

# Release Notes

## Viedoc 4.19

Available for users on  
2015-10-22

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### New functionality



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

#### PDF Export

In version 4.19 the export feature is extended with yet a new format. This time it is pdf format that is introduced. The export will create a zip archive that contains one pdf file for each site in the study. All subjects including deleted ones are included with visits and filled in forms.

There's one option that can be applied to pdf export and that is to exclude any deleted subject, visits and forms from the pdf export. If this option is selected it will be clearly indicated on the first page of each document that deleted items were excluded from the export.

The pdf export will override options such as site, subject or item selection, and no filters can be applied in export. Instead it will create a total export of the study.

**Note:** Since the pdf export adds all study data to the files it is a time consuming operation. While the zip archive is being created it is indicated with 'In queue' in the Latest Exports list.

#### Roles listing

The Roles listing feature provides full transparency when it comes to roles, users, and who has contributed with data to the studies you have access to.

Roles listing is accessible via a button on the study overview page. The Roles page base all information on the currently logged in user, showing only information about studies and sites that the user has access to.

The roles listing shows the roles that the current user holds within the scope of the selected site(s). It is also possible to launch the study with a specific role.

It also shows all roles that exist in the scope of the selected site(s). Information of the number of users holding a role is given and an informative log over users that currently hold or previously have held the specific role can be viewed. Information is also shown about the accesses granted and revoked as well as useful statistics about Viedoc sessions and how much data the user entered.

**Note:** The session count will start counting from this release, information about earlier sessions in earlier releases is not included.

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### New functionality



List of new functionality continues.

#### **Delete subject**

Subjects that were added by mistake can now be deleted from the study, leaving a clear audit trail behind.

To prevent deletion by mistake the deletion of a subject is by purpose hidden inside the Study start form (Add subject form). Deletion consists of four steps: press delete, confirm deletion, give a reason and finally sign off with your password.

Existing users will have to update their role with the permission 'Delete subjects', while users in new studies that are assigned a role with edit/write permission will have the permission to delete subjects set by default.

Information about the deleted subjects, visits and forms can be viewed in a read-only mode.

#### **Delete unscheduled visit**

Unscheduled visits added by mistake can be deleted from the subject, leaving a clear audit trail behind.

Deletion of an unscheduled visit is done from inside the Visit Date form. The deletion possibility will only be available for visits without any entered data. Forms that have entered data must be reset before the visit can be deleted. The action will require a reason for deleting the visit. It will still be possible to select and view a deleted visit and the forms that eventually were reset in read-only mode.

The same permission is needed for deletion of unscheduled visits as to reset forms.

#### **Reset scheduled visit**

Scheduled visits planned or initiated by mistake can be reset but never removed from the visit schedule. Reset visits contain a clear audit trail.

Reset of a scheduled visit is done from inside the Visit Date form. The reset possibility will only be available for visits without any entered data and forms that have entered data must be reset before the visit can be deleted, in the same way as for unscheduled visits. The reset action will also require the user to give a reason for reset. A reset visit will not go away, it will go back to an unplanned state from where it can later on be planned again.

The same permission is needed to reset scheduled visits as to reset forms.

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### Updated functionality and bug fixes



List of functionality that has been updated in this release.

#### Updated Functionality

- The Subject Status now include three fields where Java script conditions can be expressed for the three different statuses Enrolled, Completed and Withdrawn. Settings made in previous releases will still be valid and shown as a Java script condition.
- Patient Id Generation Settings has been renamed to Subject Id Generation Settings.
- Reset/Delete forms permission has been renamed to Reset/Delete events and forms.
- Visit date form now include a Form history link similar to any other form.

#### Bug Fixes

- The locked subject info bar will no longer be shown in the PDF's that are generated when a new revision is applied.
- The PDF that is generated when a form is reset will now show who, when and why.
- The reason for changing a field can be expressed with free text, when that text is written as a long sentence it will now be fully shown in PDF's.
- The built in check for required number of characters now show correct error messages.
- Security question now show correct again.

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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.

- Only one (selected) language can be imported from each CDISC ODM file
- Only one (selected) design can be imported from each CDISC ODM file
- When the study workflow is saved, the language in the design settings is lost and has to be reset
- Visibility conditions (entry conditions) cannot be set for activities in common events.
- The next and previous links may not correctly reflect the number of subjects filtered in some instances. Going back to subject selection and re-selecting a patient solves the problem.
- Opening a form might fail in some instances when using IE 8.
- The PDFs generated as Empty CRFs will not display all code list items for radio and checkboxes if these have been configured with many code list items in a vertical layout.
- The code list tables for dropdowns are not displayed completely in the CRF PDF if the code list has many items.
- 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.
- Selection View settings (former Patient Card settings) is limited to 5 variables. Designs created in version 4.13 or earlier may have settings containing more than 5 variables. When importing such a design the variables 1-5 will be used and all other variable will be ignored.
- Validation of alerts, selection view settings and patient id generation settings for deleted items are not performed.
- Export preview with graph pages result in a Java script error on IE8.
- Visit date form history will not be included in pdf export if no forms where filled in, or if forms where initiated from ViedocMe.
- When using Windows 7, file names added to the zip archive during PDF Export gets 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.

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### Signoff



Signature Confirmation by  
the product owner.

**Uppsala, Sweden 2015-10-15**

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PCG Solutions