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ellumiNotes - 26.2

This article provides release highlights and detailed release notes for elluminate 26.2.0. Use the Table of Contents to navigate to the areas of the platform most relevant to you. Each section includes applicable release videos, training micromodules, and detailed information about new features and improvements.

Release Schedule

Milestone	Date
Go Live	09/09/2026
Internal Upgrades	09/09/2026
Available for Client Upgrades	09/15/2026

Key Release Highlights

Analytics

Update! Modernized Sample Management Analytics (SMA) User Experience

SMA has been refreshed with a modernized look and feel and reorganized navigation to provide a cleaner, more intuitive analytical experience. Updated styling improves readability and emphasizes analytical content, while sheets are now grouped into five categories, Informed Consent, Sample Tracking, Collection Schedule, Data Quality, and Reporting, making related analytics easier to find and navigate.

Update! Redesigned SMA Home Page

The SMA Home Page has been redesigned as a comprehensive operational dashboard that provides at-a-glance visibility into sample collection, movement, storage, reconciliation, and data quality. New KPIs, visualizations, and direct navigation to related sheets help users identify trends, monitor key sample management metrics, and manage sample lifecycle activities more efficiently.

A new Sample Destruction Status sheet in SMA provides visibility into when samples are scheduled for destruction and whether destruction is complete or overdue. Visualizations and detailed tables allow users to evaluate destruction status alongside informed consent and retention requirements, supporting appropriate sample lifecycle management.

New! Added Informed Consent Overview and Sample ICF Tracking

Two new sheets in SMA expand informed consent tracking across subjects, samples, studies, and sites. Informed Consent Overview provides visibility into ICF coverage, validity, sample associations, and retention policies, while Sample ICF Tracking focuses on sample-level ICF collection status across studies and sites, helping users identify missing or invalid consent information and investigate consent gaps.

[Apps Hub](#)

New! Apps Hub

The new Apps Hub provides a centralized location in illuminate for users with the Apps Hub Viewer privilege to discover and launch published custom Shiny analytical applications built in R or Python. Users can view application details, including name, type, and status, and access interactive dashboards and visualizations based on their study data access.

[Data Central](#)

Update! Redesigned Filter Panel

The redesigned Filter Panel provides a single location to view and manage filters applied across Data Central, with Global and Local sections that clearly distinguish filters affecting the broader sheet from those specific to individual panels. Redesigned filter pills, enhanced tooltips, and improved visibility into applied filters make it easier to understand and manage their effect on displayed data.

New! Added Column Statistics to Data Listings

Data Listings now provide on-demand column statistics with data type-specific metrics, distributions, and visualizations for String, Date/Time, and Numeric data. Users can explore unique values, identify patterns and outliers, and select values directly from the statistics summary to filter the listing for deeper analysis. This enhancement accelerates exploratory analysis and reduces manual data investigation.

Update! Enhanced Review Plan Status Tracking

Review Objectives now provide more granular progress tracking for programmatic review materials and overall completion. Progress bars, reviewed versus total counts, completion percentages, and a detailed Overall Progress breakdown provide greater visibility into partially completed reviews and work remaining in the current review cycle.

New! Added Relevant Review Material Suggestions Panel

A new Relevant Review Materials panel recommends and prioritizes study review materials based on the configured Review Objective, helping users identify and link relevant materials without searching across multiple selectors. Users can quickly accept suggestions to populate the corresponding Review Material fields, reducing the effort required to configure Review Objectives.

New! Added support for External Review Materials

Review Objectives can now link to externally managed review materials, allowing review activities performed outside of elluminate to be incorporated into the Review Plan. External materials can be centrally configured and maintained for a study, accessed directly from linked Review Objectives, marked as reviewed, and included in Review Objective status calculations.

New! Added Issue and Query Quick View

Issue and Query counts in Data Listings are now interactive, allowing users to review record- and field-level activity without leaving the grid. Expanded details and direct navigation to associated Issues and Queries provide immediate context and help users identify existing review activity before taking further action.

Issues

Update! Context-Aware Filtering Experience

Filtering in Global Issues now provides a more intuitive, context-aware experience that helps users quickly identify relevant values based on current selections. These improvements make multi-step filtering more efficient, reduce trial and error, and help users refine results with greater confidence and clarity.

Platform

New! OpenStudyBuilder (OSB) as a Standards Data Source

elluminate now supports OpenStudyBuilder (OSB) as a Standards data source. Users with appropriate permissions can configure and validate an OSB connection as a System Data Source, then import sponsor-defined SDTM standards and controlled terminology directly into Standards, removing the need for file-based imports. Imported standards are available for validation and mapping activities.

New! Clinical Ink Connector

Users can now configure a new eSource data source to establish connections directly to the underlying Clinical Ink database, ingest data from the Clinical Ink platform into elluminate, and use it for clinical trial workflows.

Update! Rave ODM Adapter Supporting Medidata Rave's ODM V2 Upgrade

Users can now ingest data exposed through Medidata Rave's updated ODM V2 API. The Audit and Query datasets in elluminate now include a new InstanceName column that provides detailed visit-level information, especially for complex or repeating visit structures.

Update! Traceability for Data Exported from elluminate

Exported files now include the filename wherever previous exports are displayed, making it easier to identify and trace exports across the system. Filenames also include the applicable UTC offset to provide greater transparency into when data was exported.

New! Snowflake Key Pair Authentication

Snowflake ODBC data sources now support Key Pair Authentication, enabling connections to Snowflake environments that require MFA or other security controls for non-system accounts.

Update! Modernized Platform User Experience

Audit Logs, Configuration, Exporter, Snapshots, and Validator have been redesigned to provide a more streamlined and consistent user experience across the platform. Updates include modernized filtering, sorting, navigation, pagination, search, and data presentation based on the functionality available in each area.

Update! Enhanced Database Import Definition Management

Database import definitions now provide more efficient domain management, including multi-domain deletion for Databricks, Snowflake ODBC, and SQL RDS sources. Databricks Import Definitions also include a new Pre-Load Domains option that automatically identifies available tables and columns, reducing the need to manually create queries for each domain.

Risk Management

New! Study Risks Analytics

Risk Managers can now use two new RACT Analytics pages, Overview and IQRMP, to monitor risk performance across finalized assessments and evaluate alignment between study Risks and IDRP Review Objectives. The Overview page provides summary metrics, interactive visualizations, and detailed views of risk trends, mitigation activity, monitoring coverage, and functional ownership, while the IQRMP page provides integrated views of Risk coverage, Review Objective alignment, reviewer responsibilities, and IQRMP details. Assessment, CTQ, and Risk Control Action filters support focused analysis across the Analytics pages, while exportable Risk and IQRMP details help streamline routine risk reviews, governance reporting, review planning, and inspection readiness.

New! Reassessment Workflow

Risk Managers can now create a reassessment in RACT from a previously finalized assessment, carrying forward existing Risks and their associated details to maintain continuity across assessment versions. This streamlined workflow preserves risk identity and provides a reliable risk history for Analytics.

New! Generic CTQs

RACT Assessments now include the system-defined Study Specific and Unaffiliated CTQs, providing Risk Managers with a standardized way to capture study-specific Risks and Risks that do not align with an existing CTQ. These CTQs support standard risk management actions and exports, helping maintain consistent risk organization across assessments.

New! Move Risks Across Considerations

Users can now move Risks across CTQ Considerations within the same RACT Assessment while retaining the Risk content and Risk ID. This enhancement provides greater flexibility when refining assessments and helps teams align Risks with the most appropriate Consideration as study understanding evolves.

