Release Notes
Viedoc 4.42

**Available for users on
2018-05-27**

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New functionality

★ List of new functionality that has been added to this release.

Delete study

It is possible to delete a locked study. Deletion is initiated by the Study Manager, who can submit a request to delete the study from Viedoc to the Organization Administrator. The Organization Administrator can then approve or reject the request for study deletion.

After study deletion is requested by the Study Manager and approved by the Organization Administrator, the study is shelved on Viedoc's database for 180 days. A shelved study will not be visible in Viedoc Clinic or Viedoc Designer anymore, the study will only be displayed in the study overview page for the Organization Administrator.

This is described in the Viedoc eLearning in *Delete study* lesson, under *Introducing Viedoc Admin™* module.

View study access

Viedoc users have now the possibility to see a list showing all the study memberships and roles owned by them.

This is described in the Viedoc eLearning in *Manage your Viedoc account* lesson, under *Introducing Viedoc Clinic™*.

Approve/Reject study invitation(s)

When a user is invited to a new role within a study, the user is prompted to approve or reject the invitation before the respective user role is assigned. This applies only to the invitations sent from Viedoc version 4.42 and onwards.

Note! All the pending role invitations for a user are automatically approved when the API method GetToken/Token is used.

This is described in the Viedoc eLearning in *Manage your Viedoc account* lesson, under *Introducing Viedoc Clinic™*.

Remove user role(s) and user account

A Viedoc user can remove a certain role owned within a study.

A Viedoc user can delete the Viedoc account when having no roles left. If a new invitation is sent to the same email address, after the account was removed, a new user account will be created (having a new user ID).

This is described in the Viedoc eLearning in *Manage your Viedoc account* lesson, under *Introducing Viedoc Clinic™* module.

Note! The new/updated lessons in the Viedoc eLearning are being published on the release date.

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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 user ID is now displayed in all the user listing views in Viedoc Admin.

- The activation password, if set in Viedoc Admin (at study level), will be requested to be entered when the user accepts the first role invitation to the respective study.

- The font in pdf headers and footers was changed in order to be able to fit more text.

- The activity name is printed in the form pdf header, if set.

Bug fixes

This section lists the bug that were fixed in this release, for each bug describing the following:

- *Affected studies:* 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 that was fixed and how the system worked before the bug fix. In case there were consequences on existing data, this is mentioned as well in a "**Note!**".

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

- *Affected studies:* Studies with randomization where *SiteCode*, *CountryCode* or free text have been used as factors, and for which the randomization distribution list was downloaded.
  Bug description: The Current distribution tab of the randomization list excel file (downloadable from Viedoc Admin) did not show the correct info as the data was misaligned. This happened when there was a value for a stratification variable for which no subjects have been randomized. Note that the bug did not affect the randomization process, but only the way the current distribution data was displayed in the excel file.

- *Affected studies:* Studies with randomization where an allocation list was uploaded.
  Bug description: The upload of the allocation list failed if the allocation list file had empty header(s) or header(s) containing white spaces.

- *Affected studies:* Studies that have been using the now() function and that have site(s) using time zone(s) with UTC +/- hh:mm, where mm≠00.
  Bug description: The *now()* function did not return the correct minutes (minutes were always based on UTC) for the site(s)) using time zone(s) with UTC +/- hh:mm, where mm≠00.
  Note! If your study was affected, you have been contacted by a Viedoc representative.

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List of bug fixes continues.

- *Affected studies:* Not study specific, related to Viedoc user accounts with capital letters in the email address.
  Bug description: When editing the user profile and having a primary or secondary email address with capital letters, incorrect notification emails were sent to the user regarding removing the email address with capital letters (e.g. *MyEmail@domain.com*) and adding a new email address, which was the same one but with lowercase (e.g. *myemail@domain.com*).

- *Affected studies:* Studies with Viedoc/ViedocMe user accounts having email addresses that contain special whitespace characters.
  Bug description: Sending Viedoc emails failed when the email address contained one of the whitespace characters: ZERO WIDTH SPACE (U+200B), ZERO WIDTH NO-BREAK SPACE (U+FEFF), NON_BREAKING SPACE (U+00A0). Therefore, account activations could not be performed for users invited using such an email address as the invitation email could not be sent out. This is now fixed, and the mentioned whitespace characters are removed automatically. Note that the mentioned whitespace characters are commonly used in the Japanese language.

- *Affected studies:* Studies with large amount of sites/stored data.
  Bug description: There were problems with deserialization for large amount of data in the following areas: Reference data editor, apply revision, download study workflow pdf.
  Note! If your study was affected, you have been 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.

- The Issue list does not take role visibility into account.

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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).

- 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 in in any type of expressions inside a form to refer to an item within the same form but a different activity within the current event always refers to the same form instance where the function is executed, i.e. the current activity.

- 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.

- The system roles that were removed from a user are not listed in Viedoc Admin, under *User Settings > Studies and Roles*.

Signoff

Signature Confirmation by
the product owner.

Uppsala, Sweden 2018-05-25

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