The Pursuit of Interoperability within Today's Clinical Trials

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Bringing drugs to market quickly and efficiently is the ultimate goal for all pharmaceutical companies.

Conducting clinical trials efficiently is essential to this process by providing the foundational methods for testing, the process for analyzing metrics, avenues for market branding, and the steps toward submission and approval. Learn how well-organized, clearly-defined, thoroughly documented, and easily-accessible data contribute significantly towards the success of a drug or device trial in all stages of development.

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The challenge of handling disparate data through the clinical trial process.

Contract research organizations (CRO's) are almost exclusively utilized in the process of operating clinical trials. However the need for oversight and collaboration between the CRO and the Sponsor still remains a critical factor in the success of any trial. To this we add the increased complexity of studies and hence it has become increasingly difficult to manage data seamlessly across sponsor companies and their partner CROs. This challenge of data integration is not isolated to small firms, but spans the spectrum of organizations that utilize multiple systems to conduct clinical trials. Integration of data is often a challenge and in some cases is simply not possible among systems that are not designed to be open and therefore unable to "talk" to other complimentary system or in the worst case share critical information.

It is often said that an estimated 20 to 26 different systems partake in a clinical trial. When considering the fact that they each have been purpose built – in many cases by different vendors - It's apparent that this seamless integration of clinical trial data is critically needed among CROs and sponsor - not merely for the end result of a successful trial, but at any point during the trial to ensure that healthy progress is taking place and that the insights gathered are comprehensive and actionable. Why is this so crucial among clinical trial operations? Because not being able to achieve this level of interconnectedness affects the clinical trial in both cost and time. Significant delays and increased errors are frequently the outcomes of not being able to monitor and transmit data easily between systems. Furthermore, the correction or redirection of such missteps exponentially adds to the overall cost.

Adopting the Adaptive Approach to Capturing and Passing Data

Adaptive clinical trials refer to a statistically driven method of analyzing data. Unlike clinical trials using a more traditional methodology, today many operations don't wait until all the data is fully collected to then process it, and disperse it among other requiring systems. Instead, companies are using a more flexible approach to data collection where they purposefully analyze interim data to be able to discover problems early and respond accordingly. The FDA describes it as the "prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study. Analyses of the accumulating study data are performed at prospectively planned time-points within the study, can be performed in a fully blinded manner or in an unblinded manner, and can occur with or without formal statistical hypothesis testing."

In summary – to effectively conduct clinical trials using this innovative methodology, one needs to have a holistic view of "all" data that had been gathered to date and more importantly it is required that one be able to analyze operational data in real-time. In contrast to traditional trials where data – sometime as old as several years – were analyzed looking for trends is an easy argument for the need to real-time data interoperability.

Further accelerating trails through Risk Based Monitoring

A new dimension to holistic statistical analysis of data in recent years is the increased focus and attention on Risk Base Monitoring (RBM). RBM practices emphasize directing onsite monitoring of data to an at-risk subset of data. In the past, monitoring and reviewing 100% of the data from every site was the fool proof way of ensuring data accuracy during trial conduct. That was effective when studies were simpler and protocols did not require extensive data collection from every subject and every visit arm. As complexity of studies grew so did the task of monitoring 100% of data.

RBM is yet another data-analysis intensive approach to clinical trials where – even more than the case of adaptive trials – it require up to the minute review of all data in the context of the protocol. Again, the first challenge for attempting such approaches is a fluid interoperability amongst disparate systems that are used at the site, at the CRO and at the sponsor.

Why the Solution Is Found in the Cloud

Clinical trial issues are common where data is coming from various sources, and when that information cannot be shared quickly and efficiently. It adds unnecessary time to the trial, increases the potential for human error (when manual data exchange is used to bridge the gap) and adds cost to the operation – all key contributors to poor or strained decision-making. Cloud-based solutions are well suited for such needs because they leverage scalable technology where traditional software is limited and help consolidate all data centrally and make it easily accessible for later use.

Additionally, cloud-to-cloud based systems help you better connect disparate data sources. Traditional data management techniques still face significant challenges with true integration and collaboration because the complexity of these varying systems don't inherently embody communication mechanisms to communicate between each other, or to do so bi-directionally. Cloud-hosted systems make it easier to access the data at any point in time and offer the accessibility traditional systems don't.

7 Key Benefits of a Cloud-Based Interoperability Solution

Faster Data flow

- Significantly reduce data distribution and synchronization time
- Faster data integration offers more opportunity to resolve issues and make adjustments

Enhanced Flexibility

- Ability to analyze interim data
- Potential for planned decision points throughout trial

Increased Scalability

- Connect and pass data bi-directionally at any volume throughout the clinical trial
- Ability to handle multiple trials simultaneously

Improved Data Quality

- Seamless integration improves efficiency and accuracy of data
- Decreased need for duplicative manual data entry and potential human error

Faster Data Mapping & Reporting

Decreased Trail Setup Times

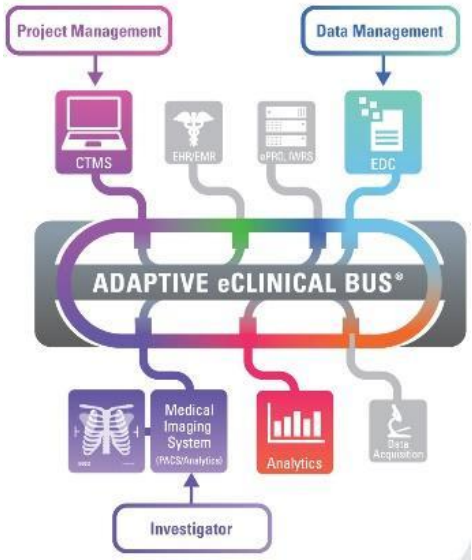
- Single-source data offers faster setup times and the elimination of wasted resources at the conclusion of the clinical trial

Reduced Costs

- Simple and straightforward trial setup offers cost efficiencies
- Reduce or eliminate extra cost of custom solution to meet legacy system requirements or customization of the existing CTMS

Adaptive Clinical System's eClinical Bus® Solution

Adaptive eClinical Systems provides clinical trial solutions that optimize the interoperability of sponsor and CRO operations. Using proprietary cloud-based technology, Adaptive Clinical specializes in solutions that integrate eClinical components to ensure accurate and efficient integration of clinical data for any study of any complexity.



Adaptive's flagship solution, the eClinical Bus®, is a secure, validated, compliant (FDA CFR 21 Part 11 and GxP), and cost-effective solution for clinical data integration – specifically designed to improve the way EHR and EMR systems communicate with each other to save you time and money. The software helps:

- Eliminate duplication of data by capturing and transmitting electronic source data
- Auto-populate electronic study forms from EHRs
- Reduce transcription errors and improve the quality of data
- Encourage entering source data at the point of care
- Facilitate remote monitoring of data to reduce the number of onsite visits
- Improve site monitoring to minimize the need for cross-reference data in multiple sources
- Make it easier for investigators to conduct clinical research
- Facilitate the inspection and reconstruction of clinical investigations by FDA

Discover how to easily improve your clinical trial data integration and increase the efficiency of your operation, from shortened setup times to streamlined process improvements.

Contact Adaptive Clinical Systems to learn more.

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