



illuminate 24.1.0  
Release Notes v2  
Updated 13Sep2024

## Document Version History

Version	Date	Section(s) Updated	Description of Modification
1	09July2024	<ul style="list-style-type: none"> <li>Initial Version Created</li> </ul>	<ul style="list-style-type: none"> <li>Initial Version Created</li> </ul>
2	13Sep2024	<ul style="list-style-type: none"> <li>Document Version History</li> <li>New Features and Functionality &gt; Platform</li> <li>Platform</li> </ul>	<ul style="list-style-type: none"> <li>Added Document Version History</li> <li>Updated Platform section &gt; illuminate Reporting Database</li> <li>Added EL-6209 Reporting Database configuration and access</li> </ul>

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## Purpose and Scope

illuminate® is a clinical data hub that provides one unified platform for all your clinical data from acquisition through analytics. It delivers self-service access to data ingestion, mapping, and comprehensive analytics that answer clinical and operational questions with speed and accuracy.

The purpose of this document is to provide Release Notes for eClinical Solutions' illuminate platform, version 24.1.0. These notes include details of new features, improvements, and addressed defects within the illuminate platform. Reviewing the Release Notes will help users understand the benefits of upgrading from previous versions.

## Supporting Documentation

There are additional resources for information on the illuminate platform.

The illuminate Help Center provides detailed information on how to use and configure the platform, including the new features and functionality. The Help Center can be found at: <https://support.eclinicalsol.com/hc/en-us?version=24.1>.

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

eClinical Solutions also offers a validation accelerator which can be used to help facilitate and streamline the documentation around upgrades to our product. Please contact your project manager for details.

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## New Features and Improvements

illuminate Release 24.1.0 includes several new features and improvements. The major items targeted for the release are as follows:

### Analytics

**New! CDA Snapshot: Added Oncology-specific sheets.** The CDA Snapshot app now supports Oncology-specific sheets, allowing for more complete data snapshots.

**New! CDA: Added Support for 'In Screening' Subject Status.** In an effort to cover the entire cycle of a Subject, support for an 'In Screening' status has been added, showing the period between evaluation and result. This aims to provide a more comprehensive view of a subject's progression.

**New! CDA: Added KPI navigation to the Home Page.** Similar to CTOA, for efficient and seamless navigation, KPIs are now clickable and will bring users to their related sheet within CDA to allow for further analysis.

## Data Central

**New! Two new Field Type options added to Annotation configuration.** 'Pick List - SQL' and 'Pick List - Custom' are now available for creating custom annotations.

**New! Visit ID configuration for Issues.** A default identifier can now be configured for issue creation, automatically prepopulating the Visit ID in the Create Issue window.

**New! Improved tooltip and new icons added to the Data domains.** In the left navigation, the Data domain tooltip was expanded to include the domain's Name, Label, Data Store, Last Refresh date, Total Records, and Records To Review. A gray dashed circle icon now indicates domains with records needing review, while a green circle with a check icon indicates domains with no pending records to review. This enhancement provides users with key details at a glance and helps quickly identify domains requiring attention, making the review process faster and more efficient.

**New! Records Review Summary panel accessible directly within Data Central.** Users can now access the Records Review Summary panel directly within Data Central, bypassing the need to navigate through Data Central Studies. The 'Open Records Review Summary' icon (clipboard with a checkmark) in the left navigation to the right of Data quickly and easily launches the Records Review Summary panel.

**Updated! Redesigned Records Review Summary panel.** The redesigned Records Review Summary panel now displays detailed information compactly and review metrics broken out by role while improving the panel's readability and performance. Users with a Reviewer role can toggle between a 'My Role' view (default), displaying review metrics relevant to the logged-in user's role, and a 'Show All Roles' view, displaying review metrics for all roles set up to review, using a switch in the panel toolbar.

**Updated! Create a field-level Issue in a Data Central listing.** Users can now create an issue on a field by using the right-click context menu in a listing.

## eIQ Review

**New! Pre-configured Audit Trail Review Workspace in Data Central.** Users can now easily identify irregular data patterns across various indicators using pre-defined sheets with visualizations and data listings, facilitating efficient issue identification.

**Updated! Confidence Scores are now available in Anomalous Records panels.** A new 'Confidence Indicator' or 'Score' column has been added, providing users with model confidence levels for predictions and ensuring prioritization of the most significant anomalies.

## Operational Data Repository

**New! Shipments subsection / form has been added to the Studies and Study Sites forms.** This addition facilitates the storage and tracking of shipment details at the Study and Study Site level.

**Updated! The Primary Contact field drop-down list now includes a consolidated list of the first and last names from the Personnel and Investigators top-level form data.** This allows users to easily select the Primary Contact from investigators and personnel as a single value in both the Sites and Study Sites forms.

**Updated! Ability to rename and delete Custom Picklists.** This provides flexibility, enabling users to easily rename and delete Custom Picklists directly from the Picklists window.

## Platform

**New! Read Only User type added to User Management in Administration.** Users can now be assigned platform-level read-only access for audit events.

**New! Automatic and manual cancellation of Tasks.** Tasks can now be canceled by the system when they remain stalled for a user-defined period. Users can also cancel a task within the task details.

**Updated! Complete UI overhaul of Metadata.** The Metadata module has been redesigned for better presentation, performance, user experience, and consistency with the platform. The new UI offers a modern look and feel with improved functionality, making navigation smoother and more intuitive. Panels now update automatically, actions are more visible, and on-screen splitting replaces nested tables for a cleaner layout. Enhanced filtering options, fewer clicks for actions, and improved color and iconography make the data easier to analyze.

**New! Data Classification model integration in Metadata and Data Central.** This model can now be enabled, allowing users to explore common data classification concepts with added similarity scores for confident matches, accessible in Metadata and the Data Central Visualization Designer window.

**New! illuminate Reporting Database.** The illuminate Reporting Database provides users with a secure and structured way to access their data outside of illuminate. By using external services like Amazon Web Service Relational Database (AWS RDS) or Snowflake, users will be able to query and access any imported or mapped data configured as a part of the Reporting Database for a given study.

