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Release Notes
Viedoc 4.68

Planned for 2021-11-24

New functionality

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

This release introduces the following new features in Viedoc:

- Viedoc Connect is introduced, our telemedicine solution that enables meetings between Clinic and ViedocMe users through video calls. Site staff now have the possibility to conduct visits and make follow up calls with the subjects in a remote manner. Viedoc Connect requires the "Connect" feature in the study license and the Study Manager must enable it in Viedoc Admin

- A drawing pad is introduced as a new form item that allows the subjects to for example make drawings of symptoms as well as write their signature in Viedoc Me.

- In the Selection page a new view is available: the Event view. The view offers a quick overview of the event status and can be filtered on several factors.

- Drop zone is introduced in Viedoc eTMF. There are two kinds of drop zones, private and shared. Files in the drop zones are accessible by users who upload them. Files in the shared drop zone are also accessible by users who have the permission "Manage drop zone". The drop zones can be enabled/disabled from the Settings tab in TMF Admin. The drop zone functionality replaces the need for the Not classified category, and therefore this category won't exist anymore for newly created studies and will disappear for existing studies once there are no documents available in it for the user.

- eTMF archive can now be generated from the TMF Archive view for the users who have any of the permissions "Archive sponsor TMF" or "Archive investigator TMF". The archive respects the user permissions and access to documents and is compatible with the Exchange Mechanism Standard (EMS).

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Updated functionality and bug fixes

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

Updated functionality

- Terminology:
    - "Unscheduled events" in Viedoc Clinic is renamed to "Common events" to align with industry terminology and Viedoc Designer.
    - "Visit" is replaced with the term "Event" throughout the system and eLearning.

- In Viedoc Reports, two new reports are introduced: Audit trail review and Key Risk Indicators (KRI) report. The Audit trail review report shows divergences to the normal data entry pattern as well as the general performance. The KRI report gives a quick overview of the key risk indicators.

- In Viedoc eTMF, the following functionalities are introduced:
    - The review process can now be configured from the Settings tab in TMF Admin such that documents can automatically be locked upon approval, and a reason can be set to be mandatory given by the reviewer when unlocking a document.
    - The eTMF is now available in Japanese, Simplified Chinese, and Swedish.

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 4.68 release:

- *Affected area(s):* Excel exports in Viedoc Clinic
Bug description: Due to the limitation of number of rows in an Excel sheet, Excel exports failed when the number of rows exceeded that limit(1 048 576 rows). This is now solved in a way that when the limit is reached, a new sheet is added suffixed with _1, _2, and so on.

- *Affected area(s):* Excel exports in Viedoc Clinic
Bug description: Excel exports containing a large amount of data occasionally failed. This is now solved.

List of updated functionality and bug fixes continues.

- *Affected area(s):* Excel and CSV exports in Viedoc Clinic
  Bug description: The performance has been improved.

- *Affected area(s):* PDF export in Viedoc Clinic
  Bug description: PDF data export had performance issues, especially for larger files with several thousand pages. The performance has now been improved by optimizing the file creation. One optimization in the new export version (4.68) is that the system will create one PDF per subject in a zip file if the number of forms for a site exceed 1000.

- *Affected area(s):* Data exports in Viedoc Clinic
  Bug description: The browser was significantly slowed down when the filter included many single selected items in the export template. This is now solved by improved performance.

- *Affected area(s):* Several tabs opened in Viedoc Clinic
  Bug description: When working in Clinic with several tabs opened, there was an error when the user tried to edit a form in one of the tabs. This is now handled properly, and an error message is displayed to user.

- *Affected area(s):* Two-factor authentication
  Bug description: When the user had to enter the two-factor authentication code to log in, a timeout occurred if the user did not enter the code within a certain time period, resulting in an error in the system. This is now solved, and the user will be redirected to the login page for a new login attempt, if the code is not entered within 10 minutes.

- *Affected area(s):* Viedoc Reports in PMS study
  Bug description: The Viedoc Reports link was missing for PMS studies on the sponsor side, even though Viedoc Reports was enabled in the Study settings. This is now solved.

