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WHITE PAPER

Clinical Trial Research

The Reasons this Industry is Booming

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Clinical trials are a critical tool that help us better understand and improve human health and healthcare. They empower us to evaluate medical interventions – including new drugs, devices, vaccines, and lifestyle modifications – and identify those that are most likely to benefit patients. They show us what we cannot learn in a lab or in animal testing – how these interventions affect actual people.[1]

What Are Clinical Trials?

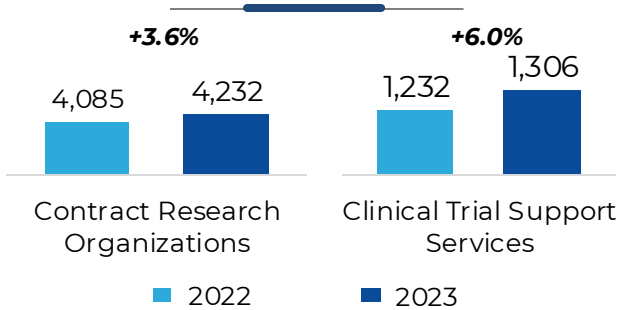
The US clinical trials industry represents a dynamic and pivotal component of the nation's healthcare landscape, embodying the relentless pursuit of scientific advancement and medical innovation. At its core, clinical trials serve as the vanguard of medical research, orchestrating meticulously designed studies that evaluate the safety, efficacy, and benefits of new medical interventions across diverse patient populations.

A Catalyst for Medical Progress[2]: Clinical trials, rather than just being scientific exercises, are complex processes that link scientific discovery to actual patient outcomes. They represent cooperative efforts between pharmaceutical and biotechnology firms, academic institutions, research outfits, care providers, regulatory agencies, and most importantly patients themselves. By adhering strictly to ethical standards, these hypotheses validate therapeutic concepts aiding in designing new therapies.

Empowering Precision Medicine and Personalized Care[3]: In today's era of fast-growing personalized medicine, clinical trials are essential in adapting therapeutic decisions to the genetic, molecular, and clinical profiles of individual patients. Such a method not only improves the effectiveness of treatment but also reduces side effects. It allows for unique medical conditions through customized care pathways that capture every aspect of their complexity. The future of clinical trials is influenced by advances in genomics, biomarker identification, and data-driven insights.

Collaborative Ecosystem and Outsourcing Trends[4]: The clinical trial ecosystem thrives on collaboration with stakeholders fostering synergies to drive innovation and scientific excellence. A notable trend in recent years is the outsourcing of activities to specialized service providers, including Contract Research Organizations (CROs), Contract Development and Manufacturing Organizations (CDMOs), and Site Management Organizations (SMOs). This strategic outsourcing model not only optimizes costs but also enables access to niche expertise, accelerates trial timelines, and ensures compliance with regulatory standards.

Number of Businesses in US[5]



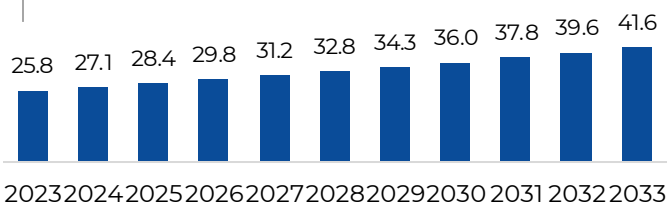
1. https://www.clinicaltrialsastellas.com/why-is-clinical-research-important/
2. https://medicover-mics.com/what-are-clinical-trials/
3. https://www.researchgate.net/publication/379822664_Evolving_role_of_clinical_laboratories_in_precision_medicine_a_narrative_review
4. https://www.appliedclinicaltrialsonline.com/view/outsourcing-model-usage-and-its-relationship-to-clinical-trial-performance
5. IBIS World – Industry Stats

