



illuminate 25.2.0  
Release Notes  
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## Notice

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## Purpose and Scope

illuminate® is a clinical data hub providing a unified platform for all your clinical data, from acquisition to analytics. It offers self-service access to data ingestion, mapping, and comprehensive analytics, enabling fast and accurate answers to clinical and operational questions.

This document provides release notes for eClinical Solutions' illuminate platform, version 25.2.0. These notes detail new features, improvements, and resolved defects. Reviewing them will help users and business stakeholders understand the benefits of upgrading from previous versions.

## Supporting Documentation

Additional resources for information on the illuminate platform are available.

The illuminate Help Center provides detailed information on using and configuring the platform, including new features and functionality. It can be accessed at: <https://support.eclinicalsol.com/hc/en-us?version=25.2>.

Access the illuminate Community Conversations from within illuminate or via the Help Center.

eClinical Solutions also offers a validation accelerator to facilitate and streamline documentation for product upgrades. Contact your project manager for details.

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## New Features and Improvements

illuminate Release 25.2.0 includes several new features and improvements. The major items included in this release are as follows:

### Analytics

Analytics includes several enhancements that improve flexibility and consistency across CDA, CTOA, SMA, and OO.

- **All Apps - Hide Out-of-the-Box Base Sheets:** CDA, CTOA, SMA, and OO now support hiding selected or all out-of-the-box sheets, allowing organizations to display only the sheets relevant to their users. Base sheet hiding must be done through eCS Support so Engineering can apply the configuration.
- **CTOA, SMA, & OO - User-Group Sheet-Level Access Control:** CTOA, SMA, and OO now support role-based sheet visibility, allowing organizations to control which sheets users can access through illuminate user-groups. Sheet-level control must be done through eCS Support so Engineering can apply the configuration.
- **CTOA - Support for Study-Level Planned Enrollment:** CTOA now supports study-level planned enrollment across all enrollment dashboards, ensuring values are displayed correctly whether defined at the study level or more granular levels.
- **SMA - Externalized Anomaly-Detection Rules:** SMA now supports externalized anomaly-detection rules, allowing organizations to define their own criteria for identifying potential issues in the Data Anomalies sheet. Custom rules must be done through eCS Support so Engineering can apply the configuration.

### Data Central

Data Central and Data Central Configuration now offer expanded capabilities to support the Integrated Data Review Plan (IDRP), deepening integration across modules and strengthening alignment, collaboration, and oversight throughout the data review process.

- **RACT Integration:** Users can now link Review Objectives to risks from the latest finalized Risk Assessment in RACT, reinforcing prioritization and alignment with study risks.
- **Approval & Versioning:** A new versioning workflow introduces structured version control for Review Objectives. Approved objectives become read-only and require versioning before modification. A Version History panel allows users to compare versions side-by-side and view highlighted changes.
- **Configuration Collaboration:** A new Comments & Activity panel is available when configuring each version of a review objective, capturing comments and status transitions. Users can also @-mention collaborators to trigger email notifications with direct links, improving communication and follow-up.
- **Bulk Editing:** A new Bulk Edit grid allows users to update multiple Review Objectives at once using an editable spreadsheet-style interface. Users can copy and paste values, edit directly in cells, and validate changes before saving.
- **Global Library Integration:** Users can now import Review Objectives from the Global Library or promote approved Review Objectives to the Global Library for reuse across studies, improving configuration efficiency and consistency.
- **Review Cycle Oversight:** A new Review Cycles sheet has been added to the Review Plan Dashboard, providing cycle-level visibility into completion status across Review Objectives. Interactive charts, a comprehensive Review Cycles listing, and a new Missed status help teams track timeliness, accountability, and review performance across roles.

- **Notification Integration:** Reviewer Roles can now be configured to receive automated email notifications for key Review Objective events, including submissions, approvals, rejections, reminders, and missed review cycles, ensuring timely visibility and strengthening proactive review management.

These enhancements improve transparency, control, and efficiency in the data review process.

### Protocol Deviations Enhancements

The Protocol Deviations Dashboard has been enhanced to provide a more consistent user experience with other panels in Data Central. New functionality includes exporting Protocol Deviation data from the dashboard, setting user domain preferences for field hiding, clicking and dragging columns to rearrange them, and exposing Protocol Deviation data for Data Central Visualization development supported by eCS representatives.

### Veeva CDMS Query Connector Enhancements

The capabilities of the Veeva CDMS bi-directional query connector have been expanded in this release. Functions previously unavailable through Veeva's API are now supported, including:

- Ingesting Event or visit-level queries through the Importer
- Displaying, creating, or acting on Event queries in Data Central
- Reopening Veeva CDMS queries that are in a closed status
- Providing improved access to source data from Query records in Data Central

## Platform

### Expanding Configuration Migration Capabilities

Several illuminate configurations have been enhanced to allow users to extract completed configurations from their studies or URLs and migrate them to other studies or URLs as needed. This eliminates the need to reconfigure the modules listed below:

- Orchestrator Rules (*additional migration support coming shortly after release*)
- Blinding Configuration
- Validator
- Dynamic Mapping Templates
- Study ETL Keys

## Risk Management

Key enhancements across Risk Management Configuration, RACT, and RBQM improve alignment, usability, and traceability throughout the risk assessment and monitoring process. Highlights include:

- **Improved linkage between Risks and Review Objectives** with new Review Plan indicators, warnings for linked risk deletions, and tighter integration with the Integrated Data Review Plan.
- **More intuitive RACT workflows**, including prioritized Risk suggestions based on CTQs and redesigned Risk tracking and identification screens.
- **Updated navigation in RBQM and RACT** with a new left navigation panel, consistent layout, and smoother movement between related areas.

- **Streamlined RBQM configuration** with direct linkage to CTQs, QTLs, and KRIs from Risk Management Configuration and improved synchronization and audit traceability.
- **Enhanced RBQM monitoring visibility** through timestamped Snapshots and new KRI side-panel details in Sites and Countries Overview.
- **Support for versioned Assessment Settings** for managing multiple RACT configurations across programs and studies.

## Mapping Automation (*coming shortly after release*)

### Specification Generation

illuminate will provide accelerators for automated SDTM transformations. The process will begin with AI-powered variable matching, where source variables are automatically aligned with the most appropriate SDTM targets using SDTM Implementation Guide knowledge, natural language processing of variable metadata, and historical mapping patterns. Building on this foundation, an agentic AI approach will then evaluate each source-target pairing to determine the appropriate transformation logic. The agent will experiment with combinations from a library of standard transformation functions, validate results against the source data and expected sample SDTM outputs, and select the optimal approach, which will be returned for user evaluation.

The output will be a structured, human-readable specification that includes both the suggested variable alignments and transformation functions. By automating specification creation, illuminate will reduce manual effort, accelerate one of the most time-intensive steps in preparing clinical trial data for standardization and submission, and maintain full transparency for expert human oversight and control.

### Code Generation

Once specifications are finalized, illuminate will convert structured specifications into executable Python or R code using a library of validated algorithms. Each domain operation and variable transformation will be translated to code by validated deterministic functions, ensuring consistency and reproducibility. The generated code will be fully transparent, allowing users to review, refine, and supplement programming logic as needed.

Generated mapping programs will execute directly within illuminate Compute Environment as part of an automated pipeline, triggered by data refresh and integrated with downstream workflows. Execution will produce complete logs and outputs, maintaining full traceability from specification through runtime. For the most complex derivations, generated code can be edited and extended using established programming PDLC practices, allowing programmers to augment the automation with their specialized expertise. By automating routine transformations while enabling human oversight and intervention for edge cases, illuminate will allow teams to maximize the value of their programming resources, reduce manual effort, and streamline the production of submission-ready datasets.

## Module Specific Details

For each module of the elluminate platform, we provide detailed information on new features and improvements, as well as any notable defects addressed in that module. Users can navigate directly to the modules most relevant to them to understand how this release will impact their experience and plan for the upgrade.

