Release Notes Viedoc 4.45

Available for users on 2018-10-04

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Updated functionality and bug fixes



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

Bug fixes

This section lists the bug that were fixed in this release, for each bug describing 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/how it was fixed.

The following corrections have been implemented in this release of Viedoc:

- Affected area(s): Related to the randomization, where kit allocation is used.
 Bug description: If no kits were available during the initial randomization of a patient, it was not possible to allocate a kit later on, when more kits were uploaded. This is now fixed
- Affected area(s): Related to the export to Excel using 1 row per subject layout.
 Bug description: When 1 row per subject layout was used to export data, data were split into multiple rows. Please note that the exported data was correct, it was only the layout that was affected. This is now fixed, so that the data for the same subject is grouped on the same row for 1 row per subject layout.
- Affected area(s): Related to the access to user settings in Viedoc Admin, see below.
 Bug description: Admin users could no longer open their user settings in admin after deleting a study that they had access to. This is now fixed.
- Affected area(s): Related to duplicating instances of the same form.
 Bug description: It was possible to create duplicate instances of the same form within the same activity by opening a form in a new tab. When the form was opened in a tab, as opposed to the modal window, it was possible to submit multiple times by entering the data, saving, and then refreshing the page which allowed entering the data again. Multiple instances of the same form might have been created if the described workflow has been used.

Note! If your study was affected, you will be contacted by a Viedoc representative.

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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:

- Uploading 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* document.
- 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, dropdown menus 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) cannot normally 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 summary shown in admin while applying a study design is implemented only for production sites. Demo/Training site forms are not included in this summary 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.
- · The task count includes tasks for hidden forms.

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List of known limitations continues.

- The Issue list does not take role visibility into account.
- 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).
- Checkbox items with choices having long text set in Viedoc Designer might not be shown properly in Viedoc Clinic. The choice text might be truncated and not completely visible although it looks good in Viedoc Designer. The problem is also visible in the form preview in Viedoc Designer, which shows an identical form as what the users will see in Viedoc Clinic. Therefore, make sure you always check the form preview after designing a form to make sure that everything looks as expected.
- In Viedoc Clinic, on the subject selection page, the SDV task count, the green
 checkmark, as well as the issue list do not take into consideration role visibility, meaning
 that, if for example forms or items are hidden to that Viedoc Clinic role, it will still appear
 that there are tasks to be performed even if the user does not have access to perform
 those (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/study event
 pdfs were generated on or after 2017-03-10 (Viedoc 4.33). Generating PDF/A compliant
 archives that contain form/study event pdfs generated before this date will still work but
 might have warnings related to transparency.
- 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).

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List of known limitations continues.

- The API method SubmitData allows submitting data to a form that exists in the
 effective design but not 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.
- When importing, in Viedoc Admin, an ODM file that was exported from Viedoc, 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.
- Importing, in Viedoc Admin, an ODM file that was exported from Viedoc including the
 Event Dates, is not working, and the following error message is displayed: "An item
 with the same key has already been added".

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Signoff



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