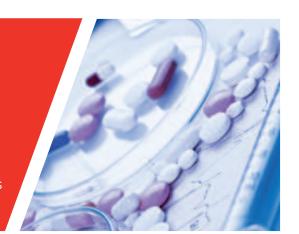
Training Course on Paediatric Investigation Plans (PIP)

Course #12580 23-24 April 2012 Hotel NH Amsterdam City Centre, Amsterdam, The Netherlands



Faculty

Mette Due Theilade (Course Director)
Principal Scientist
Novo Nordisk A/S, Denmark

Sophie Olivier Paediatric Coordinator, Human Unit EMA, EU

Continuing Education

DIA meetings and trainings 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 and certificates are available

This course has limited capacity. Register early.

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



MONDAY | 23 APRIL 2012

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
- How to answer the PDCO Request for Modifications at Day 60
- Company Interactions with PDCO
- Aspects on global paediatric plans

12:30 LUNCH

14:00 Session 3

THE PIP LIFECYCLE: PART 1 (continued)

Group work

- 1) Why and when is a PIP needed?
- 2) How do you ensure a global paediatric plan?
- 3) The perfect PIP synopsis

14:45 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 | 24 APRIL 2012

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

HOTEL INFORMATION

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

Hotel NH Amsterdam City Center

Spuistraat, 288-292

1012VX Amsterdam

The Netherlands

Email: nhcitycentre@nh-hotels.com

Tel: + 31 20 420 4545 - Fax: +3120 420 4300

at the special rate of:

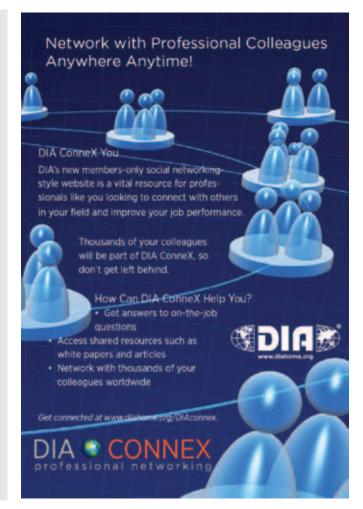
EUR 134.00 per room, exclusive of breakfast at EUR 20.00 and taxes.

To make your reservation please use the following link:

http://www.nh-hotels.com/events/en/event-detail/11082/drug_information_association_europe.html

Important: Please complete your reservation by Sunday 26 February 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

In case of cancellation: In case of no show or late cancellation the costs will be charged to credit card of the guest. Guests who have reserved a room may cancel it without any charges up to 24h prior to arrival. In case the reservation is cancelled later, the hotel has the right to charge guests for the total cost of the first night as compensation (taxes included).



Upcoming DIA Training Courses

Building the eCTD - Practical solutions to compile electronic submissions

8-9 March 2012 | Barcelona, Spain | ID 12564 October 2012 | Berlin, Germany | ID 12577

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3

25-27 April 2012 | Prague, Czech Republic | ID 12557

Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe

May 2012 | Basel, Switzerland | ID 12559

Comprehensive Training on European Regulatory Affairs: Keeping your finger on the pulse of Marketing Authorisation

May 2012 | Location to be confirmed | ID 12563

European Regulatory Affairs: In-depth review of current registration procedures in the European Union

16-17 February 2012 | Vienna, Austria | ID 12553 14-15 June 2012 | Berlin, Germany | ID 12583 15-16 November 2012 | Paris, France | ID 12569

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics:

Legal and practical aspects as used in personalised medicine

November 2012 | Location to be confirmed | ID 12576

Health Technology Assessment (HTA)

November 2012 | Location to be confirmed

REGISTRATION FORM

Training Course on Paediatric Investigation Plans (PIP) 23-24 April 2012 | Hotel NH Amsterdam City Centre, Amsterdam, The Netherlands



If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fees are inclusive of lunch and coffee breaks and other catering services to the amount of € 125.00.

CATEGORY	Member Fee		Non-Member Fee
Industry	€ 1'365.00 🗖	Industry	€ 1'480.00 □
Academia/Government /Non-profit (Full-Time)	€ 683.00 □	Academia/Government /Non-profit (Full-Time)	€ 798.00 □
Join DIA now to qualify for the member rate		Fee	€ 115.00 🗆
TOTAL AMOUNT DUE: € NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT			
			12580DIA
RESPONSIBILITY/INTEREST AREA Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.			
CMC Clinical Data Management/ eClinical Clinical Research & Development Clinical Safety/Pharmacovigilance Document Management/ eSubmissions Medical Communications	Medical WritingNon-clinicalOutsourcingComparative Effectiveness ment/ Evidence-based MedicinePricing/ReimbursementProject Management	— Professional Education & Training — Public Policy/Law — Quality Assurance/Quality Contro s/Health Technology Assess- — Regulatory Affairs — Statistics — IT/Validation	I
ATTENDEE DETAILS		PAYMENT METHODS - Credit cards are the preferred payment	ent method.
PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGIST	RATION EVEN		
SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE		☐ Please charge my credit card - Credit card payments by VISA, Mastercard	
□ Prof □ Dr □ Ms □ Mr		by completing the relevant details below. Please note that other types of accepted.	of credit card cannot be
Last Name		UVISA UMC AMEX	
First Name		Card Number	
Company		Expiry Date	
Job Title		Cardholder's Name	
Street Address / P.O. Box		Date Cardholder's Signature	
Postal Code City		☐ Cheques should be made payable to DIA and mailed together with a copy for identification to: DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, S	=
Country Telephone		☐ Bank transfers: When DIA completes your registration, an email will be se	nt to the address on the
Fax Email (Required for confirmation)		registration form with instructions on how to complete the bank transfer. Pa be addressed to "Account Holder: DIA." Please include your name, comp well as the invoice number to ensure correct allocation of your payment.	ayments in EURO should
Please enter your company's European VAT number: Payments must be net of all charges and bank charges must be borne by the payer.			
Please indicate your professional category: 🔲 Academia 🔲 Gov	ernment tract Service Organisation		

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Academia/Government/Non-profit (Member/Non-member) = € 100.00

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 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.

IMPORTANT:

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

www.diahome.org

Fax +41 61 225 51 52

Email diaeurope@diaeurope.org

Mail

DIA Europe Postfach, 4002 Basel, Switzerland