

ENGAGE 2026

WHEN ?

Monday, October 12 –
Wednesday, October 14

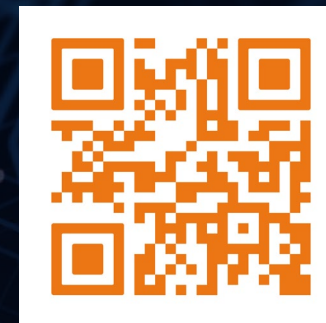
WHERE ?

W Philadelphia
1439 Chestnut St,
Philadelphia, PA 19102

WHAT ?

ENGAGE is our **annual conference** where we will explore the latest advancements in AI-driven automation, Agentic AI and data analytics to accelerate clinical trials.

HOW ?



Scan to register

Questions about ENGAGE 2026? Contact marketing@eclinicalsol.com

illuminate 26.2

Lisa Clough

October 01, 2026

Thank you for joining. We
will be starting shortly.



Agenda

1

Overview of
26.2 illuminate
Release

2

- Study Advisor
- Risk Management
- Data Central
- Apps Hub + Posit Shiny
- Sample Management Analytics

3

Questions

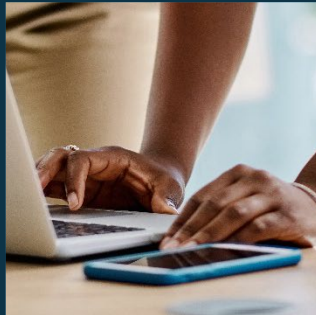
Questions





26.2 Highlights

- *Study Advisor*



Study Advisor

AI-powered Study Advisor uses the Study Protocol to streamline study set up and review planning by centralizing study documents, extracted study detail, and Review Objective recommendations.

It can:

- Create studies from an uploaded **Study Protocol** (PDF/DOCX)
- Extract key configuration fields and push them into Study Configuration
- Manage protocol documents and versions
- Suggest and manage Review Objectives for review planning
- Feed protocol context to Data Advisor for smarter analyses

Study Advisor helps teams move from
Protocol to Configured Study and Actionable Review Plans
with less manual effort, while maintaining **human review** and **control** throughout the process.

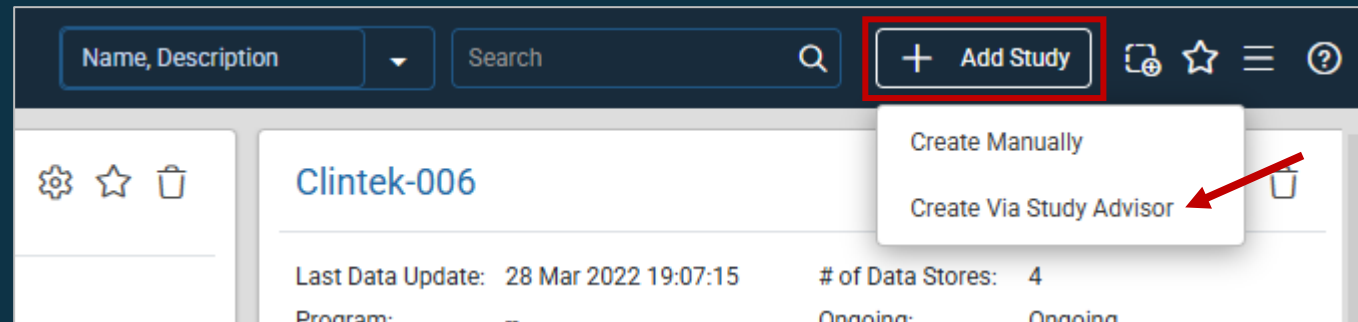


Study Advisor

Required Privileges for new study creation

Administer

Study Configure



Study Advisor

- Extracts key information to populate the Configuration tab.
- Any configuration items not already defined within elluminate can easily be added.
- Review, edit, confirm / save.

Add Study

Configuration

Standards

Dictionaries

Settings

ETL

✱ Study Name: ⓘ

AOC 1001-CS2

✱ Compound: ⓘ

Required

Suggested: AOC 1001

Add to Configuration

✱ Description: ⓘ

MARINA-OLE (AOC 1001-CS2) is a Phase 2 open-label extension study sponsored by Avidity Biosciences to evaluate the long-term safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of AOC 1001 administered intravenously to adult patients with Myotonic Dystrophy Type 1 (DM1). All participants who completed the prior Phase 1/2 randomized, placebo-controlled AOC 1001-CS1 study are eligible to

✱ Phase: ⓘ

Phase II

✱ Indication: ⓘ

Myotonic Dystrophy Type 1 (DM1)

✱ Therapeutic Area: ⓘ

Neurology

Program: ⓘ

Select...

Program Type: ⓘ

☐ Randomized ☐ Stratified

✱ Blinding: ⓘ

Open Label

✱ Control: ⓘ

None

✱ Study Type: ⓘ

Interventional

✱ Primary Endpoint: ⓘ

safety profile determination

Suggested: Number and severity of treatment-emergent adverse events (AEs)

Add to Configuration

Healthy Subjects: ⓘ

☐ Yes ☒ No

Cancel

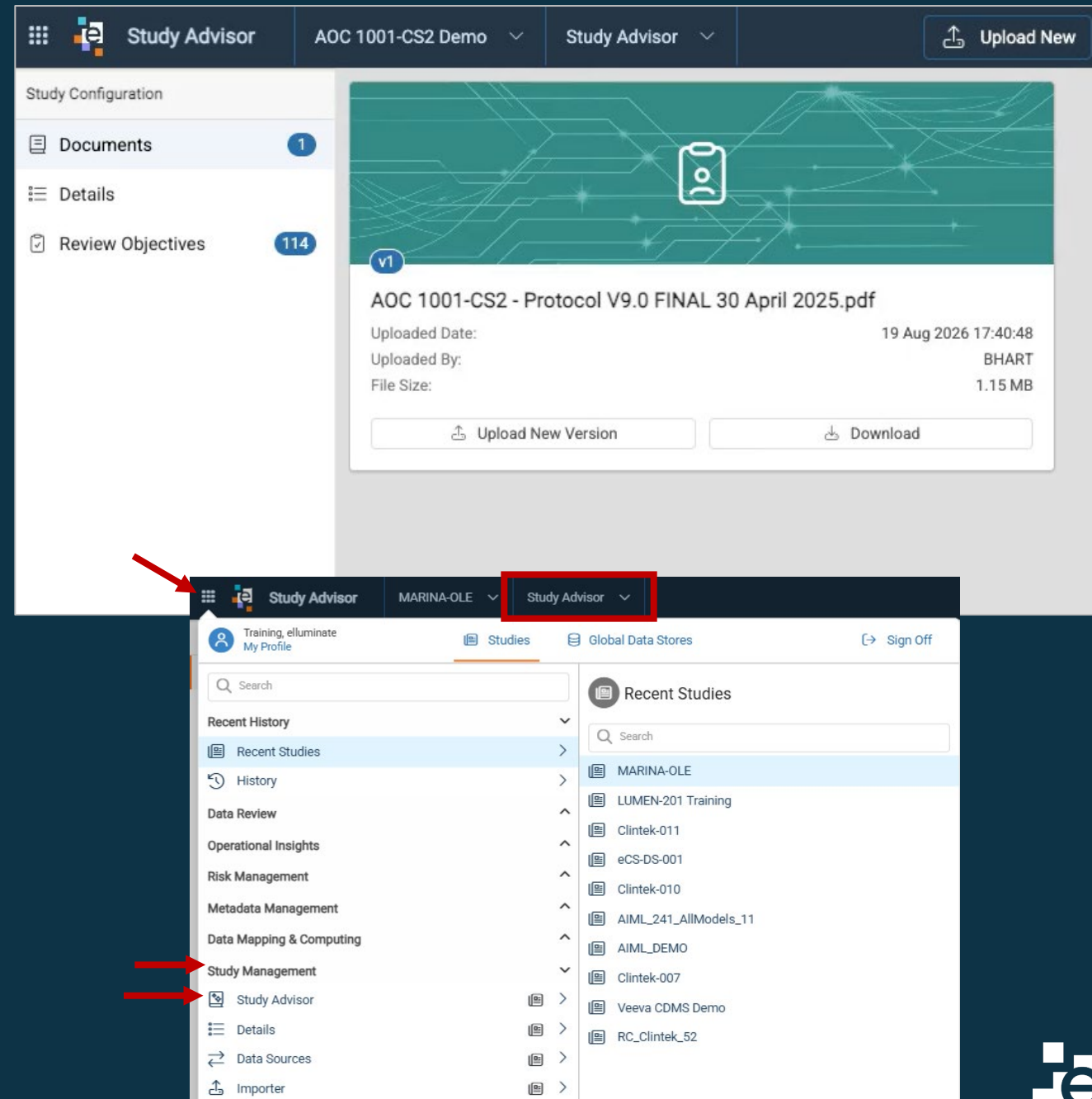
Save as Template

Save



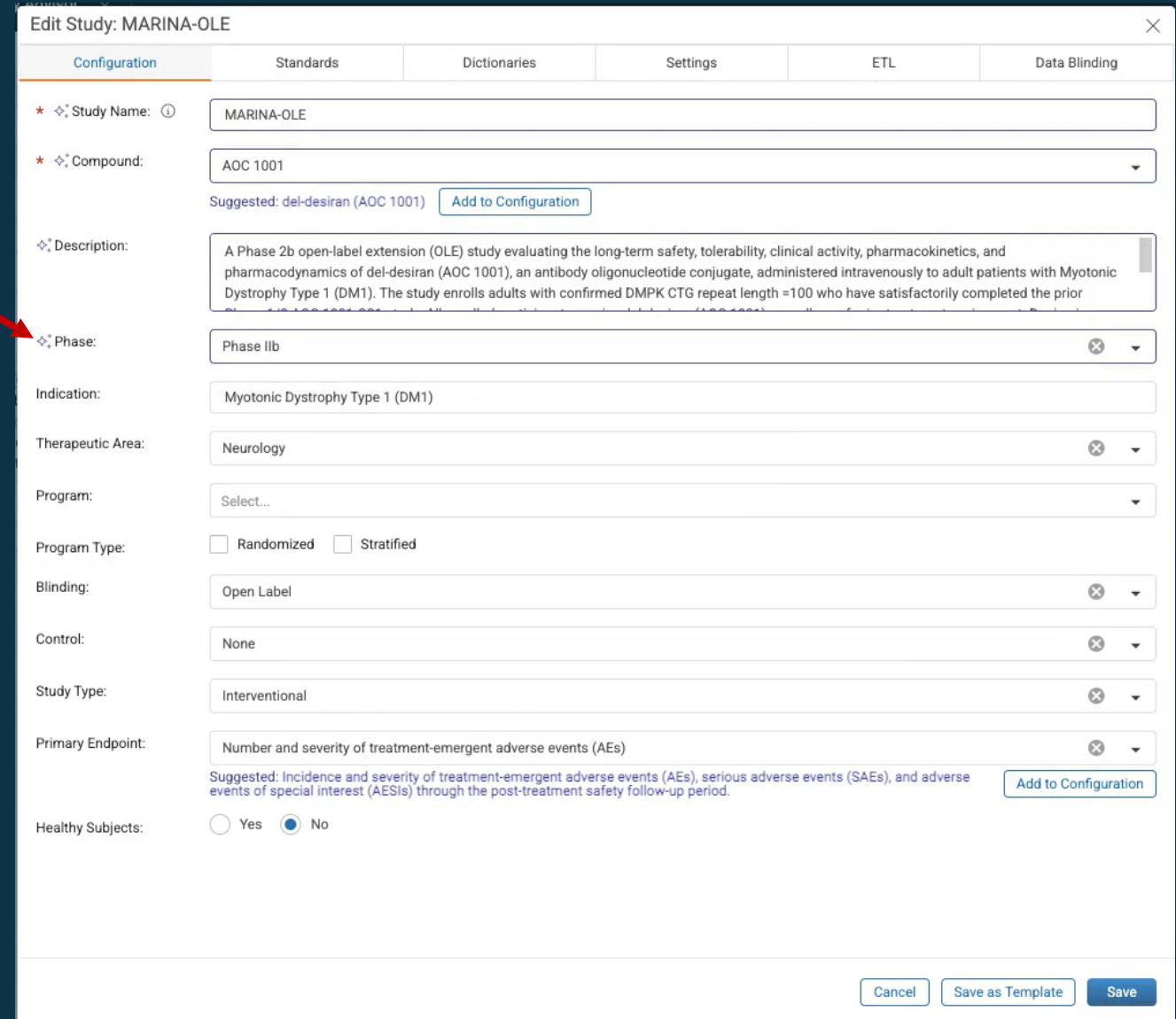
Study Advisor

- Document management is handled from the Study Advisor section of elluminate.
- Users with the following privileges can upload new versions of the protocol as well as other study documents:
 - Administer
 - Study Configure
 - eDrive Read Write



Study Advisor

- When a new version of the protocol is uploaded, you can push the extracted information to study configuration – any new information is identified by a sparkle icon.
- Review and edit as needed and then save.



Edit Study: MARINA-OLE

Configuration Standards Dictionaries Settings ETL Data Blinding

★ ✦ Study Name: ① MARINA-OLE

★ ✦ Compound: AOC 1001
Suggested: del-desiran (AOC 1001) [Add to Configuration](#)

✦ Description: A Phase 2b open-label extension (OLE) study evaluating the long-term safety, tolerability, clinical activity, pharmacokinetics, and pharmacodynamics of del-desiran (AOC 1001), an antibody oligonucleotide conjugate, administered intravenously to adult patients with Myotonic Dystrophy Type 1 (DM1). The study enrolls adults with confirmed DMPK CTG repeat length ≥100 who have satisfactorily completed the prior

✦ Phase: Phase IIb ✕

Indication: Myotonic Dystrophy Type 1 (DM1)

Therapeutic Area: Neurology ✕

Program: Select...

Program Type: ☐ Randomized ☐ Stratified

Blinding: Open Label ✕

Control: None ✕

Study Type: Interventional ✕

Primary Endpoint: Number and severity of treatment-emergent adverse events (AEs) ✕
Suggested: Incidence and severity of treatment-emergent adverse events (AEs), serious adverse events (SAEs), and adverse events of special interest (AESIs) through the post-treatment safety follow-up period. [Add to Configuration](#)

Healthy Subjects: ☐ Yes ☒ No

[Cancel](#) [Save as Template](#) [Save](#)

Study Advisor

Study Advisor

AOC 1001-CS2 Demo

Study Advisor

Review Plan

Study Configuration

Global Library Suggestions 18 0 0

Study Document Suggestions 100 0 0

Documents 2

Details

Review Objectives 118

Viewing Protocol v2 (Current)

Search

Q

✓

✕

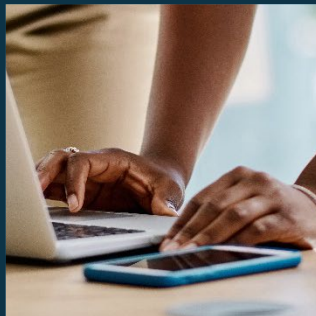
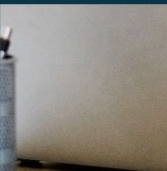
☐	Identifier	Review Objective	Status	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Risk(s)	Reviewer Role(s)	Programmatic Review
☐	1	If AE Action Taken is drug withdrawn, ou...	Pending Review	Clinical.AE	Exception Listings.SLP	Clinical.AE.AEACN	High		Data Manager, Medical Data Reviewer	Weekly
☐	1	If AE Action Taken is drug withdrawn, ou...	Pending Review	Clinical.AE	Exception Listings.SLP	Clinical.AE.AEACN	High		Data Manager, Medical Data Review...	Weekly
☐	2	AE Serious response is Yes, 'Results in D...	Pending Review	Clinical.AE		Clinical.AE.AEOUT, Clinic...	Medium	CTQ: Safety ID: 05 Score: 700 Control: Mitigate Desc...	Data Manager, Medical Data Review...	Weekly
☐	3	Review AE Term, CTCAE Grade, Start Dat...	Pending Review	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium	CTQ: Safety ID: 06 Score: 900 Control: Mitigate Desc...	Data Manager, Medical Data Reviewer	Monthly
☐	5	1. Ensure there is no AE, Conmed, Conm...	Pending Review	Clinical.AE	Clinical.CM		Medium		Data Manager	Weekly
☐	6	If Other Action Taken = Concomitant Me...	Pending Review	Clinical.AE	Clinical.CM	Clinical.AE.AEACN, Clinic...	High		Data Manager, Medical Data Reviewer	Monthly
☐	8	Random one with all review materials wi...	Pending Review	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEONGO, Clini...	High		Data Manager, Medical Data Review...	Weekly
☐	10	1. Ensure there is no AE, Conmed, Conm...	Pending Review	Clinical.CM	Clinical.AE, Clinical.CM, C...		Medium		Data Manager, Medical Data Review...	Weekly
☐	14	Ensure there is no visit dates, conmeds, ...	Pending Review	Clinical.AE	Clinical.CM, Clinical.DS		Medium		Data Manager	Weekly
☐	15	Random one with all review materials wi...	Pending Review	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEONGO, Clini...	High		Data Manager, Medical Data Review...	Weekly
☐	CDM_001	Purpose: Reconcile Biomarker sample h...	Pending Review	Clinical.BE			☐ Primary ...		Data Manager	Monthly
☐	CDM_001	Purpose: Reconcile Biomarker sample h...	Pending Review	Clinical.BE			☐ Primary ...		Data Manager	Monthly
☐	CDM_004	Purpose: Cross check between the Deat...	Pending Review	Clinical.DS	Clinical.AE		☐ Safety		Data Manager	Monthly
☐	CDM_005	Purpose: Cross Check Death across all t...	Pending Review	Clinical.DS	Clinical.AE, Clinical.DS		☐ Safety		Data Manager	Monthly
☐	CDM_006	Purpose: Review data recorded in 'Specif...	Pending Review	Clinical.DS			☐ Particip...		Data Manager	Monthly
☐	Risk-3	Assess adherence to dosing and assess...	Pending Review	Reporting.EX		Reporting.EX.EXDOSE, Re...	Medium	CTQ: Data Accuracy ID: 01 Score: 280 Control: Mitig...	Data Manager	Weekly
☐	SM_001	Verify pregnancy status and contracepti...	Pending Review	Clinical.SUBJ	Clinical.PE	Clinical.SUBJ.SUBJECTID...	High		Site Monitor	Daily
☐	SM_002	Confirm subjects are not enrolled in anot...	Pending Review	Clinical.IE		Clinical.IE.IEYN, Clinical.I...	High		Site Monitor	Daily





26.2 Highlights

- *Risk Management*



RBQM

- Root Cause Analysis Dashboard added to support KRI investigation workflows
- Accessed from a site KRI – click **Go to Root Cause Analysis** at the panel at the right

RBQM

Overview

Sites 90

Countries 19

Trial Level Risks

KRIs

Sites

Countries

Study Report

Risk Signals

Profiles

Sites 90

Countries 19

RBQM Snapshot

05 May 2026 13:42:13 - Late...

Site ID	Subjects	Country	Site Score	Data Integrity		Data Quality		Safety	
				DENTRY	QUERY_RT	SBPRT	AE_ENTRY	DBP_CSM	
978	3	BE	2	259	0	2	303	2	
709	2	DE	2	190	0	No Data	453	No Data	
3	8	US	1.8	362	1	2	8	2	
987	19	BE	1.8	672	1	2	137	2	
102	2	IL	1.8	213	1	2	82	2	
64	1	US	1.8	134	0	2	213	2	
5	16	US	1.8	1040	1	2	115	2	
2603	2	IN	1.6	18	0	2	15	2	
592	3	FR	1.6	197	0	2	234	0	
688	2	GB	1.6	53	0	2	94	2	
602	6	GB	1.6	948	0	2	790	0	
670	9	GB	1.6	394	0	2	28	0	
47	1	US	1.6	6	0	2	75	2	
8806	2	PL	1.6	32	0	2	187	2	
8307	1	AU	1.6	0	0	2	24	2	
986	2	BE	1.6	547	0	2	73	0	
48	1	US	1.6	22	0	2	364	2	
485	5	ES	1.6	981	0	2	127	0	
2686	1	IN	1.6	98	1	2	68	2	
678	2	GB	1.6	199	0	0	22	2	
539	7	FR	1.6	85	1	2	125	2	
532	8	FR	1.6	89	1	2	162	2	
490	4	ES	1.6	46	0	2	11	2	

KRI Details

Trial Level Risks

QUERY_RT (QUERY_RT for Site 688)

