Medrio R42.15 Minor Release Notes

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Introduction

Release Notes Overview
Medrio's R42.15 release is nearly here! The release notes below are intended to provide you with specific details on each of the updates, including an in-depth feature description, why the update was implemented, how to use the update, and the impact on existing and future studies.

Release Preparation
To successfully use the updates in R42.15, we recommend checking out our Release Webinar once live.

For all information related to R42.15, visit the Medrio Community at: Release Notes.

If you have any questions or require assistance accessing the Medrio Community, please submit a support ticket by clicking **Help** > **Contact Us** > **Submit a Ticket** in Medrio.

What's New
Our R42.15 minor release features exciting enhancements for several of our products, including Medrio EDC, Medrio ePRO, and Medrio eConsent. This release brings enhancements for the Data Dictionary and Annotated Forms exports, and the ability to restrict past dates. Additional updates for ePRO include a new Back button for forms with required fields in the participant portal and localization support for footer text. For eConsent, form rules can now apply to the Informed Consent eCRF.

Continue reading below for specific details regarding R42.15 changes.

Note: *Fixed and Resolved Issues will be posted on 2026-09-14 to Medrio Community.*

Medrio EDC

Data Dictionary Enhancements v1

Description: The information tracked within the Data Dictionary now includes information regarding skip logic, grids, and bulk upload mappings.

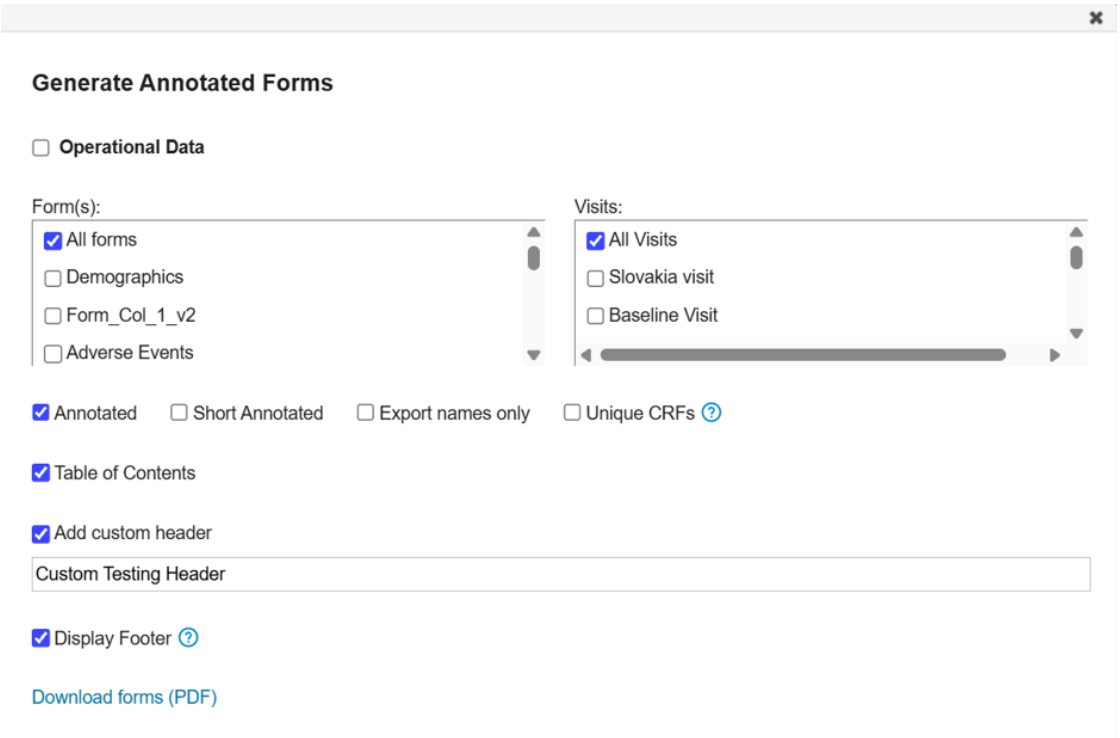
Context: The expanded Data Dictionary provides even more information to study builders regarding the configuration details of their studies.

Activation: No action needed - this feature is automatically enabled.

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low - there is little to no risk involved in this epic as we are merely surfacing more configuration settings within the Data Dictionary.

Annotated Forms Enhancements v2

Description: The Annotated Forms exports now include a cover page, two sets of tables of contents, and bookmarks for easier navigation.



Context: These enhancements ensure that exported study documentation is even more informative and more navigable, providing an even smoother version control experience.

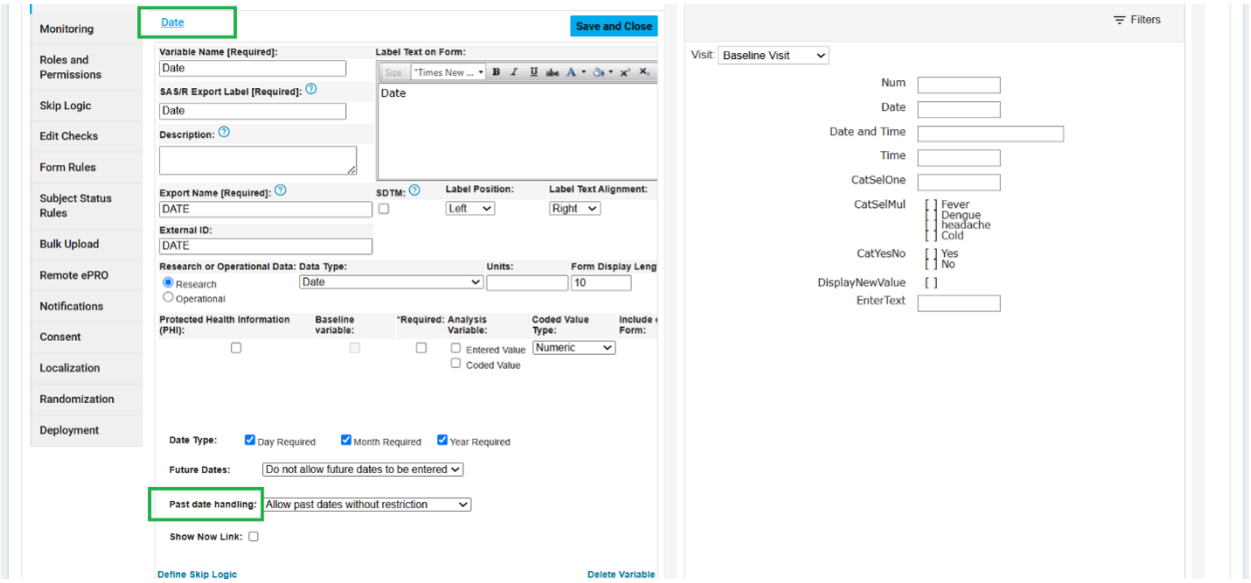
Activation: No action needed - this feature is automatically enabled.

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low – there is very low to minimal risk with this feature as we are simply enhancing existing functionalities, making sure the customers are provided more information and details in their

		annotated forms, such as a cover page, or table of contents.

Restricting Past Dates

Description: Users can now restrict the entry of past dates on Date and Date/Time variables.



Context: We are giving users more control over which dates are going to be valid for data entry by allowing users to restrict past dates from data entry into Date and Date/Time variables.

Activation: No action needed - this feature is automatically enabled.

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low - this feature does not involve a lot of risk, as we are just adding another option on how to control what the user can and cannot input into the Date and Date/Time variables, by adding the functionality to restrict if past dates are allowed to be entered.

Medrio MCP Server

Description: Medrio is publishing an MCP (Model Context Protocol) connector that allows users to authenticate their Medrio EDC account and expose study data to a compatible AI assistant. This capability is currently available to early adopters. If you're interested in becoming an MCP server early adopter, please reach out to your account manager. Once configured, users can query live EDC data through natural language within their AI tool without manually navigating the Medrio interface or pulling reports.

Note: This is not automatically enabled on your account, and no AI tool will have access to your data unless you choose to set up the connector yourself.

