

viedoc™

Release Notes

Viedoc 4.79

Planned for 2024-06-17

Release Notes

Viedoc 4.79



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

New and updated functionality

Viedoc Coder

- Viedoc Coder has been updated with the following new features, which are only available for new studies started after the 4.79 release. For Viedoc Coder, new studies are defined as when a dictionary instance is added to a study's scope for the first time. At a later date, all studies, existing and new, will be updated to use the new Viedoc Coder. This update will be communicated well in advance.

For studies using the new Viedoc Coder

- Viedoc Coder now launches in a new browser tab.
- We've changed the coding terms to 'Approve/Reject/Reset'.
- There is a new look and feel for statistics on the Overview page.
- Export of coding has taken a new shape where we rearranged the columns to fit a better order. As well, all dictionary-specific items are shown together.
- To improve searching in the dictionaries, we have made it easier to copy the text of an item to be coded. This way, the text can be easily pasted into the search field of the coding area.
- We've updated dictionary support for MedDRA so that non-current terms are shown with a warning in the results list and LLT field.
- We've also updated dictionary support for WHODrug so that: the fields Cntr, MAH, Form, and Strength are always visible; The search result shows unique values only; The selected value is always the least specific; And ATC assignment is automatically selected if one code is present (if two or more are present, the user must manually assign the ATC code).
- You can apply sorting to the columns.
- In the 'Find and apply code' section, for easier access, the comment field is now always visible.
- Access to subject data is improved which allows for easier query raising.
- We've removed the sequence column, providing more space for other columns.

Viedoc Admin

- The Design Revision Impact Analysis tool is introduced. This lets Admin users with the new system role Design Impact Analyst see what impact a design revision will have on existing form instances before applying the revision. A user with the new role can see the new Impact analysis button on the Apply revision tab in the Design settings window. When the user performs the impact analysis, the new revision summary column, called Req confirmation, shows the number of existing form instances per site that will require confirmation by site staff. The design impact analysis report can be downloaded in

Release Notes

Viedoc 4.79



List of new and updated functionalities continues.

Excel format. Please note that before inviting a user with this role, we recommend that you read the Viedoc Admin User Guide in the Viedoc eLearning to understand in which scenarios the design revision impact analysis report might reveal blinded information.

Viedoc Designer / Viedoc Admin

- In Viedoc Designer, in Study settings, this release introduces the option to edit the following settings in a design revision: Selection View Settings, Subject ID Generation Settings, Subject status settings, eLearning settings, and Miscellaneous settings. This removes the need to create a new design version for updates. The settings used are those in the latest effective design revision at a respective site.

Viedoc TMF

- In the Trial Master File view, in the Document properties window, a validation for the year part of the dating convention value is added. The validation makes sure that the entered value is a valid date.

Viedoc Me

- We introduce a new identity provider for authentication of Viedoc Me users, offering better support for enhanced security and centralized user management. For example, automatic logout will occur after a certain time of inactivity or if the network connection is lost. For more information about the automatic logout, see the Viedoc eLearning.
- When Viedoc Me subjects enter the URL from the login information PDF in a browser, they are redirected to a URL that contains the string "idp". This is the expected behavior.

ODM data export/import

The following updates to the ODM data export/import have been made to fix compatibility issues.

- Support for partial datetime, date, and time is introduced for the ODM data export. This is now the default type when exporting designs and data in ODM format. Partial dates as per the ISO 6801 standard are written up to the most detailed value available. This makes the export compliant with CDISC ODM. This is implemented in a new export version, version 4.79.
- When exporting a design to ODM, multi-selection code lists are handled as follows:
Checkbox item definitions are split by code list items.
 - During metadata export, checkbox ItemDef is replaced with one for each code list item.
 - For clinical data export, the comma-separated values are replaced for the checkbox with ItemData for each respective value.

Release Notes

Viedoc 4.79



List of new and updated functionalities continues.

For example, when splitting a checkbox ItemDef with OID="CHK" and code list IDs "Yes" and "No", the split checkbox ItemDefs will have the OIDs "__CHK__Yes" and "__CHK__No", respectively. That is, the original OIDs and the code list IDs are prefixed with two underscore characters and separated by two underscore characters. This has been introduced to be compliant with CDISC ODM. The update is implemented in a new export version, version 4.79.

In Viedoc Designer, checkbox items are exported as multiple ItemDefs – one for each selection value. In Viedoc Clinic and the Viedoc API: In the latest export version, checkboxes are exported as separate items for metadata and clinical data. In previous export versions, checkboxes are exported as one item.

- Upon import of a design, multi-selection for code lists (checkboxes) is handled as follows: If checkbox items are found during data import, the data is combined as comma-separated values. If the checkbox data is imported as one ItemData, the structure is preserved. This has been introduced to achieve ODM-compliant designs.

Note! If you are using the ODM format for an integration and have used the data structure version "Latest Viedoc version", the changes to the ODM export that are implemented in a new export version will be effective in your study and might potentially affect your integration. If you instead lock the data structure version to the current version, only some of these changes will be effective in your study. See also section 'Bug fixes' of this document.

Release Notes

Viedoc 4.79

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 4.79 release:

- **Affected area(s):** Viedoc Clinic
Bug description: Changing the subject ID generation setting in a design version did not update existing subject IDs. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: In some rare cases, it was possible to save a form that contained reference data before the reference data had been populated from the server. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: When a study site had the time zone set to UTC or GMT and the site user was in another time zone, for example CET (+1), using the Viedoc provided function now() in Designer returned the site user’s local time, for example +1 instead of the study site time. This is now solved so that all areas/controls in Viedoc Clinic with date time handling respect the time zone of the site.
- **Affected area(s):** Viedoc Clinic
Bug description: When a form was removed from the study workflow in a study design, and a subject had data saved in Viedoc Clinic for that form (in an older design version), if a user selected the Data Export page, and then tried to open the subject card, the subject card did not open. This was because selecting the Data Export page modified the set of forms in the design definitions in the memory, (until the design cache expired). This is now solved.
- **Affected area(s):** Viedoc Clinic/ Viedoc Me/PDF Export
Bug description: The Study event summary was not shown correctly if the data it referenced was in another event or form that was in a different study design version. This is now solved.
- **Affected area(s):** Viedoc Me
Bug description: When users added 4-byte characters, like emojis, in Viedoc Me, it caused the data to be submitted incorrectly, even though it appeared to be correct to the users. This has now been solved so that an error message is displayed ensuring that the user is aware that the data was not submitted correctly.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** Viedoc Me
Bug description: When selecting the Greek language from the dropdown menu, only uppercase letters for delta and omega were displayed, lowercase letters were not shown. This is now solved.
- **Affected area(s):** Viedoc Me
Bug description: Viedoc Me users could not view their correct compliance statistics for their Viedoc Me account status. This is now solved.
- **Affected area(s):** Viedoc Me
Bug description: Submitting a scheduled event caused the availability span to use the event date, thus displaying an incorrect availability window. This is now solved.
- **Affected area(s):** Viedoc Coder
Bug description: The visibility of supportive values in the medical coding user interface was influenced by the initial scope entered in the user interface. When launching the medical coding with a scope that didn't have the supportive values, the supportive value columns were not visible even when changing to the scope that had the supportive values defined. This is now solved for new studies using Viedoc Coder after this release.
- **Affected area(s):** Viedoc Coder
Bug description: All searches in IDF dictionaries were performed as 'contains'. This is now solved so that the different search options, 'Contains', 'Exact', 'Begins with', work as expected.
- **Affected area(s):** Viedoc PMS
Bug description: In some scenarios, when updating the variables to be shown on the subject card (in Designer>Study settings>Selection view settings) in a new design version that becomes the latest effective design, there were some inconsistencies between the variable name and the corresponding value shown on Clinic/Sponsor side after the new design version was applied. This is now solved, and the latest effective design is immediately used on both clinic and sponsor side when it has been applied. The data that exists on the respective side is used to populate the card variables. The subject card header and value are the same on both sides in the first receive of the subject, regardless of if the forms of data are received or not.
- **Affected area(s):** Viedoc PMS
Bug description: For a deleted subject that had previously had an individually submitted form with either a linked, or a linking form that was received and returned from the Sponsor side, selecting the Manage link of that form resulted in an error and therefore the history of the actions performed on the form (for example, when the form was submitted/received) was not visible on the Clinic side. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: On the Data Export page, when selecting to include 'a single subject or event', and then reverting the selected option to select to export 'all subjects or events', the original selected option was still visible in the UI. This did not affect the data included in the data export. This is now solved.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** All Viedoc applications including Viedoc Me
Bug description: Due to a new feature in the Firefox browser, a user could translate any page in Viedoc (to a language supported by Firefox), without using Viedoc's language settings. This is now solved to prevent translations of Viedoc pages in the Firefox browser.
- **Affected area(s):** Viedoc Clinic, Viedoc PMS
Bug description: In a PMS study, if the booklet had an available ghost (copyable) form that was not copied to the event (booklet) before submission and if the new "subject edit lock permission" was not enabled for the PMS study, the Freeze booklet button was not visible for users on the Sponsor side. This is now solved.
- **Affected area(s):** Viedoc Admin
Bug description: In Viedoc Admin, in study settings, creating a study license with a valid Reference ID, and omitting to add a value for a mandatory field, resulted in the error indication of mandatory empty fields not showing. This is now solved.
- **Affected area(s):** Viedoc Admin
Bug description: When double-clicking on the Save button in the Study settings after attaching a dictionary to a medical coding scope, multiple requests were sent to the server to save the scope. Before the first scope was saved to the database, the second request also started to create a new scope which led to two medical coding instance scopes being created instead of one. The duplicates only appeared in the medical coding console, and were not visible in Viedoc Admin. This is now solved.
- **Affected area(s):** Viedoc Admin
Bug description: In Viedoc Admin, when a Study Manager reset a user's password, the password, the reset link only remained valid for 3 hours, instead of for 12 hours. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: For a user role with permission to "Delete subjects", but no edit permission, the option to delete a subject was not available in Viedoc Clinic. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: In data export, applying a template with a selected form item that was no longer in the study design for a site, correctly caused the apply export template to fail. However, there was no indication of the error in the Forms and items field, only an empty indication of a selected form was shown. This has been solved so that the removed form item is clearly indicated.
- **Affected area(s):** Viedoc Clinic
Bug description: When exporting data using the Viedoc Web API with the API client status set to production and using a site ID from a demo site, the export contained data from both production and demo sites. This has been solved so that the Web API client exports only the relevant site data. This means that if the API client status is set to production, the export contains data from the production site only, and if the API client status is set to demo, the export contains data from the demo site only. If an attempt is made to perform an export with the API client set to production using a site ID from a demo site, or vice versa, an error message is displayed.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** Viedoc Clinic
