Society for Clinical Data Management
DATA DRIVEN

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

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

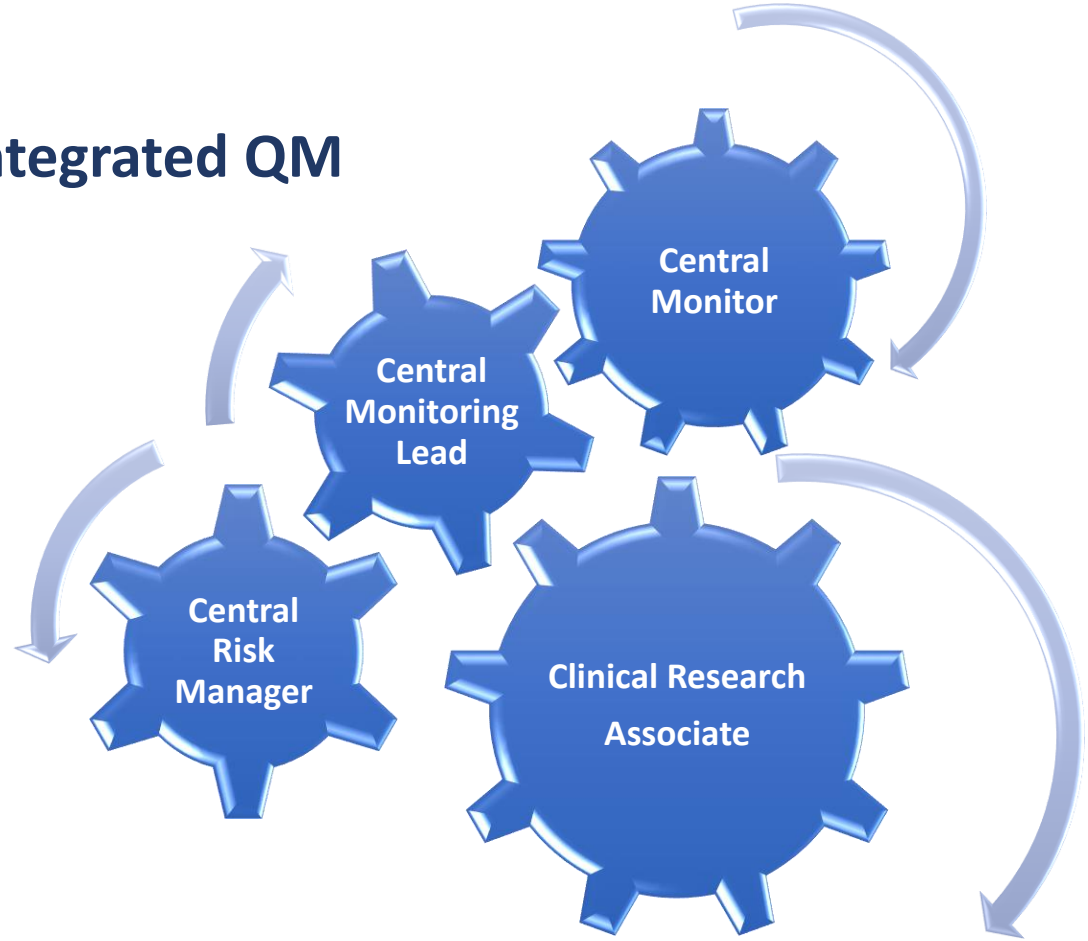
CASE STUDIES

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



CASE STUDIES

Cross-Functional Approach

Integrated Quality Risk Management

STUDY MANAGEMENT

STRATEGY

- CENTRAL MONITORING
- CENTRAL DATA REVIEW
- ON-SITE / REMOTE MONITORING

TEAM

- CENTRAL MONITOR
- MEDICAL MANAGEMENT
- BIOMETRICS
- SAFETY
- SITE MONITOR

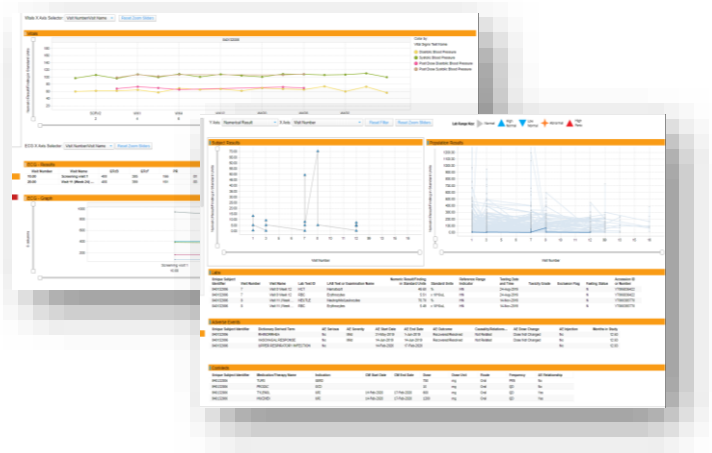
RISK AREA

- Data Quality & Protocol Compliance
