12 November 2021
EMA/745207/2021

Final Minutes – Third DARWIN EU Advisory Board meeting

12 November 2021, 10:00 – 12:00, Virtual meeting

Role	Name
Chair	Emer Cooke
Present:	Almath Spooner (EFPIA, EuropaBio, EUCOPE); Aurora Di Filipo (AIFA, IT); Claudia Furtado (INFARMED, PT); Edward van Straten (ECDC); Elizabeth Vroom (UPPMD); Katharina Schneider (BfArM, DE); Licinio Kustra Mano (EC); Magali Boers (LHD, LU); Aldo Maggioni (ESC); Malek Bentayeb (HDH, FR); Markus Kalliola (SITRA, FI); Niklas Hedberg (TLV, SE); Wim Goettsch (ZINL, NL); Hugues Malonne (FAGG – AFMPS, BE); Johanna Seppanen (THL, FI) Peter Arlett (EMA); Xavier Kurz (EMA); Francois Domergue (EMA); Sophie Groeneveld (EMA); Andrej Segec (EMA); Gianmario Candore (EMA)
Apologies:	Karl Broich; Ioana Maria Gligor (DG SANTE); Sara Rafael Almeida (EC); Mahmoud Zureik (ANSM, FR); Julien Beaute (ECDC, EU)
Minutes:	Andrej Segec (EMA)
Admin. support	Jolanta Palepsaitiene (EMA)

Item	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 b. Industry Stakeholders meeting – feedback	 Niklas Hedberg (TLV, SE) Almath Spooner (EFPIA, EuropaBio, EUCOPE)	 For discussion For discussion	 30’ 15’
4.	First discussion on communication strategy	Sophie Groeneveld (EMA)	For discussion	20’

Item	Agenda	Name	Action	Mins
5.	Tour de Table	All	For discussion	5’
6.	AOB • Information items: ○ the draft guidance, Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products issued by the U.S. Food and Drug Administration. ○ An article published by the Association of the European Self-Care Industry (AESGP), How can real-world evidence aid decision making during the life cycle of non-prescription medicines? ○ A report produced by the Open Data Institute and commissioned by Roche on Secondary use of health data in Europe ○ New TEHDAS reports published ▪ TEHDAS probes matrix of data altruism definitions ▪ TEHDAS scrutinises European data sharing initiatives ▪ TEHDAS identifies barriers for data sharing ▪ EU should rethink policies on health data access	All		

Emer Cooke (EMA) opened and chaired the meeting and welcomed members to the third Advisory Board meeting. Karl Broich (HMA) was unable to attend and sent apologies.

1. Adoption of draft agenda and minutes from the last meeting

The draft agenda and minutes from the previous meeting were adopted. There was a question from the HTA representative (Niklas Hedberg) about whether there would be a public log of open actions for transparency purposes. It was concluded that routine publication of the DARWIN EU Advisory Board (AB) minutes, combined with the Big Data website serve to deliver the necessary level of transparency.

2. DARWIN EU Project Update

Francois Domergue (EMA) presented an update on the progress of the DARWIN EU project. The selection of the Coordination Centre is progressing through the evaluation of the tender launched in June 2021, with the aim to appoint the Coordination Centre in early 2022. Work is ongoing on complementary activities to establish the list of metadata for regulatory purposes (under consultation with stakeholders), metadata repository, and catalogue of observational studies. Integration of the use of Real World Evidence (RWE) with EMA scientific committees is progressing through a series of pilots.

More pilots will begin next year as well as engagement to identify NCA's needs for analyses, potential use cases for HTA bodies, and the ongoing pilot with EHDS.

3. Listening to Stakeholders

a. Use cases for HTA

Niklas Hedberg (TLV) presented the use cases of RWE for HTA bodies.

There is wide-ranging need for RWE by HTA bodies including for appraisals of safety, effectiveness and drug utility and utilisation, both for first assessments and reassessments and to use as external control. The use cases for HTA bodies that DARWIN EU could support include natural history of diseases, standards of care, inform on design, feasibility and representativeness of studies, representativeness of clinical trials populations versus the target population, external controls, etc. Identifying relevant data sources, pooling of resources for rare diseases and improving the quality of RWD remain issues for which European collaboration will be crucial.

