

THE CATENION ACADEMY

Decision Analysis for Early Clinical Development Portfolio Managers

An In-depth Training in Supporting Decision Analysis
for Early Clinical Development Projects and Portfolios

4 days programme

COURSE OBJECTIVES

- > Take the Portfolio Managers through a real life example of determining the optimal strategy going forward for a Phase IIa compound
- > Provide an understanding of the different perspectives of project team members, Decision Makers, and Portfolio Managers
- > Enable Portfolio Managers to understand and use Catenion's processes, methods and tools for Portfolio Management of Early Clinical Development Projects and Portfolios
- > Familiarise Portfolio Managers with the possibility to use their role, function and tools to drive project teams to creative insights and new perspectives on their projects

DESIGN

- Prior to the course each participant should spend a couple of hours to familiarise themselves with the project materials
- Each session will be introduced by a Catenion moderator who will explain the question to be addressed, the methodology and information to be used and the tools/programmes at the participant's disposal
- The participants will then work as a group or split into subgroups to work through the tasks at hand and prepare the analyses and take different perspectives of all parties involved
- A Catenion moderator will be available to answer questions, facilitate the discussion and help with technical issues

PROGRAMME

Overview of Processes, Methods and Tools including

- Option Space Mapping
- Competitive Product Profile
- R&D Risk Assessment
- Innovativeness Screening
- Decision Tree Analysis
- Project Synthesis
- Portfolio Prioritisation
- Case Study: SMOL Phase IIa project example Oncology

MATERIALS

Print materials and CD containing

- Presentations and templates used
- Excel models for R&D Risk Assessment and Innovativeness Screening
- Case Study information including compound dossier, list of recommended market research reports, etc

COURSE AGENDA

DAY 1

MORNING SESSION: OPTION SPACE MAPPING

Overview of Processes, Methods and Tools in Portfolio Management

In-depth introduction to Option Space Mapping method

Case Study

Preparation of Option Space Maps

- What indications are accessible as supported by strong pre-clinical/clinical data?
- How does the project compare with other pipeline projects?
- Where do competitors stand?
- What are potential differentiators?
- What strategic options can be defined?

AFTERNOON SESSION: COMPETITIVE PRODUCT PROFILE

In-depth introduction to Competitive Product Profile approach

Case Study

Preparation of Competitive Product Profile

- What is the relevant present/future competitor/gold standard?
- How can the project be positioned vs. the gold standard, what are the major differentiators?
- How well does the development plan support the envisioned claims?

Discussion of stakeholder perspectives

- Project Teams
- Decision Makers
- Portfolio Managers

Summary of session results

DAY 2

MORNING SESSION: R&D RISK ASSESSMENT I

In-depth introduction to R&D Risk Assessment method

Case Study

Preparation of R&D Risk Assessment

What are the technical & scientific uncertainties of the project in terms of ...

- Target & concept
- R&D infrastructure
- Compound properties
- Clinical indication & biomarkers
- Company experience
- Regulatory requirements

AFTERNOON SESSION: R&D RISK ASSESSMENT II

Discussion/presentation of R&D Risk Assessment for Case Study project

Discussion of stakeholder perspectives

Summary of session results

DAY 3

MORNING SESSION: INNOVATIVENESS SCREENING

In-depth introduction to Innovativeness Screening method

Case Study

Preparation of Innovativeness Screening

- Novelty
- Relative Usefulness
- Theoretical Market Potential
- Exploitability by Company

Discussion/presentation of Innovativeness Screening for Case Study project

Discussion of stakeholder perspectives

Summary of session results

AFTERNOON SESSION: DECISION TREE ANALYSIS

In-depth introduction to Decision Tree Analysis method

Case Study

- Transfer of development objectives and strategies for selected indications into decision trees including duration & likelihood of success of clinical phases
- Documentation of go/no go milestones and interdependencies between different possible development paths
- Critique & adaptation of benchmark probability of success figures for the project based on the R&D Risks

Summary of session results

DAY 4

MORNING SESSION: PROJECT SYNTHESIS

In-depth discussion of decision-making at the Project Level

Case Study

- Discussion of results of modules
- Synthesis of key results
 - Strategic options forward
 - Risk mitigation planning
 - Milestones & key no-gos
 - Value enhancing actions

What are possible options for the project forward?

Summary of session results

AFTERNOON SESSION: PORTFOLIO PERSPECTIVE

Introduction of additional projects to generate a portfolio case study

Presentation of different scenarios for portfolio considerations

In-depth discussion of decision-making at the Portfolio Level

Case Study

- What are possible scenarios and how would the project be viewed in different Portfolio Options?
- Resource constraints
- Need to fill a pipeline gap
- Steady state output requirements

Summary of session results

Who are the trainers?

- The Catenion Academy use partners and senior consultants from their sister consulting company Catenion as trainers
- Each trainer has gained significant experience as a consultant in the pharmaceutical industry over several years on all aspects of R&D with particular focus on Portfolio Management and Project Evaluation

Who should attend?

- The course is aimed at Portfolio Managers in pharmaceutical R&D interested in deepening and expanding their knowledge of approaches to Portfolio Management
- No previous knowledge of the project evaluation methods is assumed
- The course is designed to give an overview as well as hands on experience with all relevant methods and tools and includes a pharmaceutical R&D project Case Study to be assessed by the participants
- It will be of particular benefit to professionals working in Portfolio Management departments responsible for Early Development projects

Tailored Training Solutions

- All of The Catenion Academy's training courses can be customised to meet the exact requirements and delivered by our experienced trainers on-site
- Save valuable time and expenditure
- Address your professionals' specific needs with a tailored training approach
- Find solutions to real problems by incorporating your own case studies as examples
- Increase communication and performance by training your team in a group

CATENION ACADEMY CERTIFICATION

Upon successful completion of the course and the Case Study, each participant will receive a Certificate issued by The Catenion Academy

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4 days programme

Three good reasons why Portfolio Managers should attend

- > Participants will be introduced to Catenion's Portfolio Management methods and tools for Early Clinical Development Projects
- > Portfolio Managers will gain hands on experience in the effective use of real-life processes, methods and tools for future use
- > Participants will learn how to balance the different perspectives of project teams, Decision Makers and Portfolio Management

Fees

€ 3,250 plus VAT/participant

Course fee includes

Print materials and CD containing

- Presentations and templates used
- Excel models for R&D Risk Assessment and Innovativeness Screening
- Case Study information

How to register

Please contact us via one of the following options below or fax the registration form



Catenion

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www.catenion-academy.com

Venue/reservations

Course will be held at the premises of The Catenion Academy.

Delegates are responsible for the arrangement and payment of their own travel and accommodation.

Registration form

Title..... Name

First Name

Position

Company

Department

Phone: Fax:

Mobile:.....

Email:

Address:.....

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