elluminate 26.1.0
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 26.1.0. 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=26.1.

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.

New Features and Improvements

elluminate Release 26.1.0 includes several new features and improvements. Major items in this release include:

Risk Management

New! Risk Signals and Communication

Risk Signals introduce a structured and compliant approach for communicating risk-related observations and root cause analysis outcomes to relevant stakeholders. The release enables the documentation of observations with supporting evidence, the definition of issues, the monitoring of open observations and issues, the promotion of observations to higher levels, and the consolidation of related observations. Signals are categorized by communication outcome and are traced to originating metrics. The feature provides visibility at the site, country, subject, and study levels and aligns with industry best practices and regulatory expectations.

New! Collaboration with Non-Licensed Users via RBQM Alerts and Risk Observations

RBQM communication supports assignment to and collaboration with non-licensed users, including CRAs, site monitors, and external partners, on alerts, risk signals, and issues. The enhancement enables cross-functional communication with all individuals involved in or impacted by risk management and aligns with ICH E6 R3 guidance.

New! Sites & Countries Profiles Tab

A dedicated Sites & Countries Profiles tab is available in RBQM. The tab provides a centralized view of site- and country-level performance, primary KRI drivers, and related actions such as risk observations and issues. The feature supports the identification of underperforming sites and countries for additional monitoring or audit.

New! Comments & Activities Log in Risk Assessments

A Comments & Activities panel is embedded within Risk Assessments. The panel enables collaborators to add feedback and review comments prior to approval and finalization. The feature supports transparent collaboration and establishes a foundation for a structured RACT review and approval workflow.

New! Review and Approval Workflow

An optional review and approval workflow is available for configuration in Risk Assessments. Assessments progress through a multi-stage workflow with traceability: In Progress → Pending Review → Pending Approval → Pending Finalization → Finalized. Owners, Reviewers, and Approvers can be assigned defined responsibilities for each assessment. The ‘Comments & Activities’ panel supports feedback capture and iteration. When review and approval steps are not configured, assessments are finalized directly.

New! Contingency Actions

A Contingency Actions option is introduced in Risk Assessments and the Risk Library. The option enables the definition of actions to execute if risks are realized despite mitigations. This standard field supports continuity of response and alignment with industry-standard risk management practices.

Platform

New! OAuth2 Configuration for SSO Connections

Single Sign-On (SSO) configuration options support identity management systems such as Microsoft Entra ID or Google Cloud Identity that use the OAuth2 OpenID Connect (OIDC) framework. The release enables identity provider configuration using this protocol for secure authentication.

New! SCIM (System for Cross-domain Identity Management) API for Automated User Provisioning

elluminate API endpoints for user management enable the creation, provisioning, and deactivation of user accounts through secure connections with external systems that integrate directly with these endpoints. Administrators can synchronize users from an Identity Provider (IdP) to elluminate and provision permissions through user groups configured in elluminate and assigned via the API.

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-36448	SCIM API: Added endpoints for user provisioning, deprovisioning, and group assignment	Added REST API endpoints to support System for Cross-domain Identity Management (SCIM)-compliant integrations in elluminate. These endpoints enable external identity management platforms to manage users and predefined user groups. Supported user actions include: • Provision user • Deprovision user • Update user Supported user group actions include: • Retrieve groups • Create group • Update group, including user assignment This update enables organizations to manage users externally through identity management platforms and control platform access through user authentication and group-based privilege assignment.
EL-35485	SCIM API: Added support for managing users and groups through external identity platforms	Added support for integrations with System for Cross-domain Identity Management (SCIM)-compliant platforms for automated user provisioning and deprovisioning through external identity providers such as Azure Entra ID and Okta in elluminate. This allows organizations to manage user access through existing identity systems, reducing manual administration and improving consistency when provisioning or deprovisioning user accounts and assigning users to predefined user groups using REST API endpoints.
EL-35483	SSO Configuration: Added OAuth2 OIDC support	Added support OAuth2 OIDC for single sign-on authentication in elluminate. This update expands SSO configuration options beyond SAML and enables integration with a broader range of external identity providers. Users can now work with eCS Administrators and IT personnel to provide required parameters and configure OAuth2 OIDC connections between identity access management platforms and elluminate.

