Bridging the Gap: How Real-World Evidence (RWE) Is Reshaping HTA Submissions in Emerging & Middle East Markets

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Introduction

In recent years, the healthcare evidence landscape has evolved beyond traditional randomized controlled trials (RCTs) toward more pragmatic, data-driven approaches. Among these, Real-World Evidence (RWE) has emerged as a critical pillar in Health Technology Assessment (HTA) submissions, especially as global health systems strive for value-based care and sustainable reimbursement models.

While RCTs remain the gold standard for demonstrating efficacy, their strict protocols and homogeneous populations often fail to capture the complexities of real clinical settings. This is especially true in rare diseases, where limited patient numbers constrain trial feasibility, and in oncology, where long study durations drive higher costs and delays. RWE derived from sources such as electronic health records (EHRs), registries, insurance claims, and patient-reported outcomes, offers complementary insights into efficacy, safety, and cost-effectiveness in everyday practice.[1]

In emerging markets and particularly across the Middle East and North Africa (MENA), RWE plays a pivotal role in bridging data gaps. Many of these countries are still developing HTA infrastructure, facing challenges such as limited local trial data and varied payer frameworks. Doing so at this time allows them to incorporate more current thinking into the designs of their evaluative frameworks. By integrating RWE into HTA processes, policymakers and pharmaceutical companies can support more relevant, equitable, and context-specific access decisions.

This article explores the expanding role of RWE in HTA submissions, with a focus on evolving policies, regional challenges, and opportunities related to evidence-based market access in the MENA region.

The Global Landscape of RWE in HTA

Across the globe, HTA bodies are increasingly integrating RWE into their evaluation frameworks to complement RCT data. This shift reflects the growing emphasis on evidence that demonstrates effectiveness in real-world settings, particularly when clinical trial populations or controlled conditions fail to capture everyday patient experiences and health system constraints.

HTA agencies recognize that RWE can:

- Provide insight into long-term safety, adherence, and outcomes post-launch,
- Support comparative effectiveness assessments where head-to-head trials are absent,
- Enhance economic and budget impact models using real-world cost data, and
- Enable reassessment and value-based contracting under ongoing market access agreements.

Globally, HTA bodies are increasingly incorporating RWE alongside RCT data to support reimbursement and pricing decisions. This shift reflects the growing emphasis on demonstrating value in real-world settings, especially in therapeutic areas such as oncology, rare diseases, and cell and gene therapies where traditional trial data are often insufficient. Recent analyses, including a review conducted in 2022, indicate that over 60% of HTA submissions worldwide now include RWE, signaling its emergence as a mainstream component of evidence generation. Agencies such as NICE in the UK, HAS in France, and CDA in Canada have established structured frameworks for RWE integration, focusing on data quality, transparency, and post-launch outcome monitoring.[2,3,4]

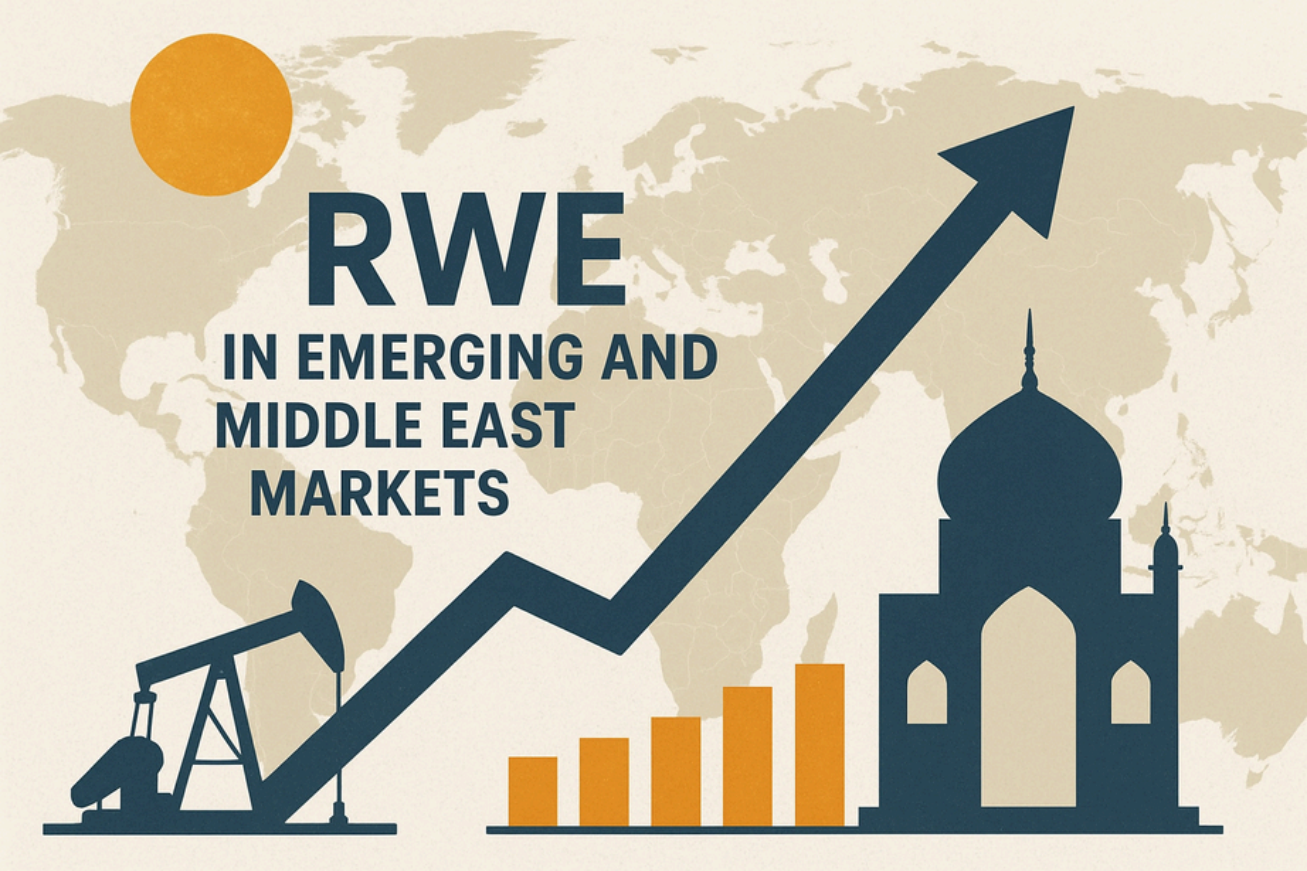
While mature HTA systems in Europe, North America, and Asia have formalized how RWE informs reassessment and value-based contracting, the relevance for emerging and MENA markets lies in strategic adaptation rather than replication. Global frameworks offer a foundation, but their success depends on how effectively local agencies align RWE use with national payer priorities, healthcare infrastructure, and available data systems. As MENA countries advance their HTA capacity, these global experiences provide practical blueprints for integrating real-world data into evidence-based access and pricing frameworks that reflect local realities.

RWE in Emerging and Middle East Markets

The MENA region is witnessing a significant transformation in health policy and evidence-based decision-making. Countries such as Saudi Arabia, United Arab Emirates (UAE), Egypt, and Qatar are introducing national HTA frameworks or pilot programs to guide pricing and reimbursement (**Table 2**).

However, the lack of local RCT data remains a critical barrier. In many cases, global trials do not reflect local epidemiology, healthcare infrastructure, or patient characteristics. As a result, RWE serves as a bridge, offering local validation for clinical and economic models.

Recent studies underscore that policymakers in the region are actively seeking RWE collaborations with pharmaceutical partners to inform value-based decisions. For example, the Saudi Health Council's National HTA Center (NHTAC) has begun incorporating RWE in therapeutic area evaluations since 2022.[1,5]



RWE in Emerging and Middle East Markets

Table 2: Status of HTA and RWE Integration in MENA

Country	HTA Development Stage	Use of RWE in Decision-Making	Key HTA Policy, Framework, and Application Examples
Saudi Arabia (5)	Established HTA Agency (NHTAC, 2022)	Structured use of RWE for pilot appraisals, post-market reassessments, and local cost-effectiveness analyses.	The National HTA Center (NHTAC) under the Saudi Health Council leads structured HTA submissions. Since 2022, pilot evaluations have mandated local data use for high-cost biologics and oncology therapies. RWE supports reassessment of therapeutic value, budget impact, and inclusion on the National Formulary. Ongoing projects explore outcomes-based contracting linked to RWE reporting systems.
UAE (6)	Established HTA framework (Department of Health – Abu Dhabi, 2025)	Formal incorporation of RWE into economic evaluations, pricing submissions, and post-launch reassessments.	The HTA guidelines (2025) issued by the DOH Abu Dhabi marks the country's transition from pilot initiatives to a structured HTA system. The guidelines mandate inclusion of local RWD, including clinical outcomes and resource-use metrics, to demonstrate therapeutic value and support price renewals. RWE is also integral to early access schemes and value-based procurement decisions. Meanwhile, the Dubai Health Authority (DHA) continues to develop digital registries for ongoing therapy monitoring.
Egypt (1)	Early-stage HTA roadmap under Ministry of Health (2021)	Selective use of RWE in budget impact and pharmacoeconomic evaluations.	Egypt established an HTA Unit within the General Authority for Healthcare Accreditation and Regulation (GAHAR) to evaluate health technologies under Universal Health Insurance (UHI) reforms. While formal RWE guidance is not yet available, economic evaluations increasingly use local epidemiological data and retrospective studies to contextualize model assumptions.

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Qatar (7)	HTA framework in design phase (Ministry of Public Health)	Exploratory use of RWE for hospital formulary inclusion and therapy renewal reviews.	The Ministry of Public Health (MOPH), in collaboration with Hamad Medical Corporation, is designing a national HTA framework aligned with WHO standards. Pilot HTA assessments integrate RWE from Qatar's national health information exchange to evaluate high-budget therapies for chronic diseases.
Jordan (1)	Early-stage HTA capacity (MOH and RMS partnerships)	RWE applied through retrospective cost and utilization studies.	HTA activities are coordinated through the Jordan Food and Drug Administration (JFDA) and Royal Medical Services (RMS). RWE is mainly used for cost-effectiveness models and utilization studies, particularly in diabetes and cardiovascular disease management. A national data strategy is under development to standardize RWD capture from tertiary care centers.
Turkey (2)	Mature HTA structure (TITCK and SSI collaboration)	Integration of RWE for reassessment and reimbursement renewals.	The Turkish Medicines and Medical Devices Agency (TITCK) collaborate with the Social Security Institution (SSI) on HTA and pharmacoeconomic evaluations. RWE is routinely used to verify real-world effectiveness and safety, especially in oncology. The Reimbursement Evaluation Commission includes RWE in renewals and budget impact submissions.

The diverse pace of HTA development across the region reflects differing policy objectives, from cost containment to innovation access. This variability highlights the need for localized evidence strategies that align with each market's HTA maturity. Early partnership with national HTA bodies, participation in pilot data programs, and development of disease registries can help shape how RWE informs future access and pricing decisions in the Middle East and beyond.

Key Challenges and Barriers

Despite growing recognition of RWE's value, implementation challenges persist across the MENA region and other emerging markets.

1. **Data Infrastructure Gaps**
   Health data in many Middle Eastern countries is fragmented across public and private sectors, with varying degrees of digitization. Although EHR adoption is increasing, interoperability and standardization remain limited.[8]

2. **Methodological and Quality Concerns**
   HTA bodies often question the methodological rigor of observational data, particularly regarding confounding and bias. Adoption of frameworks like the Causal Roadmap and ISPOR RWE Good Practices can help strengthen analytic credibility.[9]

3. **Regulatory Uncertainty**
   Unlike in the US or EU, there is no formal RWE guidance yet in most MENA countries. Without clear expectations, pharmaceutical companies face uncertainty when submitting evidence packages.[1,2]

4. **Capacity and Skills Gaps**
   Local HTA and payers often lack experience in appraising RWE. Collaborative capacity-building programs are key to developing sustainable expertise.[5]

5. **Cultural and Legal Barriers to Data Use**
   Data sharing across borders, as well as privacy regulations, can complicate access to RWD sources. Balancing compliance with innovation remains an ongoing policy challenge.[1,8]

Strategic Roadmap for Pharma: Leveraging RWE for Access in Emerging Markets

Pharmaceutical companies can play a pivotal role in strengthening HTA systems by embedding RWE generation early in the product lifecycle and aligning with local policy objectives.

Phase 1: Market Readiness Assessment
Evaluate each market's HTA maturity, data infrastructure, and payer priorities to identify where RWE can meaningfully support access and reimbursement decisions.

Phase 2: Co-Development of Local Evidence
Collaborate with HTA agencies, payers, and research institutions to generate relevant local RWE focused on priority therapeutic areas. Such partnerships enhance evidence credibility and policy alignment.

Phase 3: Policy Engagement and Integration
Work proactively with HTA and payer bodies to integrate RWE into pricing, reimbursement, and reassessment processes. Participation in adaptive access or outcome-based models can further reinforce trust and transparency.

