An Executive Summary

Beyond EDC: Don't Just Capture Data, Collect it

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The fundamental shifts in clinical trial complexity demand better data collection methods.

Overview

From their inception nearly 30 years ago, electronic data capture (EDC) systems replaced manual paper-based processes helping to move the industry toward digital clinical trials; however, the shape of clinical trials has continued to evolve, introducing new technology requirements. Hybrid, virtual, and umbrella trials, the expansion of electronic health records (EHR), and the decentralization of trial design have introduced new challenges for sponsors and vendors. The COVID-19 pandemic onset has accelerated this trend and added urgency to remote monitoring and trial flexibility.

These changes require increased agility when it comes to delivering the clinical systems that capture data. The burden on both sponsors and site to procure, build, use, and maintain a myriad of niche technologies to conduct clinical trials involves a significant resource investment and can jeopardize trial timelines.

Oracle's Clinical One platform reimagines the way technology supports clinical trials, leveraging the firm's deep experience in delivering clinical solutions and their next-generation cloud computing expertise. This article will discuss the challenges posed by traditional EDC systems and how Clinical One Data Collection empowers sponsors, CROs, and trial personnel to collect trial data from a wide range of sources in a lean, cost-effective, and efficient manner.

A Brief Survey of EDC Challenges

The use of digital technologies has historically centered on distinct systems supporting individual trial functions. This has resulted in data duplication in clinical trials, as EDC systems would capture data also contained in interactive response technology (IRT) systems, clinical trial management software, and others, creating arduous data reconciliation efforts. While each system improved the gathering of source data, it also mandated having enough resources to manage procurement, study builds, integrations, data migrations, UAT, training, and ensuring compliance.

Speed and efficiency have also always been important in clinical research. With traditional EDC systems, validation lifecycles often stretch to six months or more, and the time required to make mid-study changes in response to FDA feedback or protocol amendments typically takes months, delaying overall study timelines. Testing to ensure functionality and regulatory compliance generates volumes of documentation and evidence and system upgrades and downtime add more delays.

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Figure 1: e-Clinical platforms span several degrees of depth and integration.

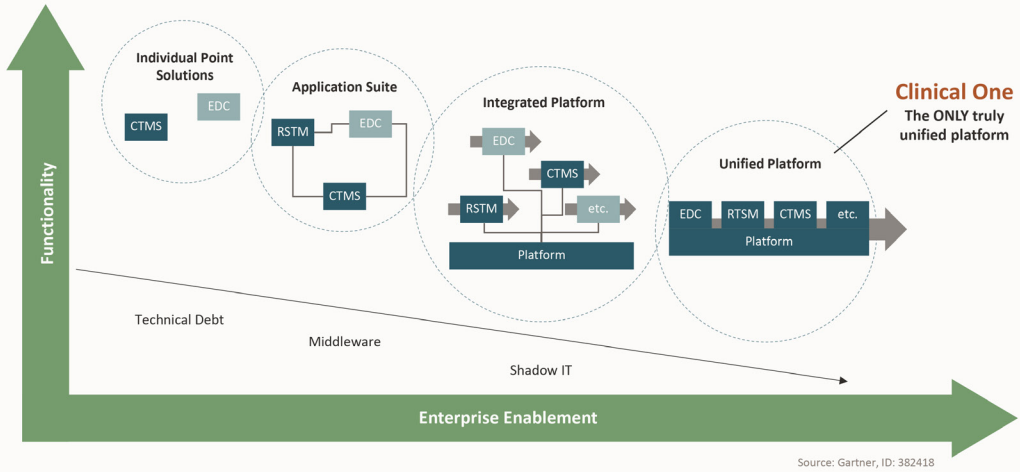
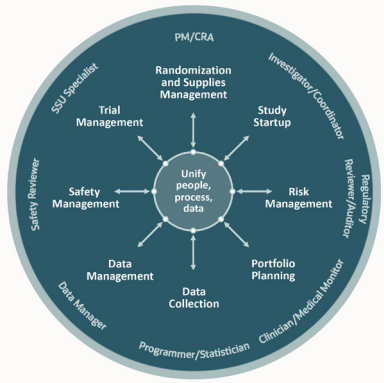


Figure 2: The unified platform – Clinical One.



