

2025

CLINICAL TRIAL

TRENDS

New technologies continue to drive innovative changes in the life sciences space, including clinical research. Transformations in data infrastructure, predominantly the shift from on-premises data storage to cloud-based systems, are pushing companies to reevaluate their data storage and processing systems to improve efficiency and expand their capabilities. While the uptick in decentralized clinical trials (DCTs) is not new, it is also indicative of this larger trend towards capitalizing on technological advancements in the virtual world. With this trend comes a push for Artificial Intelligence (AI), a tool that can streamline patient recruitment, improve the utility of real-world data, and increase the efficiency of the entire trial process. This is requiring companies to evaluate their current operating processes and is potentially revealing other areas for implementation projects to serve as steppingstones to effective AI use.

Clinical trial organizations need to be able to quickly pivot and adapt to changing circumstances, the globalization of the market, and changes in the collaborative elements of clinical research. Adapting requires moving away from the traditional clinical trial process to a leaner and more cost-effective model. [Increasing diversity and representation within trials](#) remains a priority going forward, and change is coming as regulators are more amenable to considering new ideas and innovations and as sponsor companies are brave enough to think outside the box and embrace a new way of doing clinical trials.

In this report, we outline these trends and highlight their impacts on the clinical trials industry going into 2025:

1 MODERNIZED DATA INFRASTRUCTURE

2 INTEGRATION OF AI: DISTINGUISHING UTILITY FROM FAD

3 RISE OF CONTRACTOR MODELS AND GLOBAL OUTSOURCING

4 DIVERSITY AND EQUITY AT THE FOREFRONT

5 RESILIENCE IN THE CHANGING R&D LANDSCAPE

The clinical trials space is no exception to the plethora of benefits introduced by the implementation of cloud-based data platforms, including [Software as a Service \(SaaS\)](#) systems. Switching to the cloud can produce cost savings, expedite trials, improve data security, make data storage more efficient, and allow better [access to real-time data](#). The shift toward the cloud has pushed leading suppliers of SaaS systems to [expand their portfolios](#) to explicitly support clinical trials, offering tools including trial management, payments, site connection, and training.

Change is a key factor with cloud-based service, and although it does require an upfront investment in underlying services, application remediation, and building new organizational capabilities, the ROI will soon be met as companies are able to complete the phases of a digital transformation faster and more efficiently. Clinical trials organizations also need to work to ensure that stakeholders are prepared for these changes to prevent the all-too-common failure of a system due to [poor user adoption](#). Throughout an implementation of a new cloud-based service, it is important to keep stakeholders informed and involved and ensure proper hands-on training and preparation of end users.

Many companies, especially in the [cell and gene therapy industry](#), are increasingly outsourcing clinical research, creating issues with the aggregation of information and data from a variety of organizations and sources. Switching to cloud-based data storage can help mitigate these issues by [establishing a central repository](#) in which to store data from several sites. Additionally, some vendors offer analytics services to standardize and present data, further aiding in the integration, sharing, and analysis of the data gathered in the clinical research process.

With the uptick in the use of cloud-computing across all industries, the implementation of [cloud-based services](#) becomes more and more advantageous due to the benefits of integration with other platforms. Cloud-based data storage opens doors to integration and collaboration as well as the implementation of Artificial Intelligence tools to streamline activities in every part of clinical trials.

Cloud-based clinical trials can reduce the huge expense and long lead times of traditional clinical trials.

SOURCE

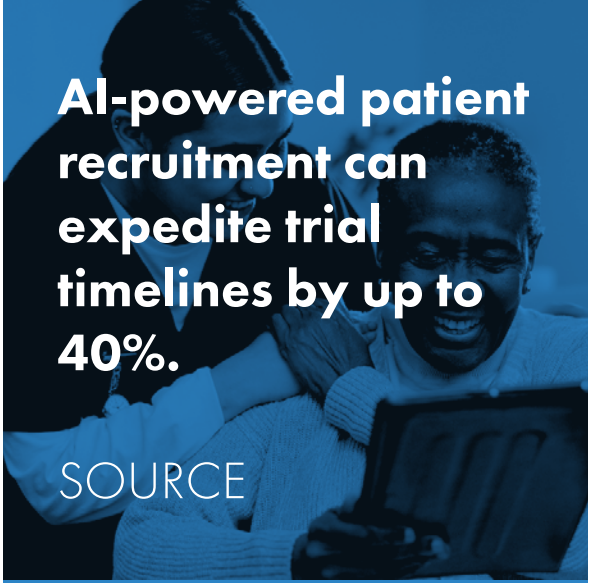
2 INTEGRATION OF AI: DISTINGUISHING UTILITY FROM FAD

Artificial Intelligence (AI) has applications in virtually all spaces of clinical trials and is undeniably beneficial when implemented and applied appropriately. Its future success will rely on real, specific applications. It is vital to approach the [implementation of AI strategically](#) and with great care to prevent wasting time and resources without thinking of [long-term sustainability](#).

