

ISPOR Trends for 2026 and 2027

Executive summary

This report analyzes what senior HEOR and Market Access teams should expect from ISPOR over the 2026–2027 period, using the best currently available signals: the published ISPOR 2026 annual-meeting program, the announced framing for ISPOR Europe 2026, the published ISPOR Europe 2025 program, and ISPOR’s official 2026–2027 Top 10 HEOR Trends report. Exact ISPOR 2027 session titles are not yet published on ISPOR’s conference pages, so forward-looking statements below should be read as evidence-based forecasts rather than confirmed agenda items. [1]

The strategic hierarchy is now unusually clear. ISPOR places **artificial intelligence** at the top of its 2026–2027 trends list, with **real-world evidence** second, **value-based healthcare** third, **drug pricing** fourth, **health technology assessment** eighth, and **value measurement** ninth. The 2026 annual program then turns that ranking into operational content: short courses on applied generative AI, issue panels on AI-assisted systematic review methods and AI-enabled curation, workshops on agentic AI for economic models, short courses on decision-grade RWE, a spotlight on FDA regulatory RWE, a forum on Living HTA, and panels on HEMA recommendations and value-based pricing for CMS negotiation. [2]

For HEOR and Market Access leaders, the practical message is straightforward. AI is moving from experimentation to governed workflow orchestration; EU HTA is moving from regulatory awareness to execution discipline; RWE is moving from descriptive support evidence to decision-grade and causal evidence; and value discussions are becoming simultaneously broader and harder because expanded value claims must now coexist with affordability pressure, CMS negotiation dynamics, and tighter scrutiny of opportunity cost. Official signals from the European Commission, EMA, FDA, NICE, HEMA, and CMS all point in the same direction. [3]

My central forecast is that the defining ISPOR conversation of 2026–2027 will not be “Should we use these methods?” It will be “Under what governance, reporting, validation, and decision-use conditions do these methods become acceptable?” That shift matters because it moves HEOR from innovation theater to operating model design. Teams that arrive with documented quality controls, auditable workflows, and integrated evidence planning will look prepared. Teams that arrive with isolated pilots and no traceability will look behind. [4]

ISPOR TRENDS FOR 2026 AND 2027

From Innovation to Implementation: Methods, Evidence, Value, and Access Converge

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ISPOR 2026–2027 TOP 10 HEOR TRENDS (OFFICIAL RANKING)

- 1 Artificial Intelligence
- 2 Real-World Evidence
- 3 Value-Based Healthcare
- 4 Drug Pricing
- 5 Innovative Therapies
- 6 Patient Centricity
- 7 Relevance of HEOR
- 8 Health Technology Assessment
- 9 Value Measurement
- 10 Digital Health

AI leads the agenda — but all top trends are interconnected.

OFFICIAL SIGNALS CONVERGE

- European Commission**
JCA and JSC rolling out in phases; EU HTA in implementation.
- EMA**
RWE Hub expansion, guidance, and accelerated multi-country RWE production.
- FDA**
Committed to fit-for-purpose RWD and increased regulatory use of RWE.
- NICE**
Advancing distributional CEA and health inequalities methods.
- HEMA**
Framework for broader value: relevance, valuation, opportunity cost.
- CMS**
Medicare drug price negotiation in effect; transparency improving but still limited.

FROM TRENDS TO CONTENT: WHAT ISPOR 2026 PROGRAMMING IS ALREADY DELIVERING

AI: FROM EXPERIMENTATION TO GOVERNED WORKFLOWS

- ✓ Short course: Applied Generative AI in HEOR
- ✓ Issue panel: AI-assisted systematic review methods
- ✓ Issue panel: AI-enabled curation for evidence synthesis
- ✓ Workshop: Agentic AI for economic models
- ✓ Focus on governance, validation, human-in-the-loop review, and responsible use

RWE: FROM DESCRIPTIVE TO DECISION-GRADE EVIDENCE

- ✓ Short course: Developing Decision-Grade RWE
- ✓ Issue panel / Spotlight: FDA Regulatory RWE
- ✓ Forum: Living HTA in an AI-enabled environment
- ✓ Focus on causal methods, target trial emulation, data suitability, and evidence refresh

VALUE & PRICING: BROADER AND HARDER

- ✓ Panel: HEMA recommendations on broader value elements
- ✓ Panel: Labor market effects in HTA
- ✓ Panel: Value-Based Pricing for CMS Drug Negotiation
- ✓ Focus on opportunity cost, affordability, negotiation realities, and implementation

HTA & MARKET ACCESS: EXECUTION DISCIPLINE

- ✓ EU HTA execution, JCA & JSC operationalization
- ✓ Evidence planning aligned to regulatory & HTA timelines
- ✓ Integration of clinical, HEOR, and access strategies
- ✓ Cross-functional governance and end-to-end launch architecture

MY CENTRAL FORECAST FOR ISPOR 2026–2027

The defining conversation will shift from...

"Should we use these methods?"

↓ ...to

"Under what governance, reporting, validation, and decision-use conditions do these methods become acceptable?"

★ AI, EU HTA, RWE, and Value are not independent trends.
They form a connected system that will reshape how evidence is generated, evaluated, and used to inform access and coverage decisions.

KEY IMPLICATIONS FOR HEOR & MARKET ACCESS LEADERS

- Build Integrated Launch Architecture** → Start evidence planning early with aligned inputs from clinical, regulatory, HEOR, pricing, and market access.
- Institutionalize Quality and Governance** → Define standards for AI use, RWE methods, reporting (e.g., ELEVATE-GenAI, TARGET, CONSORT-AI, CHEERS-AI), and human review.
- Invest in Decision-Grade RWE Capabilities** → Develop causal methods expertise, target trial emulation, and data suitability frameworks; plan for Living HTA.
- Balance Broader Value with Affordability Reality** → Use a core-plus-extensions value framework; stress-test against opportunity cost and pricing negotiation dynamics.
- Strengthen Cross-Functional Governance** → One accountable body should oversee evidence strategy from pivotal design to HTA submission to post-launch evidence commitments.

ISPOR 2026–2027 will reward teams that combine method rigor, operational excellence, and strategic alignment to deliver trusted evidence that informs real-world decisions.

SOURCES
 ISPOR Top 10 HEOR Trends 2026–2027 • ISPOR 2026 Annual Meeting Program
 ISPOR Europe 2026 (Announced Framing) • ISPOR Europe 2025 Program
 European Commission JCA Factsheet & Q&A (May 2024) • EMA RWE Hub & RWE Report 2025
 FDA RWE Framework (Oct 2024) • NICE Health Inequalities Work (2024–2025)
 HEMA Report: Consideration of Broader Elements in HTA (March 2026)
 CMS Medicare Drug Price Negotiation Program (2026–2028)

CONFERENCES TO WATCH
 ISPOR Europe 2026
 8–11 November 2026
 Barcelona, Spain
 ISPOR 2027 (Global)
 Dates TBC

Strategic comparison and timeline

The table below is an analyst synthesis of the official ISPOR 2026 program, the ISPOR Europe 2026 conference framing, the 2026–2027 Top 10 Trends report, and the relevant external policy environment. “Strategic priority,” “regulatory risk,” and “required capabilities” are interpretive assessments intended to support portfolio planning rather than quoted classifications from any single source. [5]

