RELEASE NOTES

eBinders R88.0.0

Columbus Release

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Release Summary

eBinders - R88.0.0 (Major release)

Document Management Enhancements:

Our latest release enhances your document management experience. Users will now have the ability to copy text directly from documents inside of Florence. In addition, users can also use a new strikeout feature to strike through outdated or inaccurate information. The extended expiration date limit allows you to enter dates further back than two years, supporting better historical record-keeping and regulatory compliance. Additionally, a new document date field ensures your metadata aligns seamlessly with regulatory systems and eTMF integration, providing more accurate tracking and management.

Study Roles and DOA Log Improvements:

Our new features are designed to improve your study management experience. You can now quickly find and manage study roles, enhancing navigation and efficiency. The bulk upload feature allows you to import multiple roles and responsibilities via Excel, saving you valuable time. Additionally, entry validation in the dropdown fields of eLog templates ensures accuracy and prevents duplicate entries, streamlining your logging process. Lastly, with the improved view-only mode for Study Profiles, users can access information they need without having the permission to make changes to existing Study Profiles.

Reporting Updates:

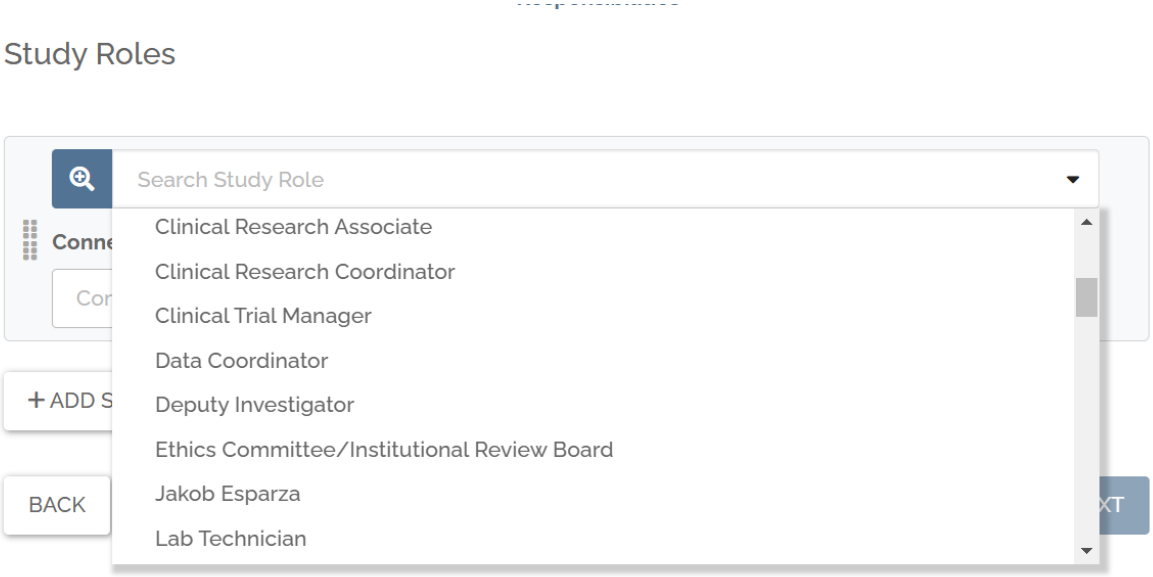
Monitor Review Module (MRM) status has been added to the Documents Overview All report. Users can leverage this report to easily track document statuses and quickly identify documents that need further attention.

