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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 across the frame, with the tip pointing towards the bottom right. The hand is visible on the left side, with fingers gripping the pen. The document has some faint lines and text, but it is mostly out of focus. The background is a solid blue color.

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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

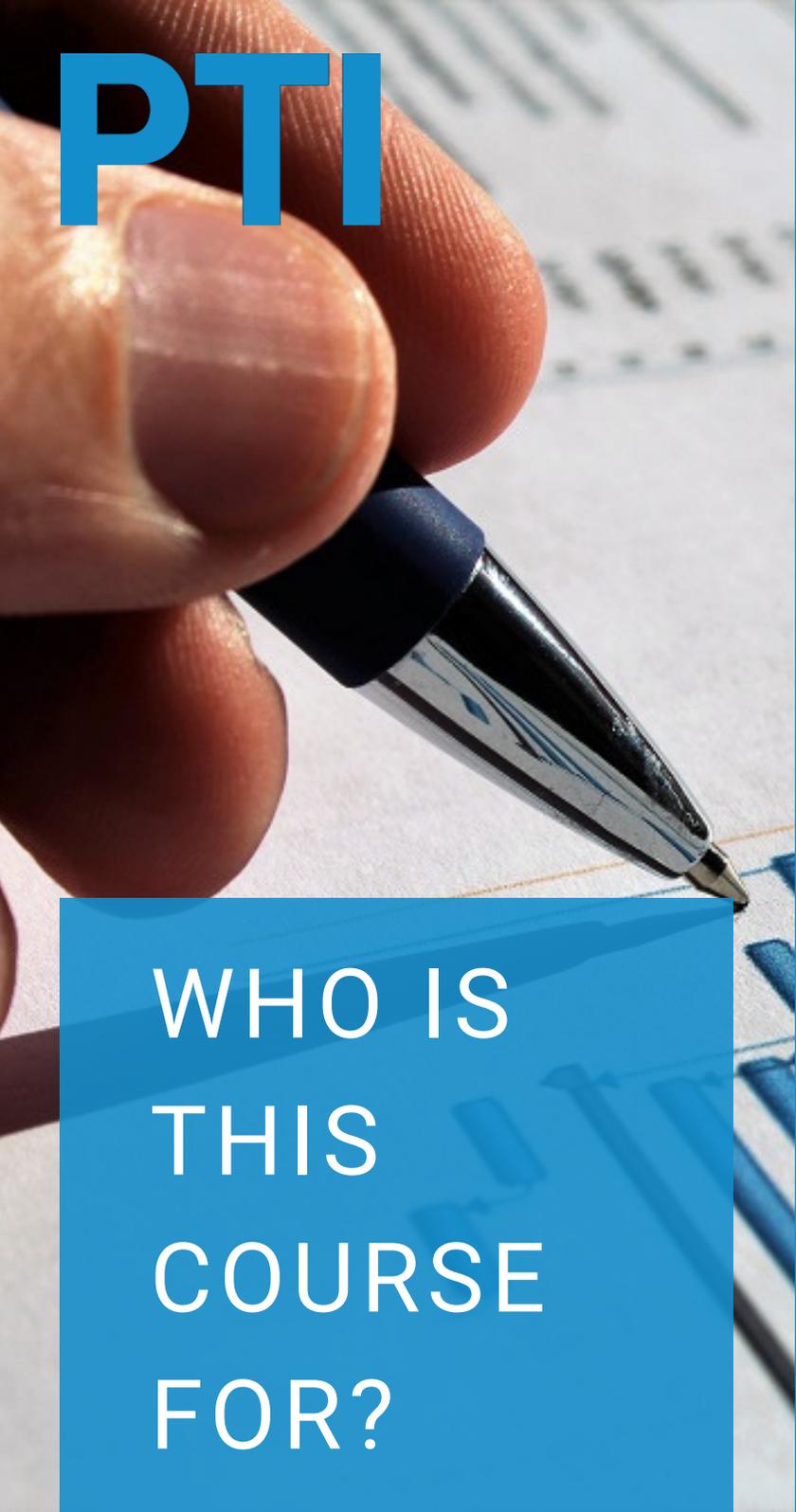
SESSION THREE

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. The PTI logo is overlaid in the top left corner. A blue semi-transparent box is in the bottom left, and a larger blue semi-transparent box covers the right side of the image.

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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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