

Release Notes

Viedoc 4.12

Available for users on
2015-03-18

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New functionality



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

Messages

This release includes the first release of the Viedoc 4 messaging system, consisting of upgrade revision messages. The messages will show up in a list on the study landing page when the user logs on. When pressing the envelope icon a message view is shown where all messages will be listed.

When completed, the new messaging system in Viedoc 4 will be an integrated way for a study manager, site manager, or any other person who like to notify the site users of different study events. A message may be addressed to a specific site-user or to entire groups; such as all study users on a site.

Reset / Delete forms

We all make mistakes sometimes. This new functionality allows site users to reset visit forms and delete common events if mistakes have been made. Reset and deleted forms / events will be removed from the CRF. A full audit trail of all changes is kept and it is possible to display the form history. Default roles holding the Reset / Delete permission are Investigator and Study coordinator.

Design revisions

Support for design revision is now implemented to allow design upgrades to already existing data and forms. The difference between design versions and revisions is described further below.

Version vs Revision:

Viedoc 4 provides two ways of updating a study design – versions and revisions.

A new version of the design is used when you like to have full flexibility in terms of what changes you want do to the design, almost everything in a design can be changed in a new version. A new version only applies to new data, it cannot be applied to historic (already entered) data.

New revisions of the design have some restrictions, but also have the advantage that a new revision can be applied to already existing data and forms.

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List of new functionality continues.

Revising the design allows the following kinds of changes:

- Add, delete, and change fields in forms (incl. question text, choices, functions, visibility conditions, etc)
- Add, delete, and change item groups in forms (incl. title, visibility conditions, etc.)
- Add, delete, and change forms in Activities (incl. item event visibility conditions)
- Add, delete, and change Activities (incl. title, description, visibility conditions, etc.)
- Add, delete, and change Visits (incl. title, description, visit window, visibility conditions, etc.)

The following restrictions apply to revisions:

- No ID's can be changed in a revision. (e.g. IDs on Form, Activity, Event, Items in forms, Code lists, etc.)
- Roles cannot be changed in a revision.
- Study settings cannot be changed in a revision.

Batch upgrade of design revisions

Batch upgrade of design (forms and workflow) provide a fast, easy, and controlled way of applying a new revision. Study managers can assign a revision upgrade to a site. The site users will receive a message on the landing page informing them about the upgrade. All forms and workflow of the design can then be upgraded through the batch upgrade message (per site). The batch upgrade requires the user to confirm the changes with their password.

The revision workflow:

The scenario below will describe an upgrade of the design revision, trying to show what steps have to be taken in the different applications.

Designer:

- A new revision of the design is created and published in the Designer.

Admin:

- Study manager assigns a new revision to selected sites (or all), sets an assignment date and also provides an upgrade message describing what is changed in the revision.

Clinic:

- The upgrade message will appear that inform the user about the upgraded revision. Site user can batch upgrade to the new revision by confirming with the password.

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Updated functionality and bug fixes



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

Updated Functionality

Export is extended with information about the time format used for different fields. It is clarified that date / time fields set by the system is in UTC and that all other date / time fields are user edited.

Bug Fixes

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

- Functions are no longer triggered on hidden items, thus avoiding hidden items containing values.
- Site managers that are also marked as Helpdesk can now invite other users to site.
- Data is now stored with correct metadata when using the patient shortcut functionality.
- Modal windows are now possible to open in IE9.

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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.
- 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.

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Signoff



Signature Confirmation by
the product owner.

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