eBinders

What's New

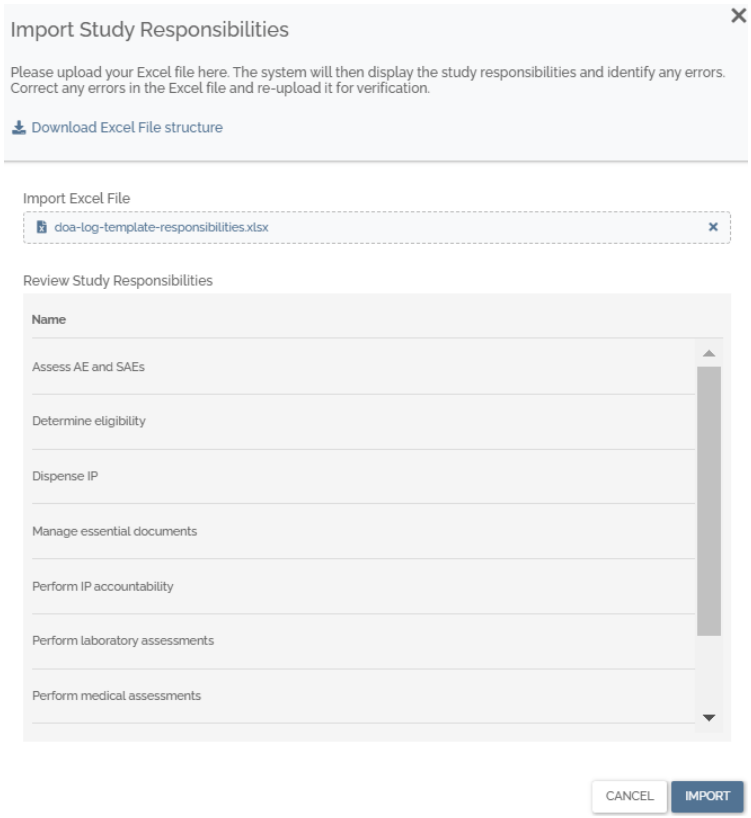
Search Capability for Study Roles

Users can now quickly locate the exact study roles they need, enhancing workflow efficiency. Search for roles in DOA logs, study profiles, automation modals, and role management screens. The result is a streamlined study role management process, enabling users to access relevant information more quickly.



Bulk Upload of Study Roles and responsibilities

This new feature saves you time by allowing bulk uploads of study roles and responsibilities using an Excel template. It simplifies adding multiple roles and responsibilities in a single action during study role management or responsibilities entry.



Copy Text Functionality in the Document Viewer

This feature enhances usability by making it easy to extract text from documents with just a click. When highlighting text, a copy icon will automatically appear on the document allowing the user to copy the text to their clipboard.

<Protocol Title>
Protocol <#>

Version <x.x>
<DD Month YYYY>

STATEMENT OF COMPLIANCE

Provide a statement that the trial will be conducted in compliance with the protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable state, local and federal regulatory requirements. Each engaged institution must have a current Federal-Wide Assurance (FWA) issued by the Office for Human Research Protections (OHRP) and must provide this protocol and the associated informed consent documents and recruitment materials for review and approval by an appropriate Institutional Review Board (IRB) or Ethics Committee (EC) registered with OHRP. Any amendments to the protocol or consent materials must also be approved before implementation. Select one of the two statements below:

(1) [The trial will be carried out in accordan International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the ring:

