16 February 2022
EMA/191243/2022

Minutes – Fourth DARWIN EU® Advisory Board meeting

Wednesday 16 February 2022, 13:30 – 15:00, Virtual meeting

Role	Name
Chair	Emer Cooke (EMA)
Present:	Almath Spooner (EFPIA, EuropaBio, EUCOPE); Aurora Di Filipo (AIFA, IT); Claudia Furtado (INFARMED, PT); Elizabeth Vroom (UPPMD); Aldo Maggioni (ESC); Malek Bentayeb (HDH, FR); Niklas Hedberg (TLV, SE); Wim Goettsch (ZINL, NL); Hugues Malonne (FAGG – AFMPS, BE); Johanna Seppanen (THL, FI); Jesper Kjaer (DKMA); Sari Palojoki (ECDC); Sara Rafael Almeida (EC) Peter Arlett (EMA); Xavier Kurz (EMA); Francois Domergue (EMA); Sophie Groeneveld (EMA); Andrej Segec (EMA); Gianmario Candore (EMA); Louis Malherbe (EMA)
Apologies:	Karl Broich (BfArM); Katharina Schneider (BfArM, DE); Markus Kalliola (SITRA, FI); Ioana Maria Gligor (DG SANTE); Mahmoud Zureik (ANSM, FR)
Minutes:	Andrej Segec (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	Andrej Segec (EMA)	For information	10’
3.	Introduction by the DARWIN EU® Coordination Centre	Peter Rijnbeek (Erasmus MC)	For information	40’
4.	Stakeholders’ views • Payers’ use cases	Wim Goettsch (ZINL)	For discussion	30’
5.	Tour de Table	All	For discussion	5’
6.	AOB	All		

Emer Cooke (EMA) opened and chaired the meeting and welcomed members to the fourth Advisory Board meeting. Karl Broich (HMA) was unable to attend and sent apologies. The Chair welcomed Sari Palojoki who replaces Julien Beauté as the ECDC representative to the Advisory board.

EMA announced that a dedicated meeting is planned to be organised by EMA for the beginning of Q3 2022 on patient experiences and patient reported outcomes. Further information will be shared in due time.

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

The draft agenda and minutes from the previous meeting were adopted. The minutes will be published on the DARWIN EU® webpage.

2. DARWIN EU® project update

Andrej Segec (EMA) presented an update on the progress of the DARWIN EU® project. The Board was informed of the appointment of Erasmus University Medical Centre Rotterdam as the Coordination Centre for DARWIN EU®, following a public procurement procedure initiated in June 2021. A number of communication activities surrounded the launch of the Coordination Centre establishment, including a press release, targeted communication to stakeholder groups including industry, academia, patients and healthcare professionals, HTA bodies and payers, as well as the EU Medicines Regulatory Network (EMRN). A multi-stakeholder information webinar is organised for 24 February 2022, to which the Board members were kindly invited as panellists.

EMA will work with the Coordination Centre in overseeing the establishment of the network, set standards and ensure progress on deliverables according to the agreed plan. Throughout 2022, work on DARWIN EU® will include performing an initial Data Protection Impact Assessment (DPIA), receipt of milestone deliverables at three-month intervals, onboarding of data partners and conduct of first studies. In parallel, work is ongoing on establishing a list of metadata for real-world data and establishing a Catalogue of real-world data sources and a Catalogue of observational studies, on which EMA is consulting stakeholders via a survey open until 28 February 2022.

3. Introduction by the DARWIN EU® Coordination Centre

Professor Peter Rijnbeek (Erasmus MC), director of Erasmus MC and of the DARWIN EU® Coordination Centre (CC) presented an introduction to the CC, together with deputy directors Professor Katia Verhamme (Erasmus MC), Professor Daniel Prieto Alhambra (Oxford University) and Carlos Diaz (Synapse Managers).

The importance of improving the interoperability of data and removing barriers was highlighted in order to achieve a scaled up network for RWE generation, including the use of a Common Data Model (CDM). The proposed CDM to be used is the OHDSI Observational Medical Outcomes Partnership (OMOP) CDM which is widely used in Europe. A large number of data partners are already available with data converted into this CDM and validated, which will accelerate the onboarding process. Standardising the analytics via a catalogue of open source standard analyses will facilitate the scale up for increasing the number of studies to be performed over time. The CC will work on prior work and experience in building a strong analytics platform and training for users.

In order to operate a high-quality data network, the CC proposes as a priority in their outreach strategy to prioritise the sources already converted to a CDM, mapping highly valued data sources to a CDM, targeting defined data sources and open calls to increase the outreach. Data sources already mapped to a CDM will undergo a final assessment of their data at the onboarding step; for sources to be mapped there will be a quality control assessment first. The CC operates a data quality dashboard for data quality control, with in excess of 3300 automated checks on the data.

The CC structure will be governed by an Executive board, to which the director will report, with five main pillars reporting to the director: Advisory boards, Development, Operations, Technology and Management. The Operations pillar will be responsible for performing studies and maintaining the network. The CC is currently in regular contact with the EMA through two meetings held every week.

A question was asked related to whether data partners who are not yet mapped to the CDM can be onboarded. It was reassured by EMA colleagues and the CC that efforts would be made to accommodate data partners who have not yet converted their data to a CDM.

4. Stakeholders' views

Wim Goettsch (ZINL) presented the payers' use cases. The landscape for payers is slightly different from regulators and often closely related to HTA bodies. A number of payers organisations and network exist in Europe, including European Social Insurance Platform (ESIP) and the Medicine Evaluation Committee (MEDEV) within it. Association of Mutual Benefit Societies (AIM) also represents payers, with a global representation. Network of Competent Authorities on Pricing and Reimbursement (NCAPR) is a voluntary network of Member States representation coordinated by the EC, usually with Ministries of Health, national social security organisation and other payer/HTA bodies. These bodies have overlaps in membership, with some payers also sharing the HTA function.

The payers' preference is usually for Randomised Clinical Trial (RCT) data when possible for their decision making and payers remain cautious regarding RWD use. Some of the organisations only have a remit for an initial assessment based on RCT data, and do not expect RWD use. RWD use is traditionally perceived as additional to RCTs, on long-term effectiveness (otherwise not available in the initial trials), on pharmacoeconomic assessment, comparing users to trial patient populations and dose-regimens used in trials and for reassessment/re-evaluation of reimbursement.

RWD collection is recommended for highly innovative technologies. This includes use in initial assessments for defining the standard of care, external comparator and cost effectiveness; in managed entry agreements (to evaluate outcomes in clinical practice and address uncertainties) and for re-assessment.

The preferred use cases from the payers' perspective are the use of (ultra-)orphan drugs and ATMPs, oncology agnostic treatments, for products with limited information after marketing and treatments targeting small patient groups and products with high uncertainty, high price and high heterogeneity. Information on historical/external controls is often necessary. The disease areas where use of RWD is included by payers include haemophilia, beta-thalassemia, spinal muscular atrophy, metachromatic leukodystrophy and oncology agnostic treatments. Additionally, an overlap of the benefits of some use cases with HTA bodies was highlighted and viewed as an opportunity for bringing stakeholders together around the particular use cases. It is foreseen to pilot a use case for payers and HTA bodies in 2022 via DARWIN EU®.

Action: EMA, HTA and payers representatives to agree on the use cases to be piloted in Q3-Q4 2022.

5. Tour de Table

No issues were raised.

6. AOB

No additional information items.

Potential topics for future meetings include: Benefits analysis, Repurposing, EHDS and Pharmaceutical strategy legal proposal.

Next meeting: **20 April 2022**