A short overview of procedural aspects, the roles of the EMEA and the PDCO

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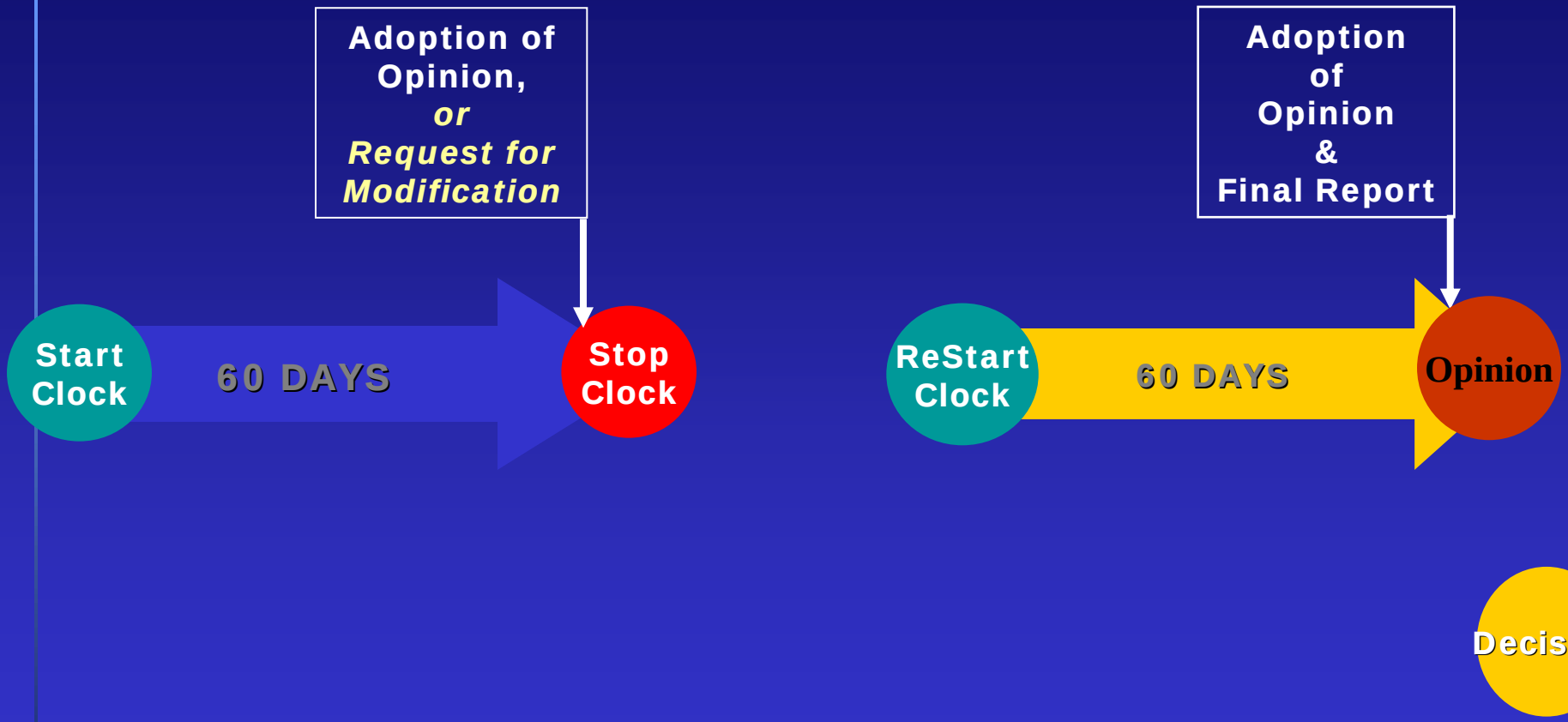
1. Paediatric Investigation Plan (PIP)

Overview of PIP Procedure



How is the PIP assessed from D -30 to D60?

	EMEA	Rapporteur/Peer-reviewer
D-30	- Validation (meeting) - Draft Summary report (write + comment)	
D 0		Adding comments the draft Summary Report
D30	- Participate in PDCO - Draft the PDCO request for modification (RfM)	- Present the PIP to PDCO - PDCO make comments - Need for experts identify
D60	- Include other comments - Participate in PDCO - Final RfM	- PDCO adopt the RfM

How is the PIP doing in the Clock-stop?

EMEA	Rapporteur/Peer-reviewer
- to assist companies when regulatory and (some) scientific clarifications are required - to organise TCs* with Rapporteur/Peer reviewer/company	- to address companies' request for clarifications on RfM

*TC are for clarification and an exchange of information; not assessment. PDCO remains the decision makers

How is the PIP assessed from D61 to D120?

	EMEA	Rapporteur/Peer-reviewer
D61	- comment the company responses to RfM	- comment the company responses to RfM
D 90	-Participate in PDCO -Draft the PDCO opinion -Collect PDCO comments	-Present the company position -Present the remaining issues -Discuss negative/positive opinion for D120
D120	- Participate in PDCO - amend **details** of the opinion according to the discussion	-opinion adopted by PDCO

Who else assesses the PIP?

- **Working Groups**
  - Formulation WG, Non-Clinical WG, Extrapolation WG (under construction); others to come (e.g. methodology?)
  - Members:

    PDCO Members and Alternates, NCA assessors, EMEA staff (Quality, Safety, Efficacy, Stats, etc), External Experts
  - Working Groups are advising the PDCO
  - Chaired by a PDCO Member
  - Respond to specific questions
  - Review PIPs on request or on their own motion
  - Provide written responses in the **Summary Report**

Opinion into decision?

PDCO opinions are transformed into decisions by EMEA

2. Modification of an agreed PIP/ Compliance (60 days procedure)

	Modification	Compliance
D-30	**EMEA:** Draft Summary report	
D 0	Raporteur **and** Peer-reviewer: Comment the draft Summary Report	Rapporteur **only**: Comment the draft Summary Report
D30	EMEA: Participate in PDCO + Draft request for clarification Rapporteur and/or peer-reviewer: Present to PDCO PDCO: make comments *Opinion can be adopted unless need for clarifications*	
D60	EMEA: Participate at PDCO/Write the final opinion PDCO: adopt the opinion	

To summarise

EMEA Scientific Administrators in paediatric team

- Coordinator of the procedure
- Acts as interface between companies and PDCO
- Performs regulatory checks (validation)
- Writes and comments draft version of Summary Report, opinion, …
- Participates in PDCO meeting
- Assist and initiate preparation of scientific and regulatory procedural advice

PDCO members

- Members and Alternates share the work
- Rapporteur and Peer Reviever both review and comment the Summary Report
- Other Members/experts comment during and after discussion (verbally or in writing)
- Possible teleconference with applicants on request
- Discussion with Applicants in Oral Explanation Meetings

Conclusion

- EMEA and PDCO members have a complementary input
  EMEA: regulatory and scientific
  PDCO: scientific only

- EMEA assists PDCO and companies
  (e.g: preliminary discussions, TC in clockstop/D90)

DO NOT HESITATE TO LIAISE WITH US!

Thank you

http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm

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