- *Affected area(s):* Visit reminders in Viedoc Designer
  Bug description: When configuring a visit reminder in Viedoc Designer and clicking the "?" symbol, the information shown was not correct. This is now solved.

- *Affected area(s):* Dynamic randomization list in Viedoc Designer
  Bug description: There was a misspelled system variable name "FactorWeghts" ("i" is missing) for Factor Weights in RandomizationList. This is now solved.

- *Affected area(s):* Pending forms in Viedoc Clinic
  Bug description: Duplicated pending forms caused revision application to fail. This is now solved by mitigating the possibility to get duplicate pending form entries, and in the occurrence of duplicates, the system ignores all except the first, in order to make the revision being applied.

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List of updated functionality and bug fixes continues.

- *Affected area(s):* PDF/A compliant archives
  Bug description: In some instances, generating PDF/A compliant archives resulted in a export failure due to a bug in the PDF generation component. The component has now been upgraded to the latest version in which this issue has been solved.

- *Affected area(s):* Booklet receive on sponsor side in Viedoc PMS
  Bug description: Affected area(s): In rare scenarios due to a transaction issue in the booklet receive action, the booklet was not getting received fully and forms were missing in the receive action. This is now solved.

- *Affected area(s):* Study plan plot in Viedoc Reports
  Bug description: In some studies, the "Today" marker was incorrectly displayed in the Study plan plot. This is now solved.

- *Affected area(s):* PDF export in Viedoc Reports
  Bug description: PDF download of the Summary of disposition reports resulted in an error if the labels in the report contained certain Unicode characters. This is now solved.

- *Affected area(s):* Data sync in Viedoc Reports
  Bug description: Data sync was not functioning properly for all studies. This is now solved.

- *Affected area(s):* Footer in Viedoc Reports
  Bug description: The page footer showed an incorrect version number after uploading a custom report to the study. This is now solved.

- *Affected area(s):* Custom names in Viedoc eTMF
  Bug description: When the user typed in characters in the beginning or middle of already entered text in Custom name textbox, the cursor jumped to the end. And when the entered text in Custom name textbox was long and the user entered characters at the end, the last character typed in was not visible. This is now solved.

- *Affected area(s):* Unpublished documents in Viedoc eTMF
  Bug description: Unpublished documents were visible to all users once they were linked to a country or site, and it was possible to review them by reviewers. This is now solved such that only users that have access to the country/site that the unpublished document is linked to can see them, and unpublished documents are not possible to be reviewed.

- *Affected area(s):* Audit trail report in Viedoc eTMF
  Bug description: Not all set artifact properties were listed in the Structure Management sheet. The Trial level document was misspelled as Trail level document. Several changes that were applied at the same time to a Zone/Section/Artifact/Milestone were presented as one row per change. The structure name was not stated for the Apply changes and Instantiate actions. These are now solved.

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List of updated functionality
and bug fixes continues.

- *Affected area(s):* Audit trail report in Viedoc eTMF
  Bug description: The original file name was not listed in the Upload action on the document in the complete audit trail report. This is now solved.

- *Affected area(s):* TMF Archive
  Bug description: TMF Archive view was not correctly displayed in IE11. This is now solved.

- *Affected area(s):* Deleted artifacts in Viedoc eTMF
  Bug description: In some cases, the dating convention label became empty in the Document properties window for documents that were in a deleted artifact. This is now solved.

- *Affected area(s):* Name change in Viedoc eTMF
  Bug description: Document name was referred to as "Name" both under the History section in Document properties window and in the complete audit trail report. This is now solved, and the document name is referred to as "Document name".

- *Affected area(s):* Changes to deleted artifacts in Viedoc eTMF
  Bug description: When an artifact was edited and then deleted in maintenance mode and the changes got applied, these changes were only visible in TMF Admin and not in Document properties window of the documents filed to that artifact. 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.
- 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

![!] List of known limitations continues.

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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- 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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- 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".

 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.
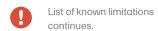
Viedoc Logistics

- 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.

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(!) List of known limitations continues.

Viedoc eTMF

- Viedoc eTMF is currently available in English only.
- Viedoc eTMF is only running in Production mode.

Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2021-11-17

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