2nd annual EU Big Data Stakeholder Forum 2021

07 December 2021

Session 1: Report on implementation of the HMA-EMA Big Data Task Force priority recommendations - Overview of 2021 deliverables and plan for 2022

Presented by Peter Arlett
Head of Data Analytics and Methods Task Force (EMA),
Co-chair of HMA-EMA Big Data Steering Group

HMA EMA Big Data Task Force vision

"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."

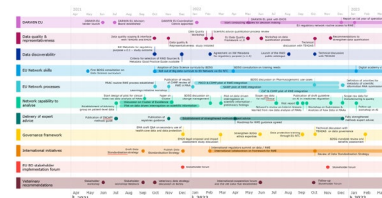Big Data Task Force final report December 2019

Big Data: from recommendations to implementation

Jan. 2020

'Ten recommendations to unlock the potential of big data for public health in the EU'

Sep. 2020

Publication of the 1st BDSG workplan 2020/2021
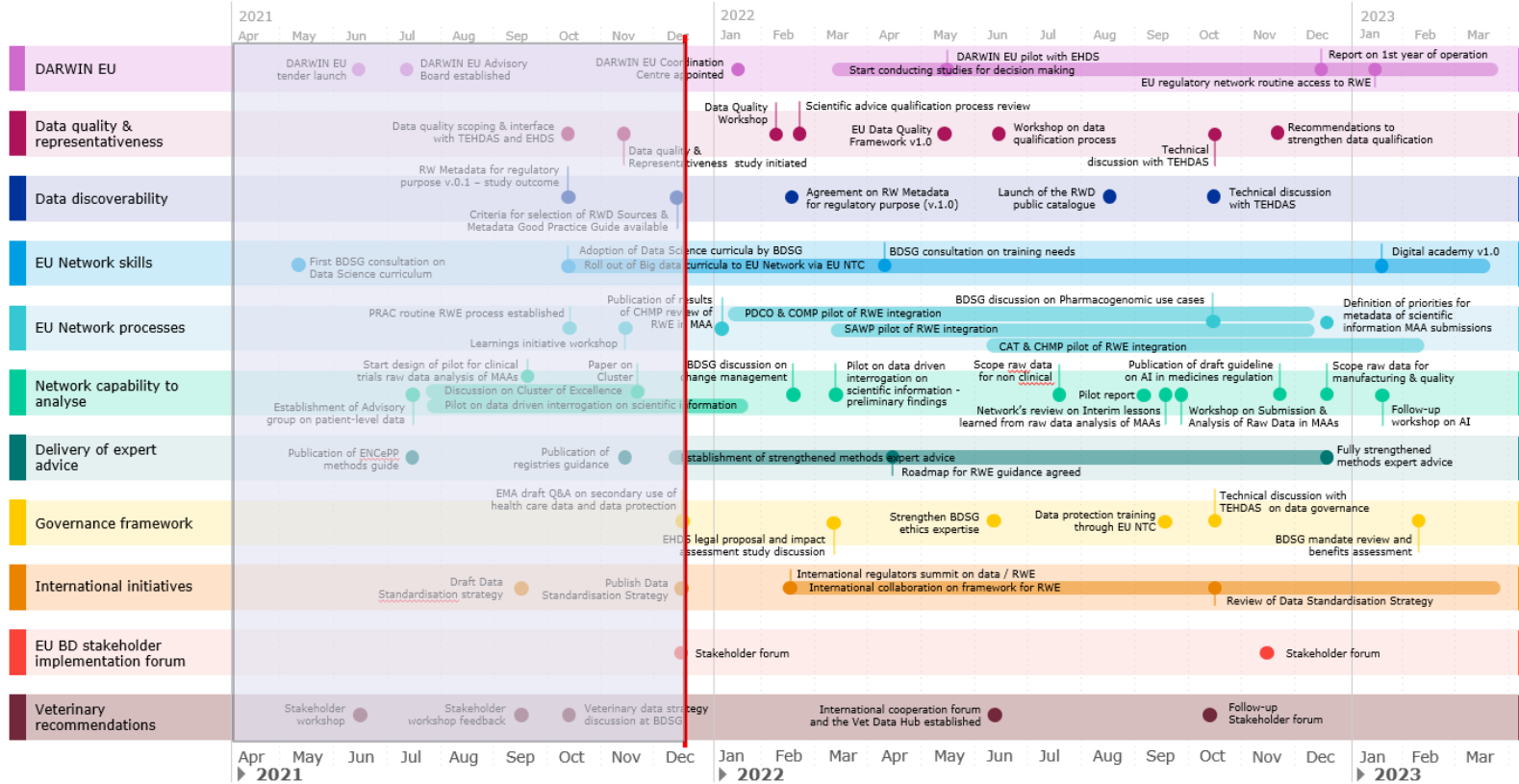
1st Big data steering group meeting in May 2020