New! Root Cause Analysis for KRI Investigation

A new Root Cause Analysis dashboard in RBQM, accessible from the KRI Details panel, enables built-in KRI root cause analysis. The dashboard includes visualizations that help users analyze KRI score changes over time, compare scores across sites and countries, and identify drivers of score differences. Configurable supporting graphs allow Central Monitors to create and reuse visualizations based on their investigation needs.

SCE

New! Posit Shiny Integration and Apps Hub

The Posit suite now integrates with elluminate, enabling customers to develop, publish, and interact with Shiny applications directly within elluminate. This integration enables programmers to build interactive data visualizations in R or Python within the Statistical Computing Environment (SCE) and publish them through Posit Connect. Published applications are available to authorized users in the new Apps Hub, where users can discover and launch interactive dashboards and visualizations, delivering dynamic insights and enhancing collaboration around study data.

Specifications

Coming soon! Mapping Automation: Spec-Driven SAS Code Generation

Expected in the September 2026 batch update.

This capability will generate SAS code directly from mapping specifications within elluminate. This will enable automated SDTM mapping implementation while preserving compatibility with established SAS-based programming workflows.

Study Advisor

New! AI-Assisted Study Setup and Review Objective Recommendations

Study Advisor is a new AI-powered addition to elluminate that uses the Study Protocol to streamline study setup and review planning by centralizing study documents, extracted study details, and Review Objective recommendations.

- **AI-Assisted Study Creation:** Users can create a new study directly from an uploaded Study Protocol using Study Advisor. AI extracts key study information and prepopulates Study Configuration for review and confirmation, reducing manual data entry and helping ensure the Study Configuration aligns with the Study Protocol from initial setup.
- **Study Documents & Details:** Study Advisor provides centralized management of the Study Protocol and supporting study documents, including document versioning and access to previous versions. Uploading a Study Protocol automatically extracts key study details using AI, which users can review and use to align the Study Configuration with the latest protocol.
- **AI-Powered Review Objective Suggestions:** Study Advisor analyzes the Study Protocol to identify reusable Review Objectives from the Global Library and generate new study-specific Review

Objective suggestions when appropriate. Users can review, edit, accept, or reject suggestions and add accepted objectives directly to the study's Review Plan, accelerating review planning while maintaining user control.

Together, these capabilities help accelerate study setup and review planning, improve consistency, reduce manual effort, and keep study activities aligned with the latest Study Protocol.

Administration Release Notes

Issue ID	Summary	Administration Release Note Description
EL-42410	Reports: Added the Study Access and Blinding View report	A new Study Access and Blinding View report is now available within Admin Reports, providing administrators with a centralized view of user access across studies. The report lists each user's study assignments, Data Central reviewer role, and associated blinding privileges, enabling sponsors and administrators to efficiently review study access, user roles, and blind data permissions from a single report. The report can be run or scheduled like other Admin Reports and is exported in CSV format to support large datasets.
EL-34260	SSO integration for Veeva Vault CDMS bidirectional query actions in Data Central	Users can now authenticate Veeva Vault CDMS query actions by signing in with individual EDC user accounts through Single Sign-On (SSO). This enhancement eliminates the need to manage separate EDC usernames and passwords. The integration uses OAuth 2.0 OpenID Connect (OIDC) to redirect users from Data Central to the organization's SSO login page while remaining within illuminate. After successful authentication, users who have access to Veeva Vault CDMS and a corresponding EDC user account can create, answer, close, and reopen queries from illuminate using the same workflow previously available with basic authentication. This enhancement provides a more seamless authentication experience for organizations that manage both Veeva Vault CDMS and illuminate access through SSO. Query actions in Veeva Vault CDMS are attributed to the authenticated user instead of a shared system account, which improves auditability and traceability.
EL-33879	User Management - Groups: Added Persona to User Groups	Added the Persona field to user groups. Select or update a Persona from a preconfigured list of common clinical trial roles to enable sponsors to more closely align functional user groups that share similar privileges but require different configurations for different business roles. Persona values also provide

Issue ID	Summary	Administration Release Note Description
		clearer tagging and visual distinction in illuminate and exported User Group content.
EL-36083	User Management - Settings: Added Export File Naming options	Added new Export File Naming options under User Management > Settings. These URL-level configuration options provide ISO 8601-compliant date formats and can append the selected UTC offset to timestamps in exported file names. These options help reduce confusion for organizations with international users by clearly identifying the time zone used for exports and eliminating ambiguity between date formats such as DDMMYYYY and MMDDYYYY, which can be interpreted differently across regions.
EL-41279	User Management: Enhanced handling for duplicate usernames in user file imports	Fixed an issue where importing a user file containing duplicate usernames could result in an incomplete user import without notifying the administrator. The user import process now validates import files for duplicate usernames during import. If duplicate usernames are detected, the import is blocked, and a validation message instructs administrators to correct the file before retrying the import.

Analytics: Clinical Data Analytics (CDA) Release Notes

Issue ID	Summary	CDA Release Note Description
ECCA-832	CDA - Adverse Events Overlay Labs & Vitals sheet: Added support for Adverse Events and Vital Signs overlay	The Adverse Events Overlay Labs sheet has been renamed Adverse Events Overlay Labs & Vitals and now supports overlaying Vital Signs with Adverse Events. The existing Event filter has been expanded to include Vital Signs test names, allowing users to select Laboratory or Vital Signs measurements alongside Adverse Events for comparison. Based on the selected Event values, the chart and listing automatically update to display either Adverse Events and Laboratory data or Adverse Events and Vital Signs data, allowing users to evaluate measurement results, reference limits, and the timing of Adverse Events within a single view. This enhancement helps users more easily identify potential relationships between Adverse Events and changes in Laboratory or Vital Signs data, supporting faster and more informed clinical data review.

Issue ID	Summary	CDA Release Note Description
ECCA-851	CDA - SMQ Comparison Analysis and Application Information sheets: Updated MedDRA Version indicator to reflect custom configurations	The SMQ Comparison Analysis and Application Information sheets now indicate when a custom Standardized MedDRA Query (SMQ) configuration is being used instead of the standard, published MedDRA Version. When a custom SMQ configuration is used, the existing MedDRA Version indicator is updated to specify that a custom SMQ version is in use. This enhancement provides greater visibility into the source of the SMQ data used for analysis, helping users more easily validate and troubleshoot study-specific SMQ configurations.
ECCA-819	CDA - SMQ Comparison Analysis sheet: Added distribution and scatter plot analysis	The SMQ Comparison Analysis sheet now includes two additional visualizations to help users compare adverse event patterns across group assignments: • SMQ Terms By Proportion distribution plot: Displays the proportion of subjects with adverse events for each SMQ term by group assignment, making it easier to identify groups with unusually high or low event rates. • SMQ Terms By Adverse Events & Subjects scatter plot: Compares the number of adverse events with the number of affected subjects by group assignment, helping users identify potential safety signals, concentrated event patterns, or data anomalies. The existing pivot table has also been updated with clearer labeling and additional context explaining how adverse event proportions are calculated. This enhancement provides a more visual and efficient way to evaluate SMQ trends across group assignments, helping users identify outliers and determine meaningful thresholds for further investigation.

Analytics: Clinical Trial Operational Analytics (CTOA) Release Notes

Issue ID	Summary	CTOA Release Note Description
ECCA-833	CTOA - Queries by Open Date sheet: Added Answered Date and Closed Date analysis to the Queries By Date & Site line chart	The Queries By Date & Site line chart on the Queries by Open Date sheet now allows users to analyze query activity by Open Date (default), Answered Date, or Closed Date. Each date option supports drilldown from Year to Month, Week, and Day. This enhancement provides greater flexibility for evaluating query trends over specific periods, making it easier to track

Issue ID	Summary	CTOA Release Note Description
		when queries were opened, answered, and closed and assess changes in query management per site over time.
ECCA-536	CTOA: Configured for Insight Advisor	The Clinical Trial Operational Analytics application has been configured to support Qlik's Insight Advisor, enabling users to explore operational study data using natural language. Users can ask questions in plain English about topics such as enrollment, screening failures, protocol deviations, query management, data entry timeliness, and site performance, and receive AI-generated answers and supporting visualizations. Additionally, Insight Advisor allows users to explore data and generate new visualizations either by selecting fields or master items or by starting with an analysis type and then selecting the data to analyze. Insight Advisor generates multiple chart options that users can review and add directly to their sheets. This enhancement provides a faster, more intuitive way to explore operational study data, helping users uncover insights, answer questions, and generate visualizations for further analysis.

Analytics: Operational Oversight (OO) Release Notes

Issue ID	Summary	OO Release Note Description
ECCA-845	OO - Enrollment Summary, Enrollment Trend, Protocol Deviations, Recruitment and Retention, Site Monitoring, and Site Milestone Calendar sheets: Added Site Number to tables and updated Site Name	The tables on the Enrollment Summary, Protocol Deviations, Recruitment and Retention, and Site Milestone Calendar sheets now display Site Number alongside Site Name, making it easier to identify and distinguish study sites using configured site identifiers. The existing Site column has been renamed Site Name for improved clarity. Additional charts, tables, and KPIs across the Enrollment Summary, Enrollment Trend, Protocol Deviations, Recruitment and Retention, Site Monitoring, and Site Milestone Calendar sheets have also been updated to consistently use StudySites.SiteName instead of InvSiteAssoc.Name. This enhancement improves site identification throughout Operational Oversight by displaying consistent site information across analyses and helping users more easily interpret study metrics and differentiate sites with similar names.
ECCA-808	OO - KPI Summary sheet: Improved KPI target calculations for incomplete	The KPI Summary sheet's bullet charts (Investigator Sites, Active Sites, Non-Performing Sites, Screened Count, Screen Failures, Failure Rate, Enrolled Count, Enrollment Rate,

Issue ID	Summary	OO Release Note Description
	study data and added KPI footnotes	Completed Count, and Discontinued Count) have been enhanced to improve the accuracy of KPI target calculations when studies contain incomplete Actual or Planned data. KPI target indicators now exclude studies with missing values required for a given KPI calculation, preventing incomplete data from affecting aggregate target metrics. Bullet chart footnotes have also been enhanced to clearly indicate when KPI calculations exclude incomplete data or when planned targets have been exceeded. • Incomplete Actual Data: Displayed when any Actual value required for the KPI is missing. • Incomplete Planned Data: Displayed when any Planned value required for the KPI is missing. • Exceeded plan of Planned KPI value: Displayed when the Actual KPI exceeds the Planned KPI and all required Planned values are available. • Target Sites, Subjects, or Rate <= Planned KPI Value: Displayed when the Actual KPI is equal to or below the Planned KPI and all required Planned values are available. These messages help users quickly understand whether KPI targets are based on complete study data and provide additional context when interpreting KPI performance. This enhancement improves the accuracy and transparency of KPI reporting, helping users make more informed operational decisions based on complete and reliable study data.

Analytics: Sample Management Analytics (SMA) Release Notes

Issue ID	Summary	SMA Release Note Description
ECCA-967	SMA - All sheets: Modernized look and feel	The Sample Management Analytics application has been refreshed with a modernized user interface designed to improve readability and place greater emphasis on analytical content. Updated styling includes rounded object corners, subtle shadows, and gradient sheet headers for a cleaner and more appealing presentation across the application. To reduce visual clutter, hover menus have been removed from filter panes, variable inputs, and text boxes, while object

Issue ID	Summary	SMA Release Note Description
		disclaimers and details buttons have been hidden where not needed. Sheets have been reordered, and their thumbnails reclassified in the Sheets panel to group related analytics into five categories: Informed Consent, Sample Tracking, Collection Schedule, Data Quality, and Reporting, in addition to the Home Page. This enhancement provides a cleaner, more focused analytical experience that emphasizes the data and improves consistency and navigation throughout the application.
ECCA-945	SMA - Home Page: Enhanced and redesigned	The Home Page has been redesigned to provide a more comprehensive, at-a-glance view of sample management operations, giving users immediate visibility into sample collection, movement, storage, reconciliation, and data quality instead of only sample location metrics and report navigation. New KPIs highlight Total Studies, Sites & Subjects, Sample Types & Total Samples, Samples on Query, Duplicate Samples, Unreconciled Samples, and # of Data Anomalies. Additionally, clicking the Sample Types & Total Samples KPI navigates users to the Sample Details By Collection Status sheet, clicking the Unreconciled Samples KPI navigates users to the Unreconciled Samples sheet, and clicking the # of Data Anomalies KPI navigates users to the Data Anomalies sheet, allowing users to quickly investigate areas requiring attention. New visualizations summarize Collection Status, Schedule Status, Samples by Last Status, Samples by Type, Samples by Current Location, and Samples by Collection Schedule, helping users quickly identify operational trends, bottlenecks, and exceptions across sample management workflows. The standard Derived Sample Histories table is also included on the sheet. This enhancement transforms the SMA Home Page into a centralized operational dashboard, improving visibility into sample lifecycle metrics and helping users more efficiently monitor sample operations, identify exceptions, and prioritize follow-up activities.
ECCA-966	SMA - Sample Details By Location sheet: Improved chart layout	The Samples and Avg Days in Transit (default), Samples and Avg Days at Intermediate Location, and Samples and Avg Days to Process combo charts are now organized within a

Issue ID	Summary	SMA Release Note Description
		single tabbed view, providing more space for displaying dimensional values. This enhancement reduces chart crowding and improves readability, helping users more easily analyze sample movement and processing timelines across locations.
ECCA-242	SMA: Added Sample Destruction Status sheet for sample destruction tracking	A new Sample Destruction Status sheet is now available in Sample Management Analytics, providing visibility into when samples are scheduled for destruction and whether destruction has been completed or is overdue. Users can filter the sheet by Study, Country, Site, Cohort, Subject, Sample Type, ICF Type, and Destruction Status to focus on specific populations or sample groups. The sheet includes the Total Samples by Destruction Status, Destruction Status by Location, and Destruction Status by Sample Type visualizations. Detailed Sample Destruction Status, Informed Consents, and Retention Policies tables are also included, allowing users to review sample-level destruction information alongside the consent and retention details that inform destruction requirements. This enhancement helps users track sample destruction timelines effectively, identify overdue samples, and support compliance with informed consent and sample retention requirements.
ECCA-261	SMA: Added two new sheets to support informed consent tracking	Two new sheets have been added to the Sample Management Analytics application to support informed consent tracking across subjects, samples, studies, and sites. The Informed Consent Overview sheet provides a high-level view of ICF coverage and validity through KPIs and visualizations comparing: • Subjects with and without ICFs • ICFs with and without associated samples • Samples with and without an associated ICF • Valid and invalid ICFs The sheet also includes detailed tables for all samples, ICF-matched samples, sample-matched ICFs, unmatched or invalid ICFs, and retention policies, helping users investigate consent

Issue ID	Summary	SMA Release Note Description
		gaps and review the relationships between subjects, samples, ICFs, and applicable retention requirements. The Sample ICF Tracking sheet focuses on sample-level ICF collection status. Visualizations summarize total samples by ICF collection status and break down status by study and site, while a pivot table provides a detailed comparison across study, country, and site. Both sheets can be filtered by Study, Country, Site, Cohort, Subject, Sample Type, ICF Type, and ICF Scope, allowing users to focus their analysis on specific populations, consent types, or sample groups. This enhancement helps users monitor informed consent coverage, identify samples or subjects with missing or invalid consent information, and support appropriate sample collection, use, storage, and retention.

