



Risk-based Quality Management in Clinical Data Management

The Journey so far

PSDM Networking Event, CHDR, Leiden
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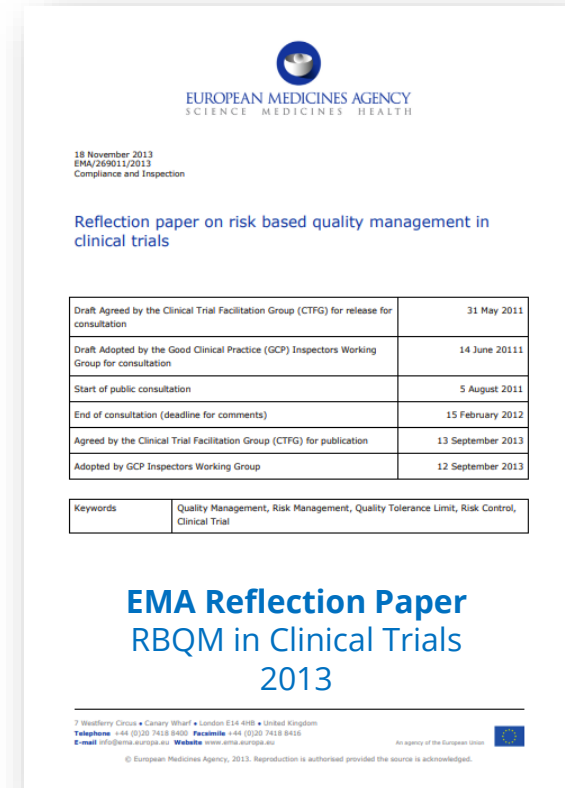
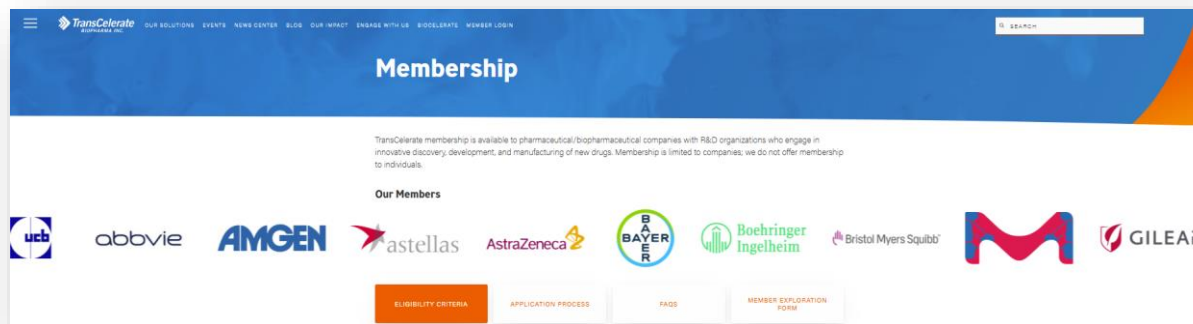




RBQM in CDM – the journey so far

Storyline

- // Inspiration & guidance
- // Developing tools & processes
 - // CDM
 - // Centralized Monitoring
 - // RBQM at the sites
 - // Pharmacovigilance/Site Audit Management
- // Some Examples
- // Further evolution

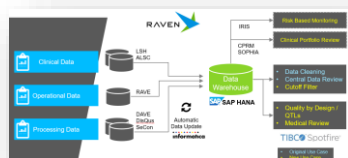




RBQM in CDM – the journey so far



RBM



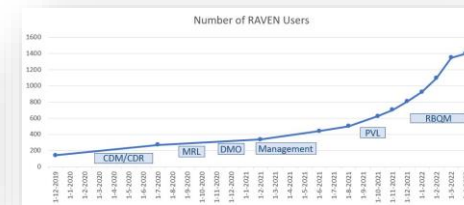
Start RAVEN development for CDM & CM



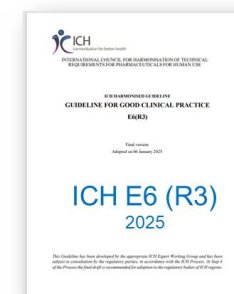
Initial QTLs



Development of RAVEN RBQM Dashboards



Roll out of RAVEN RBQM Dashboards for site management



Further

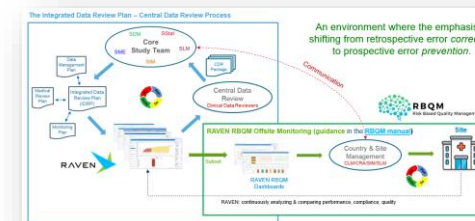
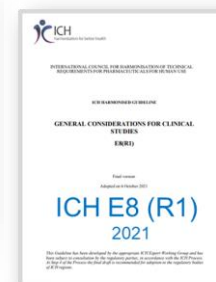
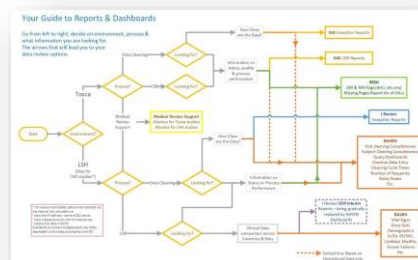
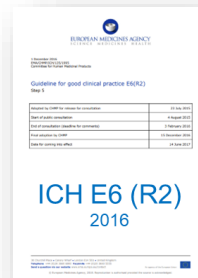
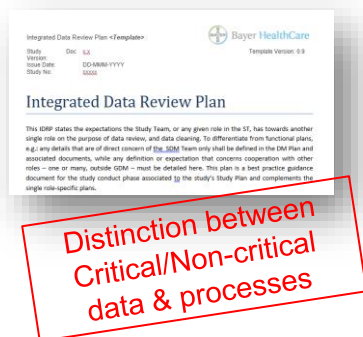
- inclusion of CtQ
- parsimony



Process changes: IDRP + CDR/CSM function

Developing RAVEN dashboards & growth of use cases, finding a place in the existing reporting environment

Query Control Initiative embedded in the new context

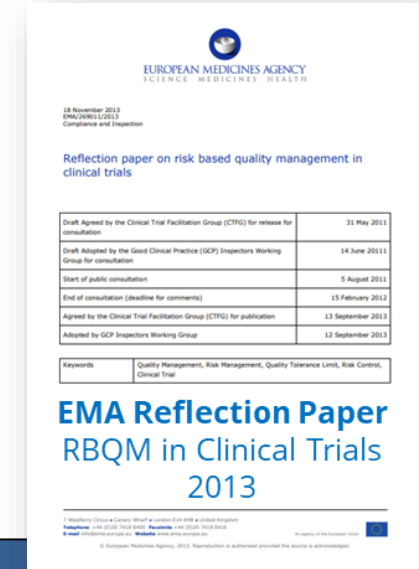




RBQM in CDM – the journey so far

Inspiration & Indicators

- // Inspired by the EMA Reflection Paper RBQM in Clinical Trials 2013
- // Guided by the Transcelerate's Risk Indicator Library
Blinded survey on Risk Indicators => [Risk Indicator Library](#) : 140 Risk Indicators
- // Insights as a Service by Clinical Data Management



Risk Indicator Categories & Sub-Categories							
Monitoring				CDM/Central Statistical Monitoring			
Investigational Product	Essential Documents	Staffing, Facilities and Supplies	CRA/On-site Workload	Data Quality	Issue Management	Safety	Subject Recruitment and Discontinuation
CRA compliance	Responsibility for Data Quality	PI Oversight	CRA Compliance	Adverse Events	CRA compliance	Adverse Events	Enrollment
Dispensing compliance	Site Compliance	Site Compliance	CRF Review	CRF Completion	Discrepancy (Query) Management	Lab Data	Screen Failures
Drug Accountability	Study compliance	Site/Staff Turnover		Data Trends	Protocol Compliance	Outcome or Endpoint Issues	Subject Discontinuation
Patient compliance				Diagnostic Testing	Site Compliance	Serious Adverse	
Shipment				Discrepancy (Query) Management	Subject Discontinuation	Study Drug Discontinuation	
Site compliance				Patient Compliance			
Storage				PI Oversight			
				Protocol Compliance			



RBQM in CDM – the journey so far

Examples of Indicators (KRI, KPI, KQI)

Analysis per: Study, Country, Site; Current QTLs E6 (R2) (=> Acceptable Ranges E6 (R3); [Transcelerate ICH E6 Asset Library](#))

// Compliance

Protocol (PDs/VFs, In/Ex)

// Timeliness

Subject visit, Sampling, Data Entry, SAE reporting

// Recruitment & Retention

Enrolment, Screen Failure rate/reason,
Discontinuation Rates/Reasons, Dropouts, LFU,
Withdrawal of IC

Compliance

// AE/SAEs

Incidence, Frequency, Distribution, AEs of
special interest, Discontinuations

Safety

// Transcription Errors

Changes due to SDV

// Issue Resolution

Data Entry, Turnaround Times, Query aging

// Queries

Counts (per site/CRF page), Re-queries, Query Rate,
Query Quality, Changes due to Queries

// Missing Pages/Data

Identification

// Numerical & Categorical Data (values/time series)

Variance, Outliers, Anomalies

// Advanced Analytical approaches

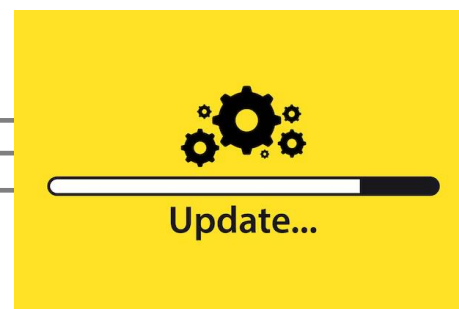
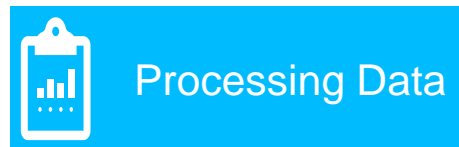
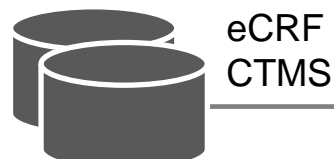
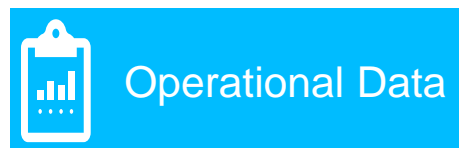
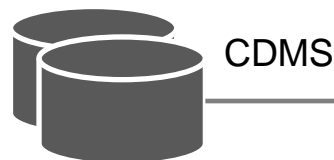
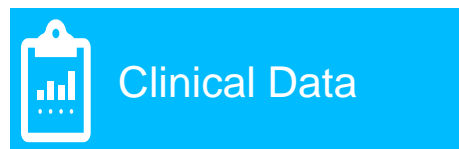
Duplicate randomization, AE underreporting,
Exploring unsupervised approaches, ML/AI

Data Quality &
Issue Management



RBQM in CDM – the journey so far

The Reporting And Visualization ENvironment



RAVEN data is
refreshed daily

CDM/Centralized Monitoring

- Data: Quality/Status/Performance
- Central Data Review/IDRP
- Quality Tolerance Limits
- Data Management Oversight

