

Valuing Our Value: Can We Demonstrate the Return on Investment in HEOR?

ISPOR Europe 2024 Monday 18 November – 17:00-18:00 1

Introduction and Welcome

Laura Pizzi



Panel



Laura T. Pizzi ISPOR



Sissi V. Pham AESARA



Jens Grueger University of Washington



David Thompson Rubidoux Research

It's Time for a Poll!

Has your job been affected by reorganizations or layoffs in the past 2 years?

- a) Yes
- b) No

It's Time for a Poll!

What type of organization do you work for?

- a) Biopharma
- b) Device or diagnostics
- c) HEOR Solutions Provider (e.g., Contract Research Organization, HEOR Consultancy, Real World Data Provider/Analyzer)
- d) Investment firm
- e) Academia
- f) None of the above



HEOR is at a Crossroads

- Healthcare and innovation is rapidly changing worldwide; increasing price pressures and influence of governments and HTA
 - A few examples: IRA (US), HTAR (EU), HTA/CE (Japan)
- Drastic changes and/or cuts to the HEOR function in pharma
 - GSK, Merck, Abbvie, BMS, and others
 - Spillover effects to HEOR solutions companies
- Urgency to demonstrate our value as a field
- Need for actionable ideas as to how ISPOR and HEOR professionals can demonstrate the value of HEOR





VALUE & OUTCOMES SPOTLIGHT

Many large

pharmaceutical

companies have

restructured HEOR by

teams and moving

The decision to

the industry

associates to Medical

Affairs or Market Access.

restructure HEOR raises

important questions about the value and

future of HEOR within

There is still a need

for HEOR evidence

clinically integrated.

and generated quickly.

that is pragmatic.

eliminating standalone

A magazine for the global HEOR community.

HEOR Articles

Big Pharma Says, "Thanks, but No Thanks" to Its Own HEOR Groups

Scott D. Ramsey, MD, PhD, Curta, Inc, Fred Hutchinson Cancer Center, University of Washington, Seattle, WA, USA

Last spring, I had a wonderful time at the 2024 annual ISPOR conference in Atlanta, Georgia. I attended some fantastic sessions and colleagues. Overall, the vibe was very positive. Still, there was a darker undertone that was palpable: several very large pharmaceutical firms had substantially reorganized or eliminated their health economics and outcomes research (HEOR) groups. The story was remarkably similar for each of them: the HEOR leads were sacked and the midlevel employees were sent to other groups—most often Medical Affairs or Market Access.

"Is HEOR losing clout in pharma?"

So many things played through my mind as I heard these remarkably similar stories. Honestly, my first thought was how harsh the corporate world can be. Unlike my familiar world of academics, individual performance on the job is a second-order issue relative to the bottom line of corporate revenues. But this leads to another question: If a big company is facing tough times, how does it decide what is fat versus muscle? One person confided that they were pretty sure that the senior leadership simply drew a line, with those above the salary limit removed and those below kept (and scattered). If rue, I think that Lester Thurow's quote about bad business decisions might apply here:

"If a group of people has no sense where they came from, it is difficult for them to have a sense where they should go."



Vol. 10. No. 5

September/October 2024

DOWNLOAD ISSUE





≡ ৭

Wednesday, November 6, 2024



COUNTRY REPORTS INTERVIEWS INFOCUS EUROPE ASIA-PACIFIC AMERICAS MIDDLE EAST & AFRICA LEGAL & REGUL



"ISPOR sits at the nexus of science and policy, and we advocate that the best policies always rest on a foundation of good science

Rob Abbott - CEO & Executive Director, ISPOR

9.10.2023

Tags: Global, ISPOR, HTA, Health Economics, USA, Inflation Reduction Act, Patients, Europe

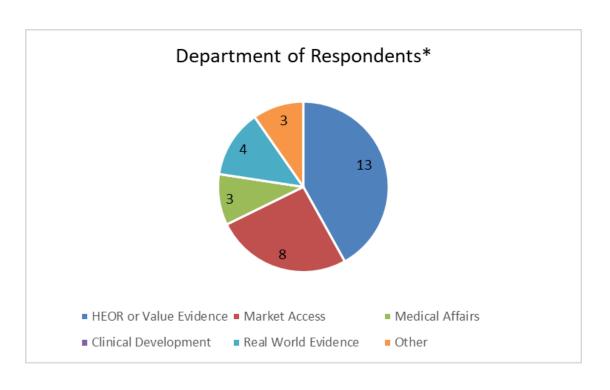
Well-informed and data-driven healthcare decision making has never been more important. Healthcare systems across the world – in both developed and developing contexts – are grappling with the challenge of providing quality treatments and services to patients while ensuring that their more is well spent. At the forefront of helping address this conundrum through the promotion of health economics and outcome research (HEOR) within healthcare decision making is ISPOR—The Professional Society for Health Economics and Outcomes Research. In an exclusive conversation with PharmaBoardroom, new ISPOR CEO Rob Abbott tackles some of the big issues in the HEOR field today, including the rollout of the Inflation Reduction Act (IRA) in the US, as well as Health Technology Assessment (HTA) legislation in the EU; foregrounds ISPOR's commitment to scientific rigour, excellence, and evidence in all its work; and scans the horizon for how stakeholders will need to adapt to healthcare in 2030.

Recent Articles about HEOR Industry Changes



Industry Changes: Findings from Recent ISPOR Institutional Council HEOR Workforce Survey

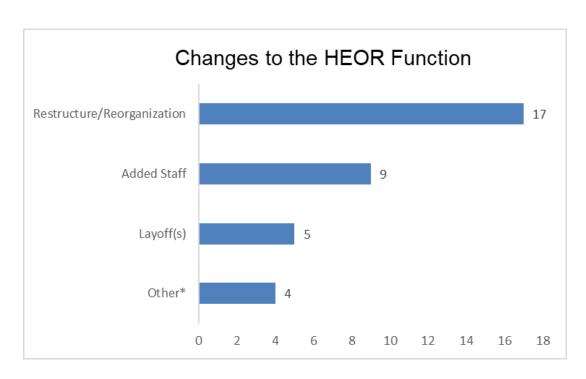
- 21 companies participated
 - 12 pharma (57%)
 - 5 HEOR solutions providers (23%)
 - 3 device or diagnostic (14%)
 - 1 not reported (5%)
- Fielded October 2024
- Lookback period: past 2 years



^{*}Respondents could choose more than 1 option. Other departments included Commercial, Health Policy and Reimbursement, and Executive Leadership.

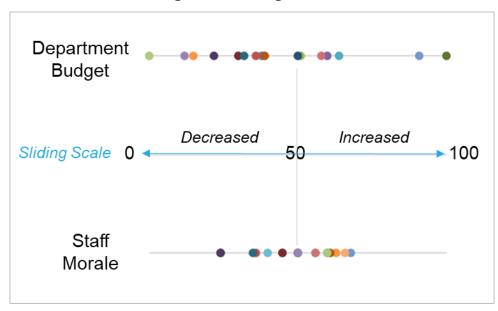


Workforce Survey: Changes in Organization, Budget, and Staff



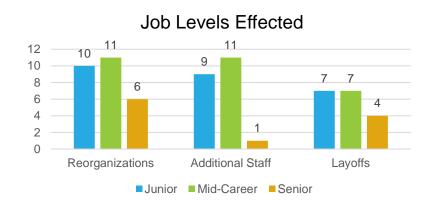
^{*}Other responses: strengthened technical skills; removed leadership layer but retained overall head count; became new function; and addressed unclear reporting line.

Sliding Scale Responses on Changes in Budget and Morale





HEOR Workforce Survey: Reorganizations, Additional Staff, and Layoffs



Global vs. Affiliate Impacts



Features of the Reorganizations

- Most (81%) of the companies had HEOR reorgs in the past 2 years
- Of those, trend was toward decentralization of HEOR into other functions
 - Integration into market access, medical, and statistics functions or into therapeutic areas
 - Transition from a matrix staffing model to a project team approach
 - Change in reporting lines and management structures, accordingly
 - Layoffs were reported by about a third of companies and at varied job levels
- One company reported <u>centralization</u> of outcomes functions

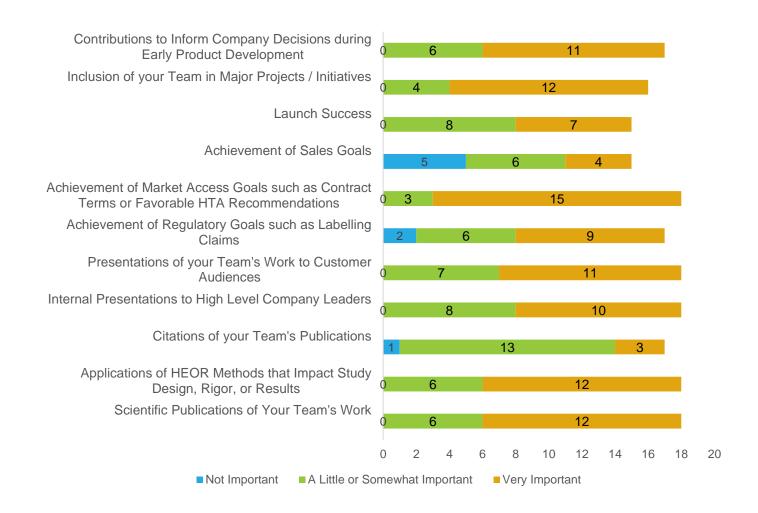


HEOR Workforce Survey: Performance Metrics

8 companies (38% of respondents) have formal Key Performance Indicators for their department:

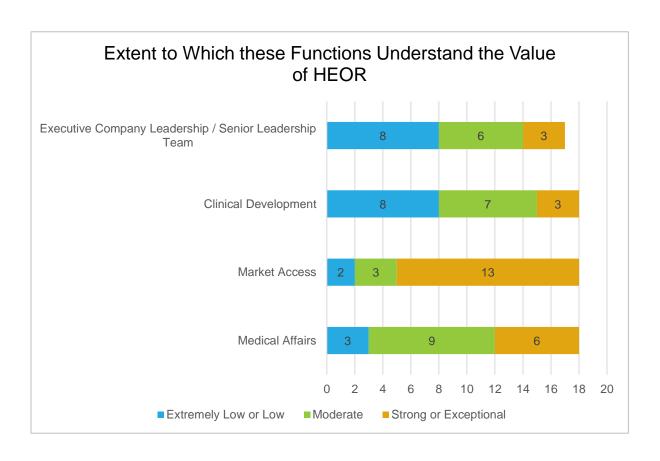
- "Scorecard indicators which revolve around "payer" input into investment decisions, timely provision of HTA deliverables to markets, and reimbursement success
- "Scientific achievements with focus on application of novel techniques in submissions as well as scientific community presentations and publications"
- "P&L targets, publication targets"
- "Time to patient access"
- "Work in progress-too complex to be measured"
- "Achieve access after launch in key markets, achieve changes in guidelines based on appropriate evidence"
- "Access decisions, practice decisions, impact of evidence, clinical program build, regulatory" implications, publications, policy shaping"
- "Number of publications based on strategy weighted by impact factor"
- "Number of citations (including guidelines); Frequency of utilization of publications by field (medical and commercial)"

Importance of HEOR Performance Metrics





HEOR Workforce Survey: Gaps and Opportunities



Key Gaps in HEOR Professionals' Skills

- Business Acumen and Strategic Thinking: Strong technical skills but limited training in broader business strategy, commercial implications, and understanding the "business why" behind their work
- 2. Effective Communication: Need for HEOR professionals to communicate their value in non-technical terms to senior leaders and to have stakeholder engagement skills
- 3. Adapting to Emerging Technologies: Gap in understanding and leveraging Artificial Intelligence to enhance HEOR methodologies and outcomes



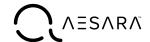
HEOR Workforce Survey: Key Takeaways

- Reorganizations were common; mostly involved decentralizing HEOR function into Market Access, RWE, Medical Affairs, Clinical Development
 - Of these departments, Market Access was felt to have the best understanding of HEOR's value
- Number of companies reporting staff additions > those reporting layoffs
- Achievement of market access goals was most important performance metric but internal successes (e.g., involvement in major projects) were also very important
 - Underscores need for business acumen, leadership, and communication skills
- Executive/Senior Leadership rated as having lowest understanding of HEOR's value
 - Critical need to address this gap

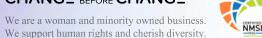
HEOR Organizational Changes in the Industry

Sissi Pham













AESARA conducted a benchmarking study to empower HEOR leaders with contemporary industry practices to optimize the HEOR organization

2024 benchmark was based on qualitative and quantitative data from 7 biopharmaceutical companies and 60+ interviews conducted with HEOR leaders and team members worldwide



Evolving HEOR remits

- Policy developments (e.g., IRA, JCA, PDABs) expand the end users of HEOR and elevate the importance of value evidence
- Regulatory developments (e.g., PED, CFL, HCEI) create further opportunities for application of HEOR expertise
- Expansion of RWE responsibilities to other functions to capitalize on the external demand for RWE has led to an unclear RWE remit for HEOR
- HEOR data analytics provide valuable insights for evidence generation planning and field engagements



