## 2<sup>nd</sup> annual Big data multi-stakeholder forum



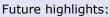


HMA EMA BDSG Recommendation: Regulatory processes for data



## Achievements:

- Review of Real World Evidence (RWE) in Marketing Authorisation Applications (MAA) and extensions of indications (Flynn et al., 2021)
- Learnings initiative workshop to systematically learn from applications to the Network
- Proof of concepts and pilots for delivery of RWE generated by the network started with SAWP, COMP, PDCO and CAT. Amending processes to routinely support PRAC based on the pilot lessons



- Investigate qualitative aspects of the RWE submitted in applications to characterise their contribution to the B/R evaluation and decision making
- Extend use cases, define processes and start pilots for the delivery of RWE generated by the network to CHMP, NCA, HTA and Payers
- BDSG discussion on **pharmacogenomic use cases**
- By 2025 RWE enabled and value established



## Benefits:

- Better understanding of the use and characteristics of RWE in applications submitted to EMA by medicines developers
- Support individual product submission and guidelines by learning from current experience
- Processes for the delivery of RWE generated by the network established and optimised, clear understanding of the type of data sources needed
- Enable more use of RWD, which can accelerate the availability of treatments for patients
- Regulation more data-driven and better understanding of the role of RWE across the spectrum of regulatory use cases

How to engage with the ongoing activities:

- Results of the contribution of RWE to the B/R decision making will be presented to EMA committees and working parties; a publication will follow
- Results of the proof of concepts, pilots and lessons learnt will be presented to internal and external stakeholders and process aspects will be discussed e.g. transparency for research questions and results from regulators