Data Central

New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-32617	Clean Progress Tracking: Updated labeling for features	To improve discoverability and consistency, the ‘Subjects’ folder in the Visualizations drop-down in the left navigation has been renamed to ‘Clean Progress Tracking.’ Workspace sheet tabs and visualization titles have been updated to remove the ‘Subjects’ prefix. This update aligns with elluminate’s by-feature folder structure and makes it easier to locate and launch Clean Progress Tracking features.
EL-34335	Configuration - Data Review: Improved error handling and dependency guidance	Enhanced the Data Review configuration workflow to provide clearer guidance and prevent incomplete setup when required identifiers are missing. Subject ID and Site ID must be configured under the Default Identifiers tab before accessing Identifier Overrides and Review Settings. When these identifiers are not defined, dependent tabs are disabled and a tooltip indicates that Subject ID and Site ID are required. Existing validation messaging continues to display upon Save if required fields are removed. Previously configured settings are preserved when navigating between tabs.
EL-34331	Configuration - Review Plan: Added ‘Show Relevant Only’ option to several review material selectors	Updated the Add / Edit Review Objective window to include a ‘Show Relevant Only’ radio button within review material selectors, allowing users to filter Data Central Listings, Visualizations, eIQ Review Models, and Orchestrator Rules based on the selected Primary Domain, Secondary Domains, Fields, and Review Objective description. When selected, the drop-down displays the most relevant materials while allowing users to toggle back to the full list without losing selections. This enhancement reduces manual searching, simplifies configuration, and helps users easily identify and select the most appropriate review materials.
EL-24156	Data Listings, Subjects, Issues, Queries, and Records Review Summary Panels: Added support for column layout and width persistence	Data Central now retains personalized column layouts and widths in Subjects, Issues, Queries, Data Listings, and Records Review Summary panels per user and per listing, even after refreshing, navigating away, or logging back in. This reduces repetitive setup and helps maintain a consistent, workflow-specific view during data review. Saved preferences are retained even if columns are removed. To reset column visibility, order, and width to system defaults, select the gear icon in the panel toolbar to access Domain Settings, then click Restore Default Variable Settings.

Internal Issue #	Summary	Release Note Description
EL-32334	Data Listings, Visualizations, Workspaces, eIQ Review, Orchestrator: Added in-context linking to Review Objectives	Users can now link Review Materials directly to Review Objectives within Data Central, eliminating the need to navigate to Data Central Configuration. A new 'Link to Review Objective' option (clipboard with link icon) is available in Data Central Listings in the toolbar '+' menu, Visualizations, eIQ Review Models, and Orchestrator Rules in their toolbars, and Workspaces in the more (ellipsis) menu next to the Workspace dropdown, providing a consistent way to associate review materials in context. Selecting this option opens a window where users can search, sort, filter, and link one or more Review Objectives. Review Objectives already linked to the selected material appear pre-selected at the top of the list and cannot be unselected without navigating to Data Central Configuration. Additions follow the standard approval workflow, accepting edits for objectives in Configuring status and versioning those already approved. The window also includes a gear icon that navigates directly to the Review Plan in Data Central Configuration. This enhancement streamlines workflows, reduces context switching, and ensures Review Objectives are linked accurately at the point of use.
EL-27260	Graphical Patient Profile Configuration: Added export and import for single GPP configuration	Users can now export and import a single Graphical Patient Profile (GPP) configuration as a JSON file directly from the GPP configuration view. This enables reuse and migration of profiles across studies and URLs without requiring a full Data Central configuration export. Each export captures the complete configuration of the active GPP and generates a timestamped file name for traceability. The import process validates profile names, required fields, study-specific domains, and chart configurations to ensure compatibility with the target study. Imported profiles populate supported GPP settings through the standard Data Central import workflow. Users are prompted to resolve naming conflicts and validation issues before saving. Export and import actions are recorded in the audit trail, providing visibility into when and which GPP configurations were exported.
EL-34294	Queries Panel: Contextualized by EDC API type	The Queries panel in Data Central now dynamically displays columns, actions, and query options based on the study's configured EDC API type, including Medidata Rave, Veeva CDMS, or Oracle InForm. Users only see query fields and actions applicable to the configured EDC system, including API-specific columns in the grid and details view, relevant query actions in the action menu, and appropriate options in the Create Query window. This update reduces unnecessary options and ensures that query management aligns with the configured EDC integration.

Internal Issue #	Summary	Release Note Description
EL-36126	Queries: Improved consistency across Data Central query action windows	Query action windows in Data Central have been standardized across supported EDC systems, including Medidata Rave, Veeva CDMS, and Inform, to provide a more consistent user experience. Required fields are clearly indicated, character counts display where applicable, and confirmation button labels are aligned across common query actions such as open, answer, close, cancel, requery, and reopen. These updates reduce confusion and provide a more predictable workflow when managing queries across studies.
EL-36086	Review Plan - Objective Statuses: Updated in real time for configuration and reviewability changes	Review Objective statuses now update in real time to reflect changes in linked review materials, ensuring statuses represent the current configuration and reviewability. Status recalculation is automatically triggered when review settings or linked materials are modified, including changes to domain and data store reviewability; enabling or disabling eIQ Review models, RBQM, and Analytics apps; deletion of Orchestrator rules or updates to action configuration; and deletion, scope, or visibility changes to listings, visualizations, and workspaces. This update eliminates stale statuses and provides accurate, up-to-date visibility into review readiness without requiring manual recalculation or waiting for the next scheduled review cycle.
EL-24663	Visualizations - Chart Designer: Updated Field Search behavior	Updated the Field Search in the Chart Designer to align with the standard search behavior used throughout elluminate. The 'X' icon now appears inside the search field and is visible only when text is entered. Clicking the icon clears the search and resets the field list to its unfiltered state, providing a more consistent user experience.
EL-34989	Visualizations - Dynamic Filters: Added 'Label' field for custom dynamic filter names	Added a 'Label' field to the Dynamic Filter configuration in Data Central Visualizations, allowing users to override the default field name with a more user-friendly label and revert to the original value if needed. This update improves readability and usability by enabling filters to display clearer, more meaningful names, especially when source field names are long or not user-friendly.

