PCG Solutions

Release Notes
Viedoc 4.28

**Available for users on
2016-08-25**

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New functionality

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

Medical coding: additional dictionary support

The medical coding package of Viedoc 4 has been extended with support for two new coding dictionaries:

- WHO Drug Dictionary
- IDF Dictionary

The preparation steps for the new dictionary types are the same as for all supported dictionary types. The steps include:

- Dictionary instances of WHO DD and IDF are loaded in the Admin application.
- Coding scopes using the WHO DD and IDF dictionaries are defined in Designer.
- Finally, the coding scopes are attached to an instance of a dictionary type in Admin.

As a medical coder working in Clinic you will have coding scopes for the new dictionary types available as well, the medical coding page where codes gets applied will look the same as before.

WHO Drug Dictionary

The release of Viedoc 4.28 adds support for WHO Drug Dictionary, WHO Drug Dictionary Enhanced and the WHO Herbal Dictionary. The WHO DD files loaded into Viedoc must be in the C-format containing extensive details for each drug. These details can optionally be shown and used when performing the coding task in Clinic. If you choose to not use the extensive details, this information will by default be set as "Not applicable" or "Unspecified".

IDF Dictionary

For the Japanese market the Viedoc 4.28 release adds support for the Iyakuhinmei Data File (IDF) for domestic usage.

New functionality

⭐ List of new functionality continues.

Export in CDISC ODM format

In version 4.28 the export feature is extended with yet a new format. This time it is CDISC ODM that is introduced. The export is in snapshot mode and contains Clinical data (grouped by metadata design version) and Admin data (i.e. sites and users)

No data grouping or layout options will be available when CDISC ODM format is selected as format.

If you choose to include the EventDate option, all event dates will be included with the latest effective design version applied to the scope you set for export

API extended with method: GetClinicalData

Viedoc API (Application Programmable Interface) provides a way for external software components/applications/clients to insert and store data into Viedoc. The API has been extended with

the new method GetClinicalData to allow retrieval of the clinical data stored in Viedoc.

The method accepts the following set of arguments where all except SiteCode are optional:

- SiteCode (Code set in Admin, Required)
- SubjectKey
- StudyEventOID
- FormOID
- ItemOID
- TimePeriodDateType (SystemDate, EventDate)
- TimePeriodOption (Until, From, Between)
- FromDate
- ToDate
- ExcludeExtensions (true/false)
- IncludeAdminData (true/false)

More documentation can be found in the Viedoc 4 Public API documentation which can be requested from PCG Solutions AB.

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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:

- Export of medical coding has been extended with a column named "Term" which contains the value which the code was assigned to.
- Exports in the state "In progress" have been extended with a progress counter to indicate the percentage done.
- In Export, the column "Query type" included when "Queries" is selected will now say:
  - Unconfirmed missing data
  - Missing data (for confirmed missing data)
- Links in Admin used for loading files (ODM design import, eCRF language) into Viedoc have been highlighted with blue color.
- The Global design settings will not appear until a design has been created.

Bug Fixes

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

- It is now possible to import partial data in subsequent API calls in order to fill up a visit/form completely.
- Email alerts will no longer show "2016" when the month is unknown, it will now populate the year correctly.
- Subject cards showing the date field on the Selection page will now display the year correctly.
- Inconsistencies in date format were corrected when exporting in PDF-format.
- Logging in to Viedoc in two different browser tabs after auto logout (timeout) will no longer cause any problem.
- In Admin there is no longer a need to apply a new revision twice in order for it to take effect.
- Double clicking when adding new sites to a study in Admin will no longer create multiple sites.
- Pdf's generated during bulk upgrade or during pdf export will now include the design version in the footer.

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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

- The PDFs generated as Empty CRFs will not display all code list items for radio, dropdowns 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 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.

- 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 on some instances.

- 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.

- The Issue list will not be visible for sites that have more than 1000 subjects.

Known limitations

⚠ List of known limitations continues.

- Alerts will only be triggered on the first initiated form within an event if that form occurs more than once in the event. The workaround is to specify the activities in the alert condition.

- ViedocMe study event date form can be unlocked by monitor.

- Applying a design revision will also make it the latest effective design.

- Permissions in the user role log are displayed based on the effective design date instead of the date when the design was applied.

- The form history view does not display all form versions when bulk upgrade has been performed, however all are correctly stored in the database.

- Task count include tasks for hidden forms.

- Issue list do take role visibility into account.

- When fields previously hidden in study workflow are made visible in a revision, they will be directly visible in Clinic when that revision is applied.

- Switching the study design language from the default English to any other language in the middle of study setup, i.e. after already designing and saving some forms, will leave the study design in an inconsistent state.

- Ready checkmark on subject details shows green even though some hidden forms are not yet completed.

Signoff

Signature Confirmation by
the product owner.

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