

viedoc™

Release Notes

Viedoc 4.71

Planned for 2022-06-16

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

New and updated functionality

Viedoc eTMF

- In Viedoc eTMF, a powerful new function for displaying, sorting, and filtering documents by their metadata is introduced. The Details page is available to all users of the Trial Master File view, and it can show all the documents that a user has access to. The Details page is automatically opened when a user performs a search for documents. It can also be opened from sections, drop zones, and artifacts to show the documents in the respective location. From the Details page, it is possible to toggle back to the Structure page. The Details page has:
 - A powerful filtering function, operating on column level
 - A feature to sort data based on the values in a column, in ascending or descending order
 - Options to select which columns to include
 - A range of display options, including the possibility to pin columns to the left or the right, to auto size column width, and to freely rearrange the order of the columns

Once the document data has been filtered, sorted, and arranged according to the users' settings, they can perform an export that exactly reflects their view.

Viedoc Reports

- In Viedoc Reports, there is a new Dashboard page for Japanese PMS studies which gives snapshots of the registration and study progress. The PMS dashboard has the following specific terms:
 - Registration status:
 - Pre-registered - the total number of pre-registered subjects and the number of days since the latest pre-registration.
 - Registered - the total number of registered subjects and the number of days since the latest registration.
 - Registration progress - the actual number of registered subjects divided by the expected number of registered subjects.
 - Registration rate - the speed at which the subjects are being registered across the sites. Note! A subject is pre-registered when the registration booklet has been completed and submitted.
 - Study plan:
 - FSFB - the date of the first booklet for the first subject.
 - LSLB - a last subject last booklet marker, estimating the date of the last submitted booklet for the last subject.
 - Booklets initiated: The number of booklets initiated in the study.

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List of new and updated functionalities continues.

- In Viedoc Reports, a new PMS dashboard report is introduced as a standard report for Japanese PMS studies. Data can be sorted to focus on the booklet status by site, subject, booklet, booklet history, or timelapse as described below.
 - by Site: This shows a site level summary of booklets status along with the number of provisionally registered and registered cases. Booklet freeze progress as a percentage is shown as a bar plot.
 - by Subject: This shows a subject level summary of booklet status along with the Subject added date and Subject complete date. Booklet freeze progress as a percentage is shown as a bar plot.
 - by Booklet: This shows a booklet level summary of current booklet status and last activity date along with the number of open, resolved, and closed queries.
 - By Booklet (history): This shows the Booklet status history- the user can filter for a specific date along with the Subject added date from the subjectAddedDate.rds file.
Note! This does not include “Not Initiated” records.
 - Timelapse: This shows the time lapse between the Initiated Date and first Submitted Date for each booklet status, summarized at Subject level, along with the lapse in days of resolved and closed queries.
Note! This is for subjects that have at least one booklet that has been Initiated and submitted. Also, the lapse in Resolved and Closed queries for a subject is obtained from Queries and displayed.

Viedoc Admin

- In Viedoc Admin, the API configuration now has two tabs – one for Web API client and one for WCF API client. The tab for the WCF API client contains the same functionality as the previous version of the API configuration. The tab for Web API client has been added for Viedoc 4.71. There, users can add new Web API clients and edit or delete existing ones. When adding a new Web API client, the following are obtained:
 - Client secret
 - Client ID
 - Token URL
 - Grant type
 - API URL

Viedoc Me

- Viedoc Me now has a modernized user interface. This will also serve as a soft introduction to wider UI optimization across Viedoc suite.
- Users can select, in both production and training sites, which Viedoc Me interface trial patients will interact with. The selection can be made in the Study Settings.

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List of new and updated functionalities continues.

- In Viedoc Me, there is increased functionality with Viedoc Connect:
 - The user can now minimize and maximize the Viedoc Connect window when there is an ongoing call.
 - The user can also navigate to other Viedoc Me pages and fill in forms while in a call on Viedoc Connect.
- In Viedoc Me, there is a new button notification that alerts the user when there is an active video call from anywhere in the app. The user can select the button at any time from any page within the application to join a call.

Viedoc PMS studies

- In Viedoc Admin, the Study settings for PMS studies now include two new options:
 - Require Contract for booklet submission
 - Require Responsible Investigator for booklet submissionWhen selected, these options can be set to mandatory or optional.
- In Viedoc PMS, if the options for Contract and Responsible Investigator have been selected in Viedoc Admin, the Submit booklet dialog has fields for Contract and Responsible Investigator.
- For PMS studies that have the options enabled in Viedoc Admin for linking the booklet to Contract and Responsible Investigator, the Excel export now contains two new columns on the Booklet status sheet:
 - Contract Number
 - Responsible InvestigatorBecause the new columns are at the end of the Excel sheet, no new export version is created.

Viedoc API

- It is now possible to use the Viedoc Web API to create and invite users.
- It is now possible to add Contracts, Sites and User properties through the Viedoc Web API. This information is included in the ODM formatted data export.

