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
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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

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### DARWIN EU
- Present business case to BDSO
- Draft project plan
- Project funding strategy established

### Data quality & representativeness
- Study specifications consultation with BDSO
- Data quality and representativeness study initiated
- Workshop
- Scientific advice qualification process reviewed
- Follow-up Workshop
- EU Framework

### Data discoverability
- Data discoverability roadmap discussion with BDSO
- Workshop on Metadata for regulatory purpose
- Agreement on Metadata for regulatory purpose

### EU Network skills
- BWS curriculum
- Training program available
- Survey of EU Network skills agreed and concluded
- BDSO advice on training survey results
- BDSO consultation on Data Training Strategy
- Digital academy V2.0

### EU Network processes
- BDSO discussion on EU PAS register upgrade
- Review results of PHAC analytics pilot
- Roadmap for guidance discussion
- EU training initiative proposal
- Roadmap for guidance agreed
- Learnings initiative workshop
- Review results of CHMP analytics pilot

### Network capability to analyse
- Review of experience with Patient Level Data (PLD) from clinical trials
- Discussion paper on national centre of excellence
- Review pilot of PLD website for new MAAs

### Delivery of expert advice
- Discussion on strengthened methods expert advice

### Governance framework
- Data protection training through EU MDC
- Stakeholder workshop on Data Protection Q&A
- Ethics advice options page
- EMA draft Q&A on secondary use of health care data and data protection

### International initiatives
- Discussion on standardisation roadmap
- Discussion on international collaboration roadmap
- International regulators summit on data/RWE

### EU BD stakeholder implementation forum
- Stakeholder forum proposal
- Stakeholder forum
- Stakeholder workshop

### Veterinary recommendations
- Advice on applicability of BDSO recommendations to veterinary domain

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**Standardisation workshop**
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
Strategy outline

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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