DARWIN EU® to support HTA and payers' research RWE needs

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Multi-stakeholder workshop on Real World Data (RWD) quality and experience in use of Real World Evidence (RWE) for regulatory decision-making
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Presenter name and surname, TDA

An agency of the European Union

Key stakeholders for the establishment of DARWIN EU®

Patients & **Healthcare Professionals**

European commission, including Agencies (ECDC) and initiatives e.g. EHDS & TEHDAS

EU Regulatory Network, e.g. National Competent Authorities, Head of Medicines Agencies, and EMA committees

Health Technology Assessment bodies & **payers**

Data Holders & Partners, e.g. NCAs as data holders, Data permit authorities, Disease Patient registries

Industry

Academia and Research organisations

- Representatives from each group are member of the DARWIN EU® Advisory Board. Members have been and will continue to support the implementation of DARWIN EU®, the alignment with EU initiatives and the engagement with stakeholders
- Consultation and dialogue with all stakeholders planned through fora and workshops
- Implementation will be transparent including on processes and operations

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Workshop: How can DARWIN EU® support HTA/Payer decision-making?

- Virtual workshop held on 6th October 2022
- Participation: 30+ representatives from HTA and Payers organisations across the EU
- Objectives:
  - To raise awareness of the possibilities of RWE generation via DARWIN EU®;
  - To better understand the HTA/payers research questions of interest suitable for RWE analyses;
  - To identify simple and complex use cases from HTA/payers perspective that could lead to studies conducted by DARWIN EU®.
- Structure: 3 presentations (DARWIN EU, HTA perspective, Payers perspective) followed by open discussion

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Workshop outcomes

General aspects:

- Need to address concerns that may be an obstacle to use RWD for decision making, mainly related to RWD quality
- Transparency on how DARWIN EU® will operate will be helpful
  - All protocols and reports of DARWIN EU® studies will be published in EU PAS register

Data:

- RWD volume and variety will increase as network of DPs of DARWIN EU grows
- Availability of some data (e.g. PROs) relevant for HTA decision making in RWD?
- Registries better suited than RWD sources?

Topics for studies:

- Effectiveness
- Natural history of disease
- Methodology (e.g. digital data, AI/ML)

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Specific ideas for studies

- Several suggestions made at the Workshop
- Two studies agreed to progress subject to the feasibility assessment:
  - **Natural history of multiple myeloma**. Study to characterise MM patients, including treatments received (monotherapies, in combination), treatment sequences and survival
    - Study Protocol being finalised
  - **Study to characterise patients with non-small cell lung cancer treated with immunotherapies (pembrolizumab, nivolumab, atezolizumab, etc.) as first line**.
    - Specific study objectives currently under development

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Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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