Real-World Evidence (RWE) in Pharma Training Course

Professional Development Training Course Outline

Category	Research and Data Analysis	**Duration**	5 Days
Base Fee	$1,500 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The pharmaceutical industry is undergoing a transformative shift where Real-World Evidence (RWE) has become a cornerstone for drug development, regulatory decision-making, and market access strategies. RWE leverages data from electronic health records (EHRs), patient registries, claims databases, and wearables to provide insights into treatment effectiveness, safety profiles, and patient outcomes outside controlled clinical trials. By integrating data-driven analytics, predictive modeling, and health economics, RWE enables pharma companies to make evidence-based decisions that optimize clinical trials, accelerate approvals, and enhance patient-centric care.

Real-World Evidence (RWE) in Pharma Training Course is designed to equip professionals with practical skills, advanced analytical techniques, and regulatory knowledge required to implement RWE in pharmaceutical development. Participants will explore methodologies, data sources, statistical frameworks, and case studies demonstrating real-world applications. The program emphasizes strategic insights, regulatory compliance, and commercialization opportunities, ensuring learners gain actionable expertise that drives innovation, patient engagement, and healthcare outcomes in a competitive pharma landscape.

Programme Curriculum

Real-World Evidence (RWE) in Pharma Training Course

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Course Duration

5 days

Course Objectives

1. Understand the fundamentals of RWE and its role in pharma.
2. Explore RWE data sources: EHRs, claims, registries, and digital health.
3. Apply statistical and analytical methods for real-world data (RWD).
4. Integrate health economics and outcomes research (HEOR) in decision-making.
5. Evaluate regulatory frameworks for RWE submission.
6. Leverage predictive modeling and AI/ML in RWE studies.
7. Design RWE studies for post-marketing surveillance and safety monitoring.
8. Optimize patient recruitment and retention using real-world insights.
9. Implement data governance, quality, and privacy best practices.
10. Conduct comparative effectiveness research (CER) for treatment outcomes.
11. Translate RWE into market access and reimbursement strategies.
12. Interpret case studies of successful RWE implementation in pharma.
13. Develop actionable insights for stakeholder communication and decision-making.

Target Audience

1. Clinical researchers and trial managers
2. Pharmacovigilance and safety specialists
3. Health economics and outcomes research (HEOR) professionals
4. Regulatory affairs professionals
5. Market access and commercial strategy teams
6. Data scientists and biostatisticians
7. Medical affairs and clinical operations professionals
8. Pharmaceutical consultants and policy advisors

Course Modules

Module 1: Introduction to Real-World Evidence (RWE)

- Definition and evolution of RWE in pharma
- Difference between RWE and randomized clinical trials (RCTs)
- Regulatory landscape and guidelines
- Key use cases across drug lifecycle
- **Case Study:** FDA approval of a drug using RWE

Module 2: Data Sources for RWE

- Electronic Health Records (EHRs) and claims databases
- Patient registries and disease-specific datasets
- Wearables, mobile health apps, and digital biomarkers
- Data integration and interoperability challenges
- **Case Study:** Multi-source RWD integration for oncology outcomes

Module 3: Study Design & Methodologies

- Observational studies: cohort, case-control, and cross-sectional
- Pragmatic clinical trials and hybrid designs
- Statistical methods for bias reduction
- Handling missing data and confounders
- **Case Study:** Real-world study on diabetes medication effectiveness

Module 4: Data Analytics and Artificial Intelligence

- Predictive modeling and machine learning in RWE
- Natural language processing for unstructured data
- Data visualization and interpretation techniques
- Risk stratification and patient segmentation
- **Case Study:** AI-driven RWE for cardiovascular drug safety

Module 5: Health Economics & Outcomes Research (HEOR)

- Cost-effectiveness and budget impact analysis
- Quality-adjusted life years (QALY) and patient-reported outcomes
- Comparative effectiveness research (CER)
- Integration of RWE in payer and formulary decisions
- **Case Study:** HEOR-driven reimbursement strategy in oncology

Module 6: Regulatory & Compliance Considerations

- FDA, EMA, and other global regulatory frameworks
- Guidelines for RWE submission and post-marketing studies
- Privacy laws: HIPAA, GDPR, and ethical considerations
- Risk management and audit readiness
- **Case Study:** Regulatory approval of a rare disease therapy using RWE

Module 7: Commercialization & Market Access

- Translating RWE into pricing and reimbursement strategies
- Stakeholder engagement: payers, physicians, and patients
- Real-world evidence in product lifecycle management
- Strategic insights for market differentiation
- **Case Study:** RWE-driven market access strategy in immunotherapy

Module 8: Implementation & Future Trends

- Best practices for RWE project execution
- Data governance and quality assurance

- Emerging trends: decentralized trials, blockchain, and digital twins
- Future opportunities for AI-enabled RWE
- **Case Study:** Integration of RWE in digital therapeutics adoption

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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	27 Nov 2026	Online	$1,000
23 Nov 2026	27 Nov 2026	Physical	$1,500
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$4,500
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$6,000

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