DIA Training Course on
Paediatric Investigation Plans (PIP)

Course #13503
15-16 April 2013
Mercure Hotel Amsterdam City, the Netherlands

Faculty
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(Course Director)
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Overview
Overview of the Paediatric Investigation Plan (PIP) procedure, including in-depth discussion of specific scientific/regulatory issues in relation to PIPs, case-studies and instructor-led group work on specific cases.

This course will provide a full introduction to PIPs and the EU Paediatric Regulation. The course faculty are European-based leading experts from EMA and industry. Topics will be presented through interactive lectures and hands-on workshop training.

Key Topics
- EU paediatric regulation
- PIP lifecycle
- How to get your PIP approved
- PIPs after approval

Who Will Attend
Professionals in regulatory affairs, clinical research, project management, toxicology, product development. Participants should preferably have a fair understanding of aspects of paediatric medicines development.

Level: Intermediate

Learning Objectives
At the conclusion of this course, participants should be able to:
- Describe the EU paediatric regulation
- Discuss the PIP approval procedure
- Identify the expectations and requirements from the Paediatric Committee (PDCO)
- Demonstrate how to prepare a PIP eligible for evaluation by PDCO
- Explain the modification of an agreed PIP procedure
- Describe the compliance check procedure
- Demonstrate an overview of procedures after initial PIP approval

Continuing Education
DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.
MONDAY | 15 APRIL 2013

08:00  REGISTRATION

09:00  Session 1

INTRODUCTION AND DEFINITIONS
• EU paediatric regulation
• PIPs, waivers, deferrals, PDCO
• Guidelines and EMA website
• EMA PIP experience

10:30  COFFEE BREAK

11:00  Session 2

THE PIP LIFECYCLE: PART 1
Introduction: Preparation, submission, amending PIP after Day 60, opinion
• How to build your PIP and/or waiver request
• Conditions/indications
• How to answer the PDCO Request for Modifications at Day 60
• Company Interactions with PDCO

12:30  LUNCH

14:00  Session 2 continued

THE PIP LIFECYCLE: PART 1
Group work
• How to ensure a global paediatric plan
• Definition of conditions/indications

14:45  Session 3

THE PIP OPINION
• Key binding elements
• Best practice for synopsis/outline

15:30  COFFEE BREAK

16:00  Session 4

THE PIP LIFECYCLE: PART 2
PIPs after approval:
• Modifications
• Changing the scope of the PIP (“Merging & splitting”)
• Validation and compliance check
• Annual deferral reports
• Rewards - Supplementary protection certificate (SPC) extension

Group work
How to minimise the number of modifications of your PIP

17:30  DRINKS RECEPTION
18:30  END OF DAY ONE

TUESDAY | 16 APRIL 2013

09:00  Session 5

SPECIAL ISSUES
• Paediatric pharmaceutical forms and formulations
• Non-clinical studies to support paediatric development
• Paediatric clinical studies - specific issues
  - PK/PD in children
  - Orphan drugs
  - Newborns/neonates

10:30  COFFEE BREAK

11:00  Session 6

WORKSHOP ON CASE STUDIES: PART 1

12:30  LUNCH

14:00  Session 7

WORKSHOP ON CASE STUDIES: PART 2

15:30  COFFEE BREAK

16:00  Session 8

COURSE SUMMARY

16:30  END OF TRAINING COURSE

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe. Speakers and agenda are subject to change without notice. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.
HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

Mercure Hotel Amsterdam City
Joan Muyskenweg 10
1096 CJ Amsterdam
Netherlands

Email: H1244@accor.com
Tel.: +31 20 72 19176
Fax: +31 20 69 48735
Website: http://www.mercure.com/gb/hotel-1244-mercure-hotel-amsterdam-aan-de-amstel/index.shtml

at the rate of:
139.00 EUR per single room per night inclusive of breakfast, exclusive of city tax.

To make your reservation, please use the booking form available on the DIA website.

Important: Please complete your reservation by 15 February 2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

DIA 2013 Training Courses in Regulatory Affairs

- Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe
  18-20 September 2013 | Basel, Switzerland | ID 13546

- European Regulatory Affairs: In-depth review of current registration procedures in the European Union
  6-7 June 2013 | Basel, Switzerland | ID 13550
  21-22 November 2013 | Paris, France | ID 13553

- Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices
  10-12 June 2013 | Amsterdam, the Netherlands | ID 13547

- Health Authority Interactions – Preparation, consultation and implementation
  15-16 October 2013 | Vienna, Austria | ID 13575

- Health Technology Assessment (HTA)
  26-27 November 2013 | Zurich, Switzerland | ID 13561

- Paediatric Investigation Plans (PIP)
  15-16 April 2013 | Amsterdam, the Netherlands | ID 13503

- The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)
  2-4 October 2013 | Basel, Switzerland | ID 13532

- US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US
  6-8 November 2013 | Paris, France | ID 13552

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.
FEES

Member* | Non-Member*
---|---
Industry | € 1'365.00 | € 1'480.00
Academia/Charitable/Government/Non-profit (Full-time) | € 683.00 | € 798.00
Join DIA now to qualify for the member rate | | € 115.00

*All fees will be subject to the Dutch VAT at 21%.

Please advise your European VAT number: ____________________________

TOTAL AMOUNT DUE: ____________________________

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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 # 13503 as well as the invoice number to ensure correct allocation of your payment.

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 Europe.

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

Date: ____________________________  Signature: ____________________________

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days 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
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe office of any such substitutions as soon as possible.

Photography Policy

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