

9 November 2023
EMA/488460/2023

Agenda – biannual Big Data Steering Group and industry stakeholders meeting

15.00-17.00pm (CET) 27 November 2023, virtual

Co-Chairs: Jesper Kjaer (DKMA) and Peter Arlett (EMA)

Item	Preliminary draft agenda	Initials	Mins
1.	Welcome and opening remarks <ul style="list-style-type: none"> Update on BDSG workplan, mandate and membership Reminder on HMA EMA big data stakeholder forum on 4 December 2023 	Jesper Kjaer (BDSG, DKMA), Peter Arlett (BDSG, EMA)	10'
2.	Launch of the EMA-HMA catalogues of data sources & non interventional studies <ul style="list-style-type: none"> Industry feedback on Validation activities EMA update and next steps <i>Open discussion</i>	Sigrid Behr (EFPIA) Ana Cochino (EMA) All	40' 10' 20' 10'
3.	Real World Evidence <ul style="list-style-type: none"> Industry priorities on guidance on data and methods (to inform future workshop on RWE methodologies/research) Update on RWE and DARWIN EU activities <i>Open discussion</i>	Marieke Schoonen (EUCOPE) Patrice Verpillat (EMA) All, Almath Spooner (EFPIA), Industry representative at the DARWIN EU Advisory board	40' 15' 10' 15'
4.	Artificial Intelligence <ul style="list-style-type: none"> AI workshop – Smart regulation in a rapidly evolving world: next steps Industry reflections on AI workshop (20-21 November 2023) <ul style="list-style-type: none"> Industry experimentation on AI and potential collaboration <i>Open discussion</i>	Gabriel Westman (MPA)/ Luis Pinheiro (EMA) Thomas Brookland (EFPIA) All	25' 5' 15' 5'
5.	Wrap-up and conclusions	Peter Arlett (EMA)	5'

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6.	Info items (time permitting) <ul style="list-style-type: none"> • Multistakeholder workshop patient registries – 12-13 February 2024 • Data Quality Framework: publication coming in the coming weeks 		