Release Notes
Viedoc 4.62

**Available for users on
2020-12-10**

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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:

- **Setup for new applications.** The roles and settings in Admin and Designer are added to prepare for the introduction of new applications in the Viedoc eClinical suite.

  - Setup of Viedoc Reports in Designer, with a new permission available, "Reports" (visible when "Metrics" is selected). The Global design settings is also extended with the section "Reports configuration". Here, you set up what data should be displayed in Viedoc Reports, visibility settings for each role, and more.

  - Setup of eTMF in Admin, where you can enable the eTMF application for your study, and then launch it in either Production mode or Demo mode. This is also where you can map the Viedoc study roles to the eTMF roles.

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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 Clinic, the data export preview has been greatly improved. It now has

    - a powerful filtering mechanism, operating on both the complete preview data set and on individual columns

    - a feature to sort data based on the values in a column, in ascending or descending order

    - options to select which columns to include

    - a range of display options, including the possibility to pin a column to the left or to the right, to autosize column width, and to freely rearrange the order of columns

    Once the preview data has been filtered, sorted, and arranged according to your settings, you can perform an export that exactly reflects your preview.

- Improvements to the API: the method GetClinicalData now includes a flag that lets you include the subject status.

- In Viedoc Designer, extended subject status settings are available. The status "Screened" is now included, and, for each status, the designer can define a date condition for when the subject gains each status.

- The complete configuration report is updated to include the new settings for the upcoming features Viedoc Reports and Subject status.

- Viedoc Clinic is now available in traditional Chinese as system language.

- ViedocMe is now available in Slovenian.

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List of 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 4.62 release:

- *Affected area(s)*: Data export in Viedoc Clinic
  Bug description: Forms that were not in use were selectable in the "Forms and items" filter. This is now solved.

- *Affected area(s)*: Data export in Viedoc Clinic
  Bug description: The selection in the "Forms and items" filter was not always reflected in the export/preview. This is now solved.

- *Affected area(s)*: Data export preview in Viedoc Clinic
  Bug description: The drop-down menu items in the data export preview did not reflect the selected choices in the export configuration. This is now solved.

- *Affected area(s)*: SDV Settings in Viedoc Designer
  Bug description: When selecting single forms and items for SDV, the checkboxes next to each form were sometimes checked when they should not be. This is now solved.

- *Affected area(s)*: SDV Settings and Alert tracker actions settings in Viedoc Designer
  Bug description: When selecting items for the Alert Tracker or SDV settings, the checkbox was only selected when all items were selected. The form checkbox was not automatically selected when any item in the form was selected. This is now solved.

- *Affected area(s)*: PDF export in Viedoc Clinic
  Bug description: The FDA submission format was improved to include bookmarks for all items in the TOC, and the expected default settings for the file was corrected.

- *Affected area(s)*: Subject status calculation in Viedoc Clinic
  Bug description: When applying a revision and a form item had gone from mandatory to optional, the status calculation for the subject showed misleading information. This is now solved and only affects new changes when applying a revision (the bug still exists in previously applied revisions).

- *Affected area(s)*: Viedoc Designer and Viedoc Clinic
  Bug description: Some errors in Javascript expressions were not handled correctly, causing expression execution to fail. This is now solved.

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List of functionality and bug fixes continues.

- *Affected area(s)*: Viedoc Clinic
  Bug description: Visibility conditions on Event or Activity was not working correctly when the condition contained a date comparison together with one or more additional conditions, for example ADDS.DM.SEX == 1 && (V1.$EVENT.EventDate >= new Date(2020,7,1)). This is now solved.

- *Affected area(s)*: SSO login and validation flows
  Bug description: When the IdP endpoint URL already contained a query string, appending the SAML Request parameter to the URL resulted in a malformed URL. This is now solved.

- *Affected area(s)*: Queries in Viedoc Clinic
  Bug description: Visit window queries were re-raised when subject was modified, when the previous query answer was rejected by the Monitor/Data Manager, and another manual query was raised. This is now solved.

- *Affected area(s)*: Forms in Viedoc Clinic
  Bug description: In a Visit date form, before initiating a visit, the Form History link was visible although there was no form history, causing the view to crash. This is now solved, and the Form History link is only visible if there is history.

- *Affected area(s)*: Forms in Viedoc Clinic
  Bug description: When a visit was planned, there was no Form History PDF created in the forms. This is now solved.

- *Affected area(s)*: Forms in Viedoc Clinic
  Bug description: Form and/or study event PDFs were in some cases not generated correctly when the Viedoc application was taken down during the maintenance window. This is now solved.

- *Affected area(s)*: Forms in Viedoc Clinic
  Bug description: Form and/or study event PDFs were in some cases not generated correctly when the CSS (styling) was not properly loaded during PDF creation. This is now solved.

- *Affected area(s)*: Drop-down menus on mobile devices
  Bug description: Some drop-down menus did not work correctly on mobile devices. Either they were not shown at all or they were not styled correctly. This is now solved.

- *Affected area(s)*: SDV Settings in Designer
  Bug description: Form item labels enclosed with "<" and ">" caused errors when saving SDV settings. This is now solved.

- *Affected area(s)*: Excel Configuration Report in Viedoc Designer
  Bug description: Hide Always, Hide on simple condition, and Hide on advanced conditions were not displayed correctly in the reports. This is now solved.

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List of functionality and bug fixes continues.

- *Affected area(s)*: Forms in Viedoc Designer
  Bug description: After deleting items/item groups in a new revision, it was not possible to add new items to a form without them ending up as "orphans". This is now solved.

- *Affected area(s)*: Subject status in Viedoc Designer
  Bug description: The system was not supporting the $EVENT in the status condition and date expressions, causing it to always return as FALSE. This is now solved.

- *Affected area(s)*: Excel Configuration Report in Viedoc Designer
  Bug description: The "Show to Role" value for the item groups in the forms (which was added from the global template) was blank in the "Items and Groups" sheet. 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:

- The subject must have at least one status (Screened/Enrolled/Completed/Withdrawn) set to TRUE to show up in the data export. When no subject status is set, the subject is not calculated and included in the data export.

- The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.

- 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*.

- Only one (selected) design can be imported from each CDISC ODM file.

- 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.

- 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.

- 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.

- 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.

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

- 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, file names 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.

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List of known limitations continues.

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

- 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.

- 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.

- 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.

- The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (e.g. an OID defined as *AE* in design version 1 and *ae* in design version 2).

- The SDV task count, the green checkmark and the issue list on the subject selection page in Viedoc Clinic 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).

- Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.

- 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.

- 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).

- 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.

- 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*.

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- 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".

- 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.

- 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).

- 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).

- When using "START" as the Event ID for the *Study Start* event, 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, not "START".

- In Viedoc Designer, 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.

- 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.

- ODM export fails when subject data contains large uploaded files.

- If, in the study workflow in Viedoc Designer, 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.

- 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.

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List of known limitations continues.

- 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).

- It is not possible to delete unscheduled visits if automatic visit dates are enabled.

- Queries of the type "Required value missing" responded with "Confirmed as missing" and cannot be rejected by the sponsor side.

- When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.

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

- In the exported stock list from Viedoc Logistics, 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.

- In Viedoc Designer, 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.

Signoff

Signature Confirmation by the product owner.

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