

PDCO workplan 2026

Adopted by the committee on 12 December 2025

23 January 2026
EMA/PDCO/348308/2025
Human Medicines Division





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Introduction by the PDCO Chair



Sabine Scherer

In 2026, PDCO will continue working to increase the feasibility of paediatric investigation plans (PIPs) to allow for a timely completion of the programs and to fulfill the unmet paediatric therapeutic needs. Among others, activities will include the development of therapeutic area strategies and further strengthening the co-operation with the Clinical Trials Coordination Group (CTCG). PDCO will also continue exploring innovative ways to generate and use the data necessary for a marketing authorisation in the paediatric population for example by advancing the implementation of the ICH E11 Guideline on paediatric extrapolation. The potential of the mechanism of action PIP to address unmet needs in the paediatric population will also be explored further.

The activities outlined in this workplan have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme.

Workplan structure

1

Evaluation activities for human medicines:

- Pre-authorisation activities

2

Horizontal activities and other areas:

- Committees and working parties
- Partners and stakeholders

1

Evaluation activities for human medicines

Pre-authorisation activities

Development of therapeutic areas strategies

Key objective:

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

Activities in 2026:

Multi-stakeholder paediatric oncology strategy forum in Q1 2026 and Q3 2026 on topics to be confirmed

Publication of the outcome of above workshops

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Pre-authorisation activities

Implementation of the ICH E11A Guideline on paediatric extrapolation

Key objective:

- To implement the ICH E11A Guideline on paediatric extrapolation

Activities in 2026:

Feasibility assessment in the newly added databases in DARWIN EU for testing extrapolation

Further increase the understanding of the use of extrapolation in PIP procedures through a focused discussion in the submission documents and the summary report and a clear reflection of the extrapolation plan in the PIP opinion

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Pre-authorisation activities

Use of Artificial Intelligence in paediatric development

Key objective:

- To explore possibilities for using Artificial Intelligence (AI) in paediatric development
- Increase AI literacy among the assessors

Activities in 2026:

To develop recommendations to explore how AI can be utilised in PIP assessments and paediatric development programmes

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Pre-authorisation activities

PIPs based on mechanism of action

Key objective:

- To explore possibilities for PIPs based on mechanism of action

Activities in 2026:

Continuing work of the focus group on this topic in oncology and non-oncology PIPs and to use the experience from oncology in non-oncology related PIPs

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Pre-authorisation activities

Review of PIPs/Waivers for fixed dose combinations (FDC)

Key objective:

- To review past PDCO decisions on FDCs by therapeutic area to identify criteria to determine if a FDC product could fulfill a paediatric medical need

Activities in 2026:

To review previous PDCO decisions on fixed-dose combinations (FDCs) by therapeutic area, in order to support informed decision-making and address unmet paediatric medical needs

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

2

Horizontal activities and other areas

Committees and working parties

Collaboration with CTCG

Key objective:

- Using agreed pathway for interaction and information sharing between EMA/PDCO and CTCG, including clinical trial assessors and ethic committees, to exchange on trial design and product specific challenges to further mutual understanding of the interplay between assessment of PIPs and of clinical trials

Activities in 2026:

Establish continued dialogue between PDCO and CTCG using agreed paths for interaction, e.g. via discussions of specific PIP cases

Assess the feasibility and scope for creating an assessor best practice guide focused on ethical and scientific considerations unique to paediatric clinical trials

Initiate structured discussions between the PDCO and MedEthicsEU to align on ethical frameworks for paediatric, including neonatal, trials

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Committees and working parties

PDCO involvement in PIP-related CHMP procedures

Key objective:

- 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 2026:

Explore methods to incorporate feedback from CHMP procedures at the conclusion of the assessment process, building on the emphasis placed at the start of the process in 2025 as outlined in the PDCO workplan in 2025

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Partners and stakeholders

Collaboration with stakeholders

Key objectives:

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

Activities in 2026:

Organise an interactive training session for EMA patient experts, in collaboration with the Stakeholder engagement department, to explain the PIP process, its objectives, and key decision points—ensuring participants understand how their input influences paediatric development plans and equipping them with practical guidance for providing constructive feedback

See Annex for details on the Lead(s)/Contributor(s) and key deliverables



Annex

Leads and contributors for the activities

Activity	Lead(s)	Contributor(s)
Development of therapeutic areas strategies	Sylvie Benchetrit	
Implementation of the ICH E11A Guideline on paediatric extrapolation	Sabine Scherer	Sylvie Benchetrit, Cinzia Ciceroni, Sara Galluzzo, David Khan, Maaïke van Dartel, Sara Vennberg, Siri Wang
Use of Artificial Intelligence in paediatric development	Brian Aylward	Sylvie Benchetrit, Liisa Sare, Karen Van Malderen, Sabine Scherer
PIPs based on mechanism of action	Sylvie Benchetrit	Sabine Scherer
Review of PIPs/Waivers for fixed dose combinations (FDC)	Siri Wang	Hugo Tavares, Helena Fonseca
Collaboration with CTCG	Anette Solli Karlsen	Sabine Scherer
PDCO involvement in PIP-related CHMP procedures	Peter Sisovsky	Dana Gabriela Marin, Siri Wang
Collaboration with stakeholders	Sabine Scherer	Pernille Skovby, Viviana Giannuzzi

Main deliverables and achievements of 2025

Activity	Deliverables
Development of therapeutic areas strategies	<ul style="list-style-type: none">Multi-stakeholder paediatric oncology strategy forum on anti-drug conjugate (ADC) completed in June 2025Publication of the outcome of the Q4 2024 forum
Real-world evidence	<ul style="list-style-type: none">DARWIN and neonates studies are ongoing such as EMA funded project on the Description and assessment of fitness-for-purpose of real-world data (RWD) sources on Duchenne Muscular Dystrophy (DMD) for regulatory decision-makingDrug utilisation study in HIV, the results of which can be used in assessment of new PIP submissionsContribution to finalisation of a framework to use RWE in support of extrapolation: completed with production of a paper published in the British Journal of Clinical Pharmacology
Stepwise PIP	<ul style="list-style-type: none">A report is in the process of being drafted and will be published in Q1 2026Guidance on sPIP updated in November 2025
Summary report and key elements form	<ul style="list-style-type: none">Updated templates of the summary report and KEF updated in August 2025
Implementation of the ICH E11A Guideline on paediatric extrapolation	<ul style="list-style-type: none">PDCO implementation group formedA 'points to consider' document aiding PIP assessment on use of extrapolation has been draftedTraining material developed via the ICH E11A groupImplementation: completed in the PIP summary report, Q&A publishedFormation of temporary OEG on extrapolation (under MWP) guiding network implementation
Utilisation of Artificial Intelligence in paediatric development	<ul style="list-style-type: none">PDCO defined the information fields to be processed and queries to be carried outFocus group has been definedPresentation on digital transformation to PDCO
PIPs based on mechanism of action	<ul style="list-style-type: none">Reviewing current experience of mechanism of action PIPs in oncology, in collaboration with NcWP
Collaboration with CTCG	<ul style="list-style-type: none">ACT EU workshop on paediatric clinical trials took place in July 2025; publication of workshop reportIdentification of next priority actions to work on together with MWP and CTCG, such as development of assessors' guidance on interpretation of Art 32 of CTR to be developed (led by CTCG)
Collaboration with HMPC	<ul style="list-style-type: none">Reflection paper on data recommendations for herbal medicinal products and traditional herbal medicinal products used in children and adolescents, in public consultation until end of August 2025
PDCO involvement in PIP-related CHMP procedures	<ul style="list-style-type: none">Establishing the process of evaluation of PIP-related CHMP procedures and updated to reflect the changes to the new IT systems
Collaboration with stakeholders	<ul style="list-style-type: none">Started planning for a training for patients and healthcare professionals for the event to take place in Q2-Q3 2026



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