

viedoc™

Release Notes

Viedoc 4.73

Planned for 2022-11-29

Release Notes

Viedoc 4.73



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

New and updated functionality

Viedoc eTMF

- In TMF Admin, the version number of the structure is now appended to the end of the structure name instead of the “Customized” text. This change is available going forward, and the previous structure names won’t be affected.
- In the Trial Master File view, the document preview now supports displaying the contents of zipped folders without having to download them.
- In the Trial Master File view, the Details page now indicates deleted and inactivated zones, sections, and artifacts.
- In Viedoc eTMF, the page header and the icon on the browser tab have a new design. This is another step in the implementation of a wider UI optimization across the Viedoc suite.
- In TMF Admin, the Settings tab has a new option under Structure: Show zone, section, and artifact numbers. When this option is selected, the Structure view in the Trials Master File view and the TMF structure page in the TMF Admin view display the zone, section, and artifact numbers and names in the same way as in the tooltip text that is displayed when hovering over them. The option is selected by default for new studies and deselected by default for existing studies.
- In the Trial Master File view, for Excel and CSV exports from the Details page, the file name of the generated file has been updated to be more informative. The file name is now StudyName_DetailsPage_YYYYmmDDHHMMSS. The timestamp is in UTC format. For Excel files, the included sheet name is now Details page.
- In the Trial Master File view, the Details page now includes the dating convention and the dating convention value in separate columns.

Viedoc Admin

- In Viedoc Admin, when sending email alerts with an attachment, it is now possible for Study Managers to enable password protection for the attached files.

Viedoc Clinic

- In Viedoc Clinic, if the option to enable password protection for alert email attachments has been selected for a study, Clinic users will need the password provided by the Study Manager to open the attachments.

Release Notes

Viedoc 4.73

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 4.73 release:

- **Affected area(s):** Viedoc eTMF
Bug description: When uploading a template for a new study it was not possible to cancel the upload. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: To see the new features of a release, users needed to clear the cache in their browsers. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In the TMF Admin view, on the Templates tab, the checkmark on the Select button was displaying incorrectly. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When switching between the Trial Master File and Archive tabs, the radio button for the archive view reset itself without user interaction. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: While bulk uploading files in the drop zone area, a portion of the files were duplicated and remained in the uploading state. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In the Document properties window, document name labels were not changing dynamically when changes to the metadata should have caused them to change. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In the Trial Master File view, when an error message was displayed in the document preview, the UI was misaligned. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In Viedoc Viewer, unsupported file types were still selectable. This is now solved.

Release Notes

Viedoc 4.73



List of bug fixes continues.

- **Affected area(s):** Viedoc eTMF
Bug description: When an artifact was edited for the first time; a window popped up asking the user to apply or revert changes. In that window, the artifact was listed as “Added” instead of “Edited.” This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When artifacts were edited in maintenance mode, they were displayed as red when maintenance mode was turned off. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When comments were generated by the system on a document, they lacked a space separating them from each other. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When the user changed the TMF location of a document, the document’s metadata was cleared even though the new location has the same metadata properties. This has now been solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When editing document metadata that affect the document name labels, sometimes the changes were not reflected dynamically in the Document properties window. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: If the value ‘NO’ was in both the Sponsor and Investigator columns when editing an artifact within a template, then an instantiation of the template occurred. If followed by a re-edit of the same artifact, an error would occur. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When changes from maintenance mode had been applied to sub-artifacts within artifacts, the removed sub-artifacts were still shown in the View Artifacts window after they had been removed. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: Attempting to cancel a file upload was not possible after the upload reached a certain percentage of completion. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: Users could download only published documents from the Details page. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When changing artifact properties in maintenance mode without changing the main or sub-artifact links, the corresponding audit trail record in the Structure management sheet of the Complete audit trail report indicated changes in the main and sub-artifact links. This is now solved.

Release Notes

Viedoc 4.73



List of bug fixes continues.

- **Affected area(s):** Viedoc eTMF
Bug description: When navigating to the Details page from a known location, it was not possible to change the filter to see documents from other locations. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: When importing a file that did not have an 'X' in the following columns: Trial Level Document, Country/Region Level Document, or Site Level Document; yet, they had values in the following columns: Trial Level MILESTONE/EVENT, Country Level MILESTONE/EVENT, Site Level MILESTONE/EVENT, the template was imported. The existing values in the following columns: Trial Level MILESTONE/EVENT, Country Level MILESTONE/EVENT, Site Level MILESTONE/EVENT were then removed when exporting the template. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: On the Details page, after searching by document name or content, users could, if the search criteria matched the document names or content, see artifacts that they did not have access to, based on their role and artifact access permissions for that role. However, the users were not allowed to open, access, or download the documents that they did not have access to – they were merely listed among the search results. This is now solved, and the Details page takes the trial, country, and site permissions into consideration.
- **Affected area(s):** Viedoc eTMF
Bug description: It was possible to upload empty files to artifacts that were configured to accept the file type in question. This is now solved, and an error message is displayed, and the empty files cannot be uploaded.
- **Affected area(s):** Viedoc Me
Bug description: In the newly optimized version of Viedoc Me, the date was incorrectly displayed for the African languages: Zulu, Setswana, and Southern Sotho. This is now solved.
- **Affected area(s):** Viedoc Admin
Bug description: When uploading medical coding dictionaries, some users experienced an internal server error. This is now solved so that the upload processes are run in the background. This allows users to move away from the upload page. Users will see two messages, "Upload in queue" and "Upload in progress" for new instances while the dictionary import takes place.
- **Affected area(s):** Viedoc system
Bug description: When signing up for a new Viedoc account, if a user created a password containing a blank space, they would get an error message while fulfilling the password criteria. This is now solved, so that if a user creates a password with a blank space, they will get an error message telling them that spaces are not allowed.

Release Notes

Viedoc 4.73



List of bug fixes continues.

- **Affected area(s):** Viedoc PMS
Bug description: For PMS studies, when including the Booklet status in the ODM export, the LatestReceivedDateTime was incorrect in the exported ODM file after a return recall action was performed on the booklet from the Sponsor side. This has now been solved.
- **Affected area(s):** Viedoc Reports
Bug description: In Viedoc Reports, plots displayed incorrectly when the plot height was greater than 500 pixels. This has now been solved.

Release Notes

Viedoc 4.73



List of limitations that have been found with this and earlier releases of Viedoc, and will be changed in future releases.

Known limitations

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
 - The SDV task count, the green checkmark and the issue list on the subject Selection page 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).
 - 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.

Release Notes

Viedoc 4.73



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.
- 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.

Release Notes

Viedoc 4.73



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.

Release Notes

Viedoc 4.73



List of known limitations continues.

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.
- 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.

Release Notes

Viedoc 4.73



List of known limitations continues.

- **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).
- 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.

Release Notes

Viedoc 4.73



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 only running in Production mode.
- For security reasons, the document preview in the Trial Master File view does not support ActiveX components.

Release Notes

Viedoc 4.73

Signoff



Signature Confirmation by
the product owner.

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