Move confidently through the drug development process

Fuel your clinical development and decision-making with insights from fit-for-purpose data and evidence

Navigating the data-driven future of drug development

Today's clinical research data landscape is increasingly complex and costly. As the volume of data collected in clinical trials continues to expand, and as the industry moves toward more complex trial designs and patient-centric approaches, efficient, rapid and transparent consolidation, validation and review of disparate data sources is critical.

Big data and analytics (data science) and real-world data are transforming drug development by leveraging artificial intelligence (AI) and machine learning (ML) to accelerate drug discovery, enhance clinical trials, enable personalized medicine, and improve drug safety and efficacy. These innovations promise more accurate, efficient and ethical drug development, reducing dependence on traditional methods, which are labor intensive, slow, costly, and often yield results with low accuracy. AI and ML tools have the ability to improve efficiency and effectiveness across the drug discovery process. However, with these tools come new challenges related to data privacy, AI analysis and data integration.

To enable drug developers to stay ahead in this rapidly evolving environment, the PPD™ clinical research business of Thermo Fisher Scientific, publishes ***The Pulse***: our annual survey of 150 leaders at global biotechnology and pharmaceutical organizations. The report provides valuable insights into clinical development trends and strategies with key takeaways that empower sponsors with approaches for employing data to shape drug discovery, development and market access.

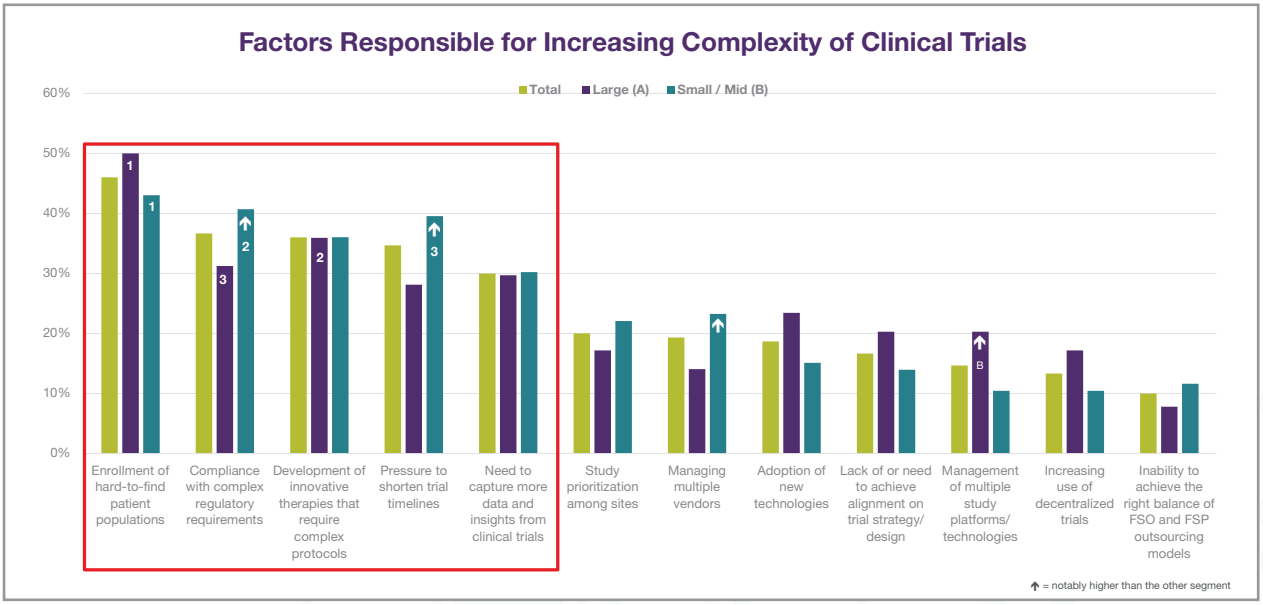
Derived from ***The Pulse***, this report serves as a guide for drug developers navigating today's new data paradigm. Use it to:

- Understand how the emphasis on data impacts the increasing cost and complexity of clinical trials.
- Keep abreast of key trends, innovations and approaches to using data in clinical development.
- Leverage data to overcome common challenges in clinical trials.

The future of drug development is centered around data, which enables sponsors to bring a more precise, efficient, and humane approach to the creation of life-changing therapies. By harnessing the power of big data and AI, researchers gain access to more exhaustive information and insights to better understand the complexities of human biology and disease, paving the way for innovative treatments.

Lack of sufficient trial data contributes to rising trial costs

While multiple factors are responsible for increasing clinical research costs, sponsors at both large and small/midsize biopharma companies report that data plays a part. Specifically, the need to capture more data and insights from clinical trials and the increasing amount of trial data collected per study drive up both study costs and trial complexity.



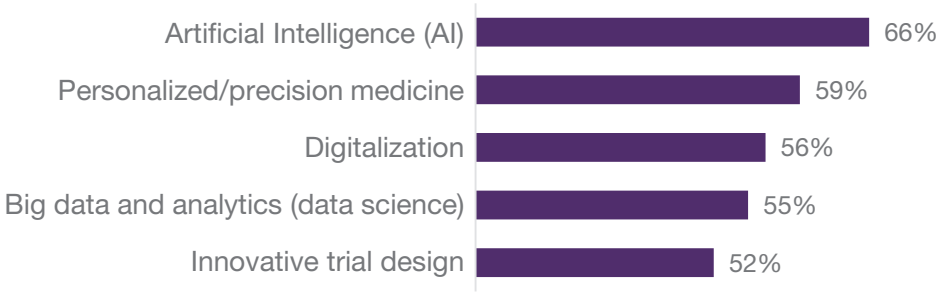
Data-driven technologies are paving the way

Across the industry, sponsors at both large and small/midsize biopharma companies are using a variety of data technologies and innovations to revolutionize their clinical development journey. The most common include innovative trial design, AI and personalized/precision medicine, which all lead to more efficient, patient-centric and data-driven clinical trials.

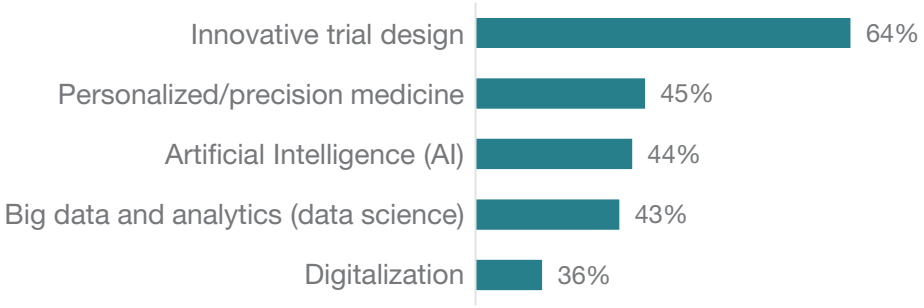
Biopharma companies also are pursuing multiple strategic initiatives. Maximizing asset values is the most common overall. Other leading strategies for large biopharma include patient-centricity, greater use of RWD/RWE and patient diversity.

Small/mid biopharma are pursuing strategies that include new approaches to investment and funding, vendor rationalization and greater use of RWD/RWE.

