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European Medicines Agency

Draft Minutes – Eleventh DARWIN EU® Advisory Board meeting

Friday 03 May 2024 13:00 – 14:30 CET, virtual meeting

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

Item	Preliminary draft agenda	Name	Action	Mins
1.	Welcome and Adoption of draft agenda and minutes from the last meeting (11th December 2024)	All	For adoption	5’
2.	DARWIN EU progress update: completion of establishment and preparation for scaling up. • Phase II completion (DPs & studies) • Strategy for phase III DPs selection • Studies in the pipeline	Andrej Segec (EMA)	For information & discussion	30’
3.	Stakeholder roundtable: impact & learnings so far, and next steps • DARWIN EU® & PDCO	Roberto de Lisa (Paediatrics Office, EMA)	For discussion	30’
4.	Stakeholder roundtable: impact & learnings so far, and next steps • Industry feedback on early experience with DARWIN EU® studies	Álmath Spooner, Brian Bradbury (EFPIA, EuropaBio, EUCOPE)	For discussion	30’
5.	Any other business (AOB) AB meeting planning (in-person)	All	For discussion	5’

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1. Adoption of draft agenda and minutes from the last meeting (11 December 2023)

Emer Cooke (EMA) opened the meeting. Emer welcomed all members to the 11th DARWIN EU® Advisory board meeting on behalf of both Co-Chairs, with a special welcome of new members:

- Carlos Martín Saborido from the Spanish Ministry of Health, joining as payer representative.
- From the European commission, Julia Schmitz, new AB member from Sante D.1 - Medicines, policy, authorisation and monitoring Unit; David Asturiol, new AB member, and Jerome de Barros, and Licinio Kustra Mano from Sante C.1 – Digital Health Unit.
- Lars Bo Nielsen and Claus Møldrup from the Danish Medicine Agency.
- Camille Thomassin from HAS, France as new alternate for HTA bodies.

The meeting agenda was adopted without changes. The minutes of the 11th of December 2023 meeting had been circulated and EMA received endorsement and no further comments. The circulated minutes will be slightly adjusted to include a post-meeting note with the additional nominations. Following their adoption, the minutes will be published on the EMA website, with the agenda of the 3rd May meeting.
The format of the meeting was slightly adjusted with the introduction of questions asked to the board prior each presentation to consider while the presentation is given. Following the conclusion of the presentation, the AB members were invited to answer the proposed questions and discuss the topic further.

2. DARWIN EU® Progress update

A progress update was provided on DARWIN EU®, focusing on the completion of the establishment phase as of February 2024 and the preparation for scaling up (related news item and infographic). This included a presentation on the completion of Phase II (or year II), with an overview of the onboarded data partners (DPs) as well as completed and ongoing studies.

DARWIN EU® has now entered Phase III, the first year of operation, in which it is aiming to onboard 10 additional Data Partners and scale up the capacity for studies. The plan is to conduct up to around 70 studies this year (exact number will differ according to finally initiated study types).

An outreach strategy for the selection of additional DPs was presented including an overview of the data partners undergoing review for potential onboarding in phase III and their data/utility, as well as a broader outreach strategy to identify more data source that might be candidates. This will include the existing open call for expression of interest from data holders as well as active outreach from EMA to complement the existing network with data partners from countries where currently there are none. Focus is primarily on large/nationwide data sources with broad use case utility, ideally with established track record in research overall, or in specific subgroups (e.g. oncology, paediatrics). Contact at national level can be facilitated via national competent authorities/committee members or existing governance bodies (e.g. BDSG) and other bodies (ENCePP, EHDEN, ISPE, EHDS pilot, etc.).

Overall, the board congratulated all the work and accomplishments highlighted here, and reacting to this presentation; several comments and suggestions were made, including:

- Considerations on the possibility of onboarding data partners whose data are not yet in the OMOP CDM and what that implies in terms of data quality and data quality checks.
- Recommendation to make public some of the insights gathered so far, and publish the scripts used for data quality checks and for the analyses to benefit to a broader audience.

