ShareCRF Version: 2022.03

Release Notes 2022.03 (major)

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

New features

- New field type for date and time in a single variable
- New transport for ePRO reminders to send them using SMS.
- ★ Hide fields only for the ePRO application for patients, while remaining visible in the CRF application for investigators.
- ★ Visual Build Identifier for any CRF, so two different configurations can be compared (for example between test and production environment) to check if they are the same or they differ. Included also in PDF files such as Certified Copies or Annotated CRF that include information about the CRF.

Functionality improvement

- ★ The sent reminders list holds also the messages that were not effectively sent due to any reason (ePRO form already completed, user without email address or phone number for SMS, etc.) to make easier the notification messages tracing.
- More complete header for PDF files such as Annotated CRF or Certified Copy, containing information in all pages about the study, environment, date, etc. as well as the page numeration in the footer.
- ★ Publishing report summary with data integrity process also shows information about non-data changes such as form approval status.
- ★ In the ePRO application the current PIN is required now in order to change it for a new PIN number.
- ★ Visual widget for the Hour field type is changed so there is no need to type the colon separator between the hour and minutes components.

Bug fixes

- ✓ In grids, when a field value was changes and the reason was required, it was not possible to identify the column that the reason was referring to. Now it displays before the reason the column header name for the corresponding field.
- ✓ Included the status change for users in the PDF file with the user audit changes.
- ✓ Incorrect variable type in the SPSS and SAS syntax files for auxiliary variables holding the information about the unknown value for fields configured with that possibility (the additional column with _na suffix).

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- ✓ In the ePRO application, in individual mode, if a step hold a non visible field, still showed an empty step with only previous and next buttons. Now that step is skipped.
- ✓ Security fixes and protection increase in several API endpoints.
- ✓ In some occasions in the CRF application frontend, a rule triggering an error was not executed until the user entered in the form containing it. Although the API backend would always guarantee the data integrity and execute all rules properly, it could confuse the user as an error appeared saving the data, but it was not reported visually before.

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.
- Medical Coding dictionaries cannot be deleted once uploaded to the platform.

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X Changing the site timezone after a reminder has been programmed does not update the time when it will arrive, it will still have the original date and time scheduled to be delivered.

- ✗ In the data importer, in the preview screen with the simulation of the process, if a line reports more than one error, the line number reported can be wrong and not reflect the corresponding line in the CSV original file
- In the ePRO patient configuration, the Country selected for the SMS phone number cannot be deleted, only the phone number.