By following this roadmap, pharmaceutical companies can transform RWE from a supporting element to a core access enabler, strengthening relationships with payers while demonstrating local relevance.

Case Examples: RWE Driving HTA and Reimbursement

Several health systems have successfully integrated RWE into their HTA and reimbursement processes, offering valuable insights for emerging markets such as those in the MENA region. These examples illustrate how structured RWE frameworks strengthen evidence-based decision-making, improve payer confidence, and promote value-based access.

In the United Kingdom, NICE has institutionalized the use of RWE in post-launch reassessments and managed entry agreements. Through data sources such as the Systemic Anti-Cancer Therapy (SACT) dataset and national electronic medical records, NICE evaluates real-world outcomes, safety, and quality of life for oncology and high-cost therapies. This approach enables conditional reimbursement, allowing treatments to remain covered while additional data are collected, with subsequent price renegotiations tied to observed performance. The UK experience demonstrates how national data infrastructure and mandatory reporting can create adaptive reimbursement systems that reward real-world value.

In Germany and Australia, RWE also plays an essential role in payer negotiations and post-market evaluations. Germany's Federal Joint Committee (G-BA) uses RWE to validate therapeutic benefit under the AMNOG framework, often adjusting or withdrawing reimbursement for drugs that fail to meet expected real-world outcomes. Similarly, Australia's Pharmaceutical Benefits Advisory Committee (PBAC) incorporates RWE into cost-effectiveness models, using longitudinal data and claims analyses to refine assumptions for chronic disease therapies. These systems underscore how structured RWE collection can inform performance-based pricing and maintain payer accountability without delaying access.

Within the MENA region, Saudi Arabia and the UAE are leading in adopting RWE for market access. The Saudi National HTA Center (NHTAC) under the Health Council has begun applying RWE in formulary decisions and value-based pricing evaluations, leveraging hospital and registry data to assess local effectiveness and budget impact. This initiative positions Saudi Arabia as a regional model for evidence-driven reimbursement, fostering collaboration between payers and manufacturers through outcomes-based contracting. The release of Abu Dhabi's HTA Guidelines (2025) represents a major milestone for the region, formalizing how RWE will inform both reimbursement and pricing decisions, setting a new benchmark for structured, payer-aligned evidence generation in the Gulf region. These pilots demonstrate how MENA countries can adapt global best practices embedding RWE within national HTA frameworks while tailoring them to local health system needs.

Collectively, these case examples highlight a clear pattern: RWE enhances the credibility, flexibility, and sustainability of reimbursement systems. For emerging HTA markets, the strategic lesson lies in adopting a phased approach building robust data infrastructure, defining transparent evidence standards, and fostering multi-stakeholder collaboration. By doing so, MENA countries can move confidently toward evidence-based and value-driven market access.

Future Outlook: Building an Evidence Ecosystem in MENA

MENA's HTA landscape is moving rapidly toward integrated, evidence-based decision systems. The coming decade will be defined by deeper collaboration between agencies, payers, and data providers, transforming RWE from a supporting data source into a central mechanism for access, pricing, and value reassessment.

HTA bodies are evolving into central decision partners, embedding RWE into post-launch evaluations, outcome-based assessments, and shared data governance frameworks. This shift is enabling more transparent and consistent payer decisions grounded in local evidence. In parallel, payers are adopting value-based procurement and performance-linked reimbursement, using RWE to forecast budgets, guide formulary inclusion, and design adaptive contracts that balance innovation with affordability.

Sustaining this progress will depend on coordinated investments in data infrastructure, interoperability, and analytic capacity. Regional efforts such as the GCC HTA Network and the Arab Health Value Forum are paving the way for harmonized evaluation standards and shared data platforms. Together, these initiatives signal a regional move toward a unified, evidence-driven approach, where RWE underpins every stage of HTA and payer decision-making to support equitable and sustainable access to innovation.

Conclusion

Real-world evidence has evolved from a supplementary data source into a strategic asset for market access. For emerging and Middle East markets, RWE offers a path toward localized, equitable, and sustainable healthcare decisions.

By investing in data infrastructure, fostering partnerships, and developing methodological capacity, governments and pharmaceutical firms can co-create a robust regional evidence ecosystem. In doing so, they will not only accelerate access to innovative therapies but also lay the foundation for evidence-informed policymaking across the region.

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