25 September 2021
EMA/371416/2021

Final minutes - DARWIN EU Advisory Board meeting

20/09/2021 – chaired by Emer Cooke and Karl Broich

Role	Name
Chair/Vice-chair	Emer Cooke, Karl Broich
Present:	Sara Rafael Almeida (DG SANTE); Claudia Furtado (INFARMED); Hugues Malonne (FAGG- AFMPS); Magali Boers (LHD); Mahmoud Zureik (ANSM); Wim Goettsch (ZINL); Niklas Hedberg (TLV); Louisa Stuwe (HDH); Johanna Seppanen (THL); Markus Kalliola (SITRA); Julien Beaute (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); Katharina Schneider (BfArM, DE); Emmanuel Bacry (HDH); Malek Bentayeb (HDH); Gianmario Candore (EMA); Marie-Helene Pinheiro (EMA).
Not present:	Ioana Maria Gligor (DG SANTE);
Minutes:	Francois Domergue (EMA)
Admin. support	Jolanta Palepsaitiene (EMA)

Agenda Table

Item	Preliminary draft agenda	Initials	Action	Mins
1.	Adoption of the draft agenda and minutes	All	For adoption	5’
2.	DARWIN EU project update	F.Domergue	For information	10’
3.	EC legislative and policy initiatives – continued discussion a) EC legislative proposal b) TEHDAS and link with DARWIN EU c) EHDS2 pilot	 I.M. Gligor/ S. Rafael-Almeida M. Kalliola E. Bacry	For discussion	30’
4.	RWE integration in decision making	G. Candore	For discussion	10’

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5.	1st discussion on stakeholder analysis and engagement	F. Domergue	For discussion	10’
6.	Industry perspective on DARWIN EU	A. Spooner	For discussion	10’
7.	Round table discussion	All	For discussion	10’
8.	A.O.B.	All	For discussion	5’

1. Adoption of draft agenda and minutes

The draft agenda and minutes from the previous meeting was adopted with no further comments from the Advisory Board (AB) members.

2. DARWIN EU project update

Francois Domergue (EMA) presented the AB with an update on the DARWIN EU project. The project is progressing as per the agreed plan and the appointment of the Coordination Centre is on track for early 2022. The project continues to collaborate with the European Commission and the joint action for the European Health Data Space (TEHDAS) and EMA has confirmed its commitment to participate in the EHDS2 pilot.

Complementary to the DARWIN EU project, other ongoing projects at EMA will also contribute to increase access to the real-world data sources and expertise and will ultimately support the DARWIN EU services (e.g. the catalogue of real-world data – RWD - sources, the metadata repository for RWD sources, the catalogue of observational studies and the EU data quality framework).

It was clarified that the new catalogue of observational studies will be built on the foundation of the current EU PAS register.

3. EC legislative and policy initiatives – continued discussion

a. EC legislative proposal

The discussion focused on the Pharmaceutical Strategy for Europe.

Sara Rafael Almeida (DG SANTE B5) reminded the AB the key milestones of the preparation of the Pharmaceutical Strategy for Europe. In parallel of the ongoing Public Consultation (until December 2021) and of the external impact assessment study (until Q1 2022), targeted consultations are being organised with key stakeholders including the collection of several concept papers from the EU regulatory network on specific technical topics (e.g. real-world evidence and disease registries). Adoption of the Commission proposal for the Pharmaceutical Strategy for Europe is expected for Q4 2022.

Niklas Hedberg (TLV) asked if the Pharmaceutical Strategy for Europe will include any actions or suggestions to support gathering and sharing of the information on access and availability of medicines (as additional source of information) and it was confirmed that several actions are already initiated (e.g. collection of market launch intention from MAH) and that this is one of the key pillar of the future strategy. Sara Rafael Almeida offered the AB members the possibility to discuss further directly with her on specific items of the strategy. Emer Cooke (EMA) and Karl Broich (Bfarm) also confirmed that

increase access and availability to treatments is part of the Network Strategy to 2025. Use cases for DARWIN EU from HTA and payers will also be discussed in a future meeting of the AB.

Upon request from Markus Kalliola (SITRA), Sara Rafael Almeida agreed to support future discussion at the AB to navigate the complex landscape of the various EC initiatives and legal proposals (e.g. EHDS, Pharmaceutical strategy, Health Union proposal, European Health Emergency Preparedness and Response Authority (HERA)). She also offered to be contacted directly if needed.