The connector exposes 35 endpoints at launch, supporting:

- **Study and site overview:** Subject counts, status distributions, site lists, and enrollment progress against targets
- **Subject-level queries:** Individual subject summaries, demographics, and form-level clinical data
- **Data completeness:** Missing forms by visit and site, completion rates by study, site, group, or portfolio
- **Anomaly detection for five checks:** Digit preference, data entry velocity, bulk entry, site outlier flagging, and off-hours entry detection
- **Audit trail analysis:** Field-level change history filterable by date, user, site, and form; data entry session reconstruction
- **Data discrepancy tracking:** Open query lists and full per-query comment history
- **Anomaly report generation and retrieval**: Compiled detection findings available within the AI session

There are no changes to the Medrio EDC interface in this release. The connector operates entirely within your chosen AI tool environment.

Context: Data managers, CRAs, and monitoring professionals spend significant time on manual data review, audit trail analysis, and anomaly detection — particularly when preparing for monitoring visits and regulatory inspections. Regulatory agencies, including the FDA and MHRA, have begun requiring sponsors to demonstrate systematic audit trail review, without prescribing how it must be done, creating both operational burden and compliance uncertainty.

The Medrio MCP connector enables AI assistants to access live EDC data on behalf of the user, reducing the time and manual effort required for routine study review tasks, and enabling teams to work within AI tools they are already adopting. Scope was informed by user research with data managers and CRO partners, with risk-based monitoring and pre-monitoring visit preparation as the primary launch use cases.

Activation: The Medrio MCP connector is available as a Pilot feature in this release, and the MCP connector is not enabled by default. Activation requires:

- **MCP toggle enabled by Medrio Admin**: The MCP connector must be activated at the organizational level via Medrio Support before any user can connect. This is the prerequisite step. Without it, the connector will not function regardless of how the user configures their AI tool.
- **Compatible AI tool**: The user must have access to an AI platform that supports MCP connectors (e.g., Claude Enterprise). We strongly recommend using an enterprise-tier subscription with documented data privacy protections for any use involving clinical trial data. Consumer-tier AI subscriptions must not be used.
- **Connector configuration**: The user adds the Medrio MCP server URL to their AI tool's MCP connector settings. Configuration steps vary by AI platform; users should follow their platform's MCP setup process.
- **Authentication**: The connector authenticates using the user's existing Medrio EDC credentials. Study and data access mirror the permissions already assigned to that user within EDC.

We recommend restricting initial use to users with full, unblinded read access to study data. Customers should review their internal AI use policies and consult their QA team before connecting study data to any external AI tool.

Note: Some key considerations to note include:

- Read-only. No data is modified through connector-mediated queries.
- Data access through the connector is governed by the user's existing Study and Site permissions within Medrio EDC. The connector does not grant access to any study or site the user cannot already access through the EDC interface. Users without permission to a given study or site will not be able to retrieve data from it through AI-assisted queries.
- Role-based blinding is not enforced at the connector layer in v1. This is the most significant known limitation for clinical use. Customers with blinded studies should not use this feature until addressed in a future release.

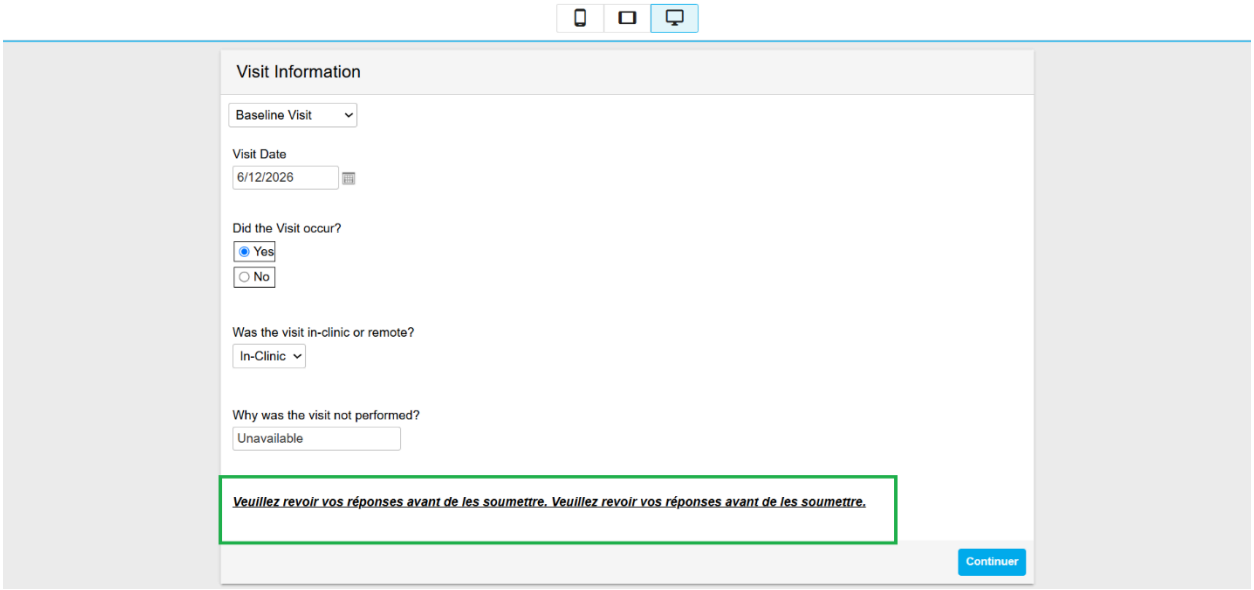
- AI-generated outputs are not validated data products and are not a substitute for formal data management or SDV processes.
- Connector interactions are not recorded in the Medrio EDC audit trail. Users who need a record of AI-assisted review activity should retain output from their AI tool session.
- Customers subject to GxP validation requirements may need to perform internal qualification of both the connector and their chosen AI platform before using this on regulated study data.

