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elluminate 23.2.0
Release Notes v2
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Document Version History

Version	Date	Section(s) Updated	Description of Modification
1	27Sep2023	• Initial Version Created	• Initial Version Created
2	17Nov2023	• Document Version History • New Features and Functionality > eIQ • elluminate IQ	• Added Document Version History • Updated elluminate IQ section • Added EL-21920 Concomitant Medication (CM) Indication model • Added EL-22936 Shift in Labs and Vitals (SILV) model update • Added EL-22040 Concomitant Medication (CM) Consistency model update • Added EL-22470 Domain Classification (DMCL) model update

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Purpose and Scope

elluminate® 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 the Release Notes for version 23.2.0 of eClinical Solutions' elluminate platform. The Release Notes provide details of the latest enhancements to the elluminate platform. Review of the release notes should provide an understanding of how the updates will benefit users of the platform when upgrading from previous versions.

Supporting Documentation

There are additional resources for information on the elluminate platform.

The elluminate 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=23.2**

Access the elluminate Community from within elluminate 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 Functionality

elluminate Release 23.2.0 includes several new features and enhancements. The major items targeted for the release are as follows:

Analytics

New! CDA supports custom subject statuses. In an effort to make the Clinical Data Analytics application even more configurable and strive to provide consistency across apps, CDA now supports custom subject statuses allowing customers to override the standard definitions with their own.

Updated! Enhanced Home Page experience in CTOA. The Home Page was redesigned and optimized to provide a more concise, logical, and intuitive experience making it easier than ever to navigate your data. The charts are now presented in a logical order that provides a natural progression and establishes clear visual connections. Multiple charts have been improved to boost visibility and allow for better analysis and effortless comparisons.

Data Central

New! Data Cuts feature. Data Cuts can be defined and used to expedite data cleaning objectives. Defining a Data Cut by adding an Advanced Filter allows users to easily apply the Data Cut to specific data and view associated subject metrics and unresolved issues and queries.

New! Cell & Row Highlighting feature in listings - Domain Highlight Conditions. The Highlights tab has been introduced within the Domain Settings window, accessible via the gear icon in a listing. This feature empowers users with the Study Configure privilege to configure cell and row highlighting, and all users to view the configured conditions and to turn the cell and row highlighting off or on. This functionality enhances data review efficiency by visually emphasizing specific values or records.

New! Column Header Highlighting feature in listings - Field Emphasis. Field Emphasis was added under the Highlights tab in the Domain Settings window, accessible by clicking the gear icon in a listing. This feature empowers users with the Study Configure privilege to set the background color of column headers within a listing, and all users to view the configured fields and to turn the column header highlighting off or on. This functionality serves to emphasize or de-emphasize specific columns, making it easy to distinguish important information.

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elluminate IQ

New! Added a new model. The Concomitant Medication (CM) Indication model is available.

New! Ability to provide feedback on model predictions. Users with review privileges now have the option to provide feedback on the accuracy of anomalous detection.

New! eIQ Review privilege. For users to access eIQ Review in Data Central, they must be assigned the eIQ Review privilege in User Management.

New! Auto-populated Issue text. For all the models in eIQ Review, auto-populated issue text is added based on the model and provides a recommendation to correct the issue.

Updated! The Anomalous Subjects listing in the AE Durations, and Shift in Labs and Vitals models is now an Anomalous Records listing. Users now have a record-based view which allows them to easily access and review anomalous records for each subject. The record-based view provides additional information about the anomalous records, and users can easily create an issue directly from the listing.

Updated! The Concomitant Medication (CM) Consistency model. This model now includes the ability to predict Dose Route and Frequency of administration.

Operational Data Repository

Updated! Cumulative rates. The Cumulative Enrollment Rate and the Cumulative Screen Failure Rate fields have been updated to be system calculated and auto populated.

Updated! Export option. The Export option from within the Operational Data Repository has been updated to use the Exporter module, and exports the contents of the associated ODR views. This removes a prior limitation that only exported content of top-level forms displayed in the grid, and now includes the lookup value for ID fields obtained from the associated linked tables, as well as provides additional options available from the Exporter module.

