

illuminate 23.3.0  
Release Notes v2  
Updated 07Mar2024

## Document Version History

Version	Date	Section(s) Updated	Description of Modification
1	06Feb2024	<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	07Mar2024	<ul style="list-style-type: none"><li>Document Version History</li><li>Analytics - CDA</li></ul>	<ul style="list-style-type: none"><li>Added Document Version History</li><li>Updated Release Note Description text for ECCA-164</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 23.3.0. 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=23.3>.

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

elluminate Release 23.3.0 includes several new features and improvements. The major items targeted for the release are as follows:

### Data Central

**New! Raise Query on a cell in a Data listing.** Queries can now be raised from a specific cell in a Data listing configured for bidirectional queries.

**New! Identify fields as critical in the Issues and Queries listing.** Metadata for variables within a domain listing can be marked as Critical and identified in the Issues and Queries listings.

**New! Access to the Rave EDC System from the Record Details panel.** Users can now access the Rave EDC system for records sourced from Rave when viewing details in Data Central.

**Updated! New Data Central listing header functionality.** The header of data listings now displays domain-specific information and enables users to control panel filters.

### eIQ Orchestrator

**New! eIQ Orchestrator for streamlined Clinical Data Management, and auto-opening and closing of Issues, and Queries.** The eIQ Orchestrator is a new addition to Study Management, designed to facilitate data import and review processes by allowing users to create basic conditional rules. eIQ Orchestrator automatically identifies records that meet these established rules and creates Issues on the specified fields, as well as closes Issues for records that are no longer flagged by the rules, aiding in efficient and more accurate clinical data management. It features a user-friendly rule management interface, an easy-to-follow rule creation process, and a dual condition-building experience. Users have the option to include automatic opening and closing of Queries along with the default Issues generation.

### Operational Data Repository (ODR)

**New! The Study Alerts section has been added to the ODR Home page.** The study card for any study that meets the criteria based on default calculations will be included in this section.

**New! Customize the view of the ODR Home page.** Users can use two new icons to change the display of their ODR Home page based on Study Status or Study Phase.

**New! The Protocol Versions sub section / form has been added to the Study top-level form.** This will help track protocol versions at the country level.

**New! Custom Picklists can be created and defined.** Custom picklists can be created and also configured as a field choice.

**New! Group and reorder custom fields.** Custom fields can be grouped and reordered, determining how they will display in a form.

**New! Restore archived ODR records.** Two new icons have been added to a panel listing, allowing users to access and restore archived records.

## Platform

**Updated! Record-level security when assigning an Issue.** When creating or editing an Issue, the 'Assign To' drop-down now adjusts based on users' permissions for the selected record.

## Statistical Computing Environment (SCE)

**New! SAS Studio integration available for interactive program development.** Users can launch programs in a SAS Studio session for interactive development, library management, macro management, and exploratory work. Changes made in SAS Studio can be synchronized back to SCE.

**New! Difference highlighting comparison of text-based files.** Users can compare text-based files, including programs, logs, and lst files, using difference highlighting. This feature supports comparisons between files and across versions of the same file.

## 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 as part of 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.

## Analytics

### Clinical Data Analytics (CDA)

#### New Features/Improvements

Internal Issue #	Summary	Release Note Description
ECCA-224	CDA - SMQ Comparison Analysis, Treatment Emergent AE Analysis, Exposure Summary, and Objective Response Rate sheets: Added applicable filter to each sheet	Added a Subject filter to the SMQ Comparison Analysis, Treatment Emergent AE Analysis, and Exposure Summary sheets, as well as a Group Assignment filter to the Objective Response Rate sheet. This allows users to narrow down their results to individual subjects for a more targeted analysis.

