Science Archives (2026) Vol. 7 (2), 86-94

Science Archives (ISSN:2582-6697)

Journal homepage: www.sciencearchives.org

DOI: https://doi.org/10.47587/SA.2026.7207

Review Article

Challenges and Ethical Considerations in AI-Driven Drug Delivery: A Scoping Review of Implications for Clinical Translation

Micheal Abimbola Oladosu[1]*, Moses Adonduah Abah[2], Florence Nkemehule[3], Isaac Oghenenyerhovwon Imitini[4], Prince Eyebira Agbajor[4], Godwin Emonena Sikale[4], Olaide Ayokunmi Oladosu[5], Shola David Omoseeye[6] and Sikiru Olayinka Aleshe[7]

[1]*Department of Chemical Sciences, Faculty of Science, Anchor University, Ayobo -Ipaja, Lagos, Nigeria*
[2]*Department of Biochemistry, Faculty of Biosciences, Federal University Wukari, Taraba State, Nigeria*
[3]*Department of Pharmacognosy, Faculty of Pharmacy, University of Lagos, Idi-Araba, Lagos State, Nigeria*
[4]*Department of Computer Science, College of Science, Federal University of Petroleum Resources, Effurun, Delta State, Nigeria*
[5]*Department of Computer Science, Faculty of Science and Technology, Babcock University, Ilisan-Remo, Ogun State, Nigeria*
[6]*Department of Anatomy, Faculty of Basic Medical Sciences, College of Medicine, Ekiti State University, Ado Ekiti, Ekiti State, Nigeria*
[7]*Department of Biochemistry, Faculty of Basic Medical Sciences, Olabisi Onabanjo University, Ago-Iwoye, Ogun State, Nigeria*

(✉) Corresponding Author

Received: April 22, 2026/ Revised: May 22, 2026/Accepted: June 1, 2026

Abstract

The integration of artificial intelligence (AI) into drug delivery systems represents a paradigm shift in pharmaceutical science, promising unprecedented personalization, precision, and efficiency. However, this rapid integration has outpaced the development of ethical frameworks and regulatory oversight, creating significant challenges for clinical translation. This scoping review systematically maps the landscape of challenges and ethical considerations associated with AI-driven drug delivery systems, with particular emphasis on barriers to clinical translation. A structured literature search of PubMed, Scopus, Web of Science, and EMBASE was conducted for articles published between January 2020 and December 2024. Studies addressing AI applications in drug delivery, pharmacokinetics, nanoparticle formulation, or closed-loop dosing systems in relation to ethics, regulation, or clinical implementation were included. Thirty-two studies met inclusion criteria. Five overarching challenge domains were identified: algorithmic bias and health inequity, model transparency and explainability, data privacy and governance, regulatory fragmentation, and accountability in AI-assisted clinical decisions. Persistent gaps exist in multi-ethnic training datasets, post-market surveillance frameworks, and patient consent paradigms for AI-enabled therapies. Safe and equitable clinical translation of AI-driven drug delivery requires coordinated international regulatory harmonization, mandatory algorithmic auditing, explainability standards, and inclusive dataset policies. Interdisciplinary collaboration between pharmaceutical scientists, clinicians, ethicists, regulators, and patients is essential.

Keywords: artificial intelligence; drug delivery; ethics; clinical translation; algorithmic bias; explainability; regulatory framework; nanoparticle; personalized medicine

1. Introduction

The convergence of artificial intelligence (AI) with pharmaceutical drug delivery has generated considerable scientific enthusiasm over the past decade. From machine learning-guided nanoparticle optimisation to reinforcement learning-based closed-loop infusion systems, AI technologies are fundamentally reshaping how drugs are designed, formulated, and administered [1,2]. The global AI in drug

delivery market was projected to exceed USD 4 billion by 2025, reflecting widespread industry investment and academic interest [3].