Apps Hub Release Notes

Issue ID	Summary	Apps Hub Release Note Description
EL-41848	Apps Hub: Access published Shiny applications	Users can now discover and launch published custom Shiny analytical applications from the new Apps Hub, available from the Platform menu under Data Review in elluminate. 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. The Apps Hub displays each application's name, type, and status, making it easy to identify available applications and distinguish between R- and Python-based Shiny applications. 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.

Data Central Release Notes

Issue ID	Summary	Data Central Release Note Description
EL-35954	Configuration - Query: Added Authentication	Added new authentication configuration options for Veeva CDMS studies. When a Veeva CDMS data source is

Issue ID	Summary	Data Central Release Note Description
	Controls and SSO Client ID for Veeva CDMS Studies	configured and selected, the Query configuration section includes a new Query Authentication Controls section with the following options: • Use User Credentials: Requires each user to enter individual Veeva CDMS credentials to perform query actions. • Use Stored Credentials: Uses the username and password stored in the selected Veeva CDMS data source for all query actions. • Use SSO Only: Redirects all users to the configured SSO identity provider to authenticate before performing query actions in Veeva CDMS. • Use Mixed Authentication: Supports both SSO and Basic Authentication users. SSO users are redirected to the configured identity provider, while Basic Authentication users enter individual Veeva CDMS credentials. Added a new SSO Client ID field that is available only when Use SSO Only or Use Mixed Authentication is selected. Enter the Application Client ID configured for the OAuth 2.0 OpenID Connect application in Veeva CDMS and the associated SSO identity provider. If users have access to multiple SSO configurations, the Client ID directs authentication to the correct SSO configuration.
EL-36225	Configuration - Review Plan: Added a new Relevant Review Materials panel	The Add and Edit Review Objective windows now include a Relevant Review Materials panel that consolidates suggested review materials from across the study into a single, prioritized list. Suggestions are generated based on the configured Review Objective description, Primary Domain, Secondary Domain(s), and Field(s), making it easier to identify and link relevant review materials without searching across multiple selectors. Each suggested review material displays its name, type, match level (High, Medium, or Low), the reason it was recommended, and actions to Accept or Reject the suggestion. Users can Accept a Review Material to populate the corresponding Review Material field in the Add Review Objective window, or Reject it when it is deemed irrelevant. Accepted and rejected suggestions persist across sessions until the Review Objective details change, eliminating the need to review the same recommendations repeatedly. A summary of pending, accepted, and rejected suggestions is displayed at the top of

Issue ID	Summary	Data Central Release Note Description
		the panel, and users can refresh the suggestions after updating the Review Objective details to generate updated matches. This enhancement reduces the effort required to configure Review Objectives and helps ensure the most relevant review materials are included in the Review Plan.
EL-41110	Configuration - Review Plan: Added Study Advisor Review Objective import	The Review Plan configuration now includes an 'Import From Study Advisor' option that allows users to review and import AI-generated Review Objective suggestions directly into a study's Review Plan without leaving Data Central Configuration. Users can browse Global Library Suggestions and Study Document Suggestions from any protocol version, search, filter, sort, select one or more suggestions, and import them after standard validation completes. Imported Review Objectives are identified with a sparkle indicator to show they originated from Study Advisor. Hovering over the sparkle indicator displays the associated protocol name and version. Review Objectives imported from Global Library Suggestions are added in an Active state with a Configuring approval status unless all Review Materials are unavailable in the study, in which case the Review Objective would be in a Draft state. If the configured Primary Domain is not available in the target study, users can update the Primary Domain before accepting the suggestion in Study Advisor or importing it into the Review Plan, helping ensure imported Review Objectives align with the study's domains. Review Objectives imported from Study Document Suggestions are added in a Draft state with a Configuring approval status, allowing users to complete Review Material configuration before progressing through the standard approval workflow. This enhancement streamlines the transition from AI-generated recommendations to an actionable Review Plan, reduces context switching, accelerates review plan creation, and promotes consistent reuse of Review Objectives across studies.
EL-35951	Configuration - Review Plan: Added support for External Review Materials	Review Objectives now support linking to External Review Materials, enabling review activities performed outside of illuminate to be included as part of a single, centralized Review Plan. External Review Materials are configured once per study from the new External Material(s) drop-down in the Add and Edit Review Objective windows, where users can

Issue ID	Summary	Data Central Release Note Description
		create, edit (directly in the table cells), delete, and link materials with a name, description, and URL. Built-in Excel import and export capabilities are also available directly from the drop-down, making it easy to maintain a consistent library of External Review Materials across a study. All additions, updates, and deletions are captured in the Audit Logs for traceability. Review Plan import, export, bulk edit, and Excel templates have also been updated to support External Review Materials. Linked External Review Materials are displayed throughout the Review Plan in Data Central, including Review Objective details, grids, panels, listings, and charts. Material names appear as clickable links that open the configured URL, with descriptions available on hover. As manual review materials, they can be marked as reviewed and contribute to Review Objective status calculations. These enhancements enable organizations to maintain a single source of truth for Review Plans by incorporating both illuminate and externally managed review materials into a unified review workflow.
EL-37286	Configuration - Review Plan: Added 'Show Relevant Only' option to Primary Domain, Secondary Domain(s), and Field(s) selectors	Updated the Add / Edit Review Objective window to include a 'Show Relevant Only' radio button within the Primary Domain, Secondary Domain(s), and Field(s) selectors, allowing users to filter values based on the entered Review Objective description. When selected, the drop-down displays the most relevant domains and fields while allowing users to toggle back to the full list without losing selections. Field suggestions automatically re-evaluate as selected domains change, helping ensure that only fields relevant to the selected domains remain configured. This enhancement reduces manual searching and simplifies configuration by helping users identify and select the most appropriate domains and fields for their Review Objectives.
EL-36908	Data Listings - Data Variance: Redesigned popout and added row filtering	The Data Variance popout has been redesigned to support row filtering, allowing users to display only new or updated records within a selected date range. Filtering can be used independently or combined with the existing highlighting

Issue ID	Summary	Data Central Release Note Description
		capability to quickly isolate changed records while visually distinguishing new and updated data. The updated layout organizes domain details on the right and interactive options for filtering, highlighting, and date range selection on the left, making the popout easier to read and interpret. Active Data Variance filters are reflected in the filter popout accessed from the panel's badge and in the Local section of the Filter Panel, making them easier to identify and manage. This enhancement streamlines incremental data review, helping users quickly identify and focus on recently changed data.
EL-37259	Data Listings - Record Details: Added field-level Issue and Query indicators	The Record Details panel now displays Issue and Query indicators next to fields that have field-level Issues or Queries, making existing review activity visible at a glance. Indicator colors reflect the highest-priority status for the field: • 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 and at least one Answered Issue or Query. • Black: All Issues or Queries for the field are Closed. Hovering over an indicator displays a tooltip summarizing field-level Issues or Queries grouped by status. Clicking an indicator automatically expands the corresponding Related Issues or Related Queries section and filters the table to display only the Issues or Queries for the selected field. Selecting a field-level Issue or Query highlights the corresponding field in the Record Details panel and automatically scrolls it into view when needed. This enhancement helps users quickly determine whether review activities already exist for a field, helping prevent duplicate Issues and Queries while streamlining record-level data review.
EL-36511	Data Listings: Added column statistics popout	Data Listings now include a Column Statistics option in each column header that provides immediate insights into the data in a selected column. The Statistics popout displays metrics and visualizations based on the selected column's data type:

