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Building End-to-End Pharmaceutical Traceability in India: A Multi-Stakeholder Assessment of Interoperability, Data Quality and Supply-Chain Integration Readiness

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ABSTRACT: India's pharmaceutical supply chain relies on an interoperable digital system, but inefficiencies in regulatory pathways, outdated information systems, inconsistent data quality, and inconsistent stakeholder readiness make end-to-end traceability difficult, and allow room for counterfeit and diverted medicines. The objective of this study is to evaluate the pharmaceutical supply-chain readiness for end-to-end traceability based on the organizational characteristics, regulatory compliance, the adoption of digital-standard, integration of traceability, and the readiness of the supply-chain. The survey was of a quantitative, cross sectional design utilizing a questionnaire with 200 pharmaceutical stakeholders, such as manufacturers, distributors, wholesalers, retail pharmacists and regulatory/compliance officials. Data was analyzed by descriptive statistics, Pearson correlation and regression analysis in MS Excel and SPSS 27. The results showed strong positive moderate association between organizational characteristics and integration of traceability systems ($r = 0.373$, $p < 0.001$); there was a weak but significant positive association between regulatory compliance and readiness to integrate traceability systems in the supply chain ($r = 0.212$, $p = 0.003$). Reducing counterfeit or diversion incidents had a moderate positive relationship with digital standard adoption ($R = 0.456$, $R^2 = 0.208$), which was statistically significant ($F = 51.849$, $p < 0.001$), and had a positive coefficient ($B = 0.496$). The paper concludes that organizational preparedness, regulatory adherence, and the establishment of uniform digital systems and data management, along with multi-stakeholder cooperation, are essential for pharmaceutical traceability.

1. INTRODUCTION

1.1 Background and Significance

The pharmaceutical supply chain is one of the most complex and safety-critical supply chains in the global economy, with fragmented information systems (IS) supporting its operations, including manufacturers, distributors, wholesalers, retail pharmacies, and regulators (Sunny et al., 2020). Pharmaceutical products are subjected to various custodial changes before they reach the patient, and every transfer provides room for diversion and substitution as well as for the establishment of substandard or falsified medicine supply chains. (Bandhu et al., 2023) The vulnerability has established end-to-end traceability (the ability to trace, capture, and share information regarding a product's origin, custody, and movement) as a key element of pharmaceutical supply-chain security and regulatory compliance around the world (Mishra et al., 2024).

1.2 The Indian Context

India is also one of the key producers of generic drugs which export to over 200 countries and have a huge and diversified domestic market (Nawaz et al., 2024). However, there are persistent challenges in quality and in traceability with this scale. Current estimates of counterfeit and spurious drug prevalence in India have been found to be as low as single-digit percentages in official surveys conducted in the country and as high as significantly higher in the scientific and trade literature (Suryaprakash et al., 2022). The impact of the false and faulty medicines is real, whether the extent is small or large, it compromises the therapeutic outcome, reduces trust in health systems, and carries reputational and regulatory risk for India's pharmaceutical export credentials, as evidenced by leaked adverse events associated with Indian-made medicines, which have been subjected to international scrutiny over the past few years (Barnett, 2021). The incidents have brought attention to the need of the regulators and industry to create traceability systems that can pass the global test.

1.3 Regulatory Evolution and Fragmentation

India's regulatory response to these pressures has not been through a coherent architecture, but instead has been incremental. The requirements for serialization for export purposes were first introduced in the early 2010s and subsequently deferred and revised for a decade thereafter before the responsibility for the authentication shifted towards the Central Drugs Standard Control Organization and the Ministry of Health and Family Welfare and culminating in the introduction of barcode and QR-code labelling requirements for high-value drug brands under Schedule H2 of the Drugs Rules (Islam & Islam, 2024). This transition from an export-compliance model to a health-regulator-led domestic authentication model is indicative of a larger problem in the Indian system: that the various obligations for traceability have been set and enforced separately for exports, the authentication of top brand, and active pharmaceutical ingredients, with no common data architecture or commercial entities linking manufacturers, distributors, retailers, and regulators (Yadav & Singh, 2024). Consequences include a disparate compliance regime with individual stakeholders meeting individual compliance requirements but not benefiting from, or contributing to, a single, interoperable product movement record throughout the entire supply chain.

