



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

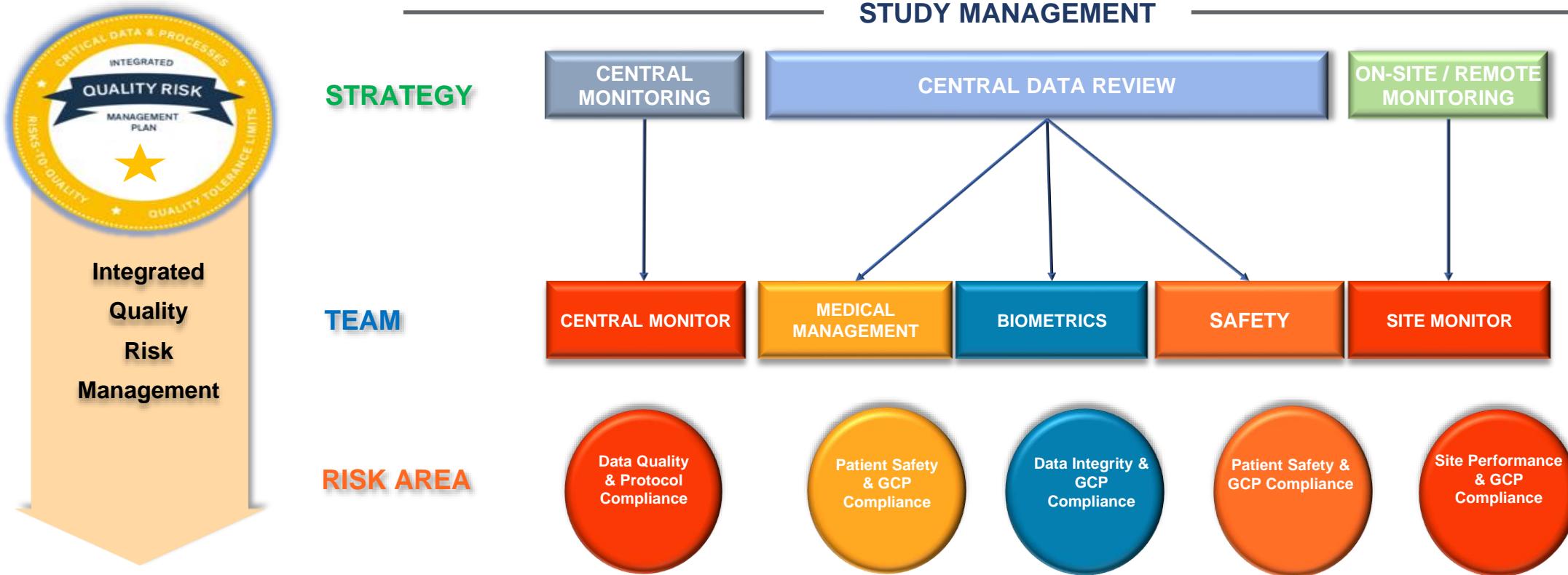
Risk Based Quality Management- Integrated QM

- **Risk Management**
 - Web-based RACT
 - IQRM Planning Tool
 - QTL
- **Central Monitoring Solutions**
 - CMCR Patient Level
 - Key Risk Indicators (KRI)
 - CMCR Study Surveillance



