

Artificial Intelligence in Pharmaceutical Commercialization: Transforming Market Access, Customer Engagement, and Commercial Strategy

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DOI: [10.56201/ijhpr.vol.10.no8.2025.pg45.82](https://doi.org/10.56201/ijhpr.vol.10.no8.2025.pg45.82)

Abstract

Background. Artificial intelligence (AI) entered pharmaceutical research and development more than a decade ago, but its migration into the commercial function has been slower and less well documented. 2025 is widely described in industry literature as the year commercial AI moved from isolated pilots toward embedded infrastructure, driven by the convergence of generative and agentic model capability with acute commercial pressure from pricing reform, patent expiry, and constricting physician access.

Objective. This paper reviews and synthesizes the evidence on AI adoption across three commercial domains: market access and reimbursement, customer engagement, and enterprise commercial strategy. It assesses claimed value, the governance environment, and the structural reasons that reported deployment consistently outpaces reported return.

Methods. An integrative, narrative review of peer-reviewed literature, regulatory guidance documents, industry benchmarking surveys, consultancy analyses, and vendor product disclosures published through December 2025, with 2025 as the focal period.

Findings. Three findings recur across sources. First, the highest-confidence value in 2025 was realized not in autonomous decision-making but in compression of documentation-heavy workflows: medical, legal, and regulatory (MLR) content review, prior authorization case preparation, evidence dossier drafting, and field force administrative burden. Second, market access is undergoing a structural change that has attracted little scholarly attention: as payers themselves deploy AI in coverage policy development and utilization management, manufacturer evidence must increasingly be legible to algorithmic as well as human reviewers. Third, the binding constraint on value capture is not model capability but data infrastructure, particularly entity resolution across customer identifiers, and the absence of a governed semantic layer that encodes commercial business logic.

Conclusions. The regulatory perimeter for commercial AI in pharmaceuticals remains notably thin. The U.S. Food and Drug Administration's January 2025 draft guidance explicitly excludes operational and commercial uses, while horizontal instruments such as the EU AI Act impose transparency and risk obligations that most commercial organizations have not yet operationalized. This creates a governance gap in exactly the domain where deployment velocity is highest. A research agenda is proposed around measurement, algorithmic payer interaction, equity effects of predictive targeting, and the accountability architecture for agentic systems.

Keywords: *artificial intelligence; generative AI; agentic AI; pharmaceutical commercialization; market access; health economics and outcomes research; next best action; omnichannel engagement; prior authorization; AI governance*

1. Introduction

The commercial function in pharmaceuticals has absorbed sustained structural pressure for two decades. Field forces have contracted, physician access has tightened, portfolios have shifted from primary care blockbusters toward specialty and rare disease assets with concentrated prescriber bases, and the decision unit has migrated from the individual physician to integrated delivery networks, pharmacy benefit managers, and health technology assessment bodies. The underlying problem is familiar from health systems research: scientific innovation does not convert into patient outcomes without the delivery, financing, and access infrastructure to carry it (Ilodigwe & Adesemoye, 2019b), and commercialization is the principal mechanism of that conversion. In the United States, the Inflation Reduction Act added a further layer: the Medicare Part D redesign took effect on 1 January 2025, imposing a \$2,000 annual beneficiary out-of-pocket cap, eliminating the coverage gap, and shifting a share of catastrophic-phase liability onto manufacturers, with the first negotiated prices taking effect on 1 January 2026. These provisions sit within a longer arc of coverage expansion and provider payment reform whose effects on access and financial protection have been examined across health systems (Ilodigwe & Adesemoye, 2019a).

Against this backdrop, AI in pharmaceuticals has been studied overwhelmingly through the lens of discovery and development. Bibliometric attention concentrates on target identification, molecular generation, trial design, and pharmacovigilance. Market sizing reflects the same skew, with drug discovery accounting for roughly 41% of AI-in-pharmaceuticals revenue in 2024 and remaining the largest application segment through 2025 (Renub Research, 2025). Commercialization, which absorbs a comparable or larger share of operating expenditure at most large manufacturers, is comparatively under-examined in the scholarly record even as it becomes a primary site of enterprise AI investment.

This paper addresses that gap. It takes 2025 as its focal year because that period marks a qualitative shift in the character of deployment, and it is written from the close of that year. Prior to 2025, commercial AI in pharmaceuticals largely meant supervised machine learning applied to targeting and segmentation, plus a proliferation of generative pilots concentrated in content drafting. During 2025, three things changed simultaneously: agentic architectures became commercially available inside the regulated platforms that pharmaceutical commercial teams already use; payers began deploying AI on the other side of the access negotiation; and the regulatory environment began to acquire structure, though not, importantly, in the commercial domain itself.

Three research questions organize the review:

RQ1. Where in the commercialization value chain did AI generate documented, as opposed to projected, value during 2025?

RQ2. How does the diffusion of AI among payers and other access gatekeepers alter the strategic requirements placed on manufacturers?

RQ3. What governance architecture is required for commercial AI, given that the principal pharmaceutical AI guidance instruments explicitly exclude commercial and operational applications from scope?

2. Background: The 2025 Commercial Environment

2.1 Economic pressure

The commercial context of 2025 was defined by margin compression from several directions at once. IRA price negotiation, gross-to-net erosion, aggressive PBM contracting, and a heavy near-term patent cliff combined to raise the value of each incremental prescription retained and each dollar of commercial spend redirected. Analyses of IRA impact have projected material revenue reductions across the sector through the late 2030s, with corresponding effects on approval volumes, though such projections carry wide methodological uncertainty and are contested (ConnectiveRx, n.d.). The relevant point for this review is directional rather than numerical. When revenue per unit is constrained by policy, commercial advantage shifts from price and share-of-voice toward execution efficiency: speed of content deployment, precision of resource allocation, and reduction of leakage between prescription written and prescription filled. Each of these is a plausible target for AI, which partly explains why commercial AI investment accelerated precisely as commercial budgets tightened. Work on pharmaceutical supply chain governance and medicine affordability reaches a compatible conclusion from the access side, finding that the constraint on therapy reaching patients is increasingly systemic rather than clinical, spanning financing, distribution, and coordination failures (Asiedu, 2025; Eze et al., 2023).

2.2 Access constriction and channel fragmentation

Physician access continued to narrow through restrictive health system policies and no-see practices, while promotional content volume expanded across an increasingly fragmented channel mix spanning field, email, portal, search, connected television, and social formats. Industry reporting through 2025 described promotional material production rising sharply year over year while a large majority of approved content was rarely or never deployed by field teams. This combination, rising production alongside low utilization, indicates a content supply chain optimized for volume rather than for match between asset and moment. It is an important framing for Section 6: much of what AI achieved in 2025 was not creating more content but reducing the cost and cycle time of a system already producing more content than it could deploy.

2.3 Technological inflection

Two capability shifts distinguish 2025 from prior years. The first is the maturation of large language models sufficient to operate over regulated document corpora with citation traceability, enabling application to claims substantiation, reference matching, and dossier drafting. The second is the arrival of agentic architectures inside validated life sciences platforms rather than as external experiments (SDG Group, 2025). Veeva announced AI agents in October 2025 and launched agents for Vault CRM and PromoMats in December 2025, with additional functional agents announced for subsequent release. IQVIA released field force and market insight agents in the same period, following an August 2025 partnership with Veeva enabling integration of IQVIA data into Veeva platforms (IntuitionLabs, 2025; IQVIA, 2025). The significance of this is architectural rather than merely commercial: agents operating natively against a validated data model inherit the platform's audit, entitlement, and access controls, which is a materially different compliance posture from a general-purpose assistant operating on exported data.

3. Methodology

This paper is an integrative narrative review rather than a systematic review, and its methodological limits should be read accordingly.

Scope. Sources published through December 2025, with priority given to material describing calendar year 2025 activity. Because the review closes at the end of the focal year, developments after December 2025 are outside its evidentiary scope, and claims about the trajectory of 2026 are stated as expectations rather than findings.

Source classes. Four classes were used, with differing evidentiary weight assigned to each:

1. *Regulatory and statutory instruments* (FDA draft guidance, EMA reflection papers, EU AI Act, CMS rules). Treated as primary and authoritative for questions of obligation.
2. *Peer-reviewed literature*, including critical reviews of regulatory guidance and systematic reviews of generative AI in healthcare. Treated as primary for methodological and ethical claims.
3. *Industry benchmarking surveys* from consultancies and analytics vendors. Treated as indicative, with sample sizes and sponsorship noted where disclosed. Several widely cited surveys in this domain rest on samples of a few dozen executives.
4. *Vendor and consultancy value claims*. Treated as hypotheses about achievable value rather than as evidence of realized value, given commercial interest in the outcome.
5. *Adjacent applied literature* on marketing analytics and automation, health system strategy and transformation, pharmaceutical regulatory science, and AI governance. Used for conceptual framing and causal mechanism rather than for sector-specific fact, on the reasoning that several of the problems examined here appear in more developed form in neighbouring regulated settings. Roughly four fifths of the works cited in this paper come from this class. Where such work is used, the claim being supported is a mechanism claim rather than a sector claim: that a described failure mode, control, or measurement difficulty is structural and should therefore be expected to recur in pharmaceutical commercialization, not that a finding obtained elsewhere holds numerically here.

Analytical approach. Sources were mapped onto a three-domain framework (market access, customer engagement, commercial strategy) and a three-layer capability stack (data foundation, intelligence layer, orchestration layer). Claims were then classified by evidentiary status: documented outcome, reported adoption, or projected value.

Principal limitations. Much of the available material is grey literature produced by parties with a commercial interest in AI adoption. Independent, controlled evaluation of commercial AI interventions in pharmaceuticals is close to absent from the published record, in part because manufacturers treat commercial performance data as competitively sensitive. Selection bias toward successful deployments is likely and should be assumed throughout. Figures reported in Sections 5 through 8 are attributed to their sources and should not be read as independently verified.

4. Conceptual Framework

4.1 The three-layer stack

Analysis of the 2025 deployment record suggests that outcomes correlate less with model sophistication than with the maturity of the layers beneath it.

Layer 1: Data foundation. Entity resolution, reference data, consent and privacy controls, and lineage. The recurring failure mode described across sources is identity fragmentation: the same prescriber appearing under inconsistent name forms across CRM, claims, and digital engagement data, sometimes under multiple national provider identifiers issued through different vendors. Where identity cannot be resolved reliably, every downstream calculation, from targeting to attribution to incentive compensation, inherits the error. This is not a pharmaceutical-specific pathology. Health system data architecture research identifies interoperability, data quality, and

governance as the precondition for any advanced analytics capability operating at national scale (Ilodigwe & Adesemoye, 2021), and platform-level analysis of CRM in regulated healthcare environments locates failure in integration design and governance rather than in application functionality (Badmus et al., 2019a, 2019b).

Layer 2: Intelligence layer. Analytics-ready data products and, critically, an encoded semantic layer that captures commercial business logic: what a tier change implies for prescribing, what constitutes adequate reach, how to adjust for payer mix, how territories map to health systems. One reported evaluation found that supplying an LLM with proper business context moved accuracy on complex commercial questions from single digits to approximately 80%. If robust, this finding relocates the performance problem from the model to the context supplied to it. Related work on marketing analytics governance makes the same point from the executive side, arguing that decision quality depends on how compliance and risk logic is encoded within the analytical layer rather than applied to its outputs after the fact (Sanni, Iwuanyanwu, et al., 2022).

Layer 3: Orchestration layer. Decisioning and execution, including next best action engines, omnichannel sequencing, and agentic workflows that take action rather than only recommending it. The architectural consequences of this shift have been argued directly in the product marketing literature, which holds that autonomous agents dissolve the interface through which customers were historically reached and therefore demand a different design object rather than an incremental redesign of the existing one (Ogundairo & Ayivi-Donkor, 2024b).

The practical implication is that organizations investing at Layer 3 while Layers 1 and 2 remain immature will produce fluent recommendations grounded in unreliable inputs. This is a plausible mechanism for the widely reported finding, circulating in enterprise technology analysis through 2025, that the large majority of enterprise generative AI pilots fail to reach production value. That claim has been repeated more often than it has been interrogated, and its methodology deserves scrutiny, but the direction is consistent with the implementation literature. That literature converges on a specific diagnosis: initiatives fail less from technical inadequacy than from an adoption gap between what a system can do and what the organization is configured to absorb (Ogundairo & Ayivi-Donkor, 2024a), and organizational readiness rather than technology access is the variable that separates institutions realizing value from those running perpetual pilots (Afrihyia et al., 2025).

4.2 Three modes of AI participation

It is useful to distinguish three modes, because they carry different governance requirements:

- **Augmentation.** AI produces a draft or a summary; a qualified human decides. Most 2025 commercial value falls here, consistent with clinical-side analyses framing near-term AI gain as amplification of expert capacity rather than substitution for it (Ilodigwe & Adesemoye, 2025a). Human-in-the-loop research supplies the design vocabulary for this mode, including the annotation and review workflows through which human judgment is applied to generative output (Ladapo et al., 2022; Ladapo et al., 2024).
- **Recommendation.** AI ranks or prioritizes; a human executes. Next best action and dynamic targeting sit here.
- **Execution.** AI takes action within defined boundaries. Agentic systems in benefit verification, case triage, and content pre-check began moving here during 2025.

The governance literature is well developed for augmentation and thinly developed for execution, which is where deployment velocity was highest by late 2025. Legal scholarship on algorithmic accountability anticipates the difficulty, observing that responsibility for automated output becomes hardest to locate precisely where proprietary protection limits inspection of the system that produced it (Annan, 2024).

4.4 The data foundation in practice: platforms, identity, and classification

Section 4.1 identified the data foundation as the binding constraint. It is worth being concrete about what that foundation consists of, because the commercial data estate in a pharmaceutical company is a regulated estate rather than a general enterprise one, and the applied literature on enterprise data governance is more developed than the pharmaceutical commercial literature that depends on it. Four capabilities recur. The first is sensitivity classification with regulatory traceability, so that every field carries a machine-readable statement of what it is, where it came from, and what may lawfully be done with it (Aliliele et al., 2024a). Without this, privacy obligations must be enforced at the point of use by human judgment, which does not scale to agentic systems acting on the estate. The second is an architecture designed for protected health information from the outset rather than adapted to it, a requirement examined in detail for community health analytics and directly transferable to patient support and hub operations (Aliliele et al., 2024b). The third is identity and access governance across hybrid and multi-cloud environments, since the commercial estate is rarely consolidated in one platform and access decisions have to be consistent across all of them (Mbonu et al., 2020). The fourth is a control layer that is itself automated, since manual attestation cannot keep pace with the volume of AI-generated activity; work on AI-enabled general controls and audit automation, and on continuous auditing in technology risk oversight, describes the mechanism (Mbonu et al., 2022; Aliliele et al., 2025a). Underlying all four is a legal and ethical risk model for data protection governance that treats obligation as a design input rather than a compliance review stage (Mbonu et al., 2018), and an awareness that data protection regimes differ materially across the jurisdictions in which a global commercial organization operates (Mbonu et al., 2019). Configuration drift and interface sprawl are the two most common ways these controls fail in practice, which is why continuous misconfiguration monitoring and formal API governance appear consistently in the enterprise risk literature (Aliliele et al., 2023a; Aliliele et al., 2023b).

At the platform layer, the commercial systems that hold this data are CRM and content platforms rather than clinical systems, and their governance has been examined specifically for regulated healthcare settings (Badmus et al., 2019b). Integration design determines whether customer identity resolves at all (Badmus et al., 2019a; Badmus et al., 2022b), release governance determines whether a validated system stays validated as it changes (Badmus et al., 2018; Badmus et al., 2022a), and privacy-by-design role-based architecture determines whether the least-privilege principle survives contact with commercial urgency (Badmus et al., 2024). The most directly relevant recent work addresses governance frameworks for AI-assisted CRM workflows, including agentic deployment, risk management, and the control questions raised when an assistant acts inside the customer record rather than beside it (Badmus et al., 2025), alongside comparative analysis of the deployment tooling that determines how safely such systems can be changed (Badmus et al., 2020). Two further disciplines are usually treated as unrelated to commercial AI and should not be. Service management determines whether the systems field teams depend on are reliable enough to be trusted, and the IT service management literature documents both the benefits and the recurring implementation failures (Ladapo et al., 2023b; Ladapo et al., 2023a). Migration decisions determine what is possible: much of the pharmaceutical commercial estate moved to

cloud infrastructure only recently, and the lessons from that migration constrain what AI can be deployed against it (Ladapo et al., 2025).

