Advanced Due Diligence in Clinical Development Assets 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 modern biopharmaceutical landscape is characterized by increasingly complex, high-stakes transactions, where the acquisition or licensing of clinical development assets from novel gene and cell therapies to platform technologies carries significant financial and regulatory risk. Traditional due diligence is no longer sufficient; success demands a cross-functional, advanced methodology that rigorously scrutinizes the scientific, regulatory, commercial, and operational integrity of an asset. This necessitates a deep dive into real-world evidence, adaptive trial designs, pharmacovigilance data, and intellectual property strength to uncover latent liabilities and accurately assess a target's true pipeline value.

Advanced Due Diligence in Clinical Development Assets Training Course is designed to empower Business Development, Search & Evaluation, R&D, and legal professionals with the expert-level skills needed to navigate this intricate environment. Participants will master a structured, risk-mitigation framework for asset valuation and deal negotiation. By integrating real-world case studies including those involving regulatory red flags and flawed clinical outcomes with best practices in data integrity and competitive landscape analysis, the course ensures professionals can move beyond basic checklists. The ultimate goal is to enable data-driven decision-making that protects investment capital, optimizes the R&D portfolio, and ultimately secures a successful and compliant path to market access for novel therapeutics.

Programme Curriculum

Advanced Due Diligence in Clinical Development Assets Training Course

Introduction

The modern biopharmaceutical landscape is characterized by increasingly complex, high-stakes transactions, where the acquisition or licensing of clinical development assets from novel gene and cell therapies to platform technologies carries significant financial and regulatory risk. Traditional due diligence is no longer sufficient; success demands a cross-functional, advanced methodology that rigorously scrutinizes the scientific, regulatory, commercial, and operational integrity of an asset. This necessitates a deep dive into real-world evidence, adaptive trial designs, pharmacovigilance data, and intellectual property strength to uncover latent liabilities and accurately assess a target's true pipeline value.

Advanced Due Diligence in Clinical Development Assets Training Course is designed to empower Business Development, Search & Evaluation, R&D, and legal professionals with the expert-level skills needed to navigate this intricate environment. Participants will master a structured, risk-mitigation framework for asset valuation and deal negotiation. By integrating real-world case studies including those involving regulatory red flags and flawed clinical outcomes with best practices in data integrity and competitive landscape analysis, the course ensures professionals can move beyond basic checklists. The ultimate goal is to enable data-driven decision-making that protects investment capital, optimizes the R&D portfolio, and ultimately secures a successful and compliant path to market access for novel therapeutics.

Course Duration

10 days

Course Objectives

1. Master the Advanced Due Diligence Framework for high-stakes biotech M&A and licensing.
2. Critically evaluate Clinical Data Integrity and robustness, focusing on Phase II/III trial design and statistical power.
3. Assess the scientific validity and differentiation hypothesis of novel modalities, including Cell and Gene Therapies.
4. Conduct comprehensive Regulatory Pathway Analysis to identify and mitigate compliance red flags and expedited program risks.
5. Perform a rigorous IP & Freedom-to-Operate assessment, particularly for platform technologies and composition-of-matter patents.
6. Accurately model Commercial Viability using advanced market access and competitive landscape analysis.
7. Analyze Real World Evidence and patient-reported outcomes to validate clinical benefit and market potential.
8. Uncover and quantify Pharmacovigilance and Drug Safety liabilities in preclinical and clinical data.
9. Develop robust Asset Valuation methodologies that integrate technical, legal, and financial risks.
10. Structure and lead a high-performing Cross-Functional Due Diligence Team under intense timelines.
11. Navigate the complexities of virtual data rooms and implement secure data governance protocols.
12. Identify operational and cultural risks within the target company's clinical operations infrastructure.
13. Apply negotiation strategies to leverage due diligence findings for favorable deal term optimization.

Target Audience

1. Business Development and Search & Evaluation Professionals in Pharma/Biotech.
2. Venture Capital and Private Equity Analysts focused on Life Sciences investments.
3. R&D and Portfolio Strategy Leadership.
4. Clinical Operations and Clinical Development Managers.
5. Regulatory Affairs and Pharmacovigilance Specialists involved in transactions.