## Protocol Deviations

**New! Protocol Deviations module added to illuminate.** The Protocol Deviations module provides users with new interfaces for configuring Global and Study Protocol Deviation Assessment Plans (PDAPs), along with an interface in Data Central for users to view Protocol Deviation data. This enables users to apply PDAPs and assign review statuses as needed to support the management of their study Protocol Deviations.

## Statistical Computing Environment (SCE)

**Updated! Expanded Editor keyboard shortcuts.** New keyboard shortcuts have been added to allow users to manage their files and program executions faster while programming in the Editor.

**Updated! Expanded program dependency management.** SCE users now have more options to manually and automatically add file and dataset dependencies to their programs. They can trace backwards and see which programs utilize a particular file as a dependency. Additionally, SAS programmers can track defined libraries as part of their dependency management.

## Module Specific Details

For each module of the elluminate platform, we provide detailed information regarding new features and improvements, as well as any notable defects that were addressed within that module. Users of the platform can navigate directly to the modules they care about the most in order to better understand how this release will impact their experience and plan for the upgrade.

### Administration

#### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-26172	Protocol Deviation Edit privilege	Access to create and edit Protocol Deviations can now be granted to users within User Management. Users with the Protocol Deviation Edit privilege will be able to manually create new protocol deviations, and edit existing protocol deviations by assigning necessary standards and statuses to Protocol Deviation data.
EL-26171	Protocol Deviation View privilege	Access to the new Protocol Deviation module in Data Central can now be granted to users within User Management. Users with the Protocol Deviation View privilege will be able to view the Protocol Deviations Dashboard and any Protocol Deviation data within the dashboard on any studies they have access to with Protocol Deviations configured.
EL-26170	Global Protocol Deviation Assessment Plan Configuration privilege	Access to the new Global Protocol Deviation Assessment Plan (PDAP) can now be granted to users within User Management. This privilege allows users to access the Protocol Deviation Assessment Plan interface under the Metadata Management section of the platform menu. These users will also be able to configure the Global PDAP as needed.
EL-22310	Platform Read-Only privilege	Read-only access to the elluminate platform can be granted to users within User Management. The 'Read Only User' type allows access to the elluminate platform for comprehensive visibility of audit events across all users and actions in the URL. When creating or editing a user, a checkbox has been added to indicate the user as read-only. Read-only users can view the platform without the ability to make changes to the database.

## Analytics

### Clinical Data Analytics (CDA)

#### New Features/Improvements

Internal Issue #	Summary	Release Notes Description
ECCA-325	CDA - All Sheets: Updated filter order	Throughout our core CDA app, identical filters at the top of each sheet have been repositioned in a consistent order. This change has been made to provide consistency and make the filters easier to track and interact with. The rule of thumb followed was to go from left to right, from generic/broad to more specific/narrow.
ECCA-294	CDA - Tumor Measurement Spider Plot sheet: Added toggle to view All Study Days or Study Days >= 0	To allow users to focus on the data from the start of the study onward, a toggle has been added to render the chart with either <b>All Study Days</b> or only the non-negative study days, <b>Study Days &gt;=0</b> . This gives users the flexibility to choose between a full view or a focused view.
ECCA-277	CDA - Home Page, Demographics, and Subject Status sheets: Added support for an In Screening Subject Status	To provide more granular detail regarding Subjects' status, support for an 'In Screening' status has been added, indicating that a subject is still being evaluated and is neither enrolled nor screen failed. <ul style="list-style-type: none"> <li>As part of this update, the Screening KPI on the Home Page was updated to show 'In Screening' as well.</li> </ul>
ECCA-208	CDA - Home Page: Added footnote to MH Coding Progress gauge chart	A footnote was added to the MH Coding Progress gauge chart, clarifying that by default, all medical history categories are included in the metrics. If a user wants to limit the metrics to a particular category, they need to apply a filter.
ECCA-168	CDA - Survival Summary sheet: Removed 'Screen Failed' and 'In Screening' subjects and increased month precision on the Subject Duration - Months bar chart	On the Survival Summary sheet, subjects that have a status of 'Screen Failed' or 'In Screening' have been removed, as they did not receive treatment and do not need to be part of the analysis. Additionally, the precision of the Subject Duration - Months bar chart has been increased to show two decimal places for months.
ECCA-167	CDA Snapshot - Added Oncology-specific sheets	To support more comprehensive and robust snapshots, 10 Oncology-specific sheets have been added to the CDA Snapshot app. Now, when users take a snapshot of their data and access it in the CDA Snapshot app, they will be able to see their Oncology sheets as well. <ul style="list-style-type: none"> <li><b>Oncology-Specific Sheets:</b> Survival Summary, Tumor Identification, Tumor Results, Tumor Results - RANO, Tumor Response, Response Duration, Swimmers Plot with Subjects' Overall Response, Waterfall Plot, Tumor Measurement Spider Plot, and Objective Response Rate.</li> </ul>

Internal Issue #	Summary	Release Notes Description
ECCA-45	CDA - Home Page: Added KPI navigation	<p>KPI navigation links on the Home Page have been enabled so that double-clicking on a KPI takes the user to a sheet containing visualizations related to that KPI. This provides users a faster, easier, and more efficient navigation experience that keeps them within the flow of the dashboard.</p> <ul style="list-style-type: none"> <li>• Screened, Enrolled, Randomized, Treated, Discontinued Treatment, Completed Treatment, Discontinued Study, and Completed Study bring users to the Demographics sheet.</li> <li>• Screen Failure brings users to the Inclusion/Exclusion Criteria Not Met sheet.</li> <li>• Death brings users to the Death Summary sheet.</li> <li>• Rate of AEs and Rate of Related AEs brings users to the Adverse Event Summary sheet.</li> <li>• Serious Treatment Emergent Rate brings users to the Treatment Emergent AE Analysis sheet.</li> </ul>

Defects Addressed

Internal Issue #	Summary	Release Notes Description
ECCA-271	Subjects who completed treatment and subsequently discontinued the study had their treatment status incorrectly changed to Discontinued	Updated the Subject Status definition for Discontinued Treatment and the Subject Status hierarchy so that subjects who have completed treatment and then discontinued the study maintain their treatment status as Completed and have a final status of Discontinued Study.

