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Release Notes
Viedoc 4.81

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New and updated functionality

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

Viedoc Share

- Possibility to add document fields (open text fields and radio buttons) to a document. When a document with required fields is shared with a subject, all required fields must be completed before the document can be signed.

Viedoc Coder

- The new Viedoc Coder, first released in Viedoc 4.79, is enhanced with auto coding possibilities. Auto coding can now also be enabled, in Viedoc Admin, on any scope using an Anatomic Therapeutic Chemical (ATC) dictionary. Coding is performed by exact match in ATC. When auto coding is enabled, all existing uncoded items as well as any new items entered in the EDC will be auto coded.

Viedoc Designer

- In the form design view, the left-side panel is now locked in view and always visible for the study designer, regardless of the length of the form. When the content in the left-side panel does not fit onto the page, the left-side panel is scrollable with a separate scroll bar to ensure global group templates can be accessed.

- In the global design settings, a study designer can now download a published reference data scope. The reference data scope is downloaded as a JSON file. In the Viedoc 4.82 release, it is planned to add support to import a reference data scope.

Viedoc Reports

- Custom reports can support XML as output when an E2B file is uploaded as a Custom report in Designer.

Viedoc Account Management

- It is now possible to instantly log in to Viedoc without entering the user name and password if accessing via IQVIA One home for sites.

Viedoc Admin, Viedoc Clinic

- The User & Administration Log now contains all users who have access or have previously had access with any system roles in the study. This occurs regardless of whether you generate the log from Viedoc Admin or Viedoc Clinic. Organization level users, for example, Organization Administrator, are not included.

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 4.81 release:

- Affected area(s): Viedoc Admin
  Bug description: MedDRA in Chinese from version 26.0 and onwards could not be uploaded. This is now possible, using an interim solution which removes the character causing the problem. This is documented in Known limitations.

- Affected area(s): Viedoc Admin
  Bug description: It was possible to create multiple studies by double-clicking the "Add study" button. This has now been solved.

- Affected area(s): Viedoc Admin
  Bug description: When applying a new revision, the impact analysis report could not be downloaded if the new revision had no impact on the existing data. This is now solved, so that an empty impact analysis report can be downloaded.

- Affected area(s): Viedoc Admin
  Bug description: In Study settings, the labels for some of the settings were not properly displayed when the selected system language was German. This is now solved.

- Affected area(s): Viedoc Admin
  Bug description: When applying a new design revision, the link for generating the impact analysis report was not visible in some situations. This is now solved, and the link is available for all users with the user role Design Impact Analyst.

- Affected area(s): Viedoc Admin
  Bug description: When applying a new design revision, the impact analysis report marked certain forms as requiring confirmation, even though they were automatically upgraded. This is now solved so that only the forms requiring site approval are marked.

- Affected area(s): Viedoc Admin
  Bug description: When configuring Web API Clients, the mandatory fields for Role and Site(s) did not appear for users with a system language other than English or German. This is now solved.

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List of bug fixes continues.

- Affected area(s): Viedoc Admin
  Bug description: In Study settings, when the user who last edited the documentation section no longer has an active account, it was not possible for a Study Manager to edit that documentation section. This is now solved.

- Affected area(s): Viedoc Clinic
  Bug description: In Data Export, exporting data that included pending forms failed if the pending forms were in deleted events. This is now solved.

- Affected area(s): Viedoc Clinic
  Bug description: Users with the system language set to Chinese (Traditional) could not download a training certificate. This has now been solved so that training certificates can be downloaded in all supported system languages.

- Affected area(s): Viedoc Clinic
  Bug description: When a form with a file upload item was reset or deleted, the file could only be downloaded by the user who uploaded the file. This is now solved, so that the file can be downloaded by any user who has access to the form and item.

- Affected area(s): Viedoc Clinic
  Bug description: When rejecting a query, the system did not always respect the user's selected system language. This is now solved so that the system always uses the system language selected by the user.

- Affected area(s): Viedoc Clinic
  Bug description: On the subject pages, the icon to indicate the number of unread messages and a link to the message page have been removed to improve the performance of page loading. As the link had not been functioning, the impact on usability is considered negligible.

- Affected area(s): Viedoc Clinic
  Bug description: In some cases, completed Data exports remained in the "In progress" state instead of the "Ready". state. This is now solved, so that all completed data exports will display as "Ready".

- Affected area(s): Viedoc Clinic
  Bug description: When a user approved an invitation for a study role that was sent by a user without an active Viedoc account, the approval of the study role failed. This is now solved.

- Affected area(s): Viedoc Clinic
  Bug description: When creating a new subject from the Selection page, the study start form used the UTC time zone instead of the site time zone. This is now solved.

- Affected area(s) Viedoc Me
  Bug description: If a subject uploads a file but does not submit the form within a 10-minute window, and submits the form later, the uploaded file may be missing even though the form submission was successful. This is now solved.

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List of bug fixes continues.

- Affected area(s): Viedoc Designer
Bug description: The search field for design versions on the design overview page was non-functional and has been removed.

