



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA workshop on Adaptive pathways: PCWP and HCPWP contribution

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Francesca Cerreta  
EMA – Scientific Advice





## AP report published in August 2016

Prospective multi-stakeholder dialogue feasible and desirable for complex cases

RWD can offer advantages in *supplementing* RCTs

RWD use might accelerate development –if all goes well, particularly if requirements from different stakeholders are prospectively optimised.



# Workshop 8 December

Three sessions:

- Patient and HCP contribution
- Methodological challenges for RWD
- Downstream decision makers participation



## **PCWP and HCPWP help welcome!**

Prioritisation of the issues for discussion among those raised by civil society

- How is “unmet need” to be understood for the selection of AP products?
- Are Real World Data an adequate source of information for marketing authorisation and reimbursement decisions?
- How can it be ensured that post marketing obligations will be honoured by industry?
- Is it possible to ensure appropriate utilisation after initial marketing authorisation?



## PCWP and HCPWP help welcome! (cont.)

- Is the process reversible if information is not forthcoming or if the benefit-risk balance does not meet expectations? (Are there exit strategies?)
- How can patients be optimally involved in the discussion?
- Will patients be exposed to increased risk?
- Is there a risk of lowering the regulatory requirements for applications going through adaptive pathways
- Is affordability a criterion to be taken into account for AP?
- Is the objective to apply adaptive pathways to all Marketing Authorisation Applications at a later stage?



# **Survey will be sent tomorrow by email**

Pick up the 5 topics most important to you

Rank them in order of importance

Reply within 1 week

Thanks for your help

Come to the workshop!