Available for users on 2018-11-15

New functionality

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

New eLearning

Viedoc 4.46 introduces a completely new eLearning that provides a more comprehensive user guide with detailed step-by-step instructions and more images and examples. The new eLearning content has an improved structure, more attractive lay-out, and is easier to navigate. The content is searchable, and the lesson overview will show which lessons are new and/or updated when a new Viedoc version will be released.

For Viedoc Clinic users

For site staff, the following role-based user guides will become available from Viedoc Clinic:

- Viedoc User Guide for Site Users
- Viedoc User Guide for Monitors

New studies receive access to these two user guides by default. In addition to these, the following role-based user guides can be added manually:

- Viedoc User Guide for Data Managers
- Viedoc User Guide for Project Managers
- Viedoc User Guide for Medical Coders

Information on how to add these user guides can be found in the lesson *eLearning settings* in the new Viedoc Designer User Guide.

Ongoing studies continue to have access to the current Site User Training (V4) and Monitor Training Program (V4) as default. The current Site User Training (V4) and Monitor Training Program (V4) are also available for new studies as a configurable option.

Note! The content of the current Site User Training (V 4) and Monitor Training Program (V4) will not be updated with new functionality in the future. It is possible to add the new user guides to any of your ongoing studies by configuring the eLearning settings in your study design. Instructions for this can be found in the lesson *eLearning settings* in the new Viedoc Designer User Guide.



Description of new functionality continues.

For Viedoc Admin and Viedoc Designer users

For all users with a system role (study builders, administrators etc), the following user guides will become available from Viedoc Admin and Viedoc Designer. These user guides cover all functionality within Viedoc Clinic, Viedoc Admin and Viedoc Designer:

- Viedoc Clinic User Guide
- Viedoc Admin User Guide
- Viedoc Designer User Guide

The Viedoc Clinic User Guide, Viedoc Admin User Guide and Viedoc Designer User Guide replace the current User Guide Viedoc 4 on the day of the release.

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:

- The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- For security reasons, it is not allowed to upload executable files. The complete list of unsupported file types can be found in *Viedoc 4.34 Release Notes*.
- 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 buttons, drop-down lists 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) can normally not be marked as having been verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.
- The affected forms count shown in Viedoc Admin while applying a study design revision is implemented only for production sites. Demo/Training site forms are not included in this count.
- Validation of alerts, selection view settings, event visibility, subject status condition, common event summary format and subject ID generation settings for deleted items is not performed.
- The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
- 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 get 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 upon form save will be generated and stored based on the role visibility conditions applied to the user that last saved the form. Items that were hidden to the 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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List of known limitations continues.

- The task count includes tasks for hidden forms.
- The Issue list does not take role visibility into account.
- It is only possible to import values (choice numbers), not strings (choice labels), when importing data into data fields where multiple checkboxes can be checked.
- Edit checks are not triggered on dates when the event date is used as default value, and the calendar picker is used to choose the date.
- If additional languages are imported (to be used in ViedocMe) and after that code lists are combined via "Formats" (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
- The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (e.g. an OID defined as *AE* in design version 1 and *ae* in design version 2).
- Checkbox items with choices having long text set in Viedoc Designer might not be shown properly in Viedoc Clinic. The choice text might be truncated and not completely visible although it looks good in Viedoc Designer. The problem is also visible in the form preview in Viedoc Designer, which shows an identical form as what the users will see in Viedoc Clinic. Therefore, make sure you always check the form preview after designing a form to make sure that everything looks as expected.
- The SDV task count, the green checkmark and the issue list on the subject selection
 page in Viedoc Clinic do not take role visibility into consideration. This means that
 if forms or items are hidden to a certain clinic role, it might look as if there are still
 tasks to be performed, even if the user with that role does not have access to
 perform these tasks (due to visibility conditions).
- Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
- Fully PDF/A compliant archives are only supported if all the included form PDFs and study event PDFs were generated on or after 2017-03-10 (Viedoc 4.33). It is still possible to generate PDF/A compliant archives that contain form and study event PDFs generated before this date, but you might receive warning messages related to PDF transparency issues.
- In the PDF/A export output, the header, footer and the text on the respective *Contents* page are missing for the deleted forms/events/subjects.

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List of known limitations continues.

- Using \$THIS inside a form to refer to an item within a different instance of the same form, does not work, as it always refers to the same form instance. This is true when referring to an item in the same form within another activity, or when referring to another form instance within the same activity (applicable for repeating forms).
- The API method SubmitData allows submitting data into a form that exists in the effective design but does not exist within the respective event according to the study workflow. In such a case, a new form is created and added to the event.
- Any of the Organization Administrator, Organization Designer, and Site Manager roles that were removed from a user are not listed in Viedoc Admin, under User Settings > Studies and Roles.
- When importing an ODM file that was exported from Viedoc into Viedoc Admin, the following error message is displayed: "Following users do not have email id: SYSTEM". This can be fixed by manually removing the SYSTEM user entry from the xml file.
- It is not possible to import an ODM file that was exported from Viedoc including the *Event Dates* into Viedoc Admin. The following error message is displayed: "An item with the same key has already been added".
- If the condition for an alert is set within a form for which the option to auto-update functions is enabled, and the alert is triggered, the alert message will be sent twice.
- If two scheduled events have the same event date, and both events contain a form with a function or data check that uses the \$PREV function, the \$PREV functions in these two events refer to each other as the previous event, and not to the event that occurred earlier in the study workflow. This creates a circular reference and makes it impossible to refer to earlier event(s).

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2018-11-08

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