Release Notes
Viedoc 4.41

**Available for users on
2018-04-24**

Updated functionality and bug fixes

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

Updated functionality

The following functionality updates were implemented in this release of Viedoc:

- The study lock report summary shows the number of training sites until the first production site is added. After that, it shows the number of production sites only.

- The phone number is now excluded from the roles and users pdf report.

- Event scheduling settings and repeating forms are now included in the study workflow pdf.

- The PDF export contains now only subjects/sites in demo mode or only subjects/sites in production mode, depending on which operation mode is set for the respective study (demo/production).

Bug fixes

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

- *Affected studies:* describes shortly which area(s) of Viedoc the bug is related to, so that it is easy to identify if any of your active studies is affected.

- *Bug description:* explains the issue that was fixed and how the system worked before the bug fix.

- *Consequences for your data:* describes the impact the respective issue and/or the fix might have on the existing data for active studies.

- *Check this in your study:* depending on the consequences for your data, 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:

- *Affected studies:* Not study specific, related to removing a user from an organization, see bug description below.
  Bug description: When a user was removed from the last organization it was assigned to, it is marked as deleted. Afterwards, when the user was invited again to a Viedoc study, a new account was created. After the bug fix, when a user is removed from the last organization, only the roles will be removed, but the account will still be active.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

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List of bug fixes continues.

- *Affected studies:* Studies where API is configured to retrieve data via GetClinicalData with the Viedoc version set to Latest Viedoc version was not working properly.
  Bug description: Using the GetClinicalData API method with the Viedoc version set to Latest Viedoc version (in the API settings) returned an error. This is now fixed.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Studies that contain ViedocMe forms with date items having "prevent dates after" set.
  Bug description: The PDF was generated with blank page (loading icon) when the ViedocMe form contained a date item with 'Prevent dates after' settings enabled. After the bug fix, the invalid PDFs will be removed, and new ones will be generated together with the first export performed.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Any studies could be affected.
  Bug description: At random(rare) scenarios, form content was not displayed in PDF archive export output. After the bug fix, the invalid PDFs will be removed, and new ones will be generated together with the first export performed.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Studies with deleted common events.
  Bug description: The deleted common events were shown with the form name in strikethrough instead of the summary format details. This is fixed, and the deleted common events are now shown with the summary format details.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* All studies, metrics on the landing page.
  Bug description: The percentage of the "Locked forms" shown on the landing page was using a positive rounding, meaning that for an actual value of 99.7%, a value of 100% was displayed. This is now fixed by using a negative rounding, so that for a value of 99.7%, a value of 99% will be displayed.
  Consequences for your data: No consequences on the data, only the way of displaying this on the landing page is changed.
  Check this in your study: N/A.

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✓ List of bug fixes continues.

- *Affected studies:* Studies where events were removed in a new design version.
  Bug description: In Viedoc Clinic, in the subjects listing, subject details page, reviewing and signing, as well as in the PDF export, if the event summary formats were used but the event was removed in a design version or revision, then the event could be shown without summary format (or name). After the bug fix, latest design version is used for summary formats if the event is present there, otherwise the event design version is used. Note that changing the event OID in a version/revision is the same as deleting the event (with the old OID) and creating a new event (with the new OID).
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Not study specific, related to form history stamp after a combination of bulk upgrade and apply revision.
  Bug description: When a form was edited after combination of bulk upgrade and apply revision, the form history stamp showed the bulk upgrade as apply revision.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Studies where a function used in a text field returns only white space.
  Bug description: When only whitespace was returned by a function and the function was executed via auto-update or apply revision, the respective field was not marked with the required error.
  Consequences for your data: No consequences on the data.
  Check this in your study: If your study is affected, please note that the behavior can be made consistent by manually saving the form.

