

viedoc™

# Release Notes

## Viedoc 4.72

Planned for 2022-11-01

# Release Notes

## Viedoc 4.72



List of functionalities that have been added and updated in this release.

## New and updated functionality

### Viedoc Reports

- Viedoc Reports now has a modernized user interface. This is another step in the implementation of a wider UI optimization across the Viedoc suite.
- In Viedoc Reports, there is a new option in settings, which allows users to customize the page appearance by selecting to view the page in either light mode or dark mode.
- In Viedoc Reports, the Signature lag report is introduced as part of the Key risk indicator report and is included in the following subreports: Overview, by Site, by Key Risk Indicators. This report calculates the Signature lag (in days) for each form after the form has been signed. This is calculated as the number of days between the last edit date and time and the signature date and time.
- In Viedoc Reports, two new columns have been added to the Queries Report: Raised By and Raised On. The Raised By column shows whether the queries were raised by the Viedoc system or the name of the user who raised the query. The Raised On column shows the time and date the query was raised.
- Because of the rise in popularity of the Viedoc Reports application, very large amounts of data are handled in the data sync. To reduce response times, the daily data sync now operates on production data only. To sync demo data, use the on-demand sync option.

### Viedoc Designer

- As of Viedoc version 4.71, the design version is printed on each page of the PDFs generated (annotated CRF, blank CRF, workflow, and configuration report) from Viedoc Designer. This is so users can easily identify which design version the respective settings belong to.
- In Viedoc Designer, it is now possible to configure email alerts to send the form PDF as an attachment.

### Viedoc Admin

- In the Study settings dialog, users can now generate and download the Admin audit trail report from the new Logs tab. The report contains information about all settings and changes of study settings that have been made by authorized users in Viedoc Admin. For a detailed description of the contents of the report, see the Viedoc Admin User Guide in the eLearning.

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List of new and updated functionalities continues.

- For PMS studies, in the API configuration window, there is now a new option for the Web API client configuration. This new option is Data controller, and it lets the API manager select Clinic side or Sponsor side to further define the scope of the API client.

### Viedoc API

- It is now possible to use the Web API to retrieve user information in a study.
- It is now possible to invite multiple users to different roles simultaneously through the Web API. API Managers can also add a list of additional properties for specific users.

### UI optimization: New Sign-in and Sign-up look

- In accordance with our UI optimization process, we have updated the look of the sign-in page, as well as the sign-up process.

### Viedoc Clinic

- In Viedoc Clinic, it is now possible to search by Subject ID using the 'Subject key' parameter. This is a much faster search parameter than the 'All data', which must be selected in order to run; it is not the default search parameter. Also, the user can now cancel an ongoing search.
- In Viedoc Clinic, as a clinic user, it is now possible to receive the form PDF attached to the alert email if configured in the study design.

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### Bug fixes



List of bug fixes that have been updated in this release.

This section lists the bugs that were solved in this release. For each bug, it describes the following:

- **Affected area(s):** describes briefly which area(s) of Viedoc the bug is related to, so that it is easy to identify if any of your active studies are 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 4.72 release:

- **Affected area(s):** Viedoc Designer  
**Bug description:** When the ID of a form was changed in the Start event in a new design version, all previously entered forms in the starting event were not shown in Viedoc Clinic. This is now solved.
- **Affected area(s):** Viedoc Designer  
**Bug description:** For very large designs, changes that were made in Study Workflow in Designer were not saved after selecting to save changes. This is now solved.
- **Affected area(s):** Viedoc Admin, Viedoc Clinic, Viedoc Designer  
**Bug description:** For study sites that did not have designs assigned to them, it was possible to invite users for roles not relevant to the site. Further, it was possible for users to select sites when the user did not have permissions. This affected the sites' abilities to add subjects. This is now solved, so that users can be invited to clinic roles only when a design with that role enabled is assigned to the site or to any of the sites in the site group.
- **Affected area(s):** Viedoc Admin, Viedoc Clinic, Viedoc PMS  
**Bug description:** In Viedoc Clinic, when the first participant was added, this set the FPA (first patient added) date. If, at a later date, a user added a second participant, then deleted the first participant, the FPA date was reset to when the second participant was enrolled. This is now solved, so that the FPA is always the date when the first subject was added, regardless of whether it is deleted at a later point.
- **Affected area(s):** Viedoc Admin  
**Bug description:** In a limited number of cases, design versions were not ordered correctly in the list of design versions when assigning a design or applying a revision in Admin > Study design. This is now solved, so that the most recent design version is always shown at the top of the list of available designs.
- **Affected area(s):** Viedoc Me  
**Bug description:** When a study participant filled out forms in the new Viedoc Me, certain non-required items listed in the UI behaved as if they were required. This is now solved.