Persisting challenges

- Lack of understanding of HEOR as a function and its clear business impact
- Perception of being overly academic/publication focus and lack of effective dissemination of HEOR evidence to endcustomers
- Organizational positioning continues to evolve; more common shift has been to fold HEOR within Value & Access in effort to unlock its direct impact on access
- Limited seat at the table, direct strategic role in value evidence generation for access is not recognized

While the scope of HEOR responsibilities is expanding, recognition of its impact to the business remains limited



Key recommendations

- Develop strong communication skills
 - o Elevate HEOR's impact through C-Suite & cross-functional engagements with targeted, clear messages
 - o Couple evidence communication planning with best-in-class evidence synthesis and HEOR/value storytelling skills
- Invest in evidence generation & communication planning
- Partner with Compliance to establish business impact linked KPIs for HEOR
 - o Promote our work, take ownership for our role in the successes
- Be the trusted, strategic thought partner for Value & Access
- Lead the delineation of RWE responsibilities across functions
 - Evolve HEOR remit to include RWE governance

3

Growing Emphasis on Market Access

Jens Grueger

BCG Market Access Roundtable Benchmark

- Currently 26 major pharma companies
- Benchmark conducted every 3 years since 2013
- Includes global, region and major countries (US, EU, JPN, CHN, BRZ)
- Activity based approach focused on "core access capabilities":
 Access Strategy, pricing, evidence generation, evidence synthesis,
 health policy
- Organisational structure, resources, key topics and trends

Key observations

- Significantly increasing access resources in 2013 and 2016, slowing in 2019, flat in 2022
- In 2013, 2/3 companies with separate Pricing & Access (Commercial) and Value & Evidence (Medical) teams; in 2022 2/3 have integrated access teams (reporting into Product Strategy/ Commercial)
- With the overall increase in access resources, the number of companies with Regional Access teams has been steadily declining
- Access FTEs correlate with number of late-stage assets (and revenue)
- Key topics have evolved from elevating access to better collaboration and influencing across global functions

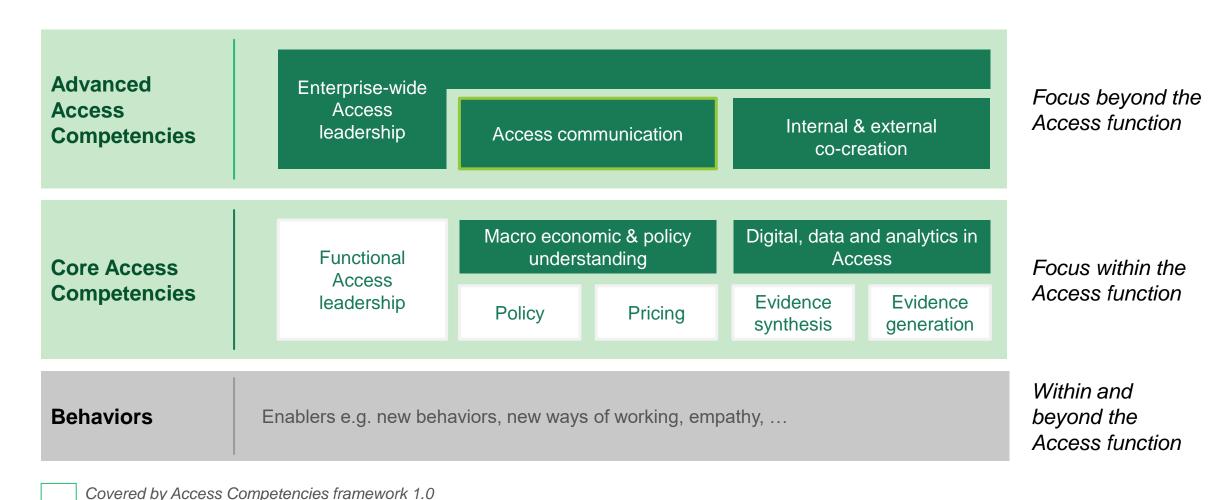
Source: BCG Market Access Roundtable

Three potential roles for Access going forward

Driving strategic trade-offs Steering organization on Access decisions Translating and communicating on "Access" Providing technical expertise Integrator & Driver **Expert Steward**

Source: BCG Market Access Roundtable

Market Access Roundtable Competencies Framework



Source: BCG Market Access Roundtable

What does this mean for HEOR

- Technical expertise remains important
- Additional expectations around enterprise-wide leadership, communication and collaboration
- Traditional and GenAl will transform the technical work
- Commoditized activities will increasingly be delegated/ outsourced to focus more on strategy, collaboration and communication
- Focusing on technical deliverables does not suffice anymore

How Do We Measure Our ROI?