### Analytics

#### Clinical Data Analytics (CDA)

##### New Features/Improvements

Internal Issue#	Summary	Release Note Description
ECCA-688	CDA - Adverse Events Cross Tabulation sheet: Enhanced System Organ Class to drill down to Preferred Term	<p>The 'Counts by Study &amp; Toxicity' pivot table on the Adverse Events Cross Tabulation sheet now supports drill-down functionality. Users can expand any System Organ Class (SOC) to view the corresponding Preferred Terms (PTs) directly within the table.</p> <p>This enhancement provides an additional level of detail, allowing reviewers to quickly explore and analyze adverse events within each System Organ Class without leaving the current view.</p>
ECCA-745	CDA - Exposure Data sheet: New Treatment filter and dose-change analysis added	<p>On the Exposure Data sheet, a new 'Treatment' filter has been added to the top filter row (between 'Subject' and 'EX Start Date'), allowing users to focus their analysis on a specific treatment when subjects are receiving multiple regimens.</p> <p>Additionally, the 'Dosing Trend Over Time Per Subject' line chart has been converted into a container with two tabs: 'Dosing Over Time/Subject' (existing default chart) and 'Dose Change Over Time/Subject' (new chart). The new chart displays how a subject's dose has changed over time, with a y-axis toggle for '% Change' (default) or 'Unit Change.' The % Change shows the percent difference from the previous dose while the Unit Change shows the dose change (e.g., in mg).</p> <p>These enhancements provide clearer visibility into dose adjustments and support more focused analysis for subjects on multiple treatments.</p>
ECCA-689	CDA - Lab Result Review Over Time sheet: Added baseline reference (Visit 0) in all line charts	<p>All four 'Lab Results Over Time' line charts have been enhanced to include a baseline reference point (Visit 0), providing a consistent anchor for interpreting changes over time and reducing ambiguity during review. When using the y-axis options '% Change from Baseline,' 'Change from Baseline,' or 'Absolute Change from Baseline,' the baseline visit now displays a value of 0. When using '% Change from Previous Visit' or 'Change from Previous Visit,' the earliest recorded visit displays as blank since no prior visit exists for comparison.</p>

Internal Issue#	Summary	Release Note Description
ECCA-793	CDA - Lab Result Trends, Lab Result Review Over Time, Comparative Lab Results, and LB and VS Listings sheets: Added 'Character Result in Standard Format' column to listings	On the Lab Result Trends, Lab Result Review Over Time, Comparative Lab Results, and LB and VS Listings sheets, a new 'Character Result in Standard Format' column has been added next to the existing Result in Standard Units column, which is now named 'Numeric Result in Standard Units' to provide clear distinction, to display non-numeric lab results. This update ensures that both numeric and non-numeric lab results are visible for each subject.
ECCA-763	CDA - Subject Status: Updated default derivation of Randomized and Enrolled	<p>The default logic for Randomized and Enrolled has been updated to use Consented instead of just Eligible. In other words, a subject now must have a consent date before being considered Enrolled or Randomized.</p> <ul style="list-style-type: none"> <li>• In non-randomized studies, subjects who pass screening and have a consent date are considered Consented and then Enrolled.</li> <li>• In randomized studies, subjects who pass screening and have a consent date are considered Consented until they are randomized.</li> </ul> <p>This update ensures more accurate and realistic tracking of subject progression through consent, enrollment, and randomization milestones.</p>
ECCA-397	CDA, CTOA, SMA, and OO: Added ability to hide out-of-the-box sheets	<p>Clinical Data Analytics, Clinical Trial Operational Analytics, Sample Management Analytics, and Operational Oversight now support the ability to hide selected or all out-of-the-box sheets, allowing organizations to display only the sheets relevant to their users or highlight their own community-created content.</p> <p>At this time, hiding base sheets must be configured in the Sheet_Visibility.qvs configuration file; clients wishing to enable this capability should contact eClinical Solutions Support.</p> <p>This enhancement provides greater flexibility in tailoring the analytics experience to each organization's needs.</p>

## Clinical Trial Operational Analytics (CTOA)

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
ECCA-397	CDA, CTOA, SMA, and OO: Added ability to hide out-of-the-box sheets	<p>Clinical Data Analytics, Clinical Trial Operational Analytics, Sample Management Analytics, and Operational Oversight now support the ability to hide selected or all out-of-the-box sheets, allowing organizations to display only the sheets relevant to their users or highlight their own community-created content.</p> <p>At this time, hiding base sheets must be configured in the Sheet_Visibility.qvs configuration file; clients wishing to enable this capability should contact eClinical Solutions Support.</p> <p>This enhancement provides greater flexibility in tailoring the analytics experience to each organization's needs.</p>
ECCA-682	CTOA - AE and SAE Rate sheet: New KPI, updated filters, and optimized charts and tables	<p>The AE and SAE Rate sheet has been enhanced to improve usability, layout clarity, and analytical accuracy.</p> <ul style="list-style-type: none"> <li>• A new AE Outcome filter has been added.</li> <li>• All filters have been realigned to the top-left for a cleaner, consistent, and more intuitive layout.</li> <li>• A new '# of AEs &amp; SAEs Per Site' KPI has been added inline with the existing KPIs.</li> <li>• Both bar charts now sort descending by their measures, ensuring highest-impact sites appear first.</li> <li>• Both bar charts' legends have been moved to the bottom of each chart for improved readability.</li> <li>• The table has been streamlined: <ul style="list-style-type: none"> <li>○ Removed standalone 'Site Name' column.</li> <li>○ A single Site column now displays the site number and name together (<i>Sites.Site Name</i>).</li> <li>○ Several columns, including 'Adverse Event,' 'Serious,' 'Outcome,' 'Relationship with IP,' and 'Ongoing,' have been resized to eliminate unnecessary width while keeping titles fully readable.</li> </ul> </li> <li>• All visualizations on the sheet have been repositioned to optimize the presentation.</li> </ul> <p>These updates enhance readability, improve navigation, and deliver a more efficient and informative review experience on the AE and SAE Rate sheet.</p>

Internal Issue#	Summary	Release Note Description
ECCA-44	CTOA - Enrollment Summary, Recruitment and Retention, and Enrollment Trend sheets: Added support for study-level data	<p>Support for study-level planned enrollment has been added to CTOA, ensuring planned enrollment is displayed correctly whether it is defined at the study level or at more granular levels such as country, site, or cohort.</p> <ul style="list-style-type: none"> <li>• <b>Enrollment Summary sheet:</b> Updated the Total Planned Enrollment KPI to display values when planned enrollment is stored at the study level, in addition to country / cohort / site levels.</li> <li>• <b>Recruitment and Retention sheet:</b> Updated all planned enrollment-based metrics to recognize study-level planned enrollment.</li> <li>• <b>Enrollment Trend sheet:</b> <ul style="list-style-type: none"> <li>○ Updated the Planned vs Actual chart to incorporate study-level planned enrollment.</li> <li>○ Updated the # of Planned Subjects KPI to support study-level values.</li> </ul> </li> </ul> <p>These enhancements provide greater flexibility and ensure planned enrollment is accurately reported across all CTOA dashboards.</p>
ECCA-700	CTOA - Post SDV and Post Query Changes sheet:	<p>The Post SDV and Post Query Changes sheet has been enhanced to ensure all horizontal bar charts use a unified dimension, ensuring consistent analysis across the sheet and eliminating the need to adjust each chart individually.</p> <p>A new seven-button dimension control has been added to the upper-right corner of the sheet, allowing users to choose from Study (Default), Country, Site, Subject, Folder, Form, and Data Field. Selecting any of these options automatically updates all three horizontal bar charts: 'Data Changes After SDV,' 'Query Actions After SDV,' and 'Number of Queries Resulting in a Data Change.' To support this unified control, alternative dimension selectors have been removed from each chart's y-axis.</p> <p>These enhancements provide a more consistent, streamlined review experience, enabling quick one-click alignment of all charts for easier comparison and analysis.</p>

Internal Issue#	Summary	Release Note Description
ECCA-702	CTOA - Queries By Open Date sheet: Filters added, pivot tables consolidated, improved line charts, and added new stacked bar chart	<p>The Queries By Open Date sheet has been enhanced to provide more filtering options, clearer organization, and improved insight into query trends over time:</p> <ul style="list-style-type: none"> <li>• Added two new filters, Country and Query Status, and reordered all filters for clarity: <i>Study, Country, Site, Subject, Folder, Query Status, Sender-Recipient</i>.</li> <li>• Consolidated pivot tables into a single container with two tabs: 'Queries By Site &amp; User' and 'Queries By Subject,' and removed chart titles and hover menus to reduce spacing and maximize data visibility.</li> <li>• Added a new Current Query Status Over Time stacked bar chart that supports Yearly → Monthly → Weekly → Daily drill-downs with color-coded query status counts.</li> <li>• Renamed the Cumulative Queries Per Subject By Date &amp; Site line chart to 'Queries By Date &amp; Site' and added a '# of Queries' alternative measure on the y-axis.</li> <li>• Renamed the Cumulative Queries Per Subject By Date &amp; User / Sender-Recipient line chart to 'Queries By Date &amp; User / Sender-Recipient' and added a '# of Queries' alternative measure on the y-axis.</li> </ul> <p>These enhancements provide more flexible filtering, a streamlined layout, and clearer visibility into how queries evolve over time, helping teams analyze trends, identify patterns, and monitor progress toward query resolution.</p>

