Release Notes - 2026.01 (major)

This is a major release which includes a host of new features, improvements and bug fixes:

New features

- ★ New study information editor in the Control Panel. The "Edit study info" screen moves from the Portal to the Control Panel, where it becomes a study information editor organised in tabs that are controlled through a specific permission in the Control Panel ("Manage study"). For existing users, this permission is initialized for any profile who had permission to edit the eCRF configuration. It is not versioned, so changes apply to both Test and Production without publishing a new eCRF version. The Portal's per-study actions no longer offer "Edit study info" or the study license. This contains:
  - **General information**: the study details (Study name, acronym, logo etc.) previously edited from the Portal, reorganised into four groups: Identification, Protocol details, Team and sponsor, and Security.
  - **Contact, Co-branding and Landing page**: optional features, described below. Each has its own activation switch and save button; while a tab is switched off, its feature is not shown in the eCRF.
  - **License**: a view-only tab showing the study's current plan, modules, features and limits.
- ★ **New "Contact" tab**. Lets you configure who eCRF users should contact with operational questions. When active, the help menu in the eCRF top bar shows the study contact entry alongside "ShareCRF user guides", and opens a popover with the configured details.
- ★ **New "Co-branding" tab**. Adds a branding banner across the eCRF, in both Test and Production, with a background colour and logo, and an optional sponsor name and text.
- ★ **New "Landing page" tab**. The configuration of the study's public start page moves from the eCRF editor to this tab. You can choose whether the page is shown on entry to the study, and edit its content with a rich text editor that supports headings, lists, links and images.
- ★ **New bulk actions mode in the patient**. Users can now apply one operation to many elements of a patient at once, instead of one by one. Only operations the user has permission for are offered.
  - Field operations: clear value, mark/unmark missing data, mark/unmark SDV, and create query.
  - Form operations: lock/unlock, and apply or withdraw each configured approval status.
  - SDV is now applied through the bulk actions mode only, replacing the previous way of applying SDV, entering in the review mode.
- ★ **New CRF overview in the patient.** Entering a patient now opens a general overview of its CRF, also available for each visit, repetition list and instance. It lists the contents with their different alarm icons (errors, warnings, changes), approval statuses, and SDV and completion progress, all gated by relative permissions.

Improvements

- ★ **New look for the eCRF application**. The patient, the patient list, the global queries list, and the Randomization, Documents, Notifications and Reports sections all have a new layout and colour palette. Beyond the visual changes:
  - **Patient**: a header above every open element shows its location, previous/next navigation, a Save button and a summary of its indicators. Banners report errors that prevent saving and unsaved changes, and each field with an unsaved change is marked. The sidebar menu is simplified, and SDV and completion progress are now shown as donut charts.
  - **Patient list**: the patient is opened by clicking its ID, the ID and actions stay visible when scrolling horizontally, and columns follow a fixed, defined order. The Excel download adds who applied each approval status and lock, and when.
  - **Global queries list**: a new Query ID column and filter, the full query thread viewable inline from each row, and a new Last responder column. The Open and Closed tabs are replaced by a status filter, and the Description, Value and Started by columns are removed.
  - **Randomization**: timestamps include timezone and seconds, the Blocks tab names sites by name and code, and supply history adds a User column.
  - **Medical coding**: the codable field is chosen from the list title, the assigned dictionary and version are shown, and a select-all checkbox is added.
- ★ **Dates shown in the patient's site timezone.** All system timestamps in the eCRF application (audit trail, approval and lock tooltips, queries, randomization, notifications, certified copies, ePRO and reminders) are now shown to the second in the timezone of the patient's site, labelled with that timezone. Previously they were shown in the browser's local time. Study-wide lists offer a selector to switch to UTC. Downloaded files are unchanged and continue using UTC. eCRF date and time field values are not affected. A timezone is now mandatory for every site. Existing sites without a timezone set, will use UTC time as a default.
- ★ **Data import tool reworked**. The user flow is unchanged, but the import is no longer all-or-nothing: format errors in the files still stop the import, while a validation error in one patient now marks only that patient as invalid and the rest of the import can be continued. The "first data line" option is removed, the data is read from the line after the header line.
- ★ **Data cleaning in lists**. When a list is hidden by a hide rule with data cleaning, its existing list elements are now deleted when the patient is saved, instead of being left in place with empty fields. The deletion is recorded in the audit trail, and the queries and SDV of the deleted elements are removed. In existing studies, list elements in this situation are deleted when rules are re-executed on the patient.
- ★ **Filter rules always clean the data**. When an option selected in a field is filtered out by a filter rule, it is now always removed from the field's value. The option "Clean up answer values not accessible in the field when the set of answers are filtered" is removed from the eCRF editor. In studies with filter rules configured without cleaning, values already saved for filtered options are removed when rules are re-executed on the patient.