Changing the EDC Paradigm

The proliferation of systems and integrations required to obtain data from the various sources of clinical data has made the current model untenable. A new paradigm is needed to simplify system sprawl, which has been recognized by industry experts. As mentioned in a recent Gartner publication (1), "The e-clinical platform provides an opportunity for IT leaders to rethink legacy solution boundaries and look for new ways to optimize and speed trial processes."

The Oracle team understood this opportunity and began to reimagine the development of clinical systems. By challenging entrenched approaches, a new model emerged with several imperatives:

- Move from a model of organizing systems around visits and forms to "collection events," drawing data from various sources.
- Support the needs of a protocol with capabilities in a single environment instead of with multiple, distinct systems.
- Build a study once, instead of multiple times across siloed systems.
- Accelerate the build and validation process by empowering teams to create and rapidly test their studies and integrations in real-time.
- Streamline and unify workflow to eliminate redundant activities.

Clinical One: A Unified and Scalable Solution

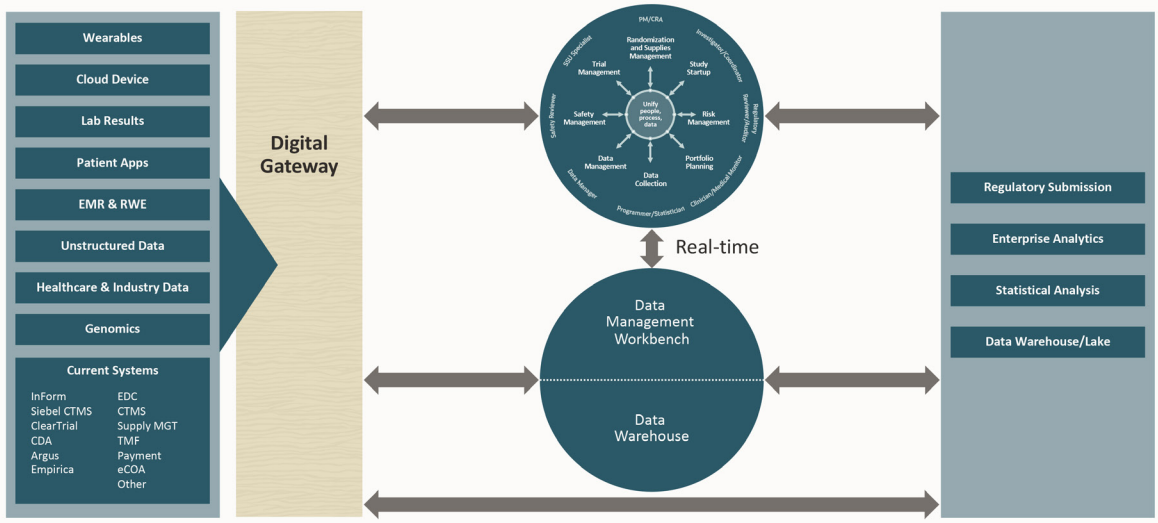
Clinical One is a unified clinical platform created to overcome the challenges faced by sponsors and sites related to having to use many independent systems for a single trial and having to collect an ever-increasing volume of data from an ever-increasing number of sources. Rather than continuing the old method of capturing data in digital forms, Clinical One transforms the "subject visit" paradigm into a stream of "collection events." Clinical trials have traditionally centered on subjects coming into clinics; however, the decentralization trend is reshaping the way trials are conducted with the increased use of wearables, remote monitoring, home health visits, and e-diaries.

Clinical One represents an innovation in the way clinical data is collected. **Figure 1** shows that Clinical One moves beyond an integrated platform by creating a unified architecture with capabilities previously spread across multiple systems. Study start-up, risk management, portfolio planning, data collection, randomization and trial supply management, safety, and trial management activities are no longer isolated. They are combined into a single solution. **Figure 2** illustrates how Clinical One unifies people, processes, and data, enabling diverse roles to enter and view data in one place, significantly increasing data transparency and efficiency.