Impact		
Product	**Availability**	**Risk**
EDC	This is only available for existing studies and studies provisioned after the release that enroll in the MCP Server Early Adopter program.	Low - we are introducing a new data access layer that exposes live clinical trial data — including subject records, clinical data fields, and audit trail history — to external AI tools. Role-based blinding is not enforced at the connector layer in this release, and connector interactions are not recorded in the Medrio EDC audit trail. We recommend restricting use to users with full, unblinded read access and advise customers operating under GxP requirements to consult their QA and compliance teams before connecting study data to any AI platform.

Medrio ePRO

Localization Support for Footer

Description: Footer text on forms can now be localized into any of the study's supported languages.



Context: This allows users to completely localize forms into any required language, including the footer text.

Activation: No action needed - this feature is automatically enabled for all ePRO studies that use localization mapping.

Impact		
Product	**Availability**	**Risk**
ePRO	Available for existing studies and studies provisioned after release	Low - there is little to no risk associated with this feature as it merely displays text in footers of eCRFs in various languages that the users can configure.

Participant Portal: Ability to Use the Same Email for Multiple Participants

Description: Animal health studies can now link multiple subjects to the same participant portal.

Context: By linking multiple subjects to the same participant portal, a single user can fill out ePRO forms for multiple study subjects, thus eliminating the need to create a separate login for each subject.

Activation: This feature is for animal health studies only. Contact the Support team to request activation.

Impact		
Product	**Availability**	**Risk**
ePRO	Available for existing studies and studies provisioned after release	Low - risk is relatively small as we are adding the ability to link multiple subjects into the same participant portal, so caution needs to be exercised when adding/updating email addresses to subjects, and for this reason, multiple types of warnings have been implemented.

ePRO VAS v2 Configuration Enhancements

Description: The VAS variable now has additional configuration options.

Note: As part of this enhancement, the NRS variable also has additional formatting options for text: autowrap text and line breaks for the Location labels.