- ★ **Automatic rules will always be executed in creation**. Previously a rule could be configured to only be executed in edition. This has been modified, and now all automatic rules will always be executed upon creation.
- ★ **Data cleaning takes precedence over set-value actions**. When a field hidden by a hide rule with data cleaning is also the target of a set-value action, the field is now always left empty. Previously, depending on the order in which rules were evaluated, the field could keep the set value. Existing patients in this situation have the value removed when rules are re-executed.
- ★ **"Study not published" page.** Opening a study environment that has no published eCRF version now shows a "Study not published" page, explaining that the study will be available at that address once its first version is published.
- ★ **eCRF configuration options removed.** The Customization section is removed from the eCRF editor: the colour palette, font family, header logo and footer are no longer configurable or shown in the eCRF, and the system colours and fonts apply to every study. There is no replacement for these options. The study start page configuration moves to the new Landing page tab. Additionally the options "Show mandatory fields percentage (in Subject and list of Subjects)" and "Hide number of mandatory fields pending completion in the eCRF menu" are removed from the eCRF configuration. The completion percentage is now always shown in the patient and the patient list and the patient sidebar no longer shows the number of mandatory fields pending completion.

Bug fixes

- ✔ Fix the global queries list so that it only shows queries on fields the user's access profile can access. Queries on fields hidden by a display rule or by the hidden property are still listed. Additionally, an improvement has been added so that when the access profile restricts field access, the global queries list and the patient's queries section state that some queries are not listed. Query counts in the patient and the patient list are not reduced and still include all queries of the patient.
- ✔ **Rules referencing elements moved within a repeating list.** When a field or form used in an automatic rule condition was moved within a repeating list, the condition could read the wrong value from the patient data, so its actions did not run when expected. The configuration of the rule from the study control panel did show this evaluation correctly. Missing list positions in these references are now completed when the eCRF is published, so the conditions are evaluated correctly, as they have been configured.

Known limitations

- ✗ When a value is written to a field the user's profile cannot edit, for example a field made read-only by an eCRF version published while the form was open, the value is correctly not stored, but the save is reported as successful instead of showing an error.

- ✗ With the Import tool, a partial date field that requires the year accepts a value without one (for example xx-Mar-xxxx) and stores the current year.
- ✗ In the bulk actions mode within a patient, the Clear value operation offers the option to select fields of locked forms. The save is then rejected with an error and nothing is cleared, including the fields of unlocked forms.
- ✗ In the Control Panel, the password expiration count in the study's General information tab cannot be changed: saving a new value shows "Unexpected error". The current expiration period still applies.
- ✗ In the Randomization record, the Blind revealed column is shown only to profiles with permission to view the reveal of the blind, instead of to every profile with access to the record.
- ✗ Opening a closed or blocked study shows an empty grey page instead of a message saying that the study is closed.
- ✗ In the patient list, after a patient is deleted while filters are applied, the number of patients hidden by the filters is one too high until the page is reloaded.
- ✗ When a save is rejected because of an error in a field the user's access profile cannot see, the message does not say that the field is not accessible to the profile.
- ✗ Changes in fields hidden by a display rule that previously contained a value are still listed and counted in the patient's pending-changes breakdown, and still mark the row of a repetition list as changed.
- ✗ In the patient sidebar, clicking beside the name of a section or list opens it instead of expanding or collapsing it.
- ✗ In an English Control Panel, the save confirmation messages of the Contact and Landing page tabs are shown in Spanish.
- ✗ In the eCRF application, the Documents section does not show the creation date of each document.
- ✗ Data import through CSV files cannot create or update items in lists included in another list, only first level lists are allowed.
- ✗ Queries and audit trail for encrypted fields will be shown as *Encrypted* in the CRF application, but they don't have any means to decrypt the original value even with the right permissions
  The only way to obtain the original encrypted data for queries and audit trail is through the Export module
- ✗ CRF studies with a very high number of forms and events cannot obtain the Annotated PDF file, when it reaches thousands of pages long. A manual intervention is needed to finish the PDF generating process.
- ✗ CRF studies in the order of thousands of forms experience problems when generating the CRF application in the Control Panel, and need manual intervention.

- ✗ Warning message indicating that there is not enough space in the study for new files is not displayed when combining data changes with other actions, such as opening a query at the same time or changing the form or record status.
- ✗ In the CRF application in iOS, the visual input for the field type Select has a refresh delay, so when selecting a value the first time, if we immediately open again the select, the offered values are misaligned, and apparently the wrong option is selected. It is necessary to wait a few seconds so iOS refreshes the options presented.
- ✗ In the CRF application, rule conditions of a field inside an event list, with the operator Empty, will evaluate to true if there are no elements in the list, and sometimes it is not the desired result. In those cases it is necessary to add an additional condition to check the length of the event list, and ensure it has at least one item.
- ✗ Medical Coding dictionaries cannot be deleted once uploaded to the platform.
- ✗ In the ePRO patient configuration, the Country selected for the SMS phone number cannot be deleted, only the phone number.
- ✗ When a user loads an export template that filters by forms or fields, using an access profile that does not have access to some of those forms or fields, those items are excluded from the export file without any clear indication in the export interface.
- ✗ When a date-time field from the eCRF is added to the patient list, the filter available from the patient list for this field will always use the ISO format ‘YYYY-MM-DD HH:mm‘ to filter the list, independently of the date format that has been configured and is displayed from the patient list.
- ✗ The maximum allowed time to schedule an export is 6 months (179 days specifically) in the future.