elluminate 25.1.0
Release Notes
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Purpose and Scope

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

This document provides release notes for eClinical Solutions' elluminate platform, version 25.1.0. These notes detail new features, improvements, and resolved defects. Reviewing them will help users and business stakeholders understand the benefits of upgrading from previous versions.

Supporting Documentation

Additional resources for information on the elluminate platform are available.

The elluminate Help Center provides detailed information on using and configuring the platform, including new features and functionality. It can be accessed at: https://support.eclinicalsol.com/hc/en-us?version=25.1

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

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

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New Features and Improvements

elluminate Release 25.1.0 includes several new features and improvements. The major items included in this release are as follows:

Analytics

New! Missing or Delayed Samples Sheet in SMA. Quickly identify potential sample delays or misplacements with the new Missing or Delayed Samples sheet. Color-coded by status, this sheet highlights samples that exceed user-defined thresholds for Days At Site, In Transit, or At Lab. The data can be easily filtered across multiple dimensions and is displayed in both graphical and tabular formats for clear insights and analysis.

Updated! Enhanced Integration and Usability of Protocol Deviations sheets in CTOA. To support elluminate's new Protocol Deviations module, the CTOA app has been enhanced to work seamlessly with studies using this new data source, while still supporting studies that rely on external sources, ensuring consistent integration and streamlined configuration across all use cases. Updates span both the Protocol Deviations – Overview and Protocol Deviation Details sheets, with a focus on improving usability, flexibility, and data analysis.

Updated! Added support for Subject-Level AESIs in CDA. CDA now supports both study-level and subject-level AESI (Adverse Events of Special Interest) criteria, allowing for more flexible and granular handling of AESI data across studies.

Updated! Redesigned the Demographics sheet in CDA. The Demographics sheet has been redesigned to improve usability, reduce redundancy, and enhance data visualization. A new unified control now lets users select Country, Site, Group Assignment, Sex, Race, or Ethnicity, with all visualizations dynamically responding to the selected variable. Chart types and layout have been refined for clearer comparisons and a more streamlined, intuitive analysis experience.

Updated! Added support for all Disposition Event Categories on the Disposition sheet in CDA. The Disposition Summary sheet has been updated to provide more flexible and transparent analysis of all disposition event categories. The chart, pivot table, and data table now dynamically update based on the selected category—ensuring no data is excluded by default.

Data Central

New! Integrated Data Review Plan (IDRP). Users can now build, manage, and execute Review Plans entirely within elluminate, starting in the new Review Plan tab in Data Central Configuration. Define Review Objectives with key attributes like Primary/Secondary Domains, Reviewer Roles, Priority, and Review Frequencies, and seamlessly link relevant review materials such as listings, visualizations, workspaces, Analytics apps, and RBQM dashboards.

Once configured, reviews can be tracked and executed in a dedicated Review Plan section within Data Central. This guided workflow ensures reviewers always know what needs attention and can access all supporting materials with a single click.

Visualize progress using dashboards and panels that break down objective completion by domain, priority, and reviewer role—with both role-specific and cross-role views available.

Use Excel import/export tools and templates for bulk setup, and rely on comprehensive audit logs for full traceability across all configuration and review actions.

Updated! New Issues Related Fields tab added to Domain Settings. A new Issue Related Fields tab has been added to Domain Settings in Listings, allowing users to configure a list of fields to be automatically associated with Issues created within each domain. These related fields are displayed in the Issue Details panel and the Related Fields column in Global Issues.

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Updated! Data Central Visualizations now support custom colors for Pie and Combo Charts. Users can now assign custom colors to each segment in Pie and Combo charts, including values in Dynamic Dimensions to highlight important data, reinforce meaning, or apply brand-aligned color palettes.

elluminate Assist

Updated! elluminate Assist Expanded Capabilities. elluminate Assist now features an updated toolbar with a More icon for new chats or to view chat histories, a Pin icon to keep the window open, and a Maximize icon for full-screen viewing. The underlying model has also been enhanced to improve performance.

Operational Data Repository

New! Data Model for Operational Data (DMOD) Standard. DMOD is an eCS-built standard data model designed for Operational Data. Built upon the original ODR (Operational Data Repository) structure with significant expansions, DMOD maximizes coverage of Operational Data elements, addressing the needs of Clinical Trial Operations.

Available within the Standards module, DMOD enables efficient versioning management and allows users to create and customize their own data models, ensuring flexibility and scalability for handling clinical trial data in a structured and adaptable manner.

DMOD can be used similarly to other Standards models with any data store and can be selected in a Mapping and used within Validator.

Updated! Configuration items available for custom field Picklists. In Fields Config, elluminate Configuration items (Therapeutic Areas, Investigational Products, Programs, Phases, Study Type, Endpoints, Controls, Blindings) can be assigned to Picklists for custom fields, allowing seamless integration within ODR forms.

Updated! Customize ODR Grid Visibility for OOTB fields. The ODR grid can now be customized by enabling or disabling the visibility of top-level out-of-the-box fields within Fields Configuration.

Updated! Expanded ODR Export Capabilities. In addition to exporting data through the Exporter module, users now have the option to export the filtered grid data to Excel.

Orchestrator

Updated! Enhanced visibility for Orchestrator-generated Issues and Queries. The 'Opened By' column in Issues and Queries listings now displays the full name of the Orchestrator rule that created them. Filtering by Orchestrator rule is also now available for easier rule-based reviews.

Platform

New! Clario eCOA Clinical Trial Data API connection. Users can now import data from the Clario eCOA Clinical Trial platform, including Subject data, Subject activation and continuation, any data recorded in the Clario system, as well as valuable system information like audit logs and metadata.

New! SAS Life Science Analytics Framework (LSAF) API connection. Users can now import data stored in the SAS LSAF platform, allowing the ingestion of data files contained within repositories configured in the LSAF platform.

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Risk Management (RACT & RBQM)

The risk-management suite has been rebuilt end-to-end to provide a faster, clearer, and more connected experience while staying fully aligned with ICH E6(R3).

Updated! Redesigned RACT. The RACT workflow and assessment process have been overhauled to align with modern UI standards, improving customization and enhancing adaptability for diverse industry practices.

Updated! Redesigned RBQM. The RBQM updates are designed to simplify risk monitoring, improve visibility, and enhance the overall efficiency of your quality management processes. The improved RBQM dashboards feature an enhanced interface layout, offering better visibility and a more intuitive presentation of key metrics.

New! Risk Management page. The Risk Management page is introduced to provide centralized access to all RBQM and RACT-related studies, featuring study overviews, and quick actions, such as running the RBQM Engine and starting a new assessment directly from the page.

Updated! Risk Management Configurations. All RACT configurations are now managed from one place and seamlessly shared with RBQM for improved consistency.

New! Risk Library. The Risk Library allows users to document, manage, and import risks for easier integration into risk assessments. It also comes with out-of-the-box recommended mitigations and monitoring metrics to support effective risk management strategies.

New! AI-Powered Risk Statement Generation. A new AI-powered Risk Statement generation tool has been added to RACT to help users generate risk statements ('if - due to - then' fields) more accurately and efficiently.

New! Risk Management Plans. Customized Risk Management Plans can now be generated in Excel or PDF formats to facilitate risk assessment and risk mitigation documentation.

New! RACT Reassessment Reminder. To help teams stay proactive, RACT reassessment intervals and due date reminders can be set up within the elluminate.

Statistical Computing Environment (SCE)

New! Ability to create Domain Issues. SCE users can now create and manage data Issues directly on study datasets within the Statistical Computing Environment. This new capability enables programming teams to document abnormalities and route Issues to relevant users or groups, streamlining collaboration with data management teams. Previously, Domain Issues were managed exclusively in Data Central. Now SCE users can initiate Issue workflows without switching contexts, eliminating the need for external tracking methods and improving cross-team communication. All Issues raised in SCE are logged in the Issues module for full traceability.

