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Value communication and training solutions to deliver strategic market access

LTEN 2022 Workshop
2:00-3:00 PM
June 14, 2022

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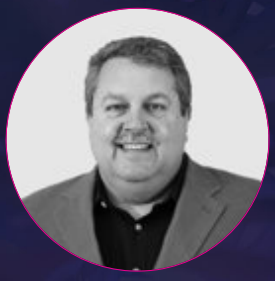
The team today

Jess Ingram
Executive Vice President,
Learning & Development



Mark Bernauer, BPharm, RPh
Associate Director,
Strategic Market Access

Rosemary Jose, PhD
Senior Director,
Strategic Market Access

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Value communication and training solutions to deliver strategic market access

Why is this particularly CHALLENGING?

WHO do we need to train?

What is the KNOWLEDGE gap?

What is the COMPETENCE gap?

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Speakers Biography

Rosemary Jose, PhD
Senior Director
E & A, Strategic Market Access
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Rosemary Jose is Senior Director and Commercial Lead for the Strategic Market Access Center of Excellence, and is based out of the Rotterdam office, the Netherlands. Her main areas of focus are business development, payer value communication, payer/HTA landscape assessments, recent trends in EUnetHTA and HTA policy, market access insights into clinical trials and observational studies, HEOR evidence generation plans, value dossiers, payer objection handlers, HTA newsletters, strategic workshops and advisory boards.

Rosemary has >16 years of experience across the pharmaceutical industry, including >14 years in market access and health economics, both in global and consulting roles – leading strategic projects, managing international clients and mentoring multi-cultural teams. She has also provided on-site support to pharmaceutical clients in Europe, driving the market access strategy through cross-functional collaboration, to facilitate reimbursement. Her experience covers multiple therapeutic areas including oncology, neurosciences, ophthalmology, infections and immunology, gastroenterology and cardiovascular medicine. Rosemary holds a PhD in Pharmacogenetics, and Certifications in HTA and Market Access from the Galbraith Wight Business School, the UK., and a Postgraduate Certificate in Health Economics from the University of Aberdeen, the UK.

Mark Bernauer, BPharm, RPh
Associate Director
E & A, Strategic Market Access
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Mark Bernauer, BPharm, RPh is an Associate Director in Strategic Market Access group, located in the Bethesda, MD office. He has more than 25-years of experience across a breadth of roles including medical functions, health economics and outcomes research (HEOR), and as a registered pharmacist.

His expertise includes medical writing (e.g., systematic and targeted literature reviews, manuscript development, and global and AMCP product-value dossiers), communication and evidence generation plans, market access recommendations, value propositions, conducting competitor and stakeholder analyses and is published with several manuscript and congress presentation during his career.

Prior to joining OPEN Health, Mark worked within the consulting industry at Precision Health Economics and Optum across a variety of medical writing/market access projects. Mark also worked in the pharmaceutical industry at Eli Lilly and Company in several medical/HEOR positions supporting the neuroscience portfolio. Mark has therapeutic experience in the following areas: neurology, dermatology, endocrinology, immunology, oncology, pulmonology, ophthalmology, and infectious disease.

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Objectives

- Accelerate the understanding of the importance of strategic market access in the rapidly evolving environment we are facing in the pharmaceutical industry
- Develop cutting-edge strategies and the agility to adapt to a rapidly changing landscape

1. What is “Strategic Market Access”?
2. How does market access fit in the product development life-cycle?
3. What stakeholders are important for market access decisions?
4. How are access decisions made by payers?
5. What tools are used to manage access to healthcare services and products?
6. What evidence is needed to build an effective market access strategy?
7. Why is market access training important to pharmaceutical companies?

NOTE: Abbreviations and references are provided in the speaker notes of each slide

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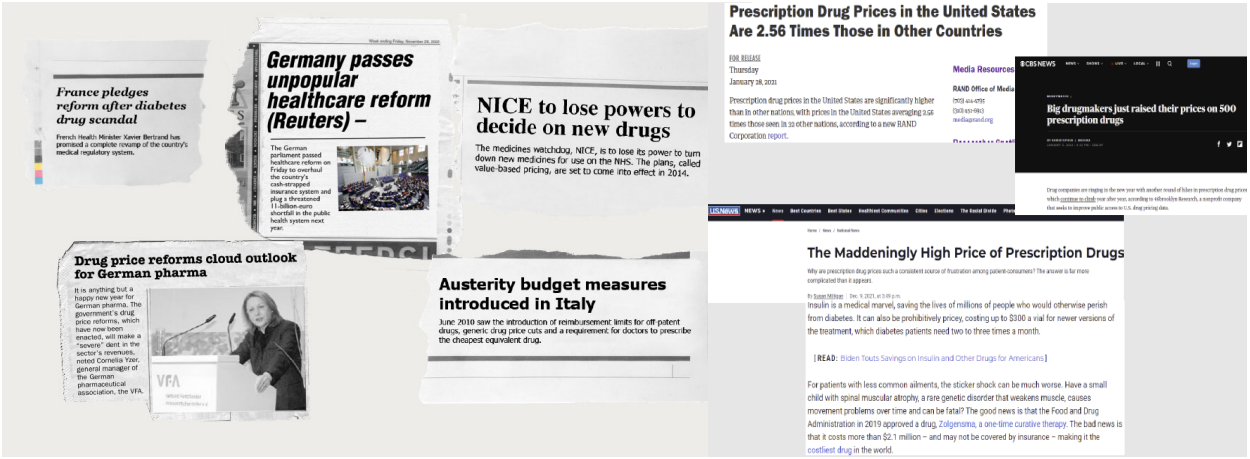
What is “Strategic Market Access”?

