QUANTUM THREAT INTELLIGENCE REPORT: HEALTHCARE & PHARMACEUTICAL INDUSTRY





THREAT LEVEL EXTREME

Healthcare/pharma face the MOST SEVERE quantum threat across all industries due to permanently sensitive medical/genomic data, complex IT infrastructure, and multi-decade clinical trial timelines coinciding with quantum computer arrival.

CRITICAL FINDINGS:

- Permanent Sensitivity
 - Medical records sensitive 50+ years; genomic data forever identifiable across generations
- Active HNDL Attacks
 - Nation-states harvesting encrypted clinical trials, R&D data, patient information NOW
 - Infrastructure Challenge
- 77 SaaS applications average; 500-1,000+ APIs; only 4% encrypt 80%+ cloud data; 27% don't know where data stored
- Quantum Concern
 59% fear encryption compromise; 68% worried about HNDL; 69% key distribution fears (Thales 2025)
- Breach Statistics
 \$10.9M average cost (highest industry); 238M US residents affected (2024); 287 days to identify breach
- Global Mandates
 US federal PQC by 2027; HIPAA quantum updates 2025-2026; EU NIS2 by 2030; GDPR penalties €20M
- Financial Impact
 \$85-130B industry investment required; \$500B-\$2T potential quantum breach exposure

GLOBAL REGULATORY MANDATES & COMPLIANCE TIMELINE

1.1 | UNITED STATES HEALTHCARE QUANTUM MANDATES

Federal Legislation (Source: https://www.safelogic.com/compliance/pqc-standards)



- Quantum
 Cybersecurity
 Preparedness
 Act (Dec 2022)
- Memorandum
 M-23-02
 (Nov 2022)
- C NSA CNSA 2.0 (National Security Systems)
- D Executive Order 14144 (Jan 2025)

A | Quantum Cybersecurity Preparedness Act (Dec 2022)

Scope

Federal agencies + contractors (Medicare/Medicaid providers, VA hospitals, military medical facilities)

Requirements

Inventory quantum-vulnerable systems; develop PQC migration plans; annual OMB reporting

Healthcare Impact

All federal healthcare IT systems and contractors

Timeline

Initial inventory Q4 2025; migration plans Q2 2026

C | NSA CNSA 2.0 (National Security Systems)

Jan 1, 2027

New NSS acquisitions <u>CNSA 2.0</u> compliant (Defence Health Agency, military hospitals)

Dec 31, 2025

Existing NSS meets CNSA 1.0 or requests waiver

2033

Final mandatory compliance for all system types

Required Algorithms

ML-KEM (CRYSTALS-Kyber), ML-DSA(CRYSTALS-Dilithium), LMS/XMSS

B | OMB Memorandum M-23-02 (Nov 2022)

Mandate

Annual cryptographic inventories through 2035

Priority

High-Value Assets (patient health information systems, clinical trial databases, genomic repositories)

Source: https://www.whitehouse.gov/wp-content/uploads/2022/11/M-23-02-M-Memo-on-Migrating-to-Post-Quantum-Cryptography.pdf

D | Executive Order 14144 (Jan 2025)

Trump Administration

Maintains PQC urgency, streamlines roadmap

TLS 1.3 Requirement

All federal systems by January 2, 2030

CISA/NSA Deliverable

Quantum-safe product categories by December 1, 2025

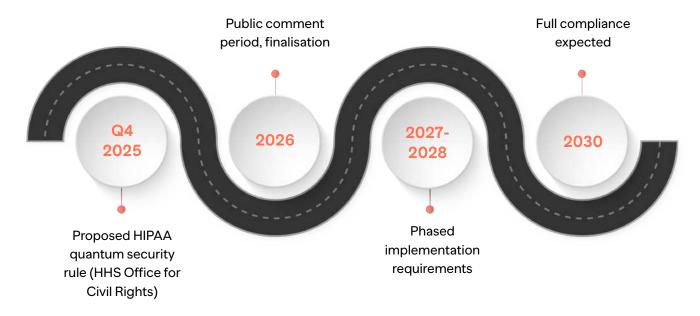
Healthcare Systems

Must support quantum-safe TLS for health information exchange



HIPAA QUANTUM SECURITY UPDATES (Expected 2025-2026)

Expected Timeline:



Current Status

HIPAA Security Rule requires "addressable" encryption (no explicit quantum requirements yet)

Source: https://www.federalregister.gov/documents/2025/01/06/2024-30983/hipaa-security-rule-to-strengthen-the-cybersecurity-of-electronic-protected-health-information

New Requirements (Anticipated):



Mandatory <u>PQC</u> implementation for covered entities storing PHI



Business Associate Agreements (BAA) must include quantum security provisions



Breach notification updates for quantum compromise scenarios



Penalties for quantum-vulnerable systems storing PHI after the deadline

Penalties

Existing HIPAA framework (\$100-\$50,000 per violation, max \$1.5M/year per violation category) + potential quantum-specific penalties

NIST POST-QUANTUM STANDARDS (Finalised Aug 2024)

 ┙	-	•,	ш	174

ML-KEM (CRYSTALS-Kyber)

Key encapsulation for data encryption

FIPS 204

ML-DSA (CRYSTALS-Dilithium)

Digital signatures for authentication

FIPS 205

SLH-DSA (SPHINCS+)

Hash-based signatures for long-term security

FIPS 206

FN-DSA (FALCON)

Compact signatures for constrained devices (pending)

Source: https://www.nist.gov/news-events/news/2024/08/nist-releases-first-3-finalized-post-quantum-encryption-standards

1.2 | EUROPEAN UNION HEALTHCARE & PHARMA MANDATES



■ NIS2 Directive

(Effective Oct 2024; Member State Implementation Oct 2026)

https://www.nis-2-directive.com/

GDPR Quantum Implications

Source: https://digital-strategy.ec.europa.eu; https://industrialcyber.co/regulation-standards-and-compliance/eu-begins-coordinated-effort-for-member-states-to-switch-critical-infrastructure-to-quantum-resistant-encryption-by-2030/

NIS2 Directive (Effective Oct 2024; Member State Implementation Oct 2026)

Covered Healthcare Entities:

Essential Entities

Hospitals, pharmaceutical manufacturers, medical device companies, large clinical labs

Important Entities

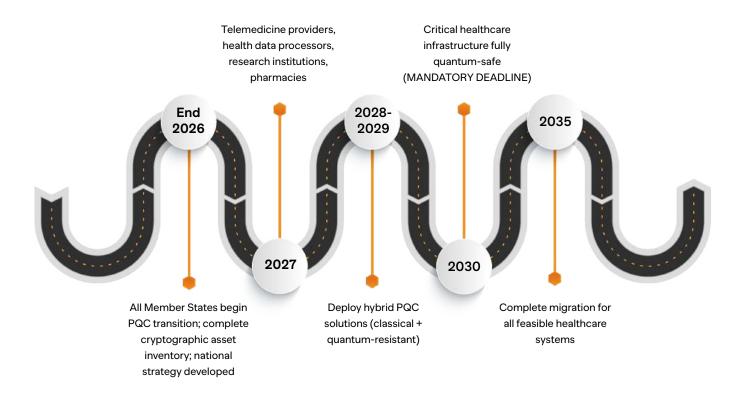
Telemedicine providers, health data processors, research institutions, pharmacies

Penalties

Up to €10M or 2% of global annual revenue (whichever is higher) for non-compliance



PQC Implementation Timeline:



Penalties

Up to €10M or 2% of global annual revenue (whichever is higher) for non-compliance

GDPR Quantum Implications

PQC Implementation Timeline:

- Patient data classified as "special category" under GDPR Article 9
- Quantum decryption of patient data = data breach under GDPR
- Controllers/processors liable for inadequate encryption measures
- "Right to be forgotten" (Article 17) complicated by HNDL attacks (data collected today, decrypted later)

Technical Requirements:

- Technical measures must be "state of the art" (Article 32) quantum threat redefines adequacy
- Data Protection Impact Assessments (DPIA) must address quantum risk
- Data Protection Officers (DPOs) must understand <u>PQC</u> implications



Financial Penalties:

- Up to €20 million or 4% of global annual revenue (whichever is higher)
- Quantum breach could trigger maximum penalties
- Class action lawsuits from affected patients (GDPR Article 82)

European Medicines Agency (EMA) Guidance:

- Clinical trial data must be quantum-safe for submission
- Drug approval documentation requires <u>PQC</u> protection
- Pharmacovigilance systems quantum-secure by 2028
- Manufacturing process data protected with quantum-resistant encryption
- Good Manufacturing Practice (GMP) updates for quantum security

EU Cyber Resilience Act (CRA) - Effective Dec 2027:

- All medical devices with digital elements must support cryptographic agility
- Manufacturers must provide security updates for the product lifecycle
- Quantum-safe updates mandatory for connected medical devices

1.3 | OTHER MAJOR MARKETS

UNITED KINGDOM



- NCSC
 Healthcare sector prioritised in <u>PQC</u> migration roadmap
- NHS Digital
 Leading national implementation across the National Health Service
- MHRA (Medicines and Healthcare products Regulatory Agency)
 PQC mandatory for connected medical devices 2026-2028; Software as Medical Device (SaMD) quantum standards



Timeline

Critical NHS systems by 2028; full migration by 2032



JAPAN



Investment\$7.4B in quantum technology (2025 announcement)

Healthcare Focus

Genomics research protection, medical Al security

PMDA (Pharmaceutical and Medical Devices Agency)
 Developing <u>PQC</u> standards for drug approval systems

 $Source: \underline{https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-year-of-quantum-from-concept-to-reality-in-2025$



Timeline

2027-2029 implementation for regulatory submission systems

SOUTH KOREA



- KDCA (Korea Disease Control and Prevention Agency)
 Quantum security initiatives for public health data
- National Health Insurance Service
 <u>PQC</u> pilot program (2025-2026)



Timeline

2026-2029 phased rollout

INDIA



- National Quantum Mission
 ₹6,003.65 crore (\$800M) budget allocation
- Healthcare Application
 Telemedicine security, digital health records (Ayushman Bharat), genomic research
- AIIMS Partnership
 Pilot quantum security programs at All India Institute of Medical Sciences
- Focus

Indigenous quantum security solutions, satellite-based QKD for remote healthcare



Timeline

2025-2030 phased implementation



CHINA



Investment
 Billions in quantum research, 2,000 km operational quantum network

Healthcare Priority
 Traditional Chinese Medicine (TCM) database protection, genomic sovereignty



Aggressive Timeline

Mandating quantum-safe systems for healthcare data by 2026-2027

CANADA



- Health Canada
 Updating medical device cybersecurity requirements to include <u>PQC</u>
- Provincial Health
 Ontario, Quebec leading quantum security pilots



Timeline

Critical systems 2027-2029

AUSTRALIA



- ASD (Australian Signals Directorate)
 Post-quantum planning guidance since 2023
- TGA (Therapeutic Goods Administration)
 Medical device quantum security requirements
- My Health Record
 National EHR system quantum migration planning



Timeline

2026-2030 implementation



Adversaries collecting encrypted healthcare data TODAY



Business Associate Agreements (BAA) must include quantum security provisions



Breach notification updates for quantum compromise scenarios



Penalties for quantum-vulnerable systems storing PHI after the deadline



HEALTHCARE THREAT LANDSCAPE & ATTACK INTELLIGENCE

2.1 | WHY HEALTHCARE IS THE HIGHEST QUANTUM RISK

Source: https://www.weforum.org/stories/2025/09/pharma-life-sciences-quantum-threat-cybersecurity/

World Economic Forum Assessment - Unique Healthcare Vulnerabilities:

Risk Factor	Healthcare Reality	Quantum Threat Impact	Severity
Data Lifecycle	50+ years (lifetime + post-death retention) Decades of encrypted records become decryptable		CRITICAL
Genomic Data	Permanent, unchangeable identifier	,	
Clinical Trials	10-15 year duration (Phase I-IV)	Overlaps with CRQC arrival window (2026-2031)	CRITICAL
R&D Value	\$2.6B average per new drug development	Billions in IP vulnerable to theft	EXTREME
Regulatory	HIPAA, GDPR, and FDA mandatory compliance Quantum breach = massive penalties + litigation		CRITICAL
National Security	Pandemic response, biodefense research	State-sponsored quantum espionage target	EXTREME
Patient Safety	Medical device control, treatment data	Physical harm potential from compromised systems	CRITICAL

Harvest Now, Decrypt Later" (HNDL) Specific Threat:



Adversaries collecting encrypted healthcare data TODAY



Expectation

Quantum computers

will decrypt 2026-2031



Once decrypted, genomic/medical data exposure is PERMANENT and IRREVERSIBLE

2.2 | 2025 HEALTHCARE CYBERSECURITY DATA

Thales Data Threat Report - Healthcare & Life Sciences Edition 2025

Quantum-Specific Healthcare Concerns:

ᄃ	a	0	/_

of healthcare leaders are concerned about future encryption compromise

69%

fear problems with quantum-resistant key distribution

68%

worry about "harvest now, decrypt later" attacks

50%+

already prototyping or evaluating postquantum cryptography But Only 50% means half the industry NOT Yet preparing

Healthcare IT Infrastructure Complexity Crisis:



- 77 SaaS applications average per healthcare organisation
- Nearly 2 laaS platforms average (multi-cloud complexity)
- 500-1,000+ APIs per organisation
 - 33% manage more than 500 APIs
 - 14% juggling over 1,000 APIs
- 5+ data discovery tools used by 59% of firms (conflicting policies, overlapping processes)
- 27% have little or NO confidence in identifying where their data is stored
- Only 4% have encrypted 80% or more of sensitive cloud data
- Nearly 50% of all cloud-stored data is sensitive (but unprotected)

Breach Trends - Mixed Picture:

2021

35% of healthcare organisations reported recent incidents

2025

12% report breaches (25-point improvement over 4 years) However, a Quantum threat Could catastrophically reverse this progress

Multi-Factor Authentication (MFA) Success Story:

2021

Only 14% of firms had 40%+ staff using MFA

2025

86% achievement (72-point leap in 4 years)

Lesson

When stakes are clear and urgent, healthcare CAN adapt rapidly

Al Security Emerging Concern:

27%

in GenAl integration or transformation phases 67%

cite fast-moving Al ecosystem as their #1 security worry 50%

of AI security spending from existing budgets; 18% from new allocations

- Primary Concerns
 - Model integrity, data reliability, third-party trust, potential misuse
- Asymmetry Fear

Compromise at machine speed, remediation at human pace

Healthcare Breach Cost Statistics (IBM 2024):



- \$10.9 million average cost per healthcare data breach (HIGHEST of any industry)
- 287 days average time to identify a breach
- 80 days average time to contain breach
- 2+ years total lifecycle cost (breach costs persist long-term)
- **238 million** US residents affected by healthcare breaches (2024)
- 14 breaches involving 1 million+ records each



2.3 | CRITICAL ATTACK VECTORS

A | ELECTRONIC HEALTH RECORDS (EHR) EXPOSURE

Scale

Billions of patient records globally (Epic, Cerner/Oracle Health, Allscripts, Athenahealth)

Sensitivity Duration

Lifetime + 50 years' post-death (regulatory retention requirements)

HNDL Activity

Active collection of encrypted medical database backups

Quantum Impact

Complete patient medical history exposed (diagnoses, treatments, medications, mental health, substance abuse, genetic predispositions)

Consequences

Identity theft, insurance discrimination, employment impact, social stigma, blackmail potential

B | CLINICAL TRIAL & PHARMACEUTICAL R&D DATA THEFT

IP Value

\$2.6 billion average cost to develop one new drug (Tufts Centre study)

Timeline Overlap

Phase I-IV trials span 10-15 years, overlapping CRQC arrival (2026-2031)

Target Data

Patient outcomes, efficacy results, adverse events, drug formulations, manufacturing processes