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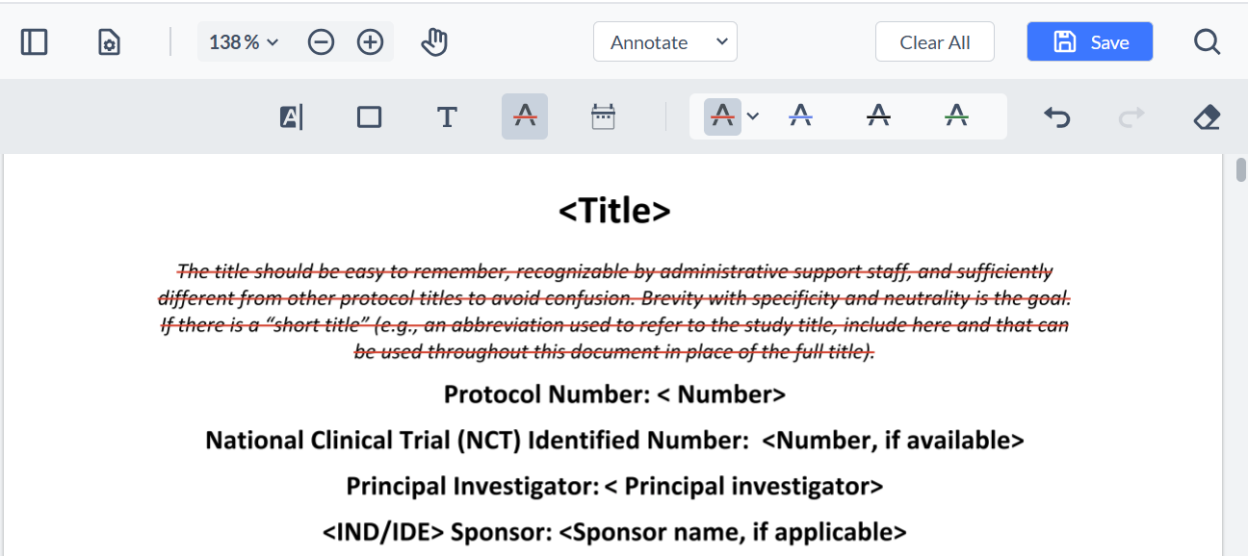
- United States (US) Code of Federal ions (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

Strikeout Text Functionality in the Document Viewer

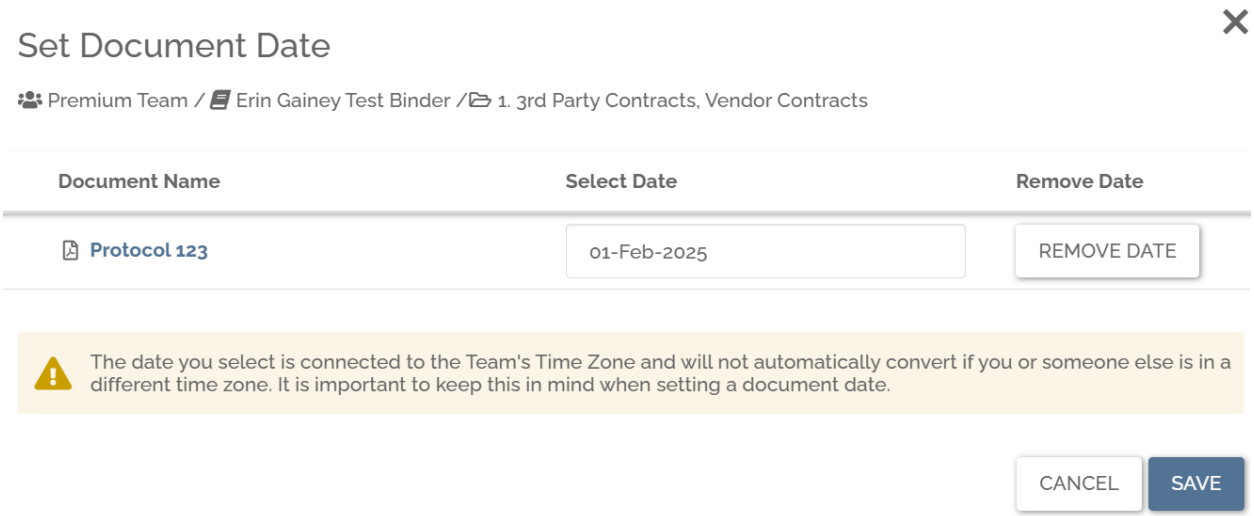
This feature allows reviewers to easily mark obsolete or invalid information in documents while maintaining traceability. The strikeout functionality is available in the annotations menu and is available for all supported document types.



Document Date Field

This feature enhances compliance and data integrity by allowing users to specify the document date, ensuring alignment with eTMF system requirements. The Document Date field is available

via the Actions drop-down menu from the folder view or in the left-hand Document Details section in the document view. The new permission, Manage Document Date, is required to be able to update Document Dates.



