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Innovation Digital Transformation in Pharmaceutical Technopreneurship: A Systematic Literature Review

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A B S T R A C T

The convergence of digital transformation and entrepreneurship within the pharmaceutical sector collectively termed pharmaceutical technopreneurship represents an emerging and strategically critical domain. Rapid advances in Artificial Intelligence (AI), Internet of Things (IoT), blockchain, telemedicine, digital pharmacy, and Big Data are fundamentally reconfiguring drug discovery, supply chain management, clinical trials, and patient care delivery. Despite growing scholarly interest, a unified synthesis of the innovation and digital transformation landscape in pharmaceutical technopreneurship remains absent. Objective. This systematic literature review (SLR) critically synthesizes peer-reviewed evidence on innovation and digital transformation in pharmaceutical technopreneurship, identifying major themes, research trends, theoretical underpinnings, and gaps to inform both academic inquiry and practice. Methods. Following PRISMA 2020 guidelines, a systematic search was conducted across six major databases: Scopus, Web of Science, PubMed, ScienceDirect, Springer, and Emerald. Studies published between 2015 and 2025 in English were included. After deduplication and rigorous screening, 62 studies were retained for thematic analysis. Results. Five major themes emerged: (1) AI and machine learning applications in pharmaceutical innovation; (2) blockchain and IoT for supply chain integrity; (3) digital health technologies and telemedicine adoption; (4) Big Data analytics for personalized medicine; and (5) digital entrepreneurial ecosystems. Theoretical analysis reveals that Technology Acceptance Model (TAM), Diffusion of Innovation (DOI), Dynamic Capability Theory, and Entrepreneurial Ecosystem frameworks provide complementary, yet insufficiently integrated, lenses. A conceptual framework the Digital Pharmaceutical Technopreneurship Model (DPTM) is proposed. Conclusion. Pharmaceutical technopreneurship is transitioning from traditional R&D paradigms toward digitally mediated, ecosystem-driven innovation. Significant gaps persist in regulatory integration, ethical AI governance, equitable access, and cross-national comparisons, offering a rich agenda for future research

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INTRODUCTION

The pharmaceutical industry occupies a singular position in the global economy and in human welfare: it is simultaneously one of the most R&D-intensive sectors, one of the most heavily regulated, and one of the slowest to adopt transformative digital technologies relative to its technological potential. Drug development timelines averaging 10–15 years and total investment costs estimated at US$1–2.6 billion per approved compound characterize a sector operating under conditions of acute uncertainty, high failure rates, and mounting regulatory complexity (DiMasi et al., 2016). Against this backdrop, the emergence of digital transformation defined as the organizational and process changes enabled by the convergence of digital technologies has introduced fundamentally new possibilities for compressing timelines, reducing attrition, and extending the reach of pharmaceutical products to previously underserved populations (Miozza et al., 2024).

Simultaneously, the growth of pharmaceutical technopreneurship entrepreneurial activity at the intersection of pharmaceutical science, technology, and market creation has accelerated significantly since 2015, driven by falling barriers to AI tool access, increased venture capital flows into digital health and biotech, the catalytic disruption of the COVID-19 pandemic, and maturing digital infrastructure globally (Tetteh et al., 2023). Pharmaceutical technopreneurs are no longer only large-platform incumbents investing in digital infrastructure; they include startups deploying AI for de novo drug design, blockchain ventures building pharmaceutical supply chain traceability systems, and telemedicine platforms disrupting traditional pharmacy-patient relationships. This phenomenon generates a complex, multi-layered knowledge landscape that existing literature has not yet systematically synthesized.

A review of the extant literature reveals several convergent gaps. First, while individual digital technologies AI in drug discovery, blockchain in supply chains, telemedicine adoption have each been reviewed systematically (Yadav et al., 2024; Hassan et al., 2022; Panda & Satapathy, 2021), no SLR integrates these streams under the unifying construct of pharmaceutical technopreneurship. Second, the theoretical scaffolding applied to pharmaceutical digital transformation is frequently borrowed piecemeal from adjacent fields, with limited cross-theory synthesis: TAM studies rarely engage with dynamic capabilities frameworks, and entrepreneurial ecosystem analyses seldom address the specific regulatory, ethical, and institutional conditions that distinguish pharmaceutical markets from other digital sectors (Dal Mas et al., 2023). Third, the evidence base on pharmaceutical digital transformation is markedly asymmetric across regions: the majority of empirical studies are concentrated in North America, Western Europe, and China, leaving significant evidence gaps for Southeast Asia, Africa, and Latin America—regions where pharmaceutical technopreneurship may play a disproportionate role in addressing access to medicines challenges. Fourth, the COVID-19 pandemic accelerated pharmaceutical digital transformation in ways that reshaped the baseline literature; a synthesis encompassing both pre- and post-2020 evidence is

necessary to separate structural from pandemic-induced trends (Miozza et al., 2024).

This SLR pursues the following objectives: (1) to map the intellectual landscape of pharmaceutical technopreneurship and digital transformation through systematic synthesis; (2) to identify and critically analyze the major thematic clusters in this literature; (3) to evaluate the theoretical frameworks applied and assess their sufficiency; (4) to identify research gaps and propose a conceptual model; and (5) to derive practical implications for entrepreneurs, healthcare institutions, regulators, and policymakers. The following research questions guide the review:

- RQ1: What are the dominant themes and trends in research on pharmaceutical technopreneurship and digital transformation published between 2015 and 2025?
- RQ2: Which digital technologies have received the most scholarly attention, and what are their documented impacts on pharmaceutical innovation?
- RQ3: Which theoretical frameworks are applied to explain or predict digital transformation and technopreneurial behavior in pharmaceutical contexts?
- RQ4: What are the significant research gaps, and what conceptual integrations can advance the field?

