viedoc

Release Notes Viedoc 4.80

Planned for 2024-10-07

New and updated functionality

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

Viedoc Share

 With this release, a new application called Viedoc Share is introduced. It allows viewing and signing of documents shared with Viedoc Clinic and Viedoc Me users from Viedoc TMF. This application is only accessible by authenticated Viedoc Clinic and Viedoc Me users. The signature is executed using OTP (One-Time Passcode) shared with the signees via email and text messages.

Viedoc Admin

- Viedoc Admin has a new Viedoc Me setting for sharing the Viedoc Me account invitation via email and/or SMS. This new option is only available for studies configured to use the new Viedoc Me application for both demo and production sites. Moreover, the study must be configured to force the subject to change the login PIN upon the first login (this setting is now the default for all new studies).
- The User Administration Log has been improved and now includes the following information:
 - Organization name is added to the 'Reports Info' sheet
 - Study name is added to the 'Reports Info' sheet
 - Latest system login date/time is added to the 'User Access Log' sheet
 - The Certified column on the 'User Access Log' sheet is aligned with the Certification log to reflect when a user has signed the documentation and training certificate.
- In Viedoc Admin, the Web API client setup now has additional settings, which must be configured in some situations. The setup now requires an associated role and associated site(s) to be set for a Web API client. This restricts a Web API client to only access data specified as visible to the role as configured in the study design. This is a breaking change that will require all existing Web API clients to be updated. If this is not done, the API request will result in an error. Please contact your Viedoc representative for support in avoiding export failures.
- A new option is available under the Study Settings, to 'Enable role-based queries'.
 By default, this is:
 - Disabled for ongoing studies.
 - Enabled for new studies.
 When enabled, the approval or rejection of the query resolution is restricted to the same role as the user who raised the query, for example, a query raised by a Data Manager can be approved or rejected only by a Data Manager.
 Note! The restriction does not apply to validation queries or data confirmed as

missing. These are still open to any role with the "add/change queries" permission.

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List of new and updated functionalities continues.

 In the eTMF management section, two new TMF role permissions are available: "Manage document sharing for Viedoc Clinic users" and "Manage document sharing for Viedoc Me users". The Clinic roles that are mapped to any of these permissions can access the eTMF from the study landing page and can share documents from Viedoc TMF with Viedoc Clinic and/or Viedoc Me users.

Viedoc Clinic

- When the role-based queries option is enabled for the study:
 - Users with permission to "add/change queries", such as Monitors or Data Managers, can see which role raised the query. Additionally, users are only allowed to perform actions on queries raised by users with the same role as themselves.
 - For the roles without the permission to "add/change queries", such as Investigators, the role of the user who raised a query is not shown, but it is visible in the query history dialog box and on the Issue list.
 - A new filter "My role's queries"- is available in the Issues list. This option is only available to roles with permission to "add/change queries." It is applied by default when opening the Issues page. This filter option lists all of the open queries (in the "Awaits approval" or "Awaits answer" state) raised by the same role.
- Two new columns are added to the Excel/CSV export output, to the "Queries" sheet, when queries (with or without the "Query history") are included under "Type of data":
 - User role the role of the user who performed the action. This can be a different user role for different actions performed on the same query.
 - Query raised by role the role of the user who raised the query this is always the same for all of the actions performed on the same query. This allows for filtering the queries (including the history), raised by a specific role.

Note! The two new columns are added as the last columns in the Queries sheet, for all existing export versions.

Viedoc Me

- When creating a Viedoc Me account, if the study is set up to enable sharing the account activation information via email and text messages, the user is prompted to enter the subject's email address and/or telephone number twice. The telephone number field has a country code field that defaults to the site's country. The possibility to share the account activation information by PDF is still available. The PDF generated when activating an account in Viedoc Me now matches the style of the new UI (only applicable when the new UI is activated). It also has a QR code linking to the Viedoc Me login page.
- Subjects are now forced to change their PIN code upon account creation if they
 received their Viedoc Me account credentials via QR code, SMS, or email link.
 After changing their PIN code, when the subject logs in for the first time using the
 account activation shared via email, text message, or by scanning the QR code in the
 PDF, the subject is directly authenticated and prompted to change their PIN code. After
 changing the PIN code, a welcome page is presented to the user with information about

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List of new and updated functionalities continues.

the study and the subject username for future reference. An email and/or text message are also sent to the provided email address and/or telephone number of the subject with their username and link to Viedoc Me for future reference.

 In the UI-optimized version of Viedoc Me, when the subject has documents shared with them from Viedoc TMF, a link to Viedoc Share is added to the landing page for ease of access to the shared documents. The link also indicates the number of actions required by the subject on the shared documents. The link also indicates the number of actions required by the subject on the shared documents.

Viedoc Coder

- The new Viedoc Coder, first released in 4.79, is enhanced with auto coding possibilities. Auto coding can be enabled, in Viedoc Admin, on any scope using MedDRA. This first version of auto coding can code an exact match in MedDRA, in any language (except MedDRA-J). When enabled, all existing uncoded items as well as any new items entered in the EDC will be auto coded.
- The UI has been improved with a new user menu.

Viedoc Reports

- Query terminology in Viedoc reports has been updated to align with the EDC, that is, Viedoc Reports will also have the query states *raised, resolved, closed, approved, rejected* and *removed*. As a consequence of the updated query states, some of the standard updates have been updated. Furthermore, some additions and modifications were made to improve the standard reports.
 - Query Table (previously called "Queries")
 - The current report "Queries" has been moved to a sub-report under "Manual and Validation Queries" and renamed to "Query Table".
 - The column "Query State" has been changed to include all 6 query states to better align with Viedoc Clinic.
 - Two new columns "Latest Action By", "Latest Action On" and "Query Resolution" have been added.
 - The column "Raised By", "Raised On" and "History" has been moved to the right and grouped with the user action data.
 - The logic in the column "Open to Resolved Days" has been updated to show the time from "raised" to "resolved" or "closed", and the label is changed to "Time to Resolution (days)".
 - The logic in the column "Resolved to Closed Days" has been updated to show the time from "resolved" to "approved" or "rejected", and the label is changed to "Time to Approval (days)".
 - The label "Open to Closed Days" has been changed to "Time of Query Cycle (Days)".
 - The column "Open to Removed Days" has been removed as it was considered redundant.

List of new and updated functionalities continues.

 The logic in the column "Age of Query" has been changed to display only queries in the raised state, i.e. not yet actioned.

- A new column has been added: "Age of Resolved Query (Days)" calculating the time from when the query is resolved until today for all queries that are still in a resolved state i.e. not yet actioned by the query reviewer.
- Missing data
 - In the sub report "by item", the column "Query Status" now includes all 6 query states to better align with Viedoc Clinic
- KRI
 - The label "Closed queries per subject" has been changed to "Processed queries per subject". "Processed" means that a query is no longer in a raised status, i.e. it is either in resolved, closed, rejected or approved state (removed queries are not included).
 - The label "Query response lag (in days)" has been changed to "Time to query resolution (in days)" to be consistent with the other reports. The logic remains unchanged.
- PMS dashboard
 - The sub report "by Booklet" now includes columns for all 6 query states to better align with Viedoc Clinic.
 - In the sub report "Timelapse", the column "Queries Resolved lapse days" has been changed to show the time from "raised" to "resolved" or "closed" and the label is changed to "Time to resolution" to align with the other query reports.
 - In the sub report "Timelapse", the column "Queries Closed lapse days" has been changed to show the time from "resolved" to "approved" OR "rejected" and the label is changed to "Time to Approval (days)" to align with the other query reports.
- To align with the updates on query states and other changes described above, there
 have been some associated modifications to the dataset ProcessedQueries (this
 dataset can be used for configuring custom reports). The updates to the columns in
 the ProcessedQueries dataset include changes to the logic to get the most useful
 metric, updated labels to make them more descriptive, as well as additional new
 columns made available for use in custom reports. Altogether, these modifications
 enable users to create better and more relevant query reports more easily

Important! If you are using the ProcessedQueries dataset as part of your custom report configuration, we strongly recommend that you check which columns you are using and if they will be affected by the upcoming change. If any of the modified columns are being used in your custom reports, the report will either generate an error or display another value after the release of 4.80. It is therefore important that you review the impact and analyze if the custom reports script will need to be updated or not.

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List of new and updated functionalities continues.

If you are not using the ProcessedQueries dataset as part of your custom report configuration, or if you are only using the parts of the ProcessedQueries dataset that have not been modified, you are not affected by this change.

Changes to the ProcessedQueries dataset are specified in the eLearning.