David Thompson





VALUING OUR VALUE: CAN WE DEMONSTRATE THE RETURN ON INVESTMENT OF HEOR?

DAVID THOMPSON, PHD

My Perspective in Five Bullet Points

- This is important
- BUT NOT STRAIGHTFORWARD
- BECAUSE THERE IS NOT MUCH PRIOR RESEARCH TO GO ON
- SO WE NEED TO FIND A NEW PATH FORWARD
- ISPOR SHOULD LEAD THE WAY



HEOR ADDS VALUE ACROSS PRODUCT TIMELINE

PRODUCT TIMELINE	EARLY CLINICAL	PHASE II-III	PERI-LAUNCH	COMMERCIALIZATION
ECONOMIC MODELING	EARLY MODELING	MODEL REFINEMENTS	CEAs & BIAs	GLOBAL ADAPTATIONS
Real-World Data	Trial Design Optimization	FACILITATE TRIAL RECRUITMENT	REGULATORY USE- CASES (EG, ECAS)	COMPARATIVE/RELA- TIVE EFFECTIVENESS
CLINICAL OUTCOMES ASSESSMENT	EARLY COA STRATEGIZING	ESTABLISH COA PSYCHOMETRICS	COA ENDPOINT ANALYSIS/REPORTING	COA DISSEMINATION /POST HOC ANALYSES
EVIDENCE SYNTHESIS	Systematic Literature Reviews	Network Meta-Analyses	VALUE DOSSIERS	HTA SUBMISSIONS



RETURN ON INVESTMENT (ROI) FORMULA

$$ROI = \frac{\Delta TR - I}{I} \cdot 100\%$$

Where,

 Δ TR is the change in total revenue *attributable to* the investment; and I is the monetary value of the investment

So, for example, an investment of €250 that led to a change in total revenue of €375 would have an ROI of [(€375 - € 250) / € 250] · 100% = 50%



ATTRIBUTION TO HEOR IS A CHALLENGE

ΔTR IS DETERMINED MULTIFACTORALLY, SO ...

$$\Delta TR = f(I, MANY OTHER FACTORS)$$

HOW TO ASCERTAIN INVESTMENT IN HEOR'S IMPACT ON CHANGES IN TOTAL REVENUES?

HOW TO DISENTANGLE IMPACT OF INVESTMENTS IN HEOR FROM THAT OF OTHER FACTORS?

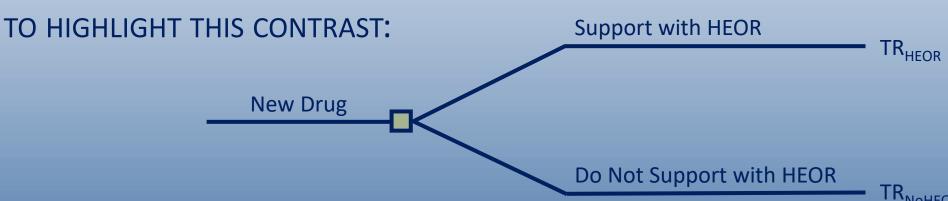


SIMPLE APPROACH IS STRAIGHTFORWARD IN THEORY

ΔTR COULD BE CALCULATED BY CONTRASTING TOTAL REVENUES WITH VERSUS WITHOUT HEOR:

