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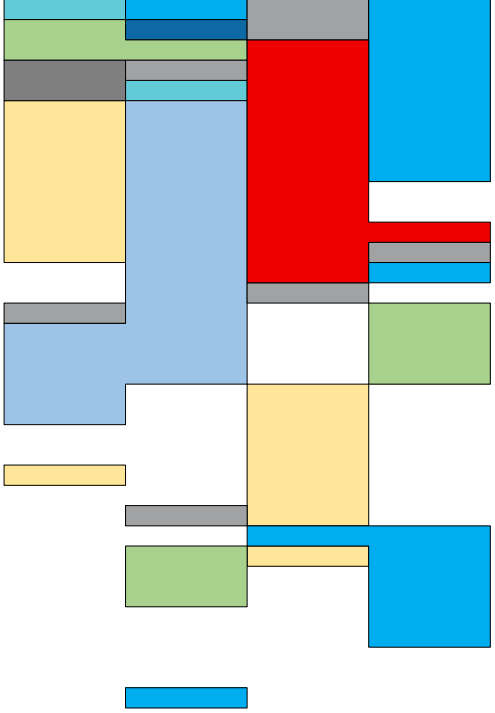

ARTIFICIAL INTELLIGENCE AS THE STRATEGIC LEVER IN PHARMA PRICING AND MARKET ACCESS

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ABSTRACT

The pharmaceutical market access and pricing landscape is undergoing unprecedented transformation, driven by three converging forces: regulatory reforms (EU Health Technology Assessment Regulation, US Inflation Reduction Act), technological innovation centered on artificial intelligence, and evolving payer demands for real-world evidence and value transparency. This white paper examines how AI has emerged as an operational imperative, not a differentiator, enabling pharmaceutical companies to optimize dynamic pricing, forecast reimbursement outcomes with over 90% accuracy, accelerate market access timelines by up to 30%, and navigate multi-tiered healthcare systems spanning Medicare negotiation, Most Favored Nation pricing, and direct-to-consumer channels. The paper synthesizes three critical strategic pillars: AI-driven optimization across the market access lifecycle, innovative clinical trial designs that generate evidence faster and more efficiently, and real-world evidence combined with health economics research that demonstrates credible value to regulators and payers. For pharmaceutical companies to succeed in this complex, multi-jurisdictional environment, adaptive, AI-enabled strategies must integrate clinical, economic, and real-world data while maintaining transparent governance and stakeholder engagement. Organizations that harness AI alongside evidence innovation will accelerate market access and deliver sustainable patient access to transformative medicines.

1. INTRODUCTION

The pharmaceutical industry is standing at a critical inflection point where artificial intelligence has emerged as the operational imperative reshaping how drugs are priced, valued, and accessed in real time. Scientific breakthroughs in gene therapy, oncology, and precision medicine continue to expand clinical possibilities, yet their commercial success increasingly depends on AI-powered strategies that forecast market dynamics, optimize pricing across multi-tiered healthcare systems, and accelerate evidence generation beyond what traditional approaches can achieve. In today's value-driven environment, AI-driven pricing and market access have become as critical as scientific discovery itself. Governments are tightening price controls through initiatives like the EU Health Technology Assessment Regulation and the US Inflation Reduction Act; payers demand stronger real-world evidence of value; and patients face mounting affordability barriers, yet pharmaceutical companies increasingly leverage AI to predict HTA outcomes with over 90% accuracy, reduce reimbursement timelines by 30%, and segment payers for hyper-personalized negotiation strategies. Simultaneously, AI is revolutionizing how companies approach clinical trial design innovation, enabling adaptive trials, enrichment strategies, and decentralized models that accelerate evidence generation while AI-powered analytics synthesize real-world evidence and health economics data to provide payers and regulators with credible, defensible value demonstrations beyond controlled trials. In the United States specifically, the convergence of IRA-driven Medicare negotiation, Most Favored Nation pricing, and direct-to-consumer platforms creates a multi-tiered pricing architecture that demands AI-enabled dynamic pricing and sophisticated market access orchestration. Industry investment in pharmaceutical AI is projected to reach $22 billion by 2027, reflecting recognition that AI is no longer a competitive differentiator but an operational necessity.