4.5 Security and resilience of the commercial data estate

Commercial AI concentrates sensitive data. Prescriber-level engagement records, patient support case files, payer contract terms, and pricing models are assembled into unified estates precisely so that models can operate across them, and that consolidation raises the consequence of compromise. The security literature on healthcare environments is directly applicable and rarely cited in commercial AI discussions. Three findings matter for the commercial function. Investment in security correlates with financial performance rather than trading against it, which reframes the budget argument that commercial leaders typically lose (Ozowara et al., 2022). Ransomware economics in healthcare networks illustrate the asymmetry between prevention cost and disruption cost (Ozowara et al., 2025), and cyber risk pricing models for health technology platforms provide a way to express that asymmetry in terms a commercial organization already uses (Adebayo et al., 2023). Architecturally, zero trust models have been assessed specifically for cost effectiveness in healthcare infrastructure (Adebayo et al., 2025), and compliance-driven network design for HIPAA and HITRUST alignment describes the operating constraints under which commercial systems holding patient data must run (Ozowara et al., 2022). Where data must cross organizational or national boundaries, as it does in global commercial operations, distributed ledger approaches to exchange and regulatory transparency offer one structural answer (Kumuyi et al., 2023). For governance, the useful contributions are those that translate security posture into executive decisions: quantification of cyber risk for investment prioritization (Dosunmu & Ogundele, 2024b), continuous validation of controls in regulated digital infrastructure rather than periodic testing (Dosunmu & Ogundele, 2024c), and performance measurement frameworks designed for board-level oversight (Dosunmu & Ogundele, 2025b). Comparable architectures developed for critical infrastructure show how risk quantification and zero trust principles operate where consequence is high and downtime is unacceptable (Adegbite et al., 2025; Ahmed et al., 2021), and the broader literature on cybersecurity governance frameworks addresses how such controls are selected and justified (Jimoh et al., 2023). The human layer is the one commercial organization most often neglect. Field and marketing personnel handle sensitive data under time pressure on mobile devices, and evidence on awareness training and insider-threat behaviour indicates that targeted capability building for non-technical staff, rather than generic training, is what shifts behaviour (Onche et al., 2024).

5. Market Access: The Under-Examined Frontier

5.1 Why market access is the highest-leverage domain

Market access determines whether a therapy reaches patients at all. It is also, of the three domains, the one where AI adoption is most consequential and least studied. Three characteristics make it structurally attractive for AI: the work is document-dense, the decision environment is adversarial, and the counterparty is itself automating. It is also the point at which commercial performance and patient access coincide, since supply chain inefficiency, affordability failure, and coverage friction all terminate in the same outcome of therapy not reaching the patient (Asiedu & Asiedu, 2023b; Asiedu, 2025).

5.2 Payer-side adoption and the emergence of algorithmic readers

The most strategically significant development of 2025 in this domain occurred on the payer side rather than the manufacturer side. Research from 2025 characterized payers as moving from preliminary discussion toward active application of AI in automated data retrieval, competitive analysis, and initial screening within prior authorization review, with further use anticipated in coverage policy drafting, utilization trend analysis, and formulary design. The direction of travel through the focal year is clear even though the endpoint is not yet observable.

This inverts a long-standing assumption in access strategy. Value dossiers, budget impact models, and health economic analyses have historically been written for a human pharmacy and therapeutics committee reviewer working under time pressure. If a growing share of first-pass evidence review is performed or assisted by machine, then discoverability, structural consistency, and machine parseability become access variables in their own right.

The practical implications identified in the access literature are concrete. Clinical publications should use consistent terminology, standardized endpoints, and clearly defined outcome measures. Economic models should carry transparent assumptions, reproducible methods, and complete documentation. Dossiers should present findings through structured headings, standardized tables, and clear reference linkage rather than burying key results inside narrative sections. None of this is novel good practice. What is new is that it now carries a direct access consequence, and that it requires alignment across medical affairs, HEOR, regulatory, and commercial functions that in many organizations still operate as parallel silos. For manufacturers operating across jurisdictions the burden compounds, since the same evidence base must satisfy divergent national requirements simultaneously, a problem that regulatory harmonization frameworks address structurally rather than submission by submission (Eze et al., 2024a).

This suggests a proposition worth empirical testing:

P1. As payer-side AI-assisted review increases, the structural machine-legibility of a manufacturer's evidence base becomes a statistically significant predictor of formulary outcome, independent of the underlying clinical and economic evidence quality.

To the author's knowledge, no published study tests this. It is testable, using formulary decisions as the outcome and structural features of submitted dossiers as the predictor.

5.3 Prior authorization and patient access

Prior authorization is where access friction converts most directly into lost revenue and lost therapy. Published analyses of Medicare Advantage utilization management report tens of millions of prior authorization determinations annually, a single-digit percentage denied in full or in part, and a large majority of appealed denials subsequently overturned. The last observation is the operationally important one. When most appealed denials are reversed, the initial denial is functioning less as a clinical judgment than as an administrative filter, and the capability that matters commercially is the ability to prepare and pursue appeals efficiently.

Administrative burden on the provider side compounds the problem. Survey data indicates physicians and staff spend on the order of 13 hours per week handling roughly 39 prior authorization requests per physician, with a manual authorization call averaging around 24 minutes. Consultancy estimates through 2025 suggested that a substantial majority of that manual task volume is automatable. Capital followed. Disclosed venture investment directed at prior authorization automation grew by roughly an order of magnitude between 2024 and 2025, within a healthcare AI funding environment that expanded several-fold over the same period. The

cautionary precedent is the 2023 collapse of a heavily capitalized healthcare administrative automation company whose systems could not absorb real workflow complexity. That history recommends interpretive discipline: transaction volume processed is not the same as outcome improved. For manufacturers, the commercial return sits in field reimbursement capability. Teams equipped with payer-specific documentation requirements, real-time authorization status, and AI-assisted case preparation generate measurable return in prescriptions recovered from abandonment. This is one of the clearer instances in the 2025 record where AI value is directly attributable to revenue rather than to productivity proxies. The mechanism is analogous to funnel leakage analysis in other high-value sectors, where the largest recoverable value sits not in generating additional demand but in preventing the loss of demand already generated (Sanni & Wedraogo, 2024). The clinical equivalent of that loss is discontinuity of therapy, which carries consequences well beyond the commercial (Asiedu & Asiedu, 2024a).

5.4 HEOR, evidence generation, and dossier development

Generative AI in HEOR settled during 2025 into a defensible set of applications: literature synthesis, evidence gap identification, drafting of dossier sections and value narratives, scenario modeling, and structured content workflows. This is continuous with a broader movement toward real-world evidence and predictive analytics as routine inputs to health system decision-making rather than as specialist outputs (Ilodigwe & Adesemoye, 2024a). Comparative cost-effectiveness modelling in adjacent pharmaceutical contexts illustrates the methodological demands such analyses place on data quality and assumption transparency (Asiedu & Asiedu, 2023a). Benchmarking of real-world evidence practice found that nearly all surveyed biopharma leaders planned to increase real-world data and evidence investment over the following two to three years, and that roughly 80% expected generative AI to significantly reshape evidence generation within twelve months (Deloitte, 2025). Reported barriers were data privacy and security, a shortage of hybrid expertise combining evidence methodology with AI literacy, and regulatory uncertainty. The sample was small, at 25 global leaders, and the results should be read as indicative of sentiment rather than of practice. The access literature is appropriately more skeptical about a second class of claims: that AI can replace primary payer research, independently predict payer behavior, or automate high-stakes coverage decisions without human oversight. Payers evaluate products through several simultaneous lenses including clinical value, comparative evidence, budget impact, utilization risk, operational feasibility, policy precedent, and regulatory context. Modeling that decision function from historical formulary outcomes is an inference problem with limited, noisy, and non-stationary training data. Skepticism here is methodologically warranted, not merely conservative. Regulatory science offers a useful framing for the underlying tradeoff, treating speed, safety, and evidence quality as jointly optimized under explicit risk tiering rather than independently maximized (Eze et al., 2024b).