Top 5 Technologies Pursuing: Large Biopharma

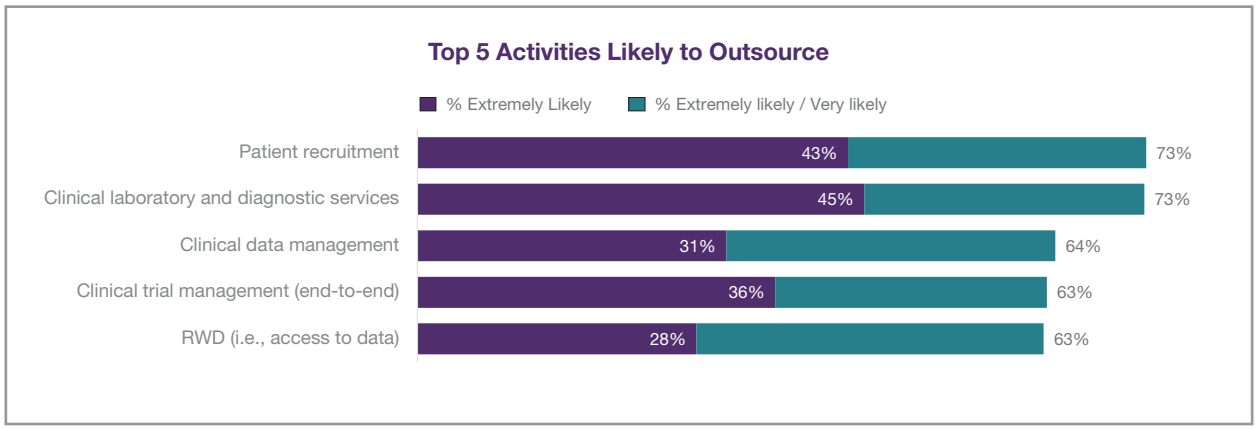


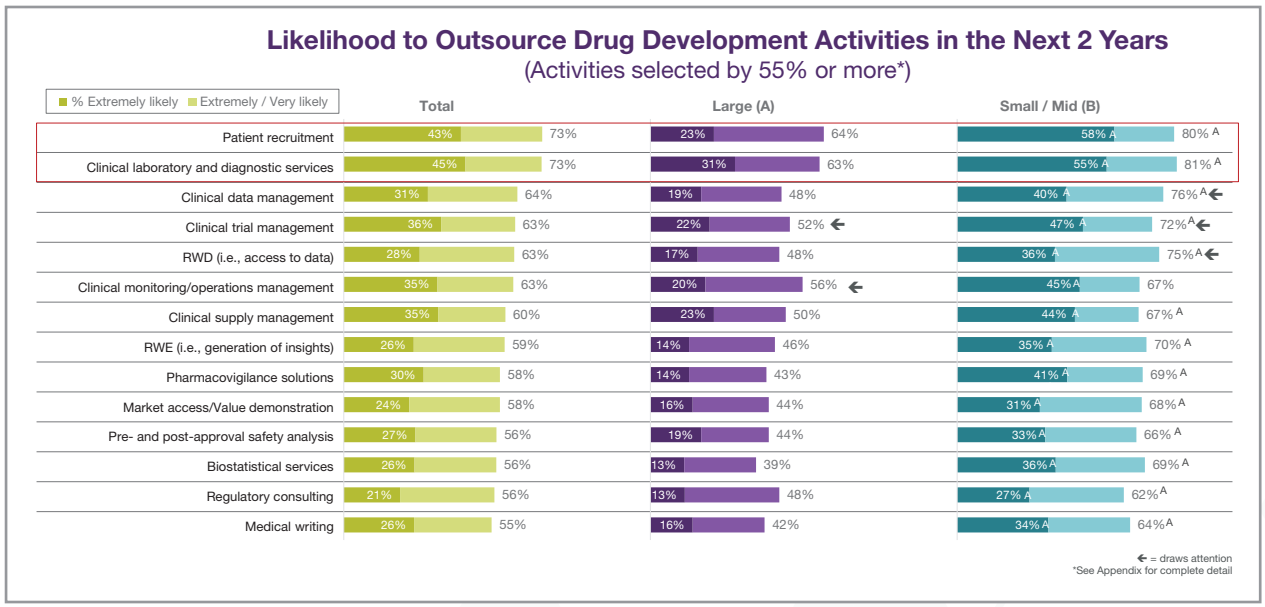
Top 5 Technologies Pursuing: Small/Mid-size Biopharma



Sponsors are leveraging FSP outsourcing to manage data functions

Functional service partnership (FSP) outsourcing continues to grow — outpacing full-service outsourcing (FSO). Sponsors are increasingly using FSP to outsource top drug development activities like clinical data management (CDM) and access to real world data (RWD). With the volume of clinical trial data increasing exponentially, leveraging an FSP partner enables sponsors to safeguard the integrity of their clinical trial data and empowers study teams to make faster and smarter decisions, enhancing patient outcomes.