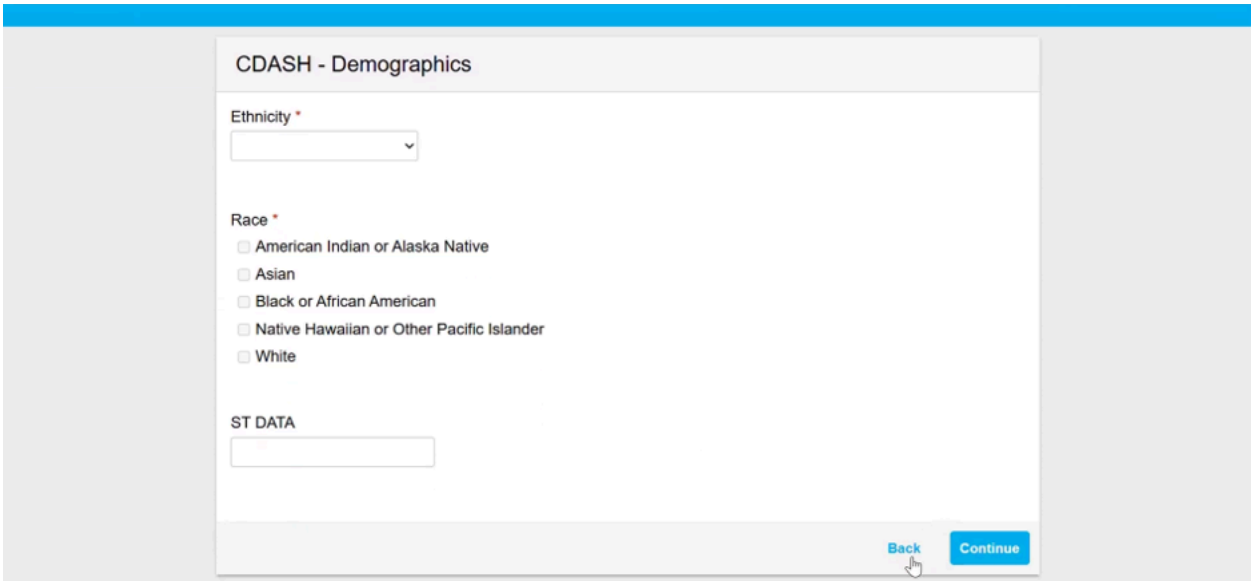
Context: Users have expanded options for configuring their VAS variables, such as increment sizes, label positions, or label text formatting.

Activation: No action needed - this feature is automatically enabled for all studies.

Impact		
Product	**Availability**	**Risk**
ePRO	Available for existing studies and studies provisioned after release	Low - should be relatively small here as we are merely expanding the capabilities the users have at their disposal when configuring their VAS (or NRS) variables.

ePRO - Back Button with Required Variables Fix

Description: The workflow for ePRO subjects has been adjusted to allow them to navigate back, even if there are required questions on the active page.



Context: This allows ePRO users to navigate back whenever they need to change their previous answers without having to input answers into variables that are marked as required.

Activation: No action needed - this feature is automatically enabled for all ePRO studies.

Impact		
Product	**Availability**	**Risk**
ePRO	Available for existing studies and studies provisioned after release	Low - this is small as we are merely addressing an issue where the users weren't previously able to navigate back to the previous screen of questions if the current screen contained a question marked as "required". This should improve user experience, as they will no

		longer have to input fake answers into the required questions just to be able to navigate back.

Medrio eConsent

Form Rules Apply to the Informed Consent eCRF

Description: The Informed Consent eCRF can now be enabled/disabled via configured form rules.

Context: This gives users more control over the special Informed Consent eCRF, which can be disabled if a configured form rule's conditions are not met.

Activation: No action needed - this feature is automatically enabled for all eConsent studies.

Impact		
Product	**Availability**	**Risk**
eConsent	Available for existing studies and studies provisioned after release	Low - risk is small, as we are expanding the system's capabilities when it comes to form rules. Post R42.15, the system can apply form rules, even to the special "Informed Consent" eCRF, which was not possible until now.

eConsent - Remove Attachments Field in eConsent

Description: The "Add Attachments" button in the eConsent module is removed for all future studies.

Context: As a separate, dedicated workflow for paper uploads already exists in the system, the "Add Attachments" button is removed from eConsent as it is a redundant feature.

Activation: This applies only to eConsent studies provisioned after the R42.15 release.

Impact		
Product	**Availability**	**Risk**
eConsent	Available only for studies provisioned after the release	Low - we are merely removing the ability to add attachments in the eConsent module; we are removing it for future studies only.

eConsent - Consented Date Revision/Update

Description: We have enhanced the logic of the system. The latest date of signature across all applicable forms (paper or electronic) can now be used as the date for the subject's Consented Date value.

Context: This enhanced logic provides users with an even more precise consented date value calculation.

Activation: This applies only to eConsent studies provisioned after the R42.15 release.

Impact		
Product	**Availability**	**Risk**
eConsent	Available only for studies provisioned after the release	Low - the enhanced logic of the system only applies to studies created after R42.15.