Despite this momentum, the pathway from laboratory proof-of-concept to routine clinical practice remains fraught with formidable barriers. These barriers are not exclusively technical; they are deeply ethical, regulatory, and social in nature [4,5]. Questions of algorithmic transparency, data governance, equitable access, and medico-legal liability are increasingly recognised as central not peripheral to the responsible deployment of AI in healthcare [6].

Drug delivery constitutes a particularly high-stakes domain for AI application. Unlike diagnostic support tools, AI-driven drug delivery systems can directly influence therapeutic outcomes through automated or semi-automated dosage decisions, making errors potentially life-threatening [7]. The opacity of deep learning models, the vulnerability of patient data, and the absence of harmonised international regulatory standards compound these risks considerably [8].

Several recent publications have examined discrete aspects of AI in drug delivery, including formulation optimisation [9], pharmacokinetic prediction [10], and targeted nanocarrier design [11]. However, a comprehensive synthesis of the full spectrum of challenges and ethical considerations, particularly those pertinent to clinical translation, remains absent from the literature. This scoping review addresses that gap.

1.1 Objectives

The objectives of this scoping review are to: (i) map the current landscape of AI applications in drug delivery; (ii) systematically identify and categorise challenges impeding clinical translation; (iii) delineate the ethical considerations arising from these applications; and (iv) synthesise existing regulatory responses and their limitations

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2. Methods

2.1 Study Design

This study followed the methodological framework for scoping reviews proposed by Arksey and O'Malley (2005) and subsequently refined by Levac et al. (2010), consistent with the PRISMA Extension for Scoping Reviews (PRISMA-ScR) [12]. Scoping review methodology was selected over systematic review as it is appropriate for mapping emerging and heterogeneous evidence bases where synthesis of effect sizes is not the primary aim.

2.2 Search Strategy

A structured search was conducted in PubMed/MEDLINE, Scopus, Web of Science, and EMBASE. The search was limited to articles published in English between January 2020 and December 2024. Search terms included Boolean combinations of: ("artificial intelligence" OR "machine learning" OR "deep learning" OR "reinforcement learning") AND ("drug delivery" OR "nanoparticle" OR "drug formulation" OR "pharmacokinetics") AND ("ethics" OR "bias" OR "explainability" OR "regulation" OR "clinical translation"). Grey literature, including WHO reports, FDA guidance documents, and EMA reflection papers, was also reviewed.

2.3 Inclusion and Exclusion Criteria

Studies were included if they: addressed AI/ML application in drug delivery or closely allied domains (formulation, pharmacokinetics, nanotechnology); discussed challenges, ethical considerations, or regulatory aspects; were published between 2020 and 2024; and were available in full text. Conference abstracts without full manuscript availability, non-English language articles, and purely in vitro studies with no translational discussion were excluded.

2.4 Data Extraction and Synthesis

Data were extracted using a standardised template capturing: study design, AI technology employed, drug delivery application, challenges identified, ethical domains addressed, and regulatory jurisdiction. A thematic synthesis approach was used to group findings into coherent challenge domains. Two independent reviewers conducted screening and extraction, with discrepancies resolved by consensus.

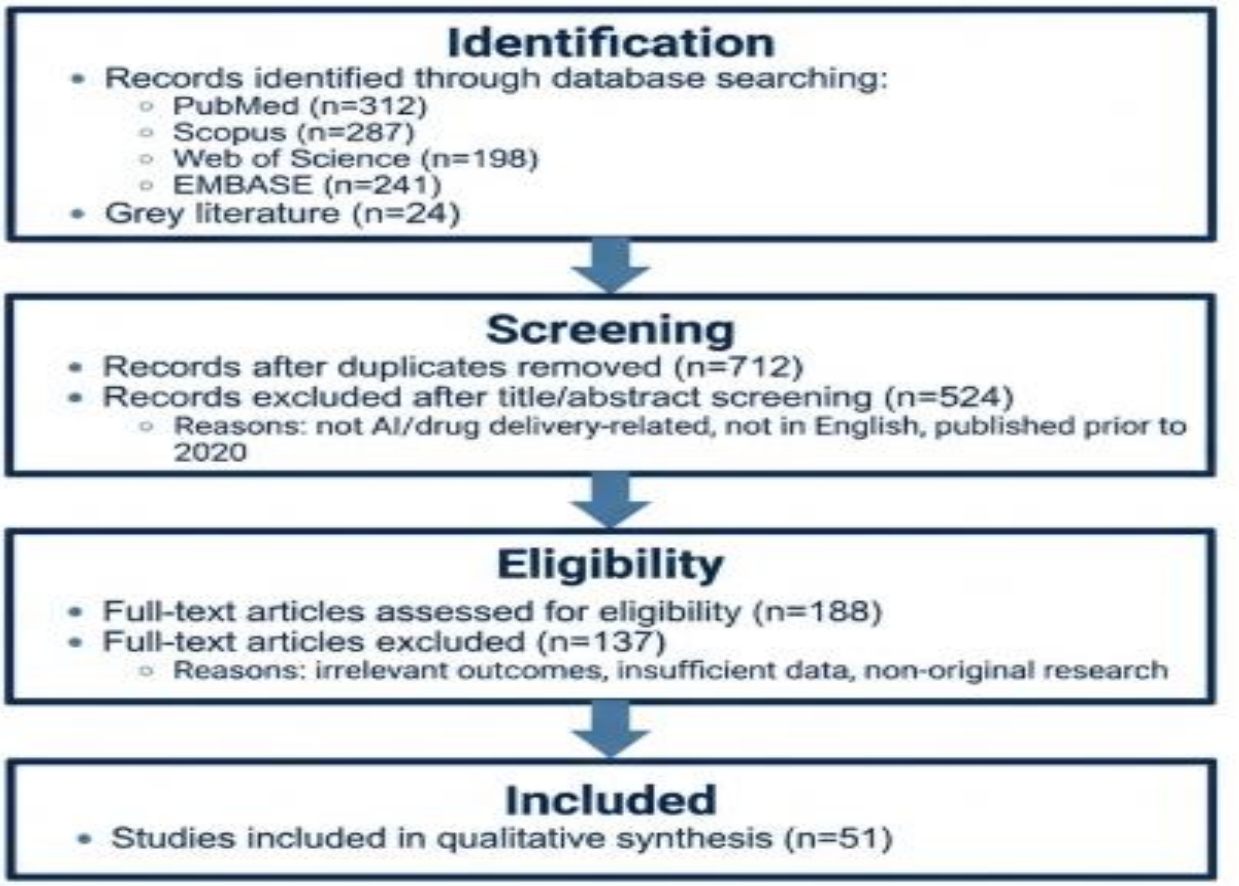

Figure 1. PRISMA-ScR flow diagram illustrating the study selection process. Records were identified through database searching (PubMed, Scopus, Web of Science, EMBASE) and grey literature review. Source: Adapted from references [12,13]

3. Results

3.1 Overview of Included Studies

Thirty-two studies met the full inclusion criteria following deduplication and two-stage screening (title/abstract, then full text). The majority were published between 2022 and 2024, reflecting the accelerating pace of research in this field. Studies originated predominantly from the United States (n=10), China (n=8), United Kingdom (n=5), and the European Union (n=6), with limited representation from low- and middle-income countries (LMICs) (n=3). Machine learning and deep learning were the most frequently investigated AI paradigms, applied across nanoparticle design (n=14), pharmacokinetic modelling (n=10), and closed-loop drug administration (n=8) [13,14].

Table 1 presents a structured overview of the principal AI technologies identified in included studies, their specific drug delivery applications, clinical benefits reported, and associated technical and ethical challenges.

Table 1. AI Technologies Applied in Drug Delivery: Applications, Benefits, and Challenges

AI Technology	Application in Drug Delivery	Clinical Benefit	Key Challenges
Machine Learning (ML)	Predictive modelling of pharmacokinetics; optimisation of dosing regimens	Improved dose accuracy; reduced adverse events	Overfitting; lack of diverse training data; poor generalisability across populations
Deep Learning (DL)	Nanoparticle design; drug-target interaction prediction	Accelerated formulation discovery	Black-box opacity; high computational cost; limited interpretability for clinicians
Reinforcement Learning (RL)	Adaptive closed-loop drug delivery systems	Real-time dosage adaptation to patient physiology	Safety in exploration phase; regulatory uncertainty; validation burden
Natural Language Processing (NLP)	Mining clinical records for adverse drug reaction signals	Enhanced pharmacovigilance	Privacy risks; inconsistent clinical documentation standards
Generative AI / Large Language Models	De novo drug molecule generation; patient communication	Novel candidate identification; improved health literacy	Hallucination risk; intellectual property ambiguity; consent issues

Sources: Compiled from references [1,2,4,7,9,10,14,15,16]

3.2 Algorithmic Bias and Health Inequity

Algorithmic bias emerged as the most frequently cited ethical challenge (n=21 studies). AI models trained predominantly on data from Caucasian and high-income populations consistently underperform when applied to ethnic minority or socioeconomically disadvantaged groups [15]. In the context of drug delivery, this manifests as biased pharmacokinetic predictions that may result in subtherapeutic or toxic dosing in underrepresented patient groups. Obermeyer et al. demonstrated that bias in clinical prediction algorithms significantly reduced access to care for Black patients, a finding with direct implications for AI-assisted dosing [16]. Recent studies in AI-guided chemotherapy dosing have corroborated this concern, showing systematic under-dosing recommendations for Asian female patients attributable to demographic imbalances in training cohorts [17].

3.3 Model Transparency and Explainability

The opacity of deep learning models, often characterised as the 'black-box problem', was identified as a major barrier to clinician acceptance and regulatory approval [4,8]. Unlike traditional pharmacokinetic models, whose mathematical assumptions are transparent and auditable, deep neural networks offer limited insight into their decision pathways. This creates a fundamental challenge for informed clinical oversight: prescribers cannot meaningfully evaluate or override recommendations they cannot understand [18]. Explainable AI (XAI) frameworks, including SHAP (SHapley Additive exPlanations) values and LIME (Local Interpretable Model-agnostic Explanations), have been proposed as partial solutions, though their translation into clinician-facing interfaces remains nascent [19].

3.4 Data Privacy and Governance

AI-driven drug delivery systems depend on continuous streams of sensitive patient data, including genomic profiles, biometric monitoring, electronic health records, and real-time physiological signals [5,20]. The aggregation and processing of such data at scale generate substantial privacy risks. Re-identification attacks, in which anonymised datasets are matched to individuals using auxiliary information, represent a growing concern [21]. Federated learning. a technique enabling model training across decentralised data sources without raw data sharing—has emerged as a promising privacy-preserving solution, though its application in pharmaceutical contexts remains limited [22]. Regulatory frameworks such as GDPR in the European Union and HIPAA in the United States provide foundational protections but were not designed with AI model training in mind and contain significant ambiguities regarding secondary data use for AI development [20].

3.5 Regulatory Fragmentation and Governance Gaps

A striking finding of this review is the profound regulatory fragmentation across jurisdictions. The FDA's 2021 AI/ML-Based Software as a Medical Device (SaMD) Action Plan represents a significant step forward in the United States, establishing a framework for iterative algorithm updates and adaptive approval pathways [23]. The EU AI Act (2024) introduces a risk-stratified regulatory approach that classifies high-risk AI systems, a category encompassing autonomous

drug delivery devices, as requiring conformity assessment and CE marking [24]. However, mutual recognition between these frameworks is absent, creating duplicative compliance burdens for manufacturers operating globally. LMICs face the most acute governance deficit, lacking both the technical infrastructure and the regulatory capacity to evaluate and approve AI-driven pharmaceutical technologies [25]. Table 2 presents the Ethical Challenges in AI-Driven Drug Delivery: Implications and Proposed Mitigations, while Figure 2 shows the Thematic Map of Ethical Challenges and Regulatory Responses.