Platform

New! Ability to add in row level conditions for Data Blinding. Within Study Configuration, users can now add in row-level blinding conditions via a SQL expression box with wildcard options for Domain and Field.

Statistical Computing Environment (SCE)

New! Python language support. Users can now author and execute programs in Python within the SCE.

New! MS Office file support. Users can now view Excel and Word files within the SCE Editor.

New! Ability to create an Issue. Users can now create Issues on any SCE file, which can be assigned to any SCE user or role. Issues created in the SCE can be viewed and managed in the Issues module.

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Module Specific Details

For each module of the elluminate platform we provide detailed information regarding the 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 most care about in order to better understand how this release will impact their experience and plan for the upgrade.

Administration

Internal Issue #	Summary	Release Note Description
EL-21526	Unlicensed user has account access prior to assignment of an issue	Unlicensed users will receive an elluminate welcome email at the time of account creation, and they can log into elluminate and confirm account access prior to an issue being assigned. Previously, unlicensed users received a welcome email when an issue was assigned to them.

Analytics

Internal Issue #	Summary	Release Note Description
ECCA-73	CTOA - Timeliness sheet: Converted the three Average Days charts to combo charts	Converted the three Average Days charts to combo charts to more accurately represent the data and allow for a better comparison experience within a site as well as against other sites.
ECCA-72	CTOA - Time To SDV And Details sheet: Converted Initial Entry To Verification chart to a combo chart	Converted the Initial Entry To Verification chart to a combo chart to more accurately represent the data and allow for a better comparison experience within a site as well as against other sites on their number of enrolled subjects and average number of days of initial entry to verification.

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Internal Issue #	Summary	Release Note Description
ECCA-23	CTOA - Enrollment Summary sheet: Improved presentation of sheet	The presentation of the Enrollment Summary sheet was optimized to clearly and compactly display the information. • Updated the Enrollment Details chart to display as a stacked bar chart for a better side by side comparison (study to study, site to site, and country to country) as well as status comparisons (with segment labels on each status). A footer was added to ensure users are aware that subjects may appear in more than one category. • Standardized the look and feel of the KPIs to maintain consistency throughout the sheet. • Resized the columns in the table to display more data. • Added the Group Assignment filter.
ECCA-11	CDA: Updated standard definitions for several subject statuses and added the ability to override the standard definitions with custom definitions	Standard Subject Status updates: • Changed denominator to count of enrolled subjects for: Discontinued Study Rate, Discontinued Study n (%), Completed Study Rate, Completed Study n (%), Deaths Rate, and Death n (%). • Updated Discontinued statuses to exclude screen failures. Custom Subject Statuses: • Clients who need to deviate from the current standard definitions can map to a custom CustomSubjectStatus table to override the standard definitions with their own (this is optional).
ECCA-6	CDA - Exposure Data sheet: Updated Exposure Metrics By Group Assignment chart	Updated the Exposure Metrics by Group Assignment chart to a standard bubble chart for a consistent look and feel, smoother interaction, and increased responsiveness.

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Internal Issue #	Summary	Release Note Description
ECCA-3	CTOA - Home Page: Redesigned layout, optimized presentation, and improved subject status chart	The layout of the Home Page 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. • Updated the Subject Status chart to display two versions of the chart: users can view by Current or Historical Subject Status. The current subject status displays where subjects are presently in the trial process, and the historical subject status displays the progression of subjects from status to status allowing users to visually compare the segments and see how much smaller they get the further they get in the trial. The Historical Subject Status chart has a footer to ensure users are aware that subjects may appear in more than one category. Both charts now appear as stacked bar charts for a better study to study (and site to site) comparison as well as status comparisons (with segment labels on each status). In addition, both charts have been updated to sort descending by total number of subjects per study. • Updated the Site Initiation Status chart to show as a stacked bar chart with segment labels on each status for better country and status comparisons. This chart has also been updated to sort descending by total number of sites per country. • Converted the Query Status treemap chart to a donut chart for better visibility and comparison. • Added a Site Enrollment table that shows all sites, the number of enrolled subjects, and their enrollment rate. • All KPIs are clickable now (except the screen failure rate KPI) and will navigate users to an applicable sheet to allow them to explore further. • Added the Group Assignment filter.

