

viedoc™

# Release Notes

## Viedoc 4.75

Planned for 2023-04-25

# Release Notes

## Viedoc 4.75



## New and updated functionality



List of functionalities that have been added and updated in this release.

### Viedoc System

- As part of our ongoing efforts to abide by our values, we've decided to update the User role avatars in Viedoc to be more broadly representative of the plurality of our users. These new avatars will be in Viedoc Designer and Viedoc Clinic. Our eLearning will also reflect these changes in the coming releases.

### Viedoc eTMF

- In the Trial Master File view, on the Structure page, documents can now be filtered by Trial level. At the top of the filter menu, the option All documents is introduced, and Trial level is now an option on that menu. The Trial level option means that users can filter out the documents that are linked to that level only.
- In the Trial Master File view, on the Structure page, it is now possible to see when documents are being uploaded even when there are filters set. Reloading the web page does not reset the filters anymore.
- In the Trial Master File view, the format for date, time, and datetime is now inherited from Viedoc Admin>Study settings>Date & time format. This way, the eTMF follows the same pattern as the other Viedoc applications.

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### Bug fixes



List of bug fixes that have been updated in this release.

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

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

The following corrections have been implemented in the Viedoc 4.75 release:

- **Affected area(s):** Viedoc WCF API  
*Bug description:* When data was imported to a form in an initiated event (with a burned-in design version), and the imported file had a different event date to an event date in Viedoc Clinic, the imported form was initiated in the latest effective design version. This is now solved so that the imported form and the event have the same design version.
- **Affected area(s):** Viedoc WCF API  
*Bug description:* When importing data, if multiple **Unscheduled Events** were initiated in the same imported file and they had different event dates, the names of the forms that were not initiated by the import were displayed incorrectly. This is now solved.
- **Affected area(s):** Viedoc WCF API  
*Bug description:* If multiple **Unscheduled events** were initiated in the same imported file but had different event dates, the same **StudyEventRepeatKey** was given. This is now solved and unique **StudyEventRepeatKeys** are generated per study event.
- **Affected area(s):** Viedoc WCF API  
*Bug description:* When a study event was planned or reset, the WCF API method “**GetMetaDataVersionForKeySets**” did not return the correct **MetaDataVersionOID**. This is now solved so that the returned version is the latest effective version at the site.
- **Affected area(s):** Viedoc WCF API  
*Bug description:* When an imported file contained two or more different event dates for two different parameters, multiple events were created using the two different event dates. This is now solved so that only one event will be created.
- **Affected area(s):** Viedoc Clinic, Viedoc PMS  
*Bug description:* In some study design configurations, the warning message: “The booklet has **Adverse Event** which must be reported immediately”, was displayed when the **AE** form had been deleted. This is now solved.

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List of bug fixes continues.

- **Affected area(s):** Viedoc Admin  
*Bug description:* In the Admin audit trail, the action “Remove user role from study” is listed when it is performed by users with a current Study Manager or other system authorized roles. If those roles were revoked, the action was not listed in the Admin audit trail. This is now solved.
- **Affected area(s):** Viedoc Me  
*Bug description:* The Dutch language system translations have been improved and updated.
- **Affected area(s):** Viedoc Reports  
*Bug description:* In Viedoc Reports, when the ‘Revert Icon’ was hovered over, the text displayed ‘reset selection’ in English when a language other than English was selected for the system. This is now solved by displaying the message in the chosen language.
- **Affected area(s):** Viedoc Reports  
*Bug description:* In Viedoc Reports, the report “Missing Data” when looking at the “by Form” sub report, the “Days Elapsed” category displayed an incorrect number based on an incorrect date calculation. This is now solved.
- **Affected area(s):** Viedoc Reports  
*Bug description:* The SampleReportCode program mentions that SDV data is present in the edcData.rds. The SDV data is no longer included in edcData.rds. This is now solved.
- **Affected area(s):** Viedoc System  
*Bug description:* When exporting data as a PDF in Japanese, in an appendix which includes a description about the meaning of a signature, the system displayed the incorrect Japanese characters. This is now solved.
- **Affected area(s):** Viedoc Designer  
*Bug description:* When inserting certain characters into text fields inside Designer, errors resulted in the ODM file. This is now solved by allowing for previously unaccounted for characters to be used in the text. For example, a smiley emoji 😊.
- **Affected area(s):** Viedoc Designer  
*Bug description:* When XML characters not identified by the system are entered into Designer, the design validation was not completed. This resulted in a design version that could not be opened and a system error message that said, “Your action is not accepted.” This is now solved by allowing for the design to be usable despite the presence of unidentified XML characters .
- **Affected area(s):** Viedoc Designer  
*Bug description:* In Designer, in the roles section, if no avatar was selected, a default avatar was chosen and displayed incorrectly. This is now solved.

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List of bug fixes continues.