Internal Issue #	Summary	Release Note Description
ECCA-210	CDA - Home Page: Updated denominator of AE / SAE Rates and Related AE / SAE Rates to Enrolled Subjects	Updated the denominator of the AE / SAE Rates, and Related AE / SAE Rates to Enrolled Subjects to provide a more accurate representation of the rate of adverse events in the trial.
ECCA-180	CDA - Tumor Identification sheet: Redesigned and optimized presentation	<p>The layout of the Tumor Identification sheet was redesigned and optimized to clearly and concisely display the information.</p> <ul style="list-style-type: none"> <li>• Instead of having a 2-option button group, the size of the right bar chart was increased by placing it into a container with 2 tabs. Users can still select either New Lesion Counts By Study Days or Subject Counts By Study Days, but now the data is easier to read and interact with.</li> <li>• The treemap chart, which showed the exact same data as the bar chart but in a less optimized way, was removed. This provided the space to move the pie chart up, allowing all three charts to be aligned side by side in a single row, and to extend the table to take up the full width of the dashboard (now displaying more columns simultaneously).</li> <li>• The Lesion Count for Location by Lesion Type bar chart has been updated to a stacked presentation for an easier and more compact Lesion Type and Location comparison.</li> </ul>
ECCA-164	CDA - Survival Summary sheet: Optimized presentation	<p>The layout of the Survival Summary sheet was optimized to clearly and concisely display the information.</p> <ul style="list-style-type: none"> <li>• The Subject Duration bar chart has been updated to a stacked presentation for an easier and more compact Subject and Duration (Treatment, Follow-up, and Overall) comparison. <ul style="list-style-type: none"> <li>◦ The stand-alone Overall Duration bar was removed, as it is now represented in each subject's stacked total.</li> </ul> </li> <li>• Instead of having a 2-option button group, the size of the Subject Duration bar chart was increased by placing it into a container with 2 tabs. Users can still select either Months or Days, but now the data is easier to read and interact with.</li> <li>• Additionally, a Progression-Free Survival column was added to the table and all column sizes were adjusted to display more columns at once.</li> </ul>
ECCA-143	CDA - Vital Signs Result Trends sheet: Added low and high limit input boxes	Similar to the Vital Signs Results Over Time sheet, the ability to set a range (lower and upper limit) on the fly via two input boxes was added, giving users greater flexibility and personalization. The range is clearly displayed by red and green lines that serve as the limit indicators.

Internal Issue #	Summary	Release Note Description
ECCA-138	CDA - Liver Lab Test Analysis sheet: Updated Category for Lab Test filter	Updated the Category for Lab Test filter to only display those related to liver lab tests to make filtering easier and more straightforward.
ECCA-124	CDA - SMQ Comparison Analysis sheet: Added Uncategorized section and footer to the pivot table	<p><b>Uncategorized Bucket</b></p> <ul style="list-style-type: none"> <li>Added an Uncategorized section in the pivot table that lists all the Adverse Events that do not fall into any of the SMQ Terms/Categories.</li> </ul> <p><b>Footer</b></p> <ul style="list-style-type: none"> <li>Added a footer to the pivot table that states, 'Adverse Event may appear in multiple categories depending on the SMQ Term and whether the term is both Broad and Narrow.'</li> </ul>

Internal Issue #	Summary	Release Note Description
ECCA-122	CDA - Adverse Event Summary sheet: Redesigned and optimized layout, updated Treemap footer, and updated AE Duration buckets	<p><b>Redesigned Layout</b></p> <p>The Adverse Event Summary sheet was redesigned and optimized to make it more concise, logical, and intuitive. The charts are now presented in a logical order that provides a natural progression and offers visual connections.</p> <ul style="list-style-type: none"> <li>• All filters have been arranged in a single line and the 2-option Subject/Event Counts button group has been moved beside the filters. Below, the 5-option Term classification button group is placed to the left of the 8-option classification button group. <ul style="list-style-type: none"> <li>○ Additionally, support for the High Level Term and High Level Group Term classification options was added in both the treemap and bar chart. Now, selections made in the 5-option Term classification button group update all 3 charts on the sheet.</li> </ul> </li> <li>• The title of the distribution plot was updated to AE Subject % by System Organ Class (or by whichever button is selected in the 5-option Term classification button group), the x-axis calculation was updated to reflect percentages, and the size of the chart was increased to better present the values shown.</li> </ul> <p><b>Updated Treemap Footer</b></p> <ul style="list-style-type: none"> <li>• The treemap's footer was updated to 'Total Number of Subjects' to more accurately reflect the data being shown.</li> </ul> <p><b>Updated AE Duration Buckets</b></p> <ul style="list-style-type: none"> <li>• In CDA, on the Adverse Event Summary sheet, when a user clicks on the AE Duration button, the dynamic bar chart (AE Subject Counts by System Organ Class and AE Duration) updates to show a bucketed legend for the duration of the adverse events. <ul style="list-style-type: none"> <li>○ The buckets have been updated to include a Less Than or Equal to 5 days bucket, and the existing bucket has been updated to Between 6-10 days. This addition provides a more granular and comprehensive breakdown of AE durations, allowing for a more detailed analysis.</li> </ul> </li> </ul>

Defects Addressed

Internal Issue #	Summary	Release Note Description
ECCA-159	CDA - Swimmers Plot With Subjects' Overall Response sheet - On Treatment bar was larger than the Continued Treatment	When a subject has more than one disease type, the Group Assignment toggle now properly displays the durations by showing the maximum duration instead of the sum.