This white paper explores how pharmaceutical companies can harness AI as a strategic lever integrated with innovative trial designs, real-world evidence, and responsive US market strategies to optimize pricing, accelerate market access, and ensure transformative medicines reach patients sustainably.

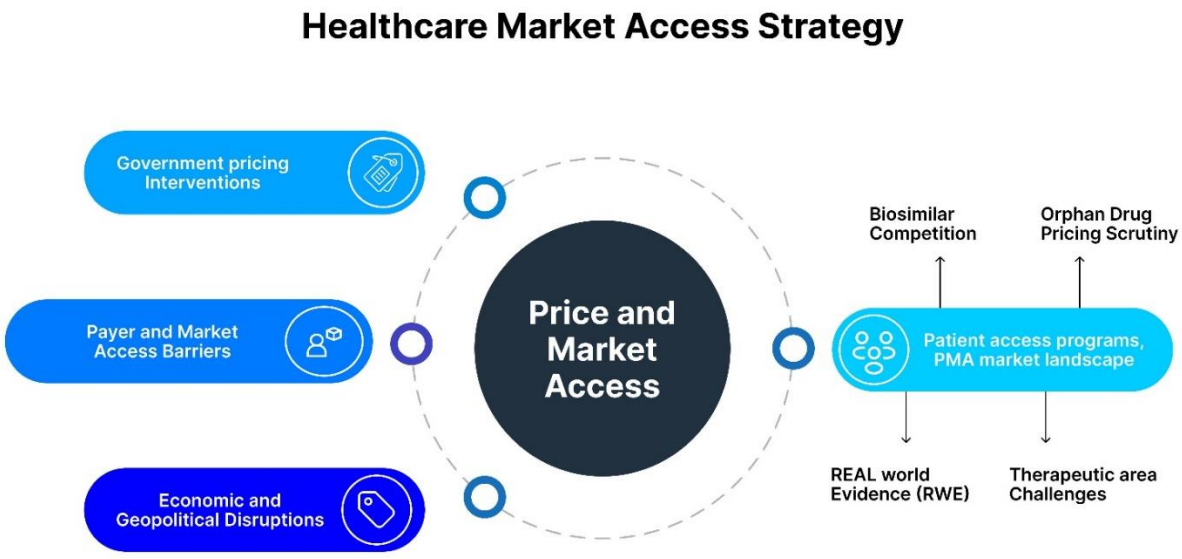
2. STRATEGIC INSIGHTS INTO PHARMACEUTICAL PRICING AND MARKET ACCESS

The primary goal in the pharmaceutical market access ecosystem is to balance clinical value, economic sustainability, and patient access while maintaining innovation incentives within constrained healthcare budgets. Core pricing strategies operate across three dimensions:

- **Value-based frameworks** that align prices with demonstrated clinical benefits (measured through QALYs and cost-effectiveness thresholds)
- **Health Technology Assessment (HTA)** processes that evaluate clinical and economic value before coverage decisions are now streamlined through the EU HTA Regulation 2025
- **Diverse global reimbursement systems** ranging from government-controlled pricing in European universal healthcare to insurance-based models, each creating distinct negotiation and pricing pressures through reference pricing benchmarks and complex stakeholder dynamics
- **Effective evidence generation and value demonstration** are crucial for success, requiring integrated strategies that extend beyond traditional clinical trials to include real-world data, economic analyses, and patient-reported outcomes

Early evidence planning during drug development and continuing through the product lifecycle helps address varied stakeholder needs, satisfy regulatory and payer requirements, and support favorable pricing and reimbursement outcomes through collaborative efforts that generate relevant, high-quality evidence and adapt to evolving policies[1,2].