- Affected area(s): Viedoc Designer
Bug description: When importing a design, the UI showed incorrect step numbers. This is now solved.

- Affected area(s): Viedoc Designer
Bug description: When importing a design, clicking "import design" multiple times in quick succession sometimes imported the design multiple times, and created unwanted design versions. This is now solved so that only one design can be imported at a time.

- Affected area(s): Viedoc Designer
Bug description: When a form containing a form link item was added from the global form library, the information in the source dropdown lists in the form link item were not populated as expected. Then, when saving the form, an error message was issued, requesting the missing information. This is now solved for new forms saved to the global form library, so that the information in the "source" dropdown lists is preserved, and when adding the form from the global form library to a design, the source dropdown lists are populated as expected.
Please note that for forms already saved to the form library before the 4.81 release, although the source dropdown list is populated as expected, a "false" error is issued which is resolved when the form is saved. If the forms in your library need corrections, you can save the form to the library again when the errors have been rectified and the form saved.

- Affected area(s): Viedoc Designer
Bug description: In the form design section, even though it was not possible to save changes, after selecting the checkbox "prevent dates after", it was possible to select an option in the dropdown list in the validation tab in a locked design version. This is now solved so that the dropdown list is read-only when a design is locked.

- Affected area(s): Viedoc Designer
Bug description: In the form design page, the text "Allows form save" was always displayed in English, and not in other user-selected languages. This is now solved, and the text is displayed in the expected language.

- Affected area(s): Viedoc Designer
Bug description: If auto-update was selected for a form, and the form was hidden, clearing the auto-update checkbox did not automatically clear the "Hidden form" checkbox as expected. Consequently, the study designer could not see that the form was still hidden in the UI. This has now been solved, so that when saving a form in Designer, the "Hidden form" checkbox will always be cleared when the auto-update checkbox is cleared. The forms that have already been saved are not affected by this update.

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List of bug fixes continues.

- Affected area(s): Viedoc Designer
  Bug description: In the form design section, in the advanced form settings, selecting the checkbox "allow form to be initiated based on copied data…" incorrectly selected/cleared the checkbox "Hidden form…". This is now solved so that selecting the checkbox "allow form to be initiated based on copied data…" will select/clear the corresponding checkbox.

- Affected area(s): Viedoc Designer
  Bug description: In a fully customizable design version, when an item was deleted in a form, and this item was used in a simple visibility condition for another item in the form, the visibility condition was automatically updated to use the first radio button or dropdown item in the form. This is now solved by adding a new default option, "Choose item", in the simple visibility condition dropdown lists. The new option is the default until a value has been actively selected by the study designer. Saving the form without actively selecting a new item for the simple visibility condition will trigger a validation.

- Affected area(s): Viedoc Designer
  Bug description: In a design revision, when an item was deleted in a form, and this item was used in a simple visibility condition for another item in the form, the user had no indication that the visibility condition was no longer active. This is now fixed so that a validation is triggered to inform the user that the variable has not been declared.

- Affected area(s): Viedoc Designer
  Bug description: When an event was deleted from the workflow, and the event date from that event was used as a reference date for scheduling another event, the reference date defaulted to use the first event in the workflow. This is now solved by adding a new default option, "Choose item", for the event in the reference date. The new option is the default, until an existing event has been actively selected by the study designer. A validation will also inform the designer when no event has been selected.

- Affected area(s): Viedoc Designer
  Bug description: In the study workflow section, adding an event by using an existing event to duplicate settings, activities, and forms, resulted in the automatic event date settings still being visible. This was because the settings for the event date were read from the event that was being copied. The user could then set conflicting settings for the event date of the new event. This is now solved, and when an event is added as described above, the settings for the automatic event date are hidden. Settings for the event date will still be read from the event that is being copied.

- Affected area(s): Viedoc Designer
  Bug description: In the study workflow section, in the event settings, if the automatic event date is enabled, and "form item" is selected in the dropdown list, the form item must be specified. Previously, if the automatic event date was disabled again before specifying the form item, a warning message prevented the user from saving the page. This is now solved so that the form item must only be specified when the automatic event date is enabled and "form item" is selected in the dropdown list.

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List of bug fixes continues.

- Affected area(s): Viedoc Designer
  Bug description: A translation file could be imported to a study design when the design was locked. This is now solved so that translation files can only be uploaded to unlocked designs.

- Affected area(s): Viedoc Designer
  Bug description: When duplicating a design, clicking multiple times in quick succession on "Revised version" sometimes created multiple revisions. This is now solved so that only one revision can be created at a time.

- Affected area(s): Viedoc Designer
  Bug description: In the Roles page, when clicking permission labels, the corresponding checkbox remained unchecked, but the sub-permissions were displayed and clickable. This is now fixed so that clicking the label will select or clear the permission checkbox as expected.

- Affected area(s): Viedoc Designer
  Bug description: In study settings, on the page selection view settings, if the sample image was clicked, it could not then be closed. This is now solved so that the image will be closed by clicking anywhere on the screen or by using the Escape key.

- Affected area(s): Viedoc Designer
  Bug description: In outputs and validation, on the edit check page, adding new edit checks and clicking "save" multiple times in quick succession, sometimes created duplicates of the added edit checks. This is now fixed so that creating the same edit check more than once is prevented.

- Affected area(s): Viedoc Designer
  Bug description: In the edit checks page, in the outputs and validation section, when clicking the search icon in the search field, the value typed in the search field was deleted and the page reloaded. This is now solved so that clicking the search icon triggers the search.

- Affected area(s): Viedoc Designer
  Bug description: In the Output and validation section, on the OIDs and Labels page, as well as in the complete configuration report, labels were displayed without space characters when a non-breaking space character was used in the form design page. This is now fixed so that non-breaking space characters are preserved in the OIDs and Labels page and the complete configuration report to correctly display all space characters as in the form design page.

- Affected area(s): Viedoc Designer
  Bug description: When a form contained a half- width item group, the item group placed to the right, and all items within it, were not included in the complete configuration report. This is now solved so that all item groups and items are included in the complete configuration report.

List of bug fixes continues.

- Affected area(s): Viedoc Designer
  Bug description: In the abbreviated configuration report (pdf), in the section for selection view settings, the first item (gender) displayed the name of the ID rather than the label. This is now solved so that the configuration report will consistently display labels in the selection view settings.

- Affected area(s): Viedoc Designer
  Bug description: In the global design settings, the last edited date/time stamp and user information did not consider the last edited date/time stamp and user information for the report configuration setting. This is now solved so that the last edited time and user information at the top is now updated when the reports configuration is updated.

- Affected area(s): Viedoc Designer
  Bug description: In the global design settings, adding a medical coding scope, and then opening a saved medical coding scope for editing, failed to preserve the values initially saved for "Supporting value 1" and "Supporting value 2". These values had to be specified again by the study designer. This is now solved so that supporting values are preserved when they are opened in edit mode.

- Affected area(s): Viedoc PMS
  Bug description: Submitting a form with a form link item, then reverting the booklet submit, deleting the linked form, and replacing it with a new linked form caused the booklet receive action on the sponsor side to fail. This is now solved.

- Affected area(s): Viedoc Reports
  Bug description: In some scenarios, there were some values mismatch in the 'Reason for Withdrawal' plot in the Dashboard module, 'Recruitment' and 'Disposition' report, if data originated from a form with checkbox fields. This is now solved.

- Affected area(s): Viedoc eTMF
  Bug description: Documents filed on Country or Site level were excluded from the archive generated by users with "Read-only Trial Master File" and "Archive Sponsor TMF"/ "Archive Investigator TMF" permissions. Note that the users were able to view and download all the documents they have access to, but when they were generating the archive, only the Trial level documents were included. This is now solved.

- Affected area(s): Viedoc eTMF
  Bug description: The default setting ("None") for Document sharing in Document properties was lost for:

  - Unpublished documents, if manually located within an artifact and then moved while still being unpublished

  - Existing documents, either awaiting review or finalized - when the location was changed via a new version. Any other changes to existing documents (edit properties) retained the default selection.

  - This is now solved, so that the Document sharing metadata is by default set to "None" for artifacts that do not have sharing enabled.

List of bug fixes continues.

- Affected area(s): Viedoc Coder
  Bug description: Some special characters are shown incorrectly in Medical coding, for example, the characters "µ", in the WHODrug dictionary and "à" in the MeDRA dictionary. This is now solved so that when the dictionaries are uploaded again, the correct characters are shown. WHODrug dictionaries prior to 2023, however, will not be corrected.

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:

We no longer support SMS notifications in the following countries

- +7 Russia
- +92 Pakistan
- +994 Azerbaijan
- +967 Yemen

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 is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.

- Data review
  - 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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- 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.

- Medical coding
  - The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
  - The MedDRA Chinese translation version 26.0 and onwards has the term 牙开龄 This term will be displayed as 牙开 in the Viedoc system, as the last character is not supported.

- 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.
  - In the PDF export output, each event should have a "Contents" section. The "Contents" list can in some scenarios be truncated and not show everything for the event.

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.
- API configuration
    - After creating new and editing existing Web API clients, it is not possible to save the setup unless the user system language is set to English or German.

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.

! 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".

⚠ 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.
- Design configuration report
  - When using Chinese or Japanese characters to label sites in Designer, the name of the design configuration file report will display an incorrect text string.

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.
- When using the WCF API to push data into forms, if there are items that have functions setup to calculate data from other items, or item groups, those calculations will not be automatically updated. However, if an item that relies on a function is added to the same item group it relies on, it will perform the calculation.

ViedocMe

- 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).
- Viedoc Me does not support forms with form link items.
- The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.
- Long option labels for radio buttons and check boxes do not have line breaks.

List of known limitations continues.

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.

- 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 Viedoc Me events. 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 not working in Safari version 16.3 and later versions.

- Viedoc eTMF is only running in Production mode.

- For security reasons, the document preview in the Trial Master File view does not support ActiveX components.

- The search for document content is disabled on the training server.

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2025-02-04

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