# MOVING CLINICAL TRIALS TO THE CLOUD

# A New Paradigm to Transform Clinical Trials

Contributed by

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Clinical trial sponsors are facing intense pressures to change the way clinical research is conducted in order to decrease costs and speed up the R&D process. This will bring new treatments to market sooner and address unmet patient needs more quickly.

A new paradigm is emerging that moves the conduct and management of clinical trials to cloud-based applications. With cloud-based technologies, sponsors can implement an end-to-end data management strategy to transform their clinical development life cycle processes, including data acquisition, storage, aggregation, and analysis. Different applications such as electronic data capture (EDC), clinical trial management systems (CTMS), safety systems, and data repositories can be seamlessly integrated.

**Cloud-based clinical trial platforms enhance collaboration and increase productivity.**

Cloud-based applications provide sponsors with access to data in real time as large amounts of data are stored in a central location. Additionally, cloud-based clinical trial platforms enhance collaboration between sponsors and investigators, and allow information to be shared and managed quickly and securely, which leads to increased productivity.

## Leveraging Cloud-Based EDC for Data Acquisition

Many sponsors have adopted EDC in conducting clinical trials, and these systems have brought tremendous efficiencies into clinical trial data management and operations compared with paper-based systems. For sponsors to maximize their cloud-based EDC system it must be leveraged in several key areas.

### 1. Global library of electronic case report forms

Establish a global library of electronic case report forms (eCRFs) and related components based on the CDISC CDASH standard that can be used to set up new trials. A library of validated sets of standard forms and components, including fields, pick lists, and edit checks enhances efficiencies and decreases start-up time for new clinical trials.

### 2. Management of lab data

Ensure the EDC system is configured appropriately to manage both central and local labs. This allows the ability to monitor lab data alongside eCRF data, including tracking against reference and alert ranges, which decreases the time needed to clean and consolidate data for analysis. It also reduces errors that can occur during manual data processing.

### 3. Integrate with clinical systems

Ensure the EDC system is flexible and interoperable with other cloud-based systems such as CTMS, coding, ePRO, IXRS, and clinical data warehouses. Leverage these capabilities to achieve efficiencies with centralized coding, subject randomization, clinical supply management, and advanced reporting and analytics across trials.

### 4. Targeted source data verification

Technology advances provided through the use of EDC systems provide sponsors with the ability to redefine how site monitoring is structured and conducted. There are many acceptable forms of source data verification (SDV) in clinical trials, including targeted SDV based on verification of critical trial data, and monitoring through a mixture of on-site visits, central monitoring, adaptive monitoring, and remote monitoring. The key to new forms of SDV are that all require data to be centrally stored and accessible. New approaches to SDV and clinical trial monitoring have the potential to improve safety, data quality, regulatory compliance, and overall trial validity while reducing monitoring costs and time needed to "lock" the database[1].

## Maximizing Cloud-Based Clinical Trials

Emerging trends in developing robust data standard models and clinical trial data analytics offer opportunities for sponsors to effectively utilize their trial data to gain meaningful insights earlier in development and extract maximum value from existing data.

### Increased emphasis on standardization

Data standardization allows data to be easily shared with research partners, vendors, and regulatory agencies. Data standardization models and processes are critical to successfully leverage cloud-based clinical technologies. Standardization models need to be de-

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fined at the onset of clinical trial implementation, which ensures high-quality data are collected in an efficient manner and ensures the data can easily be analyzed for insights downstream.

An exciting development is the implementation of CDISC SHARE (Shared Health And Research Electronic Library). CDISC SHARE is a "global repository for developing, integrating, and accessing CDISC metadata standards in electronic format." SHARE will help users find, understand, and use rich metadata and controlled terminologies in clinical studies more efficiently and consistently. Additionally, SHARE will improve integration and traceability of clinical data from protocol through analysis[2]. Ultimately, CDISC SHARE will make it easier to standardize data across the industry and with various partners, including sponsors, research institutions and sites, and clinical research organizations.

### Technology to provide actionable insights

Until recently the ability to easily gain insights from clinical data has been a cumbersome and costly process. There are now cost-effective and robust cloud-based platforms available to provide insights into your data quickly, easily, and in a format that enhances decision-making.

A secure cloud-based platform that standardizes, aggregates, and analyzes clinical data from multiple systems and sources such as EDC, CTMS, legacy studies, clinical research organizations, and partners is becoming essential to achieve these efficiencies. Additionally, a best-in-class platform will enable information consumers across the organization to interact with data, run ad hoc queries, and access data visualizations to proactively analyze clinical and operational data across multiple trials.

**Best-in-class cloud-based platforms provide insights into your data quickly, easily, and in a format that enhances decision-making.**

A key feature of a best-in-class platform is the use of advanced Extraction, Transformation, and Load (ETL) technologies to enable data mapping and standardization based on CDISC standards. Additionally, platforms that offer scalable warehousing, efficient data computing capabilities, a document management system for clinical teams to easily access and use in their trial activities, and a communication portal that streamlines communication between sites and sponsors are able to leverage technology in an integrated manner to meet complex regulatory requirements efficiently.

The benefits of using cloud-based technologies are:

- Increased transparency and real-time visibility into clinical trial operations and data.
- Enhanced collaboration between investigators, sponsors, and partners.
- Increased efficiency and speed to conduct trials.
- Decreased frustration and costs in completing trials.

An important consideration that should not be overlooked is 21 CFR Part 11 compliance requirements for any clinical system, whether it is cloud-based, hosted by a service provider, or installed on local on-site servers and computers.

## Next Steps in Moving Into Cloud-Based Clinical Trials

Increasing financial and time pressures on the life sciences industry will continue to drive changes in how clinical trials are conducted. In the future more sponsors will move their clinical trials to the cloud in order to speed up the clinical trial process and reduce costs. There are many tools and platforms available to use in conducting cloud-based clinical trials. As companies evaluate partners to work with through this process, they need to look for service providers that have experience in developing and implementing cloud-based clinical data platforms. Companies should evaluate three key areas for each service provider.

### 1. Service Provider Capabilities

- Existing clients are using their platforms in conducting and managing clinical trials.
- Staff members have experience and qualifications in managing clinical trials and data management.
- Proof that the platform and data centers meet regulatory and industry expectations.
- 24/7 support for any issues that arise with the platform.

### 2. Data Security

- Understand where the data will be stored and processed.
- Sufficient physical and electronic security measures are in place.
- Data encryption for applicable data.
- Robust back up and disaster recovery procedures and plans are in place.
- Confirm the data are isolated from other data sources and other clients' platforms.
- Understand who owns and has access to your data.

### 3. On-Site Audit

- Conduct an on-site audit to evaluate the areas outlined above

Qualified service providers are expecting to address these criteria, and they will willingly share information with you on their cloud-based clinical trial capabilities and data security standard operating procedures. PV

*Editor's Note:*

*1. Sourabh, De. Perspectives in Clinical Research, 2011. Jul-Sep; 2(3); 100-104.*
*2. CDISC SHARE, www.cdisc.org/cdisc-share, website accessed October 15, 2013.*