Available for users on 2018-06-24

Updated functionality and bug fixes

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

Updated functionality

- The invitations sent by a user to self (i.e. invitations sent out to the same primary email address as the inviting user has) are automatically approved.
- If you have pending invitation(s), a message about the number of pending invitations together with the link to the *Access Settings* (where you can approve/reject the invitation(s)) is displayed on the top of the landing page.
- Data import application the transaction ID is now shown in the log.
 Note! Please note that you need to download the latest version of the data import application to be able to benefit of the updates. The download link is available in Viedoc Designer under *Global design settings > Data mapping*. Please contact your Viedoc representative to get the latest version of the *Viedoc Data Import Application* document.

Bug fixes

This section lists the bug that were fixed in this release, for each bug describing 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 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/area(s):* Not study specific, related to the user listings in Viedoc Admin. *Bug description:* A set of issues were fixed on user listings in Viedoc Admin, related to the displayed approval and removal dates for system roles.
- Affected studies/area(s): Not study specific, related to the clinic user roles.
 Bug description: In some scenarios where a user had clinic access to a site and a site group, the user ended up retaining access to the demo mode of the site after removing the user access.
- *Affected studies/area(s):* Not study specific, related to passwords containing angle brackets characters.

Bug description: Users resetting the password, using the "forget your password" page, to one containing angle brackets < >, where not able to log in. This is now fixed, angle brackets are allowed in passwords set from the forget your password page, or the change password page and the users are still allowed to log in.

List of bug fixes continues.

• *Affected studies/area(s):* Not study specific, related to users with system roles, see description below.

Bug description: If a user with system role(s) had changed the primary email address and that address was re-used by another user account, then the wrong user ID was shown in the users and roles PDF.

 Affected studies/area(s): Not study specific, related to the multiple user invitation to system role(s).

Bug description: When sending an invitation for system role(s) to multiple users at the same time, not all the users were included in the users and roles PDF.

 Affected studies/area(s): Not study specific, related to the icon shown in the activation password pop-up.

Bug description: Wrong icon was shown in the activation password pop-up.

- Affected studies/area(s): Not study specific, related to the API import.
 Bug description: When importing data through API, the first available site code was used, regardless if the API client key was limited to production (i.e. if production data was submitted to site 01 and there was a demo site with site code 01, the system tried to import data to that demo site because it was the first match).
- Affected studies/area(s): Not study specific, API related.
 Bug description: IncludeAdminData was not included in the response from the GetClinicalData request.
- Affected studies/area(s): Not study specific, related to the approval of Terms of Use and Privacy Policy.

Bug description: Newly invited users had to approve the *Terms of Use and Privacy Policy* twice, first when creating the Viedoc account, and then again when logging in for the first time.

- Affected studies/area(s): Not study specific, related to system roles removal.
 Bug description: The system roles that were removed from a user were not listed in Viedoc Admin, under User Settings > Studies and Roles.
- Affected studies/area(s): Not study specific, related to the Viedoc emails.
 Bug description: The Viedoc emails format was updated, and therefore, depending on the email client used, it might be required to explicitly approve downloading the pictures in the email, or alternatively add the address to the safe senders list, for the images to be properly shown in the email body.

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 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.



List of known limitations continues.

- 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.

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2018-06-15

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