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AI-Enabled Drug Discovery Platforms: Navigating the Confluence of Software, Medical Device, and Pharmaceutical Regulation in Sino-African Trade Relations

Yapay Zeka Destekli İlaç Keşif Platformları: Çin-Afrika Ticaret İlişkilerinde Yazılım, Tıbbi Cihaz ve İlaç Mevzuatının Kesişim Noktasında Yol Bulmak

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ABSTRACT

The integration of artificial intelligence into drug discovery platforms presents a fundamental challenge to established regulatory taxonomies worldwide, raising a deceptively simple question with profound implications: Should AI-enabled drug discovery platforms be regulated as software, as medical devices, or as pharmaceuticals? This article examines this regulatory trilemma through the dual lens of comparative global frameworks and Sino-African trade relations. The analysis reveals that major jurisdictions—including the United States, European Union, and China—have adopted hybrid approaches that defy simple categorization, with the FDA emphasizing Predetermined Change Control Plans for adaptive algorithms, the EU layering AI Act requirements atop Medical Device Regulation frameworks, and China advancing a specialized AI medical device guidance architecture. For African regulatory environments, where the African Medicines Agency is newly operational and most National Regulatory Authorities function at WHO Maturity Level 3, this global fragmentation presents both peril and opportunity. The article argues that China's emergence as a leading developer of AI-enabled drug discovery technologies, combined with its deepening pharmaceutical trade relationships across Africa under FOCAC frameworks, creates unprecedented possibilities for regulatory leapfrogging through Sino-African cooperation. By examining trade patterns, investment flows, and capacity-building initiatives, this research demonstrates that the regulatory classification question is not merely a technical matter of legal taxonomy but a strategic determinant of market access, technology transfer, and ultimately, health equity

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across the African continent. The article concludes with concrete recommendations for harmonized approaches, South-South regulatory cooperation mechanisms, and African-specific adaptation of global AI governance principles.

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ÖZ

Yapay zekanın ilaç keşif platformlarına entegrasyonu, dünya genelinde yerleşik düzenleyici sınıflandırmalara yönelik temel bir meydan okuma ortaya çıkarmakta ve son derece önemli sonuçlar doğuran aldatıcı derecede basit bir soruyu gündeme getirmektedir: Yapay zeka destekli ilaç keşif platformları yazılım olarak mı, tıbbi cihaz olarak mı yoksa farmasötik ürün olarak mı düzenlenmelidir? Bu makale, söz konusu düzenleyici açmazı karşılaştırmalı küresel çerçeveler ve Çin-Afrika ticari ilişkileri perspektifinden incelemektedir. Analiz, Amerika Birleşik Devletleri, Avrupa Birliği ve Çin dâhil olmak üzere başlıca yargı alanlarının, basit sınıflandırmaları aşan hibrit yaklaşımlar benimsediğini ortaya koymaktadır. Bu kapsamda Amerika Birleşik Devletleri Gıda ve İlaç Dairesi, uyarlanabilir algoritmalar için önceden belirlenmiş değişiklik kontrol planlarını vurgularken; Avrupa Birliği, Yapay Zeka Yasası gerekliliklerini Tıbbi Cihaz Düzenlemesi çerçevelerine eklemekte; Çin ise yapay zeka tabanlı tıbbi cihazlara yönelik uzmanlaşmış bir rehberlik yapısı geliştirmektedir. Afrika'daki düzenleyici ortamlar açısından bakıldığında, Afrika İlaç Ajansı'nın yeni faaliyete geçmiş olması ve ulusal düzenleyici otoritelerin çoğunluğunun Dünya Sağlık Örgütü Olgunluk Seviyesi 3 düzeyinde faaliyet göstermesi nedeniyle, bu küresel parçalanmış yapı hem riskler hem de fırsatlar yaratmaktadır. Makale, Çin'in yapay zeka destekli ilaç keşif teknolojilerinin önde gelen geliştiricilerinden biri hâline gelmesinin ve Çin-Afrika İş Birliği Forumu çerçevesinde Afrika genelinde derinleşen farmasötik ticaret ilişkilerinin, Çin-Afrika iş birliği aracılığıyla düzenleyici sıçrama için benzeri görülmemiş imkânlar sunduğunu ileri sürmektedir. Ticaret örüntülerini, yatırım akışlarını ve kapasite geliştirme girişimlerini inceleyen bu araştırma, düzenleyici sınıflandırma meselesinin yalnızca hukuki sınıflandırmaya ilişkin teknik bir konu olmadığını; aynı zamanda pazar erişimi, teknoloji transferi ve nihayetinde Afrika kıtasındaki sağlık eşitliğini belirleyen stratejik bir unsur olduğunu göstermektedir. Makale, uyumlaştırılmış yaklaşımlar, Güney-Güney düzenleyici iş birliği mekanizmaları ve küresel yapay zeka yönetişimi ilkelerinin Afrika'ya özgü uyarlanmasına yönelik somut önerilerle sonuçlanmaktadır.

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1. INTRODUCTION

Artificial intelligence has moved decisively from experimental curiosity to regulatory priority in the life sciences sector. On January 14, 2026, the United States Food and Drug Administration and the European Medicines Agency jointly released ten guiding principles for Good AI Practice in drug development, signalling that AI applications across the medicines lifecycle—from early discovery through post-market surveillance—now demand coherent regulatory treatment. This landmark collaboration, building upon the Good Machine Learning Practice principles established in 2021, represents transatlantic consensus that AI requires dedicated regulatory attention. Yet beneath this apparent convergence lies persistent fragmentation regarding the most fundamental question: What exactly is an AI-enabled drug discovery platform from a regulatory perspective? The classification question carries enormous practical stakes. Software applications are generally subject to lighter-touch oversight focused on functionality and cybersecurity. Medical devices, by contrast, trigger conformity assessment requirements, clinical evaluation obligations, and post-market surveillance regimes that can add years and millions of dollars to development timelines. Pharmaceuticals face the most intensive scrutiny of all, requiring exhaustive demonstrations of safety, efficacy, and manufacturing quality that define the drug approval paradigm. An AI platform that identifies novel drug candidates,

predicts protein structures, or optimizes molecular properties sits uncomfortably at the intersection of all three categories, eliding the tidy boundaries upon which regulatory systems have been constructed over decades. The question becomes still more complex when examined through the prism of international trade and regulatory cooperation, particularly between China and Africa. China has emerged as a global leader in AI-enabled drug discovery technologies, supported by deliberate industrial policy, substantial research investment, and a regulatory framework that the National Medical Products Administration has developed through over 19 guidance documents and more than 110 approved Class III AI medical device products . Simultaneously, Chinese pharmaceutical firms are accelerating their African market presence through manufacturing localization, technology transfer, and trade relationships formalized under the Forum on China-Africa Cooperation. Meanwhile, African regulatory systems are undergoing transformative change with the operationalization of the African Medicines Agency and the gradual attainment of WHO Maturity Level 3 status by a growing cohort of National Regulatory Authorities. This convergence of technological disruption, regulatory evolution, and shifting trade patterns creates both unprecedented opportunities and novel risks. For African regulators and patients, the classification question determines whether AI-enabled drug discovery platforms developed in China can enter African markets efficiently, under what evidentiary standards, and with what assurances of safety and performance in local populations. For Chinese firms, it determines market access pathways, compliance burdens, and the viability of technology transfer arrangements. And for the broader project of global health equity, it will shape whether AI's transformative potential in accelerating drug discovery reaches populations long underserved by traditional pharmaceutical innovation. This article proceeds in five parts. Section 2 examines the global regulatory landscape, comparing approaches in the United States, European Union, and China to AI-enabled drug discovery platforms, with particular attention to classification frameworks and emerging convergence points. Section 3 analyzes the current state and trajectory of Sino-African pharmaceutical trade and regulatory cooperation. Section 4 investigates the specific implications of regulatory classification choices for trade flows, technology transfer, and health outcomes in African contexts. Section 5 proposes cooperative mechanisms and policy recommendations for navigating the classification trilemma. A brief conclusion reflects on the broader significance of this moment for regulatory governance in an era of algorithmic medicine.

2. THE GLOBAL REGULATORY TRILEMMA: SOFTWARE, DEVICE, OR PHARMACEUTICAL

2.1. The Fundamental Classification Problem

The regulatory classification of AI-enabled drug discovery platforms is complicated by the fact that these technologies can manifest across multiple phases of the pharmaceutical lifecycle, each traditionally governed by distinct regulatory regimes. A single AI system might screen compound libraries during early discovery (traditionally unregulated or lightly regulated as research), predict toxicity during preclinical development (potentially triggering good laboratory practice requirements), stratify patients during clinical trials (implicating investigational device or drug regulations), and monitor safety post-market (engaging pharmacovigilance obligations). This functional fluidity defies the static classification assumptions embedded in most regulatory frameworks (Lognoul 2025). The EU AI Act, which entered into force as Regulation 2024/1689, adopts a horizontal, risk-based approach that applies across all sectors, including life sciences (Act 2024). Under this framework, AI systems that constitute or form safety components of medical devices subject to the Medical Device Regulation or In Vitro Diagnostic Medical Device Regulation are classified as "high-risk" and subject to stringent obligations including data governance, transparency, and human oversight requirements. Critically, however, the AI Act does not duplicate MDR obligations but rather layers AI-specific requirements atop existing conformity assessment procedures. For drug discovery platforms that do not meet the definition of a medical device—for instance, those used purely for early-stage molecular screening without direct patient application — the regulatory pathway remains less clearly defined, potentially falling into lower-risk categories or escaping specific AI Act provisions altogether. The United States Food and Drug Administration has approached the classification challenge through a different lens, grounded in its established framework for Software as a Medical Device. The FDA's guidance distinguishes between software intended for administrative, financial, or operational purposes (generally not regulated as medical devices) and software with medical purposes including diagnosis, treatment, or prevention. For AI-enabled drug discovery, the key determinant is the "intended use" articulated by the developer: platforms used solely for internal research and development may fall outside FDA jurisdiction, while those marketed to third parties for clinical trial optimization or treatment selection likely trigger device regulations. The FDA has recognized that this binary approach strains when applied to adaptive AI systems, prompting the development of novel regulatory mechanisms including the Predetermined Change Control Plan framework, which allows manufacturers to prospectively specify planned algorithmic modifications without requiring new marketing submissions for each iteration (Group 2022).

2.2. The European Union's Layered Approach

The European framework exemplifies the complexity of layering new AI-specific requirements onto established

product-specific regulations. Under the MDR, stand-alone software qualifies as a medical device if it serves a medical purpose and is intended for use with individual patients. An AI system that analyzes patient data to recommend specific therapeutic interventions would clearly meet this definition, triggering both MDR conformity assessment and AI Act high-risk classification. However, an AI platform used exclusively for in silico compound screening during early drug discovery—before any patient data is involved and before any specific therapeutic candidate is identified—likely falls outside both MDR and AI Act high-risk provisions, governed instead by general product safety and liability laws alongside emerging standards for scientific AI.

This layered approach creates significant compliance complexity but offers important nuance. The AI Act's requirements for high-risk systems—including robust data governance, technical documentation, record-keeping, transparency, human oversight, and accuracy specifications—address legitimate concerns about algorithmic bias, performance drift, and explainability that are particularly salient in life sciences applications. Yet by tying these requirements to the medical device definition, the EU framework leaves substantial AI activity in drug discovery either lightly regulated or subject to interpretive uncertainty. This regulatory gap may prove problematic as AI systems increasingly automate critical decisions throughout the drug development pipeline, from target identification through clinical trial design. Intellectual property considerations further complicate the European landscape. The European Patent Office requires disclosure sufficient to enable a person skilled in the art to carry out the invention, which for AI-based inventions increasingly requires disclosure of training data—information that may be commercially sensitive or subject to data protection constraints. The EPO's requirement that inventors be natural persons also creates unresolved questions regarding AI-generated drug candidates or molecular designs . These IP uncertainties intersect with regulatory classification: if AI systems cannot be recognized as inventors, and if their training data cannot be adequately disclosed, the resulting drug candidates may face both patent protection gaps and regulatory data exclusivity challenges.

2.3. The United States' PCCP Innovation

The FDA's response to AI-enabled medical devices, including those used in drug development, has been shaped by recognition that traditional regulatory paradigms designed for static products cannot accommodate adaptive algorithms that learn and evolve. As of August 2025, the FDA's AI/ML-enabled medical device inventory included 1,247 devices, with the vast majority (1,195) cleared through the 510(k) pathway, 36 through De Novo classification, and 16 through the more rigorous PMA process . This distribution reflects both the relative novelty of AI/ML technologies and the FDA's reliance on the substantial equivalence framework for moderate-risk devices (Rosen and Mandl 2025).

The Predetermined Change Control Plan represents the FDA's most significant regulatory innovation for adaptive AI. Under the PCCP framework, manufacturers can prospectively specify planned modifications to AI-enabled device software functions, including the modification description, the protocol for developing and validating changes, and an impact assessment analyzing benefits and risks. FDA approval of the PCCP as part of the initial marketing submission then permits implementation of specified modifications without additional regulatory review . This approach addresses the fundamental tension between algorithmic adaptability and regulatory predictability, allowing responsible innovation while maintaining oversight of safety and effectiveness. For drug discovery platforms specifically, the PCCP framework offers a potential pathway for managing iterative improvements to predictive models without triggering repeated regulatory submissions. A platform that identifies novel drug-target interactions, for instance, could specify in advance how it will incorporate new training data, validate model updates, and assess performance drift. However, the PCCP framework was developed primarily for clinical diagnostic and monitoring applications; its extension to drug discovery tools that do not directly impact patient care remains somewhat ambiguous. Moreover, the FDA's guidance explicitly notes that PCCP is only one component of an AI-enabled device submission and does not eliminate the need for comprehensive demonstration of safety and effectiveness.