Note! The ProcessedQueries dataset will be updated to include the new columns only when there is a new sync with the EDC. For production studies this happen automatically every day, as long as there has been a data change. For training studies, and for production studies without data modification in the past 24 hours, there will be no automatic data sync. As soon as the data is synced after the release, the new columns in the ProcessedQueries dataset are populated correctly and the standard reports using data will also display correctly.

Until the data has synced, the new Queries reports, and other reports that use data from the ProcessedQueries dataset, such as Missing Data, Form Status, PMS, and KRI will result in error/incorrect data. This is because they use the old ProcessedQueries data which would not have the required columns/column values for populating all reports.

Viedoc Designer

 In Viedoc Designer, in Study settings, this release introduces the option to add and edit alerts in a revision. This removes the need to create a new design version for alert updates. The alert settings used are those in the latest effective design revision at a respective site.

Viedoc TMF

- In TMF Admin, a new configuration section is introduced to the artifacts called "Document sharing", where the eTMF Manager can configure the artifact to include documents that can be shared with either Viedoc Clinic users and/or Viedoc Me users. To maintain backwards compatibility, the document sharing is disabled by default for all artifacts.
- In TMF Admin, the previous sharing functionality for main artifacts and sub-artifacts by creating links is no longer available. Moreover, the possibility to grant SIGN and AGREE permissions to roles under each artifact is removed. When applying changes to the structure the first time after this release, the existing links will be disabled, and the respective SIGN and AGREE permissions will be replaced by NO ACCESS.
- In the Document properties window, a new section called Sharing is available when sharing is enabled for the document and the user has access to create binders, view existing ones, or revoke them. A binder is an envelope that contains a document version that can be shared with Viedoc Me or Viedoc Clinic users.

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List of new and updated functionalities continues.

- In the Document properties window, under the Document info section, the TMF side, as configured in the artifact the document is filed to, is shown in read-only mode. Under the File info section, the File version and File integrity fields are shown in read-only mode.
- In the Document properties window, a new section of metadata called Sharing is
 introduced. The Sharing metadata is mandatory and must be configured by an eTMF
 user with WRITE permission to the corresponding document prior to publishing it. To
 maintain backwards compatibility, the Sharing is set to None for all existing documents.
- Clicking the Sharing section generates the Sharing dialog box that shows an overview of the existing binders that the eTMF user has access to. It is also possible to create binders from this dialog box.
- · It is not possible to delete a document that has active shared document versions.
- When archiving the eTMF, the signed documents are included in the zipped folder under a sub-folder called "signatures" next to the original shared file. The XML files also include the signature attribute with its relevant metadata.
- A new sheet called "Sharing" is added to the Complete audit trail report which includes an audit trail associated with the shared documents.

Viedoc Clinic / Admin

• The email templates have been updated for improved design consistency for the following emails: User invitation, Study status changes, Purge study results and Metrics/Export Email PDF.

Viedoc Admin / Designer

- Three new system languages have been added:
 - Spanish
 - French
 - Traditional Chinese

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 4.80 release:

- Affected area(s): Viedoc Admin Bug description: In Study settings when downloading the study lock report, the report did not state that the time was given in UTC. This has now been clarified in the report.
- Affected area(s): Viedoc Admin Bug description: In Study settings, the Documentation and Logs tabs were missing for users with the system language set to German or Swedish. This is now solved, and the tabs are available for all supported system languages.
- Affected area(s): Viedoc Admin Bug description: The Admin audit trail contained a typo: "Clinic roles to be administrered by Site Manager" which appeared in the columns for old and new values. This is now corrected.
- Affected area(s): Viedoc Admin Bug description: Changes to the file protection password under Study settings only appeared as "Edit study settings" in the Admin audit trail. For consistency, the old and new values are now populated with asterisks.
- Affected area(s): Viedoc Admin Bug description: When adding a Documentation and Training section applicable to "All production sites" or to a specific country, the Admin audit trail was incorrectly showing "All sites". This is now solved.
- Affected area(s): Viedoc Admin Bug description: The activation password set in Study settings was displayed in clear text in the Admin audit trail. This is now solved, and the password is displayed with asterisks instead.
- Affected area(s): Viedoc Admin Bug description: The Admin audit trail did not include the operation of removing a role for a user in the study. This is now solved, and the role removal operation is included from this release onward.

List of bug fixes continues.

• Affected area(s): Viedoc Admin

Bug description: In API client configuration, it was possible to select the Save changes button even though nothing was changed, and consequently a new record in the Admin audit trail was added. This is now solved, and the Save changes button can only be selected when the configuration has changed.

