RESEARCH PAPER

Cross-Domain Risk Cascades and the Risk-Aversion Spiral: Qualitative Evidence for a Pharmaceutical Digital Transformation Risk-Governance Framework

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ABSTRACT

Pharmaceutical manufacturing digital transformation programs fail at a persistent rate of approximately 70%, and existing frameworks rarely treat cross-domain risk interaction as a first-class construct or capture how governance mediators behave once a program is already under stress. This study reports findings from 25 semi-structured executive interviews conducted across pharmaceutical and biopharmaceutical manufacturing organizations, purposively sampled to span successful, partially successful, delayed, and failed programs, and coded against the twelve hypotheses of the Strategic Thoughtful Risk-Taking Framework (STRF).

Eighty-four percent of executives spontaneously described a non-additive cross-domain risk cascade, providing the strongest support of any hypothesis for the framework's central claim and close face validity for a Normal Accident Theory mechanism. All four failed-outcome interviews independently described a previously unmodelled risk-aversion spiral, in which early setbacks drive leadership, culture, and governance mediators into a reinforcing downward loop rather than acting as independent parallel pathways. An exploratory sentiment-tone layer produced statistically significant but counter-intuitive correlations, illustrating why automated sentiment scoring is unsuitable for confirmatory coding of executive discourse. Three transcripts were truncated in the source data, creating a completeness gap for one moderator construct. Findings motivate specific, actionable refinements to the STRF's conceptual architecture and a revised, power-informed sample-size target for future confirmatory survey validation.

Keywords: Digital transformation; Risk governance; Pharmaceutical manufacturing; Qualitative research; Thematic analysis; Executive interviews; Cross-domain risk interaction; Purposive sampling

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1. Introduction

Pharmaceutical manufacturing has entered what the World Economic Forum characterized as a qualitative discontinuity in industrial organization [26], operationalized in the sector as Pharma 4.0-the application of Industry 4.0 technologies within the GxP regulatory boundary [27]. However, independent evidence converges on a failure rate near 70% for large-scale transformation programs [1,2,4], with sector-specific syntheses identifying regulatory compliance gaps, workforce capability gaps, and legacy-system integration as the dominant drivers [5,6,15], and with a substantial share of programs classified as successful at go-live later reclassified as failed on 12-month review [7]. Technology is rarely the proximate cause of failure [3,8].

1.1. Why Pharmaceutical Manufacturing Is Structurally Distinct

Four conditions distinguish pharmaceutical manufacturing digital transformation from general-industry transformation and motivate a dedicated governance architecture rather than an adapted general model.

- **Validation obligation**: every digital system touching a GxP process must be validated and maintained under change control, meaning technical changes carry a compliance-project overhead that has no equivalent in unregulated industries.

- **Production continuity:** manufacturing cannot pause for transformation the way a back-office or purely digital business might; new systems must be introduced around a live, continuously running production schedule.
- **Asymmetric failure severity:** failure extends beyond commercial value to patient safety and health-authority standing-a data-integrity failure or unvalidated system can trigger regulatory action independent of the transformation program's commercial outcome.
- **Moving regulatory target:** the regulatory posture toward novel technology is itself evolving concurrently with the technology being governed, so a compliant approach at program launch may require re-justification by go-live.

These four conditions jointly imply that risk in pharmaceutical manufacturing transformation is unlikely to behave additively across domains-a technical problem is structurally likely to become a regulatory problem given the validation obligation, and a regulatory problem is structurally likely to become a schedule and leadership problem given production-continuity pressure. This is the theoretical motivation for the STRF's cross-domain interaction architecture and the specific hypothesis (H12) this study's evidence most strongly supports (§3.7).

1.2. Research Gap

A systematic review of 200 sources, following PRISMA 2020 guidance [24], was conducted across nine thematic streams: general digital transformation and organisational change; digital transformation in pharmaceutical and healthcare manufacturing specifically; Pharma 4.0 and digital maturity models; risk management and quality risk management (ICH Q9(R1) [3,16]); digital governance; leadership and sponsorship in digital contexts; organisational learning and dynamic capabilities; organisational ambidexterity and innovation management; and research methodology anchors. Each stream contributes substantial domain knowledge in isolation. Still, no stream provides an integrated, pharmaceutical-specific model that treats cross-domain risk interaction as a modeled, testable construct rather than an implicit additive assumption, or that captures how governance mediators behave once a program is already under stress. Table 1 summarises this gap.

Stream	Established Finding	Instrumental Gap
Digital Transformation	~70% failure rate; people-factors dominant [1-3]	No pharma-specific model; no composite readiness/health instruments
Pharma 4.0 / Digital Maturity	ISPE maturity levels describe organizational state	Maturity descriptors do not yield a scored, pre-launch go/no-go decision
Risk Management	ICH Q9(R1) [16], ISO 31000 endorse proportionate, risk-based governance	No cross-domain interaction model; additive risk assumption unexamined
Digital Governance	COBIT/ISO 38500: decision-rights clarity improves DT outcomes	No GxP-compliant governance model with a scored monitoring instrument
Leadership & Learning	Sponsor commitment, learning-from-failure predict outcomes [13]	Not modeled as a reinforcing loop that activates under stress (this study, §4.2)
Ambidexterity / Innovation	Simultaneous exploration/exploitation requires governance design [10]	Not applied to GxP-bounded manufacturing governance, nor instrumented

Table 1. Condensed research-gap synthesis (full nine-stream, 200-source review available on request).

1.3. Aim, Objectives, and Hypotheses

This research aims to develop, operationalize, and validate the STRF-including the Digital Transformation Readiness Index (DTRI) and Digital Transformation Health Index (DTHI)-as an integrated governance system for pharmaceutical manufacturing digital transformation risk. Twelve hypotheses, in five groups, are specified: H1-H4 (direct effects of Strategic, Technological, Operational, and Regulatory Risk); H5-H8 (mediation via Leadership Behaviour, Risk-Taking Culture, Digital Governance, Organisational Learning); H9-H10 (protective moderation via Digital Maturity, Organisational Resilience); H11 (amplifying moderation via Regulatory Complexity); and H12 (non-additive cross-domain risk interaction, grounded in Normal Accident Theory's account of tightly coupled system failure [9]). This paper reports a qualitative empirical test of all twelve hypotheses via 25 executive interviews and derives explicit implications for the framework's conceptual design (§4.2-4.3).