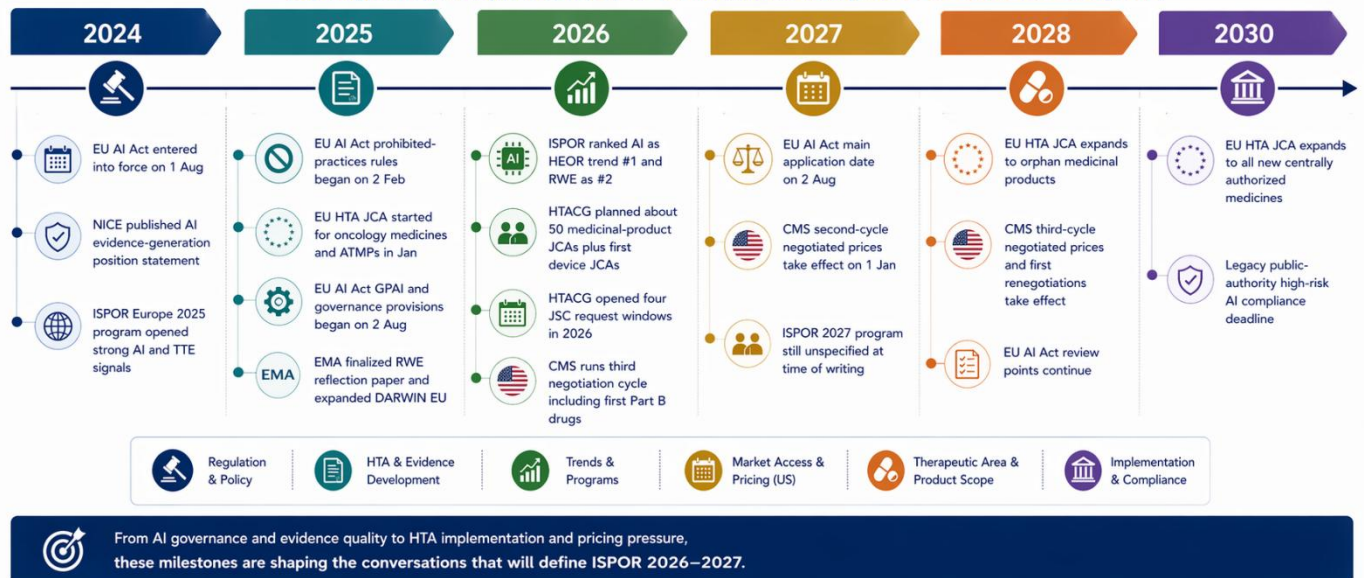
Topic	Strategic priority	Time horizon	Regulatory risk	Required capabilities	Likely ISPOR session types
AI in HEOR and Market Access	Very high	Immediate to 24 months	Medium to high, depending on use case and governance maturity	RAG/LLM workflow design, validation, QA, privacy, IP, model governance, prompt and agent orchestration	Short courses, workshops, issue panels, research podiums

Topic	Strategic priority	Time horizon	Regulatory risk	Required capabilities	Likely ISPOR session types
EU HTA and JCA evidence planning	Very high for EU launches	Immediate to 2030	High	Integrated evidence planning, comparator strategy, PICO readiness, cross-functional governance, country adaptation	Educational symposia, issue panels, forums, theater sessions
Decision-grade RWE and target trial emulation	High	Immediate to medium term	High	Epidemiology, causal inference, estimands, data engineering, protocoling, interoperability, statistical programming	Short courses, spotlight sessions, workshops, issue panels, research podiums
Evolving value frameworks, affordability, and pricing	High	Immediate to 3 years	High policy and payer risk	Traditional and expanded value assessment, budget impact, equity analysis, payer evidence strategy, pricing and negotiation analytics	Issue panels, educational symposia, forums, research podiums

The milestone path below highlights the external events most likely to shape ISPOR discourse from the near term into the medium term. It combines official EU AI Act application dates, EU HTA/JCA rollout dates, posted JSC windows and planning numbers, DARWIN EU growth and RWE throughput, and CMS negotiation-cycle milestones. [6]

HEOR and Market Access Milestones Shaping ISPOR Discussion

Key Regulatory, Policy, and Evidence Developments Driving the 2026–2027 ISPOR Agenda



A final planning note: ISPOR has already posted dates for ISPOR 2027 and ISPOR Europe 2027, but not their session programs. That matters because the most defensible way to predict 2027 content is to extrapolate from the published 2026 annual meeting, the published Europe 2025 program, the Europe 2026 theme, and ISPOR’s own two-year trends report. [7]

Artificial intelligence becomes the organizing theme

Artificial intelligence is no longer just one topic among many in HEOR; it is increasingly the organizing theme through which other topics are being reframed. ISPOR’s 2026–2027 Top 10 Trends report moves AI to the number-one position and explicitly frames the challenge as “transforming HEOR through responsible use of AI.” The official ISPOR AI topic page then reinforces that this is not a one-off conference fad: ISPOR is curating a durable methods agenda around the GenAI taxonomy, ELEVATE-GenAI reporting guidance, HTA-focused AI policy considerations, CHEERS-AI, and PALISADE. The 2026 annual program operationalizes that agenda with short courses on applied generative AI, prompt engineering, RAG, and agents; issue panels on AI guidance and AI-assisted systematic review tools; and workshops on agentic AI for building health economic models in both R and Excel. [8]

The reason AI is becoming central is not simply productivity. It is because AI now touches the full HEOR pipeline: literature identification and screening, extraction from clinical narratives and pathology reports, model specification and implementation, real-world data curation, dossier drafting, and evidence communication. The ISPOR Working Group taxonomy is explicit on this point. It identifies systematic reviews, health economic modeling, RWE generation, and dossier development as major use cases, while also stressing that scientific validity, reproducibility, bias and fairness, and operational deployment remain unresolved

enough that autonomous use is not yet appropriate. ELEVATE-GenAI pushes the field further by offering a reporting structure across ten domains, including model characteristics, accuracy, reproducibility, and fairness and bias. In practical terms, that means AI at ISPOR is maturing from “what can the tool do?” to “how do we report and defend its use?” [9]

Official HTA and evidence bodies are converging on the same stance. NICE’s position statement says AI methods should be used only when they add demonstrable value, when the rationale is clear, and when transparency, rigor, and trust can be maintained. It explicitly warns about algorithmic bias, cybersecurity, reduced human oversight, and the difficulty of defending black-box methods. Crucially for HEOR teams, NICE identifies causal inference as a higher-risk application of AI and expects sensitivity analysis, checking against other methods, and triangulation against available clinical evidence. NICE also makes plain that AI should augment human involvement, not replace it. That is now close to being the consensus operating principle for regulated HEOR. [10]

The 2025-to-2026 ISPOR program arc confirms that the field is moving from introduction to industrialization. ISPOR Europe 2025 still had a strong “what is possible?” flavor, with short courses on applied GenAI, LLMs for RWE research, and panels on integrating AI into market access workflows. By ISPOR 2026, the topics are already more operational: how to operationalize AI guidance for abstraction and curation, whether there is consensus on AI-assisted systematic review evaluation, how to use agentic systems to build economic models, and how to support Living HTA at the pace of evolving evidence. This is exactly what one would expect when a technology crosses from curiosity to infrastructure. [11]

