

Paediatric Investigation Plans

10-11 April 2018

Hilton Canary Wharf, London, United Kingdom



OVERVIEW

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.

LEARNING OBJECTIVES

At the conclusion of this course, participants will 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

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

FACULTY

Mette Due Theilade Thomsen

Managing Director
PIP Adviser, Denmark

Andrea Ecker

Scientific Officer, Paediatric Medicines Office
European Medicines Agency, European Union

DAY 1

08:00 REGISTRATION

08:30 SESSION 1

INTRODUCTION AND DEFINITIONS

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

10:00 COFFEE BREAK

10:30 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
- 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

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 GROUP WORK

HOW TO MINIMISE THE NUMBER OF MODIFICATIONS OF YOUR PIP

09:15 SESSION 4 CONTINUED

THE PIP LIFECYCLE: PART 2

- Annual deferral reports
- Rewards – Supplementary protection certificate (SPC) extension

09:45 SESSION 5

SPECIAL ISSUES

- Paediatric pharmaceutical forms and formulations

10:00 COFFEE BREAK

10:30 SESSION 5 CONTINUED

SPECIAL ISSUES

- Non-clinical studies to support paediatric development
- Paediatric clinical studies – challenges and opportunities

12:00 LUNCH

13:00 SESSION 6

WORKSHOP ON CASE STUDIES

15:30 COFFEE BREAK

16:00 SESSION 7

COURSE SUMMARY

16:30 END OF THE TRAINING COURSE

| Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

Training Course Venue

HILTON LONDON CANARY WHARF

South Quay, Marsh Wall

London, E14 9SH

Tel: +44 203 002 2300

Fax: +44 203 002 2350

Email: LONCW_Hotel@hilton.com

From London City Airport, take the Docklands Light Railway to Poplar station. Change at Poplar for a DLR train to South Quay station. The Hilton London Canary Wharf hotel is next to the station.

From the London Underground Canary Wharf Tube station, take the Jubilee Place main exit. Once out of the station turn left and proceed to the pedestrian traffic crossing. Cross the road and walk straight ahead towards the glass building, go through the glass building continuing to walk straight. Once out of the glass building walk up the little steps to cross over the footbridge, at the end of the footbridge turn left and walk straight and then turn right after first parking bays into Admirals Way. The hotel is situated towards the bottom of the road on your left hand side.



Accommodation

FRASER PLACE CANARY WHARF

80 Boardwalk Place

London, E14 5SF

Tel: +44 20 7068 7000

Fax: +44 20 7068 7020

Email: canarywharf@frasershospitality.com

For detailed rates please view the booking information file on DIA website.

To book an apartment please contact reservations department at Frasers Hospitality directly with a reference "DIA":

Tel: +44 20 7341 55 99

Fax: +44 20 7341 55 88

Email: sales.london@frasershospitality.com

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 12.50 credits.

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.

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REGISTRATION FORM

Paediatric Investigation Plans # 18552

10-11 April 2018 | Hilton Canary Wharf | London, United Kingdom



REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>

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

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

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

The DIA 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: Basel@diaglobal.org **Mail:** DIA, Kuchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

TERMS AND CONDITIONS

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA 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 AND VIDEO 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

Attendee email required for course material access

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 #18552 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.**

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

Date

Signature