

Release Notes

Viedoc 4.57

Available for users on
2020-03-12

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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:

- An export function is now available in Logistics that lets the user export the stock list into an Excel file. The user can select to export data that reflects the current stock list or a more detailed export with the current stock list including history data.
- A new selection page is introduced in Clinic, a ViedocMe account overview, where the site users can monitor and follow up on the subjects' expected ViedocMe events submissions. The overview shows details about the user account such as compliance, study completion, next scheduled event, and more.

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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 field is now visible in Study settings in Admin to make it clear what features are included in the license.
- A new option is introduced in Study settings in Admin regarding navigation in Clinic, which enables extended navigation in the Selection page. This includes navigation to the newly introduced ViedocMe account overview.
- A confirmation pop-up is now displayed in Logistics when performing a transfer with the Shipment ID shown as a clickable link.
- A search field in the study slider of the landing page is now available in Clinic, so that users with plenty of studies quickly can search for a specific study.
- A new lesson is introduced in Viedoc Admin User Guide on how to archive a study.
- The eLearning curriculum Viedoc Admin User Guide is now available in Chinese and Japanese.

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 4.57 release:

- **Affected area(s):** Study roles in Viedoc Admin
Bug description: The help desk role was not removed when all the roles were removed from a study. Removed users could still show up in the help desk users list. This is now solved.
- **Affected area(s):** Randomization and allocation in Viedoc Clinic
Bug description: If the Global allocation list was not defined, the randomization was failing when both randomization and allocation were in the same form. This is now solved.

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List of functionality and bug fixes continues.

- **Affected area(s):** Edit lock in Viedoc Clinic
Bug description: Under some rare circumstances, a condition occurred that made it possible for two users to gain edit lock for the same subject. Then no studies could launch. This is now solved.
- **Affected area(s):** Chinese form PDF export in Viedoc Designer
Bug description: Some characters in the PDF were different from what was shown in Viedoc Designer. This is now solved, and the PDF has the same characters as in Viedoc Designer.
- **Affected area(s):** ODM data import
Bug description: Parallel execution of ODM Data import queue sometimes created duplicate forms. This is now solved.
Note! Already duplicate forms must be removed manually by the site user.
- **Affected area(s):** Designer configuration report
Bug description: The system was not showing the reference data permissions in the Designer configuration report. This is now solved.
- **Affected area(s):** Event dates in Viedoc Clinic
Bug description: The system did not identify the correct event date for repeated events. Due to this, the system always applied the last study event date. This is now solved.
- **Affected area(s):** Study selection page in Viedoc Clinic
Bug description: For studies with many issues (including resolved issues), the study selection page took a long time to load. This is now solved.
- **Affected area(s):** Generated PDFs with embedded font
Bug description: When exporting PDF with the option to embed the complete fonts was enabled, all PDFs were generated with the font regardless of the language, which resulted in unnecessarily large files. This is now solved.
- **Affected area(s):** Generated form event and study event PDF files
Bug description: During the period 2019-09-30 to 2019-10-01, there were some configuration issues which lead to incorrectly generated PDF files. This is now solved.
Note! Incorrectly generated PDF files will be removed and automatically regenerated.
- **Affected area(s):** PDF/A files
Bug description: Garbled characters were showing on deleted forms in generated PDF/A files. This is now solved.
Note! You can regenerate any affected file and the garbled characters will disappear.
- **Affected area(s):** PMS Booklet status
Bug description: When a booklet was unfrozen on the sponsor side, the information was not synchronized with the investigator side. This is now solved.
- **Affected area(s):** Site settings for max number of subjects
Bug description: Changes to the maximum number of subjects in the Site settings were not tracked correctly. 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 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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List of known limitations continues.

- 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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Signoff



Signature Confirmation by
the product owner.

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Andreas Hedlund

PCG Solutions