



HMA EMA BDSG Recommendation: Collaborate with international initiatives on Big Data and deliver a data standardisation strategy




Achievements:

- Based on extensive stakeholder consultation, a data standardisation strategy (DSS) created and adopted by the BDSG and EU Network Data Board (EUNDB), to be published by January 2022.
- The EMA-FDA-HC Big Data Cluster working towards a RWE collaboration roadmap.
- PMDA and FDA were consulted on the DARWIN EU design.
- Collaboration workshops on COVID-19 observational studies organised through ICMRA (EMA & HC Cochair)




Future highlights:

- Veterinary requirements to be added to the DSS in 2022.
- The BDSG & EUNDB will make proposals for actions needed to implement the recommendations.
- A RWE workshop with international regulators is in planning.
- Development of the ICH pharmacoepidemiology safety studies guideline is planned



Benefits:

- The DSS will support collaboration & coordination within the EU regulatory network and internationally.
- The ongoing collaboration activities with international regulatory parties on common requirements will enable a quicker development and implementation of harmonized systems and data standards.
- Convergence between international regulators will optimize design, conduct and reporting of studies



How to engage with the ongoing activities:

- Stakeholder input will be sought on the planned revision of the DSS in 2022
- Information on international regulatory initiatives will be placed on the Big Data website
- Information on the COVID-19 observational collaboration via ICMRA website.