The best empirical evidence currently available also points toward guarded optimism, not indiscriminate automation. A 2025 JAMIA paper describing an LLM-assisted, human-in-the-loop system for systematic literature reviews in HTA submissions reported high abstract-screening sensitivity, substantial agreement with human reviewers, and strong data-extraction performance, while still positioning the workflow around expert control and iterative refinement of PICOS criteria. That is a meaningful signal for ISPOR discussions because it shows the likely acceptable pattern: AI to accelerate and structure, humans to review, adjust, and sign off. [12]

My forecast for ISPOR 2026–2027 is therefore specific. AI discussions will increasingly center on five things. First, **workflow architecture**: RAG, agents, prompting strategy, document routing, and orchestration across tasks. Second, **validation**: benchmark tasks against human reviewers, agreement statistics, quality thresholds, and error taxonomies. Third, **governance**: privacy, cybersecurity, vendor due diligence, licensing, and traceability. Fourth, **reporting standards**: ELEVATE-GenAI, PALISADE, CHEERS-AI, and method declarations that make AI use auditable. Fifth, **acceptability in regulated settings**: not whether AI can help, but whether outputs are robust enough for HTA, payer, and regulatory scrutiny. The strongest ISPOR sessions are likely to be the ones that connect all five, rather than merely demonstrating text generation. [13]

For HEOR and Market Access teams, the practical implication is that AI should now be governed like a research capability, not piloted like an office productivity app. The near-term

value pool is obvious: TLR/SLR acceleration, evidence landscaping, structured abstraction from unstructured records, technical writing support, model prototyping, and faster portfolio scanning. But the real differentiator will be who can wrap those applications in standard operating procedures, quality checkpoints, source-grounding, reproducibility controls, and clear disclosure language. In the next two ISPOR cycles, “AI maturity” will increasingly mean operational discipline, not breadth of experimentation. [14]

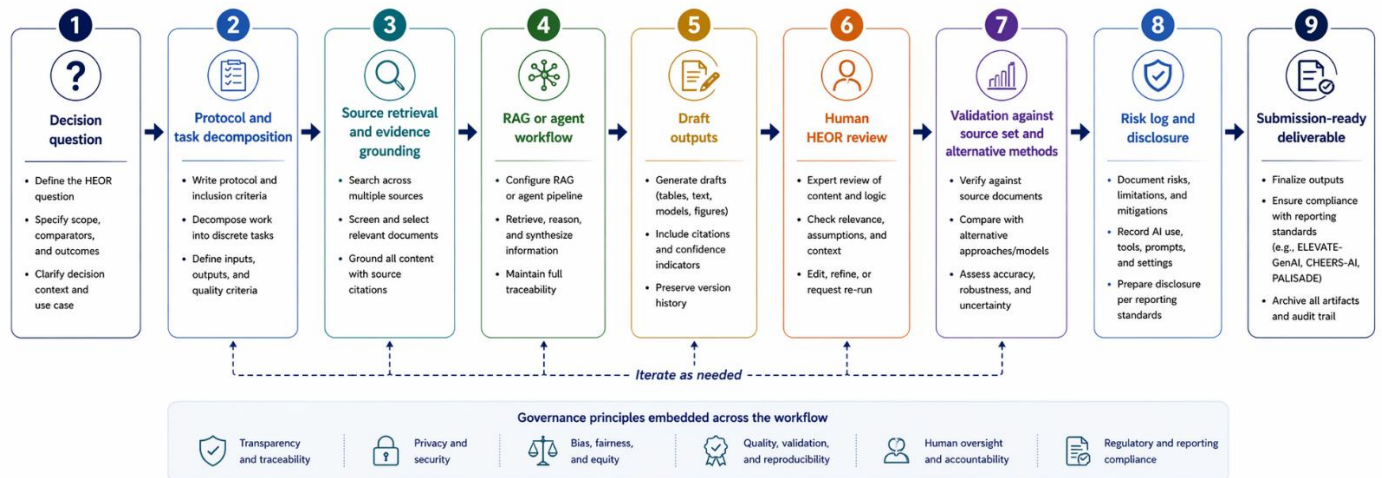
ARTIFICIAL INTELLIGENCE BECOMES THE ORGANIZING THEME