1.4 Technological Enablers and Their Limits

The technological solutions proposed to these fragmentation issues have been growing over the last few years, and most notably, block chain-based architectures have been considered due to their ability to provide trusted, unalterable and decentralized transaction records, thereby limiting the need for a central trusted entity (Taqui et al., 2023). The Internet of Things (IoT) is also included in the complementary lines of research on cold-chain and condition monitoring enabled by sensors (Mangala et al., 2024), as well as on the use of machine-learning models for predicting the risk of vendors and logistics (Detwal et al., 2023), and artificial-intelligence-based coordination mechanisms for vaccine and essential-medicine distribution systems (Gao et al., 2023). For preventing counterfeit infiltration at the point of packaging and distribution, unique identification and smart-contract based frameworks have been also proposed (Kalpana et al., 2023). Although these studies show technical feasibility, most test single components – a single ledger design, a single machine-learning model, or a single sensing layer – in controlled or simulated environments (Havaeji et al., 2023; Wu et al., 2023), and don't adequately address the performance of such technologies specifically in the Indian context of multiple independent players, institutions, and data-quality challenges.

1.5 Interoperability and Data Quality as the Missing Link

In addition to technology, the adoption of technology does not ensure traceability as disparate systems must exchange data in mutually intelligible formats. Global standards organizations have responded by developing frameworks like the GS1's Electronic Product Code Information Services (EPCIS) that set a common data model of "who, what, when, where, why" for a supply chain around a common set of standard identifiers, to allow cross organization visibility (GS1, 2024). The adoption of such standards, however, is not widespread among pharmaceutical stakeholders in India, with a significant number of the business using legacy enterprise systems that lack the ability to exchange real-time, standardized data (Mishra et al., 2024). This challenge is similar to but has evolved independently from India's larger digital health interoperability initiative under the Ayushman Bharat Digital Mission (ABDM), which has been rolling out federated registries, unique health identifiers, consent-based data exchange architecture for clinical records, since 2021 (Sharma et al., 2023). Even within a nationally-coordinated digital health program, there was significant variation between the states in terms of registry completeness and readiness of the system for the implementation of pharmaceutical traceability (Mishra et al., 2024b), which highlights that interoperability

infrastructure and data quality assurance are likely to be the constraints on the rollout of pharmaceutical traceability. On the community level, it has also been observed that digital health integration often fails at the institutional readiness, data governance, and coordination between stakeholders level, in India (Samudyatha et al., 2023).

1.6 Problem Statement and Research Contributions

India's pharmaceutical traceability system is disjointed and lacks a single data system for serialization in exports, local barcode/QR code authentication, and API tracking, across manufacturers, distributors, retailers and regulators. Previous studies have generally suggested individual technical answers blockchain ledgers, IoT sensing, machine learning risk assessment but have not explored how these solutions could coexist, interact, and function within India's complex and fragmented legacy systems and digital maturity. This study aims to fill this gap by offering an integrated multi-stakeholder analysis of interoperability, data quality and readiness for interoperability and integration throughout the traceability chain, mapping the adoption of standards like GS1 EPCIS at each tier of the supply chain, learning from the other implementing bodies of Ayushman Bharat Digital Mission, and translating the results into actionable recommendations for regulators and industry.

1.7 Aim and Significance of the study

The purpose of this study is to measure the preparedness of the pharmaceutical supply chain in India for implementing end-to-end traceability by testing data-system interoperability, data quality at the manufacturing, distribution and retail stages and the institutional factors influencing their levels of integration. Academically, it shifts the focus from the performance of individual technologies to the systemic, cross-stakeholder conditions that account for the ability or not of technologies to operate at scale—that would not be investigated in existing literature. In practice, with India supplying medicines to more than 200 countries under the magnifying glass of international scrutiny, the findings provide regulators, manufacturers and standards bodies with objective and evidence-based recommendations to reduce interoperability gaps, limit the counterfeit supply chain and ensure the credibility of Indian exports.

