

Release Notes

Viedoc 4.50

Available for users on
2019-04-05

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New functionality



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

It is now possible to create customized eLearning material at the Organization level. A new user role at Organization level is available – eLearning Admin – who will get access to the eLearning platform.

When logging in to the Viedoc eLearning platform, the eLearning Admin user will receive read-only access to the existing Viedoc curriculums and lessons, being able to:

- copy existing content (curriculums and/or lessons) and customize it for the organization.
- create new content (curriculums and/or lessons) that can be made available to the organization.

The customized curriculums can then be made available for the clinic users in the same way as the existing Viedoc documentation.

Access to the Viedoc eLearning platform is organization-specific, which means that users from other organizations cannot view or access anything that was created/customized for your organization.

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Updated functionality and bug fixes



List of functionality and bug fixes that has been updated in this release.

Bug fixes

This section lists the bugs that were fixed in this release. For each bug, it describes the following:

- **Affected area(s):** describes shortly which area(s) of Viedoc the bug is related to, so that it is easy to identify if any of your active studies is affected.
- **Bug description:** explains the issue and/or how it was fixed. In case there are consequences for existing data, this is clearly mentioned in a “**Note!**”

The following corrections have been implemented in Viedoc 4.50 release:

- **Affected area(s):** User information reference in the <AdminData> section of the exported ODM file.
Bug description: The <AdminData> section of the exported ODM xml file did not include the user details for the users who performed only one or more of the following actions (i.e. no other actions than the ones mentioned below):
 - Performed Medical Coding
 - Raised/Approved/Rejected queries or pre-queries
 - Performed review, i.e. Clinical Review/SDV/Lock/DM Review
 - Performed signing of form(s).This is now fixed and the user details are included in the ODM exports performed in Viedoc version 4.50 and onwards.
- **Affected area(s):** ODM Import in Viedoc Admin of a file previously exported from Viedoc.
Bug description: When importing in Viedoc Admin an ODM file that was exported from Viedoc, the following error message was displayed: “Following users do not have email id: USR.0, SYSTEM”. This is now fixed and both the “SYSTEM” user and the “USR.0” (ViedocMe) user now have an email address “no-reply@viedoc.net” in the ODM exported file.
- **Affected area(s):** PDF export in the specific scenario mentioned in the description below.
Bug description: PDF export was failing after a clinic user had batch approved a design revision that included changes to forms containing items hidden for that user’s role. This is now fixed, and the PDF export is working properly in the described scenario.
- **Affected area(s):** File upload.
Bug description: Uploading files with file size greater than 20 MB was failing. This is now fixed.
Note! If your study was affected, you will be contacted by a Viedoc representative.

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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:

- 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.

- 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).
- 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.
- 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*.

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List of known limitations continues.

- 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).
- For ViedocMe translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content, before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated ViedocMe form).
- When using “START” as the Event ID for the *Study Start* event, and scheduling other events based on the *Study Start* event, this results in an error. The workaround is to use a different ID for the *Study Start* event, except for “START”.

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Signoff



Signature Confirmation by
the product owner.

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