Advanced Health Economics and Outcomes Research (HEOR) Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The landscape of global healthcare is undergoing a rapid, value-driven transformation, making Advanced Health Economics and Outcomes Research (HEOR) expertise a mission-critical requirement for modern biopharmaceutical, medical device, and public health organizations. Advanced Health Economics and Outcomes Research (HEOR) Training Course is meticulously designed to move beyond foundational principles, equipping participants with the highly specialized, analytics-driven skills needed to master complex valuation methodologies. We will delve into the strategic generation and application of Real-World Evidence (RWE), sophisticated Health Technology Assessment (HTA) submission strategies, and the integration of Artificial Intelligence (AI) and Machine Learning (ML) into HEOR workflows. The primary focus is on generating robust, payer-centric evidence to effectively navigate challenging global pricing and market access decisions, ultimately driving the shift toward true Value-Based Healthcare.

The complexities of novel, high-cost therapies such as gene therapies, precision medicine, and digital therapeutics demand a new echelon of HEOR professional capable of not only constructing intricate economic models but also translating complex scientific data into a compelling value story for diverse decision-makers. This intensive course provides a deep dive into advanced techniques, including causal inference from observational data, advanced survival analysis, and the application of Multi-Criteria Decision Analysis (MCDA) in HTA. Participants will learn to design and execute a comprehensive Global Value Dossier, articulate a product?ÇÖs clinical and economic impact with precision, and champion strategies that foster health equity and patient-centricity. Graduates will emerge as strategic leaders poised to directly influence the development, reimbursement, and sustained commercial success of innovative medical technologies worldwide.

Programme Curriculum

Advanced Health Economics and Outcomes Research (HEOR) Training Course

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Course Duration

10 days

Course Objectives

1. Master the generation of Real-World Evidence (RWE) by applying advanced statistical techniques for causal inference from large claims and EHR datasets.
2. Design and program sophisticated health economic models to accurately estimate long-term cost-effectiveness.
3. Critique and adapt global Health Technology Assessment (HTA) methodologies, focusing on emerging requirements like the EU Joint Clinical Assessment (JCA).
4. Formulate a comprehensive and persuasive Global Value Dossier (GVD) that meets the requirements of multiple international pricing and reimbursement agencies.
5. Integrate Artificial Intelligence (AI) and Machine Learning (ML) approaches to enhance data extraction, predictive modeling, and outcomes forecasting in HEOR.
6. Develop robust strategies for the inclusion and validation of Patient-Reported Outcomes (PROs) in clinical trials and real-world studies.
7. Conduct advanced Budget Impact Analysis (BIA) and design innovative risk-sharing models like Managed Entry Agreements (MEAs).
8. Employ advanced Biostatistics to address confounding and bias in observational HEOR studies.
9. Evaluate the unique HEOR challenges and strategic approaches required for Precision Medicine and specialized Gene and Cell Therapies.
10. Apply principles of Multi-Criteria Decision Analysis (MCDA) to inform complex value decisions beyond the single-metric ICER.

11. Analyze the impact of policy and regulatory changes, specifically concerning US drug pricing transparency and international HTA shifts.
12. Champion the integration of Health Equity considerations into HEOR study design, data collection, and resource allocation models.
13. Communicate complex HEOR findings into a clear, strategic Value Story tailored for payer, regulator, and clinician audiences.

Target Audience

1. HEOR Managers and Directors
2. Market Access and Pricing Specialists
3. Medical Affairs and Medical Science Liaisons (MSLs)
4. Health Economists and Modelers
5. RWE Scientists and Epidemiologists
6. HTA/Regulatory Affairs Professionals
7. Public Health Researchers and Policy Analysts
8. Clinical Development and Biostatistics Leads

Course Modules

1. Advanced Biostatistics and Causal Inference for HEOR

- Survival Analysis methods.
- Propensity Score matching and weighting to reduce confounding in observational RWE studies.
- Instrumental variables and difference-in-differences for advanced causal inference.
- Handling missing data.
- Case Study: Applying PSM and double-robust estimation to an EHR database to determine the causal effect of a new cardiac drug on long-term resource utilization.

2. Mastering Real-World Evidence (RWE) Generation Strategy

- Strategic framework for RWD source selection.
- Data harmonization, quality assessment, and regulatory considerations for RWD.
- Developing RWE protocols and analytical plans that satisfy HTA and payer requirements.
- Practical and ethical challenges of using social media and patient-generated health data.
- Case Study: Designing a multinational RWE study using federated data networks to support a label extension for a novel oncology immunotherapy.

3. Sophisticated Health Economic Modeling

- Programming and validation of complex Markov and Semi-Markov Models
- Advanced concepts in Partitioned Survival Models and incorporating time-varying covariates.
- Introduction to Individual-Level Simulation for infectious disease or complex chronic care.
- Second-order Probabilistic Sensitivity Analysis (PSA) and interpreting the Cost-Effectiveness Acceptability Curve
- Case Study: Building and running a fully probabilistic simulation model in Excel/R for a new diabetes treatment, including validation checks against published literature.

4. Global Health Technology Assessment (HTA) Deep Dive

- Comparative analysis of major HTA bodies requirements and submission templates.

- Strategic preparation for the EU Joint Clinical Assessment (JCA) and its impact on multi-national evidence generation.
- Technical and strategic nuances of indirect treatment comparisons and Network Meta-Analysis.
- Pre-submission strategy and managing scientific advice meetings with HTA agencies.
- Case Study: Preparing a mock submission dossier for a new rare disease orphan drug, addressing specific methodological critiques from a major European HTA body.

