

5 September 2022
EMA/656750/2022
European Medicines Agency

Agenda – Seventh DARWIN EU® Advisory Board meeting

Thursday 8 September 2022 15:00 – 17:00 CET, virtual meeting

Co-Chairs: Emer Cooke (EMA) and Karl Broich (HMA)

Item	Preliminary draft agenda	Name	Action	Mins
1.	Adoption of draft agenda and minutes from the last meeting (6 July 2022)	All	For adoption	10'
2.	Update on DARWIN EU®	Andrej Segec and Sabine Brosch (EMA)	For information	10'
3.	Criteria for prioritisation of studies beyond Year 2	Juan Jose Abellan (EMA)	For consultation	20'
4.	Process for consulting/informing industry	Andrej Segec (EMA)	For consultation	20'
5.	EHDS2 pilot – link to DARWIN EU® EMA use case	Malek Bentayeb (HDH), Mario Jendrossek (HDH), and Xavier Kurz (EMA)	For discussion	30'
6.	Tour de Table	All		10'
7.	AOB - Information items Big Data Steering Group workplan 2022-25 and news announcement 3rd Big Data Stakeholder Forum on 1 December 2022 Multistakeholder workshop on Patient experience data in medicines development and regulatory decision-making – 21 September 2022	All		

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Topics for future meetings: Benefit analysis, repurposing, role of DARWIN EU® in the international RWE landscape

Next meeting: November TBA