Issue ID	Summary	Data Central Release Note Description
		• String columns: Data Type, Critical Data Indicator, Unique Value Count, Null Count, a distribution bar chart, and a sortable summary table of unique values with counts and percentages. • Date/Time columns: Data Type, Critical Data Indicator, Unique Value Count, Null Count, Minimum and Maximum values, a distribution bar chart grouped by Day, Week, Month, or Year, and a sortable summary table of unique values with counts and percentages. • Numeric columns: Data Type, Critical Data Indicator, Unique Value Count, Null Count, Minimum, Median, Mean, and Maximum values, Box Plot and Standard Deviation Plot visualizations, and a sortable summary table of unique values with counts and percentages. The summary table remains synchronized with the displayed chart, ensuring the visualization automatically reflects the current table sort order. Users can also select values from the summary table to filter the listing and focus on specific subsets of data. String columns support selecting multiple values, while Date/Time and Numeric columns support selecting a single value. This enhancement enables faster exploratory data analysis by helping users better understand data distributions, identify outliers and data quality issues, and make more informed review and filtering decisions.
EL-34333	Data Listings: Added Issue and Query counts to Domain Details popout	The Domain Details popout in Data Listings now includes counts for Open/In Progress Issues and Open Queries, providing users with a more complete at-a-glance summary of domain-level data review activity. Issue counts include Domain-, Record-, and Field-level Issues, while Query counts are displayed only for studies with Queries enabled. These additions help users quickly identify domains requiring attention, prioritize review efforts, and monitor overall data quality and review progress directly from the Domain Details popout.
EL-30960	Data Listings: Added multi-select for Data Central users with the Read Only reviewer role	Users with the Data Central Read Only reviewer role can now multi-select records in Data Listings, enabling them to perform actions such as creating issues, adding comments, and adding annotations across multiple records. While record selection is now available, review-related actions remain hidden, ensuring

Issue ID	Summary	Data Central Release Note Description
		these users continue to have access only to the functionality appropriate for their role. This enhancement improves usability for users with the Data Central Read Only reviewer role by supporting more efficient issue management and collaboration without expanding review privileges.
EL-37203	Data Listings: Added quick view of Issues and Queries	Issue and Query counts displayed in Data Listings are now interactive, allowing users to quickly review record-level Issue and Query activity directly within the listing. Clicking a count expands the record to display detailed information for the associated Issues or Queries without leaving the listing. The expanded view includes: • Open and In Progress Issues: Issue description, Issue ID, Priority, Field (for field-level Issues), Assigned To, Due Date, and Progressed By or Pended By details, where applicable. • Open Queries: Query description, Query ID, Field, Notification Group, and Opened Date. • Answered Issues and Queries: Separate Answered and Closed tabs display the Issue or Query description, response, and the responding or closing user and date. If no Answered Issues or Queries exist but Closed ones do, the 0 in the Answered column remains clickable and opens the Closed tab. If no Answered or Closed Issues or Queries exist, the 0 is not clickable. • Direct Navigation: Issue IDs and Query IDs are clickable, allowing users to open the associated Issue or Query details directly from the expanded view. • Panel Behavior: Clicking the same Issue or Query count again or pressing Esc closes the expanded view. Clicking a different Issue or Query count automatically closes the current view and displays the corresponding Issues or Queries for the newly selected record. This enhancement provides immediate visibility into existing record-level and field-level review activity, helping users avoid creating duplicate Issues and Queries while streamlining data review.
EL-36230	Data Listings: Export record-level audit history	Users can now export record-level audit history from any Data Central listing, providing a detailed history of review activities for each record. To generate the report, select Export from the

Issue ID	Summary	Data Central Release Note Description
		listing toolbar, then select the 'Export Audit History' option. Users must specify a date range to include only audit actions that occurred within the selected period. The exported Excel file preserves all columns from the original listing and adds the following audit-related columns at the beginning of the report: Action, Action Type, Action Role, Action User, Action Date, Action Detail, and Action ID. Each audit action for a record is exported as a separate row, allowing users to view the complete review history for each record. Supported audit actions include Reviewed, Comment Added (includes the comment text), and Annotation Updated (includes the updated field name and value). This enhancement provides greater visibility into record-level review activity and supports audit and compliance workflows by making detailed audit history available directly from Data Central exports.
EL-24454	Filter Panel: Redesigned for centralized filter management	The Filter Panel has been redesigned to provide a centralized view of all filters applied within Data Central. Filters are now organized into 'Global' and 'Local' sections, making it easier to distinguish filters that affect the entire sheet from those that apply only to an individual panel. Global filters are also displayed in the master header, making it easier to understand what is affecting the current view. Supported filter types include Data Cuts, Advanced Filters, Subject filters, Subject Focus filters (Filter subject in other panels), Visualization filters, and panel-specific filters (row filters). Applied filters are still represented as interactive filter pills, now redesigned with filter-specific icons and more informative details that display the most relevant information for each filter type, such as the associated table, field, and selected values, or configured Data Cut or Advanced Filter name. Enhanced tooltips make applied filters easier to identify and understand, while selecting a filter pill allows users to review, modify, or remove the associated filter. Visualization filters applied from the filter icon in the chart's toolbar are now included in the Local section of the Filter Panel and the Applied Filters popout. The 'Set & Advanced' section has also been updated with a modernized design and a new name that better reflects support for both Filter Sets and Advanced Filters. This enhancement provides a single location to review and manage all applied filters, improving transparency, reducing

Issue ID	Summary	Data Central Release Note Description
		navigation between filtering tools, and making it easier to understand how applied filters affect displayed data.
EL-37420	Review Plan - Review Objective and Material Status: Added progress tracking	Review Objectives now provide enhanced progress tracking for programmatic review materials, including Data Central Listings, eIQ Review, and Orchestrator Rules. Programmatic review materials now display progress bars with reviewed versus total counts and completion percentages on progress bar hover, based on the current review cycle. This allows partially completed reviews to display as In Progress instead of Not Started, providing a more accurate representation of their current review status. A new Overall Progress section in the Review Objective Details panel displays the Review Objective's overall completion percentage and progress bar. Selecting the progress bar opens a detailed breakdown of how each attached review material contributes to the overall progress calculation. All progress calculations update automatically as review activity changes. This enhancement provides greater visibility into Review Objective progress, helping users monitor review activity, understand overall completion, and identify remaining work within the current review cycle.
EL-36559	Subjects Panel: Added the 'Unclean Reason(s)' column to exports when Clean Participant Tracker is enabled	When Clean Participant Tracker is enabled, exports from the Subjects listing now include the Unclean Reason(s) column. This column captures the reasons a subject is marked as unclean at the time of export, making information previously available only from the Clean Status tooltip available in exported data. This enhancement improves audit readiness and supports documentation.
EL-35955	Veeva Vault CDMS query authentication: Updated to support flexible authentication workflows	Data Central now supports multiple authentication workflows when creating or actioning queries in Veeva Vault CDMS. Based on the study's configured authentication settings, users can authenticate using stored credentials, individual credentials, SSO, or a combination of password and SSO authentication. This enhancement provides organizations with greater flexibility to align query workflows with security requirements while delivering a streamlined authentication experience for end users.