Health Systems Struggle to Fund Expensive New Therapies



Payers (non clinical budget holders) are now major decision makers in pharmaceutical reimbursement

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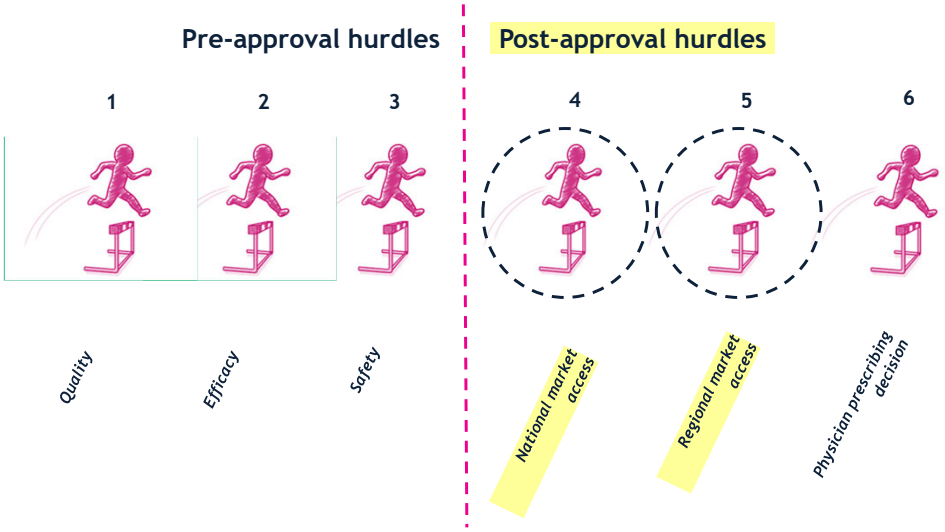
The Fourth and Fifth Hurdle



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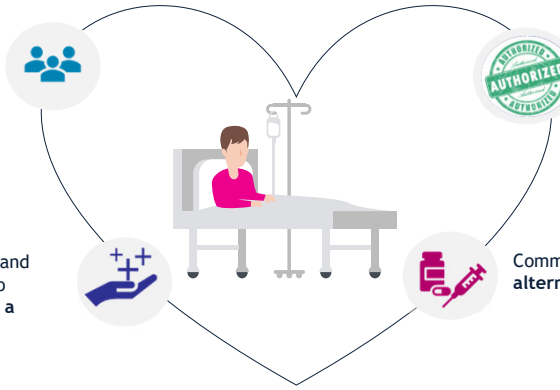
What is Strategic Market Access?

The core objective is to ensure that **all appropriate patients** who would benefit from a new product
… get **rapid and maintained access** to the new treatment, at the **right price**
… by demonstrating the **clinical and economic value** of an authorized product
…in order to obtain **optimal reimbursement**

Considers the adoption, positioning and funding of a product throughout its life cycle

Demonstrates the value of an **authorized product** to society and payer



Understands implications and requirements necessary to demonstrate the **value of a potential solution**

Communicates the value vs **alternative treatments**

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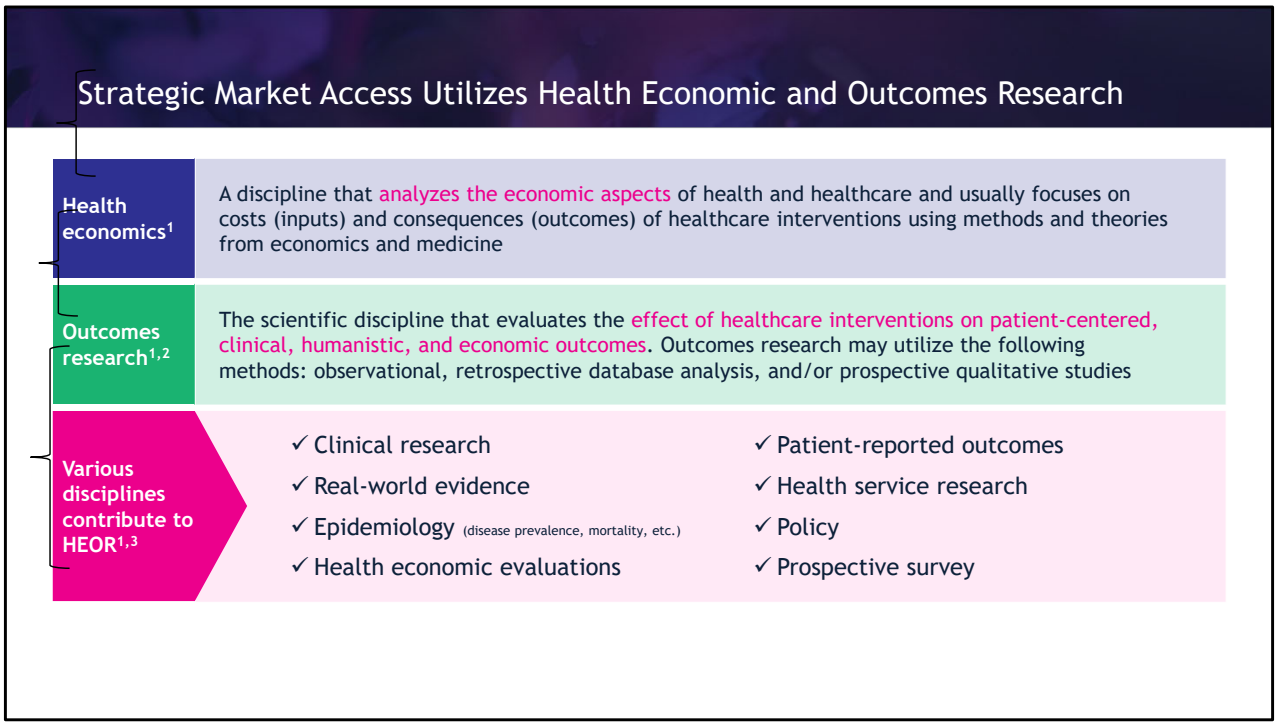
How does strategic market access fit in the product development life-cycle?



NOTES:

Clinical research[1] includes clinical trials, which are research studies intended to test the safety, efficacy, and/or the effectiveness of a healthcare intervention.

Phase 3 clinical trials confirm the efficacy of an experimental drug and further establish its safety profile (as observed in phase 1 or 2 studies). Regulatory approval is often granted after successful completion of phase 3 trials.

Phase 4 clinical trials are conducted after a product has been approved and are often called "postmarketing studies." These trials assess the effectiveness and sometimes the costs and patient-reported outcomes related to the treatment.

Epidemiology[1] is a branch of public health intended to understand the distribution, causes, and effects of disease in communities. A descriptive epidemiological study, for example, may describe the incidence, prevalence, mortality, or fatality morbidity rates in a population.

Health economics evaluations[1] include assessments of direct and indirect costs compared to consequences of medical treatment alternatives (eg, cost minimization, cost-effectiveness, cost utility, and cost benefit ratios).

Patient-reported outcomes[1] include patient self-assessments of the impact of disease or treatment on their lives and well-being (eg, quality of life, or satisfaction with treatment).

Health service research[3] is a multidisciplinary field that evaluates how health technologies, social factors, personal behaviors, financing systems, and organizations and their processes affect access to, the quality of, and cost of, healthcare.

