

# Healthcare & HealthTech

Protecting patient data and clinical integrity through institutional-grade compliance programs — built for healthcare providers, healthtech innovators, and Africa’s rapidly expanding health sector.

## OUR VALUE PROPOSITION

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|----------------|--------------|-----------------|-----------------------|
| HIPAA / HITECH | GDPR ALIGNED | POPIA COMPLIANT | AFRICA HEALTH MARKETS |
|----------------|--------------|-----------------|-----------------------|

*In the rapidly evolving healthcare landscape, data privacy is not just a legal requirement — it is a cornerstone of patient trust.*

The Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) establish the administrative, physical, and technical safeguards required to assure the confidentiality, integrity, and availability of Electronic Protected Health Information (ePHI). Compliance is mandatory for covered entities, business associates, and any healthcare SaaS provider that carries out transactions in electronic form.

Our service offerings leverage the world’s most robust privacy frameworks — HIPAA and GDPR — to help healthcare providers and healthtech firms navigate complex regulatory landscapes. By aligning your operations with these international gold standards, we provide a compliance foundation that naturally meets and exceeds the requirements of South Africa’s Protection of Personal Information Act (POPIA) and the evolving data protection frameworks across African nations.

|       |        |      |       |           |           |       |           |
|-------|--------|------|-------|-----------|-----------|-------|-----------|
| HIPAA | HITECH | GDPR | POPIA | ISO 27001 | ISO 27799 | SOC 2 | KENYA DPA |
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01

Healthcare Compliance & Regulatory Framework Alignment

Know the Rules. Own the Roadmap.

Healthcare organizations and healthtech firms operate at the intersection of some of the world’s most demanding regulatory regimes. HIPAA and HITECH establish mandatory administrative, physical, and technical safeguards for any entity handling ePHI — and a single compliance failure can trigger penalties, mandatory breach notifications, and lasting reputational harm. For organizations seeking a globally recognized technical standard that speaks directly to health information security, ISO 27799 provides the health informatics-specific extension of ISO 27001 — offering sector-tailored security controls purpose-built for protecting personal health information across clinical, administrative, and digital health environments. Together, ISO 27001 and ISO 27799 form the most comprehensive internationally recognized framework for healthcare information security, and carry significant weight with regulators across African markets where ISO standards are the benchmark for institutional credibility.

United Allied maps your existing processes against HIPAA’s technical and administrative safeguard requirements, GDPR’s transparency and data subject rights obligations, and ISO 27799’s health informatics controls — creating a unified, high standard compliance roadmap that eliminates duplication and closes gaps across all three frameworks simultaneously. For organizations with operations across African markets, we tailor global best practices to satisfy POPIA’s specific requirements under South Africa’s Information Regulator, as well as Kenya’s Data Protection Act and other applicable national frameworks — ensuring your organization is simultaneously compliant across every jurisdiction it serves.

Our Certified Information Systems Security Professionals (CISSPs) bring deep healthcare sector knowledge to every engagement — from hospital networks and private practices to software vendors and health insurance payors — guiding your organization through the regulatory complexity that defines this industry.

CORE DELIVERABLES:

- HIPAA / HITECH compliance program development
- ISO 27799 health informatics security alignment
- Africa market data protection framework advisory
- ISO 27001 & ISO 27799 unified control environment
- Compliance training programs

- POPIA readiness & Information Regulator alignment
- GDPR framework mapping & data subject rights program
- Multi-jurisdictional compliance roadmaps
- Policy development & management
- Ongoing regulatory monitoring & change management

02

Risk Assessment & Cybersecurity Assurance

Identify Vulnerabilities Before They Become Breaches.

Healthtech companies manage a massive volume of highly sensitive Protected Health Information (PHI), making them prime targets for cyberattacks including ransomware, data breaches, and insider threats. A breach exposes your organization to severe risks — costly HIPAA penalties, expensive legal defense fees from class-action lawsuits, and mandatory breach response costs including forensic investigation, patient notification, and credit monitoring — all of which can be devastating to an organization’s finances and destroy the patient trust that took years to build.

HIPAA requires a formal risk analysis as a core component of ePHI protection — encompassing vulnerability scans, penetration testing, and a documented risk register for continuous management use. United Allied conducts deep-dive audits of your data lifecycles, identifying vulnerabilities in how patient information is collected, stored, accessed, and shared. Our HIPAA Security Compliance Assessments combine rigorous policy and procedure review, staff interviews, and technical control testing to deliver a comprehensive picture of your security posture and a prioritized remediation roadmap.

Beyond the assessment, we help your organization leverage cybersecurity findings directly into your broader compliance program — ensuring that risk management is not a one-time exercise but a continuous discipline embedded into operations.

CORE DELIVERABLES:

- HIPAA Risk Analysis & ePHI vulnerability assessment
- HIPAA Security Compliance Assessment
- Prioritized risk register & remediation roadmap
- Network segmentation & architecture review
- Gap analysis against HIPAA, GDPR & POPIA controls

- Security architecture review
- Penetration testing & vulnerability management
- Incident response planning
- OT-specific incident response planning
- Business continuity & disaster recovery integration

03

Healthtech GRC & Clinical Risk Advisory

Governance Built for the Complexity of Digital Health.

As healthtech products — diagnostic software, AI-driven clinical decision tools, remote monitoring devices, and digital health platforms — become integrated into patient care pathways, the governance stakes rise significantly. Any malfunction, error, or system failure can lead to incorrect diagnoses, delayed treatment, or device failure that directly causes patient harm. This exposes organizations to medical malpractice and professional liability claims, regulatory investigations, and financial settlements that no early-stage company is equipped to absorb without a structured GRC program in place.

The healthcare sector is simultaneously one of the most heavily regulated and most rapidly innovating industries in the world. Compliance mandates including HIPAA, GDPR, and FDA guidelines for Software as a Medical Device (SaMD) are complex, constantly evolving, and carry significant financial penalties and legal exposure for non-compliance. Digital health platforms whose core services fail — through bugs, outages, or data loss — expose their clients, hospitals, clinics, and payers to financial damages that frequently result in errors and omissions lawsuits.

United Allied’s GRC advisory practice embeds compliance, clinical risk management, and security governance directly into your product development and market expansion strategy. For healthtech firms expanding into African markets, where mobile health platforms and digital diagnostics are reshaping healthcare delivery at scale, we provide the compliance architecture needed to satisfy local health regulators, international partners, and institutional investors simultaneously.

CORE DELIVERABLES:

- GRC program architecture & build-out
- Risk management planning
- SaMD & FDA regulatory advisory
- Africa healthtech market entry compliance strategy
- Clinical liability risk framework development

- vCISO advisory services
- Audit management
- Security awareness training
- Continuous compliance monitoring dashboards
- Investor-ready security posture documentation

## FRAMEWORKS & STANDARDS WE WORK WITH

|       |        |      |       |           |           |       |          |
|-------|--------|------|-------|-----------|-----------|-------|----------|
| HIPAA | HITECH | GDPR | POPIA | ISO 27001 | ISO 27799 | SOC 2 | NIST CSF |
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# Protecting Patients. Securing Trust.

Contact United Allied to discuss how we can strengthen your organization’s healthcare compliance posture and cybersecurity resilience across global and emerging markets.