

Paediatric Investigation Plans

Face-to-Face Training Course

11-12 October 2022
Amsterdam, The Netherlands*



OVERVIEW

This training course will provide a full introduction to Paediatric Investigation Plans (PIPs) and the EU Paediatric Regulation. The course faculty are European-based leading experts from European Medicines Agency and industry.

Topics will be presented through interactive lectures and hands-on workshop training.

LEARNING OBJECTIVES

- 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
- Prepare a global plan in compliance with EU, US and UK requirements
- Understand expectations for Covid19 PIPs

KEY TOPICS

- Definitions, Regulation, Guidelines
- PIP Lifecycle: Preparation, submission, modifications
- Global Paediatric Plan
- PIP Opinion
- Special issues: Pharmaceutical forms and formulations, non-clinical studies, clinical studies

WHO WILL ATTEND

This training course is designed for professionals in regulatory affairs, clinical research, project management, toxicology, and product development.

Participants should preferably have a fair understanding of aspects of paediatric medicines development.

Level: Intermediate

FACULTY

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CEO
PIP Adviser
Denmark

Janina Karres
Scientific Officer
European Medicines Agency
The Netherlands

* In case the epidemiological situation does not allow a face-to-face course, this offering will take place in a virtual setting.

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 I

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

12:00 LUNCH BREAK

13:00 SESSION 2 CONTINUED

THE PIP LIFECYCLE: PART I

- Company interactions with PDCO
- Global Paediatric Plan
- Group work
 - How to ensure a global paediatric plan
 - Definition of conditions/indications

14:30 SESSION 3

THE PIP OPINION

- Key binding elements
- Best practice for synopsis/outline

15:30 COFFEE BREAK

16:00 SESSION 4

THE PIP LIFECYCLE: PART II

PIPs after approval

- Modifications
- Changing the scope of the PIP ("Merging & splitting")

17:30 END OF DAY 1

DAY 2

08:30 SESSION 4 CONTINUED

THE PIP LIFECYCLE: PART II

- MAA Validation and compliance check
- Group work
 - How to minimise the number of modifications of the PIP
- Annual deferral reports
- Rewards – Supplementary protection certificate (SPC) extension

10:15 COFFEE BREAK

10:45 SESSION 5

SPECIAL ISSUES

- Paediatric pharmaceutical forms and formulations
- Non-clinical studies to support paediatric development
- Paediatric clinical studies

12:15 LUNCH BREAK

13:15 SESSION 6

CASE STUDIES

PIPs after approval

15:30 COFFEE BREAK

16:00 QUESTIONS AND ANSWERS

16:30 END OF THE TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

| Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary 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 does not apply to the already discounted fees for government or charitable nonprofit/academia.

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 via email to basel@diaglobal.org.

| Course Venue

Holiday Inn Amsterdam - Arena Towers

Hoogoorddreef 66a

1101 BE Amsterdam

Netherlands

Tel: +31 20 7979 198

Email: info.amsaa@hiex.nl

Web: <https://www.ihg.com/holidayinn/hotels/us/en/amsterdam/amsaa/hoteldetail>

How to get there

On of the largest train stations of Amsterdam; Amsterdam Bijlmer ArenA is located on 5 minute walk of the hotel. When leaving the train station walk along the Heineken Music Hall in south-east direction and you will almost already see the hotel in front of you.

Estimated distance to the hotel: 0.25 MI/ 0.4 KM

Bedroom booking

DIA has booked a limited number of hotel rooms at the rate of EUR 169.00 per standard single occupancy room per night including breakfast and VAT, but excluding local city tax at 7% per room per night and EUR 3.00 per person per night.

If you would like to make a booking, please do so here:

Bedroom booking

The room rate is available until 9 September 2022 or until the room block is sold-out, whichever comes first.

| Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore **eLearning** to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

| Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8 credits.



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REGISTRATION FORM Face-to-Face Training Course

Paediatric Investigation Plans # 22552
11-12 October 2022, Amsterdam, The Netherlands*

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REGISTRATION FEES

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

FEES	MEMBER EARLY-BIRD valid until 16 Aug 2022	MEMBER valid from 17 Aug 2022	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'305.00 <input type="checkbox"/>	€ 1'450.00 <input type="checkbox"/>	€ 1'635.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 725.00 <input type="checkbox"/>	€ 910.00 <input type="checkbox"/>

A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

All registration fees are subject to Dutch VAT if applicable.

Please enter your company's VAT number: _____

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 nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at [DIAglobal.org/Membership](https://www.diaglobal.org/Membership).

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at [DIAglobal.org](https://www.diaglobal.org). If you would like to decline complimentary membership, please indicate your preference below.

I would like to decline a one year complimentary DIA membership.

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: Basel@DIAglobal.org **Mail:** DIA, Küchengasse 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.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click <https://www.diaglobal.org/general/photography-policy>.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click <https://www.diaglobal.org/about-us/privacy-policy>.

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

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 #22552 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.**

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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