



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 April 2023
EMA/200171/2023

Agenda – biannual Big Data Steering Group and industry stakeholders meeting

09.00-11.00 (CET) 26 May 2023, virtual

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

Item	Preliminary draft agenda	Initials	Mins
1.	Welcome and opening remarks	Peter Arlett (BDSG, EMA) Jesper Kjaer (BDSG, DKMA)	10 min 09.00-09.10
2.	DARWIN EU - Consultation on the catalogue of standard data analyses - Engagement with HTAs - Experience from piloting an RWE framework to support regulatory decisions BDSG sponsors: Sabine Straus (PRAC), Markus Kalliola (Sitra) <i>Open discussion</i>	Andrej Segec (EMA)/ Prof Daniel Prieto-Alhambra (DARWIN EU(®) Coordination Centre) Juan Jose Abellan (EMA) Stefanie Prilla (EMA)	60 min 09.10-10.10
3.	Data quality & representativeness Data quality framework including its development on RWD and preparations for workshop BDSG sponsors: Pasquale Marchione (AIFA, IT), Markus Kalliola (Sitra), Anja Schiel (SAWP) <i>Open discussion</i>	Ana Cochino (EMA)	20 min 10.10-10.30
4.	International initiatives Update on international collaboration, including progress with advancing priority areas outlined in the RWE ICMRA statement BDSG sponsors: Peter Bachmann (BFARM, DE), Markus Kalliola (Sitra) <i>Open discussion</i>	Catherine Cohet/Kelly Plueschke (EMA)	20 min 10.30-10.50
5.	Wrap-up and conclusions	Peter Arlett (EMA)	10 min 10.50-11.00

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