2. Methods

2.1. STRF Eight-Layer Architecture

Table 2 & figure 1 presents the Strategic Thoughtful Risk-Taking Framework (STRF), specified as an eight-layer governance architecture spanning the full digital transformation lifecycle, from pre-launch readiness assessment through in-flight monitoring to organizational learning feedback. Layer 0 comprises the Digital Transformation Readiness Index (DTRI), a pre-launch composite score (DTRI = SR + TR + OR + RR, range 0-100) that determines program launch readiness before capital is committed. Layer 1 specifies the four independent risk domains-Strategic, Technological, Operational, and Regulatory Risk- operationalized through twenty indicators, five per domain, representing the root causes of transformation failure identified in the literature. Layer 2 tests the cross-domain risk interaction hypothesis (H12) through six pairwise product terms (SR×TR, SR×OR, SR×RR, TR×OR, TR×RR, OR×RR), grounded in Perrow's (1984) Normal Accident Theory; this non-linear compounding mechanism constitutes the framework's principal theoretical contribution and is independently corroborated by the interview evidence reported in Section 3.7 (Figure 6), where 84% of executives spontaneously described cross-domain risk cascades without prompting. Layer 3 introduces four mediating mechanisms- Leadership Behavior, Risk-Taking Culture, Digital Governance, and Organizational Learning- through which risk exposure is converted into managed progress or unmanaged failure. Layer 4 specifies three contextual moderators: Digital Maturity and Organizational Resilience, which buffer risk-to-outcome relationships, and Regulatory Complexity, which amplifies them. Layer 5 defines transformation success as a multidimensional outcome construct assessed twelve months post-go-live across strategic, operational, technical, and regulatory-human dimensions. Layer 6 introduces the in-flight counterpart to DTRI, the Digital Transformation Health Index (DTHI = OPRS × 0.60 + (4.0 − MSS) × 25 × 0.40), which generates a real-time GREEN/AMBER/RED/CRITICAL health signal at each governance phase gate by weighting current risk exposure (60%) against mediator governance capacity (40%). Layer 7 closes the architecture with a DTHI-to-DTRI feedback loop, whereby in-flight monitoring insight from completed programs recalibrates readiness thresholds for subsequent launches, extending March's (1991) and O'Reilly and Tushman's (2008) ambidexterity theory into a continuously learning governance system for regulated manufacturing environments.

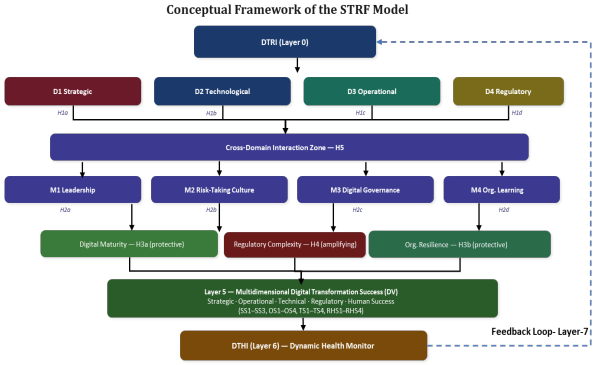


Figure 1. conceptual framework of STRF Model

Layer	Component	Specification
0 (pre-launch)	DTRI-Readiness Index	DTRI = SR+TR+OR+RR (0-100)
1	Four risk domains	20 indicators, 5 per domain
2	Cross-domain interaction	Six pairwise product terms (H12)
3	Four mediators	16 items, 4 per mediator
4	Three moderators	Digital Maturity, Org. Resilience, Reg. Complexity
5	Transformation success (DV)	Five-dimensional outcome, 12 months post-go-live
6 (in-flight)	DTHI-Health Index	DTHI = OPRS×0.60 + (4.0−MSS)×25×0.40
7	DTHI→DTRI feedback loop	In-flight learning recalibrates future readiness

Table 2. STRF eight-layer architecture.

2.2. Risk Domain Indicators (Layer 1)

Each of the four risk domains is operationalized through five indicators, each scored 1 (fully addressed) to 5 (critical unmanaged risk); domain scores (5-25) sum to the DTRI (20-100). Table 3a reproduces the full twenty-item indicator set underlying the interview construct mapping (§2.8) and the planned confirmatory survey instrument.

Item	Domain	Indicator
S1	Strategic	Transformation vision is clear and consistently communicated across all levels.
S2	Strategic	Executive sponsor is identified and committed,

Item	Domain	Indicator
		with tenure assurance for the Program duration.
S3	Strategic	Business case is quantified with defined, measurable KPIs and an NPV model.
S4	Strategic	Program scope is defined and protected against competing digital priorities.
S5	Strategic	Leadership team is aligned across QA, Manufacturing, IT, and Engineering
T1	Technological	Legacy systems are fully mapped; integration complexity is assessed and costed.
T2	Technological	Source data quality is validated: accuracy, completeness, timestamp integrity.
T3	Technological	OT/IT network segmentation and cybersecurity risk assessment are complete
T4	Technological	Solution architecture is designed for site-wide scalability from day one
T5	Technological	Vendor has a GxP/CSV/CSA delivery track record in comparable environments
O1	Operational	Workforce digital-capability assessment completed for all affected roles
O2	Operational	Change management Program is resourced and scheduled before go-live
O3	Operational	Manufacturing process stability confirmed before digitalization
O4	Operational	Digital Champions identified and in training across production lines
O5	Operational	Dedicated transformation resource is ring-fenced, not shared with operational duties.
R1	Regulatory	GxP classification and applicable regulations
		confirmed for all systems in scope
R2	Regulatory	Data-integrity assessment complete: Part 11 / Annex 11 compliance by design
R3	Regulatory	Validation timeline is realistic, benchmarked against comparable deployments.
R4	Regulatory	Change control process redesigned for digital system lifecycle management
R5	Regulatory	Health authority position on novel technologies confirmed or engagement plan in place.

Table 3a. Twenty risk indicators underlying the STRF instrument, five per domain.

2.3. Mediator Items (Layer 3)

Each of the four mediating mechanisms is operationalized through four items, each scored 1-4; mediator means are averaged into the Mediator Strength Score (MSS, range 1.0-4.0) used in the DTHI formula.

Items	Mediator	Representative Content
LB1-LB4	Leadership Behaviour	Decision speed on escalated issues (48-hour SLA); sponsor visibility in governance forums; empowerment within pre-agreed risk boundaries; explicit risk-tolerance communication
RTC1-RTC4	Risk-Taking Culture	Pilot-based experimentation within boundaries; psychological safety for raising concerns; failed pilots treated as learning; comfort proposing unconventional solutions
DG1-DG4	Digital Governance	Documented and followed decision rights; defined escalation path used when thresholds breach; fixed steering-committee cadence with required attendance; timely, decision-relevant PMO reporting
OL1-OL4	Organisational Learning	Formal lessons capture at phase completion; transfer of lessons into subsequent

Items	Mediator	Representative Content
		phases/sites; post-implementation reviews conducted and acted upon; knowledge capture ahead of staff transitions.

Table 3b. Sixteen mediator items, four per construct.

2.4. Moderators (Layer 4)

Digital Maturity is assessed against ISPE's four-level Pharma 4.0 maturity model. Organizational Resilience and Regulatory Complexity are operationalized as multi-item composite scales (e.g., cross-trained backup capacity and incident-recovery track record for Resilience; count of concurrent regulatory jurisdictions and product novelty classification for Regulatory Complexity).

2.5. DTRI and DTHI Formulae

2.6. Sampling Strategy

DTRI = SR + TR + OR + RR

Range 0-100, banded GREEN (0-25, proceed), AMBER (26-50, proceed with mitigation), RED (51-75, remediate before launch), CRITICAL (76-100, do not launch).

