

viedoc™

Release Notes

Viedoc 4.70

Planned for 2022-05-05

Release Notes

Viedoc 4.70

New functionality



List of new functionality that has been added to this release.

This release introduces the following new features in Viedoc:

- In Viedoc Clinic, a form link item is introduced. It allows links to be created between events and forms containing related/dependent data for Clinic users, this means that information from different forms or events can be easily connected and viewed by clicking the link in a form. This can be useful, for instance, to show the reason(s) why a particular concomitant medication was taken by a subject and when it was taken. Different events, such as an Adverse event or a Medical History event, can be linked to the concomitant medication, as well as items from these forms: start/stop dates, etc. Note! Viedoc Me does not support forms with form link items.
- In Viedoc eTMF, a document preview is now available in the Document properties dialog and in the file dialog for documents in the drop zones. It allows users to view the file in the browser, without downloading it. The preview shows the latest version of a document, side by side with its metadata. No files are stored on the user's computer when previewing. This might be helpful if they want to avoid storing potentially sensitive data on their hard drives. The document preview is available to all eTMF users with at least read permission.
- In Viedoc Reports, two new standard reports are included: the Overdue Events Report and the Form Status Report.
 - The Overdue Events Report shows events that have the Proposed date and Event Window End Date set to a past date. The data in the report can be grouped to show the number of overdue events by country, site, subject, event, or by the past proposed date.

This report is also included as part of the Key risk indicator report

Note! This 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.

- The Form Status Report allows users to see an overview of the status of forms, for example, initiated, pending, (and triggered which includes both initiated and pending forms), saved with issues, signed, unsigned, or completed. The data in this report can be grouped to show the numbers of forms with the above status as well as the progress of form initiation as a percentage for initiated forms and triggered forms.

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List of new functionality continues.

- In Viedoc Reports, the Pending forms per subject report is introduced as part of the Key risk indicator report and is included in the following subreports: Overview, by Site, by Key Risk Indicators. This report calculates the average number of pending forms for each subject. The site value is the average number of pending forms per subject for each site. **Note!** Pending forms is not shown if there are no pending forms in the study.
- In Viedoc Reports, the Rejected queries per subject is introduced as part of the Key risk indicator report and is included in the following subreports: Overview, by Site, by Key Risk Indicators. This report calculates the number of rejected queries for each subject. The Site value is the average number of queries with query status as rejected per subject for each site. **Note!** Rejected queries is not shown if there are no rejected queries in the study.
- In Viedoc Admin and Viedoc Clinic, three different Communication logs are available to download for SMS and emails in Excel file format. This means that Study/ Site Managers and Investigators can now access email/SMS communication logs for specific studies and users, and Investigators can access the email/SMS communication logs for a specific subject. The following Communication logs are available to view and download.
 - In Viedoc Admin, the study-specific User Communication Log. This log contains the following communication related to a study: Alerts, Invitation to a specific role within a study, Notifications (study access deletion). This log does not include any user-specific information or subject-related information (Viedoc Me).
 - In Viedoc Admin, the user-specific Communication log, which is accessed on a new Communication Log tab in User settings. Users with access to the User settings in Viedoc Admin can access the Communication Log tab and download the complete Communication log for that specific user. The Communication Log tab shows: date and time, type of message and message status and displays the latest 20 rows of the log. The downloadable Communication logs file contains information about all SMS and emails to the study users that are unrelated to a specific study, such as: Reset password, verification, and notifications (for example changing a telephone number or email address), two-factor authentication (email/ SMS). The Communication Log tab is only visible once the user has activated the Viedoc account and has accepted at least one invitation. This log does not include any subject-related communication (Viedoc Me or any study-specific user information).
 - In Viedoc Clinic, the subject-related Communication log. In a subject's Viedoc Me account a new subject-related Communication log is added as a separate sheet to the ViedocMeLog Excel file that is downloaded from the ViedocMe account Status page. This Communication log contains information about all emails and SMS communication sent to the subject. This includes message ID, the Viedoc username (user account), communication type (email/SMS), message type (reminder, date and time of the communication), site type (training/production), the status of the message (success/failed) and the provider name used to send the communication to the recipient (this information is used if needed for troubleshooting purposes).

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Updated functionality and bug fixes



List of functionality and bug fixes that has been updated in this release.

Updated functionality

- In Viedoc Reports, in the Disposition Report, the following functionalities have been updated:
- The dropdown options have been renamed as follows:
 - Event (table by Study) - previously named Event Summary Table (by Study)
 - Event (table by Country) - previously named Event Summary Table (by Country)
 - Event (table by Site) - previously named Event Summary Table (by Site)
 - Event (plot by Country) - previously named Event Summary Plot (by Country)
 - Event (plot by Site) - previously named Event Summary Plot (by Site)
 - Subject status (table by Study) - previously named Disposition Summary Table (by Study)
 - Subject status (table by Country) - previously named Disposition Summary Table (by Country)
 - Subject status (table by Site) - previously named Disposition Summary Table (by Site)
 - Subject status (plot by Country) - previously named "Disposition Summary Plot (by Country)
 - Subject status (plot by Site) - previously named Disposition Summary Plot (by Site)
 - Event dates by Subject - previously named Details
- In Event dates by Subject, and in Subject status (table by Study) the column name is now Subject Status, replacing Disposition status.
- In the plots, the y-axis label name is now the % of subject status replacing the % of disposition status.
- The Subject status plots are now named Subject Summary (by Country) and Subject Summary (by Site) replacing Disposition Summary (by Country) and Disposition Summary (by Site).
- In Viedoc Reports, the report Summary of subject disposition has been renamed Demographics summary. It is now possible to export this report as a standard table in the standard export formats (XLSX / CSV / XPT / XPTV8 / RDS). It is also possible to download the plot as a PNG file by clicking on a new camera icon.

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List of updated functionality and bug fixes continues.

- In Viedoc Reports it is now possible to download reports on the Reports page in one of two ways. You can either download a selected Standard report or download all the Standard reports.
 - Note! The Key risk indicator report has the download behavior *Download selected subreport* by default due to user selections available in subreports. The Audit trail review report does not have a download feature.
- In Viedoc Reports, on the Data Browser page, it is now possible to download the data from the selected CRF (Case Report Form) or download the data from all CRFs simultaneously.
 - Note! When Download all forms is selected, all the columns of the CRF are downloaded irrespective of the columns chosen in Select columns. When downloading all the CRF data, there is no difference in the downloaded file when selecting Standard mode or Cross-check mode.
- Viedoc Me now supports the following new system languages:
 - Chinese (Traditional, Taiwan)
 - Chinese (Traditional, Hong Kong S.A.R.)
 - Setswana
 - Sotho
- In Viedoc Me, there is now increased language support when using Viedoc Connect. Users can select a language and change the language during an ongoing call. Arabic and Hebrew languages are not supported.
- In Viedoc Connect, the user's selected system language is now used.
- In Viedoc Reports, in the Data browser module, when the XPT file (name of the SAS dataset) is downloaded (selected form only or all forms), and then imported to the SAS work library, the SAS dataset name is now the same as the form OID.
- In Viedoc eTMF, artifacts now have unique ID numbers. The unique IDs are optional and can be edited. When importing a template to Viedoc eTMF, the system validates the unique ID fields as follows:
 - If the value exists, it should be an integer.
 - Empty values are allowed. In the TMF Archive, an empty value is translated to 0.
- In Viedoc eTMF, the eTMF Manager can now select the option "Populate TMF level value automatically" on the Settings tab of the TMF Admin view. Then the TMF level field in the Document properties dialog in the Trial Master File view will be automatically filled in (when there is only one TMF level option available for the user for the selected document). This means that users will not need to explicitly select a TMF level for documents that they upload or move. This option is deselected by default for ongoing studies. For studies starting after the release of Viedoc 4.70, the option is selected by default.

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List of updated functionality and bug fixes continues.

