



HMA EMA BDSG Recommendation: Develop EU Network skills in Big Data. Develop a Big Data training curriculum and strategy based on a skills analysis across the Network, collaborate with external experts including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI.



Achievements:

- April 2020: Real-world data curriculum adopted
- Jun 2020: Biostatistics curriculum adopted
- July 2020: Training signpost made available in EU-NTC
- May 2021: Results of Survey of EU Network skills
- Sep 2021: Data Science curriculum adopted

Future highlights:

- Q1 2022 launch procurement for external training providers for the three Big Data curricula
- April 2022: BDSG consultation on additional training needs (e.g., pharmacogenomics)
- 2022 - 2023: Roll out of trainings of Big Data curriculum (Pharmacoepidemiology, Biostatistics, Data Science) to EU Network via EU Network Training Centre
- Jan 2023: Establishment of EU Network Digital Academy



Benefits:

- The level of expertise on pharmacoepidemiological methods and biostatistics will be increased throughout Europe
- Increased contribution from regulators to the definition of research questions, study protocols and interpretation of study results, informed advice on strengths and weaknesses of using certain types of data sources



How to engage with the ongoing activities:

- Follow EMA announcements and publications
- Consider the EMA call for training providers
- Provide feedback following attendance of courses
- Highlight additional training needs

