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Update on big data activities

Veterinary Big Data Stakeholder Forum, 1-2 June 2021

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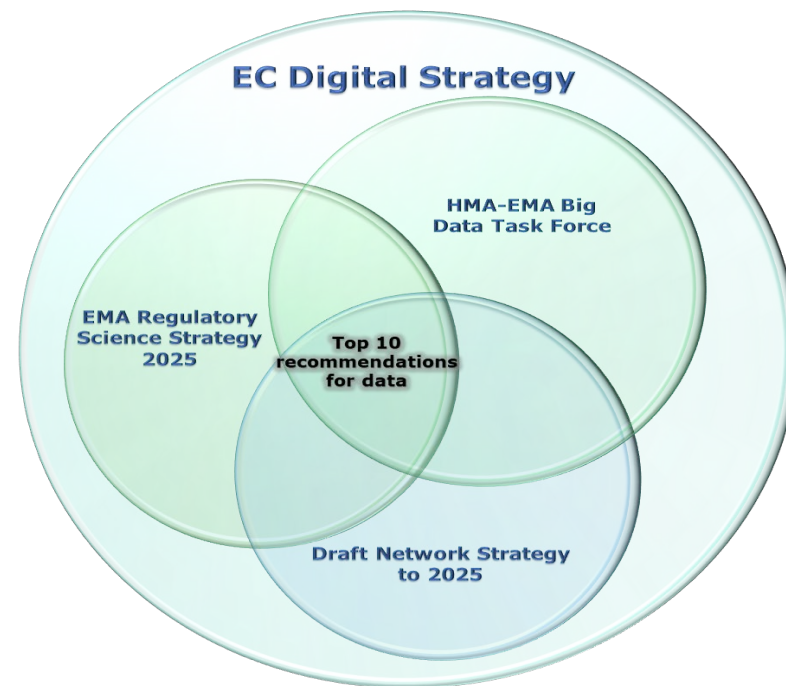
Content

1. Big Data work by EU regulators
2. Explanation on DARWIN EU
3. Looking to the future



The timing is now

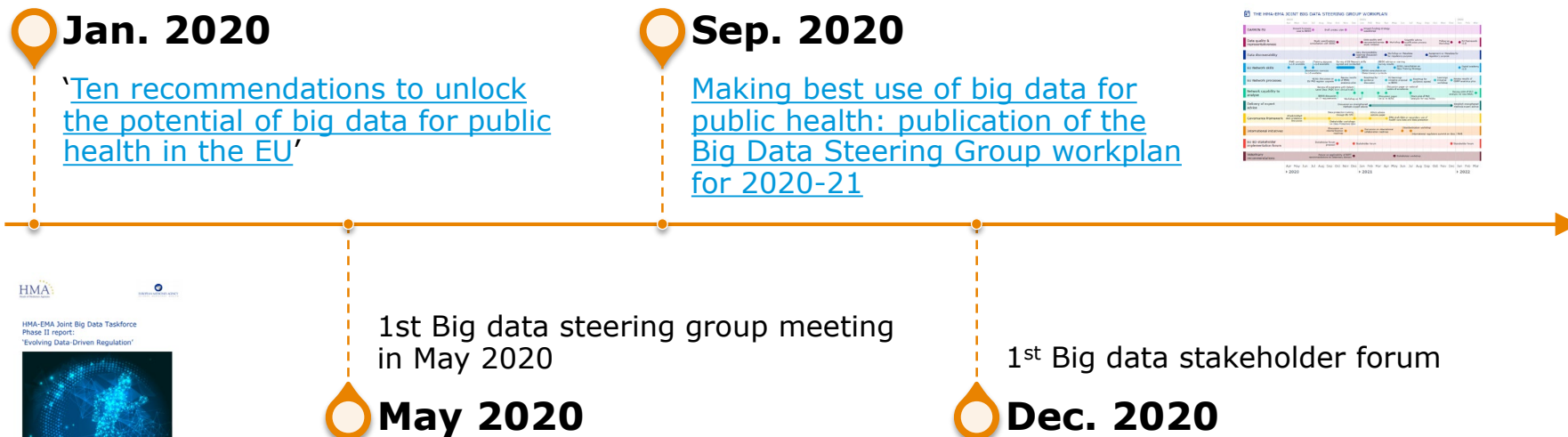
- Commission digital strategy: **“EU health data space”**
- Joint HMA EMA Big Data Task Force **Top-ten data recommendations**
- **EMA Regulatory Science Strategy to 2025**
- **EU Network Strategy to 2025** includes data and digital pillar
- EC **Pharma Strategy** and **Health Union**