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Module Specific Details

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

Administration

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-27635	Enhanced context in the audit trail for re-opened issues in elluminate	Users experienced confusion when examining the elluminate Audit Trail for issue-related information, specifically differentiating between users opening and re-opening issues. To clarify this, audit trail records for re-opened issues have been updated with additional text to indicate that the issue was re-opened.
EL-28964	Enhanced exported user files to indicate license status	Previous exports of configured users from elluminate did not indicate whether users were licensed or unlicensed. To address this, a new ‘Unlicensed’ column has been added to exported documents to clarify the license status of each user.
EL-29562	Enhanced unlicensed user configuration study assignment	User feedback indicated a need to improve data review workflows for unlicensed users. Specifically, users requested the ability to assign elluminate studies to unlicensed individuals, such as vendors or non-client personnel. Previously, unlicensed users lacked study-specific access, potentially exposing them to sensitive data. To address this, the platform has been enhanced to allow the assignment of a limited subset of studies to unlicensed users within a URL. In many cases, these users require access to only one or two specific studies. A new configuration option, ‘Study Access,’ has been added to user management. When enabled, this option allows administrators to assign a specific list of elluminate studies to an unlicensed user, ensuring data security.
EL-31306	User Management - Analytics privilege: Added support for app-level access	In User Management, when assigning privileges to a user or user group, a new ‘Apps' accordion has been added to the bottom of the ‘Analytics’ privilege list (below Therapeutic Areas). This section lists all Analytics apps deployed to the URL, allowing those managing users to specify which apps each user or user group can access within the Analytics module (all apps, a single app, or a subset). This enhancement helps reduce noise and streamline the user experience by limiting visibility to only the apps relevant to each user’s role; for example, displaying only CTOA to those reviewing operational data or only CDA & CDA Snapshot for users focused on clinical data.
EL-31102	User Management - Risk Management: Updated Privileges	The user privileges for the Risk Management Suite have been modified to better reflect user roles. The 'RBM' privilege has been renamed to 'RBQM.' Additionally, the former 'RACT Configure' privilege has been renamed to 'Risk Management Configuration.' This new privilege includes all existing access from both 'RACT Assessment Read Write' and 'RBQM,' plus enhanced configuration capabilities.

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Analytics

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-31004	Analytics and Customize Analytics: Easier bi-directional access	In the Analytics module master header, users with the appropriate privileges will now see a Customize Analytics (venn diagram) icon, providing direct access to the Customize Analytics module for easier configuration. Similarly, in the Customize Analytics module master header, users with the appropriate privileges will see an Analytics (bar chart) icon, offering quick navigation back to the Analytics module for easier app access.

Clinical Data Analytics (CDA)

New Features/Improvements:

Internal Issue #	Summary	Release Notes Description
ECCA-608	CDA - Adverse Event Comparison sheet: Optimized layout	The filters have been realigned to achieve better visual symmetry, making them easier to distinguish and navigate. Selectors that impact all charts are now centered between the bar charts and positioned above the pivot table; they are presented as drop-downs to clearly indicate their shared effect and streamline selection. Additionally, each selector label now explicitly defines the aspect of the charts it controls, improving overall clarity and usability.
ECCA-607	CDA - Adverse Events Cross Tabulation sheet: Optimized layout	The control layout has been consolidated from three lines to two, enhancing the visibility of the pivot table and improving usability. All filters are now displayed on a single line, keeping them visually grouped and aligned with layouts used in other sheets. Configurable controls have been moved to the second line for easier access and selection. Drop-downs are now used consistently instead of buttons, simplifying interactions and, via labels, clearly indicating which control affects which aspect of the pivot table data.
ECCA-520	CDA - All Sheets: Consistently display Site in listings	All sheets with listings displaying subject data now consistently include Site. This update ensures key information is always visible across all relevant tables for easier reference and filtering.
ECCA-603	CDA - Application Information sheet: Added Data Model Profile bullet chart	Added a Data Model Profile bullet chart to the Application Information sheet that, on hover, displays both the total number of data cells (rows × columns) in each table (Actual Cells) and the number of base data cells (those defined by the standard application) (Target Cells). This allows users to easily assess how much additional, non-standard data, such as custom domains and fields, has been added to the app, helping them better understand the scale and impact of customizations.

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Internal Issue #	Summary	Release Notes Description
ECCA-387	CDA - Demographics sheet: Consolidated existing controls, reduced redundancy, and improved layout and data presentation	Several enhancements have been made to the Demographics sheet to improve usability, analysis, and presentation: • Added Country and Site as options to the primary variable input control and removed the redundant Site & Country and 6-button controls above the area chart, streamlining everything into a single set of controls that updates all charts on the sheet. The unnecessary Age Range option was also removed for simplicity. • The Subject Counts By Group Assignment combo chart now responds to the Country and Site filters, ensuring consistent updates across all visualizations. • Converted the existing area chart to a bar chart to make comparisons clearer and easier to interpret. • Deleted the Subject Count by Site (or by Country) bar chart to reduce duplication and simplify the sheet. • Introduced a Subject Counts By Group Assignment pie chart to enable quick, percentage-based comparisons between groups, offering greater insight into diversity, equity, and inclusion initiatives. • Arranged all three charts side by side, with their associated tables positioned below, for a cleaner, more intuitive presentation and improved analytical workflow.
ECCA-400	CDA - Disposition Summary sheet: Expanded and improved support for all categories for disposition events	Replaced the Category for Disposition Event filter with a drop-down that displays all available categories for selection, with Disposition Event set as the default. The chart, pivot table, and table now dynamically update based on the selected category. With this update, no data is automatically filtered out of the sheet, providing improved validation, greater transparency, and a more comprehensive analysis. Additionally, a new column called 'Subcategory for Disposition Event' has been added to the table, positioned after the Category for Disposition Event column, to offer further detail and context.
ECCA-523	CDA - Lab Results Review Over Time sheet: Added Group Assignment filter and the ability to toggle reference range lines off	Users can now toggle reference lines on or off to reduce visual clutter and improve chart readability. Additionally, on each chart, the tooltip for data points now includes the Upper Limit of Normal (nxULN), making it easier to compare the actual value to the upper limit of normal at a glance, especially when the reference lines aren't visible. Finally, we added a Group Assignment filter, allowing users to narrow to a particular group of subjects.
ECCA-364	CDA - Lab Results Review Over Time sheet: Added support for absolute change from baseline on all charts	All four Lab Results Over Time line charts now support an alternative measure on the y-axis drop-down called 'Absolute Change from Baseline,' which graphs the absolute value of the numeric change from baseline. This allows users to focus on the magnitude of change, regardless of direction, providing a clearer view of overall variability and shifts over time.

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Internal Issue #	Summary	Release Notes Description
ECCA-522	CDA - Several sheets: Added support for subject-level AESI	CDA has been updated to support both study-level and subject-level AESI (Adverse Event of Special Interest) criteria. This ensures more flexible handling of AESI data across studies. If no subject-level AESIs are present, the application will continue to function as it does today. If subject-level AESIs are present, the existing Special-Interest filter and column in tables across all relevant sheets will now display 'Y*' and 'N* values, indicating that the AESI is subject-level.
ECCA-542	CDA - Tumor Measurement Spider Plot sheet: Added table & additional data point in tooltip of line chart	On the Tumor Measurement % Change from Baseline by Subject and Group Assignment line chart, the Number of Lesions is now displayed in the tooltip for each data point, providing additional context directly within the chart. The footnote has been updated to clarify: "Please select the desired Response Criteria. The # of lesions in the tooltip only displays those that are included in the calculation (those with numeric results)." Additionally, a new Tumor Measurements table has been added below the chart. This table provides a tabular view of the data represented in the chart, along with a few additional fields to support deeper analysis. These enhancements enable users to more easily identify whether a lesion measurement was missed or if there was a change in the number of lesions being monitored for a particular subject over time.
ECCA-449	CDA - Tumor Results 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 'All Study Days' or only the non-negative study days, 'Study Days >=0'. This gives users the flexibility to choose between a full view or a focused view.

