SCDM Live
India conference
2\textsuperscript{nd} - 3\textsuperscript{rd} December 2022
Radisson Blu Hotel, Bengaluru

Theme:
Capabilities | Collaboration | Change on the way to Clinical Data Science
Connecting dots in Biometrics-Collaboration

Leadership and effective collaboration animated video - YouTube
Collaboration - Soft skills the key drivers

- Communication
- Conflict resolution and Team-work
- Being Inclusive - Accepting Diversity
- Challenge existing skill sets
- Positive Outlook
Case study

A Respiratory study for an XYZ Multinational Pharmaceutical company

Interim analysis was planned for the study with 20,000 subject population. However, the study team was changing the scope frequently, also the Data Management Lead observed that some critical data review checks were missing, there was adhoc protocol amendment leading to post go live changes. Also there were resourcing challenges from the Vendor and programming team. This led to a challenging situation for data delivery for Interim analysis.
Case Study contd..

**Scope**
- Frequent Scope Change by study team during study team meetings.

**Post Go-Live changes**
- Post Go-Live changes (Protocol amendment, misfiring checks).

**System Downtime**
- System Downtime (Database downtime, leading to data entry delay).

**Resourcing**
- Resourcing challenges leading to conflicts/delay in metrics etc.
CASE STUDY cont.. Mitigation

01 Communication
- Defining and aligning the scope for Interim analysis with study team
- Clear demarcation of activities and escalation pathway
- DM team came together to understand gaps redefine metrics for leadership and study team

02 Critical Thinking
- DM team performed data review through data that was available through tools and reports during database downtime
- Protocol amendment changes were discussed and implemented, which were utmost required

03 Resource Planning
- Churning and back up planning of resources
- Sub team leads to lead respective teams
- Alignment across time zones

04 Proactive Meetings
- Discussion with prog team to get Data review reports in place instead of Edit checks considering volume
- Proactive meetings with Prog team and STATs for Data issues
- Addressing errors identified by STATs and PROG team ongoing basis

05 Focused Meetings
- DM, Prog Stats, Study management came in together to address the outstanding issues
- Daily Scrum meetings with DM team
Clear and on the top communication
Each group was aligned for a clear communication channel

Efficient and fast resolution to Open issues
Due to Scrum and focused meetings, there was real time address of open issues

Interpersonal relationship
Across time zones support by team to work towards metrics, summary logs etc.

Milestone Achieved
Interim Analysis achieved as planned
“Collaboration is key, it takes innovation and creativity to the next room.”

— Shawn Lukas