Release Notes
Viedoc 4.60

Available for users on 2020-08-27

Release Notes
Viedoc 4.60

New functionality

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

This release introduces the following new features in Viedoc:

- **Download VIRP.** In Viedoc Admin, organization administrators can now download Viedoc Inspection Readiness Packet (VIRP). It provides the information you need to fulfil regulatory expectations on the documentation of a computerized system used in a clinical trial.

- **Masking of data.** It is now possible to mask sensitive data, that was entered by mistake, in audit trail records related to single line text, paragraph text, and file items in Viedoc Clinic. In Viedoc Designer, it is possible to configure role permissions to allow masking of data and/or viewing of masked data.

Release Notes
Viedoc 4.60

Updated functionality and bug fixes

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

Updated functionality

- In Viedoc Clinic, it is no longer possible to undo the allocation of a kit for an unblinded subject.

- ViedocMe now supports the following new system languages: Chinese (traditional), Croatian, Estonian, French (Belgium), Georgian, Latvian, and Lithuanian.

- In Viedoc Logistics, email alerts upon low stock levels can now be sent to users with permission to view IP on study level.

- In Viedoc Logistics, the kit history now includes mandatory reasons for all kit actions.

- The eLearning now includes Chinese and Japanese translations of the Viedoc Designer documentation.

- The eLearning curriculum Viedoc User Guide for Supply Managers changed name to Viedoc Logistics User Guide. This is an editorial change only, and it has no effect on functionality.

Bug fixes

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

The following corrections have been implemented in the Viedoc 4.60 release:

- *Affected area(s)*: Reference data in Viedoc Clinic
  Bug description: When using two different reference data scopes connected to the same form and updating both scopes, an error occurred when the affected subjects were opened. This is now solved.

- *Affected area(s)*: Global form templates in Viedoc Designer
  Bug description: There was an error when saving global templates for forms and when adding forms from global templates to a study design. This is now solved.

Release Notes
Viedoc 4.60

List of functionality and bug fixes continues.

- *Affected area(s)*: Data exports from Viedoc Clinic
  Bug description: For data exports including event dates with time period filtering, the exports failed. This is now solved.

- *Affected area(s)*: Data exports from Viedoc Clinic
  Bug description: For revised study designs, data exports that included event dates resulted in an error when additional filtering was made, for example including only signed data. This is now solved.

- *Affected area(s)*: PMS studies – Viedoc Admin
  Bug description: For Study Managers and Site Managers in PMS studies, duplicate studies were incorrectly displayed on the organization overview page. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: A user with the permission to view or manage IP on study level for some sites could incorrectly view or manage IP for all sites in the study. This is now solved.

- *Affected area(s)*: ViedocMe
  Bug description: Some users could not log in to ViedocMe, even though their accounts were activated. This is now solved.

- *Affected area(s)*: Viedoc PMS studies
  Bug description: Medical coding was not available even though the study license included this feature. This is now solved.

- *Affected area(s)*: Viedoc Clinic
  Bug description: In some cases, the Details page incorrectly showed subject-initiated visits even though a filter was set to not show them. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: The details export did not show the shipment ID for a received kit until all kits in the transfer were received. This is now solved.

- *Affected area(s)*: ViedocMe
  Bug description: In revised forms, deleted items were incorrectly displayed. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: When trying to download a detailed export, a timeout occurred. This is now solved.

- *Affected area(s)*: Viedoc Clinic and the kit stock list and the kit details in Viedoc Logistics
  Bug description: When two users simultaneously performed actions on the same kits, the kit history and the export included duplicate records. This is now solved.
  Note! Duplicates will not be removed

Release Notes
Viedoc 4.60

List of functionality and bug fixes continues.

- *Affected area(s)*: Viedoc Logistics
  Bug description: Email alerts regarding low stock at site were incorrectly sent to users in the Production environment when the stock was low in the Training environment. This is now solved.

- *Affected area(s)*: Event PDF export from Viedoc Clinic
  Bug description: When a revision was applied to a study event, a new version of the study event PDF was incorrectly created. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: For users with the permission to manage IP on site level, the kit action drop-down list did not include the country depots (in a study with country scope). This is now solved.

- *Affected area(s)*: Viedoc Designer–print form
  Bug description: Some Japanese characters were not correctly displayed when printing a form. This is now solved.
  Note! Already generated PDFs with incorrectly displayed unified characters need to be re-generated

- *Affected area(s)*: Viedoc Logistics
  Bug description: For users with the permission to view or manage IP on site level, the export from Kit details was empty when kits were in transit to depot. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: The export from the stock list and the kit details view incorrectly displayed "Missing" in the Action column for kits that had been invalidated with the reason "Missing". This is now solved.

- *Affected area(s)*: PDF exports from Viedoc Clinic
  Bug description: Chinese characters in unified CJK font were displayed in different fonts. This is now solved.
  Note! Already generated PDFs with characters in unified CJK font need to be re-generated

- *Affected area(s)*: Data export templates in Viedoc Clinic
  Bug description: It was not possible to edit or delete data export templates. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: If some kits in a kit transfer were cancelled and some were received, the kit details view history incorrectly showed all kits in the transfer as received. This is now solved.

- *Affected area(s)*: Viedoc Logistics
  Bug description: Error messages incorrectly included error codes. This is now solved.

Release Notes
Viedoc 4.60

List of functionality and bug fixes continues.

- *Affected area(s)*: Viedoc Logistics
  Bug description: In the stock list and the kit details view, if an error occurred for a kit action, it was not possible to perform any actions for other kits without refreshing the page. This is now solved.

- *Affected area(s)*: Viedoc Clinic–form history
  Bug description: In the form history pop-up, an error occurred when trying to download a file that another user had uploaded and then deleted. This is now solved.

- *Affected area(s)*: Viedoc Clinic
  Bug description: It was not possible to resolve queries for visits with automatic event dates. This is now solved.

- *Affected area(s)*: Viedoc Clinic
  Bug description: For date only items in forms, if time was also supplied, either by a function or via the API, the time was stored in the database, but it was not visible or exportable. However, when these variables were used in expressions, the time was included. This is now solved, and no time is saved for date only items.
  For date and time items in forms, if a date with time including seconds was supplied, either by a function or via the API, the seconds were stored in the database, but they were not visible or exportable. However, when these variables were used in expressions, the seconds were included. This is now solved, and no seconds are saved for date and time items.
  Note! Existing data can be updated on request

Release Notes
Viedoc 4.60

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.

Release Notes
Viedoc 4.60

- 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*.

Release Notes
Viedoc 4.60

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.

- 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.

- If, in the study workflow in Viedoc Designer, there are more activities with the same activity name within the same event, then the forms in these activities are incorrectly displayed in the Bookmarks list in the study workflow PDF. Please note that only the Bookmarks list is affected, the events/activities/forms are correctly displayed within the document.

- When adjusting the font size in a form item this is not respected by Internet Explorer 11. This may result in a change to the layout of the form.

Release Notes published 2020-08-20

Page 9 of 11

Release Notes
Viedoc 4.60

- The descending sorting in the subject list view is not working properly.

- When clicking to sort a column containing dates in the subject list view, Viedoc sorts all dates using a numeric variant of US date representation (for example, 1977-NOV-16 comes before 1967-DEC-16 because the first is sorted like 11/16/1977 and the latter is sorted like 12/16/1967).

- It is not possible to delete unscheduled visits if automatic visit dates are enabled.

- Queries of the type "Required value missing" responded with "Confirmed as missing" and cannot be rejected by the sponsor side.

- When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.

- The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with state "Removed".

- In the exported stock list from Viedoc Logistics, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.

- In Viedoc Designer, when creating forms for ViedocMe, visibility conditions can only include variables that have already been introduced, and that are in the same form and on the same page. This behavior differs from the one in forms for Viedoc Clinic.

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2020-08-20

Andreas Hedlund

Viedoc Technologies