

19 April 2024
EMA/149470/2024
European Medicines Agency

Agenda – 11th DARWIN EU® Advisory Board meeting

Friday 3rd May 2023 13:00 – 14:30 CEST, virtual meeting

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

Item	Preliminary draft agenda	Name	Action	Mins
1.	Welcome and Adoption of draft agenda and minutes from the last meeting (11 th December 2024)	All	For adoption	5'
2.	DARWIN EU progress update: completion of establishment and preparation for scaling up. <ul style="list-style-type: none"> Phase II completion (DPs & studies) Strategy for phase III DPs selection Studies in the pipeline 	Andrej Segec (EMA)	For information & discussion	30'
3.	Stakeholder roundtable: impact & learnings so far, and next steps <ul style="list-style-type: none"> DARWIN EU® & PDCO 	Roberto de Lisa (Paediatrics Office, EMA)	For discussion	30'
4.	Stakeholder roundtable: impact & learnings so far, and next steps <ul style="list-style-type: none"> Industry feedback on early experience with DARWIN EU® studies 	Álmath Spooner, Brian Bradbury (EFPIA, EuropaBio, EUCOPE)	For discussion	30'
5.	Any other business (AOB) <ul style="list-style-type: none"> AB meeting planning (in-person) 	All	For discussion	5'

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

Next meeting: September 2024 TBC