- **Affected area(s):** Viedoc eTMF  
**Bug description:** In the Trial Master File view, when downloading a file that had some special characters in its filename, followed by normal characters, those normal characters would get truncated from the name of the downloaded file. This is now solved, and the special characters are replaced by underscores and the normal characters are included in the filename.
- **Affected area(s):** Viedoc eTMF  
**Bug description:** In TMF Admin, when the option Download template on the Settings tab included a # character, the downloaded template would get a GUID as its filename. This is now solved.
- **Affected area(s):** Viedoc eTMF  
**Bug description:** In the Trial Master File view, when previewing MS Word or Excel documents, the pagination was incorrect. This is now solved.
- **Affected area(s):** Viedoc eTMF  
**Bug description:** In the Trial Master File view, when something went wrong with the document preview, an error message was shown, but the corresponding error image was missing. This is now solved.

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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:

### Viedoc Clinic

- CSV export
  - The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (for example, an OID defined as AE in design version 1 and ae in design version 2).
  - Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
  - The Excel/ CSV export does not include items set to “Hide Always” in visibility conditions when a single form is selected for export.
- Data export
  - The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
  - The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Data review
  - Queries of the type “Required value missing” responded with “Confirmed as missing” and cannot be rejected by the sponsor side.
  - 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.
- Edit/enter data
  - For scheduled and unscheduled events, when the visit date form (\$EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a visit includes the \$EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or visit). If you sign forms on a visit individually you will not be able to sign the \$EVENT form. This in turn makes it so that the sign symbol that appears on the visit when everything is signed does not appear, even though it looks like everything is signed.
  - When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.
  - It is not possible to delete unscheduled visits if automatic visit dates are enabled.

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List of known limitations continues.

- File upload
  - 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.
  - The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- Issues and task
  - The Issue list will not be visible for sites that have more than 1000 subjects.
- Layout
  - When adjusting the font size in a form item this is not respected by Internet Explorer 11. This may result in a change to the layout of the form. The descending sorting in the subject list view is not working properly.
- Medical coding
  - The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Metrics
  - The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with state "Removed".
- PDF export
  - 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, filenames 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.
  - 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.

- Selection page
  - The descending sorting in the subject list view is not working properly.
  - When clicking to sort a column containing dates in the subject list view, Viedoc sorts all dates using a numeric variant of US date representation (for example, 1977-NOV-16 comes before 1967-DEC-16 because the first is sorted like 11/16/1977 and the latter is sorted like 12/16/1967).
  - The event overview page is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Documentation and Training
  - When downloading a PDF of the Viedoc User Training Certificate, the generated PDF is limited to two pages. This means that when there are more training sections completed than can fit onto two pages, the PDF will not generate a third page and some of the training sections will be missing.

### Viedoc Admin

- Apply revision
  - 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.
- Data import
  - 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.
- ODM import/export
  - 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”.
  - Only one (selected) design can be imported from each CDISC ODM file.
  - ODM export fails when subject data contains large, uploaded files.
- User management
  - 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 sorting studies by group and generating a “User and Roles” or “User Administration Log” report, the Download link is not exposed for the newly generated file until the page is refreshed.



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List of known limitations continues.

- **Study Settings**
  - The Logs tab for generating the Admin audit trail report does not appear on the Study Settings page if the system language is German or Swedish.
  - The Documentation tab for the documentation and training feature, do not appear on the Study Settings page if the system language is German.

### Viedoc Designer

- **Alerts**
  - 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.
- **Edit checks**
  - 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.
  - 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).
  - 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).
- **Form and workflow PDF**
  - If, in the Study Workflow, 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.
  - 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.
- **Item settings**
  - 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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List of known limitations continues.

- JavaScript
  - The setMonth function with negative values is not supported. The date is not saved into the system correctly when the function is run on the server-side.
- Roles and permissions
  - 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.
- Study workflow
  - When the Event ID for the Study Start event contains the word “START”, including combinations with other words and punctuation, 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, one that doesn’t contain the word “START”.
- Validation of study design
  - 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.
- Visibility conditions
  - When creating forms for ViedocMe, visibility conditions can only include variables that have already been introduced, and that are in the same form and on the same page. This behavior differs from the one in forms for Viedoc Clinic.

### Viedoc API

- 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.

### ViedocMe

- In the UI-optimized version of Viedoc Me, when a simple visibility condition has been set to make a form item show depending on the selection of a radio button, and a subject selects the radio button, an error message is displayed
- 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.
- 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).

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List of known limitations continues.

- The drawing pad item is not working on IE 11. For Safari it only works on Safari 12+ versions.
- Viedoc Me does not support forms with form link items.
- The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.
- Long option labels for radio buttons and check boxes do not have line breaks.

### Viedoc Logistics

- In the exported stock list, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.

### Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.
- Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.
- The Overdue Events Report does not include any Viedoc Me events. Events without a proposed date are not included in this report. Events that have been planned or initiated are not included in this report, even if the planned/initiated event is outside of the event window.

### Viedoc eTMF

- Viedoc eTMF is only running in Production mode.
- For security reasons, the document preview in the Trial Master File view does not support ActiveX components.
- The search for document content is disabled on the training server.

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### Signoff



Signature Confirmation by  
the product owner.

Uppsala, Sweden 2023-04-18



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