Internal Issue#	Summary	Release Note Description
ECCA-670	CTOA - Query Details sheet: Redesigned and enhanced	<p>The Query Details sheet has been redesigned to improve readability, reduce white space, and provide more flexible ways to analyze query activity. Key enhancements include:</p> <ul style="list-style-type: none"> <li>• Added 'Study' and 'Country' to the existing dimension controls, with Study now set as the default.</li> <li>• Resized and reorganized filters to create a more logical top-row layout.</li> <li>• Added a new three-tab container, each containing a redesigned stacked horizontal bar chart: Queries By Sender &amp; Study, Queries By Recipient &amp; Study, and Queries By Sender-Recipient &amp; Study. All charts now dynamically respond to the selected dimension (Study (default), Country, Site, Subject, Folder, Form, or Data Field), have had alternative dimensions removed (to support the unified control), and include updated stacking logic, labeling, and presentation for clearer interpretation.</li> <li>• Added a pivot table that enables detailed exploration of queries by the selected dimension (Study, Country, Site, etc.), user who opened the query, Sender-Recipient pairing, and Query Status.</li> </ul> <p>These enhancements provide a cleaner, more consistent review experience, enable deeper analysis of query patterns across studies, sites, roles, and data fields, all within a more space-efficient, intuitive layout.</p>
ECCA-701	CTOA - Recruitment & Retention sheet: Added instructions, default values, and 'Group Assignment' filter	<p>The Recruitment and Retention sheet has been enhanced with clearer in-app guidance to make it easier to understand and use. A new instructional banner now appears in the top-right corner of the sheet, explaining how to enter threshold values that classify results as 'On Target,' 'Under Target,' or 'Action Required.' Default target values are pre-populated to help users begin analysis immediately. Additionally, a new 'Group Assignment' filter has been added beside the Site filter, enabling easier cohort-level analysis. These updates provide clearer direction and more relevant filtering, helping users quickly assess recruitment and retention performance at a glance.</p>

Internal Issue#	Summary	Release Note Description
ECCA-686	CTOA - Timeliness sheet: Enhanced layout, unified dimension control, and added pivot table	<p>The Timeliness sheet has been enhanced to maximize visibility, reduce white space, and provide more consistent and intuitive chart interactions. All charts and filters have been resized and reorganized for improved readability and more efficient use of the layout.</p> <p>A new dimension control has been added beside the Audit Action Type filter, allowing users to switch all four charts between 'Study' (default), 'Country,' 'Site,' 'Subject,' 'Folder,' 'Form,' or 'Data Field' with a single click. Selecting a dimension automatically updates each chart's x-axis and title accordingly (e.g., <i>by Site, by Country</i>). To support this unified control, alternative dimension selectors have been removed from each chart's y-axis.</p> <p>The three combo charts have been reconfigured so that blue bars display the Avg Days metrics on the primary axis and red diamonds display the '# of Enrolled Subjects' on the secondary axis. Their y-axis labels have also been updated for clarity: 'Avg Days Entry to Review,' 'Avg Days Entry to Verification,' and 'Avg Days Entry to Query Open.'</p> <p>A new drill-down pivot table has been added to the bottom of the sheet, allowing users to explore metrics from Study → Country → Site → Subject. Each row displays: 'Avg Days from Initial Entry to Review,' 'Avg Days from Initial Entry to Verification,' and 'Avg Days from Initial Entry to Query Open.'</p> <p>These enhancements provide a cleaner layout, unified controls, and additional drill-down capabilities, helping users analyze timeliness metrics more efficiently.</p>
ECCA-552	CTOA, SMA, and OO: Added support for user group sheet-level access	<p>Like Clinical Data Analytics (CDA), Clinical Trial Operational Analytics (CTOA), Sample Management Analytics (SMA), and Operational Oversight (OO) now support role-based sheet visibility, enabling organizations to control which sheets users can access based on their assigned illuminate user groups. Users in restricted groups will see only the sheets assigned to their group, while users not assigned to any restricted group will continue to see all sheets by default. The Home Page and Application Information sheets remain visible to all users to ensure consistent navigation and context.</p> <p>At this time, sheet visibility must be configured in the database; therefore, clients wishing to enable this capability should contact eClinical Solutions Support. In a future release, this functionality will be made available directly within illuminate, allowing administrators to manage sheet-level access without backend assistance.</p> <p>This enhancement strengthens content governance and ensures users see only the analytics relevant to their role.</p>

## Operational Oversight (OO)

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
ECCA-397	CDA, CTOA, SMA, and OO: Added ability to hide out-of-the-box sheets	<p>Clinical Data Analytics, Clinical Trial Operational Analytics, Sample Management Analytics, and Operational Oversight now support the ability to hide selected or all out-of-the-box sheets, allowing organizations to display only the sheets relevant to their users or highlight their own community-created content.</p> <p>At this time, hiding base sheets must be configured in the Sheet_Visibility.qvs configuration file; clients wishing to enable this capability should contact eClinical Solutions Support.</p> <p>This enhancement provides greater flexibility in tailoring the analytics experience to each organization's needs.</p>
ECCA-552	CTOA, SMA, and OO: Added support for user group sheet-level access	<p>Like Clinical Data Analytics (CDA), Clinical Trial Operational Analytics (CTOA), Sample Management Analytics (SMA), and Operational Oversight (OO) now support role-based sheet visibility, enabling organizations to control which sheets users can access based on their assigned illuminate user groups. Users in restricted groups will see only the sheets assigned to their group, while users not assigned to any restricted group will continue to see all sheets by default. The Home Page and Application Information sheets remain visible to all users to ensure consistent navigation and context.</p> <p>At this time, sheet visibility must be configured in the database; therefore, clients wishing to enable this capability should contact eClinical Solutions Support. In a future release, this functionality will be made available directly within illuminate, allowing administrators to manage sheet-level access without backend assistance.</p> <p>This enhancement strengthens content governance and ensures users see only the analytics relevant to their role.</p>

Internal Issue#	Summary	Release Note Description
ECCA-671	OO: Updated to align with latest Operational Insights Investigational Product data model	<p>Operational Oversight has been updated to align with recent enhancements in Operational Insights related to Investigational Product (IP) data. The data model now uses the new ODR StudyIPs view, replacing legacy compound fields previously sourced from the Studies table. To support this change, the following updates were made:</p> <ul style="list-style-type: none"> <li>• Added the StudyIPs view to the Operational Oversight data model for improved handling of Investigational Product data.</li> <li>• Deprecated references to Studies.CompoundId and Studies.CompoundName in favor of IP.IPID and IP.CompoundName.</li> <li>• Updated all visuals that previously relied on the deprecated fields to use the new IP fields.</li> </ul> <p>These updates ensure that Operational Oversight continues to display Investigational Product data accurately, maintaining consistency with the latest Operational Insights data model.</p>

### Sample Management Analytics (SMA)

#### New Features/Improvements

Internal Issue#	Summary	Release Note Description
ECCA-397	CDA, CTOA, SMA, and OO: Added ability to hide out-of-the-box sheets	<p>Clinical Data Analytics, Clinical Trial Operational Analytics, Sample Management Analytics, and Operational Oversight now support the ability to hide selected or all out-of-the-box sheets, allowing organizations to display only the sheets relevant to their users or highlight their own community-created content.</p> <p>At this time, hiding base sheets must be configured in the Sheet_Visibility.qvs configuration file; clients wishing to enable this capability should contact eClinical Solutions Support.</p> <p>This enhancement provides greater flexibility in tailoring the analytics experience to each organization's needs.</p>

Internal Issue#	Summary	Release Note Description
ECCA-552	CTOA, SMA, and OO: Added support for user group sheet-level access	<p>Like Clinical Data Analytics (CDA), Clinical Trial Operational Analytics (CTOA), Sample Management Analytics (SMA), and Operational Oversight (OO) now support role-based sheet visibility, enabling organizations to control which sheets users can access based on their assigned elluminate user groups. Users in restricted groups will see only the sheets assigned to their group, while users not assigned to any restricted group will continue to see all sheets by default. The Home Page and Application Information sheets remain visible to all users to ensure consistent navigation and context.</p> <p>At this time, sheet visibility must be configured in the database; therefore, clients wishing to enable this capability should contact eClinical Solutions Support. In a future release, this functionality will be made available directly within elluminate, allowing administrators to manage sheet-level access without backend assistance.</p> <p>This enhancement strengthens content governance and ensures users see only the analytics relevant to their role.</p>
ECCA-685	SMA - Data Anomalies sheet: Added totals to numeric columns and updated highlighting logic	<p>In the 'Derived Sample History Issues' table, the '# of Samples' column is now highlighted only when the count is not equal to 1, making it easier for reviewers to spot unexpected sample quantities.</p> <p>In the 'Subjects Without a Site' table, the 'Count' column has been renamed to 'Sample Record Count' for improved clarity.</p> <p>In the 'Sites With No Subjects or Samples' table, totals are now displayed for the '# of Subjects' and '# of Subjects w/ Samples' columns.</p> <p>These updates provide clearer visual cues, more intuitive labeling, and more meaningful summary information, supporting faster and more accurate anomaly review.</p>
ECCA-735	SMA - Sample Details Report Builder sheet: Added 'In Storage' metric	<p>The Sample Details Report Builder sheet now includes a new 'In Storage' metric within the pivot table. This metric counts the number of samples where InStorageYN = 'Y*', giving users clearer visibility into which samples are currently stored.</p> <p>This enhancement provides a more complete view of sample status and supports operational tracking across storage workflows.</p>
ECCA-756	SMA - Sample Overview Report Builder and Sample Details Report Builder sheets: Added cell highlighting for mismatched expected and collected values	<p>On the 'Sample Overview Report Builder' sheet, in the 'Expected vs Collected Samples by Site and Subject' table, and the 'Sample Details Report Builder' sheet, in the 'Sample Details by Site and Subject' table, the 'Expected' and 'Collected' cells are now highlighted whenever the collected value does not match the expected value.</p> <p>This enhancement makes discrepancies immediately visible, helping users quickly identify missing, delayed, or unexpected sample activity and improving the efficiency of sample review workflows.</p>

Internal Issue#	Summary	Release Note Description
ECCA-548	SMA - Several sheets: Added Collection Date/Time column to Derived Sample Histories table	A new Collection Date/Time column has been added to the Derived Sample Histories table, after Time Point and before Sample ID, across all SMA sheets. This column combines the sample's collection date and collection time into a single field, providing clearer visibility into when each sample was collected.
ECCA-30	SMA: Added ability to customize anomaly detection rules	<p>Sample Management Analytics (SMA) now supports externalized anomaly detection rules, allowing organizations to define their own criteria for what constitutes a potential data issue. Previously, anomaly detection (e.g., <i>Shipped Date without a Received Date</i>) relied on a fixed set of hard-coded rules. These rules can now be customized, expanded, or replaced without requiring product changes.</p> <p>At this time, customizing the anomaly detection logic can only be done by modifying the <code>SMACustomAnomalies.qvs</code> configuration file; clients wishing to enable this capability should contact eClinical Solutions Support. Any conditions defined in this file will be reflected in the Possible Issues column across listings in the Data Anomalies sheet.</p> <p>This enhancement provides greater flexibility and enables teams to tailor anomaly detection to their specific operational workflows and data quality expectations.</p>

## Data Central

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
EL-31805	Configuration - Review Plan: Added ability to import Review Objectives from the Global Library	<p>In Data Central Configuration, within the Review Plan section, users can now import Review Objectives from the Global Library, streamlining reuse and standardization across studies. From the Import icon in the Review Objectives table toolbar, a new 'Import From Global Library' option opens a window where users can browse and select one or more Review Objectives stored in the Global Library. The list is pre-filtered to match the study's Therapeutic Area, Compound, or Program, with options to adjust or clear filters as needed.</p> <p>Before import, users can review each selected objective and update Identifier values if required. The system performs full validation, consistent with Excel imports, and the Import Summary clearly indicates whether each Review Objective is new, updated (up-versioned), or unchanged, along with any warnings or errors.</p> <p>Imported Review Objectives appear in the Review Objectives table in Configuring status and are marked with a globe icon in the Identifier column; hovering over the icon displays the Library Display Name. All import actions are recorded in the Audit Log for traceability.</p> <p>This enhancement simplifies reuse, promotes consistency, and improves scalability in Review Plan management across studies.</p>

Internal Issue#	Summary	Release Note Description
EL-34529	Configuration - Review Plan: Added ability to promote Review Objectives to the Global Library	<p>In Data Central Configuration, within the Review Plan section, users can now promote approved Review Objectives to the Global Library, enabling centralized reuse and standardization of Review Objectives across studies. For users with Study Configure, Global Library Configure, or Administer privileges, the Export icon in the Review Objectives table toolbar includes a new 'Promote To Global Library' option. Alternatively, users can right-click one or more approved Review Objectives and select 'Promote To Global Library' from the context menu.</p> <p>The promotion workflow allows users to select one or more objectives, specify a destination folder, define scope, and confirm the promotion. If a Review Objective with the same identifier already exists in the Global Library, users are prompted to overwrite or rename it. Promoted Review Objectives appear in the Global Library under a new 'Review Objective' object type, displaying details such as description, status, source study, and last updated date. Clicking a Global Library Review Objective opens a side panel showing its configured fields. All promotion actions are captured in the Audit Log for traceability.</p> <p>This enhancement aligns with existing Global Library workflows for Mapping Domains and KRIs and improves consistency and reusability of Review Objectives across studies.</p> <p>As part of this update, the Global Library interface was refined to provide a cleaner, more intuitive filtering experience. All filters are now unchecked by default, displaying all objects until one or more filters are selected. Empty folders are automatically hidden when filters are applied, and the Clear Filters button is now icon-only with a tooltip and disabled when inactive. The Types and Scope headers are bolded for clarity, the left panel width standardized for consistency, and the object list now defaults to sorting by Object Name (A–Z). These updates deliver a more consistent and streamlined user experience across the platform.</p>
EL-33141	Configuration - Review Plan: Added comments and workflow history for Review Objectives	<p>A new expandable 'Comments &amp; Activity' section has been added to both the Edit window and the Review Objective Details panel in Data Central Configuration. This section displays version-specific comments and status transitions, providing clear context and traceability. Users can leave comments (up to 4,000 characters) to provide rationale, context, or clarification during configuration and approval workflows, with Reject actions requiring a comment to ensure transparency and actionable feedback. Workflow transitions are logged in real time, even when no comment is provided, and color-coded badges clearly indicate status changes (e.g., Configuring → Pending Approval → Approved or Rejected). This enhancement improves collaboration and transparency in managing Review Objectives.</p>

Internal Issue#	Summary	Release Note Description
EL-33953	Configuration - Review Plan: Added Completion Timeframe for Review Objectives with 'On Data Refresh' Review Frequency	Review Objectives configured with a Programmatic Review Frequency of 'On Data Refresh' now include a required Completion Timeframe selector, with options of 24 Hours, 48 Hours, 3 Days, 5 Days (default), 1 Week, 2 Weeks, or 1 Month. Upon upgrade, all existing Review Objectives set to 'On Data Refresh' will default to a Completion Timeframe of 5 Days. This new field ensures reviewers have a clear deadline to complete reviews after each data refresh, supporting timely, consistent, and accountable evaluations.
EL-33205	Configuration - Review Plan: Added right-click menu for Review Objectives grid	Users can now access key actions from a right-click context menu in the Review Plan tab of Data Central Configuration. Right-clicking a single Review Objective opens a menu with quick access to Action, Copy, Edit, Delete, Activate/Deactivate, and Filter Rows By Value options. When multiple Review Objectives are selected, the context menu adapts to display the applicable bulk actions. This enhancement improves efficiency by streamlining access to common configuration tasks directly from the Review Objectives table.
EL-30231	Configuration - Review Plan: Added versioning and version comparison for Review Objectives	<p>A new versioning workflow has been introduced in Data Central Configuration to enhance traceability and control over Review Objective updates. Once a Review Objective is approved, it becomes locked for editing and must be versioned before further changes can be made. Each version is automatically numbered and displayed in the Review Objectives table, details view, and Edit window for easy reference.</p> <p>Additionally, users can now view a detailed Version History by clicking the version number to compare any two versions side by side, including unsaved changes, and see exactly what has been modified. The Version History view highlights changed fields, displays approval statuses, and includes associated comments and status transitions for full context.</p> <p>When deleting Review Objectives, users can now choose to remove only the most recent unapproved version or delete all versions entirely. These enhancements improve transparency and governance of Review Objectives throughout the study lifecycle.</p>
EL-34356	Configuration - Review Plan: Enabled @ mention tagging in Review Objective comments	When configuring Review Objectives, users can now tag collaborators in comments using @ mentions to streamline communication and trigger email notifications. Typing '@' displays a list of study-accessible users (their names and emails) for easy selection, and tagged users automatically receive an email with a direct link to the relevant Review Objective. This capability is supported across all comment-enabled workflows, including submission, approval, rejection, and versioning, as well as regular comments. This enhancement improves collaboration by ensuring timely visibility and follow-up on key discussions.

Internal Issue#	Summary	Release Note Description
EL-32916	Configuration - Review Plan: Introduced approval workflow for Review Objectives	<p>A new approval workflow has been introduced in Data Central Configuration to strengthen governance and traceability for Review Objectives. Each Review Objective now includes an Approval Status (Configuring, Pending Approval, Approved, or Rejected), clearly indicated by color-coded badges and supported by streamlined status transitions. Review Objectives can be transitioned individually or in bulk, provided they all have the same Approval Status. Approvers can be designated at the study level (in the Reviewer Roles section of Data Central Configuration), enabling them to formally approve or reject Review Objectives once stakeholder checks are complete. Review Objectives in Approved status are locked for editing and must be versioned before further changes, ensuring uninterrupted data review and preserving the approved configuration.</p> <p>The same approval workflow is supported through the Excel-based import process, with appropriate warnings and errors displayed in the Import summary if they occur. Upon upgrade, Review Objectives in an Inactive or Active state will be assigned an Approved status, while those in a Draft state will be assigned a Configuring status. These enhancements ensure that Review Objectives are formally validated before use.</p>
EL-34354	Configuration - Review Plan: Introduced Bulk Edit grid for multiple Review Objective updates	<p>In Data Central Configuration, within the Review Plan section, users can now update multiple fields across multiple Review Objectives simultaneously using the new Bulk Edit grid, accessible from the toolbar via the 'Bulk Edit Grid' icon. This editable spreadsheet-style interface allows copying, pasting, dragging, and typing directly into cells to quickly modify domains, priorities, risks, reviewer roles, frequencies, and more. All changes are validated before saving, with in-grid error and warning messages and audit logging to ensure data integrity and traceability. This enhancement streamlines bulk updates, reduces manual effort, and promotes consistency across review objectives.</p>
EL-33386	Configuration - Review Plan: Standardized filter indicator and behavior	<p>In Data Central Configuration, on the Review Plan tab, the filter indicator for the Review Objectives table has been standardized to align with listings in Data Central. Instead of appearing in the toolbar, the filter indicator now displays in the badge next to the table title. Hovering over the badge shows the number of filtered Review Objectives out of the total, and clicking the badge opens a popout with the applied filters, which can be adjusted directly.</p>

