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WHITE PAPER

Clinical Trial Data Management: Challenges and Trends

Research organizations turn to outsourcing to manage labor costs and data quality.

Multiple industry factors are causing a backlog of data entry

Many research organizations and clinical trial sites have implemented a clinical trial management system (CTMS) that tracks completed patient visits and protocol management, and an electronic data capture system (EDC) which can streamline data collection, management, and compliance. However, because of multiple industry factors, including increasing demand for clinical trials, a shortage of skilled resources, and the lack of capacity to curate research quality data, facilities continue to have a backlog of data entry. This puts organizations at risk of not meeting industry compliance requirements and causes delays in providing research ready data. Clinical trials that are delayed, postponed, or cancelled can have negative financial implications for both the trial sponsors and administrators.

CTMS and EDC systems were not designed to abstract, curate, or manage large volumes of clinical trial data, and they are only as good as the resources entering the data.

Although the CTMS and EDC systems are an advance in technology, they were not designed to abstract, curate, or manage large volumes of clinical trial data, and they are only as good as the resources entering the data. As organizations lag in data entry and curation, there's a ripple effect across stakeholders involved in the clinical trial process. The 21st Century Cures Act puts even more emphasis on the use of these types of data to support regulatory decision making and the approval of new indications for approved drugs.

In the effort to drive efficiency, reduce timelines, and address the rising costs of clinical trials, many research organizations are partnering with experienced outsourcing providers to either supplement or fully manage their clinical trial data curation process. Outsourcing has become an accepted best practice enabling organizations to scale resources, reduce labor costs, and engage specialized expertise to help ensure high-quality data for successful clinical trial programs.

Market drivers influencing outsourcing of clinical trial data management

The global clinical trials outsourcing market size is expected to reach USD 67.62 billion by 2030, up from 2022 estimated global market value $40.28 billion at a compound annual growth rate of 6.7%.[1] Research organizations, cancer centers, and clinical trial sites are experiencing an increasing demand for clinical trials in response to the rising need for new and advanced drugs and therapies to address the rising prevalence of diseases such as cancer.

In the current high-pressure clinical development environment, there's a huge challenge in meeting the requirements for cleaning and curating high-quality clinical trial data. In-house clinical teams are spending valuable time cleaning data rather than analyzing it.[2] In a survey of clinical data management professionals, 95% of respondents reported that manual effort is involved in aggregating, cleaning, and transforming clinical trial data, and two out of three respondents experienced issues with the process.[3]

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Ultimately, the cost of bringing a new drug to market—around $350 million, which doesn't include the cost of failures and delays—continues to be a key driver in improving clinical trial data management. Clinical trial delays in 2022 averaged approximately 4.3 months. They were influenced by small and midsize biotech funding challenges and labor availability issues, which are the primary reasons there were not record levels of clinical trial starts.[4]

Many organizations lack the resources and budget to effectively manage and curate the resulting clinical trial data in house. As a result, clinical trial sites and research organizations are evaluating operational efficiencies and establishing partnerships with service providers and sponsors to help address these challenges. Initiatives are under way to improve clinical trial management to accelerate research and treatments.

INDUSTRY OUTLOOK FOR CLINICAL TRIALS

- Approximately 50% of all clinical trials started in 2022 were in oncology, which is expected to continue.
- Approximately 30% of phase 2 and 3 clinical trials have experienced delayed start dates due to funding challenges and availability of labor.
- Phase 3 clinical trial durations increased from 2 years in 2010 to 3.5 years in 2022.
- Clinical trial cost will be emphasized over timeliness. Uncertainty around technology investment will lead sponsors toward legacy clinical trial models versus virtual options.