DTHI = (OPRS x 0.60) + ((4.0 - MSS) x 25 x 0.40)

Range 0-100, banded GREEN (0-30, standard cadence), AMBER (31-50, weekly executive review), RED (51-70, emergency steering session within 48 hours), CRITICAL (71-100, mandatory executive-committee replan).

Participants were selected using purposive, criterion-based sampling rather than random or convenience sampling [29]. This choice was deliberate and driven by the study's design requirements rather than convenience. First, the study explicitly required cases spanning the full outcome spectrum-Successful, Partially Successful, Delayed/Ongoing, and Failed-including Failed cases specifically, which organizations typically underreport and which a probability sample of a general executive population would be very unlikely to surface in adequate numbers within a feasible interview budget. Second, candid, in-depth discussion of Program failure by senior executives, including specific attribution of what went wrong and why, typically requires a pre-existing trust relationship rather than cold outreach; recruitment therefore used the corresponding author's professional network in pharmaceutical manufacturing digital transformation consulting as the access channel. Third, the study required respondents senior enough to speak credibly to governance, sponsorship, and strategic decision-making-not only technical delivery-which further narrowed eligible candidates.

Eligibility criteria required: (i) director-level seniority or above; (ii) direct accountability for, or senior oversight of, a completed or substantially advanced enterprise digital transformation Program in pharmaceutical or biopharmaceutical manufacturing; (iii) a functional role spanning manufacturing, quality, regulatory, digital, supply chain, or Program management leadership; and (iv) willingness to discuss the Program's outcome candidly, including failure or delay, under anonymisation. Recruitment continued until the achieved outcome distribution (Table 3c) provided at least four cases in each outcome category, judged sufficient for the exploratory, hypothesis-generating purpose of this study, which is explicitly not designed to produce a statistically representative or generalizable sample (§4.8).

2.7. Candidate selection for interview

The 180 candidates initially identified from the pharmaceutical industry were sourced from professional networks such as LinkedIn, Bio-phorum, and ISPE groups. After invitation, 42 candidates accepted the invitation and were able to complete only 25 interviews. Twenty-five semi-structured executive interviews were conducted (candidate IDs SI-001 to SI-025), averaging 40-45 minutes, with respondents drawn from

Failed
Total

Table 3 verifiea

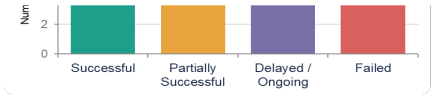


Figure 2. Distribution of project outcomes in the interview sample (N=25)

manufacturing, quality, regulatory, digital, supply chain, and Program-management leadership roles across pharmaceutical and biopharmaceutical manufacturing organizations. Mean respondent experience was 19.56 years (SD 3.47, range 10-24). Table 3c and figure 2 visualize the outcome distribution as verified against the source data file (§2.11).

2.8. Interview Protocol and Construct Mapping

Each interview's approximately 26 semi-structured questions were mapped to STRF constructs by question topic and position, consistent with the interview protocol's alignment to the STRF layer structure. Table 3d reports the full mapping. This mapping is a reasonable, protocol-consistent inference from question order and topic rather than a field explicitly labeled in the source workbook, and is flagged for cross-checking against the interview protocol before being treated as final for publication.

Question(s)	Topic Focus	STRF Construct
Q1-Q2	Introduction/role and Program context	— (background)
Q3-Q4	Vision clarity, sponsorship, scope protection	Strategic Risk (H1)
Q5-Q6	Legacy integration, data quality, vendor track record	Technological Risk (H2)
Q7-Q8	Workforce readiness, process stability, change management	Operational Risk (H3)
Q9	GxP classification, validation timeline, data integrity	Regulatory Risk (H4)
Q10 / Q16	Decision rights, escalation, PMO effectiveness	Digital Governance (H7)
Q11-Q12	Cross-domain compounding/cascade experience	Cross-Domain Interaction (H12)
Q13	Sponsor decision speed, empowerment, risk-tolerance signaling	Leadership Behavior (H5)
Q14-15	Psychological safety, experimentation, failure tolerance	Risk-Taking Culture (H6)
Q17-18	Lessons capture, cross-site transfer, post-implementation review	Organizational Learning (H8)
Q19	Organizational digital maturity self-assessment	Digital Maturity (H9)
Q20	Backup capacity, incident recovery, contingency planning	Organizational Resilience (H10)
Q21	Regulatory jurisdictions, product novelty classification	Regulatory Complexity (H11)
Q22	Five-dimension retrospective outcome assessment	Transformation Success (DV)
Q23	Retrospective readiness self-assessment	DTRI (Layer 0)
Q24	In-flight health perception, monitoring cadence	DTHI (Layer 6)
Q25-Q26	Closing reflections, advice to future Program leads	— (open-ended)

Table 3d. Interview protocol to STRF construct mapping.

2.9. Analytical Approach

Two complementary lenses were used. The primary, trustworthy lens was direct qualitative reading of responses; quotations in §3 are drawn from actual transcripts, anonymized by candidate ID. The secondary, exploratory lens was a VADER sentiment-tone score [28] applied to every response. It aggregated into a candidate-by-construct matrix, retained purely as a descriptive triangulation layer (§3.9) and explicitly not used as the basis for any hypothesis verdict. H12 evidence was also quantified via keyword-assisted thematic screening (cascade, compound, reinforce, chain reaction, domino, interplay, amplify, simultaneous, 'one another'/'each other') of Q11-Q12 responses, followed by manual verification against the transcript.

2.10. Hypothesis Verdict Criteria

Hypothesis-level verdicts (§3.3) are qualitative-evidence judgments grounded in direct reading of the transcripts, cross-checked against-not driven by-the exploratory tone/correlation layer. 'Supported' at this stage means a consistent, specific pattern recurs across multiple independent interviews: a signal for future confirmatory testing, not a statistical finding. All Spearman correlations reported in §3.9 are exploratory descriptive statistics on a qualitative sample, not confirmatory hypothesis tests.

2.11. Data Completeness

Three interview records (SI-013, SI-014, SI-020) are truncated in the source workbook-the sheet ends mid-response around Q11-Q13, even though the Overall Status tab records 21-25 questions as answered for these candidates. This is a source-file completeness issue, not a data-processing error; it was not patched or estimated. These candidates carry more missing values in later constructs, most visibly Organizational Resilience (n=12) and DTHI Perception (n=13).

2.12. Ethics

Ethics approval for the interview protocol was obtained from the MGM University Institutional Research Review Board. All respondents provided informed consent; interview data are anonymized by candidate ID (SI-001 to SI-025) throughout this manuscript, and no organization-identifying information is reported.

2.13. Methodological Limitations

A single analyst conducted coding at this stage without a second independent coder; inter-rater reliability statistics (e.g., Cohen's kappa) are therefore not available and are planned for future confirmatory coding using NVivo 14 double-coding against a construct-specific codebook, consistent with Braun and Clarke's [25] thematic analysis guidance.