Clinical Trial Operational Analytics (CTOA)

New Features/Improvements

Internal Issue #	Summary	Release Notes Description
ECCA-246	CTOA - Protocol Deviations Overview sheet: Added missing category to Protocol Deviations Over Time line chart	To support instances in which customers do not have Protocol Deviations linked to Visits, a 'missing' bucket has been added to the Protocol Deviations Over Time line chart. When the user selects Visits on the x-axis, this bucket indicates that those protocol deviations occurred unrelated to a visit.

Internal Issue #	Summary	Release Notes Description
ECCA-18	CTOA: Improved reload time and made minor adjustments on the Data Changes, Post SDV and Post Query Changes, and Timeliness sheets	<ul style="list-style-type: none"> <li>Improved reload time of CTOA by increasing the summarization of the Audit table.</li> <li>On the Post SDV and Post Query Changes sheet, the Number of Data Changes by Role combo chart's title has been updated to Number of Queries Resulting in a Data Change by Role, the primary y-axis label has been updated to # of Queries Resulting in a Data Change, and the secondary y-axis label has been updated to % of Queries Resulting in a Data Change.</li> <li>On the Data Changes sheet, the Data Changes Over Time line chart's dimensions and reference line use Audit fields instead of AuditItemMetrics fields.</li> <li>Deprecated the use of Audit.zDateTimeStamp (Year) and Audit.zDateTimeStamp (Month) in favor of Audit.zYearMonth.</li> </ul>

Defects Addressed

Internal Issue #	Summary	Release Notes Description
ECCA-371	The Home Page's Current and Historic Subject Status definition of Discontinued was using hardcoded reasons instead of flags	The definition of Discontinued in the Current and Historical Subject Status bar charts has been updated to match that in the Subject Early Discontinued sheet, using the DropoutYN, Early Termination YN, and WithdrawalYN flags.

Sample Management Analytics (SMA)

New Features/Improvements

Internal Issue #	Summary	Release Notes Description
ECCA-200	SMA - Home Page: Consolidated layout of KPIs and added Total Samples KPI	For a cleaner and simpler display, the Sample Management KPIs on the Home Page have been consolidated into a single object. All KPIs are now consistent in format and positioning, enhancing readability and presentation. Additionally, a KPI for Total Samples has been added to indicate the number of samples that have been collected and are actively tracked.

## Data Central

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-26124	Protocol Deviations: Review status updates from changes in imported PD data	<p>For Protocol Deviations imported from an external file or client source system that have been marked as 'Reviewed' by users in the Protocol Deviations dashboard, changes to priority fields from the external data source will update their statuses to 'Re-Review.'</p> <p>This ensures the integrity of the 'Reviewed' status by identifying any Protocol Deviations with changes from newly imported data for additional attention, confirming that the deviation is still considered reviewed and advanced through the Protocol Deviation management workflow.</p>
EL-26123	Protocol Deviations: Manually create new Protocol Deviation records	<p>Users can now manually create new Protocol Deviation (PD) records from the Protocol Deviations dashboard in Data Central, offering a selection of four different types of protocol deviations: Study, Country, Site, and Subject. Users can create PDs of these types and additionally:</p> <ul style="list-style-type: none"> <li>• Enter a reported description for the created PD</li> <li>• Enter key dates like the Identified Date, Start Date, and End Date of the deviation, if applicable</li> <li>• Assign the initial status for the PD</li> <li>• Apply PDAP standards to the PD, if applicable</li> <li>• Enter comments related to PD workflow activities</li> </ul>
EL-26121	Protocol Deviations: Edit Protocol Deviations and their review status	<p>On the Protocol Deviations dashboard, users can now select and edit a Protocol Deviation record. allowing them to:</p> <ul style="list-style-type: none"> <li>• Change the review status of the PD</li> <li>• Assign PDAP standards to the PD</li> <li>• Change previously assigned PDAP standards on the PD</li> <li>• Cancel and un-cancel the PD</li> <li>• Enter comments related to PD workflow activities while editing</li> </ul>
EL-25771	Added support for Data Cuts to the Records Review Summary panel	<p>Support for Data Cuts has been added to the Records Review Summary panel. Now, when a Data Cut is applied, the Records Review Summary panel will automatically update with the relevant records/values for the affected domains. Additionally, hovering over the Data Cut filter pill in the master header will highlight the entire row of the impacted domains, providing a clear indication of the data changes.</p>

Internal Issue #	Summary	Release Note Description
EL-25604	Study Protocol Deviation Assessment Plan and the Data Central Protocol Deviation module user interface	<p><b>Study Protocol Deviations Assessment Plan Interface</b></p> <ul style="list-style-type: none"> <li>• Added a new user interface for configuring a Study Protocol Deviation Assessment Plan (PDAP) under Data Central Configuration for the study. A Study PDAP defines the content used to standardize and manage Protocol Deviations.</li> <li>• This new interface provides users options to: <ul style="list-style-type: none"> <li>○ View the configured Study PDAP</li> <li>○ Manually create new Study PDAP entries</li> <li>○ Edit existing Study PDAP entries</li> <li>○ Delete unneeded Study PDAP entries</li> <li>○ Import new PDAP entries from the Global PDAP</li> <li>○ Import new PDAP entries into the Study PDAP from an excel file</li> <li>○ Export the Study PDAP out to an excel file or export a blank template Study PDAP</li> </ul> </li> </ul> <p><b>Data Central Protocol Deviations Module Interface</b></p> <ul style="list-style-type: none"> <li>• Added a new Dashboard in Data Central for Protocol Deviations. Users can access the Protocol Deviations (PD) dashboard from the left navigation in Data Central for any studies where the PD module is configured.</li> <li>• The PD Dashboard presents the following: <ul style="list-style-type: none"> <li>○ Deviation Breakdown metrics outlining deviation counts and review progress</li> <li>○ An interactable Protocol Deviations panel where users can view, create, review, comment on, and standardize Protocol Deviations</li> </ul> </li> </ul>
EL-25314	Selected values in text data type filters display at the top of the list	In Data listings, Subjects panel, Issues panel, Queries panel, Records Review Summary panel, eIQ Review panels, and the Filter panel, the filter capability for text data types has been enhanced so that the selected values will now always appear at the top of the list. This ensures that the values selected for filtering are prominently displayed, making it easier and faster to manage and modify filters, eliminating the need to scroll through the entire list.

