

viedoc™

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Release Notes

Viedoc 4.83

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New and updated functionality



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

Viedoc Share

A Viedoc Me user can now add a note with comments/questions to a document that has been shared with them and a co-signatory. The clinic user assigned as co-signatory can view the user's notes in the document and reply to them in Viedoc Share. Notes and replies can only be added before the document is signed. It is also possible to download the document with the added notes by using the "Download with notes" option, both from Viedoc Share and Viedoc TMF.

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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 4.83 release:

- **Affected area(s):** Viedoc Suite
Bug description: In some rare scenarios, users received duplicate email alerts triggered from Viedoc or Viedoc Me. This is now solved, so that users will only receive one email as expected.
- **Affected area(s):** Viedoc Designer
Bug description: When the study name contained Chinese or Japanese characters in Viedoc Designer, the configuration report in Excel displayed an incorrect text string, this only affected the Excel file name. This is now solved, so that when generating a new configuration report in Excel, the file name has the expected format even if Chinese or Japanese characters are used in the study name.
- **Affected area(s):** Viedoc Admin
Bug description: When creating a new study in Viedoc Admin, and the required fields for the study name and/or the study manager were not filled in, the red frame around the field indicating that the field was blank was incorrectly displayed. It was still not possible to save the form. This UI issue is now solved.
- **Affected area(s):** Viedoc Admin / Viedoc Clinic
Bug description: When a study had only a demo site registered, and a user and administration log was exported from Viedoc Clinic, the log incorrectly contained the study GUID for production and therefore differed from the GUID shown in Viedoc Admin. When the production site was added to the study, the correct study GUID was then reflected in the user and administration log. This is now solved so that the log includes the correct GUID even if there is only a demo site added to the study.
- **Affected area(s):** Viedoc Admin / Viedoc Clinic
Bug description: In Admin Study settings, and in Viedoc Clinic’s Viedoc Me account activation pop-up window, some texts were displayed in English instead of the language selected by the user. This is now solved, and the correct selected system translations have been added.

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List of bug fixes continues.

- **Affected area(s):** Viedoc Coder
Bug description: In some circumstances, when a form was saved, terms related to a coding scope in Viedoc Coder were not synced to Viedoc Coder. This occurred when the form was saved again, before the update could reach Viedoc Coder, and if the new form updates did not affect items within a coding scope. This has now been solved, and we are currently working on a solution to sync the already missing items.
- **Affected area(s):** Viedoc Coder
Bug description: When a scope was enabled for coding, and items with a visibility condition for specific roles (created in Viedoc Designer), already existed in Viedoc Clinic, the initial sync excluded all items related to that scope in Viedoc Coder. This has now been solved.
- **Affected area(s):** Viedoc Clinic
Bug description: When a CRF revision was performed in a study which included Viedoc Me events, the metrics on the landing page and on the selection page incorrectly counted Viedoc Me forms and event dates as pending SDV. However, no review tasks were flagged on the subject page. This is now solved, so that Viedoc Me forms and event dates are not flagged as needing SDV on the landing page or on the selection page.
- **Affected area(s):** Viedoc Clinic
Bug description: SDV checkboxes that were not displayed for Viedoc Me forms and event dates, could still be selected in the review console. This is now solved, and SDV checkboxes for Viedoc Me events can no longer be selected.
- **Affected area(s):** Viedoc Clinic
Bug description: If a query was raised in a Viedoc Me form or Viedoc Me event date, the form was unlocked and the query resolved by a user with data entry permission, SDV tasks were incorrectly displayed for these forms on the selection and landing pages. This is now solved, and Viedoc Me forms are no longer flagged as requiring SDV.
- **Affected area(s):** Viedoc PMS
Bug description: When a study was locked, the PDF exports failed on the sponsor side. This is now solved, and the exports are generated as expected.
- **Affected area(s):** Viedoc eTMF
Bug description: It was not possible to add form fields (radio buttons, checkboxes, free text fields) to a new version of a document. This is now partially solved, so that it is possible to add/edit form fields in a new document version that was created as a copy of the previous version.
- **Affected area(s):** Viedoc eTMF
Bug description: The printed date/time in the Report Info section of the Complete Audit Trail report excel file was wrong. This issue was introduced in Viedoc 4.82 release and is now solved, so that the correct date is shown in the newly generated reports after 4.83 release.

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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:

We no longer support SMS notifications in the following countries

- +7 Russia
- +92 Pakistan
- +994 Azerbaijan
- +967 Yemen

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 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.

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List of known limitations continues.

- 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.
- 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.
- Medical coding
 - The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
 - The MedDRA Chinese translation version 26.0 and onwards has the term 牙开殆. This term will be displayed as 牙开 in the Viedoc system, as the last character is not supported.
- 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.
 - In the PDF export output, each event should have a "Contents" section. The "Contents" list can in some scenarios be truncated and not show everything for the event.

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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.

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.
- API configuration
 - After creating new and editing existing Web API clients, it is not possible to save the setup unless the user system language is set to English or 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.

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List of known limitations continues.

- 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.
- 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".

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List of known limitations continues.

- 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.
- When using the WCF API to push data into forms, if there are items that have functions setup to calculate data from other items, or item groups, those calculations will not be automatically updated. However, if an item that relies on a function is added to the same item group it relies on, it will perform the calculation.

ViedocMe

- 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).
- 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.
- Sharing the Viedoc Me access details via text message does not work for studies that are running on the Viedoc China instance.
- In Viedoc Clinic, when activating a Viedoc Me account, there is the option of sharing the access details via a PDF file. This PDF file is translated to the supported system languages only, and not to all supported Viedoc Me languages. This is also applicable to the test email and test text message that are used solely to verify the subject’s contact information, and not to verify the selected Viedoc Me language.

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List of known limitations continues.

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 not working in Safari version 16.3 and later versions.
- 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.

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