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..

SCDM Live
India conference
2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru
Society for Clinical Data Management
DATA DRIVEN

Scope | **Post Go- Live changes** | **System Downtime** | **Resourcing**

Frequent Scope Change by study team during study team meetings

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

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

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

CASE STUDY cont.. OUTCOME

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