viedoc™

Release Notes
Viedoc 4.84

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New and updated functionality

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

Viedoc Designer

- A study designer can now compare two different design versions within a study. The compared output is presented to the user in a new browser tab and shows additions, removals, and modifications from a source design to a target design. The changes are listed in the same order as in the design ODM file and include references to the relevant sections in the ODM file. For information about limitations when comparing with designs created prior to this release, and for additional information, please see the Viedoc Designer User Guide.

- Viedoc Designer is now supported in Polish and Portuguese.
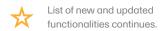
Viedoc TMF - New UI

- We are introducing a new user interface (UI) for Viedoc TMF that offers simplified and structured navigation, improved visual clarity, and enhanced user experience.

- When launching Viedoc TMF, the user is presented an option to launch the new interface or continue using the old interface. It is possible for users to switch between the old and new UI at any time.

- The new interface introduces a new left-hand menu for easier navigation across the TMF. Here users can easily move between the different areas and pages (Trial Master File, TMF Admin, TMF Archive), access new Viedoc Learning lessons, or switch back to the old UI.

- In the new interface, the term "Documents" is replaced by "Records" to align the industry terminology trends.

Viedoc Admin/Clinic

- The user administration log now contains a new tab, "User Invitation Log", with information about pending and rejected invitations. The new tab includes:
  - Email address of invited user
  - Details about the initial invitation
  - Number of times an invite has been resent
  - Invitation status (pending or rejected)
  - Invitation rejection date/time

- When a user accepts an invite, there will no longer be a record in the "User Invitation Log", but instead the details will be included in the "User Access Log".

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List of new and updated
functionalities continues.

Viedoc Clinic

- On the Viedoc Me activation screen, when sending test emails and text messages, there is now a delay of 15 seconds before the link to trigger new test emails and text messages appears. This is to prevent users from triggering multiple test emails and text messages in quick succession.

- When sending emails from the metrics page, there is now a delay of 15 seconds before the link to send a new email reappears. This has been introduced to prevent users from triggering multiple emails in quick succession.

Viedoc Admin

- When resending invitation emails to users, there is now a delay of 15 seconds before the resend invitation link is shown again. This is to prevent users from triggering multiple emails in quick succession. To harmonize the UI, the resend link has been moved to the rightmost side of the row.

- Viedoc Admin is now supported in Polish and Portuguese.

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Bug fixes

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

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

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

- Bug description: explains the issue and/or how it was solved. In case there are consequences for existing data, this is clearly mentioned in a "Note!".

The following corrections have been implemented in the Viedoc 4.84 release:

- *Affected area(s):* Viedoc Admin
  Bug description: When adding a new site, the format of the site manager email address was not validated to confirm it was a valid email address. This has been solved so it will no longer be possible to save a new site with an incorrect email format entered for the site manager.

- *Affected area(s):* Viedoc Admin
  Bug description: In study settings, in the Documentation tab, the columns in the table for configuration of the Documentation and Training section were sometimes misaligned and poorly displayed. This has been solved so the table is displayed as intended.

- *Affected area(s):* Viedoc Admin
  Bug description: When users launched Viedoc Admin, a banner at the top stated the user has access to multiple organizations, regardless of how many organizations the user had access to. The information in this banner was considered redundant and has been removed for all users.

- *Affected area(s):* Viedoc Admin
  Bug description: In study settings, on the Logs tab, some labels were not translated from English. This is now solved and the labels are displayed in the language selected by the user.

- *Affected area(s):* Viedoc Admin
  Bug description: When adding a new study, the format of the Study Manager email address was not validated to confirm that it was a valid email address. This is now solved, and it will no longer be possible to add a new study with an incorrect email address format entered for the Study Manager.

- *Affected area(s):* Viedoc Admin
  Bug description: In the study design settings, "effective designs per site" always stated "multiple designs in use", even if only one design version was used. This field was considered misleading and redundant and has been removed.

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List of bug fixes continues.

- *Affected area(s):* Viedoc Admin/Clinic
  Bug description: In the user administration log, the phone numbers of the users were not always displayed as expected, and the log had to be re-generated. This is now solved, so that, as long as a user has provided a phone number, it will be displayed in the user administration log.

- *Affected area(s):* Viedoc Clinic
  Bug description: When applying a revision to a site, if the revised version was not the latest effective design at the site, visit windows for initiated scheduled events (including Viedoc Me events) were calculated according to the latest applied revision. This has been solved so that the design version used for the event is used when calculating visit windows for scheduled events (including Viedoc Me events) in the study workflow.