For clinical research, AI can expedite trial design and patient recruitment and aid in data management. A computer scientist at the [University of Illinois Urbana-Champaign](#) developed algorithms to predict trial success and prioritize more recent trials for cross-referencing data. This can save time by reducing the manual efforts usually required by these tasks. In another example, a group at Stanford developed Trial Pathfinder, an AI system that suggests ways to adjust participation criteria to expand the number of eligible patients without increasing the hazard ratio for a trial. These examples illustrate targeted applications of AI that prove successful in achieving specific results. Research organizations do not need to bring on teams to develop AI programs internally. There are also [software companies](#) that can be brought on specifically to leverage AI to achieve an organization's goals.

It is important to [evaluate business needs for AI](#) implementation; within a given organization, there will be no one-size-fits-all solution. Clinical research organizations must consider which parts of their processes can stand to benefit from AI solutions and how best to implement them. Additionally, despite common misconceptions, AI is simply a tool for researchers, not a replacement. To make efficient use of it as a resource, proper training procedures must be created to effectively eliminate excessive manual processes and ensure accurate results.

AI cannot operate independently, and it is also necessary to ensure that proper systems are in place to perform quality checks and protect sensitive information.



AI-powered patient recruitment can expedite trial timelines by up to 40%.

SOURCE



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RISE OF CONTRACTOR MODELS AND GLOBAL OUTSOURCING

The number of clinical trials that are either partly or wholly outsourced continues to grow going into the new year. Outsourcing clinical trials is often more flexible and cost-effective than hiring large teams with special or individualized functions, especially for smaller companies. This allows a dedicated space for all activities related to clinical research and can expand access and budget availability to tools specific to clinical trials.

For an organization whose specialty and primary purpose is to execute clinical research, the entirety of the budget will be allocated to clinical trials directly or indirectly, enabling other trends such as the digitization of trials and increased use of AI. The challenge for clinical research organizations is [planning ahead](#) by ensuring [effective vendor selection](#) and high-level management of cross-functional relations to prevent siloed roles.

Increased outsourcing forces companies to rethink the methods they utilize to contract external organizations for clinical trials. Solutions such as contract lifecycle management (CLM) services can be pivotal in automating and streamlining many [aspects of the contracting process](#). CLM services can reduce administrative burdens and shorten negotiation times, supporting critical research initiatives.

The [contractor model](#) has been on the rise for several years and is only increasing in prevalence; currently nearly 64% of all clinical services are outsourced. The rise in outsourcing emphasizes the need for data storage platforms conducive to collaboration and integration of data from a variety of sources. Life sciences companies should be preparing for the continued shift towards utilization of contractor models due to increases in efficiency. This preparation involves knowledge management, the implementation of platforms compatible with decentralized trials, and data storage services that allow simple collaboration.