Transforming HEOR Through Responsible, Transparent, and Validated Use of AI

<p>WHY AI IS NOW THE ORGANIZING THEME</p> <ul style="list-style-type: none"> ISPOR 2026–2027 Top 10 Trends ranks AI #1 and frames the challenge as “transforming HEOR through responsible use of AI.” ISPOR AI Topic Page curates a durable methods agenda: GenAI taxonomy, ELEVATE-GenAI, HTA AI policy, CHEERS-AI, PALISADE, and more. ISPOR 2026 Annual Program operationalizes the agenda with short courses, issue panels, and workshops on applied AI, RAG, agents, AI guidance, and AI in modeling. <p>★ AI is moving HEOR from “what can the tool do?” to “how do we report and defend its use?”</p>	<p>AI TOUCHES THE FULL HEOR PIPELINE</p> <ol style="list-style-type: none"> Literature Identification & Screening Extraction from Clinical Narratives & Reports Real-World Data Curation & Linkage Model Specification & Implementation Dossier Drafting & Documentation Evidence Communication & Decision Support <p>ISPOR Working Group GenAI Taxonomy (Key Use Areas)</p> <ul style="list-style-type: none"> Systematic Reviews & Evidence Synthesis Health Economic Modeling Real-World Evidence Generation & Curation Dossier & Report Development <p>⚠️ Open challenges: scientific validity, reproducibility, bias & fairness, data privacy, and operational deployment. Autonomous use is not yet appropriate.</p>	<p>OFFICIAL EVIDENCE & HTA BODIES ALIGN</p> <ul style="list-style-type: none"> NICE NICE Position Statement (2025) Use AI only when it adds demonstrable value, with clear rationale, transparency, rigor, and trust. Warns about bias, cybersecurity, reduced human oversight, and black-box methods. Causal inference = higher risk: expect sensitivity analysis, triangulation, and checks against clinical evidence. EMA Investing in AI for medicines regulation while emphasizing human oversight, data quality, and algorithm reliability. FDA Committed to fit-for-purpose RWD/RWE and exploring AI/ML across the product lifecycle with appropriate controls. HEMA (March 2026 Report) Framework for broader value built on relevance, valuation, and opportunity cost; calls for consistent, practical, and non-duplicative use of expanded value elements.
<p>THE ISPOR PROGRAM ARC: FROM INTRODUCTION TO INDUSTRIALIZATION</p> <div style="display: flex;"> <div style="flex: 1;"> <p>ISPOR Europe 2025 What is possible?</p> <ul style="list-style-type: none"> Short courses on applied GenAI and LLMs for RWE research Panels on integrating AI into market access workflows Exploring capabilities and early use cases </div> <div style="flex: 1;"> <p>ISPOR 2026 (Global) How do we operationalize and govern?</p> <ul style="list-style-type: none"> Operationalizing AI guidance for abstraction & curation Is there consensus on AI-assisted systematic review evaluation? Agentic systems to build economic models (R & Excel) Supporting Living HTA in an AI-enabled, real-world evidence environment </div> </div>		<p>EMERGING EMPIRICAL EVIDENCE: GUARDED OPTIMISM</p> <div style="display: flex;"> <div style="flex: 1;"> <p>2025 JAMIA Study LLM-assisted, human-in-the-loop system for systematic literature reviews in HTA submissions</p> <ul style="list-style-type: none"> High abstract-screening sensitivity Substantial agreement with human reviewers Strong data-extraction performance <p>The likely acceptable pattern: AI to accelerate and structure, humans to review, adjust, and sign off.</p> </div> <div style="flex: 1;"> <p>PREROCAL EMPIRICAL EVIDENCE: GUARDEA OPTIMISR TOOL</p> <ul style="list-style-type: none"> Standard Operating Procedures (SOPs) for AI use Quality checkpoints & human-in-the-loop review Source-grounding & citation of all outputs Reproducibility controls & version management Reporting & disclosure aligned with ELEVATE-GenAI and other guidance Training, skills, and AI literacy across functions </div> </div>
<p>FORECAST: THE 5 FOCAL POINTS FOR AI DISCUSSIONS AT ISPOR 2026–2027</p> <ol style="list-style-type: none"> WORKFLOW ARCHITECTURE RAG, agents, prompting strategy, document routing, and orchestration across tasks. VALIDATION Benchmark tasks against human reviewers, agreement statistics, quality thresholds, and error taxonomies. GOVERNANCE Privacy, cybersecurity, vendor due diligence, licensing, data security, and traceability. REPORTING STANDARDS ELEVATE-GenAI, PALISADE, CHEERS-AI, and method declarations that make AI use auditable. ACCEPTABILITY IN REGULATED SETTINGS Outputs robust enough for HTA, payer, and regulatory scrutiny. Focus on evidence quality, not just capability. <p>★ The strongest ISPOR sessions will connect all five: architecture + validation + governance + reporting + acceptability.</p>		<p>PRACTICAL IMPLICATIONS FOR HEOR & MARKET ACCESS TEAMS</p> <div style="display: flex;"> <div style="flex: 1;"> <p>NEAR-TERM VALUE POOL</p> <ul style="list-style-type: none"> TLR/SLR acceleration & automation Evidence landscaping & horizon scanning Structured abstraction from unstructured data (clinical notes, pathology, imaging reports) Technical writing & dossier drafting support Model prototyping & scenario analysis Faster portfolio & competitive intelligence </div> <div style="flex: 1;"> <p>AI AS A RESEARCH CAPABILITY, NOT A CONSUMER TOOL</p> <ul style="list-style-type: none"> Standard Operating Procedures (SOPs) for AI use Quality checkpoints & human-in-the-loop review Source-grounding & citation of all outputs Reproducibility controls & version management Reporting & disclosure aligned with ELEVATE-GenAI and other guidance Training, skills, and AI literacy across functions <p>★ In the next two ISPOR cycles, “AI maturity” will mean operational discipline, not the breadth of experimentation.</p> </div> </div>
<p>AI is reshaping how evidence is generated, analyzed, and communicated. The differentiator will be governance, quality, and trust—at scale.</p>		<p>KEY REFERENCES</p> <ul style="list-style-type: none"> ISPOR Top 10 HEOR Trends 2026–2027 ISPOR AI Topic Page ISPOR 2026 Annual Meeting Program ISPOR Europe 2026 (Announced Framing) ISPOR Europe 2025 Program NICE AI Position Statement (2025) HEMA Report: Consideration of Broader Elements in HTA (Mar 2026) FDA Framework for RWE (Oct 2024) JAMIA 2025:32(4):uaaf030 (LLM-assisted SLR in HTA)

The workflow below synthesizes the controls emphasized by the ISPOR AI taxonomy, the ELEVATE-GenAI reporting framework, NICE’s AI position, and the practical content of the ISPOR 2026 AI courses. [15]

AI-Enabled HEOR Workflow with Governance and Human Oversight

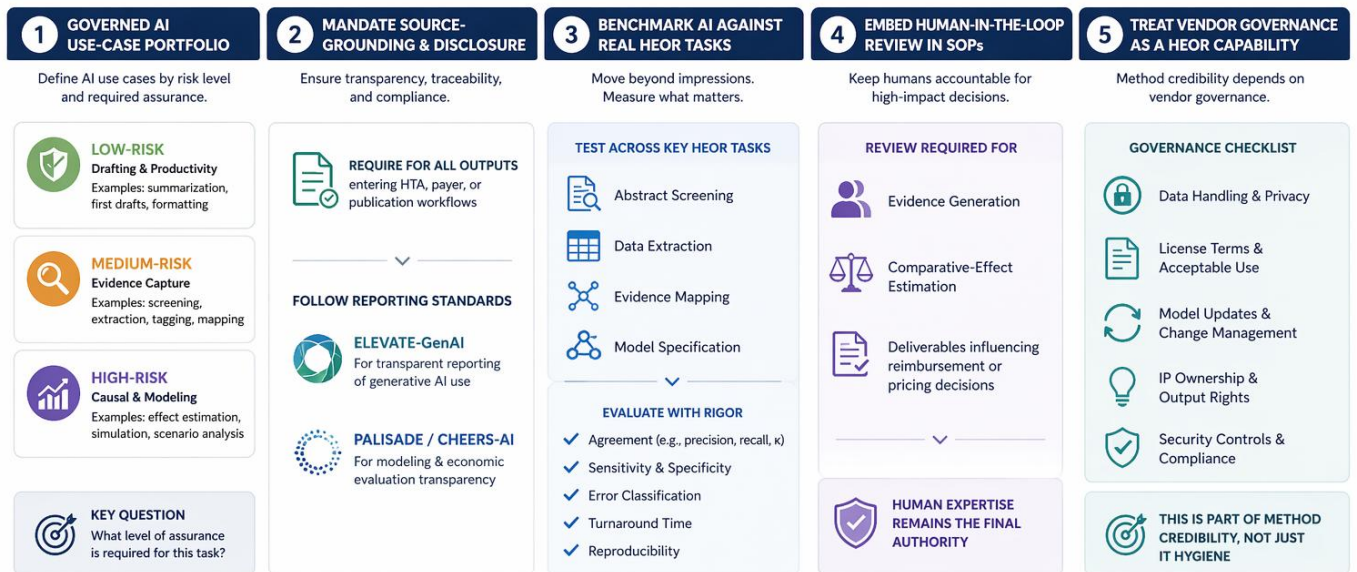


The most useful actions for senior teams are concrete rather than conceptual:

- **Define a governed AI use-case portfolio** with separate tracks for low-risk drafting uses, medium-risk evidence-capture uses, and high-risk causal or modeling uses. The key question is not “Can we automate it?” but “What level of assurance is required for this task?” [16]
- **Mandate source-grounding and disclosure** for any output that could enter an HTA, payer, or publication workflow, using a reporting structure aligned to ELEVATE-GenAI and, where relevant, PALISADE or CHEERS-AI. [17]
- **Benchmark AI against real HEOR tasks** such as abstract screening, extraction, evidence mapping, and model specification, using agreement, sensitivity, error classification, and turnaround time rather than anecdotal user satisfaction. [18]
- **Build human-in-the-loop review into SOPs**, especially for evidence generation, comparative-effect estimation, and any deliverable that could influence reimbursement or pricing decisions. [19]
- **Treat vendor governance as a HEOR capability**, including contractual review of data handling, license terms, model updates, IP ownership, and security controls, because these are now part of method credibility, not just IT hygiene. [20]

Operationalizing AI in HEOR & Market Access

From Concept to Trusted Impact



THE OUTCOME: TRUSTED, TRANSPARENT, AND IMPACTFUL AI IN HEOR & MARKET ACCESS



“ AI does the heavy lifting. Humans stay in control. Always. — Responsible AI is a HEOR capability.

