EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 July 2024
EMA/174789/2024

Agenda – 12th Industry stakeholder platform on research and development support

4 July 2024, 12:30 – 17:00 (room 1A and WebEx)

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 12:30 – 12:40
2.	**Development support offering for programme-specific evidence planning** A. Update from EMA on recent developments • Current practices and future proposals regarding discussion meetings in scientific advice *(Industry topic lead: Alexa Hunter (EFPIA))* • Progress with the implementation of PRIME recommendations *(Industry topic leads: Marcello Milano (ARM), Nadege Le Roux (EFPIA))* • Use of transitional arrangements for Parallel Consultation with HTA bodies *(Industry topic lead: Inka Heikkinen (EFPIA))* *Iordanis Gravanis (EMA)* B. Provision of scientific advice on paediatric developments • Follow-up discussions by the sounding boards • Proposal for clarification and optimisation *Alexa Hunter (EFPIA), Marcello Milano (ARM)* *Discussion involving Ralph Bax, Iordanis Gravanis, Chrissi Pallidis (EMA)* C. Consolidated advice on clinical trials • Outline of pilots under ACT EU priority action 7 on consolidated advice *Massimiliano Sarra (EMA), Marianne Lunzer (AGES)* *Bertrand Fournier (EUCOPE), Mireille Muller (EFPIA)*	25 min 12:40 – 13:05 40 min 13:05 – 13:45 30 min 13:45 – 14:15

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3.	**Action plan to future-proofing the Qualification of Novel Methodologies platform** • Final action plan following the multi-stakeholder workshop report *Thorsten Vetter (EMA)*	30 min 14:15 – 14:45
4.	**Implementation of the new Fee Regulation** • Relevance for R&D processes *Patrick Lopez Fernandez, Jean Michel Mastio, Paola Samassa (EMA)*	15 min 14:45 – 15:00
Coffee break		15 min
5.	**Completion of onboarding of R&D processes onto the IRIS platform** • Launch of the management of paediatric processes in IRIS • Value of the RPI concept *Tarita Toufexi, Aline Labejof, Giovanni Lesa (EMA)* *Angelika Joos (EFPIA), Shekhar Natarajan (EUCOPE)*	45 min 15:15 – 16:00
6.	**EMA Survey focused on early engagement meetings that foster innovation** • Update on the plans for the survey *Maria Filancia (EMA)*	10 min 16:00 – 16:10
7.	**Exploring opportunities for the use of real world data turning into evidence** • Proposal for establishing a dedicated focus group for scientific/technical discussions *Patrice Verpillat (EMA)*	10 min 16:10 – 16:20
8.	**Evidence planning for combination developments comprising of medicinal products with medical devices and/or companion diagnostics** A. Follow-up from the Focus group work • Update on the scientific publication *Stiina Aarum (EMA), Andreas Emmendoerffer (MPP), Tim Chesworth (EFPIA), Elisabeth Kapeller (Medicines for Europe)* B. Progress with the COMBINE project • Industry perspective *Lucia D'Apote (EFPIA)* • Update on latest development and next steps *Ditte Zerlang Andersen (DKMA), Isabelle Clamou (EC)*	10 min 16:20 – 16:30 20 min 16:30 – 16:50
9.	**Summary of follow-up items / Close of the meeting** *Michael Berntgen (EMA)*	5 min 16:50 – 16:55