Clinical Trial Operational Analytics (CTOA)

New Features/Improvements:

Internal Issue #	Summary	Release Notes Description
ECCA-604	CTOA - Application Information sheet: Added Data Model Profile bullet chart	Added a Data Model Profile bullet chart to the Application Information sheet that, on hover, displays both the total number of data cells (rows × columns) in each table and the number of base data cells (those defined by the standard application). This allows users to easily assess how much additional, non-standard data—such as custom domains and fields—has been added to the app, helping them better understand the scale and impact of customizations.

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Internal Issue #	Summary	Release Notes Description
ECCA-495	CTOA - Protocol Deviations Overview and Protocol Deviation Details sheets: Added support for new Protocol Deviations module	To support elluminate's new Protocol Deviations module, the CTOA app has been updated to support studies sourcing protocol deviation data from this module, while continuing to support studies using external sources, ensuring consistent data integration and streamlined configuration. To further align with this integration and improve usability, several enhancements have been made to the Protocol Deviations – Overview and Protocol Deviation Details sheets. **On the Protocol Deviations – Overview sheet:** • Added a Protocol Deviation Type filter to enable easier grouped analysis. • Updated the Site of Deviation filter to display both Site Number and Site Name, improving clarity. • On the Number of Protocol Deviations combo chart (formerly 'Protocol Deviations By Site'), added Study, Country, and PD Type as additional x-axis dimension options. • On the Protocol Deviation Details by Study, Country, & Site bar chart (formerly 'Class, Form, Field & Protocol Deviations By Site'), added Study and Country as y-axis dimension options. • In the associated table: – Added Country (after Study) and PD Type (after Level) as new columns. – Removed the redundant Current Site Number column as the Current Site column already includes both the number and name. – Replaced the original Site of Deviation column (which displayed only the site number) with a new version showing both Site Number and Name. **On the Protocol Deviation Details sheet:** • Added a Protocol Deviation Type filter. • Updated the Site of Deviation filter to display both the Site Number and Site Name. • On the Subjects With PDs bar chart (formerly 'PD Subjects'), added Study and Country as new y-axis dimension options. • Table updates mirror those on the Overview sheet for a consistent user experience.

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Internal Issue #	Summary	Release Notes Description
ECCA-543	CTOA - Protocol Deviations Overview sheet: Redesigned, enhanced, and optimized layout	Several enhancements have been made to the Protocol Deviations Overview sheet to improve usability and data analysis: • To maximize chart visibility, the toggle and KPIs were removed and replaced with a # of PDs/Subject reference line in the Protocol Deviations by Site combo chart. This reference line dynamically responds to the Level filter (previously called Severity) and conveys the same information as the prior KPIs without occupying additional space, allowing all charts to be displayed at a larger size. – As part of this change, the secondary measure was removed on the Home Page, # of PDs/Subject KPI. • Additionally, Subject and Class have been added as alternative dimensions to the x-axis drop-down in the Protocol Deviations by Site combo chart, enabling users to analyze deviations by Subject or Class. For better alignment with the rest of the sheets and easier interpretation, the visual representation has been updated—# of PDs is now shown as blue bars, and # of PDs/Subject as red diamonds (the colors and shapes have been swapped from the previous version). • To further streamline analysis, the placement of the line chart and the Class, Form, Field, and Protocol Deviations by Site bar chart have been swapped to improve visual flow. The sorting on this bar chart has also been updated to consistently display values from largest to smallest. • Finally, key columns in the Protocol Deviations table have been repositioned for consistency, readability, and presentation. The Severity column has been renamed to Level to match the filter and align with standard Protocol Deviation terminology.
ECCA-518	CTOA - Query Metrics sheet: Added # of Screened Subjects and # of Queries Per Subject columns to table	On the Query Metrics sheet, the '# of Screened Subjects' and '# of Queries Per Subject' columns have been added to the table to provide a more complete tabular view that aligns with the graphical data, enabling easier comparison and analysis.
ECCA-207	CTOA - Several Sheets: Updated Field dimension to display both its Name and Label	On the Query Details, Timeliness, Post SDV and Post Query Changes, Data Changes, and Audit Summary sheets, instead of displaying just the Field Name (acronym), both the Field Name and Label now display. This provides greater clarity, context, and usability when reviewing field-level data.

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Operational Oversight (OO)

New Features/Improvements:

Internal Issue #	Summary	Release Notes Description
ECCA-52	OO - Study Overview sheet: Redesigned for improved visibility	Redesigned the Study Overview sheet to improve usability by eliminating the need for scrolling and ensuring all visuals are visible and accessible with ease. • The sheet is now divided into two horizontal sections: – The top half has two container objects side-by-side. The left container displays the Site Status pie chart and the Site Enrollment bar chart (formerly Patient Enrollment Data). The right container displays the Site Subject Status bar chart and the Site and Subject Metrics pivot table. – The bottom half contains a single sheet-wide container with the Major Milestones pivot table, the Site Milestones pivot table (formerly Site Milestones Progress), and the Site Milestone Progress bar chart. • In the Site Enrollment chart, measures on the x-axis were renamed to # of Screened and # of Enrolled and a 'from Study Sites' footnote was added. • In the Site Subject Status chart, the measure on the x-axis was renamed to # of Subjects.

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Sample Management Analytics (SMA)

New Features/Improvements:

Internal Issue #	Summary	Release Notes Description
ECCA-171	SMA - New Sheet: Missing or Delayed Samples	Added a new 'Missing or Delayed Samples' sheet (positioned between Unreconciled Samples and Data Anomalies) that helps users track collected samples and quickly identify those that have remained in a location or in transit for an extended period, potentially indicating they are misplaced. Using red/green color-coding, the sheet highlights samples that have remained at a location or in transit beyond user-defined thresholds. Users can configure limits for Days At Site, Days In Transit, and Days At Lab via three input boxes. The report calculates the days since collection, shipment, or receipt and applies the thresholds—samples exceeding the limit appear in red; those within the limit appear in green. Users can filter the sheet by Study, Site, Cohort, Subject, Visit, Time Point, Sample Type, and Aliquot. They can also choose to display either all samples or only delayed samples for a more focused review. The samples are displayed in both tabular and graphical form, broken out by location: At Site, In Transit, and At Lab. The standard Derived Sample Histories table is included at the bottom of the sheet for additional context.
ECCA-669	SMA - Several Sheets: 'Accession Number' and 'In Transit From' label updates	To ensure accurate and consistent labeling across all sheets and charts, 'Accession Number' has been updated to 'Accession ID,' and 'In Transit From' has been changed to 'Transit Source.'

Data Central

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-29170	Added warning message for Blinded Data View users during Issue creation	In Data Central, users with the Blinded Data View privilege will now see a warning message when creating Record, Field, or Domain-level Issues. This message specifies the blinded fields and reminds users to avoid including blinded data in the Issue to avoid accidental unblinding.
EL-28322	Added warning message for Blinded Data View users when Commenting	In Data Central, users with the Blinded Data View privilege will now see a warning message when leaving a comment. This message specifies the blinded fields and reminds users to avoid including blinded data in the Comment to avoid accidental unblinding.

