

Release Notes

Viedoc 4.47

Available for users on
2018-12-06

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New functionality



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

Support for Japanese Post-Marketing Surveillance (PMS) studies

Viedoc 4.47 offers support for Japanese Post-Marketing Surveillance (PMS) studies to be conducted within the Viedoc platform. This feature includes support for setting up booklets to be filled in by investigators at sites, and for the workflow for sending booklets between the sites and the sponsor using the submit, receive, and return functions.

Automatic event date

It is possible to set an event date based on another date than the date in the Visit Date form. You can select to set the event date automatically, based on:

- date of first entry of data within any form in the event, or
- a date item or date/time item within any form in the event.

Already before release 4.47, the event date for study start events, common events and subject-initiated events was set automatically. This is now reflected in the automatic event date settings in such a way that the automatic event date option is activated and set to read-only for these types of events. It is however possible to select whether the automatic event date should be based on date of first data entry or on a form item.

For both existing and new scheduled and unscheduled events, the option to set an automatic event date is unchecked by default.

If the option for automatic event date is enabled, it is also possible to exclude the visit date form from the event. If the option to exclude visit date is activated, the visit date form will not be visible or accessible for clinic users. This means that the visit date form is not shown on the Subject Details page, in the review console, in the signing console, and in the issue list, and that it is not possible to raise queries on the visit date. The visit date form is then also not included in metrics, however it is still available in the data export.

The automatic event date functionality is described in the eLearning lesson Study workflow in Viedoc Designer User Guide.

Maximum number of subjects per site

It is possible to limit the number of subjects for a site by setting a maximum number of subjects in the site settings in Viedoc Admin. Once this limit is reached, it is not longer possible to add a new subject to the site, nor in Viedoc Clinic, neither through the import of data via the API. Deleted subjects are not accounted for in this limit.

This functionality is described in the eLearning lesson Managing study sites in Viedoc Admin User Guide.

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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 colour of the visit title displayed on the Subject Details page in Viedoc Clinic has been changed from orange to grey for improved visibility.
- When selecting a study from the landing page in Viedoc Clinic, the Study Status page is displayed in a full screen view so that scrolling down to see all the details on this page is not necessary anymore.
- The clinic role Medical Coder has been added as default to the set of pre-defined roles for new study design versions. Similarly to all other clinic roles, the Medical Coder role can be configured on the Roles page in Viedoc Designer. By default, the Medical Coder role has the following permissions:
 - View data only (no edit permissions)
 - Export data
 - Medical coding
 - Perform medical coding
 - Approve medical coding
 - Add/change queries
- In addition to the new Viedoc User Guide for Site Users and Viedoc User Guide for Monitors, the following three role-based eLearning curriculums are added as default to new study design versions:
 - Viedoc User Guide for Data Managers (added as default to the Data Manager role)
 - Viedoc User Guide for Project Managers (added as default to the Project Manager role)
 - Viedoc User Guide for Medical Coders (added as default to the Medical Coder role)
- The study status as displayed on the Studies overview page in Viedoc Admin now also includes the reference ID in the following format: "Valid license: 1234567".

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Updated functionality and bug fixes



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 4.47 of Viedoc:

- **Affected area(s):** Viewing the form history of a form in Viedoc Clinic using an iPad.
Bug description: When viewing the form history of a form using an iPad, and then closing the form history, the page sometimes froze. This is now fixed.
- **Affected area(s):** Filling in dates in a form in Viedoc Clinic using an iPad.
Bug description: When filling in a date in a form in Viedoc Clinic using an iPad, the date selector did not fit on the screen if the date item was on the right side of the form. Only a part of the date selector was displayed. This is now fixed, so that the date selector is correctly displayed.
- **Affected area(s):** Data review console.
Bug description: For the Viedoc Clinic user, it looked as if the review console did not respect user role permissions, which suggested that it was possible to review data even if a user did not have permission for that. Note that this issue only concerned the apparent behavior of the review console, not the actual action; even though the review checkbox could be selected, no review was performed upon form save if the user did not have review permissions. This issue is now fixed, so that the behavior of the review console follows user role permissions.

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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.

- 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).

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2018-11-29

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