Internal Issue #	Summary	Release Note Description
EL-25278	Redesigned Records Review Summary panel	<p>The Records Review Summary panel has been redesigned to show more detailed information compactly, display calculations broken out by role, make it easier to interpret, and improve its performance. For users set up with a <b>Reviewer</b> role, they will now see 2 versions of the Records Review Summary table: a 'My Role' view (default) and a 'Show All Roles' view. These views can be toggled between using the switch icon in the panel toolbar. Both views will still display the Domain Name, Domain Label, Data Store, and Total Records, the difference is in the review metrics displayed.</p> <p>The My Role view displays all the domains set up to review for the logged-in user's role with the metrics Records Reviewed (numeric and percentage values), Records Updated Since Review, New Records, and Records To Review (numeric and percentage values). This allows users to focus on their role and quickly identify the work they need to accomplish, a to-do list so to speak. In this view, the Records Review Summary panel's title also displays the user's reviewer role abbreviation in parentheses for reference and validation.</p> <p>The Show All Roles view displays the metrics Reviewed (numeric and percentage values) and To Review (numeric and percentage values) for every role set up to review the associated domain, with an em-dash in those columns for roles that are not set up for review for that domain. Each metric displays the role abbreviation in parenthesis in the column header for the role they pertain to. This provides users a summary of the review progress across all roles to show the review progress and remaining work. For users set up with a <b>Read Only</b> role, they will not have a switch icon in the panel and only see the Show All Roles view.</p>
EL-25198	Improved column filtering in the Records Review Summary panel	<p>In the Records Review Summary panel, users are now able to filter columns in a more efficient, intuitive, and standardized manner. Similar to data listings:</p> <ul style="list-style-type: none"> <li>• When a user filters on a text column, users will now see a unique list of all the values in that column and be able to single or multi select their desired values.</li> <li>• When the Records Review Summary panel is filtered on any column, users can now hover over the badge in the header to see a tooltip with the number of records currently being filtered out of the total number of records in the panel. Clicking the badge opens a pop-out displaying the currently applied filters and allows users to adjust the filter parameters directly from the pop-out.</li> </ul>
EL-25166	Added access to the Records Review Summary panel directly within Data Central	<p>Users can now access the Records Review Summary panel directly within Data Central, eliminating the need to navigate through the Data Central Studies page and click on the appropriate study card metric. To facilitate an intuitive, effortless, and streamlined workflow, an 'Open Records Review Summary' icon (clipboard with a checkmark) has been added to the left navigation, aligned to the right in the Data section, allowing for quick launch of the Records Review Summary panel.</p>

Internal Issue #	Summary	Release Note Description
EL-25165	Improved tooltip and added iconography to the Data domains in the left navigation	<p>In the left navigation, the existing Data domain tooltip was expanded to include the domain's 'Name,' 'Label,' 'Data Store,' 'Last Refresh' date, 'Total Records,' and, if the domain is set up for review, the number of 'Records To Review' for the user logged in. This enhancement provides users more information at a glance, helping them quickly access key domain details.</p> <p>Additionally, to easily identify which domains require review without having to open every domain listed, a gray dashed circle icon was added to the left of the domain name to indicate that there are records that need to be reviewed (New records or records that have been Updated Since Reviewed) for the logged-in user's role. For domains that have no records left to review, a green circle with a check icon was added to the left of the domain name. This capability works towards providing users a more guided experience, allowing users to focus on domains requiring review, making the review process faster and more efficient.</p>
EL-24804	Ability to configure a Visit ID for Issues	When creating an issue for a record, the Visit ID can be prepopulated when the Default Identifier has been configured in Data Central. The visit ID can also be manually entered and edited when editing an issue.
EL-24344	Ability to apply an annotation to multiple records in a DC listing	Annotations can now be applied to multiple records within a Data Central listing. When two or more records are selected, and the user selects an annotation field, a new window opens, allowing the user to add the annotation in bulk.
EL-24246	Added support for additional Zoom Types in several visualizations	The Combo, Box & Whisker, Histogram, Timeline, and Scatter charts now support the configuration of 3 zoom types: Box, X-Axis, and Y-Axis. For each chart, users can specify their preferred zoom type for interacting with the chart, enabling precision zooming and focus on specific clusters/areas or along the x or y axis. By default, newly created charts will be set to Box Zoom, and existing charts will maintain their behavior unless changed. This enhancement can be found in the chart Designer, in Advanced Settings.
EL-23867	Custom and SQL Driven Annotation options in Data Central	Annotation options for Data Central listings can now be configured to include user-defined options. SQL and Custom have been added as field type options when configuring a new annotation column. With the new SQL field type for annotations, users can define a list of values to be selected by other users in an annotation column through a SQL statement. Additionally, users can define custom values for selection by manual entry.
EL-23865	Ability to manually identify a re-query	When creating a query within Data Central, a new checkbox has been added to allow users to identify the query as a re-query. When the checkbox is selected, the created query will display a 'Y' in the Requery column, which has been added to the Queries listing. Users can also view the Requery column and its values within the exported file.
EL-23492	Automatically wrapping comments column in exported files	When exporting a listing with comments, the exported file will now automatically size and wrap the comments column, ensuring that all comments are neatly displayed and easily readable.