CASE STUDIES

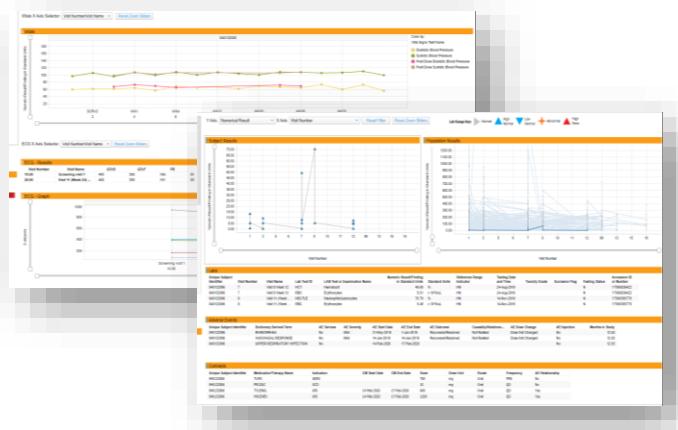
Cross-Functional Approach



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

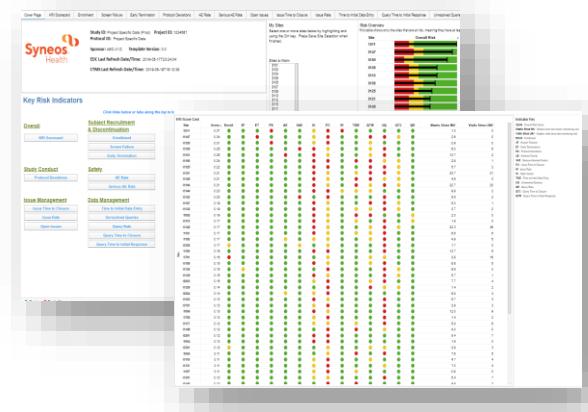
1 CMCR – Patient Level

- 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



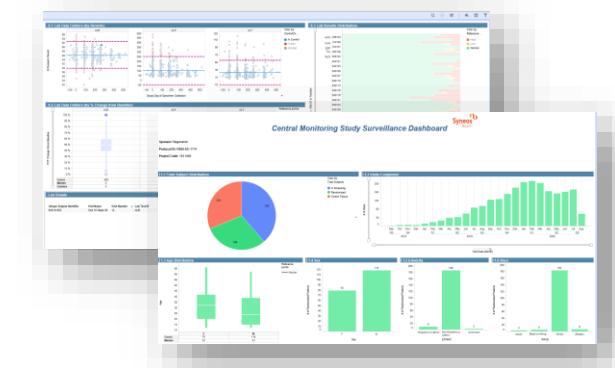
2 Key Risk Indicators

- 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 $\leq 1.5 \times ULN$ or calculated creatinine clearance or glomerular filtration rate $> 50 \text{ mL/min}/1.73\text{m}^2$ 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.

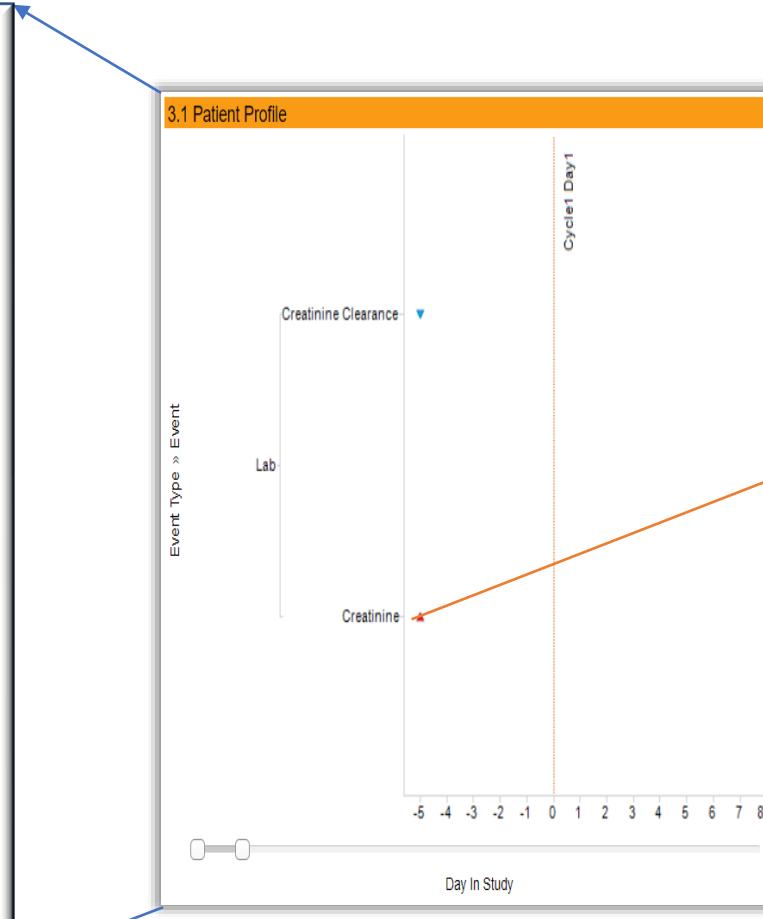
The High/Low flags are setup to easily detect criteria that require further review.

