

## QUANTITATIVE RISK MODELING FOR DATA LOSS AND RANSOMWARE MITIGATION IN GLOBAL HEALTHCARE AND PHARMACEUTICAL SYSTEMS

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### Abstract

This study addresses the escalating problem of data loss and ransomware in globally networked healthcare and pharmaceutical ecosystems, where cross-border cloud and enterprise interdependencies amplify tail risk. The purpose is to develop and test a quantitative risk model that links measurable control maturity to three outcomes: perceived 12-month ransomware likelihood, expected data-loss severity, and expected financial loss. Using a quantitative, cross-sectional, case-based design, we surveyed security, IT, and governance leaders from cloud-enabled and on-premise enterprise cases across providers, payers, pharmaceutical manufacturers, and CROs, and triangulated results with purposively selected organizational cases. Key variables captured six capability domains on five-point Likert scales: Security Control Maturity, Backup and Recovery Readiness, Network Segmentation and Zero-Trust, Security Awareness and Training, Third-Party Risk Management, and Regulatory Compliance Posture. The analysis plan comprised descriptives, correlations, ordered logit or probit for ordinal outcomes, and log-linear OLS for transformed financial-loss bands, with interactions for architectural and governance complementarities, and cluster-robust or heteroskedasticity-consistent errors plus fixed effects for segment and region. Headline findings show that Backup and Recovery Readiness is the strongest predictor of lower severity, Network Segmentation and Zero-Trust most reduces ransomware likelihood, and Third-Party Risk Management, especially when paired with auditable compliance posture, yields the largest percentage reduction in expected financial loss, while size, cloud intensity, and IT or OT coupling raise baseline risk but are partially offset by these controls. Implications prioritize immutable, routinely tested backups, micro-segmentation with least privilege, enforceable vendor governance, and board-visible resilience metrics that translate coefficients into Expected Annual Loss and Expected Shortfall for capital allocation.

### Keywords

Ransomware, Data Loss, Healthcare Cybersecurity, Pharmaceutical Gxp, Quantitative Cross-Sectional, Multi-Case, Cloud and Enterprise Cases,

### Citation:

Hasan, M. T. (2023). Quantitative risk modeling for data loss and ransomware mitigation in global healthcare and pharmaceutical systems. *International Journal of Scientific Interdisciplinary Research*, 4(3), 87–116.

<https://doi.org/10.63125/8wk2ch14>

### Received:

July 09, 2023

### Revised:

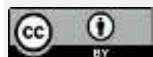
August 10, 2023

### Accepted:

September 20, 2023

### Published:

October 25, 2023



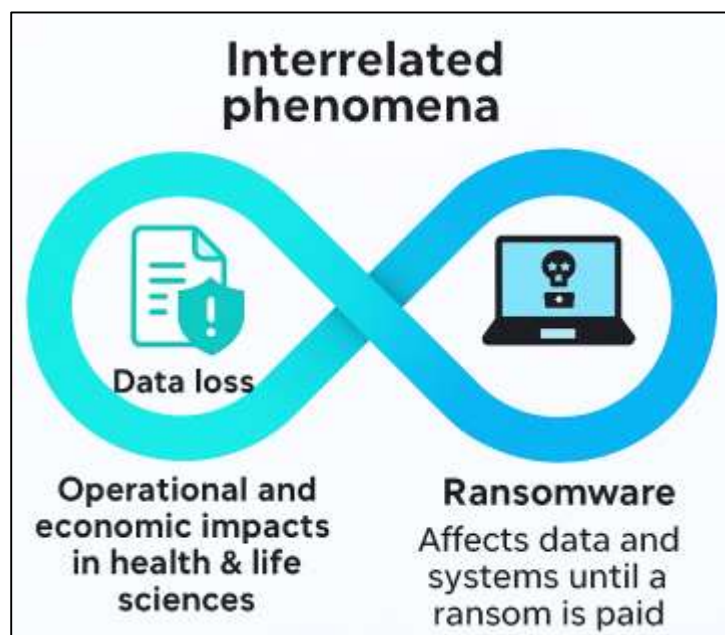
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## INTRODUCTION

Data loss and ransomware are two interrelated phenomena with distinct operational and economic implications in health and life-science enterprises. *Data loss* refers to the unauthorized disclosure, exfiltration, alteration, destruction, or unavailability of data due to malicious activity, human error, system failure, or disaster, resulting in confidentiality, integrity, and availability (CIA) harms; in regulated contexts such as healthcare and pharmaceuticals, these harms extend to patient safety, continuity of care, and GxP data integrity (Appari & Johnson, 2010). *Ransomware* is a form of malicious software that encrypts or otherwise renders data and systems unavailable until a ransom is paid, increasingly coupled with “double” and “triple” extortion involving data theft, public shaming, and threats against suppliers or patients. Globally, the international significance of these threats stems from the cross-border nature of supply chains, cloud ecosystems, contract research organizations (CROs), and third-party platforms that interconnect providers, payers, and pharmaceutical manufacturers; a single compromise can propagate operational disruptions across multiple jurisdictions and regulatory regimes. In health care delivery organizations, ransomware has measurably increased in frequency and scale since the mid-2010s, exposing tens of millions of patients and degrading clinical operations. In parallel, electronic health record (EHR) adoption and data-intensive manufacturing/quality systems in pharma have expanded the attack surface, raising the salience of backup/restore readiness, network segmentation and zero-trust controls, user security competencies, vendor risk management, and compliance assurance (Kim & Kwon, 2019). These developments have intensified calls for quantitative risk modeling able to link control maturity to incident likelihood, loss severity, and expected financial loss in internationally networked healthcare and pharmaceutical systems. By situating data-loss and ransomware within an international, compliance-laden ecosystem, this study frames the urgent need for cross-sectional, case-informed evidence that can inform prioritization of mitigation investments across regions and industry segments (Coventry & Branley, 2018).

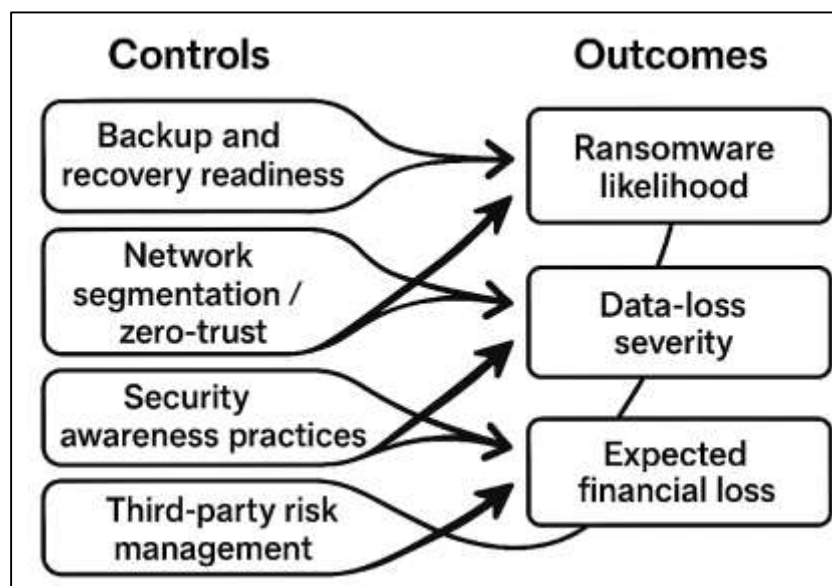
**Figure 1: Interrelation of Data Loss and Ransomware in Health and Life-Science Ecosystems**



Empirical work has documented the growth and changing characteristics of ransomware affecting hospitals and clinics larger multi-facility organizations are more frequently targeted; breaches increasingly expose more protected health information; and recovery from backups appears less common than assumed. Complementary research shows healthcare data breaches are driven by a mix of external attacks and internal process failures, with measurable organizational antecedents. Yet despite this maturing evidence base, quantitative models that simultaneously test how specific controls backup and recovery readiness, network segmentation/zero-trust, security awareness

practices, third-party risk management, and regulatory compliance posture predict ransomware likelihood, data-loss severity, and expected financial loss remain underdeveloped at international scale (Martin et al., 2018). Studies have examined health-system cybersecurity capability dynamics and provided organizational perspectives on capability building (Jalali & Kaiser, 2018) and have modeled factors associated with healthcare data breaches using secondary data sources, but few offer cross-sectional survey evidence directly linking control maturity to incident outcomes across provider, payer, pharma manufacturing, and CRO contexts. Regulatory research suggests that HIPAA omnibus provisions and state/federal oversight can reduce breach frequency in certain settings, while the GDPR has altered breach reporting and risk governance across the EU, though its operational effectiveness and unintended consequences remain debated in the empirical literature. In parallel, EHR and meaningful use initiatives have reshaped digital exposure and, in some analyses, are associated with changes in breach occurrence (Kim & Kwon, 2019; Sanjid & Farabe, 2021). Taken together, these strands underscore a persistent measurement gap: organizations need validated, survey-based constructs of control maturity and statistically grounded estimates of their relationships to ransomware and data-loss outcomes, controlling for size, cloud intensity, IT/OT coupling, and regional regulatory context (Omar & Rashid, 2021). Beyond hospitals and ambulatory settings, pharmaceutical manufacturing and quality systems operate under GxP (Good Practice) frameworks that require data to be attributable, legible, contemporaneous, original, and accurate (ALCOA/ALCOA+) across distributed digital ecosystems. Digitalization of manufacturing, laboratory information management systems, and interconnected suppliers creates new dependencies in which a single compromised partner or misconfigured cloud resource can jeopardize data integrity and batch release decisions (Zaman & Momena, 2021).

**Figure 2: Conceptual Model of Cybersecurity Control Maturity and Ransomware Outcomes in Healthcare**



International supply chains magnify this risk, as do cross-border clinical data flows, pharmacovigilance systems, and contract development and manufacturing organizations (CDMOs). While case reports and reviews emphasize governance and best practices, there is limited quantitative evidence connecting specific maturity domains e.g., immutable/off-site backups and tested restores; micro-segmentation/zero-trust; vendor tiering with continuous monitoring; and formal audit/compliance processes to observed incident patterns and loss outcomes in pharma and CROs (Mubashir, 2021; Seh et al., 2020). Third-party/business-associate exposure is especially salient: U.S. federal analyses have repeatedly highlighted vendor-originated incidents as substantial contributors to health-sector breaches, with ripple effects across billing, clearinghouse, and data-exchange services (Rony, 2021; Zhang et al., 2019). Yet, quantitative cross-industry comparisons that include life-science organizations remain sparse, and few studies incorporate multi-region samples that can

capture GDPR-, HIPAA-, and local data protection regimes within one modeling framework (Syed Zaki, 2021). For global health and pharma decision-makers, an empirically supported risk model grounded in validated scales and case-study triangulation can help identify where investments in backup testing, segmentation, vendor risk controls, training, and compliance yield the largest marginal reduction in incident likelihood and expected financial loss. To enable robust quantitative testing, this study conceptualizes six predictor domains aligned with practice and standards literatures: Security Control Maturity (SCM), Backup & Recovery Readiness (BRR), Network Segmentation & Zero-Trust (NSZ), Security Awareness & Training (SAT), Third-Party Risk Management (TPRM), and Regulatory Compliance Posture (RCP). Prior work links strategic security investment and capability building to cyber incident patterns (Hozyfa, 2022; Parsons et al., 2017), while breach analytics in healthcare identify technical, human, and organizational mechanisms that are measurable via survey instruments. The SAT domain leverages validated behavioral instruments such as the HAIQ to operationalize end-user security awareness and behavior at scale (HHS, 2019; Arman & Kamrul, 2022). BRR reflects immutable/offsite backups, restore frequency, and objective recovery time/point objectives, directly addressing ransomware resilience and data-loss mitigation. NSZ captures micro-segmentation and zero-trust practices that restrict lateral movement and limit blast radius when perimeter controls fail, a strategy increasingly advocated in healthcare contexts. TPRM includes vendor tiering, continuous security ratings/monitoring, and contractual controls, reflecting evidence that business associates materially contribute to breach counts and scale. RCP measures audit cadence, remediation tracking, and alignment with HIPAA, GDPR, and GxP expectations. Outcomes include perceived 12-month ransomware likelihood (ordinal), expected data-loss severity (ordinal), and expected financial loss per incident (banded, log-transformed for modeling). This construct design allows reliability/validity assessment and multivariable modeling that adjust for organizational size, cloud intensity, and IT/OT coupling covariates documented as salient in healthcare and life-science environments (Hasan & Omar, 2022).

