**ShareCRF** 

Version: 2025.01

## Release Notes 2025.01 (major)

This is a major release containing improvements over performance of the platform and several bugfixes:

## Bug fixes

- In queries opened over DICOM fields, the value represented as the value of the field in the moment of opening the query, or replied text, was not showing consistently in the ID assigned to the DICOM study. Now it always ensure to show the initial fixed prefix "dcm" in all cases (queries, form, audit trail, etc.)
- Direct access using API for the ePRO application, distinction between test and live environments in terms of permissions was not done properly. This behaviour does not affect the ePRO application, only an unsupported API direct usage. This has been fixed nonetheless to ensure best security practices.
- In the closed query list in the eCRF application, column Opened days (indicating for each query the number of days it remained open) was incorrectly using the current date as the end of the interval, so the value reported was not correct. It has been fixed.
- The link button in the global queries list to jump directly to the form where the field associated with the query is located. It was incorrectly linked only to the patient, but not the specific form. It has been fixed.
- The randomization system to keep track of the seed for the next generation had a scenario where the last generated seed could be wrongly selected. In studies configured with randomization blocks, when opening a new block two consecutive operations are executed to generate two random numbers, one to select the block size and one to shuffle the branches inside that block. If the generation of those random numbers occur at the same millisecond, the seed selected for the next random number in the future is undetermined, and could break the random sequence expected mathematically in the system. In order to respect at all times the mathematics validated in the system to ensure a proper random sequence at all times, this random seed management algorithm has been fixed. No studies have been affected by this bug, this rare scenario has no occurred yet, as the sequence in each study with randomization module has been analyzed to ensure

## **Improvements**

- ★ Publication of a eCRF has a faster UI response, so it shows immediately a modal dialog with the different steps in the publication. The modal dialog can be minimized, and will be shown in the page footer at all times during the publication process.
- ★ Some of the publication tasks have been parallelized, as long as they are independent one from another, to shorten the total time spent in the process.

it did not meet the conditions for the bug to happen.

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- ★ API cache implementation to improve overall performance in the operations of the eCRF application.
- ★ Refactoring of SDV update data process when publishing a new version of the eCRF or patient update, to speed up significantly the operation.
- ★ Optimization when publishing an new eCRF to precalculate hide rules for subvariables and remove entirely disabled rules, so API operations for updating a patient are improved.
- ★ Faster calculations on Set Value rules with formulas involved, as the identification of referred fields has been improved.
- ★ Optimized chained rule execution, avoiding the propagation of changes not involved in the triggered rules.

## **Known limitations**

- > 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.
- X 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.
- X 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

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- 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.
- 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.
- When publishing a new CRF version with data integrity, if there are existing fields marked as missing data, that in the new version become non-required, the publication report will show an updating error for these patients, without showing the field associated with this error properly.