



HMA EMA BDSG Recommendation 2: Data quality and representativeness: Develop guidelines, a strengthened process for data qualification through Scientific Advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure data availability.



Achievements:

- Project launched to deliver 1st version of EU data quality framework for data used for regulatory purpose
- plans initiated for industry focus group on qualification process through Scientific Advice Working Party
- Collaboration established with 'TEHDAS – Towards a European Health Data Space'.

Future highlights:

- Data Quality workshop Q1 2022
- 1st version of the EU Data quality Framework for data used for regulatory purpose (Q2 2022)
- Recommendations to strengthen data qualification informed by a review of current process and a workshop (?Q3 2022)
- Future proof data quality work through collaboration with TEHDAS (in anticipation of the European Health Data Space)



Benefits:

- Establish norms for data quality including for real world data
- Provide clarity for data collectors and data managers on quality
- Support the assessment of data sources and of study results
- Increase the impact of individual data sources through their qualification (for regulatory decision-making)



How to engage with the ongoing activities:

- Dedicated Data Quality workshop planned for Q1 2022
- Participate in stakeholder consultation on data quality framework
- Data qualification workshop Q3 2022
- Follow announcements on Big Data webpage

