

Release Notes

Viedoc 4.40

Available for users on
2018-03-15

Release Notes

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New functionality



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

Two-factor authentication

Possibility to use two-factor authentication. Two-factor authentication is a method for strengthening the security. In addition to the username and password, the user is required to provide a 6-digit code that is sent from the system during the login process. The code is sent either by email or SMS, according to the user settings.

This is described in the Viedoc eLearning in the *Introduction to Viedoc Clinic* lesson.

Multiple email addresses for a user

Possibility for a user to add up to 3 additional email addresses, except for the primary email address (used for login). It is possible to change the primary email address to one of the existing secondary email addresses.

This is described in the Viedoc eLearning in the *Introduction to Viedoc Clinic* lesson.

New system role – API Manager

A new system role is added – the API Manager is the only role who has the right to perform the API configurations. This was previously a part of the Study Manager role. The Study Manager must invite as API Manager the user who is responsible for managing the API configurations for the respective study.

This is described in the Viedoc eLearning in the *Introduction to Viedoc Admin* lesson.

Option to export to PDF in FDA compliant format

It is possible to have the PDF export output structured according to eCTD format specified by FDA. The eCTD format provides a structure where the CRFs are ordered twice, by visit/workflow and by domain.

This is described in the Viedoc eLearning in the *Data export* lesson.

Option to export PDF/A compliant archive

It is possible to have the PDF export output in a PDF/A compliant format. The PDF/A is a standardized format specialized for long-term preservation of electronic documents.

This is described in the Viedoc eLearning in the *Data export* 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

- A new section is added to the User and roles pdf report – 4. *User account logs*, containing the change history of all user accounts included in the report.

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*: All studies using numeric items where decimals are allowed.
Bug description: Editing a numeric field by adding decimal zeros were not saved (e.g. change 50.1 to 50.10 would still store 50.1). The bug did not affect initial data entry nor any other change other than trailing zeros after the decimal point.
Consequences for your data: Trailing added decimal zeroes were not saved during form edit.
Check this in your study: Export your data and review the data for numeric items for which more than 1 decimal is allowed. In case the number of decimals is not correct, this needs to be manually corrected.

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List of bug fixes continues.

- **Affected studies:** Studies having saved forms for which the design has workflow hidden items that are made visible in a revision.
Bug description: Entering data for any item made visible in the revision and re-saving the form did save the data, but, when opening the form, the items made visible were still hidden in view mode. However, the data was visible in edit mode and also available in the Excel, CSV and ODM export.
Consequences for your data: No effects on the data. The PDFs for the above mentioned forms have hidden items, but the values are shown in the audit trail.
Check this in your study: If your study was affected, you have been/will be contacted by a Viedoc representative.
- **Affected studies:** Studies in which designs have been revised with changes not requiring investigator confirmation that contain changes to item validation (Required/Optional).
Bug description:
Case 1 - After changing an item from required to optional and applying a revision, the form is still marked with x items required for items that were previously required and had no value.
Case 2 - After changing an item from optional to required and applying a revision, the form is not marked with x items required for items that were previously optional and had no value.
Consequences for your data:
Case 1 - You have forms that are marked with errors, although no required items in the form.
Case 2 - You have forms that are not marked with errors and have a green check mark, although they now contain required items with no value..
Check this in your study: If your study was affected, you have been/will be contacted by a Viedoc representative.
- **Affected studies:** Not study specific. The bug affects forms that has been reset and re-initiated.
Bug description: Forms that had been reset at least once and re-initiated before Viedoc 4.39 release were displayed without form name after the release. The bug only affected form names in the details view. Form names were displayed correctly when opening the form in view mode.
Consequences for your data: No effects on the data.
Check this in your study: You will notice the effects of the bug if you had any forms that were reset and re-initiated. However, the bugfix will restore everything as normal. No further action needed.

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List of bug fixes continues.

- **Affected studies:** Studies in which the IDF dictionary has been imported into Viedoc.
Bug description: There were issues with importing certain items from the IDF dictionary.
Consequences for your data: The IDF dictionary must be re-imported and the items that were causing import issues must be re-coded using the newly imported IDF dictionary.
Check this in your study: If your study was affected, you have been/will be contacted by a Viedoc representative.
- **Affected studies:** Studies where exports are performed using Viedoc export version 4.38 and using one row per subject.
Bug description: The ID value was accidentally changed in the export output to use <FormRepeatKey> instead of the <ActivityDefId>, i.e. to use <StudyEventDefId>.< FormRepeatKey >.<ItemDefId> instead of <StudyEventDefId>.<ActivityDefId>.<ItemDefId>.
Consequences for your data: If your study is using exports with one row per subject and Viedoc export version 4.38, then the ID header was changed in Viedoc release 4.39, according to the bug description above. Only the header row had problems, all the data was correct.
Check this in your study: If you've performed one row per subject exports using the Viedoc export version 4.38 you might have noticed that the ID header contained the FormRepeatKey instead of the ActivityDefId. This is fixed in future exports.
- **Affected studies:** Those studies running sites in Demo/Training mode.
Bug description: The gender icon on unscheduled events (common events) log was incorrectly displayed for studies running in demo mode.
Consequences for your data: No effects on the data.
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.
- 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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Known limitations



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.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2018-06-15

A handwritten signature in blue ink, appearing to read "Andreas Hedlund".

Andreas Hedlund

PCG Solutions