- *Affected area(s):* Viedoc Clinic
  Bug description: When a repeating form was used in Viedoc Clinic, the lock icon was only displayed on the event if the max number of repeats had been added and all forms were locked. If a repeating form with unlimited repeats was used, the lock icon was never displayed on the event. This has been solved so that for forms with unlimited repeats, the lock icon is displayed for the event when all required forms in the event have been locked.

- *Affected area(s):* Viedoc Clinic
  Bug description: When randomizing a subject in Viedoc Clinic, the audit trail stated that the action of randomizing the subject is performed by "system" instead of the user. This is now fixed so that the audit trail will now instead specify the user who performed this action.

- *Affected area(s):* Viedoc Clinic
  Bug description: When a user role had the permissions add/update subject/event/form data and query answers enabled, but did not have the edit rights for the kit allocation form, they could still allocate kits, and undo or perform the allocation again by selecting the Modify button. This is now solved so that a role must have add/update subject/event/form data and query answers enabled and edit rights for the kit allocation form to allocate kits and modify allocations.

- *Affected area(s):* Viedoc Clinic
  Bug description: For studies using the new Viedoc Coder, exporting to either Excel or CSV including medical coding with WHODrug resulted in the same ATC code showing for all drugs with the same Medicinal Product ID. This occurred even when different ATC codes were assigned. This is now solved, and the coded ATC is shown in the export.

- *Affected area(s):* Viedoc Clinic
  Bug description: In Viedoc Clinic, if a value was saved in an item, and that item was later confirmed as missing by a user without first clearing the value, the audit trail entry incorrectly showed that the system had cleared the value by confirming the item as missing. This is now solved, and the audit trail shows that the user cleared the value by confirming the item as missing.

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List of bug fixes continues.

- *Affected area(s):* Viedoc PMS
  Bug description: When exporting data in PMS studies, the filters "signed data" and "not signed data" did not work as expected. When using the filter "signed data" no data was included, and when using the filter "not signed data" all data was included. This has been solved so that the export filters "signed data" and "not signed data" work as expected.

- *Affected area(s):* Viedoc Designer
  Bug description: In rare scenarios, if a form was modified in a design revision (e.g. 4.3), then the design was exported and imported into a new study, and the new study was updated to that same revision version number (e.g. 4.3), the form was flagged with a red pen icon. This icon implied that there were changes to the design in that version in the new study, although the form had not been modified. This has been solved by removing the v4 attribute "v4:RevisedVersion" when exporting the design, to ensure these attributes are not transferred from one study to another. Note that importing already exported designs might still cause this issue.

- *Affected area(s):* Viedoc Designer
  Bug description: In rare scenarios, if an item was added in a revision (e.g. 4.3), then the design was exported and imported in to a new study, and that specific item was removed in the same revision number as it was previously added in (e.g. 4.3), this led to errors when applying subsequent revisions in Viedoc Admin. This has been solved solved by removing the v4 attribute "v4:RevisedVersion" when exporting the design, to ensure these attributes are not transferred from one study to another. Note that importing already exported designs might still cause this issue.

- *Affected area(s):* Viedoc Designer
  Bug description: The v4 layout attribute "DisplayThumbnail" was incorrectly added in the ODM for more item types than file upload type. For other item types than file upload, the attribute was always set to "DisplayThumbnail="none"" and therefore never caused any issues in Viedoc Clinic, but it created irrelevant information in the exported ODM design files. This has now been solved, and the layout attribute "DisplayThumbnail" is now only added for the item type file upload. The redundant "DisplayThumbnail" attributes are left as is in current designs.

- *Affected area(s):* Viedoc Designer
  Bug description: When an item or an item group was deleted, the related ConditionDefs were not deleted in the ODM. This did not impact Viedoc Clinic, but led to irrelevant information in the design ODM. This is now solved, so now, when deleting items and item groups in a design, associated ConditionDefs will be removed.

- *Affected area(s):* Viedoc Designer
  Bug description: The v4 attributes "v4:AddedVersion" and "v4:RevisedVersion" were not specific to a study, making these attributes misleading when designs were exported from one study and imported to another (for example, from a study on the training instance to a study on a production instance), for a user who would review the exported design. For this reason, these attributes will, after the release, be removed when exporting a design.

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List of bug fixes continues.