Source: Life Sciences Services Industry Outlook: Winter 2023[5]

1 "Clinical Trials Outsourcing Global Market Report 2022," Research and Markets, March 1, 2023
2 Ibid
3 "Challenges and Opportunities in Clinical Data Management," Pharma Intelligence and Oracle, September 2018
4 "Clinical trials industry outlook: Fall 2022," RSM, September 14, 2022
5 "Life Sciences Services Industry Outlook: Winter 2023," RSM, February 6, 2023

Managing multiple data sources to generate research quality data

The growing demand for clinical trials and research grade data to develop innovative treatments is driving the industry to reduce costs and time to market to maximize return on investment. This is especially true for oncology. Approximately 50% of all clinical trials started in 2022 were in oncology, and it continues to be a dominant driver in clinical research in 2023. Increasing trial complexity will also challenge clinical trial sites with narrow inclusion and exclusion criteria, multiple study arms, and an increasing number of amendments per clinical trial.[6]

Despite numerous oncology databases and use of EHRs, significant nuanced data remains locked in clinical free text, still the primary form of documenting and communicating clinical presentations. Only recently has natural language processing (NLP) technology advanced to demonstrate its capacity for oncology analysis to extract physical and biochemical characteristics from clinical text.[7]

In a survey of clinical data management professionals, 50% reported using up to five different data sources, and 37% use between six and ten.[8] Data generated from multiple sources can enable research teams to identify matches more quickly for drug candidates and develop them into potential medicines at a faster rate.[9] Insights from real-world data (RWD) will catalyze clinical care, research, and regulatory activities. This data convergence has the potential to enable new insights about cancer initiation, progression, metastasis, and response to treatment.[10]

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Biopharma R&D organizations often acknowledge that many clinical trial activities continue to use the same processes as in the 1990s, and clinical development has failed to keep pace with the growing amounts of real world evidence (RWE) data, genomics information, and emerging data sources. Utilizing this data could help demonstrate the value of new treatments in patient health and economic outcomes. Yet organizations are challenged to generate this evidence as efficiently as possible to allow for meaningful return on R&D investment.[11]

6 "Clinical Research Trends & Insights for 2023," WCG, 2023

7 "Use of Natural Language Processing to Extract Clinical Cancer Phenotypes from Electronic Medical Records," NIH National Library of Medicine, August 8, 2019

8 "Challenges and Opportunities in Clinical Data Management Research Report," Pharma Intelligence and Oracle. September 2018

9 "How Big Data Can Revolutionize Pharmaceutical R&D," Jamie Cattell, Sastry Chilikuri, Michael Levy, McKinsey Center for Government

10 Ibid

11 "Transforming the future of clinical development," Dawn Anderson, Jonathan Fox, Natasha Elsner, Deloitte Insights, February 14, 2018

Growing reliance on RWD and RWE in clinical trials

The increasing volume of data also adds to the strain of data management. As methods for managing RWD develop and improve, the use of it in drug development and approval continues to gain prominence. RWD, which relates to patient health status and delivery of healthcare, comes from multiple sources such as EHRs, claims activities, and disease registries. RWE is the clinical evidence derived from analysis of RWD and from different types of clinical trial study analyses and observational studies.

RWD is playing an increasingly important role in healthcare decisions. The 21st Century Cures Act, intended to accelerate medical product development and innovations, emphasizes the importance of capturing and curating RWE data for research. The Food and Drug Administration (FDA) uses it to monitor post market safety, and medical product developers use it to support clinical trial designs and observational studies to generate innovative, new treatment approaches.[12] In 2019, the FDA approved the first drug (Pfizer's Ibrance) where analysis was largely based on RWD.[13]

A balanced approach on the collection of RWD can help validate clinical research to facilitate evidence-based decisions at the point of care with greater precision. Selecting an appropriate data source and ensuring comparability through proper handling of the data can increase the utility of external controls, raising the efficiency of drug development.[14]

The focused collection of clinically relevant data can help clinicians bring RWE to drug development while improving quality, patient safety, and value in cancer care delivery.[15] Conducting valid RWD studies requires data quality assurance through auditable data abstraction methods and electronically capturing clinically relevant data at the point of care.