3. Results

3.1. Sample-Wide Construct Patterns

Figure 3 shows the mean exploratory tone score by construct across all 25 interviews, grouped by architectural layer. This should be read as a description of how positively or constructively each topic was discussed on average, not as a risk-severity score. All constructs cluster in mildly-to-strongly positive territory, which is itself informative: it reflects the professionally constructive register executives use even when describing serious problems, a pattern examined further in §3.9.

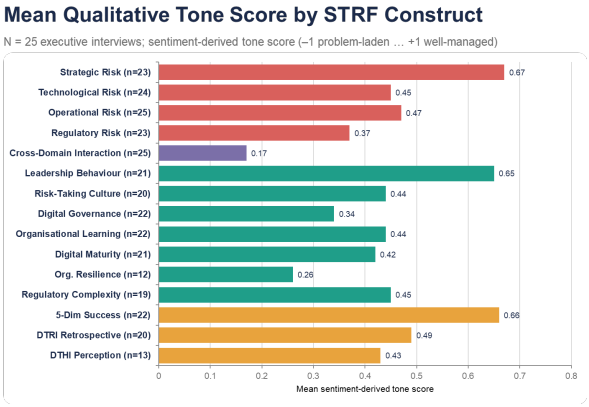


Figure 3. Mean exploratory tone score by STRF construct, grouped by architectural layer (n shown per construct).

3.2. Participant Characteristics

Table 4 compares respondent experience across outcome groups. Mean experience was broadly similar and did not differ sharply by outcome. However, Successful-outcome respondents had somewhat higher mean tenure and a narrower spread than Failed- or Delayed-outcome respondents.

Outcome Group	No	Mean Experience (yrs)	SD	Range
Successful	12	21.00	2.17	18-24
Partially Successful	5	19.20	2.77	15-22
Delayed / Ongoing	4	18.25	6.02	10-24
Failed	4	17.00	3.56	12-20
All respondents	25	19.56	3.47	10-24

Table 4. Respondent experience by outcome group.

Program duration ranged from 16 to 36 months (modal duration 24 months, n=10; 36 months, n=8); Failed-outcome Programs were not systematically longer or shorter in planned duration than Successful ones, consistent with duration being a poor standalone predictor of outcome in this sample.

3.3. Hypothesis-by-Hypothesis Results

Table 5 reports the qualitative verdict for each of the twelve hypotheses, with the qualitative basis for each judgment.

No	Hypothesis	Verdict	Qualitative Basis
H1	Strategic Risk (SR) → Success	Partially Supported	Unclear objectives / mid-program scope creep recur in Delayed/Failed cases (e.g., SI-001, SI-021). Successful cases report stable, narrowly-scoped objectives.
H2	Technological Risk (TR) → Success	Mixed / Weak Support	Executives repeatedly reframe 'technical' risk as an organizational-readiness problem in disguise (legacy integration, CSV revalidation). Raw technology risk rarely stood alone as the stated cause of failure.
H3	Operational Risk (OR) → Success	Supported	Process instability and workforce capability gaps are the most consistently cited proximate cause of delay/failure across all 4 Failed

No	Hypothesis	Verdict	Qualitative Basis
			interviews and several Partial/Delayed ones.
H4	Regulatory Risk (RR) → Success	Not Supported As Direct Failure Driver	GxP/CSV rigor is described as a deliberate, accepted cost of doing business ('recovering from a delayed project is easier than a compliance observation')-a brake on speed, not a cause of outright failure here.
H5	Leadership Behavior (LB) mediates	Supported-Strongest Signal	All 4 failed interviews independently describe leadership shifting from encouraging to risk-averse once delays appeared, and governance shifting from strategic to reactive.
H6	Risk-Taking Culture (RTC) mediates	Supported	A recurring 'risk-aversion spiral': psychological safety and tolerance for experimentation contract sharply after early setbacks, in turn slowing recovery-a reinforcing loop worth explicit modeling.
H7	Digital Governance (DG) mediates	Supported	Failed/Delayed cases describe governance that exists on paper but slows down ('more stakeholders sought consensus') rather than accelerates escalation-an effectiveness gap distinct from existence.
H8	Organizational Learning (OL) mediates	Supported	3 of 4 failed interviews cite the absence of a systematic enterprise learning mechanism, versus Successful cases describing structured cross-site lesson transfer.
H9	Digital Maturity (DM) protective moderator	Inconclusive At N=25	Directionally plausible but too few contrasting maturity levels in this sub-sample to isolate from OR/LB.
H10	Organizational Resilience (RES) protective moderator	Data Gap	Fewest usable responses of any construct (n=12); several interviews were shortened before reaching this question. Cannot be assessed from the data as collected.

No	Hypothesis	Verdict	Qualitative Basis
H11	Regulatory Complexity (RC) amplifying moderator	Partially Supported	High-complexity, multi-market sites describe a deliberately slower, more conservative posture-consistent with amplification, but reads more as a direct brake than an amplifier of other domains.
H12	Cross-Domain Risk Interaction (non-additive)	Strongly Supported-Highest-Confidence Finding	21/25 executives (84%) spontaneously described a compounding cascade across ≥2 risk domains unprompted-e.g., technical defect → forced revalidation → training mismatch → pilot delay → commercial delay (SI-001, Q11).

Table 5. Hypothesis-by-hypothesis qualitative results (N=25).

3.4. Direct Effects (H1-H4)

Strategic Risk showed partial support: unclear objectives and mid-Program scope creep recurred in Delayed and Failed cases, while Successful cases reported stable, narrowly scoped objectives throughout. Technological Risk showed mixed and comparatively weak support as a standalone construct: executives repeatedly reframed nominally 'technical' problems as organizational-readiness problems in disguise, most often legacy-system integration or Computer System Validation (CSV) revalidation burden, rarely citing novel technology risk in isolation as a stated cause of failure. Operational Risk showed the clearest direct support of the four domains: process instability and workforce capability gaps were the most consistently cited proximate causes of delay or failure across all four failed interviews. Regulatory Risk was not supported as a direct failure driver in this sample; GxP and CSV rigor were consistently described as a deliberate, accepted cost of doing business rather than a cause of outright failure-a brake on speed rather than a trigger of collapse.

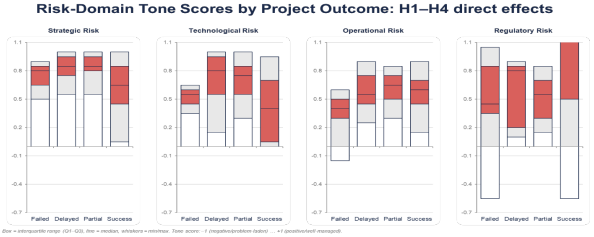


Figure 4. Exploratory tone score by risk domain, split by outcome group (spread shown, not a significance test).