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List of bug fixes continues.

- **Affected area(s):** Viedoc Me  
**Bug description:** The 'contains()' function for controlling the visibility of check boxes was not working in the new Viedoc Me. This is now solved.
- **Affected area(s):** Viedoc Me  
**Bug description:** In the new Viedoc Me, certain date formats were not supported. If an unsupported date format was set in Viedoc Admin, study participants were unable to log in. This is now solved.
- **Affected area(s):** Viedoc Me  
**Bug description:** When a user viewed Viedoc Me with the French language settings turned on, the Unscheduled events title was not completely visible. This is now solved.
- **Affected area(s):** Viedoc Me  
**Bug description:** In a limited number of cases, the translation of "Choose one" in translation files for Viedoc Me was lost after uploading the translation files. This is now solved.
- **Affected area(s):** Viedoc Me  
**Bug description:** In Viedoc Me, under the newly optimized UI, when a subject selected a choice from a radio button, the answer should result in them being shown an item with a simple visibility condition. Instead of seeing the visibility condition, they were shown an error. This is now solved.
- **Affected area(s):** Viedoc Me  
**Bug description:** Videos were not properly displaying in the newly optimized version of Viedoc Me. This is now solved.
- **Affected area(s):** Viedoc Me  
**Bug description:** When a participant enrolled in Viedoc Me, they were shown a compliance score. The score indicates the number of completed forms versus how many forms are incomplete. It had previously shown a negative number. This is now solved.
- **Affected area(s):** Viedoc Designer/PMS  
**Bug description:** In PMS studies, the subject status was not updating on the sponsor side when an Unfreeze operation takes place. This is now solved.
- **Affected area(s):** Viedoc Designer/Viedoc Admin  
**Bug description:** In a limited number of cases, when users were applying revisions to their sites, the revision failed and was stuck 'In progress'. This is now solved.
- **Affected area(s):** Viedoc Designer  
**Bug description:** In Viedoc Designer, when a new design was applied to a specific site with a date set in the future, subject-specific updates did not take place in the site they were assigned to. This is now solved.

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List of bug fixes continues.

- **Affected area(s):** System  
*Bug description:* Alerts were not triggered correctly when forms were saved in quick succession, for example, when submitted through the API. For example, data submission was initially made to a form containing the alert, and very shortly after, another submission was made to another form (for the same subject) before the alerts that were triggered in the first import were fully processed. This is now solved.
- **Affected area(s):** Viedoc Admin  
*Bug description:* In some cases, studies that had been approved for deletion by an Organization Administrator were not removed after the required 180-day period. Also, there was a backlog of non-deleted studies slated for deletion. This is now solved, whereby studies slated for deletion are deleted, and the backlog has been cleared.
- **Affected area(s):** User settings  
*Bug description:* When a user set up their profile and saved it, if they tried to change a field that was saved, but did not refresh the UI, they would encounter an error message when selecting to save. This is now solved.
- **Affected area(s):** Viedoc Clinic  
*Bug description:* When doing a data export in PDF format, it failed if an event was removed in a study design revision. This is now solved.
- **Affected area(s):** Viedoc Reports  
*Bug description:* In Viedoc Reports, checkboxes with character code list values were not appearing in Adverse events, Demographics, Dashboard and Standard reports modules. This is now solved so that checkboxes with either numeric code or character-coded values are now supported.
- **Affected area(s):** Viedoc Reports  
*Bug description:* Forms that required SDV (Source Data Verification) scope according to the study design were shown as 'SDV not required' due to an issue with the ODM XML output. This is now solved.
- **Affected area(s):** Viedoc Reports  
*Bug description:* Forms with partial items selected for SDV were identified as 'SDV not required' in the Review status standard report. This is now solved.
- **Affected area(s):** Viedoc Reports  
*Bug description:* New studies with only one pre-query and no other queries failed during the daily data sync. This is now solved.
- **Affected area(s):** Viedoc Reports  
*Bug description:* In two Standard reports, Form status and PMS dashboard, the columns Event Sequence, Form Sequence, and Booklet Sequence were treated as characters for sorting, while all the values in them are numeric. This is now solved so that if all the values are numeric, the sort order is numeric.