• 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



KRI Score Card

| Site | Score | Enroll | SF | ET | PD |
|------------|-------|--------|----|----|----|
| 2203-20... | 0.44 | ● | ● | ● | ● |
| 2203-45... | 0.34 | ● | ● | ● | ● |
| 2203-20... | 0.31 | ● | ● | ● | ● |
| 2203-20... | 0.30 | ● | ● | ● | ● |
| 2203-11... | 0.29 | ● | ● | ● | ● |
| 2203-44... | 0.29 | ● | ● | ● | ● |
| 2203-11... | 0.27 | ● | ● | ● | ● |
| 2203-20... | 0.26 | ● | ● | ● | ● |
| 2203-20... | 0.26 | ● | ● | ● | ● |
| 2203-20... | 0.26 | ● | ● | ● | ● |
| 2203-43... | 0.25 | ● | ● | ● | ● |
| 2203-20... | 0.24 | ● | ● | ● | ● |
| 2203-10... | 0.22 | ● | ● | ● | ● |
| 2203-20... | 0.22 | ● | ● | ● | ● |
| 2203-20... | 0.22 | ● | ● | ● | ● |
| 2203-42... | 0.22 | ● | ● | ● | ● |
| 2203-43... | 0.22 | ● | ● | ● | ● |
| 2203-20... | 0.21 | ● | ● | ● | ● |
| 2203-20... | 0.20 | ● | ● | ● | ● |
| 2203-45... | 0.20 | ● | ● | ● | ● |
| 2203-20... | 0.19 | ● | ● | ● | ● |
| 2203-42... | 0.18 | ● | ● | ● | ● |
| 2203-10... | 0.18 | ● | ● | ● | ● |

