10 June 2025
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Draft 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*	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* 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* 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*	60 min

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3.	Horizon scanning activities by different stakeholders • Methodologies employed by developers • Recent EMA activities on horizon scanning *EMA* *Industry*	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* *Industry*	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*	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* *Industry*	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* *Industry*	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*	30 mins

	B. Additional feedback on industry experience with Portfolio and Technology Meetings *Industry*	
9.	Delivery of the action plan to strengthen qualification of novel methodologies • Update on the activities under the action plan *EMA* *Industry*	15 min
10.	Establishment of potential alternatives to animal testing in line with the 3Rs principles • New opportunities for voluntary data submission *EMA*	20 min
11.	Summary of follow up items / Close of the meeting *EMA*	10 min