Bug description: When performing a batch approval of forms affected by a design revision where a change to a form link item was included, the approval process would crash. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: When performing a batch approval of forms affected by a design revision where any hidden items required SDV and item-level SDV was enabled, the form-level SDV was broken. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the Trial Master File view, not all texts on the Details page were translated into the supported languages. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Admin view, the Status page did not display the lock date and time for locked studies when the date and time pattern was not defined in Viedoc Admin. However, the date and time were stored in the database. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the Trial Master File view>Document properties>Actions window, the options to approve and unlock a document were not available to a user with review permission. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the Trial Master File view, when moving a record from a drop zone to the structure by updating the document properties, the version label was not visible and could not be set. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, in the complete audit trail report>Structure management sheet, when editing a role permission for an artifact, the Add artifact action showed the edited permission value instead of the original one. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, when archiving the study, if there are several documents with the same name filed to the same location and level, only one of the files would be present in the archive. This is now solved, and any documents with the same name filed to the same location and level get an appended sequence number to the document name.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, the complete audit trail report did not include the Edit artifact actions after performing a Delete action in the same version of the structure. This is now solved.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, it was not possible to generate the archive nor the complete audit trail report for a study where the dating convention value was entered in an incorrect format. This is now solved, such that the validation is moved to the Document properties>Dating convention to ensure that the entered data in that field is a correct date. The validation is of the date is removed from the archive and the complete audit trail report. For more information, see section 'New and updated functionality' of this document.
- **Affected area(s):** Viedoc TMF
Bug description: Viedoc TMF was not working on the Chinese production and training instances. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the Trial Master File view, when the drop zone had files uploaded by other users, for users with read-only permission, an error would occur when they launched the eTMF and when they opened the Details page. When users with read-only permission performed searches, no search results were presented, and when the users cleared the search field with the clear button, an error would occur. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, when the sequence of milestones was edited, the complete audit trail report displayed incorrect order information in the column Old value. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, when generating an eTMF-EMS repository and setting the TMF side to "Sponsor", the description of the generated file didn't include the sponsor filter. However, the folder structure and the XML were correct. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: When a file is moved from the drop zone to the structure, the complete audit trail report and the History section in the Document properties window showed the name of the user that uploaded the file to the drop zone for the action "Upload file to structure". This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, when generating an eTMF-EMS repository, and a document was linked to different sites/countries and the archive filters were set to include one of the sites/countries, an error occurred. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the Trial Master File view, files in the drop zone uploaded by other users would cause issues for a user with read-only permission. When launching the eTMF and when opening the Details page, the user was presented with an error message. When searching, no search results were presented, and when the user cleared the search field with the clear button, an error occurred. This is now solved.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, when the sequence of milestones had been changed in TMF Admin, the Structure management sheet showed an incorrect value for the old value of the Edit milestone action. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: In the TMF Archive view, when the archive was being generated, the process would sometimes come to a halt at 75%, due to a timeout limit of 30 minutes. This is now solved.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the content of the Question element for study event items and booklet forms was not complete. According to the CDISC standard, the element should include one of the TranslatedText attributes. This is now solved, and the Question element is populated with a string related to the corresponding OID. This is applied without a new export version.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the MeasurementUnit.Name contained HTML code, making it non-compliant with the CDISC standard. This is now solved, and the HTML code is removed from the name. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the translated text was missing for meta.Protocol.Description.TranslatedText. This is now solved, and the body is populated with the protocol name, as visible on the design overview page. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the Length attribute was incorrect, making it non-compliant with the CDISC standard. This is now solved, and Length is populated as per the ItemDef data type. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, there was a mismatch between the item data type and the code list data type for checkboxes. This is now solved, and the checkbox data is split into different items, in the same way as for CSV and Excel exports. This is implemented in a new export version, version 4.79. For more information, see section 'New and updated functionality' of this document.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the study OID and ClinicalData didn't respect the Production/Demo mode for sites. This is now solved, and the study OID and ClinicalData are populated based on the Production/Demo mode of the exported study. This is applied without a new export version.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, non-repeating forms included a repeat key, making the ODM data export non-compliant with the CDISC standard. This is now solved. This is implemented in a new export version, version 4.79.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the KeySet elements had an unregistered value for the ItemOID attribute, making the ODM data export non-compliant with the CDISC standard. This is now solved, and the KeySet elements reference items within the same MetaDataVersion. This is implemented in a new export version, version 4.79.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the attribute OrderNumber of the element StudyEventRef was not valid with respect to its type, integer. This is now solved, and StudyEventRef elements have unique and non-empty consecutive order numbers. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, there was a data type mismatch between CodeList and ItemDef, making the ODM data export non-compliant with the CDISC standard. This is now solved by always having a matching data type between ItemDef and CodeList. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the element MeasurementUnitRef had an unregistered value for the MeasurementUnitOID attribute, making the ODM data export non-compliant with the CDISC standard. This is now solved, and measurement units not referenced in any MetaDataVersion are not included in the ODM data export. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the Alias names were not correctly populated. This is now solved, and any code list item aliases with empty names are removed at import and export - and the Alias names are populated with the context values. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the SAS field name and the SAS dataset name were not populated. This is now solved, and the SAS field name is populated based on the ItemDef OID, and the SAS dataset name is populated based on the FormDef OID, which means that the OIDs are SAS-compliant. There is an option for this in the data export. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, revisions linked to study events and revisions linked to forms requiring approval of the new design revision were not included. This is now solved. This is applied to all export versions.
- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, alerts had repeating order numbers. This is now solved, and the order numbers for all study settings alerts in Viedoc Designer are removed. This is applied to all export versions.

Release Notes

Viedoc 4.79



List of bug fixes continues.

- **Affected area(s):** ODM data export/import
Bug description: In the ODM data export, the item group containing the reference data items was not added to the MetaDataVersion. This is now solved. This is applied to all export versions.
- **Affected area(s):** Viedoc Reports
Bug description: When the ExcludeEventDate was selected for an event in a study, the Review Status report showed incorrect data. This is now solved so that when the 'ExcludeEventDate' is checked for an event, the Review Status report will display 'N/A' by form in the sub-report for Sign by, DM Review by, SDV by, CR by, and Lock by all.
- **Affected area(s):** Viedoc Reports
Bug description: The CountryCode column for a custom report displayed the incorrect country code tied to the subject's country code. This is now solved so that this column now has the same country code as the medical coding dictionary export.
- **Affected area(s):** Viedoc Reports
Bug description: In the Review Status report, the columns that displayed 'N/A' in the review by columns, displayed '(blank)' in the date columns. The columns now show 'N/A' in alignment with each other.
- **Affected area(s):** Viedoc Reports
Bug description: Functions and libraries for R failed for Custom reports. We updated this so all functions and packages in SampleReportCode.R are supported in custom reports.
- **Affected area(s):** Viedoc Reports
Bug description: In the report 'Missing data' the query resolution field was left blank. We now include 'Query state, UserName, and Query Resolution' in the query resolution field.
- **Affected area(s):** Viedoc Reports
Bug description: Using SAS and the file extensions XPTV8 and XPT, the labels and the field names were not properly aligned. As well, forms downloaded in Data Browser using extensions .rds, .xpt, .xptv8, the labels and field names were not properly aligned. This is now solved.
- **Affected area(s):** Viedoc Reports
Bug description: The Disposition report gave the following error when multiple records existed for the same event in the Event Dates form, 'Error: Each row of output must be identified by a unique combination of keys.' The error shouldn't populate in this case. This is now solved as the Disposition report loads completely by selecting the earliest non-blank value even if multiple records exist.

