SOLUTION SHEET

Security and Compliance

How Medrio Keeps Your Data Safe

We frequently engage with external auditors to ensure **we've followed all of the necessary software and procedural controls**. When joining Medrio, you can be confident that **your data is secure and your participants' privacy is protected**.

With the regulatory landscape constantly shifting, how do you keep up with all the changes?

Staying informed of all the changes and adjusting your operations to adhere to them is incredibly time consuming but that's where we come in to help. Our experts stay on top of regulatory guidelines, compliance standards, and system security so you can stay focused on your patients and trials.

At Medrio, we not only understand that the success of your trial is highly dependent on regulatory compliance but we also are committed to easing this burden for your team. One way we do this is by ensuring our systems always comply with regulations in all the various countries and regions in which our clients operate. We continually perform an in-depth analysis of regulations across the globe and work with external auditors so you can be assured our solutions are compliant.

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FDA Guidance

The last thing you need is to reach the final stages of a trial only to discover you have a FDA hiccup. To ensure you can conduct your clinical investigations without the worry of regulatory compliance issues, we fully embrace the following FDA Guidance documents:

- Guidance for Industry, Electronic Source Data in Clinical Investigations
- Guidance for Industry on Computerized Systems Used in Clinical Investigations
- ICH Guidance for Industry, E6 Good Clinical Practice

Compliance Standards

- ICH Good Clinical Practice (GCP)
- FDA 21 CFR Part 11 Compliance
- Annex 11
- General Data Protection Regulation (GDPR)
- HIPAA & HITECH
- CDASH & CDISC
- ISO 9001 Quality System

Product and Information Security

Delivering solutions that exceed customer expectations and meet applicable regulations is at the core of what we do everyday. We are committed to providing quality data collection solutions assuring the security and integrity of data maintained in all Medrio systems and across all devices.

An important component of our data security plan is our contract with Google Cloud Platform to house and secure our servers in restricted access locations. Google maintains SOC 1, 2, 3 Reports, ISO 27001, ISO 27017, ISO 27018, Cloud Security Alliance, PCI Compliance, HIPAA, CJIS, EU Model Clauses, and Privacy Shield compliance. Our Medrio team also audits Google periodically as part of a Vendor Assessment program.

Key Features

- Validated Environment
- Audit Trail
- Access Level Restricted by Role
- Incremental and Daily Full Backups
- SSL Encryption
- Login and Activity Log
- Two-Factor Authentication (2FA)
- Electronic Signatures
- Session Time-Out
- Single Sign-On (SSO)
- Password Expiration
- User Lock-Out
- Operations Monitoring
- Disaster Recovery
- Business Continuity Plan
- Quality Management System / SOPs

ABOUT MEDRIO

At Medrio, we know it takes a global village to achieve a disease-free world. Since 2005, we've developed a successful ecosystem of visionary people like you who want to make the world a healthier place - our employees, customers, and partners alike. We've supported Sponsors and CROs across the life sciences spectrum, in all therapeutic areas and trial phases, to achieve critical breakthroughs and secure more than 375 regulatory approvals. Our innovative and intuitive technology solutions support your teams and sites, while reducing trial participation burden. While other eClinical vendors make these same claims, few can deliver the high-touch, white-glove customer service that makes us your most successful strategic partner and solves your most pressing challenges. To learn more, visit us at medrio.com.

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