Issues

New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-35148	Added Optional Closure Text	Users can now enter optional Closure Text when closing an issue.
EL-26532	Enhanced Issue filtering by substatus	Users can now filter and view icons for all Issue substatuses. Open – Reopened, Open – Pending, Closed – Snoozed (for KRI/QTL Issues), and Closed – Irresolvable are now visible and filterable in the Status column of both the Data Central and Global Issues listings, and are also included in exports.
EL-26645	Stopped overdue notifications for Answered issue status	Overdue issue notifications are no longer sent to assignees once an issue is marked as Answered. Notifications continue for issues in Open or In Progress status that are past due. Overdue notifications are not sent for issues in Closed, Canceled, Snoozed, or Answered status. This update reduces unnecessary reminders and aligns notification logic with issue ownership during the resolution workflow.

Platform

New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-36566	Platform Menu - History: Added access to Data Central Configuration	Users can now access Data Central Configuration directly from the History section of the Platform menu. After navigating to a study's Data Central Configuration, History displays Data Central Configuration > [Study Name] > [Tab] and links directly to the last tab viewed, such as Review Plan or Reviewer Roles. This enhancement streamlines navigation by allowing users to quickly return to specific configuration areas without re-entering Data Central and navigating through the master header settings menu.

Risk Management

New Features/Improvements

Internal Issue #	Summary	Release Note Description
EL-34102	RACT & Risk Management Configuration: Added Contingency Actions for risk response planning	Added the 'Contingency Actions' field to the Risk Control section of the Risk Assessment form in RACT to define and track contingency actions when a risk is realized despite mitigation efforts. It is also included across Risk Management workflows for consistent visibility and use: • Included in the Study Risk Management Plan, the export of a finalized Risk Assessment in RACT • Available in Risk Management Configuration > Assessment Settings, under the Form tab in the Risk Control section • Available in Risk Management Configuration > Risk Libraries, in the Add / Edit Risk form When a risk is selected from the Risk Library, any defined Contingency Actions automatically populate in the Risk Assessment form to support consistent risk response planning documentation.
EL-33635	RACT - Assessments: Added review and approval workflow, Comments & Activities, and Documentation	Added an optional review and approval workflow for RACT Assessments to improve collaboration, transparency, and control throughout the assessment lifecycle. Users can be assigned as Participants, Owners, Reviewers, and Approvers, with role-specific permissions. Owners can submit assessments for review, withdraw submissions, and finalize assessments, while Reviewers and Approvers can complete reviews or request revisions at their respective stages. Email notifications and workflow indicators provide visibility as assessments progress through each stage. Added the 'Comments & Activities' board to support collaboration during review. Users can add and track comments at the risk and assessment level for unfinalized assessments, including @mentions to involve other elluminate users. The board captures comment activity, status updates, and workflow actions, which are retained with finalized assessments to support traceability. Added the 'Documentation' button to open the Documentation window, providing a structured approach for maintaining version details, protocol changes, and change history. These updates improve the ability to configure, review, and finalize assessments while supporting governance, audit readiness, and efficient risk assessment management across studies.

