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Integration and Workflow Issues for Clinical-Services Providers to Ensure Smooth Trials

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An ongoing imperative in clinical research for pharma and biotech companies is to accelerate processes and timelines to get new products to market as fast as possible and recover the costs of development. Today, there are powerful technological tools that provide efficiencies to clinical-trial workflow by CROs and other service providers to make this happen.

There are cases when sponsors attempt to reduce the costs of development by contracting individual functions from specialty providers — EDC, data management, monitoring — for the best possible bid price. Whether this menu approach actually serves to achieve the desired outcome of lowering costs will depend on the degree that different companies charged with individual portions effectively coalesce into a unit to coordinate and build trust.

In his book, "The Speed of Trust," Stephen Covey develops the theory that high-trust relationships are characterized by faster decision-making, progress, and lowering of costs, while the reverse is true in relationships marked by suspicion. The implication for sponsors, CROs, and other service providers is that they need to develop an extra policy level to take into account intra- and inter-company dynamics, with the goal of fostering a team-building atmosphere.

Workflow Considerations

1. Intra-Organizational Considerations: Are silos preventing communications and transparency? Or are the various departments performing as a multifunctional team?

2. Multinational Considerations: As more trials expand beyond one country's borders, it is important to start with a well-designed protocol, ensure that processes are in place to maximize communications and data flow, and employ technologies that are not too modern nor too slow for a given region.

3. Inter-Organizational Considerations: A sponsor might put together a coalition of specialists based on cost factors — and of course, experience and expertise — and expect that everything will work well together. Does it happen? The answer can be yes if all the organizations involved in a given trial are committed to flexible solutions. These solutions must be backed up by a consistent, unified approach that places a premium on communication and trust to ensure the overall mission remains paramount and turf-wars are kept to a minimum.

Essential Ingredients for Integration

1. Frequent Meetings and Feedback: In many of the studies involving multiple companies, countries, and data collection sources, a weekly conference call can forestall a variety of problems and identify areas that might be in need of modification before the timeline (and hence costs) proceed too far. Also, an objective "lessons learned" survey among all key participants at various stages of the trial process can empower participants to impact the study's progress and avoid replication of problems in the future.

2. Commitment to Making Data Exchanges Seamless: Some powerful determinates for driving the study forward in a timely manner are real-time data and predetermined study edits. To achieve this, the best possible situation is a combination of Interactive Voice Response System (IVRS), Interactive Web Reporting (IWR), and Electronic Data Capture systems (EDC). IWR is a desirable way to keep the investigators and study coordinators connected to their study independent of location and provide study specific reports, such as patient diary completion and compliance. The higher percentages of valid patients as well as reduced on-site monitoring and more efficient monitoring visits all yield the benefit of lower costs.

The modern imperative is that all the organizations involved in a trial have to be passionate about managing the data in real time; recognize which technology best fits the study, personnel, and regions; and determine how these systems can be adjusted and, when possible, make the commitment to integrate systems from various providers.

The Modern Imperative

Simply put, there are some flexible systems and some that are not so easily adaptable. But the modern imperative is that all the organizations involved in a trial have to be passionate about managing the data in real time; recognize which technology best fits the study, personnel, and regions; and determine how these systems can be adjusted and, when possible, make the commitment to integrate systems from various providers. ■

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