

Medrio EDC Feature Highlights

Medrio is a cloud based electronic data capture platform with an array of integrated modules providing innovative and advanced solutions to data capture in clinical trials and registry studies.

Features That Meet Your Needs

Forms

With flexible field placement and formatting, create forms that reflect the actual nature of your data and make sense for your data capture goals. Using templates and drag-and-drop techniques, non-programmers can create forms, queries, and study configuration designs.

The image displays two screenshots of the Medrio EDC interface. The left screenshot shows a 'Resting Vital Signs' form for Subject 10002. It includes instructions for the participant to lie down and rest for 5 minutes. The form has fields for Cuff Size (Regular, Large, Adjustable) and Arm Used (Left, Right). It contains two measurement sets, each with Systolic, Diastolic, and Radial Pulse (beats per minute) fields. An ALERT field is at the bottom. The right screenshot shows an 'Adverse Event SAE - CDASH' form for the same subject. It features a table with columns for Row, Visit, AE #, Adverse Event, Other AE, Date Onset, and Ongoing. The table contains three rows of data for Baseline, Baseline, and Week 1 visits, with adverse events like 'Headaches/migraines', 'Coughs', and 'single sprain'.

Data Structure

Medrio's underlying data structure supports complex relational structures allowing you to create a study configuration that accurately reflects the nature of your data, at all levels (records, forms, and visits). With one-to-many/repeated records within a form you can collect open ended medication lists, pregnancy histories, hospitalization events, etc. Utilize repeated forms and visits to enable a variety of custom design configurations.

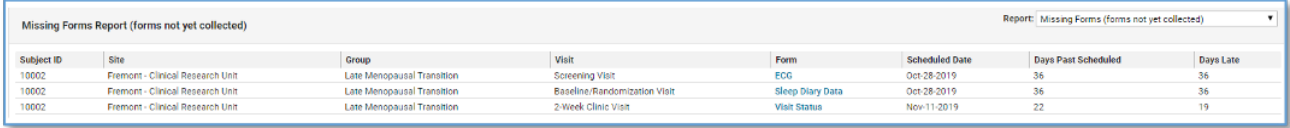
Data Quality

Medrio includes a sophisticated data query system that addresses data issues in real time, producing a clean dataset near ready for analysis. Create complex data exception flags with a simple drag and drop interface, and easily add checks for data completion, and hard (the value must be) and soft (the value should be) range checks. Send email notifications for flagged events.

A user friendly interface enables clinical coordinators to track and address data queries, correcting them or documenting reasons for the exceptions. Communication around exceptions is facilitated with responses, manual query identification, and the ability to direct queries to specific team members.

Use data based form rules to define the conditions under which each form is required, allowing you to create an accurate inventory of all forms expected, completed, and pending.

Finally, define and manage multi-stage data monitoring workflow steps that facilitate review of key data points and/or forms.



A screenshot of a 'Missing Forms Report (forms not yet collected)' interface. The report title is 'Missing Forms Report (forms not yet collected)' and the dropdown menu shows 'Report: Missing Forms (forms not yet collected)'. The table contains the following data:

Subject ID	Site	Group	Visit	Form	Scheduled Date	Days Past Scheduled	Days Late
10002	Fremont - Clinical Research Unit	Late Menopausal Transition	Screening Visit	ECG	Oct-28-2019	36	36
10002	Fremont - Clinical Research Unit	Late Menopausal Transition	Baseline/Randomization Visit	Sleep Diary Data	Oct-28-2019	36	36
10002	Fremont - Clinical Research Unit	Late Menopausal Transition	2-Week Clinic Visit	Visit Status	Nov-11-2019	22	19

Reports

Several template and custom report options assist both coordinators and data managers' workflows. Ad Hoc Reports can be viewed online or scheduled for automatic distribution to email lists.

Facilitate data completion with the Missing Forms report indicating which forms have yet to be completed (according to the defined form rules). Use the Scheduled Visits report to list which visits (without data) are overdue, in open window, and upcoming according to the study visit schedule.

Additional reports allow you to create custom data listings of select variables for online review by study team members, as well as long form datasets (one record per data point) with rich associated metadata.

On-demand reports available:

- ✓ Ad Hoc Reporting: browse data report, data audit log, linked data report, subject data trend report, form status report, clinical data report
- ✓ Data Management: coding report, double data entry report, ePRO form collection status, field status report, missing data report, missing forms report (forms not yet collected), unblinding subjects report, scheduled visits report, unblind log
- ✓ Monitoring/Approvals: approval variable report, monitor log report, monitor summary report
- ✓ Query Metrics: query aging report, query rate by field, query rate by form, query rate by site, top queries report
- ✓ Study Documentation: annotated forms, data dictionary
- ✓ Study Summary: site data summary report, subject data summary report, subgroup counts, weekly enrollment, dashboard, study data summary report
- ✓ Data Analysis: Analysis by visits, box and whisker, descriptive statistics and P-Values, histogram, linear regression, logistic regression, multiple linear regression, nonlinear regression, scatter plot, subgroup analysis, survival analysis, variable by mean, variables by percentage, variable by subject

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Facilitated Workflows

Beyond those mentioned for Clinical Coordinators, several features facilitate the workflows of additional study team members.

Data Coding | Streamline Adverse Event and Drug term classification by creating synonyms for and automatically coding recognized terms within MedDRA and WHO dictionaries. Create lab data forms with integrated lab reference ranges, specific to individual laboratories and study stratum.

Data Management | Export relational data tables in native software formats (SAS, SPSS, STATA, CSV) manually or programmatically through the API interface. Export a rich excel data dictionary with study configuration details (coded values, visit schedule, query definitions, etc.). Generate formatted blank CRF PDFs. Export the entire CDISC ODM data model. Bulk upload data with pre-formatted excel templates or create data mappings for standardized, recurring uploads.

Clinical Programming | Develop, test, and go live each in an isolated environment using controlled deployment. Easily deploy new versions, monitoring current user activity before deployment, and automatically documenting modifications with each version. Preemptively identify and avoid updates that would impact previously collected data (such as changes in value codes). Incorporate blinded randomization schemes.

Mobile

Eschew paper based forms with several eSource mobile platform based tools. Directly enter data on a tablet using Direct Data Capture. Collect Patient Reported Outcomes in clinic using a tablet or remotely through an email invitation and online portal. Create an interactive consenting process by imbedding video and interactive quizzes into a tablet based e-Consenting tool, tracking and automatically pushing new consent versions to sites.

Security and Regulation

Compliance | 21CFR Part 11 and HIPAA compliant, with GDPR design considerations.

Full Audit Trails | In addition to data edits, audit trails capture device source, changes to lab reference ranges, deployment versions, unblinding events, monitoring, and eConsent steps.

Secure PRO collection | Participants are locked from database access during tablet ePRO form completion.

Data Security and Redundancy | Cloud based redundancy, recovery, accessibility.

Agreement | UC BAA (business associates agreement) backed vendor agreement, Annual UCSF Risk Assessment.

Customized Access Permissions | Create highly customizable and granular user roles and (site specific) permissions.

Support

Several resources are available to support learning the platform and connecting with users, including: manuals, training videos, knowledge base articles, an online community social network platform, 24-hour support, and an annual conference.

24-hour support | Medrio's technical support responds to customers' "how-to" questions regarding their software, including helping users perform such tasks as unlocking a lost or forgotten password, or finding a particular feature or report on the website. Support staff do their best to resolve requests during the initial communication. All support requests are logged into Medrio's tracking system and any issues that require additional research, escalation to other support staff, or follow-up are tracked and reviewed regularly until resolved.

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