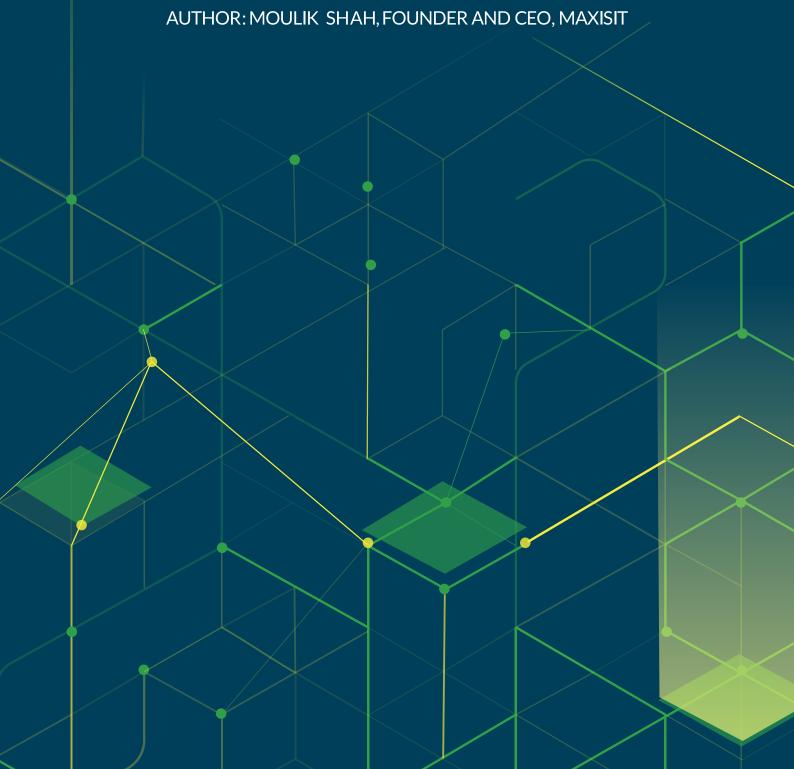


### Trends in Clinical Data Management Platforms





Data management is transforming as clinical trials evolve. Discover the 5 trends that are prompting clinical data management platform innovations.

# Trends Impacting Clinical Data Management (Including AI)

Advances in science and technology have led researchers to approach clinical trials in new ways. Clinical data management—and its technology—are undergoing their own transformations to keep up with the demands of complex, data-intensive clinical trials.

In addition to traditional randomized controlled clinical trials, scientists are using more flexible, "adaptive" models that allow for mid-study modifications. Sponsors are also incorporating real-world data more frequently and experimenting with decentralized clinical trials (DCTs) to better accommodate patient preferences. Both adaptive and DCT models are useful for evaluating the safety and efficacy of cell and gene therapies, personalized therapies, and other biologics effectively and efficiently.

To manage the increased data volume and variety produced by these complex clinical trials, data management has had to rethink both its approach and its structure, while its platforms have had to upgrade capabilities.

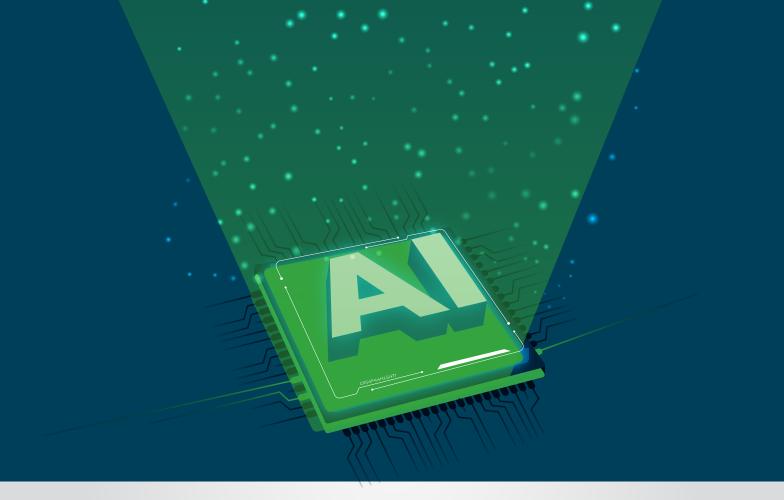
There are 5 key trends influencing data management technology.





### 1. Artificial Intelligence (AI)

Al touches almost every aspect of healthcare, and this is only the beginning. Al techniques such as machine learning (ML) and natural language processing sift through large amounts of data to identify patterns. Based on these patterns, Al-based tools generate valuable insights.



In clinical practice, an Al-based tool might analyze MRI images to identify signals that indicate high probability of disease. In data management, these tools identify potential quality issues and flag data anomalies with consistency and high degrees of accuracy.

Al and ML are being integrated into data management solutions to automate data review, identify patterns, and predict potential data quality issues. These advanced analytics capabilities improve data accuracy, efficiency, and decision-making. Implementing Al and ML also reduces risk of complications downstream.



### 2. Automation

Automation refers to the use of technology to perform mundane, repetitive tasks. In healthcare, automated appointment reminders and contract approvals utilize a specific type of automation.

