

# Release Notes

# Viedoc 4.26

Available for users on  
2016-05-19

# Release Notes

## Viedoc 4.26

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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:

- ATC dictionary
- MedDRA-J dictionary, with Japanese currency flag as the ruling

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

- Dictionary instances of ATC and MedDRA-J are loaded in the Admin application.
- Coding scopes using the ATC and MedDRA-J 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.

#### **Additional system languages**

The release of Viedoc 4.26 includes Spanish as a new system language for the Clinic application. The system language is chosen under User settings.

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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:

- When selecting any type of unscheduled event:
  - Medical history
  - Adverse events
  - Prior and Concomitant Medications

The selected part becomes expanded in the unscheduled events overview popup. If there are no existing forms in the selected part a new empty form will be opened directly, i.e. similar to when '+' is clicked.

- When a scheduled visit date is reset, any raised query on that visit date will be immediately closed by the system with the reason "due to data edit".
- Setting the visibility condition to 'Hide – Always' will store data in the background so that functions for example can be used on that data. Data will be hidden within Viedoc but will be included in exports. Whenever a condition hides an item, the value on that item will be cleared.
- SAS export now includes the medical coding information

#### Bug Fixes

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

- Significant digits will now be populated when a function returns a string value into a numeric field.
- ViedocMe reminders with text message that contain Unicode characters will no longer be truncated after 70 characters.
- The API log under Study settings will now show 2000 rows without blocking the pop-up.
- Items with a visibility condition depending on an item that is hidden will now become hidden.
- Events not yet initiated can no longer be marked as ready.

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### Updated functionality and bug fixes



List of bug fixes continues.

- It is now possible to raise queries on new questions which were added in a revision.
- Role visibility on form level is now respected for common event forms.
- The issue 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 has been solved.
- Forms in a common event will no longer be shown as done if they are hidden and non-editable for a specific role.
- Signing console now excludes the common event date from the forms count.
- Manual queries raised on missing data will now be closed automatically when data is entered.
- Mandatory fields that are populated using a function will be highlighted as missing.
- Deleted events are no longer included in the total count on unscheduled events dashboard.
- When data is imported into a form without any data changes, the signing and monitoring tags are not broken and no form pdf's are generated.
- Hidden items that have never contained any data will not be included in the audit trail.
- Forms are no longer cut off in IE11 when opening the action pop up.
- It is no longer possible to create multiple instances of events and forms by double clicking the save button.
- It is now possible to monitor lock a subject that has deleted unscheduled events, and the progress bar will now show accurate progress of the subject.
- Confirm missing data on numeric fields will no longer ask for the reason for change.
- Subject key containing data from a numeric field will now be possible.
- Non-mandatory fields that are hidden due to visibility conditions are no longer included in audit trail.
- It is now possible to lock 'All forms' from the Data Review Console.
- If a function return value did not change after a revision was applied, no audit trail will be created.

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### Updated functionality and bug fixes



List of bug fixes continues.

- Confirm missing queries are now closed when item is hidden.
- Subject initiated forms are no longer marked for SDV.
- Visit dates are now SDV'd when marking all data for SDV in the Review console.
- Using the 'Sign all' option in the Signing console will no longer sign event dates with issues.
- The export view no longer contains overlapping content when system language set to Japanese.
- All item values are now cleared when hidden due to visibility condition.

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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.

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### Known limitations



List of known limitations continues.

- Visit date form history will not be included in pdf export if no forms were filled in, or if forms were 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.

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### Signoff



Signature Confirmation by  
the product owner.

**Uppsala, Sweden 2016-05-12**

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PCG Solutions