

HOW MEDRIO PROTECTS YOUR

Clinical Trial Data

Clinical trial data serves as a sponsor's most crucial asset, enabling treatments to progress to the next research phase or ultimately receive regulatory approval.

Medrio CDMS/EDC keeps your data safe, secure, and protected by:

Staying Compliant

Industry Best Practices

- [ISO 9001 Certified](#)

ICH Guidance for Industry

- [E6 \(R2\) Good Clinical Practice](#)

FDA Guidance for Industry

- [Electronic Source Data in Clinical Investigation](#)
- [Computerized Systems Used in Clinical Investigations](#)

Regional Regulatory Requirements

European Union and United Kingdom

- [Annex 11](#)
- [GDPR](#)

United States of America

- [Health Insurance Portability and Accountability Act \(HIPAA\)](#)
- [FDA 21 CFR Part 11 Compliance](#)

Data & Information Security Best Practices

- [SOC 2 Type II Audited](#)
- [ISO/IEC 27001](#)
- [ISO/IEC 27701](#)
- [EU-US Data Privacy Framework Certified](#) providing EU Adequacy as a mechanism for data transfer
- [EU Model Clauses](#), available upon request

Maintaining an Expert-Trained Team

Medrio Team

Our experts, including a dedicated privacy officer, stay informed of regulatory guidelines, compliance standards, and system security.

Internal Standard Operating Procedures (SOPs)

Employees train on SOPs for data security and IT-related scenarios, including disaster recovery.

External Audit Experts

External auditors regularly ensure we are following all necessary software and procedural controls.

Supplying World-Class Solutions

Production Infrastructure

- Medrio is housed within Google Cloud Platform's (GCP) multi-tier virtualized architecture. Our shared security responsibility model ensures redundancy, reliability, scalability, and high availability.

- **GCP:** Responsible for the security of the underlying cloud infrastructure. For example physical infrastructure, availability zones, and edge locations.

- **Medrio:** Responsible for securing platform deployment in GCP. For example, customer data, identity access management (IAM), and encryption.

Server Protections

Redundant server facilities across the US, EU, and China protect against lost functionality. Network connectivity through multiple Tier-1 internet providers enables optimal performance and reliability.

Data Backups

We perform full backups nightly and incremental backups every 15 minutes to a secure facility, separate from the production environment, for all customer data.

Highly Configurable Roles and Permissions

While some vendors require pre-built roles or set role limits, we allow full customization to ensure appropriate data access restrictions.

Audit Trails

Our audit trail offers transparency by tracking data interactions with timestamps, providing regulators with complete visibility into data pathways.

medrio has supported over **9,500 trials in 100 countries** while capturing data from more than **1.6M+ participants** **without a single data security incident.** [Learn more about how Medrio can protect your data.](#)