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EL-27332	Data Central Visualizations - Chart Designer: Added support for custom color selection in Pie and Combo charts	In both existing and newly created Pie and Combo charts, users can now assign custom colors to each segment's value, including values in Dynamic Dimensions. This enhancement allows users to convey values' importance, meaning, and relevance, and / or apply their company's branding by using their corporate color palette. In the Chart Designer, under Advanced Settings, a new Custom Palette option (Paint Palette icon) is available next to the existing palette selector. Clicking the Paint Palette icon opens a list of all unique values within the selected dimension, each with an associated color selector. Users can choose colors using a color picker, or by entering RGB or Hex values. If the chart includes Dynamic Dimensions, a dimension selector appears, allowing users to set colors for each dimension's values. Users can also click directly on the chart to switch to their desired dimension. Users also have a Reset button, allowing them to revert back to the last saved configuration, as well as a Clear button, allowing them to restore the default palette colors. Custom colors are retained when exporting a chart's configuration and importing it into a new chart, study, or URL, ensuring consistency and easy migration.
EL-30776	Data Central Visualizations - Chart Designer: System Tables data store includes Review Objective tables	In the Chart Designer, the 'System Tables' data store, available only to eCS users, has been expanded to include four new Review Objectives tables: 'Review Objectives,' 'Review Objectives Domains And Fields,' 'Review Objectives Review Materials,' and 'Review Objectives Reviewer Roles.' eCS users will be able to build charts based on these tables, enabling additional views and summarizations using any chart type. While only eCS users can create and edit these charts, all users can view and utilize them.
EL-23770	Data Central Visualizations - Custom Listings: Added support for resizing columns	Custom Listings now support column resizing, providing users with greater flexibility to adjust column widths for improved data visibility and readability.
EL-30114	elluminate Assist: Expanded capabilities	The elluminate Assist toolbar now features updated icons for an improved user experience. These include a More icon with options to add a new chat or view chat histories, a Pin icon to keep the chatbot window open, and a Maximize icon to view the chat window full screen, all designed to improve the overall user experience. The underlying model was also enhanced to support better and more accurate performance.
EL-29560	Enhanced Domain Settings with Issue Related Fields	A new tab, Issue Related Fields, has been added to the Domain Settings configuration within Data Central to address the need for associating a configurable list of fields with each Issue. This feature allows users to select specific fields from the current domain, which will automatically be associated with any Issues created within that domain. Consequently, users will be able to view these related fields when creating or reviewing Issue records in elluminate.

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Internal Issue #	Summary	Release Note Description
EL-23473	Integrated Data Review Plan (IDRP): Create, view, and review against Review Objectives	By bringing review plan creation, execution, and tracking into a single platform, IDRP eliminates the need for external tools, streamlines workflows, and improves cross-functional collaboration. Users can now define and manage Review Objectives directly in Data Central Configuration, linking review materials such as listings, visualizations, workspaces, and Analytics apps for a guided, efficient review experience within Data Central. **Configure the Review Plan with Ease** Accessible to users with the Study Configure privilege or those assigned a Reviewer Role in Data Central Configuration, the new Review Plan tab within Data Central Configuration enables complete setup and management of Review Objectives. This tab features a full-table view with all available columns. Single-clicking on a Review Objective pulls up the details view (a transposed view of the configured fields), whereas double-clicking opens the edit window. • **Table toolbar icons and buttons:** Search, Create, Copy, Edit, Delete, Activate, Deactivate, Export, Import Review Objectives, and Get Template. – Quickly find what is needed with cross-column search, as well as filtering and sorting across all columns in the table. – Define objectives with key attributes like Primary and Secondary Domains (getting down to individual Fields, which display whether they've been marked as Critical in the Metadata module), Reviewer Roles (defaulted to the logged-in user's role), Priority (containing default values of high, medium, and low; however, users can create their own list of values in the Configuration module in the Review Objective Priority tab), and Review Frequencies (defaulted to Weekly, today's date at midnight). Additionally, link the associated Review Materials, Data Central Listings, eIQ Review Models, Orchestrator Rules, Data Central Visualizations, Data Central Workspaces, Analytics Apps and Sheets, and/or RBQM Dashboards to each Review Objective. – Easily import and/or export objectives via Excel. ▪ Use the Get Template button to download an empty Excel file containing all the column headers in the Review Plan table. ▪ Required indicators are marked with an asterisk (*) in the column header, and any format requirements (comma-delimited or date formats) are also specified in the column header. ▪ Upon import, all necessary validations, such as appropriate file type, all headers present, required fields populated, and length limits respected, will be run. A summary of Total Review Objectives In File, New Review Objectives, Updated Review Objectives, Existing & Unchanged Review Objectives, Skipped Review Objectives, and all Warnings is provided to the user before data is imported.

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Internal Issue #	Summary	Release Note Description
		– Bulk Activate, Deactivate, or Delete Review Objectives. ▪ Whether an Objective is Active or not is determined by the State column. There are three possibilities: ▪ Draft: Incomplete setup, no Review Materials linked. ▪ Active: Linked to at least one Programmatic or Manual Review Material; therefore, the objective is reviewable, displayed in Data Central, and its status is being calculated. ▪ Inactive: Objective Status is no longer recalculated, effectively 'frozen/paused' in its last state; however, the Review Objective is still displayed in Data Central. • **Audit Logs:** All configuration changes are logged for full traceability. **Track and Execute Reviews within Data Central** A new Review Plan section, located under the Study Status subsection in Data Central's left navigation, allows users to track and complete review objectives. • **Green badge:** Displays the number of objectives completed by the logged-in user's role. • **Red badge:** Displays the number of objectives not reviewed (Not Started or In Progress) by the logged-in user's role. Clicking Review Plan opens the list of Review Objectives assigned to the logged-in user's role, grouped by Primary Domain; by default, the first Primary Domain is expanded. In the expanded view, users can see all the Review Objectives (their Identifiers, Description, and Status) within that domain. • **Header:** – Clipboard icon: Returns the user to the 'regular/standard' left navigation. – Badge: Displays the number of review objectives assigned to the role with which they are logged in. – The vertical three-dot/ellipses icon: Triggers a menu with four options: Search (for Review Objective Identifier, Description, or Primary Domain), Review Plan Dashboard, Review Plan Panel, and Review Plan Details. – Filter icon: Allows users to filter the list of objectives by Critical Fields (Yes/No), Priority, and Status to focus on what matters most. – X icon: Returns the user back one level. • The Role Selector defaults to the reviewer role assigned to the user (for read only users, it defaults to Data Manager). Any user can switch to any of the roles displayed in the selector to see their status/progress or to see an overall summary of all roles, but they can only review against their assigned role.

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Internal Issue #	Summary	Release Note Description
		• Objectives display as Not Started, In Progress, or Complete based on the review frequency and the real-time status of the linked review materials. Clicking on a single review objective pulls up its configured details. All review materials can be triggered/opened from the details view. • **Programmatic Review Materials:** Display a status icon to their left, indicating whether records are left to review for the logged-in user's role or not. • **Manual Review Materials:** Display an action icon to their right, allowing users to click to mark them as reviewed or unreviewed. – These actions are logged in the Audit Logs. **Visualize Review Progress** • **Review Plan Dashboard:** Provides a graphical overview and summary of the Review Plan based on domain, priority, and reviewer role. – If a user has a Reviewer role, a switch allows toggling between Your Role and All Roles views. – If a user has a Read Only role, only the All Roles view is displayed. • **Review Plan Panel**: Opens a floating panel containing all Review Objectives. • **Review Plan Details:** Opens a new sheet with the Review Plan Panel docked on the left (containing all the objectives) and the first objective's details open on the right. **Review Objective Metrics Now in Data Central Studies** New objective-based tiles and columns available in Study Cards and Grid View. • **Renamed:** – Total (All Roles) Reviewed → Total (All Roles) Records Reviewed – Total (All Roles) To Review → Total (All Roles) Records To Review • **Added:** – Objectives To Review – Objectives Reviewed – Total (All Roles) Objectives To Review – Total (All Roles) Objectives Reviewed

