REPORT

Advanced Clinical

# Foresight in Clinical Trials: Trends Set to Reshape the Future for 2024 and Beyond

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As the clinical research industry continues to grow, are you prepared for the future? The midpoint of 2024 is showing slow signs of recovery from the last several years where we experienced market turmoil, financial unease, widespread layoffs and delayed study starts due to managing expenses and pipeline re-prioritizations. As we anticipate the future to be positive for our industry, staying ahead of the trends will be crucial to the success of our companies and for us as professionals. Two leaders from Advanced Clinical provide their insight into how the landscape of trial conduct and management is changing and the top trends to watch as our industry evolves.

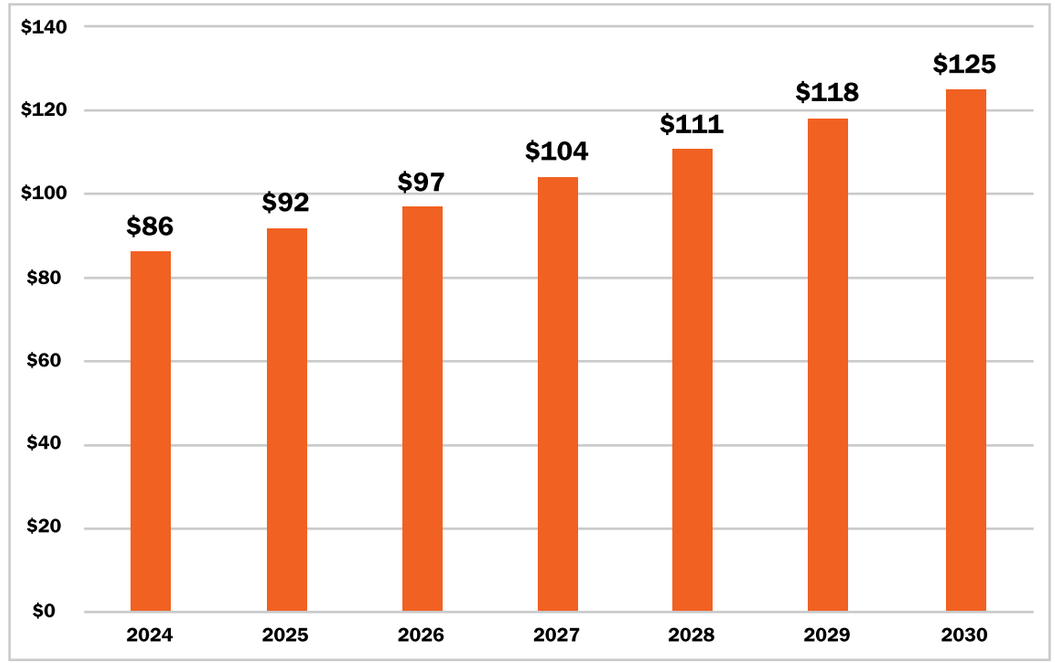
## An Increase in Investments and M&A

An examination of clinical research/trials or life science funding in 2024 so far demonstrates signs of a promising recovery, despite the presence of some delays and cutbacks. While fewer than 20 companies went public in both 2022 and 2023, about eleven have already done so in 2024 to date. From 2024 to 2030, the global clinical trials market size is projected to grow at a CAGR of 6.49%. This early momentum suggests that the industry is not only recovering in 2024 but is on track to potentially surpass the record-setting growth that we experienced in 2021.

Although these forecasts may seem optimistic and could be affected by the pace of expected upcoming interest rate cuts, even a more modest revitalization of funding represents a pivotal opportunity for growth. The types of companies attracting funding are also maturing from previous years, with a greater focus on those further in the development pipeline. High-interest areas include immunotherapy, oncology, weight loss and non-opioid pain medications, although other research areas are also garnering attention.

Mergers and acquisitions are also on the rise, particularly in the last quarter of 2023. Similar to funding trends, M&A activity in Q4 2023 often focused on later-stage research, reflecting a more risk-averse approach that has been prominent in recent years. The trend points to higher-value, strategic deals with a focus on novel technologies and innovation. Investments in provider organizations servicing the clinical research market has also shifted from contract research organizations (CROs) and technology providers to site networks and organizations that provide access to patients, including patient data and direct interaction with patients.

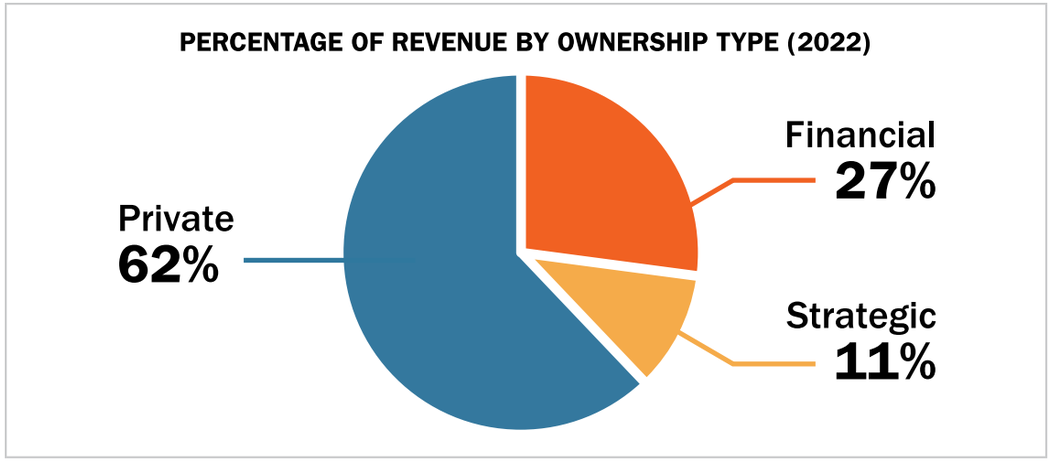
## Forecasted Market Size in Billions




Source: Grand View Research, “Clinical Trials Market Size, Share & Trends Analysis Report – Forecasts to 2030” (2023)

**Observation**
The global clinical trials market size was valued at $80.7B in 2023 and is projected to grow at a CAGR of 6.49% from 2024 to 2030.




Source: CRIO, "The Rise of Clinical Trial Site Mega Network" (November 2023)

**Q: If you could only solve one, which of these would you solve in 2024? (N=134 Sites)**

| | |
|---|---|
| **30%** Direct EMR/eSource to EDC Connectivity for Automated Data | **10%** Site Selection/Site Feasibility Process for New Studies |
| **15%** Automated Regulatory and Study Startup Workflows | **10%** Consenting of Subjects |
| **11%** Training and Credential Tracking of Study Staff | **8%** Advanced Patient/Subject Matching Integrated with EMR |
| **11%** Remote Monitoring and Document Access | **8%** Remote Source Access Workflows |

Source: Florence Healthcare, "2024 State of Tech-Enabled Clinical Trials Report" (January 2024)

**Observations**

> The top technological challenge site respondents would like solved is connectivity of direct EMR/eSource to EDC.

> This is consistent with responses from previous years.

## The Rise of Site Networks: Access to Patient Records

Over the past few years, site networks have become increasingly significant to the investment community. We are seeing growth in the number of site networks, increasing numbers of mobile sites or in-home services and an increase in private equity owned sites and/or site networks.

The obvious advantages include accelerated startup timelines and more efficient patient enrollment processes, which are primary factors driving the shift in investment by private equity. Further, access to patient records and patient information from site networks not only helps make patient enrollment more efficient, but it also provides patient insights and real world data. We have also seen larger CROs involved in acquiring access to patients through site networks.

As resources of these networks grow, they will continue to turn to technology for novel solutions. Electronic medical records (EMRs) and automatic data transfer are major priorities, streamlining data collection and reducing the need for on-site monitoring. In a 2024 report from Florence Healthcare, 30% of sites rated EMR to EDC connectivity as the technological challenge they would most like to solve. As oversight responsibilities continue to evolve, adopting EMR and automatic data transfer can offer a pathway to reduce costs, though this must be balanced with considerations for effective integration, training, data security and regulatory compliance to ensure sustained control over operations.

## Patient Recruitment & Representation Remain Top Challenges

Without patients, there can be no clinical research — and without effective recruitment, the trials will continue to experience unmet timelines or quality representation of the patient population. Patient engagement tools today start once a patient is identified, which does not really solve the problem of patient recruitment. In 2024, patient recruitment remains our industry's number one challenge: This provides great opportunity for growth and new solutions.

