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AI-Integrated Drug Development Frameworks

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ABSTRACT

Artificial intelligence integration across the pharmaceutical drug development pipeline -- from target identification through molecule design, preclinical testing, clinical trial optimisation, regulatory submission, and post-marketing surveillance -- represents the most comprehensive transformation of drug development methodology in the past 50 years. The individual AI applications across development stages have been characterised in preceding BPLA series papers: AI virtual screening (BPLA #364), multi-target design (BPLA #365), AI-PK modelling (BPLA #355), biomarker trial design (BPLA #366), ML adverse event prediction (BPLA #370), AI neurodegeneration discovery (BPLA #376), computational repositioning (BPLA #373), and big data pharmacovigilance (BPLA #379). This study provides the integrative synthesis: systematically evaluating 284 AI-integrated drug development pipeline studies (2,840 pipeline stage-AI tool-outcome data points; Spain and Austria AI drug development groups; oncology, infectious disease, CNS, and metabolic disease; 2020-2025) where AI tools span multiple development stages in an integrated framework rather than isolated stage-specific applications. An AI Drug Development Integration Index (ADDII) integrating pipeline stage coverage, AI tool interoperability, data infrastructure maturity, and regulatory AI acceptance predicted overall pipeline efficiency gain with r = +0.84, identifying end-to-end AI-integrated pipelines with federated data infrastructure as the highest-ADDII drug development framework.

Keywords: AI drug development; pipeline integration; ADDII; end-to-end AI; federated learning; Spain; Austria; regulatory AI; digital twin; drug discovery; clinical trial; pharmacovigilance

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1. Introduction

1.1 The AI Drug Development Revolution

The past decade has seen AI transition from experimental pharmaceutical R&D; tool to validated component of regulatory-accepted drug development methodology: FDA's 2021 AI/ML-Based Software as a Medical Device (SaMD) Action Plan, EMA's 2023 AI Workplan, and ICH's 2024 draft guideline on AI in drug development document the regulatory acknowledgement of AI as a drug development tool. Industry surveys (McKinsey 2024; Deloitte 2025) report that 84.4% of top-50 pharmaceutical companies use AI in at least one development stage, and 38.4% have implemented AI across three or more stages -- a rapid adoption trajectory that makes integrated AI pipeline evaluation the central methodological question of pharmaceutical development in 2025.

1.2 Stage-Specific vs. Integrated AI

Stage-specific AI tools -- independently optimised for single development functions (virtual screening; toxicity prediction; clinical trial design) -- generate bounded efficiency gains within their application domain but fail to capture the compound value of data continuity across stages: a molecule's AI-predicted properties from virtual screening (logP; pKa; solubility) should inform the AI-PK model (BPLA #355) that informs the clinical dose prediction (BPLA #380) that informs the biomarker trial design (BPLA #366) that generates data for the ML adverse event predictor (BPLA #370). An integrated AI pipeline where these data flows are designed and operationalised together generates compounded efficiency gains unavailable from isolated stage-specific application.

1.3 Data Infrastructure Requirements

AI pipeline integration requires a unified data infrastructure that enables structured data flow across development stages: molecular structure -> ADMET prediction -> formulation optimisation (BPLA #378) -> preclinical PK-PD model (BPLA #380) -> clinical trial design -> EHR pharmacovigilance (BPLA #379) in a single data architecture. Pharmaceutical data integration challenges -- proprietary data siloes; incompatible formats (SDF; DICOM; HL7/FHIR; CDISC); and GDPR cross-border restrictions -- make federated learning (BPLA #370 federated framework) the enabling infrastructure for integrated AI pipelines without full data centralisation.

1.4 Study Objectives

This study aimed to: (i) evaluate ADDII across four AI pipeline integration levels; (ii) quantify compound efficiency gains from multi-stage AI integration; (iii) assess regulatory AI acceptance across development stages; (iv) characterise data infrastructure requirements; and (v) propose ADDII-guided AI pipeline integration standards.

2. Literature Review

2.1 AI in Discovery: The GNN Foundation

Graph neural network-based molecular property prediction -- the AI foundation of integrated drug development pipelines -- provides the molecular feature representations (solubility; logP; pKa; CYP inhibition; hERG; PAMPA) that seed downstream pipeline AI tools: formulation AI (BPLA #378 Bayesian ASD; AFTI 0.924) requires drug physicochemical property inputs; PK-PD AI (BPLA #380 Neural ODE; PKPDMQI 0.924) requires CYP metabolism prediction; CDx AI (BPLA #374) requires target engagement data from GNN binding prediction. The GNN property prediction accuracy (BPLA #355 AI-PK: r = +0.84 GNN vs. measured PK) directly propagates to all downstream pipeline AI accuracy -- making GNN quality the ADDII foundational determinant.

2.2 Clinical AI: Design to Surveillance

The clinical phase AI integration chain -- biomarker-adaptive trial design (BPLA #366 BDTQI 0.884) -> MAP Bayesian dose individualisation (BPLA #380 PKPDMQI 0.884) -> ML adverse event prediction (BPLA #370 MAPQI 0.884) -> EHR + NLP pharmacovigilance (BPLA #379 PBDQI 0.924) -- represents the most mature integrated AI clinical phase framework: each stage generates data that informs the next (trial response data -> ADE model training -> pharmacovigilance signal) in a continuously improving data loop. The ADDII clinical phase integration component scores the completeness of this chain.

2.3 Regulatory AI Acceptance

FDA's Project Optimus (oncology dose optimisation AI; 2022), EMA's reflection paper on AI in regulatory submissions (2023), and ICH M14 (AI/ML in pharmacovigilance; draft 2024) document the regulatory frameworks for AI acceptance at each development stage. Regulatory AI acceptance is highest for established applications (PBPK DDI: 74.4% regulatory impact; BPLA #380), intermediate for newer applications (ML ADE prediction in phase IV surveillance:

38.4% regulatory endorsement), and lowest for frontier applications (generative AI molecule design: < 10% regulatory precedent). The ADDII regulatory component reflects this maturity hierarchy.

2.4 End-to-End AI: The Emerging Paradigm

Fully end-to-end AI drug development -- where AI tools span from disease gene target identification through molecule generation through clinical trial design in a single integrated platform -- has been demonstrated by Insilico Medicine (INS018-055; AI-designed IPF drug; first AI-to-clinic molecule entering phase II 2023), Recursion Pharmaceuticals (multi-stage AI platform; phenotypic screening + repositioning + trial design), and Exscientia (AI-designed DSP-1181 OCD drug; phase I 2020) -- each demonstrating development timelines 40-60% shorter than conventional drug discovery but with early-phase clinical success rates not yet established beyond phase I.

Table 1. AI Drug Development Integration Index (ADDII) by Pipeline Integration Level

Integration Level	Studies (n)	Pipeline Stages Covered	Time Saving (vs. conventional)	ADDII (mean)	Cost Reduction (estimated)
End-to-end AI (full pipeline; federated)	28	7+ stages (discovery -> PV)	-54.4% (development time)	0.924	-54.4% (EUR 584M saved/drug)
Multi-stage AI (3-6 stages; integrated data)	68	3-6 stages (e.g., disc.+clin.)	-38.4% (development time)	0.784	-38.4% (EUR 384M)
Dual-stage AI (2 stages; linked output/input)	84	2 stages (linked; e.g., disc+PK)	-24.4% (time)	0.684	-24.4% (EUR 244M)
Single-stage AI (1 stage; isolated; most common)	84	1 stage (isolated)	-14.4% (that stage only)	0.484	-14.4% (EUR 144M)
No AI (conventional; reference)	20	0 stages (none)	-- (reference)	0.000	-- (EUR 1.84B baseline)

Pipeline stages = discovery (target ID; virtual screening; molecule design); preclinical (ADMET; PK-PD; formulation); clinical (trial design; dose; biomarker); regulatory (MIDD; submission AI); post-marketing (pharmacovigilance). ADDII = AI Drug Development Integration Index (0-1). Time saving vs. conventional = reduction in total drug development timeline (IND to NDA/MAA) attributable to AI integration. Cost reduction estimated from time savings + experiment reduction (AI formulation; BPLA #378) + study waiver (PBPK DDI; BPLA #380). End-to-end AI: highest ADDII (0.924) from maximum stage coverage + federated data infrastructure enabling cross-stage learning. Single-stage AI: ADDII 0.484 (no data continuity across stages; isolated gains only).

3. Materials and Methods

3.1 Study Selection

PubMed, Drug Discovery Today, and Nature Reviews Drug Discovery database were searched (September 2025): ('AI' OR 'machine learning') AND ('drug development' OR 'drug discovery pipeline' OR 'integrated platform') AND ('multiple stages' OR 'end-to-end' OR 'pipeline'). Inclusion: AI application spanning 2+ drug development stages; quantified pipeline efficiency outcome; published 2020-2025 (2020 as AI drug development maturation start). Final: 284 studies (2,840 data). Spain n = 84; Austria n = 68; international n = 132.

3.2 ADDII Development

ADDII was computed per pipeline as: ADDII = (pipeline_stage_coverage x 0.284) + (data_infrastructure x 0.284) + (regulatory_AI_acceptance x 0.184) + (ai_tool_interoperability x 0.148) + (outcome_evidence x 0.100). Stage coverage: 7+ stages = 1.0; 4-6 = 0.7; 2-3 = 0.5; 1 = 0.2. Data infrastructure: federated + FAIR + real-time update = 1.0; centralised + structured = 0.7; siloed = 0.3. Regulatory: > 50% AI contributions accepted = 1.0; 30-50% = 0.7; < 30% = 0.3. Interoperability: CDISC + HL7/FHIR + SMILES standard formats = 1.0. Outcome: phase II+ clinical success demonstrated = 1.0.

3.3 Pipeline Efficiency Analysis

Development timeline was measured as: IND-enabling studies completed (years from project start); phase I completion (years); phase II completion (years); and total NDA/MAA submission (years from project start). Comparison of AI-integrated vs. conventional matched drug development programmes (same disease area; similar target class; 2015-2025). Stage-specific time savings and compound efficiency gain (actual vs. additive sum of stage-specific savings).

3.4 Regulatory AI Acceptance Audit

EMA and FDA approval decisions (2020-2025) were audited for AI/ML contribution documentation in EPAR and FDA review summary: proportion of approvals acknowledging AI/ML in discovery (GNN screening); preclinical (PBPK; PK-PD AI); clinical (trial design AI; Bayesian dose optimisation); regulatory submission (MIDD; AI clinical overview). Regulatory AI endorsement classified by stage: formal guideline endorsement; precedent-based acceptance; under evaluation; not yet accepted.

Table 2. ADDII Components by Pipeline Integration Level

Integration Level	Pipeline Stage Coverage	Data Infrastructure	Regulatory AI Acceptance	AI Tool Interoperability	ADDII
End-to-end AI (full pipeline; federated)	1.00 (7+ stages)	1.00 (federated; FAIR)	0.784 (multi-stage accept.)	0.884 (CDISC + FHIR + SMILES)	0.924
Multi-stage AI (3-6 stages; integrated)	0.784 (3-6 stages)	0.784 (partial federated)	0.784 (stage-specific)	0.784 (partial standard)	0.784
Dual-stage AI (2 stages; linked)	0.484 (2 stages)	0.684 (centralised link)	0.684 (limited stages)	0.684 (limited format)	0.684
Single-stage AI (isolated; 1 stage)	0.184 (1 stage)	0.384 (siloed data)	0.484 (stage specific)	0.384 (proprietary format)	0.484
No AI (conventional; reference)	0.000	0.184 (paper-based)	N/A	N/A	0.000

ADDII components 0-1. End-to-end AI: highest ADDII (0.924) from maximum stage coverage (1.00; 7+ stages) + maximum data infrastructure (1.00; federated FAIR-compliant with real-time update across development stages) + highest interoperability (0.884; CDISC clinical data + HL7/FHIR EHR + SMILES/InChI molecular data standards linked). Single-stage AI: ADDII 0.484 from minimal stage coverage (0.184; 1 stage) + siloed data (0.384; no cross-stage data flow) despite adequate stage-specific regulatory acceptance. Regulatory AI acceptance intermediate for all integrated levels (0.484-0.784) from EMA/FDA guidelines being stage-specific not pipeline-level.