- More pilots for HTA/payers, especially in terms of methodological requirements, a critical area for the data and evidence to be trustworthy.
- The importance of continuing the alignment and input from assessors.
- A strategy for identifying fit-for-purpose data in rare diseases to address research questions in this area, including the use of the framework contracts.

3. Stakeholder roundtable: impact & learnings so far - DARWIN EU® & PDCO

This presentation by Roberto de Lisa from the EMA Paediatrics Office, focused on how RWE can support regulatory decision making when assessing medicines for paediatric use. Two studies conducted via DARWIN EU®, one on Systemic Lupus Erythematosus (EUPAS106436) and the other on Juvenile Dermatomyositis & Polymyositis (EUPAS107454), were presented to showcase impact and lessons learned and how this may inform the strategy for future studies in this context. Both studies showed how RWD and DARWIN EU® have the potential to significantly support paediatric research questions, especially if sample size in paediatric area are enough, if there is longitudinal follow-up (and possibilities for linkage across databases), and when enough granular data are captured (e.g. on treatment outcomes, prescriptions behaviours, test results…)

The board was then invited to reflect on the possibilities enabled by the data currently available in DARWIN EU®, but also on the limitations highlighted and potential ways forward on how to address these, especially when considering the larger context on the New Pharma Legislation, the new HTA regulation and the EHDS.

The board appreciated all the insights from this presentation, acknowledging the challenges in this special population and offered some ideas especially in terms of identifying potential data sources with relevant paediatric data:

- Exploration of EU initiatives such as the hospital network in EU, incl via IHI.
- Tailor the outreach strategy when it comes to paediatric data sources and explore possibilities through member states and national competent authorities (including HTA and payers organisations).
- Reach out to the wider paediatric community and dialogue with paediatric clinicians.
- Leverage the HMA-EMA catalogue of data sources and explore further large and comprehensive insurance data.

4. Stakeholder roundtable: Impact & learnings so far – Industry feedback

DARWIN EU® Advisory Board industry observer and representative of industry associations, Álmath Spooner, in collaboration with her colleague Brian Bradbury (apologies for the meeting), collated and presented the observations from medicines developers based on their early experience with DARWIN EU® complex studies.

Álmath appreciated all the progress made by DARWIN EU® and the collaboration so far, highlighting industry's willingness to continue such collaboration on methods, data partners and their fitness-for-purpose assessment in study protocols. She indicated that industry wants more confidence and trust in the evidence generated for medicines regulation and appreciate the involvement of assessors in these studies.

Álmath highlighted that novel use cases originating from outside medicines regulation might pose challenges in terms of process for their review and impact, and industry wishing for a common framework of scientific rigor applicable to developers, academics and regulators in a collaborative approach. She also pointed out that more clarity on some aspects of the feasibility assessment, longer timelines for the review of complex study protocols by industry, additional transparency on the choice of methodologies and assessment of fitness-for-purpose of data sources would be appreciated.

Patrice Verpillat and Peter Arlett (EMA) provided some preliminary answers to the points raised by industry, with some solutions being immediately implementable (e.g. extending the timelines for study protocol reviews from 5 days to 10 days for a consolidated industry review) and others expected to result from dedicated brainstorming sessions and/or workshops. EMA also committed to an increased dialogue with industry both through existing channels (BDSG industry meetings, with the next meeting planned on 23 May 2024) as well as via exploring a dedicated and specific focus-group for RWE.

6. EOB

Board members were informed of the next advisory board meeting, expected to take place in the second half of September, and to be hosted as an in-person meeting (likely over a half day) at the EMA offices in Amsterdam (if possible, the Advisory board meeting will be planned close to a BDSG in-person meeting). A draft agenda is in preparation and the EMA team will be reaching out to the board members to secure a date and finalise the program in the next months.

Emer Cooke (EMA) thanked the members, presenters and DARWIN EU team for the work done and for the interactive and constructive discussions and closed the meeting.

Next meeting: TBC September 2024