There is great pressure on companies today to ensure that the patient demographics of each trial accurately reflect those of the population with the disease under study. The FDA's August 2023 draft guidance on obtaining data related to underrepresented populations is just one example of how a focus on representation has been at the forefront of industry considerations in recent years. Defining representation varies by disease, country and even by region. For global trials, setting specific representation goals early and having a plan in place to meet those goals are essential to a company's success in achieving approval.

Innovative approaches are being used for considering the patient voice earlier in the trial design process. These early insights help companies better address the needs and wishes of the representative patient population, including decentralized trial options. While remote trials have demonstrated value in improving patient experience and expanding reach, they are not universally applicable. Global strategies for patient engagement options and integration of data from multiple providers are topping the list of considerations when designing studies.

## Demonstrating Sponsor Oversight With More Internal Controls: Outsourcing Models Are Varying in Design Including Increasing Hybrid Models

With increased agency pressures on sponsors to demonstrate oversight of outsourced activities, as well as directives from management teams or private equity owners of sponsors demanding cost-effective ways to manage trial activities, the market has shifted to implementing a more variable approach to resourcing and outsourcing strategies. Long gone are the days of picking the largest or "most well-known CRO" as a safe bet for a partner. With the "preferred CRO" model implemented by most large pharma over the last decade, small to midsize pharma companies have a hard time competing for their CRO's attention.

As a result, many sponsors are determining what they want to own as internal core competencies versus what they will rely on others for related to functional and therapeutic expertise. Today, we see a wide range of approaches — from hiring internally to bringing in contractors, or building dedicated insourced teams, utilizing functional outsourcing or implementing full-service outsourcing. More often than not, sponsors are using a combination of these approaches across trials, compounds and divisions. This level of control is more desired by teams that are under great pressure to perform, especially when their performance can sometimes make or break a stock price or company — known as "hybrid solutions."

Determining the best strategy for each company or team is a great challenge, and that strategy can make a significant difference in both the cost and success of each program. During the SCOPE 2024 meeting this year, this topic was a consistent theme across the program tracks. In the biotech/small pharma track, many speakers were commenting that they need to be creative and cannot afford to be "less of a priority"

for the teams working on their studies. Many have brought functions in-house through a functional service provider (FSP) arrangement, using their own SOPs created to provide efficiencies. We also see a combination of resourcing contractors building dedicated teams and choosing outsourced functions. This is a new normal for many, and hybrid models allow them to build the solution that works best to fit their expertise, preferences, technology needs and budget.

Over time, sponsors have sought to achieve a clinical research execution model that balances the optimal level of control, oversight, therapeutic and functional depth — and efficiency. A mixed model, or model involving the best of staffing, CRO and FSP models, allows for standardization of process and procedures along with the ability to learn and develop a team focused on one asset or function. One of the key benefits of this model is flexibility. The organizations who can embrace and deliver flexibility, acting as an extension of their sponsors, will be best positioned for success as this market trend increases.

Within this hybrid trend, we are also seeing the rise of FSP models in order to gain efficiencies and develop core teams with expertise. FSP models provide both full time employee (FTE) models as well as unit-based models, offering sponsors more predictability of cost as well as the ability to pay only for units utilized. FSPs using FTE-based dedicated teams are effective when there is a consistent volume of work warranting the need for these teams. We see FSPs as a way that sponsors can have representatives dedicated to them as site contacts, showing a commitment from the sponsor and better engaging with the sites. There are cost savings in training time of teams, repeatable tasks, cross study site visits and others.

In addition to functional strategies, therapeutic solutions are being created to better manage trials. With the growth in development pipelines, especially in oncology, rare disease and autoimmune disorders, sponsors are investing in additional enhancements to build full therapeutic solutions. Some enhancements include CDMOs, site networks, relationships with key opinion leaders (KOLs), specialized technologies or DCT strategies and incorporating the patient voice throughout each program. Hybrid models provide the ability to create a team or function dedicated to sponsors in an outsourced model, and they also provide the ability to have resources across the globe as needed.

## 2024 — A Year Focused on Change, With Steps Toward Innovation

All signals point to change in the way we approach and manage trials, starting with incorporating the voice and journey of the patient into the clinical development planning process. Other areas of change high on the list from an operational perspective include direct-to-patient interactions (or decentralized trial components), use of data, EMR to EDC options and using technology to make trials more efficient, cost-effective and/or increasing the ability to complete trials faster.