- Patient Safety & GCP Compliance
- Data Integrity & GCP Compliance
- Patient Safety & GCP Compliance
- Site Performance & GCP Compliance

Tools used for the case studies : RBQM Dashboards – Patient, Site & Study Levels

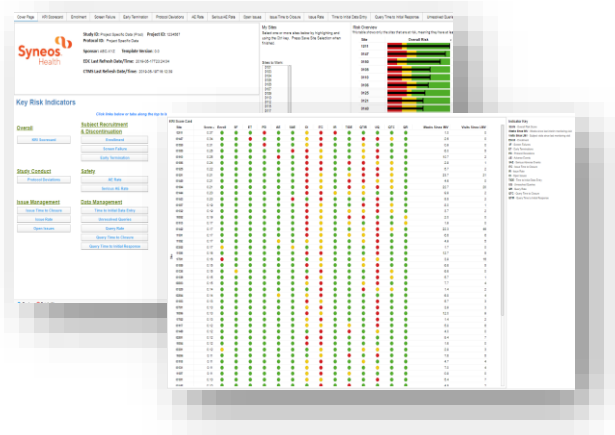
1 CMCR – Patient Level

- **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 KRIs (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 KRIs 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**

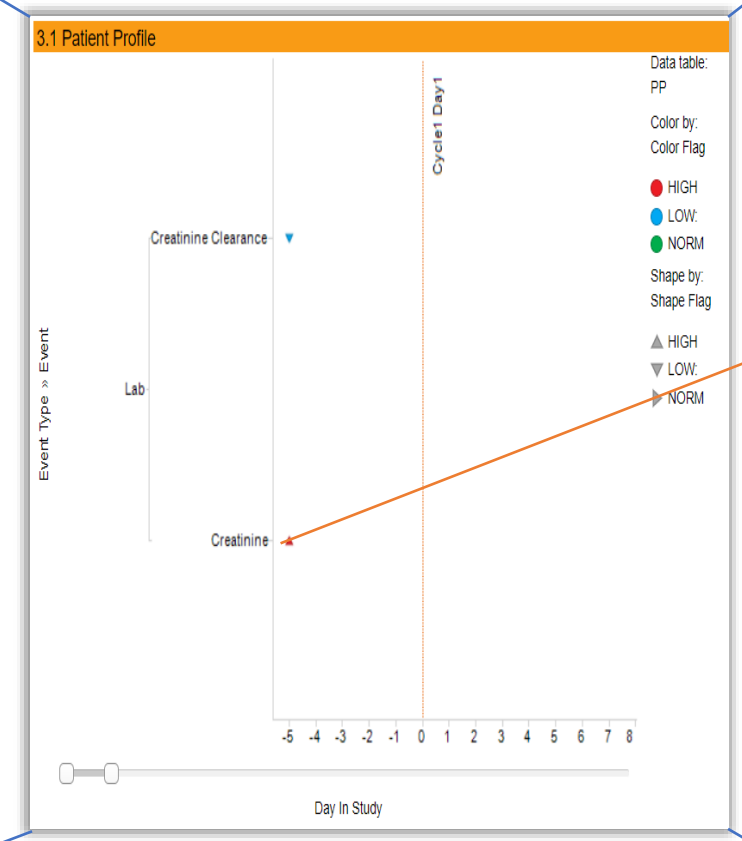
The subject level CMCR dashboard offers a comprehensive solution to review subject clinical profile, MH, Con Meds etc.

