



## Wrap-up and next steps

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Workshop on Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose

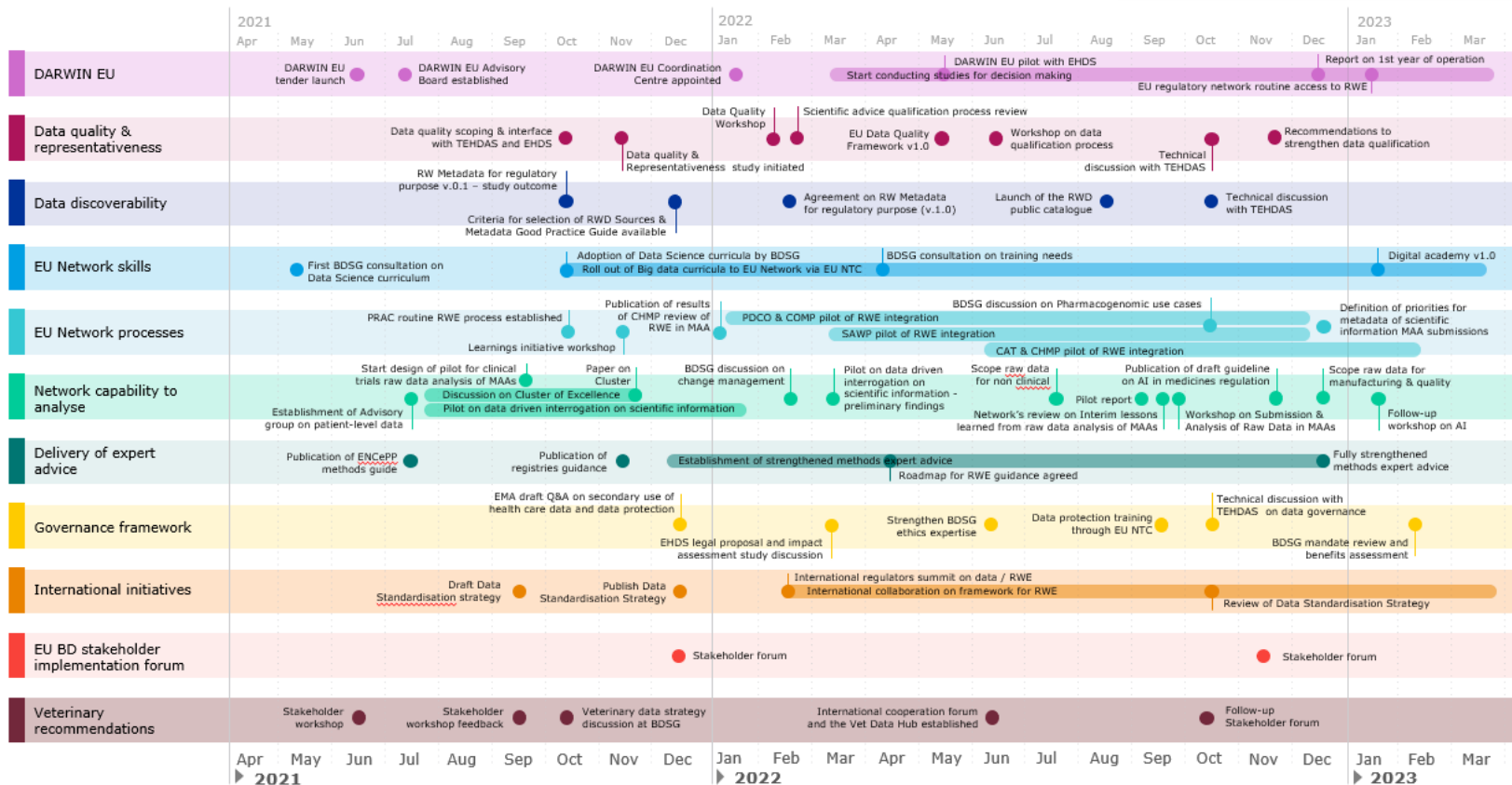
30<sup>th</sup> November 2021

Presented by Jesper Kjær, Danish Medicines Agency



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# BDSG workplan 2021-23



# Key progress towards end of 2021

DARWIN EU

**Evaluation ongoing** with the 3 short listed candidates, 3<sup>rd</sup> meeting of the **Advisory Board**

Data quality & representativeness

**Consortium selected** to deliver a draft EU data quality framework

Data discoverability

**Consultation on metadata for real-world data**

Network capability to analyse

**Design initiated of CHMP pilot for clinical raw data analysis** of MAAs

EU Network processes

**Learnings initiative workshop** November 2021

International initiatives

**Data standardisation strategy ready for HMA / MB endorsement** Nov/Dec 2021

EU BD stakeholder implementation forum

**Multi stakeholder forum Big Data organised for Dec. 2021**

# Clusters of Excellence (CoE)

- Included in BDSG workplan
- **Objective:** bring together learnings from national approaches to data analytics to provide recommendations/good practice to the EU regulatory network.
- The recommendations will be discussed in a paper on the key building blocks to establish analytics
  - Data access
  - Legal aspects
  - Capabilities
  - Infrastructure
  - Method developer
  - AI



# Future highlights for early 2022

DARWIN EU	<b>Coordination Centre appointed in early 2022.</b> Start of pilot studies.
Data quality & representativeness	<b>Initiate work on the EU Data quality Framework v1.0 – engage with TEHDAS</b>
Data discoverability	<b>Agreement on RW Metadata for regulatory purpose (v.1.0) – engage with TEHDAS</b>
EU Network skills	<b>Procure service providers</b> of big data training curricula
Network capability to analyse	<b>Deliver the pilot for clinical raw data analysis</b> of MAAs and clarify the benefits of raw data analysis
EU Network processes	<b>Initiate POC/pilots on RWE with CHMP/CAT - discuss use cases with CMDh, HTA, payers</b>
International initiatives	<b>International regulators workshop</b> on real-world evidence collaboration