Internal Issue #	Summary	Release Note Description
EL-23330	Visit ID added to Default Identifiers in Data Central Configuration	A default identifier can be configured for visit information and populated when creating an issue. Within the Data Review section of Data Central Configuration, users with appropriate privileges can select a variable to define the Visit ID within a study. Identifier selection is optional.
EL-23180	Added filter for Time-type data	Within the Data Central listings, a Time filter has been added for Time-type data, enabling users to filter the dataset based on a specified time range.
EL-23120	Added support for right-clicking to filter data	In Data listings, Custom Listings, Subjects panel, Issues panel, and Queries panel, the capability to right-click on a cell and filter by that value has been added, allowing users to quickly and efficiently view and analyze their relevant data. This filter shortcut enables users to avoid having to go to the column header, find that particular value again, and then filter, allowing them to stay within the data and easily apply their desired filter.
EL-23119	Data & Custom Listings: Added ability to search for columns by their Name and Label	For Data and Custom listings, users can now quickly and seamlessly find desired columns by using the new Search icon in the toolbar and typing in either the Name or Label of the column they are looking for. After selecting the intended column from the drop-down, users will be brought directly to that column, simplifying the experience and improving productivity, especially when working with large datasets.
EL-23114	Ability to create an issue on a field in a Data listing	Issues can now be raised directly from a data listing for a defined field and value. When the user right-clicks on a cell in the listing, the cell will be highlighted, and the option to 'Create Field Issue' will appear in the context menu. Users still maintain the ability to create an issue for a defined field and value in the record details panel.
EL-23099	Pivot Tables: Added ability to Hide Row and Column Counts	Users now have the option to show or hide row and column counts in pivot tables using the Show/Hide Counts and Totals icon in the toolbar, allowing for a cleaner and focused presentation of data. This setting can be configured when designing the chart or when the chart is already in the workspace.
EL-22224	Improved Export of Subjects panel to include field names, field labels, and comments	To provide additional flexibility and data, the Export button in the Subjects panel toolbar has been updated to have 2 options when clicked: 'Export Subjects' and 'Export Subjects with Comments.' For full context, both options will export the field names and labels of each column but only 'Export Subjects with Comments' will export every subject's comments to a single cell in excel. Multiple comments in a cell will be separated with a dotted line and carriage return.
EL-20516	Combined 'Assigned To' column in DC Issues panel	The 'Assigned To Role' and 'Assigned To Group' columns in the Data Central Issues panel have been combined with the existing 'Assigned To' column. Users can now filter and sort issues by the assigned user, role, or group within a single column.
EL-19862	Date range selection options for Data Variance in Record Details view	The Data Variance icon has been added to the Record Details view, allowing users to select or change the date range for Data Variance on a record without having to exit the Record Details view of the domain listing. The Data Variance range can now be updated without returning to the domain listing to select new dates.

Internal Issue #	Summary	Release Note Description
EL-16136	Ability to remove default filters for data listings	A new checkbox labeled 'Use Default Filters' has been added to the Data Central Settings window. When selected, data listings will automatically filter by reviewer role and review status. Deselecting the checkbox will open data listings with no filters applied.

## eIQ Orchestrator

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-24992	Added rule name tooltip for auto-created Issues from eIQ Orchestrator	Within the Issues listing, when hovering over 'Auto' entries in the 'Opened By' column, a tooltip will now display the name of the rule that generated the issue.
EL-24426	Expanded Issue Details for auto-created Issues from eIQ Orchestrator	A data table containing 'Rule Fields' and 'Related Fields' has been added to the Issue Details panel for issues created through eIQ Orchestrator, providing a detailed reference to the data that led to the issue's creation.  Additionally, the 'Opened By' field now displays the name of the rule that generated the issue, along with a hyperlink to the Rule Details panel.

## eIQ Review

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-25470	New 'Audit Trail Review' Workspace available in Data Central using the Irregular Data Patterns model	A pre-configured 'Audit Trail Review' workspace has been added to Data Central. Users can review site-level irregular data patterns in the audit trail identified by the Irregular Data Patterns model across multiple indicators such as irregular amounts of data deletions, data changes, data changes per domain, per user, after verification, and per month. Each indicator has a pre-defined sheet that includes both visualizations supporting the review and data listings supporting issue creation.

Internal Issue #	Summary	Release Note Description
EL-24907	CM Consistency model: Added Confidence Indicator and Color Highlighting of anomalous data variables	In the Record Details panel of the CM Consistency model, a Confidence Indicator has been added to the tooltip description text of anomalous data variables. Additionally, highlighting colors corresponding to the Confidence Indicator value have been incorporated for anomalous data variables. This enhancement allows users to easily assess the reliability of anomalous data and prioritize them during the review process based on the confidence of likelihood, thereby streamlining their workflow and improving overall efficiency. The color highlights serve as visual cues, simplifying the process for users to focus on critical data points and make informed decisions.
EL-24473	AE Durations & Shift in Labs and Vitals models: Added the Record Details panel to the Record-level sheet, with issue creation capabilities	In the Record-level sheet for the AE Durations and Shift in Labs and Vitals models, the Record Details panel has been added. This panel enables users to easily navigate through detailed records and create issues directly.
EL-24469	Added 'Confidence Indicator' or 'Score' column to the Anomalous Records panel	In the Anomalous Records panel, a new 'Confidence Indicator' column has been added for the AE Durations, Shift in Labs and Vitals, Univariate Outlier Detection, CM Durations, Domain Classification, and CM Consistency models. These columns display the confidence level associated with each prediction. Additionally, in the CM Indication model, a new 'Score' column has been added. These columns are sorted based on their scores, ensuring that the most anomalous records appear at the top for better visibility to users.

## Issues

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-24345	Ability to answer issues with an imported file	Issue data can be uploaded from a file and merged with open issues in illuminate. Users can export an issue file and update the file with responses and illuminate usernames. Issue responses will be accepted for eligible issues and the users identified will be recorded as the Answered By user. Upon completion of the upload, issues with a response and user will be automatically updated to Answered status.
EL-10414	Ability to remove the default filters from the Global Issues listing	A new checkbox labeled 'Use Default Filters' has been added to the Global Issues Settings window. When selected, the listing will automatically filter to open issues for the user. Deselecting the checkbox will open the listing with no filters applied.

