DIA training course on

Paediatric Investigation Plans (PIP)

Course #16552
1-2 June 2016
Holiday Inn London Kensington Forum, London, UK

OVERVIEW

Overview of the Paediatric Investigation Plan (PIP) procedure and lifecycle, 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.

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: Beginner/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

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

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

FACULTY

Mette Due Theilade Thomsen
(Course Director)
Senior director, RA
Shionogi, UK

Janina Karres
Paediatric Coordinator, Human Medicines
Special Areas/Paediatric Medicines
European Medicines Agency, EU

This course has limited capacity. Register early.

DIA DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

DAY 1

08:30 REGISTRATION

09:00 SESSION 1

INTRODUCTION AND DEFINITIONS
- EU paediatric regulation
  Janina Karres
- PIPs, waivers, deferrals, PDCO
  Janina Karres
- Guidelines and EMA website
  Janina Karres

11:00 COFFEE BREAK

11:30 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
  Janina Karres
- Conditions / indications
  Janina Karres
- How to answer the PDCO Request for Modifications at Day 60
  Mette Due Theilade Thomsen
- Company Interactions with PDCO
  Mette Due Theilade Thomsen
- Global Paediatric Plan
  Mette Due Theilade Thomsen

13:00 LUNCH

14:00 SESSION 2 CONTINUED

THE PIP LIFECYCLE: PART 1
Group work
- How to ensure a global paediatric plan
  Mette Due Theilade Thomsen
- Definition of conditions/indications
  Janina Karres

15:00 SESSION 3

THE PIP OPINION
- Key binding elements
  Janina Karres
- Best practice for synopsis/outline
  Mette Due Theilade Thomsen

15:45 COFFEE BREAK

16:15 SESSION 4

THE PIP LIFECYCLE: PART 2
PIPs after approval:
- Modifications
  Mette Due Theilade Thomsen
- Changing the scope of the PIP ("Merging & splitting")
  Janina Karres
- MAA Validation and compliance check
  Mette Due Theilade Thomsen

17:30 DRINKS RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 SESSION 4 (CONTINUED)

THE PIP LIFECYCLE: PART 2
- Annual deferral reports
  Janina Karres
- Rewards – Supplementary protection certificate (SPC) extension
  Janina Karres

08:55 GROUP WORK

HOW TO MINIMISE THE NUMBER OF MODIFICATIONS OF YOUR PIP
Mette Due Theilade Thomsen

09:40 SESSION 5

SPECIAL ISSUES
- Paediatric pharmaceutical forms and formulations
  Mette Due Theilade Thomsen

10:00 COFFEE BREAK

10:30 SESSION 5 (CONTINUED)

SPECIAL ISSUES
- Non-clinical studies to support paediatric development
  Mette Due Theilade Thomsen
- Paediatric clinical studies – Challenges and solutions
  Janina Karres

11:30 SESSION 6

WORKSHOP ON CASE STUDIES: PART 1
Mette Due Theilade Thomsen

13:00 LUNCH

14:00 SESSION 7

WORKSHOP ON CASE STUDIES: PART 2
Mette Due Theilade Thomsen

15:30 COFFEE BREAK

16:00 SESSION 8

COURSE SUMMARY
Mette Due Theilade Thomsen and Janina Karres

16:30 END OF THE TRAINING COURSE

Training Course Venue

Holiday Inn London Kensington Forum
97 Cromwell Road | London, SW7 4DN | Tel: +44 871 942 9094 | www.
hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 31 May to 2 June 2016 at the rate of GBP 160.00 per single room per night including Full English Breakfast, taxes and service fee.

In order to book a hotel room, please call the hotel directly and quote the booking reference "XRX".

The room rate is available until 27 April 2016 or until the room block is sold-out, whichever comes first. Cancellations received after 19 April 2016 will be subject to cancellation fee of 100% of the booking value.

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.

SwAPP
Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients — join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

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REGISTRATION FORM

DIA Training Course on Paediatric Investigation Plans (PIP) | ID#16552

1-2 June 2016 | Holiday Inn London Kensington Forum, UK

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FEES

Registration fee includes refreshments breaks, lunches and course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary membership

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

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52

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

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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 Fax Number

email (Required for confirmation)

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 # 16552 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, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here**.

Date	Signature