5.5 Site of care, diagnostics, and the formation of demand

Market access analysis usually begins at the point where a prescription meets a formulary. That framing omits the stage at which demand is formed, which is diagnosis, and diagnosis is constrained by physical and organizational infrastructure that varies enormously across markets. The infrastructure literature makes the mechanism explicit. Diagnostic laboratory capacity functions as a public health intervention in its own right (Aminu-Ibrahim & Ogbete, 2023), infrastructure investment expands diagnostic access in underserved and rural regions where undiagnosed prevalence is highest (Aminu-Ibrahim et al., 2020), and translating that investment

into measurable population health and diagnostic outcomes requires deliberate measurement rather than assumption (Ogbete & Aminu-Ibrahim, 2024). Molecular diagnostic capacity in particular is the gating factor for precision therapies, and scaling it depends on standardized infrastructure and operational design rather than on individual site excellence (Ogbete et al., 2019). Diagnostic workflow integration across microbiology, virology, and serology determines how quickly a patient moves from presentation to a treatable diagnosis (Asiedu, 2023), and advances in molecular quantification methods illustrate how diagnostic precision reshapes the definition of the treatable population (Asiedu, 2024). For commercial strategy this has a specific implication. A therapy's addressable population is not a fixed epidemiological quantity but a function of diagnostic capacity, which means that AI-driven patient-finding and undiagnosed-population modelling operate on a base that infrastructure decisions are actively changing. Work on AI-driven early detection systems for non-communicable disease sits precisely at this junction (Afrihyia et al., 2023). Therapeutic area evidence anchors the same point clinically. In hypertension, where guideline-directed therapy is well established and the commercial question is persistence rather than awareness, epidemiological work documents both the scale of undiagnosed and uncontrolled disease and the risk stratification tools that identify who benefits most from intensification (Abah et al., 2025; Amadi et al., 2025). Where existing therapy fails, the population that remains is defined by phenotype rather than by diagnosis alone, which is the situation in resistant hypertension and the reason phenotype-stratified evidence is becoming a commercial as well as a clinical requirement (Abah et al., 2025).

6. Customer Engagement: From Personalization to Orchestration

6.1 Next best action and the persistent gap between adoption and effect

Next best action has been the flagship commercial AI application in pharmaceuticals for the better part of a decade, and its record is instructive. Benchmarking of customer engagement planning found adoption of dynamic targeting among large pharmaceutical companies rising from 17% in 2023 to 25% in 2024 (Axtia, 2025). That is meaningful growth, and it is also a reminder that three quarters of large manufacturers were not yet doing this at the point when the industry narrative had already moved on to agentic AI. The failure analysis is consistent across sources and returns to the layered framework in Section 4. Programs fail because targeting runs on stale deciles and unreliable prescriber identity rather than because ranking algorithms are inadequate. Where the customer graph cannot link an HCP across CRM, claims, and digital data, reach and frequency metrics, territory performance, and incentive compensation all inherit the defect. The commercially relevant asymmetry is stark: a small minority of prescribers drives the large majority of prescriptions in most therapeutic areas, so errors in identifying and maintaining that set are disproportionately costly. Predictive segmentation research in other regulated professional sectors reports the same pattern, tracing targeting inefficiency to input quality and identity resolution rather than to the segmentation method itself (Atima et al., 2022; Basnet et al., 2021), and lifecycle framing treats acquisition and retention as one continuous problem rather than two sequential ones (Ogundairo & Ayivi-Donkor, 2023a). Differentiation research in regulated professional markets is a further caution, finding that positioning failures are frequently mistaken for targeting failures (Sanni et al., 2020b), and product management research on staged commercial rollouts shows what coordination across channels requires operationally (Sanni et al., 2020c).

Where next best action does work, the 2025 pattern shows four consistent use case clusters: predictive HCP targeting maintained continuously rather than annually, territory design and quota fairness, contextual coaching for representatives, and rep-controlled rather than system-imposed

omnichannel sequencing. The final point is behavioral rather than technical. Recommendations that arrive as directives are widely ignored by experienced field personnel; recommendations that arrive as explained options with visible reasoning are more readily adopted. Explainability functions here as an adoption mechanism, not only as a compliance requirement. Design work on explainable marketing automation architectures for healthcare and financial applications treats this dual function as a first-class requirement, since in regulated settings the explanation must serve the user and the auditor at once (Sanni, Iwuanyanwu, et al., 2025).

6.2 Field force augmentation and agentic assistance

Deployment during 2025 concentrated on removing administrative load. Reported agent functions included extraction of structured signals from free-text call notes, pre-call preparation assembling relevant content and history for a specific prescriber, and voice capture of meeting summaries (Pharmaphorum, 2025). Consultancy analysis through 2025 projected multi-billion-dollar cumulative value for a large biopharma company over a five-year horizon, with cost savings compounding materially by the third year. Such figures originate with firms that sell implementation services and should be treated as upper-bound hypotheses. The mechanism it proposes, however, is plausible and modest: representatives currently spend a substantial share of working hours on administration and data reconciliation, and reallocating that time toward customer interaction is a productivity gain that requires no assumption of superhuman model performance. Realizing it depends on platform-level governance, because field-facing systems in regulated healthcare environments carry entitlement, privacy, and audit obligations that constrain what may be surfaced to a representative and when (Badmus et al., 2019b), and on decision support designed around operational resource constraints rather than around whatever data happens to be available (Adelanwa et al., n.d.).

6.3 The content supply chain and MLR review

The MLR bottleneck is where the commercial content system and the compliance system collide, and it may be the clearest 2025 case of AI value.

The baseline is poor. Mid-sized and large manufacturers report MLR review cycles frequently extending to several weeks per content item (Indegene, 2025). Content volume is rising, regulatory scrutiny of promotional material has intensified, and direct-to-consumer television and digital investment has grown, amplifying both reach and compliance exposure. Meanwhile, as noted in Section 2, most approved content is never meaningfully used.

AI intervention in 2025 took three forms. First, upstream constraint: encoding master claims, approved references, and regional code requirements as machine-readable ground truth, so that drafts, whether human or machine generated, are constrained at creation rather than corrected at review. Second, automated pre-check: citation matching, claim-to-reference verification, fair balance checks, and quantitative consistency checks executed before human review begins. Third, risk-based tiering: routing low-risk material through systematic checks while reserving reviewer attention for high-risk and novel content. Comparable architectures in other compliance-heavy sectors implement this as adaptive control, with automation operating inside continuously enforced regulatory boundaries rather than being inspected after the fact (Sanni, Iwuanyanwu et al., 2022), and with content optimization treated as a constrained rather than an open generation problem (Sanni & Attah, 2023b). Reported cycle time reductions in the range of 40% to 60% appear across implementation accounts, and comparable reductions have been claimed for regulatory submission preparation in adjacent document-heavy workflows.

Two caveats are essential. First, these are vendor-reported figures from selected implementations and lack independent replication. Second, and more consequential, accelerating content generation without a corresponding change in deployment discipline expands a queue that is already overproducing relative to field utilization. Practitioner commentary makes this point directly: if generation accelerates faster than review capacity and deployment discipline, AI worsens the underlying pathology while improving its most visible symptom.

The structural insight from the MLR literature deserves emphasis because it generalizes beyond content. The correct role for the compliance function in an AI-enabled system is not reviewing more output faster. It is architecting the governance framework so that reviewer expertise is encoded into the system itself, constraining every draft at the point of creation, and reserving human judgment for genuinely novel and high-risk cases (Indegene, 2025). This is a shift from review as inspection to review as system design. Operationalizing it requires lifecycle-level observability, so that each asset carries a traceable record of how it was generated, what constrained it, and who approved it (Sanni et al., 2025). Cryptographic approaches to workflow verification offer one mechanism for making that record tamper-evident across organizational boundaries (Sanni et al., 2024).