Figure 1. Current challenges in pharmaceutical pricing and market access



3. INNOVATIVE FRAMEWORKS SHAPING PHARMA PRICING AND ACCESS DYNAMICS

3.1 AI-DRIVEN OPTIMIZATION ACROSS THE MARKET ACCESS LIFECYCLE

The global pharmaceutical AI budget is projected to expand dramatically from $1 billion in 2022 to $22 billion by 2027, reflecting industry confidence in AI's transformative potential across the product lifecycle. This capital allocation underscores a fundamental recognition: AI is no longer a competitive differentiator but an operational necessity. Rather than relying solely on historical benchmarks and expert judgment, AI-powered platforms analyze vast, integrated datasets, including clinical trial results, real-world evidence, payer behavior patterns, and market dynamics to uncover actionable insights and optimize decision-making in ways traditional approaches cannot match.

Leading pharmaceutical organizations have established multi-partner AI ecosystems, with financial commitments ranging from $20 million in equity stakes to $409 million in developmental agreements. These partnerships span target identification, molecular design, clinical documentation, and regulatory pathway acceleration, representing comprehensive AI integration strategies rather than isolated point solutions. Examples include BenevolentAI (AstraZeneca), CytoReason (Pfizer), QuantumBlack (Merck), Genetic Leap (Eli Lilly), and Aqemia (Sanofi).

Key applications where AI demonstrates transformative potential:

- **Adaptive pricing mechanisms that adjust dynamically with market trends:** Machine learning algorithms adjust pricing in real-time based on market demand, competitor activity, and product differentiation, ensuring competitive positioning while maximizing value capture. Predictive models trained on pricing data can achieve accuracy rates exceeding 90% in price forecasting and HTA outcome prediction.
- **Accelerated Reimbursement Cycles:** Natural language processing (NLP) tools and automation streamline claims processing, error detection, and compliance verification, reducing reimbursement approval timelines by up to 30% while improving administrative efficiency. AI systems extract insights from unstructured data sources, including payer policies, clinical guidelines, and HTA assessments, to align value propositions with reimbursement criteria before market launch.
- **Predictive HTA Decision Making:** AI algorithms forecast HTA outcomes with high accuracy, enabling companies to anticipate regulatory pathways and tailor evidence generation strategies accordingly. This predictive capability supports earlier stakeholder engagement

and more targeted value dossier development.

- **Payer Segmentation and Negotiation:** Machine learning enables sophisticated payer segmentation by identifying nuanced preference patterns and cost-sensitivity thresholds, facilitating hyper-personalized negotiation strategies that increase favorable reimbursement term likelihood[3].

Real-World Implementation: Use Cases in Pricing and Market Access

- **Okra Technologies ValueScope**: It uses generative AI to predict drug launch and negotiated prices by analyzing historical pricing submissions and HTA decisions. With over 90% accuracy, the platform evaluates data from 1,700+ drug launches across European markets to uncover pricing patterns that traditional analytics miss. This enables manufacturers to set defensible, competitive prices early while aligning with payer expectations across multiple jurisdictions. The tool directly supports faster, evidence-backed pricing and market access strategies.

- **Tellius Auto Insights:** The platform leverages GenAI to automatically surface key trends, anomalies, and drivers from complex commercial and market access datasets. Instead of manual querying, users receive natural-language insights explaining why performance is changing and what factors matter most. This accelerates decision-making for pricing, contracting, and sales strategy teams. The tool democratizes advanced analytics for non-technical users.

- **Glass Box Analytics Predictive Acquisition Cost (PAC) Model:** The model uses AI to forecast drug acquisition costs by tracking real-time market signals such as supply shifts, competitive dynamics, and pricing changes. The model helps stakeholders anticipate cost volatility rather than react retrospectively. This supports better contracting, budgeting, and reimbursement planning. GenAI enhances transparency in an otherwise opaque acquisition cost landscape.

- **IntegriChain ICyte Platform:** IntegriChain deployed ten AI models within its ICyte platform to improve commercial execution and access operations. Use cases include risk scoring for Field Reimbursement Managers to prioritize high-impact cases and reduce access delays. GenAI enables proactive identification of reimbursement bottlenecks and operational inefficiencies. This leads to improved patient access and stronger commercial performance.