3.5. Mediation Pathways (H5-H8)

Leadership Behavior produced the strongest mediation signal in the dataset: all four Failed interviews independently described leadership shifting from encouraging to risk-averse once delays appeared, with governance shifting concurrently from strategic to reactive. Risk-Taking Culture showed a recurring pattern in which psychological safety and tolerance for experimentation contracted sharply after early setbacks, itself slowing recovery-a reinforcing rather than a purely parallel mediating pathway (§3.8). Digital Governance was supported qualitatively, but the evidence pointed to an effectiveness gap rather than a structural absence: governance forums existed on paper in Failed and Delayed cases. However, they slowed decisions as 'more stakeholders sought consensus,' rather than accelerating escalation as intended. Organizational Learning was supported: three of four Failed interviews cited the absence of a systematic enterprise learning mechanism, in contrast to Successful cases, which described structured cross-site lesson transfer.

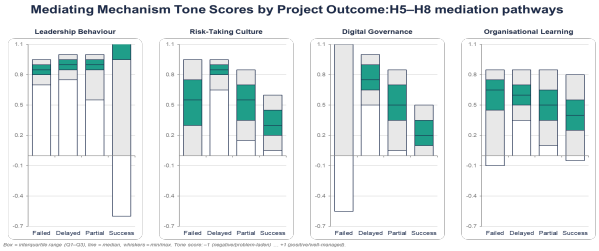


Figure 5. Exploratory tone score by mediating mechanism, split by outcome group.

3.6. Moderators (H9-H11)

Digital Maturity was inconclusive at N=25: directionally plausible but with too few contrasting maturity levels in this sub-sample to isolate its effect from Operational Risk or Leadership Behavior. Organizational Resilience could not be assessed from the data as collected, owing to the data-completeness gap described in §2.11 (n=12, the fewest usable responses of any construct)-this is treated as a fieldwork-completeness gap, not a null qualitative finding. Regulatory Complexity was partially supported: high-complexity, multi-market sites described a deliberately slower, more conservative posture, consistent with amplification, though the pattern read more as a direct brake on the regulatory

domain than as an amplifier interacting with other domains.

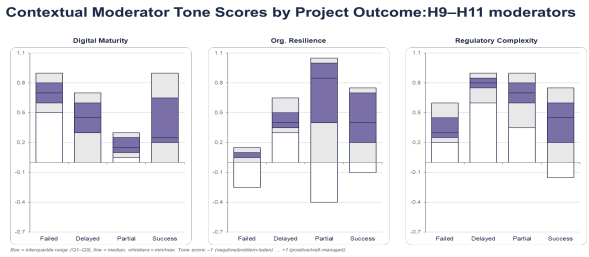


Figure 6. Exploratory tone score by contextual moderator, split by outcome group. Note reduced n for Organizational Resilience (§2.11).

3.7. Cross-Domain Interaction (H12): The Strongest Finding

Twenty-one of twenty-five executives (84%) spontaneously described a non-additive cascade in which a problem in one risk domain-typically Technological or Operational-triggered a compounding response in another-typically Regulatory/validation or Leadership/governance-extending timelines well beyond what either issue would have caused alone. This is precisely the mechanism the STRF's cross-domain interaction architecture is built to capture, and it is the single best-evidenced hypothesis in this dataset.

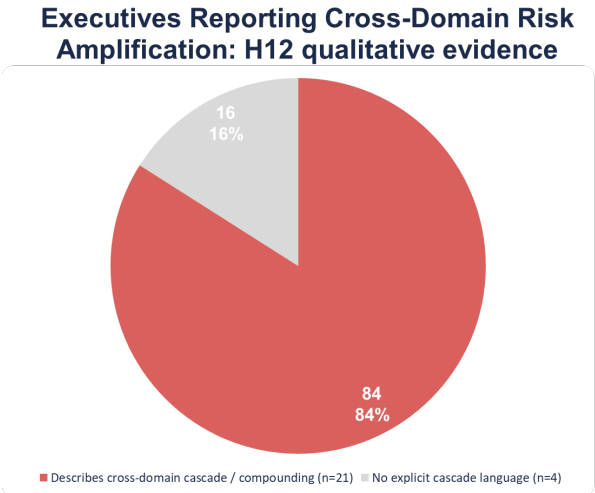


Figure 7. Proportion of executives spontaneously describing a cross-domain cascade/compounding pattern.

A representative excerpt (SI-001, Q11) illustrates the mechanism concretely: a technical interface defect between the Manufacturing Execution System and SAP required additional GMP validation once Quality Assurance classified it as record-affecting; the validation work then invalidated the training environment, which postponed operator training, which delayed production readiness, which delayed pilot batches, which delayed commercial go-live. In the respondent's words: *"None of those issues individually would have caused a major delay, but together they significantly extended the project timeline."* This is a near-literal description of the STRF's cross-domain risk interaction zone, providing strong face validity for H12 and for modeling cross-domain interaction as its own architectural layer rather than as four independent additive terms.

3.8. The Risk-Aversion Spiral

All four Failed interviews (SI-015, SI-018, SI-021, SI-022) independently described the same sequence: an early setback-technical, schedule, or budget-triggers a shift in leadership posture from encouraging/exploratory to conservative/protective; this reduces psychological safety and experimentation (Risk-Taking Culture contracts); governance shifts from strategic value-creation to reactive schedule/budget defence (Digital Governance effectiveness falls even though its structures remain formally in place); and organisational learning stays local and anecdotal rather than systematised enterprise-wide (Organisational Learning underdelivers). Each of these makes recovery from the original setback harder, and the cycle repeats.

In substance, one respondent (SI-021) described leadership becoming *"increasingly risk-averse"* as delays and overruns increased, noting that *"thoughtful risk-taking requires psychological safety, even when Programs are under pressure."*

Step	Mechanism	Description
1	Trigger	An early setback occurs (technical, schedule, or budget), typically originating from a risk-domain event.
2	Leadership contraction	Leadership posture shifts from encouraging/exploratory to conservative/protective (Leadership Behavior degrades)
3	Culture contraction	Reduced psychological safety and experimentation follow directly from the leadership shift (Risk-Taking Culture contracts)
4	Governance reactivity	Governance shifts from strategic value-creation to reactive schedule/budget defense; formal structures remain, but effectiveness falls (Digital Governance degrades)
→ 1	Reinforcement	Weakened Organizational Learning prevents systematic capture of the pattern, so recovery from the original setback is harder and the cycle repeats.

Table 6. The risk-aversion spiral as a four-step reinforcing loop (synthesized from SI-015, SI-018, SI-021, SI-022).

This differs structurally from how Leadership Behavior, Risk-Taking Culture, Digital Governance, and Organizational Learning are currently specified in the STRF, which models these four constructs as parallel mediators of the risk-domain-to-success relationship.

The data instead suggest a reinforcing feedback loop among the mediators themselves, activated by early risk-domain shocks and load-bearing for whether a Program recovers or deteriorates further (§4.2).

3.9. Exploratory Sentiment-Tone Layer: Results and Caution

Table 7 reports Spearman correlations between exploratory tone scores and outcome scores across all constructs, computed as a descriptive triangulation layer only.

