

## Agenda – Third DARWIN EU Advisory Board meeting

12 November 2021, 10:00 – 12:00, 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	All	For adoption	5'
2.	DARWIN EU project update	Francois Domergue (EMA)	For information	10'
3.	Listening to stakeholders			
	a. Use cases for HTA	Niklas Hedberg (TLV, SE)	For discussion	30'
	b. Industry Stakeholders meeting – feedback	Almath Spooner (EFPIA, EuropaBio, EUCOPE)	For discussion	15'
4.	First discussion on communication strategy	Sophie Groeneveld (EMA)	For discussion	20'
5.	Tour de Table	All	For discussion	5'
6.	AOB	All		
	<ul style="list-style-type: none"> <li>• Information items: <ul style="list-style-type: none"> <li>○ the draft guidance, <a href="#">Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products</a> issued by the U.S. Food and Drug Administration.</li> <li>○ An article published by the Association of the European Self-Care Industry (AESGP), <a href="#">How can real-world evidence aid decision making during the life cycle of non-prescription medicines?</a></li> <li>○ A report produced by the Open Data Institute and commissioned by Roche on <a href="#">Secondary use of health data in Europe</a></li> <li>○ New TEHDAS reports published</li> </ul> </li> </ul>			

See websites for contact details

Item	Preliminary draft agenda	Name	Action	Mins
	<ul style="list-style-type: none"> <li>▪ <u>TEHDAS probes matrix of data altruism definitions</u></li> <li>▪ <u>TEHDAS scrutinises European data sharing initiatives</u></li> <li>▪ <u>TEHDAS identifies barriers for data sharing</u></li> <li>▪ <u>EU should rethink policies on health data access</u></li> </ul>			

Topics for future meeting: Benefits analysis, EC initiatives and legal proposals

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Next meeting: End of January 2022 (tbc)

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