Case Study - 2

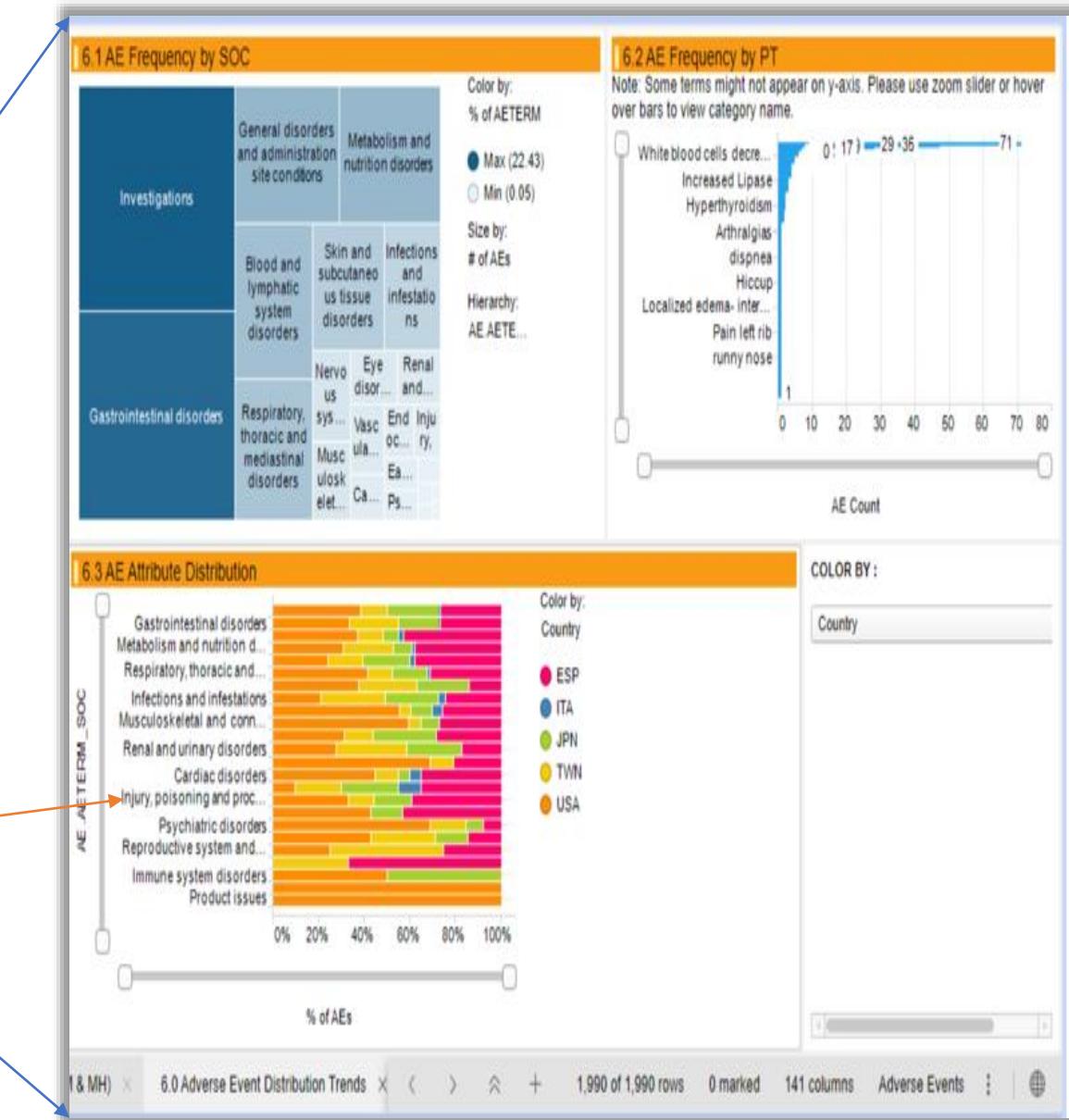
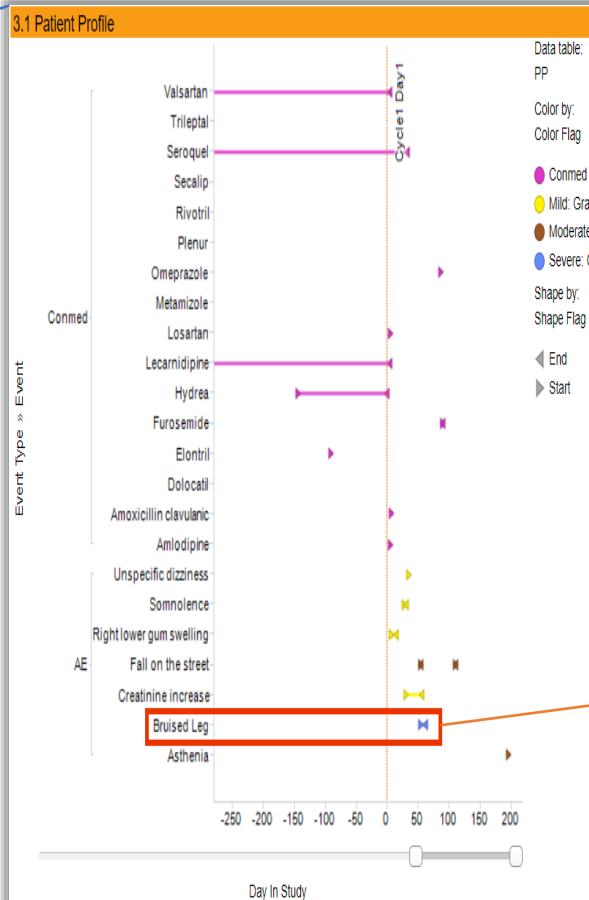
AEs, CMs, Study Drug - Correlation