Policy[1] is how nations, states, cites, and communities distribute resources to competing healthcare interventions and competing populations based on primarily anticipated benefits. Health technology assessment is a form of policy research.

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1. Berger ML, et al. Health care cost, quality, and outcomes: ISPOR book of terms. Lawrenceville, NJ: International Society for Pharmacoeconomics and Outcomes Research; 2003.

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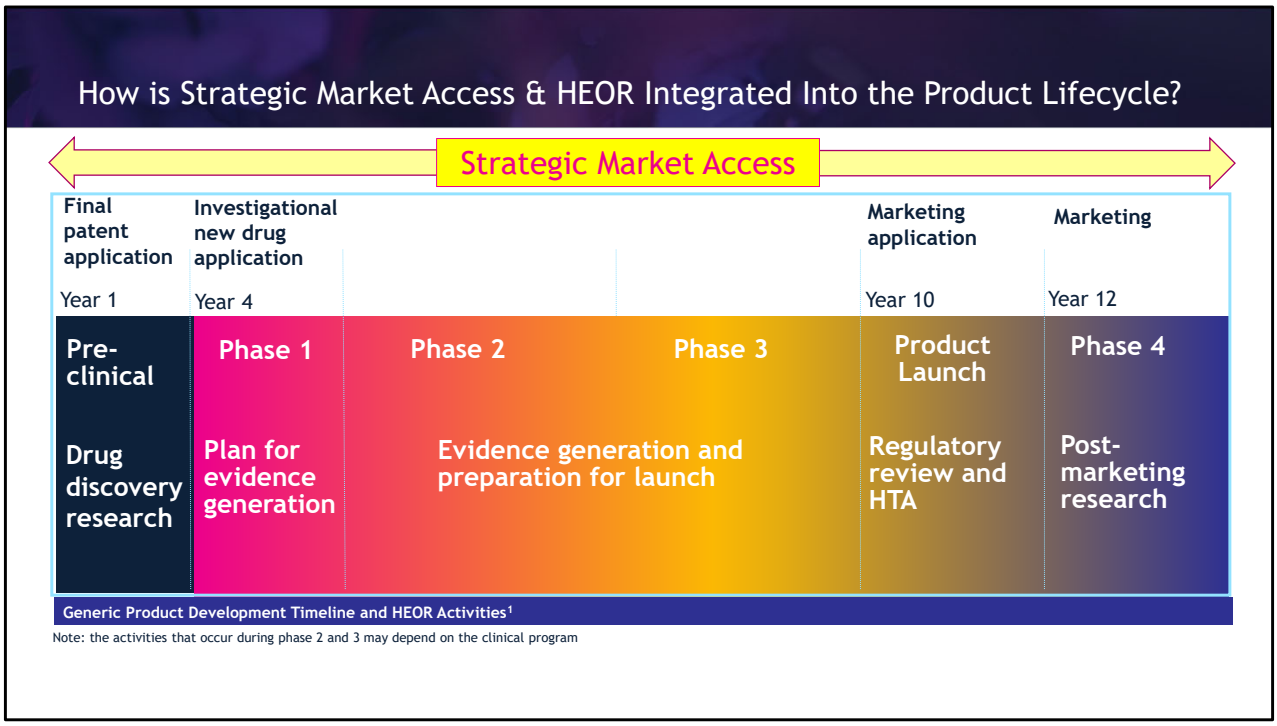

HEOR, health economics and outcomes research; HTA, health technology assessment

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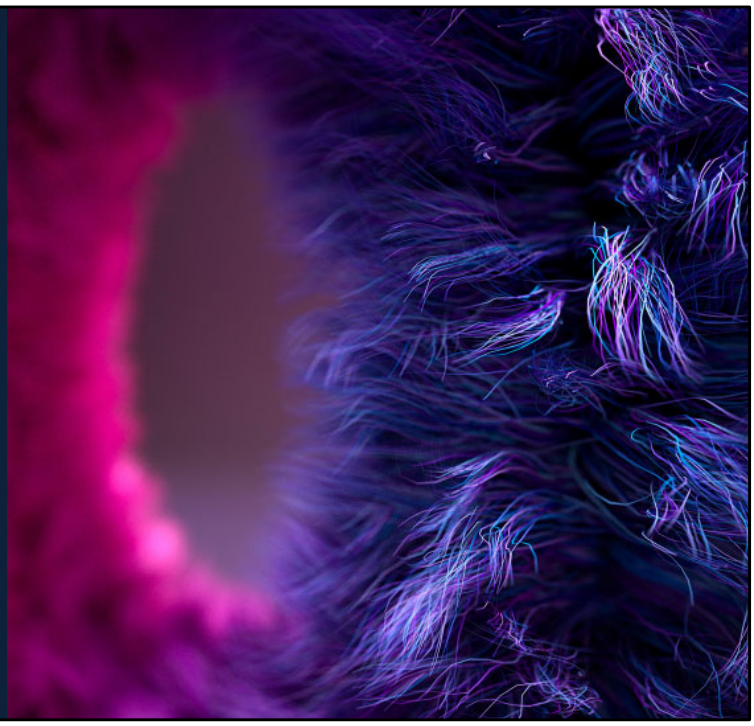
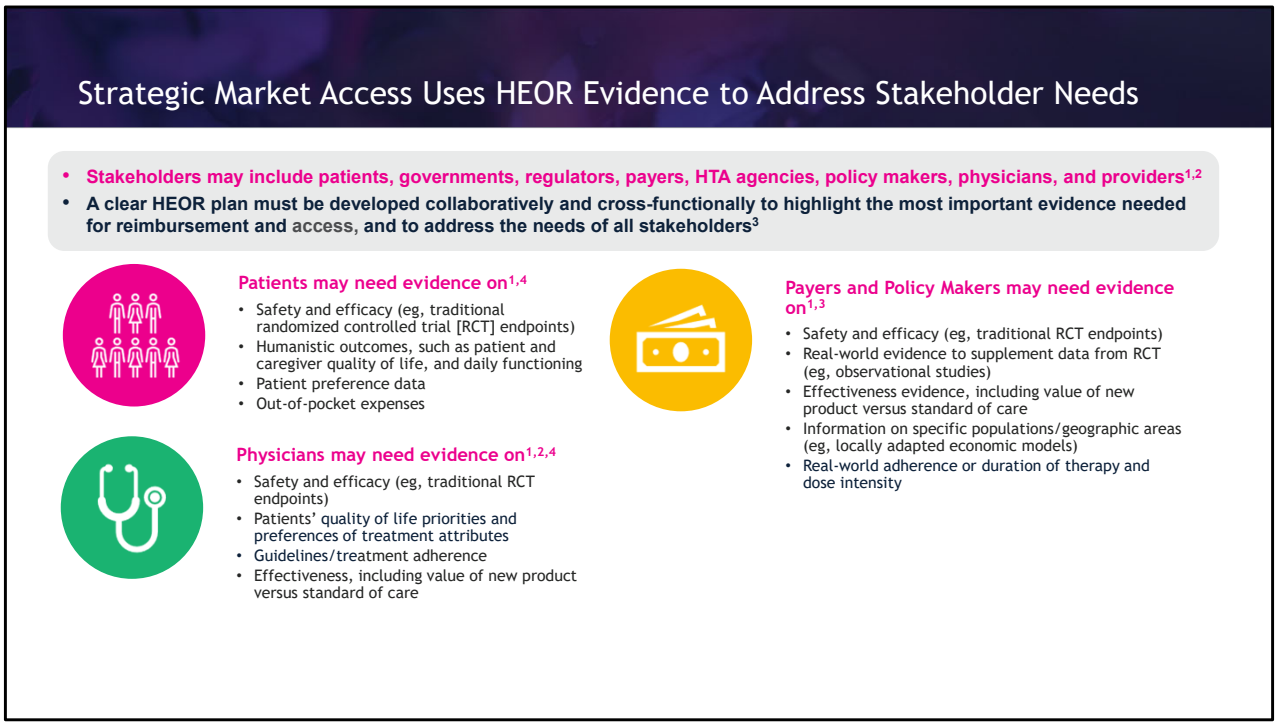
What stakeholders are important for market access decisions?





