



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop programme and objectives

Paediatric multi-stakeholder workshop, EMA London, 20 March 2018

Presented by Gunter Egger
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An agency of the European Union



Working together to overcome challenges

Today is an opportunity for an open dialogue ...



patient representatives / carers

policy makers

ethics committees

industry



HTA

regulators

academia

health care professionals

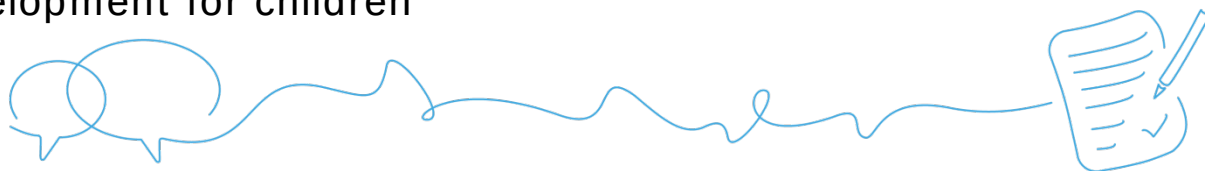


Objectives for today

- Exchange ideas for improvements of implementation of Regulation
- Learn from each other
- Focus on the future
- Propose solutions
- Explore ways of collaboration

Outcome of workshop will be basis for:

- EC/EMA action plan for 2018/2019
- Aim: boost medicines development for children





Workshop programme



Morning session:



Topic 1: Identification of **paediatric medical needs** – Methodology



Topic 2: **International cooperation** of regulators for paediatric medicines

Afternoon session:



Topic 3: **Timely completion** of Paediatric Investigation Plans (PIPs)



Topic 4: Improving the **handling of PIP applications**



Topic 5: **Transparency measures**