

Big Data Steering Group:

- a) BDSG workplan update
- b) DARWIN EU implementation approach

Agenda point B.12, for information and discussion

Management Board meeting of 16-17 December 2020

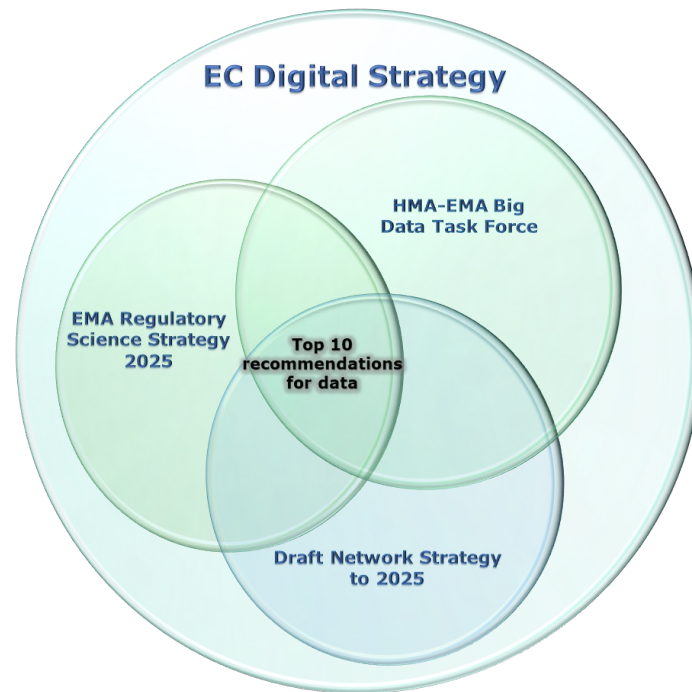


Today

- Inform on progress of the BDSG activities – **for information**
- Update on DARWIN EU project - **for discussion**
- Conclusions

Mandate: the timing is now

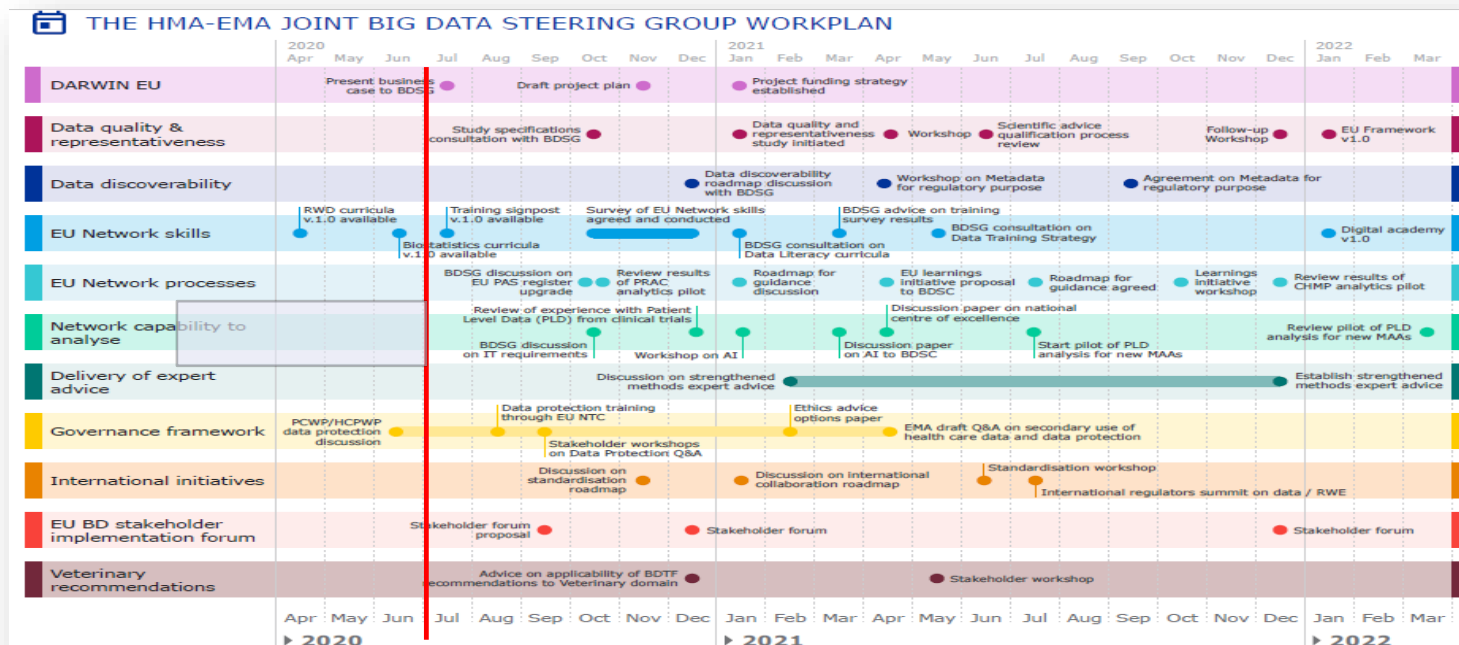
- New Commission supporting digital and “**EU health data space**” – Health Union + Pharma Strategy!
- Joint HMA EMA Big Data Task Force **Top-ten data recommendations**
- **EMA Regulatory Science Strategy to 2025**
- **EU Network Strategy 2025** data/digital pillar + DARWIN EU – now adopted!