Market Overview

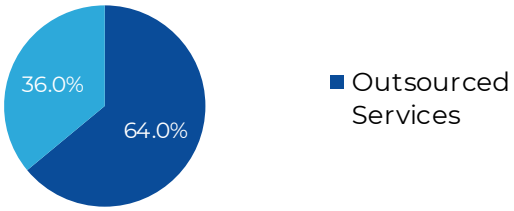
The US clinical trials market is experiencing stable growth. It was valued at US$ 25.8 billion in 2023 and is projected to surpass US$ 41.6 billion by 2033, with a CAGR of 4.9%. This growth is driven by increasing investments in healthcare R&D, the growing prevalence of chronic diseases, and rising demand for innovative treatments. While pharmaceutical companies have traditionally conducted research, most funding now flows to non-institutional players or new entrants. On average, approximately 64% of clinical development services are outsourced.

U.S. Clinical Trials Market

By Size ($B)[1]



By Nature of Clinical Trial Services[4]



Clinical Trial by Phases

What are the different Phases for pharmaceutical research ?[5]

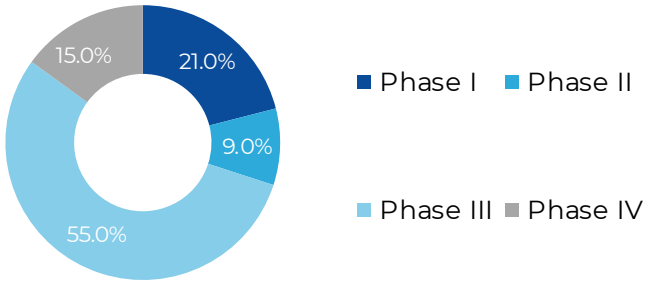
Phase I: Initial testing in a small group of healthy volunteers to assess safety and dosage.

Phase II: Testing in a larger group of patients to evaluate effectiveness and side effects.

Phase III: Large-scale testing in a diverse patient population to confirm effectiveness, monitor side effects, and compare the new intervention with existing treatments.

Phase IV: Ongoing monitoring of the intervention after it has been approved and is available to the public.

US Clinical Trials Market Share, By Phases, 2023[2]



Typically, in the clinical trial industry, Phase III clinical trials held the major market share compared to other stages primarily for determining the safety and efficacy of new medications before they are authorized for widespread use. This type of trial involves more participants usually ranging from 300 to 3,000 and it is longer than Phase II. This larger scale enables researchers to conduct extensive evaluations on its applicability to various patient populations or conditions thus providing well-rounded evidence regarding its advantages and potential risks. More significantly, Phase III trials intensify scrutiny over side effects or interactions that would present regulatory concerns hence ensuring compliance before drug commercialization. This comprehensive nature of Phase III trials makes them a pivotal element in the drug development process, essential for confirming a medication's readiness for the market.[3]

1. https://www.novaoneadvisor.com/report/us-clinical-trials-market
2. Ibid.
3. Ibid.
4. https://www.gminsights.com/industry-analysis/clinical-trials-market
5. https://www.biospace.com/article/releases/clinical-trials-market-is-rising-rapidly-up-to-usd-95-bn-by-2030/

What's driving the growth?

Advancements in Targeted Therapeutics through Healthcare Technology[1]: The rapid advancements in healthcare technology, including digital health solutions, AI, data analytics, and telemedicine, are revolutionizing the clinical trials landscape in the US. Cutting-edge innovations such as gene and cell therapy and CRISPR are enabling researchers to develop targeted treatments for increasingly specific diseases. These technologies streamline trial processes, enhance data collection and analysis, improve patient engagement, and enable real-time monitoring. This technological prowess drives operational efficiencies, reduces costs, accelerates trial timelines, and enhances overall trial outcomes, significantly contributing to the growth of the clinical trials market.

