29 November 2024
EMA/174789/2024

Agenda – 13th Industry stakeholder platform on research and development support

2 December 2024, 12:30 – 17:00 (room 0B and Webex)

Co-chairs: Michael Berntgen and Iordanis Gravanis

Item	Agenda	Time
1.	**Welcome / Introductions** • Overview of the agenda • Review of status of follow-up actions from the last platform meeting *Michael Berntgen (EMA)*	12:30 – 12:40
2.	**Experience with Portfolio and Technology meetings (PTMs)** • Summary of first experiences • Next steps for refinement based on feedback received *Enrico Tognana (EMA)* Discussion	12:40 – 13:00
3.	**Development support offering for programme-specific evidence planning** A. Update from EMA on recent developments • Latest developments in terms of discussion meetings in scientific advice • First experience with consolidated SAWP/CTCG advice on clinical trials • Update about the development of the survey on the ongoing PRIME pilots • Progress with the Action plan on future-proofing the Qualification of Novel Methodologies • Status of activities relate to evidence planning for combination developments *Iordanis Gravanis (EMA)* B. Industry reflections on selected topics • Review of options on better use of SA discussion meetings alongside the development of metrics for measuring effectiveness of the process *Alexa Hunter (Industry)* • Expectations regarding the consolidated SAWP/CTCG advice on clinical trials *Laura Oliveira (Industry)* Discussion	13:00 - 13:25 13:25 – 13:45 13:45 – 14:15

Coffee break		15 min
4.	**Supporting paediatric developments** A. Paediatric Scientific Advice • Clarifications in the scientific advice guidance based on the comments received from industry • Strengthening of the use of scientific pre-submission meetings for complicated PIPs • Review of the requirements for paediatric scientific advice *Ralph Bax, Iordanis Gravanis, Chrissi Pallidis (EMA)* *Alexa Hunter (Industry)* Discussion B. Stepwise PIP pilot • Update on progress and preliminary learnings • Development of proposals for analysing the pilot experience *Chrissi Pallidis (EMA)* *Gesine Bejeuhr (Industry)* Discussion	14:30 – 14:55 14:55 – 15:15 15:15 - 15:30 15:30 – 15:50
5.	**Focus group to explore opportunities for the use of Real-World Data (RWD) and the generation of Real-World Evidence (RWE)** • Overview of objectives and next steps *Patrice Verpillat (EMA)*	15:50 – 16:05
6.	**Operational update** A. Processing Scientific Advice requests regarding New Fee Regulation • Guidance from January 2025 *Tarita Toufexi (EMA)* B. Onboarding of paediatric procedures onto IRIS • Status update • Fixing of issues identified by applicants *Tarita Toufexi (EMA)*	16:05 – 16:20 16:20 - 16:35
7.	**Summary of follow-up items / Close of the meeting** *Michael Berntgen (EMA)*	16:35 - 16:45