Release Notes
Viedoc 4.20

**Available for users on
2015-11-19**

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New functionality

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

1 Study lock

When all visits have been performed, reviewed and approved/signed and no more information shall be added to the study, the study should be locked by the Study manager. Studies can be locked – unlocked – and locked again as many times you like. For traceability reasons, all lock changes will be audit trailed and a pdf report can be downloaded. Locking/Unlocking a study involves three steps:

1. Select to lock/unlock study

2. Provide a reason for locking/unlocking study

3. Provide password

A locked study has the following limitations:

1.1 Clinic

All access will be read-only so adding new data will be prevented. Deletion of subjects will not be possible and neither will the import of data via API or submission of data using ViedocMe be possible. Viewing and Export will however still be possible.

1.2 Admin

It is not possible to add sites or change settings to study/site. (The Study settings – API configuration is still possible to change). Nor is it possible to assign/apply design versions/revisions or to edit the randomization settings on a locked study.

1.3 Designer

It is still possible to work with the design, the only restriction in Designer for a locked study is to publish the design.

2 Role visibility on form level

Role visibility setup is now available in form settings, allowing the designer to select what roles to show or hide a form to. Multiple roles can be chosen to show or hide the form to. The default setting on a form is to show it for all roles.

Note1! If you like to hide forms for certain roles use this feature, don't experiment with advanced visibility conditions since these are not evaluated during export.

Note2! If you want to apply the role visibility to already filled in forms you need to make a new revision.

New functionality

⭐ List of new functionality continues.

3 User role listing report

The user role listing that was introduced in 4.19 has been extended with a pdf report available for download. The report will provide support when fulfilling the regulatory requirements around user access and their related roles over time, which user that has contributed with data to the study, etc.

4 Unique study mode

For new studies created in 4.20 and onward; only one mode (Production or Training) will be allowed per site. However there is a way to preserve the "old" way of having single sites in both Production and Training mode. This is accomplished in Admin/Study settings by choosing 'Show more options' and marking the checkbox to allow both modes.

5 Confirm 'All fields'

By selecting 'All fields', it is now possible to include all items with missing data state within a group scope when confirming missing data. The audit trail will still be created per item.

6 No reason is needed when confirming that data is missing

Study settings in Designer has been extended with a miscellaneous section which will be the habitat of miscellaneous settings. Under Miscellaneous there is a new option to set whether to require or not require that a reason is given along with the confirmation of missing data. The default setting is to require a reason together with the confirmation of missing data.

7 Visibility condition for Activities within Common Events

Visibility conditions can now be given for Activities within Common Events. The behavior is the same as for Scheduled and Unscheduled events.

Note! Visibility condition is not supported and shall not be set on the first activity within Common Events.

New functionality

⭐ List of new functionality continues.

8 Additional study settings

Additional study settings have been added and will be mandatory to complete when editing the settings:

- Study type

- Sponsor type

- Study phase

- Therapeutic area

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Updated functionality and bug fixes

List of functionality that has been updated in this release.

Updated Functionality

- User role list is updated to only show roles that have user(s) related to it.

- Bookmark hierarchy in Pdf export is changed for activities without a name. These activities are moved up one step in bookmark hierarchy and do not display the activity id as bookmark.

- Pdf export include lock information if the study is locked.

- The option to assign a design version immediately has been moved to the date/time scheduler where an optioned named 'Now' will do the same work as 'Immediate' did previously.

- The configuration report has been aligned with the design settings and now includes:
  - Roles and permissions set to roles
  - Role based visibility on form level
  - Subject status
  - Miscellaneous settings

- Visibility conditions on items have been aligned and is now setup in the same way as for Forms meaning that the show/hide condition can be set for several roles instead of only one role which was the case earlier.

- Additional study settings have been added and will be mandatory to complete when editing the settings:
  - Study type
  - Sponsor type
  - Study phase
  - Therapeutic area

- When applying a new revision where the visibility conditions are made in the workflow will only mark form instances that contain items affected by the changed workflow visibility condition for upgrade. Form instances where no item is affected will not be marked for upgrade.

- For unique identification, user id stored internally in Viedoc is now displayed in the form history.

- An Audit trail is added in study design settings showing when and by whom a design version was assigned and/or revision was applied.

Updated functionality and bug fixes

✓ List of functionality that has been updated continues.

Updated Functionality

- A permission has been added allowing users to add private notes in visits, forms and individual items. For existing studies the permission is given to all roles and for new studies the permission will be given to Monitor, Project Manager and Data managers by default. Note that the permission only controls when new private notes can be added, existing notes can always be edited and deleted regardless of the permission.

Bug Fixes

- It is now possible to schedule the assignment of the very first design version of a study to a future date without ending up in a dead end where the Study design settings can not be accessed until the scheduled design becomes effective.

- The validation that takes place when a form is saved will now indicate an error when item ids are duplicated. These errors were previously only indicated when running the full design validation.

- The SDV and review (DM and CRA) task count on the selection page is corrected and now matches the task count on the details page.

- Apply revision will now show who did the bulk upgrade in form history and forms that were auto updated will show the user that applied the revision in form history.

- Apply revision will now respect and no longer override the number of decimals set on numeric fields in the design.

- Configuration reports no longer include unused forms, only forms used in the workflow are included.

- The user role list will now only include users and roles from Production sites when you are in Production mode and from Demo sites when you are in Demo mode.

- SAS export is now working when queries start with quotes.

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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.

- 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

- Visibility conditions (entry conditions) cannot be set for activities in common events.

- 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.

- Session counter is not increased when data is imported via Viedoc API, but data entries are always counted. After import via API the user role listing will show for example '95/0' if 95 data entries were made via an API session instead of '95/1' as expected.

Signoff

Signature Confirmation by the product owner.

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