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An Albatross and an Opportunity

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Economic necessity is driving our industry to look hard at how more efficient services and systems can be provided to support the clinical research process. There are those who would say this necessity was present before the recent economic meltdown. However, I have personally been involved in clinical research for 12 years and from my perspective very few investments that have been made or actions taken have materially improved the research process. The proof are the statistics that show the industry is spending more money and taking longer to get drugs across the finish line.

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The Albatross

Historically budgets for clinical research projects have been compartmentalized by the various functional operation areas. These include: patient recruitment, randomization, drug supply tracking, clinical trial management, safety systems, grant payment systems, etc. They all serve different aspects of a clinical research project, but are usually run in a standalone manner and loosely coupled through assorted "interfacing" or handoff processes.

The processes associated with these operations have moved down the path toward becoming electronic, each at their own pace. The information and database systems that support clinical research have evolved in a similar fashion to the historical "siloed" mentality of the industry that we serve. Thus software has been developed to serve an individual functional area with little or no regard to the needs of other operational areas.

The result is ever-increasing amounts of data, collected via an assortment of disparate electronic systems, which need to be reconciled at the end of every research project. This reconciliation process is inefficient, expensive, and time consuming.

The Opportunity

The opportunity is not easily solved because clinical research is a hugely complex project with many moving parts. When trying to help people understand the magnitude, I ask them to add up all of the people and processes involved in global studies. To grasp the complexity, I then ask them to think about how many things have to happen perfectly in order for appropriate subjects to be recruited; the number of proper protocol compliant actions that have to be taken at a principal investigators site, imaging center, blood lab, or elsewhere; and then how the results of those actions are to be captured and verified in a regulatory compliant manner.

There are good reasons why experience is so important when a sponsor selects a clinical partner to help them with their research studies, why so many project managers are needed, and why new thinking about technology are absolutely essential to better manage this complexity.

The Solution

The time has come to use technology smarter. Yes, the tools need improvement as well, but we can combine the current tools with a comprehensive vision to create clean clinical data faster and more efficiently right now. Everyone knows that technology will not improve a process that is fundamentally flawed, right? To start, the clinical research process will become more efficient as we collectively support not only the development of standards but widespread adoption and implementation.

Next is the application of intellectual capital combined with technology. Clinical data will continue to be gathered using a wide range of interfaces. Given the complexity of the processes, technology is required to facilitate the collection and cleaning of clinical data in a cost-effective manner. The next leap forward will require joining these tributaries of data earlier in the process, ideally in real time, and that we turn the data into information that is used to make clinical trials both safer and more efficient. Waiting until the end of a study to unify data not only extends the time required to get results, but it increases the risk and cost. More timely use of information about which sites are enrolling, protocol deviations, adverse events, and yes even positive results will be required to make any substantial improvement in efficiency.

Supporting this vision requires people who have experience with both clinical trials and expertise with the specific technologies that will be used. This support will allow the scientists, the statisticians, and the investigators to better focus on their responsibilities instead of the mechanisms and get us closer to the goal of vitally needed transformation of the clinical trial process. ■