**Clinical Trial Operational Analytics (CTOA)**

New Features/Improvements

Internal Issue #	Summary	Release Note Description
ECCA-202	CTOA - Home Page, Protocol Deviations Overview, and AE and SAE Rate sheets: Updated denominators to Enrolled Subjects	<p><b>Home Page</b></p> <ul style="list-style-type: none"> <li>Updated PD Rate, AE Rate, and SAE Rate calculations to use Enrolled Subjects as the denominator to provide a more accurate representation of the rate of protocol deviations, adverse events, and serious adverse events in the trial(s).</li> </ul> <p><b>Protocol Deviations Overview</b></p> <ul style="list-style-type: none"> <li>Updated PD Rate, Major PD Rate, Minor PD Rate, Protocol Deviations By Site Combo Chart (PD Rate), Protocol Deviations Over Time Line Chart (PD Rate) calculations to use Enrolled Subjects as the denominator.</li> </ul> <p><b>AE and SAE Rate</b></p> <ul style="list-style-type: none"> <li>Updated the denominator of the AE and SAE Rates to Enrolled Subjects.</li> </ul>
ECCA-155	CTOA - Subject Early Discontinuation, Protocol Deviations Overview, Protocol Deviations Details, and AE and SAE Rate sheets: Added Group Assignment filter	Added a Group Assignment filter to the Subject Early Discontinuation, Protocol Deviations Overview, Protocol Deviations Details, and AE and SAE Rate sheets. This allows users to narrow down their results to individual cohorts for a more targeted analysis.

Internal Issue #	Summary	Release Note Description
ECCA-128	CTOA - Enrollment Trend sheet: Redesigned, simplified, and optimized presentation	<p>The layout of the Enrollment Trend sheet was redesigned, simplified, and optimized to clearly and concisely display the information, reducing the noise and complexity.</p> <ul style="list-style-type: none"> <li>• The text box and input boxes that only allowed users to select an enrollment end date have been replaced with a filter pane called 'Year-Month.' This filter allows users to select any date or date range they would like to analyze, providing them with a cleaner, more intuitive, and consistent experience, as well as greater flexibility when diving into their data.</li> <li>• Instead of having relevant charts scattered throughout the dashboard and forcing users to scroll around, three charts, Cumulative Actual Enrollment, Cumulative Enrollment, and Cumulative Screen Failure, have been placed into a single container. Now each chart is much larger, making it easier to analyze and interact with. <ul style="list-style-type: none"> <li>○ The 2-option button group was removed, as both individual charts, Cumulative Enrolled Subjects (AKA Cumulative Enrollment) and Cumulative Screen Failures, are now separate tabs in the container.</li> </ul> </li> <li>• The Planned vs Actual Enrollment by Country waterfall chart was removed because it did not provide additional insight that the other charts did not, and its presentation caused confusion.</li> <li>• The Actual Study Enrollment vs Actual Site Enrollment line chart was converted to a combo chart to show Study and Site Enrollment as bars against the primary/left Y-Axis and Study and Site Screen Failures by lines against the secondary/right Y-Axis. This makes comparing Enrollment and Screen Failures much easier and straightforward. <ul style="list-style-type: none"> <li>○ The footnote that provided instruction on selecting a site was moved from the bottom of the chart to the top as the subtitle to make it easier to identify.</li> </ul> </li> <li>• The Planned vs Actual Totals By Site bar chart was updated to support two alternate dimensions. The Planned vs Actual Totals can now be viewed By Study or By Country as well. <ul style="list-style-type: none"> <li>○ The chart's sorting was also updated to display the Actual Enrollment in descending order so that bars go from largest to smallest.</li> </ul> </li> </ul>
ECCA-2	CTOA Home Page: Site Initiation Status not double counting anymore	Updated the Site Initiation Status bar chart to display the current status of the sites, showing their current position in the enrollment process. Each site is now classified under a single status, eliminating the double counting of sites, and more accurately depicting their status.

## Defects Addressed

Internal Issue #	Summary	Release Note Description
ECCA-129	CTOA - Enrollment Trend sheet: Cumulative # of enrolled subjects was not properly displaying	The Subject Enrollment line chart (at the bottom of the sheet) is now showing the cumulative # of enrolled subjects properly.