Release Notes

Viedoc 4.79

Changes in Viedoc 4.79.1



Information of the changes
in hotfix 4.79.1

After the release of Viedoc 4.79 on the US and EU instance, the following issues were solved in a hotfix Viedoc 4.79.1. For release in Japan and China, Viedoc 4.79.1 fixes will be included in the 4.79 release.

New and updated functionality

Viedoc Admin / Viedoc Clinic

- Three new columns have been added to the user and administration log. In the sheet User Access Log, the columns “Has Secondary Email Adress” (to Display Yes/No), “Phone Number” (to Display full phone number) and “Can Receive Messages” (to Display Yes/No) are now included. The user administration log can be printed from Viedoc Admin or from the roles section in Viedoc Clinic. Note! These columns have been added to simplify identification and follow-up of cases where users do not have a secondary authentication method added to reset their passwords. For a user to reset the password himself/herself, the user will need to have the following details registered; 1. A valid phone number (including country code - starting with “+” or “00”) AND 2. Confirmed that the number can receive text messages. OR 3. At least one secondary email address. If users lack the details to recover their passwords, we recommend reaching out to them proactively and advise them to add the relevant details.

Bug fixes

- **Affected area(s):** vvViedoc WCF AP
Bug description: The WCF API method GetClinicalData failed if review status and queries were included. This is now solved.
- **Affected area(s):** Viedoc WCF API
Bug description: In data from the WCF API method GetClinicalData, date item tags changed from ItemDataDate, ItemDataDateTIme, ItemDataTIme to ItemDataPartialDate, ItemDataPartialDateTIme, ItemDataPartialTIme respectively, irrespective of Viedoc structure version. The expected behavior is that the partial date elements should only be used in Viedoc structure versions later than 4.79. This is now solved.
- **Affected area(s):** Viedoc Designer
Bug description: In the format section, under outputs and validation, the format type “string” was renamed to “text”. Formats previously set as “string” were not automatically re-mapped to “text”. This made all format appear as integer when viewed in the Designer interface. If any modification was saved, the formats previously set as string returned errors and the user had to manually set them as text. This is now solved and formats previously set as “string” will automatically show “text”.

Release Notes

Viedoc 4.79



Information of the changes
in hotfix 4.79.1 continues

- **Affected area(s):** Viedoc Designer
Bug description: In the workflow section, the preview form did not respect visibility conditions set in the workflow. This is now solved, and visibility conditions are respected when looking at the form preview from the workflow section.
- **Affected area(s):** Viedoc Reports
Bug description: Sporadic sync issues were registered for the daily sync of data to Reports, resulting in syncs sometimes failing. This is now solved.
- **Affected area(s):** Viedoc TMF
Bug description: Files with a file size greater than 1GB could not be uploaded to the TMF. This is now solved.xxx

Release Notes

Viedoc 4.79

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 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
 - 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

Release Notes

Viedoc 4.79



List of known limitations continues.

- 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.
- 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.
- 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.

Release Notes

Viedoc 4.79



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.
- Documentation and Training
 - When downloading a PDF of the Viedoc User Training Certificate, the generated PDF is limited to two pages. This means that when there are more training sections completed than can fit onto two pages, the PDF will not generate a third page and some of the training sections will be missing.

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.

Release Notes

Viedoc 4.79



List of known limitations continues.

- **Study Settings**
 - The Logs tab for generating the Admin audit trail report does not appear on the Study Settings page if the system language is German or Swedish.
 - The Documentation tab for the documentation and training feature, do not appear on the Study Settings page if the system language is 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.
- **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.

Release Notes

Viedoc 4.79



List of known limitations continues.

- 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”.
- 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

- 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.

Release Notes

Viedoc 4.79



List of known limitations continues.

- 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.
- 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.

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.

Release Notes

Viedoc 4.79

Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2024-07-19

Johannes Molin

Viedoc Technologies