

THE CATENION ACADEMY

Decision Analysis for Early Clinical Development Project Teams

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

3 ½ days programme

COURSE OBJECTIVES

- > Take the Project Teams 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 Project Teams to understand and use Catenion's processes, methods and tools for Portfolio Management of Early Clinical Development 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 sub-groups 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
- At the end of the course, the team will present its findings to a Catenion Partner and be challenged on its results

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
- 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 Decision Analysis

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?

Discussion/presentation of Option Space Maps for Case Study project

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

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 new OR established project teams between five and nine strong and at project leaders in pharmaceutical R&D
- No previous knowledge of the project evaluation methods is assumed
- The course is designed to give an overview of the methods applicable and includes a pharmaceutical R&D project Case Study to which all relevant methods and tools are applied by the participants
- It will be of particular benefit to professionals working on R&D Projects in Early Clinical Development

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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Three good reasons why Project Teams should attend

- > Team members will learn how to balance the technical and scientific project reality with patients needs, competitive dynamics and project economics
- > Team members will gain hands on experience in the effective use of real-life processes, methods and tools for future use for project decision-making
- > Team members will learn how to derive viable options forward for a project, drawing on all pieces of information gathered using the different methods of analysis

Fees

€ 2,750 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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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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