Competitive Impact

Years of R&D instantly compromised; competitor gains immediate parity

National Security

Biodefense research, vaccine development, pandemic preparedness exposed

Regulatory Risk

FDA/EMA submissions contain sensitive proprietary data

C | MEDICAL DEVICE & IoT INFRASTRUCTURE COMPROMISE

Connected Devices

Pacemakers, insulin pumps, ventilators, patient monitors, infusion pumps

Control Systems

Surgical robots (da Vinci), imaging equipment (MRI, CT, PET), radiation therapy

Quantum Vulnerability

Device authentication broken; PKI certificates compromised

Physical Harm Potential

Life-threatening manipulation (insulin overdose, pacemaker disruption, ventilator shutdown)

Scale

Billions of connected medical devices deployed globally

Regulatory

FDA medical device cybersecurity guidance insufficient for quantum threats



D | GENOMIC DATABASE BREACHES

Permanent Sensitivity

DNA sequence never changes; forever identifiable

Family Impact

Genetic data reveals information about relatives across generations (siblings, children, parents)

Discrimination Risks

- Health insurance (pre-existing genetic conditions)
- Life insurance (genetic disease predisposition)
- Employment (genetic screening)
- Social stigma (mental health, addiction susceptibility)

Collection Scale

100+ million genomes sequenced globally (23andMe, Ancestry.com, UK Biobank, All of Us)

Research Value

Pharmaceutical companies, biotech firms target genomic databases for drug discovery

HNDL Priority Target

High-value permanent identifiers being actively collected

E | HOSPITAL INFRASTRUCTURE & BUILDING SYSTEMS

Building Management

HVAC, power systems, physical security, access control

Patient Monitoring

Real-time vital signs, alert systems, nurse call systems

Supply Chain

Medication tracking, inventory management, blood bank

Emergency Systems

Life safety, fire suppression, emergency communications

Quantum Risk

Infrastructure control systems authentication compromised; operational disruption

F | TELEMEDICINE & REMOTE CARE PLATFORMS

Rapid Growth

Telehealth visits increased 38x during pandemic; remaining elevated

Video Consultations

Doctor-patient communication encryption is vulnerable

Remote Patient Monitoring

Wearables, home health devices transmitting data

Prescription Systems

E-prescribing platforms handling controlled substances

Quantum Threat

Real-time communication interception; prescription fraud

G | PHARMACEUTICAL SUPPLY CHAIN

Manufacturing

Batch records, quality control, process parameters

Distribution

Track-and-trace systems (Drug Supply Chain Security Act compliance)

Cold Chain

Temperature-sensitive medication monitoring (vaccines, biologics)

Counterfeit Prevention

Hand authentication systems

Quantum Risk

Supply chain integrity compromised; counterfeit drug insertion

QUANTUM COMPUTING CAPABILITIES & TIMELINE

3.1 | CURRENT STATE (OCTOBER 2025)

Operational Quantum Systems:

IBM Quantum System Two

1,121 superconducting qubits demonstrated

Google Willow Chip

Achieving quantum computational advantage

IonQ Forte

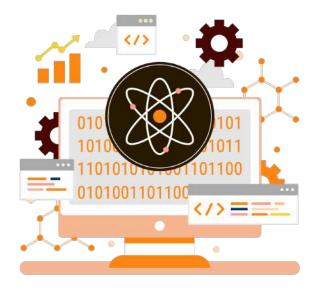
64-qubit trapped-ion commercial systems available

Rigetti

Cloud-accessible quantum processors

China

Significant quantum computing research facilities; 2,000 km quantum network operational



3.2 | CRYPTOGRAPHICALLY RELEVANT QUANTUM COMPUTER (CRQC) TIMELINE

Year	Qubit Count	Cryptographic Threat	Healthcare Impact
2025	100-500 qubits	Proof-of-concept attacks; limited practical threat	Research phase; monitoring required
2026	500-1,000 qubits	Specialised encryption breaking is possible	Early EHR system vulnerabilities
2027- 2028	1,000-2,000 qubits	RSA-2048 potentially breakable; patient data at risk	Clinical trial data exposure begins
2029- 2030	2,000-5,000 qubits	Most current encryption is vulnerable	Widespread genomic database compromise
2031+	5,000+ qubits	Complete cryptographic collapse	Total healthcare system security failure

CRITICAL RESEARCH BREAKTHROUGH

Recent study (Wei et al., 2022) suggests RSA-2048 could be broken by a quantum circuit with only **372 physical qubits** at a circuit depth of thousands - SIGNIFICANTLY lower than previous estimates of 20 million qubits.