• AE and CM inconsistency

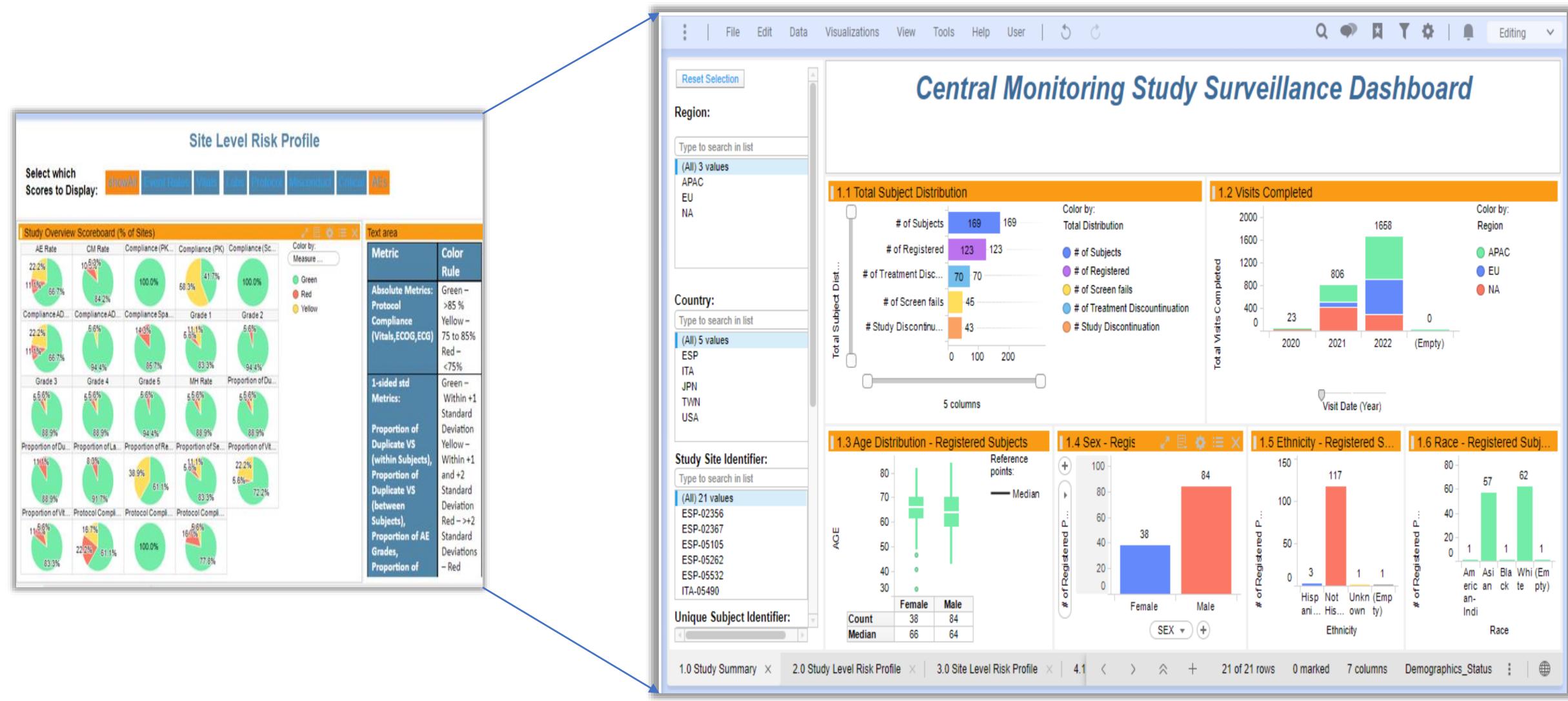
- AE with Grade 3 severity, but no record of associated CMs

• 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

QTL Definitions

QTL 1: The Right Subjects

Expectation: 4.99999999999999%
 Upper Limit: 10%

| | | |
|-----------------|---|--|
| QTL Definition: | randomized, but not met ≥ 1 inclusion/exclusion criteria | |
| QTL Formula: | The proportion (%) of randomized (enrolled for non-randomized trials) subjects who did not meet ≥ 1 of the Inclusion or Exclusion Criteria | |
| | 1.1 Inclusion Criteria | 1.2 Exclusion Criteria |
| Numerator: | Deviation Type = Eligibility Criteria/Subject did not meet inclusion criteria | Deviation Type = Eligibility Criteria/Subject met exclusion criteria |
| Denominator: | # of subjects who meet the criteria: Form: Randomization Variable: DSRANDDAT # blank | # of subjects who meet the criteria: Form: Randomization Variable: DSRANDDAT # blank |

QTL 2: The Right Treatment

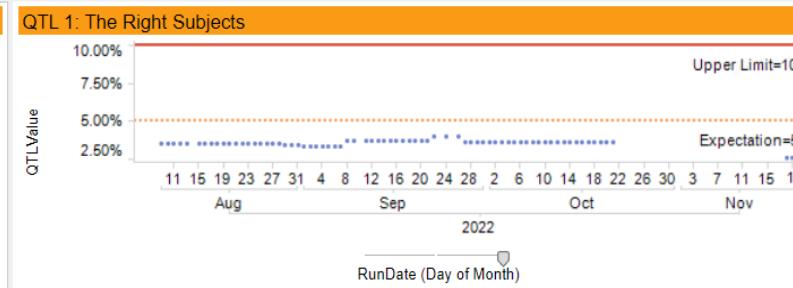
Expectation: 4.99999999999999%
 Upper Limit: 10%

| | | |
|-----------------|---|--|
| QTL Definition: | randomized, but not treated | |
| QTL Formula: | The proportion (%) of randomized subjects who did not take study treatment at all. <small>(NOTE: If randomization date exists AND the QTL Monitoring Date is ≥ 14 days from the randomization date, then count the patient.)</small> | |
| | Form: Randomization Variable: DSRANDDAT # blank | |

