

viedoc™

Release Notes

Viedoc 4.69

Planned for 2022-02-10

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New functionality



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

This release introduces the following new features in Viedoc:

- Asymmetric encryption is introduced. In Viedoc Clinic and Viedoc Me, stored subject contact information such as email addresses and phone numbers are encrypted. To ensure that this encrypted information stays secure and cannot be easily decrypted by a hostile third party when sending emails/SMS, asymmetric encryption is introduced, with a public and a private key located at different physical server instances. When Viedoc sends an email/SMS, it will now send these to the external service to decrypt and send the email/SMS. This will also be applied to existing subjects' information and previous email/SMS logs will be migrated and encrypted using asymmetric encryption. This change will not be noticeable for either the study participant or the Viedoc users and no action is required from the study team. Emails and text messages will continue to be sent according to the schedule configured in your study.
- In Viedoc eTMF, a status tab is now available in the TMF Admin view. This shows the TMF status and the location for locking/ unlocking the study eTMF. It is now possible to lock the eTMF to prevent changes from being made to the data at the time of archiving. The eTMF can be unlocked allowing users to perform actions according to their roles and permissions. All status tab changes of the eTMF are included in the audit trail. The tab shows the following eTMF status: Enabled, instantiated, and locked.
- In Viedoc Reports, two new standard reports are included: the Medical Coding Report, and Disposition Report. The Medical Coding Report lists all the medical coding data along with the "Unique Term Reports" for each coding dictionary. The Disposition Report lists event level summary (study, country, site) and disposition level summary (study, country, site) along with relevant plots.

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

Updated functionality and bug fixes

Updated functionality

- In Viedoc Clinic, for Medical coding dictionaries, the length of the substance field has been increased to handle at least 250 characters so that the new WHODrug (March 2022) format is supported and can be imported into a study. This allows for more precise naming of substances, according to global standards.
- In Viedoc Clinic, PDF export, the following functionalities are introduced:
 - The number of audit trail records in form history and form history PDFs is limited to the initial data entry and the latest 25 records. Older records are excluded from the form history and shown in one row in the audit trail with an information message to indicate that there are excluded records. This does not affect the Audit trail Excel or CSV export.
 - When exporting to a PDF archive, there is now an option to create one file per subject. For the FDA submission format (eCTD), this option is automatically set and is not possible to deselect. When the user deselects the “FDA submission format” option, the option to create one PDF per subject remains unchecked and is enabled. Thus, PDF Archive with and without FDA submission is unaffected.
 - For non-production data, the number of subjects in the PDF archive is limited to improve performance. The three most recently added subjects are included according to the date the subject card was created.
- In Viedoc eTMF the following functionalities are introduced:
 - Configure document name templates: To manage metadata included in the document name when *displaying*, *downloading*, and *archiving* the documents. The document display, download, and archive labels are added in the Document properties window and change dynamically when the related metadata is changed or set. Each of these templates has a free-text text box where the eTMF Manager can define the template that can consist of any combination of characters and document name variables. When defined in Viedoc eTMF Admin, it is now possible to apply:
 - The document *display* template to documents in the Trial Master File view, so that all document names in the Trial Master File view, search view, and Document properties follow the latest defined template.
 - The document *download* template to the downloaded file.
 - The document *archive* template to documents when archiving, so that the latest template is applied to the zip folder.

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List of updated functionality and bug fixes continues.

- Document upload: A Document identifier is introduced, so that it is now easy to distinguish between documents that have the same eTMF location and name. All existing documents in existing studies will have a unique integer Id within the study eTMF, which is assigned when a new document is created in the eTMF. The document Id is shown in the Document properties under the DOCUMENT INFO section. The complete audit trail report shows the Document Id in a new column in the Trial Master File sheet.
- When archiving the eTMF, the <UNIQUEID> element in the exchange.xml file includes the Unique ID Number of the artifact as defined in the TMF Reference Model in use.
- In Viedoc Reports, the following functionalities are updated:
 - For users with data export permissions, XPTV8 and RDS are now included as download formats for data browser and reports.
 - The Recruitment statistics report is updated with a new column for “Reason for withdrawal” as a separate column for the “by Subject” sub-report. A new sub-report “by Subject (with Date)” is introduced that includes the Screened Date, Enrolled Date, Withdrawn Date, and Completed Date.
 - In the Dashboard module, if a subject discontinues the study, it is now possible to view a plot with the reasons(s) for discontinuing if so configured in reports. The reason(s) for withdrawal are displayed as a pie chart which can be printed. If configured so that there is more than one reason for withdrawal for an individual subject, the plot will display “Multiple”.
 - The Viedoc Reports User Guide is now available in Viedoc eLearning in Chinese.

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 4.69 release:

- *Affected area(s)*: PDF exports in Viedoc Clinic
Bug description: Due to a folder name not allowing the following characters: \ / : * ? “ < > | any studies with a site name including these illegal characters caused the zipped PDF export to fail. This is now solved by replacing any illegal characters with a space whilst retaining the site name.

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List of updated functionality and bug fixes continues.