- Affected area(s): Viedoc Admin Bug description: In API client configuration, it was possible to create multiple API clients with double clicks. This is now solved.
- Affected area(s): Viedoc Admin, Viedoc Clinic Bug description: The User administration log did not contain information about the user account setting for two-factor authentication. This is now solved.
- Affected area(s): Viedoc Admin Bug description: If a user double-clicked when approving a user role invitation, multiple entries in the database were created. This caused issues for Site Managers when they wanted to open the Site settings. This is now solved, and Site settings can be opened.
- Affected area(s): Viedoc Admin Bug description: When using Japanese as the system language, the link to generate the impact analysis report was not visible. This is now solved.
- Affected area(s): Viedoc User settings Bug description: If a user selected Enter while verifying a secondary email address and the telephone number, the verification failed. This is now solved.
- Affected area(s): Viedoc User Authentication
 Bug description: The link to resend the authentication code was still visible to the user
 after they made five consecutive attempts, although no email or text message was sent.
 This is now solved, and an authentication code can no longer be requested after making
 five attempts. Users should contact study support if this situation occurs.
- Affected area(s): Viedoc User Authentication Bug description: When selecting Enter while logging in using two-factor authentication, the user did not receive the email with the code as expected. This is now solved, and the code is sent via email or text message as expected.
- Affected area(s): Viedoc User Authentication Bug description: Some of the emails sent from Viedoc were showing an incorrect version in the footer. This is now solved, and the current version of Viedoc is included in the footer of the emails.
- Affected area(s): Viedoc User Authentication Bug description: In some scenarios, when selecting the Viedoc wordmark link, users were logged out from the system, instead of being redirected to the Viedoc landing page. This is now solved.

List of bug fixes continues.

Affected area(s): Viedoc User Authentication

Bug description: When accessing the system through the WCF API, the system should approve any pending invitation for the user. If users had not previously logged in manually to the system, this did not occur. This is now solved so that a manual login is not required.

- Affected area(s): Viedoc User Authentication Bug description: The Viedoc system counted the number of requested authentication codes and the number of forgotten password requests using the same counter. This is now solved and individual counters for the two requests are introduced.
- Affected area(s): Viedoc Clinic Bug description: Users changing their primary email address could not approve their role invitation in the system although they had received the invitation email. This is now solved.
- Affected area(s): Viedoc Clinic Bug description: In Clinic, when downloading the training certificate, the certificate was limited to two pages. This is now solved, and the training certificate can consist of more than two pages.
- Affected area(s): Viedoc Clinic

Bug description: In Clinic, there was a typo in the message displayed for design structure changes pending review and signature when using Spanish as the system language. This is now solved.

Affected area(s): Viedoc Me

Bug description: In Viedoc Me, a required checkbox with visibility condition could be submitted empty. This was only possible if the checkbox was first shown and populated, then hidden and then again shown without being populated. This is now solved.

- Affected area(s): Viedoc Me Bug description: In Viedoc Me, there was a mix of formal and informal language when using Spanish as the system language. This is now solved.
- Affected area(s): Viedoc Clinic Bug description: Changes on subject, event form, and form, that required generation of form PDFs were overwriting the last saved PDF form version for a deleted form. This is now solved.
- Affected area(s): Viedoc Clinic

Bug description: In some scenarios, when the form was edited and saved multiple times in a short period of time, the latest versions of the form PDF were not available, and the previous form PDF version was overwritten by the most recent PDF version. This is now solved.

 Affected area(s): Viedoc Clinic Bug description: A user having the permission to "promote pre-query", but with no other query permissions (such as "add pre-query" or "add/change query"), was not able to promote a pre-query. 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 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 selected to be signed but can be signed if you select sign all (for subject or visit).

List of known limitations continues.

- 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.

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

- In the UI-optimized version of Viedoc Me, when a simple visibility condition has been set to make a form item show depending on the selection of a radio button, and a subject selects the radio button, an error message is displayed
- If additional languages are imported (to be used in ViedocMe) and after that code lists are combined via "Formats" (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
- For ViedocMe translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content, before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated ViedocMe form).
- The drawing pad item is not working on IE 11. For Safari it only works on Safari 12+ versions.
- · Viedoc Me does not support forms with form link items.

List of known limitations continues.

- 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.

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2024-09-30

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