Medrio R42.16 Minor Release Notes

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Introduction

Release Notes Overview
Medrio's R42.16 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
For all information related to R42.16, visit the Medrio Community at: Release Notes.

Note: There is no webinar for this release.

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 R42.16 minor release features enhancements for Medrio EDC, Medrio ePRO, and Medrio API Connect. This release moves the Standard reports to the new reporting platform and introduces report scheduling, as well as masking patient-identifiable values in reports and exports for users without the protected health information (PHI) permission. EDC also adds HLT and SOC levels in VeDDRA coding exports, Medrio MCP Server V2, and study-level control of Medrio Offline Data Capture (ODC). For ePRO, notifications can now be controlled with form rules so they stop for subjects who change to a new phase or discontinue from the study, and dates and decimal numbers are displayed in the format of the subject's language. API Connect adds Data Dictionary download via API and a $filter parameter for the ClinicalDataReports endpoint.

Continue reading below for specific details regarding R42.16 changes.

Note: *Fixed and Resolved Issues will be posted on 2026-11-16 to Medrio Community.*

Medrio EDC

eLearning Status Report Availability

Description: The eLearning report is now available again via the new reporting platform.

Context: Training completion supports user provisioning in a compliant manner.

Activation: To use the report, users must have the e-Learning Status Report permission assigned to their role.

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low - additional pathways are available to derive the information contained in the report.

PHI Handling in Reports

Description: Reports and exports now mask patient-identifiable variable values for users who do not have the PHI permission. These users see a masked indicator in place of the value, while users with the PHI permission continue to see the full values.

Note: Removing or changing a user's Standard report permissions requires waiting for the next scheduled data refresh. However, changes to PHI permissions are applied when the user first navigates to the report after the permissions change has been saved.

Context: Reports and exports previously displayed patient-identifiable values to every user who could open them, whether or not they were permitted to view PHI. Studies need to limit who can see this information.

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

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Medium - rating reflects PHI handling importance.

Update Manage Tab to Link to New Standard Reports

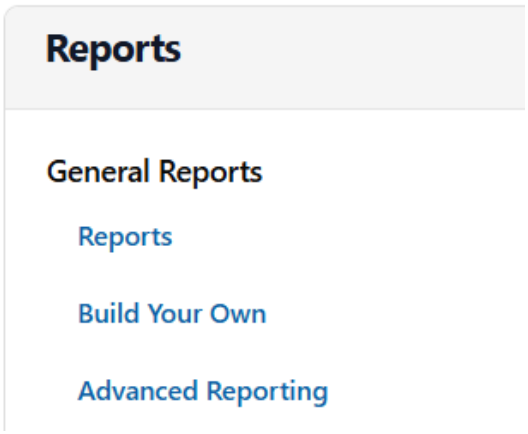
Description: The new Standard reports are available via a **Manage** > **Reports** link that directs users to the updated reports with faster data refresh rates. The categorization of the reports has been updated to be more intuitive.

The following reports are now accessible via the Reports link:

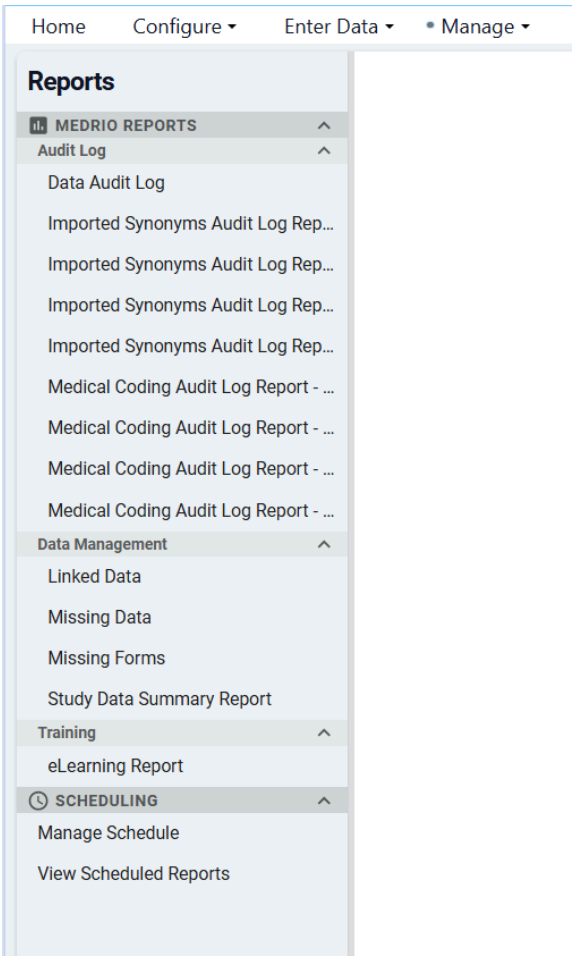
- Medical Coding Audit Log
- eLearning Status Report
- Study Data Summary Report
- Data Audit Log
- Linked Data
- Missing Data
- Missing Forms

The current Build Your Own (BYO) reports are under a new **Manage** > **Build Your Own** link.

New Links: Reports and Build Your Own



Standard Reports Under Reports Link



Context: Medrio is working to improve our reporting platform and this release represents a delivery of reports tied to that initiative.

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

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low - in the event the links are not working, reports may be generated by engaging Medrio directly.

Report Scheduling

Description: The new reporting platform supports scheduling with the existing Daily, Weekly, and Monthly options and the option to attach the report to an email.

Unlike the behavior in 42.15, the reports now respect the PHI permission. For example, if the user scheduling the report does not have the PHI permission, reports generated based on the schedule established by that user are generated with PHI-flagged data in a masked format.

Users with the PHI permission who schedule reports continue to be able to send unmasked PHI data. If the user scheduling the reports has the PHI permission and needs to send masked data as a report attached to an email, we recommend that the user create a new user account that does not have the PHI permission in order to ensure only masked data is sent.

Note that you must ensure PHI data is masked by leveraging permissions for the user scheduling the report. Medrio's existing behavior of allowing reports to be delivered either as an email attachment or as a link to download are retained. Customers are responsible for ensuring that the tool is used in adherence with the recipient's data access permissions.

Note: Existing schedules are not migrated and need to be reconfigured by customers.

Rebuilding schedules on the new platform ensures each one runs with the faster refresh rate and improved PHI handling. After the release, users need to reconfigure schedules for the following reports:

- Study Data Summary
- Data Audit Log
- Linked Data
- Missing Data
- Missing Forms

Schedules are tied directly to the user's account that created them, rather than to the report itself.

- Only the creator can modify or view their specific schedule.
- If a user's permissions are removed or the user is deprecated, their schedules cannot be modified by another user in the UI.

Context: Scheduling is currently supported in Medrio, and this feature also offers parity with the added value of allowing users to send PHI-flagged data in a masked format.

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

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low - reports may be run manually.

Include HLT and SOC Levels in VeDDRA Coding Output

Description: The HLT and SOC levels (term and ID) are now included in the data exports of VeDDRA-coded variables.

Context: This aligns VeDDRA exports with other coding dictionaries, such as MedDRA. Study teams get the full VeDDRA hierarchy to analyze adverse events and clinical signs at every level, without looking up the higher-level terms separately.

Activation: This feature is available on all existing studies that are utilizing the VeDDRA coding dictionary.

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release	Low - we are merely surfacing additional information for exports of VeDDRA-coded variables that already exist as part of the dictionary.

Medrio MCP Server V2

Description: Medrio MCP V2 changes how access to Medrio MCP is granted and expands what users can ask through their connected AI tool. The Site Time Zone and Working Hours fields now only appear in Site Management when the MCP AI API Anomaly feature is on.

