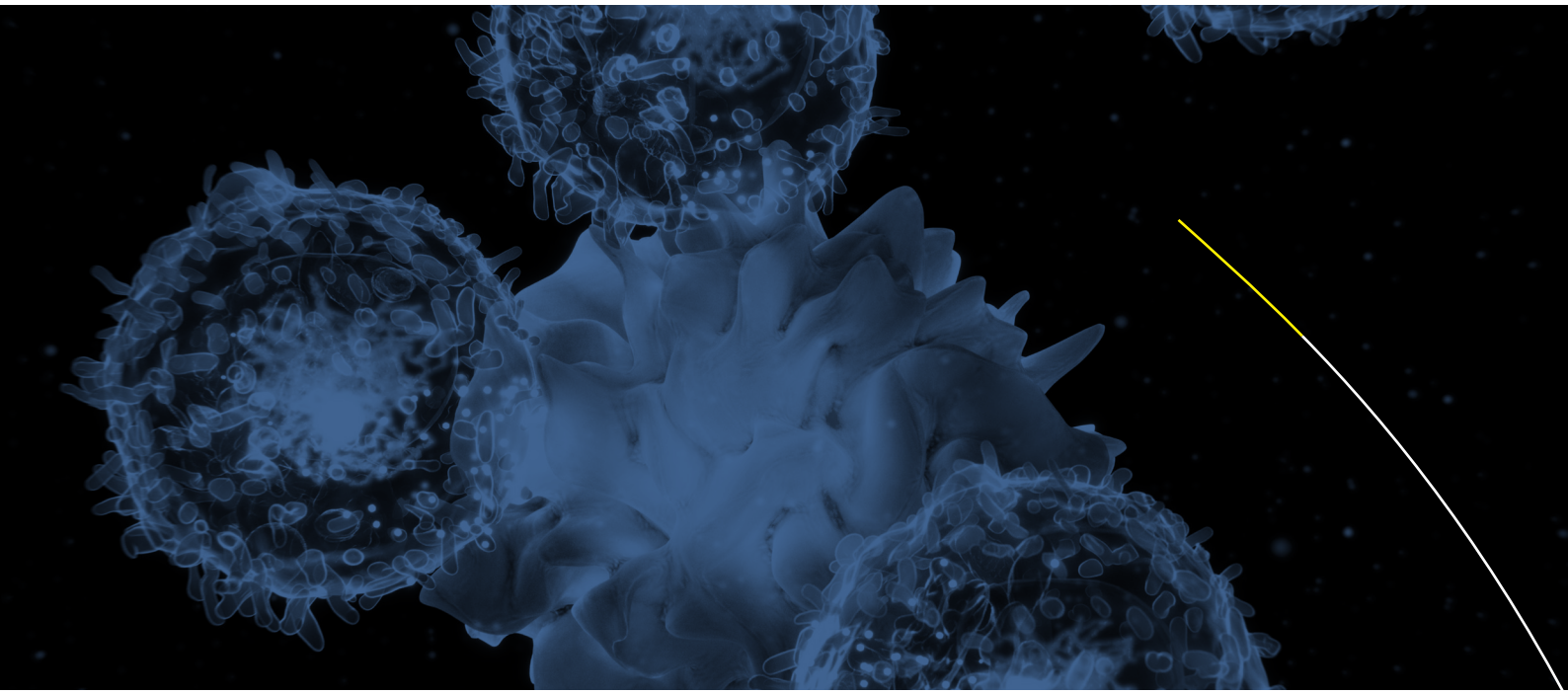
The full potential of CGTs has not yet been discovered, as they promise life-changing treatments for a broad spectrum of complex diseases. A survey in GlobalData's State of the Biopharmaceutical Industry 2024 report revealed that 18% of healthcare industry professionals believe CGT will dominate as the industry trend with the greatest impact on the pharmaceutical industry.[ix]

