

15 February 2024
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European Medicines Agency

Draft Minutes – tenth DARWIN EU® Advisory Board meeting

Monday 11 December 2023 11:00 – 13:00 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 (24 May 2023)	All	For adoption	10'
2.	AB membership renewal	Andrej Segec (EMA), All	For information	5'
3.	Update on DARWIN EU® <ul style="list-style-type: none"> Onboarding phase II Data partners Completed and ongoing studies 	Andrej Segec (EMA)	For information	20'
4.	HTA/Payers – Multiple Myeloma (and NSCLC)	Juan Jose Abellan (EMA), Niklas Hedberg (TLV)	For discussion	15'
5.	ECDC – Hepatitis B and C	Chantal Quinten (EMA), Luis Alves de Sousa (ECDC)	For discussion	15'
6.	EHDS use case	Denise Umuhire (EMA), Mario Jendrossek (HDH)	For discussion	15'
7.	Data discoverability – catalogue of data sources and studies	Ana Cochino (EMA)	For information	15'
8.	Tour de Table	All		5'
9.	AOB <ul style="list-style-type: none"> Information items Multistakeholder workshop on Patient Registries European Medicines Agency (europa.eu) 12-13 February 2024 	All		

1. Adoption of draft agenda and minutes from the last meeting (24 May 2023)

Karl Broich (HMA) opened the meeting and welcomed members to the 10th DARWIN EU® Advisory board meeting.

The meeting agenda and minutes were adopted without changes (and will be published shortly).

Post-meeting note: Minutes from the meeting on 24 May 2023 have been published on the EMA [DARWIN EU website](#).

2. AB membership renewal

The [membership](#) of the Board is being renewed for a further period of 2 years, until end of June 2025. The following changes have been implemented:

- New member for ECDC - Luis Alves de Sousa (replacing Sari Palojoki)
- New alternate for HTA bodies - Camille Thomassin (HAS, France)
- Payers representative Wim Goettsch stepped down.

The Board noted the membership renewal and update. Extra nominations are awaited from payers' organisations and the EC, and membership will be updated accordingly.

Post-meeting note: Carlos Martín Saborido was nominated on behalf of payers' organisations ESIP, MEDEV and AIM. The European Commission nominated Julia Schmitz (SANTE D.1 - Medicines, policy, authorisation and monitoring Unit) and David Asturiol (SANTE C.1 – Digital Health Unit), with Jerome de Barros as alternate.

3. Update on DARWIN EU®

Andrej Segec (EMA) presented the update on onboarding of phase II data partners and the completed and ongoing studies. The establishment of DARWIN EU has been progressing to plan with focus on enlarging the network and conducting further studies of diverse use cases which allow the preparation of further analytical pipelines. Ten data partners from further five EU countries are being onboarded into the network. In total, 18 studies are being performed in Phase II of DARWIN EU.

Further updates noted the consultation of industry and the EMA's MWP on the DARWIN EU Catalogue of standard analyses in summer 2023, the comments from which will be passed over to the Coordination centre for an update of the catalogue and the corresponding website information for increased clarity. More clarity will also be provided via FAQs on the industry consultation process for the (complex) studies, as previously discussed.

Karl Broich (HMA) welcomed the progress on the DARWIN EU network and the increase in the size of the network with additional DPs becoming available.

In discussion, questions arose on the analytical pipelines and the code which they use, and whether this can be used by other researchers. It is indeed the business model of DARWIN EU that analytical code is made available via GitHub repositories relevant for each study, which allows reuse of the code and phenotypes by other researchers or international regulators who have the data available after OMOP conversion. Supportive comments were received for more clarity to the industry via the FAQs.

4. HTA/Payers – Multiple Myeloma (and NSCLC)

Juan Jose Abellan (EMA) presented the study objectives. The study focuses on the characterisation of patients with multiple myeloma (MM), their treatments and survival in the period 2012-2022. The study report was recently finalised and will be published in the study entry ([EUPAS105033](#)) of the [Catalogue of RWD studies](#), which replaces the EU PAS Register (see agenda item 7).

The study results include patient characterisation in terms of demographics and comorbidities, and pre-specified medications. Treatments received from 1 to 365 days after diagnosis were summarised by class and by substance. Treatment sequences were analysed only by CDW Bordeaux. One-, three- and five-year Kaplan-Meier survival estimates were calculated.

Niklas Hedberg commented on behalf of HTAs with appreciation of the speed and large amount of useful data answering some of the questions HTAs have had and useful for the future understanding what data and questions can be studied. For some questions, information may need to be derived from RCTs, as done before. Further studies are foreseen for the use cases collected by HTAs/payers, which will be further informative. Further experience will be gained in dealing with the results, which vary by the size of the datasets – some being large, some small. The (other HTA/payer use case in) NSCLC will be yet another, and closer in terms of data that HTAs/payers look for, important use case for which they are keenly awaiting results. The data and progress seen so far is encouraging.

EMA will be hosting a follow-up (closed) workshop of HTA/payers use cases on 15 Dec 2023. The MM study results will be discussed in a deep dive and further research questions relevant to HTAs/payers will be worked up.

5. ECDC – Hepatitis B and C

Chantal Quinten (EMA) presented the study objectives on behalf of Dr Erika Duffell (ECDC, Principal Expert on Hepatitis) and Dr Luis Alves de Sousa (ECDC, Expert in General Surveillance and eHealth). This use case was selected as a pilot use case as part of the public health programme aiming at elimination (90% reduction in new infections and 65% reduction in mortality) of viral hepatitis by 2030. Monitoring systems for hep. B and hep. C are in place for EU member states, with indicators for monitoring the goal progress. Further work is needed to achieve complete collection of indicator data by MSs.