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Data Central

Internal Issue #	Summary	Release Note Description
EL-21787	Removed orange highlight from filtered column headers	Filtered column headers will no longer be highlighted orange; however, the filter icon will still display in the column header when a filter is applied.
EL-21643	Added column heading highlighting in domain listings - Field Emphasis	The Highlights tab has been added to the Domain Settings window (click the gear icon in a listing) allowing users with the Study Configure privilege to configure the background color of a column header in a listing, and all users to view the configured fields and to turn the column header highlighting off or on. This feature allows users to visually highlight a specific field / column header, emphasizing its appearance so that users know it is an important column or deemphasizing its appearance, implying it is unimportant. The Field Emphasis table lists all visible fields within the domain listing and users can set the background color of any column header. Every time there is a change to the column header colors, an audit log is generated indicating how many column header colors were saved.
EL-21548	Added cell and row highlighting in domain listings - Domain Highlight Conditions	The Highlights tab has been added to the Domain Settings window (click on the gear icon in a listing) allowing users with the Study Configure privilege to configure cell and row highlighting, and all users to view the configured conditions and to turn the cell and row highlighting off or on. This feature allows users to visually call out specific values or records by highlighting them for an improved and more efficient review. The Domain Highlight Conditions builder allows users to select a field (visible in the domain listing), operator (include or exclude selection: equal to, greater than, greater than or equal to, less than, less than or equal to, between, null/empty, or contains), value (from selected field, another field/column, or free text), type (individual cell or entire row/record), and color. Up to ten conditions can be created per domain, conditions can be reordered to prioritize the rendering of the highlights, and conditions can be deleted if no longer needed. Every time there is a change to the conditions, an audit log is generated indicating how many conditions were saved.

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Internal Issue #	Summary	Release Note Description
EL-19601	Added Data Cuts feature	Data Cuts can be configured by a user with the Data Central Designer privilege. A Data Cut is created for a study by adding an Advanced Filter. Advanced filters can include a variety of criteria to achieve data review goals. A Data Cut icon is available for all Data Central users. Clicking the icon opens a list of up to three enabled Data Cuts to choose from. When a Data Cut is applied, all study data, including GPP and Visualization panels, are filtered accordingly. The Subjects panel includes all subjects; however, the aggregate metrics (from Mapper) are recalculated based on the filter in the Data Cut. The Issues and Queries panels will list only those Issues and Queries related to the clinical domain(s) filtered by the Data Cut, along with Issues and Queries from other unfiltered domains. An applied Data Cut is indicated by a green pill displaying the Data Cut name in the Master Header. All panels with the Data Cut applied are highlighted with a green border.

elluminate IQ

Internal Issue #	Summary	Release Note Description
EL-21844	Updated the Anomalous Concomitant Medication (CM Durations) model	Model improvements were made to improve performance.
EL-20804	Ability to provide feedback on model predictions	For all eIQ Review models except CSM Labs and Vitals, users with the review privilege can now give feedback within the Anomalous Records listing indicating if the anomalous prediction is accurate or not. Users can use the Feedback icon in the panel toolbar, or right-click a record; they may also click the Thumbs Up or Thumbs Down icons in the Feedback column of individual records. Users can update or remove their feedback, and all feedback is captured in the Audit Log.
EL-20495	Updated the Shift in Labs and Vitals model Anomalous Subjects listing to Anomalous Records listing	Users now have a record-based view, allowing easy access and review of anomalous records for each subject. The record-based view provides additional information about the anomalous records and users can easily create an issue directly from the listing.

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Internal Issue #	Summary	Release Note Description
EL-20460	Updated the AE Durations model Anomalous Subjects listing to Anomalous Records listing	Users now have a record-based view, allowing easy access and review of anomalous records for each subject. The record-based view provides additional information about the anomalous records and users can easily create an issue directly from the listing.
EL-19758	Issue Text is auto-populated for all eIQ Review models	Issue text is auto-populated when creating an issue within any eIQ Review models. This eliminates the need to manually input the issue text. Users can update the auto-populated issue text if needed.
EL-17444	Added the eIQ Review privilege within User Management	The eIQ Review privilege can be enabled or disabled within User Management under Platform Administration by an elluminate platform administrator or a user with the Manage Users privilege. eIQ Review can be assigned to an individual user or added to a group. After selecting the eIQ Review privilege, the studies, global data stores, compounds, programs, or therapeutic areas the eIQ Review privilege applies to should be selected. All users can view their eIQ Review privileges within their profile under My Privileges and Studies. **Note**: No user will be granted default access to eIQ Review. Access to eIQ Review must be manually enabled within User Management.

