



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Big Data Steering Group progress report

PCWP/HCPWP joint meeting, 02 & 03 March 2022

Jesper Kjær (DKMA) – Co-chair of the BDSG

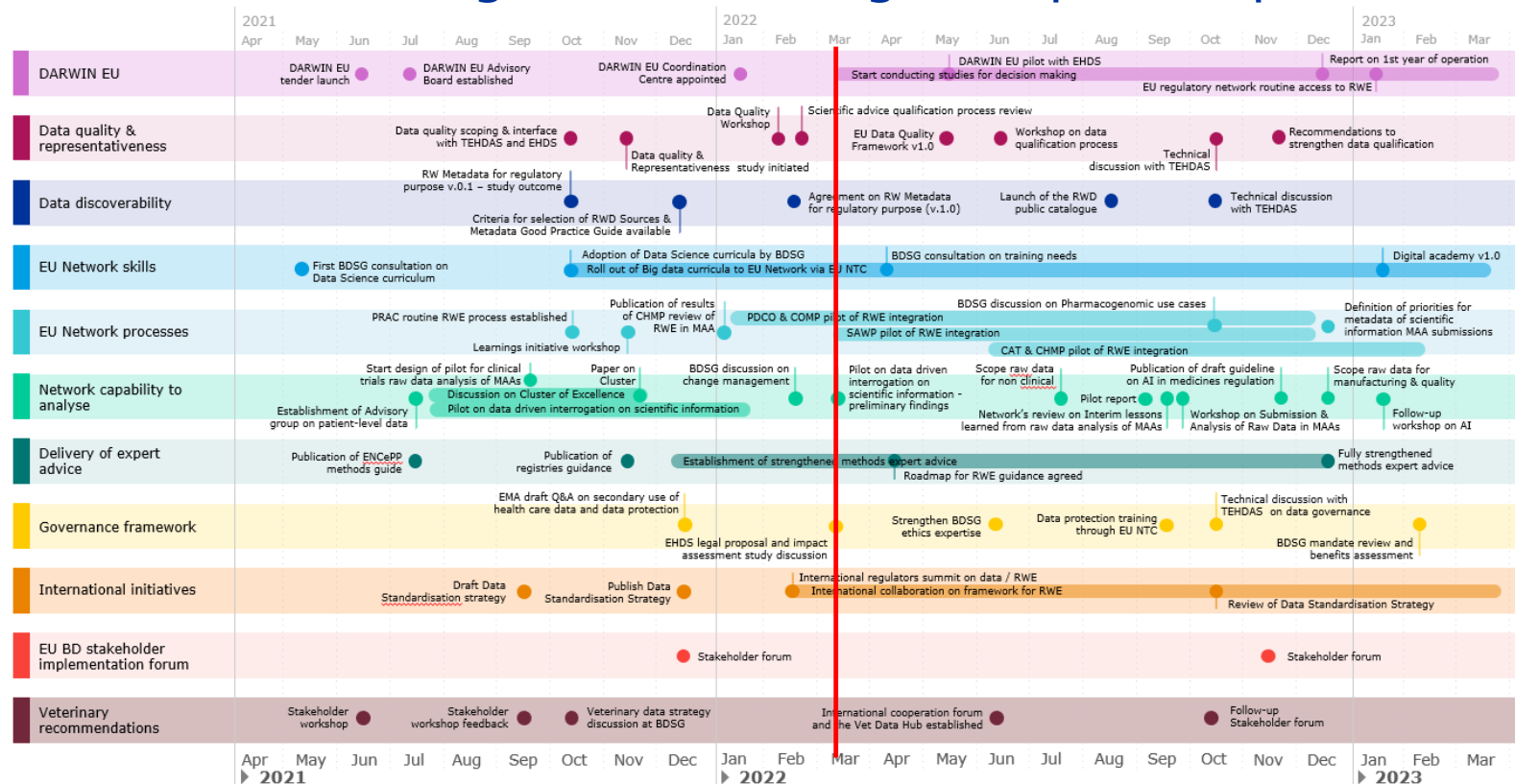




Big Data Priority Recommendations



HMA-EMA Joint Big Data Steering Group work plan

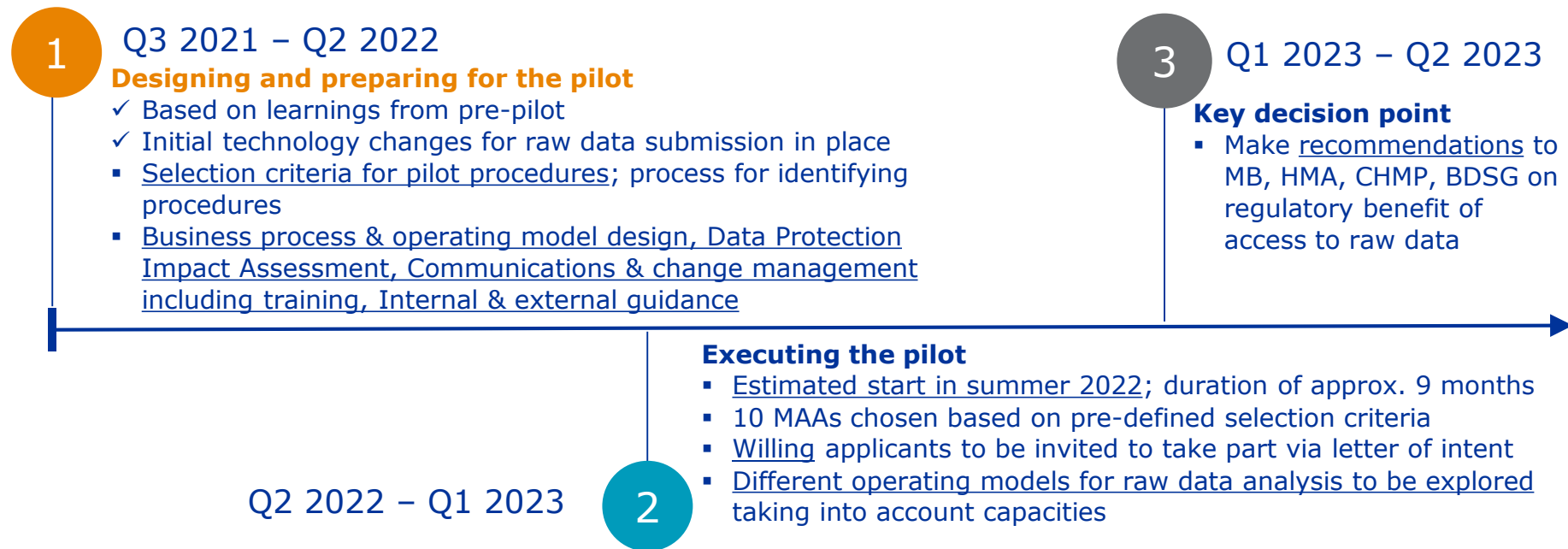


On track

BDSG progress update since September 2021 (1/2)

- BDSG workplan remains **on track**.
- Continued involvement of Patients and HealthCare representatives as part of the DARWIN EU advisory board, Raw data analysis advisory group and BDSG meetings.
- [European Medicines Regulatory Network Data Standardisation Strategy](#) endorsed by EMA MB and published.
- Consortium selected to deliver a draft EU data quality framework
- [DARWIN EU® Coordination centre](#) appointed (see next agenda item).
- 2 stakeholder workshops successfully organised:
 - [Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose](#) (see next slide)
 - [2021 multi-stakeholder Big Data Forum](#) – (see next slide)
 - Feedback from stakeholders will be integrated in the BDSG workplan and activities.
- Discussion on the place of Patient Reported Outcome initiated at EMA. Next steps as part of Patient data workshop to be organised in June 2022.
- BDSG annual report for 2021 is preparation.
- BDSG Newsletter – subscribe [here](#).

BDSG progress update since September 2021 (2/2)



Key highlights from 2021 stakeholder workshops

Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose workshop

- **Fitness of real-world data for regulatory purpose should be integrated in the processes to generate RWE** and should **consider data quality and validation** to increase confidence in the scientific evidence generated
- Stakeholder engagement is critical to allow progress in the area of real-world data and **scope of stakeholders to be involved should be broadened, e.g. data providers, health care systems and policy makers**
- **Recommendations from registry-based guideline broadly applicable to RWE** and process optimization should consider early discussions to allow better planning of pre- and post-licensing RWE generation
- **Methodological skills are necessary for analysing Big Data**, investigate **which methodologies are appropriate and acceptable** for regulators. Training of stakeholders is needed on new guidelines.
- **Heterogeneity of results between data sources is a source of knowledge**. Metadata, data quality assessments and study design choices are important to minimise “unwanted” heterogeneity.

2021 multi-stakeholder Big Data Forum

- Top priorities for 2022 indicated by the big data forum participants: **1. Data quality and representativeness, 2. DARWIN EU and 3. Regulatory processes**
- **Engage with ERNs, Rare disease registries**. Establish place of **patient reported outcome**
- **Transparency and collaboration needed beyond analysis** (on processes, methods, results). **Clarity on regulatory requirements** (e.g. data quality, processes) is important. **Need for guidelines/guidance/best practice guide/toolkit**
- Development of skills should go **beyond regulators (e.g. patients)**
- **Pilots results/lessons learned** should be discussed with stakeholders
- **More research on methodologies** is needed
- EU and **international convergence/harmonization is needed**

2021

DARWIN EU

Progress on the DARWIN EU Coordination Centre selection – Support to the EHDS2 pilot – establishment of the DARWIN EU Advisory group (3 meetings)

Data quality & representativeness

Selection of the Consortium to deliver a draft EU data quality framework

Data discoverability

Study of metadata for real-world data completed - POC for metadata repository delivered - **Consultation on metadata for real-world data, incl. stakeholder workshop**

EU Network skills

Training signpost made available in **EU science curriculum** adopted – **Survey of skills** completed – **Training delivery outsourcing** initiated

EU Network processes

Learnings from RWE workshop held – **RWE use cases developed / Pilot initiated** with PRAC, PDCO, COMP, SAWP – discussion initiated with HTA and payers

Network capability to analyse

Pre-pilot on raw data analysis completed - **Design initiated of CHMP pilot for clinical raw data analysis** of MAAs – Raw data Advisory group established - **Scientific information dossier pilot on advanced analytic** initiated - Discussion on **Clusters of Excellence** - **AI workshop held**

Delivery of expert advice

EMA Management Board agreement on the creation of a methodologies working party - **ENCEPP RWE methods guide** published - **CHMP Guideline on Registry based studies** published

Governance framework

BDSG recommendations on ethics advice completed – **collaboration with EC on EHDS and TEHDAS initiated**

International initiatives

Progress on **RWE international Collaborative workshop** – **FDA/PMDA/HC consultation** completed - **Data standardisation strategy published, incl. stakeholder consultation** completed - Collaboration workshops on COVID-19 observational studies organised through ICMRA

