

Training Course on Paediatric Investigation Plans (PIP)

Course #12580

23-24 April 2012

Hotel NH Amsterdam City Centre, Amsterdam, The Netherlands



Faculty

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Principal Scientist

Novo Nordisk A/S, Denmark

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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).



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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

ID # 12580



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 <input type="checkbox"/>	Industry € 1'480.00 <input type="checkbox"/>
Academia/Government /Non-profit (Full-Time)	€ 683.00 <input type="checkbox"/>	Academia/Government /Non-profit (Full-Time) € 798.00 <input type="checkbox"/>

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.

<input type="checkbox"/> CMC	<input type="checkbox"/> Medical Writing	<input type="checkbox"/> Professional Education & Training
<input type="checkbox"/> Clinical Data Management/ eClinical	<input type="checkbox"/> Non-clinical	<input type="checkbox"/> Public Policy/Law
<input type="checkbox"/> Clinical Research & Development	<input type="checkbox"/> Outsourcing	<input type="checkbox"/> Quality Assurance/Quality Control
<input type="checkbox"/> Clinical Safety/Pharmacovigilance	<input type="checkbox"/> Comparative Effectiveness/Health Technology Assess- ment/	<input type="checkbox"/> Regulatory Affairs
<input type="checkbox"/> Document Management/ eSubmissions	<input type="checkbox"/> Evidence-based Medicine	<input type="checkbox"/> Statistics
<input type="checkbox"/> Medical Communications	<input type="checkbox"/> Pricing/Reimbursement	<input type="checkbox"/> IT/Validation
	<input type="checkbox"/> Project Management	

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

☐ Prof ☐ Dr ☐ Ms ☐ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code

City

Country

Telephone

Fax

Email (Required for confirmation)

Please enter your company's European VAT number: _____

Please indicate your professional category: ☐ Academia ☐ Government
☐ Industry ☐ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

☐ Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

☐ VISA ☐ MC ☐ AMEX

Card Number

Expiry Date

Cardholder's Name

Date

Cardholder's Signature

☐ Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, Switzerland

☐ 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, event ID# 12580 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.

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

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