- **Amgen Infinitus Systems "Eva":** Amgen's U.S. Patient Access & Reimbursement (PAR) team partnered with Infinitus Systems to deploy "Eva," an AI platform for automating coverage verification. The system collects and processes payer coverage details, reducing manual effort and turnaround time. Faster access to accurate reimbursement information

helps patients initiate therapy sooner. GenAI thus improves both operational efficiency and patient experience.

- **Loon Inc. LOON LENS™:** LOON LENS™ is an agentic AI platform designed for regulatory-grade evidence synthesis in HTA submissions. It achieves 99% sensitivity in systematic literature review screening while automating meta-analyses, indirect treatment comparisons, and feasibility assessments. The platform significantly reduces timelines and human effort while maintaining methodological rigor. This enables faster, higher-quality evidence generation for market access decisions.

- **Cohere Unify Platform:** Cohere's Unify platform provides enterprise-grade generative AI for secure data retrieval, summarization, and decision support. It enables organizations to unify structured and unstructured data into a single AI-driven workflow. In life sciences, this supports faster insight generation across pricing, access, and competitive intelligence. The platform emphasizes data privacy and domain-specific customization.

- **PayZen:** PayZen uses AI to personalize patient payment plans by analyzing affordability, insurance coverage, and financial behavior. The platform predicts optimal payment structures that reduce patient burden while improving provider collections. GenAI enables empathetic, data-driven financial conversations on a scale. This directly addresses affordability barriers to treatment access.

The benefits of using AI in pricing and market access are significant—real-time pricing optimization, improved reimbursement forecasting, and more reliable HTA outcome prediction. However, AI should be deployed responsibly with clear governance, transparency, and in partnership with human expertise. Organizations that introduce AI gradually and with a clear strategy will be better equipped to adapt to changing pricing and market access requirements and ensure long-term patient access to innovative therapies[3].

3.2 INNOVATION IN CLINICAL TRIAL DESIGN

A clinical trial is a crucial component of drug development. Enrolling patients and completing all clinical trial phases is time-consuming and expensive; recently, there has been a shift toward improving trial designs. These improvements aim to enhance drug safety and effectiveness while reducing costs and speeding up the development process. These improvements are transforming how pharma companies demonstrate drug safety, efficacy, and value, leading to accelerated market access and supporting strategic pricing.

Table 1: Innovation in clinical trial design

TRIAL DESIGN	KEY ADVANTAGES	CHALLENGES REMAIN
Basket and umbrella trials	• Enable more efficient drug development by testing multiple therapies or disease subtypes, helping in precision medicine approaches	• Feasibility challenges due to the large sample size and longer duration of trials
Adaptive trial design	• Real-time modification is possible based on interim data • Trials can be stopped for futility or efficacy	• Type I error rate control • Trial integrity
Enrichment design	• Increase drug efficacy by tailoring treatment to patients based on their clinical, laboratory, genomic and proteomic data	• Regulatory/HTA agencies' acceptance of the enrichment strategy • Screening test performance
Master protocols	• Maximizes trial opportunities by evaluating and comparing treatments/combinations • Can be beneficial in a small trial population or rare indications	• Early involvement of regulatory agencies/HTA, ethics committee and HCPs is vital to identify and address potential issues upfront
Use of historical controls	• Use of previous trial data to identify the disease population, scientific and regulatory factors, early in the drug development	• Compatibility and relevance with the current trial population, treatment standards and data quality
Digital and decentralized trials	• Enhanced patient access and retention by allowing the patient participation from home, leading to more diverse enrollment, improved retention rates, real time data collection	• Data quality and technological challenges

3.3 REAL-WORLD EVIDENCE

Real-world evidence (RWE) is increasingly vital for ensuring patients receive the right treatment at the right time by providing data on how therapies perform in everyday clinical practice. It helps measure treatment outcomes more accurately and demonstrates the true value of interventions beyond controlled clinical trials, supporting market access and pricing decisions. The recent advances in digital technology and advanced analytics have enabled new and more powerful ways to collect, analyze, and apply RWE across the drug development and market access process.