May 2020

Publication of the 2nd BDSG workplan 2021/2023

Aug. 2021

Big Data Priority Recommendations

DARWIN
01

Data quality
02

Data discoverability
03

EU Network skills
04

EU Network Process
05

Analytics capability
06

Expert advice
07

Data governance
08

International collaboration
09

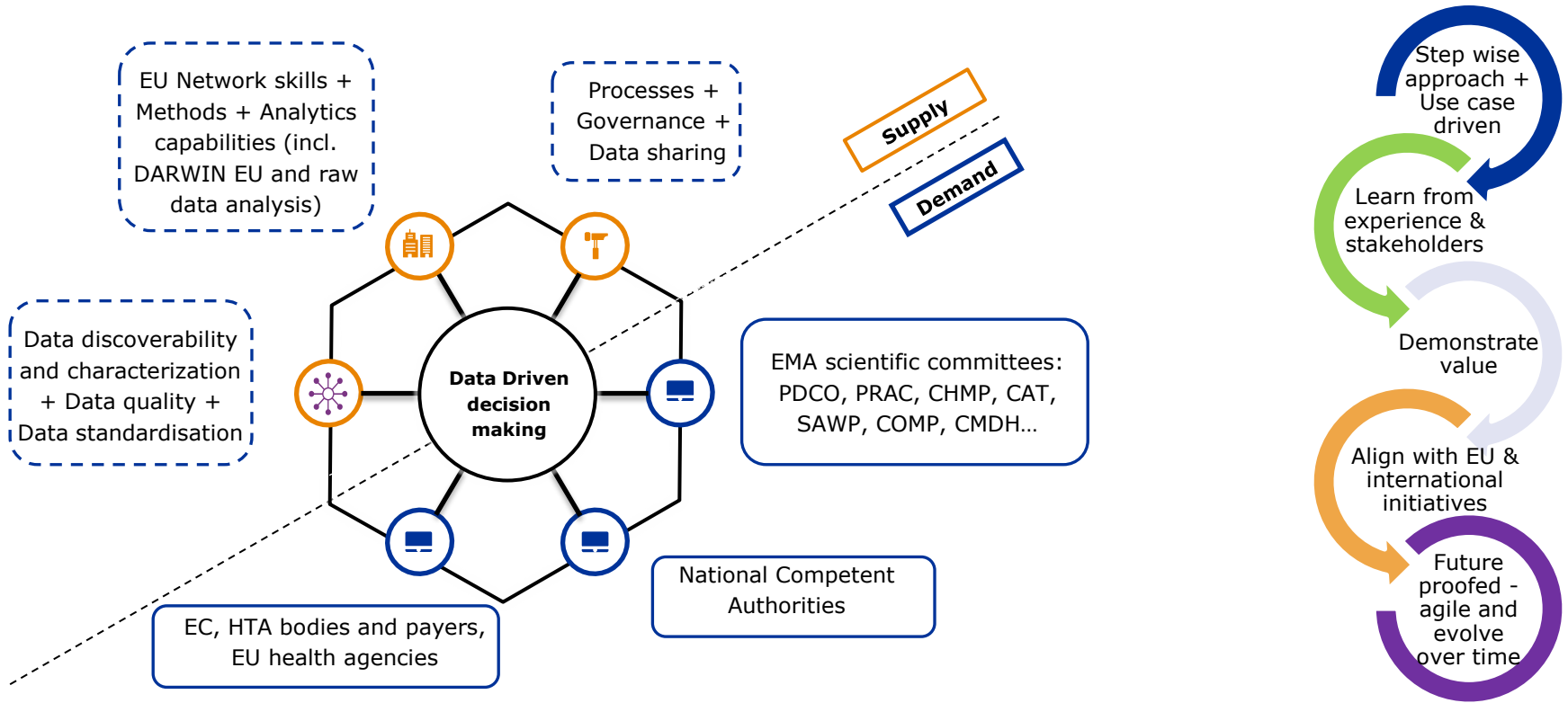Stakeholder engagement
10

Veterinary recommendations
11

BIG DATA PRIORITY RECOMMENDATIONS

HMA-EMA Joint Big Data Steering Group work plan

Approach: Enabling the use and establishing the value of Big Data

EU Network skills + Methods + Analytics capabilities (incl. DARWIN EU and raw data analysis)

