3 July 2025
EMA/119654/2025

Agenda – 14th Industry stakeholder platform on research and development support

3 July 2025, 12:30 – 17:30 (room 2A and TEAMS)

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 *EMA: Michael Berntgen*	10 min
2.	**Development support through scientific advice** A. Update from EMA on recent developments • Latest figures on volume and capacity • Application of latest guidance update, including scientific advice for paediatric developments • Experience with SAWP-CTCG pilots for providing scientific advice • Use of discussion meetings to enable scientific dialogue *EMA: Iordanis Gravanis* B. Developers' proposals to enable a more agile offering of scientific advice • Summary of outcome from a recent roundtable dialogue • Proposals to translate ideas into concrete activities *Industry: Alexa Hunter (EFPIA/EuropaBio), Laura Oliveira (EFPIA/EuropaBio)* C. Developers' proposals to enhance the SAWP-CTCG pilots • Experience with the pilots to-date • Reflections on strengthening the use of the new interface *Industry: Laura Oliveira (EFPIA/EuropaBio)*	60 min

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3.	**Horizon scanning activities by different stakeholders** • Methodologies employed by developers • Recent EMA activities on horizon scanning *EMA: Valentina Cordò, Enrico Tognana, Falk Ehmann* *Industry: Esteban Herrero-Martinez (EFPIA/EuropaBio), Seán Byrne (EUCOPE)*	30 min
4.	**Experience with the new features of the PRIME scheme** • Report from the pilot with feedback from developers of PRIME products focusing on expedited scientific advice, development tracker, and submission readiness meetings • Additional insights through an industry survey on perceptions and expectations from PRIME • Learnings from these surveys and further refinement of this development support offering for unmet medical need products *EMA: Kevin Cunningham* *Industry: Nadege Le Roux (EFPIA)*	45 min
5.	**Piloting of the product development coordinator for PRIME products** • Introduction to the concept of the product development coordinator • Discussion on expectations and metrics for measuring of value and impact *EMA: Michael Berntgen, Iordanis Gravanis*	20 min
Coffee break		15 min
6.	**Focus group to explore opportunities for the use of Real World Data (RWD) and the generation of Real World Evidence (RWE)** • Update on activities and next steps *EMA: Andrej Segec* *Industry: Almath Spooner* (EFPIA), Marieke Schoonen (EUCOPE)	15 min
7.	**Moving the stepwise Paediatric Investigation Plan (sPIP) concept from pilot to regular operations** A. Update from EMA on recent developments • Final report from the "sPIP pilot" • Progress with the preparation of a joint publication on the experience • Monitoring and performance indicators to follow-up on sPIP developments *EMA: Chrissi Pallidis* *Industry:* Gesine Bejeuhr (EFPIA), *Marcello Milano (EUCOPE)*	30 min
8.	**Early engagement meetings that foster innovation** A. Report from an EMA survey on available tools and platforms (ITF, PTM, SME briefings, QIG) *EMA: Maria Filancia (Industry liaison), Oriane Blanquie (ITF BMs), Enrico*	30 mins

	Tognana (PTM), Tomas Balloti (SMEs BMs), Giampiero Lorenti (QIG) B. Additional feedback on industry experience with Portfolio and Technology Meetings *Industry: Doerte Braumann (EFPIA)*	
9.	**Delivery of the action plan to strengthen qualification of novel methodologies** • Update on the activities under the action plan *EMA: Thorsten Vetter* *Industry:* Cathelijn De Gram (EFPIA)	15 min
10.	**Establishment of potential alternatives to animal testing in line with the 3Rs principles** • New opportunities for voluntary data submission *EMA: Stefano Ponzano, Orla Moriarty*	20 min
11.	**Summary of follow up items / Close of the meeting** *EMA: Michael Berntgen*	10 min