Data are among the trends driving clinical trial transformation

Sponsors report that one of the leading, most impactful trends is AI (e.g., to enable recruitment, advanced analytics, RWD/RWE), which is ranked high for both small/mid-size and large companies. Other top trends in data include digitalization (e.g., cloud computing, APIs, digital platforms), big data and analytics (data science) and greater use of RWD/RWE to complement data from clinical trials.

Trends^ Driving Transformation in Clinical Trials

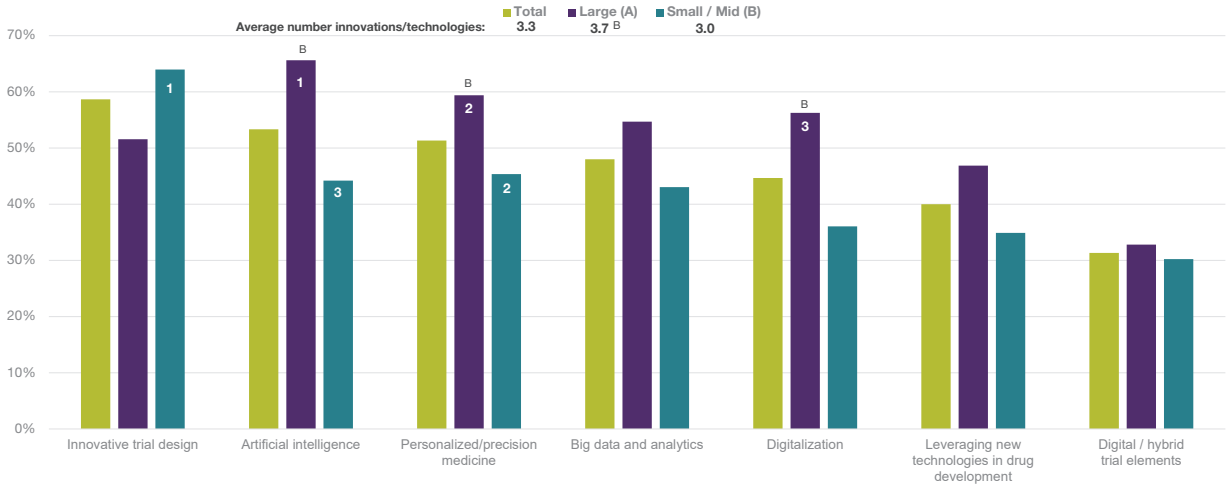
Key: % Ranked Top 2 | % Selected Top 5

	Total		Large (A)		Small / Mid (B)	
Innovative trial design	22%	52%	16%	42%	27%	59% A
Personalized/precision medicine (e.g., companion diagnostics)	22%	51%	25%	53%	20%	49%
Artificial intelligence	29%	50%	33%	50%	27%	50%
Leveraging new tech dev (e.g., mRNA, CRISPR, gene-editing)	19%	47%	20%	50%	19%	44%
Patient-centricity	18%	43%	20%	44%	16%	43%
Increasing focus on patient diversity	10%	43%	9%	42%	10%	43%
Decentralized / hybrid trial elements	15%	42%	9%	45%	19%	40%
Accelerated development/approvals in rare/orphan disease	17%	41%	17%	38%	17%	43%
Greater use of RWD/RWE to complement data from clinical trials	16%	41%	22% B	48% B	12%	35%
Big data and analytics (data science)	11%	39%	9%	38%	12%	40%
Digitalization (e.g., cloud computing, APIs, digital platforms)	15%	36%	8%	23%	20% A	45% A
Sustainability efforts	5%	15%	9% B	25% B		8%

^See Appendix for full trend descriptions provided in the survey.

As a result, sponsors are pursuing a wide variety of data technologies and innovations — chief among them is AI, big data and digitalization. They are increasingly engaging in most of the innovations and technologies below, especially AI.

Innovations and Technologies Employed by Pharmaceutical Companies



Five key considerations for maximizing data and evidence

It's difficult to efficiently distill clinical trial data in today's complex and challenging landscape, but properly managing and leveraging data tools and insights transforms your process from drug discovery to market approval.

Our survey of 150 global drug developers revealed key data-related factors that impact the cost and timelines of clinical trials. With an experienced partner, you will capture more data and insights, with greater efficiency, ensuring your trials stay on time and on budget — ultimately empowering you to be a changemaker for patients.

