Theme:
Capabilities | Collaboration | Change on the way to Clinical Data Science

SCDM Live
India conference

2\textsuperscript{nd} - 3\textsuperscript{rd} December 2022
Radisson Blu Hotel, Bengaluru
CASE STUDIES

Framework and Roles

Risk Based Quality Management- Integrated QM

- **Risk Management**
  - Web-based RACT
  - IQRM Planning Tool
  - QTL

- **Central Monitoring Solutions**
  - CMCR Patient Level
  - Key Risk Indicators (KRI)
  - CMCR Study Surveillance
Cross-Functional Approach
Tools used for the case studies: RBQM Dashboards – Patient, Site & Study Levels

1. **CMCR – Patient Level**
   - Patient Safety & Site Compliance
   - EDC + 3rd Party Data Sources
   - Benefits:
     - Performed with 72 hours of data availability
     - Ability to visualize data in meaningful ways
     - Statistical models with adjustable weighting & thresholds to improve sensitivity
     - Prevents repetitive site/patient issues as soon as possible

2. **Key Risk Indicators**
   - Site Operational Performance
   - 14 standard KRI (EDC + CTMS)
   - Benefits:
     - Identify site performance trends that may impact overall data quality
     - Ability to see issues across sites that may indicate country or regional risks
     - Track resolution of KRI as corrective actions applied

3. **CM-SSD**
   - Study level risks including QTLs
   - EDC + 3rd Party Data Sources
   - Benefits:
     - Protocol specific analytics customized by indication
     - Ability to identify patterns across countries, regions or study
     - Potential to identify misconduct early before any impact to PP analyses
Case Study - 1

Eligibility - Inclusion criterion #6: Renal - serum creatinine ≤ 1.5 x ULN or calculated creatinine clearance or glomerular filtration rate > 50 mL/min/1.73m² for subjects with creatinine levels above institutional normal

- **Capability**
The subject level CMCR dashboard offers a comprehensive solution to review subject clinical profile, MH, Con Meds etc.
The High/Low flags are setup to easily detect criteria that require further review.

- **CM Review**
Central Monitors to note High Flag for serum creatinine value and Low flag for calc creatinine clearance value

- **CM action**
- Escalation to CL/ CRA / MM
- Query the site to confirm the lab values in EDC
- Create a ‘potential’ PD in CTMS
Case Study - 2

AEs, CMs, Study Drug - Correlation

- **AE and CM inconsistency**
  - AE with Grade 3 severity, but no record of associated CMs

- **CM action**
  - Select ConMeds and AE in filter
  - Review ConMeds/AEs for consistencies
  - Raise query for confirmation
  - Raise potential PD in CTMS
  - Review other subjects at site that may have similar issue
  - Site training
Central Monitoring Study Surveillance Dashboard
QTL Dashboard
A Way to future Trial Management

- Advanced risk control
- Targeted monitoring
- Better cost management
- Adaptive trial design
- Better success rate of approval
- Enhanced access to drugs

Key Points:
- Regulations
  - ICH E6 R2 & R3
  - FDA, EMEA
- People
  - Risk Manager
  - CM & CML
- Tools
  - Spotfire
  - R, Tableau
  - SAS
- Process
  - KRI, CMCR
  - RACT
  - QTL
THANK YOU