DIA Training Course on

Paediatric Investigation Plans (PIP)

Course # 13574
28-29 November 2013
Mercure Paris La Villette, France

Faculty

Mette Due Theilade
(Course Director)
Principal Scientist
Novo Nordisk A/S, Denmark
Former Paediatric Coordinator, European Medicines Agency, EU

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Scientific Administrator, Paediatric Medicines Product Development Scientific Support Department, European Medicines Agency, EU

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.

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

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

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

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THURSDAY | 28 NOVEMBER 2013

08:00 REGISTRATION

09:00 Session 1

INTRODUCTION AND DEFINITIONS

- EU paediatric regulation
- PIPs, waivers, deferrals, PDCO
- Guidelines and EMA website

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 Modification at Day 60
- Company Interactions with PDCO
- Global Paediatric Plan

12:30 LUNCH

13:30 Session 2 continued

THE PIP LIFECYCLE: PART 1

Group work
- How to ensure a global paediatric plan
- Definition of conditions/indications

14:15 Session 3

THE PIP OPINION

- Key binding elements
- Best practice for synopsis/outline

15:00 COFFEE BREAK

15:30 Session 4

THE PIP LIFECYCLE: PART 2

PIPs after approval:
- Modifications
- Changing the scope of the PIP ("Merging & splitting")
- MAA Validation and compliance check
- Article 46
- Annual deferral reports
- Rewards - Supplementary protection certificate (SPC) extension

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

FRIDAY | 29 NOVEMBER 2013

08:30 Session 4 (continued)

THE PIP LIFECYCLE: PART 2

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

09:30 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

10:00 COFFEE BREAK

10:30 Session 5 (continued)

SPECIAL ISSUES

11:30 Session 6

WORKSHOP ON CASE STUDIES: PART 1

13:00 LUNCH

14:00 Session 7

WORKSHOP ON CASE STUDIES: PART 2

15:30 COFFEE BREAK

16:00 Session 8

COURSE SUMMARY

16:30 COURSE ASSESSMENT

17:00 END OF TRAINING COURSE

HOTEL INFORMATION

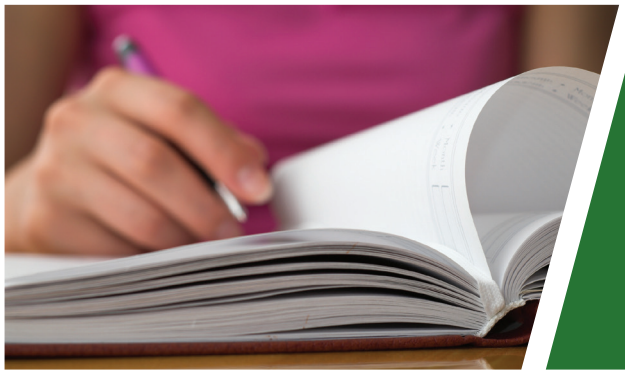
The DIA has blocked a limited number of rooms at the following hotel:
Mercure Paris La Villette
216 Avenue Jean Jaures
75019 Paris, France
Tel. : +33 (0)1 44841818 - Fax : +33 (0)1 44841820

Email: mercureparisv@alliance-hospitality.com
Website: http://www.mercure.com/de/hotel-8816-mercure-paris-la-villette/index.shtml

at the rate of:
140.00 EUR per single room per night inclusive of breakfast.

To make your reservation, please use the booking form available on the DIA website and mail it directly to mercureparisv@alliance-hospitality.com

Important: Please complete your reservation by 8 October 2013. Reservations received after this date will be subject to hotel availability and room rate may vary.



DIA EUROPE TRAINING PROGRAMME 2013-2014

Chemistry, Manufacturing and Controls (CMC) / Quality

- **Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
  1-3 December 2013 | Dubai, United Arab Emirates | ID 13562
- **Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators**
  11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research

- **Advanced GCP Study Monitoring**
  Next recurrence of this course to be announced
- **Clinical Project Management – Part I**
  18-20 September 2013 | Basel, Switzerland | ID 13572
- **Clinical Project Management – Part II**
  25-27 November 2013 | Zurich, Switzerland | ID 13501
- **Clinical Statistics for Non-Statisticians**
  24-25 October 2013 | London, United Kingdom | ID 13551
- **Essentials of Clinical Study Management**
  27-29 November 2013 | Paris, France | ID 13554
- **Practical GCP Compliance Auditing of Trials and Systems**
  23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
  February 2014 | Lisbon, Portugal

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**
  28-29 November 2013 | Paris, France | ID 13553
- **Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices**
  Next recurrence of this course to be announced
- **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)**
  28-29 November 2013 | Paris, France | ID 13574
- **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

Safety and Pharmacovigilance

- **Benefit/Risk Management**
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  19-20 September 2013 | Paris, France | ID 13563
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  7–8 November 2013 | Paris, France | ID 13556
- **ICH Endorsed Pharmacovigilance**
  22-23 September 2013 | Muscat, Sultanate of Oman | ID 13568
  28-29 November 2013 | Zagreb, Croatia | ID 13569
- **Pre-Marketing Clinical Safety**
  Next recurrence of this course to be announced
- **Signal Management in Pharmacovigilance**
  6–7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

- **EudraVigilance Information Day**
  22 October 2013 | London, United Kingdom | ID 13530
- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  18-22 November 2013 | London, United Kingdom | ID 13522
- **IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day**
  10 December 2013 | London, United Kingdom | ID 13531
- **EudraVigilance courses:**
  - EudraVigilance – Electronic reporting of ICSRs in the EEA
  - eXtended EudraVigilance Medicinal Product Dictionary
  - Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

DIA Europe Tailored Training

DIA Europe Tailored Training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. Schedule your training course when it suits you best, at the venue of your choice. You can even adapt the content to include areas specific to your environment, and to match the level of expertise of the audience.

DIA Tailored Training is available to both public and private institutions and is delivered by instructors with no conflict of interest.

The DIA Tailored Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

Contact DIA Europe to discuss your organisation's requirements.

For more information and a complete listing of all DIA conferences and training courses, please visit:
www.diahome.org > click on Meetings & Training
Call DIA Europe on +41 61 225 51 51 or email: diaeurope@diaeurope.org

DIA® www.diahome.org

REGISTRATION FORM

DIA Training Course on Paediatric Investigation Plans (PIP)
28-29 November 2013 | Mercure Paris La Villette, France

www.diahome.org
ID #13574

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 French VAT at 19.6 %

Please advise your European VAT number: _____

TOTAL AMOUNT DUE: _____

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

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

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

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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 # 13574 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

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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland