Vol 6, Issue 7, July 2026 www.ijesti.com E-ISSN: 2582-9734
International Journal of Engineering, Science, Technology and Innovation (IJESTI)

AI Capability, Organizational Preparedness, and Innovation Performance in Pharmaceutical Digital Transformation: A Multi-Actor Empirical Study

Sachin Shamrao Kurundkar
Research Scholar, Department of Management, Nirwan University, Jaipur, Rajasthan.

Dr. Sapna S Rathore
Research Supervisor, Department of Management, Nirwan University, Jaipur, Rajasthan.

ABSTRACT

The study explores how AI capabilities (technical, data and algorithmic) relate to pharma companies' readiness for transformation as well as the results of their innovative processes, products and regulatory compliance across the pharmaceutical industry. We base our research on Dynamic Capability Theory, TOE Framework, Organizational Readiness Theory, HCI theory and Stakeholder Theory, and employ a multi-actor structural model to test survey data from 400 pharmaceutical professionals in India, Pakistan and the MENA region (Jan-April 2025) using Qualtrics. Our multi-method triangulation design uses PLS-SEM with cIPMA, NCA, fsQCA and ANN. All three AI capability paths exhibited a statistically significant effect on Organizational Readiness ($\beta = 0.267$ to 0.351, $p < 0.001$; $R^2 = 0.519$). All three Organizational Readiness to Innovation paths also exhibited a statistically significant effect ($\beta = 0.324$ to 0.374, $p < 0.001$; $R^2 = 0.220$ to 0.268). All 78 HTMT pairwise tests passed with bootstrapped confidence intervals demonstrating discriminant validity, with every pair being less than 0.85. Twelve mediation indirect effects were significant, and NCA identified large ceiling effects ($d = 0.681$ to 0.738) at a minimum Organizational Readiness level of 2.55 to 5.0. MGA revealed significant actor-type heterogeneity ($\chi^2 = 11.70$, $p = 0.020$), and fsQCA produced exploratory sub-threshold patterns while ANN produced non-linear importance rankings supporting the previously mentioned results.

Keywords: *PLS-SEM; Necessary Condition Analysis (NCA); Human–Computer Interaction Quality; Regulatory Compliance; Technology Adoption; Digital Innovation Ecosystem.*

1. INTRODUCTION

Due to the impact of Artificial Intelligence (AI), there is a dramatic acceleration in the rate at which the pharmaceutical sector is undergoing digital transformation. Li et al. (2025) identified the strong positive correlation between AI adoption and pharmaceutical firms' overall capability to innovate (coefficient = 0.136, $p < 0.01$), which is mediated by dynamic capabilities. Despite continued high levels of investment by pharmaceutical organisations, the progress made by AI to create quantifiable levels of innovation performance has been inconsistent; the pharmaceutical sector continues to cite a lack of skills and talent as the primary barrier to successful digital transformation (Pistoia Alliance, 2024; GlobalData, 2024).

Existing literature has several limitations that make it difficult to understand the inconsistency of the topics discussed in this article. The first is that neither Shi et al. (2025) nor Hu et al. (2024) uses a unified structural model that incorporates AI, pharma-specific organizational readiness, and innovation performance at several levels within the same model. Secondly, current AI readiness measures are cross-industry or not specific to pharmaceuticals (Jöhnk et al., 2020; Weber et al., 2023). Thirdly, the quality of interaction between humans and AI has not been recognized as a valid mediating variable in pharma innovation models (Scharowski et al., 2025; Hoffman et al., 2023). Fourthly, innovation performance has only been measured in total rather than at different levels (Hoang & Hien, 2024). Lastly, the differences among actors in terms of pathways from AI capability to innovation have not been empirically studied (Abdallah et al., 2025; Hu et al., 2024).

This study addresses each of the five gaps cited via the articulation of four unique research questions:

- RQ1: In what ways do dimensions of AI capabilities predict the preparedness of organizations?
- RQ2: In what way(s) does organizational preparedness, as mediated by Human-Computer Interaction (HCI) quality, predict process, product, and regulatory forms of innovation?
- RQ3: What minimum conditions and exploratory configurations are associated with high levels of innovation (i.e., pharmaceutical innovation)?
- RQ4: Do the structural associations cited in RQs 1-3 differ significantly across different types of actors (i.e., pharmaceutical actors)?

The study contributes in substantive ways: (1) introduces an integrated multi-actor empirical model for pharmaceutical AI digital transformation; (2) presents a pharmaceutical-specific organizational preparedness scale that demonstrates full HTMT$_{95}$ levels of discriminant validity; (3) levels of HCI quality as a formally specified mediating construct; (4) develops the first-ever scale for measuring the performance of pharmaceutical regulatory innovation; (5) provides evidence for differing structural associations across types of actors via an emerging proliferation of an economy context.

2. THEORETICAL BACKGROUND AND HYPOTHESES

2.1 Dynamic Capabilities Theory and AI Capability

Dynamic Capabilities Theory, developed by Teece and others (1997) and Eisenhardt and Martin (2000), considers Competitive Advantage as resulting from the firm's Ability to sense, seize, and reconfigure resources. Mubarik et al. (2025) provide empirical evidence that the use of AI facilitates a firm's Ability to integrate both Internal/External Resources in order to drive Corporate Innovation. The three dimensions of Capability measured in this study were: AI Technical Capability (ATC) which refers to the infrastructure, computing power, and systems integration; AI Data Capability (ADC) which relates to data governance, interoperability, and Good Practice (GxP) data integrity; AI Algorithmic Capability (AAC) referring to model selection, lifecycle management, and explainability (ISPE, 2022). Additionally, Weber et al. (2023) confirm that these three dimensions are interrelated but are Organizationally distinct.

H1: AI Technical Capability is positively associated with Organizational Preparedness.

H2: AI Data Capability is positively associated with Organizational Preparedness.

H3: AAC is positively associated with Organizational Preparedness.

2.2 TOE Framework, Organizational Readiness, and Preparedness

The TOE framework (Tornatzky & Fleischer) defines organizational preparedness as the context in which technology capability affects outcomes. Organizational Readiness Theory (Holt et al. 2007; Weiner 2009) defines readiness as distinct from capability as a means of delivering a technology solution. This study defines organizational preparedness using four dimensions specific to the pharmaceutical industry: (a) Regulatory Compliance Readiness (OPR), (b) Workforce AI Readiness (OPW), (c) Strategic AI Alignment (OPS), and (d) Organizational Learning/Adaptation (OPL). The four dimensions incorporate regulatory requirements of Good X Practice (GxP) for validation and provisions for FDA/EMA governance of Artificial Intelligence (AI) that are not found in other readiness instruments. Organizational preparedness is the mechanism by which organizations reconfigure resources to produce measurable innovation (Teece et al., 1997).