## Sample Management Analytics (SMA)

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
ECCA-38	SMA: Improved to support multiple collection schedule types	<p>Sample Management Analytics has been improved to support multiple collection schedule assignment criteria, providing better support for additional customer use cases, such as Protocol Amendments.</p> <p>The application now supports a mechanism that allows specific schedule versions to be assigned to subjects based on sponsor-provided criteria.</p> <p>In the absence of sponsor-provided assignment criteria, default assignments will be generated based on the currently available schedules.</p>

## Data Central

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-23366	Reorganized the Data Central Issues listing	The columns in the Data Central Issues listing have been reorganized to better reflect review priority.

Internal Issue #	Summary	Release Note Description
EL-22972	Advanced Filter Configuration: Updated the delete action	<p>With this enhancement to Advanced Filters, users have a streamlined and intuitive workflow when deleting filter parameters.</p> <p>The checkbox-delete functionality in the Filter Parameters table has been replaced with an inline-delete option for every row. Users can now delete individual parameters directly from the table using the last column, which contains the Delete icon, reducing clicks and simplifying the deletion process. Deleting all parameters within an Advanced Filter reverts the table to its default state, presenting an empty row ready to be populated.</p>
EL-22968	Annotations Configuration: Updated the delete action	<p>This enhancement applies to the Annotations tab found in the configuration of Data, Subjects, Issues, and Queries listings, focusing on optimizing the deletion process and enhancing the Settings interface for an improved user experience.</p> <p>The checkbox-delete functionality in the Annotation Columns table has been replaced with an inline-delete option for every row. Users can now delete individual annotation columns directly from the table using the last column, which contains a Delete icon, reducing clicks and simplifying the deletion process. The window was also updated to include Save and Cancel buttons positioned at the bottom right side of the screen, replacing the Done button. Now, the annotation column will not be added to the listing until the user clicks Save.</p>
EL-22835	New Data Central listing header functionality	<p>The header of data listings now displays domain-specific information and enables users to control panel filters. Clicking the domain title opens a pop-out that reveals the full domain name, label, last data refresh date, data import date, and attributing data source. Additionally, record counts for reviewed, updated since reviewed, and not reviewed statuses are displayed. Hovering over the badge count in the domain header shows a tooltip with the number of records currently being viewed or filtered. Clicking the badge count in the domain header opens a pop-out displaying the currently applied filters, and users can adjust the filter parameters from the pop-out.</p>
EL-22834	Enhanced styling for filter pills	<p>Styling improvements have been applied to the filter pills within the Master Header to enhance accessibility and provide a more user-friendly experience. Notable changes include a reduction in color usage, standardized pill sizes, and more prominent display of filter types within each filter pill.</p>

Internal Issue #	Summary	Release Note Description
EL-22831	Custom Listings: Added Export to Excel capability	Users can now export Custom Listings created from Data Central Visualizations to Excel. The Export feature is accessible directly from the Custom Listing toolbar. When triggering an export, the resulting Excel file includes the data along with crucial metadata, such as the data store(s), domain(s), filter(s) applied to the custom listing, and the timestamp of the export, providing comprehensive context surrounding the exported dataset.
EL-22806	Ability to identify fields within a domain as Critical in the Issues and Queries listings	Metadata for fields (variables) within a domain listing can be marked as Critical and identified in the Issues and Queries listings. Users with Metadata Editor privilege identify and mark variables as Critical within the Metadata module. Critical columns have been added to both the Data Central Issues and Queries listings, as well as the Issues listing in the Issues module, indicating whether a field is marked as Critical.
EL-22774	Added a link to the Rave EDC System within the Record Details view	Users now have the ability to access the Rave EDC system for records sourced from Rave when viewing details in Data Central. In the Record Details view, clicking the 'View record in Rave EDC' icon allows users to open the record in the EDC system in a separate window. If the user is not already signed into Rave, they will be prompted to log in.
EL-22350	Domain Highlight Conditions Configuration: Updated the delete action	<p>This enhancement applies to the Highlights tab found in the configuration of Data listings, focusing on optimizing the deletion process and enhancing the Settings interface for an improved user experience.</p> <p>The checkbox-delete functionality in the Domain Highlight Conditions configuration table has been replaced with an inline-delete option for every row. Users can now delete individual conditions directly from the table using the last column, which contains a Delete icon, reducing clicks and simplifying the deletion process.</p>
EL-22235	Ability to raise query on field in a Data listing	<p>Queries can now be raised directly from a data listing for a defined field and value. The listing must be configured for bidirectional queries with an EDC system. When the user right-clicks on a cell in a listing, the cell will be highlighted, and the option to 'Create a Query on Cell' will appear in the context menu. Users still maintain the ability to raise a query for a defined field and value in the record details panel.</p> <p>Note: Bulk and single queries can still be raised at the record level with an undefined field using the plus icon in the action toolbar of an exception listing.</p>

