

Release Notes

Viedoc 4.48

Available for users on
2019-02-21

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New functionality



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

Unlock forms within subject initiated events (ViedocMe)

Possibility to allow roles with Lock data permission to unlock subject-submitted (ViedocMe) forms. This option can be enabled/disabled in Viedoc Admin under Study Settings. When this option is activated, users with lock permission can unlock a form submitted by subjects through ViedocMe, so that this form is open for data edit by for example the investigator. This option is activated by default for all studies started after Viedoc release 4.48 in February 2019. For studies started earlier, this option is by default set to inactive, and can be activated manually.

Viedoc PMS: Adverse Event (AE) management

In PMS studies, Adverse Event forms can be submitted, recalled, received and returned in two ways:

- As part of a complete booklet submission/recall/receive/return.
- As an individual AE report. In PMS studies, when an AE is registered before the booklet is ready to be submitted, it is possible to submit the adverse event separately, that is, without submitting the entire booklet. Similarly, the sponsor can return only the AE form instead of returning the complete booklet, even if the complete booklet has been submitted and received. A separately submitted or returned adverse event is called an AE report. AE reports follow the same Kaifu process for submit, recall, receive, and return as booklets.

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Updated functionality and bug fixes



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

Updated functionality

- Support for sending a test message by email or SMS when setting up a ViedocMe account, so that the entered contact information can be verified during the visit.
- Possibility to re-send a role invitation email in case the user has lost the previous email invitation(s).
- Possibility to reset your password and answer to the challenge question if you have no approved roles at the moment. The Password recovery page will be displayed upon request, where the user can set a new answer to the challenge question (instead of providing the previously set answer) and a new password.
- Possibility to change the *Design settings* in a study design revision.
- Improved interface of the reset password page, which makes it more clear what to do in order to reset the password.
- Small visual improvements to the Roles page in Viedoc Designer.
- The item *Validation settings* in Viedoc Designer for dropdown items included settings for minimum and maximum length. These minimum/maximum length settings had no function for dropdown items and are now removed.
- Enhancements on the ViedocMe forms: improved navigation in ViedocMe for better user experience.
- Improved visual effects on the subject details page when hovering the mouse over the form, for a better user experience.

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List of bug fixes continues.

Bug fixes

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

- **Affected studies/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 release 4.48 of Viedoc:

- **Affected area(s):** Upgrading forms in Viedoc Clinic after a revision has been applied.
Bug description: If a revision was applied on a form to revert the changes of a previously applied but not approved revision, the ‘upgrade pending’ flag would still have been shown after the second revision was successfully applied. This is now fixed so that the upgrade pending flag is not displayed anymore when the latest applied revision has been approved.
- **Affected area(s):** User Settings menu when using Safari.
Bug description: The User Settings menu was not accessible when using Safari. This is now fixed.
- **Affected area(s):** Preview form in Viedoc Designer, under Study Workflow.
Bug description: The form Save & Preview link under Study Workflow in Viedoc Designer was not visible for forms with long form names. This is now fixed.
- **Affected area(s):** Studies overview page in Viedoc Admin.
Bug description: The license number (i.e. Reference ID) was not displayed for locked studies on the studies overview page in Viedoc Admin. This is now fixed.
- **Affected area(s):** Issue flag on forms with required fields.
Bug description: Empty items were wrongly validated in some cross-form checks.
- **Affected area(s):** ViedocMe login after submitting data.
Bug description: If a subject submitted data through ViedocMe and then left the submit confirmation page open (instead of returning to the ViedocMe start page) until being logged out, the subject could not login again using the same browser page.
- **Affected area(s):** Appearance of checkbox text in Viedoc Clinic.
Bug description: Checkbox items with choices having long text might have been truncated and not completely visible in Viedoc Clinic, although it looked good in Viedoc Designer. A new option, **Allow line break**, was added to the item settings for checkboxes in Viedoc Designer. If this option is checked, the field label text will be allowed to be displayed on multiple lines within the form in Viedoc Clinic according to the text length and the label width set in Viedoc Designer.

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List of bug fixes continues.

- **Affected area(s):** PDF data export.
Bug description: When the option to 'Exclude visit date form' was set in the study design, the PDF export was failing. This is now fixed.
- **Affected area(s):** Viewing randomization lists in Viedoc Admin.
Bug description: The 'Date and time' in the Slots tab of the randomization list excel file displayed the time in a 12-hour format, although it was stored in a 24-hour format. This is now fixed and will display the time in a 24-hour format. In addition, the column header was updated to clearly indicate that the time zone is UTC.
- **Affected area(s):** "Study deletion reminder" and "Study delete completed" emails format.
Bug description: The footer of the "Study deletion reminder" and "Study delete completed" emails displayed the date format incorrectly. This is now fixed.

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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.

- 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).

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Signoff



Signature Confirmation by
the product owner.

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