

24 October 2024
EMA/466753/2024

Draft agenda – biannual Big Data Steering Group and industry stakeholders meeting

09.00-11.00am (CET) 25 October 2024, virtual

Co-Chairs: Jeppe Larsen (DKMA) and Peter Arlett (EMA)

Item	Preliminary draft agenda	Initials	Mins
1.	Welcome and opening remarks	Jeppe Larsen (BDSG, DKMA), Peter Arlett (BDSG, EMA)	10'
2.	Real World Evidence generation		40'
	<ul style="list-style-type: none"> EMA progress update Industry feedback 	Patrice Verpillat (EMA)	10'
	<i>Open discussion</i>	Almath Spooner (EFPIA), Marieke Schoonen (EUCOPE)	20'
		All	10'
3.	Rationalisation of the network data governance		20'
	<ul style="list-style-type: none"> EMA update 	Francois Domergue (EMA)	10'
	<i>Open discussion</i>	All	10'
4.	Clinical study data pilot – interim results		20'
	<ul style="list-style-type: none"> EMA update 	Eftychia-Eirini Psarelli (EMA)	10'
	<i>Open discussion</i>		10'
5.	AOB	All	10'
6.	Wrap-up and conclusions	Peter Arlett (EMA)	10'

List of events

- HMA/EMA multi-stakeholder workshop on Artificial Intelligence – 5 November 2024.
- HMA/EMA Big Data Stakeholder Forum 2024 – 28 November 2024.

For information on related past meetings and workshops, see [Big data | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/big-data)

