Release Notes Viedoc 4.27

Available for users on 2016-06-16

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New functionality



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

Date & Time CRF item added

A new CRF item has been added to Designer. The new item is a combined Date & Time field. The reason for adding this combined Date & Time field is to allow different default settings (described below) for the Date field and the Date & Time field.

The ability to define default values for CRF items

Global design settings has been extended with a Field defaults section. Under this section designers are able to make their initial default settings for the design items used inside the forms. Just set the default values that shall apply for the different fields and publish the global design settings. Once published, the default settings will apply to a field when it is added to a form.

Fields that can have their default settings customized are:

- · The width of the Time field
- · The width of the Date field
- The width of the Date & Time field.

Extended export

The Export function in Viedoc has been extended with additional useful content.

Design version

For exports made in Excel and CSV the design version is included per form. This provides useful information when reviewing what design version was used for different forms. The design version is also available in the Export preview table as a system data parameter, i.e. visible when 'Exclude system data' is unchecked.

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New functionality



List of new functionality continues.

Event date table

For exports made in Excel and CSV the option to include event dates has been introduced. The option is available under the 'Type of data' section on the Export page. When this option is selected the start event together with scheduled and unscheduled events will be presented in a table, without taking any visibility conditions into account. The table will for each event show:

- Event id
- Event name
- Event state (uninitiated, initiated, planned, proposed)
- · Event date
- · Planned date
- · Proposed date
- · Window start date
- · Window end date

Unconfirmed missing data

The option 'Queries' on the Export page will also include all unconfirmed missing data. This is to align the exported content with the content of the Issue list in Viedoc.

Form pending upgrade

The option 'Queries' on the Export page will also include all forms pending upgrade. This is to align the exported content with the content of the Issue list in Viedoc.

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Updated Functionality

The following functionality has been updated in this release of Viedoc:

- · ViedocMe events are ordered by date.
- Subject key added to the ViedocMe account activation pdf.
- When exporting data belonging to different design versions, the data will be formatted
 according to the design version it was saved with and merged together based on item
 id when applicable. If merging is not possible the data will be exported as a new column.
 See example below:

Study design ver. 1	Study design ver. 2	Export output	Comment
Item: SEX Datatype: radio	Item: SEX Datatype: string	Column: SEX Datatype string Column: SEX_2 Datatype: radio	Merging not possible due to different data types
Item SEX Datatype: radio 1=male 2=female	Item: SEX Datatype: radio 1=female 2=male	Column: SEX Datatype: radio Column: SEX2 Datatype: radio	Merging not possible due to incompatible code lists *
Item: SEX Datatype: radio 0=N/A 1=male 2=female	Item: SEX Datatype: radio 1=male 2=female 3=N/A	Column: SEX Datatype: radio 0=N/A 1=male 2=female 3=N/A	Merging possible since the code lists are compatible

^{*} the code lists can be made compatible by changing the Output format of Item SEX in any of the two versions so that they match each other

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Bug Fixes

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

- Audit trail will now show 'Initial data entry' when entering data for the first time into an
 item that was added in a revision.
- Lock/Unlock studies will no longer result in an error message, which before was the case under specific circumstances.
- Performance for pdf generation in large studies has been improved.
- Re-generated pdf will now always be included in pdf export.
- Improved 'dirty check' on forms prevent saving the form when no data is changed.
- Queries raised by a Monitor as a result of rejecting the resolution of a system raised query will now be labeled as 'Raised by [username]'
- Form history will now correctly show when SDV and Data review were performed.
- Audit trail when deleting forms and events will now properly reflect the reason chosen for deletion.
- Forms with activity hidden items used in advanced visibility conditions are now possible to save.
- Uploading of medical coding dictionaries is now also possible to do in Firefox.
- Popup will be completely shown without scrollbars when adding a new medical coding scope.
- Large randomization lists (> 3000 rows) can now be uploaded without errors.
- The selection popup for Forms and items under Export will no longer show long label texts outside of the pop up.

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Known limitations



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

- 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 is lost and has
 to be reset
- The next and previous links may not correctly reflect the number of subjects 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.
- 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.
- Selection View settings (former Patient Card settings) is limited to 5 variables. Designs
 created in version 4.13 or earlier may have settings containing more than 5 variables.
 When importing such a design the variables 1-5 will be used and all other variable will
 be ignored.
- Validation of alerts, selection view settings and patient id generation settings for deleted items are not performed.
- Export preview with graph pages result in a Java script error on IE8.

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Known limitations



List of known limitations continues.

- Visit date form history will not be included in pdf export if no forms where filled in, or if forms where initiated from ViedocMe.
- When using Windows 7, file names added to the zip archive during PDF Export
 gets scrambled when they contain Unicode characters. The extracted file content
 is not affected by this. There is a Hotfix for Windows 7 available at: https://support.
 microsoft.com/en-us/kb/2704299 that addresses this issue.
- The PDFs generated at form save will be generated and stored based on the
 role visibility conditions applied to the user that last saved the form. E.g. items
 hidden to a user due to role visibility conditions will not be shown/included in the
 generated pdf.
- The Issue list will not be visible for sites that have more than 1000 subjects.

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Signoff



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