6. Intellectual Property and Corporate Legal Counsel.
7. Financial Analysts and Valuation Experts in the Healthcare sector.
8. Internal Audit and Risk Management Teams.

Course Modules

1. The Strategic Imperative of Advanced Due Diligence

- Shifting from basic checklists to a risk-based, strategic DD framework.
- The role of DD in licensing, M&A, and strategic collaborations.
- Establishing a high-performing, cross-functional DD team.
- Defining DD scope, deliverables, and the art of asking the right questions.
- Case Study: The acquisition of a small biotech where the DD team failed to align on risk tolerance, leading to post-close litigation over undisclosed operational liabilities.

2. Clinical Data Integrity and Scientific Scrutiny

- Deep dive into raw Phase I-III clinical trial data and Study Reports
- Evaluating trial design flaws, endpoint selection, and statistical robustness.
- Assessing the validity of the Mechanism of Action and the differentiation hypothesis.
- Reviewing Preclinical/Toxicology data for early-stage red flags.
- Case Study: An asset with seemingly positive Phase II data, but the DD team uncovered a flawed randomization/blinding protocol that introduced significant bias, leading to a major valuation reduction.

3. Regulatory Due Diligence and Compliance Risks

- Comprehensive review of FDA/EMA correspondence, health authority meetings, and regulatory commitments.
- Assessing the feasibility of Expedited Programs
- GCP/GMP compliance audit of clinical sites, vendors, and manufacturing processes.
- Analyzing country-specific regulatory barriers and global submission strategies.
- Case Study: A European asset with a strong clinical profile that failed to gain US traction due to unaddressed GCP violations at key EU sites, uncovered only through an on-site regulatory DD.

4. Intellectual Property (IP) and Freedom-to-Operate (FTO)

- Verifying patent ownership and legal status for composition of matter, method of use, and formulation patents.
- Advanced FTO analysis in key commercial jurisdictions and identifying potential infringement risks.
- Reviewing licensing and collaboration agreements for change-of-control clauses and potential IP reversion rights.
- Assessing the value and enforceability of trade secrets and know-how.
- Case Study: A flagship asset's valuation was severely impacted when a DD IP counsel found a prior art patent that significantly narrowed the scope of the target company?ÇÖs core composition-of-matter claim, jeopardizing market exclusivity.

5. Pharmacovigilance and Drug Safety Liability

- Reviewing the target company?ÇÖs Pharmacovigilance System Master File and risk management plan.
- Analyzing raw Adverse Event reports, Serious Adverse Events, and aggregate safety data for hidden safety signals.
- Assessing the quality of safety monitoring and reporting systems in clinical trials.

- Quantifying the financial and reputational risk of potential drug safety liabilities.
- Case Study: An in-licensing deal where a review of pre-clinical toxicology reports revealed a dose-limiting toxicity that the target company had downplayed, leading to the termination of negotiations.

6. Commercial Viability and Market Access Analysis

- Competitive Landscape mapping and a rigorous assessment of the asset's differentiation.
- Forecasting peak sales potential using various market penetration scenarios.
- Evaluating payor landscape and reimbursement challenges for the target indication.
- Analyzing existing commercial agreements and distribution networks.
- Case Study: An oncology asset with competitive Phase III data, but DD revealed a competitor was already launching an equivalent product with a superior payor coverage strategy, significantly limiting the target's market share potential.

7. Financial & Legal Due Diligence in Asset Transactions

- Uncovering undisclosed financial liabilities specifically related to clinical trial vendor contracts and unpaid investigator fees.
- Reviewing key material contracts.
- Analyzing litigation history, specifically regarding clinical trial disputes or product liability claims.
- Assessing the tax implications and optimal deal structuring for asset transfer.
- Case Study: A platform technology acquisition where the legal DD uncovered a major breach of contract by the target with a key supplier, which had been hidden off-balance sheet and would require a massive settlement post-close.

8. Due Diligence for Novel Modalities

- Specific DD requirements for Cell and Gene Therapies, including manufacturing, quality control, and long-term follow-up data.
- Assessing the stability and scalability of platform technologies.
- Evaluating risks related to vector supply, viral shedding, and off-target effects.
- Deep-dive into CMC regulatory filings and manufacturing site compliance
- Case Study: A CGT acquisition where DD flagged significant issues with the target?ÇÖs in-house viral vector manufacturing capacity and a lack of validated scale-up protocols, forcing a substantial increase in the post-acquisition CapEx budget.