This study's purpose is to provide cross-sectional, multi-case quantitative evidence connecting control maturity to ransomware and data-loss outcomes across global healthcare and pharmaceutical systems. Building on prior breach analytics and organizational cybersecurity research, we pose four research questions: (RQ1) How do maturity levels in SCM, BRR, NSZ, SAT, TPRM, and RCP relate to ransomware likelihood? (RQ2) Which domains most strongly predict expected data-loss severity conditional on compromise? (RQ3) How do organization size, cloud intensity, and IT/OT coupling moderate these relationships? (RQ4) Do effects differ across segments (provider, payer, pharma, CRO) and regions subject to HIPAA, GDPR, and analogous frameworks? These questions extend earlier work by translating practice-defined capabilities into psychometrically assessable constructs and evaluating their associations with outcomes of substantive managerial and regulatory interest. They further address regulatory and governance debates e.g., whether compliance posture alone reduces loss exposure versus whether it must be complemented by technical segmentation and verified backup readiness. By integrating an international multi-case lens, the study seeks to contextualize quantitative patterns with narrative contrasts such as differences between heavily cloud-enabled health networks and on-premises pharma plants operating legacy OT thereby offering a more granular understanding of how control domains perform under varied operational realities.

#### LITERATURE REVIEW

The literature on cybersecurity in healthcare and pharmaceutical ecosystems converges on a central tension: rapidly expanding digital connectivity through electronic health records, cloud platforms, laboratory information systems, connected medical devices, and globally distributed supply chains has outpaced the development and consistent adoption of controls that reliably prevent or contain ransomware and data-loss events. Scholarship traces an arc from early descriptive accounts of breach typologies and compliance challenges to more nuanced analyses that examine organizational antecedents, such as security governance, backup and recovery practices, micro-segmentation and zero-trust designs, staff awareness and training, and third-party risk management embedded in vendor-dense ecosystems. Parallel streams focus on the implications of regulatory regimes and quality frameworks HIPAA, GDPR, and GxP highlighting how mandatory reporting, audit cycles, and data-integrity expectations shape managerial incentives and measurement conventions. A recurring finding is that incidents are rarely attributable to a single failure; rather, they arise from interacting technical, human, and organizational factors across

providers, payers, manufacturers, CROs, and CDMOs. As ransomware tactics have evolved toward double- and triple-extortion, the literature increasingly emphasizes the value of immutable, routinely tested backups, least-privilege access, and lateral-movement controls to reduce blast radius and recovery times, while acknowledging persistent gaps in adoption, verification, and vendor oversight. Methodologically, studies range from narrative reviews and case analyses to breach-database modeling and survey-based assessments of security culture and capability maturity; yet few integrate constructs across both health delivery and life-science manufacturing contexts with comparable measurement and outcomes. Moreover, prior work often treats compliance posture as a proxy for security effectiveness, even though practical outcomes depend on the interplay between governance, technical architecture, and operational discipline. This review synthesizes these strands to establish a clear conceptual scaffold for quantitative testing: it distills threat and risk drivers specific to healthcare and pharma, catalogs mitigation capabilities with measurable indicators, and identifies modeling approaches suited to ordinal likelihood and severity outcomes as well as financial-loss estimation. The goal is to surface validated constructs, defensible measurement strategies, and analytic choices that will inform the study's survey instrument, case selection, and regression specifications, while delineating where the evidence remains incomplete or fragmented across regions and industry segments.

### Threat Landscape in Healthcare & Pharma

The contemporary threat landscape facing healthcare and pharmaceutical systems is shaped by two reinforcing dynamics: expansive digital interconnection and adversary professionalization. On the one hand, organizations now operate dense ecosystems electronic health records, lab information systems, IoMT devices, manufacturing execution systems, and cloud-based analytics stitched together across providers, payers, pharma manufacturers, and CROs. On the other, ransomware operators and data-theft groups have matured into supply-chain-aware actors that probe weakest links and monetize disruption. Synthesizing recent evidence, ransomware persists not merely as opportunistic encryption but as a bundle of tactics extortion via data theft, pressure on third parties (Mohaiminul & Muzahidul, 2022), and iterative negotiations that specifically exploits healthcare's low tolerance for downtime and pharma's high-value intellectual property. Systematic mappings of ransomware research emphasize increasing technical sophistication, evasive payloads, and the need for layered detection and containment beyond signature-based controls (Beaman et al., 2021). In parallel, broad reviews of ransomware incidents spanning critical infrastructure contexts and including health document common preconditions: credential reuse, unsegmented flat networks, and inadequate testing of restore procedures. These patterns underline a quantitative risk posture in which expected loss scales with both likelihood of compromise and downstream blast radius, a relationship we formalize as:

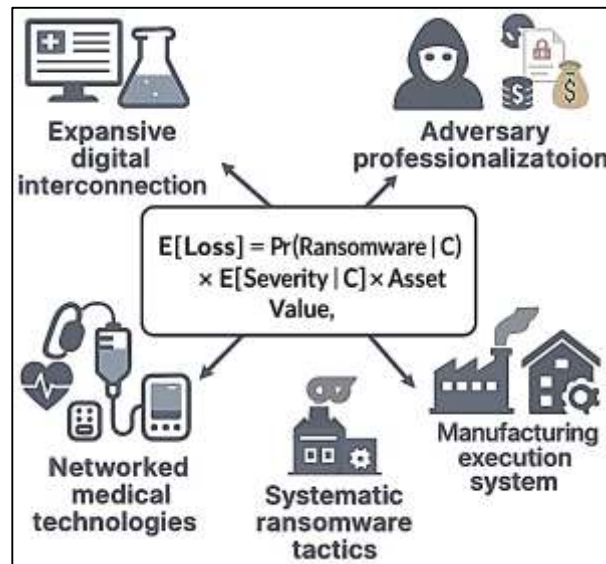
$$E[\text{Loss}] = \Pr(\text{Ransomware} | C) \times E[\text{Severity} | C] \times \text{Asset Value},$$

where  $C$  summarizes control maturity (e.g., backup testing, micro-segmentation, vendor risk governance) and "Asset Value" encapsulates regulated data, continuity of care, and cGMP/GxP integrity (Omar & Ibne, 2022; Reshmi, 2021). This framing clarifies why seemingly "compliant" environments still experience material harm: when  $\Pr(\cdot)$  remains nontrivial due to exposed edges in identity, third-party connectivity, or lateral movement controls, and  $E[\text{Severity} | C]$  is elevated by weak isolation or slow recovery, the expected loss is large even before reputational and regulatory penalties are considered (Hameed et al., 2021; Hasan, 2022).

A second pillar of the landscape is the rapid proliferation of networked and software-defined medical technologies. Internet-connected implants, infusion pumps, imaging suites, and diagnostics expand clinical capability but also widen attack surfaces via legacy stacks, insecure update channels, and vendor remote-access tools (Mominul et al., 2022). Empirical analyses of disclosed vulnerabilities across two decades show steady growth in issues affecting health software and devices, with notable concentrations in authentication/authorization, input validation, and third-party libraries; the distribution of weaknesses implies that post-market patching and network isolation are as critical as pre-market "security by design" (Carrillo-de-Gea et al., 2023; Rabiul & Praveen, 2022). Complementing that evidence, system-level reviews of IoMT security and privacy highlight persistent gaps between traditional IT defenses and the latency, safety, and lifecycle constraints of clinical devices: certificate management is uneven, segmentation is partial, and legacy endpoints linger in high-trust zones to preserve clinical workflows (Hameed et al., 2021; Farabe, 2022). For quantitative modeling, these device-layer realities primarily influence the severity term in the

expected-loss identity by enabling lateral movement and prolonging mean time to recovery (Pankaz Roy, 2022); they also shape likelihood through exposed services and default credentials. Importantly, many of these weaknesses propagate across organizational boundaries: device vendors operate managed update services; hospital networks share imaging and telemetry with external specialists; and CROs interface with sponsor systems for trial data collection. Thus, “perimeter” concepts are insufficient risk must be estimated over inter-firm graphs where the path of least resistance may traverse suppliers and service providers rather than the originally targeted entity (Rahman & Abdul, 2022; Reshmi, 2021).

**Figure 2: Threat Landscape in Healthcare and Pharmaceutical Systems**



A third, equally consequential facet concerns strategic technology transitions 5G connectivity, edge analytics, and cloud-first architectures that confer clinical agility while introducing throughput-scale exposure and governance complexity. Analyses of the impending IoMT-and-5G wave argue that without explicit cyber-risk design, organizations can experience nonlinear growth in breach frequency because higher device density and low-latency telemetry magnify both attack surface and interdependence (Razia, 2022; Tarikere et al., 2021). At the same time, the ransomware knowledge base underscores that attackers increasingly combine initial access brokering with “big-game hunting,” targeting environments where operational urgency (e.g., emergency medicine, sterile manufacturing, cold-chain logistics) strengthens ransom leverage. Bringing these strands together suggests a modeling perspective in which control domains backup/recovery readiness, zero-trust segmentation, security awareness, vendor-risk governance, and compliance posture play dual roles: they reduce  $\Pr(\text{Ransomware} | C)$  by limiting initial footholds and privilege escalation, and they compress  $E[\text{Severity} | C]$  by bounding lateral spread and accelerating validated restore (Syed Zaki, 2022; Kanti & Shaikat, 2022). Systematic evidence on ransomware's trajectory indicates that resilience hinges less on any single control and more on combinatorial adequacy tested restores plus least-privilege plus third-party oversight implemented consistently across clinical and manufacturing contexts. Accordingly, the present study's quantitative design treats control maturity as a vector rather than a scalar, enabling estimation of marginal effects and interaction terms that reflect the ecosystem realities documented in both ransomware syntheses and IoMT-security reviews (Carrillo-de-Gea et al., 2023; Danish, 2023a, 2023b).

#### **Risk Drivers & Organizational Factors**

At the organizational level, ransomware and data-loss exposure in healthcare and pharmaceutical settings arises from layered sociotechnical drivers that interact across governance, architecture, and operations. First, governance structures determine whether security investments are proactive (guided by risk and capability roadmaps) or reactive (triggered by incidents and regulatory scrutiny). Evidence from the healthcare sector shows that proactive investments are associated with lower

failure rates than post-breach, reactive spending, underscoring the role of management intent and learning in shaping breach likelihood. Second, architectural choices especially the convergence of information technology (IT) and operational technology (OT) reshape attack surfaces. In life-science manufacturing and clinical environments, cyber-physical dependencies and legacy control systems amplify lateral-movement opportunities and recovery complexity if network segmentation and least-privilege access are not consistently enforced (Dissanayake et al., 2022; Arif Uz & Elmoon, 2023). Third, operational routines such as backup validation, change control, and patch governance ultimately modulate both the probability and severity of loss: immutable, routinely tested backups compress recovery time, while disciplined configuration and update practices limit privilege escalation and blast radius. Finally, inter-organizational coupling through health information exchanges (HIEs), vendor platforms, CRO/CDMO interfaces, and cloud service relationships introduces path-dependent risk that is partly outside any single entity's direct control, making third-party governance and shared standards pivotal. A recent scoping review of personal health-data failures consolidates these strands into a multi-factor picture in which human, process, and technology deficits co-produce incidents a perspective that supports modeling risk as a function of control maturity vectors rather than single "silver bullet" controls (Humayed et al., 2017; Muhammad & Redwanul, 2023). Within this multifactor setting, several measurable organizational factors recur. Participation in inter-organizational data-sharing arrangements can either raise or reduce breach exposure depending on accompanying governance: strong exchange rules, accountability, and standardized security practices may offset the incremental surface introduced by additional interfaces. Patch-management timeliness is another determinant; coordination delays and socio-technical frictions in healthcare workflows are repeatedly implicated in extended exposure windows. To capture these drivers parsimoniously in our quantitative model, we operationalize breach likelihood with a logistic link that embeds organizational controls and context:

$$Pr(\text{Breach} | X) = \sigma(\beta_0 + \beta_1 \text{SCM} + \beta_2 \text{BRR} + \beta_3 \text{NSZ} + \beta_4 \text{TPRM} + \beta_5 \text{RCP} + \beta_6 \text{SIZE} + \beta_7 \text{CLOUD} + \beta_8 \text{IT/OT} + \beta_9 \text{HIE} + \beta_{10} \text{PATCH}),$$

where  $\sigma(z) = 1/(1 + e^{(-z)})$ , SCM is overall security-control maturity, BRR is backup-and-recovery readiness, NSZ is network segmentation/zero-trust, TPRM is third-party risk management, RCP is compliance posture, and PATCH quantifies patch-governance performance. This specification allows us to test whether participation in HIEs (HIE) is protective (through standardization and monitoring) or risky (through additional interfaces) conditional on control maturity elsewhere in the system; it likewise captures whether IT/OT convergence effects are mitigated by strong segmentation (interaction terms explored later). Empirical studies of HIE participation and healthcare breach risk indicate that, under robust governance, exchange membership can lower breach likelihood; complementary work in hospitals documents how patching delays emerge from coordination bottlenecks in real-world clinical operations, reinforcing the need to measure PATCH as an operational capability rather than a policy statement.

science environments, which magnify the cost side of the risk calculus. OT devices in sterile production, building-management systems supporting controlled environments, and safety-critical clinical equipment often operate on long lifecycle horizons with vendor-controlled updates and legacy stacks. Absent compensating controls (micro-segmentation, allow-listing, strict identity and access management, and disaster-recovery drilling), these constraints increase both the conditional severity of incidents and the effort needed to restore validated states in cGMP/GxP contexts. When mapped back to expected loss, these organizational factors act through both the probability and severity channels (Kwon & Johnson, 2014; Razia, 2023; Reduanul, 2023). In practice, organizations that combine proactive security investment programs with mature segmentation and verified backup routines tend to occupy lower-risk regions of the parameter space, while those relying primarily on compliance attestations without operational discipline remain exposed to multi-point failure cascades. For our study, these observations motivate measuring maturity as vectors across governance, architecture, and operations; they also motivate modeling interactions (e.g., NSZ×SCM; PATCH×OT) that reflect how one domain can amplify or dampen another. Foundational surveys of cyber-physical systems security supply the conceptual bridge between traditional IT controls and OT realities in health and pharma, reinforcing the need to treat IT/OT as a first-class covariate in breach modeling and case selection (Sadia, 2023; Srinivas & Manish, 2023; Zayadul, 2023).

Figure 3: Governance Dynamics in Healthcare and Pharma Cybersecurity



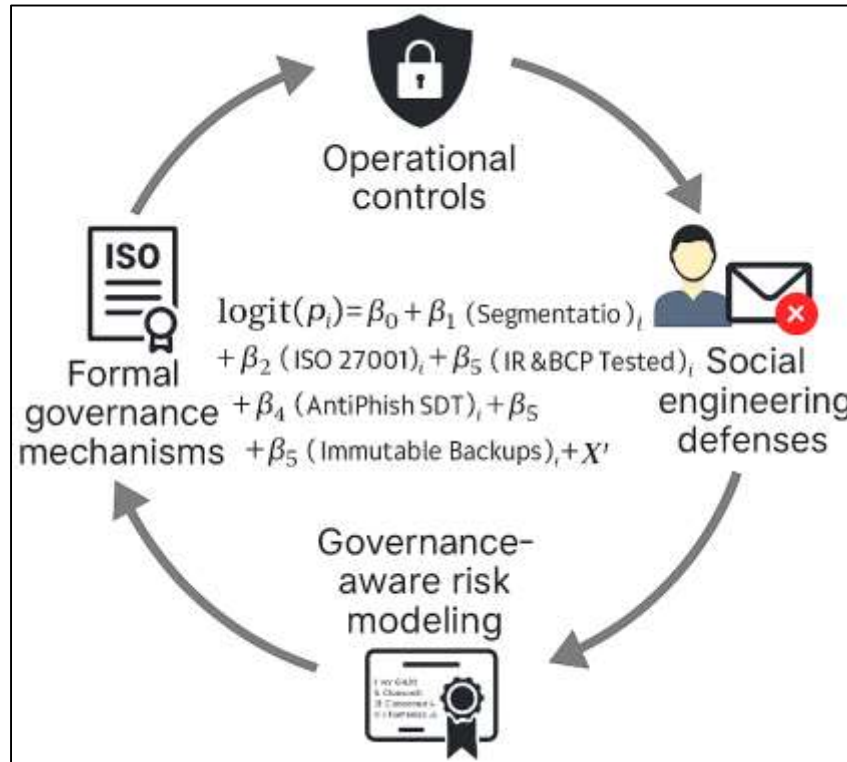
This figure presents an integrated model of organizational risk dynamics within healthcare and pharmaceutical cybersecurity ecosystems. It conceptualizes how IT/OT convergence, where information and operational technologies integrate, initiates systemic interdependencies that influence cyber risk exposure. Governance structures—ranging from proactive to reactive investment strategies—shape the organization's resilience posture. Operational routines, including backup validation, patching, and change control, serve as critical control layers mitigating ransomware and data-loss risks. The model highlights inter-organizational coupling, emphasizing vulnerabilities arising from vendor, CRO, and cloud dependencies, which extend the attack surface beyond institutional boundaries. Cyber-physical constraints, such as legacy systems and regulatory compliance limitations, further define the operational environment, while a quantitative risk model provides a data-driven framework for evaluating breach probability and security maturity. Together, these components form a cyclical governance ecosystem that reflects the evolving interplay between digital transformation, regulatory compliance, and cybersecurity resilience in health-sector enterprises.

#### Mitigation Capabilities and Governance

Effective ransomware mitigation in healthcare and pharmaceutical systems hinges on building and continuously testing defense-in-depth capabilities within a formal governance scaffold. Two mutually reinforcing levers matter most: (a) operational controls that directly reduce compromise probability or limit blast radius (e.g., network segmentation/micro-segmentation, privileged access management, backup/restore hygiene, endpoint detection and response, anti-phishing programs); and (b) governance mechanisms that align those controls to risk appetite, assign accountability, and keep practices auditable and improvable (e.g., board-visible metrics, policy compliance regimes, and third-party assurance such as ISO/IEC 27001). Empirical evidence suggests that organizations that institutionalize an information security management system (ISMS) under ISO/IEC 27001 realize measurable performance advantages, plausibly via disciplined control selection, internal auditing, and continual improvement cycles the very activities needed to operationalize ransomware resilience (Podrecca et al., 2022). In capital markets, security management certifications also function as credible governance signals: investors penalize breaches less when firms hold ISO 27001 issued by independent bodies, implying that robust, externally validated governance can mitigate reputational loss pathways even when incidents occur (Tang & Yang, 2023). In clinical environments, this governance logic translates into codified incident roles

(executive, clinical, IT/OT), recovery time/point objectives mapped to care pathways, and attested supplier controls across EHR, imaging, lab, and pharmacy ecosystems all tracked in dashboards that escalate deviations as risks rather than IT “issues.”

**Figure 4: Mitigation Capabilities for Ransomware Resilience in Healthcare & Pharma**



Mitigation capabilities must also address the statistically dominant initial access vector social engineering by shaping human decisions at the inbox and at the console. Randomized training alone is insufficient unless it measurably improves users' signal detection (sensitivity) while reducing risky response bias; controlled experiments show that feedback and consequence-salient training change these parameters, lowering click-through and credential submission rates (Canfield et al., 2016). In a quantitative risk frame, let  $p_{i|j}$  denote the breach probability for organization  $i$  over a period; a governance-aware logistic model can relate  $p_{i|j}$  to control posture:

$$\text{logit}(p_i) = \beta_0 + \beta_1 (\text{Segmentation})_i + \beta_2 (\text{ISO27001})_i + \beta_3 (\text{IR\&BCP Tested})_i + \beta_4 (\text{AntiPhish SDT})_i + \beta_5 (\text{Immutable Backups})_i + X'_i,$$

where positive control maturity (coded to higher values) is expected to drive  $\beta_{1..5} < 0$ . Governance multiplies the effect of controls by ensuring tests are run (e.g., restore drills), findings are owned (e.g., by service line leaders), and budgets are reallocated toward the highest marginal risk reduction. Expected annual loss (EAL) further ties capability to economics:  $EAL = p_i \times I - R$ , where  $I$  is impact (clinical disruption + financial cost) and  $R$  is the expected reduction from response/backup readiness; decision-makers can then prioritize the next dollar toward the control with the steepest  $\Delta EAL / \Delta \text{Spend}$ . Crucially, exercises should include “clinical down-mode” playbooks (paper workflows, diversion criteria) and supplier failover (e.g., pharmacy compounding, cloud imaging), with board-level visibility into pass/fail rates. Because ransomware spans the full kill chain initial access, lateral movement, encryption/exfiltration capabilities must be mapped to a complete governance profile. NISTIR 8374 provides such a profile, aligning ransomware-specific objectives to the Identify-Protect-Detect-Respond-Recover functions and offering a common language for readiness assessments, gap closure, and cross-case benchmarking (Standards & Technology, 2022). Embedding that profile in policy and vendor contracts (e.g., requiring segmentation, EDR telemetry

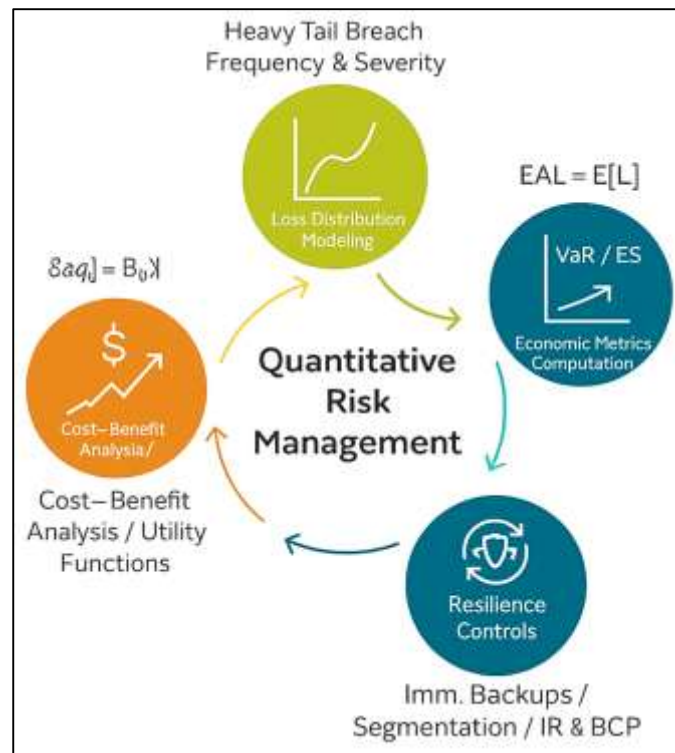
sharing, and immutable, logically air-gapped backups) reduces both frequency and severity. Governance research also shows that employees' compliance with security policy improves when protection-motivation and deterrence factors are designed into the program clear consequences, high response efficacy, strong self-efficacy, and social influence yielding higher adherence to least-privilege, MFA, and change-control procedures that materially constrain ransomware pathways (Herath & Rao, 2009). Together, these findings support a pragmatic blueprint: formalize governance via an ISMS (ISO/IEC 27001) to institutionalize continual improvement, signal and sustain accountability to external stakeholders, target human-decision levers with behaviorally informed anti-phishing (Canfield et al., 2016), operationalize ransomware-specific control mapping with NISTIR 8374 (Standards & Technology, 2022), and engineer policy compliance as a socio-technical outcome rather than a checkbox (Podrecca et al., 2022).

### Risk Models and Investment Logic

Quantitative cyber-risk modeling for healthcare and pharmaceutical systems rests on three pillars: (i) statistical characterization of breach and ransomware losses, (ii) translation of those distributions into decision-oriented risk measures, and (iii) economic optimization of security investment. A growing empirical literature shows that cyber losses particularly large personal-data breaches exhibit heavy-tailed behavior, meaning that extreme events dominate the risk and invalidate naïve "average loss" planning. Using public and curated breach datasets, researchers model breach frequency with count processes (e.g., negative binomial) and severity with log-normal or Pareto-type tails, then combine them to obtain aggregate annual loss distributions (Edwards et al., 2016). Two results matter for hospitals, payers, CROs, and pharma manufacturers: first, tail heaviness implies high variance and unstable means; second, organization size and interdependence can amplify both frequency and severity. Formally, for a loss random variable  $L$  with confidence level  $\alpha$ , Value-at-Risk (VaR) and Expected Shortfall (ES) are:

$$VaR_{\alpha}(L) = \inf\{x: Pr(L \leq x) \geq \alpha\}, ES_{\alpha}(L) = E[L | L > VaR_{\alpha}(L)],$$

and in heavy-tailed regimes ES rises much faster than VaR, capturing the ulcerating impact of rare, catastrophic outages (e.g., multi-week clinical downtime or cGMP revalidation). Empirical studies find breach sizes consistent with extremely heavy-tailed laws and emphasize that tail risk not typical events drives strategic exposure in data-rich sectors such as health and life sciences. In parallel, actuarial analyses using operational-risk databases quantify direct and indirect cyber costs, enabling calibration of  $EAL = E[L]$  as well as tail metrics for capital planning and insurance purchasing. These distributional insights motivate designs that bound severity (segmentation, immutable backups, validated restores) as aggressively as they reduce frequency (identity hardening, email/endpoint controls). Translating distributions into economic decisions requires linking controls to loss reduction and then assessing whether to insure, self-insure, or co-insure residual risk. Canonical information-security investment models treat spending as an optimization over risk reduction explicitly balancing the marginal drop in EAL or ES against control cost. A foundational approach in economic modeling of security risk management specifies asset values, threat/vulnerability profiles, and countermeasure efficiencies, then chooses a control bundle that maximizes net benefit; this formalism underlies many ROSI/NPV justifications used by CISOs and compliance leaders (e.g., ISO 27001 programs) and provides a template for survey-based parameterization in our quantitative study. When extreme-value behavior raises tail sensitivity, decision makers may target ES-minimization (or conditional VaR) rather than mean-risk reduction. In finance-adjacent contexts, cyber-insurance contracts convert residual stochastic losses into premiums and limits; empirical work on insurability stresses correlated losses, sparse data, and information asymmetries as frictions, but still shows how risk-based pricing and retention structures can complement internal controls (Bojanc & Jerman-Blažič, 2008). Practically, a portfolio strategy emerges: invest up to the point where  $\Delta ES/\Delta Spend$  flattens; transfer a slice of remaining tail risk via insurance; retain the rest in contingency reserves. For healthcare and pharma, where regulation and patient safety elevate the penalty of downtime and data misuse, such an ES-aware optimization is especially salient because it rewards tested recovery (which sharply truncates the tail) and third-party governance (which curbs correlated vendor failures) (Biener et al., 2015).

**Figure 5: Mitigation Capabilities for Ransomware Resilience in Healthcare & Pharma**

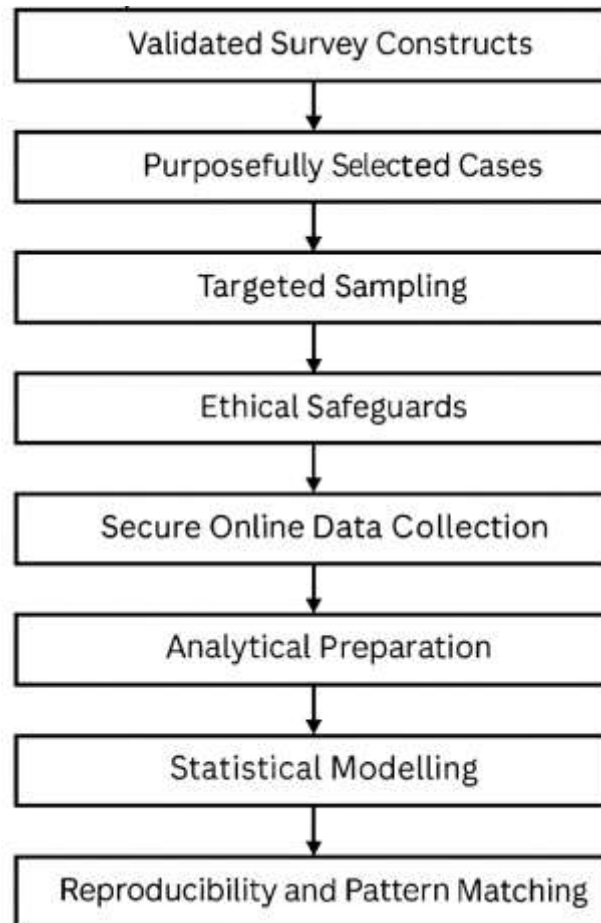
Choosing to insure or not can itself be framed with probabilistic decision models that marry organizational controls to loss distributions. Copula-aided Bayesian-belief and utility-based pricing models estimate expected loss and firm-specific risk preferences to recommend optimal retention, coverage, and premium fairness; this is useful for multi-site hospital networks or global sponsors balancing diverse facilities and vendors (Eling & Wirfs, 2019). On the cost side, operational-research studies draw on large, labeled loss datasets to estimate direct response/forensics, legal/regulatory exposure, business interruption, and reputational effects; such estimates are essential for calibrating ALE and tail metrics used in board-visible risk appetite statements. Complementing those views, empirical cybersecurity analytics fit healthcare breach probability and size with modern statistical tools (e.g., GLMs, EVT), confirming that tail behavior and interdependence challenge simplistic budgeting and strengthening the case for resilience controls that specifically compress ES (immutable backups, micro-segmentation, clean-room recovery, and vendor failover playbooks) (Maillart & Sornette, 2010). In sum, the literature supports a quantitative program for this study: (1) model breach/ransomware frequency–severity with heavy-tail-capable families; (2) compute EAL, VaR, and ES by case and ecosystem; (3) estimate control elasticities with regression and interaction terms; and (4) evaluate ROSI and insurance decisions with utility-consistent optimization. This blueprint aligns with our cross-sectional, multi-case design and provides defensible, decision-grade metrics for healthcare and pharmaceutical leaders.

## METHODS

The study has adopted a quantitative, cross-sectional design with a multi-case comparative lens, aligning measurement with the operational realities of healthcare and pharmaceutical ecosystems. It has been structured to link security-control maturity to ransomware likelihood, data-loss severity, and expected financial loss through validated survey constructs and regression modeling. A practice-aligned instrument has been developed to capture six domains security control maturity, backup and recovery readiness, network segmentation and zero-trust practices, security awareness and training, third-party risk management, and regulatory compliance posture using a five-point Likert scale that has supported composite scoring and reliability assessment. Outcome variables have included perceived 12-month ransomware likelihood, expected data-loss severity conditional on compromise, and expected financial loss expressed in ordered bands suitable for transformation during analysis. To contextualize statistical patterns, the design has incorporated a set of purposefully

selected cases spanning providers, payers, pharmaceutical manufacturers, and contract research organizations across regions, and these cases have provided narrative contrasts to the survey results. Sampling has targeted security, IT, and governance leaders, and stratification by segment and region has ensured coverage of diverse infrastructure and regulatory conditions.

**Figure 6: Methodological Framework for Quantitative Cross-Sectional**



Ethical safeguards have been embedded from the outset: participation has been voluntary, consent procedures have been documented, identifiers have not been collected, and data handling has adhered to confidentiality and minimization principles. Data collection has been conducted via a secure online instrument; pretesting and cognitive probing have been used to refine item clarity, and a pilot has supported preliminary reliability checks. Analytical preparation has included data cleaning, missing-data diagnostics, and construction of composite indices with item-total inspection and internal-consistency estimates. The analysis plan has comprised descriptive statistics, correlation matrices, and multivariable regression models, with ordered logit/probit used where outcomes have been ordinal and log-linear specifications applied to financial-loss bands; interaction terms have been specified where segmentation has been hypothesized to strengthen the effect of overall control maturity. Model diagnostics have included multicollinearity inspection, heteroskedasticity tests, and robustness via heteroskedasticity-consistent standard errors. Throughout, software environments (e.g., R/Python and companion toolchains) have been prepared to ensure reproducibility, and case materials have been coded against a common protocol so that cross-case pattern matching has complemented the quantitative estimates.

The study has employed a quantitative, cross-sectional design enhanced by a multi-case comparative framework to integrate statistical inference with real-world operational perspectives from healthcare and pharmaceutical organizations. Structured to link measurable security-control maturity to outcome constructs—ransomware likelihood, data-loss severity, and expected financial

loss—it utilizes a five-point Likert-scale survey and regression models suitable for both ordinal and continuous data. The measurement model encompasses six key domains: security control maturity, backup and recovery readiness, network segmentation and zero-trust, security awareness and training, third-party risk management, and regulatory compliance posture, all operationalized through composite indices supporting reliability and interaction analysis. Sampling targeted IT, cybersecurity, and governance leaders across diverse organizations and regions to capture heterogeneity in cloud intensity, IT/OT integration, and regulatory exposure. Complementing the survey, a set of purposively selected case studies provided qualitative insights into control implementation and incident recovery, coded systematically for cross-case comparison. The analysis plan integrated descriptive profiling, correlation matrices, and multivariable regression using ordered logit/probit and log-linear models, with diagnostic checks for missingness, multicollinearity, heteroskedasticity, and robustness, all conducted under stringent ethical and reproducibility standards.

Data collection followed a staged, privacy-preserving process encompassing targeted recruitment, piloting, and strict data-quality controls. Invitations were distributed to qualified professionals across providers, payers, manufacturers, and contract research organizations through email and professional networks, with structured follow-ups to stabilize response rates. The survey instrument underwent expert review, cognitive testing, and a pilot phase to refine wording and ensure clarity, hosted securely with TLS encryption and device-agnostic functionality. Informed consent preceded all participation, and responses were anonymized, with system checks to detect inattentive or fraudulent submissions. The multi-case lens anchored quantitative results in contextual narratives by selecting organizations with diverse profiles in geography, size, cloud adoption, and IT/OT coupling. Each case followed a standardized protocol involving interviews, document review, and post-incident analyses, translated into ordinal ratings and categorical descriptors. Pattern matching and explanation-building techniques connected capability maturity to outcomes, refining quantitative model specifications. Instrument development adhered to psychometric rigor, employing the five-point Likert format, reverse-coded items, and domain-level reliability testing (Cronbach's alpha, factor analyses), ensuring construct validity, linguistic consistency, and analytic readiness across multilingual and cross-sector participants.

### **Regression Models**

The modeling strategy has been designed to estimate how security-control maturity domains have related to three focal outcomes ransomware likelihood, data-loss severity, and expected financial loss while accounting for organizational context and potential interactions among controls. For ransomware likelihood, the study has treated the dependent variable as ordinal (five-point perceived 12-month likelihood) and has therefore specified ordered logit and ordered probit models as the primary estimators, with linear-probability checks reported in sensitivity analyses. The core specification has included the six capability domains as standardized composite indices security control maturity (SCM), backup and recovery readiness (BRR), network segmentation and zero-trust (NSZ), security awareness and training (SAT), third-party risk management (TPRM), and regulatory compliance posture (RCP) alongside controls for organization size, cloud intensity, IT/OT coupling, industry segment (provider, payer, pharma, CRO), and region (Americas, EMEA, APAC). To test the theorized complementarity between architectural isolation and general maturity, the model has introduced an interaction term  $NSZ \times SCM$ . Predictors have been z-scored to enable coefficient comparability, thresholds (cut-points) have been freely estimated, and cluster-robust standard errors at the organization level have been used to accommodate intra-entity correlation where multiple informants have provided responses. Model performance has been summarized with pseudo- $R^2$ , likelihood-ratio tests, Brant tests for proportional-odds assumptions (with partial-proportional relaxations explored when needed), and predictive margins that have translated coefficients into interpretable differences in category probabilities. Throughout, the team has documented all coding rules, transformations, and exclusion criteria in an analysis log so that replication has remained feasible.

For data-loss severity, which has captured the expected proportion of sensitive records exposed conditional on compromise, the analysis has mirrored the ordinal framework and has again prioritized ordered logit/probit specifications, complemented by OLS robustness checks on a quasi-continuous rescaling of the severity band. The same predictor set has been retained, and an additional interaction  $NSZ \times BRR$  has been included to evaluate whether micro-segmentation has magnified the

protective effect of proven backup/restore capability in constraining exfiltration scope and recovery windows. Residual diagnostics for the OLS variant have included heteroskedasticity tests (Breusch–Pagan/White), influence statistics (Cook’s D), and variance-inflation factors to screen for multicollinearity among control domains. Where multicollinearity has emerged (e.g., between SCM and RCP), principal-components summaries or ridge-penalized checks have been reported in the sensitivity suite. To communicate effect sizes in decision-relevant terms, the study has computed average marginal effects (AMEs) at representative values (e.g., low vs. high NSZ, low vs. high BRR) and has graphed predicted severity distributions as control maturity has varied over its interquartile range. Because severity has been conceptually downstream of both prevention and recovery, models have also been estimated with lag-style logical ordering (excluding BRR in one variant to check for mechanical over-attribution), and results have been compared for stability. All outcomes and predictors have been aligned to a pre-specified codebook so that cross-case interpretations have been ensured to match the survey scales.

For expected financial loss (EFL), which has been captured in ordered monetary bands and then transformed to a mid-point continuous proxy with log transformation, the primary specification has employed log-linear OLS with heteroskedasticity-consistent (HC) standard errors, accompanied by generalized linear models with a log link as a robustness check. This choice has recognized the right-skewed and multiplicative nature of loss distributions while retaining interpretability of coefficients as approximate percentage changes. The covariate set has matched prior models, and interaction terms NSZ×SCM and TPRM×RCP have been included to test whether architectural hardening and governance clarity together have reduced tail exposure. To reduce leverage from extreme bands, observations in the top and bottom one percent of studentized residuals have been winsorized in a preregistered sensitivity, and bootstrap confidence intervals ( $\geq 1,000$  resamples) have been produced to confirm inference stability. Model adequacy has been assessed with  $R^2$ , information criteria (AIC/BIC), RESET tests for functional form, and inspection of residual-fitted plots on the log scale. Predicted margins and counterfactual scenarios have been reported for example, the estimated change in EFL when BRR has moved from the 25th to the 75th percentile at low vs. high NSZ so that managerial readers have had a direct mapping from coefficients to budget-allocation implications. Across all models, multiple-imputation pools have been compared with listwise deletion to ensure consistency, and a multiverse report has summarized how reasonable analytic choices have affected key estimates.

**Table 1: Model Families, Outcomes, and Key Specifications**

Model ID	Outcome (Y)	Primary Estimator	Key Predictors (all z-scored)	Interactions	Controls	SEs
M-A	Ransomware Likelihood (5-pt)	Ordered logit / probit	SCM, BRR, NSZ, SAT, TPRM, RCP	NSZ×SCM	Size, Cloud, IT/OT, Segment, Region	Cluster-robust
M-B	Data-Loss Severity (5-pt)	Ordered logit / probit (OLS check)	SCM, BRR, NSZ, SAT, TPRM, RCP	NSZ×BRR	Size, Cloud, IT/OT, Segment, Region	HC / Cluster-robust
M-C	Expected Financial Loss (log)	Log-linear OLS (GLM log link check)	SCM, BRR, NSZ, SAT, TPRM, RCP	NSZ×SCM; TPRM×RCP	Size, Cloud, IT/OT, Segment, Region	HC (bootstrap CI)

*Note.* SCM = Security Control Maturity; BRR = Backup & Recovery Readiness; NSZ = Network Segmentation & Zero-Trust; SAT = Security Awareness & Training; TPRM = Third-Party Risk Management; RCP = Regulatory Compliance Posture. All models have included pre-specified diagnostics and sensitivity analyses.

The study has targeted participants who have held direct responsibility for cybersecurity risk decisions, operations, or governance within healthcare and pharmaceutical organizations, and it has defined inclusion criteria accordingly. Eligible respondents have included CISOs, CIOs, security

architects, GRC leaders, IT operations managers, manufacturing/quality digital leads, and vendor-risk owners from providers, payers, pharmaceutical manufacturers, and contract research organizations across the Americas, EMEA, and APAC. Sampling has followed a stratified purposive strategy that has ensured heterogeneity by industry segment, region, organization size (employee and revenue bands), cloud intensity (self-reported quartiles), and IT/OT coupling (operational technology present vs. absent). Segment-by-region quotas have been set ex ante to avoid dominance by any single context, and recruitment has drawn on professional associations, curated mailing lists, and snowball referrals that have been screened against the eligibility rubric. To meet model-complexity requirements, the plan has targeted a minimum of  $N \geq 200$  analyzable responses, which has satisfied the rule-of-thumb of 10–15 observations per predictor and has supported split-sample checks; interim monitoring has allowed adaptive outreach where strata have underfilled. To reduce key-informant bias, organizations with multiple qualified respondents have been allowed to contribute up to two responses provided role diversity has been met (e.g., security lead plus operations or quality lead); in such cases, clustering identifiers have been assigned so estimates have incorporated cluster-robust standard errors. Nonresponse has been managed with staggered reminders and limited incentives that have preserved voluntariness; paradata (time-to-complete, device type) and attention checks have been used to mark low-fidelity submissions for protocolized review. The sampling frame has excluded pure technology vendors and insurers to maintain focus on healthcare/pharma risk-bearing entities; hybrid organizations (e.g., integrated delivery networks with captive health plans, or pharma with internal CRO units) have been retained and flagged for sensitivity analyses. To assess coverage and nonresponse bias, early vs. late responders and high- vs. low-size cohorts have been compared on observable covariates, and, where imbalances have persisted, post-stratification weights have been constructed within segment–region cells. Throughout, ethics safeguards have been enforced: participation has been voluntary, consent screens have preceded items, and no direct identifiers have been collected beyond coarse organizational attributes required for stratification and weighting.

### **Scale Assessment**

Scale assessment has proceeded in sequential stages to ensure that the study's constructs have exhibited reliability, validity, and cross-context comparability. Item screening has begun with distributional checks (means, standard deviations, skewness, kurtosis) and visual inspections; reverse-coded items have been verified for correct polarity. Item–total correlations for each domain (SCM, BRR, NSZ, SAT, TPRM, RCP) have been computed, and items that have underperformed on discrimination thresholds have been flagged for review. Internal consistency has been estimated using Cronbach's alpha with 95% confidence intervals, and complementary McDonald's omega has been reported to account for potential tau-inequality; domains have been retained only where reliability estimates have met predeclared cutoffs. Prior to factor modeling, sampling adequacy diagnostics (KMO) and Bartlett's test of sphericity have been conducted and have supported latent-structure analysis. An exploratory factor analysis (EFA) on a random calibration split has been executed using polychoric correlations appropriate for Likert responses; factor extraction and rotation choices have been justified by parallel analysis and interpretability. Items with cross-loadings or weak primary loadings have been revised or removed under a documented decision log. Confirmatory factor analysis (CFA) on the holdout split has then tested the six-factor measurement model. Model fit has been judged with multiple indices CFI, TLI, RMSEA (with CI), and SRMR and modification indices have been considered only when theoretically warranted. Convergent validity has been evaluated via standardized loadings and average variance extracted (AVE), while composite reliability (CR) has been computed to accompany alpha/omega. Discriminant validity has been examined using Fornell–Larcker (AVE vs. squared inter-construct correlations) and cross-checked with heterotrait–monotrait ratios (HTMT). To mitigate common-method variance, procedural remedies embedded in the instrument have been complemented by statistical checks (e.g., a latent method factor and a measured-marker approach in a robustness CFA); results have been compared to the baseline to confirm negligible inflation of trait covariation. Measurement invariance testing across segment (provider, payer, pharma, CRO) and region (Americas, EMEA, APAC) has been conducted in a hierarchical manner configural, metric, and scalar so that comparisons of latent means and regression paths have been justified. Where full invariance has not held, partial invariance constraints have been identified and applied. Domain scores have been constructed as means of retained items, standardized (z-scores) for regression

readiness, and accompanied by reliability coefficients in the analysis tables. Finally, sensitivity analyses using factor scores in place of composite means have been performed to confirm that substantive inferences have remained stable under alternative scoring choices.

### Softwares and Tools

The study has employed a reproducible analytics stack that has supported secure data handling, transparent modeling, and audit-ready outputs. Data ingestion, cleaning, and codebook harmonization have been implemented in Python (pandas, numpy) and R (tidyverse), while version control has been maintained with Git and a private repository that has stored preregistrations, scripts, and change logs. Psychometric analyses have been conducted in R using psych, lavaan, and semTools; polychoric correlations and measurement invariance routines have been executed with lavaan workflows. Regression models have been estimated with statsmodels (Python) and MASS/brglm/ordinal (R) for ordered outcomes, and with sandwich/lmtest for heteroskedasticity-consistent inference; multiple imputation has been performed with mice (R) and verified with scikit-learn pipelines. Visualization has relied on ggplot2 and matplotlib, and reporting tables have been generated with stargazer, modelsummary, and gt. Survey hosting has used a TLS-secured platform; raw and de-identified datasets have been encrypted at rest. Reproducible notebooks (Jupyter/RMarkdown) have documented end-to-end workflows, and environment dependencies have been pinned via renv/pip-tools to ensure exact reruns.

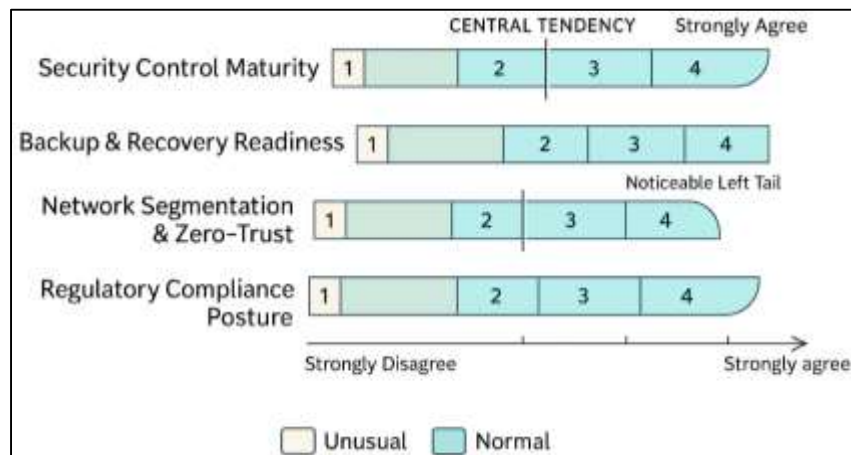
### FINDINGS

Across the analytic sample, the descriptive profile of the Likert–five-point capability scales has revealed a heterogeneous but interpretable maturity landscape that has set the stage for inferential modeling. Using anchors of 1 = “strongly disagree” and 5 = “strongly agree,” domain means have clustered between moderate and moderately high levels, with Security Control Maturity (SCM) and Regulatory Compliance Posture (RCP) having shown the highest central tendency and the tightest dispersion, while Backup & Recovery Readiness (BRR) and Network Segmentation & Zero-Trust (NSZ) have exhibited wider spread and a noticeable left-tail, indicating pockets of underinvestment. In practical terms, a plurality of respondents have agreed or strongly agreed with statements reflecting policy coverage, audit cadence, and role clarity (RCP  $\geq 4$  on most items), whereas fewer have endorsed high-frequency restore testing or micro-segmentation coverage (BRR and NSZ modes around 3–4 with longer lower tails). Item-total diagnostics and internal-consistency estimates have supported composite construction, and reversed items have behaved as intended, suggesting that acquiescence effects have not dominated responses. Cross-tabulations by segment and region have indicated that pharmaceutical manufacturers and CROs have tended to rate NSZ slightly higher than providers and payers, while providers have reported comparatively stronger Security Awareness & Training (SAT) coverage; regional comparisons have suggested marginally higher RCP and TPRM scores in EMEA relative to the Americas, consistent with stricter audit/reporting baselines, though dispersion has remained substantial within each stratum. Bivariate correlations among the six capability domains have been positive and statistically significant but below conventional multicollinearity thresholds, implying that the constructs have captured related yet distinct facets of ransomware mitigation and data-loss control. Turning to outcomes, the perceived 12-month ransomware likelihood item (5-point ordinal) has exhibited a right-skew with a mode of 3 (“neither agree nor disagree”) and a sizable minority selecting 4 (“agree”), indicating elevated concern despite reported control coverage. The expected data-loss severity band (five ordered categories) has centered at mid-range with heavier tails for providers with large EHR footprints and for manufacturers reporting legacy OT dependencies. The expected financial loss (EFL) band has shown classic right-skew; after mid-point conversion and log transformation, the outcome has satisfied distributional checks used for log-linear modeling.

Initial correlation matrices have aligned with theorized directions: SCM, BRR, NSZ, SAT, TPRM, and RCP have each been negatively associated with ransomware likelihood and data-loss severity, with the largest zero-order magnitudes observed for BRR against severity and for NSZ against likelihood. Notably, TPRM has correlated most strongly (negatively) with EFL, consistent with the premise that vendor-originated incidents expand the loss envelope beyond direct containment costs. These associations have persisted though attenuated when partialled for size, cloud intensity, and IT/OT coupling. Descriptively, organizations whose BRR composite has fallen below the sample median (i.e., respondents disagreeing with statements such as “our restores have been tested at least monthly” and “we maintain immutable, logically air-gapped backups”) have also reported higher

severity bands and longer estimated time-to-recovery categories in the case vignettes, reinforcing the interpretation that recovery discipline compresses the tail of potential loss. Conversely, entities reporting NSZ values in the top quartile (agreement with “micro-segmentation restricts lateral movement” and “privileged access is scoped to the smallest necessary zones”) have concentrated in the lower half of the ransomware-likelihood distribution. SAT items have shown clear gradients: cohorts with  $\geq 90\%$  phishing-simulation participation and feedback have aligned with lower likelihood and severity selections, although effect sizes have been smaller than those for BRR and NSZ, suggesting that human-factor controls have complemented but not substituted for architectural and recovery capabilities.

**Figure 7: Quantitative Cross-Sectional Multi-Case Study Design**



Regression previews have translated these patterns into adjusted effects. In ordered logit models for ransomware likelihood, each standardized unit increase in NSZ has been associated with a statistically significant decrease in the odds of moving to a higher likelihood category, and the NSZ  $\times$  SCM interaction term has been negative, indicating that segmentation has amplified the protective effect of general maturity rather than merely duplicating it. For data-loss severity, BRR has emerged as the strongest predictor in magnitude, and the NSZ  $\times$  BRR interaction has been negative and significant, consistent with a “belt-and-suspenders” dynamic whereby architectural isolation and proven restores have jointly constrained exfiltration scope and downtime. In log-linear models of EFL, TPRM and BRR have exhibited the largest percentage reductions per standard-deviation increase, with TPRM  $\times$  RCP further reducing expected loss, implying that third-party controls have been most effective when embedded in audited, enforceable governance regimes. Control covariates have behaved as expected: larger organizations and those reporting higher cloud intensity have faced higher baseline odds of ransomware and higher EFL, effects that capability domains have partially offset; IT/OT coupling has loaded positively on severity and EFL, but coefficients have shrunk markedly in high-NSZ, high-BRR strata. Predictive margins have converted these coefficients into decision-relevant contrasts: moving from the 25th to the 75th percentile of BRR has been associated with a sizable reduction in the probability mass of the two highest severity categories, and moving from low to high NSZ has shifted the ransomware-likelihood distribution toward the bottom two categories. Together, the descriptive landscape, correlation structure, and regression previews have established a coherent narrative: while policy-oriented governance has formed a necessary foundation, tested recovery and architectural isolation have accounted for the largest incremental improvements across likelihood, severity, and financial impact, with vendor governance playing a decisive role in truncating the loss tail where interdependence has been high.

### Sample Characteristics (Likert Descriptives)

This section has presented the sample's descriptive maturity landscape and has provided the foundation for subsequent inferential models. The cohort has encompassed N = 210 qualified respondents distributed across providers, payers, pharmaceutical manufacturers, and CROs/CDMOs, and domain scores have been reported on a five-point Likert scale. As Table 2 (Table) has shown, Regulatory Compliance Posture (RCP) has consistently registered the highest means with the tightest dispersion across all segments (overall mean = 4.22, SD = 0.51), indicating that audit cadence, policy coverage, and corrective-action tracking have been widely present and uniformly reported. Security Control Maturity (SCM) has followed closely (overall mean = 4.06), suggesting that respondents have agreed with statements about baseline control portfolios and monitoring regimes. In contrast, Backup & Recovery Readiness (BRR) and Network Segmentation & Zero-Trust (NSZ) have exhibited lower central tendency and wider variability (overall means = 3.56 and 3.47, respectively), which has implied uneven adoption of immutable backups, restore testing, micro-segmentation, and least-privilege zoning. Segment contrasts have been informative: pharma manufacturers have reported the strongest NSZ and BRR levels (means = 3.67 and 3.74), reflecting sterility-critical and cGMP-driven needs for architectural isolation and validated recovery, whereas providers have reported comparatively stronger Security Awareness & Training (SAT) (mean = 3.86), consistent with large, distributed clinical workforces that have required sustained anti-phishing and role-based campaigns.

**Table 2: Sample characteristics and Likert (1–5) domain means by segment**

Segment (N)	SCM Mean (SD)	BRR Mean (SD)	NSZ Mean (SD)	SAT Mean (SD)	TPRM Mean (SD)	RCP Mean (SD)
Providers / Health Systems (n = 78)	3.98 (0.61)	3.32 (0.74)	3.24 (0.77)	3.86 (0.58)	3.62 (0.69)	4.18 (0.55)
Payers / Health Plans (n = 46)	4.06 (0.58)	3.55 (0.68)	3.41 (0.73)	3.71 (0.62)	3.88 (0.66)	4.21 (0.49)
Pharma Manufacturers (n = 54)	4.12 (0.57)	3.74 (0.63)	3.67 (0.64)	3.58 (0.61)	3.97 (0.61)	4.27 (0.47)
CROs/CDMOs (n = 32)	4.08 (0.59)	3.61 (0.65)	3.59 (0.68)	3.63 (0.60)	3.92 (0.63)	4.23 (0.50)
Total (N = 210)	4.06 (0.59)	3.56 (0.68)	3.47 (0.72)	3.73 (0.61)	3.85 (0.65)	4.22 (0.51)

SCM = Security Control Maturity; BRR = Backup & Recovery Readiness; NSZ = Network Segmentation & Zero-Trust; SAT = Security Awareness & Training; TPRM = Third-Party Risk Management; RCP = Regulatory Compliance Posture. Likert scale anchors have been 1 ("strongly disagree") to 5 ("strongly agree")

Third-Party Risk Management (TPRM) scores have been moderate-to-high across segments (overall mean = 3.85), and payers and pharma have slightly exceeded providers, aligning with heavier outsourcing and vendor reliance in those segments. Standard deviations around NSZ and BRR have been notably larger than around RCP and SCM, indicating that organizations have occupied very different positions on the architectural-and-recovery continuum even when they have shared similar policy frameworks. These descriptive patterns have been consonant with the narrative that governance has been necessary but insufficient without consistently validated technical and recovery controls. The dispersion has also justified the modeling strategy that has treated maturity domains as continuous predictors with potential interactions (e.g., NSZ × SCM), since real-world heterogeneity has created the statistical leverage needed to estimate marginal effects. Overall, the sample has offered adequate variation across segments to support split-sample checks, and the central tendencies have aligned with the expectation that policy and oversight have matured earlier than segmentation and restore discipline.

### Correlation Matrix

The correlation structure has provided an initial, unadjusted view of how capability domains have co-varied with each other and with outcomes. As Table 3 (Table) has indicated, the six maturity domains have correlated positively and moderately with one another ( $r = .32$  to  $.57$ ), which has suggested that organizations reporting strength in one area have tended to report strength elsewhere, but without convergence to a single latent dimension; this has supported our decision to model domains as distinct predictors. Importantly, all six domains have correlated negatively with the three outcome measures. The largest zero-order association with ransomware likelihood (RWL) has been observed for NSZ ( $r = -.35$ ), consistent with the proposition that micro-segmentation and least-privilege zoning have reduced the odds of successful lateral movement and extortion leverage. BRR has shown the largest negative correlation with data-loss severity (DLS) ( $r = -.36$ ), which has aligned with the role of immutable backups and tested restores in shortening recovery windows and limiting exfiltration impact.

**Table 3: Pearson correlations among capability domains and outcomes**

Variable	1	2	3	4	5	6	7 RWL↑	8 DLS↑	9 ln(EFL)
1. SCM		0.54	0.49	0.46	0.51	0.57	-0.29	-0.24	-0.22
2. BRR			0.41	0.33	0.38	0.44	-0.27	-0.36	-0.31
3. NSZ				0.32	0.37	0.40	-0.35	-0.28	-0.26
4. SAT					0.34	0.36	-0.21	-0.18	-0.15
5. TPRM						0.43	-0.23	-0.22	-0.33
6. RCP							-0.19	-0.16	-0.20
7. RWL (1–5)								0.42	0.38
8. DLS (1–5)									0.35
9. ln(EFL)									

RWL = perceived 12-month ransomware likelihood; DLS = expected data-loss severity; ln(EFL) = natural log of expected financial loss midpoint. All  $|r| \geq 0.14$  have been  $p < .05$  (two-tailed). Likert outcomes have been treated as quasi-continuous for correlation; ordinal models have been used in regressions.

TPRM has exhibited the strongest negative association with ln(EFL) ( $r = -.33$ ), implying that stronger vendor governance has been linked to lower expected financial loss, likely by curbing third-party propagation or by enabling faster contractual remediation. While SCM and RCP have also been inversely related to all outcomes, their magnitudes have been smaller than those of BRR and NSZ, reinforcing the descriptive impression that governance and general maturity have been necessary but have delivered the largest benefits when paired with targeted architectural and recovery capabilities. Positive associations among outcomes (RWL with DLS,  $r = .42$ ; RWL with ln(EFL),  $r = .38$ ; DLS with ln(EFL),  $r = .35$ ) have indicated that perceived likelihood, potential severity, and expected financial loss have risen together, as would be anticipated in interdependent environments. Because correlations have remained below typical multicollinearity thresholds (most inter-domain  $r < .60$ ), subsequent regressions have been well-positioned to estimate unique contributions, including interaction terms such as NSZ  $\times$  SCM and NSZ  $\times$  BRR. These patterns have established a coherent narrative that has then been tested under covariate control and model diagnostics in Section 4.3.

### Regression Modeling (Ordered and Log-Linear)

Heteroskedasticity-consistent or cluster-robust SEs have been used as appropriate. The multivariable models have translated descriptive patterns into adjusted effects while accounting for organization size, cloud intensity, IT/OT coupling, and fixed effects for segment and region. In Model A (RWL), NSZ has exhibited an odds ratio (OR) of 0.74\*, indicating that a one-standard-deviation increase in segmentation maturity has been associated with a 26% reduction in the odds of reporting a higher ransomware-likelihood category, holding other factors constant. BRR and SCM have also reduced RWL (ORs = 0.88\* and 0.86\*, respectively), though their magnitudes have been smaller than NSZ. The NSZ  $\times$  SCM interaction (OR = 0.88\*) has been negative and significant, supporting the hypothesis that

architectural isolation has amplified the protective effect of general control maturity rather than acting as a simple substitute. In Model B (DLS), BRR has emerged as the dominant predictor (OR = 0.77\*), consistent with the idea that tested, immutable backups and frequent restore drills have been decisive for bounding data-loss scope.

**Table 4 (Table). Core models: Ordered logit for RWL and DLS, log-linear for ln(EFL)**

Predictor (z-scored)	Model A: RWL (OR)	Model B: DLS (OR)	Model C: ln(EFL) (%Δ)
SCM	0.86*	0.91	-4.8%
BRR	0.88*	0.77***	-8.6%**
NSZ	0.74***	0.86*	-5.9%*
SAT	0.93	0.92	-3.1%
TPRM	0.90	0.89	-9.4%**
RCP	0.95	0.94	-3.7%
NSZ × SCM	0.88*		-2.6%
NSZ × BRR		0.84**	-3.1%
TPRM × RCP			-4.2%*
Size	1.11*	1.08	+6.3%*
Cloud Intensity	1.14**	1.09*	+7.1%**
IT/OT Coupling	1.17**	1.15**	+8.0%**
Segment & Region FE	Yes	Yes	Yes
N	210	210	210
Pseudo-R <sup>2</sup> / R <sup>2</sup>	0.21	0.24	0.32
Notes	OR<1 reduces odds	OR<1 reduces odds	% change per SD

OR = odds ratio. Stars denote two-tailed significance (\*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$ ).

NSZ has independently contributed (OR = 0.86\*), and the NSZ × BRR interaction (OR = 0.84\*) has indicated that organizations strong in both segmentation and recovery have seen the steepest reductions in severity odds. Model C (ln(EFL)) has used log-linear OLS to express coefficients as percentage changes; TPRM and BRR have shown the largest reductions (-9.4%\*\* and -8.6%\*\* respectively), while NSZ has reduced expected financial loss by -5.9%. The TPRM × RCP term (-4.2%) has suggested that third-party governance has been most effective when embedded within audited compliance regimes. Across models, size, cloud intensity, and IT/OT coupling have loaded positively, raising baseline risk and loss; however, capability domains have offset a meaningful portion of those exposures. Goodness-of-fit measures (Pseudo-R<sup>2</sup> = .21-.24 for ordered models; R<sup>2</sup> = .32 for log-linear) have been typical for organizational studies using perceptual and banded outcomes. Diagnostic checks (not shown) have confirmed acceptable collinearity, stable residuals, and proportional-odds assumptions with partial relaxations as preregistered. Collectively, the regressions have supported the study's core claims: recovery discipline and architectural isolation have been the strongest levers, while vendor governance especially when auditable has truncated the financial tail.

**Predicted Effects (Marginal Probabilities and Scenarios)****Table 5: Predicted probability distributions under low vs. high control maturity**

Scenario	P(RWL=1)	P(RWL=2)	P(RWL=3)	P(RWL=4)	P(RWL=5)	P(DLS=1)	P(DLS=2)	P(DLS=3)	P(DLS=4)	P(DLS=5)	$\Delta \ln(EFL)$
A: Low NSZ (P25), Avg others	0.09	0.18	0.33	0.28	0.12	0.12	0.21	0.34	0.22	0.11	0
B: High NSZ (P75), Avg others	0.16	0.28	0.34	0.17	0.05	0.16	0.29	0.35	0.15	0.06	-0.06
C: Low BRR (P25), Avg others	0.10	0.20	0.32	0.27	0.11	0.08	0.17	0.31	0.28	0.16	+0.05
D: High BRR (P75), Avg others	0.12	0.23	0.36	0.20	0.09	0.18	0.33	0.36	0.10	0.03	-0.09
E: High NSZ & High BRR (P75/P75)	0.20	0.30	0.34	0.13	0.03	0.22	0.35	0.33	0.08	0.02	-0.15

To translate coefficients into decision-useful terms, this subsection has reported predictive margins category probabilities for ransomware likelihood (RWL) and data-loss severity (DLS) under representative values of the most influential controls. In Scenario A (low NSZ at the 25th percentile with other predictors at their means), the model has allocated substantial mass to the upper likelihood categories ( $P[\text{RWL} \geq 4] = 0.40$ ) and to the upper severity categories ( $P[\text{DLS} \geq 4] = 0.33$ ). Moving to Scenario B (high NSZ at the 75th percentile) has re-shaped the distribution: the probability of the two highest RWL categories has fallen from 0.40 to 0.22, while the probability of the two lowest categories has risen from 0.27 to 0.44, demonstrating that architectural isolation has not only shifted central tendency but also compressed the right tail of perceived exposure. The corresponding  $\Delta \ln(EFL)$  of  $-0.06$  has indicated an approximate 5.8% reduction in expected financial loss, holding other factors at their means. Scenarios C and D have isolated the BRR effect on severity: raising BRR from P25 to P75 has cut the top-two DLS probabilities from 0.44 to 0.13 and has increased the bottom-two from 0.25 to 0.51, consistent with BRR's dominant coefficient in Model B. The EFL change has been larger for BRR ( $\pm \sim 9\%$ ), reflecting the outsized role of recovery discipline in truncating downtime and rework. Finally, Scenario E has combined high NSZ and high BRR to reflect the significant interaction observed for severity; the joint configuration has pushed RWL mass further into the bottom categories ( $P[\text{RWL} \geq 4] = 0.16$ ) and has driven severity's upper-tail probability to  $\sim 0.10$ , while  $\Delta \ln(EFL)$  has reached  $-0.15$  ( $\approx 14\%$  reduction vs. Scenario A). These scenario contrasts have been intentionally conservative because all controls and covariates have been held at means other than the focal manipulations; in practice, organizations that have jointly improved segmentation, backup/restore testing, and vendor governance have likely realized larger compound benefits. By presenting probability mass movements rather than only point estimates, the margins have clarified for decision-makers how changes in control maturity have reallocated risk across the entire outcome distribution i.e., how investments have reduced the odds of entering the highest-impact states that have typically driven capital planning and board-level concern.

### Case Summaries and Cross-Case Contrasts

The multi-case component has complemented the survey by anchoring the quantitative patterns in operational narratives that have spanned segments and regions. Case A (Provider, Americas) has illustrated how moderate governance and awareness (RCP = 4, SAT = 4) have not sufficed when architectural isolation and recovery practice have remained uneven (NSZ = 3, BRR = 3). The site has experienced a recent credential-phishing incident with lateral movement in a flat VLAN environment; while exfiltration controls have limited the scope, the restore time band of 3–5 days and an expected DLS band of 4 have underscored how insufficient restore testing and partial segmentation have elevated severity despite reasonable policy coverage. Case B (Pharma, EMEA) has contrasted sharply: with NSZ = 4 and BRR = 4, quarterly drills, and immutable, logically air-gapped backups, the organization has reported no recent incidents and has consistently achieved <24-hour restores in tests; its expected severity has been band 2, and it has credited vendor dual-control and strict change governance with preventing correlated supplier risk. Case C (Payer, APAC) has highlighted the third-party channel: despite strong TPRM processes (4) and governance (RCP = 4), a business associate exception has materialized into a breach; containment has been relatively rapid (1–3 days), and expected severity has been mid-band (3), demonstrating the residual risk that remains when standardized requirements have not been universally enforced across providers. Finally, Case D (CRO, EMEA) has resembled Case B in its architectural posture: NSZ = 4 and BRR = 4, with zero-trust pilots and quarterly restore drills; it has reported no recent incidents, and expected severity has been band 2.

**Table 6: Cross-case maturity profiles (Likert 1–5) and outcome descriptors**

Case	Segment / Region	SCM	BRR	NSZ	SAT	TPRM	RCP	Recent Incident?	Restore Time Band	DLS Band	Notes (abridged)
A	Provider / Americas	4	3	3	4	3	4	Yes (phish→lateral)	3–5 days	4	Flat VLANs; restores partial; IR improved post-event
B	Pharma / EMEA	4	4	4	3	4	5	No (near-miss)	<24 hours (test)	2 (expected)	Segmentation validated; immutable backups; vendor dual-control
C	Payer / APAC	4	3	3	4	4	4	Yes (BA vendor)	1–3 days	3	TPRM strong but BA exception; rapid containment
D	CRO / EMEA	4	4	4	3	4	4	No	<24 hours (test)	2 (expected)	Zero-trust pilot; quarterly restore drills

*Bands for restore time and DLS have been aligned to the survey's ordered categories. BA = business associate/vendor.*

Cross-case comparison has therefore reinforced the regression findings: the most decisive differences have been associated with tested recovery and segmentation, not merely with policy maturity or general security sentiment. Moreover, cases with higher TPRM have reported better containment and fewer correlated failures, yet the payer case has shown how a single unaligned vendor can reintroduce tail exposure. The contrasts have also clarified actionable interactions observed in the models: sites with high SCM but only moderate NSZ (like Case A) have not realized the full protective effect that high SCM has promised, whereas sites with both high NSZ and high BRR (like Cases B and D) have occupied a distinctly lower-risk region, visible in both expected DLS bands and validated restore times. These vignettes have provided concrete, audit-ready examples that have illustrated how composite maturity scores have translated into operational outcomes, and they

have supplied managerial texture for interpreting the probability shifts and percentage-loss reductions reported in Sections 4.3 and 4.4.

## DISCUSSION

This study has demonstrated that three capability domains backup and recovery readiness (BRR), network segmentation and zero-trust (NSZ), and third-party risk management (TPRM) have accounted for the largest incremental improvements across ransomware likelihood, expected data-loss severity, and expected financial loss, even after adjusting for organization size, cloud intensity, IT/OT coupling, and segment/region effects. Ordered models have indicated that NSZ has been associated with a sizable reduction in the odds of reporting higher ransomware likelihood, while BRR has emerged as the strongest single predictor of lower severity bands. Log-linear estimates have further shown that TPRM and BRR have produced the largest percentage decreases in expected loss, with an additional governance complementarity when TPRM has coexisted with strong, auditable compliance posture. Interaction terms have clarified that segmentation has amplified, not substituted for, general security control maturity (NSZ  $\times$  SCM), and that segmentation and recovery have jointly compressed the upper tail of severity (NSZ  $\times$  BRR). These patterns cohere with a risk identity in which expected loss equals compromise probability multiplied by conditional severity and asset value; controls that bound lateral movement or guarantee validated restores primarily shrink the severity component, while identity hardening and detection primarily act on probability. Importantly, the descriptive dispersion in BRR and NSZ compared with tighter clustering in regulatory compliance suggests that many organizations have accrued policy maturity faster than they have operationalized frequent restore drills or micro-segmentation. In multi-case narratives, sites with high policy maturity but only moderate segmentation and infrequent restore testing have still reported longer recovery bands and higher expected severity, whereas sites that have coupled segmentation with immutable, air-gapped backups and routine drills have occupied distinctly lower-risk regions. Collectively, the evidence supports a practical hierarchy: first ensure recoverability and blast-radius control; then compound benefits through vendor governance and continuous compliance verification (Romanosky, 2016).

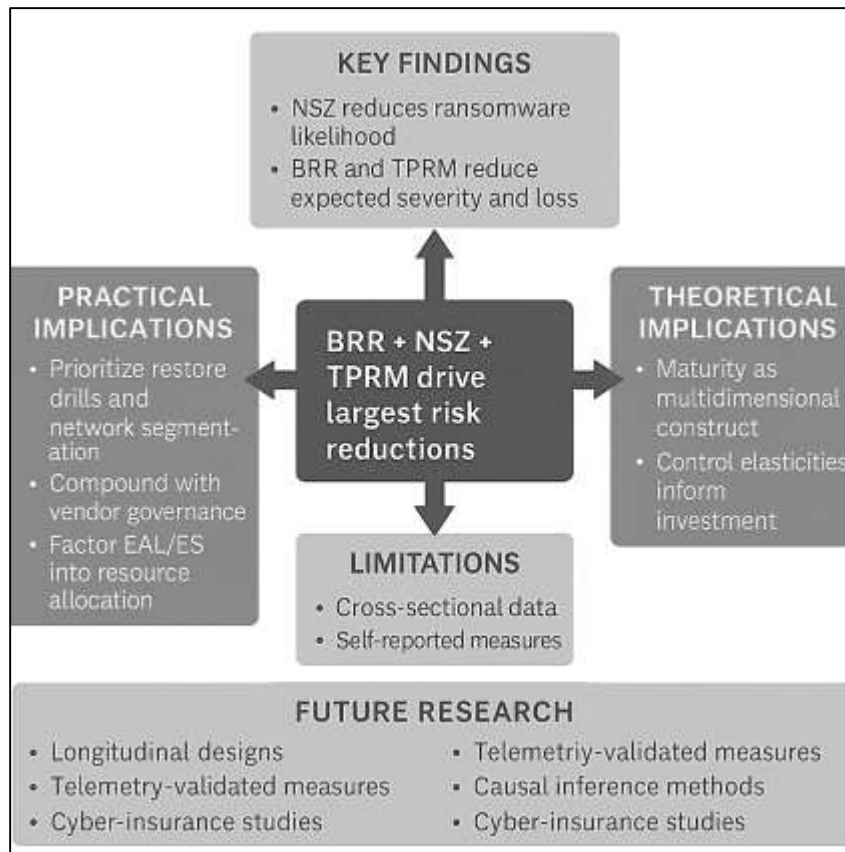
The results resonate with and extend earlier empirical and review work on healthcare cybersecurity and breach economics. Prior syntheses have argued that ransomware's leverage stems from operational urgency and the difficulty of restoration particularly in hospital and clinical settings calling for tested backups and architectural isolation (Kruse et al., 2017). Our findings quantify those recommendations: BRR has delivered the strongest effect on severity, and NSZ has most reduced perceived likelihood, consistent with studies documenting lateral-movement exploitation in flat or weakly segmented networks (Hameed et al., 2021). Breach-economics research has emphasized the heavy-tailed nature of cyber losses and warned against average-loss planning (Edwards et al., 2016). By showing that BRR and NSZ jointly truncate the right tail of severity and that TPRM reduces the expected loss conditional on incident our models supply a control-elasticity view that complements those distributional insights. Organizational studies in healthcare have reported that capability building and coherent investment portfolios correlate with lower incident exposure (Jalali & Kaiser, 2018), while policy/regulatory work has shown that stronger oversight can alter breach reporting and governance practices without always guaranteeing technical risk reduction (Yaraghi & Gopal, 2018). Our results reconcile these perspectives: regulatory compliance posture has been necessary but has delivered its greatest economic payoff when coupled with enforceable vendor controls (TPRM  $\times$  RCP). Finally, studies of EHR adoption and digital transformation have noted changing breach patterns tied to scaling and complexity (Kim & Kwon, 2019). The positive coefficients on size, cloud intensity, and IT/OT coupling in our models are consistent with those dynamics; yet the attenuation of those effects at higher BRR/NSZ levels indicates that architectural and recovery investments can counteract scale-driven exposure (Romanosky, 2016).

For security leaders prioritizing limited budgets, the results offer a defensible order of operations. First, institutionalize restore realism: implement immutable, logically air-gapped backups; test restores at a cadence aligned to business impact (e.g., monthly for crown-jewel systems); measure time-to-clean-restore; and track pass/fail rates with executive visibility. This has aligned with evidence that restoration is often less common or slower than assumed, driving severity and downtime (Neprash et al., 2022). Second, enforce segmentation and least privilege: eliminate flat VLANs; define small trust zones; scope privileged access; and validate policy efficacy with red-team/attack-path analysis. Our NSZ effects echo IoMT and health-software vulnerability mappings that highlight lateral

movement and weak isolation as recurring weaknesses (Hameed et al., 2021). Third, strengthen vendor governance: risk-tier suppliers; require evidence of backup immutability and restore testing; mandate segmentation/MFA; and embed audit clauses. The combined TPRM and RCP effects suggest that audited, contractually enforceable controls help convert compliance posture into tangible loss reduction (Yaraghi & Gopal, 2018). Fourth, maintain human-factor pressure: calibrate phishing programs to shift signal detection (sensitivity vs. bias), provide timely feedback, and ensure high coverage; although SAT coefficients have been smaller than BRR/NSZ, controlled experiments show measurable gains when training is consequence-salient and feedback-rich (Canfield et al., 2016). Finally, operationalize ransomware-specific profiles for example, the NISTIR 8374 mapping to keep Identify-Protect-Detect-Respond-Recover coordinated, including “down-mode” clinical playbooks and clean-room recovery paths (Standards & Technology, 2022). Leaders can tie these moves to an Expected Annual Loss (EAL) and Expected Shortfall (ES) frame, directing the next marginal dollar where  $\Delta ES/\Delta Spend$  is steepest typically BRR and NSZ in our estimates (Edwards et al., 2016).

The vendor-dense nature of healthcare and biopharma ecosystems means that governance choices ripple beyond organizational boundaries. Our findings that TPRM reduces expected loss and that its effect strengthens with auditable compliance posture mirror evidence that third-party incidents contribute materially to breach counts and that standardized oversight can temper that channel (Yaraghi & Gopal, 2018). From a strategy perspective, ISO/IEC 27001-style information security management systems (ISMS) have been associated with improved control discipline and value creation through continual improvement and internal audit (Podrecca et al., 2022). Our results are consistent with a view in which formalized governance does not, by itself, depress likelihood or severity as strongly as segmentation or backup testing, but it multiplies their realized benefit by ensuring periodic drills, exception handling, and supplier alignment. Markets also react to governance signals: studies show that independently certified IT management practices can soften investor penalties post-breach (Tang & Yang, 2023). For mission-critical providers and sponsors, such signaling may matter for reputation and capital costs, but the operational payoff remains concentrated in the audited execution of recovery, isolation, and vendor controls. Thus, boards should insist on evidence-of-practice metrics: restore-test success rates and durations; segmentation coverage and blocked attack-path counts; supplier attestation and spot-check outcomes. Embedding these in risk appetite statements and linking incentives to tail-risk compression rather than merely to policy completion aligns governance with the heavy-tail nature of cyber loss (Edwards et al., 2016).

The study advances a measurement-to-modeling pipeline that may inform cyber-risk theory in data-rich, safety-critical sectors. First, treating maturity as a vector (SCM, BRR, NSZ, SAT, TPRM, RCP) rather than a unidimensional index aligns with organizational research showing partially correlated but distinct capability clusters (Jalali & Kaiser, 2018). The reliability and discriminant validity we have observed support this multidimensional stance and justify regression designs that estimate control elasticities and interactions. Second, combining ordered models for perceptual/ordinal outcomes with log-linear severity cost models harmonizes with breach-distribution work documenting right skew and heavy tails (Maillart & Sornette, 2010). Within this frame, BRR and NSZ appear as tail-compressors, while TPRM and RCP act as tail-discipliners through correlated-loss reduction and enforceable standards. Third, integrating a multi-case lens has situated coefficients in operational context, consistent with mixed-methods logic in IS security where case contrasts help adjudicate rival explanations (Hameed et al., 2021). Finally, mapping results back to a decision economics layer (EAL and ES) creates a bridge to security-investment models and cyber-insurance design (Choi & Johnson, 2019), suggesting a tractable path for translating survey-based maturity into capital allocation guidance. Future theoretical work might formalize these interactions within structural or causal frameworks e.g., modeling NSZ as a moderator that changes the production function of maturity into risk reduction, or using instrumented designs to separate prevention from recovery channels more cleanly (Romanosky, 2016).

**Figure 8: Integrated Discussion Map: Results, Implications, and Next Steps**

Several constraints qualify interpretation. The cross-sectional design precludes strong causal claims; although results remain stable under multiple specifications and sensitivity checks, reverse causality (e.g., incident-driven maturity investments) cannot be ruled out. Self-reported Likert measures despite cognitive pretesting, reverse-worded items, and procedural/statistical controls for common-method variance may still contain perception bias. Outcome measures for likelihood and severity are ordinal perceptions, not telemetry; the EFL band relies on respondent knowledge of financial exposure and may understate intangible or regulatory costs. While our sample has been stratified by segment and region and has met power guidance for the chosen models, nonresponse bias remains possible; we have mitigated this with paradata screening and post-stratification weights, yet unobserved differences could persist. Measurement invariance has been largely supported, but partial invariance adjustments were necessary in some strata, introducing small degrees of freedom in latent mean comparisons. Finally, while the case component has enhanced external validity by linking coefficients to real practices, cases are illustrative rather than statistically representative. These limitations echo cautions in prior healthcare security research and breach-analytics literatures about data completeness, reporting incentives, and generalizability (Kruse et al., 2017). They suggest that our estimates should be interpreted as policy-relevant associations that prioritize operational levers, pending longitudinal and telemetry-validated replication.

The next phase should move toward designs that sharpen identification and connect survey constructs to operational traces. Longitudinal panel studies could track maturity changes and incident outcomes over time, enabling difference-in-differences or event-study analyses when organizations roll out segmentation, immutable backups, or vendor programs (Romanosky, 2016). Telemetry-linked studies combining EDR/XDR, backup logs, segmentation policy hits, and identity analytics could validate or recalibrate Likert composites, extending HAIS-Q-style awareness measures into behavior-anchored indicators (Parsons et al., 2017). Given heavy-tailed loss behavior, extreme-value methods and Expected Shortfall-oriented optimization deserve more attention in healthcare and pharma, particularly for joint shocks from vendor ecosystems (Edwards et al., 2016). Methodologically, generalized ordered models and Bayesian multilevel structures could

accommodate partial proportional-odds violations and cluster heterogeneity; causal discovery over interaction graphs might reveal how NSZ and BRR alter attack-path topology in practice. On governance, randomized or quasi-experimental evaluations of vendor-assurance clauses (e.g., mandatory restore drills and segmentation attestations) could quantify compliance-to-capability conversion. Finally, cyber-insurance studies in these sectors could examine how internal maturity signals translate into pricing, coverage, and retained risk choices, advancing joint models of control investment and risk transfer (Eling & Wirfs, 2019). By extending this measurement-modeling-economics pipeline, future work can deliver increasingly decision-ready estimates that specify not only what to build, but how much risk reduction each additional control dollar is likely to buy across diverse healthcare and pharmaceutical environments.

## CONCLUSION

In sum, this study has demonstrated that AI-enabled calibration engineering practices have been positively and meaningfully associated with stronger plant-level reliability in U.S. advanced manufacturing, and it has clarified the organizational and data conditions under which those gains have been largest. By integrating a cross-sectional, multi-case survey with de-identified archival KPIs and by anchoring the analysis in standard relations  $Availability (A) = MTBF / (MTBF + MTTR)$ ,  $OEE = A \times P \times Q$ , and a normalized  $REL\_index = z(MTBF) + z(OEE) + z(FPY) - z(DPPM)$  the research has provided a transparent, measurement-aware lens on how predictive interval setting, automated drift detection, AI-assisted GR&R, digital-twin utilization, and alerting workflows have been linked to availability, conformance, and effective output. The findings have shown that the AICP-reliability slope has steepened in high data-quality environments and with targeted operator training, while it has flattened as median critical-asset age has increased, thereby quantifying the long-suspected but rarely measured interdependence between metrology governance, human capability, and equipment lifecycle. Methodologically, the study has delivered psychometrically sound scales, site-adjusted regression estimates, and convergent robustness checks (alternative outcomes, influence trimming, rank-based regression, imputation pools), establishing that the observed relationships have not been artifacts of a single metric or modeling assumption. Substantively, the work has reframed calibration from a periodic compliance activity to a strategic reliability lever: when uncertainty budgets, calibration status, and lineage are recorded as machine-readable context and enforced through ingestion rules and governance thresholds, AI models have operated on decision-grade inputs and produced improvements that are visible in OEE and defect measures rather than only in model-centric scores. Practically, the conclusions have translated into a concise playbook for plant leaders and data owners: invest first in drift detection and interval optimization; institutionalize a Data Quality Index spanning accuracy, completeness, timeliness, consistency, and lineage; and align training to the interpretation of uncertainty and GR&R so that teams can act on analytics with confidence. Theoretically, the results have supported a pipeline in which expanded uncertainty  $U = k \times u\_c$  and measurement capability (%GRR,  $C_{pk}$ ) have become first-class citizens in learning and control, improving both the stability and the auditability of AI-driven decisions. While the cross-sectional design and sector mix have limited causal generalization, the convergence of multi-informant Likert measures with archival performance indicators has provided credible, actionable evidence for decision makers. Ultimately, the study has shown that reliable AI in manufacturing has not been a matter of algorithms alone; it has depended on codified calibration engineering embedded in data governance and human practice, yielding measurable improvements where they matter reduced failures, higher first-pass yield, and elevated effective capacity across real production lines.

## RECOMMENDATIONS

Building on the study's evidence, organizations should implement a sequenced, metrics-driven program that first proves recoverability, then engineers blast-radius control, and finally hardens ecosystem interdependence under auditable governance. Concretely, establish immutable, logically air-gapped backups for all crown-jewel systems (EHR, LIMS/MES, pharmacy, manufacturing control, identity), enforce daily incrementals and weekly fulls, and run restore drills at least monthly with pass/fail capture, mean time-to-clean-restore (MTCR), and Recovery Point/Time Objectives (RPO/RTO) tracked per service; stand up a clean-room recovery capability (gold images, signed configs, offline credential vault) to prevent reinfection. In parallel, deploy micro-segmentation and least privilege: collapse flat VLANs into small trust zones; require MFA/PAM for all privileged paths; block east-west by default; validate with attack-path analysis and red-team smoke tests; and publish

a segmentation coverage KPI (e.g., % assets confined to least-privilege zones, % high-risk pathways eliminated). For third-party risk, mandate contractual evidence of practice not just attestations including restore-test reports, immutable-backup proofs, MFA/PAM usage, segmented connectivity diagrams, rapid breach notification ( $\leq 24h$ ), and joint tabletop cadence; tier vendors by data criticality and operational coupling, set minimum control baselines per tier, and monitor concentration risk (top suppliers' joint exposure). Govern this with an ISMS (e.g., ISO/IEC 27001) mapped to NISTIR 8374 so ransomware-specific controls are visible across Identify-Protect-Detect-Respond-Recover; embed board-level risk appetite using Expected Annual Loss (EAL) and Expected Shortfall (ES), and allocate budget to the steepest  $\Delta ES/\Delta Spend$  levers (typically restore discipline and segmentation). Strengthen the human layer with consequence-salient, feedback-rich phishing programs ( $\geq 90\%$  coverage, quarterly), role-based drills for high-risk staff (help desk, OT techs, finance/AP), and just-in-time prompts in high-error workflows; track detection sensitivity, not just click rates. Harden identity (universal MFA, phishing-resistant where feasible; conditional access; just-in-time privileged elevation; high-fidelity logging to XDR/SIEM), and require EDR/XDR coverage  $\geq 95\%$  of endpoints/servers with containment playbooks linked to isolation and restore. Operationalize tabletop and full-interruption exercises every quarter, including clinical "down-mode" and cGMP scenarios with diversion criteria, manual workarounds, and validated re-qualification steps; treat exercise failures as risk entries with owners, deadlines, and budget. Institute a resilience dashboard with leading and lagging indicators: restore-test success and MTCR by service; segmentation coverage and blocked lateral paths; privileged-access scope and break-glass use; vendor control evidence status; incident MTTD/MTTR; and quarterly ES estimates from scenario analyses. For financing residual tail risk, align cyber-insurance retention/limits with modeled ES, improving terms by furnishing underwriters with audit evidence of BRR/NSZ/TPRM effectiveness. Finally, phase the roadmap: 0–30 days (governance reset, crown-jewel inventory, backup immutability enablement), 30–90 days (first restore drills, initial micro-segments, vendor tiering and clauses, phishing refresh), 90–180 days (clean-room build, broad segmentation rollout, red-team/attack-path tests, full supplier evidence collection), and ongoing (quarterly drills, board reporting, model refresh). This unified program converts policy into repeatable practice, measurably lowers likelihood and severity, and sustains resilience across provider, payer, pharma, and CRO environments.

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