Advanced Market Access Strategy for Specialty Medicines 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

Specialty medicines, including Cell and Gene Therapies and treatments for Rare Diseases, are the cutting edge of biopharma, offering curative or transformative outcomes for patients with complex, chronic conditions. However, the path from regulatory approval to patient access is fraught with challenges unique to this sector, driven by ultra-high upfront costs, limited Real-World Evidence (RWE) at launch, and the need for new Innovative Payment Models. Advanced Market Access Strategy for Specialty Medicines Training Course is meticulously designed to equip life science professionals with the strategic toolkit necessary to navigate this complex landscape. We focus on mastering the art of Value Demonstration and securing favorable Pricing and Reimbursement across diverse global markets, ensuring these life-changing therapies reach the patients who desperately need them.

This program moves beyond foundational market access concepts, delving into advanced strategy execution across the product lifecycle from early development and Target Product Profile (TPP) refinement to post-launch Outcomes-Based Agreements (OBAs). Participants will gain mastery in leveraging Health Economics and Outcomes Research (HEOR) and Digital Health Solutions to build a robust Value Story tailored for demanding Health Technology Assessment (HTA) bodies and increasingly sophisticated Payers. By focusing on proactive cross-functional integration, strategic stakeholder engagement, and anticipating policy changes, this training delivers the expertise required to maximize Patient Access and achieve optimal Gross-to-Net (GTN) performance in the highly competitive and evolving specialty pharmaceuticals market.

Programme Curriculum

Advanced Market Access Strategy for Specialty Medicines Training Course

Introduction

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Course Duration

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Course Objectives

1. Master the development of a Global Market Access Strategy for Orphan Drugs and Advanced Therapy Medicinal Products
2. Design a differentiated, evidence-based Value Proposition and a compelling Value Story for diverse payer archetypes.
3. Integrate Health Economics and Outcomes Research and Real-World Evidence into clinical development to satisfy HTA requirements.
4. Analyze and anticipate the impact of emerging Value-Based Care and Outcomes-Based Agreements on pricing strategy.
5. Develop robust Pricing and Reimbursement strategies that balance affordability, patient access, and Commercial Viability.
6. Navigate complex Payer Negotiations and manage the unique challenge of high Gross-to-Net leakage in specialty channels.
7. Structure effective Patient Support Programs and Hub Services to optimize adherence and streamline the patient journey.
8. Evaluate the market access implications for Digital Health and Companion Diagnostics integration with specialty medicines.
9. Anticipate and strategically respond to the competitive dynamics, including the entry of Biosimilar and follow-on therapies.
10. Formulate pre-launch access plans that ensure optimal Healthcare System Readiness for administration of complex therapies.
11. Leverage Stakeholder Engagement including patient advocacy groups and Key Opinion Leaders to strengthen the market access case.

12. Address the specific market access and reimbursement challenges of Gene Therapies through innovative Financing Models.
13. Build and lead an Agile Cross-Functional Team that embeds market access thinking into all stages of product development.

Target Audience

1. Market Access Directors/Managers.
2. Pricing and Reimbursement Specialists in Specialty Care.
3. Health Economics and Outcomes Research Professionals.
4. Commercial/Marketing Leaders preparing for specialty product launches.
5. R&D and Clinical Development Strategy Teams.
6. Regulatory Affairs and Medical Affairs personnel supporting value communication.
7. Business Development and Licensing professionals evaluating specialty assets.
8. Senior Leadership in Biotechnology and Pharmaceutical companies.

Course Modules

Module 1: The Specialty Market Access Ecosystem: Deep Dive

- Analyzing the unique characteristics of specialty medicines.
- Understanding the key global archetypes of Payer, HTA, and Policymaker decision-making.
- Identifying the critical market access inflection points from pre-clinical to post-launch.
- Assessing the challenge of Patient Portability and its impact on long-term value capture.
- Case Study: Analyzing the market access path for a recently approved Orphan Drug in the EU5, focusing on country-specific HTA variations.

Module 2: Integrating Market Access in Early Development

- Defining a robust Target Product Profile informed by payer evidence requirements.
- Developing an Evidence Generation Plan to fill data gaps for HTA submission
- Strategic sequencing of market entry and pricing corridors for optimal global impact.
- Early engagement strategies with Payer/HTA bodies to obtain scientific advice.
- Case Study: A biopharma company's decision to add an RWE arm to a Phase 3 trial based on early Payer feedback in Germany and the UK.

Module 3: Advanced Value Demonstration and Value Storytelling

- Quantifying the Unmet Need and the Disease Burden for rare and complex conditions.
- Building a compelling economic model that captures long-term, Curative Value vs. chronic treatment costs.
- Techniques for articulating the non-clinical, societal, and quality-of-life value to non-HEOR stakeholders.
- Tailoring the Value Story for different audiences.
- Case Study: Crafting a winning value dossier for a first-in-class oncology therapy, demonstrating superior Overall Survival to secure premium pricing.

Module 4: Pricing Strategy and Commercial Viability

- Implementing Differential Pricing strategies across global markets
- Developing sophisticated Net Pricing and Gross-to-Net forecasting models for complex contracting.
- Strategic use of competitive intelligence to inform price-setting and anticipating biosimilar entry.
- Navigating the impact of national and international reference pricing on launch sequence.

- Case Study: Simulating the impact of a 5% WAC price change on GTN Leakage and government pricing compliance.