2. LITERATURE REVIEW AND HYPOTHESIS DEVELOPMENT

2.1 Organizational Determinants of Supply-Chain Technology Integration

Empirical research using the Technology-Organization-Environment (TOE) perspective has increasingly investigated the influence of firm-specific factors on technology adoption and integration of traceability-enabling technologies. Chittipaka et al. (2023) conducted a large-scale survey with 525 supply-chain management professionals in India and identified both firm size and IT resources, monetary resources, and the higher support from authorities as significant factors influencing the adoption of Blockchain technology along with other environmental factors like regulatory pressure and business-partner pressure. In line with this, Teng et al. (2025) analyzed 362 Chinese manufacturers using the same methodology to find that all organizational readiness dimensions had a positive influence on the decision to adopt blockchain. Agi and Jha (2022) built on this thread by combining various adoption theories to demonstrate that the extent to which the organization absorbs the technology, in addition to previous technological experience, predicts the integration of blockchain in supply chains. These were echoed by Uren and Edwards (2023), who showed that an organization's trajectory of technology adoption, not the adoption event itself, was a key factor in determining the outcomes of technology adoption. Saha et al. (2022) empirically correlated the maturity of emerging technology adoption the Pharma 4.0 with measurable improvements in supply-chain performance but pointed out the existence of significant variation due to firm size and operational maturity. Overall, the literature provides consistent support for the theory that size, resource endowment and technological maturity are strong, generalizable determinants of traceability system integration, as is highlighted by the robust support for the literature and research.

H1: There is a significant relationship between organizational characteristics (firm size, stakeholder category, years of operation, and technology infrastructure) and the degree of traceability system integration.

2.2 Regulatory Compliance as a Driver of Supply-Chain Integration Readiness

Another stream of research has focused on the role of regulatory systems in influencing stakeholders' willingness to adopt traceability systems. In an exploratory study of South Africa's anti-counterfeiting laws, Moshoeshoe et al. (2022) discovered

that fragmented regulatory reporting and poor inter-agency coordination directly contributed to the lack of preparedness of manufacturers and distributors for integration in the supply chain. Likewise, in their systematic review of the regulation of Falsified Medicines, Melia et al. (2024) found a good correlation between the stringency and clarity of regulatory requirements and the speed and extent of a stakeholder's investment in adherence to the legitimate pharmaceutical supply chain. Consistency of drug legislation enforcement was identified as one of the main challenges to support integration-ready practices in the dispensing level, as obtained from converging evidence from Adigwe (2023) in Nigeria. El-Dahiyat et al. (2021) also demonstrated in a cross-sectional public-awareness study that the visibility of regulations and the credibility of enforcement influenced the trust of the downstream stakeholders on the traceability mechanisms. Lastly, Sarkar (2022) uncovered the fact that the readiness for integration in the supply chain was more hampered by the lack of harmonized RTS than by technology costs in the context of developing countries. In combination, these studies show a clear correlation across countries between the stringency of the regulation and the stakeholders' ability to implement integrated traceability, thus reinforcing H2.

H2: There is a significant association between the level of regulatory compliance and supply-chain integration readiness among pharmaceutical stakeholders.

2.3 Digital Standardization and Its Impact on Counterfeit and Diversion Mitigation

There is a considerable amount of systematic and empirical literature that has assessed the association between digital standardization and a decline in counterfeit and diverted pharmaceutical products. In their systematic review of 38 studies, Zakari et al. (2022) identified counterfeit-drug prevention as the most common application area of a block chain-based digital standardization and identified a consistent relationship between serialization and unique-identifier schemes and better identification of fraudulent products. A similar finding by Uddin et al. (2021) revealed that the use of a combination of block chain and standardized identifiers (such as GTIN serialization) considerably decreased the number of chances for counterfeit penetration, while also highlighting the need for interoperability between the technologies for block chain-based systems to be effective in real-world applications. Musamih et al. (2021) empirically tested a traceability approach and reported measurable gains in the accuracy of drug authentication after the adoption of standards based on block chain technology. In a wider systemic review of the use of block chain in health care supply chains, Fiore et al. (2023) found digital standardization as the most frequently cited enabler of anti-counterfeiting outcomes from literature reviewed. These were confirmed by Sarkar (2022), who found that the lack of digital traceability standards is associated with a continued high prevalence of counterfeits in under-regulated markets. This body of literature collectively offers multi-context evidence that the uptake of digital data standards is strongly related to the reported decrease in counterfeit and diversion incidents, which helps to confirm H3.

