PCG Solutions

Release Notes
Viedoc 4.49

**Available for users on
2019-03-14**

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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 maximum allowed file size for uploaded files in Viedoc Clinic was raised from 512 MB to 2 GB. Please note that the file size for the files uploaded in ViedocMe was not changed (i.e. this is 512 MB).

- As a result of the bug fix related to the Roles page and the download of the "Log of users and roles" report, it is now possible to:
  - Generate a new "Log of users and roles" PDF report for the country/site selection.
  - Download the latest generated "Log of users and roles" PDF report for the country/site selection.

Bug fixes

This section lists the bugs that were fixed in this release. For each bug, it describes the following:

- *Affected studies/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 fixed. In case there are consequences for existing data, this is clearly mentioned in a "**Note!**"

The following corrections have been implemented in Viedoc 4.49 release:

- *Affected area(s):* Form save where non-mandatory fields were not filled in (i.e. left blank by the user).
  Bug description: When a form contained non-mandatory fields and the form was saved without any entered data into those fields, no audit trail records were set for those items in the two specific scenarios described below:
  - If a non-mandatory item was initially hidden in Viedoc Clinic due to visibility condition, and then became visible and the form was saved without filling in that item.
  - If a mandatory item was left empty and the form was saved, and then the item was made optional in a study design revision.
  Since no data changes were made in the scenarios above, the system ignored the creation of records in the audit trail. No vital information was lost due to this behaviour, but for uniformity of records they will be available, in the scenarios mentioned above, for the forms saved in Viedoc versions 4.49 and onwards.

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List of bug fixes continues.

- *Affected area(s):* Download of "Log of users and roles" from the Roles page.
  Bug description: The download of the "Log of users and roles" PDF from the Roles page in Viedoc Clinic was sometimes failing due to a timeout. This is now fixed.

- *Affected area(s):* Launch studies in Viedoc Clinic by users with role(s) without any configured permissions.
  Bug description: It was possible, for users with role(s) without any configured permissions, to launch the study in Viedoc Clinic from the Roles page. It was possible for users having at least two roles whereof one role with view/edit permission and one role(s) without any configured permissions, to switch, in the Subject Selection page, from the role with view/edit permission to the role with no permissions, making it possible for the role with no permissions to access the data in read-only mode. This is now fixed, so that it is not possible for users with roles without any configured permissions to launch the study.

- *Affected area(s):* Date and Time format settings in Viedoc Admin.
  Bug description: If "Date & time pattern" under "Date & Time format" was set and any additional changes were performed afterwards under the Settings tab, the format set for "Date & time pattern" was lost, falling back to the default one. This is now fixed.

- *Affected area(s):* Range item.
  Bug description: While editing the range item in Viedoc Clinic within a form or within the reference data editor, decimals were lost when editing the lower or upper limit, however the change was visible in the audit trail. This is now fixed.

- *Affected area(s):* Roles page in Viedoc Clinic.
  Bug description: In some scenarios, the Roles page was not loaded. This is now fixed.

- *Affected area(s):* Reference data.
  Bug description: When a reference data source or a factor was changed, target values were reset before setting new value, which resulted in any dependent visible items being also cleared before value is set. This is now fixed.

- *Affected area(s):* Reference data.
  Bug description: When a numeric range was defined for a factor in the Reference data editor, and in the form the value corresponding to that factor was null (not entered), after the reference data source is selected in the form, the target item was populated from the first range defined in the reference data editor. This is now fixed.
  Note! If your study was affected, you will be contacted by a Viedoc representative.

- *Affected area(s):* Reference data functionality, where forms populated using reference data were revised and batch approved by site.
  Bug description: When form revision was batch approved by the site, the selected reference data source was reset. The populated values were however retained. This is now fixed.
  Note! If your study was affected, you will be contacted by a Viedoc representative.

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List of bug fixes continues.

- *Affected area(s):* Reference data.
  Bug description: In Viedoc Clinic, the existing "issue" icon on the form for pending reference data updates was removed after a form upgrade was performed via batch approval. This is now fixed.

- *Affected area(s):* Reference data.
  Bug description: The pending reference data updates were not displayed in the Issues list in Viedoc Clinic. This is now fixed, and these are listed as "Pending reference data upgrade" under "All issues" and "All open issues" filters. This is now fixed.

- *Affected area(s):* Counter for Data edits/Sessions in the "Log of users and roles" PDF.
  Bug description: For the users having access to a site both via a site group and the standalone site, the Data edits/Sessions were counted twice for that site in the "Log of users and roles" PDF. This is now fixed.

- *Affected area(s):* Review status in export output for studies using reference data.
  Bug description: : The reference data source selected in form(s) in Viedoc Clinic was included in the "Review status" export. As this item could not be SDV'd, it was removed from the review status export. This is now fixed.

- *Affected area(s):* Two-factor authentication code through email.
  Bug description: When using two-factor authentication, the authentication code was sometimes not timely received due to email delivery delays. The email delays have been mitigated by using several email servers. This is now fixed.

- *Affected area(s):* User Settings pop-up in Viedoc Admin when using Safari.
  Bug description: The User Settings menu in Viedoc Admin was not accessible when using Safari. This is now fixed.

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.

- The PDFs generated upon form save will be 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 will not be shown/included in the generated pdf.

- 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.

- When importing an ODM file that was exported from Viedoc into Viedoc Admin, the following error message is displayed: "Following users do not have email id: SYSTEM". This can be fixed by manually removing the SYSTEM user entry from the xml file.

- 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).

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Signoff

Signature Confirmation by the product owner.

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