EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DARWIN EU
Network of data, expertise and governance for medicines and public health purposes

ESMO Public Policy Webinar "General Data Protection Regulation and its impact on clinical research" 21 May 2021

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This presentation only reflects the views of its authors and does not necessarily reflect the final opinion of the European Medicines Agency.

Overview

DARWIN EU
- What is it
- Main objectives
- How it might operate

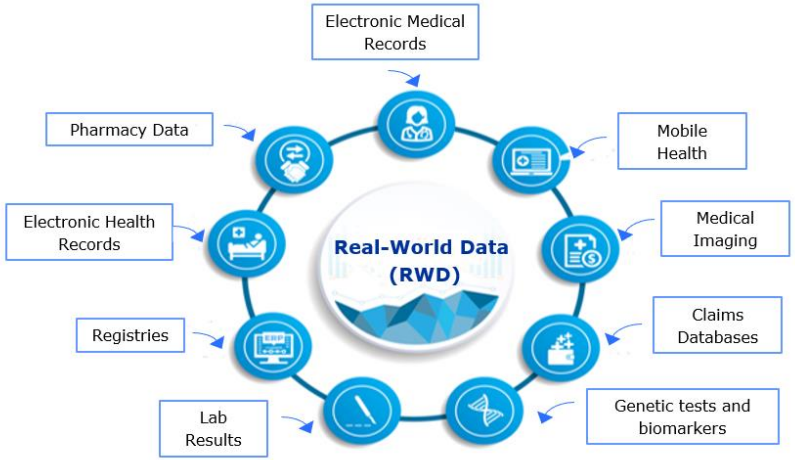
DARWIN EU & Data Protection

Relevant developments on the data protection landscape

Future goals & conclusions

Data Analysis and Real-World Interrogation Network (DARWIN EU)

Real-World Data (RWD) => data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources[1]

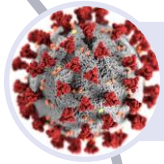


Real-World Evidence (RWE) => the clinical evidence on the usage and potential benefits or risks of a medical product derived from analysis of RWD[1]

1 FDA Real World Evidence

Pilot planned with EHDS in Q3/Q4 2021

DARWIN EU - a central pillar for health crisis planning/response



Understanding the disease natural history to support development of vaccines and therapeutics

Provide evidence for repurposing existing medicines

Monitor the safety and effectiveness of vaccines and therapeutics post-authorisation

