1 December 2023
EMA/492206/2023

Agenda – 11th Industry stakeholder platform on research and development support

4 December 2023, 12:30 – 17:00 (room 1C)

Chair: Michael Berntgen

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 12:30 – 12:40
2.	**Development support offering for programme-specific evidence planning** A. Latest updates from developers' perspective • Feedback from a survey on (intended) use of the scientific advice offering *Alexa Hunter and Andrew Gray, Industry* • Proposal for strengthening the usefulness of Discussion Meetings *Alexa Hunter, Industry* • Considerations for enhanced knowledge management across procedures *Mireille Muller, Industry* B. Insight from EMA on recent developments • Capacity and uptake, including special procedures such as parallel advice • Progress with the implementation of PRIME recommendations *Iordanis Gravanis, Kevin Cunningham, EMA*	45 min 12:40 – 13:25
3.	**Action plan to strengthen the tool for qualification of novel methodologies** • Presentation of the action plan following the multi-stakeholder workshop *Iordanis Gravanis, Thorsten Vetter, EMA*	15 min 13:25 – 13:40

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4.	**Introduction to the revamped Business Pipeline meetings** • Overview of changes with the new "Portfolio and Technology meetings (PTMs)" *Enrico Tognana, EMA*	15 min 13:40 – 13:55
5.	**Industry perspective on future-proofing the regulatory system** *Francois Hebraud, Industry*	30 min 13:55 – 14:25
6.	**Recent and upcoming developments of the IRIS platform for R&D processes** • Additions to the management of PRIME • Planned onboarding of paediatric processes *Tarita Toufexi, Anna Gross (EMA)*	25 min 14:25 – 14:50
Coffee break		20 min
7.	**Progressing agility in paediatric processes** A. Experience with the pilot on the "stepwise PIP" • Insights from applications received so far • Expected timelines for completing the pilot *Chrissi Pallidis, EMA* B. Proposals for further streamlining paediatric processes *Gesine Bejeuhr, Industry* *Discussion involving Ralph Bax, EMA*	30 min 15:10 – 15:40
8.	**Collaboration at the regulatory / HTA interface** • Industry perspective of interaction between regulatory affairs and market access, mirroring expected cooperation between public bodies *Inka Heikkinen, Industry* *Discussion involving Anne Willemsen and Paul De Boissieu, HTA*	30 min 15:40 – 16:10

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9.	**Evidence planning for combination developments comprising of medicinal products with medical devices and/or companion diagnostics** A. Feedback from the latest discussions of the Focus group • Agreed actions and next steps *Stiina Aarum, EMA* • Industry perspective *Claudia Popp, Industry* B. Introduction to recent industry positions outlining regulatory opportunities and challenges • Challenges in conducting clinical trials involving medicinal products with medical devices or IVDs *Fatima Bennai-Sanfourche, Industry* • Regulatory Pathways for Connected Combined Products (CCP's) *Christoph Joosten, Industry* C. Progress with the COMBINE project • Update on latest development *Olga Tkachenko (SANTE D3) and Isabelle Clamou (SANTE D2)*	45 min 16:10 – 16:55
10.	**Summary of follow-up items / Close of the meeting** *Michael Berntgen, EMA*	5 min 16:55 – 17:00