

Release Notes 2021.02 (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

- ★ Some features have been added in the ePRO module:
 - It can be configured so patients can receive reminders via email to complete the forms as they become available, as well as reminders when the closing date and time of a form is near.
 - There is a log of actions performed by the patient when using the ePRO application, such as logins and logouts, filling forms and events, etc.
 - The form and event states of the ePRO elements configured to be filled by the patient have been improved, so it is more clear the current status of the form or event.
- ★ Support for encryption of confidential fields, containing PHI or other sensitive data. Any field but files can be configured as encrypted. It means that the data value will be encrypted in the database through an external system, and only users with enough permissions can decrypt and retrieve the original value. This will help studies to comply with regulatory requirements that include the strong encryption of data values in the database.
- ★ In the CRF application, in the Export module, a new general format has been added. The current format dumps all data of the records in a single file with a line per record, and each event is dumped in a separate file containing all its forms. This format is still maintained. In this version there is a new selectable format, where data is dumped and grouped by form, where each file contains all records data for that form.
- ★ For the CRF application, fields can now be configured as non exportable. It means that this field will not be dumped in the CSV files in the Export module. They will still appear in certified copies.
- ★ In the CRF application, in the Queries tab inside any record, a filtering tool has been added to help users find queries.

Functionality improvement

- ★ In the CRF application, for studies with audit trail enabled with reason of change. Now the form will keep the last selected reason of change, so when a user changes more than one field in a row, every time the reason selected will be the last one, which speeds up the process.
- ★ In the CRF editor in the Control Panel, after a successful publication of a new CRF application, the summary of operations carried out in the data integrity will include a detailed description of the data changes in each record.

This will help to improve the assessment of a CRF change once the study has started.

- ★ Improvement in the deliverability of email messages using an additional queue system for the outgoing messages, including the new ePRO reminders and also all the previous messages sent by ShareCRF via email.
- ★ Improvements in the API performance regarding the main record list in the CRF application, and also in many API endpoints belonging to the Control Panel.
- ★ In the CRF editor in the Control Panel, an overall summary of elements present in the CRF (forms, events, rules, etc.) has been added.

Bug fixes

- ✓ Regarding the CRF Editor in the Control Panel of the study. There was an error when cloning fields containing incomplete rules.
If the rule definition was not complete and had missing required components, if the field was cloned no rules were copied along with it, nor even correct rules besides the incomplete rule.
Now it has been fixed and all rules, including the incomplete ones, are fully copied when a field is cloned.
- ✓ Regarding the CRF Editor in the Control Panel of the study. There was a visual error in the preview of the default value in a field of type Select. Instead of showing the label of the option selected as default value, it was showing an internal representation of the data
It has been fixed so the field shows the default value using the label of the option.

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.
- ✗ In the CRF application, user profiles with permission to change a form status, but no permission to edit the form, have no available option to change the form status; so the edition permission is wrongly linked to the form edit permission. This situation is only at form level, at record level it works as it should.

- ✗ 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.