3 November 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	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 B. Establishment of a Focus group on introducing agility in scientific advice • Expectations in terms of objectives and deliverables 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	1h05
3.	**Modernising the Qualification of Novel Methodologies framework** • Status report on the delivery of the action plan	20 min

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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	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	20 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	15 min
Coffee Break		15 min
7.	**Progressing the support to paediatric developments** ***Overview of recent developments*** • Update on recent changes to the PIP scientific document and the Key elements form • Experience with the paediatric scientific advice • Final report on the stepwise PIP (sPIP) pilot ***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	45 min
8.	**Identification of product-specific bioequivalence guidelines** Proposal for enhaced stakeholder engagement	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	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)	30 min
11.	**Summary of follow up items / Close of the meeting**	10 min