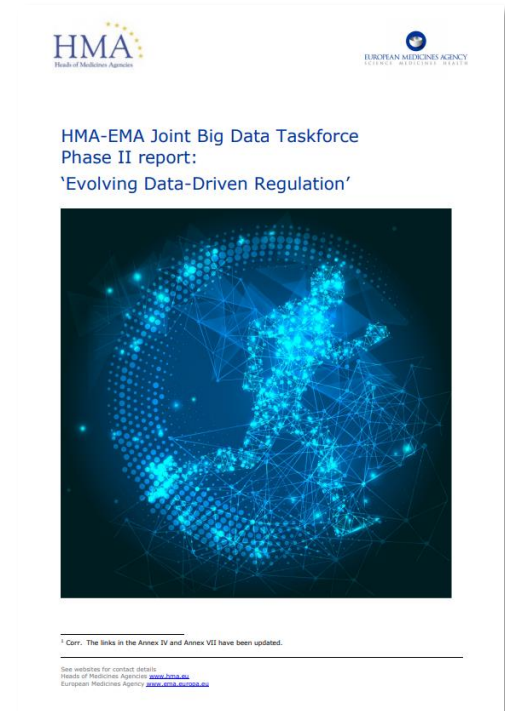# Overview of the HMA-EMA Big Data Taskforce priority 9 and the need for the EMRN Data Standardisation Strategy

Data Standardisation Strategy - stakeholder workshop

2021 May 18th

Presented by
Jesper Kjær, Director of the Data Analytics Centre, Danish Medicines Agency
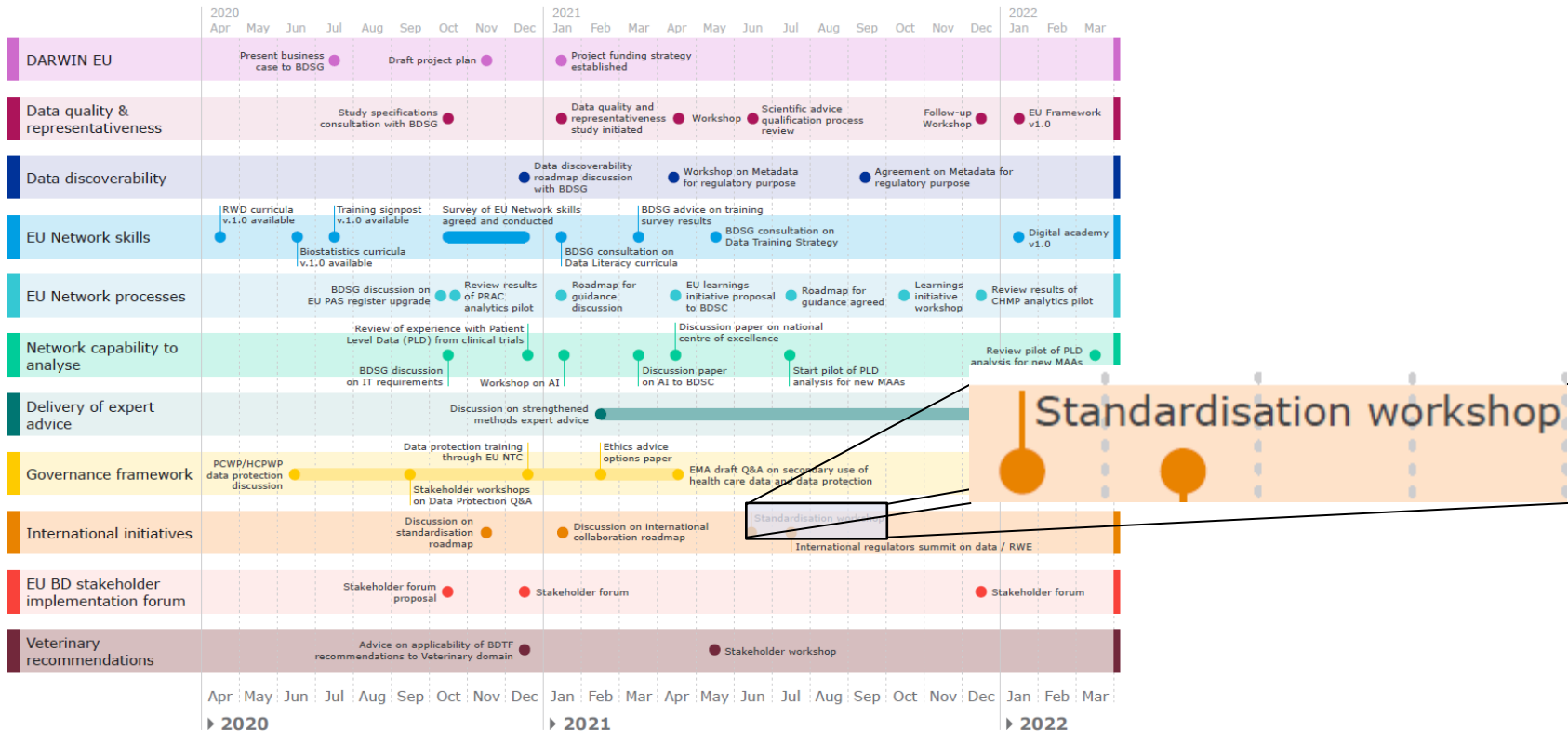
DARWIN EU

Data quality & representativeness

Data discoverability

EU Network skills

EU Network processes

Network capability to analyse

Delivery of expert advice

Governance framework

International initiatives

EU stakeholder implementation forum

Veterinary recommendations

HMA-EMA Joint Big Data Taskforce
Phase II report:
'Evolving Data-Driven Regulation'

¹ Corr. The links in the Annex IV and Annex VII have been updated.

See websites for contact details
Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

Recommendation IX. Collaborate with international initiatives on Big Data.

- Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners.
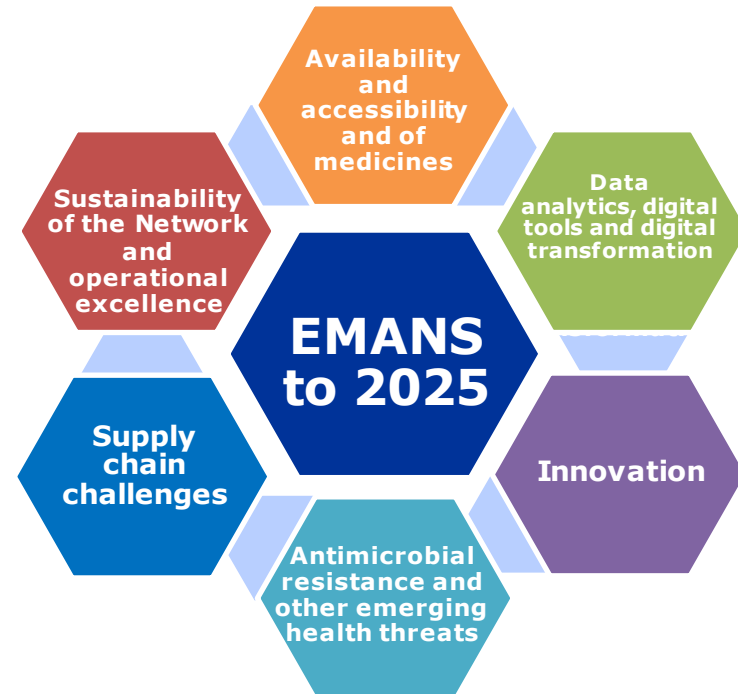
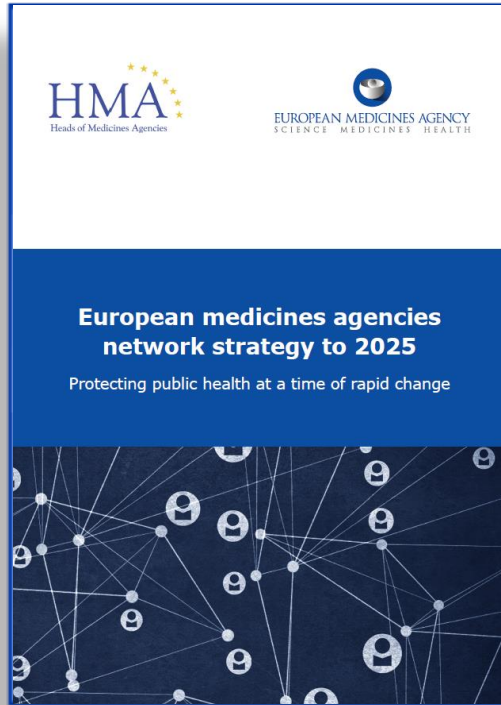THE HMA-EMA JOINT BIG DATA STEERING GROUP WORKPLAN

European Medicines Agencies Network (EMAN) Strategy to 2025

Strategic focus areas:

➢ Availability and accessibility of medicines

➢ Data analytics, digital tools and digital transformation

➢ Innovation

➢ Antimicrobial resistance and other emerging health threats

➢ Supply chain challenges

➢ Sustainability of the Network and operational excellence

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Strategy outline

European medicines agencies network strategy to 2025

Protecting public health at a time of rapid change

https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

Theme 2 : Data analytics, digital tools and digital transformation - Goals

Goal 1: Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data

Goal 2: Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics

Goal 3: Promote dynamic regulation and policy learning within the current regulatory framework

Goal 4: Ensure that data security and ethical considerations are embedded in the governance of data within the Network

Theme 2 : Data analytics, digital tools and digital transformation – Objectives (1/2)

Goal 1 - Objective 1: Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU)

Goal 1 - Objective 2: Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll out of such analysis.

Goal 1 - Objective 3: Establish collaborations with external stakeholders (including patients, academia, NGOs and industry) and with international regulatory authorities on Big Data initiatives

Goal 1 - Objective 4: Establish EU framework for data quality, discoverability and representativeness, through agreement on meta-data for regulatory purposes, a standardisation roadmap and registers of real-world data sources and of observational studies

Theme 2 : Data analytics, digital tools and digital transformation – Objectives (2/2)

Goal 2: Objective 1: Build EU Network capability to analyse Big Data

Goal 2: Objective 2: Digital transformation of the EU Network's scientific and regulatory processes to enable use of digital tool and analytics and creation of a supporting digital infrastructure – e.g. to support uptake and review of big data (from eHR, registries, devices, etc.)

Goal 3: Objective 1: Modernise the delivery of scientific advice at central and national level by developing Network skills and processes

Goal 4: Objective 1: Ensure data are managed and analysed within a secure and ethical governance framework

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union