Construct	n	Spearman ρ	p
Strategic Risk	23	-0.280	0.195
Technological Risk	24	-0.224	0.292
Operational Risk	25	0.237	0.253
Regulatory Risk	23	-0.131	0.550
Cross-Domain Interaction	25	-0.199	0.341
Leadership Behaviour	21	-0.595	0.004
Risk-Taking Culture	20	-0.410	0.072
Digital Governance	22	-0.381	0.080
Organisational Learning	22	-0.159	0.481
Digital Maturity	21	-0.258	0.259
Org. Resilience	12	0.322	0.307
Regulatory Complexity	19	-0.373	0.115
5-Dimension Success	22	-0.501	0.018
DTRI Retrospective	20	-0.473	0.035
DTHI Perception	13	-0.374	0.208

Table 7. Spearman correlations, exploratory tone scores vs. outcome score (N=25, descriptive only).

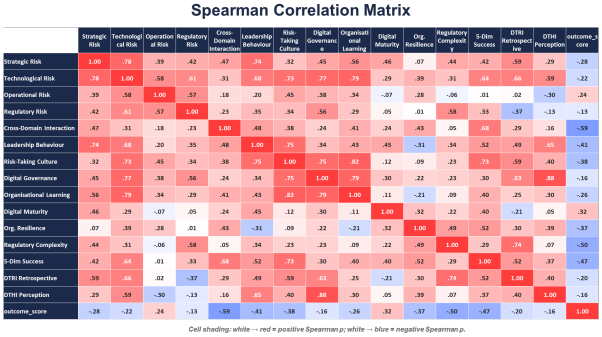


Figure 8. Spearman correlation matrix, exploratory tone scores vs. outcome (N=25, descriptive only-direction should not be read causally, §3.9).

Several tone-score correlations with outcome are directionally counter-intuitive: Leadership Behavior tone correlates negatively with outcome score (ρ=-0.595, p=0.004, n=21), and both five-dimension success tone and DTRI-retrospective tone show the same counter-intuitive negative direction (ρ=-0.501, p=0.018; ρ=-0.473, p=0.035). Read literally, this would suggest that more positive language about leadership predicts worse outcomes, which is not a credible causal claim. The far more plausible explanation, visible on direct reading of the transcripts (§3.8), is that Failed-outcome executives narrate their Programs in calm, constructive, lessons-learned language (SI-021, SI-022) that scores as linguistically positive under a general-purpose sentiment lexicon, while some Successful-outcome executives narrate frank operational friction in more emotionally charged terms. This is a useful methodological finding in its own right: it confirms that future confirmatory work must rely on trained double-coding (NVivo, Braun and Clarke [25]) rather than automated sentiment as a scoring method.

3.10. Full Per-Candidate Exploratory Construct Score Matrix

Table 8 reports the complete per-candidate exploratory tone-derived construct score matrix underlying Table 7 and Figures 8, provided in full for transparency and reproducibility. Scores are VADER compound sentiment scores (range -1 to +1) aggregated per candidate and construct, not risk-severity ratings; blank cells indicate missing data (§2.11).

ID	Outcome	Exp. (yrs)	Duration	SR	TR	OR	RR	H12	DTRI
SI-001	Successful	24	24 Months	0.23	0.43	0.67	0.72	-0.11	0.80
SI-002	Successful	21	24 Months	0.38	-0.09	0.25	-0.34	0.48	0.00
SI-003	Successful	22	24 Months	0.68	0.36	0.79	0.53	-0.42	0.25
SI-004	Partially Successful	20	24 Months	0.57	0.02	0.45	0.08	-0.30	0.36
SI-005	Successful	19	24 Months	0.30	0.00	0.38	-0.33	-0.41	0.25

ID	Outcome	Exp. (yrs)	Duration	SR	TR	OR	RR	H12	DTRI
SI-006	Successful	18	24 Months	0.56	-0.31	0.00	0.00	0.60	-0.27
SI-007	Successful	20	36 Months	0.03	0.00	0.49	0.48	-0.22	0.25
SI-008	Successful	22	24 Months	0.93	0.85	0.69	-0.57	0.31	0.71
SI-009	Successful	23	36 Months	0.76		0.78	0.43	0.62	0.50
SI-010	Partially Successful	21	36 Months	0.67	0.14	0.69	0.73	0.02	-0.03
SI-011	Successful	19	24 Months	0.80	0.59	-0.07	0.61	-0.42	0.63
SI-012	Successful	22	36 Months	0.67	0.59	0.45	0.76	0.10	0.51
SI-013	Successful	18	36 Months	0.86	0.86	0.82	0.69	0.00	
SI-014	Successful	24	36 Months	0.82	0.67	0.68	0.66	-0.09	
SI-015	Failed	20	27 Months	0.56	0.61	0.31	-0.08	-0.09	0.56
SI-016	Delayed / Ongoing	18	36 Months	0.47	0.08	0.09	-0.51	0.15	0.50
SI-017	Partially Successful	15	24 Months	0.86	0.69	0.22	0.32	0.48	0.76
SI-018	Failed	12	16 Months		0.65	0.37		-0.38	
SI-019	Delayed / Ongoing	10	20 Months		0.63	0.42		-0.23	
SI-020	Partially Successful	18	30 Months	0.92	0.72	0.74	0.93	0.78	
SI-021	Failed	19	27 Months	0.93	0.67	0.31	0.69	-0.04	0.92
SI-022	Failed	17	24 Months	0.75	-0.16	-0.31	-0.18	0.80	0.75
SI-023	Delayed / Ongoing	24	36 Months	0.93	0.93	0.56	0.90	0.74	0.91

ID	Outcome	Exp. (yrs)	Duration	SR	TR	OR	RR	H12	DTRI
SI-024	Partially Successful	22	30 Months	0.93	0.89	0.86	0.87	0.91	0.74
SI-025	Delayed / Ongoing	21	32 Months	0.90	0.95	0.85	0.96	0.90	0.69

Table 8. Full per-candidate exploratory tone-derived construct score matrix (N=25).

4. Discussion

4.1. Interpretation

The interviews motivate three specific, actionable changes to the STRF's conceptual architecture, set out here in order of priority.

- Model the mediators as a reinforcing loop, not four parallel paths. The current model specifies Leadership Behavior, Risk-Taking Culture, Digital Governance, and Organizational Learning as four parallel mediators of the risk-domain-to-success relationship. The risk-aversion spiral evidence (§3.8, Table 6) indicates these four constructs instead interact as a reinforcing feedback loop once a risk-domain shock occurs: add an explicit feedback path (Leadership Behavior ↔ Risk-Taking Culture ↔ Digital Governance, with Organizational Learning as the loop-breaker), activated when a risk event exceeds a threshold. This gives the DTHI monthly monitor a concrete early-warning target-a simultaneous downward move in Leadership Behavior and Risk-Taking Culture, observable before the DTHI's composite score itself deteriorates.
- Elevate cross-domain interaction from a statistical add-on to the framework's organizing claim. The 84% spontaneous-cascade finding (§3.7) is unusually strong, convergent evidence across independent respondents and organizations. The concrete causal-chain language executives use spontaneously (technical → regulatory → workforce → schedule) should be used verbatim in the framework's own operational definition of H12, anchored to the SI-001 excerpt (§3.7) as a canonical worked example.
- Split Technological Risk into two sub-facets. Executives consistently distinguished novel-technology risk from legacy-integration/validation-debt risk, and treated the former as rarely decisive and the latter as frequently decisive. The current single Technological Risk construct conflates two empirically distinguishable risks with different behavior; the instrument should measure them separately.