"Innovation" as a term can be defined very differently by individuals and the companies they represent. Historically, companies have wanted to understand what "magic bullet" may make their trials better, faster and cheaper. Each year there are new solutions introduced to the industry, and then companies work to incorporate the new solution into their processes. The new trend is for companies to ask the question "What problem am I trying to solve?" and then applying technologies or new approaches to solve that problem. In other words, companies will target solutions to fix a problem instead of trying to adjust their processes to fit a technological solution.

Perhaps the hottest topic in 2024 is Artificial Intelligence (AI) and Machine Learning (ML), with some confusion about where, if, or how companies should be investing in this area. Similar to the introduction of DCT components following COVID, companies are asking how to incorporate a new way of thinking with the least disruption and affordable investment. Not yet a standard or common method, the AI/ML topic remains impossible to avoid, not only in biopharma but across nearly all players and across industries. With the potential beyond the buzzwords, a more focused approach is needed and starting to take shape in 2024.

Increasingly, new providers are coming into our industry at greater volumes than we have seen in previous decades. Many providers are "AI companies" that have a tool that can be utilized to provide value to different components of the clinical development process. For example, we have seen patient-driven communities that use AI to crowdsource information that gives insight to each patient population.

Promising applications for AI/ML in the industry mostly center on automating repetitive processes and using large volumes of data to derive answers to complex problems. The obvious benefit is the potential for a better return on investment (ROI), but the jury is still out on the amount of investment that is needed and the best way to target the investment.

**We are seeing the use of AI across our business, and some examples to watch for AI/ML innovations in 2024 include:**

**Protocol writing**

**Patient screening through access to and automatic integration of data**

**Automatic informed consent generation**

**Real-time automated biostatistics**

**Automatic protocol to electronic data capture (EDC) platform**

**Artificial control arms**

**Patient population insights and modeling of patient journeys**

**Detection of signals or biomarkers that better target the patient population**

**Medical writing automation**



Across these potential applications, there is also the pressing issue of privacy. Given that analysis sometimes requires access to potentially sensitive data, companies must weigh the value of ML versus the requirements for data security and patient privacy.

In summary, there are many innovation opportunities that hold the potential to drive efficiency and value; however, focusing on the problem being solved is equally as important. We predict that 2024 will be a year for many to learn and refocus their efforts moving into 2025 on the most productive areas.

## A Future of Collaboration

Among the many changes the future is sure to bring, collaboration is going to continue to be one of the most important factors in driving efficiency. Working together makes it possible to harness the full potential of emerging opportunities in 2024 and beyond. Companies who would have competed with one another a few years ago now recognize the power of sharing knowledge and resources to accelerate innovation — and by bringing down the walls and barriers, everyone wins, especially the patients and their families.

As a partner guiding you through challenges and opportunities in your clinical trials, Advanced Clinical provides outsourcing and resourcing models, with close partners in technology, site and patient-represented organizations to tackle your biggest needs. Our goal is to add value by providing A Better Clinical Experience — helping you to achieve your goals.

CONTACT US

## Caroline Redeker

Chief Strategy Officer

Caroline is a results-oriented leader with over 30 years of clinical research experience. She is responsible for corporate growth and innovation strategies, study optimization, identifying efficiencies and creating new service offerings. She has spent much of her time over the past two years on decentralized trial strategy and approach and serves as a member of the Leadership Council for the Decentralized Trials & Research Alliance (DTRA). Caroline currently serves as a leader in the Advanced Clinical Innovation Hub that was launched in January 2024. Caroline is passionate about developing deep relationships and providing value to the clinical development process, and most importantly, accelerating access to medicines for patients.

## Jason Casarella, MBA

Executive Vice President, Business Development and Marketing

Jason is an experienced drug development professional with over 27 years in the CRO industry, overseeing business development, marketing and overall market positioning and strategy at Advanced Clinical. His expertise includes clinical research, proposal development and leading diverse teams, contributing to the growth and efficiency of organizations. Before Advanced Clinical, Jason played a key role in expanding a midsize CRO into a top-five global entity. He holds a Bachelor of Science in biology from DeSales University and an MBA in marketing and strategic management from the Villanova University School of Business.

### ABOUT ADVANCED CLINICAL

Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research – approaching each opportunity with foresight, character, resilience and innovation. Based on decades of experience, we help our clients achieve better outcomes by conducting candid conversations and anticipating potential issues through our customized solutions. Visit our website to learn more: **www.advancedclinical.com**.