Sources: ELEVATE-GenAI (2024); PALISADE (2024); CHEERS-AI (2024); ISPOR (2024-2025); NICE (2024); Vandenberg et al. Value in Health (2023); Luo et al. Value in Health (2024).

European HTA and JCA reshape evidence planning

EU HTA is now firmly in the implementation phase, and that changes the center of gravity of HEOR planning. The Commission’s JCA factsheet and Q&A make three points that matter operationally. First, Joint Clinical Assessments support national HTA processes by analyzing **clinical** evidence on relative effects; they do **not** issue value judgments or reimbursement conclusions, which remain national. Second, the rollout is phased: from January 2025 for new oncology medicines and ATMPs, from January 2028 for orphan medicinal products, and from January 2030 for all new medicinal products in scope. Third, the process runs in parallel with the EMA centralized procedure, with a defined scoping phase, developer dossier timelines, and endorsement steps after marketing authorization. This means evidence planning for Europe can no longer be left to late-stage local adaptation. [21]

The 2026 implementation program confirms the operational scale-up. HTACG’s 2026 work program expects roughly 35 oncology JCAs, roughly 15 ATMP JCAs, potential JCA initiation on three variations, and the first selected medical-device JCAs starting in June 2026. It also plans 8–12 JSCs for medicinal products and 2–5 for devices, with four request windows in 2026. The Commission’s JSC page is explicit that these consultations are intended to help developers plan clinical studies around future JCA evidence needs and improve the quality

of evidence generation. For sponsors and advisors, this is a structural invitation to move HTA thinking earlier in development. [22]

ISPOR programming already reflects that shift. ISPOR Europe 2025 included an educational symposium on strategic insights from five years of the EU HTA Regulation, emphasizing preparation for JCA submissions and integrated evidence plans for orphan products and vaccines. ISPOR 2026 adds a theater session on “Global Evidence Under Pressure,” explicitly framed around diverging evidentiary expectations across the United States, Europe, and Asia-Pacific. ISPOR Europe 2026’s public framing also underscores that value assessment, pricing policy, RWE, innovative payment models, and patient-centered outcomes are being linked more tightly to access and policy decisions. Together, these signals suggest that EU HTA will be treated less as a stand-alone regulatory change and more as a catalyst for redesigning global evidence strategy. [23]

The practical challenge is that JCA does not eliminate national HTA variation; it changes where variation sits. If the clinical backbone is increasingly shared at EU level, national assessment effort and debate will shift toward country-specific interpretation, non-clinical domains, cost-effectiveness, budget impact, implementation constraints, and access negotiation. That means teams must learn to separate what should be globally standardized from what must still be locally tailored. In other words, the right operating model is not one global dossier or many disconnected national dossiers. It is a **common evidence backbone with local decision layers**. [24]

My forecast for ISPOR is that the most substantive EU HTA discussions will cluster around five problem sets. The first is **PICO governance**: how developers anticipate likely comparators, subgroups, and outcomes before formal scoping crystallizes them. The second is **cross-functional timing**: integrating regulatory, clinical-development, HEOR, and market-access inputs early enough to matter. The third is **evidence portability**: how much a trial, indirect comparison, or post-launch RWE package can satisfy multiple decision makers at once. The fourth is **variation management**: how to bridge JCA findings into national value, budget, and reimbursement narratives without contradiction. The fifth is **organizational design**: who owns JCA readiness inside global organizations. The 2027 program, when published, is very likely to intensify rather than soften these themes because implementation volume will be higher and more sponsors will have real submission experience by then. [25]

For HEOR and Market Access teams, the direct implication is that evidence planning has to start with launch architecture, not end with it. Early comparators, endpoint hierarchy, statistical estimands, subgroup rationale, indirect-comparison strategy, and potential post-launch uncertainty-reduction plans must be considered as an integrated package. JSC is especially important here: the Commission explicitly positions it as a mechanism to align clinical-study planning with later JCA evidence needs. In practice, teams that treat JSC as a procedural option rather than a strategic instrument will likely leave value on the table. [26]

The second implication is organizational. EU HTA makes the historical separation between “global evidence,” “regional access,” and “country submissions” less sustainable. The

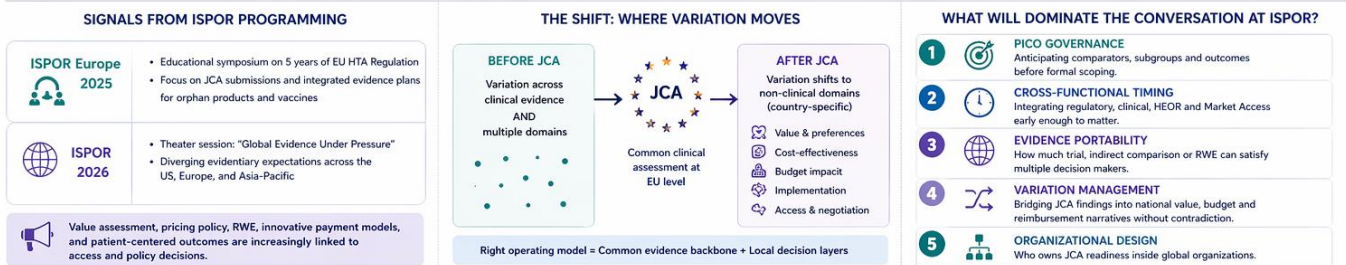
evidence questions are becoming too interconnected. For senior leaders, this means governance should move upstream: one cross-functional body should oversee evidence architecture from pivotal-trial design through JCA preparation to national adaptation, with explicit decision rights on comparators, estimands, indirect comparisons, and post-launch evidence commitments. The cost of not doing so will increasingly be inconsistency rather than just inefficiency. [27]

The actions that matter most now are the following:

- **Create an EU HTA launch-readiness workstream at asset level** no later than late phase II or early phase III, with named owners from clinical, regulatory, HEOR, and Market Access. [26]
- **Build a reusable clinical evidence backbone** that is explicitly designed for JCA clinical domains and then layered with local country-specific economic and budget-impact components. [28]
- **Use JSC strategically, not defensively**, especially where comparator choice, endpoint hierarchy, or uncertainty management could materially affect later JCA and national appraisal. [26]
- **Stress-test pivotal programs against likely European PICO challenges** before final protocol lock, including a plan for indirect comparisons and post-launch evidence generation where residual uncertainty is foreseeable. [29]
- **Separate “common evidence” from “local decision story” in governance**, so teams do not either over-centralize what remains country-specific or duplicate what can now be standardized. [30]

EU HTA & JCA: A New Era for Evidence Planning and Market Access

From Regulation to Real-World Impact: Prepare Early, Align Globally, Adapt Locally



EU HTA Implementation is not just a regulatory change — it is a catalyst to redesign global evidence strategy. *Start early. Align globally. Adapt locally. Deliver value.*

Fit for HTA scrutiny. Fit for patients. Fit for the future.

