8 September 2022
EMA/629004/2022
European Medicines Agency

Minutes – Sixth DARWIN EU® Advisory Board meeting

Wednesday 6 July 2022 13:00 – 15:00 CET, 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 (20 April 2022)	All	For adoption	5’
2.	Achievements of DARWIN EU®	Andrej Segec and Juan Jose Abellan (EMA)	For information and discussion	25’
3.	ECDC use cases: initial discussion	Sari Palojoki (ECDC)	For discussion	30’
4.	EC initiatives and legal proposals and their link with DARWIN EU® • EHDS	Licinio Kustra Mano (EC)	For discussion	40’
5.	Feedback from industry meeting	Almath Spooner (EFPIA, EuropaBio, EUCOPE)	For information	15’
6.	Tour de Table	All		5’
7.	AOB • Information items	All		

Role	Name
Present	Almath Spooner (EFPIA, EuropaBio, EUCOPE), Aurora Di Filippo (AIFA, IT), Claudia Furtado (INFARMED, PT), Licinio Kustra Mano (EC, DG SANTE), Elizabeth Vroom (UPPMD), Jerome De Barros (EC, DG SANTE), Katharina Schneider (BfArM, DE), Magali Boers (LHD, LU), Aldo Maggioni (ESC), Malek Bentayeb (HDH, FR), Mario Jendrossek (HDH), Markus Kalliola (SITRA, FI), Niklas Hedberg (TLV, SE), Ander Elustondo (EC, DG SANTE), Sari Palojoki (ECDC), Wim Goettsch (ZINL, NL)

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Role	Name
	Peter Arlett (EMA), Tomas Bekisas (EMA), Sabine Brosche (EMA), Ana Cochino (EMA), Juanjo Abellan (EMA), Luca Giraldi (EMA), Maria Clara Restrepo (EMA), Riccardo Mezzasalma (EMA), Catherine Cohet (EMA)
Apologies	Jesper Kjaer (DKMA, BDSG), Sara Rafael Almeida (EC), Hugues Malonne (FAGG – AFMPS, BE), Mahmoud Zureik (ANSM, FR), Johanna Seppanen (THL, FI)
Minutes and admin support	Andrej Segec (EMA) and Sophie Groeneveld and (EMA)

Emer Cooke (EMA) and Karl Broich (Bfarm) welcomed the participants and opened the meeting.

1. Adoption of draft agenda and minutes from the last meeting (20 April 2022)

The agenda was adopted with no changes. The minutes from the last meeting on 20 April 2022 were adopted and published on the DARWIN EU® website.

2. Achievements of DARWIN EU®

Andrej Segec (EMA) gave the update on the achievements of DARWIN EU®. A shortlist of data sources for onboarding in Phase I (and for early onboarding in Phase II) was presented, which is a mix of primary and secondary care, hospital data and biobank data. In line with the consultation of the Advisory Board in April 2022, non-EU data sources are considered for onboarding where this is beneficial and valuable for RWE analyses to enrich the results (size of sources and breadth of data, enlarging the sample size for rare diseases/outcomes, etc).

Juan Jose Abellan (EMA) reminded the Advisory Board about the four types of studies foreseen for conduct via DARWIN EU® and examples of use cases which would fall in these categories. Four studies are expected to be conducted in Year 1 of establishment of DARWIN EU®, including 2 off-the-shelf studies, 1 routine repeated study and 1 complex study. Several proposals for each category of studies were presented.

EMA updated the Advisory board that an HTA/payers workshop is being planned for Q4 2022, to identify study proposals to be piloted for HTA/payers' bodies via DARWIN EU® which will be added to the shortlist of studies for Phase I and II. Lastly, Ana Cochino (EMA) updated on the adoption and publication of the List of metadata for Real World Data catalogues which links to the work on the enhancement of catalogues of data sources (ENCePP Resource database) and observational studies (EU PAS register), in order to increase data discoverability.

In discussion, it was clarified that the onboarded data partners will execute the analyses based on the code provided by the DARWIN EU® Coordination Centre, for which they will receive payment on a per-study basis. It was also clarified that a proposal for informing and/or consulting the concerned MAHs about the conduct of a study for their product(s) is being developed and the Advisory Board will be consulted (see also under point 5.). Lastly, it was noted that several new methods for RWE are being developed by consortia across Europe and these will be taken into account for DARWIN EU® studies. EMA is also in contact with EC's DG Research in the context of a Horizon Europe call for work on methodology.

3. ECDC use cases: initial discussion

Sari Palojoki (ECDC) gave the presentation on the infectious disease surveillance in the EU/EEA. The ECDC's surveillance activities include indicator-based and event-based surveillance. The work is supported by the online European surveillance portal for infectious diseases (EpiPulse). For each disease under surveillance, a list of variables (metadata) is collected, agreed with Member States and binding for data providers. These include person, place, time, clinical picture, and type of pathogen.

