



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Big Data Steering Group update

PCWP/HCPWP joint meeting, 1-2 June 2022

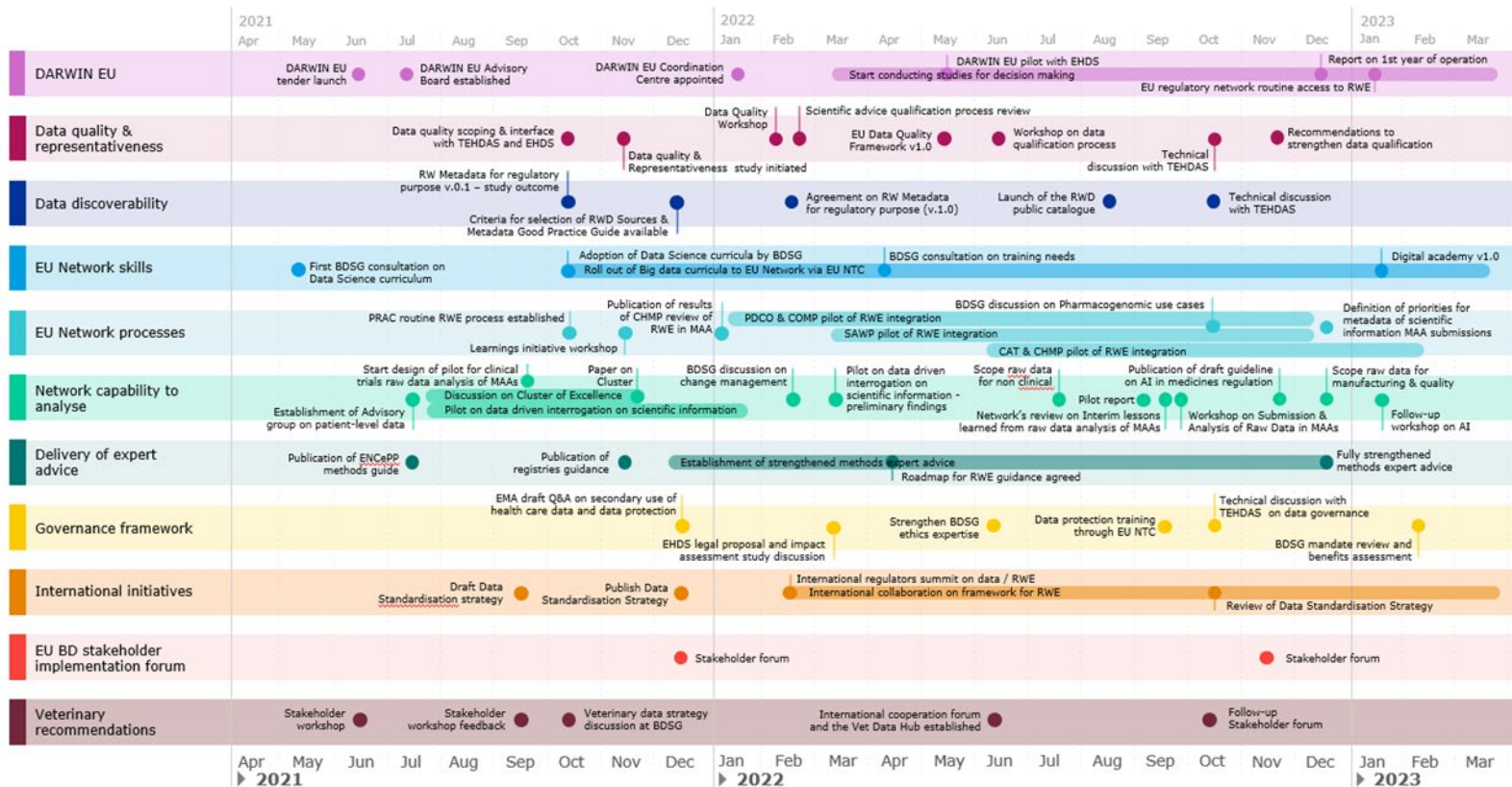
Peter Arlett– Co-chair, Big Data Steering Group