Description

Rate of Queries

Risk Levels

KRI Score for Site 688

Score Trend for Site 688

Median KRI Score across Sites

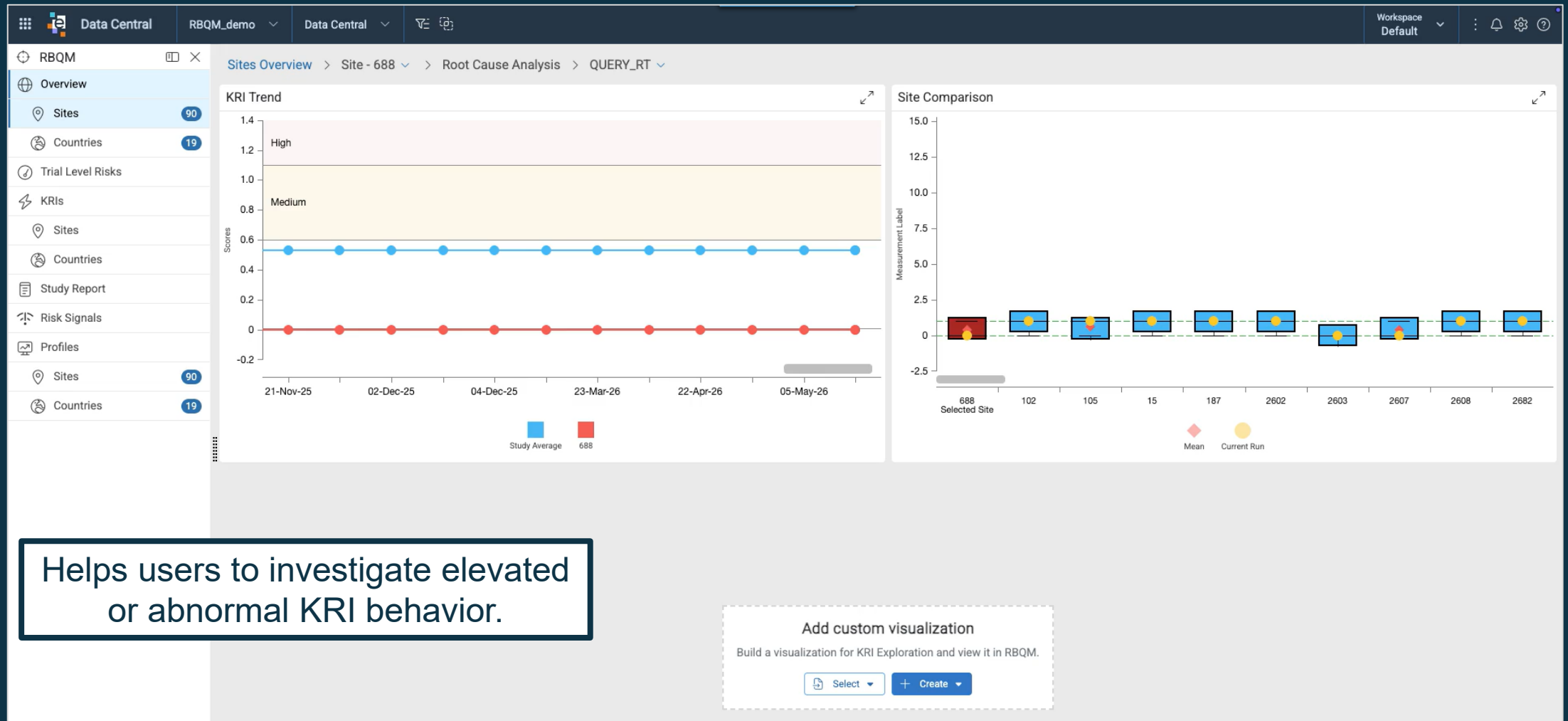
Average KRI Score across Sites

Recommendation

Go to Root Cause Analysis →

RBQM

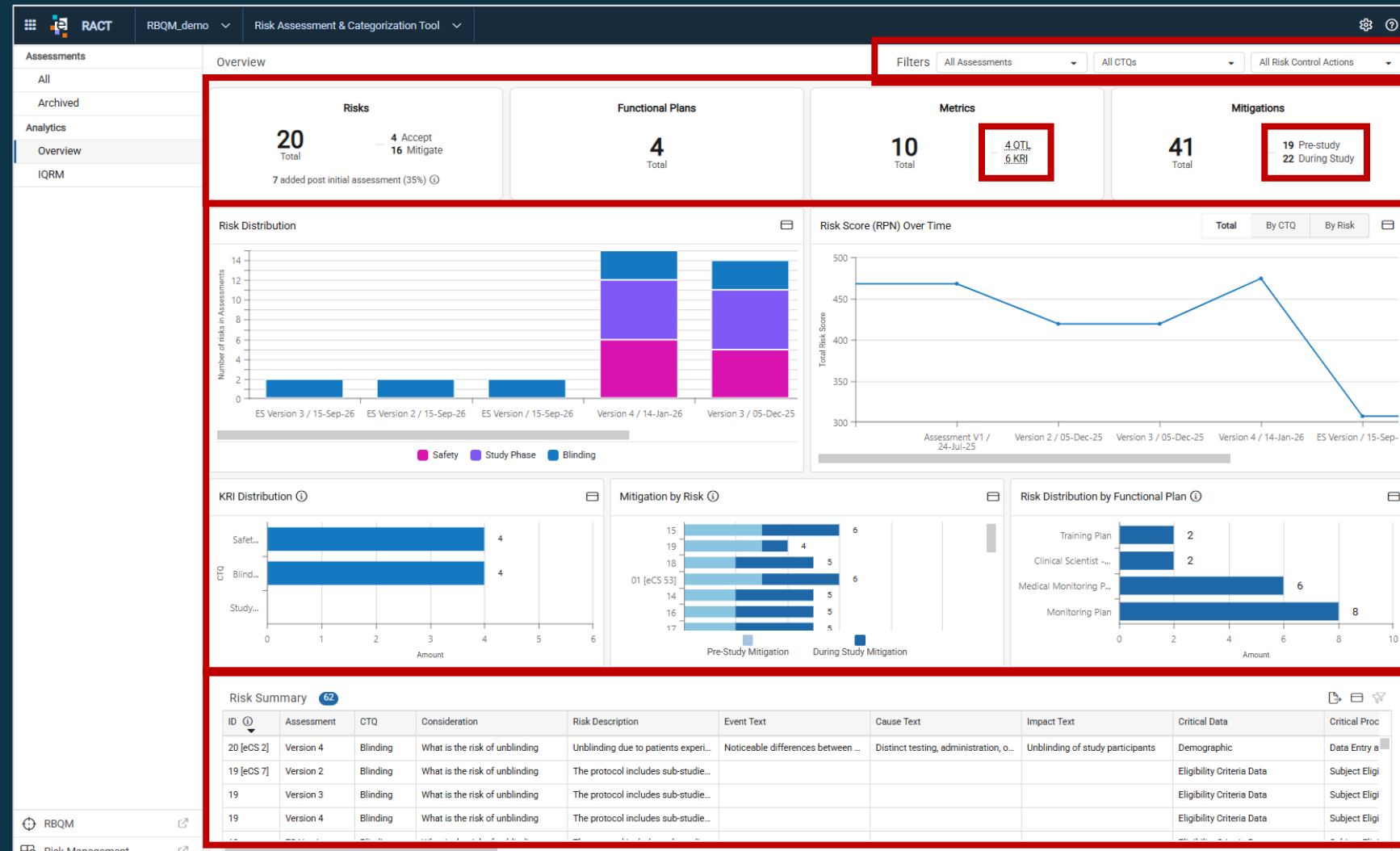
- Includes KRI Trend and Site Comparison charts, as well as the ability to add or create custom charts



RACT

A new Risk Analytics Overview Page was added. This provides:

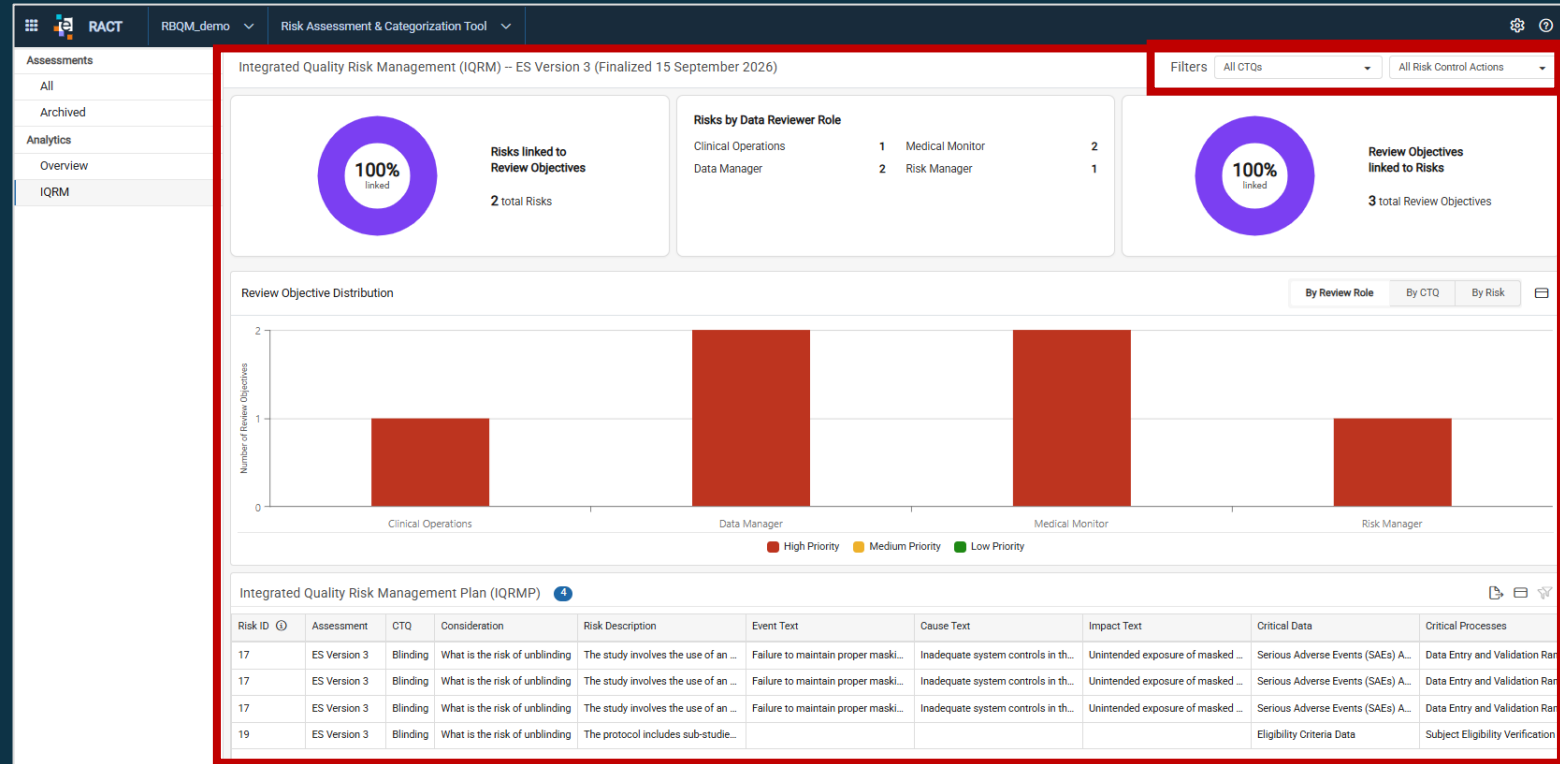
- A centralized study-level view of risk performance across finalized assessments
- Summary cards show risks, functional plans, metrics, and mitigations.
- Charts to help users monitor risk trends, mitigation activity, and risk distribution
- Exportable Risk Summary table



RACT

An IQRM page has been added under Analytics:

- Provides a consolidated view of how study risks align with IDRP review objectives.
- Metrics, charts, and an IQRM Plan help to evaluate risk coverage, review objective alignment, reviewer responsibilities, and overall risk management priorities.
- Filters and Exporting available.



RACT

- A Create Reassessment button was added giving Risk Managers the option to continue from a previously finalized assessment. This allows users to select a finalized assessment to use as the basis for the reassessment.
- The Create Assessment button was changed to Create New Assessment.

RACT RBQM_demo Risk Assessment & Categorization Tool									
Assessments	Assessment Versions 8						Create Reassessment	Create New Assessment	Archive Compare
All	Version	Status	Setting	Description	Start Date	Start User	Finalize Date	Finalize User	Total Risks
Archived	Draft	In Progress	Default xx (V1)		28 Sep 2026 09:14:14	VPOMERANTSEVA			2
Analytics	ES Version 3	Finalized	Default xx (V1)		15 Sep 2026 13:23:45	eshortell	15 Sep 2026 13:27:36	eshortell	2
Overview	ES Version 2	Finalized	Default xx (V1)		15 Sep 2026 13:13:06	eshortell	15 Sep 2026 13:14:47	eshortell	2
IQRM	ES Version	Finalized	Default xx (V1)		15 Sep 2026 10:58:16	eshortell	15 Sep 2026 13:13:05	eshortell	2
	Version 4	Finalized	Default (V1)		05 Dec 2025 09:07:02	JYAN	14 Jan 2026 13:34:58	BREINHARDT	15
	Version 3	Finalized	Default (V1)		05 Dec 2025 09:05:22	JYAN	05 Dec 2025 09:07:02	JYAN	14
	Version 2	Finalized	Default (V1)		24 Jul 2025 14:04:36	BREINHARDT	05 Dec 2025 09:05:21	JYAN	14
	Assessment V1	Finalized	Default (V1)		12 Apr 2023 14:06:55	JYAN	24 Jul 2025 14:04:35	BREINHARDT	13



RACT

- For each Risk Card, users can now move a Risk from one Consideration to another within the same Assessment.

View All RisksView IncompleteDocumentationReview and ApprovalComments & Activities 1Add Risk

Blinding

What is the risk of unblinding

✓ Score: 28 Accept

The study involves the use of an EDC system that may result in unmasking of masked data

Impact	Likelihood	Detectability
High Medium (7)	Low Medium (4)	Extreme High (1)

✓ Score: 280 Mitigate

The protocol includes sub-studies that could result in difficult adherence to procedure

Impact	Likelihood	Detectability
Extreme High (10)	Low Medium (4)	Low Medium (7)

Filter...