HEOR, health economics and outcomes research; HTA, health technology assessment; RCT, randomized controlled trial

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Who are the payers we communicate with?

Pricing, reimbursement, cost effectiveness	NICE and NHS England	GBA	CEPS	AIFA	CIPM	ZIN	ICER AHRQ/EPC DERP
Central HTA	NICE	IQWIG	HAS	AIFA	DGFPS	ZIN	N/A
Regional Control	CCGs Foundation Trusts	Sick Funds University Hospitals	Regional hospital groups	Autonomous regions	Autonomous regions	ZN / health insurers	Government (CMS, VA, etc.) Commercial Insurance

…All aim to control costs while managing access to effective treatments

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AHRQ , Agency for Healthcare Research and Quality; AIFA, Italian Medicines Agency; CEPS, Centre for European Policy Studies; CIPM, La Comisión Interministerial de Precios de los Medicamentos; CMS, Centers for Medicare & Medicaid Services; DERP, Drug Effectiveness Review Project; DGFPS, Directorate General for Pharmacy and Health Care Products; EBP, Evidence-based Practice Center; GBA, Gemeinsamer Bundesausschuss; ICER, Institute for clinical and economic review; HAS, Haute Autorité de Santé; IQWIG, Institute for Quality and Efficiency in Health Care; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; VA, Veterans Administration; ZIN, National Health Care Institute.

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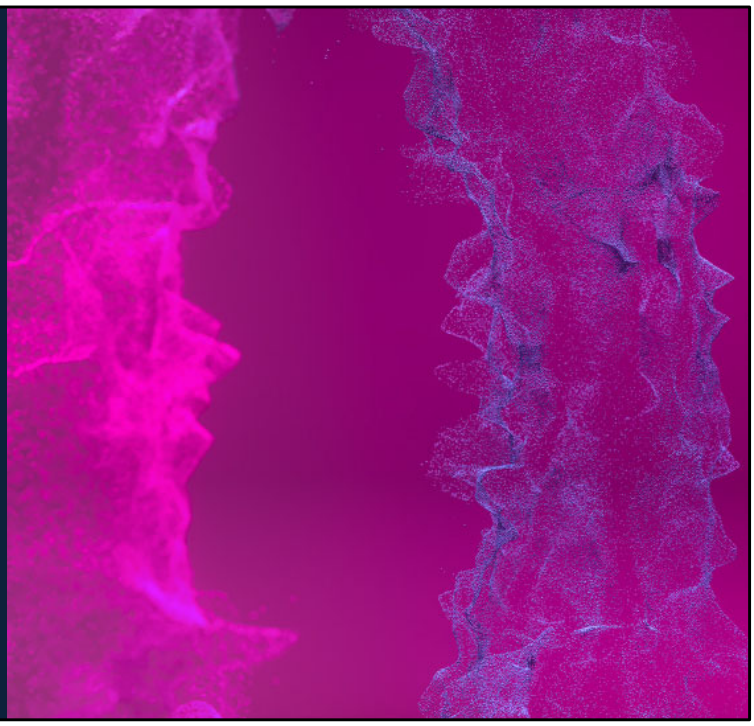
How are access decisions made by payers?



Meeting a clinical trial endpoint and gaining a product licence is not always a guarantee of success

… national and regional healthcare budget holders have additional questions

What is the unmet need?

Cost-Effectiveness

*"What **economic benefit** does the new treatment offer vs existing options and **at what extra cost?**"*

Competitive Rationalization & Budget Impact

"Is the target population easy to identify and manage vs existing options and how does this impact our budget?"

Comparative Clinical Effectiveness

"What additional clinical benefit (efficacy and safety) does the new treatment offer vs existing options?"

Budget Optimization

"Can I afford it?"

Patient Pay (Out-of-pocket)

"Is it possible to control the price?"

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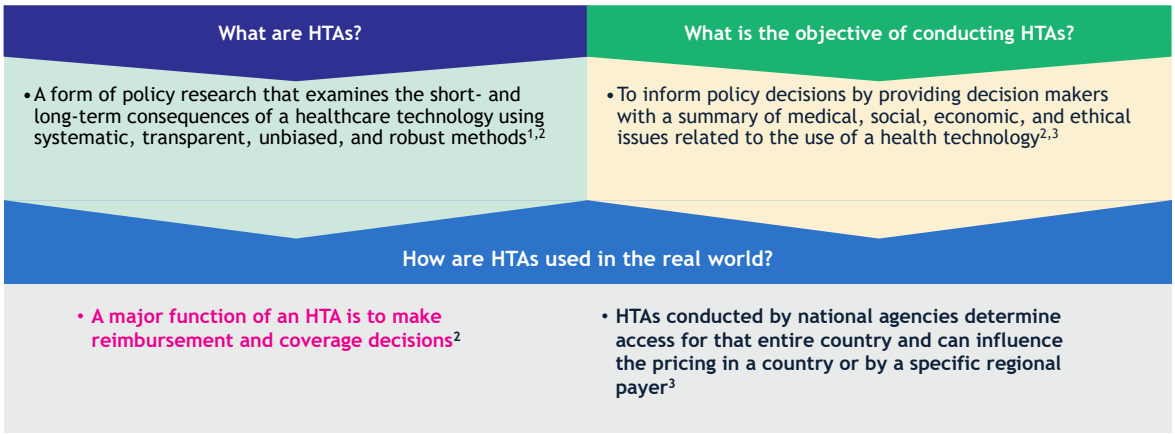
What is a Health Technology Assessment (HTA)?