6.4 Patient engagement and support services

Patient support is where commercialization touches adherence, persistence, and outcomes, and it faced acute pressure during 2025 from IRA implementation. Programme trend research through 2025 found copay assistance remaining the most utilized offering, followed by broader affordability programmes and dedicated account support, alongside a shift away from third-party hub vendors as manufacturers brought operations in-house to control patient data and journey management. Survey evidence over the same period indicated that only a small minority of pharmaceutical executives considered themselves well prepared to adapt affordability programmes to the new policy conditions introduced by Medicare price setting and out-of-pocket caps (ConnectiveRx, n.d.). AI applications here include benefit verification automation, predictive identification of patients at risk of abandonment or non-persistence, intelligent case triage, and support for enrollment in payment-smoothing mechanisms. The governance stakes are higher than elsewhere in commercialization because the data is patient-level protected health information and the decisions affect individual therapy access. Practitioner analysis makes the appropriate distinction: sustained return in patient services comes from implementation discipline, data governance, and outcome improvement rather than from headcount reduction, and organizations that treat AI in patient support primarily as a cost lever tend to capture the smaller and less durable share of available value. The access literature supports this reading. Pharmacy-led and community-level delivery models improve availability where system coordination rather than product supply is the binding constraint (Ilodigwe & Adesemoye, 2020), and continuity of therapy in chronic disease depends on structural continuity of coverage and care coordination rather than on patient motivation alone (Asiedu & Asiedu, 2024a). Handling patient-level data at this scale further requires privacy-preserving governance designed in at the architectural level rather than appended as policy (Afrihyia, Ojukwu et al., 2024). Support programs also intersect with medication safety, since the point at which a patient is enrolled and reviewed is an opportunity for interaction screening that commercial programs rarely instrument (Asiedu, 2022).

An equity concern arises here that the commercial literature has largely not addressed. Predictive models that allocate scarce support resources by likelihood of persistence will, if trained on historical utilization, systematically deprioritize populations whose historical non-persistence was

itself a product of access barriers. This is a well-characterized failure mode in clinical prediction, and there is no reason to expect commercial models to be immune. It is a live and under-examined risk. Distributional analyses of medicine access make the concern concrete: the populations most likely to be scored as low-persistence are frequently those facing last-mile distribution and affordability barriers, which a model trained on outcomes alone will read as behavioural (Asiedu & Asiedu, 2022).

6.5 Patient-facing channels, health literacy, and the personalization analogue

Most of Section 6 concerns engagement with healthcare professionals. Patient-facing channels raise a different set of questions, and the relevant applied evidence sits largely in digital health and educational technology rather than in pharmaceutical marketing.

Telehealth research identifies the variables that determine whether patients accept AI-mediated interaction at all, namely trust, privacy assurance, and visible regulatory governance (Akintola et al., 2025). These are not communication problems solved by better messaging; they are design constraints. Work on data governance in digital health learning systems and on privacy and safeguarding in healthcare educational technology describes what compliant handling looks like in practice when the audience is patients rather than professionals (Orise & Niniola, 2025; Orise & Niniola, 2023). The personalization analogue is instructive and largely unexploited in pharmaceutical commercial work. Adaptive and AI-personalized learning systems face the same core problem as patient education programs: adapting content to an individual's prior knowledge, language, and context without losing fidelity to the underlying material (Orise & Niniola, 2020; Seun et al., 2024). Evidence on real-time analytics for performance dashboards in health professional training shows how engagement signals can be used to adjust delivery rather than merely to report on it (Orise & Niniola, 2022), and data-driven approaches to progress monitoring demonstrate the same principle applied to individual trajectories (Yeboah et al., 2022). Capability on the delivery side matters as much as system design, since professional development determines whether personalized tools are used as intended (Yeboah et al., 2019).

Two cautions come from the same literature. Digital equity research in healthcare education documents systematic exclusion of underrepresented learners from digitally delivered programs (Orise & Niniola, 2024), which should be expected to recur in digitally delivered patient support. And work on trauma-informed frameworks for adolescents in underserved communities is a reminder that engagement optimization is not neutral when the audience is vulnerable (Akinse, Ohanebo et al., 2023). Health professional education is itself being restructured by these technologies, which changes the knowledge base that commercial and medical teams engage with (Orise & Niniola, 2025).

7. Commercial Strategy: Planning, Allocation, and Operating Model

7.1 Launch strategy and forecasting

Launch is the highest-variance commercial event, and the 2025 access literature converges on a specific reframing: market access should be treated as a launch input rather than a launch output. Organizations succeeding at formulary negotiation are those that embedded access strategy into Phase III design, selecting comparators, endpoints, and economic evidence to address anticipated formulary objections. By approval, the HEOR dossier, budget impact model, and payer value narrative are built and refined rather than being assembled retroactively.

AI contributes to this in a specific way that is often mischaracterized. Its value is less in improving point forecast accuracy, where the sparse-data problem is severe for novel mechanisms, and more

in expanding the number of scenarios that can be modeled at reasonable cost. This shifts the planning artifact from a single expected trajectory to a set of contingency-mapped scenarios with defined trigger conditions, which is a different and arguably more useful epistemic object. Forecasting research in volatile service environments supports the reframing, treating the objective as characterizing uncertainty rather than eliminating it (Wedraogo & Sanni, 2024; Tonoyan et al., 2021a). Go-to-market planning under compliance constraints benefits similarly from analytics designed to surface regulatory dependencies early rather than to optimize a single trajectory (Sanni & Atima, 2021a), and structured readiness assessment offers a mechanism for exposing those dependencies before launch rather than during it (Eze et al., 2022b). Market research frameworks addressing entry barriers in regulated sectors describe how those barriers are identified systematically rather than discovered on contact (Sanni & Attah, 2023c). Supply continuity is the neglected complement, since a launch trajectory is only as reliable as the availability of the product behind it, and early warning models for shortage risk address a failure mode that commercial forecasting typically treats as exogenous (Eze et al., 2022a).

7.2 Pricing, contracting, and gross-to-net

Global pricing under international reference pricing constraints, launch sequencing, and contract simulation are computationally demanding problems where AI-assisted modeling is straightforwardly useful. Specialized platforms now cover pricing and access intelligence across a hundred or more markets, including reference pricing modeling and policy tracking. In the United States, gross-to-net modeling under IRA conditions, with negotiated prices, the redesigned Part D benefit, and manufacturer catastrophic-phase liability interacting, exceeds practical spreadsheet-based analysis. A boundary condition is worth stating explicitly. Pricing decisions carry legal, ethical, and reputational weight that places them firmly outside the range of appropriate automation. AI belongs in the analysis, not in the decision. The same holds for outcomes-based contracting, where the governing design question is incentive alignment between payer and manufacturer rather than computational sophistication (Ilodigwe & Adesemoye, 2024a).

7.3 Resource allocation and the operating model question

Commercial resource allocation, spanning field size and structure, channel mix, and promotional investment by segment, is a constrained optimization problem with feedback effects, and is among the more tractable applications. The harder question is organizational.

The 2025 record suggests that commercial AI capability does not sit comfortably in any single existing function. Market access owns payer relationships but has historically lacked deep quantitative capability, which resided in separate data science or IT groups. HEOR, market access, and commercial analytics frequently operate in parallel rather than in genuine collaboration, producing the familiar failure in which methodologically sound evidence is never used in negotiation because it did not address what the payer would actually ask (IntuitionLabs, 2025). AI does not solve this coordination failure. It raises its cost, because a model trained or prompted on one function's view of the customer will produce recommendations that another function cannot act on. The organizational patterns associated with value capture in the general AI adoption literature apply with force here: demonstrated senior leadership ownership, defined processes specifying when and how model outputs require human validation, and agile delivery capability. These are management variables, not technical ones, and they distinguish high performers more reliably than model selection does (McKinsey & Company, 2024). Evidence from large-scale health system transformation programs points the same way, locating success in change execution,

operating discipline, and workforce capability rather than in the technology selected (Ilodigwe & Adesemoye, 2024b, 2025b). Transformation research in other heavily regulated sectors reports the same pattern, with operational and stakeholder complexity rather than technical difficulty determining outcome (Sanni & Attah, 2023a).

7.4 Agentic AI and the accountability question

The move from recommendation to execution is the defining architectural shift of late 2025, and it raises an accountability question that current governance frameworks do not resolve.

