Key Factors for Successful Study Implementation and Determining If You Need a Study Rescue

Three of the greatest fears that a Sponsor experiences when initiating a new trial are: "What if the study does not enroll according to corporate timelines?", "What if the study runs over budget?", and "What if the data quality is subpar?" Each of these "what ifs" can have a significant cost implication for the Sponsor company, since a delay in timeline carries with it a delay in revenue actualization.

While the majority of outsourced clinical trials are delivered according to specification, situations arise in which the trial is not adequately managed by the service provider(s). In this case, action needs to be taken to "rescue" the study. Common indicators that the study may be in trouble or headed for trouble are: missed timelines, poor communications with the project team, and inadequate data retrieval and poor data quality. A swift determination that the study is "in trouble" allows for greater opportunity for timely intervention and may help minimize the required remediation efforts and shorten the timeline delay.

A critical component of each study is the planned study timeline and clinical program development timeline. When deviation or delays in enrollment from planned timelines occur, the project team should be able to review enrollment and the reasons for slower than expected enrollment to determine whether there are additional steps that may be taken to increase the enrollment rate. Strategies to increase enrollment often include increasing advertising, opening additional study centers, and in extreme cases, investigating a protocol amendment for inclusion or exclusion criteria revision. The service provider providing project management oversight and clinical monitoring should be proactively monitoring enrollment and providing information for Sponsor consideration so that slipping timelines do not turn into missed timelines.

Effective communication is a necessary component of every positive work relationship. The successful implementation of a clinical trial requires timely quality communication between all stakeholders: Sponsor, service providers, study site personnel and physicians. Delay in communication from the service provider or incomplete communications result in the Sponsor having to invest more time to track down information from service providers and often impact the study site's ability to adequately implement the trial and achieve study goals. Early recognition by the Sponsor of communication challenges is critical to ensuring steps will be taken to prevent poor communication from snowballing into larger problems.

While issues with data quality and delays in data retrieval are often not noted until "downstream", they can present significant problems for a development plan and the Sponsor. Timely data monitoring, retrieval and data processing of clinical trial data is critical to allow for assessment of data quality and provision of data to medical reviewers and data safety monitoring committees. Data quality can be enhanced when the site is provided with timely feedback regarding case report form completion and data completion. Additionally, the timely retrieval and processing of data allows for "real-time" data clean up, study output programming and deliverable preparation. Similar to the issues of reactive management of timelines and poor communication, delays in data processing can have a significant impact on the success of a study.

As soon as the Sponsor gets the feeling that their service provider is not proactively managing their study or appropriately performing contracted services, they need to begin an investigation to determine if their concerns are justified. During this time of investigation, the Sponsor should consider engaging additional support from within their organization or from consultants who are experts in the discipline in question and have experience providing this type of support. These additional team members need to immerse themselves into the study to obtain a clear determination of potential issues. Depending on the magnitude of the issue, the scope of "study rescue" may be determined. Timely assessment of the issue may allow the Sponsor to continue to use the contracted service provider(s) while increasing additional support through the use of expert consultants to engage in the trial and help provide functional oversight on behalf of the Sponsor. This oversight would help ensure completion of tasks according to the timeline as well as monitoring data quality and processes on an ongoing basis. The addition of a "functional expert" is generally more cost effective and less time consuming than implementing a full study rescue in which the service provider is removed and a new provider employed.

While insertion of functional experts is an adequate solution for some troubled trials, other projects will need to be removed from one service provider and assigned to a different provider. These rescues require thoughtful planning on behalf of the Sponsor and an assurance that the Sponsor holds all key documentation and communications for the study. The organization assigned to take over the study, must have experience in rescuing studies and should be able to provide concrete recommendations for the successful transition. Successful rescue of a trial requires a partnership between the Sponsor and "rescuing team".

Financial concerns regarding the costs associated with "rescuing" a study often limits Sponsor companies from moving forward with implementing a rescue strategy. However, the additional costs associated with timeline delays or after-the-fact data re-cleaning are often more costly than implementing a rescue earlier in the process. In many cases, employment of a functional expert will allow the study to remain with the contracted provider, but, help provide the expertise to oversee the study progress and review data on an ongoing manner.