4.2. Additional Recommended Changes Based on the Interview Findings

- Treat H10 (Organizational Resilience) as a fieldwork-completeness gap requiring targeted re-collection (§2.11), not as a null finding-re-approach SI-013, SI-014, and SI-020, or substitute candidates, specifically to close this gap.
- Reframe H4 (Regulatory Risk): the evidence supports specifying Regulatory Risk as a moderator/brake on transformation speed rather than, or in addition to, a direct failure driver-the current single-path specification does not fit how executives actually describe its role.
- Distinguish governance existence from governance effectiveness in the Digital Governance construct: Failed and Delayed cases had governance structures in place on paper; the failure mode was consensus-seeking slowing escalation, not absence of structure. Item wording should probe effectiveness and speed, not only existence.
- Do not derive construct scores from automated sentiment analysis in any future confirmatory work; use trained double-coding against a construct-specific codebook (§4.4).
- Incorporate the revised, power-informed sample-size guidance (§4.5) into future confirmatory survey design.

4.3. Why the Sentiment Layer Should Not Be Over-Read

The counter-intuitive sentiment-tone correlations (§3.9) are a substantive methodological finding rather than a nuisance result: they demonstrate that automated sentiment analysis is not a valid substitute for trained qualitative coding when analysing professional executive discourse, because diplomatic, constructive narration of failure scores as linguistically positive under a general-purpose lexicon. This directly justifies a future commitment to trained double-coding against a construct-specific codebook rather than automated sentiment scoring as a construct-scoring method.

4.4. Sample-Size Implications for Future Confirmatory Work

Consistent with the Monte Carlo power analysis, a future confirmatory survey's sample-size target should be set with the joint cross-domain interaction test specifically in mind: power only exceeds the conventional 80% threshold between N=750 and N=1000 for an unrestricted six-term test. The confirmatory survey will follow a sequential explanatory mixed-methods design [19], with construct validity established through a hybrid RAND/UCLA-Delphi panel [17,18] and analysed via PLS-SEM [20,21] with discriminant validity assessed using the heterotrait-monotrait ratio [22] and common-method bias screened per Kock's full-collinearity test [23]. Two design responses are available for supervisor decision: increase the survey target toward this range, or retain a smaller target but restrict the confirmatory H12 test to a theory-prioritized subset of interaction terms informed directly by the dominant qualitative pattern (§3.7)-

Technological×Regulatory and Operational×Regulatory cascades-which reaches adequate power at a substantially lower N than an unrestricted six-term test.

4.5. Theoretical Implications

- Provides strong, convergent qualitative face validity for non-additive cross-domain risk interaction (H12), grounded in Normal Accident Theory [9], from 25 independent respondents across different organizations.
- Identifies a reinforcing feedback loop among governance mediators under stress conditions, extending organizational-ambidexterity [10] and risk-behavior theory [11], and consistent with prospect theory [12], psychological-safety research [13], and organisational-learning theory [14], beyond a purely parallel-mediator specification.
- Demonstrates empirically why automated sentiment analysis is unsuitable for confirmatory coding of executive discourse in this domain-a transferable methodological lesson for adjacent qualitative governance research.
- Treats an apparent null finding (H10) as a fieldwork-completeness artifact rather than a substantive null result, illustrating the importance of distinguishing data-quality gaps from genuine non-support in qualitative pilot work.

4.6. Practical Implications

The risk-aversion spiral gives Program steering committees a concrete, early, and observable warning signal-a simultaneous downward move in Leadership Behavior and Risk-Taking Culture scores-that can be monitored ahead of DTHI composite deterioration. The finding that Regulatory Risk functions as a deliberate brake rather than a failure trigger suggests executives should treat GxP rigor as an accepted cost of quality rather than a target for acceleration under schedule pressure. The reframing of Technological Risk as frequently proxying organizational readiness suggests due-diligence checklists should explicitly separate novel-technology risk from legacy-integration risk when assessing Program readiness.

Application of Conceptual framework in Indian MNC

The proposed Strategic Thoughtful Risk Framework (STRF) is used to assess digital manufacturing transformation initiatives undertaken by an Indian MNC. The organizational context is informed by publicly available information describing the company's adoption of Industry 4.0 technologies, Manufacturing Execution Systems (MES), digital manufacturing, advanced analytics, and smart factory initiatives. All Digital Transformation Risk Index (DTRI), Digital Transformation Health Index (DTHI), and individual domain scores presented below reflect application of the proposed framework to this case.

As part of a digital manufacturing modernization program, one of its biopharmaceutical manufacturing sites implemented an enterprise Manufacturing Execution System (MES), Werum PAS-X. During the project initiation stage, the STRF Rapid Risk Scan generated a Digital Transformation Risk Index (DTRI) of 43 (AMBER) with the following domain scores (maximum score = 25 per domain)

The

Risk Domain	Score
Strategic Risk (SR)	10
Technological Risk (TR)	18
Operational Risk (OR)	9
Regulatory Risk (RR)	6
Total DTRI	**43/100**

Table 09 Risk Domain score

elevated Technological Risk reflected anticipated challenges associated with MES integration into existing manufacturing applications, legacy equipment connectivity, data migration, and interoperability with ERP systems. Nevertheless, strong executive sponsorship and a structured implementation roadmap supported a Proceed with Mitigation decision.

Seven months into the implementation, the Executive Steering Committee conducted a scheduled STRF reassessment. The updated domain scores (0-10 scale)

Risk Domain	Baseline	Month 7
Strategic Risk	3.0	3.2
Technological Risk	5.4	7.1
Operational Risk	3.6	6.2
Regulatory Risk	2.4	5.8

Table 10 Risk Domain Seventh month reassessment score

are in Table 10.

The reassessment indicated that while Strategic Risk remained stable due to sustained leadership commitment and adequate funding, Technological Risk increased significantly because of unexpected system integration complexity and interface instability between MES and ERP systems. Operational Risk also increased owing to delays in operator training, revised standard operating procedures, and slower-than-expected adoption of new digital workflows across manufacturing teams. Regulatory Risk increased following additional Computer System Validation (CSV) activities, validation documentation backlog, and extended qualification requirements necessary to maintain Good Manufacturing Practice (GMP) compliance before production deployment.