Action EMA: to plan further discussion at the AB on the link between the various EC initiatives and legal proposals (e.g. EHDS, Pharmaceutical strategy, Health Union proposal, European Health Emergency Preparedness and Response Authority (HERA))

b. TEHDAS and link with DARWIN EU

Markus Kalliola presented the AB with the activities of the Joint Action Towards the European Health Data Space (TEHDS), helping the Members States and the Commission in developing and promoting concepts for sharing of data for the purposes for citizens' health, public health, as well as health research & innovation in Europe.

A clear link and opportunities of collaboration exists with DARWIN EU and more generally the implementation of the recommendations overseen by the Big Data Steering Group in its published workplan.

Initiated by Elizabeth Vroom (UPPMD), the AB discussed if Patient Reported Outcome (PRO) are part of the secondary use of data and it highlighted the need to discuss further PROs at a future AB.

Action EMA: to plan further discussion at the AB on the place of PROs in DARWIN EU.

TEHDAS has already made several publications on data governance, data sharing, data quality, infrastructure and data altruism and EMA should facilitate access to these publications for the AB.

Action EMA: to share publications from TEHDAS with the AB members.

c. EHDS2 pilot

Emmanuel Bacry (Health Data Hub - HDH) informed the board about the EHDS2 pilot and its key timelines and objectives. The French HDH is responsible to assemble and coordinate the consortium of European institutions, National data holders and European research infrastructures, taking part in the pilot that will aim to develop and test a network of federated nodes via 3 collaborative use cases that will be selected based on feasibility and impact to public health. The pilot is expected to run from early 2022 to late 2024.

4. RWE integration in decision making

Complementary to the presentation of regulatory use cases for RWE at the kick-off meeting, Gianmario Candore (EMA) presented the ongoing and planned work to embed the use of RWE into the EMA committees' decision making.

In 2021, building on the learning from an early pilot on the use of RWE by PRAC, EMA continued its effort, via proof of concept studies and pilots, to define the optimal set up for the delivery of RWE services to the EMA scientific committees (e.g. use cases, optimal process for request and delivery of RWE services, possible organisation and governance for the delivery of RWE services).

In 2022, implementation will continue with more pilots being launched with EMA scientific committees.

From 2023, request and delivery of RWE services is expected to be routinely available to the majority of EMA scientific committees.

The AB noted the importance of transparency and validation of study results while embracing additional sources of evidence to support decision-making processes.

5. First discussion on stakeholder analysis and engagement

Francois Domergue (EMA) presented the AB with the 'first' list of the DARWIN EU stakeholders (internal and external) groups identified and the proposed prioritisation to inform future project planning and activities on communication and change management.

The AB noted the importance to manage communication with stakeholders as well as their expectations and welcomed the opportunity to consider the stakeholder groups and prioritisation.

Action AB members: to comment in writing to francois.domergue@ema.europa.eu on the proposed list of DARWIN EU stakeholders groups by 15 October 2021.

6. Industry perspective on DARWIN EU

Almath Spooner (on behalf of EFPIA, EuropaBio, EUCOPE) presented industry reflections on the establishment and operation of the DARWIN EU network.

Industry supports the establishment of DARWIN EU, and emphasized that transparency, validation and demonstration, agreement on the questions and the methodology (study design, analysis and interpretation) to be used, following a stepwise approach, long term funding and synergies will be key to the success of DARWIN EU. In this way the use and acceptability of RWE for decision-making and to establish trust of stakeholders can be ensured.

EMA welcome the opportunity to hear the industry views and acknowledged the need to further discuss the industry reflections. EMA proposed to organise a dedicated discussion with industry representatives in October 2021. More discussion with industry will also take place via the upcoming EMA-industry R&D platform (November 2021), the Big Data Steering Group Learning Initiatives workshop (November 2021) and the annual Big Data Steering Group multi-stakeholder forum December 2021).

Action EMA: to organise a dedicated call with industry representatives to discuss DARWIN EU reflections from industry.

7. Round table discussion

No additional topic was discussed.

8. AOB

It was requested to send the meeting documents well in advance for future meetings to facilitate consultation of constituents prior to AB meetings.