Release Notes
Viedoc 4.64

**Available for users on
2021-03-28**

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New functionality

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

This release introduces the following new feature in Viedoc:

- **Viedoc eTMF** — a new, fully integrated digital repository for capturing, managing, sharing, and storing essential documents for your clinical trial. Viedoc eTMF is based on the TMF Reference Model by the Drug Information Association (DIA). The TMF Reference Model categorizes documents in zones, sections, and artifacts in a hierarchical structure and includes documents in all different phases of a clinical trial. Two new user guides are also released together with the feature – *Viedoc eTMF User Guide and Viedoc User Guide for eTMF Managers* – containing eLearning lessons for everything you need to know about the new functionality.

  To use the eTMF you need to have a license key (referenceID) and at least one site in production mode in your study. Testing of the eTMF can be done on the training server. To get a temporary license key to use on the training server for this purpose, please contact support@viedoc.com.

- Viedoc Designer is improved with a new JavaScript expression editor, making it easier and clearer to write expressions. The editor supports auto complete, help functions, and opens as a full screen pop-up window from the original editor field.

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Updated functionality and bug fixes

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

Updated functionality

- Viedoc Reports now contains two additional Report pages: "Pending forms" and "Data entry cycle time". The Pending forms reports contains the same information as the pending form export, but with filter functionality, and the Data entry cycle time report shows how long time it takes for the sites to enter form data.

- In the Visibility settings for Viedoc Reports in Viedoc Designer, the export permission is no longer required for a role to show up as an option when assigning roles. However, export permission must now be set for roles that should be able to download data in the Data browser and Reports pages.

- In Viedoc Designer, the "Show ID for fields" setting is now a shared setting and is reflected in both the forms overview page and on the individual form pages. The form sorting "Date edited / Date created / Alphabetic" and the "Show IDs" setting is now preserved throughout and in-between sessions and apply to all study designs that the user works with.

- When the option to hide the visit date form is set in a design, the option "Visit date" on the date and date/time picker is now removed.

- In the export preview in Viedoc Clinic, if the data size is too big, an error message is now displayed stating that the user must narrow down the selection by using the filters available on the Data export page.

- For Japanese PMS studies, there is now an option available in Viedoc Designer under Study settings/Alerts to define an alert to be triggered when the status of a booklet is changed. The alert can be triggered when changes are made to form data (default for all existing alerts) or booklet status. This means that the booklet status is now available as a system variable, and the alert is re-evaluated upon every booklet status change. The context of an alert triggered by a booklet status change is the booklet itself (Study event). Due to this update, the complete configuration report is extended with Trigger type in the Settings-Alert sheet.

- The messaging back-end infrastructure has been upgraded and migrated to Azure Service Bus instead of Redis for more reliable and scalable operation of the Viedoc applications suite.

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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 4.64 release:

- *Affected area(s)*: JavaScript expressions in Viedoc Clinic and ViedocMe
  Bug description: It was previously possible to edit form data through JavaScript programming in data checks or functions. This was enabled due to programming the edit check in a specific way. This has now been solved by running all expressions in a sandbox, preventing any change to form data intentionally, or by mistake.

- *Affected area(s)*: Viedoc Reports
  Bug description: For some studies, there was an issue with the daily data sync. The sync was not performed and the time stamp in the footer was not updated. This is now solved.

- *Affected area(s)*: Forms with code lists in Viedoc Clinic
  Bug description: In forms with checkboxes having a code list that combined text code and numeric codes, after saving the data, it was not possible to untick the checkboxes for the numeric items. Code lists having all codes as numeric but with a zero prefix were treated as having numeric as type. Data was thus stored as 1 for a code item with code 01, but the audit trail did not show the data, nor did the data come out in the export. This is now solved.

- *Affected area(s)*: Issues view in Viedoc Clinic
  Bug description: On the Selection page in the Issues view, some text was not translated correctly; it was displayed in English instead of the selected language. This is now solved.

- *Affected area(s)*: Randomization and allocation lists in Viedoc Admin
  Bug description: There was an issue in uploading and downloading the randomization and allocation lists. In case there was an issue, an error message was displayed on the screen. This is now solved.