H3: There is a significant association between the adoption of digital standards and reported reductions in counterfeit or diversion incidents.

2.4 Research Gap

Despite the wide-ranging existing research, the understanding of the readiness of pharmaceutical traceability in India is still scattered in three disjointed areas of research. Existing studies based on the technology-organization-environment framework have validated a number of factors that influence adoption of block chain infrastructure and digital technologies in general manufacturing, AI, or cross-sectoral supply-chain settings but not in the pharmaceutical regulatory context of India. The evidence-based literature has, however, examined how regulatory compliance impacts integration readiness, with his research coming mainly from South African, Nigerian and cross-national contexts (Adigwe, 2023; El-Dahiyat et al., 2021; Melia et al., 2024; Moshoeshoe et al., 2022; Sarkar, 2022b), excluding India's own fragmented regulatory transition from DGFT to CDSCO. A third strand has shown that using digital tools to standardize the supply chain reduces incidence of counterfeiting and diversion, using systematic reviews and single technology prototypes, not empirical cross-stakeholder data collected from a live national supply chain. There has been no empirical study yet that has tested the combined and independent effect of the determinants of traceability system integration on the integration readiness in a pharmaceutical supply chain in a single Indian pharmaceutical environment; there is a gap, therefore, between the theoretical knowledge of each determinant individually and the combination of determinants and their empirical effect on the integration readiness of pharmaceutical supply chains in India. The present study, therefore, attempts to fill this lacuna by testing these three relationships together in the context of India through a multi-stakeholder, quantitative evaluation.

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3. MATERIALS AND METHODS

The study employs a quantitative, cross-sectional survey research design to empirically evaluate the readiness for interoperability, data quality, and integration of the supply chain within the pharmaceutical traceability ecosystem of India. The target population is representative with key stakeholders throughout the pharmaceutical supply chain who are on a different node of the chain of custody and therefore have a different perspective on interoperability and data-quality practices. To ensure a representation of the stakeholders across categories, size of the firm and geographic regions, a stratified purposive sampling technique is used due to the reported inter-state variation in the digital health and traceability infrastructure in India. The 4 principal constructs measured are the organizational characteristics (firm size, stakeholder category, years in operation, technology infrastructure), the level of regulatory compliance, the adoption of digital data standards and the level of traceability system integration and data quality. The items used are mostly on 5 point likert scales and there are also categorical and ordinal items for firm demographic information. After data collection, descriptive statistics (frequencies, means and standard deviations) are used to describe the sample and analyses readiness indicators by group and inferential statistics (Mean, Standard Deviation, Correlation, Regression) are used to test the three hypotheses of the study using MS Excel and SPSS 27 software.

4. DATA ANALYSIS AND RESULTS

4.1 Results based on demographic profile

Table 1: Demographic Characteristics

Sr. No.	Demographic Variables	Characteristics	N	%
1	Gender	Male	103	33.3
		Female	97	32.3
2	Age - Group	21 – 30 years	50	16.7
		31 – 40 years	65	21.7
		41 – 50 years	48	16.0
		51 – 60 years	20	6.7
		Above 60 years	17	5.7
3	Education Qualification	Bachelor's Degree	69	23.0
		Diploma	17	5.7
		Doctorate	20	6.7
		Master's Degree	73	24.3
		Professional Certifications	21	7.0
4	Organization Size	Large Enterprise	46	15.3
		Medium Enterprise	70	23.3
		Micro Enterprise	31	10.3
		Small Enterprise	53	17.7
5	Type of Organization	Multinational Company	51	17.0
		Private Sector	91	30.3
		Public Sector	34	11.3
		Regulatory Authority	24	8.0