1 Data quality, integrity and accuracy

Inconsistent data collection methods, data silos and incomplete data significantly impact reliability and hinder efficient analysis.

Solution: Clinical trials play a critical role in health care, with data as the cornerstone for offering valuable insights into drug development. Ensuring data integrity, consistency and accuracy is necessary for upholding research validity, trustworthiness and credibility. High quality data is crucial for accurate clinical trial reporting and results, meeting drug safety and efficacy standards and regulatory compliance.

2 Clinical data management and complexity

With an industry shift to more complex trial designs, the volume of clinical trial data is increasing. As referenced, 64% of sponsors surveyed are increasingly more likely to outsource CDM services to safeguard the integrity of their clinical trial data.

Solution: In the realm of clinical trials, managing complex data efficiently is paramount. Employing a variety of tools, techniques and processes designed to enhance data accuracy, efficiency, and regulatory compliance is critical throughout the trial lifecycle. Advanced data modeling, simulation and adaptive designs are essential for making informed decisions in trials with evolving parameters. Ensuring high-quality, statistically sound data improves the reliability of trial outcomes and streamlines the entire clinical development process.

3 Data-driven patient recruitment

Patient recruitment and enrollment of hard-to-find populations and complex regulatory requirements are top challenges increasing the complexity of clinical trials, as named by 39% of those surveyed. Integration of data, and use of advanced technologies (like AI) are optimizing recruitment efforts.

Solution: Recruiting the right patients is crucial to a clinical trial's success—without it, delays and higher costs often occur. Alongside strategies like partnering with advocacy groups, expanding study sites, and running trials across more countries, sponsors are increasingly using data-driven tools such as predictive analytics to identify and enroll target patients. AI/ML technologies, real-world data, and advanced analytics are accelerating recruitment, reducing costs, and improving patient diversity.

4 Expansion of RWD sources

As RWD sources become vaster and more diverse, sponsors are experiencing increased complexity identifying optimal trial data. Sixty-three percent of survey respondents shared that they are extremely likely to outsource RWD (i.e., access to data).

Solution: Real-world insights are playing a growing role in drug development. Sponsors increasingly rely on RWD beyond traditional clinical trial results to inform trial design through post-marketing studies. RWD offers critical insights into a product's real-world performance, safety, and effectiveness. Partnering with a CRO for specialized data solutions streamlines studies, accelerates study startups, and delivers tailored insights for better product development and outcome monitoring.

5 Regulatory uncertainty

In our survey, 39% of respondents cited complex regulatory requirements as one of the top challenges increasing clinical trial complexity. Adhering to rigorous regulations involves ensuring data accuracy and integrity throughout the clinical trial process.[1]

Solution: Alongside enrollment of hard-to-find patient populations and pressure to shorten trial timelines, compliance with complex regulatory requirements is a major challenge in the drug development process. Accessing and analyzing high-quality clinical trial data and RWD (from EHRs, patient registries and post-market studies) provides sponsors with enhanced knowledge about a drug's performance, benefits and risks. This information strengthens compliance readiness, better preparing sponsors for regulatory submissions amid an ever-evolving landscape.

Three ways to leverage data, tools and evidence to optimize your clinical development journey

Biotech and biopharma companies continually encounter obstacles across their drug development journey, including study startup delays, inefficient site selection, challenges with data management, transparency and regulatory compliance hurdles, and operational inefficiencies. These challenges significantly hinder progress.

Although data, tools and evidence offer promise in helping sponsors better navigate these challenges, they are hesitant to embrace and integrate new technologies into their workflows due to data and regulatory uncertainties, ethical considerations, and liability concerns. However, when implemented correctly and used responsibly, data, innovative tools (particularly AI) and evidence are powerful partners in mitigating risks in drug development.

By adopting innovative approaches, sponsors will transform their clinical research model through forward-thinking, integrated digital tools and technology solutions, to accelerate and optimize every phase of their clinical development journey.