QTL Subject List

| Study | QTL Subject IDs | # of Subjects | RunDate | Version | QTL |
|-------------|------------------|---------------|-------------|---------|--------|
| US1402AU201 | 10020004, 101... | 11 | 20-Nov-2022 | 1.0 | QTL1 |
| US1402AU201 | 31010005, 330... | 4 | 20-Nov-2022 | 1.0 | QTL1.1 |
| US1402AU201 | 10020004, 101... | 8 | 20-Nov-2022 | 1.0 | QTL1.2 |

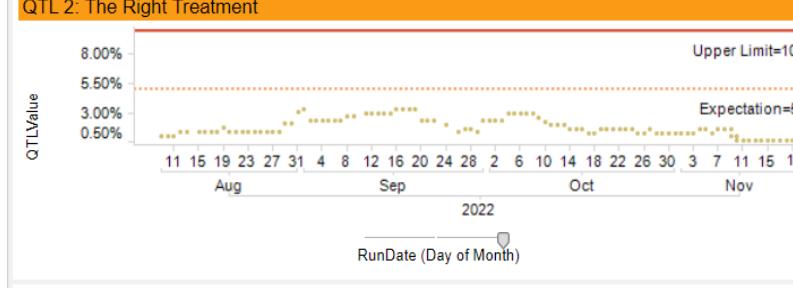
QTL 1: The Right Subjects



Upper Limit=10%
 Expectation=5%

RunDate (Day of Month)

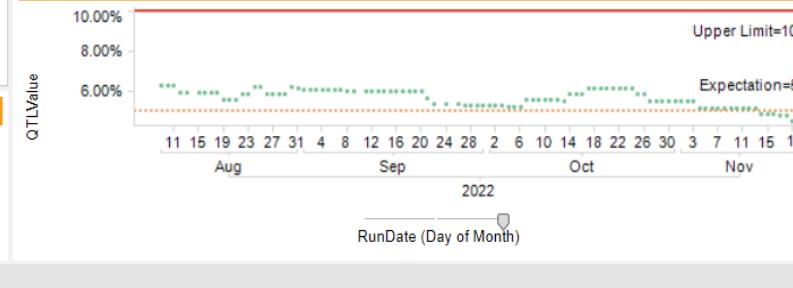
QTL 2: The Right Treatment



Upper Limit=10%
 Expectation=5%

RunDate (Day of Month)

QTL 3: The Right Efficacy Data



Upper Limit=10%
 Expectation=5%

RunDate (Day of Month)

QTL 1: The Right Subjects - Details

| Study | RunDate | Version | QTL | QTLValue | Upper |
|-------------|-------------|---------|--------|----------|-------|
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL1 | 3.53% | |
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL1.1 | 1.28% | |
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL1.2 | 2.56% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL1 | 2.56% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL1.1 | 1.28% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL1.2 | 1.60% | |
| US1402AU201 | 18-Nov-2022 | 1.0 | QTL1 | 2.56% | |
| US1402AU201 | 18-Nov-2022 | 1.0 | QTL1.1 | 1.28% | |

QTL 2: The Right Treatment - Details

| Study | RunDate | Version | QTL | QTLValue | Upper |
|-------------|-------------|---------|------|----------|-------|
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 18-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 17-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 16-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 15-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 14-Nov-2022 | 1.0 | QTL2 | 0.64% | |
| US1402AU201 | 13-Nov-2022 | 1.0 | QTL2 | 0.64% | |