USE CASES AND CHALLENGES FOR CLINICAL TRIAL RWD

Clinical Data Sources

- POC physician notes and diagnostic reports
- EHRs, PHRs
- Administrative data
- Claims data
- Patient registries
- Digital health data
- Health surveys
- Clinical trials data

Use Cases

- Delivery of healthcare services
- Research
- Development of external controls
- Development of potential clinical trials
- Post-market pharmacovigilance
- Cancer drug development
- 21st Century Cures Act requirements

Challenges Addressed Through Outsourcing

- EHRs are limited in high quality, clinically relevant structured data
- Resource intensive extraction of data from unstructured content
- Availability of trained, skilled clinical resources to ensure adherence to ethical and regulatory standards
- Application of procedures to verify quality of data

Source: JNCI - Real-world Data for Clinical Evidence Generation in Oncology[16]

12 "Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions," FDA.gov

13 "Clinical Trial Outsourcing Trends and Research in 2020," Thomas Underwood, March 10, 2020

14 "Incorporation of real-world data to a clinical trial: use of external controls," Kim TE, Park SI, Shin KH. Transl Clin Pharmacol, September 30, 2022

15 "Real-world Data for Clinical Evidence Generation in Oncology," Sean Khozin, Gideon M Blumenthal, Richard Pazdur, JNCI: Journal of the National Cancer Institute, Volume 109, Issue 11, November 2017

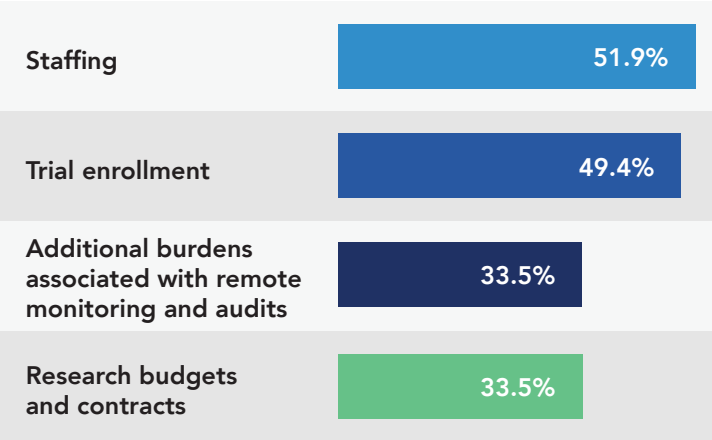
16 Ibid

Economic turbulence

Life sciences companies, particularly clinical research companies, have maintained strong growth despite economic turbulence. They will continue to encounter funding challenges and competition for experienced, highly skilled talent, as well as fallout from the economy.[17]

Many research organizations will likely pass on cost increases to trial sponsors. A funding slowdown for mid-market biotech could translate into clinical research organizations (CROs) experiencing increased pushback from sponsors. An easing of the public funding markets should mean an easing of this trend for CROs. Large CROs, have maintained healthy cash positions and report strong volume for proposals and new business.[18] This gives them more bargaining power to add fee increases to offset rising labor costs.[19]

OPERATIONAL CHALLENGES IMPACTING CLINICAL TRIAL SITES



Source: WCG Q1 2022 site survey[20]

FDA regulatory review and data governance

In a survey of top clinical data management professionals, 81% of respondents indicated data governance issues as the biggest challenge with clinical trial data meeting regulatory compliance. Many respondents cited several serious and negative risks that can result from inconsistent or incomplete data. The top three data governance issues cited were data quality, duplicated data/inconsistent data, and data lineage/traceability.[21]