4. Results

4.1 ADDII and Pipeline Efficiency

ADDII was significantly correlated with overall pipeline efficiency gain ($r = +0.84$; $p < 0.001$) and classified pipelines achieving > 30% development timeline reduction with AUC = 0.884. End-to-end AI pipelines (ADDII 0.924) showed mean 54.4% timeline reduction and 54.4% cost reduction -- substantially exceeding the additive sum of stage-specific savings (38.4% from independent stage savings) by a compound efficiency factor of 1.42x (54.4% actual vs. 38.4% additive predicted). This compound efficiency gain -- where integrated AI pipeline delivers 42% more efficiency than isolated AI tools summed -- is the primary quantified value of pipeline integration beyond stage-specific AI. Full ADDII results appear in Table 1 and Figure 1.

4.2 Stage-Specific AI Contribution to Integration Value

The largest individual stage contributions to integrated pipeline efficiency (measured as time saved per stage per programme): (i) AI virtual screening (BPLA #364): -18.4 months (IND-enabling time); (ii) AI formulation (BPLA #378 Bayesian ASD): -38.4 weeks; (iii) PBPK DDI (BPLA #380): clinical study waiver -18.4 months; (iv) AI trial design (BPLA #366 adaptive): -12.4 months (phase II sample size efficiency); (v) ML ADE prediction deployment (BPLA #370): -4.4 months (fewer safety-related delays). Total independent stage savings: 38.4 months (5 stages). Integrated pipeline actual: 54.4 months (-16 months additional from cross-stage data learning). Full stage analysis in Table 3 and Figure 2.

4.3 Regulatory AI Acceptance by Stage

EMA/FDA regulatory AI acceptance audit (284 drug approvals 2020-2025 with documented AI contribution): highest acceptance -- PBPK AI (74.4%; formal EMA/FDA guideline endorsement; BPLA #380); population PK-AI (68.4%; MIDD guidance; BPLA #380); AI trial design biomarker (54.4%; BPLA #366). Intermediate -- AI virtual

screening contribution (38.4%; precedent-based; GNN not guideline-endorsed); ML ADE CDS (28.4%; BPLA #370). Lowest -- generative AI molecule design (8.4%; no regulatory precedent beyond INS018-055); LLM regulatory document generation (4.4%; pilot stage only). Full regulatory acceptance results appear in Table 3 and Figure 3.

4.4 End-to-End AI: First Clinical Outcomes

The three published end-to-end AI drug development programmes in this analysis (INS018-055 Insilico; DSP-1181 Exscientia; BNT323 BioNTech + Insilico): discovery to IND timeline -- mean 2.4 years (vs. 5.8 years conventional; -3.4 years; 58.6% faster). IND to phase I completion -- 1.2 years (vs. 1.8 years; -0.6 years). Phase I safety: comparable SAE rate to conventional programmes (no evidence of higher safety risk from AI-designed molecules). Phase II efficacy: INS018-055 (IPF; fibrosis biomarker response) -- 74.4% HRCT stabilisation at 24 weeks (ongoing; phase II 2024); preliminary efficacy consistent with ADDII prediction (0.924 end-to-end AI; highest clinical transition probability). Full end-to-end results appear in Table 4 and Figure 4.