There are two new permissions for Medrio MCP:

- **MCP Access:** controls who can use Medrio MCP, separately from Medrio API Connect.
- **MCP Full Study Data:** controls who can use the study-wide data review and anomaly tools.

Users can now ask about:

- Study configuration change history
- E-signature events
- Variables in the study, by name
- Forms by name and the fields on each form. When a user asks to compare forms, such as Concomitant Medication indications against Medical History, the AI tool finds the forms and states which ones it selected before loading data.
- The form and visit schedule
- A Study Build Assessment report. It summarizes custom edit check usage, the fields with the most queries and data changes, CDASH naming alignment, and codelist consistency. The report has a fixed format and does not use AI. CDASH alignment measures field naming only and is not a statement of CDISC compliance. Users can also request the report as a PDF. Whether the PDF can be opened depends on the user's AI tool.

Changes for Existing Medrio MCP Users

Medrio MCP now applies the user's role permissions in more places. Users may see fewer results than before for the following questions:

- **Form data:** values from forms the role cannot view are no longer returned, and PHI values are masked.
- **Audit trail:** changes on forms and variables the role cannot view are no longer returned or counted. Asking for the audit trail of a hidden form returns an access denied message.

- **Study structure:** forms the role cannot view no longer appear, and variable counts exclude hidden variables.
- **Subject search:** subjects can no longer be found by values on forms or variables the role cannot view.
- **Subject demographics:** only subjects at the user's sites are returned. Hidden variable values are no longer returned, and PHI values are masked.
- **Clinical data:** PHI values are masked for all users.
- **Enrollment status and site details:** only the sites the user is assigned to are returned, including their time zones and subject counts.
- **Off-hours entry, bulk entry, and entry velocity checks:** only the sites the user is assigned to are returned.
- **Duplicate subjects check:** only subjects at the user's sites are returned. Hidden variable values are not returned, and initials and date of birth are masked as PHI.
- **Data queries:** when the study has Respect Form Permissions Access on Query Filter turned on, queries on forms excluded by the user's query permissions are no longer returned.
- **Missing forms:** asking about a form at a visit where that form is not scheduled now returns an error instead of an empty result.

Subject search accepts more than one site, group, or status in a single request.

Audit trail timestamps returned by Medrio MCP now use the user's configured time zone, matching EDC audit exports.

A new Anomaly Dashboard page under **Manage** > **Data Management** ranks a study's sites by six data-quality checks: digit preference, off-hours entry, bulk entry, entry velocity, site outlier, and duplicate subjects. Users can also refresh the report once per hour and download it as a PDF. Results are screening signals to guide review, not findings. The dashboard does not use AI and does not require a connected AI tool. In this release, it requires the MCP AI API and MCP AI API Anomaly study features, which Medrio Support enables, and the Anomaly Dashboard permission on the user's role. Grant this permission only to roles cleared for study-wide data, and use the dashboard only on open-label or unblinded studies. A role with both MCP Access and Anomaly Dashboard can also use the Medrio MCP study-wide tools without MCP Full Study Data.

Context: Before this release, a user needed Medrio API Connect access to use Medrio MCP, so enabling Medrio MCP also opened the API. Some audit, configuration, and schedule questions could not be answered without exporting

data or downloading the study configuration. V2 separates Medrio MCP access from API access and adds tools for these questions.

Activation: Medrio MCP is available only to customers in the Medrio MCP Early Adopter program. Medrio Support enables the MCP AI API feature for the study. The anomaly tools also need the MCP AI API Anomaly feature. A study administrator then grants the MCP Access permission in the role editor.

Access API is no longer required, and Access API on its own no longer grants Medrio MCP access. MCP Access does not grant access to Medrio API Connect.

The study-wide tools also need the MCP Full Study Data permission. This permission is offered only when the role has MCP Access. The study-wide tools are subject summary, completion rates, missing forms, data entry sessions, screening failures, digit preference, site outlier, anomaly reports, and anomaly settings.