All these features reduce the time humans spend in the database, freeing them for higher-value tasks. Because the technology is standardized and machine-driven, automating certain activities helps improve accuracy and speed.<sup>2</sup>

Clinical data management is automation and advanced workflows to optimize data acquisition, cleaning, and validation processes. Automated data ingestion, data cleaning algorithms, and automated discrepancy management reduce manual effort, enhance data accuracy, and accelerate study timelines. Meanwhile, Al-powered data pipelines automatically extract, standardize, and share data from myriad sources in a format that's actionable.





# 3. Real-time data monitoring and analytics

Are you still using spreadsheets to analyze data? If you want to improve database lock cycle times, an upgrade might be due. Analytics-based data management platforms help relevant professionals make sense of the increasing number of clinical data sources.

Analytics produce instant or near-instant information on study trends, patient enrollment, protocol adherence, and other metrics. With all data in one centralized location, sponsors can track study progress in real-time and make necessary adjustments along the way.

With advanced analytics, data managers can identify and resolve issues before the end of the trial, which helps prevent do-overs caused by missed insights. They can also generate reports for sponsors and regulatory authorities more quickly than when using spreadsheets and siloed systems.

### 4. User experience

No matter how advanced the data management platform, it won't work well if it's difficult to use. Data management platforms must provide a positive user experience and foundation for real-time collaboration for sponsor and CRO data management teams, as well as for monitors and sites.

An intuitive personalized interface design and easy-to-navigate dashboard enhance user experience. Platforms that integrate with most eClinical and CRO systems promote easier data visibility and exploration. Look for a data management platform that incorporates these features for optimal user experience.





# 5. The rise of the data scientist

As the information available becomes more complex, and as technology continues to shape clinical trials, data management teams have a more prominent seat at the table. They still design and validate clinical databases, but they also have the experience and knowledge to advise on technology investments, as well as advise on trial timelines and patient-centric study options. Automation and Al-based tools free up some of their time to take on these responsibilities.

Consecutively, the team itself is evolving. With less data entry on the horizon, positions in data science are in demand. These individuals oversee the application of Al-based tools as well as data analytics. Key responsibilities may include:



Designing data collection strategies



Performing statistical analyses



Developing data models



Providing data-driven recommendations on trial design and protocol development



Implementing data quality checks



Collaborating with biostatisticians, clinical researchers, and regulatory professionals, to ensure the accuracy, integrity, and compliance of clinical trial data

Those who pursue a clinical data management career will need a diverse set of skills to manage DCTs, adaptive trials, and complex biopharma trials. They'll be working in the cloud, which means digital document and workflow management are essential. Experience in analytics is a definite plus.

As clinical research evolves, we expect to see data scientists take a more active role in protocol development, clinical operations, and advanced decision-making, due to their ability to gain key insights.

Data scientists influence data management platform advancements due to their demand for user experience as well as advanced analytics and real-time data monitoring.



## How does the Data Management Workbench Align with the Trends?



Al, real-time monitoring, advanced analytics, and a seamless user experience are all part of MaxisIT's Data Management Workbench (DMW), including:

- A systems-and data-agnostic platform for maximum flexibility
- Out-of-the-box integrations to source clinical data from 40+ eClinical Systems and 8+ CRO systems to help eliminate silos and lower the risk of duplicative data
- Automated data ingestion, integration, management, validation, standardization, and reporting to help improve study accuracy, efficiency, and speed
- Automated data pipeline to bring together multiple data sources for new insights without excessive manual labor
- A single-source-of-truth data repository for easy data access
- Al-powered real-time monitoring and oversight for identifying trends, patterns, and anomalies, resulting in improved data quality
- Built-in, intuitive ways for users to receive personalized views of study data when necessary
- User-friendly dashboards, dynamic data listings, Al-enabled query detection, and real-time collaboration via central data review empower data managers, monitors, and sites to review and resolve queries on time

DMW is your centralized command center for end-to-end clinical data management. The data management hub allows you to move from data capture to compliant reporting weeks faster than spreadsheet-based and/or siloed systems.

DMW from MaxisIT is driving the future of clinical data platforms, and we're excited to show it off. We designed DMW to meet the demands of today's and tomorrow's clinical trials, whether controlled and randomized or fully decentralized. Our goal is to stay one step ahead of the trends to provide tools that enhance efficiency, improve data quality, and ultimately help clinical trials succeed.

#### **About MaxisIT**

MaxisIT's purpose-fit and intelligent clinical data analytics platform helps improve clinical trial performance, mitigate risk, and optimize clinical outcomes. We provide a centralized and reliable source of truth for diverse data types from various sources, giving life sciences companies real-time insight to shorten cycle time and increase return on investment.

Incorporating an end-to-end clinical data pipeline from intake to visualization, MaxisIT's solutions are powered by AI/ML and metadata-centric approaches. Our impressive portfolio of over 3,300 clinical trials and an unparalleled 100% customer retention rate affirm the quality and reliability of our services.



Moulik Shah is a passionate healthcare technology entrepreneur and the visionary CEO of MaxisIT, where he has been at the forefront of leveraging technology to transform pharmaceutical and life sciences clinical trials.

His dedication to improving patient outcomes and his leadership in directing patient-centricity, patient diversity, interoperability, and real-world-data-led collaborations have been at the core of his vision of an integrated healthcare ecosystem based on effective use of data and analytics platforms.

He has been instrumental in driving innovation and progress in the industry. Under Moulik's leadership, MaxisIT has become a leading provider of clinical data and analytics which is driving real-world impact in the pharmaceutical and life sciences clinical trials.



www.maxisit.com

connect@maxisit.com