Vision: innovate to turn data into decisions on medicines that create a healthier world



Big Data: from Task Force to implementation





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 [Share](#)

News 14/09/2020

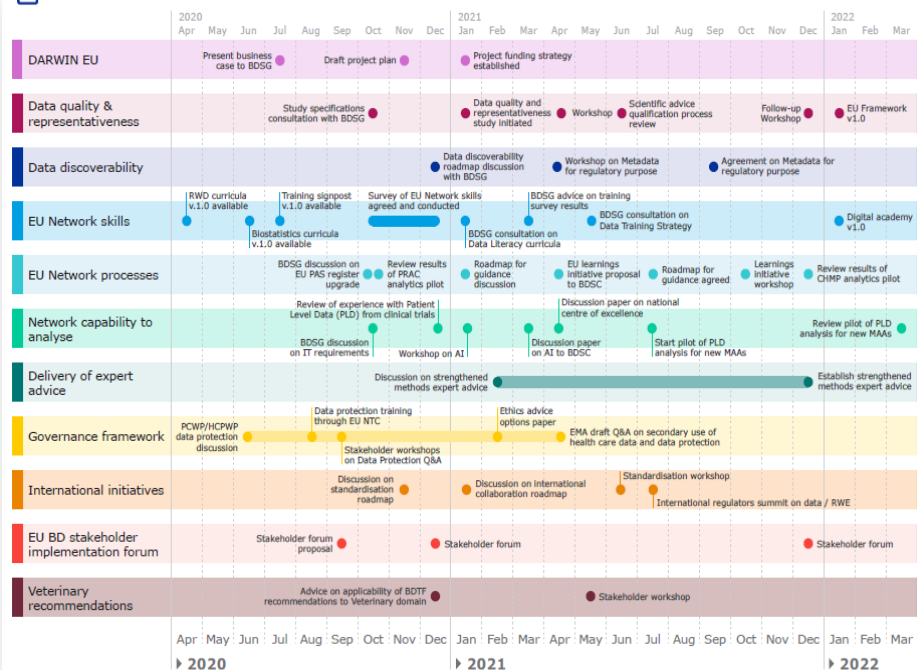
The Big Data Steering Group set up by EMA and the Heads of Medicines Agencies (HMA) has published its [workplan](#) which sets actions to be delivered in 2020-21. With the European Medicines Regulatory Network focused on the response to the COVID-19 pandemic, the workplan aims to progress evolution to 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](#)



THE HMA-EMA JOINT BIG DATA STEERING GROUP WORKPLAN





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



Deliverables in 2021

1. DARWIN EU	Coordinating centre service provider selected DARWIN Advisory Board established Pilot of the European Health Data Space initiated
2. Data Quality	Initiate Data quality and representativeness study
3. Discoverability	Initiate enhancement of EU catalogue of real world data resources Best practice guide on Metadata for regulatory purposes
4. Skills	Training curricula published at least one module delivered per curricula (stats, epidemiology, data science)
5. Processes and transparency	Publish learnings from review of RWE submissions + learnings from committee RWE analytics pilot Roadmap for guidance
6. Analytics capability	Patient level data : pre-pilot becomes pilot
7. Expert advice	RWE and advanced analytics expert advice available (even if full methods EWG not established)
8. Ethics and Security	Publish EMA Q&A on secondary use of health care data and data protection
9. International	Publish international collaboration roadmap on RWE
10. Stakeholder forum	Stakeholder forum
11 Veterinary	Agreement on applicability of the BDTF recommendations to the Veterinary domain



