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PharmaVOICE

Data Ownership: Setting Up Your Study for Success

A small- to medium-size biotech or medical device company typically succeeds or fails on one pivotal study. It cannot be underestimated how important the study and operational data are to the success of that organization. The paramount consideration needs to be, do you have ownership of that data? Let's talk about that now.

Whether you are a start-up pharma, biotech company, a medical devices innovator, or an established organization, you want to be equipped with the best possible solution for your study. Finding an eClinical partner that gives you full access and visibility into your clinical data and offers on-demand reporting is crucial to program and organizational success.

The Importance of Owning Your Clinical Data

When selecting a partner, it is important to understand and clearly define the parameters around access to your data to ensure it will be continuous and without restriction, such as limits on size, data output formats or frequency of access. Direct access to your data can also give you more autonomy by allowing you to run reports yourself with a few clicks to access real time data without having to make a request of an external party. Your ongoing access to detailed, complex, real-time data allows you to get on the phone and discuss the trends or issues in a study rather than having a call to be shown metrics for the first time.

Timely access to data can mean the difference between success and failure. Data accessibility should not be a roadblock to meeting your study milestones, making critical decisions, solving clinical issues, and managing your study data.

Single Sign-On Access to Your Entire Study

Having access to unified tools allows a seamless flow of data across the platform, and enables the user to pull cross-functional, real-time reports across integrated modules. This allows for more sophisticated analysis capabilities, as well as more detailed metrics and multi-dimensional key performance indicators to assist you with study oversight and progress tracking. A single source of data where key information is injected into forms to avoid duplicate data entry ensures that reconciliations are cut out of the clinical process.

Can you access a live patient profile report with all aggregated key subject data? Do you have access to all integrated status reporting? How many separate and distinct systems do you have to maintain data connections for?

Working with different systems jeopardizes data integrity and increases the risk of duplicate data entry, extensive data reconciliations, and potential loss of information. Ensuring that you do due diligence around these questions is essential because every integration or point of access is a potential point of failure and issues in this area will have an even more significant impact on a small organization.

An Extension of Your Study Team

A partner's team can become a true extension of your own study team. The benefits of having a team dedicated to your study's success include a single point of contact for coordination, customized reporting for all levels of your team, and strategic input from experience.

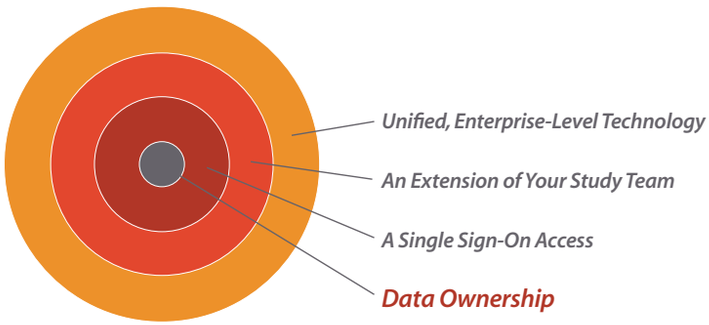
The right team will take a comprehensive and consistent approach in overall study design and management. A further success factor is selecting partners familiar with the challenges and nuances of your program and your team size, in addition to intimate knowledge of the technology you have selected.

Andrew Schachter
CEO and Founder
Axiom Real-Time Metrics

Powerful eClinical Solutions For Small to Medium

It is key for small organizations to be working with best in class and enterprise-level eClinical technology and services that can scale with them. Powerful, comprehensive tools enable smaller organizations to make data-driven decisions and take manual tasks away from your team's bandwidth to allow focus on managing the study instead of filling trackers. A powerful tool with direct compliant data outputs provides the ability to agilely respond to evolving trial requirements.

Full access and visibility into your clinical data and real-time reporting so that you can make critical decisions as soon as possible will give you the edge that you need to bring innovation to market. PV



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