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## Large CRF Data Processed In 1 Month For Twin Heart Burn Studies

### STUDY DETAILS

Involves two identical Phase III heart burn studies running parallel with data for Submission to US FDA and Study Sites and Recruitment in US

### CHALLENGES FACED

These studies involved a fairly large patient population of **>1150** in as many as 65 sites. Besides a short enrollment time of 2 months the project duration of 10 months was also short in considering number of subjects to be enrolled and consequently amount of data that required cleaning.

Team processed approximately **28,000 CRFs** in total from which greater than **45% CRFs** were processed and cleaned in the last month before database lock date. This led to greater than **1600 DCFs** being generated and resolved parallelly.

The projects posed a challenge to both SIRO's DM team and the partner CRO's Clinical Monitoring team considering the enrollment requirements co-ordination involved with the numerous sites for timely issue resolution.

### OUTCOME

With innovative management, hard work and timing, we managed to meet DB-lock timelines without compromising on quality.

Besides team work, good Co-ordination with monitoring team and constant communication and follow up with study sites to get CRFs and DCFs in house helped achieve timelines.

### SPONSOR FEEDBACK

*"I wanted to thank you for the great work you did to ensure a timely database closure and clean data set for the XXX XX study.*

*Please accept my sincere appreciation for your dedication to this project"*

**- Sponsor PM**