SOLUTION SHEET

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Clinical Data Services

Medrio Clinical Data Services are offered individually, allowing full customization to meet your specific needs.

Build Services

Set up your database quickly and accurately.

Our team collaborates with you to draft, review, and approve database configuration documents. These documents detail visits, forms, edit checks, form dynamics and field dynamics.

We then build the clinical database according to your protocol and configuration specifications, deploying it to the production environment following successful user acceptance testing (UAT).

Full Data Management Services

Ensure data quality, expedite timelines, and minimize workload.

Medrio provides comprehensive clinical data management services from database setup to database lock, with the option for biostatistics:

- Data Management Plan (DMP) development
- Data Validation Plan (DVP) development
- eCRF Completion Guidelines
- Site training
- User account management
- Third-party integrations
- Mid-study changes
- Query management
- Data review and quality control
- Medical coding
- Customized status reporting
- Interim analysis readiness
- Data reconciliation (e.g., SAE)
- Data export
- Database closure

Patient Profiles

Improve visibility into patient safety and ensure submission readiness.

We translate raw datasets into comprehensive listings of participant data. Formatting options include a raw data export and narrative profiles.

FDA 21 CFR Part 11 cdisc ICH harmonisation for better health

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Functional Service Provider (FSP)

Direct support for your internal teams.

Leverage the versatile skills of a dedicated Medrio team member as a seamless extension of your internal project teams.

You receive a customized support plan according to your organizational, departmental, or program level needs. This plan specifies provided services, timelines, project management meeting dates, and update report deadlines.

Clinical Data Services Office Hours

Get relevant answers to your technical questions.

Medrio Clinical Data Services office hours help you with any build or database challenges you may encounter.

Meet one-on-one or in a group with in-house data management subject matter experts (SMEs) to get answers to technical questions. Our experts can help with form design and edit checks, mid-study changes, CDASH implementation, form libraries, and more.

Medical Coding

Ensure consistency and compliance with trained coders.

MedDRA-trained and experienced WHO Drug coders work for you to assign medical codes to verbatim terms. They use the latest dictionaries including Medical Dictionary for Regulatory Activities (MedDRA) and World Health Organization Drug Dictionary (WHO Drug).

Data Mapping

Prepare your data for regulatory submission.

Medrio converts unstructured datasets into CDISC Standard Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) in preparation for your clinical data submission to regulatory authorities.

Biostatistics Services

Maximize your study's potential with high-quality, submission-ready data.

Maximize your data with our consultative biostatistician and programming teams that collaborate with you from study start-up. Ask to see our Biostatistics solution sheet for more information.

Have questions? Contact your business development representative to learn more.

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