## Operational Data Repository

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-24940	Import of Sites top-level form data: Enhancement for managing the grouping of Primary Contacts	<p>This enhancement provides flexibility for users when importing data into the Primary Contact field drop-down list within the Sites top-level form. Updates include:</p> <ul style="list-style-type: none"> <li>Introducing two new fields, 'InvestigatorFirstName' and 'InvestigatorLastName', in the 'InvestigatorSites' table. These fields must be mapped if the Primary Contact belongs to the Investigator group.</li> <li>Renaming the existing fields 'PrimaryContact' to 'PersonnelFirstName' and 'PrimaryContactLastName' to 'PersonnelLastName'. These fields must be mapped if the Primary Contact belongs to the Personnel group.</li> </ul>
EL-24939	Sites top-level form: Populate Primary Contact drop-down list with one consolidated list of names from Personnel and Investigators	<p>Within the Sites top-level form, the Primary Contact field drop-down list now includes a consolidated list of the first and last names from the Personnel and Investigators top-level form data. This enhancement allows users to easily select the Primary Contact from investigators and personnel as a single value.</p>
EL-24666	Picklists: Ability to rename and delete Custom Picklists	<p>In previous versions, users could create Custom Picklists. This feature has now been enhanced to include the ability to rename and delete Custom Picklists as follows:</p> <p>Rename:</p> <ul style="list-style-type: none"> <li>Users can rename a Custom Picklist, whether it is in use or not. Renaming to match an existing Picklist name is not allowed.</li> </ul> <p>Delete:</p> <ul style="list-style-type: none"> <li>Users cannot delete a Custom Picklist in use, but they can delete those not in use.</li> </ul>
EL-24571	ODR Home Page: Protocol Name is now part of the search functionality scope	<p>The ODR Home Page search feature has been expanded to include the Protocol Name in addition to the Protocol ID. The Search box will filter and display the study cards that match both Protocol ID or Protocol Name criteria.</p>

Internal Issue #	Summary	Release Note Description
EL-24570	Import of Study Sites top- and sub-level form data: Enhancement for managing the grouping of Primary Contacts	<p>This enhancement provides flexibility for users when importing the data into the Primary Contact field drop-down list within the Study Sites top- and sub-level forms. Updates include:</p> <ol style="list-style-type: none"> <li>1. Introducing two new fields, 'InvestigatorFirstName' and 'InvestigatorLastName', in the 'ProtocolSiteRef' table. These fields must be mapped if the Primary Contact belongs to the Investigator group.</li> <li>2. Renaming the existing fields 'ContactName' to 'PersonnelFirstName' and 'ContactLastName' to 'PersonnelLastName'. These fields must be mapped if the Primary Contact belongs to the Personnel group.</li> </ol>
EL-24547	Study Sites > Study Management Comm Notes: Renamed subsection/form to Study Site Management Comm Notes	Within the Study Sites top-level form, the 'Study Management Comm Notes' sub-level section / form has been renamed to 'Study Site Management Comm Notes.' This change aims to provide greater clarity for the user when capturing Study Management Comm Notes details at both the Study and Study Site level.
EL-24214	Studies: Added Shipments subsection	Within the Studies top form, a new subsection 'Shipments' has been added. Adding shipment details to the subform facilitates the storage and tracking of shipment details at the study level.
EL-24187	Study Sites: Added Shipments subsection	Within the Study Sites top form, a new subsection 'Shipments' has been added. Adding shipment details to the subform facilitates the storage and tracking of shipment details at the study site level.
EL-24165	Study Sites (top-level form and sub-level form in Studies): Populate Primary Contact drop-down list with one consolidated list of names from Personnel and Investigators	Within the Study Sites top-level form and sub-level form in Studies, the Primary Contact field drop-down list now includes a consolidated list of the first and last names from the Personnel and Investigators top-level form data. This enhancement allows users to easily select the Primary Contact from investigators and personnel as a single value.
EL-23986	Fields Config > Study: Program and Study Status fields can be configured to display in grid view	Within Fields Config > Study, the fields 'Program' and 'Study Status' can now be configured to display in the grid view. This enhancement provides users with more flexibility to efficiently interact with the data of the Studies top-level form, allowing them to filter and sort based on key parameters within the 'Program' and 'Study Status' fields.

Internal Issue #	Summary	Release Note Description
EL-23715	Protocol Deviations (top-level form and sub-level form in Study Sites): Enhanced data synchronization between the top-level form and sub-level form	<p>Data synchronization between the Study Sites, Protocol Deviation Tracking sub-level form data, and the Protocol Deviations top-level form data has been enhanced to provide ODR users with the flexibility to track and maintain Protocol Deviation data in a single location, the Protocol Deviations top-level form. Data synchronization includes:</p> <ul style="list-style-type: none"> <li>• Data added into the 'Protocol Deviation Tracking' (subform) will be accessible in the 'Protocol Deviations' (top-level form), with the addition of new data being one-directional.</li> <li>• Data editing is allowed in both forms, and the synchronization is bi-directional.</li> <li>• Data archiving is allowed in both forms, and the synchronization is bi-directional.</li> <li>• Data synchronization is scoped to pre-defined fields in the form and does not include custom fields.</li> </ul>
EL-22653	Investigational Product Alias subform: Deprecated Country free text field	In previous releases, the Country field in the Investigator Product Alias subform was a free text field and was replaced with a picklist for consistency with other forms. Now, the deprecated field is being removed completely to avoid confusion.

Defects Addressed

Internal Issue #	Summary	Release Note Description
EL-25269	Fields Config: Improved response time and performance	In Fields Config, response time and performance has been enhanced, resulting in faster interactions and improved performance in the ODR Fields configuration panel.

## Platform

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-26700	Metadata: Data Lineage visualization added	Users can now view a visual display of data lineage for domains that undergo transformations in Mapper. The visual will display the selected domain and any upstream or downstream mapping dependencies.
EL-26233	Protocol Deviations: New table added for downstream mapping and exporting	A new table, Protocol Deviations, has been added to the PD Staging data store for users to safely access Protocol Deviations data displayed in the Protocol Deviations dashboard in Data Central. Users can now map their reports or analytics datasets using any imported or manually created PDs, PDAP Standards values assigned to those PDs, and any additional columns in the PD table.
EL-26141	Importer: Auto detect column headers in Excel imports	This enhancement will allow the importer to scan the first 10 rows to automatically detect the row containing the column headers, enabling it to handle many custom-formatted sheets without needing to create a custom import definition. For sheets where the column headers cannot be detected automatically, users can still use the import definition feature.
EL-25876	Protocol Deviations: Configuration	<p>Protocol Deviations URL and Study Configuration</p> <ul style="list-style-type: none"> <li>• Users can now configure illuminate to enable the Protocol Deviations module at the URL level, allowing the configuration of the Global Protocol Deviation Assessment Plan and enabling the module for each study on the URL.</li> <li>• Users can now configure illuminate studies to enable the Protocol Deviations module. Enabling the module will make it visible in Data Central for users to access and manage their Protocol Deviations.</li> </ul> <p>Global Protocol Deviation Assessment Plan Interface</p> <ul style="list-style-type: none"> <li>• Added a new user interface for configuring the Global Protocol Deviation Assessment Plan (PDAP) under Metadata Management. This Global PDAP provides a central standard that can be applied to all studies as needed.</li> <li>• This new interface provides users options to: <ul style="list-style-type: none"> <li>○ View the configured Global Protocol Deviation Assessment Plan</li> <li>○ Manually create new Global PDAP entries</li> <li>○ Edit existing Global PDAP entries</li> <li>○ Delete unneeded Global PDAP entries</li> <li>○ Import PDAP Entries into the Global PDAP from an excel file</li> <li>○ Export the Global PDAP out to an excel file or export a blank template Global PDAP</li> </ul> </li> </ul>

