



HMA EMA BDSG Recommendation: **Secure and ethical governance framework**



Achievements:

- EMA draft Q&A on data protection and secondary use of health care data prepared
- 2020 public workshops with stakeholders on data governance and data protection
- Exploratory discussion on BDSG recommendations on data ethics => agreement to follow ongoing initiatives (e.g. TEHDAS) and to identify advisory experts



Benefits:

- Enable consistent application of EU data protection law in the context of the secondary use of health data
- Operate within an ethical framework for big data research taking into account ongoing initiatives and expert advice



Future highlights:

- 2022: Publish data protection Q&As on secondary data use (subject to availability EDBP guidelines – scientific research)
- 2022: EHDS legal proposal discussion on implications for medicines regulation
- 2022: Strengthen ethics expertise
- Q3 22: Launch data protection training through EU NTC
- Q4 22: Workshop with TEHDAS on data governance
- Q1 23: BDSG mandate review and benefits assessment



How to engage with the ongoing activities:

- Participate in data protection initiatives
- Engage in multi-stakeholder forums
- Follow latest developments at EMA Big Data webpage <https://www.ema.europa.eu/en/about-us/how-we-work/big-data>