Six DARWIN EU data partners were selected to contribute to this study, including the Clinical Data Warehouse of Bordeaux University Hospital (CHUBX), France; Clinical Practice Research Datalink GOLD (CPRD GOLD), United Kingdom; Estonian Biobank (EBB), Estonia; IQVIA Disease Analyzer Germany (IQVIA DA Germany), Germany; Institut Municipal Assistencia Sanitaria Information System (IMASIS), Spain and the Integrated Primary Care Information Project (IPCI), The Netherlands.

The study has four objectives:

1. To report the number and percentage of patients diagnosed with chronic HBV/HCV infection who initiate treatment with interferon or any specified antivirals, stratified by age, sex, calendar year, and country/database throughout the study period (2012 - 2022).
2. To report the number and percentage of patients diagnosed with chronic HBV/HCV infection who are undergoing treatment with any specified antivirals, stratified by age, sex, calendar year, and country/database during the study period (2012 - 2022).
3. To characterize patients with chronic HBV/HCV infection who initiate treatment with interferon or specified antivirals, stratified by age, sex, calendar year, and country/database during the study period (2012 - 2022).

4. To estimate the proportion of all patients with chronic HBV/HCV infection, stratified by age, sex, calendar year, and country/database during the study period (2012 - 2022).

Luis Alves de Sousa (ECDC) welcomed the collaboration and this pilot use case, as this will complement the existing data available to the ECDC and allow exploring what additional value RWE can bring. The ECDC are awaiting results with interest. The study report will be completed by January 2024 and will be published in its study entry ([EUPAS107650](#)) of the [Catalogue of RWD studies](#).

6. EHDS use case

This DARWIN EU study was selected to help inform the infrastructure of EHDS, and is one portion of the broader use case on [Thrombosis in COVID-19 patients](#). The study and use case will provide learnings on the access to data, variability of GDPR implementation and how data minimisation principle is established. A common protocol may need to be adapted for different countries – vis-à-vis the expected single application form for future EHDS. First results (this portion of the use case) will be the DARWIN EU study results, expected in January 2024. The DARWIN EU study includes five data partners from five countries and aims to address all five objectives of the main use case. The analytical code will be made available together with the study report, to aid with the other nodes involved in the use case. The DARWIN EU study report will be published in the study entry ([EUPAS106679](#)) in the [Catalogue of RWD studies](#).

Mario Jendrossek (HDH) noted the good progress with this study delivered by DARWIN EU, which also inspires the other nodes and use cases. Good feedback is received from involved study partners. It will be interesting to see how EU agencies (incl. EMA) can contribute in the larger future EHDS framework, and how DARWIN EU (and other national or international nodes) can operate while the legislation is still being implemented.

7. Data discoverability – catalogue of data sources and studies

Ana Cochino (EMA) presented the update. The EMA-HMA Catalogues of data sources and non-interventional studies will describe real-world data sources and studies through a set of collected metadata to help pharmaceutical companies and researchers identify and use such data when investigating the use, safety and effectiveness of medicines.

For the Catalogue of real-world data sources, the [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance \(ENCePP\) Resources Database](#) will migrate to the EMA corporate website and will include more metadata elements. It will be linked with the Catalogue of studies. The Catalogue of RWD studies will enhance the [European Union electronic register of post-
authorisation studies](#) (EU PAS Register®). Mock-ups of the catalogues under development, including a demonstration of the user journey and search options were provided. Post-release, further integration with the EMA medicines pages is planned, to include links to product-relevant studies in the respective medicines pages containing the EPARs, PI, RMP, etc. in one place. Communication activities for the pre- and peri-launch period were highlighted.

Questions were raised on the links with other catalogues and the Sciensano (BE)-developed DCAT health extension. Ana confirmed such links are being explored and contact between parties under WP6. Feedback provided on the health extension of DCAT has been mutually fruitful with the EMA's catalogue informed by the developments and feedback given back. The soon-to-be released EMA/HMA catalogues are expected to be compatible with the standard.

Post-meeting note: the [Catalogue of RWD sources](#) and [Catalogue of RWD studies](#) were launched on 15 February 2024. EMA will host a [webinar on the catalogues on 4 March 2024](#) from 10:00 to 12:00 CET.

8. Tour de Table

Emer Cooke (EMA) invited AB members to share any relevant information. Praise was given on the progress on all the presented updates at the meeting today.

Peter Arlett (EMA) commented on the recent meeting of the BDSG which was held in the face-to-face format. It would be an excellent opportunity to hold an AB meeting in 2024 in person, perhaps adjacent to another upcoming workshop or meeting (several planned in 2024) which would give an opportunity for detailed discussions and exchanges.

9. AOB

Board members were informed of the upcoming [Patient Registries workshop](#) to be held on 12-13 February 2024.

Members noted the utility of sharing information on similar events, for inclusion in the TdT or AOB of the agenda in the future. Further work on the visibility and communication of this achieved work and in line with parallel activities will require further reflection and re-discussion in the future.

Emer Cooke (EMA) thanked the members, presenters and DARWIN EU team for the work done and concluded the meeting with wishes of a happy end of the year and best wishes for 2024 and good progress for DARWIN EU in 2024.

Topics for future meetings: Benefit analysis, repurposing, role of DARWIN EU® in the international RWE landscape

Next meeting: TBC Q2 2024