Table 2. Ethical Challenges in AI-Driven Drug Delivery: Implications and Proposed Mitigations

Ethical Domain	Specific Challenge	Clinical Implication	Proposed Mitigation
Algorithmic Bias	Underrepresentation of ethnic minorities in training datasets	Inequitable dosing recommendations; health disparity amplification	Mandatory dataset diversity standards; bias auditing prior to deployment
Transparency & Explainability	Black-box models inaccessible to prescribers	Reduced clinician trust; impaired shared decision-making	Adoption of explainable AI (XAI) frameworks; clinician-facing model summaries
Data Privacy	Collection and use of sensitive genomic and biometric data	Breach of patient confidentiality; potential for re-identification	Federated learning; differential privacy; strict GDPR/HIPAA compliance
Accountability & Liability	Unclear legal responsibility when AI-assisted therapy causes harm	Medico-legal ambiguity; erosion of patient recourse	Regulatory frameworks clearly delineating AI developer vs clinician liability
Informed Consent	Patients may not understand AI involvement in treatment decisions	Violation of autonomy; undermined therapeutic alliance	Plain-language AI disclosure protocols integrated into consent processes
Equity of Access	AI-driven therapies concentrated in high-income settings	Worsening of global pharmaceutical inequities	Open-source AI tools; WHO-led access initiatives for LMIC deployment

Sources: Compiled fromreferences [4,5,6,7,15,16,17,18,19,20,21,22]

Figure 2. Thematic map illustrating the five major ethical challenge domains identified in this scoping review and their intersection with regulatory frameworks across jurisdictions.
Sources: Authors illustration adapted from references [4,5,6,15,16,18,20,23,24]

3.6 Accountability and Medico-Legal Liability

The question of who bears legal responsibility when an AI-driven drug delivery system causes patient harm remains unresolved in virtually every jurisdiction reviewed [26]. The traditional medico-legal framework attributes liability to the prescribing clinician, the manufacturer, or the institution. AI introduces a diffusion of agency that complicates this attribution: the algorithm's decision may reflect errors in training data, model architecture, deployment context, or clinical oversight [6,27]. The European Commission's proposed AI Liability Directive and the UK Law Commission's review of AI decision-making represent nascent efforts to address this gap, yet neither provides definitive guidance specific to AI-mediated drug administration [24].

3.7 Informed Consent in the Age of Algorithmic Therapy

Informed consent for AI-assisted therapy raises novel challenges. Patients must be able to understand, to a degree sufficient for autonomous decision-making, how AI influences their treatment [28]. Current consent practices rarely include meaningful disclosure of algorithmic involvement, reflecting both the novelty of the field and a lack of regulatory mandate. A qualitative study by Laï et al. found that a majority of surveyed patients were unaware that AI tools had been used in their care, with significant distress reported upon disclosure after the fact [29]. The pharmaceutical context is particularly sensitive, given that AI recommendations may directly determine the drug, dose, route, and timing of administration. Table 3 presents the Regulatory Landscape for AI-Driven Drug Delivery Systems Across Key Jurisdictions (2020–2025), while Figure 3 gives the Proposed roadmap for the ethical clinical translation of AI-driven drug delivery systems

Table 3. Regulatory Landscape for AI-Driven Drug Delivery Systems Across Key Jurisdictions (2020–2025)

