28 June 2021
EMA/371416/2021

Final minutes - DARWIN EU Advisory Board – Kick off Meeting

28/06/2021 – chaired by Emer Cooke and Karl Broich

Role	Name
Chair/Vice-chair	Emer Cooke, Karl Broich
Present:	Ioana Maria Gligor (DG SANTE); Sara Rafael Almeida (DG SANTE); Aurora Di Filippo (AIFA); Claudia Furtado (INFARMED); Hugues Malonne (FAGG- AFMPS); Jesper Kjaer (DKMA); Magali Boers (LHD); Mahmoud Zureik (ANSM); Wim Goettsch (ZINL); Niklas Hedberg (TLV); Louisa Stuwe (HDH); Johanna Seppanen (THL); Markus Kalliola (SITRA); Tina Purnat (ECDC); Elizabeth Vroom (UPPMD); Aldo Maggioni (ESC); Almath Spooner (EFPIA, EuropaBio, EUCOPE); Peter Arlett (EMA); Xavier Kurz (EMA); Francois Domergue (EMA); Stefan Blixen-Finecke (EMA); Aikaterini Vardalaki (EMA).
Minutes:	Aikaterini Vardalaki (EMA)
Admin. support	Jolanta Palepsaitiene (EMA)

Agenda Table

Item	Preliminary draft agenda	Initials	Action	Mins
1.	Adoption of the draft agenda	All	For adoption	5’
2.	Welcome	E. Cooke (EMA) / K. Broich (HMA)	For information	10’
3.	Tour de Table	E. Cooke (EMA) / K. Broich (HMA)	For information	15’
4.	DARWIN EU Advisory Board mandate	P. Arlett (EMA)	For information and discussion	10’
5.	The DARWIN EU project • Introduction to DARWIN EU: status update and planning Questions	F. Domergue (EMA) / S. Blixen-Finecke (EMA)	For information	15’ 15’

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Item	Preliminary draft agenda	Initials	Action	Mins
	• Use cases for RWE in EU core regulatory processes • Discussion: DARWIN EU Advisory Board perspectives	X. Kurz (EMA) / J. Kjaer (DKMA) All	For information For discussion	 15’
6.	EC legislative and policy initiatives	S. R. Almeida (EC) / I. M. Gligor (EC)	For information	20’
7.	Discussion • Collaboration with EHDS and Member state initiatives • Other advice and recommendations on the establishment of DARWIN EU	All	For discussion	10’
8.	A.O.B.	All	For discussion	5’

1. Adoption of draft agenda

The draft agenda was adopted with no further comments from the Advisory Board members.

2. Welcome

Both chairs welcomed the participants to the meeting and presented their opening remarks. The following key points were addressed:

- DARWIN EU is the first of the Joint HMA-EMA Big Data Task Force recommendations and is anchored in the Network Strategy to 2025.
- DARWIN EU will enable the use of real-world evidence generated from real-world data in regulatory decision making in Europe.
- DARWIN EU will connect the EMRN and the EMA Scientific Committees to the European Health Data Space (EHDS). It will enable the use of the EHDS in the context of medicines regulation in Europe.
- The Advisory Board will have an important role in guiding the development of DARWIN EU, supporting the coordination with European and National projects, and ensuring stakeholders business needs are heard.

3. Tour de Table

Each of the participating member of the Advisory Board introduced themselves.

4. The Advisory Board Mandate and ways of working

Key points of the Advisory Board mandate were explained by Peter Arlett (EMA). The Advisory Board will provide strategic advice and recommendations to the project team on the establishment of the DARWIN EU capability and its use of the EHDS, ensure coordination and alignment with relevant initiatives and policy at European and national level and support the communication between DARWIN EU and the EU Regulatory Network, the stakeholders and the EHDS.

Following this, the ways of working of the Advisory Board were explained. The minutes will be routinely presented to the Big Data Steering Group, and sixth-month reports will be made to the HMA and the EMA Management Board. When needed to progress its work, the Board may request input from other

committees, working parties, groups and subject matter experts, or hear representations from stakeholder groups. EMA will provide organisational and administrative support. Furthermore, the membership (names and affiliations but not contact details), the agendas and the minutes of the Advisory Board meetings will be published on the DARWIN EU webpage.

As raised by Niklas Hedberg (TLV), EMA agreed to provide advance notice of materials where members might want to consult their constituents.

5. DARWIN EU project

a. Introduction to DARWIN EU: status update and planning

Francois Domergue (EMA) and Stefan Blixen-Finecke (EMA) presented the DARWIN EU project including the different roles including that of the Coordination Centre. The scope and various technical details (as published on the ongoing tender) were also discussed, as well as the other initiatives/collaboration that will influence the work on the DARWIN EU project: the Big Data Workplan activities and the TEHDAS collaboration.

In the discussion, EMA clarified the definition of a "partner" in DARWIN EU. Indeed, data partners are organisations that have access to raw data in-house or remotely, through ownership, public contract, third-party agreement or commercial license, or who may perform analyses in a data source and provide results to the Coordination Centre. This is not limited to data permit authorities.

As such, any research network that has sufficient data quality and capacity to execute studies has the potential to be a "partner". Initially the data partnerships will likely focus on the classic real-world data sources like electronic patient health data and claims data. But as the network becomes established and new regulatory needs are identified, other type of data sources may be onboarded into DARWIN EU such as bio-markers and pharmacogenomics data sources.

EMA also clarified further the role of the DARWIN EU Advisory Board. The role of the Board is to provide strategic advice(s), and ensure coordination with relevant EU and national initiatives and policy as well as supporting communication with stakeholders. The Board will not be conducting/overseeing scientific studies run in the DARWIN EU network.

The Board noted and welcomed the ongoing collaboration between DARWIN EU and TEHDAS.

Following questions from Board members, EMA confirmed that complex studies are being planned to run from an early phase of the project, increasing the volume of studies delivered as the Coordination Centre is established over time. Each of the studies, especially for the early years, will be carefully selected to demonstrate benefits, test processes and tools, to best deliver value to EMA committees and stakeholders.

b. Use cases for RWE in EU core regulatory processes (EMA and DKMA)

Xavier Kurz (EMA) presented the use of real-world evidence and what real-world evidence do EMA committees need.

Following a question from the industry observer, EMA clarified that the process to implement these use cases for the EU regulatory network is being developed at EMA in parallel with the DARWIN EU project, including change management aspects.

After the EMA presentation, Jasper Kjaer (DKMA) presented examples of use cases for real-world evidence from a national competent authority (NCA) perspective. National use cases are similar to the EMA committees use cases, due to the nature of the committees' work 'being routed in the same evidence principles as work at national authorities. Further discussion in the Advisory Board will guide the establishment of additional use cases for DARWIN EU.

The Board discussed the complementarity and potential differences of use cases and methodologies between HTA, payers and regulation. EMA clarified that identifying such use cases was part of the mandate of the Advisory Board and as such, the various representatives of the DARWIN EU stakeholders would be welcome to provide the Board with use cases, that would in turn drive the choice of data partners, the drafting of protocols and any additional methodological work to be performed by DARWIN EU.

6. European Health Data Space & the Pharmaceutical Strategy

Ioana-Maria Gligor (DG SANTE) presented the Commission's ongoing work on the Data Governance Act and the establishment of the EHDS.

Sara Rafael Almeida (DG SANTE) presented the Pharmaceutical Strategy of Europe.

The EHDS and the Pharmaceutical Strategy for Europe will both inform the work on the establishment of the DARWIN EU network and additional time for discussion will be reserved at a subsequent meeting.

7. AOB

No AOB was raised during the meeting.