CASE STUDY:
USE OF OPRA TO IDENTIFY AND MANAGE HIGH RISK SITES

Triumph Research Intelligence 2018

What was the situation?

Our client, a mid sized North American CRO was undertaking a large, global study for a key sponsor customer. The study protocol was complex and required the use of an imaging device which was not common practice for many of the sites. The sponsor also wanted the CRO to take a risk-based approach to on site monitoring, and wanted ongoing quality risk management for the purposes of patient safety, data integrity and ICH E6 (R2) compliance.

What was the predicament?

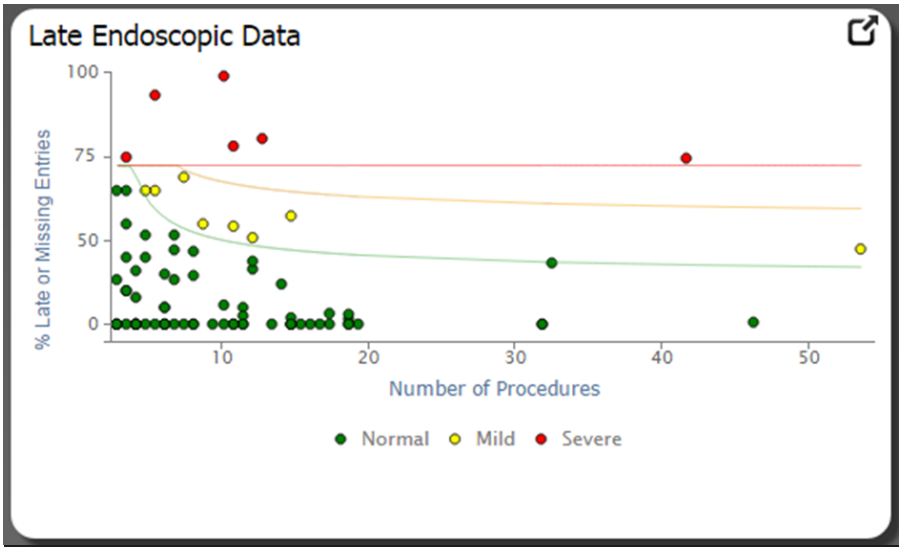
Our client needed a solution which would combine professional services and technology. Professional services expertise was required for the design of a quality management approach which would suit the complexity of the study design. Technology was required to provide continuous central statistical monitoring of the clinical data and provide a data visualization capability to identify site risk levels to enable a risk-based monitoring approach. The Sponsor required periodic reviews of the data with the CRO and wanted clear justification for decisions relating to quality management and risk-based monitoring.

TRI had worked with the CRO on previous projects and were known to be experts in both the set up and support of studies which are R2 compliant and adopt a risk-based approach to monitoring. TRI were selected to provide both the technical and professional services components of the solution.

Working with investigators early in a trial helps identify any quality or training issues and allows early remediation

Success Factors

- Early involvement with protocol risk assessment
- Central review meetings with CRO, Sponsor and TRI
- Use of pre-treatment KRIs
- Combined use of KPIs and KRIs for site risk



Study specific KRIs in OPRA allowed early indication of site level risks

OPRA

OPRA is a state of the art, but simple to use platform for quality management, central monitoring and risk-based monitoring in clinical trials.

What was the solution?

TRI designed a set of pre-treatment KRIs which assessed the site's usage of study specific equipment (an endoscope) , the quality of the images that were created by the sites and the turnaround time of image submission. The study was set up in OPRA and utilized a set of core risk indicators as well as those designed for the study. TRI worked with the CRO study management team and supported a series of central review meetings to assess the data and make informed decisions on risks to quality and sites to target for enhanced monitoring and support.

An number of interesting observations were made during the course of the study. Firstly, the sites which performed badly during the pre-treatment quality assessments tended to also perform badly during the study treatment period. These sites were targeted very early in the study for higher levels of on site monitoring and greater levels of source data review. Secondly, those sites which were identified as higher risk sites early in the study and received higher levels of support were shown to have significantly reduced risk levels within a six month period. The three highest risk sites at the start of the study had risk scores of **231**, **212** and **158** . Within six months the risk scores of those same sites were **77**, **52** and **49**.

What is the current state?

Both CRO and Sponsor now have an approach and supporting technology which allows them to be R2 compliant whilst managing quality on an ongoing basis. OPRA was used for central monitoring and RBM decision support throughout the duration of the trial.

Contact Us

For more information on our ICH E6 (R2) implementation services or OPRA, our RBM platform, please feel free to contacts us on: info@tritrials.com

TRI