viedoc™

Release Notes
Viedoc 4.82

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New and updated functionality

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

Viedoc Share

eTMF users now have the possibility to add checkboxes to a shared document, in addition to radio buttons and open text fields. When a document with required fields is shared with a subject, all required fields must be completed before the document can be signed.

A document downloaded using the "Download with sharing details" option now includes the fields filled in by the subject, if any (such as radio buttons, checkboxes or text fields).

Viedoc Admin

A new scope was added to the setup of Web API Clients. The "Manage clinical data" scope will be used for future API endpoints

Viedoc Designer

In the global design settings, a study designer can now import a reference data scope file previously downloaded from Viedoc. This enables the transfer of a reference data scope from one study to another, reducing time spent on configuring and validating reference data scopes.

When a reference data scope is imported, the designer will be taken to the edit view for the reference data scope, giving the designer the opportunity to modify the uploaded scope before saving it. Variables not present in the study design are removed during the upload process, so we recommend that you first save the form in your design, and then upload the reference data scope in the global design settings.

The OID of static text items can now be modified by the designer. Modifying the OID of static text items will follow the same pattern as other item types:

- The OID of static text items can now be changed in a new fully customizable design version.
- The OID of static text item can now be changed in a revision
- The OID of static text item of an item added in a previous design cannot be changed in a revision.

For clarity, the OID of static text items will not be displayed in the annotated CRF (aCRF) or in the form view mode.

Viedoc Reports

The SampleReportCode.R script that can be downloaded for custom reports now includes a code snippet for how to access the package versions supported for custom reports.

Release Notes
Viedoc 4.82

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 4.82 release:

- *Affected area(s):* Viedoc Clinic
  Bug description: When site users with access to a single site created 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 Clinic
  Bug description: When using Viedoc in a non-recommended way, by working in Viedoc Clinic in two browser tabs, it was possible to create duplicate repeat keys for an event and a form. This is now solved, and users receive an error message and are prevented from saving data with duplicate repeat keys.

- *Affected area(s):* Viedoc Designer
  Bug description: When a validation error is triggered by a designer, the errors are detailed in the exported design ODM. The "CanPublish" tag was previously always set to "false", regardless of the error severity and whether or not the designer was able to publish the design. This is now solved, so that the "CanPublish" tag in the design ODM correctly reflects the error severity and whether the design can be published or not.

- *Affected area(s):* Viedoc Designer
  Bug description: When a validation error is triggered by a designer, there is a differentiation in the database between warnings (allowing the designer to publish) and errors (preventing the designer from publishing the design). However, this differentiation was previously not shown to the user in the UI and all triggered validations were shown as errors in the UI. This is now solved so that when validating a design, there is a distinction between warnings and errors also in the UI. Validation warnings are branded in orange, with the text "Found X warning(s). We recommend that you fix these before you assign or apply your design to a site." To not distract users, other elements in orange colors on the design overview page have been changed to gray. There is no change to how the errors will be displayed.

List of bug fixes continues.

- *Affected area(s):* Viedoc Designer
  Bug description: In the global design settings, in the settings for the reference data scope, the study name was missing in the header. This is now solved, so that the study name is visible in the header like for all other global design settings pages.

- *Affected area(s):* Viedoc Reports
  Bug description: In some cases, for studies with many design versions, the data sync process was not completing successfully. Improvements were implemented on the data sync process so that the process is successful even for the studies with many design versions.

- *Affected area(s):* Viedoc Share
  Bug description: In a shared document with mandatory questions, the mandatory fields were highlighted in red even after the answers were filled in by the subject and the document was signed. This is now solved.

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.

Release Notes
Viedoc 4.82

! 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.

- 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 牙开骀 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.

Release Notes
Viedoc 4.82

- 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

- Share access details
  - Sharing Viedoc Me access details via text message does not work for studies that are running on the Viedoc China instance.

- 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.

Release Notes
Viedoc 4.82

! 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 2025-01-20

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