

Release Notes

Viedoc 4.54

Available for users on
2019-10-17

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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 4.54 release:

- **Affected area(s):** Static text with visibility conditions.
Bug description: Static text items with visibility conditions were incorrectly shown in Viedoc Clinic in certain scenarios. This is now fixed
Note! If your study is affected, you will be contacted by a Viedoc representative.
- **Affected area(s):** ViedocMe reminder emails sent out from Viedoc.
Bug description: ViedocMe reminder emails failed to be sent to email addresses containing non-ASCII characters. SMS reminders were not sent to subjects when the ViedocMe reminder email failed to be sent. This is now fixed, and emails are being sent even when the email address contains these characters.
- **Affected area(s):** WHODrug dictionary upload.
Bug description: Due to the increased file size of the WHODrug dictionary version 2019-09-01, it was not possible to be uploaded into Viedoc Admin. This is now fixed.
- **Affected area(s):** Form PDF generation in Viedoc Clinic and ViedocMe.
Bug description: In some scenarios (most probably related to specific form designs) the form PDF failed to be generated resulting in a zero size file. This is now fixed to prevent zero size files from occurring.
- **Affected area(s):** PDF export.
Bug description: The PDF export failed if it contained deleted forms for which the form PDF was missing. This is now fixed.
- **Affected area(s):** Form history PDF and PDF export.
Bug description: The form history PDF and the PDF export included the status (e.g. *Awaits approval*) of the *Confirm data as missing* record in the audit trail as it was when the form was saved. This might have given misleading information about the current status. This is now fixed so that the form PDFs generated after the release will not include the query state text.

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List of functionality and bug fixes continues.

- **Affected area(s):** Validation of forms automatically populated with reference data.
Bug description: When using reference data functionality, the validation of the form automatically populated with reference data sometimes failed since the reference data source selection item was included in the validation, causing an error message to be shown on the form and a red mark on the Visit date form when trying to edit the visit date. This is now fixed.
- **Affected area(s):** Forms with reference data in Viedoc Clinic.
Bug description: When updating reference data values in the Reference data editor in Viedoc Clinic, the forms automatically populated with the updated values were flagged as being updated, even if the updated fields were hidden in the form. This is now fixed, so that updates on the reference data values are not flagged in the forms where the updated items are hidden.
Note! If your study was affected, you will be contacted by a Viedoc representative.
- **Affected area(s):** Study workflow PDF in Viedoc Designer.
Bug description: In Viedoc Designer > Study workflow the deleted events/activities were still included in the study workflow PDF, if the deletion was made in a revised version of the study design. This is now fixed.
- Some corrections were performed to the German and Chinese system languages.

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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, not “START”.
- 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.
- If the role that has the permission for Emergency unblinding also has a role visibility condition that makes the blinded outcome hidden for this role, the outcome gets hidden for all roles after unblinding, and not just for the role specified in Viedoc Designer.
- ODM export fails when subject data contains large uploaded files.
- If, in the study workflow in Viedoc Designer, there are more activities with the same activity name within the same event, then the forms in these activities are incorrectly displayed in the Bookmarks list in the study workflow PDF. Please note that only the Bookmarks list is affected, the events/activities/forms are correctly displayed within the document.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2019-10-10

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