Wim Goettsch (ZINL) confirmed there is a lot of overlap of use cases from a payer's perspective. It is anticipated that Wim will present payers' use cases at a next AB meeting in early 2022.

Action: Wim Goettsch (ZINL): Payer use cases to be presented at a next Advisory Board meeting in early 2022.

It will be important to also consider progress and harmonisation in the area of methodologies to generate RWE, especially in light of the several ongoing or planned initiatives (funded by Horizon Europe, IMI, and IHI). And EMA could play an important role on methodologies.

The AB agreed that HTA bodies have a different mission/ compared to regulatory bodies, but synergies and commonalities can be identified in the data sources, methods and evidence needed. There is a common need to agree on metadata catalogue of resources to enable the optimal selection of sources, a common need for transparency of observational studies via a catalogue, and a common need to have access to a network of data sources and analytical tools as well as methodologies to support generation of RWE. Further recommendations on registries may also be extended to other data sources of interest for HTA and payers.

EUNetHTA21 will be the natural interlocutor to engage with to discuss RWE generation to support HTA, building on the work of the previous EUNetHTA Joint Actions and currently working to support the implementation of the new HTA legislation. **Action for EMA: liaison with EUnetHTA21 on RWE.**

b. Industry Stakeholders meeting – feedback

Almath Spooner (representing EFPIA, EuropaBio, EUCOPE) provided a summary from the industry meeting with EMA held on 27 October 2021. The meeting was appreciated and both parties welcomed the opportunity for in-depth insights and discussion about the development and use of DARWIN EU. There is interest in exploring how industry can collaborate on scientific methodologies and processes. Consultation on the metadata and quality framework will be beneficial. There is also interest for international and global collaboration on data sources and methodologies, which can be taken forward via various for a, for example ICH, CIOMS, ICMRA etc., and engagement with other regulators on RWE in 2022.

Niklas Hedberg (TLV) suggested that there should be a future discussion on international collaboration on data sharing or methodological developments as both are critically important. Peter Arlett (EMA)

confirmed that this will be addressed as part of the BDSG workplan activities for the recommendation on international collaboration

4. First discussion on communication strategy

Sophie Groeneveld (EMA) presented the communication strategy for DARWIN EU. The aim is to consult the AB on the communication goals and key messages for the next 9 months. Informed by the stakeholder analysis (presented at the previous AB meeting), targeted actions will be developed to engage with each stakeholder group.

The communication strategy aims for effective and consistent communication messages about the DARWIN EU coordination centre, the integration of RWE with the regulation decision making processes and the publication of the RWD metadata and observational studies.

Key messages include information about the project and its benefits, the timelines, the links with other strategic EU initiatives (i.e. EHDS2), the use of RWE by EMA committees, etc. Immediate actions include communication around pilots/studies to use of RWE with EMA committees and consultation on metadata. This will be followed by communication on the launch of the Coordination Centre in Q1 2022.

Markus Kalliola (SITRA) noted the need for lines to take (i.e. "DARWIN EU in sixty words" or "an elevator pitch" type document) to support the AB and other communication activities on DARWIN EU description and on the DARWIN EU AB itself. Additionally, EMA agreed with Markus to work collaboratively with TEHDAS on key communication activities.

Action: EMA to provide the AB members with lines to take (i.e. "DARWIN EU in sixty words" or "an elevator pitch" type document) to support the AB and other communication activities and containing a clear message on DARWIN EU description and on the DARWIN EU Advisory Board.

Action: EMA/TEHDAS to discuss collaboration and alignment of communication messages for DARWIN EU.

5. Tour de Table

Members were invited to ask for any questions or additional information. No further items were brought to the attention of the AB.

6. AOB

Emer Cooke (EMA) highlighted to the AB the reports shared in section 6 of the agenda.

Markus Kalliola (SITRA) asked how EMA communicates on the *link of EMA activities with TEHDAS, EHDS and other EU initiatives (e.g. GAIA-X) and it was agreed to discussed that further at the next AB meeting.*

To conclude, Emer Cooke (EMA) paid particular attention to the communication and interfaces discussed in this meeting. Potential topics for future meetings include: the benefit analysis, EC initiatives and legal proposals, and patient reported outcomes.

Next meeting: End of January 2022 (tbc)