PCG Solutions

Release Notes
Viedoc 4.25

Available for users on 2016-04-18

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New functionality

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

Medical coding part II

The second part of medical coding is introduced in release 4.25. In part II the coding feature is updated with the possibility to export coded terms, statistics on coded terms, support for multiple codes, interpretations and code review alert.

<u>Export coded terms:</u> Clinic Export has been extended with an option to include Medical coding in addition to data. This option is applicable for Excel and CSV and will include coded terms ordered by dictionary types.

<u>Statistics on coded terms:</u> On the first page of Medical coding there are statistics showing how many percentage of the data that can be coded that actually has been coded. There will also be statistics about approved codes once that functionality are released.

<u>Support for multiple codes:</u> Additional codes can now be added to terms when it's applicable. This is done by pressing *Add another code* in the coding console which will freeze the first code and allow the user to search and select an additional code.

<u>Interpretations:</u> Interpretation can now be added to further explain and justify the code(s) that was applied. This is done by pressing *Add interpretation* in the coding console.

<u>Code review alert:</u> Whenever a value that has been coded is changed the coding is broken and the value needs to be coded again (or the previous code confirmed). To show this an alert (in the form of a yellow pen) will appear beside values that have previously been coded when they are changed. The value will then be considered as not coded and the code will not be included in any exports. To resolve this encode the value again either by confirming the previous coding or by applying a new code.

Functionality not included in part I and II that are planned for upcoming releases is:

• Support for additional dictionaries, coming up next are: WHO DD and ATC
• Approval of medical codes

New functionality

⭐ List of new functionality continues.

Reminders in ViedocMe

It is now possible to configure reminders to subjects for studies using ViedocMe. A reminder can be sent as email and/or text message.

<u>Admin – Study settings:</u> In study settings there are options on a study level for allowing reminders to be sent out via email and/or text message.

<u>Designer – Study workflow:</u> All activities within a *Subject initiated* event will have the possibility to set a ViedocMe reminder. A reminder is defined by a message and a time when the reminder should be sent to the subject if the subject has not completed the activity by the given time on target date. The time is defined in Clinic time zone. Reminder message in multiple languages are supported.

Note: The reminder settings will be taken from the latest effective design.

<u>Clinic – ViedocMe account:</u> ViedocMe account settings have been extended with reminders via email and/or text message. Once the subjects contact information is typed in and saved it is stored in encrypted form and is no longer visible to any users.

Paging on selection page

The selection page now has a paging function at the bottom of the page where you can choose to display 20, 50, 100 or 500 subject per page. Search and sorting functions still apply to the entire set of subjects.

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Updated functionality and bug fixes

List of functionality that has been updated in this release.

Updated Functionality

The following functionality has been updated in this release of Viedoc:

- The timeout for the *reset password link* has been extended from 3 hours to 12 hours when the reset email is sent by the study manager. When the user resets their own password the validity of the link is still set to 3 hours.

Bug Fixes

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

- Filled in data will now be included in Export for users where visibility has been changed from *Hide for all* to *Show for all*.

- Medical coding scopes can no longer be set on radio buttons with text code values, the scope can only be set on text items.

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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) 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

- 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.

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Known limitations

⚠️ List of known limitations continues.

- 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.

- The PDFs generated at form save will be generated and stored based on the role visibility conditions applied to the user that last saved the form. E.g. items hidden to a user due to role visibility conditions will not be shown/included in the generated pdf.

- When applying a revision that contains a JavaScript expression that is taking a time-item from the CRF as argument to the native JavaScript Date constructor, the constructor fails and returns a date object initialized with 0000-00-00 00:00:00. E.g:

var dateObject = new Date(timeItem));

var hour = dateObject.getHours();

var minute = dateObject.getMinutes();

In the above example hour and minute will both be zero. This is a bug in the server-side revision application execution that will be addressed in a future release. The work-around implies is to take into account that time-items from the CRF are already date objects that can be used as is. If you want to extract the hour- and the minute-parts please use them as:

var hour = timeItem.getHours();

var minute = timeItem.getMinutes();

This only applies to time-items and not date nor date and time-items. If you cannot modify expressions that has this issue - before this bug is addressed - we strongly advise from applying such revisions as it will likely give you unwanted/ unintended outcome.

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2016-04-14

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