Run the Trial You Want

Transform clinical trials with better data collection

Life sciences companies are facing unprecedented pressure to deliver more treatments, faster, and with greater safety. All of this must be done at a lower cost to patients, caregivers, society, and even to the environment. Competition, advances in precision medicine, and impending patent expirations add further pressure to deliver more with less. In addition, there is a decline in the number of qualified sites. The race to match the patient to the trial, and the trial to the patient, is in full force. Sponsors are competing for a limited pool of patients so it is imperative they maximize each and every interaction. They must ensure that the right patient population is defined and available, and that trial objectives and activities match the expectations of patients and their primary caregivers.

In this environment, how can sponsors successfully accelerate their own development programs ahead of their competitors? The answer lies in science, and the use of prevailing theory to develop and execute the most effective study imaginable. Patients, investigators, sponsors, and regulators are some of the key stakeholders that can reap major benefits by optimizing trial design and execution. The ideal trial requires the least number of patients and runs at the shortest duration, in order to deliver results needed to confirm if a new treatment will be a success. Advantages of optimal trials include:

- Efficient clinical development programs with greater attention to quality and patient safety
- Greater adherence to regulations and clinical trial controls
- Reduced timelines and faster access to study results
- Increased focus of clinical trial execution in areas with a high probability of success
- Reduced study scope and complexity to drive efficiency and cost savings

This paper will focus on the challenges with collecting data required for a protocol and best practices to address them. Learn how to meet the demands of modern trials with modern, cloud based electronic data capture (EDC) systems that enable you to run the trial you want.

Challenges with Traditional EDC Systems

There is little point in designing an ideal study if the available systems are unable to support its unique requirements. As such, data collection quickly becomes the key to delivering an optimized trial. All users must be able to contribute and consume data without hindrance, and the trial must be able to utilize all available data, from all applicable areas of research. Improving data collection accelerates better decision making, which in turn facilitates swift and confident actions such as opening and closing cohorts, expanding a treatment, stopping a futile trial, or simply making database amendments.

The first remote data entry systems were deployed in the late 1970's. They matured slowly through the 1990's and into the current century. Compared to paper case report forms (CRFs), traditional EDC systems have undoubtedly helped accelerate clinical data management. However, they are not designed as full data management solutions and only replace

paper case report forms (CRFs). Today, eCRF data is diminishing in volume, and even in criticality. More often than not, critical data is now found in lab data, biomarkers, mHealth, or even genomics. A system that is designed to only manage eCRF data is unfit to serve broader requirements.

The ideal data management solution must be able to handle all of the data used in trials and prioritize its value. Traditional EDC systems fall short of this need, leading to several drawbacks:

Lack of site-centric processes. Traditional EDC systems are perceived by sites as an overhead that takes away from an investigator's time with a patient, and not as a technology enabler that empowers a patient to progress through a study. They are used as mere data entry systems that don't contribute to patient treatment and participation that is now essential for today's clinical trials. Because these EDC systems are manual and error prone, they require intensive and costly review processes, such as source data review and verification, that are largely unrelated to the treatment.

Data silos: Older EDC systems still require manual entry of paper-based source books. There is often a significant delay between a patient visit and the availability of data for review. They are slow at incorporating non-eCRF data, such as central laboratory data, if they do so at all. As a result, data is fragmented and trial decision makers are unable to review and manage all of their data in real-time.

Not built for change. Traditional EDC systems generate high overhead related to building and amending a study database. The build takes weeks or months and amendments can take just as long. This conflicts with expectations for trial updates that are often required in a matter of days. As studies continue to get more complex, it will be hard for current EDC systems to deliver faster cycle times. Tuft's research demonstrates the upward trend of clinical trial complexity, with greater variety and volume of data exerting significant pressure on database design capabilities.

Inability to support big data. Current study designs already expose the technology challenges of EDC systems. The advent of personalized medicine adds further complexity. At the heart of personalized medicine is big data. Researchers expect to gain immediate insights from massive volumes of data coming from varied sources to gain a holistic perspective on a patient. Trials today are looking to incorporate mHealth and leverage a wider array of bio-markers and/or secondary markers to evaluate treatment. There is also greater use of electronic patient-reported outcomes (ePRO) and electronic clinical outcome assessment (eCOA). Current EDC systems aren't equipped to integrate large volumes of real-time data streams that deliver critical, time-sensitive insights, making it difficult to manage all trial activity across every patient. Consequently, big data has yet to be converted into smart data.