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



Highlights

- Top priorities for the Stakeholders:
 - *Develop a framework to assess and validate AI*
 - *Build a framework that supports the development of guidelines*
 - *Build partnerships with academic and research centers*
 - *International collaborations*
- Selected quotes/paraphrases:
 - *Data is the new soil*
 - *Models are not universal - need three things: validate, validate, validate*
 - *Need to evolve to a Deep Learning Healthcare*
 - *Prediction models have been used for years, in the AI age the explosion of models will require algorithm inventories and algorithmic stewards*

- 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](#)







Business case and mandate for DARWIN EU

Problem statement

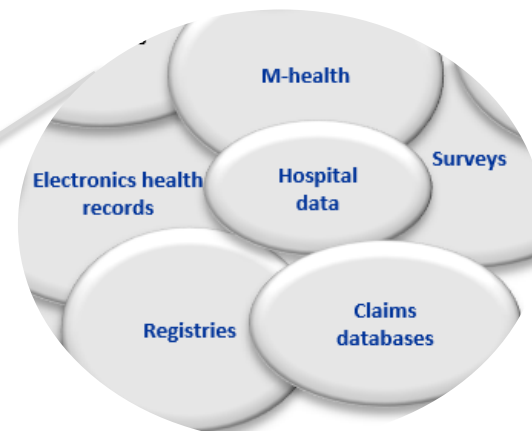
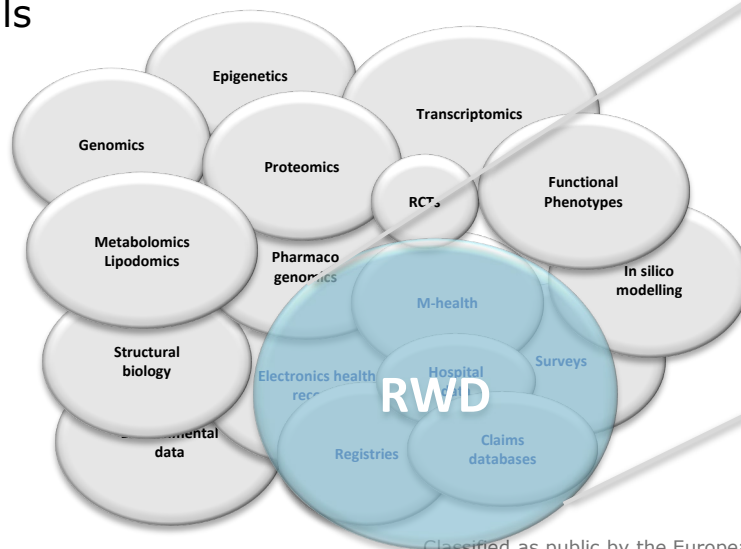
- EU has a rich and diverse healthcare data landscape
- Current limited access to data scattered across different partners: Complex and slow processes for analysis of data

Vision

- Establish and maintain a secure EU data platform that supports better decision-making throughout the product lifecycle with reliable evidence from real world healthcare
- [Published business case for DARWIN](#)

What DARWIN is – type of data

Real-World Data (RWD): routinely collected data relating to patient health status or the delivery of health care from a variety of sources other than traditional clinical trials