Translational Sciences

- Medical Review Library

Line Management

- Study Health Dashboard

Pharmacovigilance

- Pharmacovigilance Library

RBQM

- Clinical Overview Dashboard
- Site Risk Leveling
- Workload Forecast Tool

Study Audit Management (Exploratory)

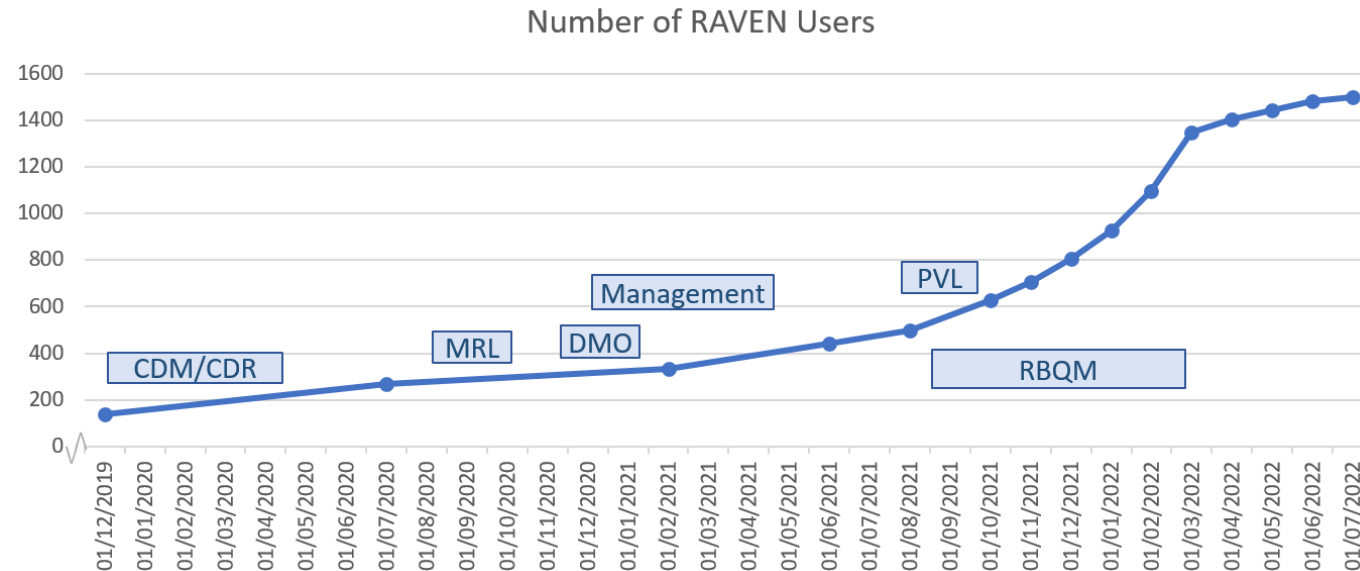
- Selected Dashboards



RBQM in CDM – the journey so far

RAVEN

- // 85+ dashboards
- // 150 In-house + outsourced studies ('Data Management Oversight' dashboard)
- // 1500+ Users (internal/external)
 - // Clinical Data Managers (in-house & outsourced), Centralized Monitoring (IDRP)
 - // Medical Review Library/Visual Patient Profile – Phase 1: Study Medical Experts
 - // Management: Study Health Dashboards
 - // Pharmacovigilance Library: Global Safety Leads
 - // RBQM: Country & Study Lead Monitors, Study Managers, Clinical Research Associates
 - // Site Audit Management (SAM): Clinical Auditors

