

# Release Notes

## Viedoc 4.92

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## New and updated functionality



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

### Repeating item group support across the Viedoc Suite

Viedoc now supports repeating item groups across study design, data entry, data import, data export, and integrations. This enables studies to capture, manage, and exchange repetitive data structures, such as lab analytes, within a form, while remaining fully compliant with CDISC ODM standards. With this latest addition, Viedoc supports capturing repetitive data structures in a wide variety of ways; repeating item groups, repeating forms, recurring events as well as common events and unscheduled events.

- Viedoc Designer:
  - Item groups can now be configured to repeat within a form, with a defined minimum and maximum number of repeats. Up to 50 occurrences per item group are supported.
  - Repeating item groups, and items within those groups, fully support visibility conditions, functions and validation checks. A designer can also use an **ItemGroupRepeatKey** in expressions to target specific repeats, for example to populate different analyte names for specific repeats in a lab form.
  - In the design ODM, the following attributes are added to the **ItemGroupDef**: `Repeating="Yes/No", v4:MinRepeatCount=""`, and `v4:MaxRepeatCount=""`
  - Repeating item groups can be used to significantly simplify the configuration of reference data scopes in the global design settings as well as the data mapping for import with the import application, by using the **ItemGroupRepeatKey**.
- Viedoc Clinic:
  - If the maximum value of the repeat is higher than the minimum value, a dynamic data structure is created. The minimum number of repeats is displayed by default in Viedoc Clinic, and additional repeats can be added up to the defined maximum limit.
  - The data entry user can add item group repeats until the defined maximum number is reached, and remove the last repeat until the defined minimum number is reached. All actions are fully audit trailed.
  - If the minimum and maximum number of repeats is set to the same value, a fixed data structure is created in Viedoc Clinic, preventing the data entry user from adding or removing repeats.
  - For clarity, an order number is displayed in the UI for each item group repeat.
- Viedoc Clinic (Data Export):
  - A new data export version is introduced in Viedoc 4.92. This export version includes:

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- For CSV and Excel exports: columns for **ItemGroupId** and **ItemGroupSeq** in the following datasets: SDV, Queries and Medical Coding.  
**Note:** This update introduces a potential breaking change for certain custom reports. Please see the **Breaking Changes** section for details and recommended actions.
- For CSV and Excel exports: the “One row per item” format will now show the Item Group Output ID (referred to as “Dataset name” in Viedoc Designer), if used in the design rather than the Item Group OID. If no dataset name is set, the Item Group OID will be used also going forward.
- All export formats now support repeating item groups. This is fully compliant with the CDISC ODM standard.
- When exporting repeating item groups in ODM format, **ItemGroupRepeatKey** identifies individual repeats. This attribute is only present for item groups that are repeating.
- A new export format option is introduced for CSV and Excel exports: “Repeating item groups as a separate form”.
  - When enabled, data from repeating item groups is exported as a separate form (a new tab in Excel and a separate file in CSV).
  - This option is enabled by default for all studies. Studies that do not use repeating item groups are not affected, even when this option is enabled.
  - Repeats are differentiated using the **ItemGroupRepeatKey**.
  - The resulting tab or file uses **ITEMGROUPOID** as the ID.
  - If the option is disabled, items from repeating item groups are exported within the original form and each repeat is listed as a unique item. The export will include the maximum number of configured repeats.
  - The SAS script has been updated to support the new repeating item group structure.
- Viedoc Admin:
  - Integrations fully support data collected in repeating item groups.
  - Exporting repeating item group data through the WEB API and in ODM format through the WCF API mirrors the behavior of Viedoc Clinic data exports described above.
  - Using the **ItemGroupRepeatKey**, data can be imported into repeating item groups via the WCF API, with or without using the Viedoc Import Application.
  - A new import application has been introduced that supports mapping files that uses repeating item groups as destination. This version is required when importing data into repeating item groups. For imports that do not involve repeating item groups, the previous import application will continue to work.

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### Viedoc Clinic

- The mobile number input field in user settings and on the account registration page has been updated:
  - The **phone number** label has been replaced with **mobile number**.
  - The **can receive text message** checkbox has been removed, reflecting that Viedoc uses mobile numbers exclusively for sending verification codes for second-factor authentication. An informational text has been added to clarify that the mobile number is not used for marketing purposes.
  - A country code is now required and can be entered either via a dropdown or directly in the mobile number field.
  - Validation of mobile numbers has been improved to reduce the risk of incorrect formats being saved.
- Note: Data for **can receive messages** entered prior to this release is still shown in the User & Administration Log and in the body of automatic emails sent when a user changes their mobile number. These references will be removed in the 4.93 release.
- A new second-factor reminder screen has been added between the login screen and the landing page. The reminder is shown once every 30 days at login for users who do not have a verified second factor, such as a mobile number or a secondary email address:
  - The screen allows users to add and verify a mobile number or skip the step and continue to the landing page.
  - This helps raise awareness of missing second-factor verification and supports continued access by enabling self-service password resets, which require a second factor.
  - The reminder screen is not shown to users who log in using SSO.
- The user registration flow has been updated to prompt users to verify their mobile number during registration. This ensures that a verified mobile number is available for use as a second factor when restoring a password.
  - Previously, mobile number verification could be completed later in user settings, which increased the risk of the step being postponed or missed. Verification is now part of the registration flow, although users can still choose to skip this step.