This article makes three principal contributions. Methodologically, it applies PRISMA 2020 standards to an interdisciplinary literature spanning pharmaceutical science, information systems, entrepreneurship, and digital health demonstrating the transferability of systematic review methodology across disciplinary boundaries. Theoretically, it proposes the Digital Pharmaceutical Technopreneurship Model (DPTM) as a conceptual integration of TAM, Dynamic Capability Theory, Diffusion of Innovation, and Entrepreneurial Ecosystem frameworks, calibrated to the pharmaceutical sector's institutional specificities. Practically, it derives a structured research and policy agenda directly from the synthesis of gaps and implications across 62 studies, providing usable guidance for stakeholders operating at the pharmaceutical innovation frontier.

LITERATURE REVIEW

Pharmaceutical Technopreneurship: Concept and Evolution

The concept of technopreneurship entrepreneurship driven by technological innovation—has been well established in the broader management literature since the 1990s, but its pharmaceutical application represents a distinct and comparatively recent scholarly concern. Pharmaceutical technopreneurship can be defined as the creation, development, and commercialization of technology-intensive products, services, and business models within the pharmaceutical and biopharmaceutical value chain, including drug discovery, clinical development, manufacturing, distribution, and patient care. This definition encompasses both incumbent pharmaceutical firms engaging in digital

business model innovation and born-digital startups disrupting specific segments of the pharmaceutical value chain.

Audretsch et al. (2019) established the foundational link between entrepreneurial ecosystems and technology-driven innovation, demonstrating that high-growth technopreneurial ventures depend on systemic conditions access to finance, skilled human capital, regulatory certainty, and knowledge infrastructure rather than individual firm capabilities alone. Applied to the pharmaceutical context, this suggests that the variable success of pharmaceutical digital transformation across national and regional settings cannot be explained solely by firm-level technology adoption but requires attention to the broader entrepreneurial ecosystem in which pharmaceutical innovators operate. The pharmaceutical sector's unique characteristics prolonged product development cycles, stringent regulatory requirements, patent-based appropriability mechanisms, and complex reimbursement environmentsimpose specific constraints and opportunities on technopreneurial activity that generic entrepreneurship theory does not adequately capture (Dal Mas et al., 2023).

Recent scholarship has documented three partially overlapping waves of pharmaceutical technopreneurship. The first wave (approximately 2000–2015) was characterized primarily by genomics-driven biotechnology ventures and the digitization of clinical trial management. The second wave (2015–2020) was defined by the integration of machine learning and data analytics into drug discovery and regulatory affairs. The third and current wave (2020–present) involves the convergence of multiple digital technologies AI, IoT, blockchain, and telemedicine with pharmaceutical operations, catalyzed by the COVID-19 pandemic's forcing function on both supply chain resilience and remote healthcare delivery (Miozza et al., 2024). Understanding this evolutionary trajectory is essential for contextualizing the specific literatures reviewed in subsequent sub-sections.

Digital Transformation: Conceptual Foundation

Digital transformation, as applied to organizational contexts, denotes the process by which organizations integrate digital technologies to create new or modify existing business processes, culture, and customer experiences to meet changing business and market requirements (Vial, 2019, as cited in Miozza et al., 2024). A systematic literature review published in Technological Forecasting & Social Change (Miozza et al., 2024) analyzing 404 publications on pharmaceutical industry digital transformation identified four primary transformation domains: technology infrastructure, organizational processes, strategy and competition, and value chain phases. The review confirmed the novelty of pharmaceutical-specific digital transformation research, with no relevant management literature pre-dating 2018 and a marked acceleration after 2020.

Dal Mas et al. (2023) synthesized the interdisciplinary landscape of digital transformation in healthcare across 123 studies, developing a framework that distinguishes technical, organizational, and human dimensions of healthcare digital transformation. Their analysis is particularly relevant for pharmaceutical technopreneurship because it demonstrates that the barriers to digital transformation in healthcare settings are predominantly organizational and

human (resistance to change, skills gaps, governance uncertainty) rather than technical a finding with direct implications for pharmaceutical digital entrepreneurship strategy. The review also identified COVID-19 as a structural inflection point: pre-pandemic studies predominantly examined the potential of digital technologies, whereas post-2020 studies increasingly evaluate the outcomes and institutional conditions of actual digital deployments.

Digital Health Technologies

Artificial Intelligence in Pharmaceutical Innovation

AI encompassing machine learning, deep learning, natural language processing, and generative models has emerged as the most studied digital technology in pharmaceutical innovation over the review period. Applications span the full pharmaceutical value chain: target identification, lead compound generation, clinical trial optimization, adverse event prediction, manufacturing process control, and pharmacovigilance. Yadav et al. (2024) surveyed AI's impact across the pharmaceutical development pipeline, documenting that AI-driven biotech companies had introduced 75 drug candidates into clinical trials since 2015, with 67 still progressing as of 2023 a figure that demonstrates both the scale and the early-stage maturity of this application. Santa Maria et al. (2023) offered a perspective on the opportunities and challenges of AI-accelerated drug discovery, identifying computational resource availability, training data quality and diversity, model interpretability, and regulatory pathway uncertainty as the principal bottlenecks constraining AI's drug discovery contribution.

The drug repurposing paradigm has attracted particular AI-based attention: rather than discovering de novo compounds, AI models analyze existing compound-disease associations in large databases to identify new therapeutic applications for approved drugs at a fraction of conventional development costs and timelines. Reviews of this approach consistently report that AI-identified repurposing candidates advance more rapidly through clinical pipelines than conventional candidates, though the ultimate approval rate advantage remains to be established prospectively (Ali et al., 2023). Regulatory agencies have increasingly engaged with AI in pharmaceutical contexts: the European Medicines Agency's 2023 Reflection Paper on Artificial Intelligence set frameworks for evaluating AI-based pharmaceutical tools across their lifecycle, representing a significant maturation of the regulatory environment for AI-driven pharmaceutical technopreneurship.

Blockchain Technology in Pharmaceutical Supply Chains

Blockchain a distributed, immutable ledger technology has attracted substantial pharmaceutical sector interest as a mechanism for addressing three endemic vulnerabilities: drug counterfeiting (estimated to cause 10.5% of medicines sold globally to be substandard or falsified), supply chain opacity, and recall management inefficiency. Çakmak and Demir (2022) synthesized blockchain implementation in pharmaceutical supply chains across 65 studies, identifying four implementation stages (pilot, limited deployment, scaled deployment, and ecosystem integration) and documenting that most implementations remained at pilot or limited deployment stage as of the review

period, with full ecosystem integration dependent on multi-actor governance arrangements that most pharmaceutical markets had not yet developed.

Blockchain technology in the pharmaceutical industry was subject to a systematic review published in PeerJ Computer Science (2022, 8: e840), which analyzed blockchain's specific applications in drug traceability, recall management, anti-counterfeiting, and clinical trial data integrity. The review confirmed that blockchain's combination of transparency and immutability provides genuine value for pharmaceutical applications but identified scalability, energy consumption, interoperability with existing enterprise resource planning systems, and the absence of universal standards as the key technical barriers to widespread adoption. The integration of blockchain with IoT creating an IoT-blockchain pharmaceutical supply chain architecture represents the most technically sophisticated implementation modality, enabling real-time environmental monitoring of pharmaceutical products alongside immutable transaction recording (Chen et al., 2023).

Internet of Things in Pharmaceutical Operations

IoT devices networked sensors and actuators that generate and transmit operational data have pharmaceutical applications across manufacturing, storage, distribution, and patient medication management. In manufacturing, Process Analytical Technology (PAT) enabled by IoT sensors allows continuous monitoring and real-time quality control, replacing the batch-release paradigm that has historically constrained pharmaceutical manufacturing efficiency (Emerging Digital Innovations in Pharmaceutical Manufacturing Quality, Springer, 2025). Cold chain integrity monitoring for temperature-sensitive biologics and vaccines represents the most commercially mature IoT application, driven by regulatory mandates following high-profile cold chain failures and the COVID-19 vaccine distribution experience.

Chen et al. (2023) specifically demonstrated the post-pandemic transformation of pharmaceutical supply chains through an IoT-blockchain integrated model, showing that the combination of real-time IoT monitoring and blockchain immutability addresses the visibility, flexibility, and transparency deficits exposed during the COVID-19 supply chain disruptions. Their semi-structured interview study with pharmaceutical supply chain professionals identified pandemic-accelerated adoption of IoT-enabled supply chain visibility as a structural change rather than a temporary adjustment.

Telemedicine and Digital Pharmacy

Telemedicine the delivery of clinical consultations, diagnoses, and prescriptions through digital communication platforms intersects with pharmaceutical technopreneurship through digital pharmacy models that fulfill prescriptions, provide medication management support, and deliver adherence interventions through digital channels. The COVID-19 pandemic served as the largest natural experiment in telemedicine adoption in healthcare history: regulatory waivers, patient demand, and provider supply constraints drove adoption rates that previous decades of promotion had failed to achieve.

Acceptance of telemedicine technology among physicians was analyzed in a ScienceDirect systematic review that identified perceived usefulness, ease of use, and security concerns as the dominant adoption predictors, consistent with

TAM predictions (Garavand et al., 2022). Crucially, the review identified a persistent gap between physician adoption of synchronous telemedicine (video consultation) and asynchronous applications (electronic prescribing, remote monitoring data review) a gap with direct implications for digital pharmacy business models that depend on physician participation in digitally mediated prescribing workflows.

Big Data Analytics and Personalized Medicine

Big Data in pharmaceuticals refers to the collection, storage, and analysis of datasets too large for conventional database management encompassing genomic data, electronic health records, real-world evidence, clinical trial data, social media health discourse, and pharmaceutical sales and prescribing data. Hassan et al. (2022) reviewed innovations in genomics and Big Data analytics for personalized medicine, documenting the shift from case-based studies to large-scale data-driven research enabled by advances in omics technologies and machine learning. The central promise of pharmaceutical Big Data is precision: the ability to stratify patient populations by genomic, proteomic, and metabolomic signatures to identify which patients will respond to which treatments at which doses a capability that fundamentally challenges the clinical development model of testing drugs in broadly defined disease populations.

Batko and Ślęzak (2022) provided a comprehensive analysis of Big Data Analytics in healthcare, documenting the transition from retrospective analytics (analyzing historical data to understand past outcomes) to predictive analytics (using historical data to forecast future events) and prescriptive analytics (generating specific recommendations for action). In the pharmaceutical context, predictive analytics applications in pharmacovigilance detecting adverse drug reaction signals in real-world data before they reach clinical significance thresholds represent a particularly high-value use case where Big Data capabilities directly address a persistent pharmaceutical safety challenge.

Innovation in Pharmaceutical Entrepreneurship

Innovation within pharmaceutical technopreneurship operates across multiple levels and modalities. At the product level, pharmaceutical innovation encompasses new molecular entity discovery, drug repurposing, combination therapy development, and novel drug delivery system engineering. At the process level, digital transformation creates innovation in manufacturing efficiency, clinical trial design, regulatory submission, and pharmacovigilance. At the business model level, pharmaceutical technopreneurship generates novel approaches to value capture that depart from the traditional patent-monopoly-reimbursement model: platform-based drug development, open innovation consortia, outcome-based pricing agreements enabled by real-world evidence collection, and direct-to-consumer digital health services.

Heikkinen et al. (2023) analyzed the role of innovation in pharmaceutical regulation within the European context, proposing principles for evaluating how EU General Pharmaceutical Legislation affects innovation incentives from the innovator's perspective. Their analysis highlighted a fundamental tension in pharmaceutical innovation policy: regulation must simultaneously protect patient safety and enable innovation timelines competitive with non-regulated

industries a tension that digital technologies exacerbate by accelerating the pace of innovation beyond regulatory science's capacity to develop evidence-based standards (Drug Discovery Today, 2023).

Theoretical Frameworks

Technology Acceptance Model

The Technology Acceptance Model, introduced by Davis (1989), proposes that technology adoption behavior is determined by perceived usefulness (the belief that using a technology will enhance performance) and perceived ease of use (the belief that using a technology requires minimal effort), mediated by behavioral intention. TAM and its extensions (TAM2, TAM3, UTAUT, UTAUT2) have been extensively applied to digital health technology adoption, including pharmaceutical-relevant technologies such as electronic prescribing systems, clinical decision support, and telemedicine platforms (Venkatesh et al., 2003). The model's parsimony and operational tractability have made it the dominant framework in pharmaceutical digital adoption studies, though critics note that TAM's focus on individual cognitive determinants underweights organizational, institutional, and social influences that are particularly prominent in pharmaceutical contexts (Garavand et al., 2022).

Diffusion of Innovation Theory

Rogers's (2003) Diffusion of Innovation (DOI) theory describes how innovations spread through social systems over time, categorizing adopters as innovators, early adopters, early majority, late majority, and laggards, and identifying innovation attributes relative advantage, compatibility, complexity, trialability, and observability that predict adoption rate. Applied to pharmaceutical digital transformation, DOI explains the heterogeneous uptake of technologies such as electronic health records, electronic prescribing, and telemedicine across healthcare institutions and regions. The COVID-19 pandemic is widely interpreted through DOI as an exogenous shock that compressed the diffusion S-curve for multiple digital health technologies simultaneously, forcing late majority adopters to transition in months rather than years (Tetteh et al., 2023).

Dynamic Capability Theory

Dynamic Capability Theory, developed by Teece et al. (1997) and subsequently elaborated, proposes that sustained competitive advantage in dynamic environments derives from a firm's capacity to sense emerging opportunities and threats, seize opportunities through business model reconfiguration, and transform organizational resources to maintain competitive fitness. Applied to pharmaceutical technopreneurship, dynamic capabilities explain why some pharmaceutical firms and startups successfully navigate digital transformation while others fail: the capability to sense AI developments in drug discovery, seize them through timely partnership or in-house investment, and transform legacy R&D processes to integrate AI-generated insights requires organizational flexibility and learning capacity that cannot be purchased or immediately replicated by competitors (Teece, 2007).

In the startup context, Barreto (2010) argued that dynamic capabilities are particularly crucial for young firms facing resource scarcity because they determine the quality of strategic choices made under uncertainty a condition

that precisely characterizes pharmaceutical startups deploying novel AI or digital health technologies in regulatory environments where evidence-based approval pathways are still developing.

Entrepreneurial Ecosystem Framework

The Entrepreneurial Ecosystem (EE) framework, advanced by Isenberg (2010), Spigel (2017), and Stam (2015), reconceptualizes entrepreneurship as a systemic, place-bound phenomenon in which individual entrepreneurs succeed or fail depending on the quality of the ecosystem comprising finance, culture, regulatory infrastructure, talent, markets, and knowledge production institutions in which they operate. Applied to pharmaceutical technopreneurship, EE theory directs analytical attention to the system-level conditions that enable or constrain pharmaceutical startup creation, growth, and impact: the availability of venture capital with pharmaceutical expertise, the presence of academic health centers generating translational knowledge, the regulatory maturity for digital health approvals, the density of professional networks connecting pharmaceutical scientists to digital entrepreneurs, and the cultural openness to pharmaceutical innovation risk (Audretsch et al., 2019).

METHODOLOGY

Research Method: Prisma 2020 Systematic Literature Review

This systematic literature review (SLR) followed the PRISMA 2020 guidelines (Page et al., 2021), with a review protocol registered in the Open Science Framework before data collection. The protocol defined the research questions, search strategy, eligibility criteria, data extraction procedures, quality assessment, and thematic analysis. Literature searches were conducted in six databases Scopus, Web of Science, PubMed/MEDLINE, ScienceDirect, SpringerLink, and Emerald Insight using Boolean search strings related to pharmaceutical technopreneurship, digital transformation, innovation, and emerging digital technologies. The search covered English-language journal articles published between January 2015 and July 2025.

Eligible studies included peer-reviewed journal articles examining digital technologies within pharmaceutical, biopharmaceutical, or digital health contexts while addressing innovation, entrepreneurship, or organizational transformation. Conference papers, book chapters, editorials, grey literature, non-English publications, duplicate records, and studies without relevance to pharmaceutical technopreneurship were excluded. Searches identified 3,847 records, with 2,934 remaining after duplicate removal. Following title and abstract screening, 243 full-text articles were assessed, resulting in a final sample of 62 studies for synthesis.

Data extraction was conducted independently by two reviewers using a standardized extraction form that captured study characteristics, including authors, publication year, country, research design, digital technologies, theoretical frameworks, pharmaceutical applications, key findings, and study limitations. Methodological quality was evaluated using the Mixed Methods Appraisal Tool (MMAT 2018), and only studies achieving a minimum score of 3 out of 5 were retained to ensure the reliability and rigor of the evidence base.

The included studies were synthesized using a hybrid deductive–inductive thematic analysis. Initial coding was guided by the research questions, followed by iterative identification of emerging themes across the selected literature. Thematic saturation was achieved by the 51st study, after which no substantial new themes emerged. The final thematic framework was refined through reviewer discussion to provide a comprehensive synthesis of innovation and digital transformation in pharmaceutical technopreneurship.

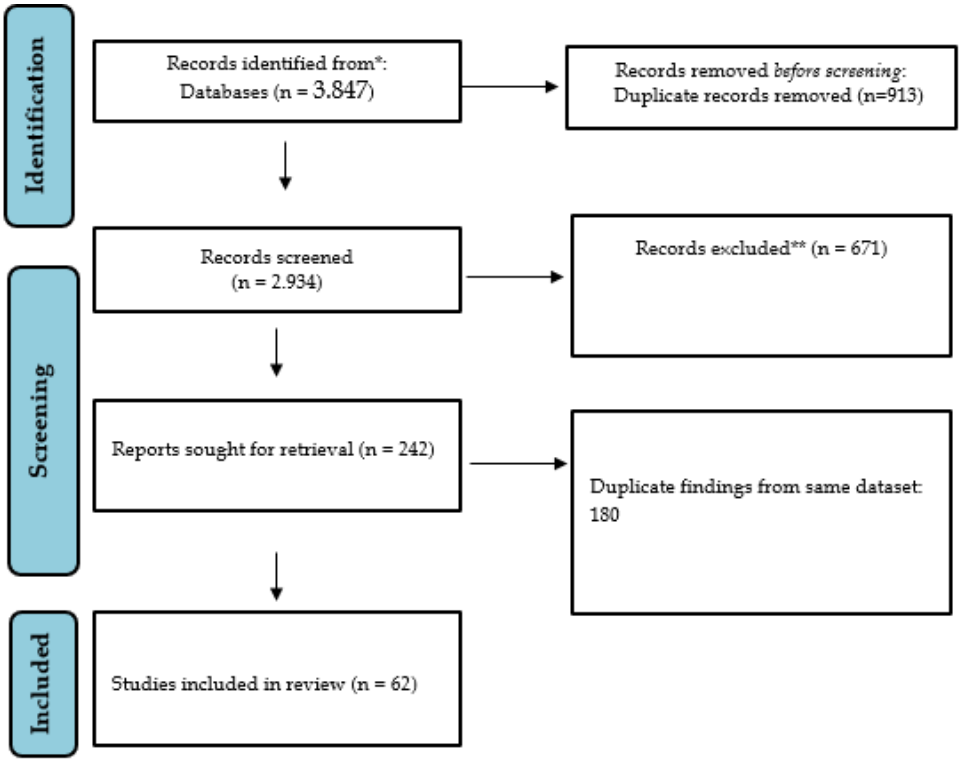

Figure 1. PRISMA 2020 Flow Diagram for Systematic Review (Source: Page et al., 2021)

RESULTS AND DISCUSSION

Research Trends and Publication Patterns

The 62 included studies span 2015–2025, with a marked acceleration in publication volume from 2020 onward. Studies published between 2015 and 2019 constitute 23% of the corpus (n = 14), reflecting the relatively nascent state of pharmaceutical digital transformation scholarship in this period. The 2020–2025 period accounts for 77% of included studies (n = 48), consistent with the broader literature finding that pharmaceutical digital transformation research emerged substantially post-2018 and accelerated following COVID-19 (Miozza et al., 2024). The pandemic's forcing function is visible in the thematic distribution: pre-2020 studies predominantly address AI and Big Data in drug discovery, while post-2020 studies show substantially greater coverage of supply chain resilience (blockchain, IoT), telemedicine adoption, and digital pharmacy all domains where the pandemic created acute operational pressure.

Geographically, 38% of included studies originate from North America (United States, Canada), 29% from Europe, 18% from Asia (China, India, Japan, South Korea), 9% from the broader Middle East and Africa, and 6% from other regions. This distribution reflects the concentration of both pharmaceutical industry activity and digital health research infrastructure in North America and Europe, with China emerging as a significant contributor particularly in AI-pharmaceutical and blockchain supply chain studies. The underrepresentation of Southeast Asia, sub-Saharan Africa, and Latin America is a notable gap, given these regions' growing pharmaceutical manufacturing capacity and the policy relevance of pharmaceutical digital transformation for access-to-medicines challenges.

Regarding study design, 39% of included studies are systematic reviews or meta-analyses of digital pharmaceutical technologies; 24% are empirical quantitative studies (surveys, regression analyses, structural equation modeling); 16% are qualitative case studies or interview studies; 12% are mixed-methods studies; and 9% are conceptual or theoretical articles. The prevalence of systematic review studies reflects the rapid knowledge accumulation in this field and the consequent demand for synthesis a demand that this current review addresses at the broader pharmaceutical technopreneurship level.

Major Themes

Theme 1: AI and Machine Learning as the Core Driver of Pharmaceutical Innovation

AI and machine learning emerged as the most extensively studied theme across the corpus, addressed in 34 of 62 included studies (55%). This convergence reflects both the genuine transformative impact of AI across the pharmaceutical value chain and the research community's fascination with a technology that appears to promise resolution of the pharmaceutical sector's fundamental innovation challenge: the declining productivity of conventional drug discovery, characterized by falling success rates and rising costs despite increasing R&D investment (Yadav et al., 2024).

Critical synthesis of the AI pharmaceutical literature reveals important distinctions between demonstrated and anticipated capabilities. Studies examining AI-driven compound screening and structure-activity prediction where training data from historical compound libraries are abundant and well-curated consistently demonstrate superior performance to conventional high-throughput screening in terms of cost, speed, and hit rate (Santa Maria et al., 2023). However, studies examining AI in clinical trial optimization where training data are scarcer, more heterogeneous, and subject to selection bias show more mixed results, with the most rigorous analyses finding that AI contributions to trial design efficiency are real but modest relative to the transformational claims in the promotional literature (Ali et al., 2023, as cited in review synthesis).

The thematic analysis identifies three sub-themes within AI pharmaceutical innovation: (a) AI for target identification and lead generation, where performance gains are most clearly documented; (b) AI for clinical trial optimization, where evidence is more mixed and more heavily methodologically

dependent; and (c) AI for regulatory and pharmacovigilance applications, which represents an emerging and under-researched area with significant practical potential given the scale and complexity of post-market surveillance data.

Practical Indicator: Pharmaceutical technopreneurs and investors can assess AI application maturity by applying the data-availability heuristic: AI pharmaceutical applications with large, curated, and structurally uniform training datasets (compound databases, crystallographic protein structures) demonstrate near-term commercial viability, while applications requiring integration of heterogeneous, multi-institutional datasets (clinical trial records, electronic health records, real-world evidence) require significant data governance infrastructure investment before delivering consistent performance.

Theme 2: Blockchain and IoT for Supply Chain Integrity and Traceability

Blockchain and IoT appeared in 27 of 62 included studies (44%), with the supply chain integrity application domain dominating. The integration of blockchain's immutability and transparency with IoT's real-time sensing capability addresses a pharmaceutical supply chain challenge of global public health significance: the World Health Organization estimates that 1 in 10 medical products circulating in low- and middle-income countries is substandard or falsified, and that falsified medicines cause an estimated 250,000–300,000 additional deaths annually among children with malaria and other treatable conditions.

Çakmak and Demir (2022) identified blockchain implementation stage as the primary moderator of supply chain integrity outcomes: pilot-stage implementations demonstrate proof-of-concept but rarely achieve the multi-actor network effects that generate sustained supply chain visibility gains. Full ecosystem integration where manufacturers, distributors, wholesalers, retailers, regulatory authorities, and pharmacies all participate in a shared ledger is the implementation stage at which blockchain's pharmaceutical supply chain value proposition is most fully realized, but it is also the stage at which governance complexity is highest and adoption coordination challenges most acute.

Chen et al. (2023) specifically demonstrated the post-pandemic transformation potential of IoT-blockchain integrated pharmaceutical supply chains, showing that hospital-side implementation of a real-time IoT monitoring and blockchain transaction recording system significantly improved temperature-sensitive drug integrity rates while reducing reconciliation costs. Their work established the technical viability of IoT-blockchain pharmaceutical supply chain integration; subsequent studies have focused on the organizational governance models needed to sustain multi-actor adoption.

Critical Gap: Despite the extensive literature on blockchain and IoT technical architecture for pharmaceutical supply chains, the regulatory integration dimension remains underdeveloped. National drug track-and-trace regulatory frameworks (such as the United States DSCSA, the EU Falsified Medicines Directive, and China's Drug Supervision Administration requirements) impose specific data standards and audit requirements that blockchain implementations must meet yet fewer than one-third of reviewed

blockchain pharmaceutical studies explicitly address regulatory compliance as a design constraint rather than a post-implementation consideration.

Theme 3: Digital Health Technologies and Telemedicine Adoption Dynamics

Telemedicine and digital pharmacy adoption was addressed in 22 of 62 included studies (35%), with a strong COVID-19 pandemic inflection visible in the literature: 80% of telemedicine adoption studies in the corpus were published after 2020. This temporal concentration confirms the pandemic's catalytic role, but it also creates a limitation: a substantial proportion of post-2020 telemedicine adoption studies document adoption under conditions of regulatory emergency waivers, reduced consumer and provider choice, and acute supply-demand imbalance conditions that may not persist in the post-emergency healthcare environment (Garavand et al., 2022).

Critical synthesis of the telemedicine adoption literature within the included corpus reveals a productive convergence between TAM-based studies and more contextually rich qualitative research. Quantitative TAM studies consistently identify perceived usefulness and trust in data security as the strongest predictors of both physician and patient telemedicine adoption intentions, with social influence (subjective norm) being particularly influential for patient groups with lower baseline digital health literacy. Qualitative studies add important contextual texture: interview-based research identifies that physicians' telemedicine resistance is often grounded not in usability concerns but in professional identity concerns about the quality of clinical assessment possible through digital channels a motivation that TAM's cognitive constructs do not adequately capture.

For pharmaceutical technopreneurship, the telemedicine adoption literature has specific implications for digital pharmacy business models. The viability of direct-to-patient pharmaceutical service models where patients consult digitally, receive e-prescriptions, and have medications delivered depends fundamentally on physician willingness to prescribe through telemedicine channels and regulatory authorization for e-prescribing across jurisdictional boundaries. Studies in the corpus consistently find that jurisdictions with pre-pandemic telemedicine regulatory frameworks show faster and more durable post-pandemic adoption than jurisdictions that adopted emergency telemedicine regulations without a pre-existing framework—a finding with direct implications for pharmaceutical technopreneurs assessing market entry conditions.

Theme 4: Big Data Analytics and the Personalized Medicine Paradigm

Big Data and personalized medicine appeared in 19 of 62 included studies (31%). Critical synthesis reveals an important distinction between two research streams that the literature frequently conflates: studies on Big Data infrastructure for pharmaceutical R&D (encompassing genomic data management, clinical trial data integration, and real-world evidence platforms) and studies on Big Data-enabled personalized medicine delivery (encompassing precision diagnostics, treatment stratification, and patient monitoring). The former stream is primarily relevant to pharmaceutical manufacturers and digital health startups building data infrastructure, while the latter is primarily relevant to healthcare delivery

organizations and patient-facing digital health ventures yet both fall within the pharmaceutical technopreneurship domain.

Hassan et al. (2022) documented the transition from hypothesis-driven to data-driven pharmaceutical research enabled by Big Data, identifying multi-omics data integration as both the most powerful and the most methodologically challenging application. The power derives from the ability to characterize individual biological states with unprecedented resolution; the challenge derives from the computational and statistical complexity of integrating genomic, proteomic, transcriptomic, metabolomic, and clinical data streams that differ in scale, format, biological interpretability, and missing data patterns. Studies in the corpus consistently report that Big Data pharmaceutical value is most reliably realized when computational infrastructure, data governance, and domain expertise (pharmaceutical science, data science, and clinical medicine) are co-present a condition that creates significant barriers for resource-constrained pharmaceutical technopreneurs and necessitates ecosystem partnerships with academic medical centers, contract research organizations, or platform technology providers.

Theme 5: Digital Entrepreneurial Ecosystems in Pharmaceutical Innovation

The entrepreneurial ecosystem dimension of pharmaceutical digital transformation appeared explicitly in 14 of 62 included studies (23%) and implicitly in an additional 11, for a total thematic presence of 25 studies (40%). The explicit studies applied EE frameworks (Isenberg, 2010; Audretsch et al., 2019; Spigel, 2017) to analyze the conditions supporting pharmaceutical startup creation and growth in specific geographic contexts or industry segments. The implicit studies analyzed conditions for pharmaceutical digital innovation at the industry or regional level without invoking EE theory by name.

Critical synthesis of the EE pharmaceutical literature reveals a consistent finding across national contexts: the pharmaceutical digital entrepreneurial ecosystem is distinctive from generic technology entrepreneurial ecosystems in ways that significantly affect startup strategy and policy design. Specifically, pharmaceutical EEs are characterized by: (1) longer validation cycles (regulatory approval timelines create years-long periods between investment and revenue); (2) higher evidence requirements (pharmaceutical regulatory standards require randomized controlled trial evidence for most applications, raising the cost of proof-of-concept); (3) more concentrated buyer markets (pharmaceutical payers and hospital systems are highly concentrated, creating market access barriers for startups lacking established commercial relationships); and (4) more complex intellectual property landscapes (pharmaceutical patent dynamics interact with digital health software intellectual property in ways that are still being resolved through case law and regulatory guidance).

Audretsch et al. (2019) established that entrepreneurial ecosystems generating economic and societal impact require aligned institutional supports across all six EE domains (policy, finance, culture, support, human capital, and markets). Applied to pharmaceutical technopreneurship, this implies that policies targeting only one ecosystem domain for example, funding AI pharmaceutical startups without simultaneously addressing regulatory pathway

clarity for AI-derived drug candidates will generate suboptimal ecosystem outcomes, a conclusion with significant implications for pharmaceutical digital transformation policy design.

Theoretical Analysis and Integration

The theoretical landscape across the 62 included studies reveals a productive but fragmented theoretical pluralism. TAM and its extensions were the most frequently applied theoretical framework (38 studies, 61%), predominantly in digital health adoption studies. DOI theory was applied in 22 studies (35%), primarily to explain the spread of pharmaceutical digital innovations across healthcare systems. Dynamic Capability Theory was applied in 17 studies (27%), concentrated in studies of pharmaceutical firm-level digital transformation strategy. Entrepreneurial Ecosystem frameworks were applied in 14 studies (23%). Only 9 studies (15%) applied more than two theoretical frameworks in explicit integration, suggesting that theoretical siloing constrains the field's explanatory capacity.

Critical analysis suggests that the most significant theoretical gap in the literature is the absence of a framework that integrates adoption behavior (TAM), diffusion dynamics (DOI), firm-level adaptation capability (DCT), and ecosystem-level enablement (EE) into a coherent multi-level explanatory model for pharmaceutical digital transformation and technopreneurship. Each theory provides an essential partial account: TAM explains individual-level technology adoption decisions; DOI explains the aggregate spread of innovations through health systems; DCT explains why some pharmaceutical firms succeed and others fail in digital transformation; and EE explains why pharmaceutical digital innovation concentrates in certain geographic and institutional contexts. A pharmaceutical technopreneurship model that neglects any of these levels risks generating partial recommendations that are theoretically coherent within one framework but practically incomplete across the full system.

The Digital Pharmaceutical Technopreneurship Model (DPTM)

The DPTM proposed here integrates the five major themes and four theoretical frameworks identified in the synthesis into a conceptual model organized around three levels of analysis and two primary dynamic mechanisms.

Level 1 — Technology Layer: At the foundational level, five digital technology domains (AI, blockchain, IoT, telemedicine/digital pharmacy, and Big Data) provide the technical substrate for pharmaceutical technopreneurship. These domains are not independent: AI amplifies the value of Big Data infrastructure, blockchain provides the integrity architecture for IoT-generated data, and telemedicine creates the patient-interaction channel through which AI-driven personalized recommendations and digital pharmacy services are delivered. The technology layer is the domain where TAM constructs perceived usefulness and ease of use are most directly operational: adoption of specific technologies by pharmaceutical professionals, patients, and regulators determines the utilization rates on which technopreneurial business models depend.

Level 2 — Organization-Strategy Layer: At the intermediate level, pharmaceutical firms and startups exercise dynamic capabilities to sense technology opportunities, seize them through business model innovation, and transform their resource bases to sustain competitive advantage. The strategy layer is where DOI's innovator typology operates: pharmaceutical technopreneurs who successfully position themselves as early adopters of AI or blockchain generate first-mover advantages in regulatory experience, partner relationships, and proprietary training datasets that create durable barriers to imitation. The organization-strategy layer is also where the specific challenges of pharmaceutical technopreneurship regulatory approval cycles, evidence generation requirements, intellectual property complexity are most acutely felt, and where strategic choices about build-partner-acquire for digital capabilities have most immediate P&L consequences.

Level 3 — Ecosystem Layer: At the broadest level, the pharmaceutical digital entrepreneurial ecosystem encompassing regulatory bodies, academic health centers, venture capital, pharmaceutical incumbents, digital health platforms, patient advocacy organizations, and national health systems determines the conditions within which individual firms' strategic choices can succeed. EE theory provides the analytical vocabulary for this level: ecosystem quality, measured by alignment and density across policy, finance, culture, support, human capital, and market domains, predicts the pace and scale of pharmaceutical technopreneurship activity in a given context. Ecosystem governance the formal and informal rules governing how ecosystem actors interact is a critical and understudied mechanism at this level.