DARWIN EU – Network

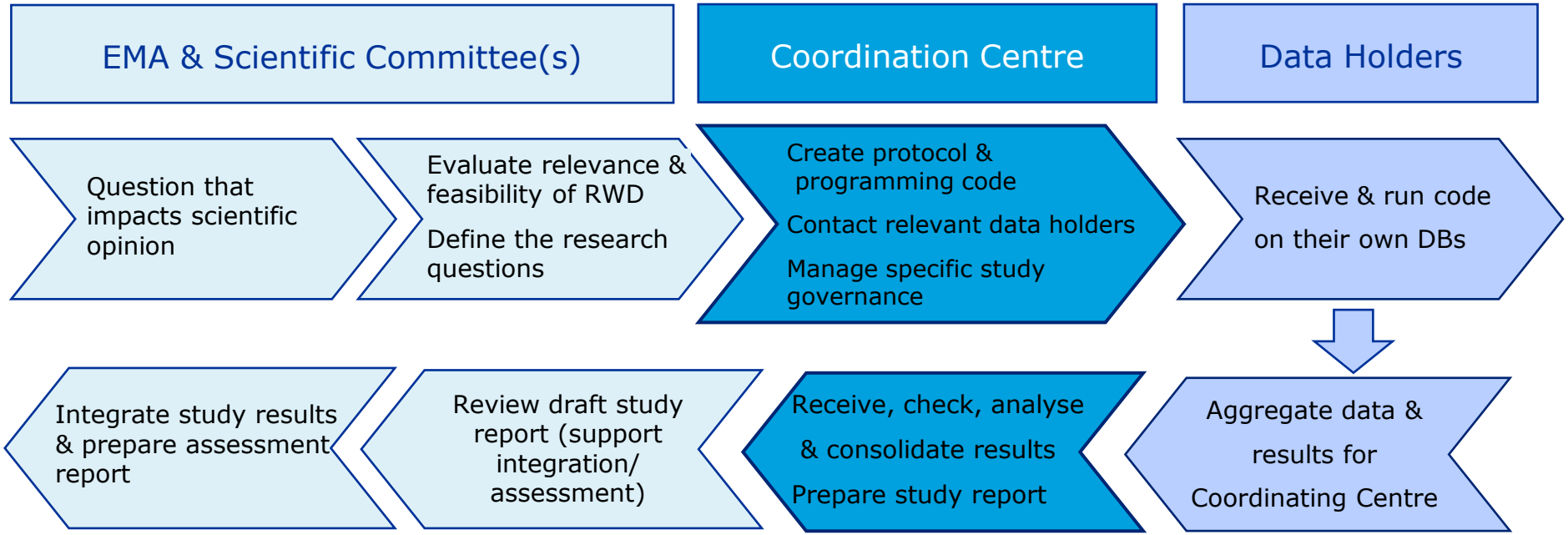
Organisational

- 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 => based on instructions and supervision of EMA and the European Medicines Regulatory Network (EMRN)
- **EMA with strategic control and oversight of operations =>** interface with EMA committees, NCAs, EMA own analysis, driving standards, specifications, guidelines, management of the coordination centre

Operational

- **Conduct scientific studies and analysis** on behalf of the EMRN and the EMA's scientific committees
- **Provide scientific expertise** in formulating and executing studies and analysis
- Maintain a **catalogue of known, relevant data holders**, continually ensuring the **quality of the data** held by data holders and **conformance to metadata**
- **Expand the federated network**, assisting potential new data holders in conforming with the standards necessary for a data source to be used in the regulatory context
- **Deliver training** and **provide governance** (DARWIN Advisory Board)

DARWIN EU – how it might operate



DARWIN EU & Data Protection

Data Protection Impact Assessment – 2 phases

I. Preliminary DPIA performed

Preliminary analysis to identify data protection concerns to be addressed at current stage:

Data controllership - roles and responsibilities

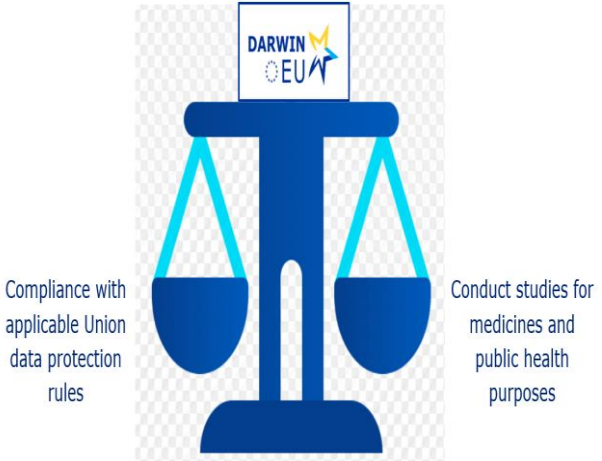
Data processing agreement

II. Detailed DPIA planned following the appointment of the Coordinating Centre

Main data protection aspects:

Anonymisation/ pseudonymisation

Secondary use and safeguards



DARWIN EU & Relevant Developments on the Data Protection Landscape

Draft Q&As on secondary use of health data for medicines and public health purposes

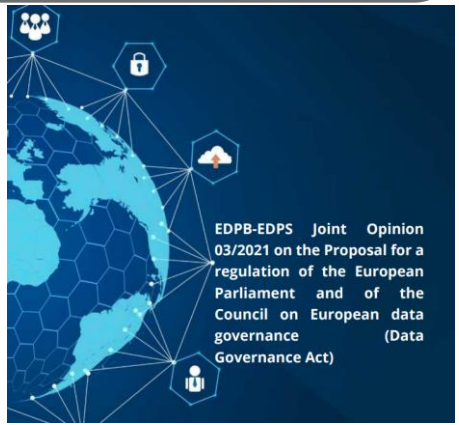
Focus and next steps:

- EDPS Preliminary Opinion on data protection and scientific research
- EDPB response to request from the EC for clarifications on the consistent application of the GDPR, focusing on health research
- *Awaiting EDPB guideline on the processing of personal data for scientific research purposes (expected in 2021)*

EC Proposal for a Regulation on European data governance (Data Governance Act)

DPA comments:

- EDPB-EDPS Joint Opinion 03/2021



Future goals & conclusions

DARWIN EU using the EU Health Data Space will support better decision-making throughout the product lifecycle through robust RWE

RWE will be a trusted and accepted source of evidence, available to EMA & the EU medicines regulatory network to support better medicines development and safety monitoring

Data will be discoverable, of known quality & representative allowing choice of optimal data sources, enabling regulators to expertly assess study results

EMA, EU Network & other stakeholders will have knowledge & experience in data science, methods and analytics

Any questions?

Thank you for your attention

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