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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 4.71 release:

- **Affected area(s):** Viedoc Designer and Viedoc Clinic
Bug description: When changing the text of the "Choose one" option in the dropdown menu in Forms, the new text changed back to the default text when importing and exporting the design ODM file. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: The "Choose one" dropdown item changed from integer to string data type in the Items tab in the Excel/CSV export after exporting and importing a design. This is now solved.
- **Affected area(s):** Viedoc Designer and Viedoc Me
Bug description: The "Choose one" dropdown list caused the Code list items to decouple from formats after exporting and importing a design and then saving a form. This also affected the Viedoc Me translations. This is now solved.
- **Affected area(s):** Viedoc Admin - Data Import Application
Bug description: A new version of the import application is released with an improved encryption mechanism for passwords. When the new import application version is run, it will always request the file path to the configuration file. Otherwise, the latest version of the import application works in the same way as the previous version. Older version(s) of the import application will continue to work for existing users using the old encryption key. However, users who are using the new import application, along with an existing import configuration file, will need to re-enter the password (for each import configuration, if more than one exists in the same file), as a new password encryption will take place.
- **Affected area(s):** Viedoc PMS
Bug description: For users with a sponsor-side role, clicking on Documentation & Training documents resulted in a redirect to the Clinic home page. This only affected documents uploaded by users. This is now solved.

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List of bug fixes continues.

- Affected area(s): Viedoc PMS
Bug description: For Clinic side users, it was not possible to delete a subject that had an AE form that was Submitted-Received-Returned-Deleted. This is now solved.
- Affected area(s): Viedoc PMS
Bug description: The study design revision was not applied to newly added AE forms within a booklet that had partially submitted- received AE(s) before the revision was applied. This is now solved.
- Affected area(s): Viedoc PMS
Bug description: The Subject status calculations based on the BookletStatus variable were not updated on the Sponsor side when the BookletStatus was set to Frozen. This is now solved.
- Affected area(s): Viedoc API
Bug description: Activities on the EventDate form were not included when returning the date and time of the latest activity on study data. This is now solved.
- Affected area(s): Viedoc Me
Bug description: When a subject changed their contact and reminder settings, their email address and telephone number were overwritten with invalid information. This is now solved.
- Affected area(s): Viedoc eTMF
Bug description: The artifact titles were still visible in the Artifacts & documents area after all documents in a deleted artifact had been deleted or moved. This is now solved.
- Affected area(s): Viedoc eTMF
Bug description: During batch upload at artifact level, while uploading a group of files containing both valid files and files with viruses, the infected files were removed from the application without displaying an error message. This is now solved.
- Affected area(s): Viedoc eTMF
Bug description: In the audit trail, the custom name field label was displayed in title case. This is now solved, and the label is displayed in sentence case.
- Affected area(s): Viedoc eTMF
Bug description: In TMF Admin, when adding a new milestone in maintenance mode, the field validation was performed prior to saving. This is now solved.
- Affected area(s): Viedoc eTMF
Bug description: In the structure view, for a document that was assigned to multiple sites, the document name was displayed with one character per line. This is now solved.
- Affected area(s): Viedoc eTMF
Bug description: There was an error when accessing the document sharing links. This is now solved.

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List of bug fixes continues.

- **Affected area(s): Viedoc eTMF**
Bug description: In TMF Admin, it was possible to import a template where the sheets had the same number of rows but a mismatch regarding artifact numbers. This is now solved, and the artifact numbers are validated upon import.
- **Affected area(s): Viedoc eTMF**
Bug description: Documents disappeared from the artifact they were filed to when the artifact was edited and the section that the artifact was in included non-sequential artifact numbers. This is now solved, and all documents have been restored.
- **Affected area(s): Viedoc Me**
Bug description: The system languages for Chinese (Traditional, Hong Kong S.A.R.) and Chinese (Traditional, Taiwan) were not correctly shown. This has now been solved.
- **Affected area(s): Viedoc Clinic – Data export**
Bug description: The export failed when data was saved according to a design version with a non-existing item. This has now been solved.
- **Affected area(s): Viedoc Designer and Viedoc Clinic**
Bug description: When approving a design revision in Viedoc Designer, when any subject on the site was locked because of an edit, the revision upgrade failed. In Viedoc Clinic, the forms for the subject were then not upgraded and the issue flag was still displayed for the forms after the batch approval. This has now been 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

- Connect
 - Viedoc Connect is not supported on IE11.
- 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

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List of known limitations continues.

- 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.
- 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.

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List of known limitations continues.

- 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.
- 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.
- Date Format
 - The following date formats are known to cause issues in study settings, please do not use them.
 - d/M/yyyy
 - dd/MM/yyyy
 - dd.MM.yyyy
 - dd M yyyy
 - dd MM yyyy
- 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.

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List of known limitations continues.

- 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.

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

- 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.
- There is an issue with the 'contains()' function' in the new Viedoc Me with the optimized UI. This issue affects the visibility of the check boxes. If you encounter this issue, we recommend that you continue using the "old" Viedoc Me application until the issue is resolved.

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 user-specific information or subject-related information (Viedoc Me). 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.

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Signoff



Signature Confirmation by
the product owner.

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