H4: Organizational Preparedness is positively associated with Process Innovation Performance.

H5: Organizational Preparedness is positively associated with Product Innovation Performance.

H6: Organizational Preparedness is positively associated with Regulatory Innovation Performance.

H7a–c: Organizational Preparedness mediates AI Capability → Process Innovation (H7a), Product Innovation (H7b), and Regulatory Innovation (H7c).

2.3 HCI Theory and HCI Quality as Mediator

The interaction quality between humans and computers can be determined by three components: usability, trust calibration, and workflow integration — they dictate whether an employee will use AI effectively (Norman, 2013; Amershi et al, 2019). In a study by Scharowski et al. (2025), the authors deem the Trust Scale appropriate for use in the AI Context; in another work by Marconi et al. (2026), they identify usability, trust, and workflow integration as the "pragmatic core" of human-AI interaction quality. HCI quality mediates the relationship between AI capability and innovation because it acts as a mechanism that converts capabilities at the organizational level to behaviors at the individual level (Preacher and Hayes, 2008; Hayes, 2018), in addition to moderating the infrastructure pathway for governance.

H8a–c: HCI Quality mediates AI Capability → Process Innovation (H8a), Product Innovation (H8b), and Regulatory Innovation (H8c).

2.4 Innovation Performance Disaggregation and the Multi-Actor Framework

Pharmaceutical companies have consistently defined their AI influence as a composite of Innovation Performance (Hoang & Hien, 2024; Shi et al, 2025). In this study, we identify three kinds of innovation based on their use of Artificial Intelligence: (i) Process Innovation; (ii) Product Innovation; (iii) Regulatory Innovation – a new construct that measures AI's impact on submission speed, compliance monitoring and first cycle approval rates in relation to the number of drug submissions made. These five actors (Research and Development; Manufacturing; Regulatory Affairs; Clinical; Digital and IT) can be defined using Freeman's (1984) Stakeholder Theory and its extension by Mitchell et al. (1997) and Parmar et al. (2010). Each actor type uses qualitatively different types of mechanisms to interact with AI, and, as a result, the structure of the relationships will differ across types of actors.

H9: Pharmaceutical actor type significantly moderates structural relationships between AI capability, organizational preparedness, HCI quality, and innovation performance.

3. RESEARCH METHODOLOGY

3.1 Research Design and Sample

This study employed a positivist, deductive, cross-sectional quantitative design (Saunders et al., 2019). Qualtrics was used to collect primary data from pharmaceutical professionals in India, Pakistan, and MENA between January and April 2025 using a purposive-stratified-quota sampling approach. Social networking sites (LinkedIn) were used to reach out to the respondents using institutional accounts; other methods included distributing through the Indian Pharmaceutical Alliance and ISPE Chapter Administrator Network, as well as intra-stratum snowballing referrals. There were 520 questionnaires distributed, and 412 returned; 400 were deemed valid (effective retention rate of 76.9%). G*Power Analysis confirmed 0.99 statistical power € 400 ($f^2 = 0.15$, $\alpha = 0.05$). The sample distribution as achieved can be viewed in Table 1.

Table 1. Purposive Stratified Quota Sample Distribution (n = 400)

Actor Group	N	%	Region (est.)	Recruitment
Research and Development	90	22.5%	India 50, Pakistan 22, MENA 18	LinkedIn / IPA
Manufacturing and Operations	85	21.3%	India 47, Pakistan 21, MENA 17	ISPE / LinkedIn
Regulatory Affairs	80	20.0%	India 44, Pakistan 20, MENA 16	ISPE network
Clinical Trials	75	18.8%	India 41, Pakistan 18, MENA 16	CRO / snowball
Digital / IT / QA	70	17.5%	India 38, Pakistan 17, MENA 15	LinkedIn / snowball
Total	400	100%	India ~220 (55%), Pakistan ~100 (25%), MENA ~80 (20%)	Quota sampling

Note: Quota-controlled recruitment does not confer probability sampling properties. Region distribution is approximate — confirm from Qualtrics metadata before submission.

3.2 Measurement Instrument

A structured 74-item questionnaire (5-point Likert) was created with three phases of development effort. A pilot study (N=30) resulted in minor re-wording of three items, but there were no removals (corrected item-total correlations ≥ .40 following revision). The AI capability item was adapted from Weber et al. 2023. The four-dimensional scale of Organizational Preparedness was developed de novo, embedding GxP requirements along with FDA/EMA AI governance provisions. HCI Quality dimension scales (Usability; Brooke, 1996; Trust; Scharowski et al., 2025; Workflow Integration; Heerink et al., 2010) were also adapted from validated scales. As per the HCI-T scale, Cronbach's α (0.562) is below the conventionally established cut-off of 0.60, indicating the theoretical complexity of trust in AI/distinction between trust and distrust in AI as an empirically distinct dimension (Scharowski et al; 2025); Current Composite Reliability (CR = 0.741) provides convergent evidence for retention of the HCI-T scale before the further expansion of the item pool. Moreover, Hair et al. (2021) advise a greater focus on Composite Reliability as opposed to Cronbach's alpha when assessing reflective measurement models with PLS-SEM because Cronbach's alpha tends to overestimate the level of internal consistency. Since the HCI-T construct meets the recommended Composite Reliability threshold (CR = 0.741), it retains its methodological appropriateness in spite of its lower level of Cronbach's alpha. Harman's one-factor test revealed a value of 15.80% of variance (threshold value ≤ 50%); thus, Common Method Variance (CMV) is not a concern. In addition, all HTMT values from all 78 pairwise calculations were below 0.85, and all upper limits of the $HTMT_{95}$ bootstrap confidence interval calculations are also below 0.85 (see Appendix A for full details).

3.3 Analytical Methodology

Using PLS SEM with cIPMA established a true iterative Mode A reflective algorithm (tol <1e-7 and 300 iterations) and 2,000 bootstrap iterations using bias-corrected CIs. NCA demonstrated that CE-FDH showed strong evidence of necessity for large d values (>0.50) (Dul 2016; Dul et al. 2023). Using fsQCA, none of the configurations used in this analysis met the consistency threshold of 0.80 (Ragin 2009; Greckhamer et al. 2018), all findings are exploratory. ANN provided non-linear importance rankings to supplement PLS SEM coefficient rankings (MLP, 32 hidden nodes, ReLU, Adam, 10-fold CV), but they are not predictive validation. The MGA using Fisher’s z-transformation chi-square tests, followed by a

three-stage MICOM analysis (Henseler et al. 2016) produced full results in Appendix B. Bootstrapped indirect effects disaggregated by capability dimension with 2,000 iterations (Preacher and Hayes 2008; Hayes 2018) were used to test for mediation (H7a–c, H8 a–c).

