EMA Paediatric Investigation Plans
In-Person Training Course
5-6 November 2026
EMA | Amsterdam, The Netherlands

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview

This specialised hands-on course provides a full overview on the EU Paediatric Regulation and Paediatric Investigation Plans (PIPs). Designed and delivered by experts from the European Medicines Agency and industry, this programme offers an exceptional opportunity to learn directly from regulators and experienced professionals.
Through interactive lectures, real-world case discussions, and practical workshop sessions, you'll build the knowledge and confidence needed to navigate paediatric regulatory requirements effectively to prepare a comprehensive submission. Whether you're new to paediatric drug development or looking to deepen your expertise, this course provides the essential foundation for success.

Key Topics

- The Paediatric Regulation, Definitions, Guidelines
- PIP Lifecycle: Preparation, submission, modifications
- Global Paediatric Plan
- PIP Opinion
- Scientific content: Pharmaceutical forms and formulations, non-clinical studies, clinical studies, modelling and simulation, extrapolation

Target Audience

This training course is designed for professionals in regulatory affairs, clinical research, project management, planning to be involved in paediatric development.
The course is open to participants working in industry, medicines regulatory authorities, academia and clinical trial researchers.
Level: Intermediate.

Learning Objectives

By the end of this training course, participants will be able to:

- Explain the EU Paediatric Regulation and its role in guiding paediatric medicine development.
- Describe the full PIP approval pathway, from initial submission to final agreement.
- Understand the expectations of the Paediatric Committee (PDCO) and the key elements they assess in a PIP.
- Prepare a high-quality PIP that meets PDCO requirements and is ready for formal evaluation.
- Explain how to request and manage modifications to an agreed PIP.
- Navigate the compliance check process.
- Summarise the procedures that follow initial PIP approval.
- Develop a global paediatric development plan aligned with regulatory requirements across the EU, US, and UK.

Faculty

Mette Due Theilade Thomsen
CEO
PIP Adviser ApS, Denmark

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

DIA

AGENDA

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION

09:00 SESSION 1

INTRODUCTION AND DEFINITIONS

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

10:30 COFFEE BREAK

11:00 SESSION 2

THE PIP LIFECYCLE: PART I

Preparation, submission, responses to PDCO

- Conditions/indications
- How to build your PIP and/or waiver request
- How to answer the PDCO request for supplementary information at Day 60

12:30 LUNCH BREAK

13:30 SESSION 2 CONTINUED

THE PIP LIFECYCLE: PART I

- Interactions with PDCO
- Global Paediatric Plan

14:30 COFFEE BREAK

15:00 SESSION 3

GROUP WORK

- How to ensure a global paediatric plan
- Definition of conditions/indications

16:00 SESSION 4

THE PIP OPINION

- Key binding elements
- Best practice for synopsis/outline

17:00 WELCOME RECEPTION

18:00 END OF DAY 1

DAY 2

08:30 SESSION 5

SCIENTIFIC CONTENT

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

10:00 COFFEE BREAK

10:30 SESSION 6

THE PIP LIFECYCLE: PART II

PIPs after approval

- Modifications
- MAA Validation and compliance check

GROUP WORK

- Minimising the number of modifications of the PIP

12:30 LUNCH BREAK

13:30 SESSION 7

PIPS AFTER APPROVAL

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

SPECIAL ISSUES

- ·The evolving EU regulatory landscape and paediatric requirements

15:00 COFFEE BREAK

15:15 SESSION 8

CASE STUDIES

16:15 QUESTIONS AND ANSWERS

16:30 END OF THE TRAINING COURSE