DIA LEARNING

Paediatric Investigation Plans

Virtual Live Training Course
17-20 November 2025 | 13:00-17:00 CET

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

At the conclusion of this training 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
- Prepare a global plan in compliance with EU, US and UK requirements

Key Topics

- The Paediatric Regulation, Definitions, 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

Mette Due Theilade Thomsen
CEO
PIP Adviser, Denmark

Roberto de Lisa
Scientific Officer, Paediatric Medicines Office
European Medicines Agency, Netherlands

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

INTRODUCTION AND DEFINITIONS

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

15:00 BREAK

15:30 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

17:00 END OF DAY 1

DAY 2

13:00 QUESTIONS AND ANSWERS

13:30 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

15:00 BREAK

15:30 SESSION 3

THE PIP OPINION

- Key binding elements
- Best practice for synopsis/outline

16:30 QUESTIONS AND ANSWERS

17:00 END OF DAY 2

DAY 3

13:00 SESSION 4

THE PIP LIFECYCLE: PART II

PIPs after approval

- Modifications
- MAA Validation and compliance check

14:30 BREAK

15:00 SESSION 4 CONTINUED

THE PIP LIFECYCLE: PART II

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

16:30 SESSION 5

SPECIAL ISSUES

- Paediatric pharmaceutical forms and formulations

17:00 END OF DAY 3

DAY 4

13:00 SESSION 5 CONTINUED

SPECIAL ISSUES

- Non-clinical studies to support paediatric development
- Paediatric clinical studies, extrapolation and other analyses

14:30 BREAK

15:00 SESSION 6

CASE STUDIES

16:45 QUESTIONS AND ANSWERS

17:00 END OF THE TRAINING COURSE

Group Discounts

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

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.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

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

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 10.5 credits.

REGISTRATION FORM

Paediatric Investigation Plans | #25552
17-20 November 2025 | 13:00-17:00 CET

DIA LEARNING

REGISTRATION FEES

Registration fee includes admission to training course, 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 material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 22 Sep 2025	MEMBER valid from 23 Sep 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats is limited.			

All registration fees are subject to 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.

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. 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 METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org**.**

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature