



HMA EMA BDSG Recommendation: **Regulatory capability to analyse data**



Achievements:

- The drafting of the discussion paper on **Clusters of Excellence** initiated to bring together learnings from national approaches to data analytics
- The **raw data pre-pilot's** lessons learned finalised and an **Advisory group on Raw Data** established
- The design of the 2022 proof-of-concept Clinical Trials raw data pilot has started
- The **Advanced analytics pilot to leverage information in documents submitted to regulators** started and successful first demo



Benefits:

- The work on **Clusters of Excellence** will provide good practice to the EU regulatory network, in the area of: Data access, Legal aspects, Capabilities, Infrastructure, Method development and AI
- The proof-of-concept **MAAs raw data pilot** will determine the regulatory benefit when accessing and analysing raw data. It will assist the Network to understand and take informed decisions on the place of analysis of raw data for future regulatory submissions.
- **Advanced analytics pilot** will enable faster identification of key procedures with similar characteristics and will enable easier and more accurate identification of patterns across procedures to enable research and support generation of guidance.



Future highlights:

- Publication of the discussion paper on **Clusters of Excellence**
- **Proof-of-concept raw data pilot kick-off** by Q2 2022
- **Scope raw data for non-clinical** in Q3 2022
- **Network's review** on interim lessons learned from raw data analysis of MAAs
- **Scope business case for raw data for manufacturing and quality** in 2022
- **Draft AI Guidance** in late 2022
- **Advanced analytics pilot preliminary findings** in Q2 2022 and **report** in Q4 2022



How to engage with the ongoing activities:

- Watch out for the **discussion paper on Cluster of Excellence**; NCAs can share lessons/recommendations to increase EU regulatory network capabilities and capacities in the area of big data
- Watch out for the **workshop on the submission and analysis of raw data** in MAAs in late 2022
- Updates related to **MAAs raw data pilot** via presentations to internal and external stakeholders
- **Follow-up AI workshop** in early 2023 (might be brought forward)
- Updates on **advanced analytics pilot** will be presented to committees and EMA working parties in early 2022