Internal Issue #	Summary	Release Note Description
EL-25545	Data Source: Veeva Clinical Data Management System (CDMS) Operational data import	<p>Added a new data source, Veeva CDMS, that provides configuration options to establish connections to Veeva's Clinical Data Management System for importing operational data. This includes table contents such as queries, subject data, site data, forms, events, etc.</p> <p>Users can now configure this data source and create a corresponding import definition to import operational data for mapping, viewing in Data Central, and exporting from elluminate.</p>
EL-25451	eIQ: The Data Classification model can now be enabled for a study to be used in Metadata and Data Central Visualizations	<p>The Data Classification model generates a list of common concepts of fields by utilizing SDTM and CDASH standards, and identifies study source fields that share these underlying concepts. Enabling this model for a study provides access to matched common concept domains, field names, and field labels, which can be viewed within Metadata. Additionally, a similarity score is assigned to each match, indicating the model's confidence level. Furthermore, these concepts are incorporated as additional labels within the Data Central Visualization Designer window.</p>
EL-25160	Metadata: Complete UI redesign	<p>The Metadata module is now more logically laid out, consistent with the rest of the platform, and optimized for better performance. This overhaul brings a fresh, modern look and improved functionality to the module, enhancing the overall user experience. Additionally, the new UI is designed to be more intuitive and user-friendly, making it easier than ever to navigate and utilize.</p> <ul style="list-style-type: none"> <li>• The panels are now more reactive, opening and updating automatically when selections are made.</li> <li>• Actions are now easy to identify and always visible.</li> <li>• Deprecated nested tables in favor of on-screen splitting, ensuring a cleaner and simpler layout.</li> <li>• Data is more filterable, allowing for a more focused view.</li> <li>• Fewer clicks are required to perform actions.</li> <li>• The updated layout makes it easier to use and more responsive.</li> <li>• Improved use of color and iconography, making the data easier to read and interpret.</li> </ul>

Internal Issue #	Summary	Release Note Description
EL-24611	Data Source: Import and Export data from and to Open Database Connectivity (ODBC) compliant databases	<p>Added a new data source, ODBC, which provides configuration options to establish connections to external Open Database Connectivity (ODBC) compliant SQL or Snowflake databases to import datasets for use within elluminate.</p> <p>Users can now configure this data source using the target server with the appropriate ODBC driver installed, relevant user credentials, target database, and other necessary options. Once configured, users can test the connection and configure import definitions to ingest data from the external SQL or Snowflake database.</p> <p>Users can also use the same data source to export data to the configured database, similar to the existing functionality where users can push files to an external file storage system like an sFTP server or Box directory. Datasets can be pushed through the configured ODBC data source to the target SQL or Snowflake database.</p>
EL-24501	Importer: Study Import Control available for importing data with configured Data Change Thresholds	<p>New configuration added under the study ETL settings allows users to configure a percentage threshold between 0 - 100 percent that limits the amount of records that have changes within an imported dataset for the file to import successfully.</p> <p>When running an import on a study with the percent of changed data threshold configured, any files being imported that have Data Change Tracking enabled and proper keys configured will be compared against the previous import of the same file. This determines if the amount of change between the current and previously imported file exceeds the configured threshold.</p> <p>When the threshold is exceeded, the import will complete with a warning that notifies the user that the change in the imported file is greater than what is allowed and has not been imported. Any files imported with a percent of change below the threshold will be imported without warning.</p>
EL-19519	Tasks: Ability to autocancel tasks	Users can now configure task actions to automatically cancel if they persist in a running status. When creating a task, users can select the number of hours a task action is allowed to run before automatic cancellation. Once canceled, the task will be ready for the next execution.
EL-18873	Tasks: Ability to manually cancel a task	Task actions that persist in a running status can now be canceled. When the task details are expanded, a Cancel icon appears for tasks that have not been completed and have not failed. Users with the System Configure privilege can click the icon to cancel the task, making it ready for the next execution.

Internal Issue #	Summary	Release Note Description
EL-6209	Reporting Database configuration and access	The illuminate Reporting Database can now be enabled and configured within Study Configuration. A list of active data stores can be selected, or all current and future data stores can be included within the study's ETL settings to identify what data will be added to the Reporting Database. Once configured, connections to external database systems can be established through SQL systems like Amazon Web Services Relational Database Services (AWS RDS) or Snowflake. This enables secure querying of the Reporting Database, allowing data to be safely accessed outside of illuminate.

## RACT

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-24727	Added 'Not Realized & Closed' option under the Risk Status drop-down	Within Assessments and Risk Statements, 'Not Realized & Closed' has been added to the Risk Status drop-down.

## Statistical Computing Environment

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-26251	Import-triggered Mapper executions automate SCE program execution	SCE programs in Production state that are selected for Automated Execution will now run when a dependent dataset is updated via a Mapping which is triggered by an Import. Users no longer have to manually initiate a program run when a dependent dataset is updated; the program will execute automatically.  Note, this does not include mapping executions that are not initiated by an Import.
EL-23555	Filtering files by study in the Add Dependencies window	Within the Add Dependencies window, SCE users now have the option to refine available file dependencies to a specific study (or Global or My Workspace) folder, so they can more easily find desired dependent files.
EL-22832	Ability to add a datastore as a program dependency	SCE users can now add an entire datastore as a program dependency in the Add Dependencies window. This enables users to quickly add all domains within a datastore as dependencies and dynamically include any future domains. Users can delete a datastore dependency just as they can delete a file or dataset dependency.

