PCG Solutions

Release Notes
Viedoc 4.16

Available for users on 2015-07-02

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New functionality

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

Metrics

Metrics provide means for monitoring key parameters in order to apply risk based monitoring. The first step towards providing study metrics was added to this release. The metrics overview page is reached by clicking the Metrics button on the landing page. The page shows three high level metrics:

Open queries

The number of currently open (not resolved) queries are shown. A column graph shows five bars indicating the progress of posted queries during the last five weeks, where each bar indicates a seven day period. The latest seven days including today are shown in orange, other weeks are grey. A percentage indicator is also displayed to indicate the trend between the current week and the previous week.

Query rate

The current query rate (# queries / # subjects) is shown. A column graph shows five bars indicating changes to the query rate during the last five weeks, where each bar indicates a seven day period. The latest seven days including today are shown in orange, other weeks are grey. A percentage indicator is also displayed to indicate the trend between the current week and the previous week.

Unconfirmed missing data

The amount of unconfirmed missing data is shown. A column graph shows five bars indicating the changes to the missing data rate during the last five weeks, where each bar indicates a seven day period. The latest seven days including today are shown in orange, other weeks are grey. A percentage indicator is also displayed to indicate the trend between the current week and the previous week. A ring graph shows the distribution of missing data over those countries / sites / patients with the most unconfirmed missing data. The user selects countries, sites or patients at the top of the page.

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Updated functionality and bug fixes

List of functionality that has been updated in this release.

Updated Functionality

- Time period filter was added to Data Export.

- Graphs can be downloaded and/or emailed from Export preview.

- An Alert overview page was added where Alerts can be added, edited and deleted.

- Viedoc Message will inform user that password will expire in 10 and 5 days.

- Form audit trail popup is shown when a historical value is clicked in a form.

- Static text field IDs are removed from annotated CRF.

- Top bar in Clinic show Viedoc Message counter.

- Top bar in Clinic show user selected role, if user has several roles, the role is clickable for fast access to the launch popup.

- Duplicate design in Designer loads the latest design from database so no manual refresh is needed anymore.

- The meaning of the signature has been updated when Forms are signed. [*]

- Export include the site code.

- When Review status is selected in Data Export, the meaning of the signature is included in Readme tab/file. [*]

* Meaning of signature

A text explaining the default meaning of signatures in Viedoc has been added to the export and the text displayed when the investigator signs data has been modified to reflect better conform with regulatory expectations. The texts now used are:

Investigator signing:

> *"By giving my password below I confirm that all data recorded for the selected forms is in accordance with applicable regulations – unless otherwise stated in supporting documentation."*

Export explanation:

> *"The meaning of all signatures is that the user has confirmed that all data recorded is in accordance with applicable regulations – unless otherwise stated in supporting documentation.*
> *The signatures are manifested by "SignBy" and "SignDate" in the "Review status" dataset."*

These are the default values that apply to all signatures in Viedoc. It is possible to write study specific texts if signatures in a particular study have a different meaning, but these must be stored separately in the TMF for that study. At present Viedoc does not support the definition of study specific signature texts in the tool.

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List of updated functionality continues.

Bug Fixes

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

- Patient table view now preserves the selection between card and table view when changing the order of display, site, or using the search capability.

- Alert mails now include recipients defined in Bcc.

- Several alerts can now base their condition on the same form.

- Keyword {SubjectKey} can now be used in the Subject and Body of Alerts.

- Patient card variables are now updated when a new revision is applied.

- Edit checks are now triggered correctly when a new revision is applied.

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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 are lost and have 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 subject 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 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.
- When Subjects to include in Data Export is switched back and forth between "all subjects" and "single subjects" it sometimes results in "No Data" error.

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2015-06-25

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