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Internal Issue #	Summary	Release Note Description
EL-29496	Protocol Deviations: Added storage of imported Protocol Deviation Assessment Plans (PDAPs) within eDrive for historical reference	Users reported difficulty verifying the latest imported PDAP source files in Global and Study PDAP configurations. To address this, an enhancement has been added to the PDAP import process and eDrive storage. Now, all imported PDAP files are stored in dedicated PDAP folders within the Global eDrive directory and within each study's eDrive folder. Users can now easily access and view all previously imported files for any PDAP on this URL.
EL-26323	Protocol Deviations: Columns reordered and renamed on the PD Dashboard	User feedback indicated difficulty with the default column order on the Protocol Deviations Dashboard in Data Central. Specifically, the most valuable columns for reviewing PDs, such as site, subject, and date information, were positioned too far to the right, requiring frequent scrolling to access key data. To address this, the column order on the PD Dashboard has been adjusted. High-priority columns have been moved closer to the left to improve visibility and reduce navigation effort. In addition, several column headers have been updated to better reflect their purpose in the UI. The 'Importance Classification' column has been renamed to 'PDAP Importance,' and the 'Importance' column to 'Source Importance.' These changes help clarify the distinction between the two: 'PDAP Importance' refers to the classification assigned through the PDAP, while 'Source Importance' reflects the original value mapped from the PD's source system.
EL-28991	Protocol Deviations: Configurable special character restrictions and case insensitivity for PDAP imports	User feedback indicated a need to handle special characters in imported PDAP files and to relax restrictions related to case-sensitive fields. In response, a new system setting has been added that allows users to provide eClinical Solutions (eCS) with a predefined list of restricted special characters. Once provided, an eCS representative will configure the backend setting for the URL, enabling validation that rejects any imported, added, or edited PDAP entries containing any of the specified special characters. Additionally, the import process has been updated to relax the case-sensitivity requirements for picklist-driven fields. Fields such as Level, Identification Method, and columns related to the importance of the PD will now accept case-insensitive values without issue. Users should no longer encounter validation failures due to minor casing differences.

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Internal Issue #	Summary	Release Note Description
EL-29003	Protocol Deviations: Dashboard can be refreshed from an import to a Global Data Store	Users were experiencing difficulty with the required import configuration needed to regularly update the Protocol Deviations Dashboard in Data Central for any imported protocol deviations. This difficulty was caused by the requirement that any imports refreshing the PD Dashboard needed to be initiated within that study. This forced sponsors who import their PD source data from a consolidated, cross-study source to configure extra imports and mappings to keep the PD Dashboard up to date. To resolve this, the backend processing that updates the PD Dashboards in Data Central has been enhanced. It now allows imports into a Global Data Store to find all required 'SourcePDs' mappings dependent on the imported domain. For all studies where that mapping runs successfully, the PD Dashboard will be refreshed from the single global import.
EL-29227	Protocol Deviations: Enhanced backend configuration for controlling data change tracking on the Protocol Deviations Dashboard	Users were reporting difficulty with the Protocol Deviation (PD) Review workflow due to unexpected re-reviews. These re-reviews were caused by the system's data change tracking being broader than sponsors intended. Specifically, the system tracked changes in a wider range of fields within imported PDs than sponsors deemed necessary for triggering a re-review. To address this misalignment and eliminate unnecessary re-reviews, a new URL backend configuration option was implemented. This option allows sponsors to specify the fields within the imported PD columns that should be tracked for changes, thereby aligning the system with their specific processes. Sponsors can now select one or more of the imported PD's Category, Description, Importance, Identified Date, Start Date, or End Date to be tracked. When changes are detected in these specific fields during import, the review status is updated.
EL-30841	Protocol Deviations: Enhanced backend views for downstream Protocol Deviations programming	User feedback indicated a need to enhance the existing *ProtocolDeviations* view and create a new *PDComments* view to address limitations in the current tables and provide access to comments on protocol deviation records. To meet these needs, the *ProtocolDeviations* table has been updated with new columns, including a user-friendly Study Name and the PD Code from the assigned PDAP. Additionally, a new *PDComments* view has been created. This view displays all comments made on PD records, including key fields such as the PD Identifier, Comment Type, Comment Text, and relevant details like the comment creator and the creation time.

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Internal Issue #	Summary	Release Note Description
EL-28958	Protocol Deviations: Enhanced columns on the PD Dashboard for better source data context on imported PD records	After user feedback reported unnecessary duplicate columns, limited field display length for some columns, and missing options to display necessary Protocol Deviation source system information, changes to the PD Dashboard and mapping process were deemed necessary. To better support client use of the dashboard, the following changes have been made: • Removed the 'Classification' column, which was redundant with the 'Importance' column. • Extended the 'Reported Description' and 'External Comments' fields to a new length of 2000 characters. • Created a new 'Deviation Source' column, which displays whether the PD is imported or manually created. • Repurposed the previous 'External Source' column, which now allows users to map the name of an external source system, process, or personnel that generated the imported PD record.
EL-28956	Protocol Deviations: Enhanced editing of PDs via new bulk editing feature	User feedback indicated a need to edit and take action on multiple protocol deviation (PD) records at the same time. This led to the addition of a new bulk editing window to the Protocol Deviations dashboard in Data Central. With this new window and new checkbox column, users can now select one or more PD records for editing. This allows users to apply a selected review status or PDAP entry to all selected records.
EL-30801	Protocol Deviations: Enhanced handling for Protocol Deviation Assessment Plan (PDAP) standard overrides on auto-coded Protocol Deviations	User feedback indicated that applied Importance Classification Overrides were being overwritten during PD refreshes. Specifically, the default Importance Classification from the PDAP entry, mapped to the deviation, was replacing the overridden value. This issue has been resolved. Applied Importance Overrides will now be preserved during refreshes, unless a new PDAP is applied via a mapping or a manual change.

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Internal Issue #	Summary	Release Note Description
EL-29000	Protocol Deviations: Enhanced handling of Protocol Deviation Assessment Plan (PDAP) imports to allow matching entries	Users were experiencing difficulty leveraging the full value of Global and Study PDAPs within elluminate's Protocol Deviation functions because imported file validations would reject an incoming file if any of the PDAP records in the imported file matched those already configured in the PDAP. To address this difficulty and limitation, import file validation has been updated for both Global and Study PDAPs in the elluminate platform. Specifics for each are below: Global PDAP Imports: • Imports of PDAP files with matching PDAP entries (both in the ingested file and the configured Global PDAP) are now allowed. – Existing global PDAP entries cannot be edited via import and will be skipped. – New global PDAP entries will be created as new records from the input file. Study PDAP Imports: • Imports of PDAP files with matching PDAP entries (both in the ingested file and the configured Study PDAP) are now allowed. – Global PDAP entries imported into the study PDAP cannot be edited at the study level and will be skipped. – Existing Study PDAP entries that are not actively applied to a PD within the study can be imported with changes. – Existing Study PDAP entries that are actively applied to a PD cannot be edited via import and will be skipped. – New Study PDAP entries will be created as new records from the input file.
EL-31034	Protocol Deviations: Enhanced ID column population and presentation on the Protocol Deviations Dashboard	User feedback indicated a need for consistent ID columns in manually generated Protocol Deviations on the PD Dashboard within Data Central. To address this, the dashboard and backend processing were updated to assign an ID value for each manually created PD. Now, when a manual PD is created for a study in Data Central, the ID column will display the format “MAN-PD-####,” facilitating easier referencing and collaboration during PD review.
EL-29499	Protocol Deviations: Enhanced PD Edit window to include comments	User feedback indicated a need for comments added to a Protocol Deviation to be visible during editing, so that any requested follow-up actions are easily accessible while reviewing the PD. To address this, the PD edit window has been updated to include a third section on the right side of the panel. This new section displays all comments associated with the deviation, allowing users to view and reference them while editing. This enhancement supports clearer collaboration and more efficient follow-up through visible, in-context commentary.