Internal Issue #	Summary	Release Note Description
EL-21744	Field Emphasis Configuration: Added Search functionality	<p>This enhancement applies to the Highlights tab found in the configuration of Data listings, focusing on improving the user experience and making the search for a field more efficient.</p> <p>We have introduced a dedicated, right-aligned search bar directly above the Field Emphasis table. The implemented search functionality enables dynamic filtering of table results based on the entered term(s) in the search bar. The search is not case-sensitive and matches entries in both the Field Name and Column Header Color columns, providing comprehensive results.</p>
EL-19679	Added Interim Changes Summary to Data Variance Record Details	<p>When Data Variance is applied to a listing, users can now view a history of the changed data within the selected variance dates. In the record details panel, users can click the Change icon to see a summary of changes for each field that has new, updated, or deleted data.</p>

#### Defects Addressed

Internal Issue #	Summary	Release Note Description
EL-22003	Error when copying Data Central configuration	<p>When copying a Data Central configuration from one study to another, deleted users are now properly removed if there is a new user present in the copied configuration.</p>

## eIQ Orchestrator

#### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-23367	'Related Query' option for auto-generated issues	<p>Within the Data Central Issues listing, a 'Related Query' option is available in the right-click menu for auto-generated issues, allowing users to navigate directly to the related queries.</p>

Internal Issue #	Summary	Release Note Description
EL-23156	eIQ Orchestrator added to illuminate	The eIQ Orchestrator is a new addition to Study Management, designed to facilitate data import and review processes by allowing users to create basic conditional rules. eIQ Orchestrator automatically identifies records that meet these established rules and creates issues on the specified fields, as well as closes issues for records that are no longer flagged by the rules, aiding in efficient and more accurate clinical data management. It features a user-friendly rule management interface, an easy-to-follow rule creation process, and a dual condition-building experience. Users have the option to include automatic opening and closing of queries along with the default issues generation.
EL-23028	Opened By column displays 'Auto' for Issues created in eIQ Orchestrator	Within the Issues listing in both Data Central and Issues, 'Auto' will display in the Opened By column for issues generated by eIQ Orchestrator. This allows users to easily filter the Opened By column and identify auto-generated Issues by eIQ Orchestrator.

Internal Issue #	Summary	Release Note Description
EL-22670	Add and Manage Rules	<p>The Add / Edit Rule window allows users to add and manage rules for a study.</p> <p>Under the Step 1: Build tab, rule conditions are created and managed using the Condition Builder. Users can select options from drop-down lists for Data Store, Domain, Field, Operator, and Value. Conditions can be organized into nested groups with assigned AND/OR logic, triggering automatic issue generation for records meeting the rule conditions.</p> <p>For advanced users, the SQL Editor tab allows direct programming of rule conditions using SQL statements. Conditions created in the Condition Builder are seamlessly transformed into SQL statements when switching to the SQL Editor, providing flexibility in rule definition.</p> <p>Under the Step 2: Information tab, basic and issue information is added. Basic Information encompasses details like Name, Tag, Description, and Status; and Issue Information includes the Primary Field that the issues will be raised on, Priority, Assign To options, Due In Days, notification preferences, and Issue Text. Related Fields can be added for reference.</p> <p>Under the Step 3 tab: Action, automatic query creation can be enabled and defined. When a rule generates an issue, a related query is automatically created.</p> <p>Users can preview defined rule conditions by clicking the 'Preview' button. A separate window displays records meeting the conditions, related fields, SQL statements used for validation, and run-time output.</p> <p>Upon saving rules, validation checks ensure data integrity, and the Audit Log is updated to document creation or editing details, including the creator's information.</p>
EL-22459	eIQ Orchestrator window	<p>The eIQ Orchestrator window features a left navigation that offers efficient sorting, filtering, and a summary of the rules at a glance. To the right, it provides a list of the rules for the study. Users can view, create, edit, activate, run, and delete rules from this list.</p>

## eIQ Review

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-22432	Global (subject) filters are now applied to eIQ Review panels	eIQ Review panels now adhere to Global (subject) filters applied in Data Central. When a user selects 'Filter Subject' when applying a column filter, all panels within the eIQ Review models will be filtered accordingly based on the applied Global filter.

## Issues

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-5999	Record-level security when assigning an issue	Record-level security now applies when assigning a user to an elluminate issue. The user or user group list in the 'Assign To' drop-down now adjusts based on users' permission to the selected record. If a user (or user within a group) does not have access to view the record where the issue is being created or edited, their name will not appear in the drop-down for assignment. Record-level security applies to all issue types.