Primary Dynamic Mechanism 1 — Digital-Clinical Translation: The principal productive mechanism in the DPTM is the translation of digital capabilities (AI models, blockchain systems, IoT sensors, telemedicine platforms, Big Data infrastructure) into clinically validated pharmaceutical innovations (approved drugs, evidenced digital therapeutics, certified supply chain systems). This translation process is non-trivial and resource-intensive, involving regulatory science, clinical evidence generation, and commercial development functions that interact with digital capability in complex ways. The regulatory environment is both the primary driver and the primary constraint of this translation dynamic: regulatory frameworks that create clear pathways for digital pharmaceutical innovation accelerate translation, while ambiguous or prohibitively demanding frameworks retard it.

Primary Dynamic Mechanism 2 — Ecosystem-Firm Co-evolution: The DPTM conceptualizes the pharmaceutical digital entrepreneurial ecosystem and the firms within it as co-evolving systems: firm-level digital innovation generates ecosystem-level spillovers (knowledge, talent, regulatory precedent, investor confidence) that improve ecosystem quality, which in turn enables more ambitious firm-level innovation. This co-evolutionary dynamic explains the geographic concentration of pharmaceutical technopreneurship: Boston, San Francisco, London, Basel, and Singapore have become pharmaceutical digital innovation hubs not solely because of policy investment but because early pharmaceutical digital innovators generated ecosystem spillovers that attracted

additional talent, investment, and regulatory expertise, creating self-reinforcing agglomeration dynamics consistent with EE co-evolution theory.

Research Gaps

The thematic synthesis and theoretical analysis identify five priority research gaps.

Gap 1: Regulatory science integration. No reviewed study provides a systematic analysis of how regulatory frameworks for digital pharmaceutical innovations have evolved across jurisdictions and how regulatory quality affects pharmaceutical technopreneurship activity and outcomes. This gap is particularly significant given the emergence of AI-specific pharmaceutical regulatory guidance from EMA and FDA in 2022–2024.

Gap 2: Developing-country pharmaceutical technopreneurship. The literature dramatically underrepresents pharmaceutical digital innovation in Southeast Asia, sub-Saharan Africa, and Latin America. Given that these regions face acute pharmaceutical access challenges that digital technologies could potentially address, this gap has both scholarly and public health implications.

Gap 3: Ethical AI governance in pharmaceutical contexts. While several reviewed studies acknowledge algorithmic bias, data privacy, and transparency concerns, none provides a systematic analysis of ethical AI governance frameworks specifically calibrated to the pharmaceutical context, where AI-generated drug development decisions can affect patient safety at scale.

Gap 4: Digital pharmaceutical business model innovation. The reviewed literature focuses predominantly on technology implementation but provides limited systematic evidence on how digital technologies enable novel pharmaceutical business models outcome-based payment, platform-based drug development, direct-to-consumer digital pharmacy and what conditions determine their commercial and clinical sustainability.

Gap 5: Integration of patient perspective. The majority of reviewed studies analyze pharmaceutical digital transformation from the perspective of industry, clinical practitioners, or regulatory bodies. The patient perspective how digital pharmaceutical technologies affect patient experience, health literacy, medication adherence, and health equity is systematically underrepresented.

Practical and Theoretical Implications

For pharmaceutical entrepreneurs and startups: The DPTM suggests that pharmaceutical technopreneurial success is most reliably predicted by the alignment of digital capability development with regulatory pathway clarity. Startups that select digital technology applications with established (or emerging) regulatory evidence standards AI-assisted clinical decision support with FDA Digital Health Center of Excellence involvement, blockchain supply chain systems aligned with DSCSA requirements are better positioned than those pursuing digital applications in regulatory white spaces, where first-mover advantage in uncertainty can be rapidly eroded when regulatory requirements eventually crystallize.

For pharmaceutical incumbent firms: Dynamic Capability Theory applied through the DPTM implies that pharmaceutical incumbents' digital transformation strategies should prioritize capability development over

technology acquisition: purchasing AI tools or blockchain platforms without developing the organizational sensing, seizing, and transformation capabilities to deploy them effectively creates costly technology portfolios without competitive advantage.

For academic researchers: The theoretical integration proposed in the DPTM identifies multi-level pharmaceutical technopreneurship research designs simultaneously examining individual adoption behavior, firm-level capability development, and ecosystem-level enablement conditions as the highest-priority methodological contribution to the field's explanatory capacity.

For policymakers: The ecosystem-level analysis consistently identifies regulatory pathway clarity as the highest-leverage policy intervention for pharmaceutical digital technopreneurship. Policies that invest in regulatory science infrastructure for digital pharmaceutical innovations faster, evidence-calibrated approval pathways for AI-derived drugs, internationally harmonized blockchain data standards, and telemedicine prescribing legal frameworks generate more durable pharmaceutical technopreneurship ecosystem benefits than direct financial subsidies.

CONCLUSIONS AND RECOMMENDATIONS

This systematic literature review analyzed 62 peer-reviewed studies published between 2015 and 2025 and identified five key themes: AI, blockchain and IoT, telemedicine, Big Data analytics, and digital entrepreneurial ecosystems. The findings indicate that digital transformation is reshaping pharmaceutical technopreneurship, although its adoption and impact differ across organizational and regulatory contexts. This review proposes the Digital Pharmaceutical Technopreneurship Model (DPTM) by integrating TAM, Diffusion of Innovation, Dynamic Capability Theory, and Entrepreneurial Ecosystem frameworks, providing a comprehensive foundation for future research. However, the review is limited by its inclusion of English-language journal articles and the methodological diversity of the selected studies. Future research should examine regulatory frameworks, digital entrepreneurial ecosystems, ethical AI governance, digital business model innovation, and patient-centered outcomes, with greater emphasis on emerging economies and equitable digital transformation in the pharmaceutical sector.

FURTHER STUDY

This research still has limitations, so further studies on the topic of Innovation Digital Transformation in Pharmaceutical Technopreneurship: A Systematic Literature Review are needed to improve this research and add insights for the authors and researchers.

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