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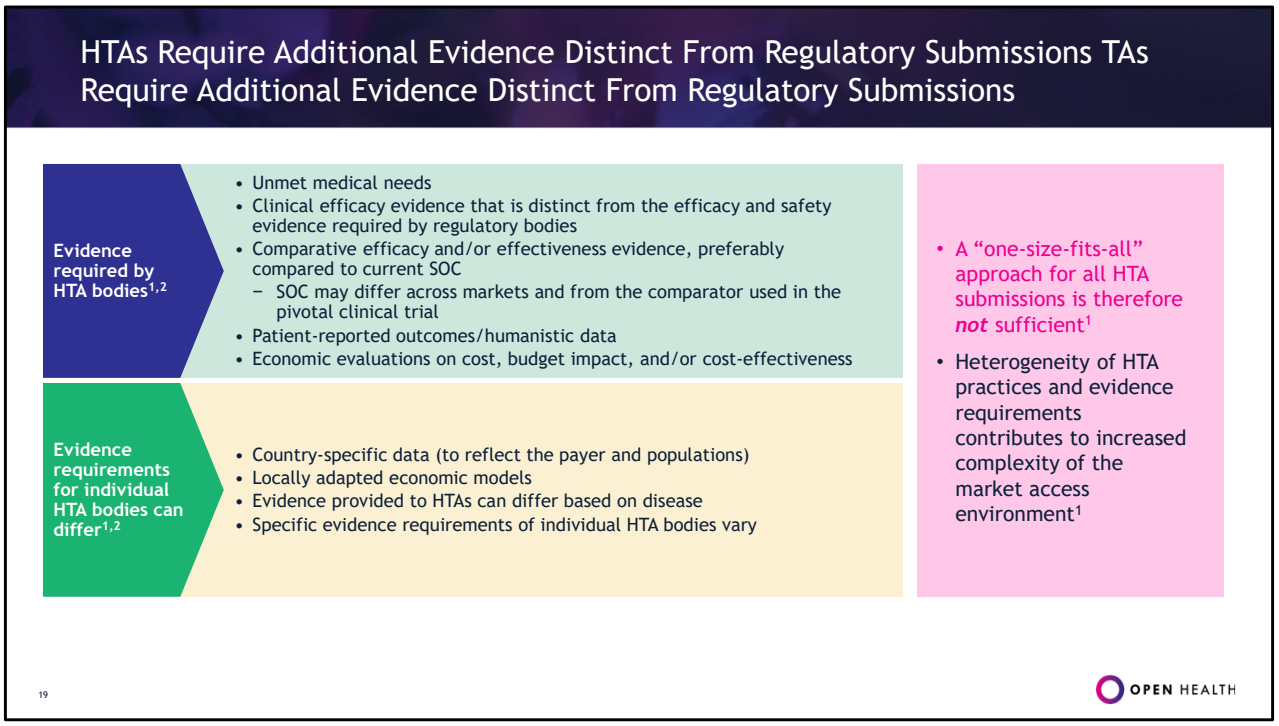

HTA, health technology assessment; SOC, standard of care.

Notes

Evidence required by regulatory bodies for product approval (ie, efficacy and safety data from clinical trials) is different than the evidence required for reimbursement and coverage decisions.[1,2]

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1. Ciani O, Jommi C. The role of health technology assessment bodies in shaping drug development. *Drug Des Devel Ther*. 2014;8:2273-2281.
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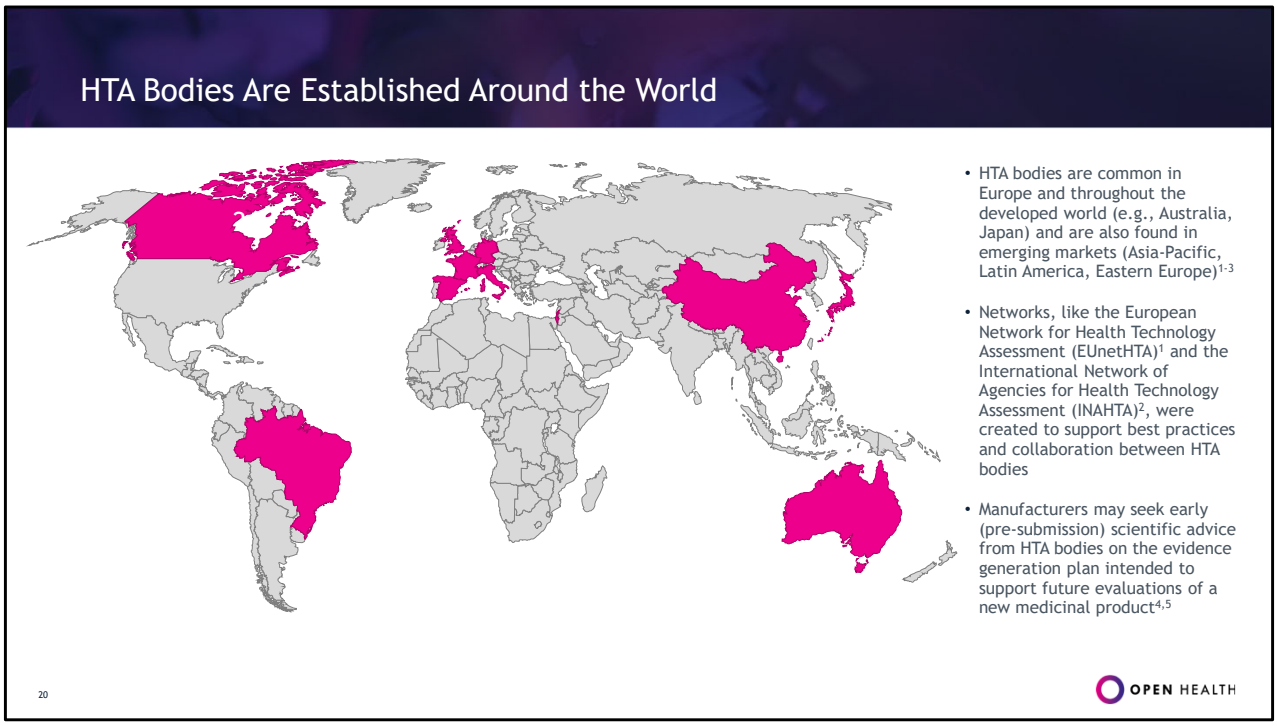

EUnetHTA, European Network for Health Technology Assessment; INAHTA, International Network of Agencies for Health Technology Assessment; HTA, health technology assessment.