Medicinal cannabis

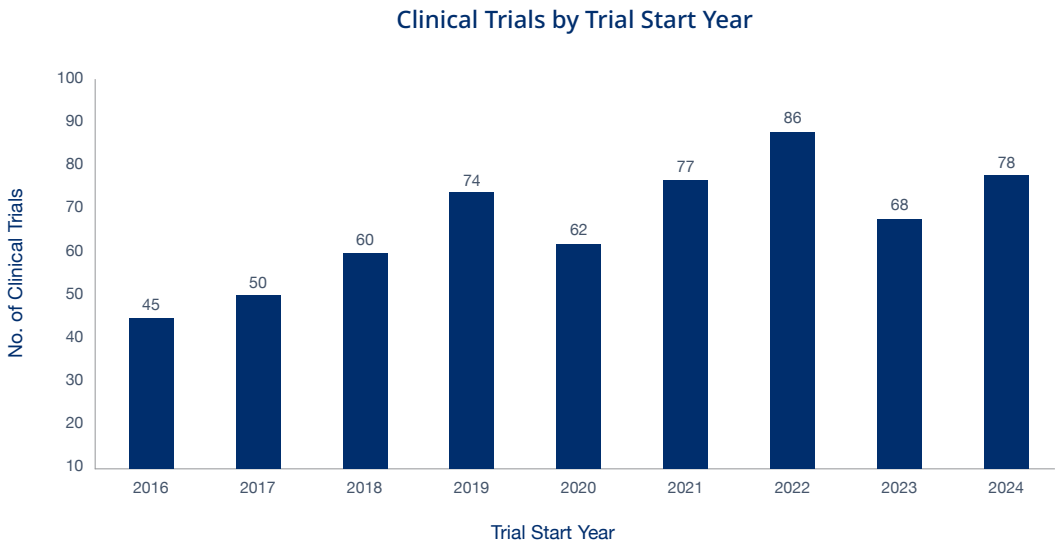
Cannabinoids, the compounds found in cannabis, are particularly promising as an alternative to opioid-based pain relief, which is linked with high addiction rates and overdose deaths. The therapeutic potential of cannabis compounds, such as CBD and THC, has driven significant interest in clinical trials and research to better understand their efficacy and long-term benefits. The medicinal cannabis sector is now gaining momentum, with anticipated regulatory approvals and a growing body of research supporting its therapeutic uses.

Medical cannabis has also shown significant benefits in treating neurological disorders. The treatment has been found to reduce seizures in epilepsy patients, particularly those with conditions such as Dravet Syndrome, as well as alleviating symptoms of anxiety and depression.[x]

The FDA's movement towards recognising cannabis for medicinal purposes[xi] is set to enhance clinical trial activities in this field. Meanwhile, the largest study of its kind took place in Latin America in 2022, with promising results on the safety, efficacy, and cost-effectiveness of CBD oil-based products to treat chronic pain.[xii]



Looking ahead to 2025, much activity is expected in medicinal cannabis. The market is growing as products gain regulatory approval around the world. Clinical trials involving medicinal cannabis reach a peak in 2022 with 88. This total fell back slightly in 2023 with 68, before rebounding with 78 in 2024.



Medicinal cannabis is gaining global recognition, with several countries expanding their markets and regulations, with Israel, Germany, South Africa, and Ukraine taking unique paths in the growing cannabis industry, each with different focuses and strategies.

However, the logistics of medicinal cannabis are complex due to its highly regulated supply chain and regulatory challenges, including variations in regulations across countries, causing delays and quality issues. Companies often require a Controlled Substance Licence to legally import or export medicinal cannabis.

Security and risk management are also significant issues, as cannabis is highly valuable and difficult to obtain legally. High-risk security measures such as GPS tracking and armed escorts can be required, along with high costs associated with securing licences and adhering to regulations often being passed on to consumers.

Cross-border transport of medicinal cannabis usually involves additional layers of complexity. Collaboration and documentation are crucial to overcome these challenges.