## Mapper

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-24051	Ability to consolidate join keys	In previous versions, when creating a join between two tables in Mapper, the variables used as join keys were listed twice in the join output. Users had to manually edit the variables list to address this issue. With this new enhancement, users can automatically consolidate join keys by clicking on the new 'Consolidate Keys' button in the join editor window. This improvement can be applied to inner, left, right, and full joins but is not applicable to cross joins. Notably, when applied to full joins, the keys are removed from both sides, and a new derived variable is added for each key condition.

Internal Issue #	Summary	Release Note Description
EL-24050	Enhanced derived variables	Multiple enhancements have been made to the Variables Editor in Mapper to facilitate the creation of derived variables. Users can now select one or more source variables (by clicking and holding down the CTRL key), then click on a 'f(x)' shortcut button to immediately convert these variables into a derived variable. The derived variable is inserted in place and will automatically reference the selected variables, thus eliminating the need to retype them in the SQL editor or reselect them in the predefined functions.
EL-23952	Enhanced search capabilities within mappings	The search within mapping domains has been improved with the ability to perform two types of searches using the search text box. When an expression is entered, an immediate search is conducted within the current mapping. With the new functionality, pressing the Enter key extends the search across all mappings. Results in the Mapping section will be filtered to display only those with matching domains. Additionally, the Domains section will show only domains with names containing the search expression, highlighted in yellow.

## Operational Data Repository (ODR)

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-23458	ODR Home page: Enhanced the display options	The Home page view has been enhanced, with the default setting displaying Study Alerts. Two icons have been added in the toolbar for view customization: the 'Study Status' toggle icon is on by default. To choose a different study status for viewing, users can click the 'Select Status' icon and choose the status from the drop-down menu. If users prefer to view by study phase, they can click on the 'Study Status' toggle icon to deactivate the view by study status. When the 'Study Status' toggle is turned off, the drop-down menu for the 'Select Status' icon shows a list of study phases, including Study Alerts, Planning, Active Pre-enrollment, Active Enrollment, Completed, and Undefined.
EL-23324	Studies: Added Protocol Versions sub section / form	Within the Studies top form, the sub section Protocol Versions has been added. Adding protocol version details to the sub form helps track protocol versions at the country level.

Internal Issue #	Summary	Release Note Description
EL-23322	Fields Config: Added Picklist field type for custom fields	Within Fields Config, a custom field can be configured as a Picklist field type. Previously, the field configuration only allowed the creation of textbox options (text, date, and numeric). This new functionality will enable users to configure the picklist by selecting an existing configured picklist as a field choice.
EL-23320	Picklists: Entries now include Code and Value combination	In the previous version of Picklists, each picklist consisted of a list of named entries. Now, each entry will include a combination of a code and corresponding value. This format adopts a concept similar to SAS formats.
EL-23319	Picklists: Ability to add a new custom picklist	At the top of the Picklists window, an 'Add New Picklist' button has been added, enabling users to create and define custom picklists.
EL-23279	Fields Config: Added '(Baseline, Planned & Actual)' to 3-part fields	In Fields Config, labels for 3-part fields within Rates and Milestones have been updated to include '(Baseline, Planned & Actual).' This modification ensures that users understand that a single field in the configuration now displays as three distinct fields (Baseline, Planned, and Actual) within the form.
EL-23258	ODR Home page: Added Study Status to study cards	Study cards on the ODR Home page now display Study Status, which is retrieved from the information entered in the Study form.
EL-23244	Programs: Added the Therapeutic Area field to the top form	The Therapeutic Area field has been added to the Programs top form. Users select from a drop-down list of defined Therapeutic Areas. When a study is assigned to a program, the therapeutic area for that program is automatically assigned to the study.
EL-23237	Top-level forms: Breadcrumb information added	Within ODR top-level forms, the Edit window now displays the name of the selected item. For instance, if editing Program XYZ, the top of the window will show 'Edit Program: XYZ.' This feature aids users when editing and viewing respective sub-level forms.
EL-23199	Fields Config: Ability to reorder custom variables within a form	Within Fields Config, a user with the ODR Configure privilege can organize custom variables. They can use the 6-dot icon to drag and drop these variables into the desired order for each group, determining how they will be displayed in the form.
EL-23198	Fields Config: Ability to group custom variables in a form	Within Fields Config, custom fields can be added to a uniquely defined group within a form. This capability allows for the grouping of related custom fields together.
EL-23085	Restricted the editing of archived ODR records	Archived records cannot be edited, which includes the ability to add sub-level data. The Edit icon in the toolbar is grayed out, preventing users from editing the record.
EL-22999	Permissions to Operational Oversight	Only users with the 'ODR Analytics' privilege will see Operational Oversight under the category Operational Insights in the Platform Menu.