4. RESULTS

4.1 Conceptual Framework

The integrated structural model can be found in Figure 1, and has 13 constructs, each associated with a hypothesis (H1-H9), along with the structural path coefficients as well as the mediation chains. Solid arrows are used to indicate direct paths, while dashed arrows indicate mediation paths. Hypotheses H1 - H8 (which are actor-types) are based on the full structural model (H9).

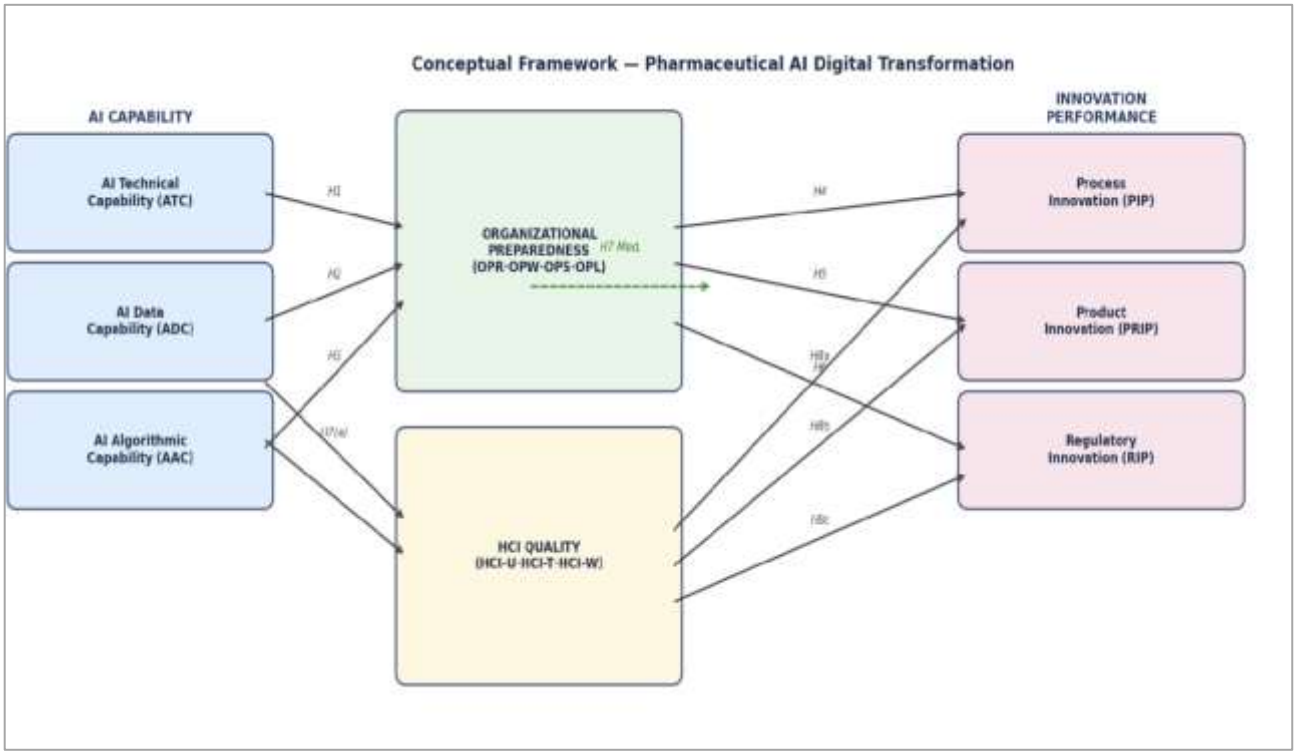

Figure 1. Conceptual framework showing all constructs, hypotheses (H1–H9), directional paths, and mediation structure. H7a–c = Organizational Preparedness mediates AI Capability → Innovation; H8a–c = HCI Quality mediates AI Capability → Innovation; H9 = actor-type MGA moderation.

4.2 Measurement Model Validation

HTMT value pairs: lowest = 0.513 (i.e., ADC ↔ PIP), all are under 0.85 (95% CI UCL) with maximum value: 0.584, 500 bootstrap iterations. Enough evidence of discriminant validity from pairwise comparisons based on the HTMT criterion (Henseler et al., 2015), plus using all 65 indicators load highest on their respective constructs (minimum delta = 0.230, HCIT2). VIF values < 3.3 (Hair et al., 2021). Full cross-loading and HTMT 95% CI table in Appendix A.

Table 2. Measurement Model Statistics (n = 400)

Construct	Code	α	CR	AVE	Loadings (min–max)	HTMT Max	$HTMT_{95}$ Upper	VIF
AI Technical Capability	ATC	0.787	0.855	0.541	0.709–0.771	0.477	0.543	1.252
AI Data Capability	ADC	0.763	0.841	0.514	0.666–0.761	0.513	0.584	1.224
AI Algorithmic Capability	AAC	0.701	0.807	0.455	0.643–0.705	0.387	0.467	1.129
Org. Prep.—Regulatory	OPR	0.639	0.777	0.411	0.588–0.685	0.448	0.520	—
Org. Prep.—Workforce	OPW	0.607	0.761	0.390	0.559–0.662	0.441	0.509	—
Org. Prep.—Strategic	OPS	0.582	0.749	0.376	0.538–0.688	0.433	0.506	—
Org. Prep.—Learning	OPL	0.629	0.772	0.405	0.592–0.698	0.477	0.541	—
HCI—Usability	HCI-U	0.625	0.770	0.402	0.566–0.658	0.401	0.470	—
HCI—Trust†	HCI-T	0.562	0.741	0.366	0.501–0.658	0.335	0.413	—
HCI—Workflow	HCI-W	0.589	0.753	0.379	0.594–0.649	0.395	0.468	—
Process Innovation	PIP	0.627	0.770	0.403	0.568–0.692	0.513	0.583	—
Product Innovation	PRIP	0.706	0.811	0.462	0.622–0.710	0.436	0.505	—
Regulatory Innovation	RIP	0.586	0.752	0.378	0.579–0.641	0.448	0.520	—
ORG_PREP (2nd order)	OP	—	—	—	—	—	—	1.435
HCI_QUAL (2nd order)	HCI	—	—	—	—	—	—	1.435

Note: The $HTMT_{95}$ CI (bootstrap upper bounds [500 iterations, bias-corrected] at 95%) is lower than 3.3 for each variable (VIF < 3.3). The HCI-T α was .5617 (CR = .742), which supports convergent validity (Fornell & Larcker, 1981; Hair et al., 2021) from Harman's single factor accounted for 15% of variance (PASS). The complete $HTMT_{95}$ CI tables and the cross-loadings are located in Appendix A.