Increasing R&D Investments[2]: The US continues to lead in research and development (R&D) spending, with significant investments from pharmaceutical companies, biotechnology firms, academic institutions, and government agencies. The robust R&D ecosystem fosters innovation, drives scientific discovery, and fuels the development of novel therapies and treatments. These investments support a diverse pipeline of clinical trials across therapeutic areas, contributing to the growth and expansion of the clinical trials.

Increasing Demand for Personalized Medicine[3]: The shift toward personalized medicine, tailored to individual patient characteristics, genomics, and biomarkers, is a significant driver shaping the clinical trials industry in the US. Precision medicine approaches require extensive clinical research, biomarker validation, and targeted therapies, driving the demand for specialized clinical trials.

Growing Prevalence of Chronic Diseases[4]: The rising prevalence of chronic diseases, such as cardiovascular disorders, cancer, diabetes, and neurological conditions, presents a compelling need for innovative therapies and treatment modalities. Clinical trials targeting chronic diseases are at the forefront of research priorities, driving substantial investments, collaborations, and partnerships in the US. The imperative to address unmet medical needs, improve patient outcomes, and mitigate disease burden fuels the expansion of clinical trials in chronic disease management.

Growing Outsourcing of Clinical Trial Services[5]: Pharmaceutical companies are increasingly outsourcing their clinical trial activities to specialized service providers, including CROs, CDMOs, and SMOs. Outsourcing allows companies to access expertise, reduce costs, and accelerate trial timelines, driving the clinical trial outsourcing market.

Increased Patient Engagement and Inclusion[6]: Efforts to enhance patient engagement and inclusion in clinical trials are gaining momentum, driven by initiatives to improve diversity, equity, and accessibility in research. Patient-centric approaches, such as virtual trials, decentralized trials, and patient advocacy groups, are helping to overcome barriers to participation and accelerate recruitment, fostering growth in the industry.

1. https://www.precedenceresearch.com/clinical-trials-market
2. https://www.marketsandmarkets.com/Market-Reports/clinical-trials-market-405.html
3. Ibid.
4. Ibid.
5. https://www.biospace.com/article/releases/pharmaceutical-cdmo-industry-is-rising-rapidly-up-to-usd-295-95-bn-by-2033/
6. https://acrpnet.org/2024/01/enhancement-efficiency-equity-and-engagement-four-trends-shaping-clinical-trials-in-2024/

M&A Landscape

The clinical trial research landscape has witnessed significant transformation in recent years. Since COVID-19, the market saw a surge in mergers and acquisitions (M&A) activity in 2021, which has since slowed down somewhat. The following analysis delves into the key trends and dynamics shaping the M&A landscape within the clinical trial research sector, particularly focusing on the US.

Fragmentation and Consolidation[1]: The clinical research site market, historically fragmented, has experienced a notable shift toward consolidation. The emergence of approximately 30 private equity-backed site platforms, representing around 15% of the global market, highlights the growing trend of consolidation within this segment.

Impact of COVID-19 Pandemic[2]: The COVID-19 pandemic acted as a catalyst for rapid scaling and consolidation within the clinical trial research sector. The necessity to adapt to pandemic-related challenges, coupled with the imperative to accelerate drug development timelines, prompted increased M&A activity among large CROs.

Diverse M&A Strategies[3]: M&A activities within the sector have showcased diverse strategic approaches, including acquisitions focused on specialized capabilities, geographic expansion, and technology-driven solutions. For instance, acquisitions targeting firms with expertise in specific therapeutic areas, such as ophthalmology, dermatology, oncology, and medical devices, have been prevalent, reflecting the industry's emphasis on tailored solutions and niche services.

Private Equity Interest[4]: Private equity investors have shown considerable interest in the clinical trial research sector, viewing CROs and research sites as attractive assets with robust cash flow potential. The influx of private equity capital has fueled M&A transactions, enabled strategic expansions, and facilitated the development of innovative service offerings.