The FDA's regulatory review process contains several measures directed at validating appropriate conduct of clinical research, including site inspections for source document verification and random audits on data sets to verify accuracy. In alignment with the 21st Century Cures Act, the FDA launched the Oncology Center of Excellence Real World Evidence Program (OCE RWE) with the goal of engaging in evidence development modernization through scientific collaboration and policy development to advance the appropriate fit-for-purpose application of RWD to generate RWE for regulatory purposes.[22]

Currently, practical insights on the design and analysis of regulatory-grade RWE are lacking to support registration of new therapies and label expansions by the FDA. In a 2022 study analyzing attributes of real-world studies in FDA's decision-making and identifying best practices for adequate RWE,[23] the FDA critiqued the lack of the prespecified study protocol, inclusion/exclusion criteria matching to the trial, comparability of endpoint definitions, methods to minimize and address unmeasured confounding, and plans to handle missing data.

81%

Survey respondents indicated data governance issues as the biggest challenge with clinical trial data meeting regulatory compliance.[21]

17 "Life sciences industry outlook: Winter 2023," RSM, February 6, 2023
18 "Clinical trials industry outlook: Fall 2022," RSM, September 14, 2022
19 "Life sciences industry outlook: Winter 2023," RSM, February 6, 2023
20 "Clinical Research Trends & Insights for 2023," WCG, 2023
21 "Challenges and Opportunities in Clinical Data Management Research Report," Pharma Intelligence and Oracle. September 2018
22 "Oncology Real World Evidence Program: Fostering Regulatory Science and Collaboration to Translate Real World Data into Real World Evidence," FDA oncology center of excellence
23 "Real-World Evidence in Support of Oncology Product Registration: A Systematic Review of New Drug Application and Biologics License Application Approvals from 2015-2020," NIH, January 2022

Lack of skilled resources and rising costs of maintaining in-house experts

For the first time in two decades, staffing shortages replaced financial challenges as the top concern among healthcare CEOs.[24] Clinical research sites are stretched thin from balancing limited resources and the lack of experienced staff to manage the growing volume of trial requests.

In addition, clinically relevant data is often difficult to capture because it's buried in unstructured content such as physician notes and diagnostic reports. The increasing complexity of trial and data management results in a higher risk of noncompliance due to processes that require more training and time, and skilled resources which aren't always covered in the budget.

The U.S. labor demand in life sciences services remains high coming out of the pandemic. Based on analysis of the clinicaltrials.gov database, approximately 5,200 new clinical trials were started in 2022, less than the approximately 5,650 starts in 2021.[25] Strong starts and increasing clinical trial duration translate into continuing high demand for skilled labor in 2023. Turnover persists, and training new hires and less experienced research personnel will remain critical.

Pharmaceutical companies are looking for ways to reduce expenses, which involve cost cutting in research and development and downsizing research staff. As a result, they are frequently outsourcing research and development work to a third party to increase the success rate, accelerate drug approvals, and increase profits.[26]

Engaging an experienced partner to supplement or manage clinical trial data has become a best practice to address the rising costs of bringing a drug to market, researching cancer, and increasing the speed of curating data for research. Advantages of outsourcing include lower labor costs, specialized expertise, better scalability, shorter turnaround times, and better results.

Top Challenges in Aggregating, Cleaning and Transforming Clinical Trial Data

In a clinical data management survey, **58%** indicated they are not confident in the quality or completeness of their clinical data from an audit and compliance perspective.

- ✕ No central place to view data real time
- ✕ Lag time in getting the data
- ✕ Difficult to correct errors

The most urgent challenge: finding experienced resources that can manage and clean new forms of data

Top Cited Operational Challenges with Clinical Trial Data

- **51%** Data completeness
- **43%** Cleaning
- **45%** Quality
- **39%** Inconsistent data

Source: Challenges and Opportunities in Clinical Data Management Research[27]

24 "Clinical Research Trends & Insights for 2023," WCG, 2023

25 Ibid

26 "Global Clinical Trial Outsourcing Market Report 2022: Cost Efficiency, Minimum Timeline & Timely Result Delivery Drive Adoption," Research and Markets, October 18, 2022

27 "Challenges and Opportunities in Clinical Data Management Research Report," Pharma Intelligence and Oracle. September 2018

Omega Healthcare helps research organizations achieve their data management and research goals.