5. Pricing, Reimbursement, and Managed Entry Agreements (MEAs)

- Advanced concepts in Value-Based Pricing (VBP) and alternative payment models.
- Designing a robust Budget Impact Analysis (BIA) that forecasts financial implications for different payer types.
- Structural and legal frameworks for performance-based, financial, and outcome-based Managed Entry Agreements (MEAs).
- Strategic negotiation techniques and communicating financial risk to payers.
- Case Study: Developing a regional MEA proposal for a high-cost gene therapy, balancing manufacturer risk with payer budget certainty.

6. Value Communication and Global Value Dossier (GVD)

- Structuring and maintaining a modular, customizable Global Value Dossier (GVD) for diverse stakeholders.
- Translating technical HEOR results into a non-technical, compelling Value Story.
- Designing effective data visualizations and infographics for payer communications.
- Strategies for responding to specific HTA technical questions and clarifying model assumptions.
- Case Study: Drafting a payer executive summary based on the results of a cost-effectiveness study for a new medical device.

7. Patient-Reported Outcomes (PROs) and Patient-Centricity

- Advanced methods for selecting, validating, and establishing measurement equivalence of PRO instruments.
- Psychometric properties of HRQoL and utility instruments
- Incorporating patient preferences and stated preference methods into HEOR.
- The role of e-PROs and digital health in real-time data collection.
- Case Study: Evaluating the psychometric properties of a novel PRO measure used in a late-stage clinical trial for chronic pain.

8. HEOR for Precision Medicine and Diagnostics

- Economic valuation of companion diagnostics and stratified treatment strategies.
- Modeling the uncertainty and cost-effectiveness of next-generation sequencing and genomic data.
- The HEOR challenge of small patient populations and rare diseases.
- Integrating clinical, genomic, and economic data into a single value framework.
- Case Study: Building a decision tree model to assess the cost-effectiveness of a new diagnostic test used to guide therapy selection for a cancer subtype.

9. Digital Therapeutics (DTx) and Health IT Valuation

- Frameworks for assessing the economic value of software-as-a-medical-device
- Measuring and monetizing the indirect outcomes of DTx

- Designing RWE studies for digital interventions using log data and app usage metrics.
- Regulatory pathways and their intersection with HEOR/Reimbursement for DTx.
- Case Study: Developing a BIA for a prescription digital therapeutic for insomnia, focusing on reduced resource use

10. Artificial Intelligence (AI) and Machine Learning (ML) in HEOR

- Introduction to supervised and unsupervised ML algorithms for outcomes prediction.
- Leveraging AI/ML for automated data extraction, literature reviews, and evidence synthesis.
- Ethical considerations, bias detection, and transparency in using AI-generated RWE.
- Predictive modeling for patient risk stratification and personalized intervention targeting.
- Case Study: Using a random forest algorithm on claims data to predict high-cost patients for targeted intervention and demonstrating the potential HEOR savings.

11. Health Equity and Social Determinants of Health (SDoH)

- Integrating Social Determinants of Health (SDoH) variables into HEOR data models.
- Methodologies for identifying and quantifying health and economic disparities.
- Conducting equity-focused economic evaluations and disaggregated cost-effectiveness analyses.
- The policy role of HEOR in resource allocation to reduce health inequalities.
- Case Study: Analyzing a cost-utility model to assess whether a new policy disproportionately benefits or harms specific demographic or socioeconomic patient subgroups.

12. Advanced Indirect Treatment Comparisons and Evidence Synthesis

- Technical requirements and reporting standards for Network Meta-Analysis (NMA) in HTA submissions.
- Handling complex networks: incorporation of multi-arm trials, heterogeneity, and inconsistency.
- Advanced systematic review and meta-regression techniques for evidence gap filling.
- Interpreting and communicating the limitations of indirect evidence to decision-makers.
- Case Study: Critically appraising a published NMA to identify methodological flaws that could affect an HTA recommendation.

13. Comparative Effectiveness Research (CER) and Observational Study Design

- Advanced cohort and case-control study design for RWE and pragmatic trials.
- Methodological and regulatory differences between CER and traditional HEOR.
- Bias correction techniques.
- The process and communication of evidence generation in learning healthcare systems.
- Case Study: Designing a quasi-experimental study to evaluate the real-world effectiveness of a new public health policy intervention.

14. Decision Theory and Multi-Criteria Decision Analysis (MCDA)

- Theoretical foundations of decision analysis under uncertainty.
- Principles and practical application of Multi-Criteria Decision Analysis (MCDA).
- Weighting and scoring non-traditional value elements
- Using MCDA to facilitate transparent, accountable resource allocation decisions.
- Case Study: Facilitating a mock stakeholder panel using an MCDA framework to rank three competing medical technologies based on clinical efficacy, cost, patient preferences, and societal impact.

15. HEOR Leadership and Strategic Planning

- Developing a multi-year Value Evidence Plan aligned with global product lifecycle stages
- Integrating HEOR evidence generation into clinical development and regulatory strategy.
- Managing HEOR vendor relationships and ensuring quality assurance in outsourced projects.
- Building and scaling a high-performing internal HEOR team and competencies.
- Case Study: Creating a strategic plan for a pipeline asset, outlining key HEOR deliverables required at each stage before launch.

Training Methodology

The course employs an intensive, blended-learning methodology designed for advanced professional development, moving beyond lectures to focus on practical application and strategic decision-making:

- Hands-on Workshops.
- Real-World Case Studies.
- Interactive Simulations.
- Expert-Led Lectures
- Capstone Project.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price

23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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