



An Agile Approach to Benefit Biotechnology Research

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The biotechnology industry can take advantage of building upon the lessons learned by experienced contract research organizations that have performed clinical studies on behalf of pharmaceutical and medical-device sponsors.

One of the best practices that biotechnology companies can adopt is an "agile" approach to clinical investigation, which can help to meet or shorten study timelines.

rix —are technologically appropriate for the given geographic region that a study is taking place.

As an analogy, consider transportation; to get from point A to point B, one may need to walk, drive, travel by train, fly, or in many cases use several of these modes to get to the destination. The agile approach works best when every possible method is available to employ and one can choose what works best. But since it's not practical to walk across a conti-

Each morning everyone involved with the clinical trial should expect to have a snapshot about how the study is progressing, how sites are performing, and how patients are behaving.

Rule No. 1: Patient Recruitment

The process begins with a well-designed and thought out protocol. This hopefully incorporates a recommendation from the CRO as to where in the world are the best areas to recruit the largest pool of potential patients in the shortest time frame. A CRO's previous experiences with therapeutic areas, history of site performance, and factors such as seasonality, if appropriate, all come into play during this part of the process. The first rule of an agile approach is maintaining geographic flexibility: go where the patients are. Patient availability is what truly drives a study forward; medical practice, available therapies, and racial factors also help determine where to conduct a study.

Rule No. 2: Technology Capabilities

The second imperative for an agile trial is technological flexibility. As the trend continues for studies to become more global, an agile approach will aggressively match the best technology for the geography rather than using a favorite technology that might not be the best choice for a given location. Indeed, all technologies that are available have their good and bad points for remote data collection, and it is very important to use an application that the regional infrastructure will support.

In most cases, a global study will need to incorporate a combination of tools to be at peak efficiency. An important point is to make sure that the combination of data-collection forms — IVR/Web board, PDF forms, Smart Fax Forms, Web forms, and/or VPN reporting — and information transmission vehicles — e-mail, facsimile, Internet, telephone, and/or Cit-

ment or contract a jet plane to go across town — when looking at sites where the study will occur, it is important to avoid technological bottlenecks that negatively impact your timeline. For example, using three-part NCR forms in developing countries when fax technology is readily available. It is just as important to be aware of and avoid overcapacity situations, in which highly advanced technological approaches are employed in an area that cannot yet handle the volume. For example, using EDC technology in a region with slow, unstable Internet connections would not be the best option.

The key is to have data from various source materials collected by matching technologies from different areas of the globe received at a central location. The data are then reviewed, edited, queried in as close to real-time as possible and then applied to a working database. Each daily update is then compared with data that already exists in the database.

Out of this process, a clinical-study team derives two major decision-making tools: at any point a snapshot can be obtained of how the study is progressing, how sites are performing, and how patients are behaving; and decisions can be made immediately that affect the study.

Because data are cleaned and reviewed as part of the ongoing procedural flow of a study, sites can be managed daily from a distance. This provides savings for on-site monitoring visits and allows for the evaluation of the sites' productivity in terms of patient enrollment, data completion, and accuracy of the information being provided.

In today's global studies, it is more important than ever to adopt an agile approach, which means finding the appropriate patients and combining various data collection tools with a standardized, centralized workflow, which allows timelines to stay on track and costs to be kept in line. ■

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