2nd annual Big data multi-stakeholder forum

EUROPEAN MEDICINES AGENCY

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

Future highlights:

- 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