Release Notes
Viedoc 4.11

Available for users on 2014-12-19

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New functionality

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

Application Programming Interface (API)

An API has been added to Viedoc allowing customers to integrate directly with Viedoc when importing data into Viedoc from other sources (e.g. for data migration from other systems) and when exporting data from Viedoc (e.g. for data analysis).

All data imported to or exported from Viedoc through the API is in CDISC ODM format.

The API is implemented as a web service, and supports the following operations:

- API authentication (logon and identification service)
- Post Data (send data to Viedoc)
- Get Transaction Status (to check on the status of data uploaded to Viedoc with Post data)
- Get Transaction Data (to retrieve the data that was uploaded to Viedoc with Post data)
- Import API
- Get Metadata (export the study design from Viedoc for use in an external application)
- Import Queue (if the patient is locked for use by another user then the Post Data operation is queued)
- API Study Settings (the Admin user for a project, usually the Study Manager)

Risk Based Monitoring (RBM) support stage 1

Functionality allowing the user to specify which data fields, forms and visits are to be Source Data Verified (SDV). This is a first step in introducing risk based monitoring. The following have been added in this release:

Designer:

- The designer sets the scope for SDV in the study design, defining which fields in which forms and visits are to require SDV.
- If a new field is added to a form and all other fields on that form require SDV then the new field will automatically require SDV. Otherwise the new field will not require SDV. If the designer does not want these settings then they must be altered manually.

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List of new functionality continues.

Admin:

- When exporting data it is possible to include the SDV status of the data

- It is possible to choose to export only data that requires SDV, so that an SDV status report can be generated easily

Clinic:

- A new task will be created for each form containing at least one field that requires SDV

- Only items requiring SDV will show the SDV check box

- Checking the SDV check box on a data field will mark that data field as SDV:ed

- Checking the SDV check box on form level will mark all fields in that form that are specified for SDV as SDV:ed

- Checking the SDV check box for a visit will mark all fields in all forms for that visit that are specified for SDV as SDV:ed

- If a data field that has been SDV:ed is changed, then the SDV is broken and must be performed again

- A form is only considered SDV:ed once all fields requiring SDV on that form have been SDV:ed.

- Statistics of the amount of SDV performed only count forms containing fields that should be SDV:ed. In this way 50% SDV performed means 50% of the forms that contain fields requiring SDV have been marked as SDV:ed, and not 50% of all forms in the eCRF.

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Updated functionality and bug fixes

List of new functionality that has been updated in this release.

Updated Functionality

A new patient selection view has been added. Besides the patient card view, the user can now also choose to display patients in a table view with configurable columns. The user can choose which columns they would like to see in the table, and the table can be sorted by any of the columns (i.e. patient id number order, age, inclusion criteria, etc.).

Bug Fixes

The following bugs have been corrected in this release of Viedoc:

- The study workflow could take 30 minutes to save if the study had 2000 visibility conditions defined

- A duplicate of a form could be created when saving under special error conditions related to poor internet connections, resulting in two identical forms with the same (or nearly the same) time stamp

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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 export preview feature is heavy to load and might cause the application to feel unresponsive

- 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 are lost and have 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 subject 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.

- When using the new patient table view some options default back to the patient card view, for example choosing the order of display, the site, or using the search capability. The user has to enter the table view again, but the option chosen is preserved and is then displayed correctly in the table view.

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Signoff

Signature Confirmation by
the product owner.

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