Issue ID	Summary	Data Central Release Note Description
EL-36520	Visualizations: Added Visualization Details popout	Visualizations now include a new Visualization Details popout that provides quick access to key configuration details by clicking the chart title. The popout displays Dimensions, Measures, Chart Configuration Filters, and any linked Review Objectives, providing greater visibility into the data being displayed and making it easier to validate the chart and interpret results. Linked Review Objectives are interactive, allowing users to open their details directly from the popout for additional context. The popout also displays chart metadata, including the Created By user and date, as well as the Last Modified By user and date. This enhancement helps users understand, validate, and analyze charts by surfacing key configuration details, related review context, and chart metadata in one location.

Issues Release Notes

Issue ID	Summary	Issues Release Note Description
EL-37146	Create, Edit, and Reopen Issue windows: Redesigned layouts and enhanced workflows	Redesigned the Create, Edit, and Reopen Issue windows across Data Central, RBQM, SCE, Specifications, eIQ Review, Analytics, ODR, and Issues to provide a more consistent, readable, and efficient user experience. Updated layouts separate editable issue details from read-only record details, improving visibility of key record information and configured related fields while streamlining issue entry and review workflows. Additional enhancements include support for priority color indicators, character counters for the Issue Text and Reason for Reopening fields, updated Due Date labeling, Receive Notifications for Changes options during issue reopen, and improved bulk issue messaging.
EL-35076	Enabled separate prepopulation of Issue Text and Query Text using distinct Mapper columns	Users can now define a dedicated IssueText column in mappings to control the text that is prepopulated when creating an Issue. When an IssueText column is defined, its value is used only for Issue creation, while QueryText continues to be used only for Query creation. If an IssueText field does not exist, the system uses QueryText to prepopulate the Issue,

Issue ID	Summary	Issues Release Note Description
		preserving existing behavior. Prepopulated Issue text remains editable before the Issue is created.
EL-36739	Improved filtering experience highlighting relevant values	Global Issues now provides a more intuitive filtering experience for string-based columns. When filters are applied in one column, opening the filter popout in another column now visually distinguishes which values remain in the filtered dataset. - Values still present in the filtered results appear at the top of the list with a white background, sorted A–Z. Selecting these values further refines the results. - Values no longer present in the filtered results appear below with a gray background. Selecting any of these values resets existing filters and displays only the newly selected data. This enhancement helps users quickly identify relevant filter values and make more context-aware filtering decisions.
EL-37080	Updated Site ID and Subject ID column filters to unique value selectors	In Global Issues, the Site ID and Subject ID column filters have been updated from free-text entry to unique value selectors, allowing users to search for and select one or more values from the available list. Additionally, when searching within a column filter, users can press Enter to automatically select all matching results at once, making it faster and easier to narrow down data. However, a minimum of three characters is required in the search field to use this capability.

Orchestrator Release Notes

Issue ID	Summary	Orchestrator Release Note Description
EL-36085	Expanded Orchestrator auto-closure for queries and issues	When an Orchestrator rule no longer meets its criteria, Orchestrator automatically resolves all associated queries and issues. Open Rave queries are canceled, while open Veeva and InForm queries and illuminate issues are closed. Queries and issues that were previously answered, marked In Progress or Pending, or manually reopened are also closed when they are no longer applicable. This enhancement helps keep issue tracking accurate and up to date.

Platform Release Notes

Issue ID	Summary	Platform Release Note Description
EL-25181	Audit Logs: Improved user experience	The Audit Logs user interface has been redesigned to provide a more streamlined and consistent experience aligned with the rest of the platform while preserving existing functionality. Key improvements include: - Streamlined column filtering by removing the dedicated filter row. Users can now filter directly from each column header using the standard filter popout, including support for Include and Exclude filtering on string-based columns. - Updated date filters to use the standard combined date and time picker. - Moved the Reset and Clear filter actions to the filter icon in the master header, while allowing individual filters to be cleared directly from the filter popover. - Added sorting support for the Object Data column. - Updated pagination controls with page navigation, jump-to-page functionality, and a Rows Per Page selector centered at the bottom of the table.
EL-25180	Configuration: Improved user experience	The Configuration user interface has been redesigned to provide a more streamlined and consistent experience aligned with the rest of the platform while preserving existing functionality. Key improvements include: - Updated the Export button to open a popout with the available export options in a single click. - Added the ability to right-click column headers to sort or fix columns to the left or right. - Added truncation and tooltips for values that exceed the available cell space, allowing users to view the full value on hover. - Updated pagination controls with a Rows Per Page selector, page selection, and previous and next page navigation centered at the bottom of each table. - Updated the Issue Priorities and Review Objective Priorities grids to display configured priority colors as color swatches alongside the priority name instead of applying the color to the entire cell.

Issue ID	Summary	Platform Release Note Description
EL-34030	Data Sources: Added Clinical Ink as an eSource Data Source	Added Clinical Ink as an eSource data source. Configure a Clinical Ink data source to connect directly to the underlying Clinical Ink database, providing direct access to collected eSource data without requiring additional systems to generate and store file-based extracts. This approach streamlines importing Clinical Ink data into elluminate.
EL-28626	Data Sources: Added Key Pair Authentication for Snowflake Data Sources	Added Key Pair Authentication support for Snowflake ODBC data sources. This enhancement supports Snowflake security policies, including environments that require MFA or other security controls for non-system accounts. A new Authentication Type field is available for Snowflake ODBC data sources. When Key Pair Authentication is selected, users can configure the required Private Key and Passphrase to authenticate Snowflake imports and exports.
EL-37373	Data Sources: Added OpenStudyBuilder as a Standards Data Source	Added support for OpenStudyBuilder (OSB) as a Standards data source. Users with the appropriate permissions can configure an OpenStudyBuilder connection as a System Data Source by providing the required connection information and validating the connection. After the connection is configured, users can import sponsor-defined SDTM standards and associated controlled terminology directly into the Standards module. This enhancement allows sponsors that manage custom standards in OpenStudyBuilder to integrate those standards into elluminate without relying on file-based imports. Imported standards are available for standards-related activities, including data validation and mapping.
EL-41028	Data Sources: Improved options for removing selected Data Source Types and System Data Sources	Added an 'X' option to the Use System Data Source and Data Source Type fields to make it easier to remove selected values. Previously, users had to select a blank option from the drop-down list to clear either field. This limitation often required users to delete or deprecate an existing data source when reconfiguring it. The new option allows users to quickly clear a selection and reconfigure an existing data source without deleting or deprecating it.
EL-36084	Exporter: Added Filename column to export history tables	Added the Filename column to export history tables in Exporter, Study Details Exports, and Import & Export pages. Previously, these tables did not consistently display the name of the exported file. The exported filename now appears alongside the existing export history details, making it easier to

Issue ID	Summary	Platform Release Note Description
		identify and trace exported files by using the timestamp included in the filename.
EL-25169	Exporter: Improved user experience	The Exporter user interface has been redesigned to provide a more streamlined and consistent experience aligned with the rest of the platform while preserving existing export functionality. Key improvements include: - Renamed the Recent Exports tab to Export History, which provides access to the full export history. - Moved the Export History and Export Definitions tabs into the master header and added badges displaying their respective counts. - Moved the Export and New Definition buttons into the master header. - Updated the New Definition window to clearly indicate that Name and Filename Format are required fields. - Updated Available Domains to use checkboxes for multi-select, replacing the previous Ctrl-click interaction. - Updated the [Include All] option to a separate Include All Current & Future Domains checkbox, with explanatory text clarifying its function. - Updated the Tags grouping to use the standard tag icon instead of the previous hash symbol for each tag. - Redesigned Export History as a sortable and filterable table displaying Format, Data Store/Tag, Filename, Created By, Created Date, Status, and Download. - Created Date now uses the standard date and time format, and status icons provide a clearer visual indication of export status. - Added a split-screen detail view when an export is selected from Export History, displaying the domains included in the export along with their Description, Duration, Status, and Last Refreshed date and time. - Enhanced the Export History and Export Definitions tables with sorting, filtering, and updated pagination controls, including page navigation, jump-to-page functionality, and a Rows Per Page selector centered at the bottom of each table. - Added confirmation messages when an Export Definition is created, edited, or deleted.

