PCG Solutions

Release Notes
Viedoc 4.36

**Available for users on
2017-08-24**

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New functionality

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

Reference data

Reference data makes it easy to enter data shared by many subjects. It is possible to have centralized reference data for different data sources (the provider of the reference data values, such as a lab), that makes it possible to fill in only once the reference values and these will be automatically populated to the subject forms, instead of having to edit each subject form to enter the same reference values multiple times.

Setting up reference data is done in Viedoc Designer and Viedoc Admin. In Viedoc Clinic, the reference data values are entered/updated for each data source (the provider of the reference data values, such as a lab). The entered referenced data values are then automatically populated in the respective subject forms in Viedoc Clinic.

Range item

A new item type is available to be added to forms, for defining a range of values.

The following comparators are available for defining a value range:
- "-" – Inclusive in between
- "<" – Less than
- "≤" – Less than or equal to
- ">" – Greater than
- "≥" – Greater than or equal to
- "=" – Equal

Notes!

- The range item is not supported in subject initiated events (ViedocMe).
- The data mapping during import is not supported for range item.

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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:

- Export to Excel was crashing when having included uploaded files with the output label set. This is fixed now.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- The *Readme* file in the CSV export output had a .csv extension instead of .txt. This is fixed now.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- On a form in Viedoc Clinic, when alternating on performing changes manually, respectively through the API, the changes were shown in the form history in the following order: imported changes first, followed by the manually changes, regardless of the order the operations were performed. This is now fixed, and the changes displayed in the form history are now ordered first by item and then by change date and time.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- Changing the width of a file upload item in Viedoc Designer was not reflected accordingly in Viedoc Clinic. This is now fixed, so that the width of a file upload item is correctly shown in both Viedoc Clinic as well as in the form preview in Viedoc Designer.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- When applying a revision, all the forms were validated, causing the same edit check to be triggered multiple times if multiple revisions were applied. This is now fixed, and only forms affected by the applied revision are being checked, so that the edit checks are triggered only once.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- Some labels were not being translated in ViedocMe when selecting another language (than the default English). This is now fixed and all the labels are displayed in the selected language in ViedocMe.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

Updated functionality and bug fixes

List of bug fixes continues.

- When applying a new revision, in the subject details page, the "revision applied" message was replacing the reason for deletion for deleted subjects (this was though correctly stated in the audit trail). This is now fixed and, for deleted subjects, the displayed audit record will always be the reason for deletion.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- The "Print all forms" was not ordering the forms alphabetically. This is now fixed.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

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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:

- Visibility conditions in auto update forms are not evaluated automatically and thus items becoming hidden when executing auto update form functions will not be reset.

- Items set to hide always are not populated if they are a single item in an itemgroup.

- Uploading password protected zip files is not supported, as Viedoc is not able to scan these files for viruses.

- For security reasons, it is not allowed to upload executable files. The complete list of unsupported file types can be found in Viedoc 4.34 Release Notes document.

- Only one (selected) design can be imported from each CDISC ODM file.

- The PDFs generated as Empty CRFs will not display all code list items for radio buttons, dropdown menus and checkboxes if these have been configured with many code list items in a vertical layout.

- 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 verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.

- The affected forms count summary shown in admin while applying a study design is implemented only for production sites. Demo/Training site forms are not included in this summary count.

- Deletion of a common event is shown with the form name in strikethrough instead of the summary format details.

- Validation of alerts, selection view settings and patient ID generation settings for deleted items is not performed.

- The export preview with graph pages results in a Javascript error on Internet Explorer 8 on some instances.

- Visit date form history will not be included in PDF export if no forms were filled in, or if forms were initiated from ViedocMe.

- When using Windows 7, file names added to the zip archive during PDF export get 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.

Known limitations

(!) List of known limitations continues.

- The PDFs generated upon form save will be generated and stored based on the role visibility conditions applied to the user that last saved the form. Items that were hidden to the 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.

- The form history view does not display all form versions when bulk upgrade has been performed, however all form versions are correctly stored in the database.

- The task count includes tasks for hidden forms.

- The Issue list does not take role visibility into account.

- It is only possible to import values (choice numbers), not strings (choice labels), when importing data into data fields where multiple checkboxes can be checked.

- Edit checks are not triggered on dates when the event date is used as default value, and the calendar picker is used to choose the date.

- If additional languages are imported (to be used in ViedocMe) and after that code lists are combined via "Formats" (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2017-08-17

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