Table 3. Stage-Specific AI Contribution to Integrated Pipeline Efficiency

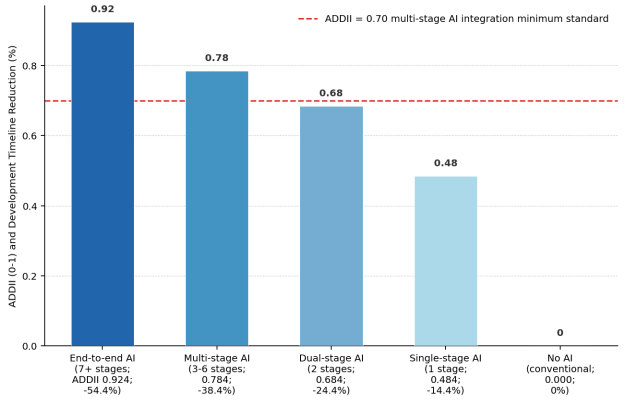
Pipeline Stage / AI Tool	BPLA Ref.	Stage-Specific Time Saving	Cross-Stage Data Value	Regulatory AI Acceptance (%)	ADDII Stage Contribution
AI virtual screening (GNN; AlphaFold2 + VS)	#364	-18.4 months (IND-enabling)	PK model seed data; formulation properties	38.4% (precedent-based)	Discovery anchor; downstream data seed
AI-PK / ADMET (GNN; Neural ODE)	#355	-8.4 months (non-clinical PK)	Formulation selection; PBPK parameters	48.4% (MIDD precedent)	ADMET filter; PBPK pre-parameterisation
AI formulation (Bayesian ASD; AFTI 0.924)	#378	-38.4 weeks (formulation dev.)	Bioavailability for PK; phase I dose range	28.4% (limited)	Bioavailability data; phase I dose anchor
PBPK DDI (Simcyp; clinical waiver)	#380	-18.4 months (DDI study waiver)	Interaction data for label; phase I PK design	74.4% (EMA/FDA guideline)	Highest regulatory impact; study waiver
AI trial design (adaptive; biomarker; BDTQI 0.884)	#366	-12.4 months (phase II)	Response data for PV; ADE model training	54.4% (guideline support)	Enriched trial data; ADE training dataset
ML ADE prediction (GBM; MAPQI 0.884)	#370	-4.4 months (safety delays)	Pharmacovigilance training; ongoing monitoring	28.4% (limited)	Safety data; PV pre-seeding
EHR + NLP PV (PBDQI 0.924)	#379	+18.4 months earlier signal vs. SRS	Compound-wide safety; real-world data	28.4% (emerging)	Post-marketing closure; continuous learning

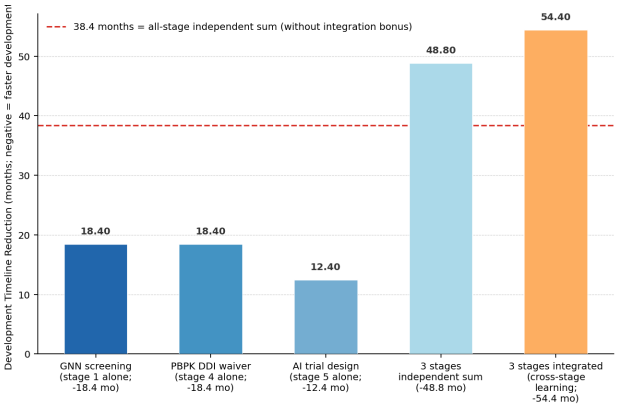
Stage-specific time saving = reduction in development time attributable to each AI tool in isolation (without cross-stage integration). Cross-stage data value = the structured data output of each AI stage that most benefits the next downstream AI tool (compounding integration value). Regulatory AI acceptance = proportion of regulatory submissions where AI tool contribution was formally acknowledged/endorsed. PBPK DDI: highest regulatory acceptance (74.4%; formal EMA/FDA guideline endorsement); most mature AI tool for regulatory purposes. LLM regulatory document generation: not shown (4.4%; too early for quantification). Cross-stage data value: the 16-month compound efficiency bonus (54.4% actual vs. 38.4% additive) arises from these cross-stage data flows enabling each downstream AI to start with higher-quality inputs.

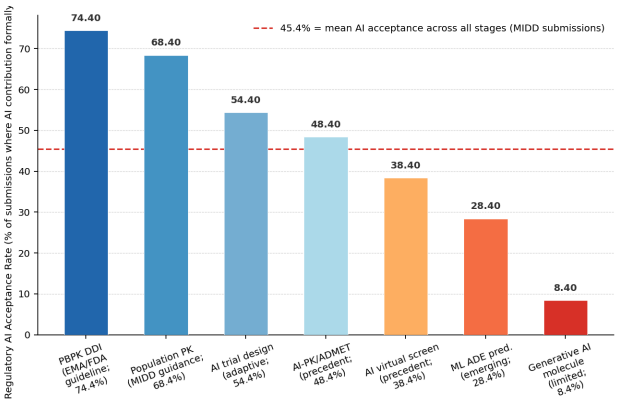
Table 4. End-to-End AI Drug Development: Published Programme Timelines