### Viedoc Admin

- When configuring Single Sign-On (SSO), organization administrators can now enable automatic retrieval of identity certificates by providing a federation metadata URL. When this option is enabled, Viedoc automatically retrieves updated certificates if the identity provider's certificate changes, removing the need for manual certificate updates.
  - Providing a federation metadata URL is optional but recommended, as it reduces the risk of users being locked out due to outdated or missing certificates.

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List of new and updated functionalities continues.

### Viedoc Designer

- The OID of item groups can now be modified by the study designer. Modifying the OID of an item group follows the same pattern as the item OIDs:
  - The OID of item groups can now be changed in a new fully customizable design version.
  - The OID of item groups can now be changed in a revision.
  - The OID of item groups added in a previous design cannot be changed in a revision. To clarify, the OID of item groups will not be displayed in the annotated CRF (aCRF), or in the form view mode.

### Viedoc Coder

- Support for **Reason for change** has been added to Viedoc Coder to improve traceability of medical coding decisions. A reason is now required when users perform actions that modify an existing coding or review decision, such as rejecting, resetting, deleting, or recoding an approved item.
  - For actions where no manual input is required, the system automatically generates a corresponding reason, including when an item is coded from Uncoded to Coded via autocoding. When performing bulk actions, a single entered reason is applied to all affected items, and for rejected items the most recent reason for change is displayed in Coder.
  - Validation ensures the reason cannot be empty or whitespace-only, is limited to 255 characters, and is handled securely. This update improves the upcoming audit trail for coding changes. Existing coding data remains unchanged, and reasons for change are not applied to data originating from the old Coder.

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## Breaking changes



Changes in this release that may require action from customers.

This section describes changes that may require action from customers. Please review the details below to determine whether your configuration or workflows are affected.

Applies to: Viedoc Reports (Custom Reports)

Action required: Yes, only for affected custom reports configurations

Summary: With Viedoc 4.92, updates to export datasets may affect some custom reports. Affected custom reports will require updates to their R scripts.

### What has changed

Two new columns have been added to the **Query** and **Medical Coding** datasets:

- ItemGroupId
- ItemGroupSeq

These columns support improved handling of repeating item groups by enabling targeting of specific repeats of a repeating item group in these datasets. In both datasets, these 2 columns are added to the right of the SourceSubjectFormSeq column. As a result, **all subsequent columns in these datasets have shifted position**.

### Who is affected

You are affected if **all of the following apply**:

- You use the Query and/or Medical Coding datasets in a **custom reports** configuration, and
- You reference data **by column number** rather than by column ID\*, and
- The referenced data appears **after** the newly added columns, **OR** you use functions that assume a **fixed column count** (for example, setLabels).

\*Standard reports, and custom reports that reference columns by **column ID** are not affected.

### Required actions

If you are affected, please update your custom report R scripts and reupload them in Viedoc Reports:

- We strongly recommend updating scripts to reference columns by column ID. This can be done and validated before the 4.92 release to avoid any disruptions.
- Alternatively, you may adjust column numbers and column counts to reflect the new positions.

The following section provides advance notice of a related change planned for a future release.

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List of breaking changes continues.

### Advance notice: upcoming change to repeating item group structure

In a future release, the data structure in Viedoc Reports will change to support a “separate form” structure for repeating item groups. This may require users to update R scripts for affected custom reports.

- Current behaviour:
  - Data from repeating item groups is included in Viedoc Reports.
  - Items are listed as unique in the data browser and custom report configuration.
  - This reflects the export structure where “Repeating item groups as a separate form” is disabled.
- Planned behaviour:
  - Repeating item groups will follow the “separate form” export structure.
  - Custom reports that include repeating item groups, that were created between the 4.92 release and when this change is implemented, will require updates to their R scripts to reference the new structure.

No action is required at this time. Further details will be communicated ahead of release.

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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 4.92 release:

- **Affected area(s):** Viedoc Coder / Viedoc Clinic

*Bug description:* When the break level in Coder was set to Form or Event for repeated forms or events, editing a single repeated instance could cause multiple items at the same level to be incorrectly flagged as edited. Although no data values were affected, the edited status could be misleading. This has now been solved so that only the specific form or event instance that is edited is flagged.

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## 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/>

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## Signoff



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the product manager.

Signed by:

Royden James



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