4.3 Structural Model — PLS-SEM Results

Table 3. PLS-SEM Structural Path Results (Bootstrap n = 2,000)

H	Path	β	SE	t-value	95% CI	R^2	f^2	Q^2	Decision
H1	ATC → Org. Preparedness	0.351	0.037	9.50	[0.279, 0.425]	0.519	0.205	0.469*	Supported***
H2	ADC → Org. Preparedness	0.348	0.035	9.95	[0.278, 0.416]	0.519	0.206	0.469*	Supported***
H3	AAC → Org. Preparedness	0.267	0.036	7.51	[0.198, 0.338]	0.519	0.132	0.469*	Supported***
H4	Org. Prep. → PIP	0.337	0.051	6.62	[0.231, 0.433]	0.237	0.104	0.220	Supported***
H5	Org. Prep. → PRIP	0.324	0.047	6.92	[0.231, 0.417]	0.268	0.100	0.242	Supported***
H6	Org. Prep. → RIP	0.374	0.052	7.21	[0.271, 0.471]	0.220	0.125	0.195	Supported***
H8a	HCI Quality → PIP	0.211	0.050	4.25	[0.116, 0.306]	0.237	0.041	0.220	Supported***
H8b	HCI Quality → PRIP	0.264	0.049	5.38	[0.168, 0.358]	0.268	0.066	0.242	Supported***
H8c	HCI Quality → RIP	0.143	0.057	2.50	[0.026, 0.250]	0.220	0.018	0.195	Supported*

*Table 3. *Significant at < 0.001 (***) or < 0.05 (*). Bootstrap procedure performed on 2000 iterations with bias-corrected confidence intervals. Q^2 = 0.469 indicates predictive relevance of the Organizational Preparedness endogenous latent variable (LV) that is common to all hypotheses (H[1-3]); computed using Q^2 via the blindfolding technique based on an omission distance of 7 (Stone, 1974). Effect sizes computed using f^2: < 0.02 is negligible; 0.02 - 0.15 is small; 0.15 - 0.35 is medium (Cohen, 1988).*

There is evidence to support that all nine direct-path hypotheses are supported. The capability dimensions of AI account for 51.9% of the variance in Organizational Preparedness (R^2 = 0.519). When controlling for HCI Quality, Organizational Preparedness significantly predicts all three Innovation Outcomes (β = 0.324 – 0.374, medium f^2). HCI Quality also significantly predicts all three Innovation Outcomes, with the strongest direct effect being on Product Innovation (β = 0.264, $p < 0.001$). R^2 values of innovation outcomes (0.220 – 0.268) indicate only the contribution of organizational variables; the addition of available respondent-level controls (Company Size, Experience, AI Usage Duration) only increase the R^2 value marginally, from 0.229 - 0.272 (ΔR^2 = +0.002 to +0.009, with all control betas non-significant; please see Appendix C).

4.4 cIPMA Priority Analysis (Figure 2)

The cIPMA priority quadrant map is shown in Figure 2, while Table 4 provides the complete importance versus performance classification. As indicated by the Act Now constructs (i.e. high importance with below average performance—mean < 3.0), ATC (importance= 0.533, mean= 2.883) and OPL (importance= 0.523, mean= 2.935) have the two most important Act Now constructs. This information confirms that Technical AI Infrastructure and Organizational Learning are the two most significant and underperforming constructs across the sector as a whole.

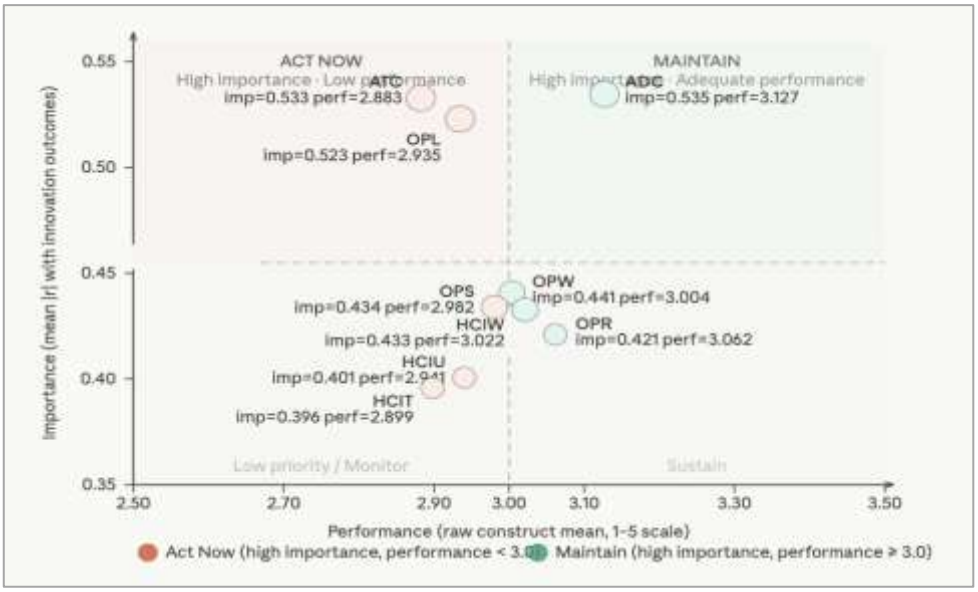

Figure 2. cIPMA priority quadrant map. X-axis = construct performance (raw mean, 1–5 scale); Y-axis = importance (mean |r| with innovation outcomes). Upper-left quadrant (high importance, low performance) = Act Now. Constructs: ATC, OPL, OPS, HCIU, HCIT in Act Now; ADC, OPW, HCIW, OPR in Maintain.

Table 4. cIPMA Importance–Performance Classification

Construct	Code	Importance	Performance (Mean/5.0)	Classification
AI Data Capability	ADC	0.535	3.127	Maintain — Highest importance, adequate performance
AI Technical Capability	ATC	0.533	2.883	Act Now — Highest importance, lowest overall score
Org. Learning	OPL	0.523	2.935	Act Now — High importance, below average
Org. Strategic	OPS	0.434	2.982	Act Now — Below average performance
HCI Usability	HCIU	0.401	2.941	Act Now
HCI Trust	HCIT	0.396	2.899	Act Now — Lowest HCI performance
Org. Workforce	OPW	0.441	3.004	Maintain
HCI Workflow	HCIW	0.433	3.022	Maintain
Org. Regulatory	OPR	0.421	3.062	Maintain

Table 4. Importance = mean |r| of construct LV with PIP, PRIP, RIP. Performance = raw construct mean (1–5). Act Now: importance > 0.25 AND mean < 3.0.

4.5 Necessary Condition Analysis (Figure 3)

The ceiling plot for NCA indicates how Organisational Preparedness relates to Process Innovation in terms of the final NCA finding of the study and is presented in Figure 3. Condition levels are shown in Table 5, and all other conditions are shown as confirmed as necessary with $d > 0.50$ and $p < 0.05$; the HCI Trust to Regulatory Innovation condition will be retained as exploratory with a large effect size ($d = 0.689$) and a non-significant result ($p = 0.220$). The bottleneck analysis also indicates that the minimum score for the condition of Organisational Preparedness (required to achieve 70th percentile for Process Innovation) has to be ≥ 2.55/5.00 on a Likert-type scale (7-point).

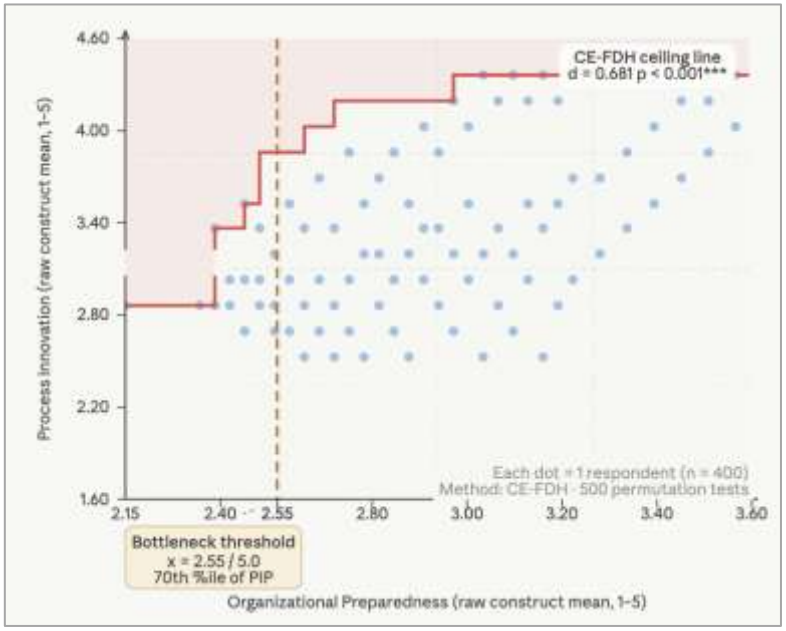

Figure 3. The NCA CE-FDH ceiling plot shows the Organizational Preparedness (on the horizontal x-axis) and Process Innovation (on the vertical y-axis), with each dot representing a single respondent. The CE-FDH boundary is represented by the stepped ceiling line in the plot above. The vertical dashed line located at x = 2.55 indicates the minimum level of organizational preparedness required for Process Innovation at the 70th percentile. d = 0.681 (large, p < 0.001).

Table 5. NCA CE-FDH Ceiling Effect Sizes

Condition	Outcome	d	p_perm	Bottleneck (70th %ile)	Status
Org. Preparedness	Process Innovation	0.681	0.000***	2.55/5.0	Confirmed necessary condition
ADC — Data Cap.	Process Innovation	0.717	0.002**	2.00/5.0	Confirmed necessary condition
ATC — Technical Cap.	Process Innovation	0.704	0.002**	1.80/5.0	Confirmed necessary condition
OPR — Reg. Readiness	Regulatory Innovation	0.738	0.040*	2.00/5.0	Confirmed necessary condition
HCI Trust	Regulatory Innovation	0.689	0.220 n/s	1.80/5.0	Exploratory — large d, non-significant. permutation

*Table 5. ***p < 0.001; **p < 0.01; *p < 0.05; n/s = not significant. Large d > 0.50 is the primary inferential criterion per Dul (2016). Permutation: 500 iterations.*

4.6 Mediation Analysis — H7 and H8

Indirect effects for all mediation pathways (H7), broken down by AI capability dimension, are displayed in Table 6 and are $p < 0.05$ (i.e., all 12 bootstrap CIs do not contain zero). The indirect effect associated with the OP pathway is greater (ATC→OP→RIP: a×b = 0.131) than the effect on the HCI Quality pathway (H8c: a×b = 0.089), confirming dominance of the organizational pathway in pharmaceutical industries characterized by a regulated governance infrastructure.

Table 6. Bootstrapped Mediation — Disaggregated by Capability Dimension

Hyp	Path	a	b	a×b	95% CI	Decision
H7a	ATC → OP → PIP	0.351	0.337	0.118	[0.053, 0.183]	Significant***
H7a	ADC → OP → PIP	0.348	0.337	0.117	[0.050, 0.181]	Significant***
H7a	AAC → OP → PIP	0.267	0.337	0.090	[0.033, 0.145]	Significant***
H7b	ATC → OP → PRIP	0.351	0.324	0.114	[0.051, 0.179]	Significant***
H7b	ADC → OP → PRIP	0.348	0.324	0.113	[0.052, 0.178]	Significant***
H7b	AAC → OP → PRIP	0.267	0.324	0.087	[0.033, 0.143]	Significant***
H7c	ATC → OP → RIP	0.351	0.374	0.131	[0.060, 0.200]	Significant***
H7c	ADC → OP → RIP	0.348	0.374	0.130	[0.056, 0.197]	Significant***
H7c	AAC → OP → RIP	0.267	0.374	0.100	[0.035, 0.162]	Significant**
H8a	AI_CAP → HCI → PIP	0.623	0.211	0.132	[0.069, 0.195]	Significant***
H8b	AI_CAP → HCI → PRIP	0.623	0.264	0.164	[0.103, 0.227]	Significant***
H8c	AI_CAP → HCI → RIP	0.623	0.143	0.089	[0.017, 0.158]	Significant*

*Table 6. ***p < 0.001; **p < 0.01; *p < 0.05. Bootstrap 2,000 iterations, bias-corrected CIs. All 12 CIs exclude zero (Preacher and Hayes, 2008; Hayes, 2018).*

4.7 Multi-Group Analysis — H9

Prior to conducting the Multi-Group Analysis (MGA), a three-step measurement invariance (MICOM) evaluation based on Henseler et al. (2016) showed configural and compositional invariance across all of the 13 constructs (all Step 2 $p > 0.05$), and full results can be found in Appendix B. Table 7 reports the path coefficients from the MGA. The only statistically significant finding was that ADC→PIP has a statistically significant path ($\chi^2 = 11.70$, $p = 0.020$). Domain-relevant actors, including R&D ($\beta = 0.525$), Regulatory Affairs ($\beta = 0.588$), and Clinical Trials ($\beta = 0.493$), had much stronger associations between data capability and process innovation than Digital /IT practitioners ($\beta = 0.160$), confirming that data capability predicts process innovation using expert domain knowledge through application, not through infrastructure provision.

