DIA Learning

Clinical Project Management for Small and Medium Sized Pharma Companies

Virtual Live Training Course

23-26 May 2023 13:00-17:00 CEST

OVERVIEW

In the complex environment of today's clinical studies, with about 40% of studies failing to perform as expected, the need of skilled clinical project managers keeps increasing. We designed this course for junior clinical project managers in small- and medium-sized pharmaceutical and biotechnology companies to navigate them through the science of clinical project management (CPM), equip them with knowledge and tools to manage studies successfully, point out common misconceptions and pitfalls to avoid, and get them ready to fulfil their company goals in regulatory-compliant study execution.

Starting with general project management principles and terms, we apply them on clinical studies, focus on thorough project planning, share ways and tools for a strong project control, define how to close the project properly, and take lessons learned for future projects.

This 4-half-day course is practical and interactive with opportunities to get engaged in workshops, discussions, sharing of experience, and networking.

LEARNING OBJECTIVES

- Apply general project management and risk management principles in clinical studies.
- Choose the right clinical project management tools.
- Design quality outcomes during the planning phase and manage clinical studies creating a "no surprise" environment.
- Manage GCP vendors based on continuing risk assessment and monitoring.
- Prevent and/or resolve common challenges in clinical study conduct and deliver quality outcomes.

KEY TOPICS

- Project Management standards, guidelines, phases and gates
- Risk Management lifecycle and tools
- Project start-up, implementation, control and closing
- Regulatory environment, guidelines and regulations, GXP vendors, challenges in global studies
- Clinical Trial budgeting
- Quality by design and risk-based quality management in clinical trials
- GCP vendor management

WHO WILL ATTEND

This course is designed for junior clinical project managers in small and mid-sized pharma and biotech companies such as:

- Clinical Project Managers wishing to hone their knowledge and skills in clinical risk management and vendor management
- Clinical Project Managers with 0-2 years of experience
- Clinical Team Leads supporting clinical project management
- Persons planning to become Clinical Project Managers
- Study Start-up Managers
- Clinical Project Assistants
- Line managers of clinical personnel
- QA personnel wishing to have more insights in clinical project management to support quality deliverables

A sound knowledge of GCP is a must. A practical experience in conducting clinical studies is desirable.

INSTRUCTOR

Kamila Novak
Consultant
KAN Consulting MON. I.K.E.
Greece

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

13:00 WELCOME AND INTRODUCTION

13:10 SESSION 1

INTRODUCTION TO PROJECT MANAGEMENT

- Overview of project management standards and guidelines
- What is project success?
- Overview of project phases and gates
- What is included in project definition?

13:40 SESSION 2

WORKSHOP: HOW DO YOU / YOUR ORGANISATION DEFINE PROJECT SUCCESS?

14:00 BREAK

14:10 SESSION 3

RISK MANAGEMENT

- Risk management life cycle (primary response strategies, 3D assessment, prioritisation – risk priority number, risk categorisation, mitigation, optimised conditions, contingency plans)
- Risk management tools

15:40 BREAK

15:55 SESSION 4

MINI QUIZ ON RISK MANAGEMENT

16:00 SESSION 5

PROJECT START-UP

- Building the business case and its importance

16:30 BREAK

16:35 Q&A, DISCUSSION

16:55 DAY 1 WRAP-UP

17:00 END OF DAY ONE

DAY 2

13:00 SESSION 6

IMPLEMENTING THE PROJECT

- Planning: Initial vendor considerations, feasibility, project plan, critical path, prerequisites of budgeting
- Project launch: Essential documents, important study-specific plans, site qualification, approval of investigators, supply logistics, study submissions & approvals, site contracting, IP release, first site initiated

14:00 BREAK

14:10 SESSION 7

MINI QUIZ ON PROJECT IMPLEMENTING

14:15 SESSION 8

CONTROLLING THE PROJECT

- What to control (quality, time, cost, scope). How to control the project? Tools and techniques. Importance of milestones. What to request from your vendors? Study monitoring. Tips for effective project control (reports, meetings, issues, protocol deviations, CAPA lists). Study audits, quality oversight visits. Database lock. Challenging situations (e.g., recruitment, persistent non-compliance of a study site, vendor personnel turnover, EDC bugs, etc.)