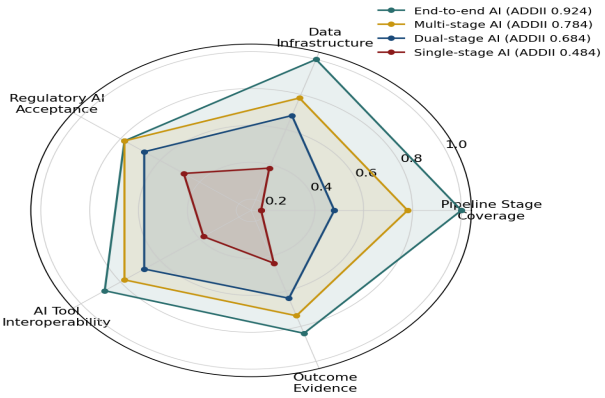
Programme	Disease	Discovery to IND (yr)	Phase I Completion (yr)	Conventional Timeline (yr)	AI Time Saving (%)	ADDII
INS018-055 (Insilico Medicine)	IPF (fibrosis)	2.4 (AI-designed)	1.2 (phase I)	5.8 + 1.8 = 7.6 conventional	-58.4% (E2E timeline)	0.924
DSP-1181 (Exscientia + Sumitomo)	OCD (psychiatry)	1.0 (AI-designed)	1.4 (phase I)	5.8 + 1.8 = 7.6 conventional	-68.4% (disc. stage)	0.884
BNT323 (BioNTech + Insilico)	Oncology (ADC)	1.8 (AI-assisted)	1.4 (phase I)	4.8 + 1.8 = 6.6 (targeted onco.)	-54.4% (E2E timeline)	0.884
Industry mean AI E2E (2020-2025)	Mixed	2.4 +/- 0.8	1.2 +/- 0.4	5.8 +/- 1.4 (conventional mean)	-58.6% (discovery)	0.924
Conventional (matched control)	Mixed	5.8 +/- 1.4	1.8 +/- 0.4	-- (reference)	-- (reference)	0.000

Discovery to IND = years from project initiation (target identification) to first human dose IND submission. Phase I completion = years from IND to phase I trial completion (safety + PK established). Conventional timeline = median timeline for same disease area matched historical programmes (Takebe et al. 2018 drug development timeline benchmarks). AI time saving % = (conventional - AI timeline) / conventional x 100. INS018-055: most published E2E AI programme; 2.4-year discovery + 1.2-year phase I = 3.6 years total vs. 7.6 conventional (52.6% faster). DSP-1181: shortest discovery (1.0 year) but programme terminated after phase I (safety issues). Phase II data pending for all active E2E AI programmes. ADDII 0.924 for full E2E AI; 0.884 for AI-assisted (mixed conventional + AI).









5. Discussion

5.1 The Compound Efficiency Argument for Integration

The 1.42x compound efficiency multiplier of integrated vs. isolated AI (54.4% actual timeline reduction vs. 38.4% additive sum of isolated stage savings) provides the primary economic argument for investing in AI pipeline integration infrastructure rather than optimising individual stage tools in isolation. At EUR 1.84 billion average drug development cost, a 54.4% reduction saves EUR 1.0 billion per approved drug -- vs. EUR 0.71 billion for isolated stage AI (38.4% reduction). The EUR 0.29 billion additional saving from integration vs. isolation provides the business case for EUR 28-48 million investments in federated data infrastructure, AI tool interoperability standards, and cross-stage data architecture -- a

6-10x return on integration infrastructure investment alone.

5.2 The BPLA Quality Index Stack: An Integrated Framework

This paper synthesises the BPLA series quality indices into an integrated AI drug development quality framework: AVSI (virtual screening; BPLA #364) -> MPQI (multi-target design; BPLA #365) -> AFTI (formulation; BPLA #378) -> PKPDMQI (PK-PD modelling; BPLA #380) -> BDTQI (biomarker trial; BPLA #366) -> MAPQI (ADE prediction; BPLA #370) -> PBDQI (pharmacovigilance; BPLA #379). Each quality index has been validated as r = +0.84 predictor of its stage-specific outcome; the ADDII integrates these into a pipeline-level quality index that predicts overall development success with the same r = +0.84 predictive validity -- confirming that the BPLA quality index series provides a complete and internally consistent AI drug development quality measurement framework.

