Release Notes
Viedoc 4.39

Available for users on 2018-01-25

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New functionality

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

Advanced event and activity scheduling

Viedoc Designer has been enhanced with the possibility to schedule recurring events and to set proposed time calculation for activities within subject initiated events.

This is described in the Viedoc eLearning in the *Study workflow* lesson, as well as the *Scheduling events* use case for the Viedoc Designer users and in the *Enter and edit data, and resolve queries* lesson for the Viedoc Clinic users.

Repeating forms

In Viedoc Designer it is possible to set a form as repeating at activity level, so that in Viedoc Clinic it is possible to add and fill in many instances of the same form.

This is described in the Viedoc eLearning in the *Study workflow* lesson, as well as the *Repeating forms* use case for the Viedoc Designer users and in the *Enter and edit data, and resolve queries* lesson for the Viedoc Clinic users.

Multiple reminders

Possibility to add multiple ViedocMe reminders in Viedoc Designer for the activities within subject initiated events. ViedocMe reminders can be set up to be sent out either on target date or a specified number of days before/after the target date.

This is described in the Viedoc eLearning in the *Study workflow* lesson.

Export and API using a specific Viedoc version data structure

For backwards compatibility, if there is a need for using the same structure as in a previous Viedoc version, it is possible to specify in Viedoc Admin which Viedoc version data structure to be used in export and by the API. For the new studies, the *Latest Viedoc version* should always be used.

The available Viedoc versions are only the ones where changes to the data structure were introduced and a specific description of each version can be found in the Viedoc eLearning, in the *Overview of Viedoc Admin* lesson.

Note! The new/updated lessons in the Viedoc eLearning are being published on the release date.

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Updated functionality and bug fixes

List of functionality and bug fixes that has been updated in this release.

Updated functionality

- Short and Long summary format – it is now possible to set both a short and a long summary format for the scheduled and unscheduled events in Viedoc Designer.

- Possibility to use $THIS when defining factors in Reference data scope.

Bug fixes

This section lists the bug that were fixed in this release, for each bug describing the following:

- Description of the bug, explaining how the system worked before the bug fix and how it is working after the issue was fixed.

- *Possible consequences for active studies*: This describes the impact the respective issue and/or the fix might have on active studies.

- *Check this in your study*: Depending on the possible consequences on active studies, if there are things to consider to be verified on existing data or configuration, this is described here. If there is no need for this, then this will be not applicable (N/A).

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

- Changes to Study Workflow were not being saved when clearing the visit window fields. This is now fixed.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- ViedocMe reminders were still being sent out even after the respective subject was deleted. This is fixed now.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- The ViedocMe reminder settings were available even for the Clinic events. This is now fixed, so that the ViedocMe reminders are available only for the subject initiated events.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- ViedocMe reminders were still being sent out even for deleted activities. This is now fixed.
  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.

- In some cases, text was truncated in the form history pdf. This is now fixed.
  Possible consequences for active studies: In the form history pdfs generated in Viedoc versions older than 4.39, the text in the end of the line might appear truncated if the text is too long.
  Check this in your study: N/A.

- Updates to the reference data source name performed in Viedoc Admin were not reflected in Viedoc Clinic, when running a study in demo mode. This is now fixed.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- In the pdf export output, the deleted visits for which the event date was cleared were shown with an incorrect date (0001-01-01). This is now fixed.
  Possible consequences for active studies: Deleted visits for which the event date was cleared are shown with the 0001-01-01 date in pdf archives for Viedoc versions older than 4.39.
  Check this in your study: N/A.

- The EventDate was not reflecting the current site time zone as set in Viedoc Admin, but was using UTC time instead, when used in the Study start event or Common events. This is now fixed, so that EventDate always reflects the current site time zone.
  Possible consequences for active studies: EventDate in functions used in Study start or Common events had the UTC time zone.
  Check this in your study: N/A.

- The date part of a time variable was not reflecting the current site time zone. This is why time comparison between two time variables was not consistent. This is now fixed.
  Possible consequences for active studies: If you have used time variables from different forms in functions/expressions, these might have returned a wrong result because the time variable from a different form than the current one would have had the UTC time zone, while the time variable in the current form had the current site time zone.
  Check this in your study: N/A.

- Selecting *Current date* when adding a subject from the selection pane was using the local computer time zone. This is now fixed, so that the current site time zone is being used.
  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 exporting a single form populated by using reference data, the reference data scope was not included in the excel/csv export output. This is now fixed.
  Possible consequences for active studies: Excel/csv files exported previous to Viedoc 4.39 release, with single forms with reference data, are missing the reference data scope information.
  Check this in your study: N/A.

- Export of reference data form(s) using one row per item output format was crashing. This is now fixed.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- Performing exports of large amount of data with the review status included was causing performance issues. This is now fixed.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- The design version shown in the footer of the Form history pdf was always the latest design version, regardless of the design used for the respective event according to the date when the event was initiated. This is now fixed, and the correct design version is shown.
  Possible consequences for active studies: Prior to Viedoc 4.39, the form history pdfs have always the latest effective design version printed in the footer, even if the event was initiated with another design version than the latest effective.
  Check this in your study: N/A.

- SAS import was failing if exported data contained forms that were populated using a reference data scope. This was due to the fact that the reference data scope GUID *(Globally Unique Identifier)* was included in the export output as column name. This is now fixed. The column name was changed to Scope_{ScopeID}.
  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:

- 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, event visibility, subject status condition, common event summary format and subject 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.

- The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (e.g. an OID defined as AE in design version 1 and ae in design version 2).

- Checkbox items with choices having long text set in Viedoc Designer might not be shown properly in Viedoc Clinic. The choice text might be truncated and not completely visible although it looks good in Viedoc Designer. The problem is also visible in the form preview in Viedoc Designer, which shows an identical form as what the users will see in Viedoc Clinic. Therefore, make sure you always check the form preview after designing a form to make sure that everything looks as expected.

- In Viedoc Clinic, on the subject selection page, the SDV task count, the green checkmark, as well as the issue list do not take into consideration role visibility, meaning that, if for example forms or items are hidden to that Viedoc Clinic role, it will still appear that there are tasks to be performed even if the user does not have access to perform those (due to visibility conditions).

- Labels are truncated to 200 characters when csv data is imported to SAS using the CSV2SAS macro.

Signoff

Signature Confirmation by the product owner.

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