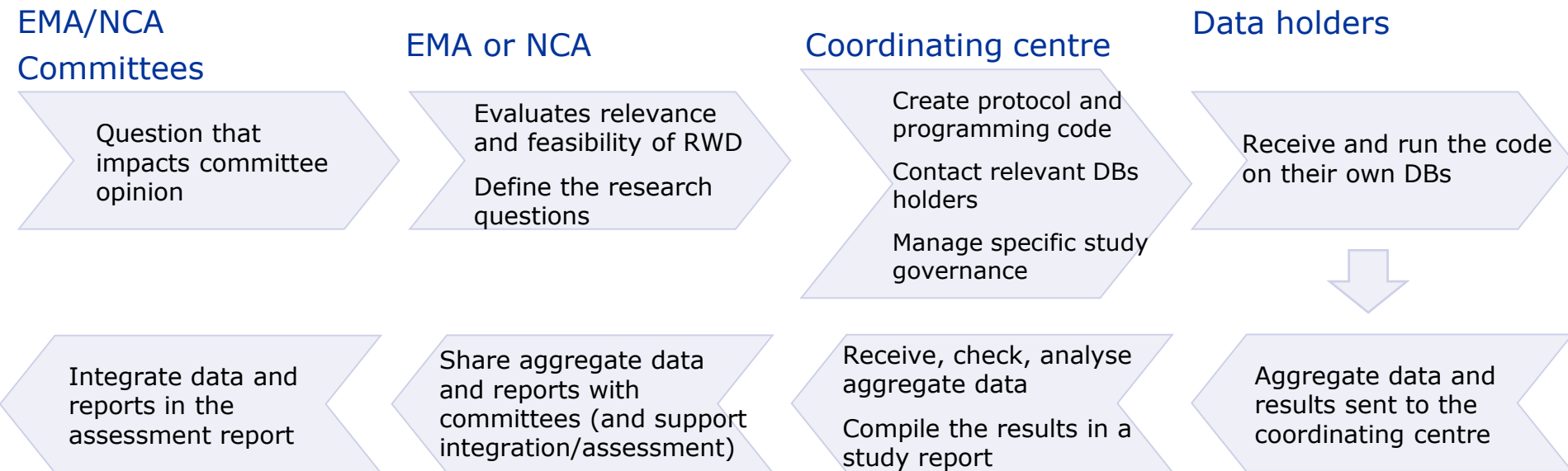
Real-World Evidence (RWE): information derived from analysis of real-world data



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 strategic control and oversight of operations**, e.g. interface with EMA committees, EMA own analysis, driving standards, specifications, guidelines, management of the coordination centre.

How the DARWIN EU network might operate: EMA committee initiates an analysis

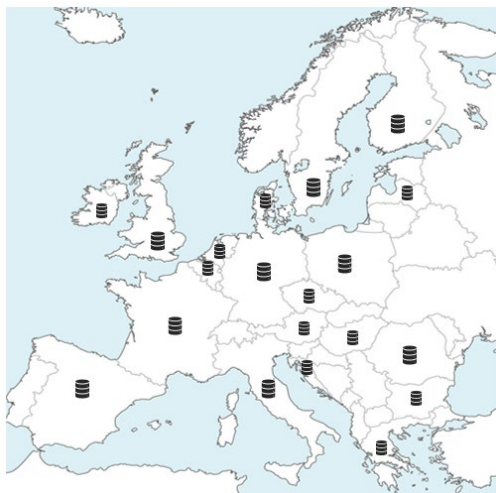




Evolution: from early delivery to fully leverage of the EU Health Data Space

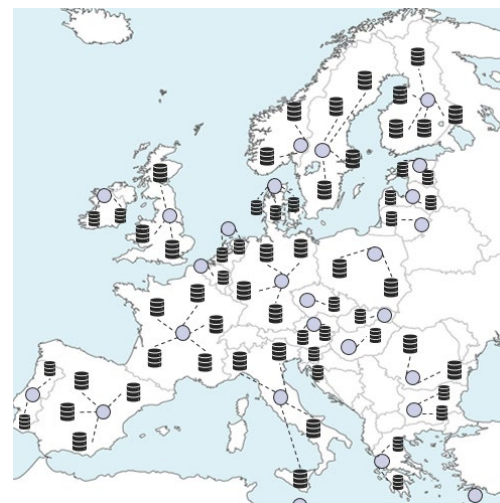
DARWIN EU 2022

- Coalition of existing datasets with medicines regulators
- Federated access to data holders



DARWIN EU **evolution**

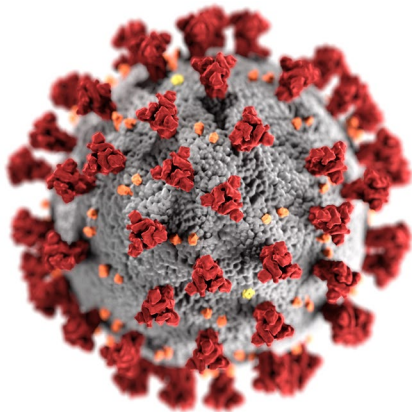
- Using the EHDS
- Access including Data Permit Authorities (● DPerA)



