Release Notes
Viedoc 4.67

Planned for 2021-09-05

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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:

- In Medical coding, new functionality is introduced:
  - There is now support for approving the medical coding directly in the Medical coding console, and the approved coding statistics can be seen on the landing page. A new export version is also introduced that includes the two new approval columns.
  - Two optional columns are introduced in the Medical coding console that shows supporting values when coding, for example "route" and "indication". The supporting values are set up in Viedoc Designer.
- Scheduled data exports are introduced via an export application. Certified designers can reach out to support@viedoc.com to get the latest version of the export application.

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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 Medical coding, the search and filtering possibilities have been improved to make it easier and quicker to find data.

- In Japanese PMS studies, the following updated functionality is introduced:
  - There is now support for deleting subjects on the Clinic side and functionality for acknowledging the deleted subjects on the Sponsor side.
  - The sponsor can now recall returned booklets before it has been edited by the Clinic side.

- In Viedoc Reports, the following enhanced features are introduced:
  - For custom reports, you can define the order of the plots as well as set the mode (production/training).
  - For custom reports, you can now add custom plots.
  - The plots are now expandable and include legend, data labels, and data tables.
  - There is now support for Swedish, Japanese, and Chinese (Simplified and Traditional) as system languages.

- There are enhancements to the SSO login process so that users don't need to renew their Viedoc passwords while logging in using SSO.

- In Viedoc eTMF, the following functionalities are introduced:
  - Read-only TMF Admin and Read-only Trial Master File permissions are introduced. Users that have these permissions will gain read-only permission to the corresponding view.
  - A Milestones functionality is added. Users are now able to filter artifacts by milestones or milestone groups in the Trial Master File view. eTMF Managers can manage milestones for the study and link artifacts to them from TMF Admin view.
  - A Settings tab is added in TMF Admin view. eTMF Managers are now able to enable/disable the Milestones filter in Trial Master File from the Settings tab.
  - A TMF Archive view is added, and a new permission called "Download audit trail" is introduced. Users that have this permission can access the TMF Archive view and generate the complete audit trail report from there.
  - A complete audit trail report is introduced. It is a report that includes all user actions in the eTMF. The report respects the user roles and permissions to TMF Admin view, Trial Master File view, and access to countries and sites.

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List of updated functionality
and bug fixes continues.

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 4.67 release:

- *Affected area(s)*: Viedoc API
  Bug description: When using the API method GetMetaData and requesting a design that has been superseded by a revision, for example version 1.0 was replaced with version 1.1, a "Permission denied" error was returned. This is now solved.

- *Affected area(s)*: Medical coding console in Viedoc Clinic
  Bug description: It was possible to open the Medical coding console and perform coding on items in a locked study. This has now been solved.

- *Affected area(s)*: Medical coding console in Viedoc Clinic
  Bug description: The Medical coding console did not handle large number of items well and was unresponsive and froze when loaded with too large number of items. This has now been fixed.

- *Affected area(s)*: Medical coding console in Viedoc Clinic
  Bug description: The interpretation field was limited to 100 characters, causing an error to be thrown if more than 100 characters were entered into the interpretation field. This has now been solved by making this field of unlimited length.

- *Affected area(s)*: Data export in Viedoc Clinic
  Bug description: Exports that included medical coding could in some instances take long time to finish. This has now been solved.

- *Affected area(s)*: Landing page in Viedoc Clinic
  Bug description: Studies with long names pushed the progress bar outside of the study card in the bookshelf. This has now been solved, and long study names will be truncated.

- *Affected area(s)*: JS expression editor in Viedoc Designer
  Bug description: The JS expression editor did not contain type definitions for forms in an activity. This has now been solved.

- *Affected area(s)*: User and roles report and User administration log in Viedoc Clinic and Viedoc Admin
  Bug description: The report and log showed role names from an earlier design when a revision was applied after a new version. This has now been solved.

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- *Affected area(s)*: User administration log in Viedoc Clinic and Admin
  Bug description: User administration log did not display two-factor authentication (2FA) correctly if the user was invited on site level and the user had two-factor authentication enabled for the account. This has now been solved.

- *Affected area(s)*: Start page in ViedocMe
  Bug description: The system generated dates was scrambled and mixed up when the Hebrew language was used by subjects in ViedocMe. This has now been solved.

- *Affected area(s)*: Time selection in ViedocMe
  Bug description: After entering and submitting a time item, ViedocMe displayed the time reversed for subjects using Hebrew and Arabic in ViedocMe. This has now been solved.

- *Affected area(s)*: Horizontal display of the VAS scale in ViedocMe
  Bug description: When viewing a horizontal VAS scale in ViedocMe using Hebrew or Arabic language, the scale labels were switched. This is now solved.

- *Affected area(s)*: Design validation in Viedoc Designer
  Bug description: It was possible to enter invalid and not applicable settings for form items in Designer. This has now been solved and proper validation error messages are displayed.

- *Affected area(s)*: Organization settings in Viedoc Admin
  Bug description: It was not possible to open the organization settings page and edit the settings. This has now been solved.

- *Affected area(s)*: Launching Viedoc Reports
  Bug description: It was possible for users with Viedoc Reports permission to launch Viedoc Reports without having any module visibility set. Viedoc Reports then displayed a blank screen. This has now been solved with improved error messages.

- *Affected area(s)*: Document properties in Viedoc eTMF
  Bug description: It wasn't visible to users that have access to only some of the sites/ countries the document is linked to that the document is linked to more sites/countries. This has now been solved.

