

Release Notes

Viedoc 4.32

Available for users on
2017-01-29

Release Notes

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New functionality



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

Export to CDISC ODM

Viedoc 4.32 release adds an improvement of the export to CDISC ODM. Export to CDISC ODM format will now also include all data queries, the data review status information for each item and the medical coding.

Fetch clinical data through the API

The clinical data that are fetched through the API in ODM format will now be extended with data queries, data review status information for each item and medical coding.

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Updated functionality

- Faster handling of large numbers of log forms:
Viedoc 4.32 release adds support for faster handling of large numbers of log forms. This results in an improved responsiveness of the patient details page, even if the patient data comprise a large number of log forms.
- Export data to SAS:
The CSV2SAS macro has been updated to enable the use of the terms “high”, “low”, or “other” in code lists, without them being recognized as SAS key words when creating SAS formats for these code lists.

Bug fixes

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

- The ODM export will no longer contain item data with value ‘IsNull = true’, or item data of which the value is confirmed as missing or the value is cleared. **This is a breaking change!**
Possible consequences for active studies: Items that do not contain data will no longer be present in the data export to CDISC ODM format.
Check this in your study: No need to check anything in your study.
- All alert messages will now be delivered, even if the alert message is triggered by a form item that is used in multiple activities within the same visit.
Possible consequences for active studies: Previously, alerts were evaluated and triggered based on the first time a form was saved within one of the activities in a single visit. Now, alerts will be evaluated and triggered for each saved form separately, even if the same form is used multiple times within one visit.
Check this in your study: You are only affected if your study design uses the same form in multiple activities within a single visit. For example, you are affected if you have set the alert \$THIS.VS.YN == 1 in the vital signs (VS) form, and the VS form is used in multiple activities within one visit.
Important: All studies have been checked, and affected clients have been notified. If you have not been notified, the bug fix does not affect your study.
- When selecting dates around the change of the month, the date picker will now select the correct date.
Possible consequences for active studies: The bug fix only affects new date selections, and has no consequences for already existing data.
Check this in your study: No need to check anything in your study.

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Updated functionality and bug fixes



List of bug fixes continues.

- System site groups will now also be created if the first sites are added to the study via the import of an ODM file in Viedoc Admin.
Possible consequences for active studies: If all sites in your study are created via the import of an ODM file in Viedoc Admin before the release of Viedoc 4.32, no system sites groups have been created. One solution to create the system site groups is to re-import the ODM file in your study after the release of Viedoc 4.32. Another solution is to manually create one random site in training mode, Viedoc will then automatically create all system site groups.
Check this in your study: You can check for the existence of system site groups in your study as follows:
 1. In Viedoc Admin, open the study crew window and go to the **Add study users** tab.
 2. Enter your own e-mail address, select a clinic role (for example investigator) and click the **Select site** field to open the drop down menu for site selection.
 3. If system site groups are created in your study, you should see the system site groups in the drop down menu.
 4. Close the window to cancel any changes.
- New Viedoc users that were invited to a study by inviting them to the 'All sites' system site group are now also listed in the study crew list in Viedoc Admin.
Possible consequences for active studies: No consequences for active studies.
Check this in your study: No need to check anything in your study.
- Invitation e-mails now always display the name of existing users in the opening. For new users, the opening will say 'Dear Viedoc user'.
Possible consequences for active studies: No consequences for active studies.
Check this in your study: No need to check anything in your study.
- Clinical data export from Viedoc Clinic and through API will now give a date stamp that includes the time zone.
Possible consequences for active studies: When exporting to ODM, dates in Coordinated Universal Time (UTC) will now have a "Z" appended to indicate that the date is in UTC. This will not have any consequences for active studies.
Check this in your study: No need to check anything in your study.
- When applying medical coding for multiple terms at once, the codes will now be applied in the correct sequence.
Possible consequences for active studies: No consequences for active studies.
Check this in your study: No need to check anything in your study.

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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.
- 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 result 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.
- When switching the study design language from the default English to any other language in the middle of study setup, for example after some forms have already been designed, the study design will remain in an inconsistent state.
- 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.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2017-01-19

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

Andreas Hedlund

PCG Solutions