Applying the best practices of the pharmaceutical industry to improve the efficiency of claim studies of a global consumer goods leader

Situation: Conduct a claim study for toothpaste to measure the extrinsic stain removal properties in 140 subjects

Challenges:

- **Significant number of overlaps in documentation**:
  There were numerous checklists for each task for every site personnel, with several overlapping points. This led to loss of time, error in data collection and difficulty in review.
- The sponsor had a third party recruitment agency which needed to be trained in the collection of requisite documentation of the subjects.
- There was a large turnout for the trial which needed to be effectively managed during subject screening in order to avoid duplication of participants. Additionally, the chosen subjects needed to be segregated during the study so that a biased test result was avoided.
- The sponsor had an in-house ethics committee which was against the spirit of the ICH-GCP guidelines.
- The data generated in this study was being captured by the sponsor using rudimentary processes. This posed a significant challenge in ensuring data quality.
- Adverse events were not being recorded since the sponsor lacked the awareness about the concept of adverse event.

SIRO Strategy:

- Although, FMCG products do not fall under purview of DCGI, SIRO recommended following of ICH-GCP guidelines.
- SIRO specialists created new checklists which were succinct and precise.
- SIRO recommended formation of an ethics committee according to the regulatory guidelines even though the study did not fall under the purview of the DCGI.
- SIRO recorded the clinical assessment procedure. This enabled generation of 'source data' which could then be referred to during QC.
- SIRO provided comprehensive training to the site investigators about the importance of adverse events

Result:

- The succinct checklists led to a reduction in errors during data capture, in time spent and significantly eased the difficulty of reviewing the data. This led to an increase in the efficiency of the site staff.

- The audio recording of clinical assessment procedure enabled SIRO to conduct source data verification which improved data quality markedly. The sponsor made this recommendation a standard practice in all future claim studies.

- The Sponsor and the investigator were impressed with the manner in which the study was conducted and SIRO's assistance was requested in other studies as well.