- *Affected area(s)*: Viedoc eTMF
  Bug description: When changing a document name from a custom name to "Use artifact name" or "Use original file name", the audit trail wasn't captured. This has now been solved.

- *Affected area(s)*: Document properties in Viedoc eTMF
  Bug description: In some scenarios when several users were working on the same document at the same time, the first users that saved got their changes saved, while the other users got unclear error messages when they tried to save. This has now been solved such that the user will receive clear error messages that the document data was changed, and they need to refresh or reload to receive the latest changes.

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List of updated functionality
and bug fixes continues.

- *Affected area(s)*: Viedoc eTMF
  Bug description: It was not possible to upload files larger than 4MB into the system. This has now been solved.

- *Affected area(s)*: Trial Master File view in Viedoc eTMF
  Bug description: It was not possible to cancel a file upload, nor see the progress bar for uploading a file. This has now been solved.

- *Affected area(s)*: TMF Admin view in Viedoc eTMF
  Bug description: If the user selected a template from the Templates tab in TMF Admin view and quickly switched to the TMF structure tab, the selected template structure was not presented in the TMF structure tab and exporting the structure failed. This has now been solved such that when the user selects a template from the Templates tab, the system presents a progress bar and the user won't be able to switch to another tab in TMF Admin unless the operation is done.

- *Affected area(s)*: TMF Admin view in Viedoc eTMF
  Bug description: Templates uploaded on organization level showed "imported by [blank]" if the user who imported the template didn't have access to the study eTMF. This has now been solved such that the word "by" is removed and only the date and time is shown, if the user who imports the template doesn't have access to the study.

- *Affected area(s)*: Viedoc eTMF
  Bug description: When an eTMF Manager changed any artifact property that shouldn't affect the data/metadata of the documents filed to that artifact, all the documents, except the locked ones, in that artifact were updated by the system and the published documents' statuses were changed to Flagged by QC. This has now been solved.

- *Affected area(s)*: Trial Master File view in Viedoc eTMF
  Bug description: The trash bin button to the rightmost of the unpublished documents in the artifact view was not visible and the users could still click on the invisible button and delete the unpublished documents. This has now been solved.

- *Affected area(s)*: Trial Master File view in Viedoc eTMF
  Bug description: Deleted artifacts that do not include documents that the user has access to were still visible to the user. This has now been solved such that deleted artifacts that do not include documents that the user has access to won't be displayed to the user.

- *Affected area(s)*: Trial Master File view in Viedoc eTMF
  Bug description: The view got broken when a file with a long filename was uploaded to an artifact, and errors were encountered during the upload. This has now been solved.

- *Affected area(s)*: TMF Admin view in Viedoc eTMF
  Bug description: When enabling and launching the eTMF for the first time, a page is displayed to the user informing that the eTMF is being set for the study. Clicking the eLearning button from that page launched the Viedoc eTMF User Guide. This has now been solved such that clicking the eLearning button from the information page launches the Viedoc User Guide for eTMF Managers.

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- *Affected area(s)*: TMF Admin view in Viedoc eTMF
  Bug description: Empty new lines in the Sub-artifacts column in the V 3.1.0 sheet of the template were considered as valid sub-artifacts. This has now been solved such that empty new lines are ignored if present at the Sub-artifacts column when importing a template.

- *Affected area(s)*: Search view in Viedoc eTMF
  Bug description: When the search criteria included a phrase, the search results included documents that had any word from the given criteria in their content. This has now been solved such that only documents that include the complete search criteria are included in the search result.

- *Affected area(s)*: Viedoc eTMF
  Bug description: When changing properties on an artifact in TMF Admin the metadata of the locked documents filed to that artifact was affected. This has now been solved such that locked documents are not affected by changes done to the artifact that they are filed to.

- *Affected area(s)*: TMF Admin view in Viedoc eTMF
  Bug description: When maintenance mode was on and the eTMF Manager made changes to the structure and reverted those changes, the reverted changes were marked as edits to the structure and were displayed in the Apply/Revert changes pop-up. This has now been solved such that only actual changes are marked as edits and displayed in the Apply/Revert changes pop-up.

- *Affected area(s)*: Viedoc eTMF
  Bug description: An authenticated eTMF user could manipulate the URL for downloading a document by entering the GUID of any document filed to the study eTMF and download it even if they didn't have access to that document. This issue was limited to a very short time window and only if the user gave a valid GUID of another document. This is now solved.

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.

- Data export
  - The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
  - The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.

- Data review
  - The SDV task count, the green checkmark and the issue list on the subject Selection page do not take role visibility into consideration. This means that if forms or items are hidden to a certain clinic role, it might look as if there are still tasks to be performed, even if the user with that role does not have access to perform these tasks (due to visibility conditions).
  - Queries of the type "Required value missing" responded with "Confirmed as missing" and cannot be rejected by the sponsor side.
  - A field that is required for SDV but is hidden on a form (due to for example visibility conditions) can normally not be marked as having been verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.

- Edit/enter data
  - For scheduled and unscheduled events, when the visit date form ($EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a visit includes the $EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or visit). If you sign forms on a visit individually you will not be able to sign the $EVENT form. This in turn makes it so that the sign symbol that appears on the visit when everything is signed does not appear, even though it looks like everything is signed.

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- 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.

! 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, so not as per the system requirement which states safari 7+.

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.
- Viedoc Reports is not supported on the sponsor side in Japanese PMS Studies.
- 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.

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Viedoc eTMF

- Viedoc eTMF is currently available in English only.

- Viedoc eTMF is only running in Production mode.

- When an instantiated structure has no Viedoc milestones sheet, it is only possible to work with milestones in the group "Other".

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2021-08-27

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