Market Access 2030: AI-Driven Dossier Transformation and Therapeutic Value Communication Across Global Health Systems

HTA228

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INTRODUCTION

The FDA's Enterprise-level Structured Application (ELSA) itiative represents a structural turning point in how clinical evidence, particularly for novel and high-impact therapies, winill be submitted and evaluated. It introduces machine-readable dossiers and AI-compatible formats, laying the groundwork for intelligent regulatory and payer interfaces. As high-cost therapies in oncology, neurology, and rare diseases become increasingly complex, the role of AI in translating real-world outcomes into structured value propositions becomes central to future access.

METHODOLOGY

A multidisciplinary analysis was conducted combining policy review, organizational change theory (Kotter, Lewin), and historical analogues from regulatory science (eCTD adoption), precision oncology (genomic-driven submissions), and adaptive licensing models. Use cases from gene therapy, diabetes digital therapeutics, and multi-arm oncology trials were analyzed to project AI's role in shaping evidence generation, dossier structure, and HTA alignment.

RESULTS

By 2030, value dossiers for complex therapies are expected to evolve into living, AI-generated assets that integrate:

(1) Real-time real-world data (RWD) pipelines from wearable, genomic, and biomarker platforms;

(2) AI-based simulation models to optimize pricing and risk-sharing scenarios for subpopulations;

(3) Dynamic, versioned dossier components enabling adaptive reimbursement aligned with clinical updates.

Structured Health Technology Assessment (HTA) frameworks, such as those implemented by agencies like NICE (National Institute for Health and Care Excellence) and G-BA (Gemeinsamer Bundesausschuss), are increasingly anticipated to incorporate modular appraisal models enhanced by artificial intelligence (AI) in order to better manage therapeutic diversity and mitigate uncertainty. This paradigm shift mirrors previous transformative trends in regulatory and scientific domains. For instance, the adoption of the electronic Common Technical Document (eCTD) format in 1997 streamlined regulatory processes by reducing bureaucratic obstacles. The integration of genomic data into oncology further revolutionized evidence generation, establishing novel standards for clinical trial design and biomarker validation. Similarly, adaptive licensing initiatives within Europe, aimed at accelerating access to treatments, fostered inter-agency collaboration and adaptive regulatory frameworks.

Current European policy alignment through initiatives such as the European Health Data Space (EHDS), the AI Act, and the Joint Clinical Assessment (JCA) mechanisms collectively provide a robust infrastructural foundation to scale these ongoing changes. These policy frameworks facilitate cross-border harmonization and the integration of AI-driven approaches in the evaluation of health technologies, creating a more responsive and evidence-based healthcare ecosystem.

CONCLUSIONS

To ensure equitable access and long-term sustainability, stakeholders must collaborate to develop AI-compatible standards that accurately reflect the therapeutic diversity and evidentiary complexity inherent in modern medicine. These standards must incorporate diverse data types, including clinical trial results, genomic information, and real-world evidence, to guide accurate and personalized healthcare decisions. For example, AI applications in oncology, such as IBM Watson for Oncology, leverage genomic data to recommend individualized treatment plans based on tumor mutations. Similarly, precision medicine in rare genetic disorders requires AI models that integrate genetic, phenotypic, and environmental factors for tailored interventions. Also, with MArS DO-BO AI-assisted Dossier creation is already available and functioning. Furthermore, regulatory frameworks, such as the European Union's AI Act, ensure that AI technologies are implemented ethically, transparently, and in compliance with safety standards. These collaborative efforts will ensure that AI innovations are both clinically effective and sustainable.

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