Sponsor Preferences and Challenges[5]: Sponsors' preferences in outsourcing clinical trials have evolved in response to M&A dynamics within the CRO sector. Concerns about large CRO instability, disruptions to project teams, and challenges in service delivery have led sponsors, particularly small and emerging companies, to reevaluate their partnerships. Midsize CROs have emerged as preferred partners, offering specialized services, personalized attention, and cost-effective solutions.

US M&A Deal History[6]

Year	Deal Volume	Deal Value ($M)	Median EV/Revenue
2019	75	9,929.1	4.4x
2020	67	5,118.3	2.1x
2021	128	52,815.32	3.8x
2022	95	7,913.0	0.9x
2023	81	9,831.4	0.5x
2024YTD	50	18,970.0	3.4x

1. https://www.edgemont.com/insights/clinical-research-site-market-overview/
2. https://www.clinicaltrialsarena.com/features/cro-mergers-impact-clinical-trial-sponsors/
3. https://informaconnect.com/cro-deal-making-dominated-by-skills-and-reach-focused-mergers-in-2023/
4. https://www.clinicaltrialsarena.com/features/cro-mergers-impact-clinical-trial-sponsors/?cf-view
5. Ibid.
6. Pitchbook

M&A Activity

Select US M&A Deals[1]

Deal Date	Target	Acquirer	Target Description	Deal Size ($M)	EV/Revenue
May 2024	Elixia	American Clinical Research Services	Provider of multi-site clinical research services specializing in complex therapeutic areas with a focus on nephrology, neuroscience, and infectious diseases, operating across multiple states.	-	-
Apr 2024	Innovation Medical Research Center	Alcanza Clinical Research	Provider of Phase I to Phase IV clinical site trials services in key therapeutic areas such as cardiology, dermatology, endocrinology, etc.	-	-
Feb 2024	Catalent	Novo Holdings	Operates as a CDMO under four segments: biologics, soft gel and oral technologies, oral and specialty delivery, and clinical supply services.	16,500.0	4.0x
Feb 2024	Societal CDMO	CoreRx	Operates as CDMO that offers capabilities spanning pre-Investigational New Drug development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms.	130.0	1.3x
Oct 2023	National Institute Clinical Research	Kingsway Financial Services	Provider of SMO and recruitment services specializing in nephrology, cardiometabolic, infectious diseases, and gastroenterology.	7.9	-
Sep 2023	Elite Clinical Network*	Surge Private Equity	Operator of an integrated network of clinical research sites across the southwestern United States, specializing in diverse study types and therapeutic areas to deliver high-quality research data.	~200.0	-
Sep 2023	Syneos Health	Elliott Investment, Patient Square Capital, Veritas Capital	Provider of biopharmaceutical research services for pharmaceutical and biotech firms, offering clinical trial support and other services.	7,100.0	1.3x
Jan 2023	Ayala Pharmaceuticals	Advaxis	A clinical-stage biopharmaceutical company focused on developing and commercializing small molecule therapeutics.	15.0	18.2x
Jan 2023	OncoBay Clinical	Moffitt Cancer Center, Neuca	Operator of a boutique CRO designed to provide responsive and custom-curated services for clinical trials.	335.0	9.7x
Jan 2023	Mercury Clinical Research	Netura	A SMO comprised of a network of physicians conducting clinical trials in and around the greater Houston Area.	-	-
Oct 2022	Sarah Cannon Research Institute	US Oncology	Operator of an oncology research company that offers clinical trial site management, clinical monitoring, contract research, and personalized medicine services.	173.0	-
Oct 2022	Concentrics Research	IQVIA	Provider of clinical research services for the drugs, dietary supplements, and medical devices industries, offering project management, site management, monitoring, data collection, and analysis.	-	-

(*) Note: Merritt Healthcare Advisors served as the exclusive advisor to Elite Clinical Network private equity partnership with Surge Private Equity.