Extended Expiration Date Limit

The expiration date feature has been updated and can now be set beyond two years in the past. This update ensures compliance with regulatory requirements and supports accurate historical record-keeping for older studies and documents.

eLog Up-version Logic

This enhancement optimizes versioning logic in eLogs and DOA logs, ensuring that entries are only up-versioned when existing data is modified. Users can now add data to previously empty fields without triggering a new version, which prevents unnecessary signature removals and reduces administrative effort. This improvement streamlines workflow efficiency, enhances data integrity, and supports compliance, making it easier to manage and maintain accurate records. For example:

Scenario 1:

(1) Log entry field name: [Team Member] Before: John Williams; After: (no change)
(2) Log entry field name: [Start Date] Before: 01JAN2024; After: (no change)
(3) Log entry field name: [End Date] Before: (empty); After: 01DEC2024
Up-version = NO, only the third field was updated from an non-populated field.

Scenario 2:

(1) Log entry field name: [Team Member] Before: John Williams; After: (no change)
(2) Log entry field name: [Start Date] Before: 01JAN2024; After: 02JAN2024
(3) Log entry field name: [End Date] Before: (empty); After: 01DEC2024

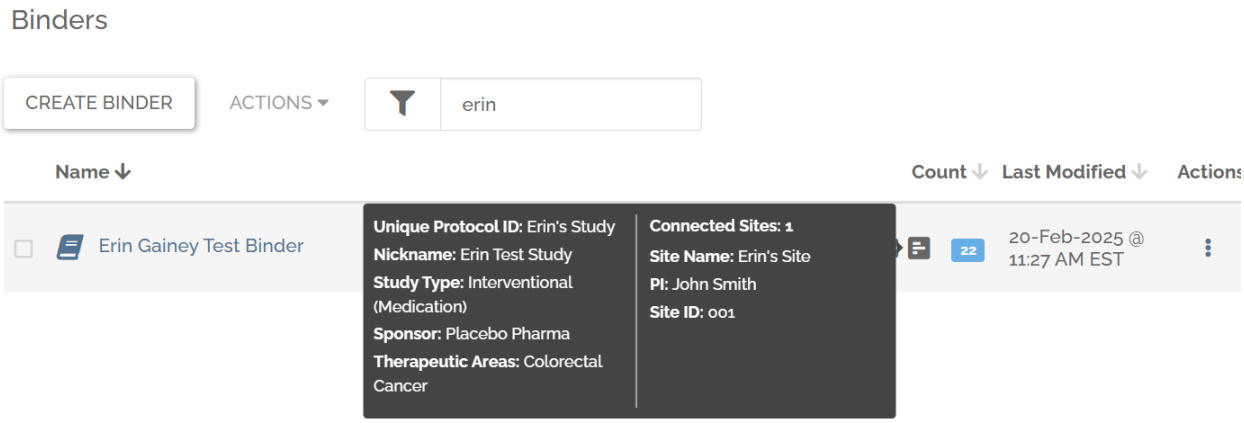
Up-version = YES, the existing entry in the second data field [Start Date] was modified prompting the system to create V2 of the log row.

View Mode for Study Profiles

Users with the View Study Profiles permission will now be able to view all study profiles and the associated information. This view-only permission ensures users have access to the information they need without the ability to create new study profiles or edit existing study profiles.

Study Profile Information in Hover Tooltip

The Study Profiles tooltip visible by connected binders and folders has been updated to include all of the required fields added with the Atlanta Release in November 2024. In addition to the *Unique Protocol ID*, *Nickname*, *Sponsor*, *CRO*, *Device/Drug*, and *Condition/Disease* fields, users will also be able to see the *Study Type* and *Therapeutic Area* when hovering over the tooltip.



