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SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

Recent progress on data and analytics and looking to the future

Agenda item 6.1

PCWP/HCPWP joint meeting, 1&2 June 2021

Presented by Dr Peter Arlett
EMA, Head, Data Analytics and Methods Task Force,
HMA-EMA Big Data Steering Group co-chair

Content

1. Update on Big Data work
2. Update on DARWIN EU
3. Looking to the future

Big Data Steering Group workplan 2020-21

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Making best use of big data for public health: publication of the Big Data Steering Group workplan for 2020-21

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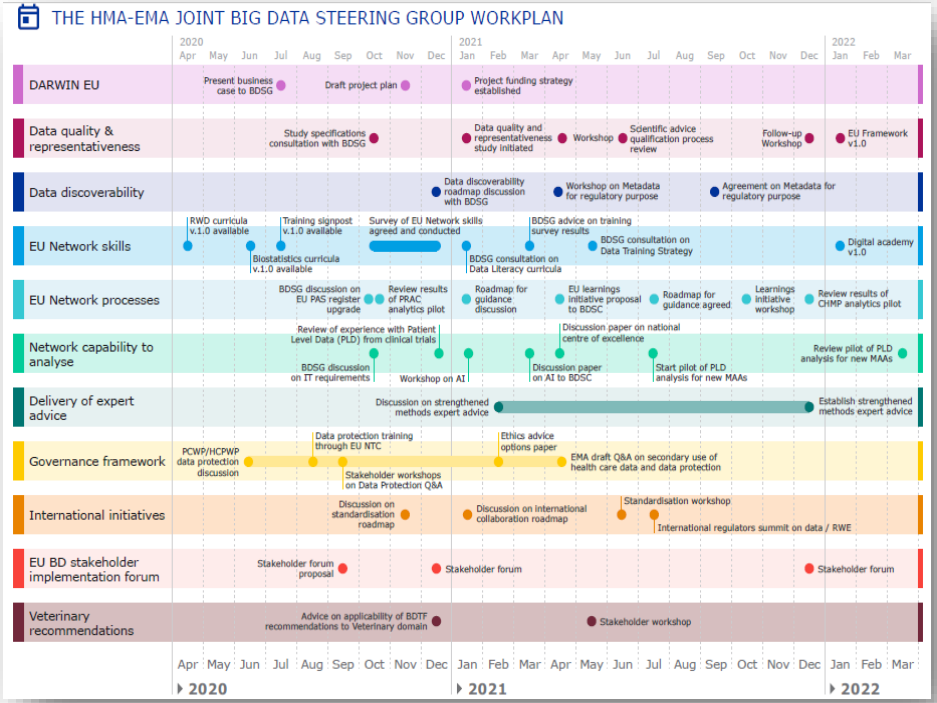
News 14/09/2020

The Big Data Steering Group set up by EMA and the Heads of Medicines Agencies (HMA) has published its workplan which sets actions to be delivered in 2020-21. With the European Medicines Regulatory Network focused on the response to the COVID-19 pandemic, the workplan aims to progress evolution to data-driven regulation through smart working, leveraging collaboration with stakeholders and the use of remote expert workshops.

In the past three years, EMA and HMA have led a thorough assessment of the challenges and opportunities posed by big data in medicines regulation. This culminated in January 2020 with the publication of recommendations for regulators to evolve their approach to data use and evidence generation.



[Making best use of big data for public health: publication of the Big Data Steering Group workplan for 2020-21]

Big Data Steering Group: 2020 Report (Link)

1. DARWIN EU: Established project, funding and operating model + initiated planning for pilot of European Health Data Space
2. Data Quality: Defined scope for a study on a data quality framework for medicines regulation
3. Discoverability: Initiated a study to establish 'meta-data for real world data (RWD)'
4. Skills: Delivered a training signpost, a real-world evidence (RWE) curriculum and biostatistics curriculum
5. Processes: Progressed a PRAC RWE analysis pilot + initiated a CHMP review of RWE in MA submissions
6. Analytics capability: Initiated a CHMP pre-pilot of CT raw data analysis + selected software for RWD analytics
7. Expert advice: Initiated review of methods domain of EMA working parties
8. Ethics and Security: Delivered data protection workshops + initiated a data protection Q&A
9. International: Initiated analysis for an international collaboration roadmap on RWE
10 . Stakeholder engagement: Delivered a multi-stakeholder forum in December 2020
11 . Veterinary: Established a veterinary data workstream

Make data discoverable: workshop on real-world metadata

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Scope : The objective of this workshop was to collect stakeholders' feedback on:

- Preliminary list of metadata and their definitions
- The process to collect them
- Proof-of-concept catalogue that is currently being developed

Participants :

- ENCePP members
- EHDEN project
- BDSG members
- International Society for Pharmacoepidmiology (ISPE)
- International Society of Pharmacovigilance (ISoP)
- The Professional Society for Health Economics and Outcomes Research (ISPOR)
- FDA Sentinel (US)
- PCORnet (US)
- CNODES (Canadian Network for Observational Drug Effect Studies)
- OHDSI (Global)
- EMIF (Europe)
- FAIRplus (Europe)
- GetReal initiative (Europe)
- BD4BO -Big Data for Better Outcomes (Europe)
- AsPEN (Asia)
- GoFair