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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:

### Viedoc Clinic

- CSV export
  - The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (for example, an OID defined as AE in design version 1 and ae in design version 2).
  - Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
  - The Excel/ CSV export does not include items set to “Hide Always” in visibility conditions when a single form is selected for export.
- Data export
  - The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
  - The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Data review
  - The SDV task count, the green checkmark and the issue list on the subject Selection page 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).
  - Queries of the type “Required value missing” responded with “Confirmed as missing” and cannot be rejected by the sponsor side.
  - 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.
- Edit/enter data
  - For scheduled and unscheduled events, when the visit date form (\$EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a visit includes the \$EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or visit). If you sign forms on a visit individually you will not be able to sign the \$EVENT form. This in turn makes it so that the sign symbol that appears on the visit when everything is signed does not appear, even though it looks like everything is signed.

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List of known limitations continues.

- When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.
- It is not possible to delete unscheduled visits if automatic visit dates are enabled.
- File upload
  - 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.
  - The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- Issues and task
  - The Issue list will not be visible for sites that have more than 1000 subjects.
- Layout
  - 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. The descending sorting in the subject list view is not working properly.
- Medical coding
  - The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Metrics
  - The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with state "Removed".
- PDF export
  - 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, filenames 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.
  - 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.



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List of known limitations continues.

- Selection page
  - 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).
  - The event overview page is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.

### Viedoc Admin

- Apply revision
  - 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.
- Data import
  - 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.
- ODM import/export
  - 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”.
  - Only one (selected) design can be imported from each CDISC ODM file.
  - ODM export fails when subject data contains large, uploaded files.
- User management
  - 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 sorting studies by group and generating a “User and Roles” or “User Administration Log” report, the Download link is not exposed for the newly generated file until the page is refreshed.

### Viedoc Designer

- Alerts
  - 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.

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List of known limitations continues.

- Edit checks
  - 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.
  - 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).
  - 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).
- Form and workflow PDF
  - If, in the Study Workflow, 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.
  - 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.
- Item settings
  - 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.
- JavaScript
  - The setMonth function with negative values is not supported. The date is not saved into the system correctly when the function is run on the server-side.
- Roles and permissions
  - 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.
- Study workflow
  - When the Event ID for the Study Start event contains the word "START", including combinations with other words and punctuation, 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, one that doesn't contain the word "START".

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List of known limitations continues.

- Validation of study design
  - 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.
- Visibility conditions
  - 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.

### Viedoc API

- 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.

### ViedocMe

- In the UI-optimized version of Viedoc Me, when a simple visibility condition has been set to make a form item show depending on the selection of a radio button, and a subject selects the radio button, an error message is displayed
- 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.
- 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).
- The drawing pad item is not working on IE 11. For Safari it only works on Safari 12+ versions.
- Viedoc Me does not support forms with form link items.

### Viedoc Logistics

- In the exported stock list, 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.

### Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.

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List of known limitations continues.

- Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.
- The Overdue Events Report does not include any user-specific information or subject-related information (Viedoc Me). Events without a proposed date are not included in this report. Events that have been planned or initiated are not included in this report, even if the planned/initiated event is outside of the event window.

### Viedoc eTMF

- Viedoc eTMF is only running in Production mode.

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### Signoff



Signature Confirmation by  
the product owner.

Uppsala, Sweden 2022-10-31

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