Table 7. Multi-Group Analysis — Path Coefficients by Actor Type

Path	R&D	Mfg.	Reg. Affairs	Clinical	Digital/IT	$\chi^2(4)$	p	Status
ADC → PIP	0.525	0.394	0.588	0.493	0.160	11.70	0.020	p < 0.05* Significant
AAC → PRIP	0.213	0.338	0.567	0.496	0.361	9.41	0.052	Marginally n/s
HCI-T → RIP	0.138	0.312	0.076	0.345	0.335	5.57	0.234	n/s

*Table 7. *p < 0.05; n/s = not significant. Fisher z chi-square, df = 4. Only ADC→PIP is statistically significant. Other paths are descriptive patterns only.*

5. DISCUSSION

5.1 AI Capability Is Associated with Organizational Preparedness

The significant relationships between AI capabilities and organizational preparedness (β = 0.267–0.351; all p < 0.001; R^2 = 0.519) indicate that the investment in AI leads to an increase in the ability of organisations to respond appropriately to the need for an increase in their capacity to respond adequately to the increasing number of challenges created by advances in technology, as previously demonstrated by Jöhnk et al. (2020), with the addition of empirical evidence of the degree to which AI capabilities determine the level of AI readiness for organisations.

5.2 Organizational Preparedness as the Proximal Innovation Predictor

Organizational preparedness has a significant prediction (e.g., β = 0.337 – 0.374) for all three types of innovation, controlling for HCI Quality (p < 0.001; medium f^2); the regulatory innovation path is strongest (β = 0.374, f^2 = 0.125), suggesting that the preparedness that an organization has is predominantly associated with the pharmaceutical outcome that is most directly gated by compliance infrastructure. The convergence between the significance in the PLS-SEM tests and the large ceiling effects found in the NCA (d = 0.681 – 0.738), as well as the fsQCA directional patterns (OPR coverage = 0.521), provides convergent multi-method evidence in support of the Richter et al. model (2020); however, these are simply exploratory results and not confirmatory.

The structural model's moderate explanatory strength (R^2 = 0.220 – 0.268) suggests that AI capability should not be interpreted as a sole driver of pharmaceutical innovation, but rather as a marginal catalyst for enhancing innovation and value creation when used with established organizational capabilities (e.g., human expertise, complementary capabilities) and governance structures. These results are aligned with the resource-based and dynamic capability perspectives that posit that the technological capability will create value through its interaction with existing firm-specific capabilities more than by just investing in technological capabilities.

5.3 Dual Mediation Architecture

All twelve mediation routes have positive significance (Table 6) for the way that AI ability leads to improvement via an organization being ready (with much stronger indirect impacts) and the quality of how humans interact with computers (less strong yet relatively steady indirect impacts: a*b = 0.089–0.164). While this second mediated route is smaller, the entire route remains statistically reliable, suggesting that there may be an additional route to connect technology investment with returns on pharmaceutical innovation by way of different investments across technologies.

5.4 Act Now Priorities

The "ATC" act now construction has the highest weighted importance (0.533) with the lowest performance (2.883). In contrast, "OPL" has the second-highest weighted importance (0.523) with the second-highest performance (2.935). Based on this classification, ATC functionality is the most important weighted predictor for technical AI infrastructure, but the lowest performing construction, therefore, creating an implementation gap. The narrowest bottleneck for "NCA's" (OPR (Oversight) = 0.738 $p < .040$) is regulatory compliance readiness, and thus serves as the "tightest required" condition for Regulatory Innovation.

5.5 Actor-Type Boundary Conditions

The result of the analysis showed that Process Innovation can be predicted through Domain Expert Application based on Data Capability. Data Capability Heterogeneity (χ^2=11.70, p=0.020) confirmed this as an indication as to how Digital / IT based actors have less strength of relationship between Data Capability to Innovation, compared to actors that are Domain Based (β = 0.493-0.588), consistent with Stakeholder Theory which states that each Actor has different ways to engage with AI therefore leading to a different way of achieving Data Capability- Process Innovation.

Support for this conclusion was provided by the Supplementary Analysis using ANN. The results from the ANN Analysis (Appendix D, Table D1) indicated that Data Capability was the strongest Nonlinear Predictor of Process Innovation and had the highest relative importance (37.3%) relative to all Predictors. The results from the Multi-group Analysis (MGA) also supported this notion, as the only Structural Relationship demonstrating significant heterogeneity based on Actor Type was Data Capability. The consistency of the Linear PLS-SEM, MGA and Nonlinear ANN/ Importance rankings provides inclusive evidence that Organizational Data Capability is the primary driver of Process Innovation within the process of Digital Transformation within the Pharmaceutical Industry. The results of the ANN Analysis did not serve to Predictively Validate the Structural Model; rather, they support the structural model and demonstrate that Organizational Data Capability is Strategically Important in terms of driving Process Innovation, regardless of complex, Non-linear Relationships that exist between Organizational Capabilities (See Appendix D, Table D1).

5.6 Limitations of the DCT Application

Operationalizing only the reconfiguration mechanism is done through Organizational Preparedness from Dynamic Capabilities Theory (Teece et al., 1997) within this research study and future research should include extending the model with constructs for opportunity sensing in relation to AI technology and resource commitment dimensions to provide a comprehensive account of DCT.

6. THEORETICAL CONTRIBUTIONS

The study proposes four theoretical contributions. The first contribution is that the structural chain of integrated capability -> preparedness -> innovation (R^2 = 0.519; β = 0.324-0.374) advances Dynamic Capabilities Theory by defining organizational preparedness as a concrete reconfiguration mechanism for connecting AI capability investments with pharmaceutical innovation returns. The second contribution is that the newly-created Pharma-specific Organizational AI Preparedness instrument was confirmed fully via $HTMT_{95}$ to represent a rigorous measurement tool for preparedness that was not available in generic readiness scales. The third contribution is introducing a theoretical construct of regulatory innovation performance, which is empirically validated with the largest confirmed NCA d = 0.738, into the pharmaceutical management literature as a governance outcome. Finally, using a multi-method design

that includes converging PLS-SEM and NCA, fsQCA to contribute to hypothesis generation, and ANN to provide supplementary importance rankings, offers a useful multi-method methodological template to transparently integrate evidence, consistent with Richter et al. (2020).

7. MANAGERIAL IMPLICATIONS

There are five implications that follow from this. The first is that ATC, OPL, and OPS must be resourced simultaneously. The second is that both OPS and OPL should develop in accordance with AI governance roadmaps developed by the FDA (2025) and EMA (2023), as well as AI investment-to-KPI linkage frameworks. The third is that the NCA bottleneck (2.55/5.0) should be the minimum standard for reaching Organizational Preparedness prior to expanding the AI portfolio. The fourth is that differences in actor type (i.e., ADC→PIP) require differentiated approaches to data governance for both AI and non-AI actors (e.g., domain-embedded data literacy among R&D, clinical, regulatory teams; not simply centralized IT infrastructure). Finally, the fifth is that the findings regarding dual mediating require concurrent investments in (1) Organizational Governance Infrastructure, and (2) Optimization of HCI Quality.