Adverse Events and Subject Safety

AE documentation

Dose limiting toxicities

General Risk(s)

Blind test

General Risk(s)

Blinding

Blinding Description

Blinding Assignment Tech

CancelMove Risk



RACT

- Two system defined CTQs were added to assessment settings and active RACT assessments: Study Specific and Unaffiliated.
- Provides a standardized way to capture study-specific Risks and Risks that do not align with an existing CTQ.

 Study Specific	
 C1: Study Specific Risk(s)	 0
 Unaffiliated	
 C1: Unaffiliated Risk(s)	 0

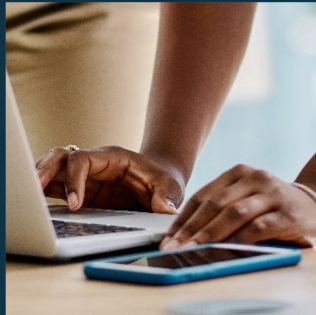
- Because they are system defined, they cannot be modified.





26.2 Highlights

- *Data Central*



Data Central - Configuration

New authentication configuration options for Veeva CDMS studies was added.

- For Veeva studies, a new Query Authentication Control section displays to include Use User Credentials, User Stored Credentials, User SSO Only, Use Mixed Authentication.
- Added an SSO Client ID field that is available only when Use SSO Only or Use Mixed Authentication is configured for the OAuth 2.0 OpenID Connect application in Veeva CDS an associated SSO identity provider

Query Authentication Controls:

☐ Use User Credentials

☐ Use Stored Credentials

☐ Use SSO Only

☒ Use Mixed Authentication

SSO Client ID:

Client ID is required for SSO enabled Query configuration.

☐ Append illuminate username to all query text



Data Central – Review Plan Configuration

Review Plan:

The option to add Relevant Review Materials was added.

Add Review Objective (v1) Configuring 16/16

*** Identifier:**

*** Review Objective:** 5000/5000

*** Primary Domain:**

Secondary Domain(s):

Field(s):

Priority:

Risk(s):

*** Reviewer Role(s):**

*** Programmatic Review Frequency:**

*** Manual Review Frequency:**

Programmatic ⓘ

Data Central Listing(s):

eIQ Review Model:

Orchestrator Rule:

Manual ⓘ

Data Central Visualization(s):

Data Central Workspace:

Analytics App:

App Sheet(s):

RBQM Dashboard:

External Material(s): 2500/2500

Additional Instructions:

State: ⓘ ☐ Inactive

Relevant Review Materials ⓘ Comments & Activity ⓘ

Review Materials systematically tracked and factor into the Objective Status.

Review Materials not systematically tracked but factor into the Objective Status.

Cancel Save & Submit For Approval Save



Data Central – Review Plan Configuration

Add Review Objective (v1) Configuring

10/16

4927/5000

★ Identifier: ⓘ

RO1234

★ Review Objective:

Confirm that any TG less than three but identified as an SAE is accurate.

★ Primary Domain: ⓘ

Clinical.AE

Secondary Domain(s): ⓘ

Select...

Field(s): ⓘ

Select...

Priority:

Select...

Risk(s):

Select...

★ Reviewer Role(s):

Data Manager

★ Programmatic Review Frequency:

Weekly - Wednesdays @ 00:00, Starting 30 Sep 2026

★ Manual Review Frequency:

Weekly - Wednesdays @ 00:00, Starting 30 Sep 2026

Programmatic ⓘ

Review Materials systematically tracked and factor into the Objective Status.

Data Central Listing(s):

Select...

eIQ Review Model:

Select...

Orchestrator Rule:

Select...

Manual ⓘ

Review Materials not systematically tracked but factor into the Objective Status.

Data Central Visualization(s):

Select...

Data Central Workspace:

Select...

Analytics App:

Select...

App Sheet(s):

Select...

RBQM Dashboard:

Select...

External Material(s): ⓘ

Select...

Additional Instructions:

Enter additional instructions

State: ⓘ

☐ Draft

2500/2500

Relevant Review Materials

Comments & Activity 0

Based on the Review Objective details, we've identified 29 relevant Review Materials.

● Pending: 29

● Accepted: 0

● Rejected: 0

AE Tox Listing

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

AEOutcome2

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

aesev by ser

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

aesev by seriousness

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

AEToxGrade2

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

Clinical.AE

Medium Match

Data Central Listing

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

Combo AEREL - Ethnicity

Medium Match

Data Central Visualization

Cancel

Save & Submit For Approval

Save



Data Central – Review Plan Configuration

Add Review Objective (v1) Configuring

10/16

4927/5000

★ Identifier: ⓘ

RO1234

★ Review Objective:

Confirm that any TG less than three but identified as an SAE is accurate.

★ Primary Domain: ⓘ

Clinical.AE

Secondary Domain(s): ⓘ

Select...

Field(s): ⓘ

Select...

Priority:

Select...

Risk(s):

Select...

★ Reviewer Role(s):

Data Manager

★ Programmatic Review Frequency:

Weekly - Wednesdays @ 00:00, Starting 30 Sep 2026

★ Manual Review Frequency:

Weekly - Wednesdays @ 00:00, Starting 30 Sep 2026

Programmatic ⓘ

Review Materials systematically tracked and factor into the Objective Status.

Data Central Listing(s):

Clinical.AE

eIQ Review Model:

Select...

Orchestrator Rule:

Select...

Manual ⓘ

Review Materials not systematically tracked but factor into the Objective Status.

Data Central Visualization(s):

AE Tox Listing, aesev by seriousness

Data Central Workspace:

Select...

Analytics App:

Select...

App Sheet(s):

Select...

RBQM Dashboard:

Select...

External Material(s): ⓘ

Select...

Additional Instructions:

Enter additional instructions

State: ⓘ

☒ Active

Relevant Review Materials

Comments & Activity 0

Based on the Review Objective details, we've identified 29 relevant Review Materials.

Pending: 26

Accepted: 3

Rejected: 0

AE Tox Listing

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accepted ☐ Reject

AEOutcome2

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

aesev by ser

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

aesev by seriousness

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accepted ☐ Reject

AEToxGrade2

Medium Match

Data Central Visualization

Suggested because it is configured for Primary Domain AE.

☒ Accept ☐ Reject

Clinical.AE

Medium Match

Data Central Listing

Suggested because it is configured for Primary Domain AE.

☒ Accepted ☐ Reject

Combo AEREL - Ethnicity

Medium Match

Data Central Visualization

☐ Accept ☐ Reject

Cancel

Save & Submit For Approval

Save

Data Central – Review Plan Configuration

The option to External Review Materials was added.

Includes study level review materials that live outside illuminate.

The link is shared across the study so any material added here can be linked to multiple Review Objectives without recreating it.

Once linked, External Material displays under Manual Review Materials in the Review Plan and can be manually marked as reviewed and contribute to the Objective Status.

Add Review Objective (v1) Configuring 16/16

Identifier: 5000/5000

Review Objective:

Primary Domain:

Secondary Domain(s):

Field(s):

Priority:

Risk(s):

Reviewer Role(s):

Programmatic Review Frequency:

Manual Review Frequency:

Programmatic Relevant Review Materials Comments & Activity

Review Materials systematically tracked and factor into the Objective Status.

Data Central Listing(s):

eIQ Review Model:

Orchestrator Rule:

Manual

Review Materials not systematically tracked but factor into the Objective Status.

Data Central Visualization(s):

Data Central Workspace:

Analytics App:

App Sheet(s):

RBOM Dashboard:

External Material(s):

Additional Instructions:

State: ☐ Inactive

Cancel Save & Submit For Approval Save



Data Central – Review Plan Configuration

Show Relevant Only was added to the Domain drop-downs.

Reduces manual searching and simplified configuration by helping users identify and select the most appropriate domains and field for the Review Objectives.

This screenshot shows the 'Review Plan Configuration' interface with the 'Show All' view selected. The 'Primary Domain' is set to 'Clinical.AE'. The 'Secondary Domain(s)' dropdown is open, showing a list of domains under the 'Clinical' category. The 'Field(s)' dropdown is also open, showing a list of fields. The 'Priority' dropdown is set to 'Show All'. The 'Risk(s)' dropdown is set to 'Show All'. The 'Reviewer Role(s)' dropdown is set to 'Show All'. The 'Programmatic Review Frequency' dropdown is set to 'Show All'. The 'Manual Review Frequency' dropdown is set to 'Show All'.

Primary Domain: Clinical.AE

Secondary Domain(s): Select...

Field(s):

Priority: Show All Show Relevant Only

Risk(s):

* Reviewer Role(s):

* Programmatic Review Frequency:

* Manual Review Frequency:

Clinical

- AE
- AEYN
- B2MIG
- BDIGVH
- BDK
- BMA
- BS
- CM
- CM2
- CMYN
- CMYN2
- CP
- CPYN
- CS
- DA
- DH
- DISPENSE
- DISPENSE2
- DM
- DS
- DS_D
- DS2
- EC
- EG
- EQ
- EX
- IE
- LAB
- LB_CHEM

This screenshot shows the 'Review Plan Configuration' interface with the 'Show Relevant Only' view selected. The 'Primary Domain' is set to 'Clinical.AE'. The 'Secondary Domain(s)' dropdown is open, showing a list of domains under the 'Clinical' category. The 'Field(s)' dropdown is also open, showing a list of fields. The 'Priority' dropdown is set to 'Show Relevant Only'. The 'Risk(s)' dropdown is set to 'Show All'. The 'Reviewer Role(s)' dropdown is set to 'Show All'. The 'Programmatic Review Frequency' dropdown is set to 'Show All'. The 'Manual Review Frequency' dropdown is set to 'Show All'.

Primary Domain: Clinical.AE

Secondary Domain(s): Select...