- *Affected area(s)*: Data export using the Viedoc API
  Bug description: The API method "GetClinicalData" took unusually long time. The performance is now improved.

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List of functionality and bug fixes continues.

- *Affected area(s)*: Date changes using the Viedoc API
  Bug description: Using the API, when changing an event date including time to an event date excluding time, no audit record was created. This only occurred when the date was the same, that is, changing from for example "2021-01-01 14:00" to "2021-01-01". This is now solved.

- *Affected area(s)*: Log of users and roles PDF in Viedoc Clinic
  Bug description: There was an issue in generating the "Log of users and roles" PDF. Furthermore, in some scenarios, the inactive roles count did not match the counts specified in the "User log per sites" section. This is now solved.

- *Affected area(s)*: Study event dates in Viedoc Clinic
  Bug description: When changing an event date on a subject's visit that had initially been set to a date including time*, the time part (hours, minutes, seconds) would be retained, even though the date changed. This is now solved. As a part of this fix, the audit trail of the event date will from now on show the time, if the event date contains it. Since subject-initiated events are initiated with the date and time of the first submitted form, the time part will from now on be shown.
  * For example, from the first data entry, subject-initiated event, or an event initiated by the API import including a time.

- *Affected area(s)*: ViedocMe forms in Viedoc Clinic
  Bug description: In ViedocMe forms, there were options visible indicating it was possible to reset scheduled events and delete common events. This is now solved, and the links are removed.

- *Affected area(s)*: Configuration report in Viedoc Designer
  Bug description: Some sheets in the complete configuration report contained additional text from ViedocMe translations, system checks for the Date and Time data types showed up incorrectly, and the Roles sheet displayed incorrect information about the role permissions. This is now solved.

- *Affected area(s)*: Interface of Viedoc Logistics
  Bug description: Some text in the interface of Viedoc Logistics was not translated. This is now solved.

- *Affected area(s)*: Designer settings in Viedoc Designer
  Bug description: Adding Chinese as an additional language resulted in adding several languages in the designer settings. This is now solved.

- *Affected area(s)*: Metrics in Viedoc Clinic
  Bug description: The links to the different pages in metrics were not translated. This is now solved.

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List of functionality and bug fixes continues.

- *Affected area(s)*: Data export in Viedoc Clinic
  Bug description: There was a slow response when selecting individual forms for export. This is now solved.

- *Affected area(s)*: Copy form conditions in Viedoc Clinic
  Bug description: Copy form conditions were evaluated even though the form was not copyable, leading to performance degradation when selecting a subject. This is now solved, and the copy form conditions are not evaluated when the forms are not set as copyable.

- *Affected area(s)*: Interface of Viedoc Reports
  Bug description: There was an issue with the zooming feature as well as some graphical elements being trimmed, hidden, or misaligned. This is now solved.

- *Affected area(s)*: Excel export in Viedoc Reports
  Bug description: When a visit had all the forms and data marked as "SDV not required", the downloaded Excel file displayed errors for such data. This is now solved.

- *Affected area(s)*: Drop-down lists in Viedoc Reports
  Bug description: In the Data browser and Reports pages, when selecting the export format from the drop-down list, the drop-down list did not close properly. This is now solved.

- *Affected area(s)*: Data sync in Viedoc Reports
  Bug description: If the date format for expected date of completed enrollment was other than "dd-mmm-yyyy", the system failed. This is now solved.

- *Affected area(s)*: WHO Drug dictionary in Viedoc Clinic
  Bug description: When uploading the new WHO Drug dictionary version 1 March 2021, an error message was received. 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

- 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.

- 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.

- 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.

- Subject list

  - 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).

- Data export

  - The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.

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! List of known limitations continues.

- 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.

- 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 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.

- Issues and task
  - The Issue list will not be visible for sites that have more than 1000 subjects.

![!] List of known limitations continues.

- Metrics
  - The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with state "Removed".

Viedoc Admin

- 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.

- 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.

- 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.

Viedoc Designer

- General
  - Viedoc Designer is not working properly in Internet Explorer 11.

- 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.

- 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.

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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".

- 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.

- 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.

- 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).

- 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.

- 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.

! List of known limitations continues.

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).

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 currently available in English only.
- 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.

Viedoc eTMF

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

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Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2021-03-25

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