

# Release Notes

# Viedoc 4.52

Available for users on  
2019-06-30

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## Viedoc 4.52

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### New functionality



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

#### Advanced allocation

The *Randomization settings* in Viedoc Designer have been renamed to *RTSM (Randomization and Trial Supply Management) Settings* and upgraded with advanced allocation settings. The advanced settings allow to setup allocation of investigational products (IP) in a flexible way. It makes it possible to allocate IP at one visit or to have the allocation scheduled at multiple visits during the study, in one or multiple forms.

The advanced settings include:

- option to customize the button label that will appear on the assigned randomization and allocation forms.
- configuring individual randomization and allocation forms, to keep the two steps separated in the study workflow.
- the possibility to perform multiple allocations at different visits during the study.
- the possibility to replace an already performed allocation with a new allocation; to handle possible loss or damage of IP.
- the possibility to undo an already performed allocation; to handle possible mistakes where the IP can be allocated to another subject.

#### Emergency unblinding

In cases of any medical emergency or serious medical condition that occurs while the participant is taking part in a study, the participant may not be able to be treated adequately unless it becomes known which treatment they have been receiving. In such situations, unblinding may become necessary.

This can now be accomplished in Viedoc with a new CRF permission – *Emergency unblinding* – that allows the user having this permission to unblind a subject in emergency situations by revealing the blinded outcome of the randomization.

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## Updated functionality and bug fixes



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

### Updated functionality

- Completion status evaluation for a form with hidden mandatory items for a role has been changed.  
Before the Viedoc 4.52 release, when a form with hidden mandatory items was saved by a user for which the hidden items were not visible, the form status was shown as completed (green checkmark) for all roles, even though it might have contained missing mandatory items.  
In the Viedoc 4.52 release, this has been changed so that the form status is evaluated in a role neutral way. As a consequence, a form with missing required items will be marked with an issue after it has been saved by a user for which the missing items are hidden.
- A new system language was added for ViedocMe – Romanian

### Bug fixes

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

The following corrections have been implemented in Viedoc 4.52 release:

- **Affected area(s):** Event status (green checkmark) for events containing hidden forms.  
**Bug description:** When form(s) were hidden in Viedoc Clinic due to visibility conditions, the event status (green checkmark) was not displayed correctly, as the hidden form was included in the completed forms count, so even though all the visible forms were completed, the event status was not shown as completed. E.g. if Pregnancy test form was set to be visible only for Female subjects, the completion icon would not be displayed for Male subjects when all applicable forms were completed.
- **Affected area(s):** Excel export output when using the *1 row per item* layout for output versions Viedoc 4.38 and/or Viedoc 4.39.  
**Bug description:** When performing an excel export with the layout set to *1 row per item* and the output version set to one of Viedoc 4.38 or Viedoc 4.39, the form sequence numbers (*SubjectFormSeqNo*, *OriginSubjectFormSeqNo* and *SourceSubjectFormSeqNo*) were included in the export output, even though they should be included only when the selected output version is Viedoc 4.51. This is now fixed, and the three above mentioned sequence numbers are included in the export output only if the output version is Viedoc 4.51 or “Latest Viedoc version”.

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List of functionality and bug fixes continues.

- **Affected area(s):** Design revision upgrade message(s) shown in Viedoc Clinic.  
**Bug description:** If a study design revision was batch approved and any of the affected forms were not upgraded, due to locked forms and/or forms for which the approving user did not have permission to see/edit, the study design revision upgrade message shown was displaying the incorrect message. E.g. if version *n.2* was approved but forms were not possible to upgrade, the revision message shown again would be revision message from revision *n.1*. This is now fixed, so that the message that is shown again due to forms not being upgraded corresponds to that particular revision.
- **Affected area(s):** Form save with hidden non-mandatory fields.  
**Bug description:** For the non-mandatory field(s), hidden in Viedoc Clinic due to visibility condition, the record in the audit trail was showing the item being changed from empty to empty after the form was edited and saved. The export output (except for the PDF archive) was though correct, i.e. did not include the record in the audit trail for non-mandatory hidden field(s). This is now fixed and there is no record shown in the audit trail for these items, for the forms saved in Viedoc 4.52 and onward.
- **Affected area(s):** Processing and sending tracker messages.  
**Bug description:** On the Chinese server instance, trackers were not processed correctly and an exception was thrown leading to tracker messages not being sent. This is now fixed, so that the tracker messages are properly sent.
- **Affected area(s):** Data export including medical coding.  
**Bug description:** Exporting data including medical coding took significantly longer time than when medical coding was not included. This is now fixed.
- **Affected area(s):** Table of Contents of the PDF export output for Chinese language.  
**Bug description:** Some characters were not rendered correctly in the Table of Contents of the PDF export output for the Chinese language. This is now fixed.
- **Affected area(s):** Uploaded files larger than 200MB.  
**Bug description:** Uploaded files larger than 200MB became corrupted upon upload in Viedoc. This is now fixed.  
**Note!** If your study was affected, you will be contacted by a Viedoc representative.
- **Affected area(s):** PDF export when deleted forms were included.  
**Bug description:** The PDF export was failing if deleted forms were included in the export. This is now fixed.

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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:

- 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.

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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).
- 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*.

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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, except for “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.
- The form history PDF and the PDF export include the status (e.g. *Awaits approval*) of the *Confirm data as missing* record in the audit trail as the status was when the form was saved. This may give misleading information about the current status.
- If the role that has the Emergency unblinding permission, also has a role visibility condition that makes the blinded outcome hidden for this role, after unblinding the outcome gets hidden for all roles and not just the role specified in designer.

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### Signoff



Signature Confirmation by  
the product owner.

**Uppsala, Sweden 2019-07-02**

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