Field(s):

Priority: Show All Show Relevant Only

Risk(s):

* Reviewer Role(s):

* Programmatic Review Frequency:

* Manual Review Frequency:

Clinical

- AEYN
- BMA
- CP
- EX
- SFU_30
- SRF
- SV_T
- CTOA
- Exception Listings
- Operational
- Reporting
- Safety



Data Central – Review Plan Configuration

The ability to import Review Objectives from Study Advisor was added

Review Plan

Review Objectives 5

Search

Go to Data Central

Identifier	Version	State	Review Objective	Approval Status	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Risk(s)	Reviewer(s)
CDM_004	1	⚠	Confirm that all AE records indicating st...	Configuring	Clinical.AE	Clinical.CM	Clinical.AE.AEDET, Clinica...	High		Reviewer
CDM_007	1	⚠	Verify that AEs associated with a study d...	Pending Approval	Clinical.AE		Clinical.AE.AEDET, Clinica...	High		Reviewer
DM_018	1	⚠	Verify that sex assigned at birth, age, an...	Configuring	Clinical.SUBJE...			High		
DM_022	1	⚠	Confirm urine pregnancy tests performe...	Configuring	Clinical.PC		Clinical.PC.PCDAT, Clinic...	High		Data Manager
DM_023	1	⚠	Ensure pregnancy testing is not perform...	Configuring	Clinical.PC		Clinical.PC.PCDAT, Clinic...	Medium		Data Manager

Import From Excel

Import From Global Library

Import From Study Advisor

Suggested Review Objectives

Global Library Suggestions 12 0 0 Study Document Suggestions 95 0 0

Viewing Protocol v9.5 (Current)

Identifier	Review Objective	Status	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Risk(s)	Reviewer Role(s)	Programmatic Review Frequency	Ma
2	AE Serious response is Yes, Results in D...	Pending Review	Clinical.AE		Clinical.AE.AEOUT, Clinic...	Medium		Data Manager	Weekly	We
3	Review AE Term, CTCAE Grade, Start Dat...	Pending Review	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium		Data Manager, Medical Data Reviewer	Weekly	We
3	Review AE Term, CTCAE Grade, Start Dat...	Pending Review	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium		Data Manager, Medical Data Reviewer	Monthly	Mo
6	If Other Action Taken = Concomitant Me...	Pending Review	Clinical.AE	Clinical.CM	Clinical.AE.AEACN, Clinic...	High		Data Manager, Medical Data Reviewer	Monthly	Mo
7	If Ongoing is checked and Resolution da...	Pending Review	Clinical.MH		Clinical.MH.MHONGO	Medium		Data Manager, Medical Data Reviewer	Daily	We
14	Ensure there is no visit dates, conmeds, ...	Pending Review	Clinical.AE	Clinical.CM, Clinical.DS		Medium		Data Manager	Weekly	We
DM_002	Verify that all AEs recorded with Grade 1 ...	Pending Review	Clinical.AE		Clinical.AE.AESTDAT, Clin...	Medium		Data Manager	Weekly	We
DM_003	Confirm that emergency room holds of 2...	Pending Review	Clinical.AE		Clinical.AE.AEHENDAT, CL...	High		Data Manager, Medical Data Reviewer	Weekly	We
DM_019	Confirm that all medications, vitamin su...	Pending Review	Clinical.MH	Clinical.EX	Clinical.EX.EXDRUG, Clini...	High		Data Manager	Weekly	We
DM_021	Verify serum β-hCG pregnancy test perfo...	Pending Review	Clinical.PC		Clinical.PC.PCDAT, Clinic...	High		Data Manager	Daily	Dai

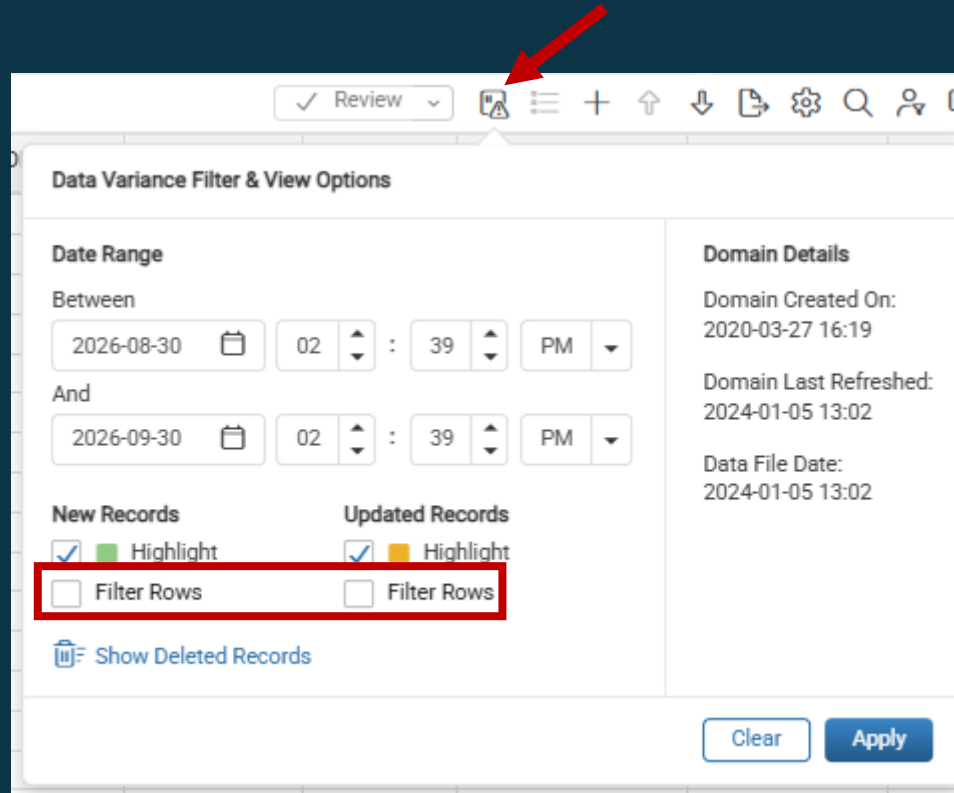
Rows Per Page: 50 Page: 1 of 1

Close Import



Data Central – Data Variance

The ability filter rows for the new or updated records has been added.



The screenshot shows the 'Data Variance Filter & View Options' dialog box. A red arrow points to the 'Filter Rows' checkbox under the 'New Records' section. The dialog includes the following sections:

- Date Range**
 - Between: 2026-08-30 02 : 39 PM
 - And: 2026-09-30 02 : 39 PM
- Domain Details**
 - Domain Created On: 2020-03-27 16:19
 - Domain Last Refreshed: 2024-01-05 13:02
 - Data File Date: 2024-01-05 13:02
- New Records**
 - ☒ Highlight
 - ☐ Filter Rows
- Updated Records**
 - ☒ Highlight
 - ☐ Filter Rows

At the bottom, there is a 'Show Deleted Records' link and 'Clear' and 'Apply' buttons.



Data Central – Issue and Query Identification

The Details view now shows the fields with issues or queries.

Clinical Record Details: Adverse Events (AE) - 0016-008

Details

Variable	Data
AEENDAT_RAW (End Date(RAW))	31/DEC/2015
AEENDAT_INT (End DateInterpolated)	12/31/2015 12:00:00 AM
AEENDAT_YYYY (End DateYear)	2015
AEENDAT_MM (End DateMonth)	12
AEENDAT_DD (End DateDay)	31
AEONGO (Ongoing)	0
AEONGO_RAW (Ongoing(RAW))	0
AETOXGR (Standard Toxicity Grade)	Grade 4
AETOXGR_STD (Standard Toxicity GradeCoded Value)	4
AESER (Serious Event)	No
AESER_STD (Serious EventCoded Value)	N
CASENO (Case ID - Safety Gateway)	
CASENO_STD (Case ID - Safety GatewayCoded Value)	
AESCONG (Serious Event Type - Congenital Anomaly or Birth Defect)	0
AESCONG_RAW (Serious Event Type - Congenital Anomaly or Birth Defect(RAW))	0
AFSDISAB (Serious Event Type - Persistent or Significant)	0

Comments 0

Related Queries 2

Related Issues 2

Red: The field has at least one Issue or Query in Open or In Progress status.

Green: The field has no Open or In Progress Issues or Queries but at least one Answered Issue or Query.

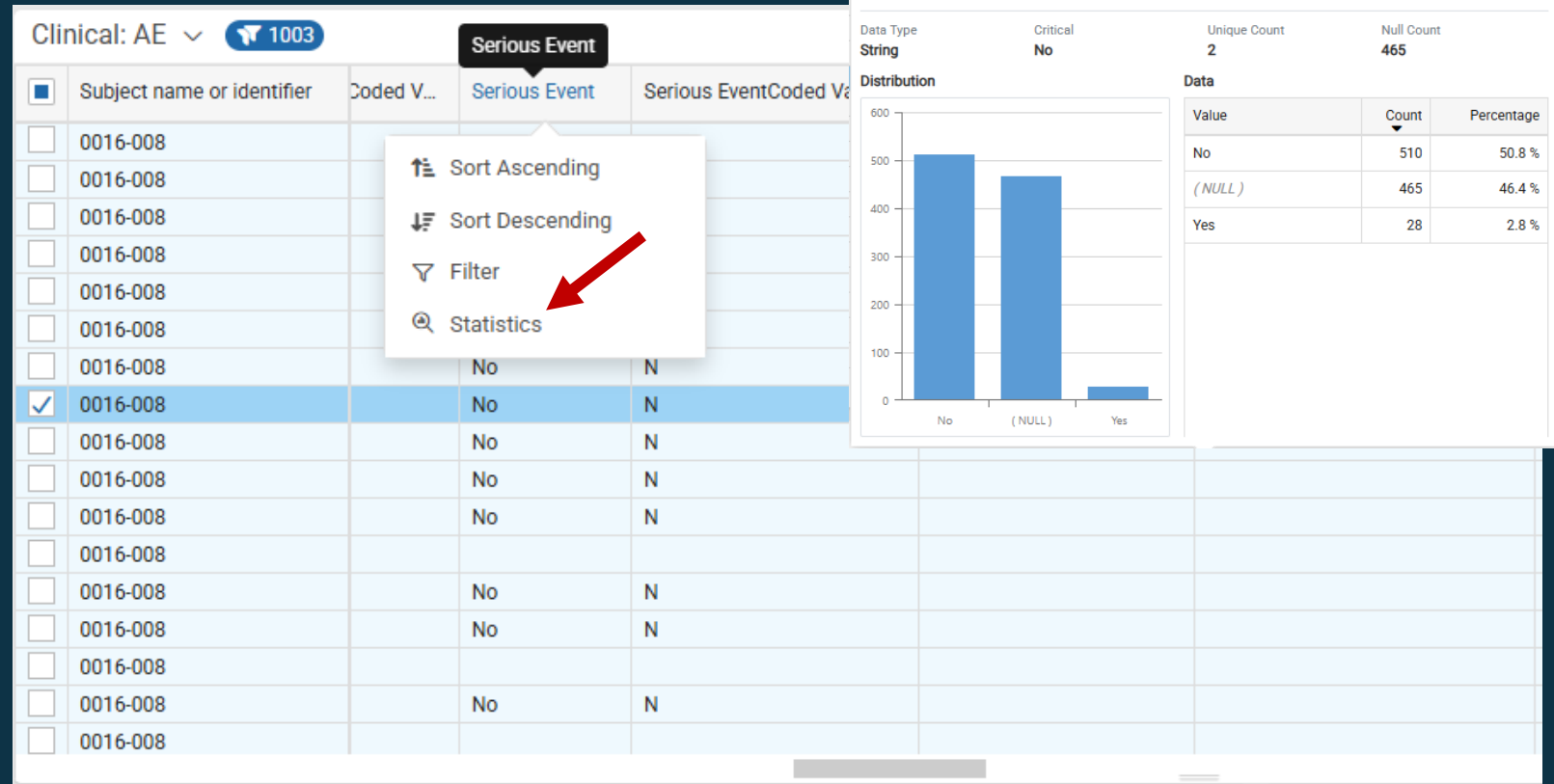
Black: All Issues or Queries for the field are closed.



Data Central – Statistical Data Popouts

From the data listings, users can now select Statistics from a column header that provides immediate insights into the data in the selected column.

- Right-click on a column header
- Select Statistics
- A popout window opens with metrics and visualizations based on the data in the column selected



Data Central – Issues and Queries

From the Data Listings, users can click the domain drop-down and now view Open Issues and Queries numbers.

Clinical: AE 1003

Domain Details

Data Store: Clinical

Domain: Adverse Events (AE)

Last Refresh: 2024-03-13

Data Date: 2024-03-13

Source: Rave

Total Records: 1006

Reviewed: 3

Updated Since Reviewed: 0

Not Reviewed: 1003

Open/In Progress Issues: 12

Open Queries: 3473

The Issue and Query numbers are now links that when clicked on display the list of Issues or Queries just below the record.

Clinical: AE 1003

Subject name or identifier	DM	MDR	Q	Q	Site name	SiteNumber	SiteGroup	Internal id for data page	eCRF
0016-008			1	0	Alabama	0002	World	279451	Adver
0016-008			1	0	Alabama	0002	World	279451	Adver
0016-008			2	0	Alabama	0002	World	279451	Adver
0016-008			0	0	Alabama	0002	World	279451	Adver
0016-008			1	0	Alabama	0002	World	279451	Adver
0016-008			10	0	Alabama	0002	World	279451	Adver

Open Queries (10)

None is not checked, however Other actions taken are missing. Please clarify or correct.