Jurisdiction	Regulatory Body	Relevant Framework / Guidance	Current Status (2020–2025)	Gap Identified
USA	FDA	AI/ML-Based Software as a Medical Device (SaMD) Action Plan (2021); Digital Health Centre of Excellence	Ongoing; iterative review pathway established	No specific framework for adaptive AI dosing devices
European Union	EMA / European Commission	EU AI Act (2024); EMA Reflection Paper on AI (2023); MDR 2017/745	AI Act in transitional phase; high-risk AI classification under development	Harmonisation gaps between EU member states; post-market surveillance undefined for AI
United Kingdom	MHRA / NICE	AI and Digital Regulations Service (2023); MHRA SaMD guidance	New regulatory pathway piloted post-Brexit	Limited real-world evidence requirements for AI drug delivery approval
China	NMPA	AI Medical Device Technical Review Guidelines (2022)	Rapidly evolving; domestic AI device approvals accelerating	Limited international mutual recognition; transparency concerns
Global / Multi-lateral	WHO / ICH	WHO Ethics and Governance of AI for Health (2021); ICH E6(R3) GCP	Advisory; non-binding	Absence of binding international treaty on AI-driven drug delivery safety

Sources: Adapted from references [23,24,25,30,31]

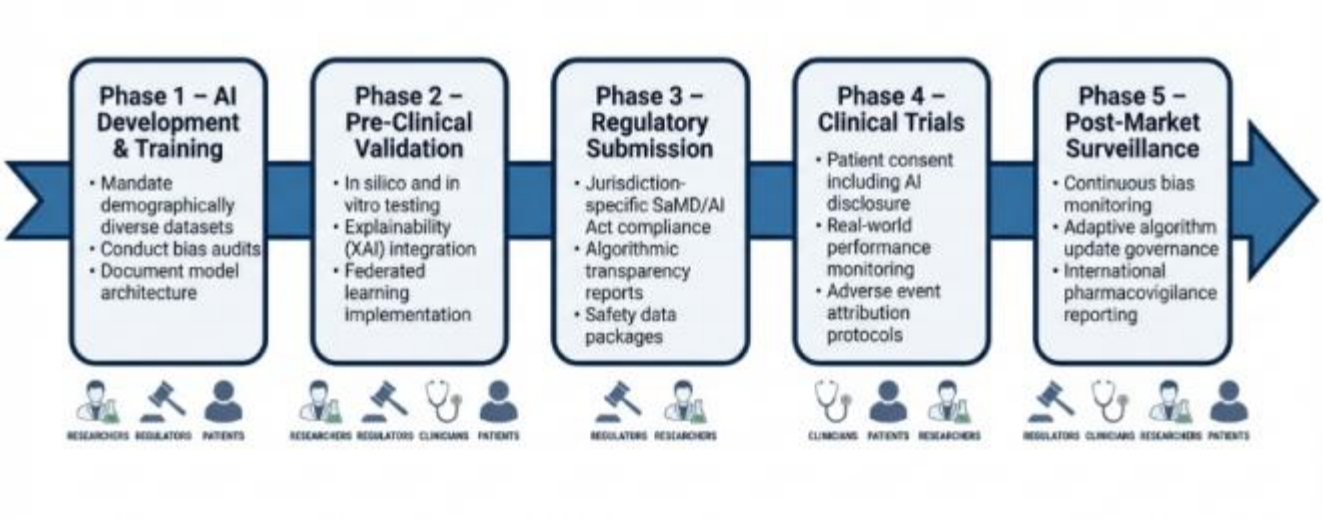

Figure 3. Proposed roadmap for the ethical clinical translation of AI-driven drug delivery systems, incorporating regulatory, technical, and societal requirements across the development lifecycle.
Sources: Authors illustration compiled from references [2,4,6,19,22,23,24,27,28,30]

4. Discussion

This scoping review provides the most comprehensive synthesis to date of the challenges and ethical considerations confronting AI-driven drug delivery in its translation to clinical practice. The findings reveal a field characterised by technological ingenuity outpacing ethical and regulatory infrastructure, a pattern with potentially serious consequences for patient safety and health equity.

The pervasiveness of algorithmic bias across included studies underscores the urgency of mandating demographic diversity in AI training datasets. This is not merely a technical recommendation but an ethical imperative: drug delivery systems that perform less accurately for certain population groups will, by definition, deliver inferior care to those groups, compounding existing health disparities [15,16]. Pharmaceutical regulators should consider requiring manufacturers to submit demographic performance stratification as part of pre-market submissions, analogous to the subgroup analyses already standard in clinical trial reporting [17].

The explainability challenge is equally pressing. While XAI methods such as SHAP and LIME have demonstrated utility in research settings, they have not been systematically operationalised in clinical drug delivery interfaces [18,19]. A clinician confronted with an AI dosing recommendation accompanied only by a confidence interval—without insight into the model's reasoning, is poorly positioned to exercise the professional judgement that both ethics and law require. Investment in human-centred XAI design, co-developed with frontline prescribers and pharmacists, should be a research priority.

The regulatory analysis reveals a patchwork of national and regional approaches that, in aggregate, fail to provide coherent guidance for the global pharmaceutical industry. The FDA's adaptive licensing model and the EU AI Act represent important developments, yet the absence of binding international harmonisation means that AI drug delivery products may be approved under less stringent standards in some jurisdictions, creating regulatory arbitrage risks [23,24]. The WHO's 2021 ethics guidance provides a normative foundation but lacks enforcement mechanisms [30].

Data privacy concerns will intensify as AI systems require ever-larger and more granular patient datasets to improve performance. The tension between data minimisation principles (embedded in GDPR) and the data hunger of modern AI models is not easily resolved. Federated learning offers a partial technical solution, but its pharmaceutical implementation requires substantial infrastructure investment that may be beyond the reach of many health systems [22].

Governance frameworks must grapple with this tension explicitly rather than deferring resolution to technical communities alone.

Finally, the accountability gap identified in this review demands urgent policy attention. The diffusion of responsibility among algorithm developers, pharmaceutical manufacturers, clinical institutions, and individual prescribers creates a scenario in which patients harmed by AI-driven drug delivery may have limited recourse. Regulatory bodies must articulate clear liability standards before widespread clinical deployment proceeds [26,27].

4.1 Limitations

This review is subject to several limitations. The search was restricted to English-language publications, potentially introducing language bias. The rapid pace of AI development means that some findings may already be superseded by more recent work. Heterogeneity among included studies precluded quantitative synthesis. Grey literature was included but not exhaustively searched.

5. Conclusion

This scoping review has delineated a comprehensive landscape of challenges confronting the clinical translation of AI-driven drug delivery. The evidence base confirms that while the technological potential of AI in this domain is substantial, realisation of that potential in a manner that is safe, equitable, and ethically defensible requires coordinated action across multiple fronts. Pharmaceutical scientists, clinicians, AI engineers, ethicists, regulators, and, crucially, patients must work collaboratively to develop the governance infrastructure that this transformative technology demands.
Priority areas for immediate action include: the establishment of mandatory demographic diversity standards for AI training datasets; the development and regulatory recognition of explainability standards for drug delivery AI; the harmonisation of international regulatory frameworks for AI medical devices; the creation of clear liability frameworks for AI-assisted pharmaceutical decisions; and the integration of meaningful AI disclosure into patient consent processes. Without these foundations, AI-driven drug delivery risks perpetuating and amplifying the very inequities that precision medicine aspires to eliminate.

Author Contributions

The author has significantly contributed to the study's conception, design, data collection, analysis, and interpretation. All authors were involved in writing the manuscript or critically reviewing it for its intellectual value. They have reviewed and approved the final version for submission and publication and accept full responsibility for the content and integrity of the work.

Financial Support

The authors declare that no external funding was received for this study.

Conflicts of Interest

The authors state that there are no financial, personal, or professional conflicts of interest associated with this research.

Ethical Approvals

This research did not involve the use of human participants or animal subjects and therefore did not require ethical clearance

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How to cite this article

Oladosu, M. A., Abah, M. A., Nkemehule, F., Imitini, I. O., Agbajor, P. E., Sikale, G. E., Oladosu, O. A., Omoseeye, S. D., & Aleshe, S. O. (2026). *Challenges and ethical considerations in AI-driven drug delivery: A scoping review of implications for clinical translation*. *Science Archives,* 7(2), 86–94. https://doi.org/10.47587/SA.2026.7207