Table 1 shows the demographic profile of the 200 respondents, which is fairly balanced and diversified, with the respondents fairly well spread across gender, age, educational qualification, and organizational size and type, thus giving a comprehensive base for examining the study variables. With regards to gender, male respondents made up 103 (51.5%) while female respondents made up 97 (48.5%) respondents with a nearly equal participation rate, and thus, the risk of gender imbalance in the sample was reduced. In terms of age, the largest group of respondents was aged (31-40) at 32.5% followed by (21-30) age group at 25.0 % and (41-50) age group at 24% indicating that the respondents were experienced and mature working class individuals who had been exposed to organizations. When asked about educational qualifications, the respondents generally had a good educational qualification, as the Master's degree holders comprised 36.5 % of the total sample while 34.5 % of them held a Bachelor's degree. Medium sized organizations had the highest representation with 35.0%, which suggests that medium sized organizations had a high level of participation. In addition, private-sector organizations represented the majority of respondents by organizational type, with 45.5% of respondents, followed by the multinational companies and public-sector and regulatory organizations. The overall distribution suggests that the sample represents respondents from diverse demographic, educational, experience, and organizational characteristics. This diversity in turn increases the representativeness of the sample and gives a wider perspective for studying study variables, which in turn increases the reliability, validity and generalizability of the results obtained.

4.2 Results based on Objectives

Obj. 1: To assess the relationship between organizational characteristics (e.g., firm size, stakeholder category, years of operation, technology infrastructure) and the degree of traceability system integration.

Table 2: Descriptive Statistics

Descriptive Statistics			
	Mean	Std. Deviation	N
Organizational Characteristics	17.5600	3.81433	200
Degree of Traceability System Integration	16.8600	3.76047	200

The descriptive statistics table 2 shows that all the 200 respondents were included in the analysis. Organizational Characteristics had a mean score of 17.56 and a SD of 3.81, indicating that the participating companies generally had a fairly high perception of organizational factors and a moderately large variance in this perception. In the same way, the Degree of Traceability System Integration was 16.86 with a standard deviation of 3.76, indicating overall good level of integration of the Traceability System with moderate variations between organizations. Overall, the standard deviations that are comparable indicate that the attitudes of the respondents are similar and that these responses can appropriately be used to investigate the relationship between organizational characteristics and traceability system integration.

Table 3: Correlations

Correlations			
		Organizational Characteristics	Degree of Traceability System Integration
Organizational Characteristics	Pearson Correlation	1	.373**
	Sig. (2-tailed)		.000
	N	200	200
Degree of Traceability System	Pearson Correlation	.373**	1

Integration	Sig. (2-tailed)	.000	
	N	200	200
**. Correlation is significant at the 0.01 level (2-tailed).			

Table 3 is the Pearson correlation analysis of the Degree of Traceability System Integration versus Organizational Characteristics, which shows a moderate positive correlation (r = 0.373, p = 0.000, N = 200). The correlation is statistically significant at the 0.01 level (2-tailed), meaning that it is unlikely to have happened by chance. The identification implies that firms of proper size, experience, involvement of stakeholders and technological infrastructure seem to have a greater degree of integration of the traceability system. Thus, the results support H1, which indicates a significant positive relationship between the independent and dependent variables.

Obj. 2: To analyze associations between regulatory compliance levels and supply-chain integration readiness using inferential statistical techniques.

Table 4: Descriptive Statistics

Descriptive Statistics			
	Mean	Std. Deviation	N
Regulatory Compliance Level	15.4950	4.33288	200
Supply-Chain Integration Readiness	18.3733	4.09918	300

The descriptive statistics table 4 displays the central tendency and variability for the variables included in the analysis. The mean score for Regulatory Compliance Level was 15.50 (SD = 4.33) suggesting the participating organizations had a moderate level of regulatory compliance with some variation in responses. Organizations generally reported a moderate level of readiness (18.37 ± 4.10) for supply-chain integration as indicated by the mean score and standard deviation for Supply-Chain Integration Readiness. Overall, the results show adequate range for both variables, which are suitable for further examination of the relationship.

Table 5: Correlations

Correlations			
		Regulatory Compliance Level	Supply-Chain Integration Readiness
Regulatory Compliance Level	Pearson Correlation	1	.212**
	Sig. (2-tailed)		.003
	N	200	200
Supply-Chain Integration Readiness	Pearson Correlation	.212**	1
	Sig. (2-tailed)	.003	
	N	200	300
**. Correlation is significant at the 0.01 level (2-tailed).			

Table 5 shows that there is a weak but positive correlation between Regulatory Compliance Level and Supply-Chain Integration Readiness (r = 0.212, p = 0.003, N = 200). The relationship is statistically significant at 0.01 level (2-tailed), which means that the higher the level of regulatory compliance, the more ready the company is for integration in the supply chain. The positive and significant correlation is relatively low, but it does nevertheless offer empirical evidence for H2; however, it

is possible to conclude that the compliance of regulations positively influences the preparedness of organizations to carry out integrated operations in their supply chains.

