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Key Drivers to Improve Data Interoperability in Decentralized Clinical Trials

Data interoperability is a critical, table-stakes capability for conducting good DCTs.

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INTRODUCTION

Sponsors, CROs, eClinical partners, and sites all struggle with data interoperability, even though the tools that they use may have APIs; they have the data, but they can't make it all work together. With the advent of new Digital Health Technologies (DHTs) and expanding use of EMR/EHR and eSources, the pharmaceutical industry has witnessed tens of millions of data points being captured per study in very short time periods. This was recently re-affirmed in SCDM's white paper, *The 5Vs of Clinical Data*, the Society notes, "today we measure m-Health data points in the billions."

The explosion of data from DHTs as well as the acceptance of decentralized clinical trials (DCTs) has altered data management norms. More significantly, it has raised the importance of data interoperability. At every stage of a clinical trial, data quality, planning and key performance indicator reporting are critical to maintaining the integrity of the clinical trials. None of these can be optimized without seamless, real-time data interoperability.

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ROLE OF THE PATIENT IN DCTS & IMPLEMENTING NEW TECHNOLOGIES WHEN THE PATIENT IS THE SOURCE

Recruitment is the largest leading indicator of study progress. How well an organization adapts to remote patient recruitment and retention in the post-COVID world is critical for how their studies will perform. The pharmaceutical industry is increasingly turning to alternative healthcare data sources that can be repurposed, such as: hospital information systems, insurance claims data, and Patient Communities. The challenge here is how to make the data uniform so that when aggregated you can meaningfully search it and use it quickly for recruitment. Carefully planning and selecting tools that let you perform that task is important.

Once the patient is identified, then you need to be prepared and expect that data collection is going to be very different in a DCT. In the past the patient would come to you, but now, sponsors and CROs must plan on going to the patient. While advancements in telemedicine have made this easier, not all aspects are completely automated. Many are conducting hybrid models where nurses visit patients at home, but less frequently.

In many cases, the patient directly enters the data. Easy to use technologies that a patient can pick up and use without extensive training are key. The choice of tools that are used for direct patient data gathering and how to best harmonize these diverse data sets become an important part of upfront planning and study managers' responsibilities. Data managers must plan for a high volume of data from multiple sources with often very complex data structures. Study managers must plan early in the study design process on how to make data actionable faster – from data generation to normalization and harmonization for a more accurate data interpretation.

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MANAGING A DIVERSE ECLINICAL ECOSYSTEM

Twenty years ago, there were a few dozen eClinical vendors. The EDC was the first tool to get established as a "must have," mostly because of FDA guidance and mandates. Stakeholders are now looking to incorporate a plethora of tools, such as: EDC, CTMS, eSource, ePRO, eCOA, analytics, site solutions, DHTs and more. These tools are available with different levels of sophistication and are often bundled with other capabilities.

As an example, CTMS is moving from something that was in use by large pharmaceutical companies to become a necessary component of small to mid-size CROs' toolkits. There is a great deal of overlap between the data that is captured and stored in an EDC and a CTMS. Keeping these "overlap" data elements harmonized is critical. Clinical operations and study managers must plan for and manage how to automate the transfer of data from each of these systems to the other. This is just as important as selecting the tool itself. DCT is forcing many clinical operations to insist on choosing tools with open APIs, and then seek an interoperability platform to fully integrate their selections. The challenge is to make these disparate, and often, overlapping data sources interoperable and allow the data to become actionable faster.

MAINTAINING COMPLIANCE WHILE PROMOTING INTEROPERABILITY

The FDA has shown foresight by encouraging integration and "hands-free" movement of data from source to submission systems. However, in every published guidance by the FDA (see references for eSource and DHT guidance), emphasis is put on ensuring compliance with GxP, FDA CFR 21 Part 11, HHS 45 CFR Part 164 and other regulatory guidelines. Data compliance and data validation is critical. Often an intermediary like a rules engine with its clinical intelligence serves as a compliance traffic cop that ensures that only data that has met certain criteria is promoted from system to system. This mediated data integration using an integration platform with configurable data flow rules is now considered mandatory by many in data management and clinical operations. These rules, as with any other function, need to be fully documented, tested and verified. This validation step is unfortunately sometimes overlooked as we race to couple APIs or use traditional Export Transform and Load (ETL) tools.

Beyond the initial setup, ongoing monitoring and surveillance of the data transfer -- be it real-time, hourly, or monthly -- calls for sophisticated monitoring tools that go far beyond simple error-logs. Take the example of a DHT capturing biometrics in real-time and a "glitch" breaks the connection. That "lost window" of data may contain critical safety information that may be reportable. With an intelligent rules engine and a mediated interoperability platform, the moment a source or destination are unable to send or receive data alerts are generated and automatic notifications are sent to address the problem. This ongoing monitoring has now become a necessary part of clinical trial data integration.

> **If data is the life blood of a clinical trial, then data interoperability is the pulse that brings that science to life.**

Remote Patient Monitoring & Integrating Medical Devices

The medical device industry and mHealth markets are booming. As DCTs take hold, the era of DaaS, or Device as a Service, is upon us. Watches, mini-ECG readers, wearable glucose monitors, pulse oximeters, and more, are all part of a medical device market that's growing at 50% annually. That growth curve will exponentially increase the volume and velocity of data that needs to interoperate into clinical trial workflows. Medical device technologies are quite different from the technologies that most clinical operations and study managers are used to using. Truly, a new wrinkle brought about to a great extent by DCT.

As "The Patient became the Source," DHTs became an important part of directly capturing data. For the most part, these devices produce data in highly proprietary formats that are only made available to select third-party tools under strict data transfer agreements. This means that whilst data can be captured directly from the patient; and in real-time, study managers have no way of easily getting it out. There are Healthcare IoT platforms, but they all operate with the premise of pushing the data to an EHR in a clinical setting. A smart interoperability platform helps its users directly capture the relevant data in a configurable way from the devices for use within the study.

TRANSFORMING STUDY DATA MANAGEMENT

The Pharma industry is now focused to transform study data management and its expanding uses. DCTs have liberated data generation throughout a distributed and disparate ecosystem. This creates new challenges for data aggregation, harmonization, and integration. At the same time, industry is under pressure to speed better medical treatments to market. This is achieved through improvements in quality, time, and cost. In the past almost all such data harmonization was performed by BioStats AFTER the data was made available through cumbersome data cleansing steps using rudimentary tools such as spreadsheets. Sometimes data managers were forced to use analytic tools such as SAS and SPSS to perform this type of data cleansing – something that neither were designed to do.

Data management and clinical operations have the added pressure of servicing other departments within the organization, other than Biostats. These operational groups have developed a need for clinical data at different stages of study lifespan and often require multiple data feeds at early stages of data collection – something that was never considered in the past. Again, an intelligent traffic-cop or intelligent rules engine that can moderate data flows has become a must for meeting the diverse clinical study data needs. This is further complicated by the requirements of ensuring the data privacy and regulatory compliance standards are met.

Data interoperability is a critical, table-stakes capability for conducting good DCTs. That means using data from all parts of the study – in real-time – to glean 360^0 views of the patient. In 2021, data management transformed itself into data science. In 2022, if data is the life blood of a clinical trial, then data interoperability is the pulse that brings that science to life.

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