Advanced RWE analytics play a vital role across the pharma value chain:

- **R&D: To identify unmet need, improve trial design, accelerate time to market, and monitor real-world outcomes**
- **Market access: Improve dossier preparation, formulary position, and achieve label expansion**
- **Sales and marketing: Redefine commercial strategies and build clinical decision support systems**
- **Medical: Improve pharmacovigilance, strengthen evidence generation in understudied populations, and identify subpopulations for which the effect outperforms trials**

The role of RWE in growing regulatory acceptance is evident from Big Pharma's recent approval and reimbursement:

- **Pfizer's use of electronic medical record (EMR) data in the Ibrance approval for male breast cancer**
- **Roche reimbursement for lung cancer drug Alecensa and**
- **AstraZeneca used RWE data to demonstrate the real-world effectiveness of Farxiga (diabetes therapy)**[4]

3.4 HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR)

With the pharma industry focusing more on real-world data, healthcare intervention value, stringent timelines, budget constraints, and tighter scrutiny of drug prices, HEOR has emerged as the critical component of the life sciences industry. HEOR combines economic evaluation and outcome research to help reveal how therapies truly affect patient outcomes, healthcare costs, and quality of life. For pharmaceutical companies, it's more than a research tool; it's a key strategy that drives decisions on market access, pricing, and long-term success in today's evidence-based industry.

Role of HEOR for different healthcare stakeholders

- **Regulators:** Use HEOR studies to gather real-world evidence on patient profiles and untreated outcomes, enabling better decisions on a drug's value
- **Payers focus on cost and value:** Analyze patient data to find effective treatments, assess drug costs, and understand the impact of covering these therapies for health plans.
- **HCPs:** Analyze available data to set treatment goals and understand patient preferences

HEOR helps in projecting drug values by connecting the dots between clinical value and real-world data. It helps in identifying the data gaps, helping with critical trial designing, creating economic projections, and sharing value with stakeholders. Nowadays, it is helping companies to determine drug engineering for high-cost therapies, rare diseases and competitive market positioning[5].

- For high-cost therapies, early cost-benefit models are used to gain support from investors or healthcare payers
- In rare diseases, burden-of-illness studies are conducted before clinical trials to measure unmet patient needs
- In competitive markets, companies develop value differentiation strategies by comparing competitor pricing and treatment outcomes

4. EMERGING TRENDS IN THE US MARKET

Since President Trump took office, significant changes have occurred in the pharmaceutical market. The **Inflation Reduction Act (IRA)**, passed in 2022, was designed to lower drug prices by empowering Medicare to negotiate directly for select Part D drugs, capping beneficiary out-of-pocket costs at $2,000 annually, and shifting more financial liability to Part D plans. Initially, the IRA applied only to a limited number of high-cost drugs in the first year, 10, 15 in the second, and expanding thereafter to reduce the government's drug spending burden.

MOST FAVORED NATION PRICING

The Most-Favored-Nation (MFN) pricing approach was established by the Trump Administration via Executive Order in July 2020 to lower Medicare drug spending. Under MFN, the Centers for Medicare and Medicaid Services (CMS) first identifies all comparator countries—any non-U.S. OECD member whose per-capita GDP is at least 60 percent of U.S. per-capita GDP. CMS then collects ex-factory or net prices for the specified drug in each of those countries, normalizes them to a common unit, and converts them into U.S. dollars at the Treasury's published exchange rate. The lowest converted price among the comparator set becomes the **MFN ceiling price for Medicare reimbursement in the U.S**. Pharmaceutical manufacturers must agree to supply the drug at or below this ceiling price to participate in Medicare Part B (and, eventually, Part D) programs. By tying U.S. reimbursement to the best international price, MFN directly drives down drug prices without additional rebates or protracted negotiations. **Pfizer** was the first manufacturer to enter into an MFN agreement with the federal government.

