

## **Data Management Rescues – Two Case Studies**

A large number of clinical trials are outsourced to Contract Research Organizations (CROs) each year. While the majority of these trials are successfully implemented and study results are delivered on-time and on-budget, situations arise when the study is not adequately managed by the vendor and the study must be “rescued”. The scope and type of study management deficiency needs to be assessed by the Sponsor to determine the type of remediation required. Rescue support may be as simple as adding third-party function experts to the Sponsor project team to aid in the management and oversight of the CRO, or as complex as selecting a new CRO to assume all responsibility for the study.

### *Case Study 1 – Rescue of Four Phase I/II Studies*

In this experience, the Sponsor contracted a contract research organization (CRO) to perform data management services for four phase I/II studies that were a part of a single development program. The studies varied ranged in size from 20 subjects to 100 subjects. In review of the clinical data, the Sponsor noted inconsistencies in data handling and data quality issues within studies. The Sponsor was unable to collapse data from various protocol versions into a single consist database structure for each protocol. Data Management documentation was also incomplete and in some cases unavailable.

PharPoint was contacted to discuss remediation plans that would involve PharPoint obtaining the data, reviewing and cleaning the data as necessary, and creating data management study documentation that the Sponsor would need if they proceeded with a NDA filing. After review of the available data and documentation, PharPoint’s team developed study specific data management plans and constructed a single clinical database for each trial that would house all variations of the CRFs that resulted from protocol amendments. The data were imported into the PharPoint database and quality control (QC) reviewed by data management personnel to ensure the database accurate reflected the Case Report Forms and Data Clarification Forms. Following the quality control review, the data were subject to programmed edit checks and data queries were issued. For the single ongoing study, PharPoint performed all data processing steps including data entry.

Remediation of the four databases was completed swiftly, with timelines ranging from approximately three-weeks for the smallest trial to three-months for the largest trial. PharPoint’s role in remediating these data provided the Sponsor the ability to use the data in aggregated reports as well as providing necessary study documentation.

### *Case Study 2 – Rescue of an Ongoing Phase III Trial*

In this experience, the Sponsor was engaged in an ongoing large multi-national clinical trial. Approximately 200 subjects had been enrolled in the trial and data processing and reporting was lagging. The quality of the data in the database also suggested that data cleaning activities were not being performed on an ongoing basis and query generation was not being performed in a timely manner. The Sponsor’s data management vendor was routinely generating changes in scope and the Sponsor was placed in a challenging situation of having to agree to increases in vendor fees, while not receiving the service to justify the increased costs.

PharPoint was engaged to take-over the data management activities, including re-databasing and cleaning all previously collected clinical trial data. Additionally, PharPoint assumed all data management activities for the remainder of the trial, which is expected to reach full enrollment of 600 subjects. Within six weeks of receiving the initial data, approximately 24,000 pages were data entered and data cleaning activities were performed on a large portion of the data. Medical data coding was also made current and reflective of all data collected. PharPoint's planned currency moving forward is completion of data entry within three days of data receipt and data query generation within five days of completion of data entry.

PharPoint research has rescued multiple studies and has provided consulting support to several clients who are assessing the potential need move ongoing studies. To discuss how our experienced team may be able to help you with your clinical programs, please contact us at 919-929-0012 or by email at [bizdev@pharpoint.com](mailto:bizdev@pharpoint.com).