Module 5: Health Technology Assessment (HTA) Mastery

- Deep dive into major HTA requirements
- Best practices for developing a high-quality, defensible Cost-Effectiveness Model
- Techniques for mitigating Clinical Uncertainty and limited long-term data in HTA submissions.
- Preparing for HTA challenge questions and developing a robust Objection Handler database.
- Case Study: Revising an HTA submission for a rheumatology biologic after an initial rejection, focusing on comparator selection and sub-population analysis.

Module 6: Innovative Payment and Value-Based Agreements

- Structuring Outcomes-Based Agreements and Risk-Sharing Contracts for high-cost therapies.
- Exploring novel Financing Models for CGTs.
- Establishing measurable, objective Performance Metrics for outcomes-based contracting.
- Legal and operational considerations for implementing and managing complex VBAs.
- Case Study: Designing an Annuity Payment model for a Gene Therapy where annual payments are contingent on sustained clinical response.

Module 7: Cell and Gene Therapy (CGT) Market Access

- Addressing the unique challenges of one-time, Ultra-High Upfront Costs and demonstrating Long-Term Durability.
- Strategies for securing Healthcare System Readiness
- The role of RWE and Patient Registries in validating value post-launch for payers.
- Navigating the regulatory-access interface for Advanced Therapy Medicinal Products
- Case Study: Developing a market access strategy for a CAR T-cell therapy, focusing on site-of-care and reimbursement for administration costs.

Module 8: Real-World Evidence (RWE) Strategy for Specialty Medicines

- Defining the strategic role of RWE across the product lifecycle.
- Identifying and leveraging appropriate RWE sources
- Methodologies for conducting high-impact Observational Studies that address payer concerns.
- Addressing methodological quality and bias concerns in RWE used for HTA.
- Case Study: Using a large patient registry dataset to prove the long-term effectiveness and reduced healthcare resource utilization of a specialty drug in a real-world setting.

Module 9: Payer Negotiation and Strategic Contracting

- Developing a Payer Engagement Plan and sequencing of negotiation efforts.
- Advanced techniques for complex Pricing and Volume negotiations.
- Mastering the role of the Key Account Manager in communicating clinical and economic value.
- Preparing for formulary exclusion, step therapy, and Prior Authorization hurdles.
- Case Study: Simulating a negotiation scenario with a major US Payer/PBM to gain preferred formulary status over a competitor.

Module 10: Patient Access Programs (PSPs) and Hub Services

- Designing comprehensive Patient Support Programs that drive adherence and manage logistics.

- Selecting and managing Specialty Pharmacy and Hub Service Providers for limited distribution.
- Implementing best practices for Benefit Verification and Prior Authorization Support to reduce time-to-fill.
- Ensuring PSP design is compliant with legal, regulatory, and anti-kickback statutes.
- Case Study: Evaluating the ROI of various PSP components on patient adherence and commercial success.

Module 11: Market Access for Diagnostics and Digital Health

- Understanding the reimbursement pathway for Companion Diagnostics that enable specialty treatment access.
- Developing value propositions for Digital Health Solutions that link to clinical and economic outcomes.
- Navigating the separate regulatory and reimbursement systems for medical devices/apps versus drugs.
- Strategies for integrating digital solutions into patient support and RWE generation.
- Case Study: Mapping the market access strategy for a biologic therapy tied to a novel CDx test required for patient eligibility.

Module 12: Policy, Regulatory, and Competitive Landscape

- Monitoring global Healthcare Policy changes and their market access implications.
- Developing strategies to manage the market entry and impact of Biosimilars and generics in the specialty space.
- AI in Drug Discovery and the resulting pipeline impact on access.
- Engaging with policymakers and industry groups to advocate for favorable access conditions.
- Case Study: Analyzing the strategic response of a manufacturer to the launch of the first biosimilar in their therapeutic area, including contracting adjustments.

Module 13: Global Market Access Execution and Launch Excellence

- Optimizing the Global Launch Sequence to maximize revenue and mitigate price erosion.
- Implementing a Cross-Functional Governance model for coordinated pre- and post-launch activities.
- Developing local market access plans that adapt global strategy to regional payer specifics.
- Metrics and KPIs for tracking and adjusting market access performance post-launch.
- Case Study: Reviewing a successful multi-country launch for a specialty medicine, contrasting the US commercial approach with the HTA-driven European approach.

Module 14: Rare Disease and Ultra-Orphan Market Access

- Developing a Patient-Centric access strategy that starts with the patient journey.
- Strategies for generating evidence in extremely small, heterogenous patient populations.
- Leveraging Managed Access Programs and Early Access Schemes for pre-reimbursement access.
- Working effectively with Patient Advocacy Groups to build a strong case for reimbursement.
- Case Study: A company?ÇÖs strategy for achieving reimbursement for an ultra-orphan drug where the primary evidence was a single-arm trial.

Module 15: Leadership and Market Access Team Building

- Fostering a Market Access Culture across R&D, Clinical, Commercial, and Medical teams.
- Skills gap analysis and talent development for the next generation of access professionals.
- Techniques for leading and influencing senior management and cross-functional stakeholders.
- Ethical considerations and compliance in all access, pricing, and PSP activities.

- Case Study: Establishing a new Global Market Access function within a mid-sized biotech firm, outlining structure, roles, and KPIs.

Training Methodology

The course employs a Blended Learning approach combining expert-led instruction with highly practical, application-focused sessions, ensuring deep knowledge transfer and skill acquisition:

1. Interactive Lectures.
2. Hands-on Bioreactor Simulation.
3. Data-Driven Workshops.
4. In-depth Case Studies.
5. Group QbD 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

Start Date	End Date	Location	Price
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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