Available for users on 2015-04-09

New functionality

List that

List of new functionality that has been added to this release.

SAS Export

The Viedoc export feature is now extended with support for SAS. The functionality becomes available after selecting CSV format and grouping the data by form. When selecting the option to include SAS script there will be a compressed zip archive created. The archive will contain study data files and script files. The script is utilized when importing the study data into SAS.

Formats

Format tables for selectable items such as checkboxes, radio buttons and drop downs are added to the release. The tables summarize all selectable items and provide the possibility to edit the name, data type and output export value of each item. Items with the same selectable options can be collected into format templates in order to streamline the output export values.

Design configuration report

An easy to read configuration report of the design is now possible to generate from the design overview page. The report gets displayed as a preview and can be saved in PDF format. The report will contain the entire study setup with information about:

- · Design settings and version/revision
- Languages
- Forms
- Workflow
- Roles
- Study settings
- · Edit checks

Updated functionality and bug fixes

List of new functionality that has been updated in this release.

Updated Functionality

Item metadata and code list values are now included in the export.

Bug Fixes

The following corrections have been implemented in this release of Viedoc:

- It is now possible to enter small negative decimal values (e.g. -0.2) without having to reinsert the negative sign.
- Double submission of revisions will no longer cause an error.
- It is no longer possible to create several revisions based on the same base revision.
- SDV export now show the output ID (if available) instead of the item ID.
- CSV export now contain ID's and Labels in correct format for queries and reviews.
- CSV export now have row breaks in correct place for queries and reviews.
- The same item; in different item groups; in different versions will no longer create duplicate columns in export.

Known limitations

List of limitations that have been found with this and earlier releases of Viedoc, and will be changed in future releases.

- The export preview feature is heavy to load and might cause the application to feel
 unresponsive
- Only one (selected) language can be imported from each CDISC ODM file
- Only one (selected) design can be imported from each CDISC ODM file
- When the study workflow is saved, the language in the design settings are lost and have to be reset
- Visibility conditions (entry conditions) cannot be set for activities in common events.
- The next and previous links may not correctly reflect the number of subject filtered in some instances. Going back to subject selection and re-selecting a patient solves the problem.
- Opening a form might fail in some instances when using IE 8.
- The PDFs generated as Empty CRFs will not display all code list items for radio and checkboxes if these have been configured with many code list items in a vertical layout.
- The code list tables for dropdowns are not displayed completely in the CRF PDF if the code list has many items.
- A field that is required for SDV but is hidden on a form (due to for example visibility conditions) cannot normally be marked as having been SDV;ed, but if the entire form is marked as having been SDV:ed then even hidden fields are included and marked as having been SDV:ed.
- When using the new patient table view some options default back to the patient card view, for example choosing the order of display, the site, or using the search capability. The user has to enter the table view again, but the option chosen is preserved and is then displayed correctly in the table view.
- The affected forms count summary shown in admin while applying a revision is implemented only for production site. Demo/Training site forms are not included in this summary count.
- Deletion of a common event is shown with the form name strike through instead of the summary format details.
- Using private designs will result in an error which requires a restart of the client.

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2015-03-31

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