TRUMPRX INITIATIVE

The TRUMPRx Initiative is a federal program built around the upcoming TrumpRx.gov website, scheduled to launch in early 2026. Its core mission is to help U.S. consumers access prescription medications at reduced prices by serving as a centralized search portal rather than directly selling or distributing drugs. When users search for a covered medication, the site confirms program eligibility and then redirects them to the manufacturer's own direct-to-consumer platform to complete their purchase. This portal approach allows the government to avoid the complexities of pharmaceutical supply logistics. **Pfizer** led the way as the first manufacturer to endorse the program's framework. Other participating pharmaceutical companies include:

- **Eli Lilly launched LillyDirect in January 2025, offering Zepbound at $500 monthly versus the $1,300 list price**
- **Novo Nordisk implemented NovoCare Pharmacy for Wegovy and Ozempic at similar discount levels**
- **Bristol Myers Squibb and Pfizer jointly launched direct-to-patient Eliquis sales in September 2025, offering over 40% discounts from list price**
- **AstraZeneca, Boehringer Ingelheim, Amgen, and Novartis have recently announced DTC programs with steep product discounts**

- **Amgen launched AmgenNow in October 2025, offering Repatha at $239 monthly, nearly 60% below list price**

STRATEGIC IMPACT OF THESE INITIATIVES

- **Pfizer's Win-Win Pricing Deal:** Pfizer secured a three-year exemption from the proposed 100% tariff on imported branded pharmaceuticals in exchange for this landmark agreement. As part of the deal, Pfizer agreed to offer all its drugs to state Medicaid programs at the lowest prices consistent with the Most Favored Nation (MFN) pricing framework
- **Transparency Concerns:** The agreement lacks a detailed, transparent methodology for calculating discounts and setting MFN prices. This opacity makes it difficult for independent parties to verify government claims or independently assess the true impact of the discounts
- **Comparison with existing Insurer system:** For example, Pfizer's drug Eucrisa has a list price of approximately $947 to $1,064 per 60g tube. Insured patients typically pay between $10 and $100 out-of-pocket using Pfizer's copay savings card. Meanwhile, on the TrumpRx direct-to-consumer (DTC) platform, even after a 40-85% discount, prices range from $141 to $568 higher than many insured patients' actual out-of-pocket costs, potentially limiting the platform's appeal to those with insurance
- **Impact Analysis:** The primary beneficiaries of these initiatives are uninsured individuals and patients with high-deductible health plans who currently bear high drug costs. Conversely, commercially insured patients and Medicaid enrollees are least likely to benefit, as their existing coverage often results in lower or no out-of-pocket expense compared to the discounted cash prices offered by TrumpRx
- **Strategic Complexity:** The coexistence of both policies reshapes traditional payer manufacturer interactions, requiring more dynamic, multi-layered pricing and market access strategies[6,7,8]

5. CONCLUSION

The U.S. pharmaceutical market is undergoing profound transformation driven by three landmark policy initiatives: the Inflation Reduction Act (IRA), Most Favored Nation (MFN) pricing, and the TrumpRx direct-to-consumer platform launching in early 2026. These policies reshape drug pricing by empowering Medicare negotiation, benchmarking U.S. prices against international lows, and providing uninsured patients direct access to discounted medications. However, they create a multi-tiered pricing architecture where commercially insured and Medicaid populations may face complexity, requiring manufacturers to operate across Medicare, private payers, and direct-to-consumer channels simultaneously.

AI has emerged as a critical operational lever to navigate this complexity. AI-driven platforms deliver measurable returns: predictive models achieve over 90% accuracy in HTA outcome forecasting, natural language processing reduces reimbursement approval timelines by 30%, and machine learning enables sophisticated payer segmentation for targeted negotiations. Industry investment in pharmaceutical AI is projected to reach $22 billion by 2027, reflecting recognition that AI is now an operational necessity. Leading manufacturers like AstraZeneca, Pfizer, Merck, Eli Lilly, and Sanofi have established multi-partner AI ecosystems, while U.S.-focused tools like Okra Technologies' ValueScope, IntegriChain's ICyte, and Amgen's Eva demonstrate tangible benefits in pricing optimization and access acceleration.

For pharmaceutical companies to succeed, integrated approaches must combine AI-powered pricing strategies with real-world evidence, flexible launch sequencing, and outcome-based contracting. Only organizations that embrace AI alongside transparent governance and stakeholder engagement will deliver sustainable patient access and long-term commercial value in the evolving U.S. healthcare landscape.

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