NOTES

HTA bodies are established in many countries. HTA bodies are common in Europe (United Kingdom, Germany, and France), and are also found in emerging markets (Asia-Pacific, Latin America, Eastern Europe)[1-3]

- Level of sophistication, influence, and knowledge varies for different HTAs[3,6]
- Different HTAs require various types of HEOR evidence[7]

Manufacturers may see pre-submission scientific advice from HTA bodies or regulators across the life cycle of a medicinal product on a prospective plan for evidence generation relevant to their medicinal product.

Parallel scientific advice occurs when manufacturers simultaneously seek consolidated scientific advice/feedback from European Union regulators and HTA bodies on their evidence generation plan to support submissions of a new medicinal product at marketing authorization and reimbursement.[4,5] Parallel scientific advice allows manufacturers to generate evidence that satisfies the needs of both the regulators and HTA bodies. Parallel scientific advice can facilitate the integration of regulatory and HTA perspectives into the evidence generation plan and potentially reconcile their data requirements. Manufacturers may also simultaneously seek consolidated scientific advice/feedback from multiple HTA bodies on plans for evidence generation to support future evaluations by these bodies.[5]

Since July 2017, EUnetHTA and the European Medicines Agency have offered "Parallel Consultations" on evidence generation plans, which allows manufacturers to obtain feedback from regulators and HTA bodies.[2] This initiative streamlines the parallel scientific advice procedures as manufacturers will not need to contact HTA bodies (ie, EUnetHTA members) individually. Additionally, since January 2017, EUnetHTA has offered multi-HTA "Early Dialogues" on evidence generation plans for new pharmaceuticals, which allows manufacturers to obtain simultaneous feedback from multiple HTA bodies.

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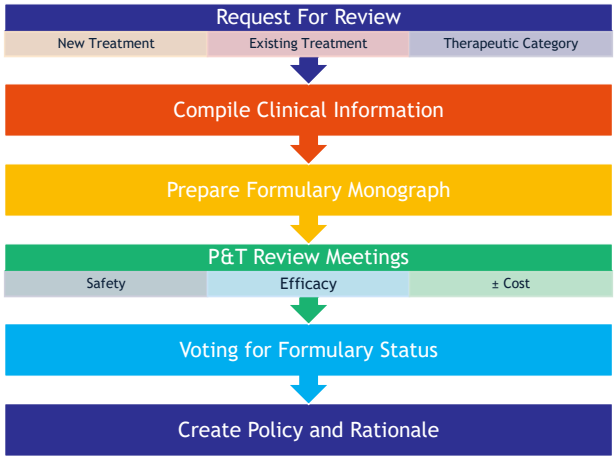
Each United States Payer Makes Access Decisions Independently

- Most US payer have a P&T committee used to make access decisions
- P&T committee is responsible for developing, managing, updating, and administering the drug formulary[1]
- Composed of actively practicing physicians, pharmacists, and other roles (administration, nurses, patient representative, etc.)[1]
- P&T committee has been adopted by the government and commercial health plans
- CMS has a "National Coverage[1] Determination" process where policies are publicly available[2,3]
- CMS requires at least 1 independent practicing physician and 1 independent practicing pharmacist free of conflict[1]

Pharmacy and Therapeutics (P&T) Review Process[1]



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CMS, Centers for Medicare & Medicaid Services; P&T, pharmacy and therapeutics.

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3. Medicare National Coverage Process. https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/8a.pdf

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What tools are used to manage access to healthcare services and products?

Tools used by payers in the US to manage drug access or cost

Drug Formularies

- Tiering (3 tier, 4 tier, etc.)
- Cost sharing (consumer copay)
- Prior Authorization
- Quantity limits
- Step therapy
- National drug code (NDC) block
- Utilization management

Contracting/ Regulations

- Rebate
- Volume discounts
- Maximum allowable cost
- Federal upper limit
- Value based contracts
- Other (drug mortgages, etc.)

Distribution Channels

- Retail pharmacies
- Preferred networks
- Mail service pharmacies
- Specialty pharmacies
- Healthcare offices (e.g., Medicare Part B, injection clinics)

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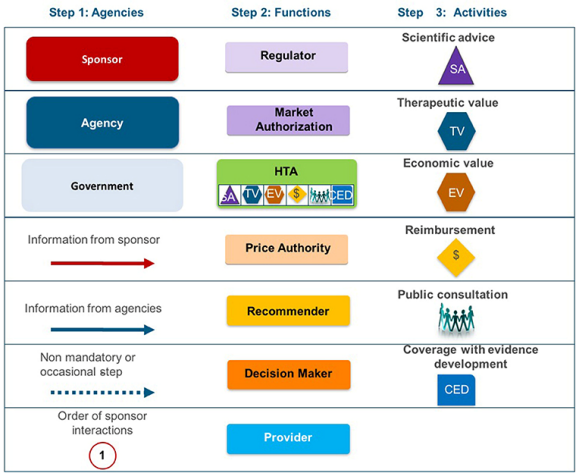
Europe Reimbursement tools



The way in which European Member States organize and finance their health systems differs considerably

- Some countries such as Iceland and Croatia organize price negotiations, assessment, appraisal and budget allocation on a national level.
- Other countries organize these decisions partly at a national level and partly at a regional level.
- In most European countries price negotiations, assessment and appraisal take place on a national level but budgets are allocated by healthcare insurers (a single payer institution or different health insurers) or on a hospital level

24 https://www.efpia.eu/media/578013/every-day-counts.pdf
https://www.frontiersin.org/articles/10.3389/fphar.2017.00384/full

