Release Notes
Viedoc 4.58

**Available for users on
2020-04-23**

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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:

- A new function is now available in Clinic that lets the user create data export templates. This means that export settings can be saved as a template, making it easy to make new exports with the same settings. The template can be used by one or several users, depending on the setup.

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Updated functionality and bug fixes

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

Updated functionality

The following enhancements to the existing functionality are introduced:

- A new kit status is introduced in Logistics, "Quarantined", which makes it possible to temporarily set aside kits that need further investigation. When kits are in quarantine, it is not possible to allocate them until they are restored by the user.

- In Logistics, it is now possible to configure emails to be sent out to users who are managing the IP when the stock is running low, making it easier to be aware of the supply status. The emails are triggered by the alert level settings made by the user.

- There is a change in the data export interface to enhance the usability. The function to delete an export is no longer available from the mini pop-up that previously was displayed when hoovering over an export in the table "Latest exports". Instead, the delete function is available when the user chooses "View all exports".

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 4.58 release:

- *Affected area(s)*: Viedoc server-side cookies
  Bug description: Not all Viedoc server-side cookies were set to be Secure and HttpOnly. This is now solved.

- *Affected area(s)*: Reset of ViedocMe forms in Viedoc Clinic
  Bug description: When trying to reset an unlocked ViedocMe form in Viedoc Clinic, an error message was displayed. This was because ViedocMe forms cannot be reset/deleted. This is now solved, and the Reset form button is no longer available for ViedocMe forms.

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List of functionality and bug fixes continues.

- *Affected area(s)*: Approval with password
  Bug description: For some approvals that require a password, there was an error if the password contained one of the characters "<" or ">". This is now solved.

- *Affected area(s)*: ViedocMe forms
  Bug description: When a subject submitted data using ViedocMe and had future submissions scheduled, the incorrect form name was displayed. The default design language was used and not the translated form name. This is now solved.

- *Affected area(s)*: ViedocMe pin codes
  Bug description: After the first login, when a subject had changed their pin code, if forced to by a setting in Viedoc Admin, the text "You need to set a new pin code before using ViedocMe" was still shown. This is now solved, and a confirmation message is shown.

- *Affected area(s)*: Viedoc Logistics
  Bug description: A transfer of kits was not set to Completed unless all kits were received. This is now solved.

- *Affected area(s)*: Viedoc in Internet Explorer 11
  Bug description: When using Viedoc on multiple tabs in Internet Explorer 11, a logout on one of the tabs made the browser enter an endless loop. This is now solved.

- *Affected area(s)*: API imports
  Bug description: When a previously locked subject was unlocked, data was not always processed in the sequence that it arrived, and if the same form was updated multiple times, duplicate forms might have been created.

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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 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.

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

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- 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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List of known limitations continues.

- 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".

Signoff

Signature Confirmation by the product owner.

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