End-to-End Build and Validation Capabilities

The unique platform infrastructure of Clinical One not only

Figure 3: The Clinical One ecosystem.



solves the problem of data housed in multiple databases, but it also unifies workflows previously spread across numerous systems. Data collection is included in the same transaction as screening, randomization, and drug dispensation, on a single platform – activities that used to have to occur in two systems, the EDC system and the RTSM system. This elimination of siloed activity reduces the site's burden of using multiple systems and entering the same data multiple times, leading to improved data integrity and more efficient processes.

With Clinical One, sponsors can build studies through an easy-to-use interface by selecting pre-validated modules and edit checks or creating new designs. Once a module is configured, it can be easily shared across other studies with the flexibility to include or exclude rules from the previous study. When study functionality is updated, the system will indicate if regression testing is needed to prevent gaps.

Clinical One not only facilitates agile study builds, but it also supports compliant validation activities. Regulatory agencies have increased scrutiny of system validation activities, so it is critical to have sufficient documentation to show the testing conducted for each build. Clinical One captures testing history automatically, streamlining the creation of test cases and objective evidence. In addition, each quarter Oracle releases new system capabilities with a Product Verification Pack, which includes an impact analysis, test requirements and cases, a traceability matrix and test results, and objective evidence. This reduces the amount of documentation generated by sponsors to show proper validation while remaining compliant and audit ready.

Smart Study Management

One of the more time-consuming aspects of using a traditional EDC system can be query resolution. Clinical One reduces the time commitment required, providing instant feedback for data entry out of the expected range. Sites can see the query generated in real-time, allowing them to correct the data before a monitor or sponsor needs to be involved.

Queries sent to the site are also easily visible when logging into the system in the study dashboard, which also displays an overview of drug supply shipments. Users see upcoming subject visits, adverse events, queries, and data coming in from integrated devices by accessing the subject screen. All events are captured in the audit trail, which is easily viewable in Clinical One. This reduces the need to log into multiple systems and makes managing subjects easier for sites, CROs, and sponsors.

Expanding the Boundaries of Digital Technologies

Although Clinical One provides a unified platform for collecting and managing trial data, it can also interact with other Oracle or third-party systems. It readily integrates with EHR systems, patient apps, RTSM and CTMS systems, wearables, and laboratories. This data unification is powered by the Digital Gateway, a SaaS engine that gives sponsors the power to quickly and seamlessly exchange data between Clinical One and any other system or source.

The Digital Gateway standardizes and simplifies integrations by allowing data managers to configure integrations quickly by entering parameters into a user interface. The gateway sends and receives data, including

filtering the sets of data sent to other systems. This gives study teams control over the process, reducing reliance on the vendors or programmers and provides real-time availability and insights into all trial data.

Figure 3 depicts how the Digital Gateway solves the problem of data availability and analysis. Study data comes into the gateway from connected apps or other databases in real-time into Clinical One. Information can be shared with other databases or locations, making Clinical One a single source of truth.

The Digital Gateway also allows the monitoring and maintenance of the configured integrations. Successful or failed events are logged, and failed attempts can be resent or canceled. The monitoring portal provides a central interface from which all integrations with Clinical One are managed, without the need to contact the vendor.

Intuitive Interface Supported by Just-in-Time Training

The goal of Clinical One was to make building studies as easy as possible. To maximize the efficiency of building studies, the system had to be intuitive. This goal was accomplished by creating a user interface that uses standard web design elements and doesn't require coding expertise. On-screen prompts simplify use, and embedded training eliminates the need to reference lengthy user manuals. Real-time access to training videos and guidance overlay the screen. Training is assigned in the system to ensure a user completes it before using a module, and the instructions can be accessed at any time in the future.

Summary

Managing clinical systems has become increasingly challenging as the use of digital technologies has increased in clinical trials. Teams and sites want more, with less: more patient information, more clinical insight, and more control, with less system complexity and burden. Clinical One builds off a new paradigm of collecting data, moving from the siloed, vendor-controlled builds of the past to a future where sponsors are empowered to build, validate, and maintain their systems. By unifying multiple systems into a single platform that consumes and sends data from any other source, it increases the speed at which a clinical trial can be operationalized in a cost-efficient, compliant, low-risk manner.

References

1. Market Guide for Life Science E-Clinical Platforms, ID: G00382418

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