

Continuous Process Improvements for Project Involving large CRF & Local Lab Data

Situation: A Phase II study for Metastatic Renal Cell Carcinoma for submission to US FDA comprising 110 subjects over a 2 year span involving multiple local labs with differing normal ranges.

Challenges:

- Handling of CRF data comprising more than 27000 CRF pages
- Ambiguity amongst the sites regarding the processes led to 20% of the data being duplicated
- Significant variation in reporting of laboratory results due to presence of more than 10 local labs

SIRO Strategy:

- 20 comprehensive checks were designed in order to streamline the varied data generated from laboratory sites
- SIRO devised special excel macros to automatically scan & identify duplicate pages
- SIRO also designed excel macros to automatically identify data for clinician review

Result:

- There was 75% reduction in review time for the duplicate pages which led to an increase in overall efficiency
- The review time for outliers was reduced by 50%
- There was reduction in manual review of documents which improved accuracy of data & led to significant time savings

- The checks designed by SIRO were incorporated by the sponsor into their “Global Lab Data Cleaning Guidelines”

Sponsor Feedback:

“I want to thank you for the amazing job that you have done on this study in order to move us to lock which it looks like we can finally do today. It is a tremendous pleasure to work with someone with such expertise, diligence and a pleasant attitude which the whole team appreciates”

- Sponsor PM