Key References • European Commission. Joint Clinical Assessments (JCA) Factsheet & Q&A. May 2024. • HTACG 2026 Work Programme. European Commission. • European Commission. Joint Scientific Consultations (JSC). • ISPOR Europe 2025 Program. • ISPOR 2026 Program.

Decision-grade RWE and target trial emulation mature

Real-world evidence remains one of the most important structural drivers of ISPOR content, even after AI overtook it in the trend rankings. ISPOR still places RWE at number two for 2026–2027, and that ranking is supported by what regulators are actually doing. FDA states that advances in the availability and analysis of RWD have increased the potential for robust RWE to support regulatory decisions and that the agency is committed to fit-for-purpose RWD across the product lifecycle. EMA has gone further in system-building: its RWE hub now includes a roadmap for guidance development, a finalized reflection paper on RWD in non-interventional studies, catalogues and good-practice materials, and a clearly defined route for regulators, HTA bodies, and payers to request studies through EMA. [31]

The most important qualitative shift is that “good RWE” is increasingly being defined in causal and operational terms, not simply in descriptive terms. EMA’s 2025 reflection paper distinguishes between descriptive and causal non-interventional studies, emphasizes that the research question must be expressed in sufficient detail to drive data-source choice and analytic design, and identifies **reliability** and **relevance** as critical data-quality dimensions. The same document highlights that explicit design elements, trial-emulation logic, and early discussion with regulators are key to regulatory usefulness. The TARGET guideline, published in JAMA in 2025, complements this by providing a consensus reporting structure

for observational studies explicitly aiming to emulate a target trial, including specification of the target trial protocol, causal estimand, assumptions, mapping to observational data, and sensitivity analyses. [32]

The infrastructure is maturing too. EMA's third RWE report states that 59 studies were conducted between February 2024 and February 2025, with DARWIN EU expanded to 30 data partners across 16 countries covering roughly 180 million patients, and with a median duration of four months from protocol approval to final study results. That is not merely a capacity statistic; it is a signal that European regulators are trying to industrialize timely, multi-country RWE production. The report also notes that research topics were requested not only by EMA committees and internal EMA functions, but also by HTA bodies, payers, ECDC, and the European Commission. For HEOR teams, that means the institutional demand for RWE is broadening, not narrowing. [33]

ISPOR's own program arc mirrors this maturation. ISPOR Europe 2025 offered an advanced short course on causal inference, causal estimands, and target trial emulation, explicitly tying these methods to external control arms, treatment switching, and HTA-agency acceptance. It also hosted an issue panel on external control studies. ISPOR 2026 then deepens the operational focus with a short course on developing decision-grade RWE, an issue panel debating whether scientists should actively architect RWD rather than remain end users, a spotlight on FDA RWE in regulatory decision making, and a forum on Living HTA in an AI-enabled environment. Taken together, these sessions show that the field is moving past the binary "RWE versus RCT" framing toward more precise questions about design quality, data architecture, and use conditions. [34]

TARGET-EU is especially important as a directional signal. Registered in the HMA-EMA catalogues in 2025, the project aims to advance regulatory use of RWD through target trial emulation and estimand methods, including work on where TTE is useful, how European RWD sources should be assessed for fitness for purpose, and how TTE results should be communicated to regulators. That combination—methods, data suitability, and communication guidance—is exactly the combination likely to show up increasingly in ISPOR sessions. In other words, target trial emulation is graduating from methodological niche to institutional method-development program. [35]

My forecast is that the most important RWE discussions at ISPOR will increasingly revolve around four implementation questions. First, **how to define the causal question and estimand clearly enough** that the resulting study is actually decision-relevant. Second, **how to prove data suitability**—including completeness, provenance, linkage quality, timeliness, and the ability to operationalize key eligibility and outcome definitions. Third, **how to report and stress-test the design**, including immortal-time risk, confounding control, sensitivity analyses, and transparent trial-emulation specifications. Fourth, **how to sustain evidence refresh over time**, especially for high-uncertainty products, post-launch expansions, or fast-moving therapy areas. That last point is where Living HTA enters: once institutions accept continuously updated evidence environments, static one-off appraisals become progressively less satisfactory. [36]

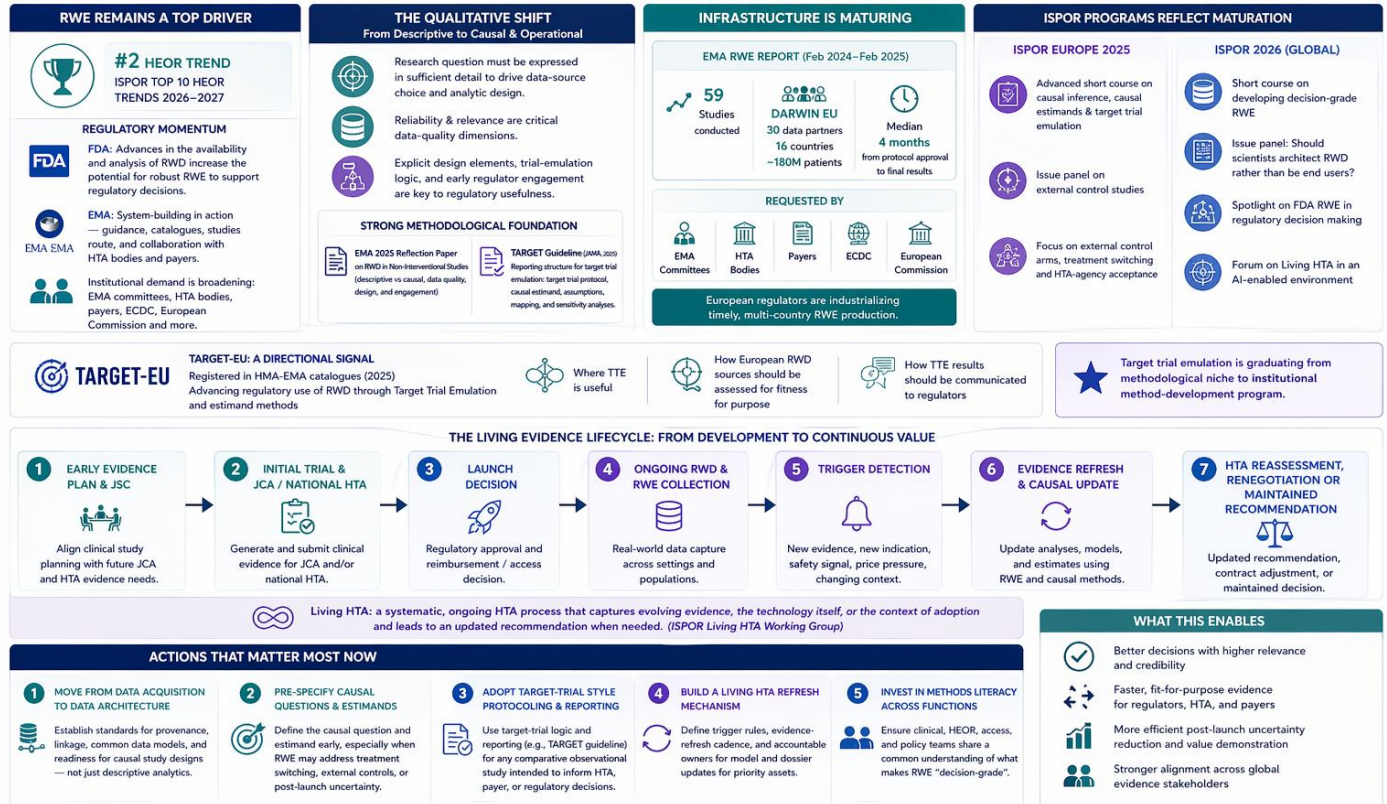
Living HTA is still an emerging construct, but its importance is rising. ISPOR's Living HTA working-group material defines it as a systematic, ongoing HTA process that captures evolving evidence, the technology itself, or the context of adoption, leading to an updated recommendation when needed. That is highly compatible with the increasing use of RWD, model updating, and post-launch uncertainty reduction. For MA/HEOR teams, the practical implication is significant: evidence strategy should increasingly be designed as a versioned system rather than a one-time dossier event. [37]

