

24/11/2025  
European Medicines Agency

## Minutes – 12<sup>th</sup> DARWIN EU® Advisory Board meeting

Monday 25<sup>th</sup> November 2024 09:30 – 11:30 CET, virtual meeting

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

| Item | Preliminary draft agenda                                                                                                                                | Name                                                                                                                                                                                                                     | Action                       | Mins |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|------|
| 1.   | <b>Welcome to the 12<sup>th</sup> Advisory board meeting and adoption of draft agenda and minutes from the last meeting</b> (03 <sup>rd</sup> May 2024) | Karl Broich (HMA), all                                                                                                                                                                                                   | For adoption                 | 5'   |
| 2.   | <b>2024 - DARWIN EU® in review</b>                                                                                                                      | Andrej Segec (EMA)<br>Alexandra Pacurariu (EMA)                                                                                                                                                                          | For information & discussion | 20'  |
| 3.   | <b>Stakeholder roundtable</b>                                                                                                                           |                                                                                                                                                                                                                          | For discussion               |      |
|      | <b>Collaboration with HTAs and payers</b>                                                                                                               | <i>Presentation by</i> Juan Jose Abellan (EMA) <i>or</i> Maria Clara Restrepo-Mendez (EMA)<br><br><i>Comments from</i> Niklas Hedberg (TLV), Camille Thomassin (HAS) and Carlos Martín Saborido (Ministry of Health, ES) |                              | 20'  |
|      | <b>Collaboration with ECDC</b>                                                                                                                          | <i>Presentation by</i> Chantal Quinten (EMA)<br><i>Comments by</i> Luis Alves de Susa (ECDC)                                                                                                                             |                              | 20'  |
|      | <b>Collaboration with industry</b>                                                                                                                      | <i>Presentation &amp; comments by</i> Patrice Verpillat (EMA) &                                                                                                                                                          |                              | 20'  |

| Item | Preliminary draft agenda                                                             | Name                                                                                                              | Action         | Mins |
|------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------------|------|
|      |                                                                                      | Almath Spooner (EFPIA)                                                                                            |                |      |
| 4.   | <b>EHDS – its implementation and how it might impact the landscape for DARWIN EU</b> | <i>Presentation and comments by</i><br>Licinio Kustra Mano (EC)<br>Denise Umuhire (EMA)<br>Mario Jendrossek (HDH) | For discussion | 20'  |
| 5.   | <b>Looking forward</b>                                                               | Patrice Verpillat (EMA)                                                                                           | For discussion | 10'  |
| 6.   | <b>AOB</b>                                                                           | All                                                                                                               | For discussion | 5'   |

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

The 12<sup>th</sup> meeting of the DARWIN EU® Advisory Board was opened, and participants were welcomed by Karl Broich (HMA) and Emer Cooke (EMA).

The agenda of this meeting and the minutes from the previous meeting, 3 May 2024, were adopted without amendments and will be published on the [DARWIN EU® website](#).

## 2. DARWIN EU® Progress update

An overall update on the progress was given by Andrej Segec (EMA) and Alexandra Pacurariu (EMA). The Board was invited to reflect on DARWIN EU® accomplishments so far, to inform recommendations for the next phase.

An in-depth presentation of three recent DARWIN EU studies requested by the PRAC was done, illustrating the impactful contribution of DARWIN EU. All three presented studies were close to finalisation but still ongoing (to be considered as confidential information until study reports are uploaded in the EMA/HMA RWD Catalogues) and the Board was informed of high-level results.

The studies were:

- [CGRP antagonists](#) - treatment patterns and users characteristics
- Duration and indications of treatment with [azathioprine](#)
- [Incidence of suicidality](#) (completed /attempted suicide, suicide ideation and intentional self-harm) in patients with specific chronic skin condition

In addition, figures from the second [RWE Annual Report](#) were shown, and a confidential overview of current study requests, ongoing phase III studies and data partners being onboarded was also presented.

## 3. Stakeholder roundtable

### HTA bodies/Payers

María Clara Restrepo-Méndez and Juan Jose Abellan (EMA) gave an update on the currently ongoing study: [Overall survival in patients with advanced or metastatic non-small cell lung \(NSCLC\) cancer treated with selected immunotherapies as first line of treatment](#). This is a pilot study being conducted on behalf of HTA bodies and payers. The interim report for this study has been completed. Niklas Hedberg (HTA) commended the EMA study team for the collaborative effort. Patrice Verpillat and Carlos Martín Saborido (Payers) both advocated for further collaborative efforts, particularly methodological discussions to be carried forward. Karl Broich (BfArM) also noted the importance of future collaboration due to the upcoming HTA regulation. There was a brief discussion on one of the other shortlisted studies, on the *Risk of major cardiovascular outcomes in overweight and obese individuals treated with GLP-1 receptor agonists, for which* Carlos Martín Saborido (Payers) gave context on why the study was not feasible.

### ECDC

Chantal Quinten gave a presentation on the recently completed DARWIN EU® [study: Use of antivirals for the treatment of chronic hepatitis B and C](#). She provided information on the ECDC's monitoring system which monitors progress to hepatitis elimination and presented the DARWIN EU® study objectives, data partners, results and study limitations.

### Industry

Patrice Verpillat (EMA) provided an update on the newly formed EMA/Industry focus group on use of RWD and generation of RWE. The main objective of this focus group is to share knowledge and experience with use of RWD and generation of RWE to advance integration of relevant and reliable RWE in regulatory decision making.

- Objective: Enhance RWE generation integration in regulatory decisions.
- Membership: Representatives from EFPIA, EUCOPE, EuropaBio, Vaccines Europe and AESGP.
- Next meeting scheduled for 3 December, focusing on Q&A processes for RWE.

Niklas Hedberg noted challenges in aligning industry expectations with unpredictable, high-quality RWE results. Álmath Spooner (EFPIA) expressed industry's commitment to DARWIN EU collaboration.

#### **4. EHDS – its implementation and how it might impact the landscape for DARWIN EU**

Licinio Kustra Mano (EC) gave a presentation on the EHDS, which included aims, improvements on how to identify the correct data and its secondary use, and overall implementation timeline going forward. Denise Umuhire (EMA) presented the HealthData@EU pilot in which EMA participated as an EU agency (alongside ECDC and other national public health institutions) and future users of EHDS. Key operational and methodological learnings were highlighted, and these will be summarised in the report of this pilot project to be considered for the preparation of the EHDS implementation. Mario Jendrossek (HDH) provided the perspective of a future Health Data Access Body that was also part of the EMA use case in this pilot, underlining important considerations in terms of infrastructures, governance and processes for the implementation of the EHDS regulation and the need to further define opportunities for DARWIN EU and ensure seamless data access.

#### **5. Looking forward**

It was decided to have an ad-hoc meeting early 2025 to address this important agenda item.

#### **6. AOB**

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. The Board agreed to have an additional meeting in January 2025 to complete the agenda.

**Next meeting: Q1 2025**

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