

Release Notes

Viedoc 4.51

Available for users on
2019-05-16

Release Notes

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New functionality



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

Documentation and Training

It is now possible to enable the certification of clinic users, by assigning mandatory training sections to clinic user role(s) and site(s). The user to whom mandatory training sections were assigned will not be able to launch the study in production mode until having read and signed all the mandatory training sections.

It is also possible to have study specific documentation made available to clinic users (as uploaded documents and/or URLs). The maximum file size is 100MB. The size of the uploaded files is counted in the total amount of data used by a study, that can be monitored in Viedoc Admin on the *Studies overview page and on the Study page - Used data storage*.

This functionality is described in the Viedoc eLearning in the following lessons:

- *Viedoc Admin User Guide > General study settings*
- *Viedoc Admin User Guide > Setting up user documentation and training*
- *Viedoc Clinic User Guide > Documentation & Training*

Copy form data from previous visit/event

It is possible to initiate a form based on copied data from a previous visit/event. This allows the reuse of data that was filled in within a previous visit/event. For this purpose, three new form sequence numbers have been introduced and made available in expressions and data export, see more details in the *Updated functionality* section below.

This is described in the Viedoc eLearning in the following lessons:

- *Viedoc Designer User Guide > Creating and editing forms*
- *Viedoc Clinic User Guide > Entering and editing data*

PMS – Medical coding on sponsor side

The medical coding functionality is now available for PMS studies, on the sponsor side, in a similar manner as for the general studies.

The medical coding functionality is described in the Viedoc eLearning in the following lessons:

- *Viedoc Designer User Guide > Configuring medical coding scopes*
- *Viedoc Admin User Guide > Managing medical coding dictionaries*
- *Viedoc Clinic User Guide > Medical coding*

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List of new functionality continues..

PMS – Reset forms

In PMS studies, users with permission to reset forms can now reset forms on the clinic side. The forms that have not been received on the sponsor side prior to reset, will not be displayed on the sponsor side. Only the forms that have been submitted and received on the sponsor side prior to reset will be included in the next submit and will be displayed as reset on the sponsor side after receipt.

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Updated functionality and bug fixes



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

Updated functionality

- The following three new form sequence numbers were introduced as system variables, to make it easier to track different form instances at subject level:
 - **SubjectFormSeqNo** – uniquely identifies the form instance on subject level.
 - **OriginSubjectFormSeqNo** – identifies the form instance from which data was copied for the first time, when initiating a form based on copied data from a previous visit/ event.
 - **SourceSubjectFormSeqNo** – identifies the source of a copied form instance (the form instance the data was copied from).

The form sequence numbers are available to be used within JavaScript expressions, in a similar manner as the existing system variables. They are also available in the export output, when the Viedoc export output version is set to Viedoc 4.51.

- A Table of Contents is now included in the PDF export output. This is included when the Viedoc export output version is set to Viedoc 4.51.
- A new Viedoc export output version is introduced, Viedoc 4.51, that includes the new form sequence numbers introduced in Viedoc release 4.51, as well as the Table of Contents in the PDF output. This will be the version used for the data structure in the export output when selecting either *Latest Viedoc version* or *Viedoc 4.51* as Output version.

The changes introduced on the data structure of the export output are described in the eLearning in *Viedoc Admin User Guide > General Study Settings*.

Note! If you have set the export Output version to be the *Latest Viedoc version*, this will now be Viedoc 4.51.

- German is now available as a system language for Viedoc Admin and Viedoc Designer. Updates on the German version of Viedoc Clinic were also performed.
- As a result of the first bug fix in the below section, the behavior of batch approving a study design revision by site users has changed. Following a batch approval, the upgrade message is shown again in Viedoc Clinic, if there are forms that were not upgraded even though they were affected by the updates in the design revision. These might be either locked forms and/or forms for which the approving user did not have permission to see/edit.
- Improvements on the system performance when loading the landing page in Viedoc Clinic.

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List of functionality and bug fixes continues.

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 4.51 release:

- **Affected area(s):** Generating PDF archives in studies in which revisions have been batch approved by users who do not have edit access to all the forms updated in the revision.
Bug description: After batch approval of a study design revision, all the forms, even those that the approving user did not have permission to see/edit were upgraded. As a result, the PDF generation for these forms failed, which also resulted in failure of the PDF export. This is now fixed, so that only forms that the approving user have access to are upgraded after a batch approval. The remaining forms will be left as is, and a new design revision message will be submitted that can be approved by another user that has permission to edit the skipped forms. As a side feature, the design revision message will also be re-submitted if any of the forms is monitor locked, thus making it possible to re-batch approve the revision after these forms have been unlocked. In addition, the known limitation regarding generation of form PDFs have been removed so that form PDFs now always include all the data in the form without any respect to role visibility conditions. This will ensure that all PDFs are complete at all time irrespective of the role permissions of the user who edited the form last. The PDFs will not be visible for the users to whom data in that form is hidden.
- **Affected area(s):** Language used in PDF export for deleted forms.
Bug description: For the deleted forms, the system language for the audit trail in PDF was not in the language used when saving the form, it was reverting to English when the form was deleted.
This is now fixed so that the system language is respected in the PDF export for the deleted forms.
- **Affected area(s):** Language of the “Log of users and roles” PDF.
Bug description: The user language was not used when generating the “Log of users and roles” PDF, it was always generated in English. This is now fixed, and the “Log of users and roles” PDF is generated in the language set by the user who is generating the report. This means that a previously generated file will be available for download, only if it was generated in the same language as the one currently in use.

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List of functionality and bug fixes continues.

- **Affected area(s):** Download of the “Log of users and roles” PDF.
Bug description: When generating the “Log of users and roles” PDF, it looked like the file was available for download while the PDF generation was still in progress, and therefore the download was failing. This is now fixed, so that during the PDF generation the progress is shown, and the file becomes available for download only after generation of the file is completed.
- **Affected area(s):** Viedoc Data Import Application.
Bug description: Files with no contents were processed by the Viedoc Import Application, but not moved to the Archive folder. This is now fixed so that for the empty files a warning message is included in the log and the files are moved to the archive folder.
Important! In order to benefit of the updates, you need to download the latest version of the Data Import Application, available in Viedoc Designer under *Global design settings > Data mapping*.
- **Affected area(s):** Alerts.
Bug description: When an alert condition was changed and the last saved form for a subject was the form containing the true condition of the alert, an additional alert was sent as soon as the site user initiated a visit, if the changed alert condition was still true. This is now fixed.
- **Affected area(s):** PMS studies – layout issue when using Safari.
Bug description: In PMS studies, when using Safari, the booklet submission date on the top right of the page was cut off. This is now fixed so that the date is split into multiple rows and it is properly displayed.
- **Affected area(s):** PMS studies – AE (Adverse Event) status.
Bug description: If in a PMS study an AE is reported, and then the booklet containing the AE is returned to the clinic side, and submitted to the sponsor side again without any changes to the AE, the status of the AE report was changed to ‘not reported’ upon receipt of the booklet. This is now fixed, so that the status of the AE form is correctly displayed.

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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.
- PDFs generated upon form save in Viedoc versions prior to 4.51 were 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 are not shown/ included in such generated PDFs.
- 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”.
- In Viedoc Admin, when generating the “Log of users and roles” PDF, the generated file is not available immediately, but it becomes available after refreshing the page.
- In Viedoc Designer, for the code list items (checkboxes, radio buttons, dropdown), it is possible to set the same code list values for multiple choices within the same item. This is not recommended, unique code list values should be used for each of the choices within the same item.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2019-05-15

Andreas Hedlund

PCG Solutions