



EMA EMA BDSG Recommendation: Modernise the delivery of expert advice. Establish a Methodologies Working Party - encompasses biostatistics, modelling and simulation, extrapolation, pharmacokinetics, real world data, epidemiology and advanced analytics. + establish Omics expertise.



Achievements:

- 2021: EMA Management Board agrees on the creation of a methodologies working party
- July 2021: Revision of the [ENCePP guide](#) on methods
- Oct 2021: new CHMP [Guideline](#) on Registry based studies
- Big Data learning initiative workshop 30 November 2021



Benefits:

- Strengthening of expert advice on Big Data and methodologies
- Development of comprehensive guidance across data and methods
- Foundation for conducting and assessing high quality studies that generate evidence for regulatory decision making



- Call Horizon Europe Cluster 1 Health: New methods for the effective use of RWD in regulatory decision-making
- Establish Methodology WP Q1/Q2 2022, include:
 - Biostatistics
 - Real world evidence
 - Advanced analytics
 - PK/PD, extrapolation, modelling and simulation
 - GCP
 - Omics



How to engage with the ongoing activities:

- Participate in future public consultation on guidance related to the use of RWE for regulatory purposes
- Follow proposals for stakeholder outreach from methodologies working party