Three Trends in Clinical Trial Data Management

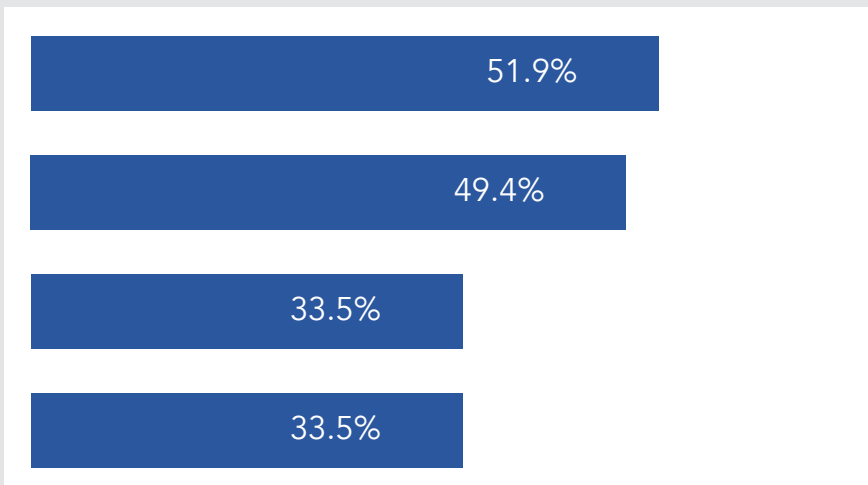
Multiple industry drivers—the increasing demand for clinical trials, accelerating volume of complex data, and shortage of skilled resources—are causing research organizations to turn to skilled outsourcing partners to manage the backlog of data entry and curation to reduce costs and provide research ready data.

1 Industry Outlook for Clinical Trials

- Approximately 50% of all clinical trials started in 2022 were in oncology, which are 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[1]

2 Operational Challenges Impacting Clinical Trial Sites



Source: WCG Q1 2022 site survey[2]

In surveys of clinical data management professionals:

- 95% reported manual effort is involved in data aggregation, cleaning, and transformation for clinical trials, and two out of three experienced issues with the process.[3]
- 58% indicated they are not confident in the quality or completeness of their clinical data from an audit and compliance perspective.[4]
- Key concerns include data completeness (51%), quality (45%), and cleaning (43%).[5]
- In-house clinical teams are spending valuable time cleaning data rather than analyzing it.[6]
- Despite use of numerous oncology databases and EHRs, significant data remains locked in clinical free text.[7]
- 50% reported using up to five different data sources, and 37% use between six and ten.[8]

Research organizations 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.

3 The Rising Costs of Trials and Data Management

The cost of bringing a new drug to market is around $350 million, which doesn't include the cost of failures and delays.[9]

Clinical trial delays in 2022 averaged approximately 4.3 months. Primary causes were funding challenges and availability of labor.[10]

For the first time in two decades, staffing shortages replaced financial challenges as the top concern among healthcare CEOs.[11]

Clinical trials that are delayed, postponed, or cancelled have negative financial implications for both trial sponsors and administrators.

Advantages of Outsourcing Clinical Trial Data Management to Omega Healthcare

- 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 and protocol management for monitoring and reporting on compliance benefits drug development, off-label FDA approval, and clinical research.
- Cancer data registry and submissions are managed by experienced Oncology Data Specialists – Certified (ODS-Cs).



Learn more about Clinical Data Solutions

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Sources

1 "Life Sciences Services Industry Outlook: Winter 2023," RSM, February 6, 2023

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

3 Challenges and Opportunities in Clinical Data Management," Pharma Intelligence report sponsored by Oracle, September 2018

4 Ibid

5 Ibid

6 "Clinical Trials Outsourcing Global Market Report 2022," Research and Markets, March 1, 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 "Clinical trials industry outlook: Fall 2022," RSM, September 14, 2022

10 Ibid

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

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