Clinical trials, in particular for oncology, will only become more complex and the volume of data will continue to increase due to continued scientific innovation in both the diagnostic and therapeutic space. While clinical and operational trial data management systems help to automate, centralize, and streamline data management, experienced resources are in short supply to maximize the value of these systems. Organizations have responded by implementing new digital technologies and engaging data management partners to analyze and clean clinical data more effectively.

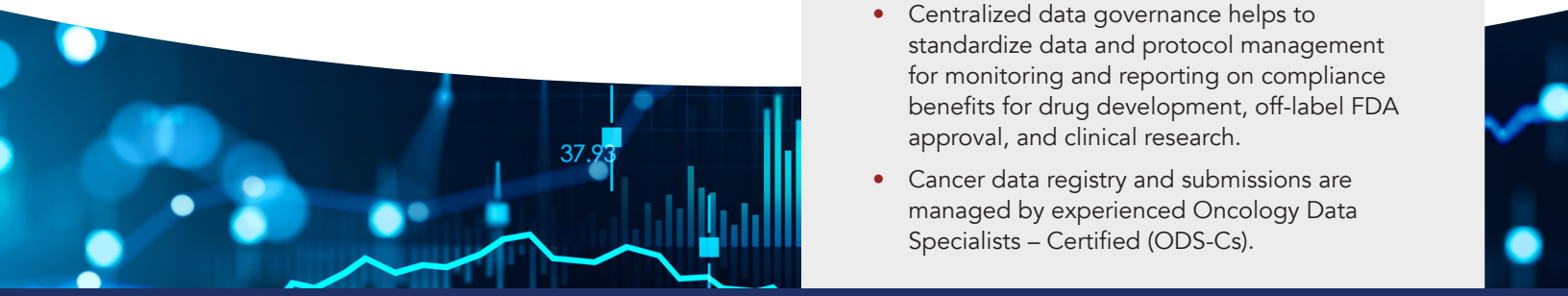
In the effort to drive efficiency, reduce timelines, and address the rising costs of clinical trials, many research organizations are partnering with experienced outsourcing providers to supplement or fully manage their clinical trial data curation process. Collaboration with a trusted expert for RWD abstraction and curation facilitates the success of clinical trials by improving the quality of data, reducing the timeline, and helping to make the data research ready.

RWE data management provides the insights that research organizations need to improve decision-making and support research findings. Omega Healthcare Clinical Data Services offers RWE data management services for data curation, abstraction, visualization, and analytics. For more than a decade, Omega Healthcare has worked to improve cancer care by providing clinical data management and cancer registry services to the oncology and clinical trial market.

An experienced team of offshore and onshore resources support clients' unique requirements by supplementing the team or managing all their needs with a full-service solution with domain expertise in curating and delivering real-world data at scale. By engaging dedicated resources where needed, Omega Healthcare improves the quality of data, expedites turnaround times, and saves clients on the expense of recruiting, hiring, training, and management of skilled resources.

BENEFITS OF OMEGA HEALTHCARE CLINICAL DATA SERVICES

- Centralized data governance and automation services help organizations standardize data.
- RWE data management provides insights to improve decision-making and support research findings.
- Data collection, curation, and analysis from multiple sources (including EHR platforms) improves data quality.
- AI/ML modeling to develop test data sets supports clinical diagnosis and predictive modeling of patient recurrence and outcomes.
- Centralized data governance helps to standardize data and protocol management for monitoring and reporting on compliance benefits for drug development, off-label FDA approval, and clinical research.
- Cancer data registry and submissions are managed by experienced Oncology Data Specialists – Certified (ODS-Cs).



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