Medidata's SOC2+ Type II Report: Earning Your Trust through Transparency

Privacy, Quality, and Security are critical enablers to successful clinical trial execution, and that's why Medidata created the Unified Protection Strategy. The Unified Protection Strategy is our Information Security, Privacy, and Quality Management teams working in unison to safeguard your data and provide solutions that ensure regulatory compliance. The foundation of the Unified Protection Strategy is transparency in our business processes, and the Service Organization Control 2 (SOC2+) Type II report reflects that commitment to our customers. Medidata is the first life sciences organization to undergo a SOC2+ Type II audit, conducted biannually by PricewaterhouseCoopers. The subsequent report is prepared based on industry standards defined by the American Institute of Certified Public Accountants (AICPA).

Benefits of the Medidata SOC2+ Type II Report (SOC2+)

Continuous Independent Party Assurance

- Provides increased trust and transparency over the robust control environment governing the Medidata Clinical Cloud® unified platform

- Demonstrates how Medidata's systems are configured and used

- Provides independent, concrete trust assurances about the security of our SaaS Platform and the controls protecting customer and patient data

- Increased customer confidence in Medidata's security, incident impact minimization, and streamlined third-party compliance responses

Audit and Assessment Support

- Increased visibility into Medidata's governance, risk, and compliance processes

- Supports vendor assessments, security assessments, prequalification reviews, and periodic audits

Addressing Common Customer Concerns

The SOC2+ report provides comprehensive answers to 90% of all inquiries related to customer audits or assessments, including:

- Routine vendor diligence

- Routine sponsor inquiries

- Computer System and Software Validation

- Infrastructure and data backup

- Information security and data privacy

Customer Enablement and Engagement

- Enables customers to adopt technology quicker rather than get stuck on outdated software

- Encourages leveraging Medidata's self-service, on-demand resources

Features of the Medidata's SOC2+

The SOC2+ report demonstrates the operating effectiveness of the controls on:

Quality Management System (QMS)

Product/Service design follows Medidata's QMS, which specifies roles and responsibilities.

Maintains the QMS within Medidata's regulatory compliant electronic document management system.

Information Security

Firewalls and network devices are in place to protect server systems.

The Medidata Clinical Cloud is designed to require only standard firewall ports for operation, preventing hacking attempts.

Ensuring system monitoring and disaster recovery protocols are implemented.

Data Integrity

The Medidata platform utilizes controls around electronic records and electronic signatures in conformance with international requirements.

Hosting Operations

The platform utilizes a Medidata-operated hybrid hosting architecture, combining Private Cloud (traditional data centers) with secure Public Cloud (Amazon Web Services).

Software Development Life Cycle

Validated software resides on a qualified infrastructure, meeting customer requirements and functions.

Compliant with applicable GCP, Data Protection/Data Privacy, and Electronic Records/Electronic Signatures regulations and guidance.
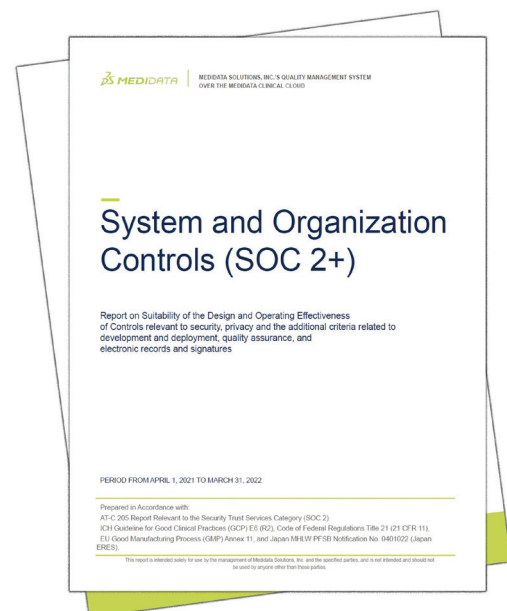
Data Privacy

Medidata's Privacy Office implements privacy principles based on our role as a data processor.

The Medidata Advantage

The SOC2+ Type II audit and subsequent report is an entirely voluntary effort by Medidata, and we've been doing it for more than a decade to benefit our customers. It continuously improves our business and earns the trust of the life sciences industry. By releasing a report every six months (covering the previous twelve months), you are assured that our business is consistently functioning in the manner you expect.

Available on-demand to all current and prospective customers (subject to a nondisclosure agreement), the SOC2+ Type II report lessens the need for comprehensive audits or assessments. It directly reduces time, effort, and costs, allowing studies to start faster and more efficiently.

Contact us at Medidata.Global-Compliance-n-Strategy@3ds.com

DS MEDIDATA | MEDIDATA SOLUTIONS, INC.'S QUALITY MANAGEMENT SYSTEM OVER THE MEDIDATA CLINICAL CLOUD

System and Organization Controls (SOC 2+)

Report on Suitability of the Design and Operating Effectiveness of Controls relevant to security, privacy and the additional criteria related to development and deployment, quality assurance, and electronic records and signatures

PERIOD FROM APRIL 1, 2021 TO MARCH 31, 2022

Prepared in Accordance with:
AT-C 205 Report Relevant to the Security Trust Services Category (SOC 2)
ICH Guideline for Good Clinical Practices (GCP) E6 (R2), Code of Federal Regulations Title 21 (21 CFR 11), EU Good Manufacturing Process (GMP) Annex 11, and Japan MHLW PFSB Notification No. 0401022 (Japan ERES).

This report is intended solely for use by the management of Medidata Solutions, Inc. and the specified parties, and is not intended and should not be used by anyone other than these parties.