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Internal Issue #	Summary	Release Note Description
EL-31169	Protocol Deviations: Enhanced PDAP import process adds validation for duplicate PD Codes	User feedback provided additional insight that some sponsor organizations, due to their internal processes, require unique PD Codes for each entry in the Global and Study PDAPs. This requirement conflicts with the current PDAP structure, where the PD Code field is optional. To better support both the existing structure and this additional business need, the import process for the Global and Study PDAPs has been enhanced. Users will now see a validation message when importing a PDAP file that contains duplicate PD Codes. Note: This validation does not prevent the import of duplicate codes. Instead, it provides an early warning, allowing users to review and correct the file before ingesting its contents into a configured PDAP within elluminate.
EL-29039	Protocol Deviations: Enhanced Protocol Deviation (PD) Review workflow requires PDAP application for 'Reviewed' status	User feedback regarding the Protocol Deviations Dashboard and workflow in Data Central indicated that the currently unrestricted workflow, allowing users to save PDs in a 'Reviewed' status without applying a selected PDAP entry, was resulting in 'unclean' or improperly organized PD Data at the end of the PD management process. To ensure better organization of the finalized PD dataset, the UI and workflow have been enhanced requiring users to apply a selected PDAP entry whenever a PD is saved in a 'Reviewed' status.
EL-28957	Protocol Deviations: Enhanced restrictions on saving Protocol Deviations in the 'Requires Follow-Up' status without an applied comment	Users reported that Protocol Deviations were being saved in the 'Requires Follow-Up' status without accompanying comments explaining the required follow-up action. To address this, the edit PD workflow window now requires a comment when a user saves a PD record. This will prevent PD records from requiring additional user action without clear instructions.
EL-29038	Protocol Deviations: Enhanced terminology and status display in the PD Edit window	User feedback indicated that some of the titles and displayed statuses in the Protocol Deviation edit window were unclear, negatively impacting the overall user experience. Specifically, the title and label for the button used to select an applied PDAP entry have been updated from 'Select PDAP Standard' to 'Select Applied PDAP Entry.' This change clarifies that users are selecting individual entries from the study's PDAP, rather than choosing from overarching standards. To further improve clarity, the edit window now displays 'Re-Review' as the pre-selected value in the status drop-down for PDs in that status. Previously, the drop-down displayed 'Select…,' which caused confusion since it was neither the current status of the PD record nor a selectable option. To address this, 'Re-Review' now appears as the default when editing PDs in that status, but it cannot be saved or assigned manually. Since 'Re-Review' is a system-assigned status, a different valid status must be selected to save any changes to the Protocol Deviation.

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Internal Issue #	Summary	Release Note Description
EL-28993	Protocol Deviations: Enhanced the Global and Study Protocol Deviation Assessment Plans (PDAPs) by incorporating PD Code into the unique record identification structure	Due to user difficulty in utilizing the Global and Study Protocol Deviation Assessment Plans (PDAPs), stemming from the need for repeating combinations of Standard Categories and Standard Descriptions, both PDAPs have been enhanced. Users can now uniquely define PDAP entries by combining the Standard Category, Standard Description, and PD Code columns within either the Global or Study PDAP. This enables the repetition of Categories and Descriptions with a unique PD Code, thereby creating multiple versions of specific PDAP entries with varying content in other applicable fields.
EL-28959	Protocol Deviations: Enhanced the PD Dashboard refresh process to automatically apply Protocol Deviation Assessment Plan (PDAP) standards to mapped PDs	Due to user concern regarding the amount of manual effort required to apply Protocol Deviation Assessment Plan (PDAP) entries to all programmatically generated PD records, the Protocol Deviations Dashboard refresh process has been enhanced. Specifically, four new columns were added to the SourcePDs mapping, which populates the Protocol Deviations Dashboard. These fields and their intended uses are: • PDAPEditLock: A True / False flag field to control whether users can manually apply a PDAP entry to the PD record. • PDAPCategory: An identifier for the Standard Category PDAP value to be matched and assigned to the PD record. • PDAPDescription: An identifier for the Standard Description PDAP value to be matched and assigned to the PD record. • PDAPCode: An identifier for the PD Code PDAP value to be matched and assigned to the PD record. Through the SourcePDs mapping, users can now populate each PDAP identifier field. If a corresponding entry exists in the Study PDAP, the contents of that PDAP entry will be automatically applied to the imported PD record. Furthermore, users can be restricted from selecting new or different PDAPs than those automatically assigned.
EL-29002	Protocol Deviations: Enhanced UI and workflow for overriding the Importance Classification assigned to a Protocol Deviation	Users were experiencing difficulty with the traceability and clear identification of Protocol Deviations with applied PDAPs when their Importance Classification values were overridden. Some sponsors consider this a quality event, given the situational need to override the existing PDAP standard. Therefore, improved accessibility for sponsors was required. To address the concern, the Importance Override field has now been moved to a separate option on the Edit PD window. This allows users to view the original Importance Classification while applying an override. Furthermore, the required comment field for saving a Protocol Deviation (PD) with an Importance Override has been renamed 'Reason for Importance Override,' and its corresponding comment type is now 'Importance Override.' These changes provide sponsors with immediate access to the context explaining why the PD's applied standard was overridden.

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Internal Issue #	Summary	Release Note Description
EL-28992	Protocol Deviations: Enhanced user activity on PD Dashboard: Added Last Updated Date and By columns / fields	User feedback indicated difficulty in identifying the last user to edit or modify a PD record. Therefore, adjustments were made to the PD Dashboard. To address this information gap, two new columns have been added: 'Last Updated Date,' which displays the last date the PD was edited and saved, and 'Last Updated By,' which shows the user who completed that last update and save. These fields are also available in the PD Details view.
EL-29036	Protocol Deviations: Enhanced validation for imported Study Protocol Deviation Assessment Plan (PDAP) files to include study name	User feedback highlighted the risk of importing study PDAP documents into incorrect studies, potentially leading to data inconsistencies. This issue was particularly relevant when users inadvertently used study-specific PDAPs instead of the global PDAP. To prevent this, the following changes have been implemented: • The exported Study PDAP and Study PDAP templates now include the study title in the tab of the exported file. • All imported study PDAPs will be validated to ensure the tab name of the sheet containing the PDAP columns matches the study title configured in elluminate. This validation will prevent incorrect or accidental uploads.
EL-30845	Protocol Deviations: Enhanced view of Importance on the PD Dashboard: Added Importance Override column / field	Users found it difficult to understand the Importance Classification and any applied Importance Overrides from the Protocol Deviation Assessment Plan as displayed on the Protocol Deviations Dashboard. To address this, an 'Importance Override' column has been added to the PD Dashboard for side-by-side comparison, and an 'Importance Override' field has been added to the PD Details view for sequential display.
EL-29498	Protocol Deviations: Improved PDAP handling for cancelled records	Users reported concerns about cancelled Protocol Deviation (PD) records retaining applied PDAP values. To improve the clarity and cleanliness of reviewed PD data, the editing functionality has been enhanced. This update allows users to remove any applied PDAP content from one or multiple PD records during the editing process. As a result, a clear visual distinction is maintained between cancelled PDs and other reviewed deviations.
EL-33332	Protocol Deviations: PDAP Re-application prevented for canceled records	Canceled protocol deviations no longer have their Protocol Deviation Assessment Plan (PDAP) contents re-applied during SourcePDs mapping refreshes. This enhancement ensures that only active deviations (e.g., Unreviewed, Requires Follow-up, Reviewed, Re-Review) are updated based on the study's PDAP configuration. Canceled records are now fully excluded from PDAP content re-application, preserving data integrity and preventing unintentional overrides during data imports or dashboard refreshes.
EL-27756	Subjects, Issues, and Queries Panels: Added ability to search for columns by their Name and Label	Within the Subjects, Issues, and Queries panels, users can now quickly and seamlessly find desired columns by using the new Search icon in the toolbar, typing 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.