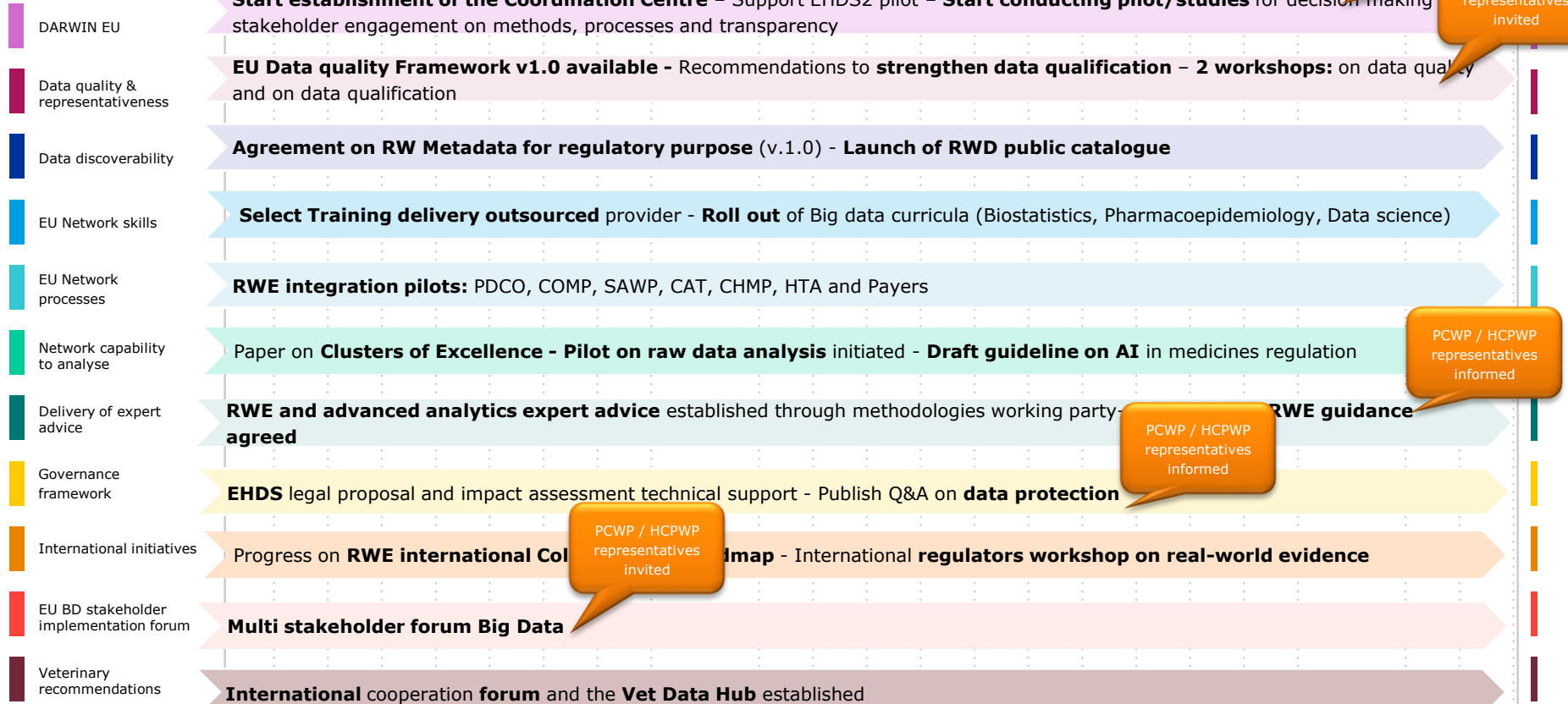
EU BD stakeholder implementation forum

2nd Multi stakeholder forum Big Data held

Veterinary recommendations

Workshop on the Veterinary Data Strategy held

2022



Conclusion: delivering the Network Strategy to 2025

- Significant progress continued in 2021 to enable data transformation of the EU regulatory network
- Plans for 2022, including establishing DARWIN EU and the pilot of clinical trials raw data analysis will provide stakeholders with tangible deliverables and future benefits.

"By delivering the vision of a regulatory system able to integrate Big Data into its assessment and decision making, we can support the development of innovated medicines, deliver life-saving treatments to patients more quickly and optimise the safe and effective use of medicines through measurement of a products performance on the market."

Thank you

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