Internal Issue #	Summary	Release Note Description
EL-22348	In SCE Editor, view programs using the current file as a dependency	In the Editor, SCE users can now review programs that are using a particular file as a dependency. This functionality allows users to understand the downstream impact of a file and track the data flow from source to transformation to output.
EL-22227	In SCE Browser, view programs using the current file as a dependency	In the Browser, SCE users can now review programs that are using a particular file as a dependency. This functionality allows users to understand the downstream impact of a file and track the data flow from source to transformation to output.
EL-21967	Display file and dataset details from the Outputs subpanel	In the Editor's Outputs subpanel, users can now hover over a program execution output to view relevant details such as the full path, version, and status of the file or dataset in a tooltip. This enhancement eliminates the need for users to open the output in the Editor to access this information.
EL-21714	Display file path in the Properties subpanel	Within the Properties subpanel and window, file and dataset properties now include the full file Path, allowing users to easily identify the location of a file or dataset and to copy and paste the path into their program code.
EL-20944	Defined SAS Libraries available in the Dependencies subpanel	SAS programmers can now review libraries defined in their program code via the Dependencies subpanel. This will update whenever the user saves the files, creates a new version, and upon copy/move of the program file. Users have the ability to jump directly to each line where their library is defined.

Internal Issue #	Summary	Release Note Description
EL-20943	Expanded SCE keyboard shortcuts for file and Editor management	<p>In addition to Editor toolbar controls, SCE users can now do the following with keyboard shortcuts:</p> <ul style="list-style-type: none"> <li>• Execute a program <ul style="list-style-type: none"> <li>○ Windows: F3, Ctrl+Alt+R</li> <li>○ MAC: Fn+F3, Cmd+Option+R</li> </ul> </li> <li>• Create a new SCE file <ul style="list-style-type: none"> <li>○ Windows: F4, Ctrl+Alt+Shift+N</li> <li>○ MAC: Fn+F4, Cmd+Shift+Option+N</li> </ul> </li> <li>• Navigate between tabs in the Editor <ul style="list-style-type: none"> <li>○ To the right <ul style="list-style-type: none"> <li>▪ Windows: Alt+3, Ctrl+F12</li> <li>▪ MAC: Option+3, Cmd+F12</li> </ul> </li> <li>○ To the left <ul style="list-style-type: none"> <li>▪ Windows: Shift+Alt+3, Ctrl+F11</li> <li>▪ MAC: Shift+Option+3, Cmd+F11</li> </ul> </li> </ul> </li> <li>• Close tabs in the Editor <ul style="list-style-type: none"> <li>○ Windows: Close active tab: Ctrl+Alt+W / Close all tabs except active tab: Ctrl+Shift+Alt+W / Close all tabs: Alt+W</li> <li>○ MAC: Close active tab: Cmd+Option+W / Close all tabs except active tab: Cmd+Option+Shift+W / Close all tabs: Option+W</li> </ul> </li> <li>• Comment and uncomment program syntax <ul style="list-style-type: none"> <li>○ Windows: Ctrl+Shift+C, Ctrl+ /</li> <li>○ MAC: Cmd+Shift+C, Cmd+ /</li> </ul> </li> </ul>
EL-20153	Configure the maximum allowed users for SCE and SCE Configure privileges	<p>elluminate User Management has been updated to allow a maximum number of users who can be assigned to the SCE and SCE Configure privileges. This allows teams to ensure adherence to the desired limit of users with either privilege in order to comply with licensing terms.</p>
EL-20085	Datasets can be saved to Global Datastores	<p>In-Production SCE programs can now write datasets to any global datastore. This capability applies to programs in both the Global and Study folders. While a program is not In Production, datasets written to a global datastore will appear in the Outputs subpanel but will not be accessible through the SCE Data subpanel or other elluminate modules.</p>
EL-20080	File size limit for viewing in Editor	<p>Files larger than 50MB are now restricted from viewing in the SCE Editor; users will instead be prompted to download the file. Users with a SAS Studio or RStudio license can also launch a large file to a Studio session to view it in an interactive environment. Rendering large files can slow down other processes related to file management or program execution, so this change is to uphold performance standards. This only applies to files and does not apply to datasets.</p>
EL-19788	Log checking expanded to include new syntax pattern	<p>Statements in log files that begin with 'error(' are now classified as errors in the automatic log checks upon completion of SAS, R, or Python program execution. This expands the breadth of statements included in the log check parsing, allowing users to easily find them via syntax highlighting or the Properties subpanel controls.</p>

Internal Issue #	Summary	Release Note Description
EL-17836	File size is indicated by kilobytes (KB) within the Browser and Editor's Properties and Outputs subpanels	The 'Size (KB)' column has been added as an attribute in the Browser, and file size is now reported in KB within the Editor's Properties and Outputs subpanels.
EL-17719	Ad hoc refresh of SCE program dependencies	Users can now refresh dependency parsing at any time, independent of automatic parsing triggered by saving or version updates. Before moving a program to In Production, users can refresh dependencies to ensure accurate input definitions. They can also refresh if files have been moved or created to resolve any missing dependencies.
EL-17715	XPT-formatted data can be saved to study and global data stores via program execution	SCE users can now write data in SAS transport file (.XPT) format to study and global data stores just as they do with sas7bdat-formatted data. This offers SCE users more flexibility when coding.
EL-17713	Enabled error, warning, and note highlighting for all SCE log files	Previously in SCE, only system log files generated by SCE program execution were highlighted to distinguish errors, warnings, and notes (where applicable). Now, any log file in SCE, whether uploaded, created manually, or generated as a user-defined program output, will be parsed for errors, warnings, and notes. This includes providing a count of each log finding in the properties of the log file.

Defects Addressed

Internal Issue #	Summary	Release Note Description
EL-24708	Dependency parsing was not detecting multiple datasets in same SAS SET statement when delimited by single space	Now, SAS program dependency parsing will detect multiple datasets referenced in a SET statement when delimited by a single space.