When an agent autonomously assembles a prior authorization appeal, drafts a payer-facing communication, or sequences an engagement journey, responsibility for the output is distributed across the model developer, the platform vendor, the deploying organization, and the individual whose role the agent supports. Pharmaceutical compliance frameworks are built around identifiable human accountability for regulated communications. Agentic execution does not fit that architecture cleanly, and the focal year closed with the technology deployed and the accountability model unresolved. This is, in the author's assessment, the most significant open governance problem in commercial pharmaceutical AI. Two adjacent legal questions compound it. Responsibility for algorithmic output is difficult to assign when a system's internals are protected as proprietary (Annan, 2024), and ownership and authorship of AI-generated material remain unsettled, which bears directly on promotional assets whose provenance must be defensible under enforcement (Annan, 2023)

7.5 Channel, distribution, and supply continuity as commercial variables

Commercial strategy conventionally treats supply as a given. The 2025 environment does not support that assumption, and the supply chain literature offers the mechanisms that commercial planning omits. Three commercially consequential findings recur. First, demand forecasting and inventory positioning are one problem rather than two, and predictive models that treat them jointly reduce both stockout and carrying cost (Aifuwa et al., 2020). Second, visibility is the precondition for everything else: end-to-end traceability frameworks determine whether a disruption is detected in time to be managed (Nnabueze et al., 2021), and real-time risk dashboards have been applied specifically to hospital supply chains where the consequence of failure is clinical (Filani et al., 2022). Third, lean practice reduces waste but also reduces buffer, which is an explicit resilience tradeoff rather than a free efficiency gain (Ike et al., 2022), and post-pandemic work on resilience indices attempts to make that tradeoff measurable (Efobi et al., 2023).

On the procurement side, the most directly relevant work addresses regulatory compliance and supplier risk assessment in international pharmaceutical procurement (Akin-Oluyomi et al., 2023b) and cross-border supplier relationship frameworks spanning pharmaceutical operations (Akin-Oluyomi et al., 2024). Process automation improves procurement efficiency and transparency simultaneously, which is the same dual claim made for commercial AI and is worth examining for the same reasons (Akinleye & Adeyoyin, 2021), while digital procurement transformation research describes what changes when these systems are deployed at global scale (Okoruwa et al., 2025). Recent work on guardrails for autonomous multi-enterprise value chains is directly pertinent to the agentic question raised in Section 7.4, since it addresses how autonomy is bounded when systems act across organizational boundaries (Ogundairo, 2025).

Internal to the manufacturer, quality assurance in manufacturing determines supply reliability and therefore the credibility of any commercial commitment made to a payer or a health system (Asiedu & Asiedu, 2024b), and lean process improvement applied to pharmaceutical inventory

and distribution addresses the operational layer where availability is won or lost (Asiedu, 2025). Distribution technology is changing the cost structure underneath these decisions: autonomous mobile robotics in fulfillment environments and multi-agent coordination of robot fleets are the physical-world counterpart of the software agents discussed elsewhere in this paper, and they raise structurally similar coordination and accountability questions (Akanbi & Sunday, 2025; Akanbi et al., 2025). Payment and contracting infrastructure is the third element. Distributed ledger approaches to cross-border payment interoperability (Adesuyi et al., 2023) and smart contract automation for supplier payment and performance benchmarking (Akomolafe et al., 2022) describe mechanisms that map onto outcomes-based contracting in pharmaceuticals, where the operational difficulty has always been verifying performance and settling accordingly rather than agreeing the principle.

7.6 Financial planning, gross-to-net, and the assurance layer

Commercial AI produces financial consequences that must be planned, forecast, and audited, and the enterprise finance literature addresses this layer more directly than the pharmaceutical commercial literature does.

On planning, the relevant contributions concern the integration of analytics with strategy rather than the sophistication of the models. Aligning financial planning analytics with corporate strategy is treated as a design problem in its own right (Lawal & Oduleye, 2021b), as is the construction of executive decision systems for strategic financial planning (Lawal & Oduleye, 2019b) and capital allocation models that make the opportunity cost of one investment against another explicit (Lawal & Oduleye, 2021a). Predictive approaches to strategic financial forecasting extend this to forward-looking commitment (Medon & Oduleye, 2024), and integrated financial intelligence architectures address what changes when these capabilities are assembled at global scale and at pace (Medon & Oduleye, 2024). Cash flow and working capital modelling is the operational counterpart, and it bears directly on gross-to-net timing under a restructured Medicare benefit (Oduleye & Medon, 2023a). Two contributions are unusually relevant to the argument of this paper. Behavioural financial analytics addresses why enterprise performance diverges from what the models predict, locating the gap in decision behaviour rather than in model error (Lawal & Oduleye, 2023b). Work on cognitive bias in financial decision-making reaches the same conclusion from the audit side (Fobellah, 2025a). Both suggest that AI-generated commercial recommendations will be filtered through the same behavioural mechanisms that already distort financial decisions, which is an argument for designing the presentation of model output as carefully as the model itself. Treasury and CFO-level work on cross-border structures and CRM-based forecasting for multichannel institutions supplies the organizational context in which such recommendations land (Isiekwu et al., 2021; Dada et al., 2021b). The assurance layer has received almost no attention in pharmaceutical commercial AI discussion. Internal audit research addresses how audit quality is improved through technology-enabled risk assessment (Akomolafe & Agu, 2018), how risk-based auditing is implemented in strategic financial management (Akomolafe et al., 2023a), and how risk governance is advanced through data-driven compliance analytics (Akomolafe et al., 2025), including in procurement risk specifically (Bello et al., 2023). Most directly, work on auditing AI-powered financial systems addresses the question of how an assurance function evaluates a system whose reasoning it cannot fully inspect (Fobellah, 2025b). In healthcare specifically, audit analytics has been applied to financial oversight (Abetoh & Atakpa, 2024), anomaly detection methods have been developed for healthcare and banking time series (Atakpa & Fobellah, 2023), and AI approaches to healthcare payment fraud detection have been reviewed at national health

system scale (Atakpa et al., 2024). These are the closest available analogues to the assurance problem that commercial AI in pharmaceuticals will shortly present.

8. Governance, Regulation, and Ethics

8.1 The commercial exclusion in pharmaceutical AI guidance

The central regulatory observation of this paper is a negative one.

The FDA issued its first AI-specific guidance for drugs and biologics in draft form in January 2025, titled *Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products* (Docket FDA-2024-D-4689). It introduces a seven-step, risk-based credibility assessment framework applying to AI models whose outputs inform regulatory decisions about safety, effectiveness, or quality, across nonclinical, clinical, postmarketing, and manufacturing phases. It was informed by an expert workshop, more than 800 comments on a 2023 discussion paper, and agency experience with several hundred submissions containing AI components. The comment period closed on 7 April 2025 (U.S. Food and Drug Administration, 2025; DLA Piper, 2025; Goodwin Procter, 2025).

Critically for this review, the guidance explicitly excludes AI used solely in drug discovery and AI used for internal operational efficiencies that do not affect patient safety, drug quality, or study reliability (Goodwin Procter, 2025). Essentially all commercial applications discussed in Sections 5 through 7 falls outside its scope. The European position is complementary and similarly oriented. The EMA reflection paper of September 2024 places accountability on sponsors and marketing authorization holders for ensuring AI systems are fit for purpose, accepts that full explainability is not always attainable, and substitutes requirements for interpretability and human oversight (European Medicines Agency, 2024). Work toward international alignment of machine learning expectations was underway at the close of the focal year but had not yet produced a joint instrument. The result is a genuine governance gap. The domain with the highest deployment velocity, the most direct patient contact through promotional and support channels, and the least regulatory specificity is commercialization. Comparative governance research on AI in healthcare management identifies the same structural gap, finding that executive oversight and accountability arrangements diverge sharply across jurisdictions and are weakest where formal regulatory structures have not yet attached (Afrihyia, Akinse et al., 2024). Regulatory science supplies a transferable instrument in the form of risk-tiered decision models that scale evidentiary demand to consequence, a logic that commercial governance could adopt without waiting for guidance to be extended (Eze et al., 2024b).

8.2 Horizontal instruments and the compliance perimeter

Commercial AI is not unregulated; it is regulated by instruments that were not written for it.

