

Release Notes

Viedoc 4.31

Available for users on
2016-12-12

Release Notes

Viedoc 4.31

New functionality



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

Automatic creation of groups of sites

Viedoc 4.31 release adds support for the automatic creation of groups of sites for easier assignment of users. When sites are added, the following site groups will automatically be created:

- All sites
- All production sites
- Country-specific groups to which all production sites in that country will automatically be added.

This enables the study manager to administer user role assignments of all sites within a group at once. Also, when sites will be added to the group at a later time, all users within that group will automatically receive instant access to the newly added site.

Reference ID

In Viedoc Admin, the study manager can now enter a reference ID for each study. The reference ID is connected to the study license, and can be found on the signed study work order (WO). Upon entry in Viedoc, the reference ID will be verified, and, if valid, the text “Valid license key” will be indicated.

Important information: A study for which the reference ID is invalid or missing can be continued in Viedoc as usual, but it will be clearly highlighted that the study is running without a valid license key. It is the responsibility of the study manager to enter the reference ID in the study settings page at study start-up. Information about the reference ID of your study is provided by your contact at PCG Solutions AB.

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Updated functionality

- In Viedoc Clinic, the Roles page and the user role log, including the downloadable PDF report of users and roles, now include the system site groups and the Dictionary manager role. Both the date when access was given and the date when access was revoked are displayed in the data change log.
- In Viedoc Admin, the 'All sites'-shortcut that appeared in the 'Study crew' window when inviting users to the study has been replaced with the system site group 'All sites'. This is a breaking change. The 'All sites'-shortcut only included the current sites in the study, whereas the new system site group 'All sites' will include all current sites and all sites that will be added to the study at a later time.
- The installation package for the Viedoc 4 Data Import Application that is available for download in Viedoc Designer will be replaced with a zip-file that contains all files needed to run the Data Import Application. When the zip-file is downloaded, it can be extracted at any location on the computer. The Viedoc 4 Data Import Application can then be run directly from that location without the need for an additional installation step.

Bug fixes

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

- It is now possible to import data into a study using a subject key in which the country code, the site code, and the subject sequence number are not separated by hyphens. However, the data import cannot create new subjects using a subject key that lacks hyphens, unless the exact length of the country code, the site code and the subject sequence number are specified in the subject ID generation settings in Viedoc Designer.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: Only when performing a data import: check whether the number of characters of the country code, the site code and the subject sequence number in the subject key is in line with the number of characters specified in the subject ID generation settings in Viedoc Designer.
- Alert notification e-mails will no longer contain undesired attachments.
Possible consequences for active studies: N/A.
Check this in your study: N/A.

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Updated functionality and bug fixes



List of bug fixes continues.

- Item units that were added or edited in a new design version or revision will no longer be mixed up with units that already existed in the design.
Possible consequences for active studies: If you have added or edited an item unit in Viedoc 4.30, you may have experienced that the changes were not reflected in the design. In that case, you should add or edit the same item unit again in Viedoc 4.31. If you have not done any changes to units in Viedoc 4.30, or not experienced any problems with editing units, there are no consequences for your study.
Check this in your study: If you added or edited any item units in your study design since the release of Viedoc 4.30, you should manually review the units in your design in Viedoc Designer.
- The user role log in Viedoc Clinic now displays the correct dates when role changes became effective. The displayed dates now reflect the date when the user was given access to that specific role, and, if applicable, the date when the access was revoked.
Possible consequences for active studies: N/A.
Check this in your study: N/A.
- Medical coding values applied using MedDRA-J will now display the correct code in all instances.
Possible consequences for active studies: N/A.
Check this in your study: N/A.
- The PDF report of users and roles will no longer include users that are not yet activated.
Possible consequences for active studies: N/A.
Check this in your study: N/A.
- The subject card variables will always be updated after each form save, so that the correct status of the subject is reflected in the subject card at any time
Possible consequences: This only affects studies where the variables displayed on the subject card are populated from a visit form.
Check this in your study: If the subject card variables are populated from a visit form, check whether the variables are displayed correctly. Subject cards with incorrect variables will be correctly updated upon the next form save.
- The displayed values for 'last edited by' and 'last edited date' of event dates in the export are now shown correctly, even when a revision has been applied to the study event.
Possible consequences for active studies: N/A.
Check this in your study: N/A.

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List of bug fixes continues.

- Changes to a code list are now correctly saved, even when the item code list has a SAS format name.
Possible consequences for active studies: N/A.
Check this in your study: N/A.
- The labels for code lists created in Viedoc Designer will now be included in the ODM export, even if a language other than English is used.
Possible consequences for active studies: N/A.
Check this in your study: If you have created a study design of which the language is not English, and you have exported that design to ODM, and re-imported it, your study may be affected. Check if any of the imported code list labels are incorrect or missing.

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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 SDV:ed, but if the entire form is marked as having been SDV:ed then even hidden fields are included and marked as having been SDV:ed.
- The affected forms count summary shown in admin while applying a revision is implemented only for production site. Demo/Training site forms are not included in this summary count.
- Deletion of a common event is shown with the form name strike through instead of the summary format details.
- Validation of alerts, selection view settings and patient ID generation settings for deleted items is not performed.
- 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. For example, items that were hidden to a user due to role visibility conditions will not be shown/ included in the generated pdf.

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Known limitations



List of known limitations continues.

- The Issue list will not be visible for sites that have more than 1000 subjects.
- Alerts will only be triggered on the first initiated form within an event if that form occurs more than once in the event. The workaround is to specify the activities in the alert condition.
- 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.
- 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, will leave the study design 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.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2016-12-05

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PCG Solutions