Issue ID	Summary	Platform Release Note Description
EL-42856	Importer: Added Pre-Load Domains and multi-domain deletion for Databricks Import Definitions	Extended Databricks Import Definition configuration by adding the Pre-Load Domains option to the Options tab. Select Pre-Load Domains to automatically generate queries that ingest all columns from every table in the schema of the selected Databricks data source. This enhancement pre-populates the list of available domains, allowing users to selectively import domains without manually creating queries for each table. Added support for selecting and deleting multiple domains in Databricks Import Definitions. This enhancement simplifies the bulk removal of manually configured and pre-loaded domains, improving the overall user experience.
EL-42983	Importer: Enhanced the Options tab for database import definitions for ODBC Snowflake and SQL RDS	Enhanced the Options tab for ODBC Snowflake and SQL RDS sourced import definitions by adding support for multi-select deletion of configured domains. Users can now select and remove multiple domains in a single action from the table header. Previously, removing multiple domains required deleting each table individually or creating a new import definition. This update streamlines domain management within the Options tab and reduces the effort required to maintain database import definitions.
EL-25172	Snapshots: Improved user experience	The Snapshots user interface has been redesigned to provide a more streamlined and consistent experience aligned with the rest of the platform while preserving existing functionality. Key improvements include: - Redesigned Snapshot cards to align with the Studies card design, with the Snapshot name and actions displayed in the card header and Status, Study Version, Created On, and Created By presented below in a structured layout for easier review. - KPIs for Data Stores and Domains are now displayed more prominently in the Snapshot card. - Added a search bar to the master header, allowing users to quickly find a specific Snapshot. - Updated the Card/Grid view toggle to a single button that switches between Card and Grid views when selected.

Issue ID	Summary	Platform Release Note Description
		○ NOTE: This update also applies to Studies, Global Data Stores, Data Central Studies, and Validator.
EL-25174	Validator: Improved user experience	The Validator user interface has been redesigned to provide a more streamlined and consistent experience aligned with the rest of the platform while preserving existing functionality. Key improvements include: • Renamed the Tile View and List View options for Validator Definitions to Card View and Grid View, respectively and updated the Add Definition button to reflect the new design. • Added a search bar to the master header, allowing users to quickly find Validator Definitions. • Updated the Definitions tab to use infinite scrolling, allowing users to continuously scroll through available definitions without selecting the number of items to display. • Redesigned the Results tab to display validation runs in a sortable and filterable table with Name, Date, Errors, and Status columns. Selecting a result opens a split-screen detail table that displays Type, Message, Domain, and Field for the selected validation run. ○ Streamlined filtering on the Results tab by removing the dedicated filter row and allowing users to filter directly from the column headers. ○ Updated pagination for validation results by moving the Rows Per Page selector from the master header to the pagination controls at the bottom of the table.

Risk Management Release Notes

Issue ID	Summary	Risk Management Release Note Description
EL-40566	RACT: Added capability for moving Risks across Considerations	Added the Move Risk option to the Risk Actions menu for each Risk card. Users can now move a Risk from one Consideration to another within the same Assessment. Moved Risks retain their content and Risk ID, preserving their identity and historical continuity.

Issue ID	Summary	Risk Management Release Note Description
EL-36563	RACT: Added reassessment workflow for continuous risk tracking across assessment versions	A new Create Reassessment option was added to distinguish between creating a new assessment and creating a reassessment, giving Risk Managers greater control over whether to create a new assessment or continue from a previously finalized assessment. This update supports continuous risk tracking across assessment versions while preserving the option to create a new assessment without carrying forward existing Risks. The Create Reassessment flow allows users to select a finalized assessment to use as the basis for the reassessment. All Risks from the selected assessment are carried forward, preserving risk identity, content, and associated IDRPCs where applicable. Carried-over Risks remain under their existing CTQs and Considerations, while Risks without valid Considerations are placed under the Unaffiliated CTQ. The Create Assessment button was renamed Create New Assessment. Assessments created through the Create New Assessment flow always start with no existing Risks. These changes provide a more consistent reassessment workflow and maintain a reliable risk identity trail for Analytics.
EL-40568	RACT: Introduced generic CTQs in RACT Assessments	Added two system-defined generic CTQs, Study Specific and Unaffiliated, to the default CTQ setup in all Assessment Settings and active RACT Assessments. These CTQs provide a standardized way to capture study-specific Risks and Risks that do not align with an existing CTQ. The generic CTQs and their Considerations function like standard CTQs and Considerations. They support Risk creation, the Move Risk action, and export. Because they are system-defined, they cannot be modified. This update does not affect existing finalized assessments and provides Risk Managers with a standardized way to capture study-specific and non-CTQ-associated Risks while supporting more consistent risk organization across assessments.
EL-34338	RACT: Introduced IQRM Analytics for integrated quality risk management insights	Added the IQRM page under Analytics to provide Risk Managers with a consolidated view of how study Risks in the latest finalized Assessment align with IDRPC Review Objectives. The dashboard includes summary metrics, visualizations, and an Integrated Quality Risk Management Plan (IQRMP) table to

Issue ID	Summary	Risk Management Release Note Description
		help users evaluate Risk coverage, Review Objective alignment, reviewer role distribution, and quality risk management priorities. The IQRMP table combines Risk and IDRP Review Objective data in a single view and supports sorting, filtering, and export to Excel and PDF. Users can also filter the dashboard by CTQ and Risk Control Action, with filter selections applied across all dashboard components. This enhancement provides Risk Managers with a consolidated view of how study Risks align with IDRP Review Objectives and reviewer responsibilities, supporting integrated quality risk management, review planning, governance reporting, and inspection readiness.
EL-33723	RACT: Introduced Risk Analytics Overview page for study-level risk insights and reporting	Introduced the Overview page under Analytics to provide a centralized, study-level view of risk performance across finalized assessments. The page includes summary cards for Risks, Functional Plans, Metrics, and Mitigations, enabling Risk Managers to monitor risk trends, mitigation activity, monitoring coverage, and functional ownership from a single location. Metrics include QTL and KRI counts with links to the corresponding RBQM pages, while mitigation metrics distinguish between Pre-Study and During-Study activities. Interactive charts provide deeper analysis through Risk Score (RPN) Over Time, Risk Distribution, KRI Distribution, Mitigation by Risk, and Risk Distribution by Functional Plan. The Risk Summary table now appears at the bottom of the page to provide supporting risk details. Page-level filters for Assessments, CTQs, and Risk Control Actions apply across all dashboard elements to support focused analysis and reporting. To support consistent reporting across reassessments, RACT now preserves risk identity when risks are carried forward from finalized assessments. The Risk Description and Risk Statement fields are read-only for carried-over risks. For Library-linked risks, the Risk Description field remains read-only until the risk is unlinked from the Library. These enhancements provide an audit-ready view of risk evolution, monitoring coverage, mitigation activity, and functional accountability across finalized assessments,