Internal Issue #	Summary	Release Note Description
EL-22890	Users with ODR Read Write privilege can create issues in ODR	In previous releases, users were required to have the ODR Configure privilege to create issues in the Operational Data Repository (ODR). Now, users with the ODR Read Write privilege can also create issues in the ODR.
EL-22702	User Profile: Ability to select Operational Data Repository or Operational Oversight as default home page	In 'My Profile,' users can now select Operational Data Repository or Operational Oversight from the drop-down. The chosen option will serve as their default illuminate home page.
EL-22361	Ability to display and restore archived ODR records	Within Panel listings, two icons have been added to help users identify archived records and restore them if desired. Using the 'Show Archived Record' icon displays the same panel listing with three additional columns on the right, 'Is Archived' (yes, no), 'Archival Reason,' and 'Restore Archival Reason.' To restore an archived record, users can highlight a row of the archived record and use the 'Restore Archived Record' icon.

Internal Issue #	Summary	Release Note Description
EL-11824	ODR Home page: Added Study Alerts	<p>A Study Alerts section has been added to the ODR Home page. The study card for any study that has met criteria based on default calculations will be added to this section. A banner displays at the top of the study card displaying the alert. Study Alerts include:</p> <ul style="list-style-type: none"> <li>• Draft Protocol Date is Approaching: If Draft Protocol Date Actual is missing and Draft Protocol Date Planned is within the next 30 days</li> <li>• Final Protocol is Approaching: If Final Protocol Date Actual is missing and Final Protocol Date Planned is within the next 30 days</li> <li>• Screening Failure Rate (%) Is Exceeding Planned: If Screening Failure Rate (%) Actual is higher than Screening Failure Rate (%) Planned</li> <li>• Enrollment Rate is Low: If Enrollment Rate Actual is Lower than Enrollment Rate Planned</li> <li>• Number of Screen Failures is High: If Number of Screen Failures Actual is higher than Number of Screen Failures Planned</li> <li>• First Site Activated Is Approaching: If First Site Activated Actual Date is missing and First Site Activated Date Planned is within the next 30 days</li> <li>• First Subject Screened Is Approaching: If the First Subject Screened Actual Date is missing and First Subject Screened Planned is within the next 30 days</li> <li>• First Subject In Is Approaching: If the First Subject In Actual is Missing and the First Subject in Planned is within the next 30 days</li> </ul>

## Platform

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-23169	User Management > Groups: Ability to configure a default landing page for a specific group	Within User Management > Groups, a Home Page tab has been added. This tab allows configuring an elluminate module as the default landing page for a specific user group, redirecting users in the group to the configured home page.

Internal Issue #	Summary	Release Note Description
EL-21684	Ability to mark fields as Critical in Metadata	In Metadata, users with Metadata Editor privilege can now designate fields (variables) as critical within a domain. In the Metadata grid, a checkbox has been added for each variable within a domain. Variables marked as Critical will be flagged in the Data Central Issues and Queries listings.

## RACT

### Defects Addressed

Internal Issue #	Summary	Release Note Description
EL-24546	The 'Accept Risk' button was incorrectly enabled.	The 'Accept Risk' button remained enabled even when Action Plan(s) were added to the Risk Statement.
EL-23799	RACT study pages would auto copy-paste from completed studies during new study configuration	During the new RACT study configuration, all pages would automatically be copied from a completed study if a user navigates to a completed study.
EL-21504	RACT Assessment Read Only users were able to view RACT studies which they do not have access to	RACT Assessment Read Only users were able to view RACT studies to which they do not have access by directly copying and pasting a RACT study URL.
EL-19777	RACT reports were not generating correctly	Both the RACT 'Assessments Overview' report and the 'Version Compare' report are now successfully generating, displaying all critical items.

## RBQM

### Defects Addressed

Internal Issue #	Summary	Release Note Description
EL-22714	Columns in KRI issue notification emails were misaligned	In KRI issue notification emails, the column titles and corresponding values are now correctly aligned.
EL-18803	The Site Summary Score was lower than the actual score	The actual Site Summary Score was lower than the score displayed when a Site does not have data in any of the study-defined KRIs.