The actions I would prioritize are these:

- **Move from data acquisition to data architecture**, with explicit standards for provenance, linkage, common data models, and readiness for causal study designs rather than only descriptive analytics. [39]
- **Pre-specify causal questions and estimands early**, especially when RWE may address treatment switching, external controls, or post-launch uncertainty reduction. [40]
- **Adopt target-trial style protocoling and reporting** for any comparative observational study intended to inform HTA, payer, or regulatory decisions. [41]
- **Build a Living HTA refresh mechanism** for priority assets, with trigger rules, evidence-refresh cadence, and accountable owners for model and dossier updates. [42]
- **Invest in methods literacy across functions**, not only among epidemiologists: clinical, HEOR, access, and policy teams all need a common understanding of what makes RWE “decision-grade.” [43]

Decision-Grade RWE and Target Trial Emulation Mature

From Descriptive Data to Causal Evidence that Informs Decisions Across the Lifecycle



Key References: ISPOR Top 10 HEOR Trends 2026–2027 • FDA Framework for RWE • EMA RWE Hub & Roadmap • EMA Reflection Paper on RWD in Non-Interventional Studies (2025) • TARGET Guideline (JAMA, 2025) • EMA RWE Report 2025 • TARGET-EU Project (HMA-EMA Catalogues, 2025) • ISPOR Europe 2025 Program • ISPOR 2026 Program • ISPOR Living HTA Working Group

Value frameworks meet affordability and pricing pressure

The value debate at ISPOR is changing in an important way. For several years, conversations about “broader value” could still be treated as mostly methodological or aspirational. That is much less true now. ISPOR’s 2026–2027 trends report puts **value-based healthcare** at number three, **drug pricing** at number four, **HTA** at number eight, and **value measurement** at number nine. Meanwhile, ISPOR Europe 2026 is publicly framed around value assessment, pricing policy, RWE, innovative payment models, and patient-centered outcomes. The 2026 annual program reinforces the same convergence through panels on HEMA recommendations, broader value elements, labor-market effects in HTA, and value-based pricing for CMS drug negotiation. [44]

HEMA is a major reason this discussion is becoming more disciplined. Its March 2026 report does not simply endorse broader value. It builds a framework for deciding which benefit elements should count in economic evaluation and on what basis. The guiding principles are relevance, valuation, and opportunity cost. That last principle matters most strategically: if decision makers expand the benefits counted in evaluation, they should also think about whether the corresponding opportunity costs must be expanded. HEMA explicitly places equity, risk attitudes, diagnostics-related process benefits, and expanded-perspective elements such as productivity within the scope of the debate, but insists that valuation be

consistent, practical, and non-duplicative. This pushes the conversation away from rhetoric and toward decision consequences. [45]

Other agencies are moving, but selectively. NICE's health-inequalities work now explicitly acknowledges distributional cost-effectiveness analysis as a way to estimate how technologies affect inequalities in QALYs, and its recent method updates explain when a technology might justifiably be analyzed for its distributional impact. Canada's Drug Agency has opened draft methodological guidance on incorporating informal-caregiver health-related quality of life and productivity outcomes for patients and informal caregivers into economic evaluations. Those developments suggest that value frameworks are broadening, but through bounded, method-specific extensions rather than unrestricted proliferation of novel value elements. [46]

At the same time, affordability pressure is intensifying. CMS has already published negotiated prices for the first ten selected Part D drugs effective in 2026 and for the second set of fifteen Part D drugs effective in 2027. For the third cycle, CMS has selected fifteen additional drugs for negotiation, including the first-ever Part B drugs, with prices to take effect in 2028; it has also established guidance for renegotiation. CMS emphasizes that comparative clinical effectiveness, unmet need, and other statutory evidence factors are considered in negotiation, but the ultimate mapping from evidence to price remains only partially transparent. This combination—greater evidence use but persistent pricing opacity—is exactly the kind of issue that tends to drive high-energy ISPOR debate. [47]

That is why I expect ISPOR discussions on value to become more dual-track. One track will center on **expanded value measurement**: whole health, broader value elements, equity, caregiver effects, productivity, and patient experience. The other will center on **budget realism**: affordability, negotiation, implementation, and opportunity cost. The interesting frontier is their interaction. HEMA makes clear that one cannot simply load more benefits into the numerator of value arguments without also considering the displaced benefits created by incremental cost. CMS, meanwhile, ensures that pricing debates are no longer theoretical background noise; they are now policy machinery with real commercial consequences. [48]

My forecast is that the most important ISPOR value sessions will ask more operational questions than philosophical ones. Which broader value elements are really decision-relevant? How should they be measured across disease areas? How do we avoid double counting between utility, productivity, caregiver outcomes, and experience measures? When does equity meaningfully change a recommendation versus simply decorate it? How should value-based pricing arguments be adapted when public programs negotiate on partially transparent rules? And how should manufacturers present a value story when payers are under simultaneous pressure to widen access and contain spend? Expect fewer generic invocations of the “value flower” and more debates about thresholds, weights, evidence standards, and feasibility. [49]

For senior Market Access teams, that means the classic single-layer value narrative is no longer enough. The likely winning structure is a **two-layer value story**. The first layer is

