The Benefits of Employing a Functional Service Provider for Data Management

For years, pharmaceutical and biotechnology companies have employed the strategy of establishing preferred provider relationships in order to streamline the process of outsourcing clinical research studies. Often the preferred provider would provide discounts to their customers based on efficiencies the service provider may realize from working on multiple trials for a single compound or the sponsor organization. Typically the preferred partnerships focused on the selection of one service organization providing all of the functional services for a clinical trial. While there were cost-savings experienced by the sponsor, often the result was that the service provider with the greatest clinical strength received the designation of preferred provider, but then the sponsor was "stuck" with that service provider or additional services from that provider that were not as good.

During the last couple of years, Functional Service Provider (FSP) relationships have increased. In the FSP model, the sponsor organization selects service providers to provide their specialty services, in a similar manner to the preferred provider relationships in the past. The difference between the two is that the FSP model supports selection of individual service providers and not necessarily a "one stop shop" solution by a full service provider. This allows the sponsor to obtain the best service provider from each discipline rather than focusing on one provider to perform all services.

Data Management is one function that nicely fits into the FSP model. Unlike other services that require quite a bit of interaction between the sponsor and service provider (i.e., clinical operations), a quality data management team will be able to initiate the study with efficient team interaction and then work independently throughout the processing phase.

Creation of a successful FSP relationship hinges on the initial interviews between the provider and sponsor organization to ensure the corporate cultures are similar and that the teams can work together seamlessly. The ideal FSP relationship allows the data management provider to be an extension of the sponsor's project team. The FSP needs to provide an experienced and industry savvy team with the ability to provide support and knowledgeable recommendations regarding best practices in providing data management support for clinical trials and programs. Review of the corporate culture and caliber of employees also allows the sponsor organization to ensure that their approaches to timeline management are congruent.

Following the selection of a FSP, the sponsor and data management provider should review and discuss established sponsor standards so that those items may be incorporated into all aspects of data management from the beginning of the relationship. Additionally, planning meetings should be initiated between the key stakeholders from both parties to ensure there is a clear understanding of upcoming studies to enable seamless budgeting and staffing. These planning meetings should be held on a quarterly or biannual basis.

Data Management FSP relationships benefit sponsor organizations by allowing them to experience numerous efficiencies. The establishment of data standards that are applied across clinical trials and programs result in financial cost-savings, as well as timeline reductions. The time required by the sponsor team to review study documentation is decreased since the documents have been consistently developed across studies for the sponsor. Additionally, the service provider is able to actualize time-savings due to the establishment of sponsor specific standards. This time-savings may then be passed on to the sponsor resulting in budget reductions.

The efficiencies gained from an FSP relationship also flow into the data finalization and submission activities. There is a direct benefit of having all data collected in a consistent manner and processed in a consistent manner. Not only does this allow the sponsor to pool the data from multiple trials to review throughout the clinical development program, it also allows for a much more efficient NDA submission. Maintaining data in a consistent format prevents the NDA preparation team from having to convert, manipulate and merge data resulting in a cleaner and quicker submission.