2.4. China's Emerging AI Medical Device Framework

China has moved with characteristic speed and scale to establish regulatory frameworks for AI in healthcare and life sciences. The National Medical Products Administration has issued over 19 guidance documents and review principles for AI medical devices, forming a five-tiered guidance system covering everything from general principles to modality-specific testing standards. As of mid-2025, NMPA had approved more than 110 Class III AI medical device standalone software products spanning auxiliary diagnosis, triage, detection, and treatment support across nine imaging modalities . This represents the largest cohort of approved AI medical devices globally and provides China with substantial regulatory experience. The Chinese framework classifies AI-enabled medical software according to established medical device risk categories, with Class II and Class III devices requiring registration approval, change applications for significant modifications, and quality management system-based handling of minor changes. The NMPA has established a dedicated AI Medical Device Standardization Technical Committee (SMD/TU 002) that has published eight industry standards as of 2025, with additional national and industry standards under development covering algorithm performance testing for specific clinical applications . This standardization infrastructure provides a foundation for predictable, transparent review that Chinese authorities are

actively promoting through innovation cooperation platforms linking industry, academia, clinical institutions, and regulators. Crucially for international trade considerations, China has aligned its pharmaceutical review standards with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines, creating conditions for global synchronized development, submission, and approval . This alignment, combined with China's extensive experience regulating AI medical devices, positions Chinese regulators as potential technical cooperation partners for African agencies developing their own AI governance frameworks. The question is whether China's approach—developed primarily for clinical diagnostic and therapeutic AI—adequately addresses the distinctive characteristics of drug discovery platforms, or whether further regulatory innovation is needed.

2.5. Cross-Cutting Themes and Global Divergence

Several cross-cutting themes emerge from comparative analysis of global regulatory approaches. First, risk proportionality serves as an organizing principle across all major jurisdictions, though the specific risk thresholds and corresponding requirements vary substantially. Second, intended use remains the critical determinant of regulatory pathway, placing enormous weight on developer representations that may not fully capture actual system capabilities or downstream applications. Third, adaptivity presents universal challenges, with the PCCP concept gaining international traction but not yet achieving full global harmonization. Fourth, data governance requirements increasingly transcend traditional regulatory categories, with expectations for training data quality, representativeness, and documentation appearing across software, device, and pharmaceutical contexts (Muehlematter et al. 2021). Despite these common themes, significant divergence persists. The EU's AI Act represents the most comprehensive horizontal AI legislation globally, layering cross-sectoral requirements atop vertical product regulations. The US approach remains more sectoral, with the FDA leading on medical applications while broader AI governance remains fragmented across agencies and state-level initiatives. China has developed a distinctive model emphasizing standardization, industrial policy coordination, and staged implementation. For African regulators and their Chinese counterparts, this global fragmentation creates both challenges—in determining which models to follow—and opportunities—in selectively adapting elements suited to local contexts.

3. THEORETICAL FRAMEWORK: REGULATORY CLASSIFICATION, TECHNOLOGICAL GOVERNANCE, AND SOUTH-SOUTH HEALTH COOPERATION

3.1. The Regulatory Trilemma as a Theoretical Problem

At the heart of this article lies what we term the *regulatory trilemma*: the inability of existing product-based regulatory taxonomies—software, medical device, pharmaceutical—to accommodate the functional, adaptive, and cross-cutting nature of AI-enabled drug discovery platforms. This trilemma is not merely a technical classification puzzle but a manifestation of deeper theoretical tensions in the governance of emerging technologies.

Drawing on the work of Jasanoff (2016) on *sociotechnical imaginaries*, we argue that regulatory classifications are not neutral technical categories but rather institutional expressions of collective visions about how technology should relate to society. The FDA's PCCP framework imagines AI as a continuously improving but controllable tool; the EU AI Act imagines AI as a horizontal risk that must be layered onto existing product regimes; China's NMPA guidance architecture imagines AI as an industrial-strategic asset requiring standardization and state-led coordination. Each imaginary produces different classification outcomes, compliance burdens, and market access conditions. For African regulators, the challenge is not to select the "correct" imaginary but to construct a context-sensitive hybrid that serves continental health priorities.

3.2. Theories of Technological Regulation: From Product to Process

Traditional regulatory theory has largely been organized around *product-based* paradigms: a discrete artifact (a pill, a device, a software executable) undergoes pre-market review, is approved for specified indications, and is subject to post-market surveillance. AI-enabled drug discovery platforms disrupt this model in three theoretically significant ways.

First, they are *process technologies* rather than end products. An AI platform that screens compound libraries or predicts protein folding does not directly interact with patients but rather shapes the knowledge base and material artifacts (drug candidates) that subsequently enter clinical pathways. This locates the platform upstream of traditional regulatory trigger points, creating what Collingridge (1980) famously termed the *dilemma of control*: early in a technology's development, when intervention is easiest, consequences are least predictable; later, when consequences become visible, control becomes difficult and costly.

Second, they exhibit *algorithmic adaptivity*, learning and evolving post-deployment. This challenges the static "locked" product assumption embedded in most regulatory frameworks. The PCCP framework represents a pragmatic response, but it remains rooted in a manufacturer-controlled change paradigm that does not fully accommodate continuous, autonomously initiated learning. Drawing on *infrastructure studies* (Star & Ruhleder, 1996), we suggest that AI drug discovery platforms are better theorized as *emergent infrastructures*: relational, evolving, and only visible upon breakdown.

Third, they generate *epistemic spillovers* across regulatory domains. A platform's training data, validation protocols, and performance metrics simultaneously implicate software quality standards, medical device clinical evidence requirements, and pharmaceutical good practice guidelines. This blurring of boundaries suggests that traditional siloed regulatory architectures are increasingly mismatched to the technologies they seek to govern.

3.3. Legal Taxonomy and Hybrid Governance

Legal taxonomy—the classification of objects into pre-existing legal categories—has long been recognized as a site of interpretive struggle (Kennedy, 1986). In the context of emerging technologies, taxonomical contests are particularly consequential because classification determines which institutional logic applies. AI-enabled drug discovery platforms are *boundary objects* (Star & Griesemer, 1989): they are simultaneously software (algorithmic code), devices (used for clinical decision support), and pharmaceutical inputs (generating novel molecular entities). Their boundary-crossing nature enables them to be adopted by diverse communities but also exposes them to conflicting regulatory expectations.

The concept of *hybrid governance* offers a way forward. Rather than forcing a single categorical assignment, hybrid governance approaches layer or combine regulatory logics based on function, risk, and context. The EU AI Act's layering of AI-specific requirements atop MDR conformity assessment is one such hybrid. The proposed Sino-African framework—differentiating internal research use, regulatory decision-support, and autonomous drug generation—represents another. Hybrid governance acknowledges that technological objects can simultaneously inhabit multiple regulatory categories and that proportionate oversight requires functional decomposition rather than monolithic classification.

3.4. Regulatory Capacity, Leapfrogging, and South-South Cooperation

From the perspective of international political economy, the classification trilemma intersects with questions of *regulatory capacity* and *technological leapfrogging*. African NRAs operating at WHO Maturity Level 3 have established pharmaceutical regulatory systems but lack specific AI governance experience. This capacity gap, often framed as a deficit, can also be understood as *institutional plasticity*: the opportunity to design AI governance frameworks from first principles, learning from the achievements and limitations of more mature systems without inheriting legacy path dependencies.