Logistical challenges and innovations

In an era marked by global uncertainty, effective logistics has become paramount for successful clinical trials. The Covid-19 pandemic highlighted vulnerabilities in supply chains, with innovative solutions required to ensure timely deliveries of biosamples and clinical trial materials.

The FDA recently issued new guidance[xiii] on the continuation of important clinical trials in response to widespread disruptions such as pandemics.

In response to demand in recent years, logistics providers have implemented innovative solutions such as the adoption of emerging technologies. One example is blockchain enhances transparency in supply chains where the product is high value or potentially toxic, and the increased use of real-time monitoring of location, along with temperature control using connected Internet of Things (IoT) devices and specialised shipping containers.

The clinical trial landscape is expected to continue to change and develop. The need for improved sustainability, enhanced patient-centric approaches and integration of digital tools will be critical in overcoming ongoing supply chain challenges. As the industry moves forward, leveraging technology and fostering strong partnerships will be essential for navigating the complexities of clinical trial logistics in an uncertain world.

The rise of near-shoring for manufacturers

Logistics providers are adapting to global disruptions such as geopolitical tensions, extreme weather events, and economic barriers such as tariffs by implementing more near-shoring strategies. These strategies move production closer to the end-user or to geopolitically stable countries, reducing exposure to tariffs and trade barriers along the way.
For instance, the US-Mexico-Canada Agreement (USMCA)[xiv] has incentivised North American countries to enhance trade among themselves, promoting near-shoring as a viable alternative to relying on suppliers in more distant regions. This strategy not only helps manage supply chain risks but also supports local economies, reduces transportation costs and is more environmentally friendly with fewer air miles. However, it remains to be seen what result the new Trump administration will have on this agreement.

With the growing threat of increased tariffs, companies are increasingly looking for ways to navigate these barriers by moving manufacturing operations to regions where they can benefit from lower costs and fewer restrictions. This focus on regionalisation reflects a broader trend towards creating more robust and flexible supply chains that can withstand future challenges.

Use of drones

The integration of drones into clinical logistics is an emerging trend to improve the speed and efficiency of transportation of sensitive shipments. This technology could revolutionise how clinical trial materials are delivered, particularly in remote or challenging locations. A prime example of the use of drones is with biospecimens. Drones play a crucial role in research and patient outcomes, providing insights into disease progression, efficacy markers and treatment effects.

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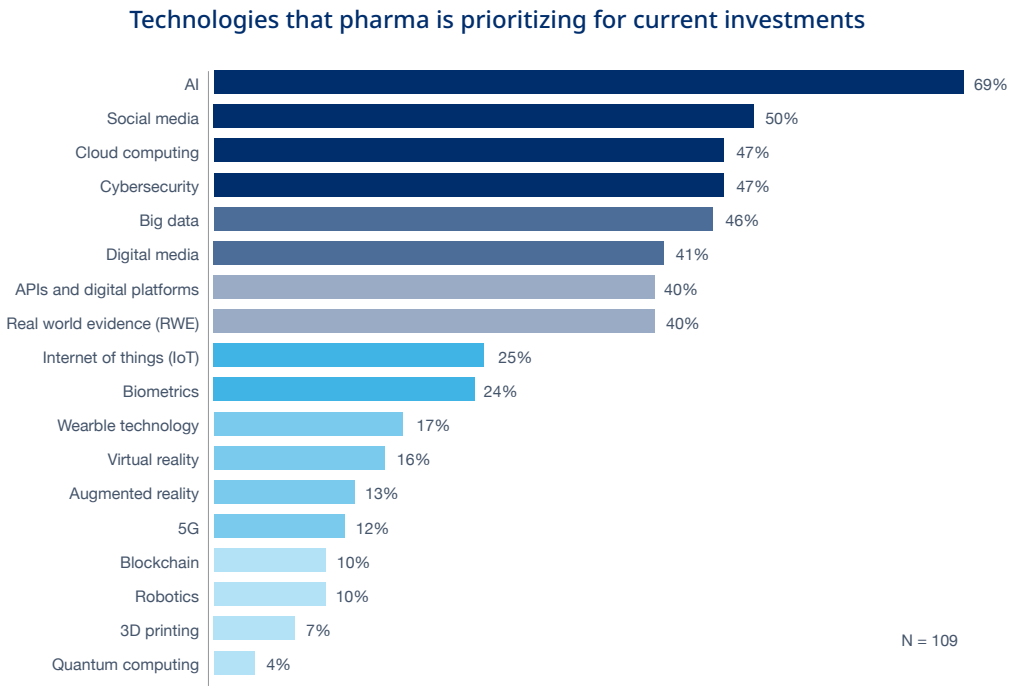
Biospecimens are essential for timely delivery of vaccines, medications and products to specialist centres and clinics. But biospecimen exports often face challenges due to the lack of dry ice for transportation. Oximio, is working with drone providers to mitigate biospecimen logistics risks by deploying dry ice-filled vessels capable of maintaining -70°C for up to 21 days.[xv, xvi]