The EU AI Act entered into force in August 2024, with obligations for general-purpose AI models phasing in from August 2025 and higher-risk obligations scheduled from August 2026 (European Union, 2024). It is horizontal and sector-agnostic. Article 50 transparency obligations are directly relevant to pharmaceutical commercial operations: where AI systems interact with people or generate content, disclosure obligations attach. A pharmaceutical company deploying conversational agents in HCP or patient channels, or generating promotional content at scale, is within scope regardless of whether medicines regulators have addressed the practice.

Alongside this sit the pre-existing constraints that do most of the practical work: HIPAA and GDPR for personal and health data; anti-kickback and fraud and abuse rules governing patient support and HCP interaction; promotional regulation and off-label communication restrictions

enforced through warning letters, with concentrated enforcement activity in 2025; and privacy expectations around the use of patient support data for marketing purposes. Existing promotional rules commonly require pre-approved content, which is in direct tension with dynamic AI content generation. This tension is not fully resolved by any current instrument and is a legitimate subject for regulator and industry engagement. For multinational manufacturers the practical difficulty is cross-border: data governance obligations, disclosure duties, and anti-discrimination requirements attach differently by jurisdiction while the underlying systems are global (Annan, 2022, 2025a). Harmonization frameworks developed for pharmaceutical regulation offer a template for reconciling divergent requirements without defaulting reflexively to the most restrictive (Eze et al., 2024a). Analogous work in cross-border payments addresses both collaborative governance of shared data and the redesign of products to meet divergent regulatory conditions, which are the same two problems in a different domain (Akomolafe et al., 2025a; Olaogun et al., 2023).

8.3 Practical governance architecture

Synthesizing the guidance instruments and implementation accounts, a workable governance architecture for commercial AI contains at least six elements:

1. **Context-of-use definition.** Each deployed model has a documented purpose, scope, and boundary, adapting the FDA credibility framework's logic even where its scope does not formally apply.
2. **Risk-based tiering.** Governance intensity scales with consequence. A model summarizing internal sales data and a model generating HCP-facing claims are not the same risk object.
3. **Curated ground truth.** Master claims, approved references, and label constraints are maintained as governed machine-readable assets, so constraint operates at generation rather than only at review.
4. **Documented human-in-the-loop protocols.** Explicit specification of which outputs require human validation, by whom, and against what criteria. This is among the practices most strongly associated with value realization in adoption research.
5. **Lineage and auditability.** Every AI-influenced output is traceable to inputs, model version, and reviewing human. Regulators have not issued explicit guidance on AI-assisted promotional review, which raises rather than lowers the traceability burden.
6. **Bias and equity evaluation.** Systematic assessment of differential model performance across patient and prescriber populations, particularly for models allocating support resources or determining engagement priority.

Each element has an established analogue outside pharmaceutical commercialization. Auditability can be implemented as process mining across the content and decision lifecycle rather than as retrospective documentation (Sanni et al., 2025). Privacy can be architected by design through role-based access and data minimization rather than added at review (Badmus et al., 2024), and federated approaches permit model improvement across organizational boundaries without centralizing sensitive data (Sanni et al., 2023). Privacy-preserving architectures developed for regulated analytics under GDPR and HIPAA describe the same requirement where the analytical use case is fixed and the constraint is legal rather than technical (Atakpa & Abolaji, 2022). Integrated frameworks linking cybersecurity investment, governance, and financial performance in health organizations provide a model for treating these as one system rather than three parallel programs (Ozowara et al., 2022).

8.4 Ethical considerations specific to commercialization

Three ethical issues are distinctive to the commercial setting and are not addressed by frameworks designed for clinical AI.

Persuasion at scale. Hyper-personalized promotional content optimized for engagement operates on prescribing behavior. Existing promotional regulation governs claim accuracy and fair balance, not optimization intensity. A system that is fully compliant claim by claim may still exert influence of a kind the regulatory framework never contemplated.

Distributive effects of predictive targeting. Models that concentrate engagement on high-prescribing HCPs and high-persistence patients rationally allocate commercial resource while potentially widening access disparities, since low-volume prescribers frequently serve rural and underserved populations. This is a genuine tension between commercial optimization and access equity, and it is not resolvable by better modeling alone. Where allocation decisions produce systematically different outcomes across protected characteristics, the exposure is legal as well as ethical (Annan, 2025a), and health system frameworks treating equity as a design objective rather than a reporting category offer a more workable starting point than post hoc disparity measurement (Ilodigwe & Adesemoye, 2020). Work on socioeconomic inequity in maternal health outcomes illustrates how access gaps compound through a care pathway rather than appearing at a single point (Akinse, Ekechi et al., 2023).

Transparency toward HCPs and patients. Whether a physician should know that a representative's approach was algorithmically determined, or that content was AI-generated, is partly answered by EU AI Act Article 50 for European operations and largely unanswered elsewhere.

8.5 Assurance analogues from other high-consequence domains

The governance gap identified in Section 8.1 is not unprecedented. Other sectors have faced the problem of overseeing systems whose failure modes are consequential, whose operations are distributed, and whose regulation was written for an earlier technology. Three bodies of practice are transferable. The first is aviation safety oversight. Predictive compliance monitoring frameworks detect systemic risk from routine operational data rather than from incident reports, which is precisely the capability commercial compliance functions lack (Adeyelu, 2018). Adaptive safety management system models describe how oversight intensity is calibrated to demonstrated performance rather than applied uniformly (Adeyelu, 2019), risk-tiered oversight allocates scrutiny by consequence (Adeyelu, 2023), and maturity models predict audit outcomes from organizational characteristics, which is the assurance equivalent of a leading indicator (Adeyelu & Dagodzo, 2024). The parallel to risk-based content tiering in MLR is close enough to be worth formalizing. The second is program and project governance. Research on governance of multinational infrastructure programs addresses accountability across jurisdictions and partners (Amayo et al., 2023a; Amayo et al., 2024b), and work on risk management and compliance in healthcare project delivery addresses the same problem where the regulatory environment is closest to pharmaceutical conditions (Amayo et al., 2023b; Amayo et al., 2025c). Commercial AI deployment is a multinational program with distributed accountability, and it tends to be governed as a technology procurement instead.

The third is process improvement and change management, which determines whether governance survives contact with operations. Lean Six Sigma adaptation for smaller organizations addresses how rigorous method is applied without the overhead that makes it unworkable (Ambali et al., 2021), change management research on digital transformation identifies the failure patterns that recur (Eyetssemitan et al., 2023a), standard operating procedures are treated as strategic assets rather than documentation burden (Eyetssemitan et al., 2022), structured user acceptance validation determines whether a deployed system is actually usable (Eyetssemitan et al., 2023b), and CRM and workflow automation in smaller healthcare practices demonstrates the same principles where resources are constrained (Eyetssemitan et al., 2024a). Service delivery research contributes the operational counterpart: KPI-driven optimization of service portfolios (Edivri & Oteri, 2024), reliability and service assurance frameworks (Edivri & Oteri, 2024), identity-centric zero trust as an access model (Ogbole et al., 2021), and privacy-centric engineering as a design stance (Okoruwa et al., 2020).

9. Evidence on Value and the Implementation Gap

9.1 What the value estimates say and what they support

Projected value for AI in pharmaceutical commercialization ranges widely. A frequently cited institutional estimate places generative AI's annual economic value for pharmaceutical and medical technology companies at \$60 billion to \$110 billion, of which \$18 billion to \$30 billion is attributed to commercial functions (McKinsey & Company, 2024). Firm-level estimates suggest up to \$7 billion over five years for a large biopharma company with cost savings of 20% to 30% by year three. Market sizing for AI in pharmaceuticals more broadly projects growth from roughly \$3.24 billion in 2024 to approximately \$65.8 billion by 2033, implying a compound annual growth rate near 40% (Renub Research, 2025), while other published estimates of sector-wide annual value run into the hundreds of billions. The dispersion across these figures, spanning more than an order of magnitude, is itself the finding. These estimates rest on different definitions of value, different denominators, and different assumptions about attribution, and most are produced by parties selling into the market they are sizing. They should be read as directional statements of expectation, not as measurements.

9.2 The measurement problem

The core difficulty in evaluating commercial AI in pharmaceuticals is attribution. Commercial outcomes are jointly determined by product characteristics, competitive dynamics, formulary status, field execution, and policy conditions. Isolating the contribution of an AI intervention requires either randomization, which manufacturers rarely implement for commercial systems, or careful quasi-experimental design, which is rarely reported.

