Release Notes
Viedoc 4.66

Planned for 2021-06-10

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New functionality

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

This release introduces the following new features in Viedoc:

- In Viedoc Designer, a visit reminder function is introduced in the Study event settings for sending out reminders if events have not been completed.

- In Viedoc Designer, new study event statistics variables are introduced that can be used in expressions when designing forms and/or alerts. The variables are on event level for query and review statistics.

- In Viedoc Reports, custom reports are introduced. Users can now write R programs that generate report tables based on CRF and operational data and upload them into Viedoc Reports.

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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 Viedoc Designer, the Excel configuration report is extended with the following:
    - The sheet named "Functions and Conditions" now includes visibility conditions for item groups.
    - The sheet "Global-Reports" is renamed to "Global-Reports configuration" and includes a section with custom reports information.

- In Viedoc Reports, the Reports menu is updated as follows:
    - The Recruitment report has been updated, with the withdrawn column divided into two separate columns, showing withdrawn subjects for Screened and Enrolled individually.
    - The drop-down menu is rearranged. The title "Operational" is replaced with "Standard Reports" and the standard report "Summary of Subject Disposition" is now included under this heading.

- In ViedocMe, Afrikaans, Xhose, and Zulu is now available as system languages.

- In the eLearning, the following updates are made.
    - Viedoc eTMF User Guide and Viedoc User Guide for eTMF managers are now available in Japanese.
    - In Viedoc Designer User Guide, the lesson "Managing translations for subject-initiated events" is updated and renamed to "Configuring subject-initiated (ViedocMe) events" and contains everything you need to know on creating ViedocMe events.
    - A new section, "Quick guides", is introduced with summarized information on how to set up some of the new Viedoc applications.
    - In Viedoc Designer User Guide, the section "Study design and Workflow" is restructured into the sections "Design initiation", "Study build", and "Design version management". The old vs. new lesson number is shown in the following table:

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List of updated functionality and bug fixes continues.

Old number	New number		Old number	New number
2.1	**3.1**		2.4	**4.7**
2.11	**3.2**		2.9	**4.8**
2.12	**3.3**		2.8	**5.1**
2.2	**4.1**		2.10	**5.2**
2.3	**4.2**		2.13	**5.3**
2.5	**4.3**		2.15	**5.4**
2.14	**4.4**		3.1	**5.5**
2.6	**4.5**		3.2	**5.6**
2.7	**4.6**		3.3	**5.7**

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 4.66 release:

- *Affected area(s)*: ViedocMe
  Bug description: The automatic logout was not performed correctly if the user put the computer into sleep. The automatic logout was done when the computer was brought back from sleep and an error was logged. This is now solved.

- *Affected area(s)*: Exports that generate .zip files
  Bug description: When two files with the same path and name were added to the resulting zip archive, an exception was thrown resulting in a failed export. This has been solved by detecting duplicate files when adding a file to the archive and renaming the file by appending (COUNTER) to the filename if it collides with another file.

- *Affected area(s)*: Sponsor side booklet listing page
  Bug description: When using the search function and there were no search results, and the user clicked on the Previous button, the page number calculation went wrong. This is now solved.

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- *Affected area(s)*: Configuration report in Viedoc Designer
  Bug description: The Show to role/ Hide to Role/ Enable edit for columns of the worksheet "Items & Groups" was only showing the Role Id. This is now solved.

- *Affected area(s)*: Alerts in Viedoc Designer
  Bug description: The StudyEventDefId was not supported for conditions in alerts when the chosen trigger type was Booklet status. This is now solved.

- *Affected area(s)*: Form lock in Viedoc Clinic
  Bug description: When Javascript function execution failed, after form submission from ViedocMe, the form lock was not applied correctly. This is now solved.

- *Affected area(s)*: Pop-up windows in Viedoc Clinic
  Bug description: In some cases, the form history popup and the audit trail popup did not show all entered reasons since it was lacking scrolling possibilities. This is now solved.

- *Affected area(s)*: Pending forms in Viedoc Clinic
  Bug description: Deleted events were not included when saving pending forms which generated an error in the logs. This is now solved.

- *Affected area(s)*: ODM export in Viedoc Clinic and Viedoc Designer
  Bug description: The Viedoc extensions were not getting removed from the XML when the user selected the option to exclude the extensions. This is now solved.

- *Affected area(s)*: Plots in Viedoc Reports
  Bug description: Adding apostrophes in the graph titles for the Demographics and AE pages caused issues in Viedoc Reports. This is now solved.

- *Affected area(s)*: PM1 marker in Viedoc Reports
  Bug description: If a study had the date format set to something else than ISO 8601 format, the PM1 marker was not displayed. This is now solved.

- *Affected area(s)*: Labels in Viedoc Reports
  Bug description: Labels with (blank) and "Missing" had the same meaning. This is now solved, and missing labels are always showing as (blank).

- *Affected area(s)*: Screen Failure Rate in Viedoc Reports
  Bug description: For studies where candidate subjects were available, the Screen Failure Rate % inside the enrollment status report was incorrect. This is now solved.

- *Affected area(s)*: Sites/countries in Viedoc eTMF
  Bug description: In some cases, only one of the sites/countries that the document was linked to was visible. This is now solved.

- *Affected area(s)*: Audit trail in Viedoc eTMF
  Bug description: When changing the name of a document from a custom name to another choice, it was not captured in the audit trail. This is now solved.

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List of updated functionality and bug fixes continues.

- *Affected area(s)*: Error messages in Viedoc eTMF
  Bug description: In some cases, after performing certain actions to documents, a misleading error message was displayed. This is now solved with a message saying "The data was changed. Refresh or reload and continue."

- *Affected area(s)*: File size in Viedoc eTMF
  Bug description: It was not possible to upload files larger than 4MB. This is now solved.

- *Affected area(s)*: Structure updates in Viedoc eTMF
  Bug description: All documents in an artifact were affected by structure updates on that artifacts, even the changes that did not affect the data/metadata of the documents. This is now solved.

- *Affected area(s)*: Trashbin icon in Viedoc eTMF
  Bug description: In the artifact view, for unpublished documents, the trashbin icon was invisible but still clickable. This is now solved, and the icon is visible.

- *Affected area(s)*: Deleted artifacts in Viedoc eTMF
  Bug description: Deleted artifacts that did not include documents were still visible in the Trial Master File view. 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

- 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.

- 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.

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![!] List of known limitations continues.

- 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.

- 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.

⚠ List of known limitations continues.

- 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.

- 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.
  - 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.

- 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.

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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.
- 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.
- 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).

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- 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.
- 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.

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.

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! List of known limitations continues.

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.

- In Viedoc eTMF maintenance mode, when making changes to the structure of an artifact, all documents within the artifact is affected as follows:
  - All documents are shown as updated by the system in the Trial Master File view.
  - All published documents, except locked documents, change the status to "flagged by QC" with no audit trail or comment.
  - Documents with status "awaiting review" change status to "flagged by QC" with the old comment.

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Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2021-06-07

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