**PCG** Solutions

# Release Notes
# Viedoc 4.30

## Available for users on 2016-11-17

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# New functionality

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

**Support for data import**

Viedoc 4.30 release adds support for the import of data, for example laboratory data, into Viedoc 4 via the Viedoc 4 Data Import Application. The application converts the data into CDISC ODM clinical data format using a data mapping file, and pushes the data into Viedoc 4 through the Viedoc 4 API.

The import of data requires a data mapping file that can be created in Viedoc Designer. The data mapping file defines how the external data will be translated into data in Viedoc 4. Internally, the data mapping will be stored in CDISC Define-XML format. It is possible to create multiple data mapping files per study. A date mapping file can be re-used by uploading it from one study into another study.

The data import also requires an API client key that can be created in Viedoc Admin. The status of the import can be monitored in Viedoc Admin, where date and time of the import, the user who imported the data, the status of the import and a log file can be viewed.

The data import application supports the import of data in both short-fat and tall-skinny formats. The data should be provided in a comma-separated value (CSV)-file.

It is possible to allow new subjects to be created and visits to be initiated via the import of data. Data can be imported into unscheduled and common events as well.

For more information on how to use the Viedoc 4 Data Import Application, see the *Viedoc 4 Data Import Application document*. The *Viedoc 4 Data Import Application document* is available on request, please contact PCG Solutions AB.

# Updated functionality and bug fixes

List of functionality that has been updated in this release.

**Updates not related to Viedoc functionality**

The definition of e-signature as used in Viedoc 4 has been described in the eLearning.

**Updated functionality**

- In Viedoc Admin, a new system role 'Dictionary manager' has been added that can manage the medical coding dictionaries. This is a breaking change. From this release on, only the Dictionary manager can upload medical coding dictionaries using the *'Medical coding. Manage your coding dictionaries here'* function. The Study Manager has no longer access to this function.

- In Viedoc Clinic, the SDV now breaks when a new version or revision of the study design is applied, so that the review status reflects which data were affected by the design change and thus should be reviewed again.
  The SDV for individual items breaks when
    - the measurement unit is changed,
    - the field label is changed, or
    - the options are changed.
  The SDV on all items within an item group breaks when
    - the group label is changed,
    - the static text in a group is changed, or
    - the order of items is changed.

- When exporting data from Viedoc Clinic, it is now possible to include the 'Edit status' of the data in the export. The Excel file with exported data will then include the following information for each form (note that these columns are included in the middle of each sheet, not at the end):
    - InitiatedBy
    - InitiatedDate
    - LastEditedBy
    - LastEditedDate

- The list of countries in Viedoc has been completed according to the ISO-3166 standard. All countries in this standard are now available and listed with two-letter codes.

- All e-mails from Viedoc are now based on the Viedoc e-mail template, and will have the recognizable Viedoc look and feel.

# Updated functionality and bug fixes

✅ List of functionality that has been updated continues.

- A breaking change has been made with regards to Alert emails. Separate e-mails will be sent to all users assigned to the roles that are specified in the To: field. Users assigned to roles specified in the CC: field will receive a separate copy of each e-mail.

**Bug fixes**

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

- When designing forms in Viedoc Designer, it is now possible to remove an existing measurement unit.
  *Possible consequences for active studies:* No consequences.
  *Check this in your study:* N/A.

- The lock checkbox on ViedocMe forms and ViedocMe events has been removed.
  *Possible consequences for active studies:* The lock checkbox is no longer visible on ViedocMe forms and ViedocMe events.
  *Check this in your study:* N/A

- ViedocMe events can no longer be unlocked by a monitor.
  *Possible consequences for active studies:* Monitors can no longer unlock events that were created through ViedocMe.
  *Check this in your study:* N/A

- Unscheduled events that have been deleted from a revision of the latest effective design will no longer be selectable in Viedoc Clinic.
  *Possible consequences for active studies:* Unscheduled events that had been deleted in a design revision, but that still could be selected in Viedoc Clinic, will no longer be visible in Viedoc Clinic and can no longer be selected.
  *Check this in your study:* Check whether you have deleted any unscheduled events in any revision of the latest effective design.

- The effective designs per site on the Design settings window in Viedoc Admin now shows the correct design version for each individual site.
  *Possible consequences for active studies:* No consequences
  *Check this in your study:* N/A

# Updated functionality and bug fixes

List of bug fixes continues.

- PDFs will be created for all form saves, even when multiple saves are performed within one second. This is only applicable when data will be sent through the API.
  *Possible consequences for active studies:* The form PDFs will have a longer file name that includes the exact date and time of creation down to milliseconds.
  An example of an old file name for a form PDF is 239734.20161109130357, an example of a new file name is 239734.20161109130357**997**.
  *Check this in your study:* N/A

- During manual or bulk upgrade of forms, all hidden functions (functions that are not visible for certain roles) will be executed and the resulting values will be stored, even if the form upgrade was performed by a user that does not have visibility rights for those hidden functions.
  *Possible consequences:* If a newly applied revision contains any new or edited functions, these functions will be executed and the resulting values will be stored upon manual or bulk upgrade. This occurs even if the role visibility conditions for the functions are set in such a way that the user performing the upgrade cannot see these hidden functions. If the user performing the upgrade does not have visibility rights for these hidden functions, the audit record will display that the value was changed by the system, not by the user performing the upgrade.
  *Check this in your study:* N/A.

- When submitting data through the API, it is now possible to execute a series of functions, i.e., functions that depend on variables that were calculated in earlier functions.
  *Possible consequences for active studies:* The complete series of functions will now be executed when data are submitted through the API.
  *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:

- 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 where filled in, or if forms where 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.

- 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.

- 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.

- Permissions in the user role log are displayed based on the effective design date instead of the date when the design was applied.

- 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.

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