Source: https://arxiv.org/abs/2212.12372

Implication

CRQC arrival timeline potentially ACCELERATED; healthcare organisations have LESS time than previously thought.

3.3 | HEALTHCARE CRYPTOGRAPHIC VULNERABILITIES

Healthcare System	Current Encryption	Quantum Attack Method	Risk Level	Breakage Timeline
EHR Platforms	RSA-2048, AES-256	Shor's + Grover's algorithms	CRITICAL	2027-2029
PACS/ Medical Imaging	TLS/SSL, AES-128	Both algorithms	CRITICAL	2027-2029



Healthcare System	Current Encryption	Quantum Attack Method	Risk Level	Breakage Timeline
HL7/FHIR APIs	OAuth2, JWT (RSA- based)	Shor's algorithm	CRITICAL	2027-2028
Medical Devices	ECC (elliptic curve), AES-128	Both algorithms	EXTREME	2026-2028
Genomic Databases	AES-256, RSA-4096 PKI	Both algorithms	PERMANENT RISK	2028-2030
Clinical Trial Systems	SSL/TLS, RSA-2048	Both algorithms	CRITICAL	2027-2029
Telemedic ine Platforms	WebRTC (DTLS- SRTP), RSA	Shor's algorithm	HIGH	2027-2029
Pharmacy Systems	TLS 1.2/1.3, AES-256	Grover's algorithm (partial)	CRITICAL	2029-2031

Quantum Attack Methodologies

Shor's Algorithm

Efficiently factors large numbers and solves discrete logarithm problems

→ breaks RSA, ECC, Diffie-Hellman

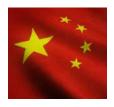
Grover's Algorithm

Speeds up unstructured search → reduces effective key length by half (AES-256 becomes AES-128 equivalent)

THREAT ACTOR CAPABILITIES & ATTRIBUTION

4.1 | NATION-STATE ACTORS

CHINA



Capabilities

Advanced quantum research; operational quantum network; significant qubit development

Healthcare Targets

Pharmaceutical IP, clinical trial data, genomic research (population health studies)

Attribution

APT groups linked to Ministry of State Security (MSS), PLA Unit 61398

HNDL Activity

Active since 2018+; massive collection of encrypted medical research databases

Motivation

Economic espionage, technology transfer, strategic advantage in biotechnology

RUSSIA



Capabilities

State-sponsored cyber operations; SVR (Foreign Intelligence Service) advanced persistent threats

Healthcare Targets

Biopharma companies, vaccine research, biodefense data

Notable Operations

2023-2024 SVR exfiltrated terabytes from Microsoft corporate email (US government accounts)

HNDL Activity

Collection of pharmaceutical manufacturing data, regulatory submissions

Motivation

Economic gain, disruption of Western pharmaceutical dominance



NORTH KOREA



Capabilities

Cyber-criminal nexus; sophisticated cryptocurrency theft operations

Healthcare Targets

Healthcare ransomware (funding regime), pharmaceutical companies

Methods

Cybercrime for revenue generation (circumvents sanctions); hacking-for-hire

Partnerships

Working with foreign criminal networks as third-party enablers

HNDL Activity

Opportunistic collection for future ransomware campaigns

4.2 | ORGANIZED CYBERCRIME GROUPS

Healthcare Ransomware Operators

IRAN



Capabilities

Increased cyberattack sophistication; regional cyber warfare focus

Healthcare Targets

Israeli healthcare institutions, Western pharmaceutical companies

Recent Activity

Escalation of cyberattacks, cyberespionage, information operations

Motivation

Political objectives, regional conflict, economic sanctions circumvention

LockBit, ALPHV/ BlackCat, Royal

Specifically targeting healthcare (highest ransom payment rates)

Average Healthcare Ransom

\$1.5 million+
(healthcare pays 65%
of the time due to
operational criticality)

