

20 January 2025
EMA/PDCO/488895/2024
Human Medicines Division

Paediatric Committee (PDCO): Work Plan 2025

Adopted by the Committee on 13 December 2024

Table of Content

1. Evaluation activities for human medicines	2
1.1. Pre-authorisation activities	2
1.1.1. Development of therapeutic areas strategies.....	2
1.1.2. Real world evidence	2
1.1.3. Stepwise PIP.....	3
1.1.4. Summary report and key elements form.....	3
1.1.5. Implementation of the ICH E11A Guideline on paediatric extrapolation.....	3
1.1.6. Utilisation of Artificial Intelligence in paediatric development.....	4
1.1.7. PIPs based on mechanism of action	4
2. Horizontal activities and other areas	5
2.1. Committees and Working parties.....	5
2.1.1. Collaboration with CTCG	5
2.1.2. Collaboration with HMPC.....	5
2.1.3. PDCO involvement in PIP-related CHMP procedures	5
2.2. Partners and stakeholders	6
2.2.1. Collaboration with stakeholders	6

The activities outlined in the PDCO work plan for 2025 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2024-2026.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Development of therapeutic areas strategies

Key objectives

- Define strategies on how to approach paediatric investigation plans (PIPs) for identified therapeutic areas or certain paediatric developments.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Multi-stakeholder paediatric oncology strategy forum on anti-drug conjugate (ADC) product developments in Q1 2025 and in Q3 2025 (on topic to be confirmed).
- Publication of the outcome of above workshops.

PDCO topic leader: Sylvie Benchetrit

1.1.2. Real world evidence

Key objectives

- To identify how real-world evidence (RWE) can support paediatric development and promote its use.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Continue the conduct of RWE studies including through DARWIN EU to support PDCO decision-making thanks to identification of potential use cases where the evidence from real-world data (RWD) could support the scientific assessment.
- Conduct an RWE interrogation and analysis for at least one paediatric condition (study on drug utilisation in HIV), the results of which can be used in assessment of new PIP submissions.
- Contribution to finalisation of a framework to use RWE in support of extrapolation.
- Provide expert input in support of the development of guidance on use of RWE for regulatory purpose.

PDCO topic leader: Sylvie Benchetrit, Sabine Scherer

1.1.3. Stepwise PIP

Key objectives

- To establish the stepwise PIP (sPIP) as a permanent procedure.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Continuing the review of the experience from the pilot scheme.
- Update guidance on sPIP.

PDCO topic leader: Sabine Scherer, Siri Wang, Sylvie Benchetrit

1.1.4. Summary report and key elements form

Key objectives

- To review the experience from the new summary report (SR) and key elements form (KEF).

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Review the experience from the new SR template.
- Ensure statistical robustness of proposals both in SR and KEF.

PDCO topic leader: Sabine Scherer

1.1.5. Implementation of the ICH E11A Guideline on paediatric extrapolation

Key objectives

- To implement the ICH E11A Guideline on paediatric extrapolation.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Development of points to consider to aid assessments using of extrapolation.
- Development of training material.
- Re-evaluation and improvement of reflection of extrapolation in PIP opinion.

PDCO topic leader: Sabine Scherer

1.1.6. Utilisation of Artificial Intelligence in paediatric development

Key objectives

- To explore possibilities for using Artificial Intelligence (AI) in paediatric development.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- To develop a focus group to explore how AI can be utilised in PIP assessments and paediatric development programmes.

PDCO topic leader: Brian Aylward, Sylvie Benchetrit

1.1.7. PIPs based on mechanism of action

Key objectives

- To explore possibilities for PIPs based on mechanism of action.

Activities in 2025

- Continuing work of the focus group on this topic and develop reflections by the end of 2025.

PDCO topic leader: Sabine Scherer, Sylvie Benchetrit

2. Horizontal activities and other areas

2.1. Committees and Working parties

2.1.1. Collaboration with CTCG

Key objectives

- In line with the EMA/EC Action plan, to improve dialogue between EMA/PDCO and clinical trial assessors and facilitate mutual understanding of the interplay between assessment of PIPs and of clinical trials.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Strengthen dialogue between PDCO, CTCG and MedEthicsEU and establish the process for future interactions.
- Elaborate on criteria for joint adolescent-adult early phase clinical trials.
- Discuss specific PIP cases, particularly related to issues commonly identified during clinical trial assessment.

PDCO topic leader: Anette Solli Karlsen, Sabine Scherer

2.1.2. Collaboration with HMPC

Key objectives

- To strengthen the interaction between PDCO and HMPC and provide input to HMPC if needed/requested on matters relevant to paediatric medicines.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Strengthen dialogue between PDCO and HMPC and establish the process for future interactions.

PDCO topic leader: Peter Sisovsky

2.1.3. PDCO involvement in PIP-related CHMP procedures

Key objectives

- To follow CHMP procedures on PIP studies, to provide input to CHMP if needed/requested and to regularly inform the PDCO about critical issues identified by CHMP during assessment of paediatric data especially in cases where issues with the studies included in the PIP opinion were identified that require further discussion on PDCO's approach.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- Evaluate the feedback to PDCO and discuss possible ways forward to further improve the work on the PIPs.

PDCO topic leader: Sabine Scherer

2.2. Partners and stakeholders

2.2.1. Collaboration with stakeholders

Key objectives

- To increase interactions with stakeholders (including patients/public) and raise awareness of the work by the PDCO.

Activities in 2025

PDCO activities to achieve the objectives set for this area:

- To organise a training session on paediatric procedures for patients with the help of the stakeholder department.

PDCO topic leader: Sabine Scherer, Pernille Skovby