Obj. 3: To evaluate the strength of association between the adoption of digital standards and reported reductions in counterfeit or diversion incidents.

Table 6: Model Summary

Model Summary				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.456[a]	.208	.204	3.76705
a. Predictors: (Constant), Adoption of Digital Standards				

As shown in the model summary table 6, the relationship between Adoption of Digital Standards and the dependent variable is moderate. The correlation coefficient (R = 0.456) indicates a positive relationship between predictor and the outcome variable. The R Square value of 0.208 indicates that the value of the dependent variable varies by 20.8 percentage points due to the adoption of digital standards and 79.2 percentage points due to other factors which were not included in the model. The adjusted R Square (0.204) indicates that the model will have a similar ability to explain the variance after accounting for the number of predictors and sample size. Also, the standard error of the estimate (3.767) is reasonable, which means that the regression model is suitable for further analysis.

Table 7: ANOVA

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	735.773	1	735.773	51.849	.000[b]
	Residual	2809.747	198	14.191		
	Total	3545.520	199			
a. Dependent Variable: Reported Reductions in Counterfeit or Diversion Incidents						
b. Predictors: (Constant), Adoption of Digital Standards						

The results table for ANOVA presented in Table 7 shows that the regression model is significant with regard to the influence of Adoption of Digital Standards on the Reported Reductions in Counterfeit or Diversion Incidents for the organizations that were surveyed. The model gave an F value of 51.849 and a significance value of 0.000 ($p < 0.01$), which means that the regression model is significant and provides a much better fit than a model with no predictor variable. This shows that the difference in the adoption of digital standards is not just random chance and is likely representative of a significant difference. The results suggest that the more organizations are using digital standards, the more successful they are at achieving better traceability, transparency in the supply chain, and fewer counterfeit/diversion incidents. Therefore, the regression model is valid and statistically reliable, and offers good empirical evidence for Hypothesis H3.

Table 8: Coefficients

Coefficients[a]						
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	8.427	1.263		6.670	.000
	Adoption of Digital Standards	.496	.069	.456	7.201	.000
a. Dependent Variable: Reported Reductions in Counterfeit or Diversion Incidents						

As shown in the regression coefficients table 8, there is a significant positive relationship between Adoption of Digital Standards and Reported Reductions in Counterfeit or Diversion Incidents. The unstandardized coefficient (B = 0.496) indicates that the reported number of counterfeit or diversion incidents would rise by 0.496 incidents for every 1-unit increase in the use of digital standards. The standardized coefficient (Beta = 0.456) indicates a moderate positive influence and the t-value is 7.201, which is statistically significant at the p = 0.000 level. As a result, the findings support Hypothesis 3, which indicates that organizations that use more digital standards have a significant reduction in counterfeiting and diversion incidents.

5. DISCUSSION AND CONCLUSION

5.1 Discussion

The results of the present study confirm a statistically significant positive correlation between organizational characteristics and the degree of traceability system integration, which means that the companies with a higher level of technological infrastructure, operational maturity and wider stakeholder participation have higher chances of achieving a good integration of a traceability system. This result aligns with the position of Bassi et al., (2021) who state that for pharmaceutical traceability to be achieved, especially in complex supply-chain scenarios, it is important that the organizations are ready and the digital systems are interoperable. In the same way, Boruah and Mohanty (2022) found that the capabilities of technology have a significant impact on the visibility and coordination of the pharmaceutical logistics network. The findings of this present study are relevant due to the experienced professionals and the abundance of medium and private sector enterprises. The moderate correlation strength, however, implies that nothing can ensure seamless system integration solely based on organizational characteristics. This is in line with what Bontridder and Poullet (2021) stated regarding the importance of data governance and regulatory harmonization for achieving interoperability. On the other hand, Erickson and Collins (2020) argued that the size of an organization has only a marginal effect on digital traceability unless it is complemented by strategic leadership and employee digital competence, indicating that institutional capacities can be more influential than structural features in shaping outcomes of a digital transformation.

