

Release Notes

Viedoc 4.29

Available for users on
2016-10-10

Release Notes

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New functionality



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

Dynamic randomization

Viedoc 4.29 Release adds support for dynamic randomization using the Pocock/Simon algorithm. The option for dynamic randomization is available in Admin. It is possible to configure the randomization by editing parameters such as Variation method (Range, Range Squared), Probability, Factor weights, Allocation ratio and maximum number of slots per randomization list.

Upon approval of the configuration, two separate copies of the configuration will be created. One for Demo mode and one for Production.

The randomization list will initially indicate status Inactive and turns to status Active once the first patient has been randomized. When status has become Active it will be possible to download the distribution and slot list in Excel format. It is also possible to restart a randomization list; this will reset the slot list.

Support for unscheduled and common events in ViedocMe

ViedocMe has been extended to support unscheduled and common events.

In order to make these events visible under Unscheduled questionnaires in ViedocMe, the events should be set as patient initiated in the Designer.

Note! Only unscheduled and common events which contain one form can be set as patient initiated.

Each submitted questionnaire will be listed under the ViedocMe account/Status tab and show:

- Name of questionnaire
- Actual date of submission
- Status (always Received)

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Updated Functionality

The following functionality has been updated in this release of Viedoc:

- In Designer, it is now possible to add Site and Country as input factors for Randomization. This applies for both Static and Dynamic randomizations.
- The process of applying design revisions has been improved to minimize the need for manual form upgrade and bulk upgrade. No manual upgrade is now needed when visibility conditions are changed according to below:
 - Hidden in old design => Hidden in new design
 - Hidden in old design => Deleted in new design
 - Not existing in old design => Hidden in new design
 - Visible in old design => visible in new design
- Auto update forms can now be added to any event type. The option to set the form as Hidden is now only applicable for Auto update forms.
- The progress when applying a new revision will be indicated in Design settings/Audit trail tab. The states are: In queue, In progress, Date and time when completed, Error.
- When including Event dates in the Export, the following information will be included:
 - InitiatedBy
 - InitiatedDate
 - LastEditedBy
 - LastEditedDate

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Updated functionality and bug fixes



List of functionality that has been updated continues.

Bug Fixes

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

- Configuration report will now correctly reflect the Validation state and Not validated, Validated or show the number of validation errors.
- Generation of the configuration report will be created without an error for all design.
- Confirm missing popup will now show correctly and will also be possible to close.
- Items that were previously hidden in study workflow and made visible in a revision will now require a manual approval.
- Only revisions based on the latest effective design will override it and become the latest effective. E.g. Revision 1.1 will not override 2.0 as effective design, however revision 2.1 will become the effective design once applied.
- Items with role visibility conditions will now require a manual approval.
- A pending revision will no longer make the data import to fail.
- Subject status will now be correctly updated when data is imported via API.
- Timeout issues when uploading large coding dictionaries was solved.
- When selecting '0' from a dropdown in ViedocMe the background color will now show the orange background as for other numbers.
- A disabled radiobutton or checkbox in ViedocMe will now show the same color as disabled dropdowns.
- Accents will now be displayed correctly in 'Output and validation' page.
- Changing the role visibility for item groups will now mark the form as changed by displaying the red pen.

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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, dropdowns 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 SDV:ed, but if the entire form is marked as having been SDV:ed then even hidden fields are included and marked as having been SDV:ed.
- The affected forms count summary shown in admin while applying a revision is implemented only for production site. Demo/Training site forms are not included in this summary count.
- Deletion of a common event is shown with the form name strike through instead of the summary format details.
- Validation of alerts, selection view settings and patient id generation settings for deleted items are not performed.
- Export preview with graph pages result in a Java script error on IE8 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 gets 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 at form save will be generated and stored based on the role visibility conditions applied to the user that last saved the form. E.g. items hidden to a 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.

- Alerts will only be triggered on the first initiated form within an event if that form occurs more than once in the event. The workaround is to specify the activities in the alert condition.
- ViedocMe study event date form can be unlocked by monitor.
- Permissions in the user role log are displayed based on the effective design date instead of the date when the design was applied.
- The form history view does not display all form versions when bulk upgrade has been performed, however all are correctly stored in the database.
- Task count include tasks for hidden forms.
- Issue list do not take role visibility into account.
- Switching the study design language from the default English to any other language in the middle of study setup, i.e. after already designing and saving some forms, will leave the study design in an inconsistent state.

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Signoff



Signature Confirmation by
the product owner.

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