Internal Issue #	Summary	Release Note Description
EL-33191	RACT: Added support for adding new options during RACT Assessments	Users with Risk Management Configuration privileges can now add new options directly from multi-select fields within a Risk Assessment in RACT. When typing a value that does not exist in the predefined list, a message appears with a '+ Add' option to create and select the new entry. This enhancement applies to Critical Data, Critical Processes, Quality Tolerance Limits, Key Risk Indicators, and Pre-Study and During-Study Mitigation Actions. Newly created entries become immediately available for reuse across all studies. Users without configuration privileges see a message indicating they do not have permission to create entries.
EL-36089	RACT: Improved window sizing and added read-only previews	Enlarged RACT assessment windows to improve visibility and reduce scrolling when reviewing form content. This update applies to the Create / Edit Risk window in RACT Assessments, the Risk Form Preview in Assessment Settings, and the preview in the Create New Assessment workflow at the study level. To preserve data integrity, the Edit Risk window is now read-only in finalized assessments, and all preview experiences are non-editable for review purposes only.
EL-33335	RBQM - Profiles: Added Sites and Countries tabs	Added the Profiles tab in RBQM with Sites and Countries subtabs to provide a centralized view of site- and country-level performance. The tab content highlights key KRI drivers and related actions, including risk observations and issues, to improve visibility into study operations. These profiles enable users to identify underperforming sites and countries, supporting targeted monitoring, follow-up actions, and audit planning for proactive risk management.
EL-34087	RBQM - Risk Signals: Added ability to change risk signal level	Added the ability to update the level of a risk signal in RBQM. Users can edit or promote a risk signal record and select the 'Change Level' button to open the Change Level window, where the scope can be adjusted between subject, site, country, and study levels to reflect the impact of the underlying issue. This enhancement supports dynamic risk management by allowing teams to escalate localized concerns or refine broader signals as patterns evolve, while maintaining traceability and context.

Internal Issue #	Summary	Release Note Description
EL-34088	RBQM - Risk Signals: Added actions for risk signal management	Added Risk Signals actions in RBQM to enable study teams to identify, manage, and escalate potential risks before they become confirmed issues. Key actions include: • Create and categorize signals: Capture emerging concerns at the study, country, or site level. • Answer and comment: Support structured communication and cross-functional collaboration. • Edit and reassign: Update ownership, priority, and due dates to maintain accountability. • Close and snooze: Close records that are answered and no longer relevant, or snooze records for later review. • Reopen signals: Reopen closed records when additional investigation is needed. • Combine signals: Consolidate related records with the same root cause to reduce duplication. • Promote to issue: Escalate confirmed problems into formal issue tracking.
EL-31278	RBQM - Risk Signals: Added Risk Signal creation feature	Added the new Risk Signal creation feature in RBQM to enable proactive capture and documentation of potential risks. Risk signals can be created at the study, country, or site level, allowing teams to accurately reflect the scope of a concern and address emerging risks early. This enhancement helps study teams document observations, collaborate on risk evaluation, and manage potential issues before they escalate into confirmed problems.

Internal Issue #	Summary	Release Note Description
EL-34085	RBQM - Risk Signals: Added Risk Signals page with table, Details panel, and Comments section	The new Risk Signals page in RBQM provides a centralized and structured view of risk signal summary data and analytics for alerts, risk signals, and RBQM issues within a study. This enhancement improves visibility, traceability, and collaboration by combining analytics with detailed record management. Key capabilities include: • Risk Signals table: Displays alerts, signals, and RBQM issues in a centralized table with sortable and filterable attributes such as status, priority, assignee, and due date, enabling quick identification of items requiring attention. • Details panel: Provides a contextual side panel with additional record details, including history, linked child records, and status changes. • Comments section: Captures discussions, responses, and actions for each record, supporting transparency and maintaining an audit-ready history of risk management activities.
EL-29535	RBQM - Risk Signals: Added support for non-licensed user collaboration	Added support for assigning risk signals and enabling collaboration with non-licensed users in RBQM workflows, including CRAs, site monitors, and external partners. These users can be included in alerts, risk signals, and issues, allowing broader participation in risk management activities without requiring a full platform license. This enhancement strengthens cross-functional communication by ensuring all relevant stakeholders can review, respond to, and address risk-related observations. It also supports alignment with ICH E6(R3) guidance by improving documentation, traceability, and timely risk mitigation across study teams.
EL-34086	RBQM - Risk Signals: Introduced workflow	Introduced the Risk Signals workflow in RBQM to improve how risks are tracked, communicated, and managed. This enhancement strengthens the end-to-end lifecycle of risk detection, collaboration, and escalation. Key capabilities include: • Export functionality: Enabled export of risk signals and alerts to Excel to support offline review, reporting, and stakeholder discussions. • Email notifications: Added automated and optional email notifications to inform assignees and relevant stakeholders when signals are updated, escalated, or become overdue. • RBQM engine alignment: Updated RBQM engine-generated issues to be categorized as alerts, ensuring a consistent workflow of Alert (potential risk derived from QTL/KRI threshold breaches) to Signal (managed risk) to Issue (confirmed problem).

Internal Issue #	Summary	Release Note Description
EL-34084	Risk Management & RBQM: Added Risk Signals card in Risk Management and Risk Signals tab in RBQM	Added a Risk Signals card to the Risk Management home page and a dedicated Risk Signals tab in RBQM to provide access to the Risk Signals page and improve visibility of risk signals. The Risk Signals card displays aggregated counts and statuses of risk signals and RBQM issues, providing a high-level snapshot of risk activity. The Risk Signals tab provides a centralized workspace to access risk signals, alerts, and RBQM issues in one place, supporting consistent risk management workflows.