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# Clinical Research Project Management

Live Online Academy  
11-13 May 2021



# PTI

Implement project management methodology to your studies to achieve deadlines, meet budgets and satisfy medical and regulatory needs

## COURSE OVERVIEW

As a complex and intricate process, the successful establishment and performance of clinical trials is reliant on a variety of factors.

Throughout the course of 3 days, this training programme will provide delegates with a foundation of project management tools and techniques to maximise the efficiency and success of their projects.

Specifically, delegates will learn to cope with the increasingly challenging cost and time standards of the pharmaceutical industry with techniques for reducing set backs, integrating financial and organisations considerations and optimising patient / subject recruitment.

A close-up photograph of a hand holding a black pen, writing on a document. The pen is positioned diagonally, and the hand is visible on the left side. The document has some faint lines and text. The background is a solid blue color.

**PTI**

## Ian Stokes

Ian Stokes is a project management practitioner, certified facilitator and trainer who delivers process and learning solutions to the pharmaceutical industry. His recent clients include Pfizer, Sanofi Aventis, Nestlé, Danone and Celgene. He delivers courses on several Masters and MBA courses in France. As chairman of several project user communities in France he believes in a customer-centric approach to projects, with frequent feedback and open teamwork.

Ian was recently certified as one of eleven 'Associated Implementation Partner' companies by the Agile Business Consortium

**MEET  
THE  
TRAINER**

# SESSION ONE

## **Review the nature of a project and project management in clinical research**

- Obtain an overview of current and emerging ways to manage projects in clinical research
- Understand the role of project managers and the potential of teamwork in clinical research
- Manage projects under conditions of volatility, uncertainty, complexity and ambiguity

## **Energizing game and discussion**

Delegates will examine the crucial elements of Good Project Management Practices (GxPs)

# SESSION ONE

## **Interactive session: Identifying the challenges of project management for medical projects**

- Outline the framework and alternative approaches to project management for better results
- Transform your outlook to agile, patient-centric and business-focused project management
- Understand the project life cycle and process steps

## **Discussion**

Delegates will explore the differences and opportunities between project management and programme management; and portfolio management for predictive, iterative, incremental and agile projects

# SESSION ONE

## **Define the project's boundaries and purpose to meet your organisation's business goals**

- Improve your company's ability to analyse, evaluate and choose the right projects to continue
- Describe and position the project, the critical success factors, principle objectives and risks
- Set the project scope, time, cost and principle objectives
- Determine what defines successful outcomes and how quality is measured and managed

## **Case Study**

Defining a vision and a sense of purpose for the project (i.e. charter / terms of reference / business case)

# SESSION ONE

## **Perform an analysis of stakeholders, risks and benefits**

- Analyse the influence, support and impact on key stakeholders
- Analyse risks (opportunities and threats) and identify response strategies
- Prepare a communication plan in order to manage benefits and customer expectations
- Practical exercises

## **Case Study**

Organising patient recruitment

# SESSION ONE

## **Structure and organise a clinical research project and/or a clinical study**

- Develop the work breakdown structure and define work packages
- Allocate responsibilities using a responsibility matrix
- Develop estimating strategies to establish the overall cost and duration of work estimates

## **Case Study**

Develop the work breakdown structure and defining the work packages

# SESSION TWO

## **Develop a project plan to manage your clinical research projects**

- Develop a comprehensive project plan to manage clinical research projects
- Define key project activities, determine dependencies and establish critical path
- Define a schedule with prioritised milestones that have clear measurement criteria

## **Exercise**

Understanding critical path analysis methods

## **Case Study**

Build the project plan and develop subsidiary plans

# SESSION TWO

## **Set up a project baseline with cost, time and scope objectives and manage changes to the baseline**

- Following risk analysis, include risk strategies and risk contingency in the baseline
- Set up a format and process to formally manage change requests, problems and incidents
- Explore criteria for decision making on change implementation

## **Case Study**

Establish and review the baseline for the project, including the project budget

# SESSION TWO

## **Effectively manage a project towards successful results that maximise benefits**

- Manage and report on progress to meet targets using a project management dashboard
- Use frequent update formats and stage gate project reviews for go/no go decisions
- Facilitate creative workshops to develop and explore options

## **Case Study**

- Decide on appropriate responses to change requests, and manage project progress
- Rescuing and improving patient recruitment challenges

# SESSION THREE

**Develop principles and methods to manage clinical research organisations (CROs) and site management organisations (SMOs) to optimise project team work**

- Develop good practices for managing outsourced clinical trial projects
- Use milestones, methods, measures and reviews to enhance visibility and deliver results
- Establish and develop communication skills to improve project partnering
- Review strengths and weaknesses, opportunities and threats in patient/subject recruitment

## **Discussion**

Management of contractors on clinical research projects

# SESSION THREE

## **Case Study**

Delegates will discuss managing patient recruitment

## **Work on your management style to get the best results in a project team environment**

- Understand the principles and practices of motivation
- Recognise personal styles that contribute to effective teamwork
- Develop the attributes of teamwork that enable high performance
- Understand team management throughout the project life cycle
- Explore techniques to resolve conflicts and to handle pressures in a project team

## **Exercise**

Group work on team development and conflict management

# SESSION THREE

## **Focus on methods and skills that improve and speed up your clinical projects**

- Evaluate emerging industry initiatives for improving, accelerating, optimising and managing the project scope, cost and timeline
- Develop tactics to optimise personal time management and motivations
- Identify and respond to the differing motivations of individuals in the team
- Adopt appropriate communication and responses for managing differences

## **Exercise**

Completion of a self-evaluation questionnaire

# SESSION THREE

## **Close out the project, identify failures fast, and build on successes**

- Close the project taking account of contractual, regulatory and administrative
- Perform retrospectives in order to learn from accomplishments, events and errors
- Learn from project successes and failures, and build project management maturity

## **Exercise**

Review project closure from several different perspectives

The image shows a close-up of a hand holding a black pen, writing on a document. The document has some faint lines and text. In the top left corner, the letters 'PTI' are written in a large, bold, blue font. The background is a solid blue color with a faint, repeating pattern of the letters 'PTI' in a lighter shade.

# PTI

WHO IS  
THIS  
COURSE  
FOR?

This training course is aimed at clinical research professionals who are or will be involved in clinical research projects, including:

- Business Transformations
- Clinical Trials Projects
- Medical Equipment Needs
- Product Development
- R&D Projects

## For information contact our training consultants

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