Release Notes
Viedoc 4.37

Available for users on 2017-10-09

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New functionality

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

Alerts and trackers

A new version of alerts is in use starting with Viedoc version 4.37. It is possible to configure notification messages and emails to be sent out when a certain defined condition turns true/false in conjunction with a selected context form (the form where the condition is evaluated).

Notes!

- Alerts created in Viedoc versions prior to 4.37 are keeping the old functionality. The context form is not being used for the alerts defined in Viedoc versions older than 4.37. By specifying a context form for an existing (old version) alert, the alert will be considered as a new one and will not be in an active state until the context form is edited and saved in Viedoc Clinic. Note also that no false or tracker action messages will be sent until the alert becomes active.
- You can still keep the "old" alert and continue to use it in the same way by not setting any context form for it. You can update the condition or the message settings for it.
- Once a context form is set and the alert is saved, this becomes a new alert and there is no way to revert to the old version (prior to 4.37).

It is also possible to track changes that are being performed on the selected forms and items, if they exist within the event where the alert was initially triggered or within the study start event. You can choose to include table of changes in the message body, providing information about the tracked item(s) that were changed and caused the notification message to be sent out (the change date and time, the form and item that was changed, the old value and the new value).

Notes!

- The forms and items available to be selected for tracking are the ones in the current design.
- It is not possible to track changes on items located in a hidden form.

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Updated functionality and bug fixes

List of functionality that has been updated in this release.

Updated functionality

- Medical coding – improved search options. There are three search options available to choose from: *Contains, Begins with* and *Exact match*. In those cases where you use the WHO DD dictionary, you have the option to choose if you want to search by: *Drugs or Active ingredients*.

- Medical coding – active ingredients are displayed for each drug in the search field, in WHO DD dictionary.

- Medical coding – preferred and drug name are included in the export for WHO DD dictionary.

- In Viedoc Clinic, if a subject is being locked for editing by another user, this is marked on the subject card with the username and user ID of the user who has locked the subject.

- Option to prevent entering a future date for the date item, as a system check under the validation tab of a date item in Viedoc Designer. It is possible to configure the date item to restrict entering a date in Viedoc Clinic that is after the respective *Event date* or after the *Current clinic date*.

- Option to include/exclude the subject initiated events in the visit overview page in Viedoc Clinic.

- System checks are summarized and displayed under Outputs and validation > Edit checks.

- VAS scale item settings to be used when configuring the VAS for the EQ5D questionnaire.

- Max file size for the file upload is now 512 MB.

Non-functional updates

- Medical coding – updated disclaimer to: *"By uploading a file you confirm you have a valid license and understand all regulations of use for each applicable dictionary. By confirming here it is also understood that file usage information may be supplied to dictionary vendors upon request"*.

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Updated functionality and bug fixes

List of bug fixes.

Bug fixes

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

- Alerts were not being sent out when the trigger was set through API. This is now fixed for the alerts created in version 4.37 or later. The problem still remains for the old alerts created before version 4.37 (without a context form set).
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- The SubjectKey in alerts did not show in the alert message when it was composed of a "patient information" variable. This is fixed now.
  Possible consequences for active studies: This does not affect active studies.
  Check this in your study: N/A.

- When linking a reference data source to 'All sites', this was not including the sites in demo mode. This is fixed now.
  Possible consequences for active studies: This does not affect active studies.
  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:

- Visibility conditions in auto update forms are not evaluated automatically and thus items becoming hidden when executing auto update form functions will not be reset.

- Items set to hide always are not populated if they are a single item in an itemgroup.

- 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 and patient 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.

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Known limitations

! List of known limitations continues.

- 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.

- 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).

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2017-10-05

Andreas Hedlund

PCG Solutions