1. Pitchbook, Capital IQ, Press Releases

M&A Activity

Select US M&A Deals[1]

Deal Date	Target	Acquirer	Target Description	Deal Size ($M)	EV/Revenue
Sep 2022	Catalina Research Institute, LLC	American Clinical Research Services	Operator of an independent clinical trials centre specializing in high-complexity trials across metabolic diseases and central nervous system disorders, serving underrepresented populations	-	-
Jul 2022	Sierra Oncology	GSK	A clinical-stage drug development company that advances targeted therapeutics for the treatment of cancer patients.	1,900.0	-
Dec 2021	Pharmaceutical Product Development	Thermo Fisher Scientific	Operates as a CRO that provides clinical trial and laboratory services to pharmaceutical, device, and diagnostic firms.	15,990.0	2.5x
Dec 2021	Navitas Life Sciences	HIG Capital	Operator of a clinical research organization intended to serve large blue-chip pharmaceutical and biotech clients across North America, Asia Pacific, and Latin America.	101.6	-
Jul 2021	PRA Health Sciences	Icon	A CRO supporting pharmaceutical, biotech, and medical device industries with drug development and clinical trial services, from early- to late-stage trials.	12,042.0	3.4x
Apr 2021	Clinipace	dMed	Operator of a clinical CRO intended to integrated clinical research services for biopharmaceutical and medical firms.	233.3	-
Apr 2021	Q2 Solutions	IQVIA	Provider of clinical trial laboratory services for new drug therapies, develops medicines and pharmaceutical products.	760.0	-
Sep 2020	Catawba Research	St. Cloud Capital	Operator of a vertically integrated CRO, providing clinical management services to pharmaceutical and biotechnology companies globally.	-	-
Jan 2020	Stephens & Associates	SGS	Provider of contract research services that offers clinical testing services, investigation site services, image analysis, pharmaceutical and medical device clinical trials, serum and biopsy sampling, and analysis.	17.4	1.2x
Oct 2019	Collaborative Neuroscience Network	Apex Innovative Sciences, Bison Capital Asset Management	Provider of clinical research services specializing in clinical trials and comprehensive site services for new medications and treatments.	-	-
May 2019	Pharmatech Oncology, Inc.	Caris Life Sciences, Inc.	Provides CRO and SMO services to pharmaceutical and biotechnology clients for the development and management of clinical research trials.	-	-
Apr 2019	Helomics	Predictive Oncology	Provider of integrated clinical contract research and personalized medicine services intended to improve the standard of care for patients.	9.7	7.1x

Mean	**5.4x**
Median	**3.4x**

1. Pitchbook, Capital IQ, Press Releases

A Vision for the Future

Looking ahead, the landscape of clinical trial research is poised for significant transformation. The growing complexity of clinical trial designs is generating vast amounts of data from diverse sources. This trend is driven by the biopharmaceutical industry's shift toward ambitious, customized drug development targeting rare diseases, and utilizing biomarker and genetic data to stratify participant subgroups.

Data-centric Approach to Drug Development[1]: The future of pharmaceutical industry leadership is expected to shift toward data scientists and technology giants such as Google, Amazon, and Apple. The centrality of data in clinical trials will empower algorithms managed by data scientists to drive drug development processes, focusing on safety and efficacy assessments through advanced analytics and AI-driven insights. Mergers and partnerships between traditional pharmaceutical companies and tech giants reflect the growing acceptance of data-driven end-to-end solutions in drug development and reimbursement pathways.

Impact of Wearables and Diagnostics[2]: Wearable technologies and implantable biosensors are poised to become commonplace by 2050, revolutionizing patient monitoring and drug delivery. Responsive drug delivery systems will enable personalized treatment regimens, optimizing medication administration based on real-time patient data. This shift toward personalized medicine and data-driven dosing strategies will not only enhance patient outcomes but also streamline clinical trial recruitment and participant identification.