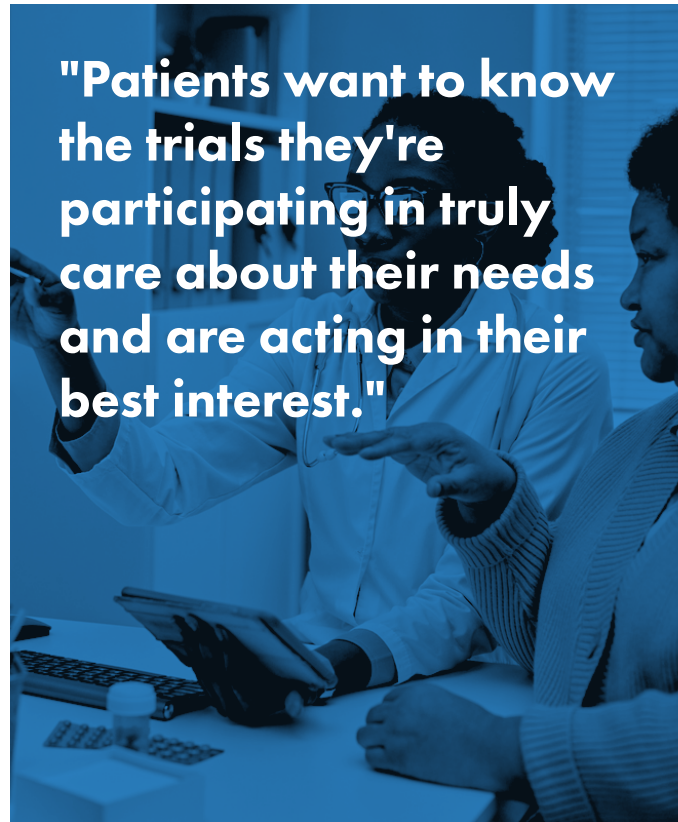
4 DIVERSITY AND EQUITY AT THE FOREFRONT

Establishing diversity and equity within clinical trials remains a key focus. Companies have a [responsibility to increase representation](#) within their clinical research to more effectively represent real-world patient groups. Underrepresentation in clinical trials can lead to incomplete or biased data, producing ineffective or even harmful treatments.

Within organizations, various [strategies are employed](#) to promote inclusivity in trials. These include community outreach and education, tailoring communication information to different cultural and linguistic groups, diversifying staff, decentralizing trials, and even [utilizing AI](#).

Additionally, the use of real-world data, an activity propelled by digitization, plays a pivotal role in expanding research capabilities to support higher diversity in clinical trials. As companies develop their project plans and product lifecycle, engagement must start sooner rather than later to build credibility and establish trust within the community. This means acting early (at least nine months to one year ahead of the trial is advisable) and with sincerity – patients want to know the trials they're participating in truly care about their needs and are acting in their best interest.

On the larger scale, the [FDA has also taken action](#) to ensure organizations are upholding high standards for achieving diversity within their clinical trials. In June 2024, the FDA released a draft of its new diversity action plan guidance. Starting in late 2025, certain clinical studies for drugs and medical devices will require the submission of a Diversity Action Plan to confirm their plans for upholding and supporting diversity initiatives throughout trials.



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RESILIENCE IN THE CHANGING R&D LANDSCAPE

Several changes are taking place within the Research & Development (R&D) space for pharmaceutical and biotechnology companies. These evolutions can be largely attributed to reduced budgets from the [Inflation Reduction Act](#), patent expirations, and cost-cutting due to declining sales projections. On top of decreased budgets, which will likely result in fewer clinical trial starts going into 2025, the success rate of new Phase I drugs going to market continues to fall, [hitting 6.7% in 2024](#). This information may seem worrying, but it is rather simply an indicator of the need for greater innovation within the industry.

With less flexible budgets, it is now vital to prioritize strategic innovations and investments that will promote long-term cost-savings in clinical research. This looks like making effective use of AI, decentralizing trials, and successful collaboration with partners. Organizations must remain resilient, make timely decisions, and prioritize [team management and communication](#) to be successful in adapting to these changes.

Additionally, there is room for innovation and growth looking towards a couple new areas of focus in clinical research. A primary area for innovation is witnessed in the push for studies involving the identification of secondary indicators in [GLP-1 drugs](#). These drugs did not follow the traditional path within clinical research and are a testament to the need to respond quickly to demand and changes in research and development. Obesity treatments once had historically low success rates in clinical research but now that many treatments have proven successful, the door has opened to identifying secondary indicators in these same drugs. The National Institute on Drug Abuse (NIDA) is supporting preclinical studies using GLP-1 drugs to [treat alcohol and opioid addiction](#), for example.

Phase I success rates have steadily declined in the past 15 years, falling from nearly 75% to 40%.

SOURCE

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LOOKING AHEAD

Life sciences companies have higher R&D costs than nearly any industry and are thus highly impacted by macro-economic trends forcing reduced spending. However, this is not to say that there isn't any room in the clinical trials space for reduced innovation and effort towards clinical research. Rather, this supports the idea that strategic changes and implementations are of the utmost importance. With well-planned [investments in new technologies](#), decentralizing trials, supporting diverse patient populations, and collaborating with sponsors, trials can run more efficiently to produce successful studies faster than ever.

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