Big Data Task Force Priority recommendations – new vet!

- 1 Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network: DARWIN EU)
- 2 Establish an EU framework for data quality and representativeness
- 3 Enable data discoverability
- 4 Develop EU Network skills in Big Data
- 5 Strengthen EU Network processes for Big Data submissions
- 6 Build EU Network capability to analyse Big Data (technology / analytics)
- 7 Modernise the delivery of expert advice
- 8 Ensure data are managed and analysed within a secure and ethical governance framework
- 9 Engage with international initiatives on Big Data
- 10 Establish an EU Big Data 'stakeholder implementation forum'
- 11 Veterinary recommendations

BDSG workplan: on track with milestones and deliverables



Achievements 2020 – delivery of network strategy has started

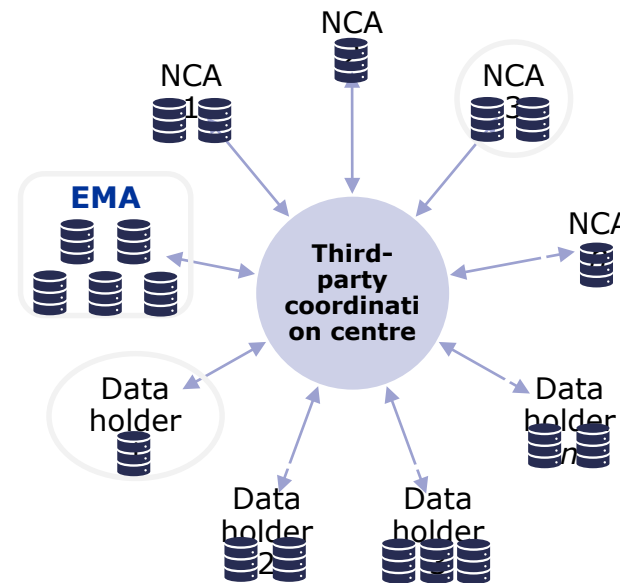
1. DARWIN	Project initiated – see later section
2. Data Quality	Scope defined for a data quality framework
3. Discoverability	Contract signed for external study to agree 'meta-data for real world data'
4. Skills	Big Data Training Sign Post Epidemiology curriculum Biostats curriculum Planning for data literacy and academy
5. Processes and transparency	PRAC RWE pilot initiated CHMP review of RWE submissions initiated in MA applications 2018-2019
6. Analytics capability	Rapid analytics software selected for EMA committee support Clinical Trials-analysis of Patient Level Data – pre-pilot initiated with CHMP
7. Expert advice	Review of working parties methods domain: initiated
8. Ethics and Security	Dedicated workshops held Data Protection Q&A initiated
9. International	ICMRA technical groups on COVID-19 RWE discussions initiated with FDA and Health Canada on a RWE collaboration roadmap
10. Stakeholder forum	First virtual forum 15 Dec 2020
11. Veterinary	Applicability of BDTF recommendations to Veterinary domain initiated