$$\Delta TR = TR_{HEOR} - TR_{NOHEOR}$$

AN RCT, RWD ANALYSIS, OR EVEN DECISION-ANALYTIC MODEL COULD BE DESIGNED





BUT STYMIED BY ABSENCE OF A COUNTERFACTUAL

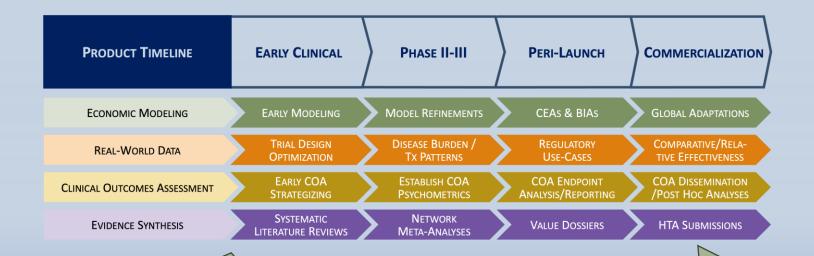
$$\Delta TR = TR_{HEOR} - TR_{NOHEOR}$$

ALL DRUGS RECEIVE SOME HEOR SUPPORT SO THIS NUMBER IS KNOWABLE

THIS COUNTERFACTUAL SCENARIO DOES NOT EXIST AND THEREFORE THIS NUMBER IS NOT KNOWABLE



AND THEN THERE ARE THE TIMING ISSUES



INVESTMENTS IN HEOR BEGIN EARLY, BUT HOW FAR BACK SHOULD WE COUNT? AND WHAT ABOUT SUNK COSTS OF HEOR PERFORMED FOR PRODUCTS THAT FAIL BEFORE LAUNCH?

REVENUES BEGIN TO ACCRUE IMMEDIATELY UPON COMMERCIALIZATION, BUT HOW FAR INTO THE FUTURE SHOULD WE ATTRIBUTE TO HEOR?



WHAT PRIOR RESEARCH DO WE HAVE TO GO ON?



ABSTRACT

Analyzing the effectiveness of digital marketing campaigns can be challenging due to the large number

ARTICLE INFO

Keywords



NIH Public Access

Author Manuscript

Contemp Clin Trials. Author manuscript; available in PMC 2013 November 0

Published in final edited form as:

Contemp Clin Trials. 2012 November; 33(6): 1117-1123. doi:10.1016/j.cct.2012.08.006.

The Value of Comparative Effectiveness Research: Projected Return on Investment of the RxPONDER Trial (SWOG S1007)

William Wong, PharmD, MS^a, Scott D. Ramsey, MD, PhD^b, William E. Barlow, PhD^c, Louis P. Garrison Jr., PhD^a, and David L. Veenstra, PharmD, PhD^a

^aPharmaceutical Outcomes Research and Policy Program, University of Washington, Seattle, WA

^bDivision of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA

°SWOG Statistical Center (Cancer Research and Biostatistics), Seattle, WA

Abstract



Tufts Center for the Study of Drug Development Value of Days Lost Approach

Approach

Tufts CSDD | White Papers

Quantifying the Value of a Day of Delay in Drug Development

Zachary Smith MA, Joseph DiMasi PhD, Kenneth Getz MBA



COMING BACK TO MY FIVE BULLET POINTS

- This is important ... because our value is being questioned and we need to respond
- BUT NOT STRAIGHTFORWARD ... FOR VARIOUS CONCEPTUAL & METHODOLOGIC REASONS WE'VE DISCUSSED
- BECAUSE THERE IS NOT MUCH PRIOR RESEARCH TO GO ON ... AND AS WE'VE SEEN THAT WHICH DOES EXIST IS NOT PERFECTLY SUITED TO THE TASK
- SO WE NEED TO FIND A NEW PATH FORWARD ... WHICH IS THE FUN PART!
- ISPOR SHOULD LEAD THE WAY ... BECAUSE, WHO ELSE?



Discussion



But First... What is ISPOR Currently Doing to Support the Profession and its Members?

5	Assessment	Institutional Council Workforce Survey
	Advocacy	Op Ed led by ISPOR CEO, Rob Abbott Conference sessions like this ISPOR policy responses to stakeholder guidance related to HEOR
8	Leadership development	"Soft skills" identified in ISPOR HEOR Competencies Framework Training through Student Network, New Professionals Network, Regional Chapters
4551	Increased content and engagement opportunities of "sister" disciplines	Global Access to Medical Innovation Special Interest Group Access Forum collaboration Continued heavy emphasis on RWE Light collaboration with Medical Affairs Professional Society (MAPS)
	Elevate HEOR's importance	HEOR Impact Cases (formerly "case studies") Amplify HEOR program and ISPOR Ambassadors
	Performance metrics	Workforce Survey Citations/clicks/conference session attendance Uptake of ISPOR science in major guidance/policies

It's Time for a Poll!

What's the single MOST IMPORTANT action that ISPOR can take to support you?

- a) Engage with senior level executives to increase their awareness about the value of HEOR
- b) Increase engagement with the functions where HEOR professionals work (e.g., Market Access, Medical Affairs, Clinical Development, RWE)
- c) Develop a quantitative ROI metric to measure the value of HEOR projects and/or the HEOR function
- d) Offer training to HEOR professionals on business communications and self-advocacy
- e) Publish a framework or list of HEOR performance metrics for industry professionals





Discussion

6

Closure and Call to Action