9. Integrating Real-World Evidence (RWE) and Digital Assets

- Critically evaluating RWE data sources for bias and data quality.
- Assessing the DD needs for Digital Health and software as a medical device asset, including data security and privacy compliance.
- Utilizing Machine Learning/AI for enhanced DD data-mining and risk signaling.
- Reviewing agreements governing the use of external Real-World Data
- Case Study: A digital therapeutic acquisition where DD discovered the company's data anonymization protocols were non-compliant with GDPR standards, creating a massive regulatory and reputational risk.

10. Operational Due Diligence: Clinical and R&D Infrastructure

- Evaluating the target company's R&D operational maturity, quality systems, and Standard Operating Procedures
- Assessing the experience, capacity, and retention risk of the key R&D personnel and clinical leadership.

- Reviewing vendor management, clinical trial oversight, and patient recruitment strategies.
- Analyzing the target?ÇÖs preparedness for post-merger integration
- Case Study: A merger where operational DD revealed the target's internal clinical trial management system was outdated and non-validated, necessitating an expensive and time-consuming upgrade immediately after closing.

11. Asset Valuation Methodologies and Deal Negotiation

- Applying Net Present Value and Risk-Adjusted NPV models, specifically risk-adjusting for DD findings.
- Structuring milestone payments and royalty tiers based on DD-identified risks and opportunities.
- Utilizing DD findings to justify favorable negotiation positions and deal term adjustments.
- Understanding common Rep & Warranty insurance limitations and exclusions.
- Case Study: A late-stage asset deal where the DD team used the discovery of a minor, correctable manufacturing defect to justify a $50M reduction in the upfront cash payment.

12. Managing the Due Diligence Process

- Best practices for organizing and managing the Virtual Data Room and document flow.
- Implementing data governance and confidentiality agreements for the DD team.
- Strategies for efficient Q&A management and follow-up on critical issues.
- Tips for writing a clear, actionable DD report with a focus on go/no-go recommendations and risk quantification.
- Case Study: A tight-timeline acquisition where a poorly structured VDR led to the DD team missing key documents, resulting in a three-week delay and nearly derailing the deal close.

13. Advanced Clinical Trial Design and Operational Review

- DD for Decentralized Clinical Trials and hybrid trial models.
- Reviewing the feasibility and data quality of adaptive trial designs.
- Assessing the statistical and operational challenges of trials in Rare Diseases and Orphan Drugs.
- Evaluating patient recruitment, retention, and diversity metrics.
- Case Study: Reviewing an asset targeting a rare disease where the DD team determined the current trial was non-replicable due to the unsustainably high cost of patient recruitment from niche specialist centers.

14. Post-Due Diligence and Integration Planning

- Translating the DD report's risk findings into a clear Post-Merger Integration action plan.
- Developing strategies for rapid remediation of discovered compliance gaps.
- Prioritizing R&D and clinical integration activities.
- Establishing a DD-to-PMI handover protocol to ensure continuity.
- Case Study: An acquired company where the DD findings of a weak R&D management team were not integrated into the PMI plan, leading to a year of organizational drift and missed clinical milestones.

15. Ethical Considerations and Future Trends in DD

- Managing conflicts of interest and ethical reporting in DD.
- Environmental, Social, Governance and supply chain resilience.
- The impact of AI/ML in accelerating and improving DD data analysis.
- The future of due diligence in a world of complex, multi-asset portfolio deals.

- Case Study: A DD assignment where the team had to navigate complex cross-border ethics and data privacy regulations for a European trial, ultimately recommending the trial design be altered to ensure local compliance.

Training Methodology

The course employs an **intensive, results-oriented methodology** blending expert-led instruction with practical, real-world application to ensure mastery of complex, multi-disciplinary concepts.

1. Expert-Led Lectures & Workshops
2. Case Study Analysis.
3. Cross-Functional Team Simulation.
4. Actionable Toolkits & Templates.
5. Interactive Q&A and Expert Panels.

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

Start Date	End Date	Location	Price
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

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com