# Medidata's Global Compliance & Strategy Program


Medidata's Global Compliance and Strategy program (GCS) is responsible for all Quality Management and Regulatory Compliance for Medidata and our customers. As a trusted advisor in the life sciences industry, GCS provides insights into existing and emerging policy, influences regulatory strategy with governing bodies, and advocates for our customers.

GCS also maintains Medidata's industry-leading Quality Management System (QMS). The QMS includes policies and procedures to ensure Medidata product offerings are developed, implemented, and maintained in a manner that exceeds customer expectations and ensures regulatory compliance throughout a clinical trial. By using a risk-based approach to improve quality and compliance in the life sciences industry continuously, Medidata provides the best-in-class Quality Management experience.

## Global Compliance & Strategy Benefits

### External Audit Support

Working with customers as they conduct routine audits of Medidata or undergo regulatory inspection.

### Dedicated Supplier Oversight

The supplier evaluation procedure covers various forms of due diligence of Medidata suppliers using a risk-based approach, including review & analysis of security and compliance certifications.

### Internal Quality System Audits

Using a risk-based approach, Medidata continuously identifies business-critical processes subject to audits to ensure they function correctly.

### Third-Party Assurance

Medidata's Quality Management function undergoes rigorous inspections by independent parties to ensure the governance of Medidata's unified platform is being performed.

### Planned Exceptions

When standard business processes are not followed, GCS creates planned exceptions to accommodate customer needs.

### Unparalleled Transparency

Medidata is the only life sciences organization to achieve SOC2+ certification issued by PricewaterhouseCoopers.

# Global Compliance & Strategy Features

### Quality Management System

Medidata's Quality Management System is our series of established governance documents that ensure that GCP and quality operations are carried out on a scalable, repeatable, and consistent basis.

### Regulatory Strategy

Medidata helps drive industry policy and regulations through insights and consistent engagement with governing bodies.

### Quality Incident (QI) Program

Medidata's QI Program has a dedicated procedure encompassing root cause analysis, impact analysis, and corrective and preventive action.

### Computer System Validation

GCS ensures that all of Medidata's solutions are released and continue to operate in a validated state. Our guide for adopting & implementing Medidata's solutions outlines regulatory expectations, customer responsibilities, and how Medidata can assist in these efforts.

### Quality-By-Design

Quality measures are built in at the design phase to ensure continuous regulatory compliance throughout the life of the trial.

### Global Compliance Infrastructure

Operating in compliance with the following global regulations and authorities:

- Clinical Data Interchange Standards Consortium (CDISC)
- International Organization for Standardization (ISO)
- Health Insurance Portability and Accountability Act (HIPAA)
- International Council for Harmonisation (ICH)
- FDA Code of Federal Regulations Title 21 Part 11 (21 CFR 11) - and EU and Japan equivalents
- EU General Data Protection Regulation (GDPR)
- EU Clinical Trials Directive (and Regulation)
- National Institute of Standards and Technology (NIST)

# What Trust Looks Like

**8M+**
Patients & healthy volunteers

**2000+**
Customers

**1800+**
Accredited Partners

**180+**
Medical Device customers including 9 of the top 10

**50%**
Existing drugs and medical devices developed on Medidata technology

**Hundred of Millions**
of Lives Saved

# The Medidata Advantage

Global Compliance & Strategy's mission is to help its customers successfully navigate and interpret the global regulatory landscape, enabling them to maximize the potential of Medidata's unified platform. Through our comprehensive and robust global compliance processes, Medidata has provided our customers with unmatched quality assurance and compliance solutions for over 20 years. As the most trusted voice in the life sciences industry, Medidata's innovative, inspection-ready regulatory and compliance functions are transforming the regulatory landscape.