- *Affected area(s):* Viedoc Designer
  Bug description: When the ODM design file was created through the study workflow, and when the value was expected to be v4:HideShow=show, the v4 attribute HideShow was not added to the ConditionDefs. This attribute was therefore not consistently defined for all of the ConditionDefs in the exported ODM design. This did not have any impact, as the absence of this attribute was treated as show by default. This is now solved, by always adding the v4 attribute HideShow to ConditionDefs when saving the study workflow.

- *Affected area(s):* Viedoc Coder
  Bug description: The new Viedoc Coder sometimes became out of sync with Viedoc Clinic and this bug was solved in 4.83, reported in the release notes for 4.83. The items that were out of sync before 4.83 require a resync which will be done after the release of Viedoc 4.84. After the resync, the items will appear correctly in Viedoc Coder.

- *Affected area(s):* Viedoc eTMF
  Bug description: Adding form fields to a PDF document was not working when a new document version was created by uploading a new file. This is now solved.

- *Affected area(s):* eTMF Archive
  Bug description: In some rare scenarios, generating the eTMF archive (eTMF - EMS repository) was failing and resulting in an error message being displayed. This is now solved.

- *Affected area(s):* Viedoc Reports
  Bug description: A user with access only to the "Reports" tab in Reports (so no access to "Dashboard", "Demographics", "Adverse Events", or "Data Browser"), was not able to load Reports directly. The message "Disconnected from the server. Reload" appeared in the bottom left of the screen. This is now solved.

- *Affected area(s):* Viedoc Reports
  Bug description: For a locked study, the data sync in Viedoc Reports was not being performed one last time to get the latest data changes made before the study was locked. This is now solved, so that once a study is locked, the latest data is synced in Viedoc Reports.

- *Affected area(s):* Viedoc Reports
  Bug description: When data was edited in Viedoc Clinic by performing ONLY one or more of the following actions: reset forms, delete events, delete subjects, the scheduled (daily) data sync was not performed in Viedoc Reports, and therefore the deleted data was still present in Viedoc Reports. This is now solved.

- *Affected areas:* Viedoc Clinic
  Bug description: When the system language was set to Polish or Portuguese, some system texts were still displayed in English. This has been solved so the system languages are displayed as expected.

Known limitations

! Constraints that define Viedoc's current capabilities, distinguishing its intended scope from defects or bugs.

Please visit Known Limitations page which describes system-wide and application-wide constraints that may affect your study setup and operations.

You can access the Known Limitations page at the following URL:

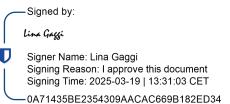https://help.viedoc.net/c/331b7a/5e2a11/en/

Signoff

Signature Confirmation by
the product owner.

Signed by:

Lina Gaggi

Signer Name: Lina Gaggi
Signing Reason: I approve this document
Signing Time: 2025-03-19 | 13:31:03 CET

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Certificate Of Completion

Envelope Id: 3E60D96E-222D-43AB-BC55-684427DFF942		Status: Completed
Subject: Please Docusign This Document		
Source Envelope:		
Document Pages: 9	Signatures: 1	Envelope Originator:
Certificate Pages: 1	Initials: 0	Lina Gaggi
AutoNav: Enabled		Stationsgatan 23
EnvelopeId Stamping: Disabled		Uppsala, 753 40
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna		lina.gaggi@viedoc.com
		IP Address: 192.103.123.72

Record Tracking

Status: Original	Holder: Lina Gaggi	Location: DocuSign
3/19/2025 1:29:30 PM	lina.gaggi@viedoc.com	

Signer Events	Signature	Timestamp
Lina Gaggi lina.gaggi@viedoc.com Product Owner Viedoc Technologies AB Security Level: Email, Account Authentication (Required)	*Lina Gaggi* Signature Adoption: Pre-selected Style Signature ID: 0A71435B-E235-4309-AACA-C669B182ED34 Using IP Address: 94.254.34.44 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 3/19/2025 1:29:56 PM Viewed: 3/19/2025 1:30:46 PM Signed: 3/19/2025 1:31:06 PM

Electronic Record and Signature Disclosure:
   Not Offered via Docusign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/19/2025 1:29:56 PM
Certified Delivered	Security Checked	3/19/2025 1:30:46 PM
Signing Complete	Security Checked	3/19/2025 1:31:06 PM
Completed	Security Checked	3/19/2025 1:31:06 PM

Payment Events	Status	Timestamps