24/11/2025
European Medicines Agency

Minutes – Ad Hoc (13th) DARWIN EU® Advisory Board meeting

Monday 20th January 2025 09:30 – 10:30 CET, virtual meeting

Co-Chairs: Emer Cooke (EMA) and Karl Broich (HMA)

Item	Preliminary draft agenda	Name	Action	Mins
1.	Welcome to the ad hoc Advisory board meeting	Emer, all	For adoption	5’
2.	DARWIN EU® - Outlook to the future	Patrice Verpillat (EMA)	For information & discussion	50’
3.	AOB	All	For discussion	5’

1. Welcome to the ad hoc Advisory board meeting

The ad hoc meeting of the DARWIN EU® Advisory Board was opened, and participants were welcomed by Karl Broich (HMA) and Emer Cooke (EMA).

2. DARWIN EU® - Outlook to the future

Patrice Verpillat (PV) (EMA) presented an update on the following topics: the expansion of the DARWIN EU® data network, increasing capacity and capabilities and finally giving a brief update on a selected number of DARWIN EU® studies. An up-to-date schematic of the DARWIN EU® data partner (DP) network was presented, now with 30 DPs successfully onboarded. The board was reminded that this information was confidential until published by the EMA.

In relation to DP onboarding strategy for 2025, the advisory board was supportive onboarding data sources outside of Europe, if their data is suitable and helpful for answering research questions. There was wide support for onboarding US data sources. Brian Bradbury provided, on behalf of industry associations, a brief overview of the potential US data sources which could bring value to the DARWIN EU® network. Brian also recommended to perform a gap analyses (what are the key gaps, key questions not yet answerable in current studies). Aldo Pietro Maggioni was also supportive of exploring

US data sources to enable obtaining results sometimes earlier (on recently authorised medicines) and for comparison of different healthcare systems. Some support was expressed for onboarding Swiss or Israeli data sources. Katharina Schneider noted that the data partner onboarding strategy should consider scientific committee needs, and any concerns the committee have should be addressed upfront. EMA responded that the team undertakes such interaction and considerations frequently.

Disease specific registries can also be considered when onboarding future DPs into DARWIN EU®. EMA will consider further which diseases should be prioritized in close liaison with committees. Industry observers queried what gaps have currently been identified in the data network, and addressing research questions related to paediatrics was provided as an example. In addition, clinical trials are not designed to address the needs for all population sub-groups. RWD available on certain populations (e.g., children, pregnant women, elderly) are of interest, provided we can find adequate and high-quality sources.

EMA will also explore the option to help in the conversion of non-OMOP data sources into OMOP common data model, or if of critical interest and use, may consider a source without using OMOP. In relation to onboarding further data partners from regions/countries already part of the network; the board supported continuing exploring and prioritizing data sources considering their readiness and benefits for the network, regardless of region.

In relation to upscaling capacity and capability, PV highlighted actions already planned for the calendar year. This included automation of additional analytical packages and update of some existing ones based on experience, accelerating study deliverables and proactive data mapping. Further actions will be pursued with newer data partners to help them to gain experience and increase participation in the network.

To conclude this topic, PV provided two examples of impactful DARWIN EU® studies. The first study was DARWIN EU® - Suicidality following exposure to doxycycline, which was conducted on PRAC request for the DARWIN EU® study in the context of a safety signal on this topic. The outcome of the signal assessment, which considered the DARWIN EU study results, was that current available evidence is not sufficient to establish a causal relationship and that no update to the product information of doxycycline is warranted.

The second impactful study stemmed from multiple signals (possible adverse drug reactions) after the use of CGRP agonists and the risk of insomnia, erectile dysfunction, and hypertension. The DARWIN EU® study results supported the assessment with incidence rates in the exposed and unexposed population (patients diagnosed with migraine) and the conclusion regarding the 3 different signals in a faster way.

To conclude, PV highlighted that proactive generation of RWE using DARWIN EU® will continue, especially in the context of procedures such as initial MAAs, signals, PSUSAs, etc. Increased capacity to perform studies conducted in DARWIN EU® is anticipated during this year (Feb 2025 – Feb 2026), with, for example, the first very complex study to be initiated.

3. AOB

There was no AOB. The Co-Chairs thanked the Advisory Board for their time and contributions and the meeting was closed.