4 December 2025
EMA/293578/2025

Agenda – 15th Industry stakeholder platform on research and development support

4 December 2025, 12:30 – 17:30 (room 1A)

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)*	10 min
2.	**Strengthening the delivery of scientific advice to efficiently support development programmes** A. Update on recent developments *EMA update* • Volume and capacity • Update on the SAWP-CTCG scientific advice pilot • Latest experience with new pre-payment requirements • Survey on parallel EMA-FDA development support *EMA: Iordanis Gravanis* *Industry update* *Industry: Alexa Hunter (Europabio), Laura Oliviera (Europabio)* *Supportive expert(s): Bertrand Fournier (EUCOPE), Shekhar Natarajan (EUCOPE)* B. Establishment of a Focus group on introducing agility in scientific advice • Expectations in terms of objectives and deliverables *EMA: Iordanis Gravanis* C. Broad scientific advice affecting multiple products • Proposal from developers to use broad scientific advice as a vehicle to get regulatory input on topics with wider implications and thus involving EU bodies and institutions beyond EMA	20 min 10 min 15 min 20 min

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	Industry: Peggy Sarah (EFPIA), Esteban Herrero Martinez (Europabio)	
3.	**Modernising the Qualification of Novel Methodologies framework** • Status report on the delivery of the action plan *EMA: Iordanis Gravanis* *Industry: Cathelijn De Gram (EFPIA)* *Supportive experts: Alison Bond (EUCOPE), Elena Stojanovska (EUCOPE), Simon Bennett (EUCOPE)*	20 min
4.	**Translating the experience from the piloting of the new PRIME features into optimised operations** • Final EMA recommendations as a result of the pilot on the new PRIME features (expedited scientific advice, development tracker, and submission readiness meetings) • Update on the piloting of the PRIME Product Development Coordinator role and development of metrics to demonstrate value from the developers' perspective *EMA: Kevin Cunningham* *Industry:* Nadege Le Roux (EFPIA), Joao Duarte (EUCOPE) *Supportive experts: Pedro Franco (Europabio), Christel Ravesteijn-Verrijt (ARM), Andrea Braun (ARM)*	30 min
5.	**HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment** • Summary report from the meeting and follow-up activities *EMA: Efthymios Manolis* *Supportive experts: Pieter Colin (EMA), Flora Musuamba (Federal Agency for Medicines and Health Products, Belgium)* *Industry: Loeckie De Zwart (EFPIA)*	20 min
Coffee Break		15 min
6.	**Proposal for the pilot of a voluntary data submission framework to establish potential alternatives to animal testing in line with the 3Rs principles** • Update on the stakeholder consultation with the NcWP and preparation for the upcoming co-creation meeting *EMA: Stefano Ponzano*	15 min
7.	**Progressing the support to paediatric developments** A. Overview of recent developments • Update on recent changes to the PIP scientific document and the Key elements form • Experience with the paediatric scientific advice	15 min

	• Final report on the stepwise PIP (sPIP) pilot *EMA: Chrissi Pallidis* *Supportive expert: Andrea Braun (ARM)* B. Advancements in the prospective design of paediatric development programmes • Sharing of experience with the Mechanism of action approach in paediatric drug development • Industry reflections regarding flexibility of sPIP requirements in rare paediatrics *EMA: Maria Sheean, Chrissi Pallidis* *Industry:* Gesine Bejuhr (EFPIA) for MoA PIP, Marcello Milano (Eucope) for sPIP requirements Supportive expert: Mariska Mulder (EUCOPE)	30 min
8.	**Identification of product-specific bioequivalence guidelines** • Proposal for enhaced stakeholder engagement *EMA: Demy van den Haak* *Supportive expert:* Carolien Versantvoort (EMA - MWP CP-OEG Chair) *Industry: Irmela Gabriel (Medicines for Europe), Indiana Castro (Medicines for Europe)*	15 min
9.	**Focus group to explore opportunities for the use of Real-World Data (RWD) and the generation of Real-World Evidence (RWE)** • Status report on the activities to deliver on the mandate *EMA: Patrice Verpillat* *Industry: Almath Spooner (EFPIA)*	20 min
10.	**Strengthening support to evidence generation for drug-IVD/MD combination products** • Considerations on importance of EMA scientific advice in advancing the dialogue: what is the expertise required? • Most prominent practical issues with development programmes for drug-IVD/MD combination products (focus on pre-authorisation interactions/dialogue) Industry: Lucia D'Apote (Eucope), Claudia Popp (EFPIA) *Supportive expert:* Marcello Milano (EUCOPE)	30 min
11.	**Summary of follow up items / Close of the meeting** *Michael Berntgen (EMA)*	10 min