



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication of difficulties with paediatric studies to PDCO

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An agency of the European Union





How can networks (NW) best communicate with PDCO

1. On general issues related to therapeutic area (not product specific)
 - Direct communication NW-EMA/PDCO possible (e.g. NW letter to EMA's Paediatric Medicines Office)
2. On challenging conduct of clinical trial(s) (CT) as part of an agreed PIP
 - NW communicates challenges to sponsor (PIP applicant)
 - NW & sponsor agree to communicate issues to PDCO together
 - In context of PIP modification procedure (see next slide)





Communication of challenges with CT in agreed PIP

1. Network (NW) identifies issues with CT which is part of agreed PIP
2. NW & sponsor decide to contact PDCO
3. Sponsor submits letter of intent for PIP modification and requests oral hearing with PDCO together with representative of network
4. PDCO secretariat invites official Enpr-EMA rep of concerned NW
5. Oral hearing during modification procedure: PDCO - sponsor – NW rep

→ Information soon to be published on EMA/Enpr-EMA website