



FOUR CORNERSTONES OF MERIT SERVICES



MERIT's commitment to quality is the foundation of our safe, reliable, and efficient data analysis and management services for clinical trials. MERIT services are built from the ground up on quality management, reliability, security, and privacy.

1 QUALITY MANAGEMENT

MERIT's Quality Management System (QMS) provides the structure and controls required for:

- ✓ ISO 13485 Certification
- ✓ 510(k) clearance for EXCELSIOR™ as a medical device for ophthalmic and radiological indications
- ✓ Compliance with 21 CFR Part 820 Quality System Regulation, ICH E6 (R2), and GxP industry standards

2 RELIABILITY

Our cloud-based EXCELSIOR solution is hosted at Microsoft Azure, providing unparalleled reliability:

- ✓ 24/7 data access with 99% uptime
- ✓ SQL database backed up incrementally every 5 minutes. Snapshot backed up daily to Azure storage account
- ✓ Geo-dispersed backup at secondary data center

3 SECURITY

With MERIT's Information Security Management System (ISMS), our partners are assured that MERIT has processes in place to manage and mitigate risk related to the security of data.

- ✓ ISMS 27001 Certified
- ✓ SSL certificates restricted to SHA-2 for all internal and external systems
- ✓ Encryption of data in transmission and at rest
- ✓ Authentication of each EXCELSIOR user via unique username and password, serving as an electronic signature that is 21 CFR Part 11 compliant

4 DATA PRIVACY

MERIT staff are continuously trained in data privacy best practices. We prioritize data privacy and comply with the following data privacy protection frameworks:

- ✓ GDPR
- ✓ HIPAA
- ✓ Data Privacy Framework
- ✓ HGRAC