Internal Issue#	Summary	Release Note Description
EL-32723	Configuration - Reviewer Roles: Added 'Review Objective Notifications' setting	<p>In Data Central Configuration, within the Reviewer Roles section, a new notification setting called 'Review Objective Notifications' has been added, allowing users to receive timely email alerts for key Review Objective events. Approvers are notified when objectives are submitted for approval, and submitters are notified when objectives are approved or rejected, including any comments added during the status transition. Additionally, assigned Reviewer Roles automatically receive reminder and missed-cycle notifications based on the defined review frequency. This enhancement promotes proactive oversight, improves communication, and helps ensure reviews are completed on time.</p>
EL-25311	Data Central - Listings: Added visual cue for fixed columns	<p>A new visual cue has been added to Data Central listings to make it easier for users to identify which columns have been fixed to the left or right. When a column is fixed:</p> <ul style="list-style-type: none"> <li>• <b>Fix to Left:</b> A thicker vertical line now appears on the right edge of the fixed column.</li> <li>• <b>Fix to Right:</b> A thicker vertical line now appears on the left edge of the fixed column.</li> </ul> <p>This enhancement does not change how column fixing works, it simply adds a clear visual indicator to distinguish fixed columns from unfixed ones, improving readability and navigation when reviewing wide datasets.</p>
EL-19652	Data Listings, Subjects, Queries, and Records Review Summary Panels: Improved filtering experience highlighting relevant values	<p>Data Listings, Subjects, Queries, and Records Review Summary panels now provide a smarter, 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.</p> <ul style="list-style-type: none"> <li>• Values still present in the filtered results appear at the top of the list (white background, sorted A–Z). Selecting these values further refines the results.</li> <li>• 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.</li> </ul> <p>This enhancement helps users quickly identify relevant filter values and make more context-aware filtering decisions.</p>
EL-34830	Enhanced Left Navigation: Switch between full and icon-only modes	<p>Data Central's left navigation has been enhanced to support an icon-only collapsed view. Users can now expand or collapse the left navigation panel using either the existing drag handle on the panel edge or the new Toggle Side Navigation icon in the Study Status header. When collapsed, the panel switches to an icon-only layout, allowing users to quickly navigate between sections while preserving more screen space for content.</p>

Internal Issue#	Summary	Release Note Description
EL-28053	Issues Panel: Added support for User Domain Settings	<p>In Data Central, the Issues panel now supports User Domain Settings, accessible via the Issues Settings (gear) icon in the panel toolbar. This enhancement allows users to customize their view by hiding columns for System Fields and Domain Variables, making it easier to focus on the most relevant information. This update helps simplify the user experience and reduce unnecessary data clutter.</p>
EL-34477	Protocol Deviations: Added ability to export PD records to Excel with optional comments	<p>Users can now export Protocol Deviation (PD) records directly from the Protocol Deviations listing in Data Central. The new Export option allows users to export PDs either with or without comments. When the 'Export PDs with Comments' option is selected, the Excel file includes a Comments column showing each record's comments in descending chronological order, along with the username, comment type, and timestamp. Comments are visually separated by dashed lines for clarity.</p> <p>This enhancement introduces flexible export capabilities, making it easier for users to share or analyze PD data with the level of detail that best fits their review or reporting needs.</p>
EL-33532	Protocol Deviations: Added access to underlying tables for Data Central Visualizations	<p>Users supported by eCS individuals can now access the underlying tables for the Protocol Deviation (PD) Dashboard to create Data Central Visualizations. Two new tables, Protocol Deviation and Protocol Deviation Comments, have been added to the System Tables section for eCS users to support client implementations.</p> <p>These tables provide access to all current data in the Protocol Deviations Dashboard and any comments created on those PDs, consistent with the views previously available in the PD Staging data store. This enhancement enables users, with eCS facilitation, to build custom charts and metrics for PD review in Data Central using data from the Protocol Deviations Dashboard.</p>
EL-29037	Protocol Deviations: Added settings to customize column visibility	<p>Users can now click the new Protocol Deviations Settings icon in the Protocol Deviations listing on the PD Dashboard to open the Settings window and configure which fields they do not use or wish to remove from view. Users can hide any columns in the PD listing to refine their review and focus on relevant data.</p> <p>This per-user, per-study setting is retained whenever the user accesses the PD Dashboard at a later date, allowing each user to customize their view for each protocol based on the columns used for PD review in that study.</p>

Internal Issue#	Summary	Release Note Description
EL-33885	Protocol Deviations: Added support for column repositioning and fixing	<p>Users can now reposition columns on the Protocol Deviation (PD) Dashboard by clicking and dragging them, consistent with other data panels in Data Central. Repositioned columns remain in their new position until the user exits the window or navigates away from the workspace with the PD Dashboard open.</p> <p>Users can also fix columns to the left or right within the PD Dashboard. Fixed columns are retained between user sessions, unlike repositioned columns.</p> <p>These options allow users to customize their PD Dashboard view and access PD data more efficiently.</p>
EL-28054	Queries Panel: Added support for User Domain Settings	<p>In Data Central, the Queries panel now supports User Domain Settings, accessible via the Queries Settings (gear) icon in the panel toolbar. This enhancement allows users to customize their view by hiding columns for System Fields and Domain Variables, making it easier to focus on the most relevant information. This update helps simplify the user experience and reduce unnecessary data clutter.</p>
EL-34013	Review Plan - Data Listings and Orchestrator Rules: Added real-time Issue and Query counts	<p>Within the left navigation, under Review Plan &gt; Review Objective Details &gt; Programmatic Review Materials, Data Listings and Orchestrator Rules now display real-time Issue and Query counts. Each material shows an Issues icon and, if Queries are enabled for the study or rule, a Queries icon, colored red when open or in-progress items exist and green when none are present. Hovering over the icons displays a tooltip with exact counts (e.g., '3 Open &amp; In Progress Issues' or 'No Open &amp; In Progress Issues' for Issues, and '2 Open Queries' or 'No Open Queries' for Queries). Clicking the icons opens the corresponding panel automatically filtered to show the related records for that Data Listing or Orchestrator Rule. This enhancement provides reviewers at-a-glance visibility into outstanding actions and enables seamless navigation to the relevant Issues or Queries.</p>

Internal Issue#	Summary	Release Note Description
EL-34139	Review Plan - Orchestrator Rules: Enhanced completion calculation and navigation	<p>With Orchestrator Rules now supporting the creation of issues, queries, or both, the calculation logic and click behavior in the Review Plan's Objective Details have been updated to reflect this expanded functionality. Completion calculations now automatically align with what each rule generates: for rules that create issues, completion is based on Open and In Progress issues created by that rule; for rules that create queries, it is based on Open queries created by that rule; and for rules generating both, the system evaluates both sets together for a unified completion status.</p> <p>Clicking a rule now opens the appropriate floating panel automatically. If the rule creates only issues or only queries, the corresponding Issues or Queries panel opens prefiltered to records created by that rule. For rules that generate both, a combined 'Review Plan - Open Issues &amp; Queries' sheet opens with both panels docked side by side and prefiltered to the correct rule and statuses. These updates provide clearer visibility into rule-driven work and faster access to items requiring action.</p>