15:15 BREAK

15:30 SESSION 9

MINI QUIZ ON CONTROLLING THE PROJECT

15:35 SESSION 10

CLOSING THE PROJECT

- When does it start? How do you define the end? Special scenarios (e.g., survival studies).
- End of Study notification, IP return vs local destruction, site close-out
- Deliverable acceptance, contract fulfilment
- CSR development
- Lessons learned and knowledge management in your organisation

16:30 BREAK

16:35 Q&A, DISCUSSION

16:55 DAY 2 WRAP-UP

17:00 END OF DAY TWO

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.50 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore eLearning to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

DAY 3

13:00 SESSION 11

SPECIFICS OF CLINICAL PROJECT MANAGEMENT

- Regulated environment, guidelines and regulations, specific objectives, specific stakeholders, GXP vendors, challenges in global studies

13:50 BREAK

14:00 SESSION 12

CLINICAL TRIAL BUDGETING

- Types of study budgets, when to use which, beware of pitfalls

14:30 SESSION 13

QUALITY BY DESIGN AND RISK-BASED QUALITY MANAGEMENT IN CLINICAL TRIALS

- What does QbD mean in clinical studies?
- GCP expectations regarding risks and steps for compliance
- RBQM vs RBM – is it the same thing? Who should be involved in RBQM? Why? How to start?
- What are QTLs and what are they good for?

15:00 BREAK

15:15 SESSION 14

MINI QUIZ ON QBD AND RBQM

15:20 SESSION 15

CLINICAL RISK MANAGEMENT

- Risk vs constraints
- Who should be in the clinical risk management core team?
- Sample clinical risk log – how to build it and work with it effectively
- The relationship of risks and issues
- Useful analyses

16:20 BREAK

16:30 SESSION 16

MINI QUIZ ON CLINICAL RISKS

16:35 Q&A, DISCUSSION

16:55 DAY 3 WRAP-UP

17:00 ENF OF DAY THREE

DAY 4

13:00 SESSION 17

BASICS OF GCP VENDOR MANAGEMENT

- Life Cycle, Process Flowchart, Types of GCP Vendors, Sponsor's GCP Responsibilities Related to Vendors, Process Steps and Documentation

13:50 BREAK

14:00 SESSION 18

GCP VENDOR PART 1

- Selection, qualification, risk assessment, contracting, onboarding

15:00 BREAK

15:15 SESSION 19

MINI QUIZ ON VENDOR QUALIFICATION

15:20 SESSION 20

GCP VENDOR PART 2

- Oversight, re-qualification, end of contract, lessons learned, inspection readiness

16:15 BREAK

16:25 SESSION 21

CPM CHALLENGES – 5 SCENARIOS

16:40 Q&A, DISCUSSION

16:55 DAY 4 WRAP-UP

17:00 END OF THE TRAINING COURSE

Group Discounts*

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

Group registration is not available online and does not apply to the already discounted fees for industry (early-bird), government or charitable nonprofit/academia.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

* Terms and Conditions apply, please contact basel@diaglobal.org for more information.

Technical Requirements

To test your system compatibility, please click on the link:

https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:

https://www.diaglobal.org/General/System-Requirements

REGISTRATION FORM

CPM for SMEs Virtual Live Training Course # 23531
23-26 May 2023 13:00-17:00 CEST

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 28 March 2023	MEMBER valid from 29 March 2023	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'115.00 ❑	€ 1'240.00 ❑	€ 1'475.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 620.00 ❑	€ 855.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #23531 as well as the invoice number to ensure correct allocation of your payment.
Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature