viedoc™

Release Notes
Viedoc 4.77

Planned for 2023-10-03

Release Notes
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New and updated functionality

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

Viedoc Admin / Viedoc Clinic

- In Viedoc Admin, a new study setting is available: Enable item-level SDV. When this option is selected, users with SDV permission can, in Viedoc Clinic, apply SDV to individual items in a form. The option in Viedoc Admin is deselected by default for studies that started before the release of Viedoc 4.77, and selected by default for studies that start after the release of Viedoc 4.77.
- In Viedoc Admin, the Admin audit trail report will include information about changes to the item-level SDV setting.
- In Viedoc Clinic, in studies where SDV is performed on item level, when exporting review status, the SDV sheet in the Excel and CSV data exports will include only the items that require SDV and are visible to the user. On the Review status sheet, items that do not require SDV will be indicated with N/A.
- In Viedoc Admin, the randomization (for both static and dynamic) configurations for studies in production mode are only available if the Randomization feature is included in the study license. A randomization can still be configured in demo mode without a study license. For existing studies which have configured the randomization, the Randomization feature is included in the license by default.

Viedoc TMF

- In Viedoc TMF, a document version functionality is introduced. This functionality will make it possible to stack documents on top of each other and be more compatible with the EMS by having one current document version where the older ones will be considered superseded. A document can have one or many document versions, and each document version can have one or many files. To maintain the backwards compatibility, all the existing documents will be considered as document version 1. The status (Unpublished, Awaiting review, Flagged by QC, and Finalized) will be on document version level. When a document version is finalized, it will not be possible to edit that version anymore, nor add comments to it. To change the metadata or upload a new file, a user with WRITE permission for the document will have to create a new document version. The metadata of the new version will initially be based on the previous version metadata, and the user can choose to either copy the latest file from the previous version or upload a new one. When there are multiple document versions in a document, a dropdown menu will appear at the top of the Document properties window to allow users to switch between document versions. The history section will show the history that belongs to the selected document version. With this functionality, there have been some updates to the document name variables. The DocumentSystemVersion is renamed to FileVersion, where FileVersion is the count of files uploaded to a document. A new variable, DocumentVersion, is added; it is the latest document version of a document. The previous Version metadata in Document properties is renamed to Version label.

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⭐ List of new and updated functionalities continues.

- In the Trial Master File view, in the Details page, the column Document system version is renamed to File version; this column shows the total count of files uploaded to a document. A new column, Document version, is introduced; this column shows the latest document version.
- In the TMF Archive, the generated XML files will have one OBJECT tag for each document version. The latest document version will have the OBJECTVERSIONSTATE Current. The older ones will have the OBJECTVERSIONSTATE Superseded.
- In the TMF Archive view, the complete audit trail report will include a column for the document version. The column Version is renamed to File Version.
- In the TMF Archive view, the complete audit trail report now has multiple sheets when one sheet is not enough for the records.
- In the Trial Master File view, users with WRITE or REVIEW permission can add and resolve notes to document versions. The notes are added by selecting Add note from the actions menu in the Document properties window. The notes are intended for communicating messages about documents within the system, without changing the status of the documents. When the metadata of a document is changed, the system automatically adds a note to inform the users about the change.
- In the Trial Master File view, the Details page has two new columns: ICH code and Unresolved notes count.

Viedoc Designer / Viedoc Admin / Viedoc Clinic
- In Viedoc Designer, it is possible to set special user permissions to view the Roles page in Viedoc Clinic. This controls which roles have access to the information provided in the Roles page, such as who can view the information about users with access to the study. This permission is selected by default. This information, the View roles page, is also included in the configuration report.

Viedoc Designer / Viedoc Clinic
- In Viedoc Designer, it is now possible to make changes to roles and permissions in a design revision. It is also possible to add new roles. In Viedoc Clinic, the roles and permissions for users are read from the latest effective design (version or revision).

Viedoc Designer / Viedoc Clinic / Viedoc Admin / Viedoc Me
- Viedoc prevents the use of a default browser translation within the system. This prevents individual users from overriding the chosen system language and agreed upon terminology and formulations.

Viedoc Me
- Fields that take numerical input will no longer allow for scrolling by the users.

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List of new and updated functionalities continues.

Viedoc Reports

- Viedoc Reports eLearning has been updated to be more explanatory concerning the sub reports and the subfields. The layout is the same, but there will be a link to the details of the reports presented in table format.
- Also, in line with the reports export, empty subfields will display "N/A" rather than "Not Required" in the Review status and Form status standard reports respectively.
- In Viedoc Reports, we have expanded the possibilities for building custom reports. Users can build using metadata, Items, and CodeLists. The edcData.rds file for each role inside the study folder will have Items and CodeLists available to them.

