

THE CATENION ACADEMY

Decision Analysis for Late-Stage Clinical Development Project Teams

An in-depth training in supporting Decision Analysis
for Late-stage 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 III 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 Late-stage Clinical Development Projects

COURSE AGENDA

DESIGN

- Prior to the course participants 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

PROGRAMME

Overview of Processes, Methods and Tools including

- Competitive Product Profile
- R&D Risk Assessment
- Decision Tree Analysis
- Competitiveness Modelling
- NPV Analysis
- Project Synthesis
- Case Study: SMOL Phase III project example Oncology

MATERIALS

Print materials and CD containing

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

DAY 1

MORNING SESSION: COMPETITIVE PRODUCT PROFILE

Overview of Processes, Methods and Tools in Decision Analysis

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

AFTERNOON 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

DAY 2

MORNING 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

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 3

MORNING SESSION: COMPETITIVENESS MODELLING

In-depth introduction to Competitiveness Modelling

Case Study

- Ranking project vs. competitors in terms of efficacy, safety & convenience
- Marketing Strength of developer behind the compound
- Importance of order of entry in the market
- Anticipated price relative to competition

Summary of session results

AFTERNOON SESSION: NPV ANALYSIS

In-depth introduction to NPV analysis

Case Study

- What are COGS, launch, marketing & sales costs and phase IV trial costs?
- What is the project value assuming technical success vs. including failure scenarios?

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
 - Probability of success to market
 - Risk mitigation planning
 - Estimated peak sales by scenario
 - Expected NPV

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 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 Late-stage 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

THE CATENION ACADEMY

Decision Analysis for Late-Stage Clinical Development Project Teams

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

3 ½ days programme

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, Competitiveness Modelling and NPV Analysis
- Case Study information

How to register

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



Catenion

Dr. Matthias Krings · Partner

Catenion

Hausvogteiplatz 12 · 10117 Berlin · Germany

phone: + 49 30 20 63 996-0

fax: + 49 30 20 63 996-22

registration@catenion-academy.com

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:.....

.....

.....