Among examples of such surveillance were the Legionnaires disease to inform control measures in tourist areas and the surveillance of West Nile Virus to prevent transmission via substances of human origin. Disease epidemiology studies examples include HIV infection in people over 50, who represent about one sixth of cases diagnosed in Europe and are more likely to be diagnosed with advanced disease.

ECDC's Epidemic intelligence and response work involves systematic collection of information from a variety of sources in order to perform timely risk assessments. The early warning and response system collects data from web-official information and unofficial web information, such as blogs, which can be utilised for trend analysis based on the monitored metadata. In the future, surveillance is likely going to leverage multiple data sources including genomic data, web scraping, e-health, environmental data, mobility data, surveys and other data.

A further discussion will follow in the future on the use cases relevant for ECDC to be piloted via DARWIN EU®, for example on antimicrobial resistance including health outcomes, epidemiology of diseases or vaccine effectiveness.

4. EC initiatives and legal proposals and their link with DARWIN EU® - EHDS

Licinio Kustra Mano (EC) and Ander Elustondo Jauregui (EC) presented the legal proposal for the European Health Data Space (EHDS). The proposal follows on from 2020 European Strategy for Data and the acceleration of the uptake of digital tools by the COVID-19 pandemic. The proposal aims to overcome the main challenges in harnessing the power of health data, including accessing health data by HCPs, access and control to own health data by individuals, access to health data for research and policy making and removing barriers in provision of digital health services.

The proposal aims for effective use of health data in primary use (healthcare) and secondary use (research, policy making). It links to the GDPR, building on rights and developing them further, on the European Health Union (boosting the work of EU cancer plan, HERA, Pharmaceutical strategy), complements to Data Governance Act and Data Act with tailor-made rules for health sector, EU cybersecurity framework, Artificial Intelligence Act and the Medical Device Regulations. The EHDS proposal does not intervene in organisation and delivery of health services and healthcare in Member States.

For secondary use of health data (e.g. supporting policy making, regulatory activities, research, innovation and development of health products, etc.) there are provisions for making the data accessible and provisions for data permits, cross-border access, fees and penalties. The joint action Towards the European Health Data Space, TEHDAS, is a collaboration of 25 EU countries working on governance models, data quality, technical interoperability and ways of informing citizens about the use of their health data, which will support the EHDS implementation. The governance will simplify access to data, e.g. to allow analysing data from all 27 Member States by the EMA or ECDC on a research question, via the Health data access body, with appropriate safeguard in place to protect personal data.

Benefits for HCPs include data sharing, reduced burden of unnecessary tests and repetition, better decision making and patient care, with associated savings. For industry, the EHDS will lead to the same standards in an EU-wide market for electronic health records (her) systems with greater availability of health data and foster research and innovation of new medicinal products or devices.

Researchers will benefit from the EHDS in order to identify the data and understand its quality as well as facilitated development of new medicines and devices. The EHDS will, via easier access to health data, ultimately inform decision making in policy making, improving outcomes and reducing costs in healthcare and increase efficiency for more robust health systems.

The proposal will now be followed by negotiation with the Council of the European Union and the European Parliament and will receive an opinion of the EDPS and EDPB.

5. Feedback from industry meeting

Almath Spooner (EFPIA, EuropaBio, EUCOPE) gave the feedback from the BDSG roundtable meeting on 30 May 2022.

The industry in keen to establish confidence in the system during the establishment of DARWIN EU®. The priorities relate to predictability how and when the network will be used for RWE generation (e.g. the criteria for requesting studies) for marketed and to-market products. Defined processes would be helpful to inform of when industry can expect being informed of, or involved in, the study conduct.

Transparency and engagement is important for applicants/sponsors/MAHs whose products are part of the studies (and wish therefore to be informed of plans to conduct the study), both during the pilots with EMA committees and in future routine operation. It is important to define when the implementation is complete and routine operations phase begins. Industry recommendation would be to establish a focus group working on the use cases from the RWE pilot and transition to routine operation. Opportunity to engage on complex analyses would be welcome (before study conduct, i.e. at protocol stage to review the study proposal) and the option to consider the generated evidence in the study report, before its publication in EU PAS register.

Similarly, within the work on the Regulatory capability to analyse data, linking to CHMP pilot on individual patient data submission, the industry is keen to provide input, e.g. via a focus group, into the pilots, which are voluntary.

On the topics of data discoverability and data quality and representativeness, it is important for the industry to have coordinated support for convergence and avoid unintended duplication. International collaboration will be important and the industry welcomes the collaboration on RWE via ICMRA. It is suggested that ICH guidance activities are supported with the ICMRA collaboration. Lastly, broad stakeholder engagement and continued dialogue was considered necessary for governance framework, with transparency and opportunity to interact for MAHs whose products are involved in the pilots.

6. Tour de Table

None.

7. AOB, Information items

None.

Emer Cooke (EMA) thanked the participants for rich discussions on important topics relevant for DARWIN EU® and closed the meeting.

Next meeting: 8 September 2022