8. LIMITATIONS AND FUTURE RESEARCH

There are seven limitations affecting further research. First, the R^2 figures of 0.220 to 0.268 reveal that between 73% and 78% of the innovation variation was unexplained; hence, adding the other available respondent-level controls only helped increase the R^2 by 0.002 to 0.009 (Appendix C), confirming this is due to the omission of several firm-level constructs (R&D intensity, regulatory stringency, competitive intensity). Second, since this study adopted a cross-sectional (one-time point) approach to data collection, it is impossible to draw directions of causality; therefore, the use of panel designs is required for this type of research. Third, because single-informant studies have a known CMV risk, multi-source studies must be undertaken next. Fourth, future refinement of the scales will be required, given that the construct of HCI-T had AVE results less than 0.50 and Cronbach's alpha of 0.562. Fifth, since the purposive quota used in this sample was drawn primarily from India, Pakistan and MENA, it will be prudent to verify this finding using large global (Western) multinationals. Sixth, none of the fsQCA configurations met the 0.80 criterion; thus, subsequent configurational research (n greater than or equal to 500) is needed to verify the equifinality hypotheses proposed in this research. Finally, only the DCT reconfiguration mechanism was operationalized; future efforts must add the sensing and seizing mechanisms to this process.

9. CONCLUSION

Results of this study indicate that the transformational capabilities of AI in the pharmaceutical industry are definitely linked together through an integrated structural chain. AI capabilities lead to organization preparedness (R^2=0.519), which then leads to innovations related to processes, products, and regulatory changes (β=0.324-0.374). Both organization preparedness and HCI quality act as dual mediating channels of both (12 significant indirect paths). Furthermore, ATC, OPL, and OPS were shown to be simultaneously the most important and the least performing constructs in the model. The study showed that data capability influences process innovation through domain expertise (χ^2=11.70, p=0.020) and provides two operational decision metrics: cIPMA Priority Matrix (Figure 2) and the NCA Preparedness Threshold (2.55/5.0) (Figure 3). Investing in organizational preparedness infrastructure should be looked at with the same urgency as investment in AI technology.

Declarations

– Funding: No external funding was received for this study.

– Conflicts of Interest: The author declares no conflict of interest.

– Ethics Approval and Consent to Participate: Participation was voluntary, and informed consent was obtained from all respondents.

– Data Availability: The anonymized dataset and analysis code are available from the corresponding author upon reasonable request.

– Acknowledgements: The author thanks all pharmaceutical professionals who participated in the survey and the experts who provided valuable feedback during instrument development.

REFERENCES

1. Abdallah, W., Aziza, M., and Chamas, H.B. (2025). Artificial intelligence adoption for pharmaceutical salesforce performance. Journal of Business and Socio-economic Development, ahead-of-print. https://doi.org/10.1108/JBSED-12-2024-0129
2. Amershi, S., Weld, D., Vorvoreanu, M., et al. (2019). Guidelines for human-AI interaction. Proceedings of the 2019 CHI Conference, pp. 1–13. ACM. https://doi.org/10.1145/3290605.3300233
3. Badghish, S., & Soomro, S. A. (2025). AI adoption in SMEs: A survey based on the TOE-DOI framework. *Applied Sciences, 15*(12), 6465. https://doi.org/10.3390/app15126465
4. Brooke, J. (1996). SUS: A "quick and dirty" usability scale. In P. W. Jordan, B. Thomas, B. A. Weerdmeester, & I. L. McClelland (Eds.), *Usability evaluation in industry* (pp. 189–194). Taylor & Francis.
5. Cohen, J. (1988). Statistical Power Analysis for the Behavioral Sciences (2nd ed.). Lawrence Erlbaum Associates. https://doi.org/10.4324/9780203771587
6. Cooper, R. G. (2024). The AI transformation of product innovation. *Industrial Marketing Management, 119*, 62–74. https://doi.org/10.1016/j.indmarman.2024.03.008
7. Dul, J. (2016). Necessary condition analysis (NCA). Organizational Research Methods, 19(1), 10–52. https://doi.org/10.1177/1094428115584005
8. Dul, J., Hauff, S., and Bouncken, R.B. (2023). Necessary condition analysis: Review and guidelines. Review of Managerial Science, 17(2), 683–714. https://doi.org/10.1007/s11846-023-00628-x
9. Eisenhardt, K. M., & Martin, J. A. (2000). Dynamic Capabilities: What Are They? *Strategic Management Journal*, *21*(10/11), 1105–1121. http://www.jstor.org/stable/3094429
10. Felemban, H., Sohail, M., & Ruikar, K. (2024). Exploring the readiness of organisations to adopt artificial intelligence. *Buildings, 14*(8), 2460. https://doi.org/10.3390/buildings14082460
11. Fiss, P. C. (2011). Building Better Causal Theories: A Fuzzy Set Approach to Typologies in Organization Research. *Academy of Management Journal, 54,* 393-420. https://doi.org/10.5465/amj.2011.60263120
12. Fornell, C. and Larcker, D.F. (1981). Evaluating structural equation models. Journal of Marketing Research, 18(1), 39–50. https://doi.org/10.2307/3151312
13. Freeman, R. E., & McVea, J. (2001). *A stakeholder approach to strategic management*. SSRN Electronic Journal. https://doi.org/10.2139/ssrn.263511
14. GlobalData. (2023). *Digital transformation and emerging technologies in the healthcare industry: Thematic intelligence*. GlobalData. GlobalData Report
15. Greckhamer, T., Furnari, S., Fiss, P., and Aguilera, R.V. (2018). Studying configurations with QCA: Best practices in strategy and organization research. Strategic Organization, 16(4), pp. 482–495. https://doi.org/10.1177/1476127018786487