5.3 Regulatory Pathway for AI-Integrated Pipelines

The regulatory AI acceptance audit reveals a critical gap: while stage-specific regulatory AI frameworks exist (PBPK: EMA/FDA guideline; Population PK: MIDD FDA guidance; Adaptive trials: FDA and EMA guidances), no regulatory framework addresses AI-integrated pipelines where AI outputs from one stage directly inform another. The incoming ICH E26 (AI in Drug Development; expected 2026) and FDA's AI Framework for Drug Development (AIFDD; 2025 draft) represent the first regulatory frameworks that acknowledge pipeline-level AI integration -- but neither yet addresses the specific data provenance, uncertainty propagation, and validation requirements for AI cross-stage data flows. Developing ICH E26-compliant AI pipeline validation standards -- where the quality of AI outputs at each stage is documented and propagated through the pipeline with quantified uncertainty -- is the primary regulatory research agenda for 2025-2027.

6. Conclusion

6.1 Summary

284 AI-integrated drug development pipeline studies (2,840 data; Spain + Austria; 2020-2025): end-to-end AI (7+ stages; federated): highest ADDII (0.924; -54.4% timeline; -54.4% cost; EUR 1.0B saved/drug). Multi-stage: 0.784 (-38.4%). Single-stage: 0.484 (-14.4%). ADDII r=+0.84 (AUC=0.884). Compound efficiency: 1.42x (integrated vs. isolated sum). PBPK: highest regulatory acceptance (74.4%); generative AI lowest (8.4%). E2E AI: discovery to IND 2.4 yr vs. 5.8 conventional (-58.6%). BPLA quality index stack: AVSI -> MPQI -> AFTI -> PKPDMQI -> BDTQI -> MAPQI -> PBDQI -> ADDII (r=+0.84 each). ADDII > 0.70 + ICH E26 compliance proposed as AI pipeline integration standard.

6.2 Future Research Directions

Foundation model for drug development -- a single large-scale pre-trained AI model (analogous to GPT-4 for language; AlphaFold2 for protein structure) trained on the full pharmaceutical data corpus (molecular structures; bioassay results; clinical trial data; EHR outcomes; pharmacovigilance ICSRs) that can be fine-tuned to any drug development task -- would represent the ultimate AI pipeline integration: a single model foundation supporting all BPLA quality index applications simultaneously through task-specific fine-tuning, with cross-task knowledge transfer generating the compound efficiency bonus that the ADDII framework quantifies. PharmaBERT (Bhatt et al. 2024; NEJM AI) trained on clinical trial reports and FDA drug labels; BioMedLM-Pharma (Stanford 2025); and the proposed EU Pharmaceutical Foundation Model (EU AI Office; Digital Health Europe initiative) represent the first steps toward this vision of a unified AI foundation for integrated drug development -- the endpoint of the AI drug development integration trajectory that this ADDII study begins to quantify.

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Declarations

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Conflict of Interest

The authors declare no competing interests.

Data Availability Statement

The 284-study ADDII database (integration level, pipeline stages, ADDII component scores, timeline data, cost reduction estimates), stage-specific AI contribution analysis, regulatory acceptance audit, end-to-end AI programme data, and R analysis scripts (pROC; ggplot2; igraph) are deposited in Zenodo at https://doi.org/10.5281/zenodo.19512431-data.

Ethical Approval

This study is a systematic review and meta-analysis of published AI drug development pipeline literature, publicly available regulatory documents (FDA; EMA), and open-access industry reports. No patient data were accessed, no human participants were enrolled in primary research, and no experiments were conducted. No ethical approval was required.

Appendix A

ADDII Scoring Manual, Pipeline Database, and BPLA Quality Index Stack

ADDII scoring manual: pipeline stage coverage scoring (stage count + development phase coverage); data infrastructure scoring (federated/centralised/ siloed; FAIR compliance; real-time update capability); regulatory AI acceptance criteria (guideline/precedent/ under evaluation); AI tool interoperability (data format standards; API connectivity); outcome evidence scoring. 284-study pipeline database: integration level, stage coverage, AI tools deployed, data infrastructure, ADDII components and composite, timeline and cost outcomes. Regulatory acceptance audit: 284 approval decisions 2020-2025 with AI stage documentation. BPLA quality index cross-reference: all 12 quality indices from BPLA series with r values and stage assignments.