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References

https://www.efpia.eu/media/578013/every-day-counts.pdf
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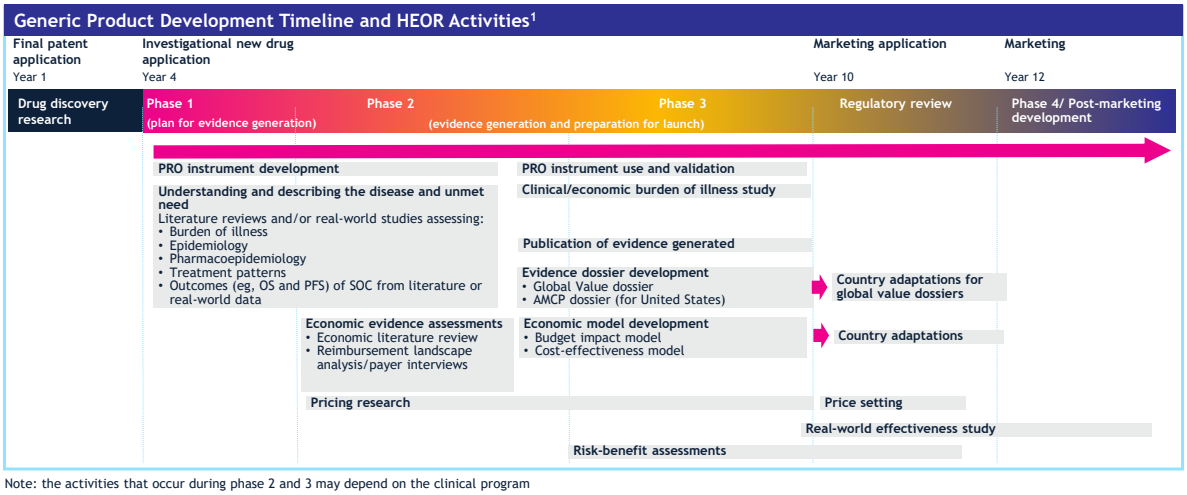
What evidence is needed to build an effective market access strategy?

How is HEOR Integrated Into the Product Lifecycle?



Note: the activities that occur during phase 2 and 3 may depend on the clinical program

AMCP, Academy of Managed Care Pharmacy; HEOR, health economics and outcomes research; OS, overall survival; PFS, progression-free survival; PRO, patient-reported outcome; SOC, standard of care

NOTES

Key HEOR related-activities during product lifecycle are described below[1]

1. Phase 1-2: the disease (including burden of illness, epidemiology, pharmacoepidemiology, treatment patterns) is assessed, and evidence generation plan is developed to support regulatory and reimbursement submissions
2. Phase 2 through remainder of lifecycle: humanistic/PRO instruments and early economic models may be developed, and key stakeholders are identified
3. Phase 3 through remainder of lifecycle: evidence is integrated into value messages and dossiers (including global value dossiers and AMCP dossiers for the United States), PROs are generated using new PRO measures (PROMs) or previously developed measures, and new PROMs are validated
4. Launch through remainder of lifecycle: country adaptations are developed for economic modeling, and real-world effectiveness studies are conducted

In summary, planning for evidence generation should begin in phase 1. During phase 2 and 3 (depending on the program), preparation for launch, generation of evidence, publication of generated evidence, and summary of evidence in value dossiers should occur[1]

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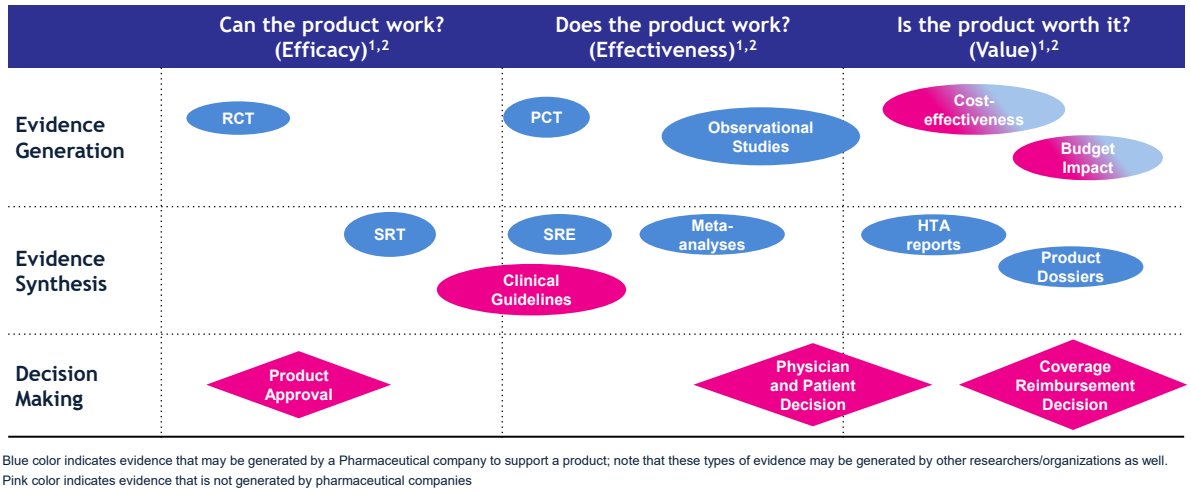
1. van Nooten F, Holmstrom S, Green J, Wiklund I, Odeyemi IA, Wilcox TK. Health economics and outcomes research within drug development: challenges and opportunities for reimbursement and market access within biopharma research. *Drug Discov Today*. 2012;17:615-622.

How Does HEOR Impact the Decision-Making Process?



Blue color indicates evidence that may be generated by a Pharmaceutical company to support a product; note that these types of evidence may be generated by other researchers/organizations as well.
Pink color indicates evidence that is not generated by pharmaceutical companies

CED, coverage with evidence development; HTA, health technology assessment; PCT, pragmatic clinical trial; RCT, randomized controlled trial; SRE, systematic review of evidence; SRT, systematic review of trials.