“Africa’s vast and diverse landscape presents unique challenges to delivering essential medical supplies, leaving many remote communities vulnerable. But with innovation taking flight, drone technology is revolutionizing healthcare logistics,” says Rob van den Bergh, Regional Development Director – APAC and LATAM at Oximio. “By bridging the gaps where traditional methods fall short, drones offer a lifeline, ensuring vaccines, biospecimens, and critical supplies reach even the most isolated regions. This is a powerful step forward in overcoming logistical barriers and bringing hope to millions.”

Technological advances

Emerging Technologies – Current Investments



Q: In which of the following emerging technologies is your organization investing?
Source: Digital Transformation and Emerging Technology in the Healthcare Industry, 2024 survey
Survey from 15 August 2024 to 11 October 2024.

The adoption of advanced technologies such as AI, blockchain and wearable devices is transforming clinical trial processes. AI is particularly beneficial in optimising trial designs, enhancing patient recruitment and improving data collection accuracy.

In addition, GlobalData's Drugs Database shows that over 3,000 drugs have been developed or repurposed using AI. One notable application is designing monoclonal antibodies, such as Aulos Bioscience's Imneskibart (AU-007), which is currently in Phase II clinical trials for treating various cancers[xvii]. As AI-driven approaches become more prevalent, drug development will become faster and more cost-effective. GlobalData predicts every segment of the AI market will grow over the next decade, with the AI market worth $103bn in 2023.[xviii]

Enhancing trial design and drug discovery

AI and ML can analyse vast datasets to identify patterns that may not be apparent through traditional analysis methods. For instance, AI models can predict the toxicity of potential drug candidates, enabling researchers to select the most suitable compounds for trials, expediting the design process. Furthermore, AI can assist in identifying existing data that can be used for new trials, minimising the need to start from scratch and further accelerating the trial design phase.

AI's capabilities extend to improving data processing and recruitment strategies within clinical trials. By analysing electronic medical records and social media content, AI can identify eligible participants more efficiently – speeding up recruitment processes. Additionally, AI algorithms enhance data collection accuracy by identifying patterns, which is crucial for managing complex datasets generated during trials.

Blockchain

Blockchain technology is a secure, transparent database mechanism that enables secure sharing and access of digitally recorded data within a business network. Blockchain technology is a promising solution for improving the efficiency and security of pharmaceutical logistics, particularly in the face of counterfeit drugs. The global pharmaceutical supply chain, valued at $1.27trn, is particularly vulnerable to fraud, with one in ten medical products in low and middle-income countries being substandard or falsified.[xix] Blockchain can enhance coordination among partners by providing timely data, ensuring the integrity of shared information, and increasing transparency across all the supply chain.

About Oximio

Oximio supports vital research into life-changing medical treatments through flexible clinical supply chain solutions worldwide. The company's vision is to deliver comprehensive solutions that support medical advances and improve the quality of life for millions of people globally. With almost two decades of experience, Oximio works with partners around the world to deliver high-quality services even in the face of immense challenges and technical complexities.

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