Highlights 2021: transformation begins to deliver

1. DARWIN	See later section
2. Data Quality	Workshop and consultation on a data quality framework and on a data standards strategy
3. Discoverability	Consultation on meta-data for real world data enhance EU catalogue of real world data resources
4. Skills	Training curricula published at least one module delivered per curricula (stats, epidemiology, data science)
5. Processes and transparency	Publish review of RWE submissions (workshop) + learnings from committee RWE analytics pilot
6. Analytics capability	AI workshop Clinical Trial 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 Q&A on secondary use of health care data and data protection
9. International	workshop on international RWE collaboration (to agree collaboration roadmap) .
10. Stakeholder forum	2 nd stakeholder forum
11. Veterinary	Veterinary stakeholder data workshop

Reminder: What is DARWIN EU?

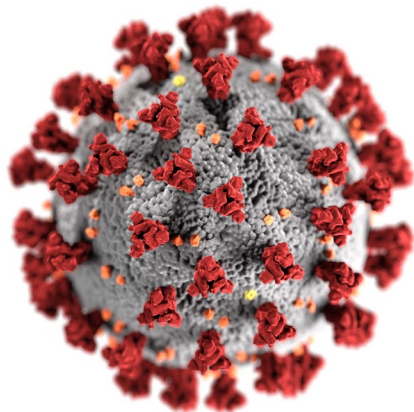
- DARWIN EU is a network of data, expertise and services, not a database
- Main characteristics:
 - **Distributed data access** for fast access and analysis
 - **Federated network**
 - Data stays local
 - Data exchanged within the network is **anonymous**
 - Queried remotely
 - Includes use of a common data model for fast analysis
 - Include a third party **coordination centre** :
 - **Data management and data quality activities:** Identification of the relevant databases, standards, individual agreements with data holders, transformation to a CDM, data quality checks
 - **Study analysis activities:** for running analyses to support EMA/NCAs/Committees
 - EMA will have responsibility for **managing the network** and **act as a data holder** within it



Business case and benefits

- 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 network that supports better decision-making throughout the product lifecycle with reliable evidence from real world healthcare
- EU patients benefit - faster access to innovative medicines and safer and more effective use
- Principal benefits relate to the national and EU regulation of medicines: drug development, authorisation and on market surveillance:
 - EMA committees served with real-world evidence
 - NCAs use DARWIN EU to address national product BR questions
 - NCAs can build their capability for data analytics by becoming a data holder node
 - If fee funded – no cost to public purse
 - Additional benefits will come as EU partners participate and access the platform
 - National governments use DARWIN EU to support health policy and delivery of healthcare systems
 - HTA bodies and payers to support better quality decisions on cost-effectiveness
 - European Commission – delivers on European Health Data Space

Proposal for amended EMA mandate foresees use of real world data to support crisis preparation and response



Critical use of DARWIN EU in crisis preparation and response. Use cases include:

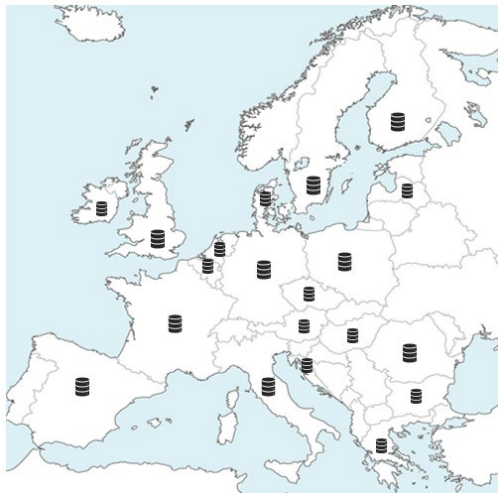
- Monitor use of medicines to predict **demand and shortages**
- Understanding of the **natural history** of the disease to support **drug development**
- **Monitor the safety of medicines and vaccines** on the market
- Provide evidence for repurposing existing medicines