Issue ID	Summary	Risk Management Release Note Description
		supporting routine risk reviews, governance reporting, and inspection readiness.
EL-30592	RBQM: Introduced Root Cause Analysis dashboard for KRI investigation	Introduced the Root Cause Analysis dashboard to support RBQM KRI investigation workflows. Users can now access the dashboard directly from KRI side panels by selecting the 'Go to Root Cause Analysis' link. The page provides centralized access to KRI Trend charts, site and country comparison visualizations, and configurable supporting graphs to help central monitors investigate elevated or abnormal KRI behavior efficiently. The Root Cause Analysis dashboard includes KRI Trend charts for site-level and country-level analysis, allowing users to track KRI score changes over time, compare KRI scores against the overall study average, and view threshold-based background shading that highlights risk levels. The charts also dynamically adjust based on whether users launch the dashboard from a study-level or specific site or country context. Site Comparison and Country Comparison visualizations use box-and-whisker charts to compare KRI scores across the study, display historical score distributions, highlight current run scores and risk levels, and automatically focus on the selected site or country during investigation. The dashboard also supports configurable supporting graphs to provide additional KRI-specific analysis. RBQM now supports configurable and reusable supporting graphs in KRI configuration within Data Central Configuration and directly from the Root Cause Analysis dashboard. Users with Data Central Designer and RBQM privileges can create new visualizations or select existing visualizations through the new Custom Supporting Graph experience. Custom visualizations can be previewed, edited, saved, reused, and are stored in the dedicated RBQM Supporting Graph folder in Data Central Visualizations. Only visualizations in this folder are available for selection as supporting graphs when configuring KRIs. These enhancements also introduce Save As support for existing visualizations, support dynamic visualizations for KRI exploration, and provide centralized management of reusable supporting graphs across studies.

SCE Release Notes

Issue ID	Summary	SCE Release Note Description
EL-37449	Build, publish, and manage custom Shiny applications	Users can now build, publish, and manage custom Shiny analytical applications from the Apps page in the Statistical Computing Environment (SCE). SCE supports Shiny applications built in either R or Python, enabling developers to create interactive dashboards and visualizations that connect to illuminate data stores. Developers can build and maintain applications alongside existing SCE programs and publish them for authorized users. Applications are hosted and delivered through Posit Connect and published to the Apps Hub, where authorized users can discover and launch them. The Apps page displays each application's name, number of files, type, deployment status, and app status, and provides actions to deploy, launch, publish, revert, and configure applications. Access is controlled through the new Apps Hub Developer and Apps Hub Publisher privileges.

Study Advisor Release Notes

Issue ID	Summary	Study Advisor Release Note Description
EL-33977	Added AI-assisted study creation from Study Protocols	Study creation now supports an AI-assisted workflow through Study Advisor, allowing Administrators and Study Configure users to create studies directly from an uploaded Study Protocol (PDF or DOCX). On the Studies page, after selecting 'Create Via Study Advisor' from the Add Study menu, Study Advisor extracts key study information, including Study Name, Study Type, Therapeutic Area, Phase, Compound, Primary Endpoint, Program Type, Description, Indication, Blinding, Control, and Healthy Subjects, and populates the Configuration tab in Study Configuration, allowing users to review, edit, and confirm the proposed values before creating the study. When extracted values do not already exist in Configuration under Platform Administration, Study Advisor suggests new configuration values for authorized users to add directly during study setup. After the study is created, users are automatically taken to Study Advisor, where the uploaded Study Protocol is stored in the dedicated Study Protocol card.

Issue ID	Summary	Study Advisor Release Note Description
		This enhancement reduces manual data entry, accelerates study setup, and helps keep study configuration aligned with the Study Protocol.
EL-34323	Documents and Details: Added study file management and AI-extracted study details	Study Advisor is a new addition to illuminate that centralizes study documents, AI-extracted study details, and protocol-driven study setup in a single location. Study Advisor is available from the Study Management drop-down within a study and from the Study Management section of the platform menu and can be enabled or disabled on a per-study basis. Study Advisor is organized into three sections: Documents, Details, and Review Objectives. The Documents section supports uploading (by users with Administer, Study Configure, or eDrive Read Write privileges), downloading, versioning, including downloading previous versions, and managing the Study Protocol and other study documents. The Study Protocol is supported in PDF and DOCX formats up to 50 MB, while other study documents have no file type constraints and a 1 GB limit. Uploading a Study Protocol to the dedicated Study Protocol card automatically triggers AI extraction of study details and generation of Review Objective recommendations. The extracted study details are displayed in the read-only Details section and remain synchronized with the latest Study Protocol version. The 'Push to Study Configuration' button updates the existing Configuration Details to align with the Study Protocol. When selected, the Study Configuration window opens with suggested values populated for fields that differ from the study's current configuration. These fields are marked with a sparkle icon, and hovering over the icon displays the previous value for easy comparison. Fields that already match remain unchanged, and if all AI-extracted details already match the study's configuration, the Push to Study Configuration action is disabled. The Review Objectives section provides a centralized location for reviewing and managing AI-generated Review Objective suggestions based on the uploaded Study Protocol. This enhancement accelerates study setup, reduces manual effort, helps keep study configuration and review planning aligned with the latest Study Protocol, and provides a foundation for AI-assisted study management. Note: For studies with Data Advisor enabled, Study Advisor's Documents tab is integrated with the eDrive Protocol folder to

Issue ID	Summary	Study Advisor Release Note Description
		provide a single location for managing study documents. When Study Advisor is enabled, the eDrive Protocol folder becomes read-only and redirects users to Study Advisor. The first time users navigate to Study Advisor, a Sync From eDrive window appears and lists all files in the eDrive Protocol folder. Users can designate one file as the Study Protocol, and any remaining files are imported as supporting documents.
EL-33972	Review Objectives: Added AI-powered Review Objective suggestions from Study Protocols	Study Advisor now uses AI to analyze uploaded Study Protocols and generate Review Objective suggestions, helping users build study-specific review plans more quickly and consistently. Suggestions are presented in two categories: Global Library Suggestions, which identify existing Review Objectives in the Global Library that closely match the Study Protocol and can be reused, and Study Document Suggestions, which generate new Review Objectives based on the Study Protocol when suitable matches do not already exist. Study Document Suggestions include AI-generated recommendations for key configuration details, including Primary Domain, Secondary Domain(s), Field(s), Priority, Reviewer Role(s), and Review Frequency, along with the supporting Protocol Reference and Rationale used to generate each suggestion. Users can review, edit, accept, or reject individual suggestions, or use multi-select actions to accept or reject multiple suggestions at once through either the toolbar or the right-click context menu. If study data has not been imported yet, suggestions use SDTM domains for Primary Domain, Secondary Domain(s), and Field(s), and the Accept button will be disabled until users select 'Connect to Study Data' to recalculate these fields using the study's imported data. Accepting a suggestion automatically adds the Review Objective to the study's Review Plan, while rejecting a suggestion prompts the user to select a predefined Rejection Reason and retains that decision so the Review Objective is not recommended again for future Study Protocol versions. Rejected suggestions can also be restored to the Pending Review state using the Unreject button. This ensures full user control over the review planning process. Both Global Library Suggestions and Study Document Suggestions can be reviewed, searched, filtered, exported, and managed independently for each uploaded Study Protocol version, allowing users to compare suggestions across Study Protocol versions while preventing duplication of previously accepted Review Objectives. Each tab includes clickable

Issue ID	Summary	Study Advisor Release Note Description
		status badges that display the number of suggestions that are Pending Review (yellow), Accepted (green), and Rejected (red). Selecting a badge filters the grid to the corresponding suggestions, providing an at-a-glance summary of suggestion progress. This enhancement accelerates review plan creation, promotes reuse of Global Library Review Objectives, and helps keep study-specific review plans aligned with the latest Study Protocol.