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Internal Issue #	Summary	Release Note Description
EL-21920	Added Concomitant Medication (CM) Indication model	The Concomitant Medication (CM) Indication model is available for studies in Data Central with eIQ Review enabled. The Machine Learning (ML) model identifies inappropriate medication-indication pairs in the study data by cross-referencing recorded indications with the openFDA dataset. It assigns a matching score between the recorded indications and the indications retrieved from the openFDA dataset to curate a list of anomalous pairs that need human review. Detection of such data discrepancies helps clinical data review teams identify data quality issues in a more efficient manner, thereby reducing the need for manual checks. Within eIQ Review, users: • Get a list of Concomitant Medications (CMs) that have an anomalous indication identified in the recorded study data. • Can drill down to underlying record data to review additional information. • Can create issues from the anomalous record panel. • Can provide feedback within the anomalous records panel indicating if the prediction is accurate or not. • Can review the data and take action without leaving the eIQ Review page.
EL-22936	Updated the Shift in Labs and Vitals (SILV) model	Model improvements were made to improve performance.
EL-22040	Updated the Concomitant Medication (CM) Consistency model	The Concomitant Medication (CM) Consistency model is updated to include the ability to predict Dose Route and Frequency of administration.
EL-22470	Updated Domain Classification (DMCL) model	Upgraded Domain Classification (DMCL) model using LLM (Large Language Model) models.

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Issues

Internal Issue #	Summary	Release Note Description
EL-21538	Updated the Global and Data Central Issues listings, and added the Visit ID field to the Create Issue window in Data Central	The Global Issues listing now includes new columns: Subject ID, Site ID, and Visit ID. Both licensed and unlicensed users can filter and sort the listing using these columns, allowing them to easily view issues assigned to them with specific data points. Also, when creating a record-level issue in Data Central, users will find an optional Visit ID field in the Create Issue window. The Visit ID column has been added to the Issues listing within Data Central.

Operational Data Repository

Internal Issue #	Summary	Release Note Description
EL-21891	Sub-form references now included in the Issue Type field	For Issues created in the Operational Data Repository, the value stored in the Type field has been updated to include the name of the sub-form in addition to the name of the top-level form.
EL-21886	Module reference for Operational Data Repository issues updated to reflect new name of this module	Previously, issues created from within the Operational Data Repository were listed as CTMS issues (which reflected earlier naming of this module). Going forward, issues created within the Operational Data Repository will have the module set to Operational Data Repository.
EL-21666	Cumulative Enrollment Rate fields auto populated	The Cumulative Enrollment Rate tripartite fields (Baseline, Planned, Actual) have been converted to read-only fields, and the content is calculated and populated by the system based on the content in their related fields.
EL-21623	Export option modified to use the Exporter module	The Operational Data Repository export button action has been modified to use the Exporter module and to use the contents of ODRViews. This improvement includes the return of lookups to associated tables so that the export includes the name of the related item in addition to the ID. This also addresses a prior shortfall, in that the export previously only included contents of the grid display for the top-level forms, now it includes all fields.