All meeting documents published *here*

Overview

- Online workshop with aims:
  - Inform on state-of-the-art AI applications
  - Engage stakeholders with key speakers
  - Collect views of stakeholders on prioritization of AI specific recommendation
- 19 and 20 April - 2 afternoons
- Stakeholders:
  - Pharma, MedTech, Academia, HCP, Researchers, Patients, EU-Innovation Network, Consumers, Inspectors, (General) Industry
- Engagement on prioritization
  - Pre-workshop survey, Panelists round table, Slido for all online
- In numbers:
  - Attendance: Day 1 (525); day 2 (310)
  - 13 presentations
  - 27 speakers

Drive up quality and utility of data: Workshop on Data Standardisation

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- Online event with the objectives of:
  - **presenting the current status** of the draft EMRN Data Standards Strategy development
  - **present the stakeholder survey results**
  - **gather stakeholders' perspectives and use cases**

- Workshop broadcast live: broadcast link

Further info available on EMA website Event Link including agenda

Accessing and analysing RWD: Update on DARWIN EU

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What is DARWIN EU - a network not a database

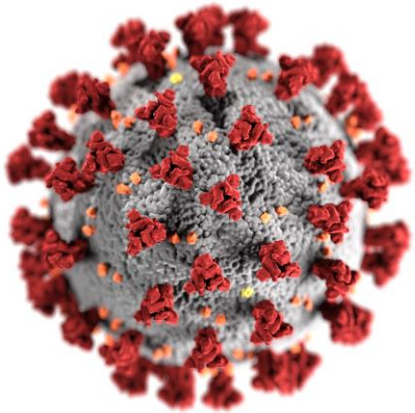
- DARWIN EU is :
  - A **Federated Network of Data Holders and expertise**, exposing data using a common data model and working under a common governance, set of standards and service levels with regards to studies and analysis of data.
  - A **Coordination Centre** that acts as the entry point into this federated network and manages the network on behalf of EMA and the EMRN.
  - **EMA with oversight of operations**, e.g. interface with EMA committees, driving standards, specifications, guidelines, management of the coordination centre.
  - **Evolution over time** – growth with European Health Data Space

DARWIN EU: Benefits

- Principal benefits relate to the national and EU regulation of medicines:
  - Drug development – disease epidemiology, unmet need, historical controls, planning
  - Authorisation – contribution to BR, controls, extrapolation to general & special populations
  - On market – benefit risk monitoring, extension of indication

- Additional benefits will come as EU partners participate and access the platform
  - European Commission – delivers on European Health Data Space
  - National governments to support health policy and delivery of healthcare systems
  - HTA bodies and payers to support better quality decisions on cost-effectiveness
  - EU health agencies - use cases specific for EFSA, ECDC, ECHA, JRC
  - EU patients - faster access to innovative medicines and safe and effective use

DARWIN EU: Central pillar for health crisis planning and response



Crisis response use cases include:

- Monitor use of medicines to predict demand and shortages
- Understanding of the natural history of the disease to support drug development
- Monitor the safety of medicines and vaccines on the market
- Provide evidence for repurposing existing medicines

DARWIN EU will support future crisis responses with an operational infrastructure for conducting rapid studies

Health Union proposal for strengthened EMA mandate

Imminent tender launch to establish Coordinating Centre

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Services

Establishment and upscaling phase

- Setting the DARWIN EU services
- Business Processes & Operating Model
- Catalogue of standard data analyses
- Assuming operation of the catalogue of Data Sources
- Data Use Agreement
- Onboarding Document
- Business plan
- Change Management Strategy & Approach
- Start running pilots/studies

Operation phase

- Run Routine/Recurring, Simple & Complex Studies
- Recurring updates of the catalogue of real-world data sources and of metadata/quality information about data sources
- On-boarding of new data holders

Coordinating Centre selected by end of 2021:

- first studies in 2022

Looking to the future: 2021 and beyond

1. DARWIN	Coordinating centre service establishment initiated | DARWIN Advisory Board established **– PCWP and HCPWP representatives** | Pilot of the European Health Data Space initiated - first DARWIN EU studies deliver for decision-making in 2021
2. Data Quality	Initiate Data quality and representativeness study: **2022 Workshop – PCWP and HCPWP invited**
3. Discoverability	Initiate enhancement of EU catalogue of real world data resources | Best practice guide on Metadata for regulatory purposes **PCWP and HCPWP invited to workshop**
4. Skills	Training curricula published | at least one module per curricula (stats, epidemiology, data science) **Better trained regulators support use of RWE.**
5. Processes and transparency	Publish learnings from review of RWE submissions + learnings from committee RWE analytics pilot | **workshop Q4 2021 - PCWP and HCPWP invited**
6. Analytics capability	Patient level data: pre-pilot becomes pilot **AI Workshop 19/20 April 2021 - PCWP and HCPWP invited**
7. Expert advice	RWE and advanced analytics expert advice available
8. Ethics and Security	Publish EMA Q&A on secondary use of health care data and data protection **- PCWP and HCPWP informed**
9. International	Publish international collaboration roadmap on RWE **Standardisation workshop May 2021 - PCWP and HCPWP invited**
10. Stakeholder forum	**Stakeholder forum December 2021 - PCWP and HCPWP invited**
11 Veterinary	Agreement on applicability of the BDTF recommendations to the **Veterinary domain Vet workshop 1 and 2 June 2021**

Thank you

Acknowledgements:

The members of the Big Data Steering Group

BDSG secretariat

HMA secretariat

Commission colleagues

Further information

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