



Sept 23 2020

Overview of Big Data Steering Group workplan

Nikolai C Brun, MD PhD

Chief Medical Officer , DKMA

Chair HMA-EMA Steering Group on Big Data

The HMA-EMA Big Data Steering Group

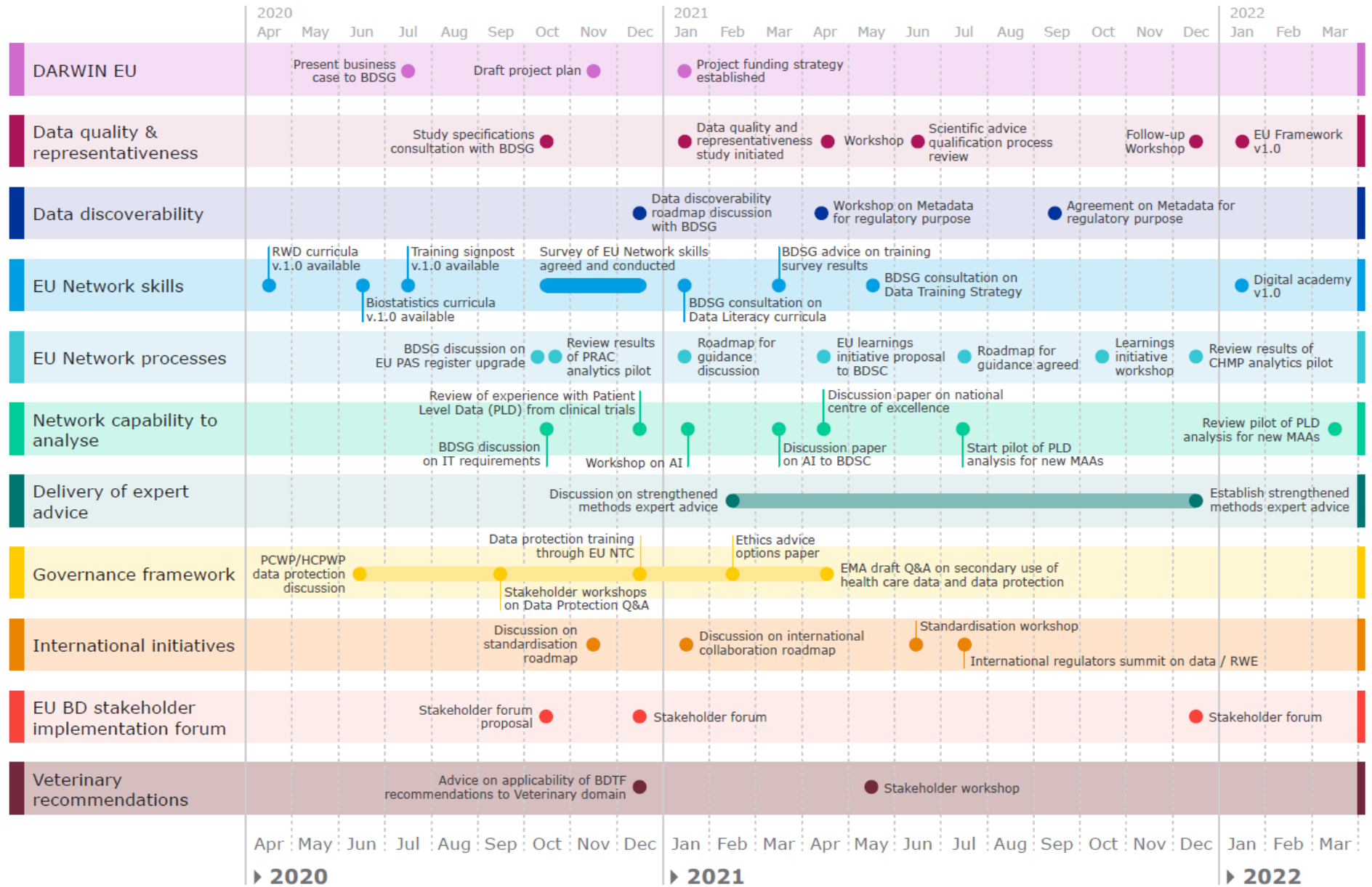
HMA/EMA JOINT BIG DATA STEERING GROUP

The HMA/EMA joint Big Data Steering Group supersedes the Big Data Task Force and covers the following tasks:

1. Making proposals to HMA and EMA MB for the prioritisation and planning of actions to implement the recommendations from the Task Force report.
 - Oversee those actions that the Network decides to run.
 - Monitor other relevant actions that are not run at Network level.
 - Maintain an inventory of ongoing EU Regulatory Network projects relevant to Big Data.
2. On request, providing input on strategic planning including the Network Strategy to 2025 and the EMA multi-annual workplan.
3. Making proposals to HMA and EMA MB for the definition and measurement success factors.
4. Supporting communication on Big Data to the Network and its stakeholders.
5. Monitoring for reports and publications on data analytics and tools relevant to advances in the science, technology, legislation, and regulation of Big Data to identify opportunities and threats and make recommendations to HMA and EMA MB.
6. Identifying product applications relevant to Big Data, not fully regulated by the current EU framework.
7. Ensuring coordination and alignment towards goals with the Commission services (including flagship policy initiatives such as Europe's Beating Cancer Plan and the European Health Data Space), HMA and EMA on any ongoing or new initiatives.
8. Identifying funding opportunities relevant to the priority recommendations on Big Data.
9. Ensuring that the perspectives of patients, pet and livestock owners and healthcare professionals are considered when making recommendations.

BDSG: The Plan

THE HMA-EMA JOINT BIG DATA STEERING GROUP WORKPLAN



Thank you for your attention!

All documents available on :
WWW.HMA.EU