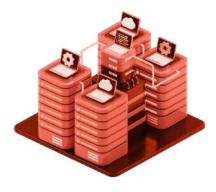
Quantum Preparation

Collecting encrypted backups for future decryption and extortion

Triple Extortion

Encryption + data theft + threatening patient notification

Data Brokerage Networks



- Underground Markets
 Medical records selling for \$250-\$1,000 each (vs \$1-\$2 for credit cards)
- Genomic Data
 Premium pricing for genetic information
- Prescription Data
 Valuable for pharmaceutical marketing, insurance fraud

4.3 | CORPORATE ESPIONAGE

Pharmaceutical Competitors:

- Domestic & International
 Stealing drug formulations, clinical trial results,
 manufacturing processes
- Methods
 Insider threats, supply chain compromises, encrypted data collection
- Value
 Billions of dollars in R&D shortcuts; accelerated time-to-market

Biotech Startups

IP Theft

Novel therapeutic approaches, gene therapy techniques, personalised medicine algorithms

Quantum Opportunity

Encrypted research communications, patent applications, investor presentations

MITIGATION STRATEGIES & IMPLEMENTATION ROADMAP

5.1 | IMMEDIATE ACTIONS (Q4 2025 - Q1 2026)

A | COMPREHENSIVE DATA MAPPING (Address 27% with no visibility)

- ✓ Identify ALL sensitive data storage locations (PHI, genomic, clinical trials, R&D)
- ✓ Create a detailed data inventory across 77 SaaS applications
- ✓ Document data flows through 500-1,000+ APIs



Priority

Patient-facing systems, genomic databases, clinical trial platforms



Tool

Implement unified data discovery platform (consolidate from 5+ tools)

B | CRYPTOGRAPHIC ASSET INVENTORY

Audit current encryption implementations across the entire infrastructure

Map dependencies: internal systems, third-party vendors, cloud providers

Create Cryptographic Bill of Materials (CBOM) - document every algorithm, key, certificate

Required for HIPAA quantum updates, OMB M-23-02, EU NIS2

Compliance

Identify quantum-vulnerable systems (RSA, ECC, DES, legacy TLS)

C | CLOUD SECURITY ENHANCEMENT (Currently only 4% adequate)

Encrypt 80%+ of sensitive cloud data (nearly 50% currently sensitive but unprotected)

Conduct cloud security posture assessments

Encrypt 80%+ of sensitive cloud data (nearly 50% currently sensitive but unprotected)

Timeline

Achieve 80% encryption by Q2 2026

Deploy Quantum Random Number Generators (QRNG) for high-entropy keys

D | API SECURITY HARDENING (500-1,000+ API vulnerability surface)

Implement quantum-safe authentication for all APIs

Establish an API gateway with centralised <u>PQC</u> enforcement

Update OAuth2, JWT implementations to use <u>PQC</u> algorithms

✓ Standard

Monitor API traffic for anomalous encrypted data exfiltration

Align with HL7 FHIR quantum security extensions (under development)

E | LEGACY SYSTEM PRIORITIZATION

Inventory systems requiring PQC upgrades

✓ Priority Order

Identify systems requiring hardware replacement vs software updates

Genomic databases

Develop sunset plans for systems that cannot be upgraded

- Clinical trial systems
- Medical devices

EHR platforms

Administrative systems



F | GOVERNANCE & POLICY

- Establish C-level quantum security oversight committee
- Board-level quantum risk reporting (required by EU NIS2)
- Update incident response plans for quantum breach scenarios
- Develop quantum security policies and standards
- Compliance

Data Protection Impact Assessment (DPIA), including quantum risk

5.2 | SHORT-TERM IMPLEMENTATION (2026-2027)

A | POST-QUANTUM CRYPTOGRAPHY PILOTS (Join 50%+ already evaluating)

- Deploy NIST-approved algorithms in test environments
 - ML-KEM (FIPS 203)
 Key encapsulation for EHR, databases
 - ML-DSA (FIPS 204)
 Digital signatures for authentication, audit logs
 - SLH-DSA (FIPS 205)
 Long-term signatures for genomic data, clinical trials

- Measure performance impact (CPU, latency, storage)
- Test interoperability with existing systems
- Validate FIPS 140-3 compliance for the US market

Source: https://www.nist.gov/news-events/news/2024/08/nist-releases-first-3-finalized-post-quantum-encryption-standards#:~:text=Federal%20Information%20Processing%20Standard%20(FIPS,Lattice%2DBased%20Digital%20Signature%20Algorithm.