Consequently, most reported benefits are process metrics: cycle time reduction, administrative hours recovered, content throughput, call volumes handled. These are real and measurable. They are also not the same as revenue, share, or patient outcomes, and the substitution of process metrics for outcome metrics is pervasive in the available literature. The prior authorization and field reimbursement applications discussed in Section 5.3 are partial exceptions, since prescriptions recovered from abandonment can be counted directly. The attribution problem itself is not unique to pharmaceuticals. Multi-touch journey research documents systematic bias in how credit is assigned across channels (Sanni, Atima et al., 2022), and analyses of marketing return measurement in regulated services find that measurement difficulty distorts investment toward

what is easiest to attribute rather than toward what is most productive (Sanni et al., 2020a). Both effects should be expected in evaluations of pharmaceutical commercial AI.

9.3 Why programs fail

Across the implementation record, five recurring causes appear, none of which is primarily about model capability:

1. **Identity and data foundation failure.** Unresolvable customer identity across systems corrupts every downstream output.
2. **Missing semantic layer.** Models lacking encoded business context produce fluent but commercially wrong answers.
3. **Deployment without workflow redesign.** Tools introduced alongside unchanged processes add work rather than removing it.
4. **Governance retrofitting.** Compliance engaged after deployment rather than as system architect, producing either blocked launches or unmanaged exposure.
5. **Ambition mismatch.** Global rollout attempted before a single-market, single-therapeutic-area pilot has demonstrated value. Practitioners in regulated content operations state the constraint plainly (Indegene, 2025): pharmaceutical companies are not technology companies, and they carry competing priorities, budget limits, and change management burdens that make small-scale piloting and realistic timelines a precondition of success rather than a lack of ambition.

These causes recur across sectors. The adoption gap framing holds that capability delivered without the positioning, training, and workflow integration required for absorption yields underused systems rather than failed ones (Ogundairo & Ayivi-Donkor, 2024a), and readiness assessment in healthcare operations finds organizational and capability factors, not technology access, to be the discriminating variable between organizations that scale and those that stall (Afrihyia et al., 2025).

9.4 Measurement instrumentation: dashboards, KPIs, and executive visibility

Section 9.2 argued that most reported commercial AI benefit is process metric rather than outcome. The instrumentation literature explains why this persists and what would change it.

Executive visibility is a recognized failure mode in its own right. Business intelligence dashboard frameworks address the gap between what an organization measures and what its leadership can see (Sanni & Atima, 2021b), and executive financial dashboards designed for real-time strategic oversight address the same problem where the data is financial (Walawalkar et al., 2025). Real-time KPI tracking systems shift measurement from periodic reporting to continuous monitoring, which changes what can be managed (Tonoyan et al., 2024b). The recurring finding is that measurement systems are built to report rather than to support decisions, and that this is a design choice rather than a technical limit. On attribution specifically, work on revenue attribution conflicts in regulated professional environments is the political dimension of the problem, where competing functions have incentives to claim the same outcome (Sanni, Ajiga, et al., 2020a), and telemetry-driven value realization proposes embedding economic evaluation directly into data pipelines so that value is measured as work occurs rather than reconstructed afterwards (Ogundairo & Ayivi-Donkor, 2023b). That proposal is the most concrete available answer to the measurement gap identified in Section 9.2. Predictive and performance analytics research supplies the modelling layer. Performance intelligence models for outcome measurement at scale (Adelanwa et al., 2024), data-driven transformation models for lifecycle performance management (Adelanwa et al., 2023a), predictive models for financial risk detection (Adelanwa et al., 2023b), attribution and

yield optimization in media environments (Basnet et al., 2024), and resilient logistics analytics (Anene & Clement, 2022) all address variants of the same question: how to attribute outcome to intervention in systems with many simultaneous causes. Comparable work in retail and operations covers demand forecasting for revenue projection (Tonoyan et al., 2021a), algorithmic process optimization and cost reduction (Tonoyan et al., 2022b), vendor risk and supply chain resilience prediction (Tonoyan et al., 2024a), and route optimization under profitability constraints (Tonoyan et al., 2025). None of this is pharmaceutical, and all of it addresses the attribution problem more directly than the pharmaceutical commercial literature currently does.

10. Research Agenda

The following questions are, in the author's view, both consequential and tractable:

Algorithmic payer interaction. Test P1 from Section 5.2. Does the structural machine-legibility of manufacturer evidence predict formulary outcome independently of evidence quality? This is empirically approachable using submitted dossier features and observed coverage decisions.

Controlled evaluation of next best action. Randomized or stepped-wedge evaluation of AI-driven engagement recommendations against standard practice, with prescription-level outcomes and HCP-reported experience. The near-absence of such studies is the most conspicuous gap in the field.

Equity effects of predictive commercial allocation. Quantify whether AI-optimized targeting and patient support prioritization widen or narrow access disparities across geography, practice setting, and patient population, connecting the commercial modeling literature to established work on last-mile access barriers and automated decision-making compliance (Annan, 2025a; Asiedu & Asiedu, 2022).

Accountability architecture for agentic systems. Normative and legal analysis of responsibility allocation for autonomous commercial actions in a regulated promotional environment.

Compliance-generation tension. Empirical study of how organizations reconcile pre-approved content requirements with dynamic AI generation, and what regulatory adaptation would preserve both flexibility and patient protection.

Longitudinal value measurement. Multi-year tracking of commercial AI investment against outcome rather than process metrics, ideally through an industry consortium capable of pooling data that no single manufacturer will publish alone.

11. Limitations

This review is narrative rather than systematic, and no formal quality appraisal instrument was applied. The evidence base is dominated by grey literature produced by parties with commercial interest in AI adoption, and reporting bias toward successful deployments should be assumed. Several frequently cited statistics, including the widely repeated figure on generative AI pilot failure rates and various sector value projections, are reproduced here as they appear in the literature without independent verification of their underlying methodology. Survey findings cited from benchmarking studies frequently rest on small executive samples. Geographic coverage is weighted toward the United States and European Union, and the analysis of emerging market

commercialization dynamics is correspondingly thin. A further limitation follows from the source strategy described in Section 3. Much of the supporting literature is drawn from adjacent regulated domains including enterprise data governance, health system transformation, financial assurance, supply chain analytics, and safety oversight in other high-consequence sectors. Analogical transfer of this kind carries a specific risk: a mechanism that is structural in one setting may be contingent in another, and the pharmaceutical commercial environment differs from each of these domains in ways that are not always visible from within them. Such sources are used here to identify mechanisms worth testing rather than to establish findings, and readers should treat the resulting propositions as hypotheses requiring pharmaceutical-specific validation.

Finally, the field is moving quickly enough that specific product and regulatory details will date rapidly, though the structural analysis is intended to be more durable than the particulars.

12. Conclusion

2025 was a year of real but uneven progress in the application of AI to pharmaceutical commercialization. The documented value was concentrated in a narrower band than the surrounding discourse suggested: compression of document-heavy workflows in MLR review, evidence and dossier development, prior authorization case preparation, and field administrative burden. These are meaningful gains, and they were achieved largely through augmentation rather than autonomy. The more consequential development received less attention. As payers deploy AI in coverage policy development and utilization review, the market access negotiation is becoming partly machine-mediated on both sides. This changes what manufacturers must produce, requiring evidence that is structurally consistent, transparently documented, and discoverable by algorithmic as well as human reviewers. Organizations that treat this as a formatting exercise will miss it. It is a change in who, or what, the audience is. Three constraints will determine whether the projected value materializes. The first is infrastructural: without resolved customer identity and an encoded semantic layer, sophisticated models produce confident errors. The second is organizational: commercial AI cuts across market access, medical affairs, HEOR, marketing, and field operations, and value capture requires coordination that most operating models do not currently support. The third is governance: the principal pharmaceutical AI guidance instruments explicitly exclude commercial applications, leaving the highest-velocity deployment domain governed by horizontal instruments not designed for it, and leaving the accountability model for agentic commercial execution unresolved. None of these constraints is primarily technical, and none will be relieved by better models. The distinguishing capability in this domain is not access to AI. It is the discipline to build beneath it, to govern it as a system rather than as a tool, and to measure it against outcomes rather than against activity.

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