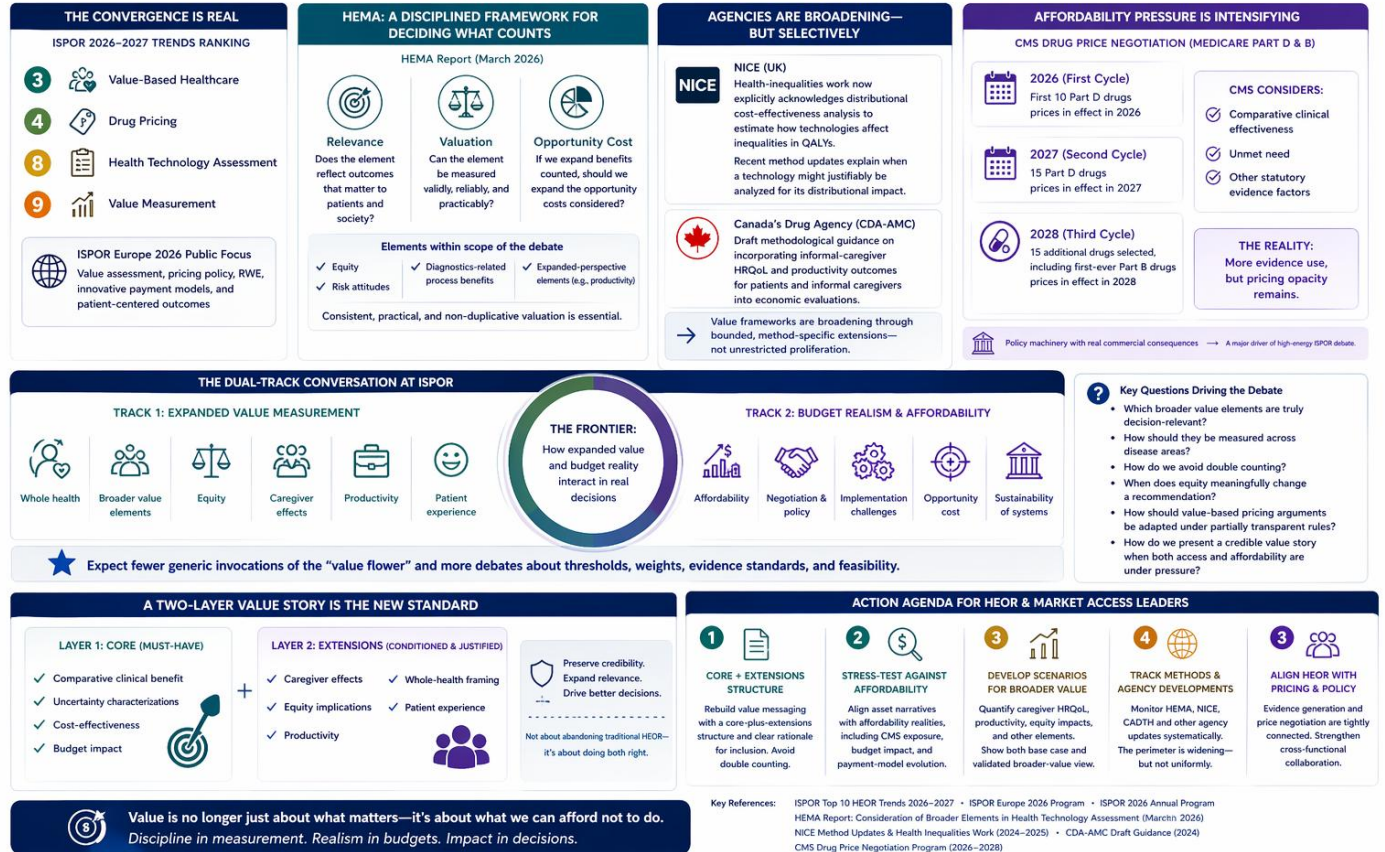
disciplined and conventional: comparative clinical benefit, uncertainty characterization, cost-effectiveness, and budget impact. The second layer is optional but increasingly important: caregiver effects, equity implications, productivity, whole-health framing, and patient-experience evidence, each included only where methodologically justified and decision-relevant. This is not about abandoning traditional HEOR. It is about preserving credibility while expanding relevance. [50]

The action agenda is therefore practical:

- **Rebuild value messaging around a core-plus-extensions structure:** core clinical and economic value first, broader value elements second, with explicit rationale for inclusion and clear avoidance of double counting. [51]
- **Stress-test asset narratives against affordability, not only value,** especially where CMS exposure, high budget impact, or innovative-payment-model discussions are plausible. [52]
- **Develop scenario analyses for expanded value inputs** such as caregiver HRQoL, productivity, and equity impacts, so teams can show both a conventional base case and a justified broader-value view. [53]
- **Track HEMA and agency-specific method developments systematically,** because the acceptable perimeter of value evidence is widening, but not uniformly across jurisdictions. [54]
- **Prepare HEOR teams to work more closely with pricing and policy colleagues,** since evidence generation and price negotiation are now more tightly connected in both Europe and the United States. [55]

Value Frameworks Meet Affordability and Pricing Pressure

From Broader Value to Real-World Decisions in a Constrained World



Annotated references

The list below prioritizes primary and official sources, with selected peer-reviewed methods papers that are directly relevant to HEOR and Market Access practice.

- **ISPOR 2026–2027 Top 10 HEOR Trends.** Best single source for ISPOR’s official prioritization of AI, RWE, value-based healthcare, drug pricing, HTA, and value measurement over the next two years. Essential for framing what will likely dominate plenary and program design. [56]
- **ISPOR 2026 Annual Meeting Program.** The strongest source for topic-level prediction because it reveals actual session architecture, including short courses, issue panels, workshops, and spotlight sessions on AI, RWE, Living HTA, HEMA, and CMS pricing. [57]
- **ISPOR Europe 2025 Program.** Useful for continuity analysis because it shows that AI in HEOR, LLM-assisted RWE workflows, TTE, external controls, and EU HTA were already rising before the 2026 program made them more operational. [58]

- **ISPOR Europe 2026 conference page.** Important for the higher-level framing of policy, access, value assessment, pricing policy, RWE, and innovative payment models, especially when the detailed 2026 Europe program is still developing. [59]
- **European Commission pages and factsheets on EU HTA, JCA, and JSC.** The most authoritative sources for JCA scope, phased rollout, parallel EMA timing, PICO scoping, JSC purpose, and 2026 request windows. [60]
- **EMA Real-World Evidence portal and RWE reports.** Best source for the European regulatory RWE infrastructure, including DARWIN EU growth, RWE guidance development, and current throughput. Particularly valuable because it is relevant not only to regulators but also to HTA bodies and payers. [61]
- **FDA Real-World Evidence pages and guidance.** Core source for the U.S. regulatory interpretation of fit-for-purpose RWD and the expanding role of RWE in lifecycle decision making. [62]
- **NICE AI evidence-generation position statement.** Probably the most practically useful public HTA-body statement on how AI should be justified, reported, risk-managed, and applied in evidence generation. Particularly important for human oversight, causal-inference caution, and cybersecurity. [63]
- **ISPOR Working Group Reports on GenAI in HEOR and HTA.** The best peer-reviewed bridge between conference signals and a durable methods agenda. Use these for taxonomy, limitations, responsible-use framing, and agency-facing policy considerations. [9]
- **CHEERS-AI.** Highly relevant for teams assessing AI-enabled health technologies, and more broadly for understanding how decision makers will expect AI-specific economic evaluation to be reported. [64]
- **JAMIA paper on LLM-assisted SLR for HTA submissions.** One of the stronger practical validation papers for AI in HEOR workflows because it reports measurable screening and extraction performance in a human-in-the-loop system. [12]
- **TARGET reporting guideline and TARGET-EU registry entry.** These are key method references for the next phase of causal RWE discussion, especially as regulators and HTA bodies ask for more explicit target-trial designs and better reporting. [65]
- **HEMA 2026 report.** Essential for understanding where the broader-value debate is heading, especially because it insists on linking any expansion of benefits to opportunity-cost reasoning rather than treating value expansion as costless. [45]
- **CMS negotiation fact sheets and guidance.** The authoritative source for what is no longer theoretical in U.S. pricing policy: effective negotiated prices in 2026 and 2027, expansion to Part B in 2028, and the emergence of renegotiation. [47]

- **Living HTA sources from ISPOR and peer-reviewed literature.** Useful for teams wanting to move from one-time evidence submissions toward an updateable evidence system. The ISPOR working-group definition is especially helpful for framing internal governance. [66]

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