In order for life sciences companies to run the most optimized trial, a modern EDC solution is needed.

A Better EDC Solution that Supports the Trial You Want

Modern EDC solutions empower researchers to build a trial around patients, not around existing processes or technology. Modern EDC systems allow for comprehensive data collection from varied sources that results in confident decision-making and real-time action. Transforming data collection provides several key benefits:

Complete and concurrent data. A modern EDC solution has the capacity to ingest vast quantities of structured and unstructured data and content. It lets users create business rules and processes to meet the needs of their clinical trials. Rather than focus on managing only a small percentage of study data, it can integrate data from varied sources and make it available as insights in real-time. In simple words, it delivers all trial data, all of the time.

End-point driven study design. Not all data is born equal. End-point driven study design is the ability for modern EDC solutions to prioritize collection, verification and cleaning of study data. Primary efficacy data is more important that secondary, or tertiary data, and far more important than non-core data. When it comes to trial complexity, more than 22 percent of data comes from non-core procedures,[1] most of them resulting from study designs that are not end-point driven, increasing costs and making trial execution unnecessarily complex. Having an end-point driven study streamlines and simplifies trial execution.

Real-time sponsor collaboration and access to source data. Modern EDC solutions are integrated with eSource, eliminating paper-based source notes and providing a single build and amendment process – all within one platform. This allows source data recorded by investigators during clinical trials to automatically synchronize with EDC and be available in real-time to sponsors. This eliminates manual processes, significantly reduces costs, makes remote monitoring a reality, and speeds up time to market for new drugs.

Agile study design and amendment. Modern EDC solutions enable upfront planning for amendments in trial designs, lowering the cost and time associated with these changes. Sponsors can course correct responsively for both planned and unplanned changes with rapid database design and amendments. Managing amendments without migrations resolves a major hurdle in protocol management and adherence. The ability to perform study upgrades with no migrations and minimal downtime ushers in a new era in adaptive data cleaning and management.

Introducing Veeva Vault EDC

Veeva is challenging every clinical data management process to provide the most effective cloud-first solution. It has built a next-generation EDC solution from the ground up that addresses all of the challenges that have prevented sponsors from building and running an optimal trial.

Built by technologists that have extensive clinical expertise, Veeva provides a better EDC solution that puts sponsors in control of clinical trials:

Run the study you want

- Run complex, yet flexible, multi-arm adaptive trials
- Make mid-study design amendments without downtime
- Integrate all necessary data to accelerate insights

Deliver better data, faster

- Create earlier actionable insights with personalized dashboards
- Prioritize user tasks and workflows through end point-driven design
- EDC and eSource together on the same platform reduces source data verification and monitoring

1. Tuft on Clinical Trial Complexity, http://www.nationalacademies.org/hmd/~/media/34D1A23404A8492998AD2DF0CB6CD4D1.ashx

Accelerate study cycle times

- Cut design time with modern user experiences and configurable workflows
- Build studies faster with agile functionality
- Reduce the time to database lock with endpoint-driven design

Vault EDC is part of a unified clinical suite that includes EDC, eSource, CTMS, eTMF, and Study Startup together on the Vault Platform, eliminating silos and streamlining clinical development processes.

Summary

In the competitive clinical market, life sciences companies must set themselves apart by designing and executing the most optimum trial, so they can successfully deliver drugs to market first. Unfortunately, they've struggled to run the trial they want due to the limitations of traditional EDC systems.

Modern EDC solutions cater to patient-centric studies and eliminate the pain of having to work around software limitations. They enable real-time data collection from varied sources, providing powerful insights that help stakeholders take quicker action. Data collection is transformed with access to complete and concurrent data that enables prioritization of data through end-point driven study designs. Modern EDC solutions provide real-time sponsor access to source data and agility to react quickly with database amendments.

Running an optimized trial empowers life sciences companies to deliver drugs to market faster. Decision makers can make confident decisions more quickly and take action in real-time. Optimum trials increase the focus of clinical trial execution on areas with a higher probability of success, while reducing study scope and complexity, to drive greater efficiency and cost savings.

To learn more about Veeva Vault EDC, please visit **veeva.com/edc**.

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About Veeva Systems
Veeva Systems Inc. is the leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 950 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. For more information, visit **veeva.com**.

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