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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 4.77 release:

- *Affected area(s):* Viedoc eTMF
  Bug description: In the document preview, PDF stamps were not visible. However, when the file was downloaded, the stamp was visible. This is now solved.

- *Affected area(s):* Viedoc eTMF
  Bug description: For eTMF users that are not Study Managers nor eTMF Managers, when setting the dating convention value of a file in the drop zone, an error occurred. This is now solved, and if an error occurs in the system when setting the dating convention value for a file in the drop zone, the system will fall back to a default format, which is DD MMM YYYY.

- *Affected area(s):* Viedoc eTMF
  Bug description: In the Trial Master File view, it was possible to upload files of blacklisted file formats if the artifact was configured to accept that file format. This is now solved.

- *Affected area(s):* Viedoc Clinic
  Bug description: In Viedoc Clinic, if a design was updated to include a linked form that referred to the original design, and edits were applied to the linked form, the system would not display the form link broken flag. This is now solved as the system flags the broken link regardless of the design version or revision the link was added to.

- *Affected area(s):* Viedoc Me
  Bug description: In Viedoc Me, it was possible for study participants to accidentally generate multiple copies of the same form and submit them. This is now solved.

- *Affected area(s):* Viedoc Clinic / Viedoc Me
  Bug description: The email and SMS notifications that are sent out to Viedoc Me users during the account registration in Viedoc Clinic contained words that caused the email and SMS notifications to be blocked for delivery. This is now solved.

List of bug fixes continues.

- *Affected area(s):* Viedoc Me
  Bug description: In Viedoc Me, the system language for German and Dutch was corrected with minor updates after feedback from users.

- *Affected area(s):* Viedoc Clinic
  Bug description: In Viedoc Clinic, the date format on PDFs was different from the date format set in the study settings. This is now solved.

- *Affected area(s):* Viedoc Clinic
  Bug description: In Viedoc Clinic, when performing a batch approval of a study revision, if a form was included in the batch where a user lacked edit permission, it was not possible to complete the batch approval, for all successive forms. This is now solved, so that the study revision batch approval will continue from the succeeding forms.

- *Affected area(s):* Viedoc PMS
  Bug description: In Viedoc PMS studies where Partial Submit Setup is not enabled, when submitting AE forms individually, it was not possible to recall a returned form on the Sponsor side. This is now solved.

- *Affected area(s):* Viedoc PMS
  Bug description: When the study setting for subject edit lock was enabled for users with edit permissions, and a booklet or an individual AE form was received on the Sponsor side, it was not possible to return the form or booklet. This is now solved.

- *Affected area(s):* Viedoc Admin
  Bug description: In the Admin audit trail report, when uploading the global allocation list, with the allocation scope set to site, and with multiple sites, the report contained additional system entries for each site linked to the single user action. This resulted in entries in the audit trail with no user listed. This is now solved so that the newly generated (after the Viedoc 4.77 release) admin audit trail reports contain only actions performed by the user.

- *Affected area(s):* Viedoc WCF API
  Bug description: In a design that uses repeating forms, if a limit is set on how many repeating forms are included, the WCF API would fail before the limit was reached, in some cases. This would cause the data to be rejected. This is now solved.

- *Affected area(s):* Viedoc PMS
  Bug description: For Viedoc PMS studies, on both Clinic and Sponsor side, some actions (such as opening subject cards, saving forms and some booklet actions) had degraded performance. Performance improvements on the above-mentioned actions have been implemented.

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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

- 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
  - 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.
  - 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.

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- File upload
  - For security reasons, it is not allowed to upload executable files. The complete list of unsupported file types can be found in Viedoc 4.34 Release Notes.
  - The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- Issues and task
  - The Issue list will not be visible for sites that have more than 1000 subjects.
- Medical coding
  - The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- 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.
- 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).

! List of known limitations continues.

- 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.
- Study Settings
  - The Logs tab for generating the Admin audit trail report does not appear on the Study Settings page if the system language is German or Swedish.
  - The Documentation tab for the documentation and training feature, do not appear on the Study Settings page if the system language is German.

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.

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 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.

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

ViedocMe

- 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.

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⚠️ List of known limitations continues.

- The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.

- Long option labels for radio buttons and check boxes do not have line breaks.

Viedoc Logistics

- In the exported stock list, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.

Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.

- Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.

- The Overdue Events Report does not include any Viedoc Me events. Events without a proposed date are not included in this report. Events that have been planned or initiated are not included in this report, even if the planned/initiated event is outside of the event window.

Viedoc eTMF

- Viedoc eTMF is not working in Safari version 16.3 and later versions.

- Viedoc eTMF is only running in Production mode.

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

- The search for document content is disabled on the training server.

Signoff

Signature Confirmation by the product owner.

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