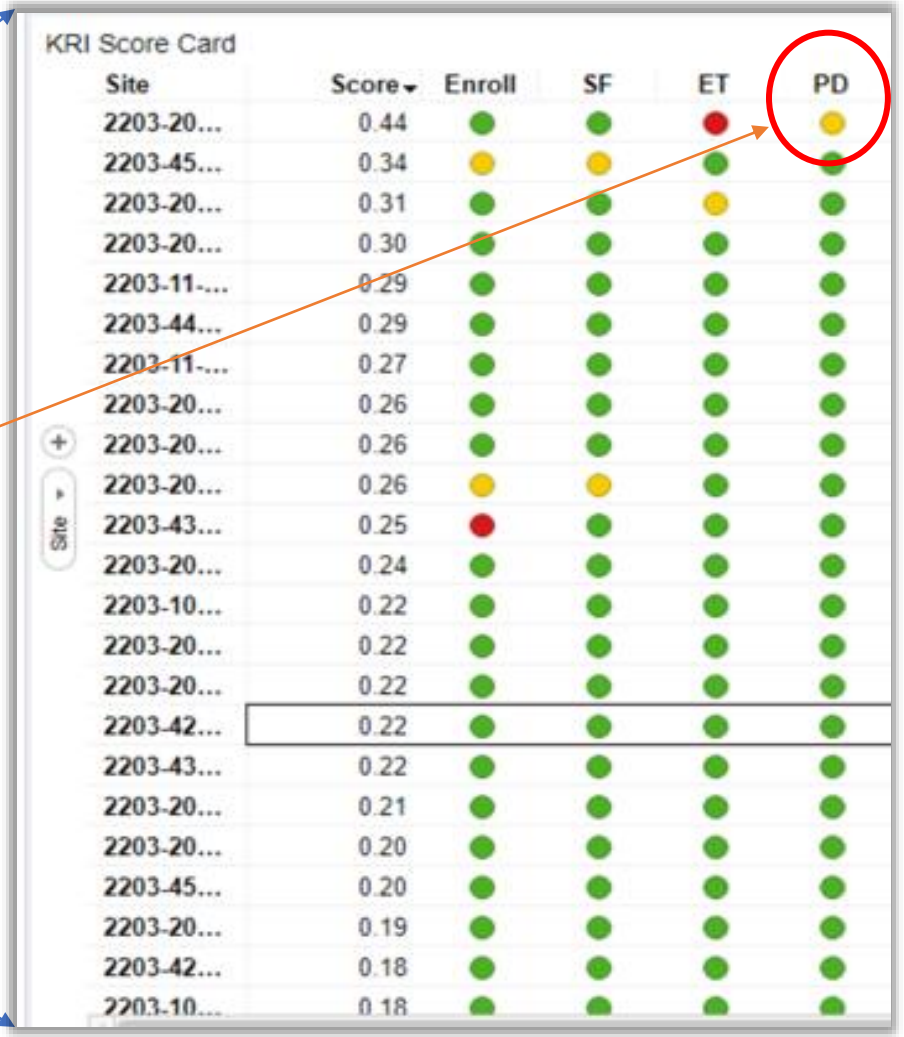
The High/Low flags are setup to easily detect criteria that require further review.