Processes + Governance + Data sharing

Data discoverability and characterization + Data quality + Data standardisation

Supply

Demand

Data Driven decision making

EMA scientific committees: PDCO, PRAC, CHMP, CAT, SAWP, COMP, CMDH…

National Competent Authorities

EC, HTA bodies and payers, EU health agencies

Step wise approach + Use case driven

Learn from experience & stakeholders

Demonstrate value

Align with EU & international initiatives

Future proofed - agile and evolve over time

Key implementation principles

Key achievements in 2021

DARWIN EU Advisory board established

Study of metadata for real-world data - POC for metadata repository

ENCEPP RWE methods guide published **– Registry studies guideline** published

Joint Action Towards the European Health Data Space – TEHDAS

The TEHDAS Joint Action project develops European principles for the secondary use of health data.

Data standardisation strategy

Data science curriculum finalised – **Survey of skills** completed

RWE use cases developed with EMA committees – Pilots initiated - **Learnings initiative workshop**

Veterinary **Data Strategy**

Discussion on **Clusters of Excellence** - **AI workshop** - **Pre-pilot on raw data analysis** completed

More in the next sessions

Stakeholder engagements in 2021

April 2021 - Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation (Rec. 6)

April 2021 - Technical workshop on real-world metadata for regulatory purposes (Rec. 3)

Rec. 9 May 2021 – Data standardisation workshop (Rec. 9)

June 2021 - Workshop on Big Data in the Veterinary Domain (Rec. 11)

June 2021 – 1st meeting of the DARWIN EU Advisory Board (Rec. 1)

July 2021 – 1st meeting of the Advisory Group on raw data analysis (Rec. 6)

October 2021 – Real world metadata survey with Industry (Rec. 3)

November 2021 - Learnings initiative workshop (Rec. 5)

More in the next sessions

Future highlights in 2022

DARWIN EU Coordination Centre appointed – **Start conducting pilot studies** for decision making

HEALTH DATA HUB
EHDS2 pilot

RWE integration pilots (EMA committees)

Publish Q&A on **data protection**

Multi stakeholder forum Big Data

Agreement on Real world Metadata (v.1.0) - **Launch of RWD public catalogue**

EU Data quality Framework v1.0 available - Recommendations to **strengthen data qualification** – **workshops** on data quality and data qualification

Roll out of training (Biostatistics, Pharmacoepidemiology, Data science)

International **regulators workshop on real-world evidence**

Clusters of Excellence paper - **Draft guideline on AI** in medicines regulation - **Workshop on Raw Data in MAAs** and **Pilot of raw data analysis** execution

International cooperation **forum** and the **Vet Data Hub** established

More in the next sessions

Stakeholder engagement in 2022

DARWIN EU methods, processes and transparency (Rec. 1)

EU data quality framework workshop and survey (Rec. 2)

SAWP qualification procedure workshop (Rec. 2)

Metadata and catalogue of studies (e.g. workshops participation, survey…) (Rec. 3)

RWE pilots/studies (Rec. 5)

Pilot on raw data analysis + workshop on submission & analysis of raw data in MAAs (Rec. 6)

Roadmap for RWE guidance (Rec. 7)

Q&A on data protection (Rec. 8)

International regulator workshop (Rec. 9)

More in the next sessions

In 2025… transformation to data-driven regulation

- **The use of RWE will have been enabled and its value will have been established** across the spectrum of regulatory use cases.

- **DARWIN EU network as part of the EU Health data space** will support better decision-making via its network of expertise, access to data and established analyses.

- **Data will be discoverable and of known quality and representativeness** allowing choice of optimal data source, enabling regulators to guide development and expertly assess study results

- **EU Network will have knowledge and experience** in data science, methods and analytics to advise companies developing products and to expertly assess application dossiers

- **Learning initiative will allow to continue to** learn and evolve to address new regulatory needs, including response to any future health crisis.

- **Suite of EU and international guidelines and standards available** will help industry and regulators develop and supervise medicines

- **Continued full compliance with data protection and ethics** of data sharing

- **Working with stakeholders to deliver data transformation to support the development and use of better medicines for patients.**

Thank you

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