ASSESSED INTELLIGENCE

CASE STUDY · AI-CASE-2026-003

Building Governance into an AI Healthcare Startup

How a pre-seed digital health startup embedded security and AI governance through the ARISE Framework™ and cleared its first health-system security review with zero remediation.

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ENGAGEMENT	vCISO retainer with vCRAIO capacity
METHODOLOGY	ARISE Framework™
CLASSIFICATION	Public

Secure & Responsible Technology.

ENGAGEMENT SNAPSHOT

CLIENT PROFILE	CORE SERVICE	METHODOLOGY	PRIMARY OUTCOME
Pre-seed digital health startup building an AI clinical workflow platform.	**Assessed Intelligence vCISO Retainer with vCRAIO (virtual Chief Responsible AI Officer) capacity.**	**ARISE Framework™**	**Zero-remediation health-system security review clearance & unified audit readiness.**

01 · THE CHALLENGE

Speed vs. Regulated AI Complexity

The startup was developing an AI-enabled clinical workflow platform designed to ingest Protected Health Information (PHI), draft documentation, and surface insights for healthcare providers. Moving rapidly toward its first health-system pilot and Series A fundraising, the company faced significant headwinds:

- **Ungoverned AI Data Flows:** Third-party model providers processed PHI without formal inventory, classification, or oversight.
- **No Formal Security Function:** The team lacked dedicated security personnel, a compliance program, or an AI governance layer.
- **High Customer & Investor Stakes:** Key commercial milestones depended on passing rigorous health-system security assessments, SOC 2 reviews, and HIPAA diligence.
- **Future Regulatory Overhead:** Potential oversight by the FDA as Software as a Medical Device (SaMD) required early, structured quality records.
- **Compounding Cost of Delay:** Modifying architectural data-handling choices post-scale creates prohibitive migration costs compared to early design fixes.

Contextually, 76% of critical-sector organizations have AI risk-governance gaps,[1] and data breaches involving AI reached an average cost of $4.63 million.[2] The startup needed to embed security controls before its product architecture hardened.

02 · THE SOLUTION

Shifting Left via the ARISE Framework™

Assessed Intelligence deployed a fractional CISO with vCRAIO capabilities to integrate security and governance directly into the engineering roadmap. By translating compliance requirements into software architecture decisions, security

became an engineering default.

Work was delivered across the seven ARISE Framework domains, sequenced strategically by leverage:

ARISE Framework Implementation Across 7 Domains

- **Govern:** Established AI acceptable-use standards (G.GV.C-01), formal AI policies (G.GV.P-04), and an owned AI risk register (G.RM-03) before building model integrations.
- **Manage:** Implemented a standing risk-management operational cadence (M.RM-02) and integrated security onboarding into early hiring processes (M.HR).
- **Identify:** Built a real-time AI system inventory (I.AM-01), completed PHI data flow mapping across schemas (I.DG-01), and performed baseline risk assessments (I.RM-01).
- **Protect:** Embedded data classification in the data model (P.DS-01), designed least-privilege tenant isolation (P.AC-02), set secure coding guardrails (P.AC-04), and provided AI risk training (P.AT-01).
- **Detect:** Provisioned centralized logging, continuous access monitoring (D.CM), and anomaly detection for sensitive data transfers (D.AD) alongside cloud infrastructure.
- **Respond:** Formulated an Incident Response Plan with tabletop testing (R.IR-01) and established HIPAA/state breach notification readiness (R.IC.E-01).
- **Validate:** Established internal security review cadences (V.CI-03) and maintained living audit readiness for SOC 2, HIPAA, and FDA SaMD classification requirements (V.EA-01).

Prioritized Build Sequence

1. **Set the Rules:** Defined acceptable-use parameters and established risk ownership.
2. **Make it Visible:** Mapped PHI paths and created an authoritative AI inventory.
3. **Enforce in Architecture:** Built least-privilege access, schema-level classification, and secure development guardrails.
4. **Detect Failures:** Deployed automated logging and anomalous movement alerting.
5. **Train & Prepare:** Trained staff and validated incident response protocols.
6. **Validate & Audit:** Maintained continuous evidence mapping for investors, health systems, and regulators.

03 · STRATEGIC OUTCOMES & BUSINESS IMPACT

Strategic Outcomes & Business Impact

By embedding security at the pre-seed stage, the startup converted compliance into a strategic growth lever:

- **Seamless Commercial Entry:** The company cleared its initial health-system vendor security assessment without the costly remediation delays that typically stall early-stage vendors.

- **Unified Compliance Efficiency:** Overlapping HIPAA, SOC 2, and enterprise security requirements were satisfied through a single consolidated body of evidence.
- **FDA SaMD Preparedness:** Documentation, data governance, and quality records were structured so that future FDA regulatory classifications can be reasoned directly from existing systems.
- **Commercial Advantage:** Governance grounded in the ARISE Framework reassured health-system buyers and served as a key discriminator that accelerated contract signing.

SOURCES

1. Assessed Intelligence Research, Q1 2026.
2. IBM, Cost of a Data Breach Report 2025.

NEXT STEP

Put the ARISE Framework™ to work for your organization.

Every engagement starts with an honest picture of where you stand. Our advisors map your environment against the ARISE Framework and build the path to governance that holds up under scrutiny.

Speak with an Advisor → assessedintelligence.com/contact

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