The concept of *regulatory leapfrogging* (cf. Perkins, 2003) suggests that latecomer regulators can bypass suboptimal intermediate stages by adopting directly the most advanced, context-appropriate practices. For AI in drug discovery, this could mean African agencies developing risk-proportionate, process-oriented, and data-sovereignty-respecting frameworks that avoid both the under-regulation of software-only approaches and the over-regulation of pharmaceutical pathways. South-South cooperation—particularly with China, which has substantial AI medical device approval experience but also shares developing-country perspectives on regulatory capacity constraints—offers a distinctive avenue for leapfrogging that bypasses the sometimes-prescriptive North-South technical assistance models.

3.5. Algorithmic Justice and Distributive Implications

Finally, any theoretical treatment of AI drug discovery regulation must engage with *distributive justice* and *algorithmic fairness* as applied to global health. Existing theories of algorithmic justice (Benjamin, 2019; Noble, 2018) have primarily focused on discrimination within high-income country contexts—biased credit scoring, facial recognition, or healthcare allocation. The global dimension introduces additional complexity: training data predominantly from well-resourced populations, research priorities shaped by commercial pharmaceutical markets, and regulatory standards calibrated to high-capacity health systems.

Drawing on *postcolonial science studies* (Anderson & Adams, 2008; Harding, 1998), we argue that the classification question is embedded in broader patterns of epistemic authority and material inequality. When African regulators adopt medical device classification requiring local clinical validation, they are not merely adding compliance burden but actively contesting the presumption that AI platforms validated in Shanghai or Silicon Valley will perform equivalently in Lagos or Nairobi. The theoretical contribution of this article is to demonstrate that regulatory classification is not a neutral technical exercise but a site of distributive politics—determining who bears the costs of validation, who benefits from accelerated access, and whose health needs shape algorithmic optimization.

3.6. Synthesis: Toward a Situated Regulatory Theory

The theoretical framework developed here rejects both technological determinism (the view that AI's inherent properties dictate a single correct classification) and legal formalism (the view that existing categories can be mechanically applied). Instead, we propose a *situated regulatory theory*: classification decisions should be informed by functional analysis of the technology, empirical assessment of risks and benefits in specific contexts, procedural legitimacy of regulatory decision-making, and distributive attention to health equity outcomes. For Sino-African cooperation, this implies that regulatory alignment should not aim for identical rules but rather for *mutual recognition of regulatory processes*—trust in each other's institutional competence to reach context-appropriate classifications, combined with mechanisms for work-sharing and capacity building.

4. SINO-AFRICAN PHARMACEUTICAL TRADE AND REGULATORY COOPERATION

4.1. Current Trade Patterns and Investment Flows

Pharmaceutical trade between China and Africa has accelerated substantially over the past decade, driven by complementary needs and capacities. Africa's healthcare market, projected to reach $259 billion by 2025 according to UNECA estimates, confronts significant supply constraints: the continent hosts fewer than 400 pharmaceutical manufacturers, produces only 3% of global medicines, and imports over 90% of its pharmaceutical and medical device requirements. China, as the world's largest producer of active pharmaceutical ingredients and a rapidly growing innovator in finished formulations and medical devices, represents a natural trade partner for addressing African supply deficits. The pattern of Chinese pharmaceutical engagement in Africa is evolving from pure product export toward manufacturing localization. Early entrants established production facilities in strategically selected markets: Shanghai Pharmaceutical in Sudan, Humanwell Healthcare in Mali, Fosun Pharma in Côte d'Ivoire, and HEC Pharm in Algeria represent notable examples in the pharmaceutical sector. In medical devices, BGI Genomics has established operations in Angola, Wanbangde Group in South Africa, and Wondfo Biotech in Kenya . This localization trend reflects both African government incentives for domestic manufacturing—motivated by health security concerns exposed during the COVID-19 pandemic—and Chinese firms' recognition that sustainable market access increasingly requires on-the-ground presence (Aniche 2023).

Recent high-level engagements underscore the priority both sides attach to pharmaceutical cooperation. In November 2025, Minister Counselor Lyu Ruihao of China's Mission to the African Union led a delegation to AU institutions in Ghana and Rwanda, where discussions with African Medicines Agency Director General Dr. Delese Mimi Darko focused on establishing cooperation mechanisms between Chinese institutions and the AMA to enhance drug regulatory capacity and medicine access across Africa . The Chinese delegation expressed support for AMA development within the FOCAC framework, while Dr. Darko signaled openness to active collaboration with Chinese regulatory and industry partners.

The dual-panel figure (Fig. 1) quantifies China's regulatory experience with AI-enabled medical products, establishing the evidentiary foundation for claims about Chinese regulatory capacity. The horizontal bar chart enables precise comparison of approval volumes across modalities, while the pie chart emphasizes the dominance of radiology applications. Together, they demonstrate that Chinese regulators have developed substantial practical competence in evaluating AI/ML algorithms, assessing clinical validation data, and establishing post-market monitoring requirements. This experience is directly relevant to AI-enabled drug discovery platforms, which share many

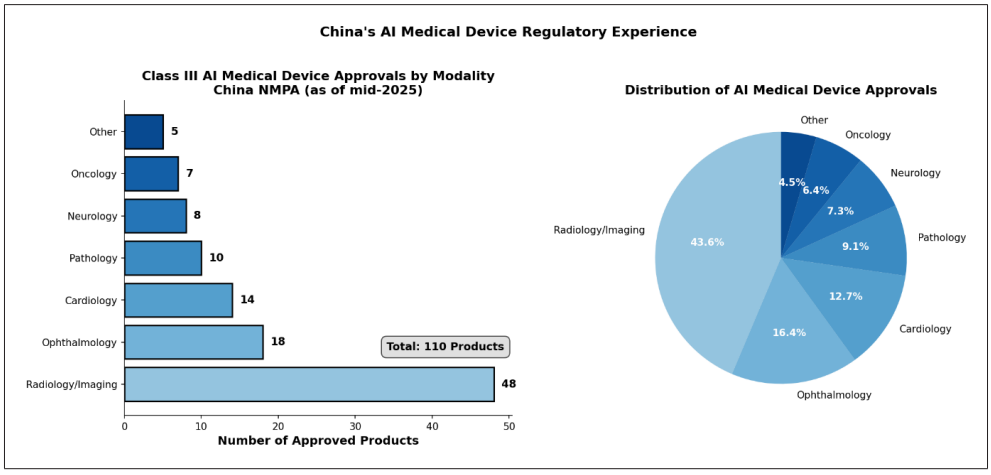

Figure 1. Distribution of China National Medical Products Administration (NMPA) Class III AI medical device approvals by clinical modality as of mid-2025. Panel A (horizontal bar chart) displays absolute approval counts across nine modalities, with radiology and medical imaging representing the largest cohort (48 products, 43.6% of total). Panel B (pie chart) illustrates the proportional distribution, highlighting the concentration of regulatory experience in imaging-based applications. Total approved products exceed 110, representing the largest cohort of regulated AI medical devices globally. Data compiled from NMPA public announcements and industry reports through June 2025. This extensive regulatory experience provides China with substantial practical expertise in AI/ML-enabled medical product evaluation, quality system oversight, and post-market surveillance that may inform technical cooperation with African regulatory authorities (Zhang and Yan 2026).

technical characteristics with approved diagnostic AI systems. The figure supports the article's recommendation that African regulators can benefit from Chinese regulatory science capacity-building initiatives.

3.2. African Regulatory Capacity and the African Medicines Agency

The African regulatory landscape is undergoing transformative institutional development. The African Medicines Agency, established under the African Union and operational since 2021, represents the continent's most ambitious effort to harmonize pharmaceutical regulation, reduce duplicative national reviews, and create a unified market for medicines and medical devices. The AMA's treaty mandate encompasses coordination of regulatory systems, scientific evaluation of selected products, and strengthening of national regulatory authorities through capacity building and reliance mechanisms (Abdulwahab et al. 2024).Complementing AMA's continental mandate, the African Medicines Regulatory Harmonization initiative has advanced regulatory convergence through regional economic communities, establishing joint assessment procedures, common technical document requirements, and information sharing mechanisms. A growing cohort of African NRAs has achieved WHO Maturity Level 3 status—indicating stable, well-functioning, and integrated regulatory systems—including agencies in Egypt, Ghana, Nigeria, Rwanda, Senegal, South Africa, Tanzania, and Zimbabwe . These ML3 agencies are increasingly entering mutual recognition and work-sharing arrangements, creating a foundation for coordinated oversight of complex technologies including AI-enabled products (Cerf 2018).

However, significant capacity gaps persist. No African NRA has yet issued comprehensive guidance specifically addressing AI in drug development or medical devices, though several agencies are actively developing frameworks. South Africa's Health Products Regulatory Authority published a communication in September 2025 outlining regulatory requirements for AI/ML-enabled medical devices, referencing international best practices and signaling expectations for ISO 13485 compliance, clinical evidence, and post-market surveillance . SAHPRA's approach—requiring establishment licensing for AI/ML device importers and manufacturers, applying the four-tier risk classification system, and monitoring international PCCP developments—illustrates how African regulators are pragmatically adapting global standards while building local capacity (African Yearbook Of International L 2019).

3.3. China-Africa Regulatory Cooperation Mechanisms

Regulatory cooperation between Chinese and African authorities has advanced through multiple channels. At the multilateral level, the FOCAC framework provides overarching political direction, with successive action plans identifying pharmaceutical manufacturing, regulatory harmonization, and health product access as priority cooperation areas. The November 2025 China-Africa Pharmaceutical Innovation and International Cooperation Forum in Wuhan convened regulatory leaders from Tanzania, Ethiopia, Uganda, Rwanda, and China's Hubei provincial authorities to discuss drug registration, clinical trial cooperation, and local manufacturing . Such sub-national initiatives complement central government engagements, creating multiple pathways for regulatory dialogue (Li et al. 2023). Chinese regulatory capacity-building support for African counterparts is emerging as a significant cooperation modality. The NMPA's experience with AI medical device regulation—documented through its extensive guidance system and over 110 product approvals—offers a potential template for African agencies developing their own frameworks. Chinese authorities have explicitly acknowledged tracking international regulatory developments from IMDRF, ITU/WHO Focus Group AI for Health, and individual agencies including US FDA, Japan's PMDA, Korea's MFDS, and Singapore's HSA, while also indicating openness to "further optimizing AI medical device regulatory approaches within China's legal framework" . This reflexive regulatory posture—learning from global peers while adapting to local conditions—may prove particularly resonant for African regulators navigating similar challenges of resource constraints and development priorities.

The operationalization of formal cooperation between Chinese institutions and the AMA remains at an early stage. Minister Counselor Lyu's November 2025 discussions with Director General Darko produced expressions of mutual interest but have not yet yielded concrete institutional mechanisms . The potential scope for such cooperation is substantial, encompassing joint training programs, regulatory science research collaborations, work-sharing arrangements for product reviews, and technical assistance in developing guidance documents for emerging technologies including AI.

The time-series visualization (Fig. 2) establishes the economic significance of Sino-African pharmaceutical trade as context for the regulatory classification discussion. The dual presentation of historical and projected data enables viewers to assess both achieved growth and anticipated trajectory. The separation of API exports from total exports is analytically significant: API trade represents inputs for African pharmaceutical manufacturing, while finished formulation exports may compete with local production. The figure supports the article's argument that regulatory classification choices affecting market access for AI-enabled platforms will have material economic consequences given the scale and growth rate of this trade relationship. The CAGR annotation provides a quantitative summary metric for rapid comprehension.

3.4. Trade Barriers and Regulatory Friction Points

Despite expanding trade and improving regulatory cooperation, significant barriers impede the full realization of

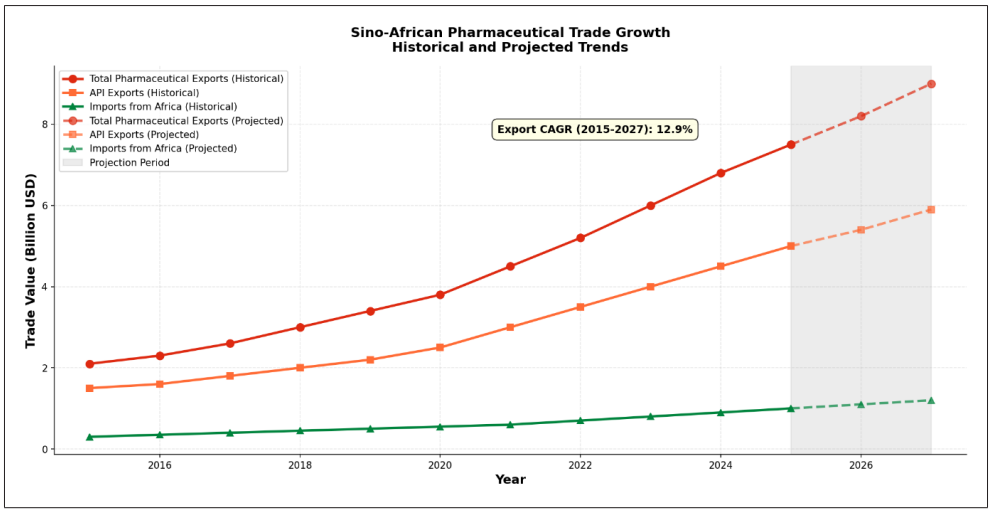

Figure 2. Historical and projected pharmaceutical trade flows between China and Africa, 2015-2027. Solid lines represent historical trade data (2015-2024); dashed lines represent projections (2025-2027) based on compound annual growth rate (CAGR) extrapolation and announced investment commitments. Three trade categories are shown: total pharmaceutical exports from China to Africa (red), active pharmaceutical ingredient (API) exports specifically (orange), and African pharmaceutical imports to China (green). The shaded region indicates the projection period. Total pharmaceutical exports are projected to reach $9.0 billion by 2027, representing a 13.1% CAGR over the full period. API exports demonstrate particularly strong growth, reflecting China's dominant position in global API manufacturing and increasing African pharmaceutical manufacturing capacity. The widening trade surplus highlights persistent African import dependence and underscores the importance of regulatory harmonization and technology transfer initiatives to support local production capacity (United Nations Conference on Trade and Development 2026).

Sino-African pharmaceutical trade potential. Product registration remains a primary friction point, with heterogeneous national requirements, variable review timelines, and limited transparency creating unpredictability for Chinese exporters. The AMA's pilot continental review procedures aim to address these challenges, but the pilot remains limited in scope and has not yet achieved full operational capacity (Ncube 2015). Market access challenges extend beyond registration to encompass procurement preferences, local content requirements, and reimbursement policies. Many African governments, seeking to stimulate domestic manufacturing, have implemented preferences for locally produced medicines in public tenders or established minimum local procurement quotas. Nigeria's Presidential Initiative for Healthcare Value Chain and Cameroon's 30% minimum local procurement requirement exemplify this trend. While these policies create incentives for Chinese firms to localize production—aligning with African industrialization objectives—they also complicate market access for Chinese exports and require substantial capital investment. Intellectual property protection presents another dimension of regulatory friction. Chinese pharmaceutical firms have historically operated in an environment with relatively flexible patent enforcement; their increasing orientation toward innovation and global markets has driven improvements in China's IP regime, but perceptions of inadequate IP protection persist among some African stakeholders. Conversely, African concerns about ensuring affordable access to essential medicines create tensions with maximalist IP enforcement. The intersection of AI and pharmaceutical IP—including questions about patentability of AI-generated inventions, disclosure requirements for training data, and trade secret protection for algorithms—adds further complexity to an already delicate balance.

5. IMPLICATIONS OF CLASSIFICATION CHOICES FOR SINO-AFRICAN TRADE AND HEALTH OUTCOMES

5.1. Market Access and Trade Flow Consequences

The regulatory classification assigned to AI-enabled drug discovery platforms carries direct implications for the volume and character of Sino-African pharmaceutical trade. If classified as software—subject primarily to general product safety requirements, cybersecurity standards, and perhaps emerging AI governance frameworks—Chinese platforms could enter African markets with relatively low regulatory friction. This pathway would maximize trade volumes and

accelerate technology diffusion, but would also concentrate regulatory scrutiny downstream on the actual drug products discovered or optimized using AI tools. The risk is that AI-specific concerns about training data representativeness, algorithmic bias, and performance drift would escape systematic regulatory oversight (Ncube 2015).

Classification as medical devices triggers a substantially more demanding compliance pathway. Chinese exporters would need to demonstrate conformity with medical device regulations in each target market—or navigate regional harmonization mechanisms where available—including quality management system certification (typically ISO 13485), technical documentation demonstrating safety and performance, clinical evidence where required, and post-market surveillance obligations. For African markets, where medical device regulatory systems vary in maturity, this could mean navigating over 50 distinct national requirements, though AMA and regional harmonization initiatives promise eventual simplification. The SAHPRA model, requiring establishment licensing for importers and applying risk-stratified review based on internationally recognized standards , suggests how African regulators may pragmatically approach this challenge (Obunike and NWAKOB 2025).

Classification as pharmaceuticals would represent the most burdensome scenario, subjecting AI platforms to drug approval pathways including clinical trial requirements, manufacturing quality standards, and pharmacovigilance obligations calibrated for molecular entities rather than computational tools. While few jurisdictions currently treat AI discovery platforms as pharmaceuticals, the question becomes acute when AI systems generate novel molecular entities with minimal human intervention. If an AI platform autonomously identifies and optimizes a drug candidate, at what point does the platform itself become subject to pharmaceutical regulation? The European Patent Office's requirement for human inventorship reflects broader discomfort with fully autonomous AI drug discovery, but regulatory frameworks have not yet systematically addressed this scenario (Nwauche 2018). For Sino-African trade, classification choices will shape not only compliance costs and timelines but also the structure of commercial relationships. A software or light-device classification favors export-oriented business models where Chinese firms develop and validate platforms in China, then deploy them globally with minimal localization. A medical device classification, particularly with requirements for clinical validation in local populations, creates incentives for deeper in-country presence, technology transfer, and joint development with African partners. This aligns with both Chinese industrial strategy—which increasingly emphasizes overseas manufacturing and local partnerships—and African aspirations for pharmaceutical sovereignty and technology capability development (Atacan and Açık 2023).

5.2. Technology Transfer and Capacity Building

The classification question profoundly influences technology transfer dynamics between Chinese developers and African adopters. Medical device classification typically requires local establishment licensing, authorized representative arrangements, and sometimes local clinical data—all of which necessitate African infrastructure and expertise. These requirements, while burdensome in the short term, can serve as catalysts for sustainable capacity building. When SAHPRA requires ISO 13485 certification for importers and manufacturers of AI/ML-enabled medical devices, it creates demand for local quality management expertise, conformity assessment services, and technical competence that did not previously exist. Chinese firms have demonstrated willingness to invest in African manufacturing and technical capacity when market access conditions reward such investment. Humanwell's pharmaceutical facilities in Mali, BGI's genomics operations in Angola, and Wondfo's diagnostics manufacturing in Kenya illustrate that localization is not merely theoretical. The key policy question is whether regulatory frameworks can be designed to maximize the developmental spillovers from technology transfer—including workforce training, quality system implementation, and research collaboration—without imposing requirements so onerous that they deter market entry altogether. The NMPA's experience with AI medical device regulation offers potential lessons for technology transfer arrangements. China's five-tiered guidance system, standardization committee structure, and innovation cooperation platforms represent institutional investments in regulatory science that could be adapted for African contexts. Chinese regulators and industry associations have already engaged in capacity-building exchanges with African counterparts, as evidenced by the August 2025 China-Africa Pharmaceutical Trade and Investment Promotion Mission to Ethiopia and Uganda, which included regulatory discussions alongside commercial meetings. Expanding such exchanges to specifically address AI governance in drug development could accelerate African regulatory readiness while creating commercial opportunities for Chinese firms (de Villiers 2021).

5.3. Health Equity and Algorithmic Justice

Perhaps the most consequential implication of regulatory classification choices concerns health equity and what might be termed "algorithmic justice"—ensuring that AI-enabled drug discovery serves diverse populations rather than exacerbating existing disparities. The FDA-EMA Good AI Practice principles emphasize that AI systems must be developed using representative datasets to avoid miscalibration when applied to populations differing from training data. This principle has particular urgency for African populations, which remain substantially underrepresented in global genomic databases, clinical trial cohorts, and the biomedical research literature that informs AI model development. The Africa Clinical Research Network

has articulated this concern with clarity, calling on regulators to "require evidence that AI tools perform well on African population data" and warning that "miscalibration caused by training exclusively on non-African populations" could undermine both safety and efficacy when AI-enabled discovery platforms are applied to diseases prevalent in Africa. This concern extends beyond clinical performance to encompass fundamental questions about which diseases receive research attention. If AI platforms are trained predominantly on data from high-income country populations and optimized for diseases of commercial interest in those markets, they may systematically underperform for neglected tropical diseases or conditions with distinct African epidemiological patterns (Antolín 2021).

Regulatory classification determines the tools available to address these concerns. Medical device regulations typically require clinical validation demonstrating performance in intended use populations—a requirement that, if properly enforced, could mandate African population validation for platforms marketed in Africa. Software regulations generally lack such requirements. Pharmaceutical regulations would trigger clinical trial obligations that, while burdensome, would generate African population data as a by-product. The challenge for African regulators is to calibrate requirements to ensure algorithmic fairness without imposing validation burdens so extensive that they discourage the application of AI to African health priorities altogether (Daneshjou et al. 2021).

5.4. Data Sovereignty and Cross-Border Governance

AI-enabled drug discovery platforms necessarily involve data flows—training data, validation data, and operational data generated through platform use—that raise complex questions of data sovereignty and cross-border governance. The African Union's Malabo Convention on Cyber Security and Personal Data Protection, which entered into force in 2023, establishes a continental framework for data protection that includes provisions on cross-border data transfers, consent requirements, and sensitive data handling. The AU Digital Transformation Strategy 2020-2030 similarly articulates aspirations for African data sovereignty and digital self-determination (Vieira et al. 2023). The classification of AI platforms intersects with data governance in several ways. Medical device and pharmaceutical classifications typically entail more stringent requirements for data integrity, traceability, and auditability—obligations that can support responsible data stewardship but may also require data localization or restricted transfer arrangements. Software classification offers greater flexibility but potentially weaker protections for sensitive health data used in AI training. Chinese firms operating across African markets must navigate not only diverse national data protection laws but also China's own data security and cross-border transfer regulations, which impose requirements on data collected overseas but processed in China (Union 2014).

The African Clinical Research Network's call to "operationalize data governance via the Malabo Convention" specifically for AI in health reflects recognition that existing legal frameworks require practical implementation guidance to address AI-specific challenges. The AMA, working with African NRAs and regional economic communities, is well-positioned to develop such guidance, potentially drawing on models from the EU's elaborate data protection regime, China's sectoral data security requirements, and emerging global standards for health AI governance.

This radar chart (Fig. 3) provides a systematic comparative evaluation of classification alternatives, moving beyond descriptive analysis to normative assessment. The multi-dimensional framework acknowledges that regulatory choices involve trade-offs across multiple values, not merely technical or legal considerations. The visual representation enables rapid identification of each classification's distinctive profile: software regulation's trade-off of safety for access, pharmaceutical regulation's inverse prioritization, and the medical device pathway's intermediate position. The hybrid approach's superior coverage across most dimensions supports the article's central recommendation that African regulators should avoid rigid categorical assignment and instead develop context-sensitive frameworks adapted to local priorities and constraints.

6. TOWARD COOPERATIVE SOLUTIONS: POLICY RECOMMENDATIONS

6.1. Pragmatic Classification for African Contexts

The preceding analysis suggests that no single classification—software, medical device, or pharmaceutical—adequately addresses the full range of regulatory concerns raised by AI-enabled drug discovery platforms. For African regulators, the optimal approach is likely a context-sensitive, risk-proportionate hybrid framework that distinguishes among different platform functions and deployment scenarios. Specifically:

For platforms used exclusively for internal research and development—for instance, AI systems that screen compound libraries or predict molecular properties during early discovery but do not directly inform clinical decisions or regulatory submissions—light-touch oversight emphasizing transparency, data governance, and algorithm documentation may suffice. Such platforms could be regulated under general research integrity frameworks and emerging AI governance standards rather than full medical device or pharmaceutical regimes.

For platforms used in regulatory decision-making—including AI systems that optimize clinical trial design, identify patient subpopulations, or support safety monitoring—a medical de-

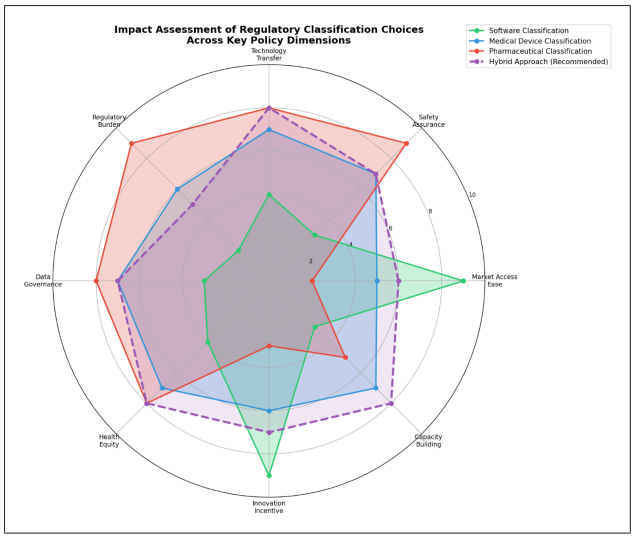

Figure 3. Radar chart comparing the relative performance of four regulatory classification approaches—Software, Medical Device, Pharmaceutical, and Hybrid—across eight policy-relevant dimensions. Each axis represents a distinct evaluative criterion scored from 0 (minimal) to 10 (maximal): Market Access Ease, Safety Assurance, Technology Transfer, Regulatory Burden, Data Governance, Health Equity, Innovation Incentive, and Capacity Building. The Software classification (green) maximizes market access ease and innovation incentives but performs poorly on safety assurance and data governance. The Pharmaceutical classification (red) provides maximal safety assurance but severely constrains market access and innovation. The Medical Device classification (blue) offers balanced intermediate performance. The recommended Hybrid approach (purple dashed line) combines elements of multiple frameworks to achieve favorable scores across all dimensions, with particular strength in technology transfer, health equity, and capacity building relevant to African contexts (Authors' own elaboration).

vice classification with appropriate risk stratification appears most suitable. This approach would require demonstration of analytical and clinical validity, quality management systems, and post-market performance monitoring, while avoiding the full pharmaceutical development paradigm calibrated for molecular entities. The FDA PCCP framework and SAHPRA's adaptive approach offer useful models.

For platforms that autonomously generate novel drug candidates—where AI systems substantially replace human decision-making in molecular design and optimization—closer alignment with pharmaceutical regulation may be warranted, particularly regarding manufacturing quality, clinical trial requirements, and intellectual property treatment. However, this scenario remains largely hypothetical for now, and premature regulatory action could stifle innovation without commensurate public health benefit.

6.2. Sino-African Regulatory Cooperation Agenda

The convergence of Chinese technological capability, African regulatory development, and shared interest in expanded pharmaceutical trade creates a compelling case for structured Sino-African cooperation on AI drug discovery governance. Priority initiatives should include:

Joint development of Africa-adapted AI guidance. Chinese regulators, drawing on their extensive experience with AI medical device approvals and standardization, could partner with AMA and regional working groups to develop guidance documents specifically addressing AI in drug discovery for African contexts. Such guidance should emphasize representative training data, performance validation in African populations, and proportionate oversight calibrated to regulatory capacity constraints.

Regulatory science capacity building. The NMPA's AI Medical Device Standardization Technical Committee and innovation cooperation platforms offer institutional models for African capacity development. Structured exchanges—potentially under FOCAC health cooperation frameworks—could support African regulators in developing technical competence in AI/ML evaluation, including algorithmic auditing, data quality assessment, and performance monitoring.

Work-sharing and reliance mechanisms. As African NRAs achieve higher WHO maturity levels and AMA operational capacity grows, opportunities emerge for work-sharing arrangements in AI platform review. Chinese regulatory approvals, particularly for platforms already validated across diverse populations, could inform African assessments through reliance mechanisms that avoid duplicative reviews while preserving sovereign regulatory authority.

Coordinated approaches to data governance. Sino-African cooperation should address cross-border data governance challenges, potentially through model agreements or mutual recognition arrangements that facilitate responsible data flows while protecting privacy and sovereignty interests. The Malabo Convention provides a continental foundation that could be operationalized through bilateral or regional implementation protocols.

6.3. Industry Engagement and Responsible Innovation

Regulatory frameworks, however well-designed, require industry cooperation to achieve public health objectives. Chinese developers of AI-enabled drug discovery platforms should proactively engage with African regulatory expectations by:

Investing in African population validation. Demonstrating that AI platforms perform adequately in African populations—through prospective validation studies, real-world evidence generation, or collaborative research with African institutions—should be viewed as both regulatory prudence and commercial opportunity. Platforms validated in diverse African populations may enjoy competitive advantages in both African markets and global settings where

demographic diversity is increasingly valued.

Supporting African research infrastructure. Technology transfer arrangements that build African capacity for AI in drug discovery—including computational infrastructure, training programs, and joint research initiatives—align with both Chinese industrial policy preferences for deep partnerships and African aspirations for technological sovereignty. The joint laboratory established between Hubei Jiangxia Laboratory and Tanzania's National Public Health Laboratory exemplifies this approach.

Transparency in intended use and limitations. Clear communication about platform capabilities, limitations, and appropriate use contexts is essential for responsible deployment and regulatory compliance. This includes honest representation of training data characteristics, known performance boundaries across populations, and appropriate human oversight requirements.

6.4. International Coordination and Standard-Setting

Finally, the global nature of both AI technology and pharmaceutical markets demands international coordination beyond bilateral Sino-African cooperation. African regulators, supported by Chinese and other partners, should actively participate in global standard-setting initiatives including:

IMDRF AI Working Group activities. The International Medical Device Regulators Forum has emerged as a key venue for developing harmonized approaches to AI/ML-enabled medical devices. African participation ensures that continental perspectives inform global guidance.

ICH reflection on AI in pharmaceutical development. As ICH considers guidance on AI applications in drug development, African and Chinese regulators should jointly advocate for attention to population diversity, data representativeness, and proportionate oversight approaches suitable for varied regulatory maturity levels.

WHO initiatives on AI in health. The World Health Organization's work on AI governance, including the Focus Group on AI for Health, provides multilateral platforms for developing normative guidance that can inform national and regional frameworks.

This area chart and line plot combination (Fig. 4) visualizes the temporal distribution of regulatory oversight across the drug development continuum. The key insight is the mismatch between existing regulatory frameworks' intensity profiles and the phases where AI platforms are most heavily utilized. Pharmaceutical and medical device regulations concentrate oversight in late-stage clinical development and regulatory submission, whereas AI platforms exert greatest influence in early discovery and preclinical optimization. The proposed AI-specific requirements (purple dashed line) address this mismatch by front-loading oversight to early phases, ensuring that algorithmic quality and

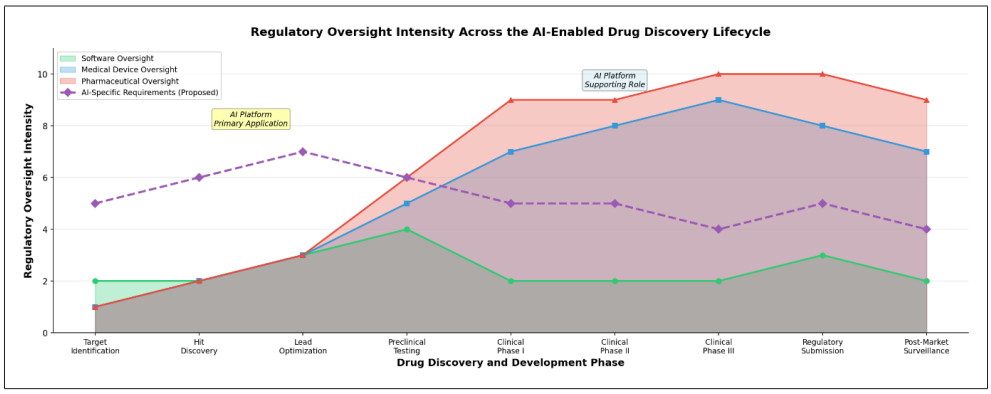

Figure 4. Intensity of regulatory oversight across the nine phases of AI-enabled drug discovery and development, comparing four regulatory frameworks: Software Oversight (green), Medical Device Oversight (blue), Pharmaceutical Oversight (red), and proposed AI-Specific Requirements (purple dashed). Oversight intensity is scored from 0-10 based on cumulative regulatory burden including documentation requirements, quality system obligations, clinical evidence expectations, and post-market surveillance mandates. Pharmaceutical oversight dominates late-stage development (Phases II-III, Regulatory Submission) with near-maximal intensity. Medical device oversight shows a bimodal distribution with peaks during preclinical validation and clinical development. Software oversight remains consistently low throughout. The proposed AI-Specific Requirements overlay addresses distinctive algorithmic concerns—training data quality, model validation, performance drift monitoring—with intensity concentrated in early discovery phases where AI platforms have greatest impact. Annotations indicate AI platform primary application domain (early discovery) and supporting role (clinical development and post-market) (Authors' own elaboration).

representativeness are established before substantial downstream investment. The figure supports the article's argument that novel regulatory approaches, rather than simple categorical assignment, are required to appropriately govern AI in drug discovery.

7. CONCLUSION

The question whether AI-enabled drug discovery platforms should be regulated as software, medical devices, or pharmaceuticals admits no single answer—nor should it. The appropriate classification depends on platform function, deployment context, and the specific risks posed to patient safety, data rights, and health equity. What emerges clearly from this analysis is that the classification choice carries profound implications extending far beyond legal taxonomy. It shapes market access pathways for Chinese exporters, technology transfer opportunities for African partners, and—most fundamentally—whether AI's transformative potential in accelerating drug discovery will reach populations historically marginalized by global pharmaceutical innovation. For Sino-African relations, the AI regulatory question presents both challenge and opportunity. The challenge lies in navigating divergent regulatory starting points: China's sophisticated but domestically-focused AI medical device framework, Africa's developing but still fragmented regulatory systems, and the absence of established cooperation mechanisms bridging the two. The opportunity lies in the possibility of regulatory leapfrogging—African regulators learning from both the achievements and limitations of Chinese, American, and European approaches to craft frameworks suited to African contexts and priorities. The institutional foundations for such cooperation are being laid. The African Medicines Agency's operationalization, growing numbers of WHO Maturity Level 3 NRAs, and explicit interest from both Chinese and African leadership in pharmaceutical regulatory cooperation create enabling conditions. The FDA-EMA Good AI Practice principles provide a global reference point that can be adapted rather than simply adopted. And the commercial imperatives driving Chinese pharmaceutical engagement in Africa create sustained incentives for addressing regulatory friction. Ultimately, the classification of AI-enabled drug discovery platforms should serve public health objectives: ensuring safety and effectiveness, promoting beneficial innovation, protecting data rights, and advancing health equity. Regulatory frameworks that fixate on categorical purity at the expense of these objectives fail their fundamental purpose. For African regulators, Chinese developers, and the patients who stand to benefit from AI-accelerated drug discovery, the task is to craft pragmatic, proportionate, and cooperative approaches that harness algorithmic innovation while safeguarding the humans it is meant to serve.

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