QTL 3: The Right Efficacy Data - Details

| Study | RunDate | Version | QTL | QTLValue | Upper |
|-------------|-------------|---------|--------|----------|-------|
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL3 | 4.49% | |
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL3.1 | 2.88% | |
| US1402AU201 | 20-Nov-2022 | 1.0 | QTL3.4 | 2.56% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL3 | 4.49% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL3.1 | 2.88% | |
| US1402AU201 | 19-Nov-2022 | 1.0 | QTL3.4 | 2.56% | |
| US1402AU201 | 18-Nov-2022 | 1.0 | QTL3 | 4.81% | |
| US1402AU201 | 18-Nov-2022 | 1.0 | QTL3.1 | 3.21% | |

QTLs (single view) QTLs (multi view)

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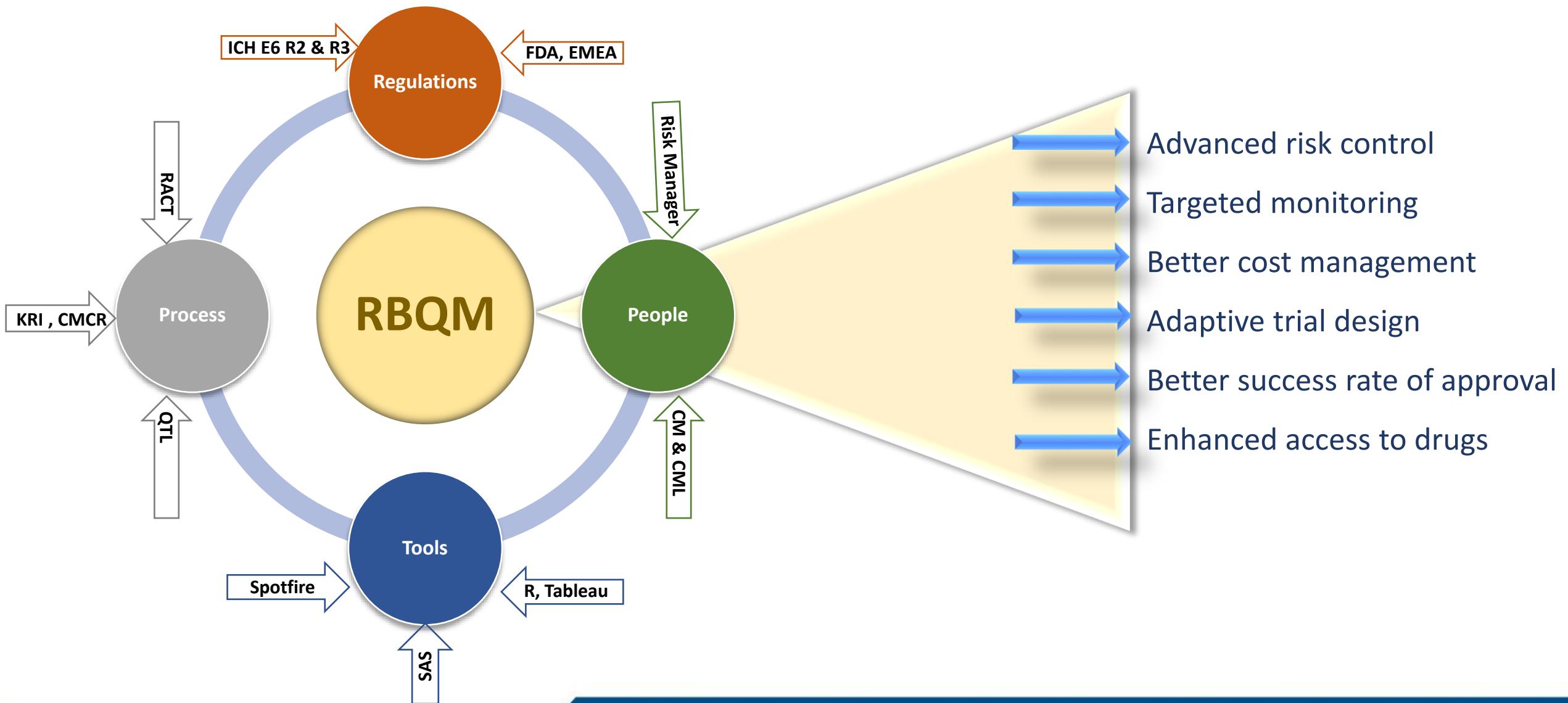
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A Way to future Trial Management



THANK YOU