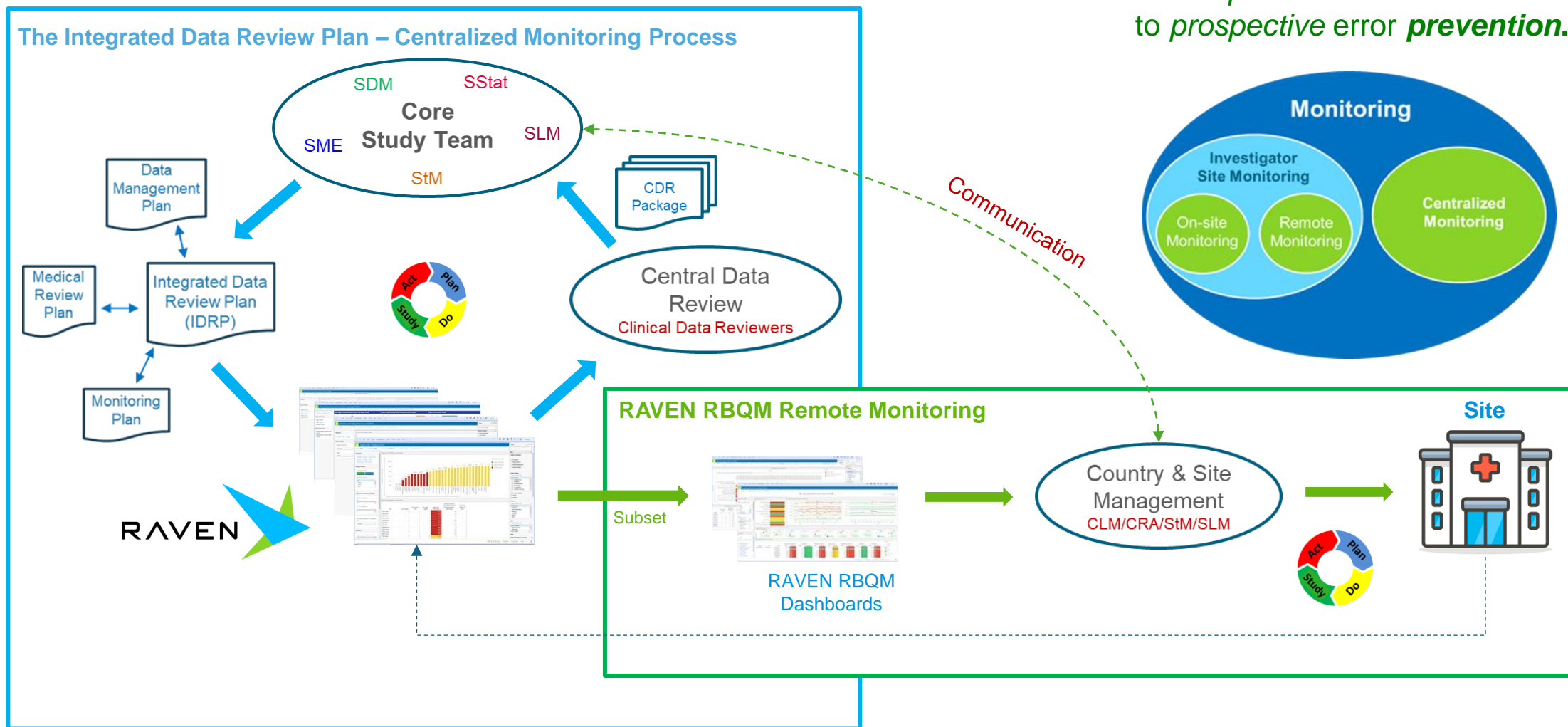




RBQM in CDM – the journey so far

The link between Centralized Monitoring & Remote Monitoring

Emphasis is shifting from *retrospective error correction* to *prospective error prevention*.





