

Release Notes

Viedoc 4.33

Available for users on
2017-03-09

Release Notes

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New functionality



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

ViedocMe – VAS scale

Viedoc 4.33 release adds support for a Visual Analog Scale (VAS) in ViedocMe, so that subjects can use the VAS scale to indicate and submit the intensity of perceived pain or disease symptoms. ViedocMe supports a 10 cm VAS on iPad Mini version 2-4 devices, and logs the device used by the subject when answering. Functionality supporting the configuration of the VAS scale (Designer) and review by site staff (Clinic) is included.

ViedocMe – additional data types

Viedoc 4.33 release also adds support for numeric fields and a date/time picker in ViedocMe, so that subjects can submit numeric values and dates.

Configurable password expiration time

It is now possible to configure the password expiration period per study (default is 90 days). When a user logs on their password will be checked against the study setting, and if their password has expired they will be prompted to change their password. If a user has access to multiple studies, then their password will be checked against all their studies when they log on, and they will be prompted to change if their password has expired in any of the studies.

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Updated functionality

- Medical Coding - the loaded dictionary version is now displayed and included in export.
- Medical Coding - when using MedDRA and MedDRA-J for coding it is now possible to view legacy codes (codes that are no longer current) when searching the dictionary. When MedDRA is used and the user wants to view only current items, then the list is filtered on the “Current” flag in MedDRA. When MedDRA-J is used and the user wants to view only current items, then the list is filtered on the “J-Current” flag.
- Medical coding with WHO DD now supports hierarchical variants and the name specifier.
 - The medical coding feature now supports coding of the C format in an hierarchical manner in the order country, MAH, form, and strength.
 - The name specifier field is included in the coding and is searchable.
- Before logging out a user for inactivity the user is checked 3 additional times at 20 second intervals, to ensure the use is not logged out due to a temporary network problem.
- Query performance has been improved when selecting the number of open queries on the Study Landing page and on the Subject Selection page.
- When exporting PDFs the user can now optionally include all embedded fonts in the PDF. This will substantially increase the size of the export file as information about all the fonts is added to the exported PDFs. This can be used when making submissions to the FDA.
- Excel and CSV report generation has been speeded up.
- When users edit data contained in crossform edit checks those edit checks will trigger irrespective of the order the data is edited (i.e. which form is edited first).

Bug fixes

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

- When switching the main study design language during study set-up in Viedoc Designer, all existing design elements will be updated to the new language.
Possible consequences for active studies: If you have a study that shows the setup in two or more languages, this can be corrected by switching the language after this Viedoc update.
Check this in your study: No need to check anything in your study.
- ViedocMe will only logout the user after 20 minutes of inactivity.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: No need to check anything in your study.

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Updated functionality and bug fixes



List of bug fixes continues.

- ViedocMe uses the form layout used at the time the form was submitted when displaying the form history to the subject.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: No need to check anything in your study.
- The audit trail shows “Initial Data Entry” as the reason for all submitted ViedocMe forms.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: No need to check anything in your study.
- Subject sequence numbers are kept when importing data from Viedoc 3.
Possible consequences for active studies: If an import from Viedoc 3 has previously been performed and subject sequence numbers in the imported file were not sequential starting at 1 for each site in the study, then new subject sequence numbers may have been assigned by Viedoc 4. If a new import is performed (to update information that has subsequently been received in Viedoc 3) then the subject sequence numbers may not match.
Check this in your study: You only need to check if you have performed an import from Viedoc 3 and the subject sequence numbers in the file imported were not sequential starting at 1 for each site.
- The name attribute for codelist items that have no output export value are now included in the ODM export.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: No need to check anything in your study.
- SAS export item data types are now set correctly for InitiatedBy, LastEditedBy and DesignVersion.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: No need to check anything in your study.
- The export filename now contains the timestamp of the export in 24-hour format.
Possible consequences for active studies: No consequences for existing data.
Check this in your study: No need to check anything in your study.
- If a site is moved from one county to another, then users that have been invited per the old country are removed from the site access list, and users that have been invited per the new country are added to the site access list.
Possible consequences for active studies: Some users assigned per country (monitors, data managers, etc.) may no longer have access to the site. Also new users may have been added to the site.
Check this in your study: If you move a site from one country to another then you should check that the user access lists for that site will still be correct.

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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:

- Only one (selected) language can be imported from each CDISC ODM file.
- 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.
- Deletion of a common event is shown with the form name in strikethrough instead of the summary format details.
- Validation of alerts, selection view settings and patient 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.

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Known limitations



List of known limitations continues.

- The form history view does not display all form versions when bulk upgrade has been performed, however all form versions are correctly stored in the database.
- The task count includes tasks for hidden forms.
- 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 new languages are imported for ViedocMe and after that code lists are combined via “Formats” (for example for SAS export) then the new ViedocMe languages are lost. The workaround is to import the new ViedocMe languages again after the code lists have been combined.

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Signoff



Signature Confirmation by
the product owner.

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