Role of Artificial Intelligence in Clinical Trials[3]: Artificial intelligence (AI) will play a pivotal role in optimizing clinical trial processes, from study design to participant recruitment and data analysis. AI algorithms will leverage historical data and real-time insights to optimize study protocols, identify disease-specific centers of excellence, and streamline patient identification for trials. Simulation-guided by AI will enable preclinical characterization of therapies, optimal dosing strategies, and large-scale population modeling, revolutionizing trial efficiency and cost-effectiveness.

Transformation of Registration and Reimbursement[4]: The registration process for new therapies is expected to evolve toward real-time coordination and adaptive trial designs. Regulatory authorities will leverage integrated data management systems and AI-powered analytics to monitor trials in real time, reducing administrative burdens and accelerating drug approval timelines. Reimbursement models will likely shift toward outcomes-based pricing, linking payment to treatment efficacy and patient outcomes, fostering a more efficient and value-driven approach to healthcare delivery.

Future of Disease Understanding and Treatment Paradigms[5]: Advancements in technology will deepen our understanding of diseases, leading to personalized treatments tailored to individual needs. Smart medicines, gene profiling, and responsive drug delivery will define the era of precision medicine while testing in diverse patient populations will ensure broader applicability of treatments.

1. https://www.capgemini.com/wp-content/uploads/2022/01/The-Clinical-Trial-of-the-Future-2021.pdf
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10259497/
3. Ibid.
4. Ibid.
5. Ibid.

Conclusion

The landscape of clinical trial research in the US, and globally, is not just transforming; it is experiencing a revolution fueled by data, technology, collaboration, and a relentless pursuit of improving human health. As we delve into the complexities and opportunities of this dynamic industry, several key insights emerge that illuminate the path forward for clinical trials and healthcare innovation.

One of the most striking aspects of the clinical trial research industry is its adaptability and resilience in the face of challenges. From navigating regulatory complexities to overcoming patient recruitment hurdles, the industry has consistently demonstrated a capacity for innovation and problem-solving. This adaptability will continue to be a driving force as the industry embraces new technologies, methodologies, and collaborative models.

Speaking of collaboration, the future of clinical trials lies in interdisciplinary partnerships that leverage the strengths of diverse stakeholders. Collaborations between pharmaceutical companies, tech giants, academic institutions, healthcare providers, and patient advocacy groups are fostering a holistic approach to clinical research. These partnerships enhance the quality and efficiency of trials and ensure that patient voices are central to the process, leading to more meaningful outcomes.

Data and technology are undoubtedly the cornerstones of the future clinical trial landscape. The integration of wearables, AI-driven analytics, real-time monitoring systems, and personalized medicine approaches is revolutionizing how trials are conducted, monitored, and analyzed. This data-centric approach optimizes trial processes and enables more accurate assessments of treatment efficacy, safety, and patient outcomes.

Looking ahead, the industry must continue to prioritize inclusivity, diversity, and patient-centricity. Efforts to enhance patient engagement, improve accessibility to trials, and address disparities in healthcare access will be crucial in ensuring that clinical research benefits all segments of society equitably.

In essence, the booming global clinical trials industry represents a beacon of hope and progress in healthcare. It embodies the collaborative spirit of innovation, the transformative power of data and technology, and the unwavering commitment to improving human lives. As we navigate the complexities and opportunities of the future, let us forge ahead with a shared vision of advancing medical science, enhancing patient outcomes, and shaping a healthier, more resilient world for future generations.

Merritt Healthcare Advisors
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Contact Us

John Carron
Partner
jcarron@merrittadvisory.com
(917) 647-8218

Zak Eisenberg
Vice President
zeisenberg@merrittadvisory.com
(914) 815-5479

Connecticut Office: 63 Copps Hill, 22A
Ridgefield, CT 06877

West Coast Office 521 Bachman
Ave Los Gatos, CA 95030

(914) 556-6266

merrittadvisory.com