Display Scheduled Role Access Indicator in Team Members List

This enhancement to user roles in eBinders provides clear visibility into role assignments, helping teams stay organized and compliant. The new indicator will be visible from the team members page.

Entry Validation in the Single and Multiselect Dropdown Fields in eLog Templates

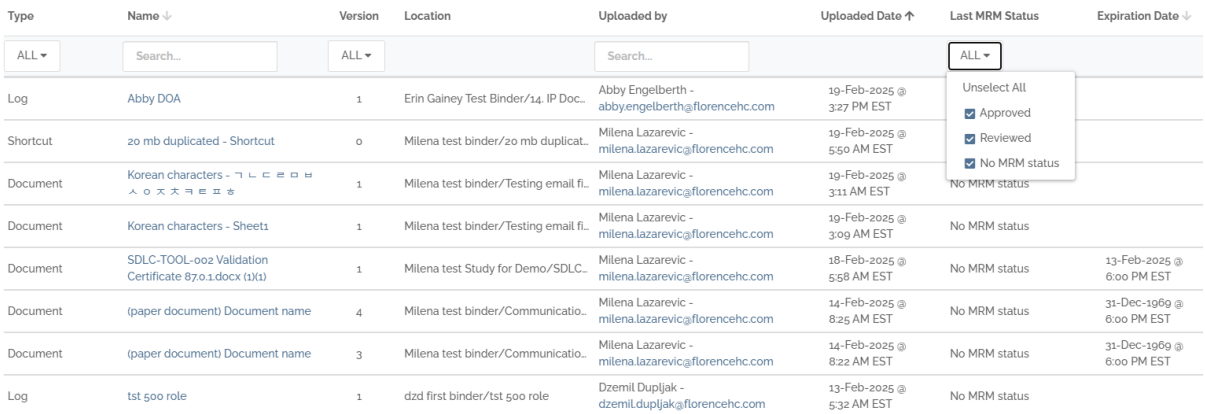
This feature helps prevent errors by alerting users when duplicate field names are entered during setup, ensuring template consistency and reducing rework. It automatically detects and highlights duplicate entries in multi-select or single-select dropdown fields when creating or editing eLog or DOA log templates. Conflicting entries are marked with a red border, providing immediate visual feedback to maintain data accuracy.

Terms and Conditions Display Improvement

The Terms & Conditions modal will now link directly to the latest Terms & Conditions page to ensure that all users have access to the most recent version of our Terms & Conditions. New users logging into eBinders for the first time will be able to view up-to-date information by clicking the Terms & Conditions link.

Last MRM Status Column in Document Reports

This feature enhances visibility into document approval workflows by adding an MRM status column to the documents report. Users will be able to filter by documents approved, documents reviewed, or documents with no MRM status. By providing clear insights into the status of document workflows, this reporting enhancement helps streamline document tracking, ensuring a more efficient document oversight.



Email Verification for Users Logging in With New Email Method

With SSO email verification, Florence users can now start using new SSO connections without Florence support and without compromising security. Previously, if there was a need to utilize new SSO connection users would have to contact Florence support.

This enhancement provides greater flexibility, particularly for users like Monitors who collaborate across multiple studies with different sponsors or sites, each requiring separate SSO credentials. By enabling email verification, we ensure a seamless and secure login experience while accommodating diverse authentication needs.

Lockout email and Password reset email changes

This new lockout email feature enhances security by protecting against unauthorized access and offering users a secure, self-service method to regain access through the "Forgot Password" option. The feature is triggered when a user enters the wrong password 10 times and needs to reset their password. This ensures a seamless and secure login experience, giving users peace of mind when managing their access.

Revision History

Document Version Number	Document Revision Date	Summary
3.0	Mar 5, 2025	Revised “Email Verification for Users Logging in With New Email Method” section
2.0	Mar 4, 2025	Updated “Display Scheduled Role Access Indicator in Team Members List” section for clarity
1.0	Feb 19, 2025	eBinders R88 features