Query ID: 129976 Field: AEACN1 Notification Group: System to Site Opened Date: 26-Jun-2020

Did the subject experience any Adverse Events? is Yes, however Adverse event that caused study discontinuation is missing. Please clarify or correct.

Query ID: 109899 Field: AEDIS Notification Group: System to Site Opened Date: 14-Aug-2017

Did the subject experience any Adverse Events? is Yes, however Outcome is missing. Please clarify or correct.

Query ID: 109898 Field: AEOUT Notification Group: System to Site Opened Date: 14-Aug-2017

Did the subject experience any Adverse Events? is Yes, however Action taken with DRUG_1 is missing. Please complete.

Query ID: 109907 Field: AEACN1 Notification Group: System to Site Opened Date: 14-Aug-2017



Data Central – Issues and Queries

Read Only users can now multi-select in Data Listings when creating Issues or adding comments.

Clinical: AE ▾ 1003

☒	Subject name or identifier	
☐	0016-008	
☒	0016-008	
☒	0016-008	
☐	0016-008	
☒	0016-008	
☐	0016-008	
☐	0016-008	
☒	0016-008	
☐	0016-008	

Users can now export Audit History from any Data Listing.

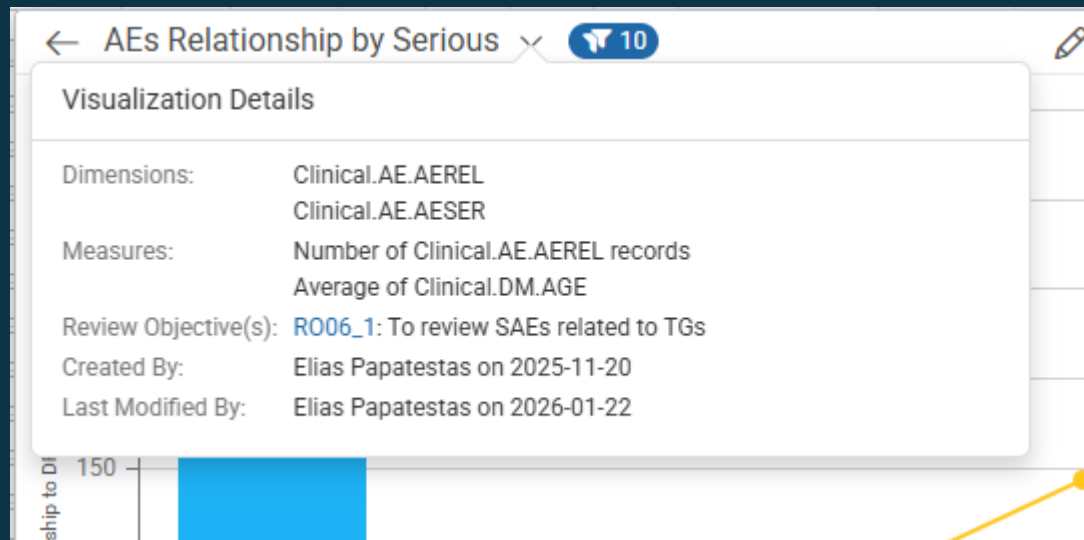
✓ Review ▾

eCRF page name	Sequence number of eCRF	
Adverse Events	0	
Adverse Events	0	
Adverse Events	0	
Adverse Events	0	619280

- Export Only My Role
- Export All Roles
- Export Audit History

Data Central – Visualizations Details Popout

Click on the title of a Visualization to see the Dimensions, Measures, any related Review Objectives, Created by, and Last Modified by.



Data Central – Additional Items

Review Objectives now include a progress bar.

Objective Details

In Progress

Overall Progress3.7%

Clinical.DM

To confirm the Informed Consent Date

Programmatic Review Materials

Clinical.DM

2/53

Objective Details

Identifier: RO12234

Primary Domain:

Clinical.DM

Field(s):

Clinical.DM.ICDAT

Priority:

Medium

Reviewer(s): Data Manager

Programmatic Review Frequency:

Monthly - 1st @ 03:00

Manual Review Frequency:

Monthly - 1st @ 03:00

When exporting a Subject Listing with Clean Participant Tracker enabled, the Unclean Reason(s) column will be added to the export.

Subjects 15												
☐	☐	DM	MDR	☐	☐	☐	☐	Clean Status	Subject	Site	Sex	Age
☐		6007	6013	21	0	91	5	☐	0016-005	0002	Female	25
☐		2481	2487	3	1	78	0	☐	0016-010	0002	Female	62
☐		21448	21451	3	0	191	1	☐	0016-013	0002	Male	57
☐		101824	101824	2	0	543	0	☐	0016-014	0002	Female	59
☐		14722	14723	3	0	152	3	☐	0016-015	0002	Female	69
☐		114357	114359	1	0	8	0	☐	0021-003	0002	Female	64

Unclean: Open / In Progress Issues, Open Queries, DM Review Count





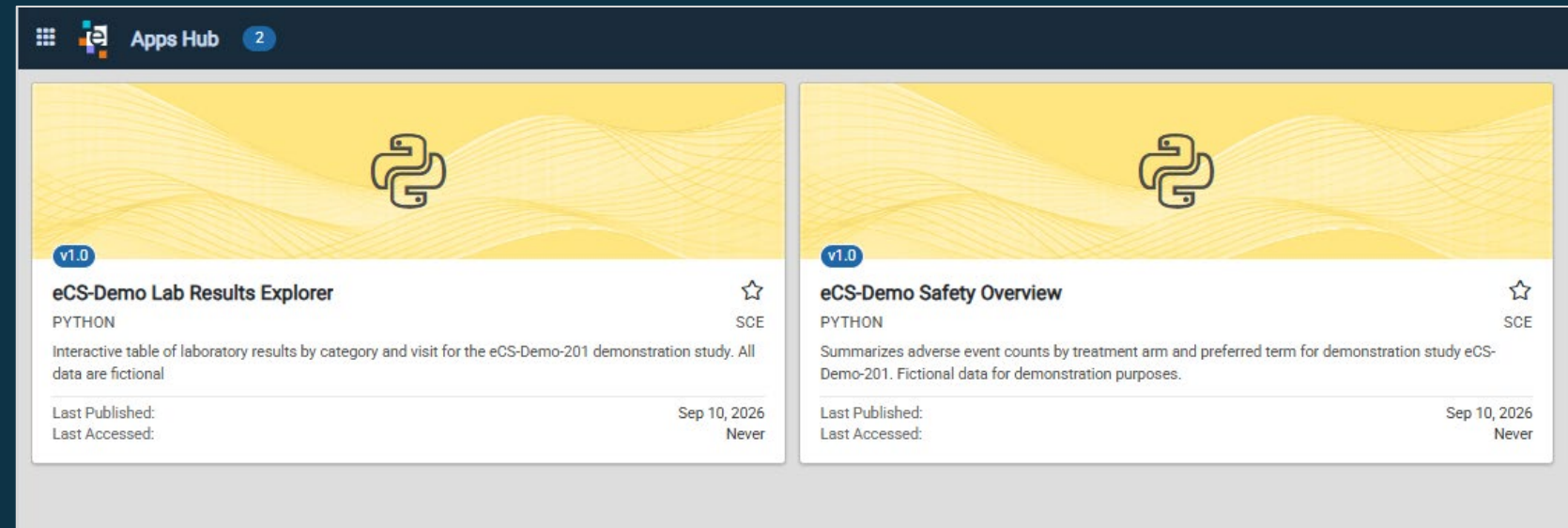
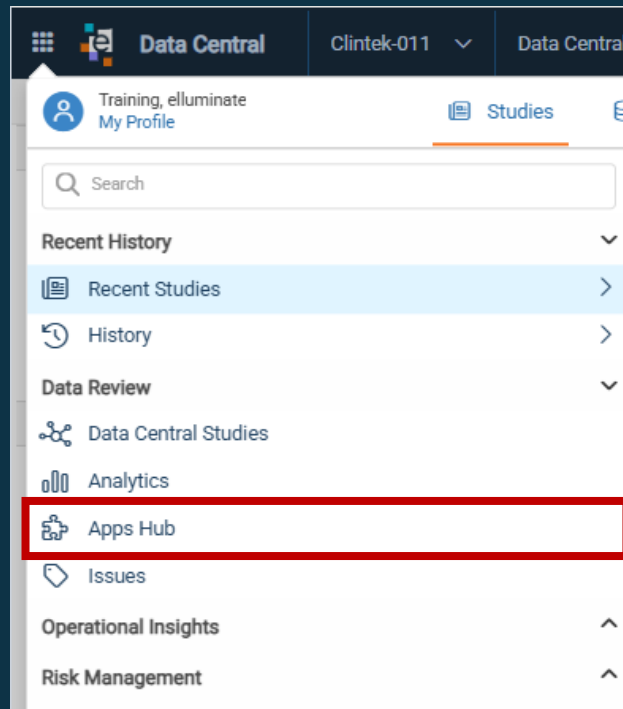
26.2 Highlights

- *Apps Hub*



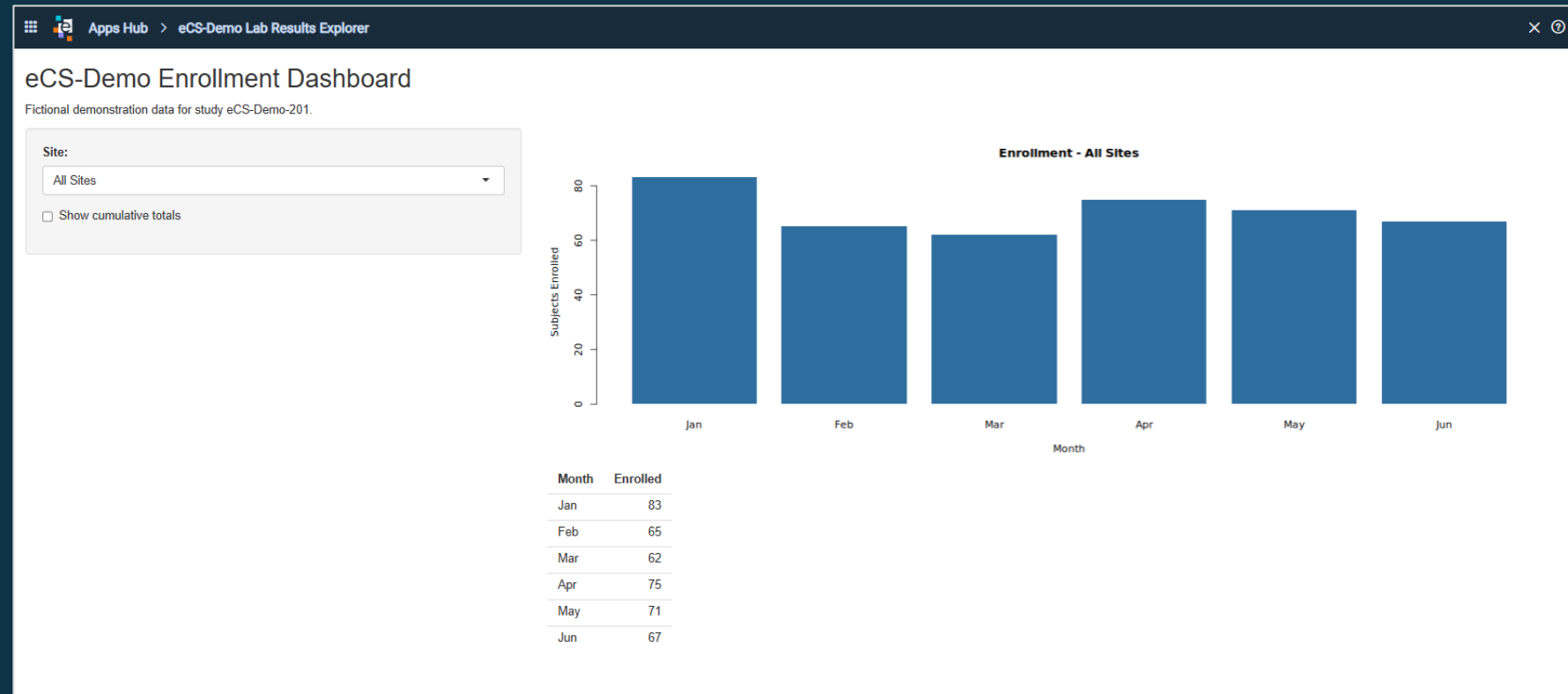
Apps Hub

Users can now discover and launch published custom Shiny analytical applications from the Apps Hub. Provides a centralized location where authorized users can browse the analytical applications available to them and launch interactive dashboards and visualizations built in either R or Python.