1. Embracing tools, trends and innovations that drive transformation

Alongside current clinical trial strategies, sponsors are also increasingly pursuing and engaging in a variety of transformational trends, and top technologies and innovations to maximize clinical development success. Survey respondents emphasized the importance of AI (50%), greater use of RWD/RWE (41%), big data and analytics (39%) and digitalization (36%) as the most impactful trends driving clinical trial transformation.

As reported in *The Pulse*, the need to capture more data and insights from clinical trials is among the key factors most responsible for the increasing complexity of clinical trials. To achieve this, sponsors must:

- Implement robust technology solutions and data tools, including data capture systems and integration platforms for efficient data collection.
- Fully integrate RWD and RWE to gain richer insights into assessing and improving trial designs, recruitment processes, patient safety and treatment outcomes.
- Leverage innovative data visualization tools and employ big data analytics, AI, and ML to provide real-time performance insights, better manage complex data and use predictive modeling to minimize risks.

2. Using AI-powered data to optimize patient recruitment

With clinical trials growing more complex, recruiting participants is increasingly challenging, often impacting study timelines and leading to costly delays. Enrollment of hard-to-find patient populations is another top factor most responsible for increasing complexity. As a result, drug developers employ a mix of strategies to encourage patient participation. Building relationships with patient advocacy groups remains the top strategy for both large and small/mid-size biopharma companies. However, 39% of sponsors surveyed shared that they also currently **leverage data/tech to identify target patients**.

AI-powered recruitment technology is advancing rapidly. Fully harnessing the power of AI-driven tools helps generate valuable insights into and a more comprehensive view of patient populations, enabling sponsors to streamline their processes and develop effective recruitment strategies.

- AI-enabled global research registries can evaluate large clinical data sets and analyze medical histories and genetic information to provide deeper insights and minimize delays in patient enrollment.
- AI-powered clinical data collection automates processes including abstraction, extraction, encoding, standardization, and submission, which increases efficiency and saves time and money.
- AI-enabled RWE analysis enables sponsors to generate more accurate evidence and targeted insights to address and advance clinical research.

3. Leveraging big data and predictive analytics to proactively identify issues and forecast trial outcomes

Data science is one of the top five technologies both large (55%) and small/mid-size (43%) biopharma companies are pursuing.

Big data entails processing large volumes of data using advanced methods, while predictive analytics harnesses the potential of big data[2], leveraging ML and statistical algorithms to analyze historical and real-time data.

By harnessing big data, **predictive analytics** technology provides valuable insights, empowering sponsors to proactively identify patterns and issues and anticipate unknown outcomes. Transitioning from a reactive to a predictive strategy enables drug developers to minimize risks, improve efficiency and increase clinical development success.

Drug developers should leverage big data and predictive analytics to:

- **Predict patient enrollment rates:** Multi-sourced data enables sponsors to select optimal sites, make predictions about enrollment trends and proactively manage risks.
- **Anticipate potential safety concerns:** AI/ML-enabled data analysis helps identify at-risk patients, predict adverse events, and improve trial designs and patient selection.
- **Optimize trial timelines and resource allocation:** AI-powered tools enable **real-time clinical trial forecasting**, facilitating effective and proactive management and mitigating trial delays.

Leveraging data, tools and evidence is essential for keeping trials on time and on budget, navigating the rapidly evolving landscape, and achieving overall excellence in drug development. The PPD clinical research business of Thermo Fisher Scientific is committed to driving innovation and excellence through advanced technologies that streamline processes, enhance data management, ensure regulatory compliance, and improve operational efficiency. With decades of expertise, advanced AI capabilities, and a vast global network to accelerate trial success, we are recognized as the No. 1 provider of clinical research solutions. We stay ahead of industry trends and provide the data and insights sponsors need to navigate evolving challenges quickly. With an experienced and agile partner by your side, you'll be poised to expedite your study with greater transparency and operational efficiency.

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Ready to drive better decisions with actionable data and insights?

The time is now.

References

1. VIARES, "Clinical Research Explained: Data Integrity," 6 April 2025, https://viares.com/blog/clinical-research-explained/data-integrity/
2. Artificial Intelligence Review, "Big data and predictive analytics: A systematic review of applications," 17 June 2024, https://link.springer.com/article/10.1007/s10462-024-10811-5

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