RBQM in CDM – the journey so far

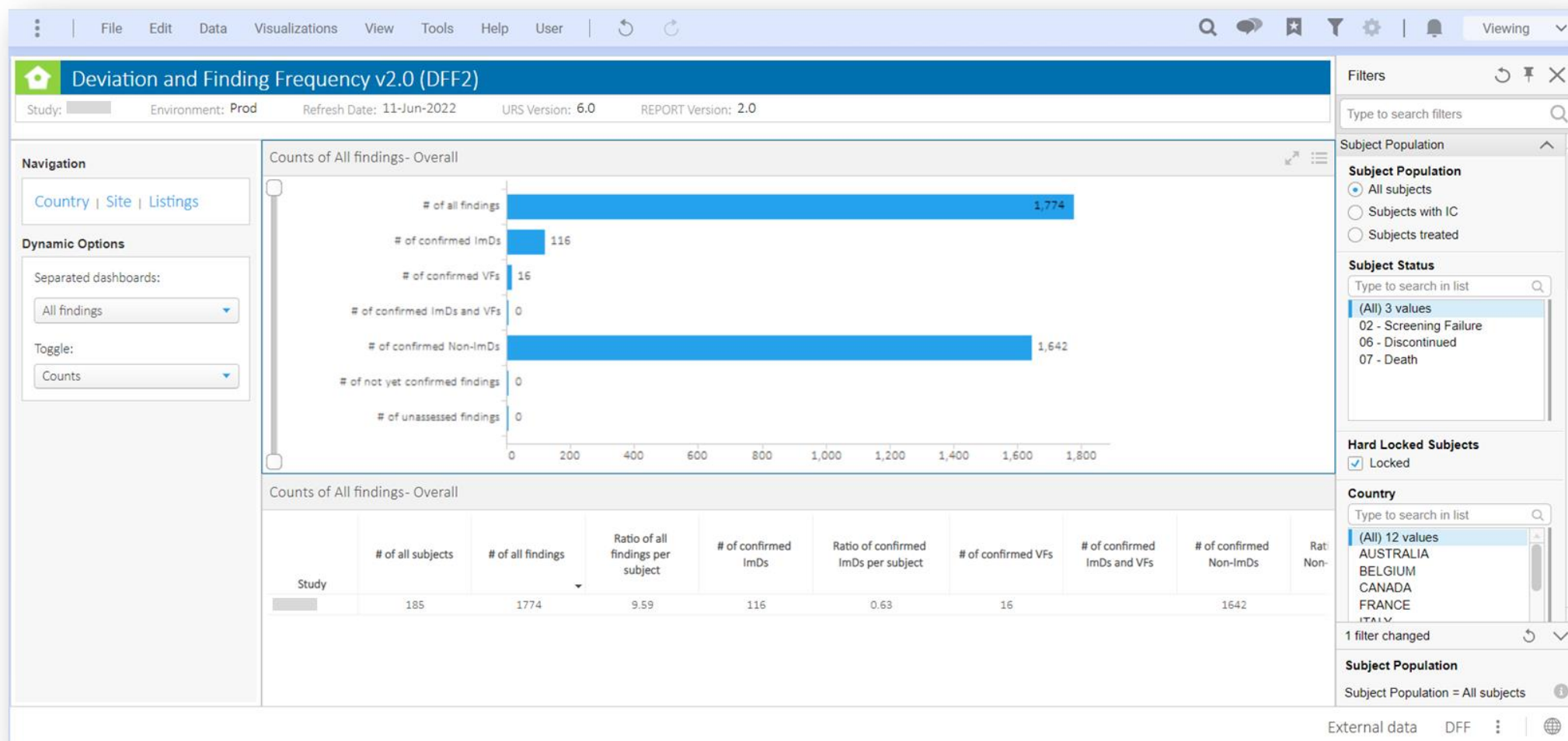
Ongoing Site Risk leveling Dashboard





RBQM in CDM – the journey so far

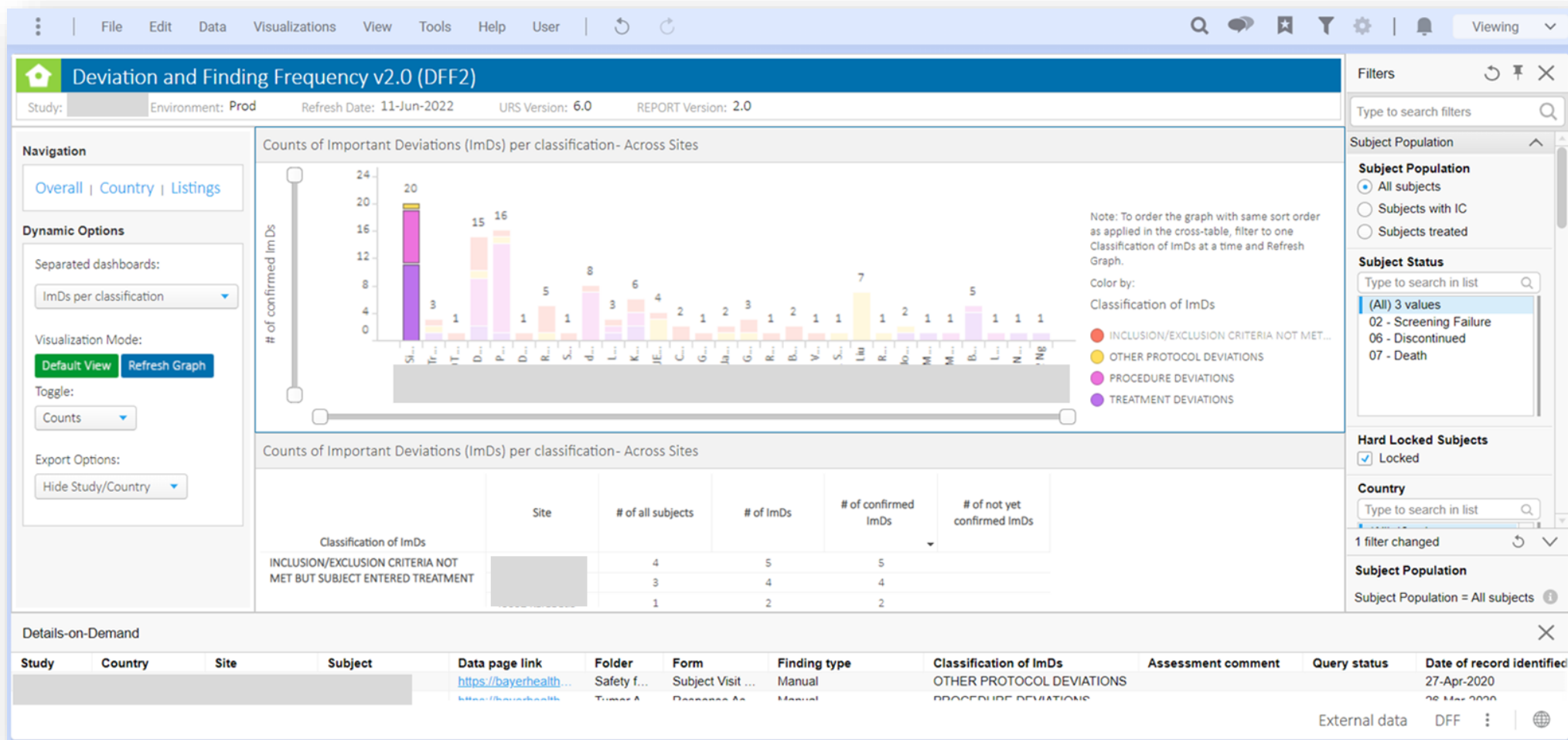
Protocol Deviations & Validity Findings at Study level





RBQM in CDM – the journey so far

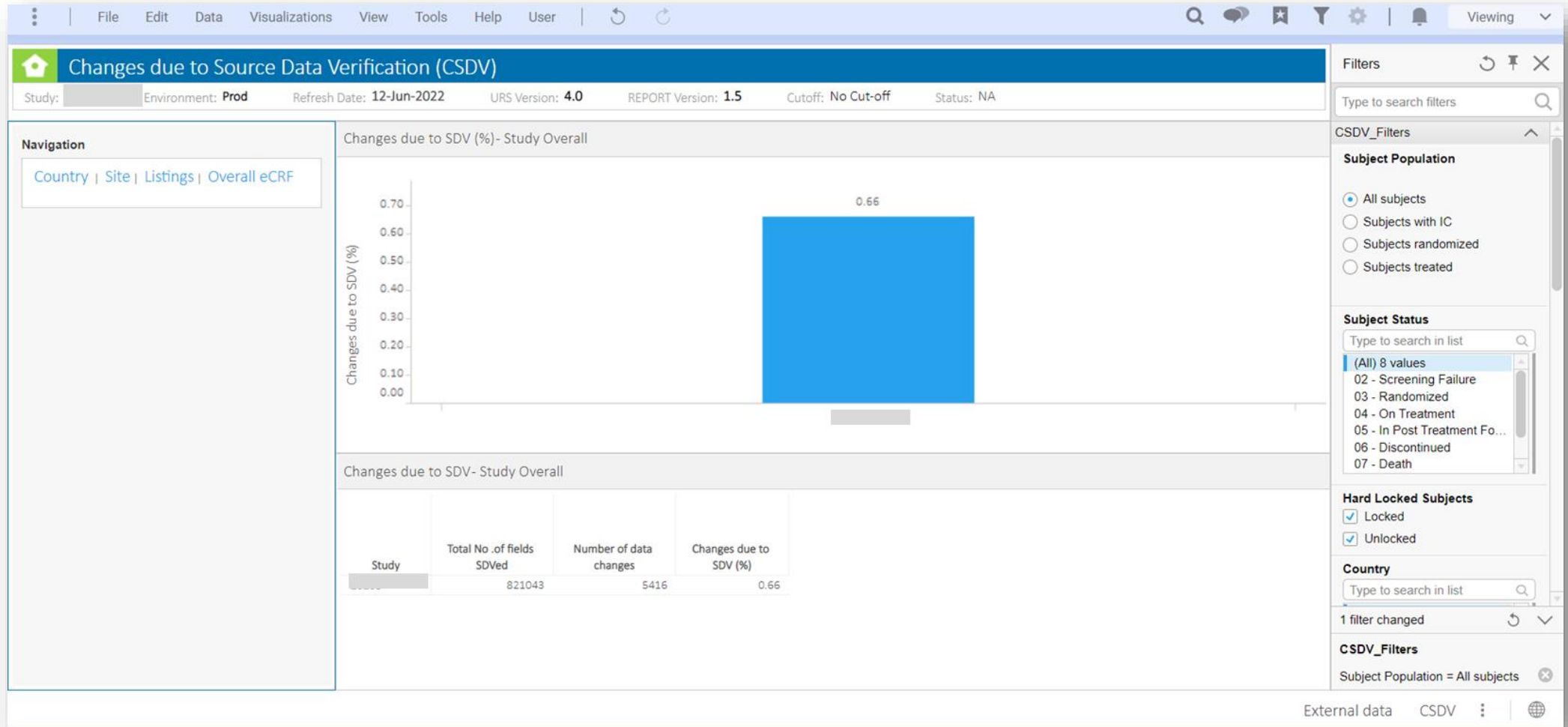
Protocol Deviations & Validity Findings: beginning of a Root Cause Analysis





RBQM in CDM – the journey so far

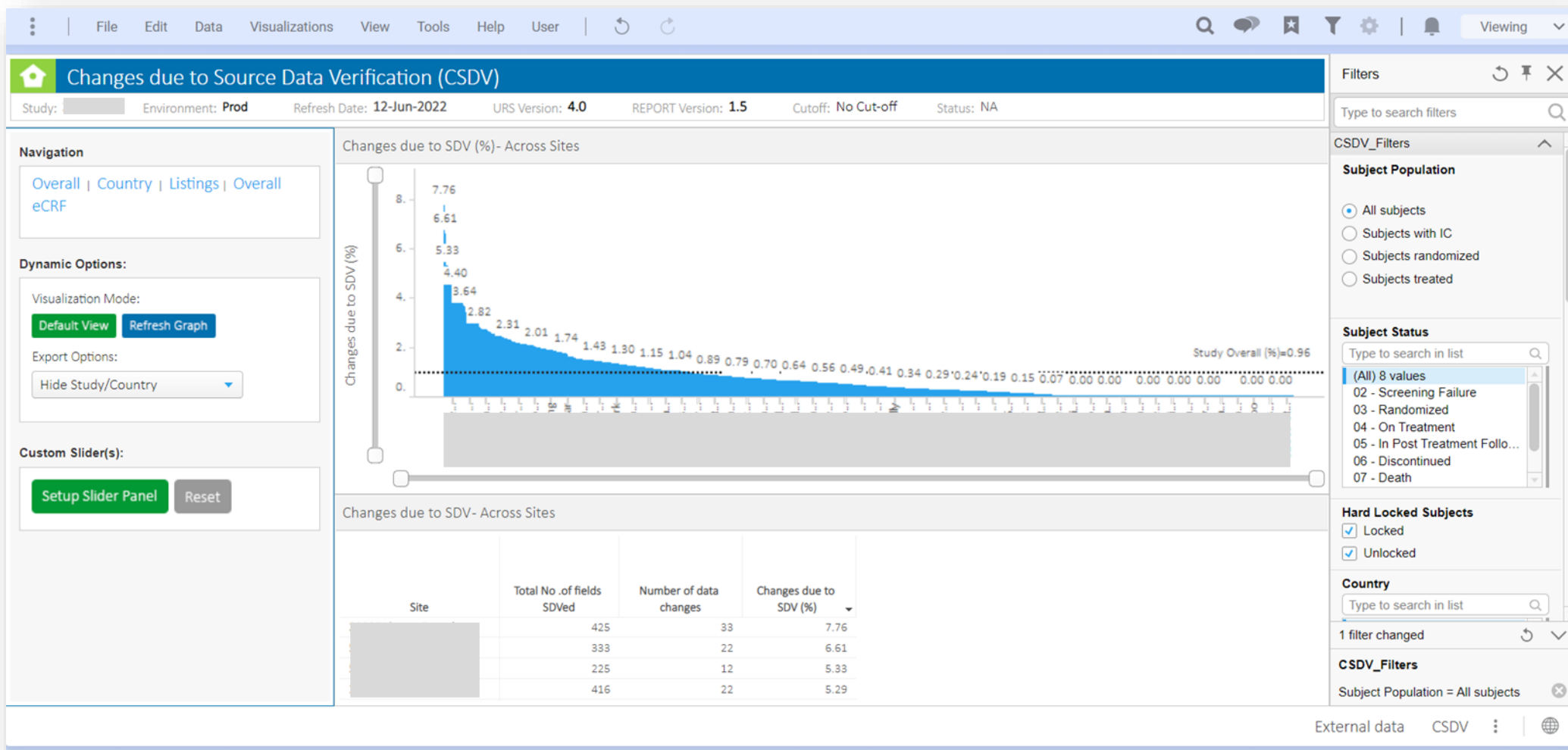
Changes Due to SDV: at study level





RBQM in CDM – the journey so far

Changes Due to SDV: at site level





RBQM in CDM – the journey so far

Example of IMPALA consortium collaboration: Clinical Trial Anomaly Spotter (CTAS)

- // Identifies site and subject level time series anomalies
- // Started in 2022 as Time Series Outlier & Anomaly at Bayer
- // Since July 2023, co-developed within the IMPALA consortium as Central Statistical Monitoring (CM) tool

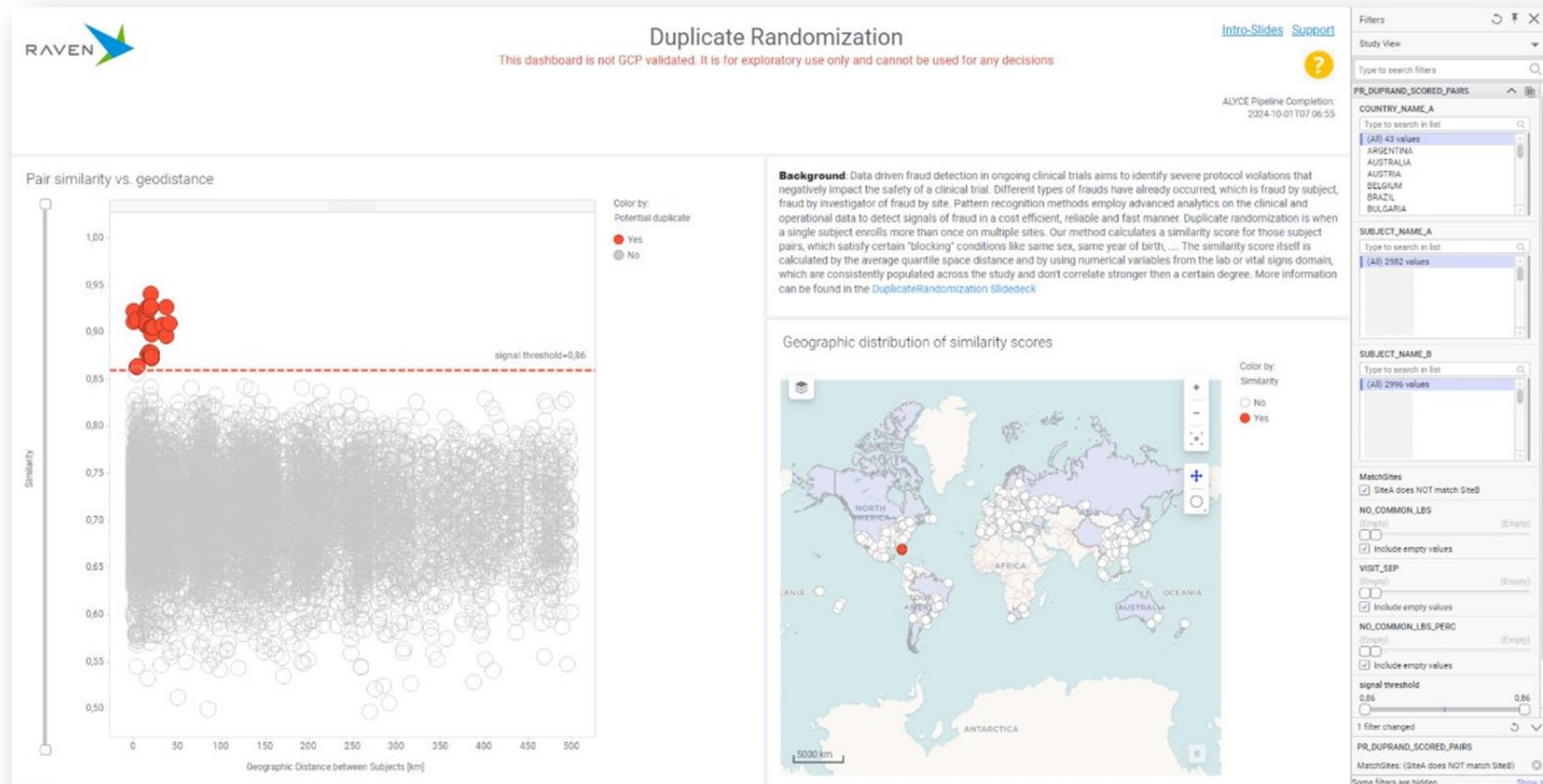




RBQM in CDM – the journey so far

Duplicate Randomization Report ('two' study participants are actually *the same person*)

- // Pair-wise comparison of in-database-fingerprint (based on DM, VS, LB)
- // Helps identifying potential duplicate randomizations

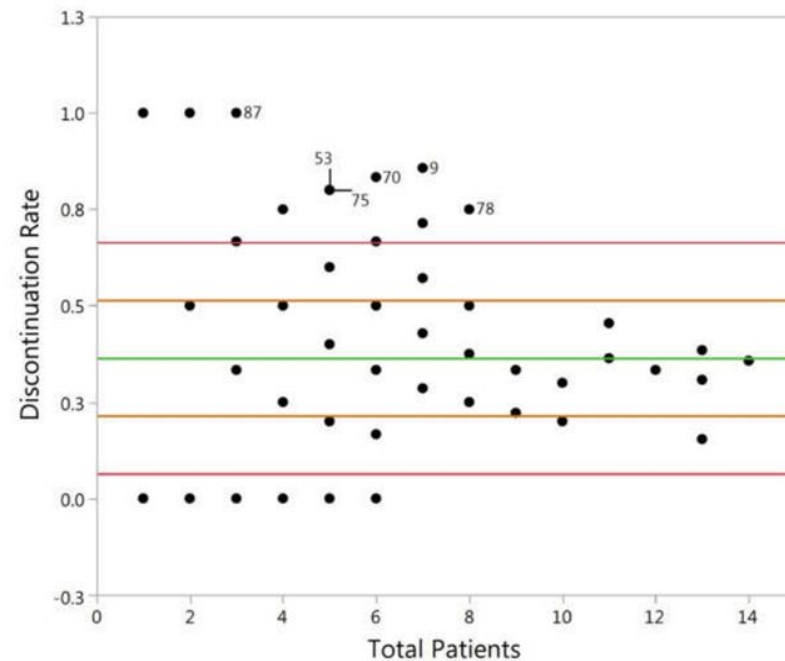




RBQM in CDM – the journey so far

Good Statistical Monitoring (GSM) applied to OsRL & CM dashboards

- // Ongoing site Risk Leveling (OsRL)/Central Monitoring (CM) dashboards: Bayer's brainchild => inhibiting lead
- // Gilead Sciences: Good Statistical Monitoring (GSM) Open-Source R Package
- // PHUSE RBQM Working group: pre-competitive cross company collaboration.
- // Standardized calculations & visualizations (funnel visualization, data pipelines, extensive framework for testing/validation)

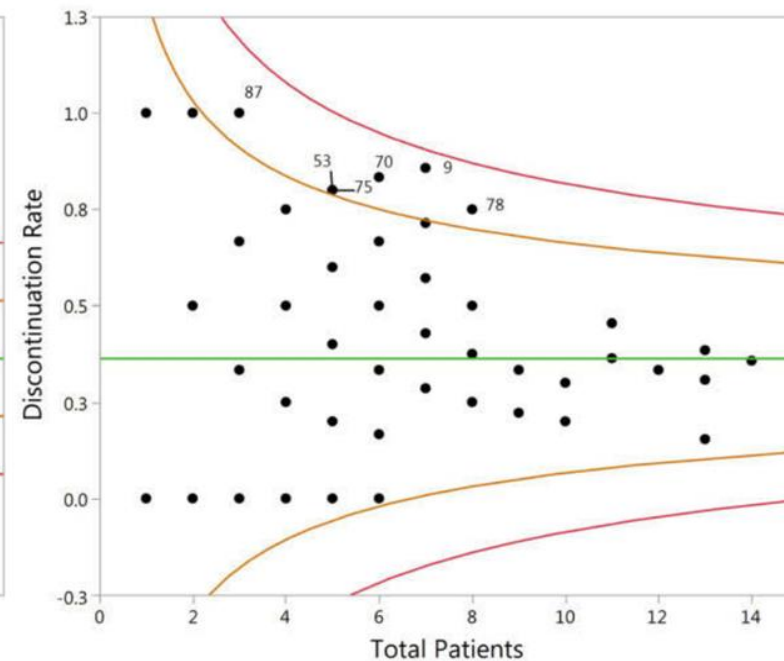


Constant Limits (Absolute)

Overall: 36.4%

Moderate Limits (Yellow): 36.4% ± 15.0%

Severe Limits (Red): 36.4% ± 30.0%



Statistical Limits

Moderate: 36.4%

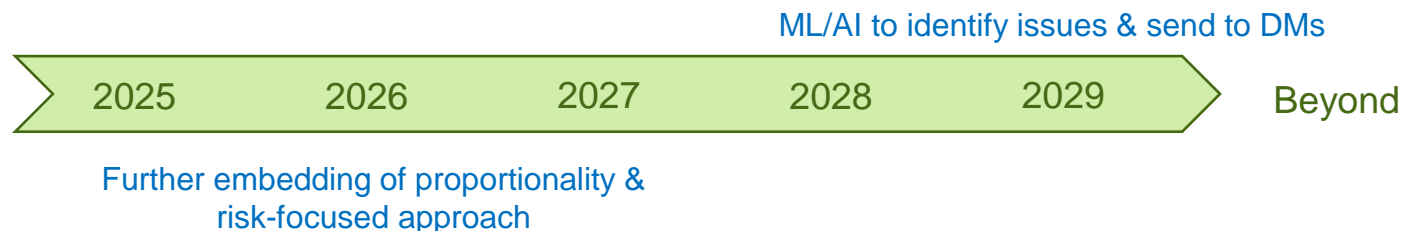
Moderate Limits (Yellow): 95% Confidence Interval

Severe Limits (Red): 99.7% Confidence Interval



RBQM in CDM – the journey so far

What's next?



=> 'Critical Thinking'

// 2025-2027: Further embed risk-focused/proportional approach in clinical development culture:

- // More explicit cross-functional CTQ assessment
- // 'Data Parsimony'
- // Continued focus on systemic issues rather than individual errors - preventive rather than corrective

// 2025-2029: Use ML/AI to identify issues & send to DMs

CTQ RISK IDENTIFICATION	
Critical to Quality Category	CtQ Factor related to:
1. Protocol Design & Maintenance	1.1 Eligibility Criteria
	1.2 Endpoints
	1.3 Randomisation
	1.4 Masking/ Blinding
	1.5 Controls
	1.6 Data Quantity 'Data Parsimony'
	1.7 IMP Handling & Administration
	1.8 Procedures & Tests
2. Data Integrity	2.1 Validation
	2.2 Security
	2.3 Access Management
	2.4 Data Privacy
	2.5 Audit trails
	2.6 End-to-end dataflow reliability
3. Feasibility	3.1 Study & Site Feasibility
4. Participant Safety	4.1 Signal Detection & Safety Reporting
	4.2 DMC/ Stopping Rules
	4.3 Informed Consent: Process
	4.4 Informed Consent: Information
5. Study Conduct	5.1 Training
	5.2 Data Recording & Reporting
	5.3 Data Monitoring
	5.4 Data Management
	5.5 Statistical Analysis
6. Study Reporting	6.1 Dissemination of Study Results
7. Third Party Engagement	7.1 Delegation of Sponsor Responsibilities/ Sponsor Oversight
	7.2 Collaborations
8. Technology	8.1 Digital Healthcare Technologies
	8.2 Advanced Analytics
	8.3 Real World Data

Health for all, Hunger for none



Thank you!

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