- **Affected area(s):** PDF exports in Viedoc Clinic
Bug description: When selecting the FDA submission format (eCTD) option, due to a folder name not allowing the following characters: \ / : * ? " < > | any studies with a subject id including these illegal characters caused the zipped PDF export to fail. This is now solved by replacing any illegal characters with a space.
- **Affected area(s):** PDF exports in Viedoc Clinic
Bug description: Generating the PDF archive when exporting large studies affected memory usage. This is now solved by splitting the PDF generation by site and subject instead of all sites and subjects simultaneously, improving performance.
- **Affected area(s):** Documentation and training in Japanese PMS studies
Bug description: Users with a Sponsor user role in Japanese PMS studies were unable to click the "Read and Understood" button for existing mandatory sections in the Documentation and Training page, as the button is unresponsive. This is now solved and users on the Sponsor side can now both view and mark mandatory sections as "Read and Understood". Users with more than one role, for example, on both the Sponsor side and the Clinic side, will see a list of all the applicable mandatory and optional sections for their roles on the Documentation & Training Page.
- **Affected area(s):** Viedoc Admin
Bug description: When applying design revisions to all applicable subjects/forms in Admin, the process queue was not functioning properly. This is now solved.
- **Affected area(s):** Viedoc Clinic - Viedoc Connect
Bug description: As a Clinic user it was possible to initiate calls with multiple subjects simultaneously when already in a call. This has been solved so that the user cannot initiate more than one call simultaneously. If the user initiates a second call while in an active call, the call function is disabled, and a message is displayed to the user.
- **Affected area(s):** Deleting a document in Viedoc eTMF
Bug description: In the Trial Master File (TMF) view, users could view deleted artifacts even though they did not include any accessible documents for the users. This has been solved so that deleted artifacts are only displayed to users with permission to access documents in the deleted artifact. For users without permission to access documents in the deleted artifact, deleted artifacts are removed from the TMF view once existing documents have been moved to a valid TMF location.
- **Affected area(s):** Changing TMF location in Viedoc eTMF
Bug description: When changing the TMF location zone of a document, the artifact drop-down menu in the document properties window was enabled before the user had selected a section. This is now solved.

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List of updated functionality and bug fixes continues.

- **Affected area(s):** Searching for documents in Viedoc eTMF
Bug description: There was an error when a search was initiated, and the user navigated away from the search view before the search result was displayed. The search was still running in the background and when the search was complete, the user was navigated back to the search view. This is now solved, and the search operation is now canceled if the user navigates away from the search view before the results are displayed.
- **Affected area(s):** Document properties window in Viedoc eTMF
Bug description: In the file information in document properties there were two extra fields. This is now solved, and the remaining fields are: original file name, file size and file date.
- **Affected area(s):** Working with drop zones in Viedoc eTMF
Bug description: Issue with inability to add a new artifact to the original zone and section after editing a zone name and reverting changes to the zone and section when in maintenance mode. This is now solved.
- **Affected area(s):** Working with drop zones in Viedoc eTMF
Bug description: File uploads to the private and shared drop zones failed when refreshing the page while the file was uploading or if the user logged out and logged in again during the upload. This is now solved so that files uploaded to the drop zone are not lost on refresh or logout if they have been uploaded to the quarantine area when the refresh/logout occurs.
- **Affected area(s):** Working with drop zones in Viedoc eTMF
Bug description: Files uploaded to the file drop zone by a user with Review or Read-only TMF permissions could be moved by another user with Manage drop zone permission to any TMF location without linking the document to a trial/country or site and save as unpublished. The file was then inaccessible for the drop zone manager who created the document. This is now solved.
- **Affected area(s):** TMF archive in Viedoc eTMF
Bug description: Issue in exchange.xml files for documents linked to several sites/countries. When a document was linked to several sites/countries, and the country code was set to ONE of the countries linked to the document, one file per country/site was created for each file under the same object with identical audit trail records. This is now solved so that the exchange xml file includes one object per country/site that is linked to the document.
- **Affected area(s):** Demographics and Subject Disposition Report in Viedoc Reports
Bug description: When working in the Demographics page, a field can be configured from a specific form. The CRF contains the values for the field, however the plot was rendered with blank values. This has now been solved by a system update so that the subject disposition PDF report uses the latest non-blank value for a subject for demographics fields.

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List of updated functionality and bug fixes continues.

- **Affected area(s):** Data sync in Viedoc Reports
Bug description: When initiating data sync for the first time for a user role, the Viedoc connection error message was shown. This is now solved so the correct error message "Initiating data sync for the role" is displayed.
- **Affected area(s):** Standard Reports in Viedoc Reports
Bug description: There was a problem with filtering columns in standard reports for studies where subject identification (SubjectID) was numerical. This is now solved so that even if the SubjectID is comprised of numbers, the system will treat it as characters.
- **Affected area(s):** Data sync in Viedoc Reports
Bug description: There was an issue with Audit data sync failing in some studies with a certain type of FormID or other metadata. This has now been solved.

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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

- 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 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.

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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Andreas Hedlund

Viedoc Technologies