Without MCP Full Study Data, these tools return a permission message. With it, they return results for every site in the study, including forms and variables the role's own permissions hide. PHI values stay masked in these tools for all users. The role editor shows a warning when this permission is granted.

All other Medrio MCP tools return only the sites, forms, and PHI the role allows. This includes the off-hours entry, bulk entry, entry velocity, and duplicate subjects checks.

After the release, the new permissions are off for all existing roles. Current Medrio MCP users lose access until a study administrator grants MCP Access to their role.

Note: Use Medrio MCP only on open-label or unblinded studies. Medrio MCP does not check the Unblind permission. MCP Full Study Data returns data from forms, variables, and sites the role cannot otherwise view.

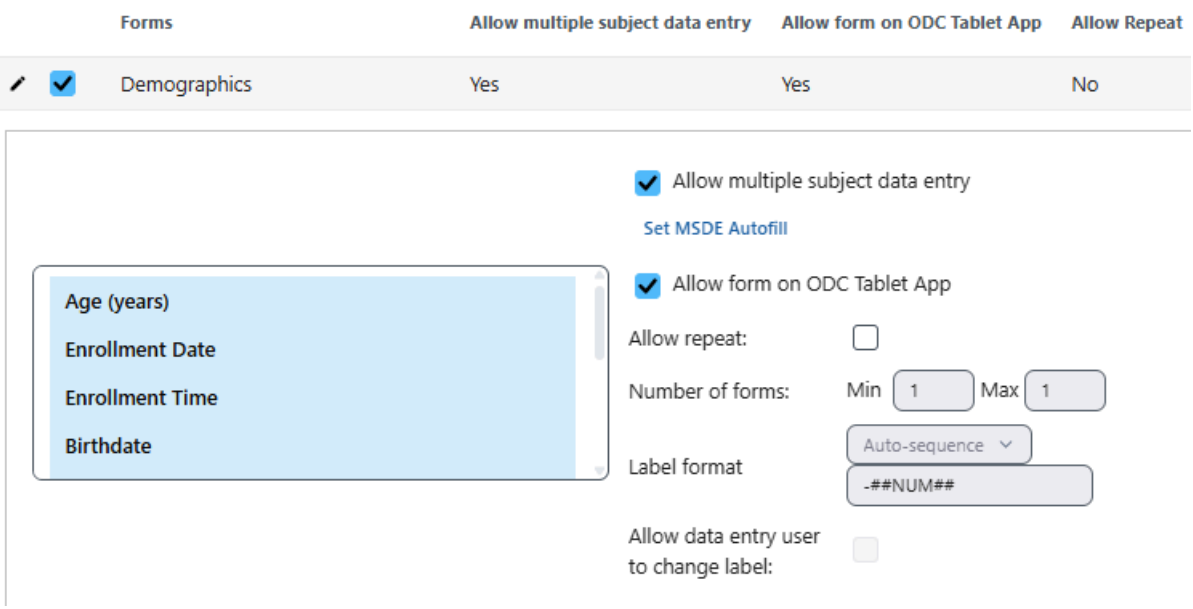
Medrio MCP does not create, change, or delete clinical data. Users with MCP Full Study Data can save the study's anomaly detection settings through Medrio MCP without the Configure permission.

Questions asked through Medrio MCP are not recorded in the EDC audit trail.

Impact		
Product	**Availability**	**Risk**
EDC	Available for existing studies and studies provisioned after release that are enrolled in the MCP Server Early Adopter program	High - this release changes who can use Medrio MCP and what data it returns. MCP Full Study Data gives a role study-wide results that include data its form, variable and site permissions hide.

ODC - EDC 42.16 Release

Description: We have added a study-level control to enable Medrio ODC and a per-form ODC Tablet App setting that no longer depends on Multiple Subject Data Entry (MSDE).



Context: Before this release, Medrio ODC was enabled for a study through the existing DDC setting, and a form appeared in the ODC Tablet App only if MSDE was enabled. ODC now has its own study-level setting, managed by Medrio Support, and study builders can choose which forms appear in the tablet app separately from MSDE.

Activation: Medrio Support can enable ODC for each study, and Dev, Test, and Live are set separately. Once ODC is on, each form shows an "Allow form on ODC Tablet App" checkbox in **Forms and variables** for the selected visit, checked by default.

Note: Customers already using ODC should contact Medrio Support to enable ODC for the study and check form settings for their visits after the release.

Impact		
Product	**Availability**	**Risk**

EDC	Available for existing studies and studies provisioned after release	Medium - the release changes how studies and forms are made available in the ODC Tablet App, which directly affects site data capture. If a study or form is not set up correctly after the upgrade, sites may be unable to enter data on tablets, or forms may appear in the app that should not.

Medrio ePRO

Discontinue ePRO Notifications for Phase Breaks or Discontinued Subjects

Description: ePRO notifications can now be controlled by form rules. This allows the notifications to stop automatically for subjects who change to a new phase or discontinue the study.

Context: Subjects could continue receiving ePRO reminders after leaving the study or moving to a new phase, which confused participants and created extra work for sites. Linking notifications to form rules keeps ePRO activity aligned with each subject's current status in the study, without manual site action.

Activation: This feature is available for all existing studies utilizing ePRO and can be enabled on the Remote ePRO Configuration page.

Impact		
Product	**Availability**	**Risk**
ePRO	Available for existing studies and studies provisioned after release	Medium - the feature controls ePRO notification behavior, which has a direct effect on subject ePRO data entry.

Localized Date Fields

Description: Dates and decimal numbers in ePRO are now displayed and entered in the format of the subject's language, instead of the study-level date format.

Context: Participants in global studies expect dates and numbers in their regional format. Matching these formats to the subject's language reduces confusion and data entry errors, such as transposed days and months, and gives subjects a fully localized ePRO experience.

Activation: This feature is automatically enabled for all studies utilizing ePRO.

Impact		
Product	**Availability**	**Risk**
ePRO	Available for existing studies and studies provisioned after release	Medium - this is related to subject data entry; however, it is regarding the format of the dates/decimal points being shown to the subjects in relation to their selected Localization language.

Medrio API Connect

Add Additional $filter Parameter Support for ClinicalDataReports Endpoint

Description: We've added the ability to filter the ClinicalDataReports API endpoint by form using the `$filter` parameter.

Context: API users often had to pull large volumes of clinical data and discard most of it. Filtering by form lets them retrieve smaller, more relevant datasets, which makes integrations faster and more efficient.

Activation: This feature is available for all studies utilizing the Data Views API, specifically the ClinicalDataReports endpoint.

Impact		
Product	**Availability**	**Risk**
API Connect	Available for existing studies and studies provisioned after release	Medium - as we are adding another filter to a customer Data View that when utilized needs to provide correct results in order to maintain data accuracy.

Data Dictionary — Unified Data Layer and API Access

Description: We've added the ability to request and download a study's Data Dictionary via API, in JSON or Excel format. There are two new endpoints for the Data Dictionary:

1. POST /api/study/{studyId}/data-dictionary
2. GET /api/study/{studyId}/data-dictionary/{jobId}

Retrieving the Data Dictionary is a two-step process: a POST request starts generation of the Data Dictionary and returns a job ID, and a GET request with that job ID returns the Data Dictionary once generation is complete.

Note: Only Non-SSO users can use the Data Dictionary endpoints in this release.

Context: Previously, the Data Dictionary could only be generated and downloaded manually through the EDC. Making it available via API lets customers build it into their automated workflows, while ensuring the content always matches the Data Dictionary available in the EDC.

Activation: The feature is available on all existing studies that are utilizing API.

Impact		
Product	**Availability**	**Risk**
API Connect	Available for existing studies and studies provisioned after release	Low - we are simply allowing another way of getting the data dictionary that already exists as a summary of study configuration details.