Internal Issue#	Summary	Release Note Description
EL-33585	Review Plan Dashboard: Added new Review Cycles sheet	<p>The existing sheet on the Review Plan Dashboard has been renamed to Review Plan Summary (previously Review Plan Dashboard) and a new Review Cycles sheet has been added. The Review Cycles sheet enables Team Leads and Managers to monitor whether Review Objectives are completed according to their defined Review Frequency for each review cycle.</p> <p>This sheet includes three interactive charts: Review Cycle Status Breakdown (pie), Objectives by Cycle Status (combo), and Objectives by Reviewer Roles (combo), along with a detailed Review Objectives Review Cycles listing. Additionally, this sheet supports a new Missed status that indicates when a review cycle is not completed by the assigned role.</p> <p>The Review Objectives Review Cycles listing provides a comprehensive, cycle-by-cycle view of each Review Objective, including Review Cycle Status, Programmatic and Manual Frequency details, cycle due dates, completion timestamps, reviewer roles, and material-level completion indicators. Each review material displays the reviewer name and completion date and time when reviewed or clearly indicates missed or pending items. The table supports filtering (via the column header and the right-click context menu), searching, pagination, a details panel, and export to Excel with color-coded statuses and clickable identifiers.</p> <p>In the Chart Designer (Visualizations), the System Tables data store (available only to eCS users) now includes a Review Cycle Status system table, enabling additional views and summarizations using any chart type. While only eCS users can create and edit these charts, all users can view and utilize them.</p> <p>This enhancement provides clear, cycle-by-cycle visibility into review progress across roles, frequencies, and review materials, enabling proactive oversight, improved accountability, and easier detection of missed reviews.</p>
EL-30237	Review Plan: Added 'Sort & Group By' options for Review Objectives	<p>Users can now customize how Review Objectives are displayed in the Review Plan objectives list in the left navigation. A new 'Sort &amp; Group By' tab has been added to the filter drop-down, allowing users to group Review Objectives by Primary Domain (default), Priority, Status, or Risk, and sort them by Identifier (A-Z or Z-A) or Status. Each group displays both a badge count and a completion summary, providing a high-level overview. Groupings update in real time as statuses change, and user preferences persist across studies and sessions. This enhancement helps reviewers better organize, prioritize, and focus their work, driving more efficient and structured reviews.</p>

Internal Issue#	Summary	Release Note Description
EL-31810	Review Plan: Added Review Objective-Risk Integration	<p>Review Objectives in Data Central can now be linked to Risks flagged as 'Include into Review Plan' in the finalized RACT assessment, enabling a more risk-based approach to data review.</p> <ul style="list-style-type: none"> <li>• <b>Data Central Configuration:</b> A new 'Risk(s)' selector has been added to the Review Objective configuration, allowing users to link one or more risks. The selector displays key details for each risk, including CTQ, Risk ID, Risk Score, Risk Control, and Risk Description, providing context to support informed configuration.</li> <li>• <b>Data Central:</b> In the left navigation, within the Review Plan, in the Objective Details, the linked risks are displayed along with the same key details shown in Data Central Configuration. Additionally, clicking the Risk ID navigates the user directly to the corresponding risk in RACT, streamlining access. On the Review Plan Dashboard, in both the 'My Role' and 'Show All Roles' views, the 'Objectives By Primary Domain' bar chart has been renamed to 'Objectives By Group' and now supports grouping by CTQ and Risk in addition to Primary Domain.</li> </ul> <p>This enhancement strengthens alignment between risk assessment and data review, enabling users to better prioritize and act on key risks throughout the review process.</p>
EL-33018	Subjects Panel: Standardized actions for Issues and Comments	<p>The Subjects panel in Data Central now provides a consistent experience for creating issues and adding comments. The toolbar tag icon has been replaced with a plus icon, which opens a drop-down menu with 'Create Issue' and 'Add Comment' options. The right-click menu has also been updated to match the design and behavior of other Data Central panels. These enhancements improve usability and align interface patterns across listings.</p>
EL-34232	Veeva CDMS: Added Role Query Actions setting to manage user ability to reopen queries	<p>With the addition of the ability for users to reopen closed Veeva CDMS queries from Data Central, a new setting has been added to manage access to this feature and prevent unnecessary query actions. The Reopen action has been added to the Role Query Actions settings in Data Central Configuration, allowing administrators to configure each role to enable or restrict the reopening of Veeva queries.</p>
EL-28440	Veeva CDMS: Added support for importing and managing Event queries from Veeva EDC	<p>Users can now import and manage Event queries from Veeva CDMS EDC. Event queries are the visit-level query equivalent in Veeva, comparable to those in other EDC systems. With no additional configuration required to connect to Veeva EDC, users can import Event queries for each study directly into the same workspace where query review activities already occur.</p> <p>In addition to importing, users can manage Event queries in the same way as item-level queries supported in prior versions. Actions such as opening, answering, and closing queries are now available for these new Event query records.</p>

Internal Issue#	Summary	Release Note Description
EL-34220	Veeva CDMS: Enabled creation of Event queries from Exception Listings built with Veeva EDC data	<p>Users can now create Event queries from Exception Listings mapped using source data from the Veeva CDMS EDC within Data Central. Similar to how item-level queries were created through Exception Listings using the mapped FormOID, ItemOID, and SourceRecordID columns, four new standard Veeva event columns can now be used as the ItemOID value to create an event query:</p> <ul style="list-style-type: none"> <li>• EVENT</li> <li>• EVENTDEF</li> <li>• EVENTEID</li> <li>• EVENTDT</li> </ul> <p>When a user creates a query through a listing using any of these four columns as the target ItemOID, the query is created on the corresponding event in Veeva EDC and assigned to the SYS_EVT domain and EVENT field in illuminate. These domain and field assignments are required due to the structural nature of event queries in Veeva, which do not have a link to a form or field within the EDC, only to the event name.</p>
EL-28394	Veeva CDMS: Enabled creation of Event queries on Veeva EDC data	<p>Users can now create Event queries directly on domains sourced from Veeva CDMS EDC within Data Central. Similar to how item-level queries were created by selecting a value in a particular column, four new standard Veeva event columns can now be used to create an Event query:</p> <ul style="list-style-type: none"> <li>• EVENT</li> <li>• EVENTDEF</li> <li>• EVENTEID</li> <li>• EVENTDT</li> </ul> <p>When a user creates a query on a value in any of these four columns, the query is created on the corresponding event in Veeva EDC and assigned to the SYS_EVT domain and EVENT field in illuminate. These domain and field assignments are required due to the structural nature of Event queries in Veeva, which do not have a link to a form or field within the EDC, only to the event name.</p>
EL-29432	Veeva CDMS: Enabled the re-opening of closed queries for additional review	<p>Users of Veeva CDMS and illuminate can now access new options in Data Central to re-open queries that were previously closed for additional review. A new 'Reopen Query' option has been added to the existing actions menu in Data Central, allowing users to set a query back to an Open status both in illuminate and the EDC.</p> <p>This feature can be configured per role in the Role Query Actions settings within the Data Central configuration, consistent with other Query Actions. It can be granted or restricted by role as needed for each client configuration.</p>

Internal Issue#	Summary	Release Note Description
EL-32855	Visualizations - Chart Designer: System Tables data store includes Review Objectives Risks table	In the Chart Designer, the 'System Tables' data store (available only to eCS users) has been expanded to include a Review Objectives Risks table, enabling additional views and summarizations using any chart type. While only eCS users can create and edit these charts, all users can view and utilize them. Additionally, the existing Review Objectives Reviewer Roles table has been expanded to include Risk CTQ, Risk ID, Risk Description, Risk Score, and Risk Control.
EL-26037	Visualizations - Custom Listing: Enhanced filtering with adaptive value selectors	Users can now filter Custom Listings more efficiently with an upgraded filter popout that adapts to each field type: checkbox selectors for text fields (supporting multi-selection), numeric range inputs for number fields, and date pickers for date fields. This enhancement makes filtering faster and more intuitive across all field types, streamlining review and analysis in Custom Listings.
EL-26681	Visualizations - Histogram: Added Series Label toggle	Users can now enable Series Labels (ruler icon) in Histogram charts to display exact values above each bar, improving data readability without the need to hover. This option is available in both the Chart Designer and rendered charts and is disabled by default.
EL-27116	Visualizations - Pie Chart: Added Value Display options	In the Chart Designer, Pie charts now include a new 'Value Display' setting within the dragged Measure's label configuration. Users can choose how values are presented with three options: Numeric (default), Percentage, or Both. This setting controls how data appears in the tooltip and the series labels within the Chart Preview and the rendered chart. This enhancement provides greater flexibility and clarity, allowing users to present data in the format most meaningful for their analysis and audience.

Internal Issue#	Summary	Release Note Description
EL-26839	Visualizations - Pivot Table: Added support for multi-selection	<p>Pivot Tables in Data Central now support interactive multi-select filtering, allowing users to click directly on data cells, column headers, or row headers to apply filters for faster, more flexible data exploration.</p> <ul style="list-style-type: none"> <li>• Clicking a data cell applies a filter on both the row and column values (for example, <i>AE Term = CHILLS</i> and <i>AESER = No</i>). Multiple cell clicks add to the current selection, and the filter badge updates accordingly (for example, <i>2 out of 80</i>).</li> <li>• Clicking a column or row header filters on that single dimension. Additional clicks expand the filter (for example, <i>AESER = Yes, No</i>), and the badge updates to show total selections (for example, <i>2 out of 2</i>).</li> <li>• Only one filter type (cell, column, or row) can be active at a time. Switching types clears the previous selection to prevent mixed filter logic.</li> <li>• Visual cues have been added for clarity: <ul style="list-style-type: none"> <li>○ Gray background on hover</li> <li>○ Blue background on selection</li> </ul> </li> </ul> <p>This enhancement improves the speed and accuracy of data review by allowing reviewers to filter and compare key metrics more efficiently across categories without navigating away or repeatedly applying filters.</p>
EL-33186	Visualizations - Timeline Chart: Added 'Group By' Advanced Setting	<p>A new 'Group By' setting has been added under Advanced Settings in Data Central's Timeline charts, providing greater flexibility in how data is displayed and analyzed. This setting allows users to define how records are consolidated and visualized within the chart.</p> <p>The Group By setting includes three options:</p> <ul style="list-style-type: none"> <li>• <b>None (default):</b> Retains the existing behavior, displaying each measure occurrence individually.</li> <li>• <b>Measure:</b> Consolidates duplicate measure values for a subject into a single row, displaying all occurrences in a compact graphical view (e.g., repeated AETERM values appear once per subject, consistent with GPP behavior).</li> <li>• <b>Subject:</b> Displays each subject only once, grouping all associated data (e.g., all Adverse Events) into a single timeline.</li> </ul> <p>As part of this enhancement, the Group by Subjects toolbar button (layer-group icon) has been removed, with its functionality now integrated into the new Group By setting. Existing charts that previously used this option will be automatically migrated, retaining their grouping behavior and showing Subject as the selected Group By value in Advanced Settings.</p> <p>This enhancement provides a more intuitive, streamlined way to analyze subject- and measure-level trends directly within Timeline charts, supporting faster data review and clearer pattern detection.</p>

Internal Issue#	Summary	Release Note Description
EL-23034	Visualizations: Added support for Advanced Filters	Visualizations now automatically update to reflect applied Advanced Filters, enabling more precise and targeted data exploration.
EL-32573	Visualizations: Added support for badge and applied filters popout	<p>All visualization charts now display a blue badge next to the chart title showing the number of data segments currently displayed. This aligns with existing behavior in Data Listings and Custom Listings, providing consistent visibility into the data being analyzed.</p> <p>When filters are applied, whether via subject filters, visualization clicks, advanced filters, or data cuts, the badge updates with a filter icon. Clicking the badge opens a popout that lists the applied filters (the filters affecting the visualization) and shows the total number of segments out of the original dataset (for example, <i>Filtered to 19 segments out of 39</i>).</p> <p>In the visualization toolbar, runtime / local filters now use a distinct visualization-specific filter icon to clearly differentiate them. The icon appears unfilled when inactive and fills when filters are applied.</p> <p>The filter popout in Custom Listings has also been standardized:</p> <ul style="list-style-type: none"> <li>• Unfiltered: <i>Viewing 39 record(s) out of 39</i></li> <li>• Filtered: <i>Filtered to 19 record(s) out of 39</i></li> </ul> <p>This update improves clarity, consistency, and context awareness when working with filters across visualizations and listings.</p>
EL-34601	Visualizations: Consolidated toolbar	A 'More Options' menu (vertical 3-dot icon) has been added to the toolbars of all Data Central Visualizations (except Custom Listings and Treemaps), consolidating less frequently used actions. This streamlines the toolbar by reducing clutter during analysis and emphasizing the most commonly used icons. However, in the Chart Designer, all icons remain directly visible in the toolbar, ordered by importance, to support quick configuration access.
EL-33890	Workspaces: Added 'Review Plan Dashboard' workspace	The Review Plan workspace is now accessible from the Workspace drop-down in the master header, under the illuminate folder, allowing users to open the Review Plan Dashboard from anywhere in Data Central. It is also available in the Role Workspace Defaults (in Data Central Settings), enabling teams to set it as the default view for roles focused on review activities. These updates provide a more consistent, intuitive, and role-aligned navigation experience across studies and users.

## Issues

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
EL-32483	Added optional Reason field when cancelling issues	Users now have the option to enter a reason when cancelling an Issue. The new 'Reason' field appears in the Cancel Issue dialog box and functions similarly to the Reason field for the Pending action. While optional, any text entered is recorded in the issue's audit trail and added as a comment, ensuring clear traceability and context for cancelled issues.
EL-12047	Row count preference preserved in Global Issues Settings	Within Global Issues Settings, a user's preferred row count (Rows Per Page) is retained when navigating away from or returning to the page. Once a user selects a new row count (e.g., 10, 20, 50, 100), that preference persists across sessions, ensuring a consistent and personalized review experience.

## Orchestrator

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
EL-27514	Added Open Issues and Queries columns to Rules listing	The Orchestrator Rules listing now includes Open Issues and Open Queries columns, giving users a quick view of unresolved actions associated with each rule. These columns use familiar icons from Data Central and support full sorting, filtering, and navigation. This enhancement helps users quickly assess rule impact and prioritize reviews based on outstanding Issues and Queries.
EL-27522	Enhanced Rule details with open Issues and Queries rows	The Orchestrator Rule Details panel now includes Open Issues and Open Queries rows, providing immediate visibility into outstanding actions associated with each rule. These additions match the data shown in the Rules Listing and enable direct navigation to relevant Issues and Queries. This update streamlines rule monitoring and aligns the Rule Details panel with the rest of the Orchestrator interface for a more consistent user experience.

Internal Issue#	Summary	Release Note Description
EL-32281	Enhanced Rule Editor with Independent Query and Issue Creation	Users can now create Orchestrator rules that generate queries without requiring issue creation. When editing a rule, the window header displays the rule name to provide additional context. The rule editor is streamlined by moving 'Basic Information' to Step 1 (Build) and renaming the second tab to 'Step 2: Action'. The Action tab includes toggles for enabling issues and queries, displays relevant fields only when enabled, and improves the layout of related fields. The Rules table and Rule Details view include both 'Issue Run Status' and 'Query Run Status' columns to improve visibility into outputs generated during the last run.
EL-25772	Enhanced Rules listing and Details panel with direct links to Data Central for Open Issues and Queries	Users can now click directly on the Open Issues and Open Queries counts in the Orchestrator Rules listing and Rule Details panel to navigate to Data Central with filters automatically applied. These links open the Issues or Queries panel showing only open items generated by the selected rule, helping users quickly assess and review rule-specific output. Hyperlinks appear only when open items exist and are disabled for users without Data Central access.

## Platform

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
EL-31273	Audit Logs: Enhanced clarity for users logging in through SSO	Users can now view additional login information in the Audit Logs. Previously, users could not distinguish between authentication through SSO and login with personal elluminate credentials. With this enhancement, the Object Data column now indicates whether SSO was used during login, allowing users reviewing the Audit Logs to easily determine if access occurred through SSO or via traditional username and password authentication.
EL-33284	Blinding: Enabled file-based export and import of blinding configuration	<p>Users can now export study blinding configurations to an Excel file for import into another study or the same study on a different elluminate URL. This enhancement allows users to directly copy an existing blinding configuration between environments or replicate it across studies where the configuration applies.</p> <p>When a blinding file is imported, the system validates the file structure and contents and checks for changes against the existing blinding configuration. Users are then shown counts of added, deleted, and modified blinding records after staging. Once reviewed, users can follow the standard blinding update process to confirm and apply the changes, significantly reducing the time and effort required to set up or update blinding configurations for a study.</p>

Internal Issue#	Summary	Release Note Description
EL-33573	Dynamic Mapping Templates: Added export and import options for configuration migration	<p>Users can now migrate completed configurations of Dynamic Mapping Templates (DMTs) in illuminate. Two new options on the DMT interface allow users to export template configurations to an Excel file, which can then be imported into an equivalent illuminate URL.</p> <p>The exported file includes all fields from the DMT configuration and is validated during import to ensure successful deployment of the templates. Any issues in the inbound file are reported to the user, preventing import until resolved. If the file is validated successfully, the system provides a summary count of new DMTs to be added and existing DMTs to be updated based on the contents of the file.</p>
EL-27725	ETL Key configuration: Added controls and enhanced handling	<p>Previously, when extracting the system configuration from illuminate, users were required to include the study's ETL Key configuration along with other exported parameters. In rare cases, updated key configurations sourced from development or testing environments included incorrect keys that were inadvertently applied to production during ingestion of the system configuration file. This occasionally caused interruptions to production activities such as data review, comments, and other Data Central functions across the platform.</p> <p>To address these issues, additional controls have been added to allow users to selectively include ETL Key configuration as part of the system configuration export. Enhanced handling has also been added during import to ensure that missing keys in the inbound file do not overwrite existing configurations. These enhancements allow users to control when key configurations are moved, improving security and stability for production environments.</p>
EL-27036	Validator: Added support for exporting and importing study Validator configuration	<p>Users can now export configured Validator definitions as a part of the overall system configuration extract Excel file. A new option in the system configuration export allows users to selectively include any configured Validator definitions as a new tab in the Excel configuration document.</p> <p>The exported file contains all relevant details for each definition, including selected validation rules, domain-specific elements for inclusions or exclusions, and information on the selected standard used for the validation. These Validator definitions can be viewed in the exported file and later imported into the associated study on another illuminate URL.</p>