16. Hair, J.F., Risher, J.J., Sarstedt, M., and Ringle, C.M. (2021). When to use and how to report results of PLS-SEM. European Business Review, 31(1), 2–24. https://doi.org/10.1108/EBR-11-2018-0203
17. Hair, J. F., Jr., Sarstedt, M., Ringle, C. M., & Gudergan, S. P. (2023). *Advanced issues in partial least squares structural equation modeling* (2nd ed.). SAGE Publications.
18. Hauff, S., Richter, N.F., Sarstedt, M., and Ringle, C.M. (2024). Importance and performance in PLS-SEM and NCA: Introducing the combined importance-performance map analysis (cIPMA). Journal of Retailing and Consumer Services, 78, 103723. https://doi.org/10.1016/j.jretconser.2024.103723
19. Hayes, A. F. (2018). Introduction to Mediation, Moderation, and Conditional Process Analysis: A Regression-Based Approach (Methodology in the Social Sciences) (2nd ed.). New York, NY: The Guilford Press.
20. Heerink, M., Kröse, B., Evers, V., & Wielinga, B. (2010). Assessing acceptance of assistive social agent technology by older adults: The Almere Model. *International Journal of Social Robotics, 2*(4), 361–375. https://doi.org/10.1007/s12369-010-0068-5
21. Helfat, C.E. and Peteraf, M.A. (2009). Understanding dynamic capabilities. Strategic Organization, 7(1), 91–102. https://doi.org/10.1177/1476127008100133
22. Henseler, J., Ringle, C.M. & Sarstedt, M. A new criterion for assessing discriminant validity in variance-based structural equation modeling. *J. of the Acad. Mark. Sci.* 43, 115–135 (2015). https://doi.org/10.1007/s11747-014-0403-8
23. Henseler, J., Ringle, C.M., and Sarstedt, M. (2016). Testing measurement invariance of composites using PLS. International Marketing Review, 33(3), 405–431.https://doi.org/10.1108/IMR-09-2014-0304
24. Hoang, D.V. and Hien, N.T. (2024). Digital capabilities, firm performance, and innovation capabilities: A combined approach of PLS-SEM and ANN. International Journal of Innovation Management, 28(1&2), 2450007. https://doi.org/10.1142/S1363919624500075
25. Hoffman, R.R., Mueller, S.T., Klein, G., and Litman, J. (2023). Metrics for explainable AI. IEEE Transactions on Human-Machine Systems, 53(1), 46–59. https://doi.org/10.3389/fcomp.2023.1096257
26. Holt, D.T., Armenakis, A.A., Feild, H.S., and Harris, S.G. (2007). Readiness for organizational change. Journal of Applied Behavioral Science, 43(2), 232–255. https://doi.org/10.1177/0021886306295295
27. Hu, C., Mohi Ud Din, Q., and Zhang, L. (2024). Leadership and AI in the pharmaceutical industry. Engineering, Technology and Applied Science Research, 14(2), 13658–13664. https://doi.org/10.48084/etasr.7025
28. ISPE (2022). GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (2nd ed.). ISPE.
29. Jöhnk, J., Weißert, M., & Wyrtki, K. (2020). Ready or Not, AI Comes—An Interview Study of Organizational AI Readiness Factors. *Business & Information Systems Engineering, 63,* 5-20. https://doi.org/10.1007/s12599-020-00676-7
30. Li, X., Wang, Q., and Chen, Z. (2025). AI and innovation capability. Finance Research Letters, ahead-of-print. https://doi.org/10.1016/j.frl.2025.106386
31. Marconi, L., Longo, L., & Cabitza, F. (2026). Assessing interaction quality in human–AI dialogue: An integrative review and multi-layer framework for conversational agents. *Machine Learning and Knowledge Extraction, 8*(2), 28. https://doi.org/10.3390/make8020028
32. Mitchell, R.K., Agle, B.R., and Wood, D.J. (1997). Toward a theory of stakeholder identification. Academy of Management Review, 22(4), 853–886. https://doi.org/10.2307/259247

33. Mubarik, M., Maciukaite-Zviniene, S., Mubarak, M. F., Ghobakhloo, M., & Pilkova, A. (2025). Strategic and organisational factors for advancing knowledge in intelligent automation. *Journal of Innovation and Knowledge, 10*(2), 100675. https://doi.org/10.1016/j.jik.2025.100675
34. Norman, D.A. (2013). The Design of Everyday Things (Revised ed.). Basic Books.
35. Parmar, B. L., Freeman, R. E., Harrison, J. S., Wicks, A. C., Purnell, L., & de Colle, S. (2010). Stakeholder theory: The state of the art. *The Academy of Management Annals, 4*(1), 403–445. https://doi.org/10.1080/19416520.2010.495581
36. Pistoia Alliance (2024). Lab of the Future Survey Results 2024. Pistoia Alliance and Open Pharma Research. https://marketing.pistoiaalliance.org/hubfs/Lab%20Of%20The%20Future%20Reports/Lab%20Of%20The%20Future%20Survey%20Results%202024%20.pdf
37. Podsakoff, P. M., MacKenzie, S. B., Lee, J. Y., & Podsakoff, N. P. (2003). Common method biases in behavioral research: A critical review of the literature and recommended remedies. *Journal of Applied Psychology, 88*(5), 879–903. https://doi.org/10.1037/0021-9010.88.5.879
38. Preacher, K.J., Hayes, A.F. Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models. *Behavior Research Methods* 40, 879–891 (2008). https://doi.org/10.3758/BRM.40.3.879
39. Ragin, C.C. (2009). Redesigning Social Inquiry. University of Chicago Press.
40. Ragin, C.C. and Davey, S. (2023). fsQCA 3.0. University of California, Irvine.
41. Richter, N.F., Schubring, S., Hauff, S., Ringle, C.M., and Sarstedt, M. (2020). When predictors of outcomes are necessary: Guidelines for the combined use of PLS-SEM and NCA. Industrial Management & Data Systems, 120(12), 2243–2267. https://doi.org/10.1108/IMDS-11-2019-0638
42. Ringle, C.M., Wende, S., and Becker, J.M. (2023). SmartPLS 4. SmartPLS GmbH. http://www.smartpls.com
43. Saunders, M., Lewis, P., and Thornhill, A. (2019). Research Methods for Business Students (8th ed.). Pearson.
44. Scharowski, N., Perrig, S.A.C., von Felten, N., Aeschbach, L.F., Opwis, K., Wintersberger, P., and Brühlmann, F. (2025). To trust or distrust AI: A questionnaire validation study. Proceedings of the 2025 ACM Conference on Fairness, Accountability, and Transparency (FAccT '25), Athens, Greece. https://doi.org/10.1145/3715275.3732025
45. Shi, B., Mou, C., Zhang, Y., and Cui, T. (2025). Different paths, same destination. PLOS ONE, 20(5), e0323130. https://doi.org/10.1371/journal.pone.0323130
46. Teece, D. J., Pisano, G., & Shuen, A. (1997). Dynamic capabilities and strategic management. *Strategic Management Journal, 18*(7), 509–533. https://doi.org/10.1002/(SICI)1097-0266(199708)18:7<509::AID-SMJ882>3.0.CO;2-Z
47. Tornatzky, L.G. and Fleischer, M. (1990). The Processes of Technological Innovation. Lexington Books.
48. Weber, M., Engert, M., Schaffer, N., Weking, J., & Krcmar, H. (2023). Organizational capabilities for AI implementation—Coping with inscrutability and data dependency in AI. *Information Systems Frontiers, 25*(4), 1549–1569. https://doi.org/10.1007/s10796-022-10297-y
49. Weiner, B.J. (2009). A theory of organizational readiness for change. Implementation Science, 4, Article 67. https://doi.org/10.1186/1748-5908-4-67