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

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

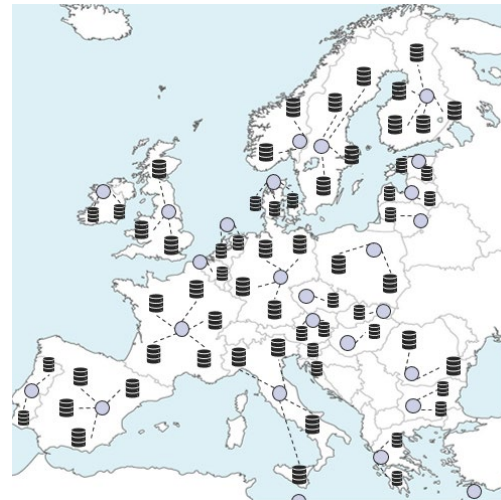
DARWIN EU 2023

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

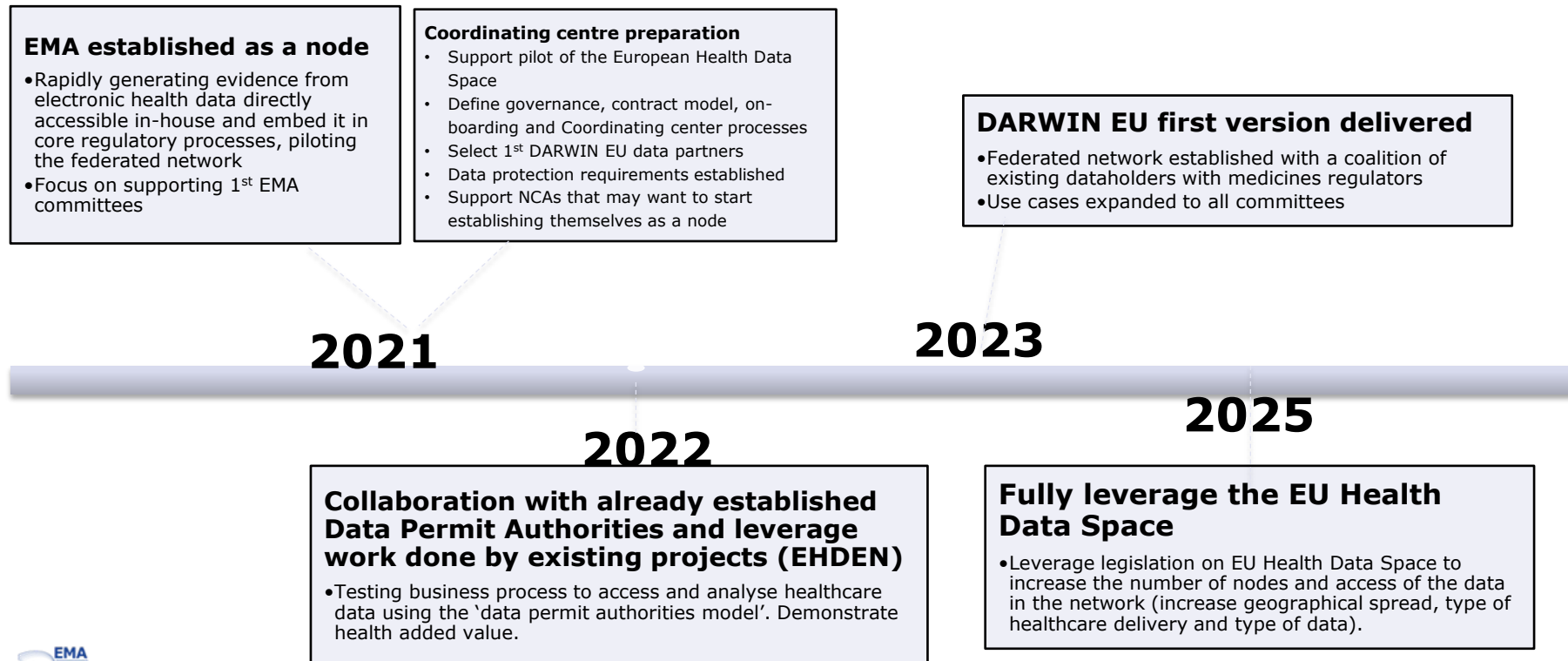


DARWIN EU evolution

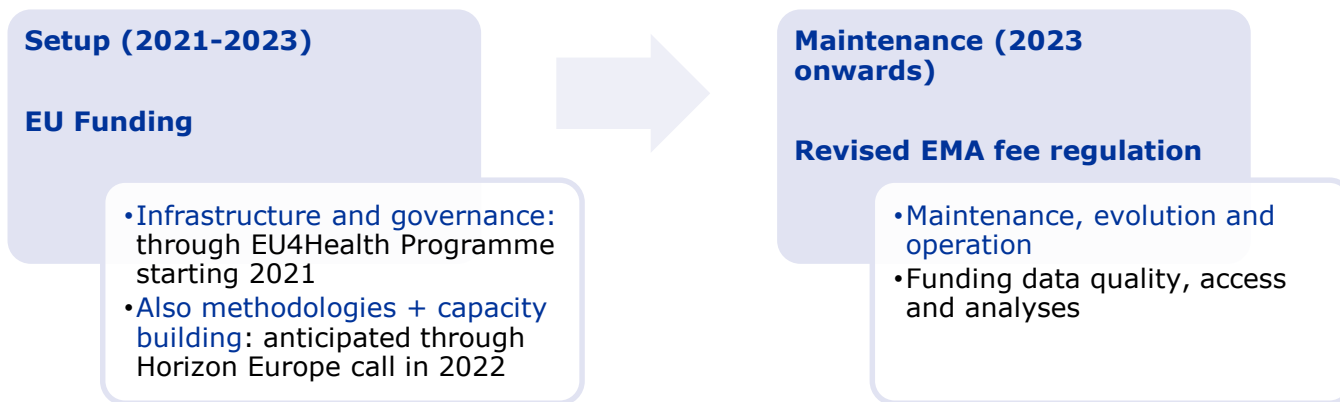
- Node in the EHDS
- Access including Data Permit Authorities (● DPerA)



Following an iterative approach



Funding



- It is important to confirm EU project funding 2021 – 2023 and funding for long-term maintenance (fees)
- increase of EU4Health budget to 5 Billion presents an opportunity to secure the project budget
- Maintenance funding from amendment to EMA fees delivers sustainability at no cost to the public purse

Main DARWIN EU objectives for 2021

- Securing project funding from EC and agree maintenance funding
- Establish DARWIN Network Coordination Group
- Conduct data protection impact assessment
- Sourcing strategy agreed and service establishment initiated
- Pilot with the European Health Data Space initiated
- Refine the regulatory use cases and pilot processes with EMA committees and NCAs
- Initiate Stakeholder engagement and change management

Conclusions: delivering data and evidence for better health

- Implementation of Network Strategy objectives on data driven regulation has started: BDSG workplan can be delivered while fully supporting COVID-19 pandemic response (although timeframes may need to be flexible if demand increases).
- DARWIN EU is a distributed and federated network of data and evidence services for the entire EU regulatory network: it is not a database nor a telematics project and data processing will be secure and GDPR compliant.
- DARWIN EU will deliver a key objective of the Network Strategy to 2025: to enable access and analysis of RWD to support decision making.
- DARWIN EU will support the Commission's vision for a European Health Data Space, as the medicines regulation 'node' and as a pathfinder initiative, demonstrating health benefits of data analysis at EU level
- DARWIN EU will bring benefits for medicines regulation at EU and national level with NCAs able to use the network to address national questions (but with no obligations for NCAs).
- To make DARWIN EU happen funding for the project phase 2021 – 2023 is needed – there is a compelling public health business case for DARWIN EU funding from the enlarged EU4Health.
- To make DARWIN EU sustainable and operable, funding long term is required (revision of the EMA fee regulation delivers sustainability at no costs to public purse).

Any questions?



Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Send us a question Go to www.ema.europa.eu/contact

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