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Continuous Process Improvements For Project Involving large CRF and Local Lab Data

STUDY DETAILS

This was a Phase II study for Metastatic Renal Cell Carcinoma for submission to US FDA. Study had close to 110 subjects over a 2 year span involving multiple local labs with differing normal ranges.

Data for this study was collected on paper CRF.

CHALLENGES

This project had difficult to manage CRF data considering there were more than 27,500+ CRF pages in total. Sites were unclear of the processes which resulted in duplicate pages being sent for 20% of the data. Had this gone unchecked it would have led to unnecessary DCFs and resource wastage in the long run.

There were more than 10 local labs for this study with different normal ranges for each one of them. This led to variations in the way lab results were reported and indirectly tedious manual review

ACCOMPLISHMENTS

Instead of manually reviewing duplicate CRFs the team devised excel macros to identify these duplicate pages.

This reduced manual review time by 75%

To tackle the lab issues of multiple local labs and lab ranges, SIRO DM team designed comprehensive checks in-house.

These checks reduced time for review lab outliers by 50%

The excel macros designed also helped in identifying the data for clinical review. This *eliminated the need for manual review* of data before sending to sponsor clinician for review

OUTCOME

Streamlining processes and thinking innovative lead to time saving and submission of more precise data based on the many automated checks SIRO's DM team had designed.

These checks were also implemented across similar studies.

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