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Internal Issue #	Summary	Release Note Description
EL-21251	Study Sites: The Personnel form now includes historic assignments	The Study Site's Personnel form previously only displayed the records of active personnel, as defined by having a missing or future stop date. The display has been expanded to include historical assignments. The benefits are: • No longer need to navigate to the Role History form to check for prior assignments. • If an error was made in the entry of the stop date, the record is still available for editing to be corrected.
EL-20858	Additional configuration options added for sub-level forms	Sub-form configuration options have been extended to match that of top-level forms. The additional options include indicating if a field is required and the ability to add a custom field.
EL-19727	Data may now be ingested into sub-forms	Data may now be ingested into sub-forms as well as top-level forms. The primary use of this would be for initial loading of existing data.
EL-19326	Protocol Deviations: Associated Subject Numbers field updated to a free text field	In the Protocol Deviation form, the Associated Subject Numbers field was converted from a picklist field to a free text field.
EL-19324	Cumulative Screen Failure Rate fields auto populated	Cumulative Screen Failure Rate tripartite fields (Baseline, Planned, Actual) have been converted to be read-only fields, and the content is populated by the system based on content in their related fields.
EL-19215	Studies: Ability to archive Study Site sub-form records	Within Studies, records in the Study Site sub form may now be archived. The user is prompted to provide a reason for archiving the record(s). If there is a dependency such that another record is tied to one of the records being archived, the record will not be archived, and an informational message will be displayed to inform the user.

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Platform

Internal Issue #	Summary	Release Note Description
EL-21636	Enhanced Data Blinding functionality with row-level conditions and wildcard options	Within Study Configuration, users can add row-level blinding conditions via a SQL expression box. The SQL statement will be validated during data import and mapping. Also, wildcard options can be used when entering the Domain and Field, and a comma-separated list can be used in the Field cell. An error message will display upon saving if duplicated Fields from the same Data Store and Domain have been added.

Statistical Computing Environment

Internal Issue #	Summary	Release Note Description
EL-20520	Macros in SAS program dependency parsing	The automatic detection of program dependencies has been enhanced to recognize dependent files based on macro call in SAS program syntax. Based on the SASAUTOS system option, SCE will automatically create a dependency to a macro program based on the presence of a macro call.
EL-20517	Service desk support for recovering deleted SCE files	Recovery of deleted files in SCE is now available by submitting a ticket to the elluminate service desk. By including the file ID (found in the audit trail) and the elluminate URL, users can have deleted files recovered to the original folder location, or to their private My Workspace folder.
EL-19773	Datastore name included in Dependencies sub-panel listing	In the SCE Editor Dependencies sub-panel, dataset dependencies are now listed by their datastore and domain name, making it easier to distinguish between datasets with the same name across datastores.
EL-18675	Ability to create and manage issues on SCE files	Users can now create issues on SCE files in the Editor and Browser and assign those issues to other SCE users or roles. This could be an issue raised on a program file during code review, or on an output file by a programmer or reviewer. Through the issue management workflow, users can track the response to and resolution of issues, ensuring that errors are addressed appropriately and by the correct user(s). Similar to issues raised on data, issues created on SCE files can be tracked and managed through the elluminate Issues module.
EL-18416	In Production files in the Global SCE folder can be added to Tasks	SCE Programs in the Global folder area can now be added to any Task through the ‘Run SCE Program’ action. As with programs from study folders, a program from the Global folder must be in a Production state in order to be eligible for inclusion in a Task workflow. This action is available in both the study-specific view of Tasks and the global elluminate Tasks module.

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EL-17995	Save SCE files with keyboard shortcuts	In addition to Editor toolbar controls, SCE users can now save file changes using keyboard shortcuts. This applies to saving changes to the current version and saving file as a new version.
EL-17709	File Size included in Properties	In the SCE Editor Properties panel, file properties now include the size (in KB, MB, or GB) of the stated version of the file.
EL-17535	Word files visible in the SCE Editor	Microsoft Word file types (.doc, .docx, and .rtf) can now be opened for viewing directly in the SCE Editor. Users maintain the ability to manage the file's lock status, SDLC workflow status, downloads, and properties. With the addition of Issue management in 23.2, users can also create and manage issues on MS Word file types in the SCE.
EL-17520	Excel files visible in the SCE Editor	Microsoft Excel file types (.xls, .xlsx, and .csv) can now be opened for viewing directly in the SCE Editor. Users maintain the ability to manage the file's lock status, SDLC workflow status, downloads, and properties. With the addition of Issue management in 23.2, users can also create and manage issues on MS Excel file types in the SCE.
EL-14620	Python language integration into the SCE	Python is now an executable programming language in the SCE. As part of the SCE configuration, Python can be installed on the compute server(s) and Python scripts can be executed and outputs returned within the SCE UI.

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