

Release Notes 2021.03 (major)

This is a major release with many new features, as well as some improvements on the current platform and several bug fixes.

New features

- ★ The ePRO application can be configured with an alternate visualization, to display variables to the user one by one, instead of presenting the full form.
- ★ Variables can be specified as Missing Data, with a required reason explaining why. These variables will count towards the completion of the subject, but will be identified and available to consult details.
- ★ There is a new global Subject Status, to indicate the different phases in which a subject can be: Screening, Screening Failure, Enrolled, etc. These statuses are completely customizable, including the label, and the subject will acquire them automatically following the rules and workflow defined in the CRF configuration.
- ★ New Reports section with aggregated charts and statistical data for the study, such as Inclusion Rate, Queries Status and Distribution, Subject Status, Approval and Revision States, etc. Some of them admit filters like dates or sites.
- ★ Individual field revision, to help the revision process on the subjects. It allows marking each separated field to easily identify any monitoring process.
- ★ Additional date formats in data exports, as well as fully compatible formats for SPSS and SAS timestamp formats.

Functionality improvement

- ★ Improvement in partial date variables in data exports, each field will dump two different columns, one with a full date format, and the other one with a generic string format.
- ★ In the ePRO reminders, the site name will be available to use in the message body.
- ★ ePRO elements will be presented in the user application using the same order as they appear in the CRF application for investigators.
- ★ ePRO elements corresponding to forms or events hidden in the CRF application will be also hidden and not available in the ePRO application.
- ★ Disabled fields will be presented in two different colors to help monitors in their work, so it will be easier to identify the origin for an empty field.
- ★ Performance improvements in the CRF application generation.

Bug fixes

- ✓ Fix an API operation when trying to remove a repetition list item at the same time as an automatic rule will trigger to add a query in the same item.
- ✓ Fix in the propagation of overridden flags in the CRF Editor from the library form to the structure instance, in which some cases it did not reflect visually to the editor user the current status of the flags.
- ✓ In the Control Panel, in the History of publications, releases published by users removed or no longer participating in the study did not appear.
- ✓ Fix in the disk space used by any study for its file or DICOM fields, in some cases when emptying the field did not correctly update the occupied size.
- ✓ Individual form Approval Status can be established by users with a profile that prevents them from changing any data in that form. Previously these users could only set the Approval Status at global Subject Level.
- ✓ The subject ID could not be modified in CRF with any configured encrypted field.

Known limitations

- ✗ 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.
- ✗ CRF studies in the order of several hundreds 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.
- ✗ With the Import tool, record data in CRF applications where the ID of each record is defined with a template, and that template includes the character slash / cannot be imported, always ends with a failure.
- ✗ 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.

X ePRO notifications by email are guaranteed to be delivered at least once. On rare occasions a user can receive the same email twice.