Joint HMA-EMA BDSG workplan 2021-2023



EUROPEAN MEDICINES AGENCY



On track

DATA QUALITY	<p style="text-align: center;">EMA/HMA/TEHDAS Data Quality Framework workshop: 7 April 2022</p> <ul style="list-style-type: none">• Objective: share progress on building a data quality framework (DQF) for medicines regulation, solicit feedback. Thank you for contributions from patients and HCP representatives• Next steps: Workshop report to be published on the EMA website in coming weeks. Feedback to be considered in drafting of the DQF. Written consultation in Q3.
DATA DISCOVERABILITY	<p style="text-align: center;">Agreement of real-world metadata list for regulatory purposes</p> <ul style="list-style-type: none">• Metadata list for real-world data sources for EMRN prepared as part of MINERVA study• Consultation of ENCePP, industry and international regulators - completed• Webinar with EU Network Data Board and TEHDAS to guide through meta-data list and collect feedback• Final update and adoption of metadata list foreseen by BDSG in Q3
EU NETWORK SKILLS	<p style="text-align: center;">Launch of the Big Data Curriculum Tender</p> <ul style="list-style-type: none">• Biostatistics, pharmacoepidemiology, data science• The open tender was published on 13 April 2022. Closing date was 31 May 2022• Framework contract signature is expected Q4 2022• Content development will therefore start from the end of the year
STAKEHOLDER ENGAGEMENT	<p style="text-align: center;">BDSG and industry forum</p> <ul style="list-style-type: none">• Why: industry is not represented on the BDSG• Objective: regular (bi-annual) engagement with industry stakeholders (human, vet, medical devices and CROs)• Scope: BDSG workplan activities• First meeting: 30 May 2022 focused on BDSG work planning 2025

DARWIN EU and Raw Data Pilot updates - to follow separately

Objective	<p>Review to re-enforce existing Big Data activities and identify gaps for 2023-2025 in line with the EU Network Strategy to 2025</p>
Input	<ul style="list-style-type: none">• Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose 30 November 2021<ul style="list-style-type: none">• <i>Contributions from patients and healthcare professionals</i>• Stakeholder feedback from Big Data Forum 7 December 2021<ul style="list-style-type: none">• <i>Contributions from patients and healthcare professionals</i>• Recommendations from existing activities• Contributions from EMRN including former HMA–EMA Joint Big Data taskforce members<ul style="list-style-type: none">• <i>Feedback from patients and healthcare professionals via BDSG membership</i>• Input from industry received at BDSG/industry meeting on 30 May 2022
Timelines	<ul style="list-style-type: none">• Adoption by BDSG in June 2022• Publication of the new workplan in July 2022



- [Big Data webpage](#)
- [Big Data Highlights](#) – Issue 2 published
- [EMA events](#)
- EMA Social media



BIG DATA HIGHLIGHTS

Quarterly update on implementation activities of the HMA-EMA Big Data Steering Group workplan

An Agency of the European Union

Editorial

Patients' perspective on real-world evidence in regulatory decision making

Patients are generally supportive of sharing their data for research.

Marilena Vrana
Manager Patients and Research, European Heart Network

“ They perceive that data sharing could lead to innovative medicines that meet their real needs and improve health outcomes, and most notably their quality of life. Public and patient motivations and willingness to share data relate to their perception of contributing to the 'common good'. Nonetheless, they expect transparency and require reassurance and mechanisms to mitigate risks so that their health data will be protected. **”**

Digitalisation has increasingly been embedded in our everyday life. Digital technologies have begun to change the practice of medicine, hence research and innovation. The availability of a broad scope of tools, whether electronic health records, mobile-health tools, wearables, registries or others, have increased tremendously the generation of health data.

Digitalisation is steering medicine to bottom-up data management that involves real-time data extraction and analysis of various data sources. This offers the opportunity to improve the generation of evidence, including the design, speed and efficacy of randomised controlled trials for the development of new medicines without compromising patient safety.

Meaningful patient involvement in both research for novel products and in medicines regulatory processes is key factor for trust in future innovations. Patient needs and expected outcomes are key to factor-in from the outset to ensure relevance, value, efficacy and adherence. Robust collection of high-quality data coming from patient reported outcomes is increasingly important to better evaluate the added value of a medicine.

BIG DATA HIGHLIGHTS
Issue 2 – May 2022

Page 2

Concluding remarks

- Steady progress on data transformation delivery as part of the EU Network strategy 2025
- Key - continued involvement of EU patients and healthcare professionals in big data work to realise future benefits
- Recent contributions:
 - Big Data Steering Group workplan 2025 (representation at BDSG)
 - Design of Raw Data Pilot (representation at Advisory Group on Raw Data)
 - DARWIN EU (representation at DARWIN EU Advisory Board)
 - Data Quality Framework workshop on 7 April 2022



Thank you

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