- In Viedoc eTMF, when maintenance mode is activated in TMF Admin, the eTMF Manager can now choose to create a link or remove an existing link for sharing finalized and locked documents linked to either the main artifact or any of the sub-artifacts. When an artifact or sub-artifact is shared, a link to the TMF location and artifact is shown in the Edit artifact and the View artifact properties dialogs. This is the first step of implementing a document sharing feature within Viedoc Application Suite. The next steps will be released with future versions of Viedoc.

Bug fixes

This section lists the bugs that were solved 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 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 4.70 release:

- *Affected area(s)*: Viedoc Clinic
Bug description: When a site was created in a new country, and a user was invited to that country group, and subsequently the site country was changed to a different country, an error occurred. This is now solved so that the user still has access to the original country group even when there are no sites. This means that they will get access to all the sites added in the future for that country.
- *Affected area(s)*: Viedoc Clinic and Viedoc Designer
Bug description: In Viedoc Designer, when creating a new revision, if an item was deleted from a form previously used, and the form was then selected from the workflow, and items were selected to include in that form for a specific visit, the deleted item remained in the form. Also, when the design was published, the item was still available for selection on the Data Export page in Viedoc Clinic. This is now solved.
- *Affected area(s)*: Viedoc Clinic
Bug description: When uploading a file, the file size displayed was KB instead of kB. This has now been solved. Note! File versions generated before this bug fix in Form history and PDF export output format in Data export will still have the file size displayed as KB.
- *Affected area(s)*: Viedoc Admin
Bug description: In Study settings, clicking the lock/unlock study button multiple times when locking/unlocking a study, resulted in an error message being shown. This is now solved.

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List of updated functionality and bug fixes continues.

- **Affected area(s):** Viedoc Clinic
Bug description: When generating a PDF output format, there was an issue with the PDF bookmarks if the subject key or site name contained a backward slash. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: If a new item was added in a revision, and the revision was batch-approved, in very rare cases there were multiple copies of the item created in the database. This is now solved. Note! If your study was affected, you will be notified by our Support team for further action.
- **Affected area(s):** Viedoc Admin
Bug description: In Viedoc Admin, importing an ODM file which included Unicode characters caused the import to fail. This has now been solved.
- **Affected area(s):** Viedoc Reports
Bug description: When the initial study data synchronization ended in an error, the study folder had incorrect access permissions set. This is now solved.
- **Affected area(s):** Viedoc Reports
Bug description: For some standard reports, site codes and sequence numbers were not treated as characters, which meant that they were left-aligned. This is now solved so that the site codes and sequence numbers are treated as characters and right-aligned.
- **Affected area(s):** Viedoc Reports
Bug description: KRI metrics that are “per subject” were missing some subjects. This is now solved.
- **Affected area(s):** Viedoc Reports
Bug description: Event names with one or more space characters at the end or beginning were not displayed. This is now solved.
- **Affected area(s):** Viedoc Reports
Bug description: The Audit trail for forms with multiple activities in a single event retained only the latest activity. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: The Automatic EventDate linked to a form item sometimes did not work correctly. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: Some UI texts were not translated into the language that the user had selected. This is now solved.
- **Affected area(s):** Document properties dialog in Viedoc eTMF
Bug description: Not all document properties were shown when the TMF location was selected for a file in a drop zone. This is now solved.

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List of updated functionality and bug fixes continues.

- **Affected area(s):** Document properties dialog in Viedoc eTMF
Bug description: There was a delay in loading the history information. This is now solved.
- **Affected area(s):** Drop zones in Viedoc eTMF
Bug description: The system did not recognize the file type for files with file names containing the following character: `. .`. This is now solved.
- **Affected area(s):** Unlock dialog in Viedoc eTMF
Bug description: The text was incorrectly “Are you sure you want to lock the eTMF?”. This is now solved.
- **Affected area(s):** Changing the dating convention in Viedoc eTMF
Bug description: When users changed the dating convention and saved the change, the value was incorrectly set to the previous day’s date by the system. 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

- 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.
- 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.

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.

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).
- 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.

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.

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List of known limitations continues.

- 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.

Uppsala, Sweden 2022-05-02

A blue handwritten signature in cursive script, appearing to read 'Andreas Hedlund', written over a horizontal line.

Andreas Hedlund

Viedoc Technologies