The results align significantly with those of Kushwaha et al. (2025), who found that GS1 serialization and standardized digital identifiers can significantly improve product authenticity and minimize the infiltration of counterfeit products into the pharmaceutical supply chain. Similarly, Chowdhury and Ghosh (2024) pointed out the added value that digital standards can offer in terms of end-to-end transparency, allowing for real-time information to be shared between manufacturers, distributors, and regulators. However, the weak determining power of this regression model suggests the remaining 79% is due to other organizational, technological and policy considerations. This partially reinforces the point made by Datta (2024), which is that digital standards are not enough without the integrated governance mechanisms and stakeholders' collaboration. In contrast, Novelli and Sandri (2024) argued that block chain-based traceability can achieve significantly more effective anti-counterfeiting results than the traditional approach of digital standardization, thereby recommending a future pharmaceutical traceability system that integrates digital standardization with innovative distributed technologies for enhanced supply chain security and resilience.

5.2 Conclusion

The study findings suggest that the development of a robust end-to-end pharmaceutical traceability system in India is not just the result of implementing cutting-edge digital technologies but also hinges on the synergistic impact of organizational readiness, regulatory compliance and standardized data interoperability. The results of the empirical analysis show that organizational characteristics (firm size, stakeholder involvement, technology infrastructure, and operational experience) significantly influence the level of integration of the traceability system, while regulatory compliance also positively influences the readiness to integrate the supply chain, albeit a little less strongly. Most notably, the regression analysis confirms that the use of digital standards is linked to a significant reduction in counterfeit and diversion incidents, showing that digital identification and interoperable data exchange in the supply chain enhances supply-chain transparency and product authentication.

However, the moderate reliability of the model suggests that other elements like institutional governance, stakeholder cooperation, data quality management, workforce digital competence, and policy harmonization will continue to play a key role in realizing the full potential of traceability across the pharmaceutical ecosystem. The varied participation of

manufacturers, distributors, retailers, and regulatory bodies further strengthens the credibility and applicability of the results, giving a comprehensive view of the existing traceability readiness in India. In general, the study has theoretical and managerial significance as it establishes the need for integrated multi-stakeholder framework with interoperable digital standards and coordinated regulatory mechanisms to increase the resilience of the supply chain, strengthen public health, reduce the circulation of counterfeit medicines and enhance the credibility of the Indian pharmaceutical industry in the global market.

5.2.1 Implications of the study

The present study provides a valuable theoretical, practical and policy implications on the enhancement of pharmaceutical traceability in India. The results show that organizational readiness, regulatory compliance and a digital standards approach each and every of these factors help to enhance the integration of traceability systems, supply chain readiness and to decrease counterfeit/diversion events. In theory, the study reinforces the Technology–Organization–Environment (TOE) concept, which focuses on technology evaluations rather than on a multi-stakeholder pharmaceutical environment. In practice, the findings offer concrete recommendations that manufacturers, distributors, retailers and regulators can use to focus on interoperable data architectures, digital data standards based on GS1 and coordinated information sharing in the supply chain. Policy level, the study recommends the national traceability policy to be harmonized, data governance frameworks to be standardized and increased collaboration between industry and regulators to increase transparency, patient safety, export credibility and resilience against counterfeit medicines in India's pharmaceutical ecosystem.

5.2.2 Limitations of the study

The study has some drawbacks and limitations that should be taken into account when interpreting the results. First, the study followed the cross sectional survey design, which made it impossible to analyse the cause and effect relationships and changes in the readiness of traceability in time. Secondly, the sample was drawn using stratified purposive sampling and it included 200 respondents, ensuring that the sample covered a wide range of stakeholders; however, the findings may not be representative of the entire Indian pharmaceutical industry, especially the smaller regional companies and informal distribution channels. Third, the study was based on data collected from mainly self-reported questionnaires, which often leads to response bias and subjectivity in evaluating organisational practices. Lastly, the regression model accounted for only 20.8% of the variance in the outcomes of counterfeit reduction, suggesting that other factors such as organizational culture, cybersecurity readiness, funding investments, employee digital competencies, and new technologies such as block chain and Internet of Things (IoT) should be included in future longitudinal and mixed-method studies to gain a deeper understanding of end-to-end pharmaceutical traceability.

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