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Issues

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-20646	Added options to Send Immediately, In Batch, or Defer Notification when reopening issues	When reopening issues, users now have the option to choose from three email notification options: • Send immediately - Sends the notification as soon as the Issue is reopened. • Send in Batch - Sends the notification as part of a scheduled task. • Defer Notification - Allows the user to delay sending and later trigger the notification from the Issues module. This enhancement supports more efficient communication by allowing users to group notifications for multiple reopened issues.
EL-31194	All-field search added to the Related Details column of the Issues module	Enhanced filtering has been implemented within the Related Details column of the Issues module. Users are now able to perform searches across all fields within the column by utilizing the 'Any' selector (the new default value) within the Field drop-down, based on the entered search criteria.
EL-28965	Enabled Multi-select for Unlicensed Users	Unlicensed users can now perform bulk actions in the Global Issues grid by selecting multiple issues using newly added checkboxes. A 'Select All' option is available, and users can perform bulk actions, such as answering issues, when the issues are in Open status.
EL-31141	Enhanced columns in the Issues grid to better display Domain info and configured Related Fields	Following the enhancement to allow users to configure Issue Related Fields for each domain in Data Central, the Issues module grid has been updated with a new 'Domain' column which displays the Data Store and Domain name the Issue was created on. The 'Related Details' column has also been enhanced to display both the Issue-configured and Orchestrator-configured related fields as a comma-separated list, with each field bolded for improved readability. Users can now view these configured related fields directly in the Issues grid as well as in any exported files from that view.
EL-29004	Enhanced the global Issues module to allow unlicensed users to import bulk responses	Currently, in elluminate, unlicensed users cannot import issues from a controlled file to apply bulk updates. This has been enhanced to allow unlicensed users to import an Excel file with populated 'Answered By' and 'Issue Response' columns to answer multiple issues simultaneously.
EL-29369	New option to Defer Notifications when creating or reopening Issues	When creating or reopening an issue and selecting 'Send Notification to the User,' users now have an additional option to Defer Notification. This allows users to delay notifications and send them at a more convenient time, instead of relying on the standard task schedule. Deferred Issue Notifications can be easily managed in the Issues module using the Filter icon to apply a Quick Filter for either 'All Deferred Issues' or 'My Deferred Issues.' Individual issues (or all issues) can then be selected, and notifications can be sent immediately using the 'Send Deferred Notifications' (paper plane) icon.

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Operational Data Repository

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-30203	Added support for Exporting filtered records from top-level grid data to Excel	The Export to Excel feature is now available for top-level grid data. Users can access this via the Export icon in the master header, which now includes two options: • Export this data: Exports the currently visible and filtered data from the grid to an Excel file. • Open in Exporter: Redirects users to the Exporter module, providing access to all existing export functionalities.
EL-30472	Fields Config: Added support for Grid Visibility control for OOTB fields	ODR Configure users can now customize the ODR grid by enabling or disabling the visibility of up to 25 top-level, out-of-the-box fields from the Basic Details section. Visible fields will display data in the grid and support standard sorting and filtering (excluding multi-select fields).
EL-30491	Fields Config: Added support to assign elluminate Configuration Picklist items to Custom Fields	Within Fields Config, elluminate Configuration items (Therapeutic Areas, Compounds (will display as Investigational Products in the drop-down list), Programs, Phases, Study Types (will display as Study Type in the drop-down list), Endpoints, Controls, and Blindings) can be assigned to custom fields with the Field Type of Picklist. This allows users to seamlessly incorporate and work with these items within any ODR form.
EL-31333	Improved ODR data Export with user-readable values	Exported ODR data now displays user-readable values instead of IDs, significantly improving readability and interpretation. In the exported file, custom fields with picklist-type values now display the actual selected entries instead of the IDs, making data analysis more intuitive. It's important to note that while this enhancement works for both export options, custom fields are not yet included in the 'Export to Excel' feature. Therefore, users will currently only see the actual picklist values when using the 'Open in Exporter' option. This enhancement streamlines the export process, ensuring that users can easily understand and work with the data, particularly when using the 'Open in Exporter' option.
EL-27993	New Standard model: DMOD (Data Model for Operational Data)	DMOD (Data Model for Operational Data) is an eCS-built standard data model designed for Operational Data. DMOD is built upon the original ODR (Operational Data Repository) structure, with significant expansions to maximize coverage of Operational Data elements, addressing the needs of Clinical Trial Operations. DMOD is available within the Standards module to enable efficient versioning management and allow users to create and customize their own data models, ensuring flexibility and scalability for handling clinical trial data in a structured and adaptable manner. DMOD can be used similar to other Standards models for use with any data store, and can be selected in a Mapping, and used within Validator.

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Orchestrator

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-27017	'Opened By' column shows Orchestrator rule names in Issues and Queries listings	For Issues and Queries generated by Orchestrator rules, the 'Opened By' column now displays the full rule names in the Issues and Queries listings. Additionally, the column filter has been enhanced to filter for Orchestrator rules, allowing for rule-based reviews.

Platform

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-26327	Added new data source: Clario eCOA API	A new data source, Clario eCOA, has been added to elluminate. This addition allows users who actively leverage Clario's eCOA Clinical Trials to establish a connection to elluminate, utilizing their system's APIs. The Clario eCOA data source enables elluminate users to import a variety of data from Clario's system including Subject data such as Site assignment, continuation and deactivation, as well as all recorded data based on the Clario study configuration. Beyond Subject data, other system-related information like Metadata, Sites, Users, Audit Trail and other Clario system data is imported. This connection will provide sponsors with up-to-date datasets of critical information stored within this external system, as well as better control over the accessibility and review of those datasets using existing elluminate tools like review marking, data variance, and other standard tools for domains imported into elluminate. Please note: This feature is also available in elluminate 24.2 and all subsequent versions.
EL-26862	Added new data source: SAS LSAF API	A new data source, SAS LSAF, has been added to elluminate. This source allows users of the SAS Life Sciences Analytics Framework (LSAF) system to connect their file repositories to elluminate, leveraging the APIs offered by LSAF. The SAS LSAF data source enables elluminate users to import data files from configured repositories within LSAF. This allows for the import of datasets programmed or generated within LSAF's computing environment, provided they are stored in a repository accessible via the credentials used to connect to LSAF. This connection will provide sponsors with improved accessibility to standardized programming and data generated using statistical programming. It now allows those same datasets generated outside the platform to be easily ingested and leveraged with standard tools for domains imported into elluminate.

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RACT

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-30214	Export Risk Management Plans from RACT	Users can export Risk Management Plans for a RACT Assessment version to Excel or PDF by using the Report icon in the toolbar. This feature helps streamline and document the processes of risk assessment and risk mitigation.
EL-31192	New AI-Powered Risk Statement Generation	A new AI-Powered Risk Statement Generation feature has been added to RACT to support users in generating risk statements faster from Risk Descriptions. If Allow Machine Learning is enabled for the URL, users will see a 'Generate Statement' button with a sparkle icon in the Create New Risk window. Clicking it fills in the 'if - due to - then' fields using AI. Users can click the button again to view additional suggestions, and the model will re-run if users make updates to the risk description. All activities are logged for audit purposes.
EL-30153	Redesigned RACT Risk Assessment	The RACT Risk Assessment has been redesigned, now offering greater customizability and flexibility, and closer alignment with ICH E6(R3) guidelines. • The former 'Risk-Statement-Form' layout has been modernized to a 'Risk-Card' view for enhanced visibility and an improved user experience. • Instead of completing Risk Statement Forms, individual risks can now be added as Risk Cards for each 'Consideration' (formerly 'Question'). Considerations are collected under 'CTQs' (formerly 'Categories'). • Adding a risk will open the assessment form based on the Risk Assessment Configuration. • Additional sections and standard fields have been added to the preset Risk Assessment Configuration for closer alignment with ICH E6(R3) guidelines. • The risk evaluation is now fully customizable and transparent, with configurable dimensions, levels, labels, and scoring methods. • Pre-defined risks from the Risk Library can now be selected to auto-populate the assessment form. • It is no longer mandatory to complete all Considerations for a Risk Assessment. An assessment can be finalized as long as all required fields from the added risks are completed. Incomplete risks, if any, will be shown when attempting to finalize an Assessment.