- **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

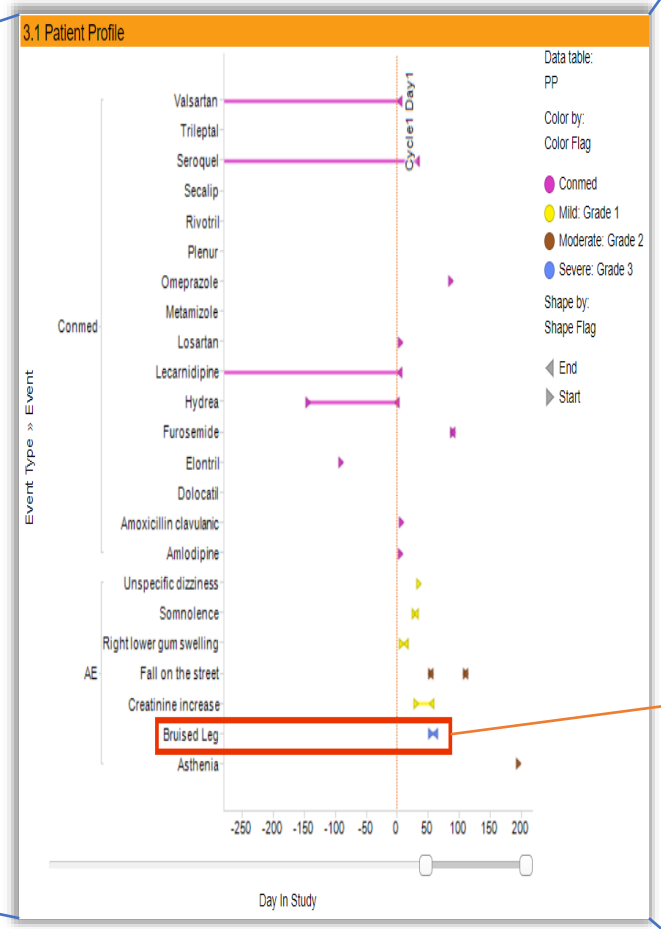


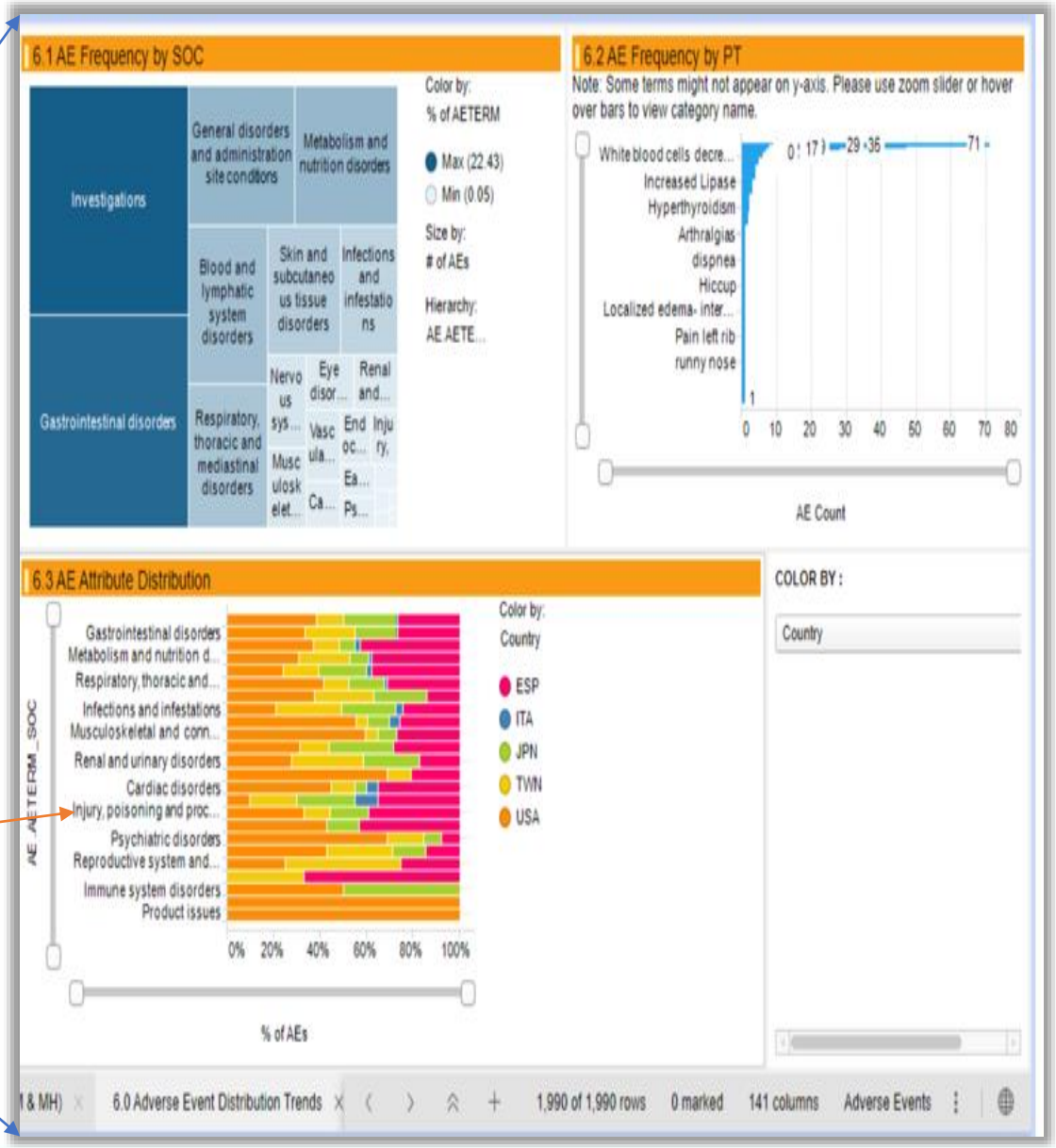