- *Affected studies:* All studies in which private notes have been enabled for any clinic role.
  Bug description: It was not possible to add new private notes on study events.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Not study specific, related to the closed query reason in excel and ODM export.
  Bug description: The reason for closed queries was not shown correctly in the excel export output and was totally missing in the ODM export.
  Consequences for your data: No consequences on the data. However, the excel files exported prior to Viedoc version 4.41 have a wrong QueryResolution for the QueryClosed state.
  Check this in your study: N/A.

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List of bug fixes continues.

- *Affected studies:* Studies with planned events containing hidden forms.
  Bug description: When applying a revision on planned study events that were not initiated and that contained hidden forms in the design, the revision threw an exception and did not complete successfully. The status got stuck to "In progress".
  Consequences for your data: No consequences on the data. The revision application failed and would need to be re-initiated.
  Check this in your study: If you have used hidden forms and have non-completed revision applications.

- *Affected studies:* Not study specific, related to edit and save forms, see bug description below.
  Bug description: In rare scenarios, when double clicking quickly on Save button for a form or when the browser was resending the request at same time, a form duplicate was created.
  Consequences for your data: Form duplicates might have been created.
  Check this in your study: If you encounter duplicate forms, please contact your Viedoc representative for further support.

- *Affected studies:* Not study specific.
  Bug description: When the summary format that was displayed in Viedoc Clinic in the form header, event, common events listing, notes, signing, data review, was resulting in a long text, it was using several lines and rendered some of the buttons unusable. The summary format is now truncated, if needed.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Studies where recurring events are used and when API/ GetClinicalData was used with IncludeVisitDates option, or ODM export.
  Bug description: StudyEventRepeatKey was missing for recurring scheduled events in the ODM export and API/GetClinicalData.
  Consequences for your data: No consequences on the data.
  Check this in your study: If your study is affected and your study is integrated with other systems, check how StudyEventRepeatKey is interpreted.

- *Affected studies:* Studies where the same form used within an activity for which the randomization was active was also used in a different activity which did not require randomization.
  Bug description: When the same form used within an activity for which the randomization was active was also used in a different activity which did not require randomization, the "Randomize" button appeared on the form even in the non-randomized activity, making it impossible to manually edit the form.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

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List of bug fixes continues.

- *Affected studies:* Not study specific.
  Bug description: Error label was missing in User Settings page in Safari web browser, when trying to set as primary an email address which already is used as primary and when activating the "phone can receive text messages" option with no phone number provided.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Studies with alert emails that contain special characters in the message body.
  Bug description: Special characters were not supported in the alert email messages.
  Consequences for your data: No consequences on the data.
  Check this in your study: N/A.

- *Affected studies:* Studies where API is configured to retrive data via GetClinicalData, as well as ODM export.
  Bug description: StudyEventRepeatKey attribute in StudyEventData element was included even though the study event was not recurring (having a value of "1" for the non-recurring events) for Viedoc versions 4.39 and 4.40.
  Consequences for your data: No consequences on the data. In ODM exports performed in Viedoc versions 4.39 and 4.40, StudyEventData element had the StudyEventRepeatKey set to "1", even though it was not a recurring event. From Viedoc version 4.41 and onward the StudyEventRepeatKey is not included in the ODM export or API configuration for the events that are not recurring.
  Check this in your study: If your study is integrated with API and accessing data via GetClinicalData API function or ODM export is integrated with other systems.

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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.

- 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.

- 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.

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⚠ List of known limitations continues.

- 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.

- Fully PDF/A compliant archives are only supported if all the included form/study event pdfs were generated on or after 2017-03-10 (Viedoc 4.33). Generating PDF/A compliant archives that contain form/study event pdfs generated before this date will still work but might have warnings related to transparency.

- In the PDF/A export output, the header, footer and the text on the respective Contents page are missing for the deleted forms/events/subjects.

- Using $THIS in in any type of expressions inside a form to refer to an item within the same form but a different activity within the current event always refers to the same form instance where the function is executed, i.e. the current activity.

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2018-04-16

Andreas Hedlund

PCG Solutions