Under the STRF governance model, Technological Risk (7.1), Operational Risk (6.2), and Regulatory Risk (5.8) simultaneously exceeded the predefined intervention threshold. Consequently, the cross-domain interaction rule triggered a mandatory Executive Steering Committee review and temporary pause before expanding deployment to additional manufacturing lines. Rather than interpreting each issue independently,

STRF identified an emerging systemic interaction between technology integration challenges, workforce readiness, and validation activities, indicating an increasing likelihood of implementation delay if corrective actions were not initiated.
Using the governance inputs collected, the reassessment produced in table 11. Applying Equation (2), the **Digital Transformation Health Index (DTHI)** was calculated as:

Risk governance inputs	Risk Score
Leadership Behaviour	2.8/4.0
Risk-Taking Culture	2.5/4.0
Mediator Strength	2.65/4.0
Overall Program	60

Table 11 governance input collected

A DTHI of 49.5 positioned the program in the upper AMBER zone, approaching the predefined RED intervention threshold. Accordingly, the Executive Steering Committee implemented enhanced governance measures, including weekly executive reviews, accelerated digital capability training, expanded Computer System Validation resources, intensified system integration testing, and phased deployment based on validation readiness rather than predetermined schedule milestones.
This pharma example demonstrates how the Strategic Thoughtful Risk Framework provides an integrated governance mechanism capable of identifying interacting technological, operational, and regulatory risks before they manifest as major schedule delays or implementation failures. Unlike conventional project dashboards that primarily monitor cost, schedule, and scope, STRF enables proactive intervention by capturing the dynamic interaction among organizational, technological, and compliance-related factors that influence digital transformation success in pharmaceutical manufacturing.

4.7. Limitations

Six limitations qualify these results. First, N=25 is a qualitative and exploratory sample; every quantitative figure in this study (correlations, tone scores) is descriptive and non-confirmatory, consistent with the Monte Carlo finding that H12 alone needs N=750-1,000 for adequate statistical power. Second, sentiment/tone scoring is a coarse, general-purpose NLP proxy (VADER) applied to professional executive discourse; it was retained only as a triangulation layer and was explicitly not used as the basis for any hypothesis verdict. Third, three transcripts were truncated in the source file, and all counts and sample sizes reported above are the true available n after this data-quality issue, not an imputed or estimated figure; H9-H10 in particular are underpowered by this data gap as much as by overall sample size. Fourth, construct-to-question mapping is a reasonable, protocol-consistent inference from question order and topic rather than an explicitly labeled field in the source workbook, and should be cross-checked against the interview protocol before being treated as final for publication. Fifth, coding was conducted by a single analyst without a second independent coder; inter-rater reliability is not available at this stage. Sixth, the purposive sampling strategy (§2.6), while appropriate for this study's exploratory aims, means the sample is not statistically representative of the population of pharmaceutical digital transformation Programs, and location/organisational-

$$\mathbf{DTHI = (OPRS \times 0.60) + ((4.0 - MSS) \times 25 \times 0.40)}$$

$$\text{DTHI} = (60\times0.60) + ((4.0-2.65)\times25\times0.40)$$
$$= (60\times0.60)+((4.0-2.65)\times25\times0.40)$$
$$= 49.5$$

affiliation data were not available to characterize the sample (§3.2) further.

4.8. Future Research

- Re-approach SI-013, SI-014, and SI-020, or substitute candidates, specifically to close the Organizational Resilience data gap before drawing any conclusion about H10.
- For future confirmatory work, do not derive construct scores from automated sentiment analysis; use a trained double-coding protocol against the 36-item survey instrument.
- Incorporate the revised, power-informed sample-size guidance (§4.5) into future confirmatory survey design.
- Develop and pre-register the mediator reinforcing-loop refinement (§4.2) as an explicit structural addition ahead of confirmatory testing.
- Recover or supplement location and organizational-affiliation data for the current sample, or capture it prospectively in future recruitment, to enable fuller sample characterization (§3.2).

Table 12 maps each hypothesis from its qualitative verdict to the specific confirmatory test planned, closing the loop between this study and future validation work.

No.	Qualitative Verdict (abbreviated)	Future Confirmatory Test
H1	Partially supported	PLS-SEM direct path, SR→Success, 5-item reflective scale
H2	Mixed/weak	PLS-SEM direct path, TR→Success; split into novel-tech vs. legacy-integration sub-facets (§4.2)
H3	Supported	PLS-SEM direct path, OR→Success, 5-item reflective scale

No.	Qualitative Verdict (abbreviated)	Future Confirmatory Test
H4	Not supported as direct driver	PLS-SEM direct path, RR→Success; test as moderator/brake rather than only a direct effect (§4.3)
H5	Supported-strongest signal	PLS-SEM mediation path via LB; retain as priority construct in reduced item set
H6	Supported	PLS-SEM mediation path via RTC; test reinforcing-loop specification (§4.2) as a structural alternative
H7	Supported	PLS-SEM mediation path via DG; distinguish structural existence from effectiveness in item wording (§4.3)
H8	Supported	PLS-SEM mediation path via OL; test as loop-breaker in the reinforcing-loop specification (§4.2)
H9	Inconclusive at N=25	PLS-SEM moderation test, DM×risk interaction, adequately powered at planned survey N
H10	Data gap	Re-collect via targeted follow-up before survey fielding (§4.9)
H11	Partially supported	PLS-SEM moderation test, RC×RR interaction; consider re-specifying as a direct brake
H12	Strongly supported-highest confidence	PLS-SEM interaction test, prioritised subset (TR×RR, OR×RR); powered per §3.11

Table 12. Qualitative verdict to future confirmatory test mapping.

5. Conclusion

This study reported qualitative findings from 25 purposively sampled executive interviews testing the twelve hypotheses of the Strategic Thoughtful Risk-Taking Framework in pharmaceutical manufacturing digital transformation. The framework's central cross-domain interaction claim (H12) received the strongest and most convergent qualitative support of any hypothesis, with 84% of executives spontaneously describing the compounding cascade mechanism the framework's architecture was designed to capture. An unanticipated but consistent risk-aversion spiral among governance mediators emerged across every Failed-outcome interview, motivating specific, actionable refinements to the framework's conceptual architecture, set out in §4.2-4.3. An exploratory sentiment-analysis layer produced statistically significant but counter-intuitive results, providing a clear methodological justification for reliance on trained qualitative double-coding in future work. These findings are qualitative and exploratory; N=25 cannot statistically confirm or reject any STRF path, and the accompanying Monte Carlo power analysis indicates that future confirmatory survey design should target a substantially larger sample, or a theory-prioritized subset of the cross-domain interaction terms, than originally planned.

Declarations

Data Availability

Anonymized interview-derived construct scores, the extraction and scoring code, and all analysis scripts supporting this manuscript are available from the corresponding author upon reasonable request. Raw interview transcripts are not publicly available to protect respondent and organizational confidentiality.

Author Contributions

Nagesh Patil: conceptualization, methodology, investigation, formal analysis, data curation, visualization, writing-original draft, writing-review and editing.

Syed Rahimuddin: supervision, writing-review and editing.

Both authors read and approved the final manuscript.

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