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Internal Issue #	Summary	Release Note Description
EL-29639	Redesigned RACT Workflow	The RACT module has been redesigned, featuring a new and improved workflow. • The former RACT study landing page has been superseded by the Risk Management page. • Similar to RBQM, RACT study-level access has been added to the Platform menu and the study selector. • Quick navigation options to the RBQM and Risk Management page have been added to the master header. • The former ‘Category-Card’ layout for RACT has been modernized into a grid view, allowing easier navigation and a more efficient display of information. • The former ‘Risk Statement' table has been renamed to ‘Risk Summary', and is now one of the three main tabs in RACT, alongside 'Assessments’ and 'Archived.’ • All study-level configurations are now handled from the global Risk Management Configuration space. • The concept of ‘Configuration Version' has been discontinued. Users no longer need to add ‘CTQs’ (formerly ‘Categories’) or ‘Considerations’ (formerly ‘Questions’) to an assessment. All ‘CTQs’ and 'Considerations’ will be made available, allowing users to choose relevant ones to assess risks. • Participants are now entered and captured when finalizing the assessments. Participants will be carried over from version to version. • Additional documentation information can also be added when finalizing the assessment. This information will be exported with the Risk Management Plans.
EL-30846	Setting Reassessment Intervals when Finalizing Risk Assessments	An optional reassessment interval can now be set up when finalizing a Risk Assessment. The 'Days Until Reassessment' field on the Risk Management page will be automatically populated with the exact number of days remaining until the next scheduled assessment. Additionally, automated reminder emails can be configured in the Task module to notify designated recipients as due dates approach.

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RBQM

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-31003	New RBQM tabs: Study Report, Issues, and Additional Review	Three new tabs – Study Report, Issues, and Additional Review – have been integrated into the redesigned RBQM layout. These tabs provide users with more direct access to key tools and study data essential for risk-based review. • The Study Report tab offers users quick access to a printable version of the study's Risk Summary Report. This tab consolidates key information from the previous Overview and Countries dashboards, with QTL Cards, the KRIs table, the Sites table, and the Countries table. All existing features and filters function as before. Additionally, a Report icon in the toolbar enables users to easily open and download the printable report as documented evidence of centralized monitoring review. • The Issues tab opens the Issues panel as a floating panel, automatically applying RBQM filters. This functionality mirrors accessing the Issues panel from the Data Central left navigation. • The Additional Review tab opens the Data Central left navigation, allowing users to explore additional study data or visualizations for a more comprehensive review.
EL-30996	Redesigned RBQM Dashboard for enhanced risk-based review	The Risk-Based Quality Management (RBQM) dashboard has been completely redesigned to enhance usability and better support risk-based review activities. Users can now also access the RBQM module through the 'Risk-Based Quality Management' card on the Risk Management page. The updated RBQM interface introduces a new layout with streamlined navigation and dedicated tabs below the master header. These tabs include: • Overview (with Sites and Countries subtabs) • Trial Level Risks • KRIs • Study Report • Issues • Additional Review The toolbar also features two links: RACT and Risk Management. The RACT link navigates users directly to the study's RACT page, and the Risk Management link navigates users to the Risk Management page. This improved dashboard simplifies access to key RBQM components and enables more efficient risk management and review.

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Internal Issue #	Summary	Release Note Description
EL-30593	Redesigned RBQM Overview: New Site and Country summary views	With the RBQM UI redesign, the RBQM Overview tab now includes both Sites and Countries summary views, making it easier for users to track and manage risk trends with the newly updated UI. In the Sites tab, users can view site-level details such as Site ID, Country, Number of Subjects, and Site Score, with visual indicators for score trends within the updated interface. Each KRI configured for the study appears in its own column, displaying its CTQ (Critical to Quality factor), score trend icons, status indicators (green check, yellow warning, red stop), and flags for missing scores or open issues. Critical KRIs are marked with an exclamation icon and include a tooltip. Users can right-click on cells to quickly create site-level issues with pre-filled site and KRI details. The Countries tab offers similar insights at the country level within the redesigned UI, including Country names, Scores, Number of Sites and Number of Subjects, along with KRI trends and status icons. Users can also right-click on cells to create country-level issues. A world map panel is displayed at the bottom of the window, allowing users to click on country or site markers to view summary cards with key information.

Risk Management

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-30443	New Risk Management Page	A new Risk Management page is introduced to elluminate to provide centralized access to all RBQM and RACT-related studies, featuring study overviews, and quick actions, such as running the RBQM Engine and starting a new assessment directly from the page.
EL-30430	Risk Management - Configuration: Critical to Quality Factors (CTQs)	The Critical to Quality Factors (CTQs) tab, accessible within the Risk Management Configuration page, streamlines configuration activities by consolidating CTQ Configuration from RBQM, Categories from RACT, and the Questions Library from RACT into a single, unified interface. In this update, ‘Questions' have been renamed to 'CTQ Considerations’ and are now organized under their respective CTQs for improved clarity and usability. Users can now create, view, edit, and activate / inactivate CTQs, as well as create, view, edit, activate / inactivate, delete, and reorder CTQ Considerations, allowing for more efficient and centralized management of CTQ-related configurations.

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Internal Issue #	Summary	Release Note Description
EL-23502	Risk Management - Configuration: Risk Libraries	The Risk Libraries tab, accessible within the Risk Management Configuration page, provides a central location for managing risk-related information. Within Risk Libraries, users can create, view, edit, and activate / inactivate risk libraries, as well as create, view, edit, and activate / inactivate individual risks within a selected library. Each risk includes key attributes such as Level, Level Specify, Associated CTQ Factor, Category, Subcategory, Description, Functional Plan, Pre-Study Mitigations, During Study Mitigations, Trial Level Metrics (QTL), Metrics (KRI), and Process Metrics. An out-of-the-box elluminate default risk library is provided, featuring a curated list of pre-defined risks to support standardization. Furthermore, users can export risks from existing libraries, download a risk template, and import updated or new risks using the template, streamlining bulk updates and configuration.
EL-30428	Risk Management: Configuration	As part of the new Risk Management page, there is a new Risk Management Configuration page. This configuration page supports configuration activities for RACT and global-level RBQM. It allows users to manage various risk-related components, including Critical to Quality Factors (CTQs), URL-level Key Risk Indicators (KRIs), URL-level Quality Tolerance Limits (QTLs), Risk Libraries, Risk Assessments, Risk Levels, Functional Plans, Critical Data & Processes, and URL-level Alerts (Actions). These enhancements streamline risk management processes by providing a centralized location within the new Risk Management page for configuring and managing these key elements at both the RACT and global RBQM levels.
EL-31191	Risk-Based Management (RBM) module retirement	The Risk-Based Management (RBM) module is now retired from elluminate to strengthen the integration between RBQM, RACT, and future Risk Management modules.

Statistical Computing Environment

New Features/Improvements:

Internal Issue #	Summary	Release Note Description
EL-23554	Raise and track Domain Issues directly from SCE	SCE users can now create and manage data Issues directly on study datasets within the Statistical Computing Environment. This new capability enables programming teams to document abnormalities and route Issues to relevant users or groups, streamlining collaboration with data management teams. Previously, Domain Issues were managed exclusively in Data Central. Now SCE users can initiate Issue workflows without switching contexts, eliminating the need for external tracking methods and improving cross-team communication. All Issues raised in SCE are logged in the Issues module for full traceability.

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