PCG Solutions

Release Notes
Viedoc 4.24

Available for users on 2016-03-31

Release Notes
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New functionality

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

Global design settings

A new type of design settings are introduced in version 4.24, the global settings. This are study specific design settings that shall apply globally to all designs in a study regardless of what version/revision being used at the different sites. The global settings are published in a similar way as versions/revisions are from Designer. The difference is that the study manager does not need to assign them to take effect. Instead, at the moment, they will be taken into effect immediately when published.

Medical coding part I

The first part of medical coding is introduced in release 4.24. The functionality in part I contain support for basic coding according to MedDRA dictionary. Setting up and performing medical coding involve the following steps:

Designer - Define scope: Under Global settings in Designer there is a section for Medical coding where coding scopes are defined. A coding scope is basically the combination of the item you like to code and the dictionary type you like to use. Note! Only text items can be coded.
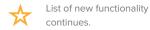
Designer - Set coding permissions: Under Roles in Designer there are three new permissions to use for medical coding:

- Medical coding: permission which allows the user to view the statistics on the coding main page.

- Perform medical coding: permission which allows the user to apply medical codes from the supported dictionaries on the coding page.

- Approve medical coding: permission which allows the user to review and approve/disapprove the medical codes that was applied.

Admin - Manage coding dictionaries: On the Study page in Admin there is a new link for creating instances of the coding dictionaries to use in the study. It is the responsibility of each organization to manage and store their dictionaries so that they can be uploaded to Viedoc when instances are created.

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New functionality

List of new functionality continues.

Admin - Attach dictionary instance to scope: The final step in the setup sequence is to relate a dictionary instance with a coding scope. This is done under Study settings where each defined coding scope gets attached with a dictionary instance.

Clinic - Perform coding: In Clinic there is a new button added on the landing page taking the user to the Medical coding pages. Based on the setup made in the previous steps each defined coding scope can be coded using the attached dictionary instance. On the coding page there are search and filtering options available to sort and distinguish the items to be coded. Searching the dictionary for codes can easily be done by typing a substring of the term and press enter. Codes matching the term will be listed, finally chose a suitable code and apply it to the selected items.

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

- Managing dictionary instances and coding scopes
- Export of medical coding
- Apply multiple codes
- Add interpretations
- Support for additional dictionaries, coming up next are: WHO DD and ATC
- Code review alert
- Approval of medical codes

Updated functionality and bug fixes

List of functionality that has been updated in this release.

Updated Functionality

No functionality have been updated in version 4.24.

Bug Fixes

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

- When using the Roles and user listing feature, users will only be permitted to see roles and users on sites to which they have access to.

- The status icon on the subject card will now show green and reflect tasks in a correct way.

- SDV tasks will now be calculated and shown correctly on Selection page when different design versions having different SDV settings are in use.

- Patient initiated forms will no longer display the SDV labels since these forms are not possible to SDV.

- The internal name of the study design is now visualized on all Study settings pages.

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.

Known limitations

⚠ List of known limitations continues.

- 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 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.

- There is an upper limit of 500 subjects that is possible to show on the Selection view, however it is always possible to access all subject by using the search function.

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Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2016-03-24

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PCG Solutions