Internal Issue #	Summary	Release Note Description
EL-15504	KRI disappeared from KRI Summary panels when it had risk actions	The KRI disappeared from the KRI Summary panel in both the Overview dashboard and KRIs dashboard upon running RBQM tasks when Site / Country Risk Actions were added in KRI Configuration.

## Statistical Computing Environment (SCE)

### New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-21941	Users with None, Read Only, or Read/Write permissions are restricted when deleting folders	SCE Folder Permissions have been enhanced with additional controls for users when deleting a folder. Now, a user is prevented from deleting a folder if they do not have the Full Control permission assigned to any of its subfolders.
EL-21667	Added an icon in Folder Permissions to differentiate between empty and non-empty folders	In the Folder Permissions grid, an icon has been added next to the Folder Name to indicate which folders do not have subfolders. If the icon is solid, the folder has subfolders; if the icon is light, the folder has no subfolders. This provides a streamlined experience for SCE Configure/Admin users who would not need to unnecessarily check for subfolder content when configuring permissions.
EL-21074	Added Role Name tooltip in Folder Permissions	In the Folder Permissions grid, a tooltip with the full role name is now displayed by hovering over a role abbreviation. If a user is unfamiliar with the role abbreviations for their URL, this tooltip will help them understand which permission levels are assigned per role.
EL-20358	New Global SAS Macro variables available in SCE	In SCE, users can programmatically access certain metadata in SAS through build-in global macro variables. In this release, additional SCE macro variables have been added to capture file and study metadata. These additions allow users to dynamically reference program status as well as study therapeutic area, compound, program, and study name. These new macro variables are populated at runtime along with the previously implemented SCE macro variables.
EL-20194	Interactively develop and run code within the fully integrated SAS Studio environment in SCE	Users can now launch SCE programs in a SAS Studio session for a fully interactive development experience! The SAS Studio environment is isolated from the production SCE area, allowing for exploratory work, library management, and development without affecting other workflows. Changes to programs in SAS Studio can be synchronized back to SCE.

Internal Issue #	Summary	Release Note Description
EL-20155	Users with None or Read Only permissions are restricted when moving or copying folders	SCE Folder Permissions have been enhanced with additional restrictions on users with the None or Read Only permission when moving or copying folders. Now, when moving or copying a parent folder, users are prevented from moving or copying any subfolder on which they have a restricted permission.
EL-20154	Ability to configure automated program execution after Import of dependent dataset	Previously in SCE, all Production programs were automatically executed upon refresh (via Importer) of dependent datasets. Now, SCE users have the option to turn this feature on and off per program. The configurable file property 'Automate Execution' determines whether the program will automatically run while In Production when a dependent dataset is updated by a new Import. Programs have this feature toggled on by default, and the property is editable in any program state.
EL-18635	SCE Role Management enhanced with Studies list	In SCE Settings, a Studies list has been added to enhance user role management. This list displays all studies that have SCE enabled. From this list, users can view the role assigned to users for a study (or the Global folder). SCE Configure/Admin users can also use this list to select a study and edit role assignments.
EL-18220	SCE Role Management enhanced with Users list	In SCE Settings, a Users list has been added to enhance user role management. This list displays all users currently with access to SCE. From this list, users can view the role assigned to each user for each of their studies. SCE Configure/Admin users can also use this list to select a user and edit study role assignments.
EL-14988	Ability to configure default folders for newly SCE-enabled studies	In the SCE Settings, SCE Configure and Admin users can now configure the default folders which are created under a study when it is first enabled for SCE. These configuration options allow studies to be more rapidly customized to fit client practices for folder structure and file organization.
EL-14465	Compare files with difference highlighting in SCE	Users can now view a side-by-side comparison of any two text-based files (e.g., programs, log files) in the SCE Editor and Browser. The Compare icon has been added to the toolbar in the Editor, and to the right-click context menu in the Browser. The difference highlighting in the file compare view allows users to quickly track changes made across file versions or understand variance across files.

Defects Addressed

Internal Issue #	Summary	Release Note Description
EL-23999	In the SAS Work Library subpanel, users were unable to see all datasets when the number of datasets exceeded the viewable area	Vertical scrolling is now available in the SAS Work Library subpanel so users can see their full list of work library datasets.
EL-22980	Users were unable to save datasets to a global datastore named 'Global' via SCE program execution	Now, through SCE program execution, users can save datasets to a global datastore named 'Global.'
EL-22376	Users were unable to delete a file that was a dependency for another file that has already been deleted	Now, the deletion does not prevent a user from deleting any dependencies associated with the deleted file.