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



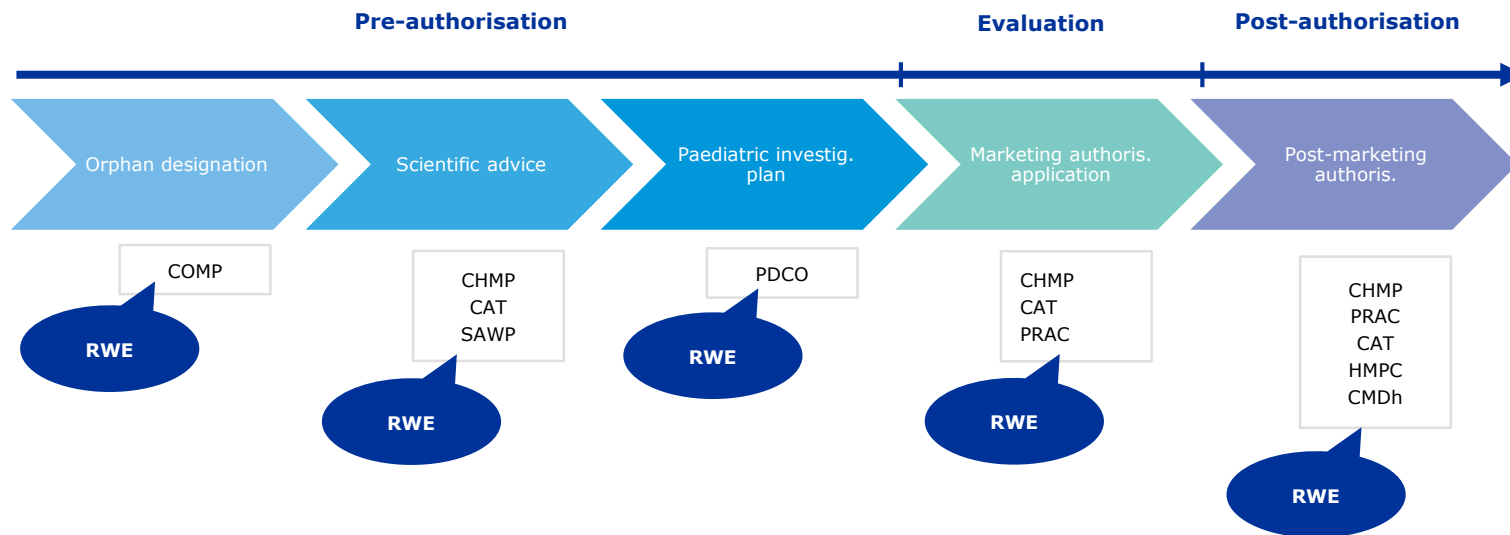
Crisis response use cases include:

- 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

Regulatory use cases through the life-cycle





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



Looking to the future: 2021 and beyond

1. DARWIN	Coordinating centre service establishment initiated DARWIN Advisory Board established 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 - vets invited
3. Discoverability	Initiate enhancement of EU catalogue of real world data resources Best practice guide on Metadata for regulatory purposes vets invited to workshop
4. Skills	Training curricula published at least one module per curricula (stats, epidemiology, data science) training content highly relevant to vets
5. Processes and transparency	Publish learnings from review of RWE submissions + learnings from committee RWE analytics pilot workshop Q4 2021 - vets invited
6. Analytics capability	Patient level data: pre-pilot becomes pilot AI Workshop 19/20 April 2021 - vets invited
7. Expert advice	RWE and advanced analytics expert advice available opportunities for vets to leverage new expert working group
8. Ethics and Security	Publish EMA Q&A on secondary use of health care data and data protection - vets informed
9. International	Publish international collaboration roadmap on RWE Standardisation workshop May 2021 - vets invited
10. Stakeholder forum	Stakeholder forum December 2021 - vets 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



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