Case Study - 2

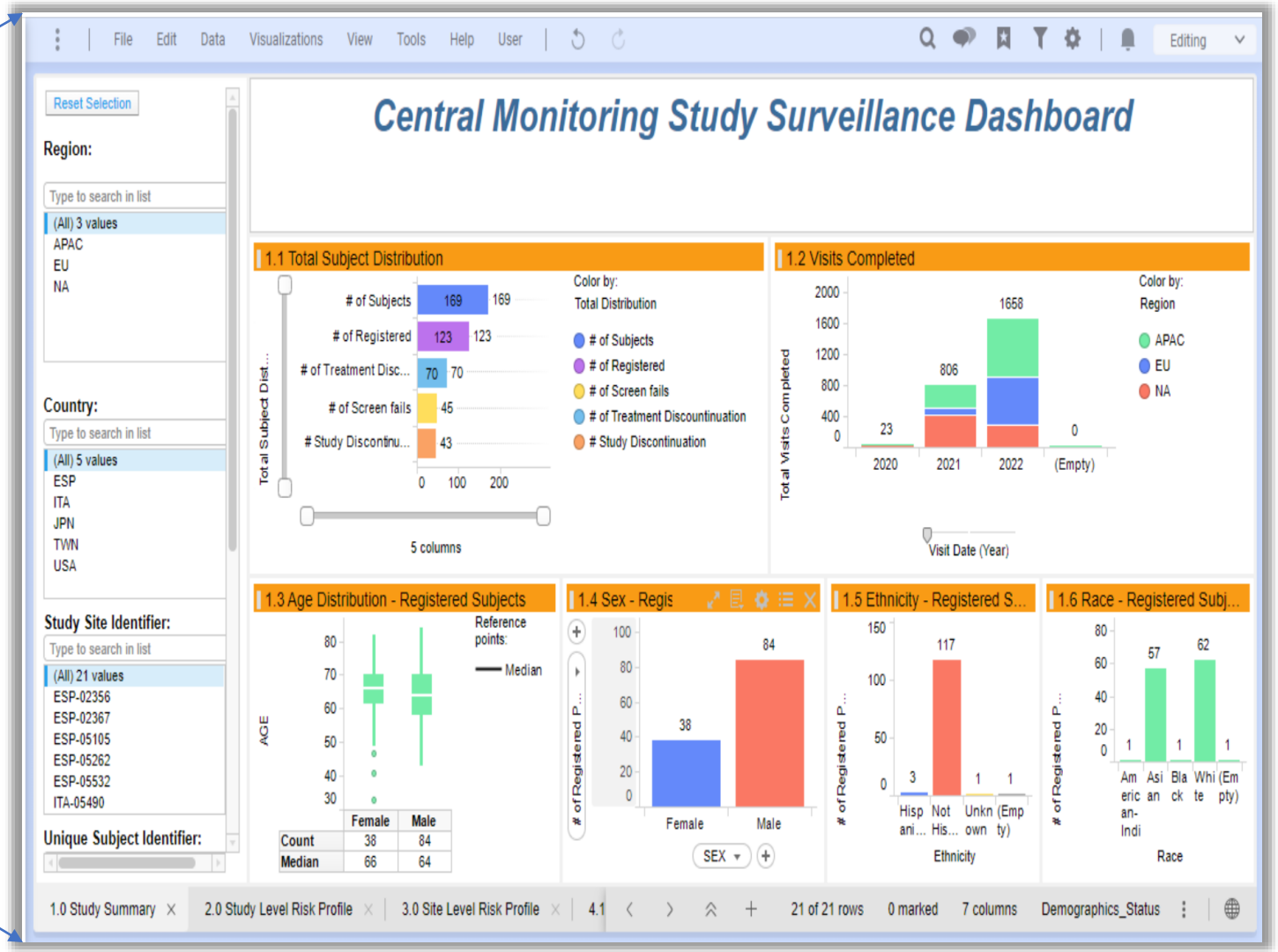
AEs, CMs, Study Drug - Correlation

