PCG Solutions

Release Notes
Viedoc 4.53

Available for users on
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Updated functionality and bug fixes

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

Updated functionality

- When setting the documentation and training settings to be performed in Viedoc Admin (by selecting *Enable documentation and training* under Study Settings), it is possible to copy the existing documentation sections from Viedoc Designer, in order to keep the existing configurations without the need to re-enter all the definitions manually.

- For PMS studies, a new system variable is introduced – *BookletStatus* – that returns the current status of the booklet, i.e. one of the following: *NotSubmitted, Submitted, Received, Frozen, Returned*.

- The Viedoc User Guides (eLearning) for Viedoc Clinic are now available in Chinese. **Note!** The eLearning updates are always published on the release date.

Bug fixes

This section lists the bugs that were fixed 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 fixed. In case there are consequences for existing data, this is clearly mentioned in a "**Note!**"

The following corrections have been implemented in Viedoc 4.53 release:

- *Affected area(s)*: Data export to Excel and CSV when *Event dates* are included in the export.
  Bug description: The values for *Initiated date* and *Initiated* by were not exported in some scenarios when multiple revisions were applied to events that had been planned/initiated at the same time. This is now fixed.

- *Affected area(s)*: Visit date outside of protocol time window queries.
  Bug description: The "Visit date outside of the protocol time window" query was re-triggered in some scenarios after applying a revision of the study design, although the query had been previously resolved and approved. This is now fixed.

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List of functionality and bug fixes continues.

- *Affected area(s)*: Form navigation in Viedoc Clinic.
  Bug description: It was possible to navigate to and open forms that were not applicable by using the event navigation dropdown in the form header. For example, it was possible to navigate to forms hidden due to visibility conditions or to forms that were not applicable to specific activities. This is now fixed so that a message is shown on the forms that are not applicable for data entry.

- *Affected area(s)*: Data export when the option to *Include history* was selected.
  Bug description: Data export failed when the option to *Include history* was selected in cases where study events had been reset and the reset study event had open queries. This is now fixed.

- *Affected area(s)*: Study design.
  Bug description: Splitting a form in a revision could cause the design to crash. E.g. if a form with two questions was duplicated in a revision and one of the questions original OID was re-used in the copied form but removed from the original, the design could have crashed in some scenarios. This is now fixed.

- *Affected area(s)*: ODM data import in Viedoc Admin and API import.
  Bug description: Data Import incorrectly added extra audit records for study events even though no changes were made to the actual data. This is now fixed.

- *Affected area(s)*: Roles page in Viedoc Clinic.
  Bug description: On the Roles page, the number of roles shown under "All roles and users for the sites I have access to" and under "Show Log", were inconsistent when users had access to "All sites". For example, the counter under "All roles and users for the sites I have access to" showed 2 but the Show Log showed only one user. This is now fixed.

- *Affected area(s)*: Data entry history.
  Bug description: If an item was saved with a value, and the value later deleted in a second save, then marked as missing in a third save, the reason for change for the delete action was incorrectly stated as "Confirm missing". This is now fixed.

- *Affected area(s)*: Documentation setup in Viedoc Admin under Study Settings.
  Bug description: Adding or updating documents under the Documentation tab in Study settings did not work when using Internet Explorer 11. This is now fixed.

- *Affected area(s)*: Form PDFs.
  Bug description: When an item in a form had an edit check referencing a date item placed after the item on which the edit check was configured, the text "Awaits answer" was included in the form PDF. This is now fixed.

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- *Affected area(s)*: Form PDF generation when the form contains any item group with role visibility conditions configured as "Show to" one (any) specific role.
  Bug description: For the forms containing item group(s) with role visibility conditions configured as visible to one specific role, the generated PDFs did not show the item group(s) with role visibility. This is now fixed.
  Note! If your study was affected, you will be contacted by a Viedoc representative.

- *Affected area(s)*: Viedoc Clinic user certificate PDF.
  Bug description: If a user had more than 7 roles, the user certificate PDF was showing only the first 7 roles. This is now fixed, and the role names are listed in the user certificate PDF separated by commas if the certified user has more than 7 roles.

- *Affected area(s)*: Data export of checkbox items.
  Bug description: When exporting data with code lists (dropdowns, radio buttons, checkboxes) that belong to multiple design versions in which the code lists have been changed between versions, Viedoc tries to merge the code lists if they are compatible, or split the data into multiple columns if the code lists for each item are not compatible between design versions.
  Exporting checkbox data based on different design versions in which the checkbox labels had been changed between the versions resulted in no data being exported, since the column merging and splitting that normally happens when code lists change between design versions did not work properly for checkboxes. This is now fixed so that checkbox data is always exported even when columns need to be merged or split.

- *Affected area(s)*: Form view in Clinic.
  Bug description: If a user role had permissions to perform Data review, Clinical review, SDV and Lock, the *Form History* and *Add note* disappeared from the form view. This is now fixed, and all the options are correctly displayed.

- *Affected area(s)*: Forms set as copyable in Japanese PMS studies.
  Bug description: In Japanese PMS studies, when a booklet was submitted with copied forms, the form instances that were copied were available to be copied again in the next booklet. This is now fixed, so that when an instance of a copyable form was copied, earlier instances of this form are not able to be copied in future booklets.

- *Affected area(s)*: PDF archive export.
  Bug description: The Microsoft YaHei font was fully embedded in all generated pdf archives, which resulted in all archives being at least 13MB each. This is now fixed so that only the needed subsets of the font are embedded in the pdf archives. The font is fully embedded only when the option "Embed complete fonts (no subsets)" is selected.

- *Affected area(s)*: Validation of designs containing randomizations in which any factor or outcome has an Export ID.
  Bug description: Validating study designs containing randomizations in which any factor or outcome had an Export ID resulted in a validation error that prevented the study design from being published. 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.

- 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.

- The form history PDF and the PDF export include the status (e.g. *Awaits approval*) of the *Confirm data as missing* record in the audit trail as it was when the form was saved. This may give misleading information about the current status.

- 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.

Signoff

Signature Confirmation by the product owner.

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