

Joint Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) working parties meeting

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1 and 2 April 2025

PDCO Work plan 2025

Development of Therapeutic Areas strategies

Key objectives

Define strategies on how to approach paediatric investigation plans (PIP) 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 Q1 2025 and on in Q3 topic to be confirmed

Publication of the outcome of above workshops

Platforms for me-too's not enough patients in therapeutic areas

Sharing individual data, setting non inferiority margins, legal hurdles

PDCO Work plan 2025

Stepwise PIP

To establish the stepwise PIP as a permanent procedure

Continuing the review the experience from the pilot scheme

Summary report and key elements form

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

Ensure statistical robustness of proposals both in SR and KEF

Implementation of the E11A guideline on paediatric extrapolation

Development of flow chart aiding assessments of use of extrapolation

Re-evaluation and improvement of reflection of extrapolation in PIP Opinion

Contribution to finalisation of a framework to use RWE in support of extrapolation

PDCO Work plan 2025

Horizontal activities and other areas

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.

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

Elaborate on criteria for joint adolescent-adult early phase clinical trials

PDCO involvement in PIP-related CHMP procedures, discuss specific PIP cases, particularly related to identified dependencies required prior clinical study initiations

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



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