Apps Hub

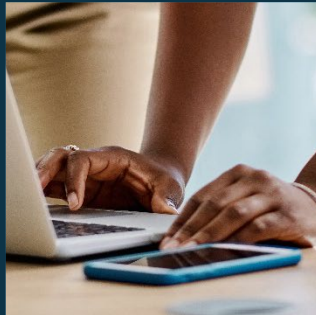
- Access is controlled through the new Apps Hub Viewer privilege.
- Developers and publishers manage applications from the Apps page in SCE before making them available through the Apps Hub.





26.2 Highlights

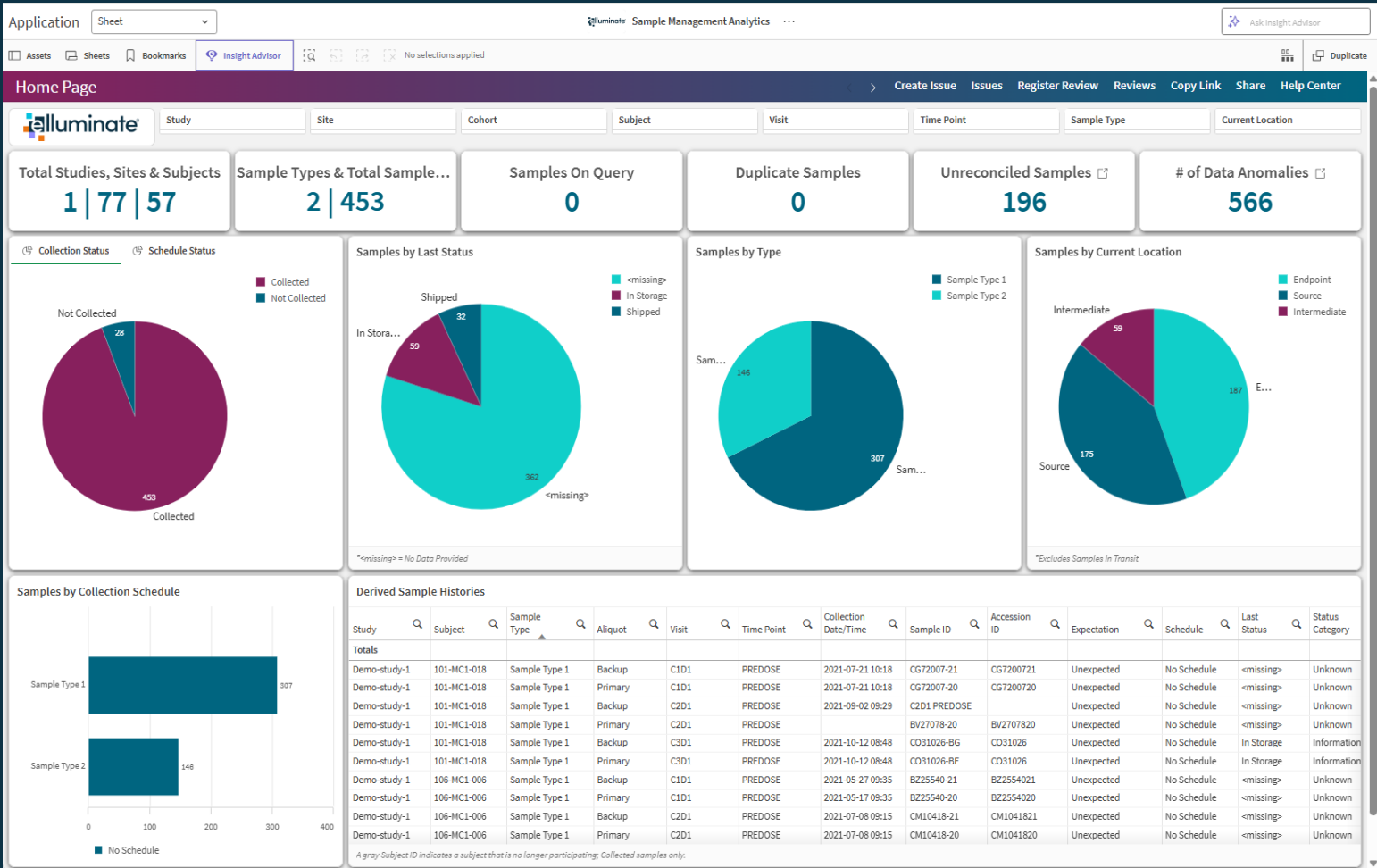
- *Sample Management Analytics*



Sample Management Analytics

SMA has been updated with a modernized user interface meant to improve readability and place greater emphasis on analytical content.

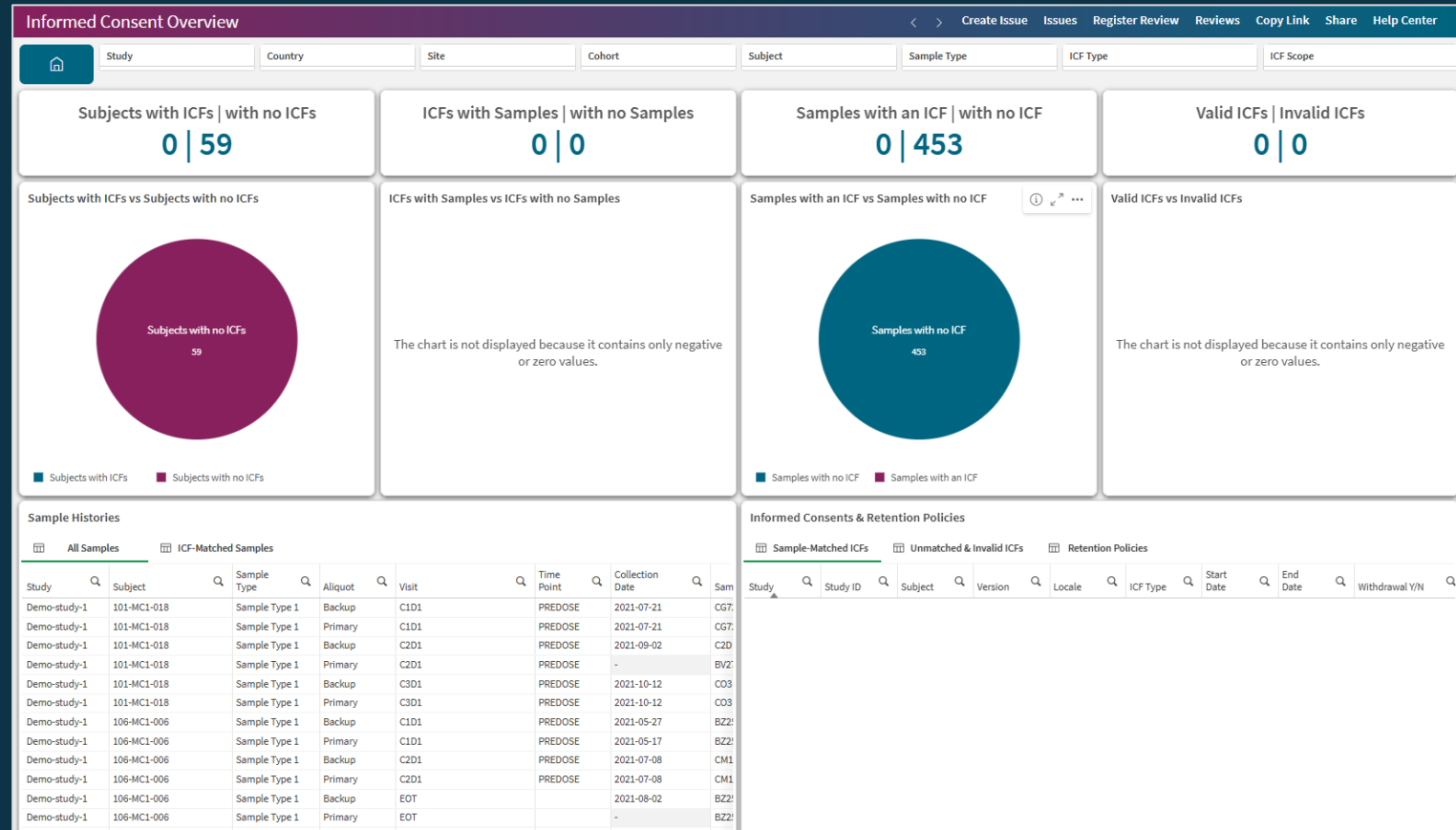
The Home Page was redesigned to provide a more comprehensive view of sample management operations.



Sample Management Analytics

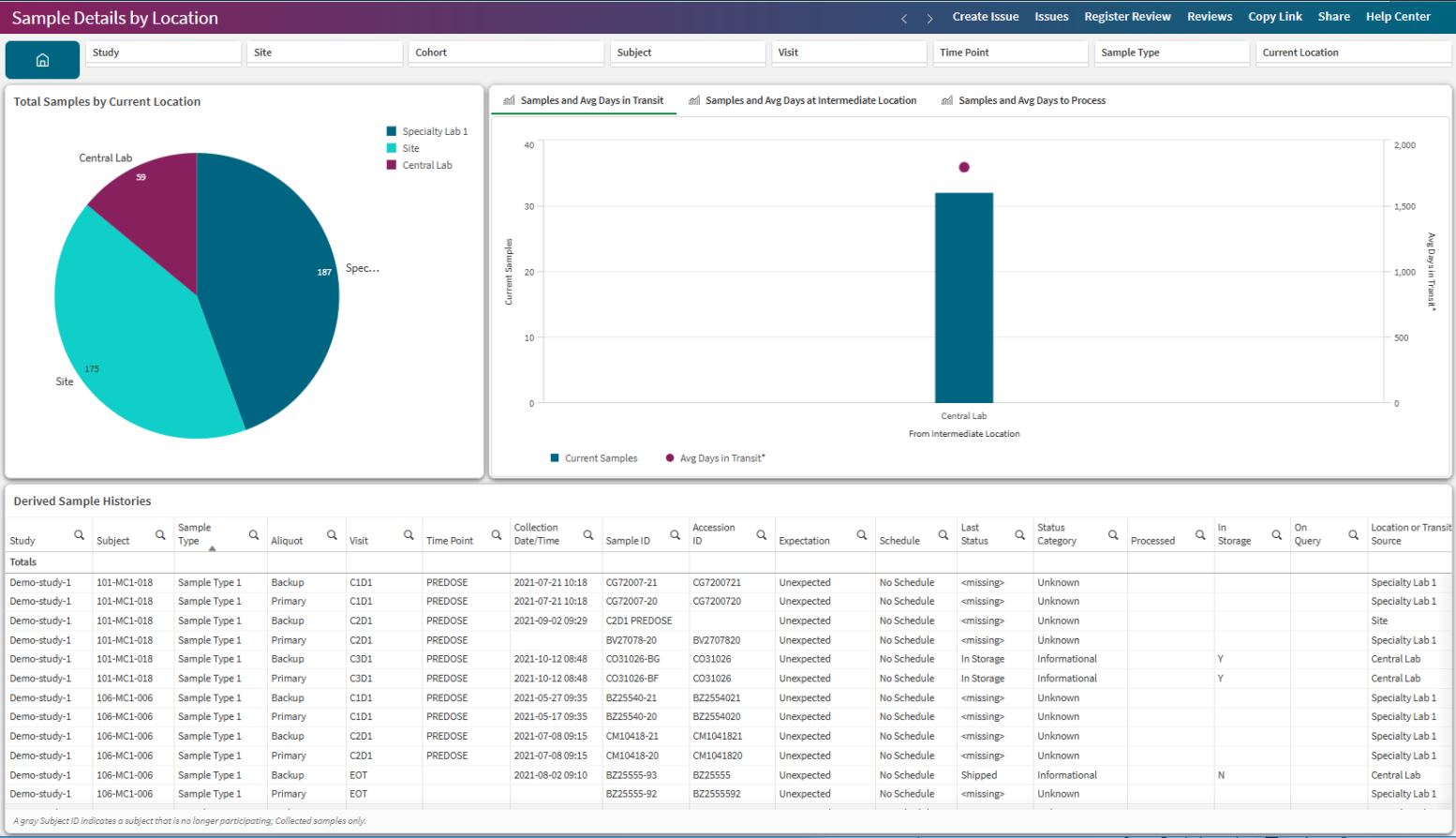
Three new sheets were added:

- Informed Consent Overview
- Sample ICF Tracking
 - Total Samples by ICF Collection Status
 - ICF Status by Study / Site
 - ICF Collection Status by Study, Country, and Site
- Sample Destruction Status
 - Visibility into when samples are scheduled for destruction and whether destruction was completed or is overdue.



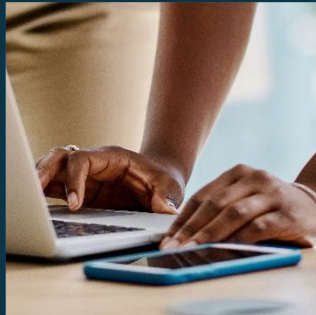
Sample Management Analytics

Sample Details by Location was updated to combine multiple charts into a single tabbed view providing more room to display the dimensional values.





26.2 Highlights - *Issues*



Issues

- Layout of the Create Issues window changed. Same fields, just looks different.
- IssueText field can be defined in Mapper applicable for Issues, rather than the QueryText.

Create Issue

* Issue Text

0 / 4000

Add text

Visit ID

Maximum of 250 characters

Priority

Moderate (Due in 5 days, excludes Saturday and Sunday)

Assign To

☒ User

☐ Role

☐ User Group

* User

Select a user...

* Due Date

10/8/2026, 8:59 AM

Send Notification to User

☒ None

☐ Immediately

☐ In Batch

☐ Defer Notification

Receive Notifications For Changes

☐ Select All

☐ Priority

☐ Reassignment

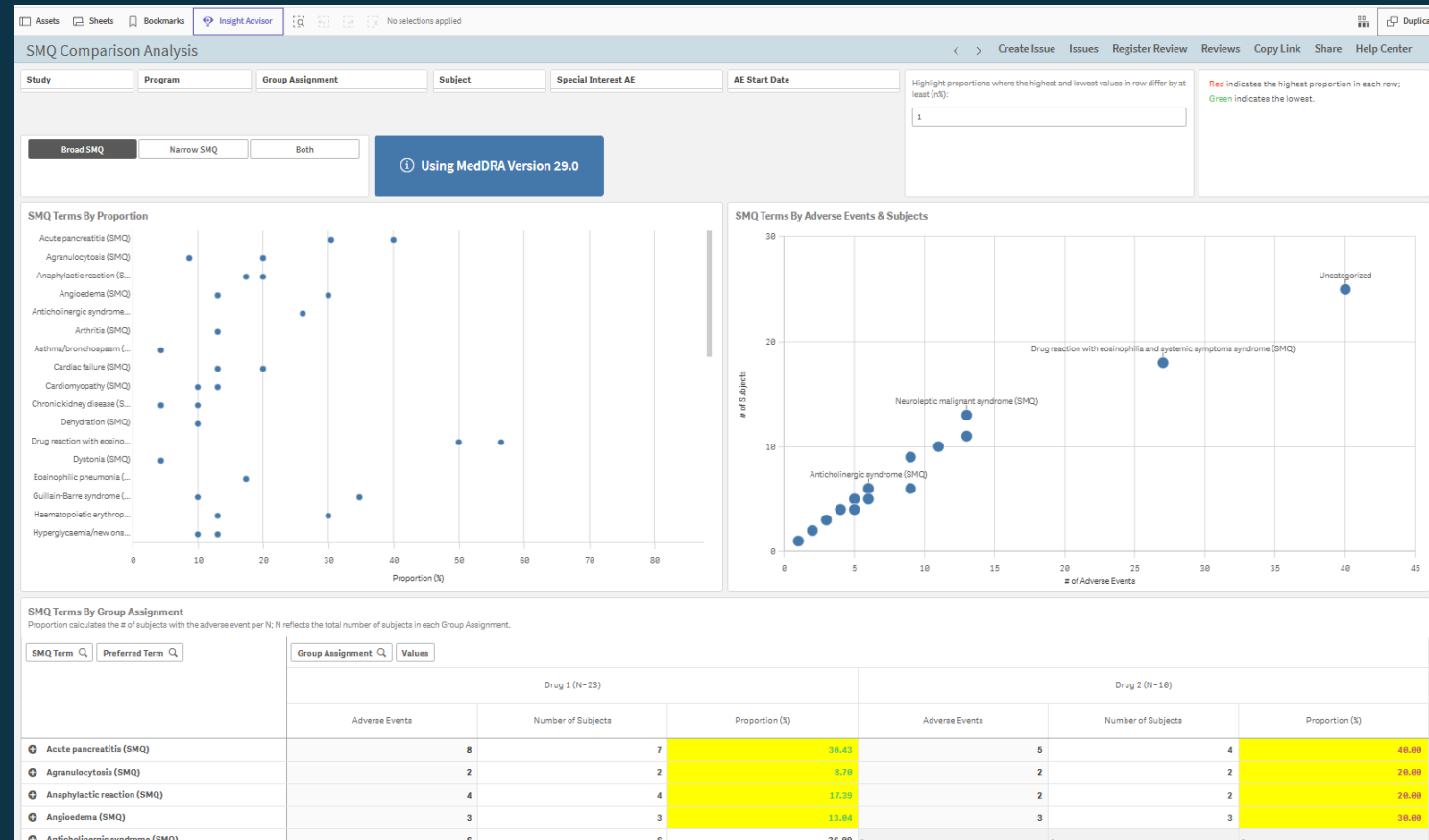
☐ Status

Information

Type	Record
Data Store	eCS_DS_001_src
Domain	Adverse Events
Subject ID	0001-001
Site ID	0001
Field Name	Standard Toxicity Grade
Field Value	Grade 3
Criticality	N

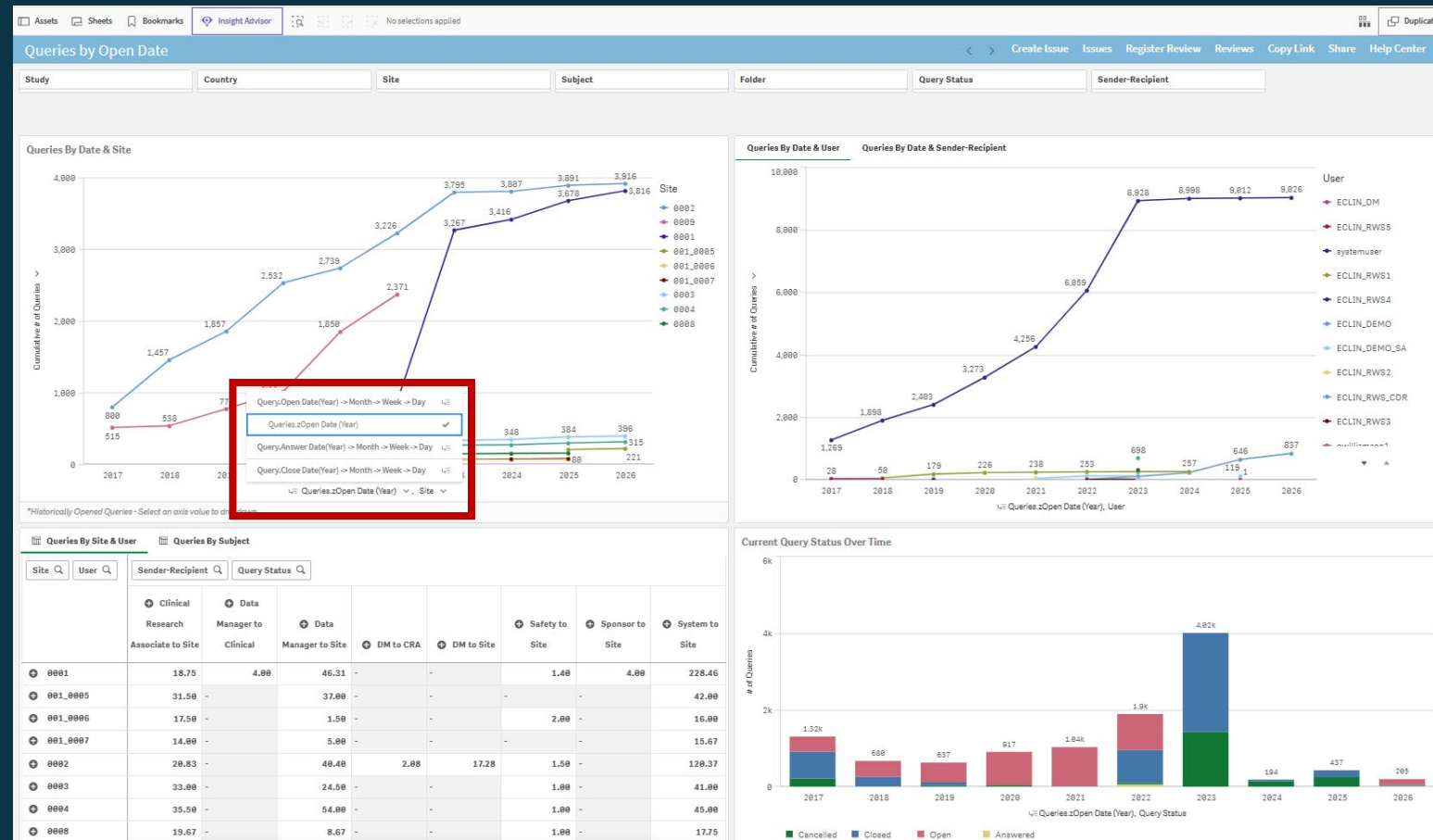
CDA

- Adverse Events Overlay Labs sheet renamed to Adverse Events Overlay Labs & Vitals
- SMQ Comparison Analysis sheet now includes 2 visualizations:
 - SMQ Terms by Proportion distribution plot
 - SMQ Terms by Adverse Events & Subject scatter plot



CTOA

- Queries by Open Date sheet allows users to view by Open Date, Answered Date, or Closed Date.
- Qlik's Insight Advisor has been enabled for CTOA.



Thank you!

