Release Notes
Viedoc 4.18

Available for users on 2015-09-24

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New functionality

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

Detailed metrics on subject status

Metrics has been successively introduced in the last two releases of Viedoc 4. In this release the detailed Performance metrics have been extended with more details.

The Performance page includes selection possibilities to compare specific countries and/or specific sites with each other.

Based on the compare selection the graphs show statistics over total queries raised and missing data (both confirmed and unconfirmed). There are also graphs to show the time to first entered data, time to resolve queries and the rate of deleted forms.

This release adds graphs and statistics to show the progress and state of subjects. Four different subject statuses are presented:

1. Screened, shows the percentage of the expected number of subjects that have been screened.

2. Enrolled, shows the percentage of the screened subjects enrolled.

3. Completed, shows the percentage of the screened subjects who completed the study.

4. Withdrawn, shows the percentage of the screened subjects withdrawn from the study.

The subject status statistics are based on settings that have to be provided before any useful data can be shown. These settings have to be provided as a basis for calculations:

1. The expected number of subjects should be given for each site. This is done under Site settings in Admin.

2. Under Study settings/Subject Status in the Designer the different statuses that a subject can have should be defined. The first status is 'Screened' and will always be defined as when the subject is added to the study, whereas enrolled, completed and withdrawn can be defined using conditions that refer to specific forms and values within the study workflow.

Patient account lock notification

It is not unusual that patients get locked out of ViedocMe. At that point monitors, investigators and study nurses will then have to take action to unlock the account. To speed up this process a notification message will be sent to the monitor, investigator and study nurse, being visible in the Viedoc Message center. The same notification is also sent as an email to the address registered for the different users.

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Updated functionality and bug fixes

List of functionality that has been updated in this release.

Updated Functionality

- The date of first patient added (FPA) is shown on Study overview page in Admin.

- Forms listed in Forms overview page can now be sorted in alphabetic order.

- Missing data queries are no longer included in Queries and Performance metrics. Instead these queries have a section of their own, named Missing data. Note! Missing data queries are also no longer counted as queries on the Landing page.

- A Home link is added in the Clinic header. Pressing the button will redirect the user back to study home page.

Bug Fixes

- Grid in export preview table is back again after being accidentally removed in previous release.

- Forms with items having both visibility conditions and default values will now show the entered values rather than default values in pdf.

- CodeList values will now show the text value rather than the code list value in the log forms summary row. **Note!** This will have effect on what is shown in Log forms.

- Improved subject save/load performance when a subject has many common events that included summary format.

- Unconfirmed missing data in Metrics overview page now shows all missing data, not only last 7 days.

- In workflow setup it is now possible to uncheck a variable in a form added to an activity without affecting the variable in the other activities that include the form.

- Export preview no longer results in 'No data' when there is data to show.

- Launch study now always requires an enabled role.

- Alerts now work for hidden forms.

- Unscheduled event description can now be changed when event is edited.

- Checkboxes with the label aligned to left and vertical will now have correct width. **Note!** This change may effect the layout of forms. If so the design will have to be updated.

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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.

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2015-09-17

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