## Risk Management

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
EL-33882	<p>RACT: Added Review Plan indicator on RACT Assessment Risk Cards for linked Review Objectives</p>	<p>RACT Assessment Risk Cards in the latest finalized assessment now display a 'Review Plan' indicator in the top-right corner (to the left of the trash can icon) when the risk is included in the Review Plan. The indicator shows the number of associated Review Objectives in parentheses, for example, Review Plan (3).</p> <ul style="list-style-type: none"> <li> <b>Hover Behavior:</b> Hovering over the indicator displays a tooltip with a table listing the linked Review Objective Identifier, Version, Description, and Approval Status. The list reflects the version specifically tied to the risk, which may vary from the latest available version. If no Review Objectives are linked, the tooltip displays 'No Review Objectives associated with this Risk.'         </li> <li> <b>Click Behavior:</b> Clicking the Review Plan indicator navigates users directly to the Review Plan tab in Data Central Configuration, automatically filtering the Risk(s) column to the selected risk. If a risk is linked to an Approved Review Objective that is not the latest version, users see the warning: 'Some Review Objectives are not displayed because Risk ID X is linked to the Approved version of the Review Objective but not the latest version.' If no Review Objectives are found, the page displays: 'No Review Objective(s) associated with selected Risk ID X.'         </li> </ul>
EL-33883	<p>RACT: Added warning message when deleting Risks linked to Review Objectives</p>	<p>To preserve linkage integrity, warning messages now display when deleting or archiving risks tied to existing Review Objectives. Users have the option to view the linked Review Objectives and their descriptions before proceeding.</p>
EL-33722	<p>RACT: Integrated with the Integrated Data Review Plan to align Risks and Review Objectives</p>	<p>RACT now integrates with the Integrated Data Review Plan (IDRP) to support stronger alignment between identified risks and associated review objectives.</p> <p>During risk assessment, setting 'Include into Review Plan' to 'Yes' makes the risk available for selection in review objectives. Adding the risk to one or more review objectives creates a linkage between the latest finalized RACT assessment and IDRP. The linkage supports tighter alignment between risk evaluation and review planning.</p>
EL-33190	<p>RACT: Prioritized Risk suggestions based on CTQ</p>	<p>When selecting risks from the Risk Library, the system now prioritizes those with CTQs similar to the current risk card, streamlining selection and improving relevance. Related risks appear at the top of the list for easier identification.</p>

Internal Issue#	Summary	Release Note Description
EL-33919	RACT: Redesigned Risk tracking and identification	<p>Risk tracking and identification have been redesigned to improve consistency, clarity, and usability.</p> <ul style="list-style-type: none"> <li>• The global-level Risk ID is now locked for editing once defined in the Risk Library (within Risk Management Configuration) to ensure traceability.</li> <li>• The study-level Risk Assessment ID has been repositioned from the Risk card to the Edit Risk window header for improved context and clarity.</li> <li>• The Risk Identification reference table and Monitoring Metrics recommendations now persist when reopening the Edit Risk window, improving continuity across sessions.</li> </ul>
EL-34754	RBQM & RACT: Updated navigation and layout	<p>The RBQM and RACT user interfaces have been updated to provide a more intuitive and consistent user experience.</p> <p><b>Within RBQM:</b></p> <ul style="list-style-type: none"> <li>• A new left navigation panel replaces the previous horizontal tab layout and organizes sections: Sites and Country Overviews, Trial-Level Risks, KRIs, and Study Report.</li> <li>• Links to RACT and Risk Management are now available in the lower section of the left navigation. These links were moved from the master header.</li> <li>• Users can expand or collapse the left navigation panel using the Toggle Side Navigation icon at the top. When collapsed, the panel displays icons that allow users to continue accessing all sections of RBQM.</li> <li>• When the RBQM panel is closed, the system automatically switches back to the Data Central left navigation, allowing seamless movement between RBQM and Data Central.</li> <li>• The Legend is now accessed by clicking the info icon Legend, which replaces the previous horizontal tab.</li> <li>• The first four columns of the listing are fixed, ensuring they remain visible when users scroll through KRIs.</li> </ul> <p><b>Within RACT:</b></p> <ul style="list-style-type: none"> <li>• A new left navigation panel replaces the previous horizontal tab layout and organizes sections: Assessments, Archived, and Risk Summary.</li> <li>• Links to RBQM and Risk Management are now available in the lower section of the left navigation. These links were moved from the master header.</li> </ul> <p>These navigation and layout enhancements ensure visual consistency and smoother navigation across both areas.</p>

Internal Issue#	Summary	Release Note Description
EL-31250	RBQM Configuration (in DC Configuration): Streamlined RBQM configuration and linkage with Risk Management and RACT	<p>Study-level RBQM configuration within Data Central Configuration has been enhanced to include direct linkage between study-level and risk management-level CTQs, QTLs, and KRIs for a more unified and efficient setup process.</p> <p>Users can now automatically pull CTQs, QTLs, and KRIs from the Risk Management Configuration library, ensuring alignment between risk assessment and monitoring configurations. CTQs, QTLs, and KRIs finalized in the latest RACT assessment are automatically added to study-level RBQM configurations.</p> <p>Key updates include:</p> <ul style="list-style-type: none"> <li>• The Add CTQ / Add QTL / Add KRI button in the toolbar now includes two options: Add CTQ / QTL / KRI and Add CTQ / QTL / KRI From Library.</li> <li>• Items added from the Risk Management Configuration library display a checkmark in the Global column, indicating active linkage to the Risk Management configuration. Updates made at the global level automatically sync to the study level while the checkmark remains selected. Removing the checkmark breaks the linkage, and the study-level version will no longer update automatically.</li> <li>• If the URL setting is enabled to require an explanation for edits and deletions, users must provide a justification when editing or deleting CTQs, QTLs, or KRIs. All changes are logged in the Audit Logs.</li> <li>• For CTQs, QTLs, and KRIs pulled from the Risk Management library, the Name and Category fields are read-only and cannot be edited at the study level. Only basic details are imported; scoring must be configured within the RBQM study configuration.</li> <li>• If a CTQ, QTL, or KRI was used in the most recent finalized RACT assessment, a checkmark appears in the Part of Current RACT column, indicating it was automatically added to the study-level RBQM configuration. Once a new RACT assessment is finalized, if any CTQ / QTL / KRI is no longer associated with the finalized assessment, the checkmark becomes an information icon indicating it was used in a previous assessment.</li> <li>• The Actions section has been renamed Alerts. Within the Study Alerts list, the Name drop-down now lists items sourced from Risk Management Configuration.</li> </ul> <p>These updates simplify configuration management, strengthen integration between RBQM, RACT, and Risk Management, and improve traceability through required explanations and audit logging.</p>

Internal Issue#	Summary	Release Note Description
EL-33748	RBQM: Added access to timestamped Snapshots for historic runs	<p>Users can now access historic runs of RBQM as timestamped Snapshots from the RBQM Snapshot drop-down. Selecting a Snapshot updates the Overview – Sites and Countries dashboards to restore the exact outcome of that run, preserving evidence of the original observation even if scores have changed.</p> <p>This feature directs action owners to the specific data view that triggered the concern. RBQM Snapshots enhance traceability, audit readiness, and facilitate follow-up actions</p>
EL-32414	RBQM: Added side panel details to Sites and Countries Overview	<p>Within the Sites and Countries Overview dashboards, each KRI now includes trend and status scores within its cell. The Details icon in the header opens a side panel on the right with KRI-level information that is not site specific. Clicking a KRI cell for a specific site opens the side panel displaying that site’s KRI details.</p> <p>The side panel contains two tabs: KRI Details and Trial Level Risks. The KRI Details tab displays site-level thresholds, trend, and pre-configured recommendations. The Trial Level Risks tab lists all QTLs, identical to the information available under Trial Level Risks in the left navigation.</p> <p>This enhancement provides a more guided and informed experience by displaying contextual information that supports monitoring workflows and promotes consistency in centralized monitoring reviews.</p>
EL-33609	Risk Management Configuration and RACT: Added support for versioned Assessment Settings	<p>Risk Management Configuration has been updated to support multiple configuration versions, referred to as Assessment Settings.</p> <p><b>Within Risk Management Configuration:</b></p> <ul style="list-style-type: none"> <li>The new Assessment Settings tab consolidates the previous tabs Critical to Quality Factors, Risk Assessment, and Risk Levels into a single versioned definition. This structure allows different RACT configurations to be defined across therapeutic areas, programs, projects, and other levels.</li> </ul> <p><b>Within RACT Assessments:</b></p> <ul style="list-style-type: none"> <li>Users can select the appropriate Assessment Setting when starting a new assessment.</li> </ul> <p>This added flexibility improves consistency across levels and accelerates setup for large-scale studies.</p>

## Specifications

### New Features/Improvements

Internal Issue#	Summary	Release Note Description
EL-35087	Redesigned Create / Edit Domain window with two-step layout	The Create / Edit Domain window has been updated with a new two-step layout. Source Table and Source Logic fields have been moved from the 'Step 1: Details' tab to the new 'Step 2: Source Tables' tab, improving clarity and separating domain metadata from source configuration. These fields retain their full functionality for viewing, editing, and saving. The window now also displays the name of the domain being edited in the header, helping users confirm context while making changes.