NOTES

Can the product work? Studies focusing on efficacy, including randomized controlled trials and systematic reviews of trials, contribute to decisions regarding product approval[1]

Does the product work? Studies focusing on effectiveness, including real-world observational data, pragmatic studies, network meta-analyses (NMAs) and reviews, support decisions made by physicians and patients[1]

> Meta-analyses combine data on clinical outcomes (eg, efficacy, mortality, adverse events), quality of life, and/or economic outcomes across studies.[2] Results of a meta-analysis can be used to evaluate effectiveness of a product, especially in cases where existing literature is composed of small cohort sizes and conflicting results[2]

Is the product worth it? Studies focusing on the value of the product, including economic evaluations (eg, budget impact models and cost-effectiveness models), support decisions made by payers/insurers[1]

Information on the real-world impact of patients, providers, payers, and policymakers are provided in Slide 13

REFERENCES

1. Luce BR, Drummond M, Jönsson B, et al. EBM, HTA, and CER: clearing the confusion. *Milbank Q*. 2010;88:256-276.
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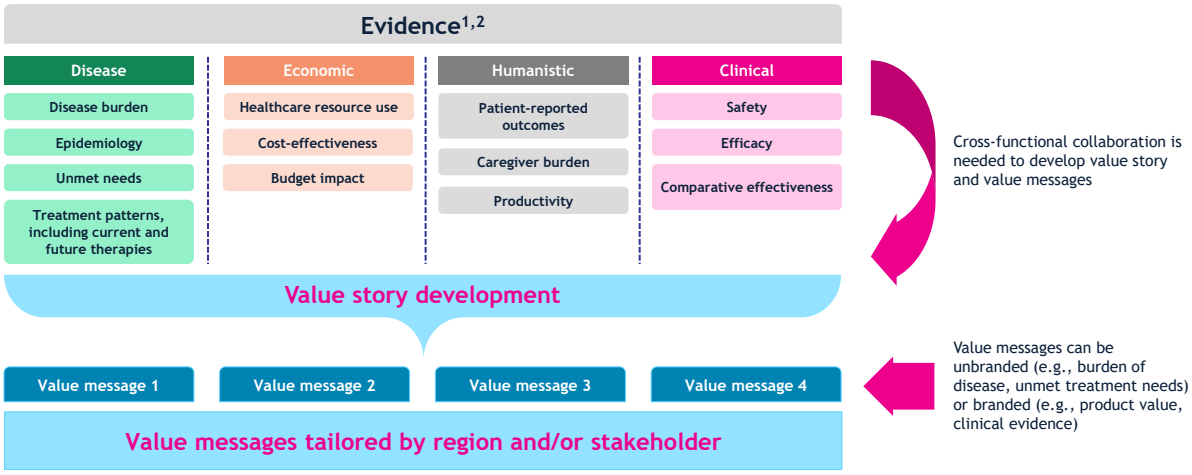
How Does HEOR Evidence Support a Product's Value Story?



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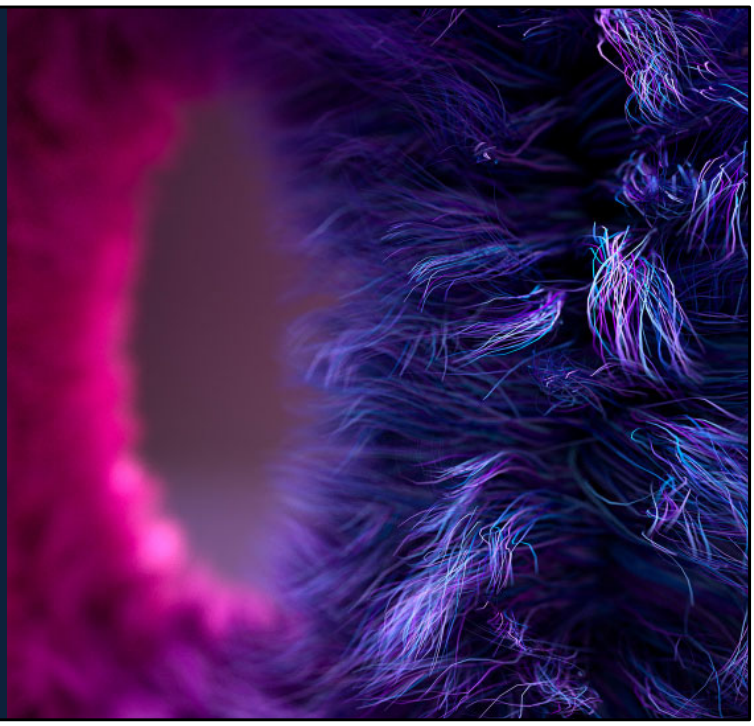
Why is market access training important to pharmaceutical companies?



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Strategic market access – Key strengths

Strategic Vision
Ability to create a coherent health economics and outcomes research perspective with a strategic vision

Maximizing Opportunities
Maximize reimbursement and market access opportunities with payers

Value Story Development
Interpret and utilize available clinical and economic evidence to develop a solid story for healthcare products

Clear Communication
Clearly communicate complex analyses and health economic methods

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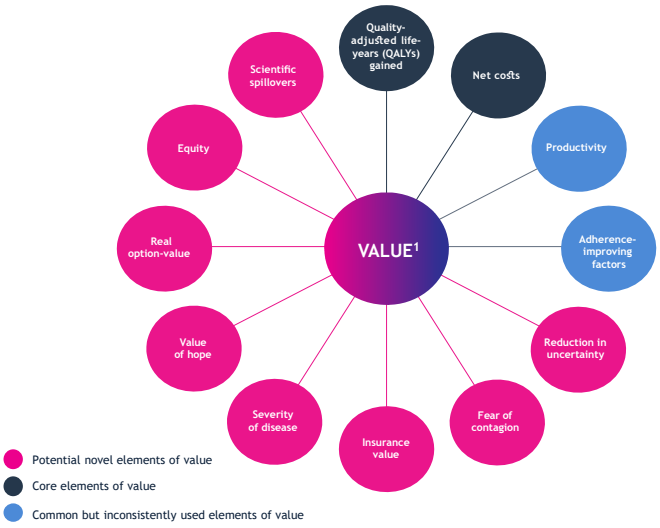
Many pharmaceutical company employees lack knowledge in payers' evaluation process, types of data used, and how to communicate product value

- What is the market access strategy to obtain optimal access to a product?
  - What data is needed for each stakeholder?
  - When is data needed during the development cycle?
- How to effectively describe evidence beyond clinical research (efficacy/safety) that is important to payers such as real-world evidence research, meta-analyses, economic models, etc.?
- What is the overarching "elevator pitch" to help convey the product value?
  - Elevator pitch is a short communication (1-2 paragraphs) that is based on stakeholder evidence needs meant to convey product value



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References

1. Lakdawalla, et al. Value in Health. 2018; 21(2) pp.131-139

How do we tackle this in L&D?

Why is this particularly CHALLENGING?

WHO do we need to train?

What is the KNOWLEDGE gap?

What is the COMPETENCE gap?

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Key takeaways

- Tailor to audience
- Global, regional and local
- Knowledge, competence and confidence
- Integrate within wider curriculum
- Make it real-world
- Measure and calibrate

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Thank You!

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Questions?

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