- **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

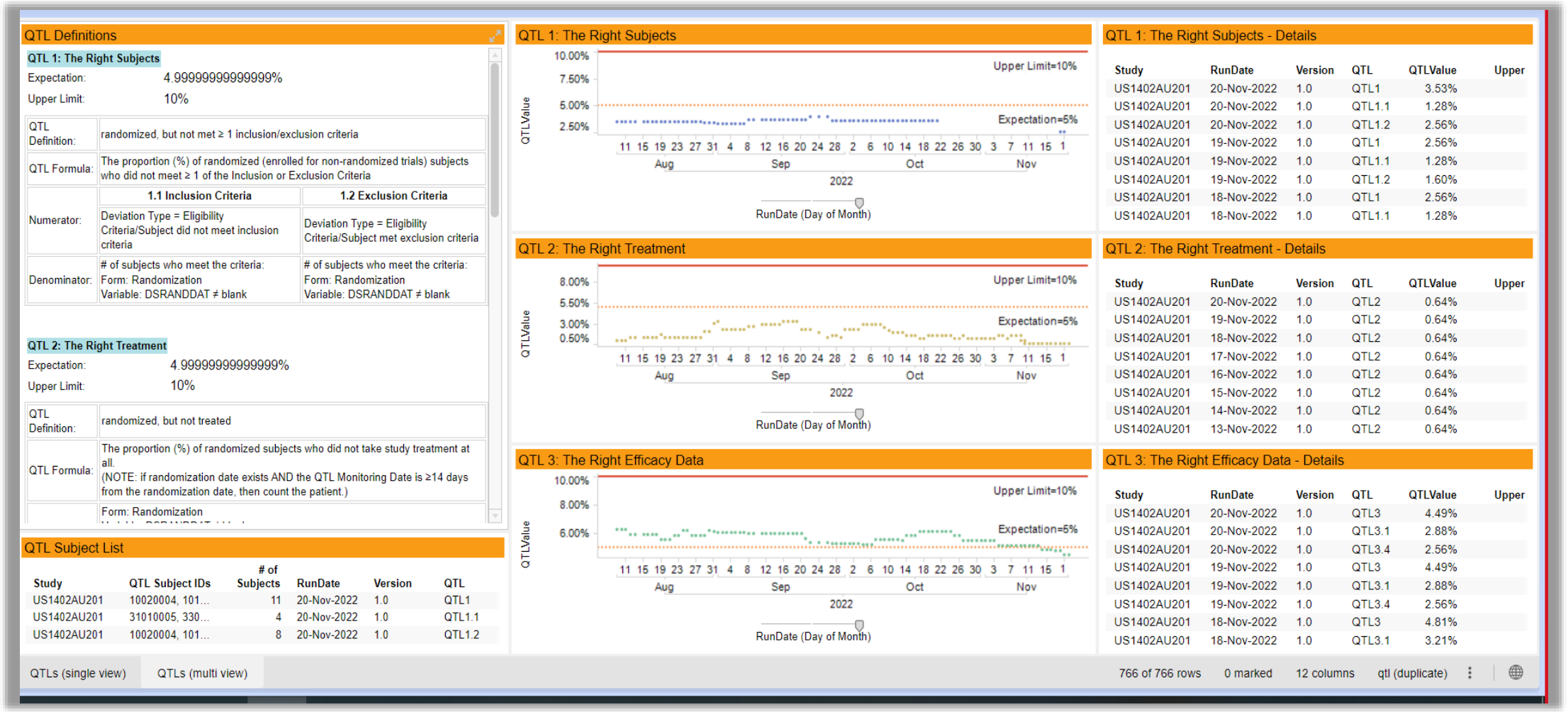




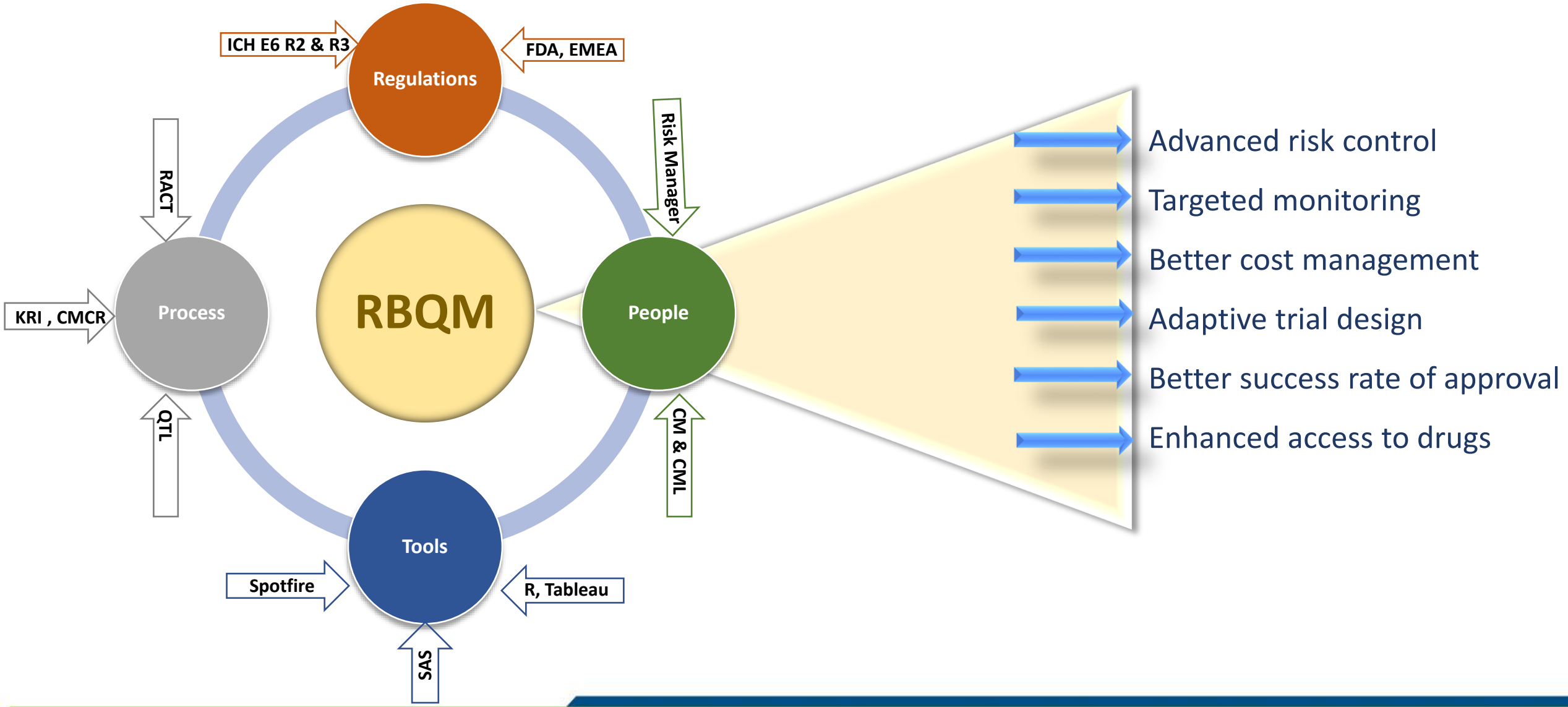
Central Monitoring Study Surveillance Dashboard



QTL Dashboard



A Way to future Trial Management



THANK YOU