B | MEDICAL DEVICE SECURITY TRANSFORMATION

- Engage manufacturers on quantum-safe firmware updates
- Update procurement requirements: mandate <u>PQC</u> support for all new devices
- Prioritise life-critical devices: pacemakers, insulin pumps, ventilators
- Timeline

Critical devices by 2028 (EU CRA requirement, FDA guidance)

Regulatory

Align with FDA medical device cybersecurity guidance updates

C | EHR PLATFORM QUANTUM MIGRATION

Coordinate with Epic, Oracle Health (Cerner),
Allscripts, Athenahealth

Patient data export/import testing with quantum-safe encryption

Implement hybrid encryption (classical + <u>PQC</u>) during transition

Timeline

Ensure HIPAA compliance throughout migration

Begin migration 2026; complete by 2029

D | QUANTUM-RESISTANT KEY MANAGEMENT (Address 69% key distribution concern)

Implement enterprise-wide Key Management System (KMS) with <u>PQC</u> support

Certificate lifecycle management automation (prepare for 47-day renewal cycle by 2029)

Deploy Quantum Random Number Generators (QRNG) for cryptographic key generation

Standard

Establish quantum-safe Public Key Infrastructure (PKI)

Align with NIST SP 800-57 key management guidance (PQC updates)

E | GENOMIC DATA SPECIAL PROTECTION (Permanent sensitivity requires the strongest security)

Implement quantum-safe encryption for all genomic databases

Anonymisation techniques resilient to quantum reidentification attacks

Consider Quantum Key Distribution (QKD) for the highest-security genomic repositories

Compliance

Strict access controls with quantum-resistant authentication

GDPR Article 9 special category data; genetic nondiscrimination laws

F | CLINICAL TRIAL SYSTEM HARDENING

Quantum-safe encryption for patient recruitment, randomisation, and data collection

FDA/EMA submission portals quantum-safe authentication

Protect statistical analysis plans, interim results, and final reports

✓ Timeline

info@qnulabs.com

Secure investigator communications, site monitoring data

New trials starting 2027+ must use

G | SUPPLY CHAIN QUANTUM REQUIREMENTS

Update Business Associate Agreements (BAA) with quantum security provisions

Third-party security audits verify PQC implementation

Vendor risk assessments, including <u>PQC</u> readiness

Compliance

Procurement contracts mandate quantum-safe

EU NIS2 supply chain security requirements

compliance timelines

5.3 | MEDIUM-TERM TRANSFORMATION (2027-2030)

A | HOSPITAL-WIDE PQC DEPLOYMENT

Roll out quantum-safe encryption across ALL hospital systems

Staff training programs

IT administrators, clinicians, compliance officers

- Electronic Medical Records (EMR), Laboratory
 Information Systems (LIS), Radiology Information
 Systems (RIS)
 - Pharmacy systems, billing, scheduling, patient portals

Patient communication

Data protection enhancements, privacy assurances

B | PHARMACEUTICAL MANUFACTURING PROTECTION

Quantum-safe encryption for batch records, quality control data

Serialisation and anti-counterfeiting systems quantumresistant

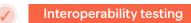
- Manufacturing execution systems (MES) with PQC
 - Secure supply chain from raw materials to distribution

Regulatory

EU GMP Annexe 11 updates for quantum security

C | HEALTH INFORMATION EXCHANGE (HIE) QUANTUM-SAFE STANDARDS

Develop quantum-safe HL7 FHIR implementation guides



National/regional HIE infrastructure PQC deployment

Ensure quantum-safe systems communicate seamlessly

Cross-border health data sharing with quantum security





Whitepaper →

Case Study →

Tomorrow's Quantum Security, Today.



Scan for more details

Registered Office:

QuNu Labs Private Limited, Centenary Building, 2nd Floor, East Wing, #28 MG Road Bengaluru - 560025. Karnataka | India

CIN: U72900KA2016PTC096629

India USA Australia Global