HMA-EMA Big Data workplan and update on DARWIN EU

SESSION 2: Update on Big Data SG and ENCePP SG

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Today's presentation

1. Big data Steering group workplan
2. Key achievements in 2021 and future highlights for 2022
3. Deep dive on 'RWE' priority recommendations
   - DARWIN EU
   - Complementary activities
4. Future collaborations

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Looking forward

"By delivering the vision of a regulatory system able to integrate Big Data into its assessment and decision making, we can support the development of innovated medicines, deliver life-saving treatments to patients more quickly and optimise the safe and effective use of medicines through measurement of a products performance on the market."

Big Data Task Force final report December 2019

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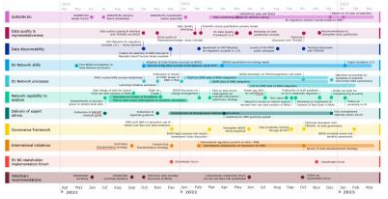
Big Data: from recommendations to implementation

Jan. 2020

'Ten recommendations to unlock the potential of big data for public health in the EU'

Sep. 2020

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



1st Big data steering group meeting in May 2020

May 2020

Publication of BDSG workplan 2021/2023

Aug. 2021

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Big Data Steering Group: Recommendations

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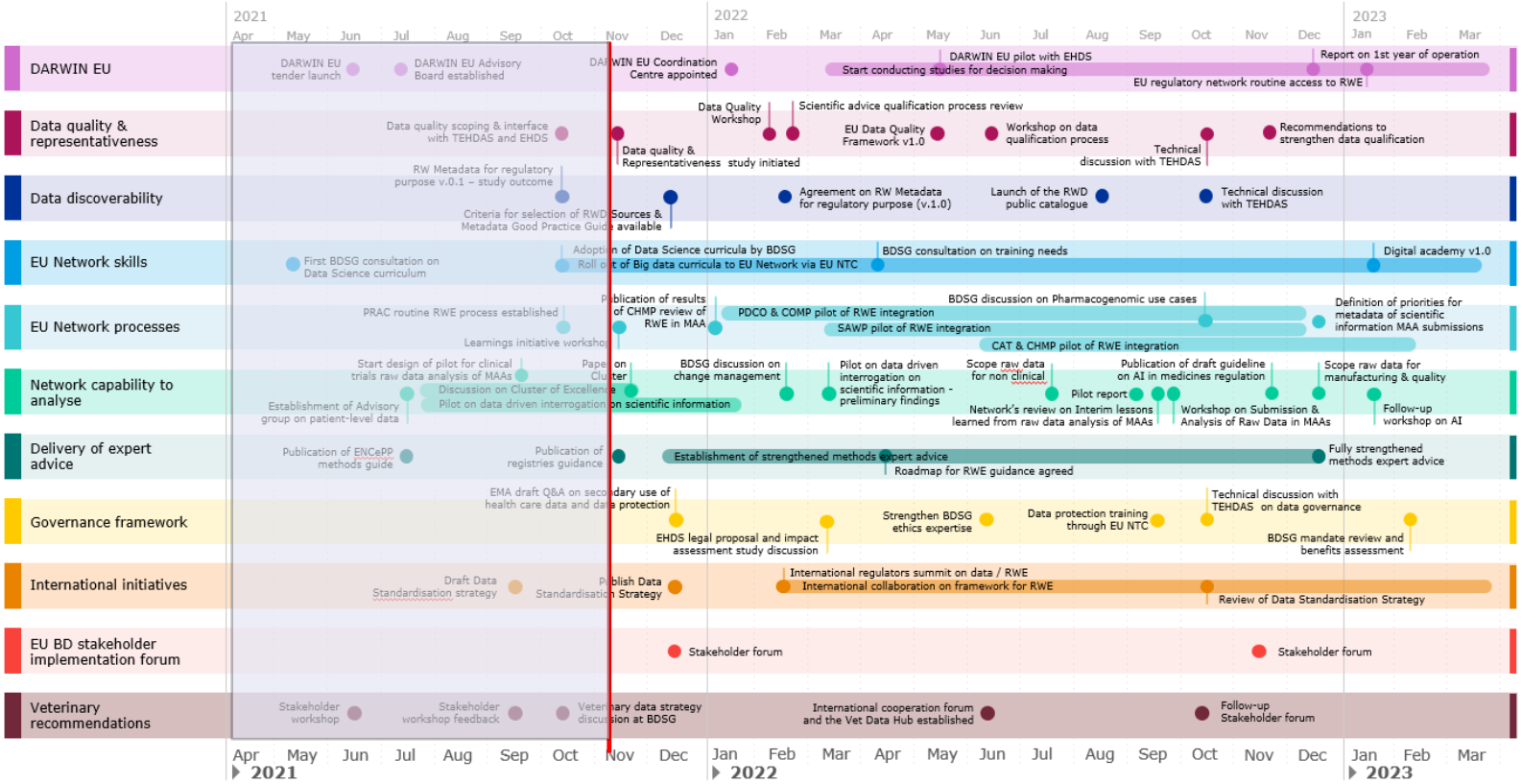
HMA-EMA Joint Big Data Steering Group work plan



On track

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Key achievements in 2021 and future highlights for 2022

HMA Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY

	2021	2022
Next slides DARWIN EU	**Procurement launched**	**Coordination Centre appointed** – Support EHDS2 pilot – **Start conducting pilot/studies** for decision making
Next slides Data quality & representativeness	**Procurement launched** for academic consortium to deliver a data quality framework	**EU Data quality Framework v1.0 available -** Recommendations to **strengthen data qualification** – **2 workshops** on data quality and data qualification
Next slides Data discoverability	**Study of metadata for real-world data**	**Agreement on RW Metadata for regulatory purpose** (v.1.0) - **Launch of RWD public catalogue**
Next slides EU Network skills	**Data science curriculum** finalised – **Survey of skills** completed - **Training delivery outsourcing** initiated	**Roll out** of Big data curricula (Biostatistics, Pharmacoepidemiology, Data science)
Next slides EU Network processes	**RWE use cases developed** with PRAC, PDCO, COMP – **Learnings initiative workshop** November 2021	**RWE integration pilots** (PDCO, COMP, SAWP, CAT, CHMP)
Network capability to analyse	Discussion on **Clusters of Excellence** - **AI workshop** **Pre-pilot on raw data analysis** completed	**Clusters of Excellence paper** - **Draft guideline on AI** in medicines regulation - **Workshop on Raw Data in MAAs** and **Pilot of raw data analysis** execution
Next slides Delivery of expert advice	**ENCEPP RWE methods guide** published **- RWE and advanced analytics expert advice** established	Publication of **registries guidance** - **Roadmap for RWE guidance agreed**
Governance framework	**BDSG recommendations on ethics advice**	**EHDS** legal proposal and impact assessment study supported – publish Q&A on **data protection**
International initiatives	**Data standardisation strategy** adopted Dec 2021 – Progress on **RWE Collaboration Roadmap** with FDA	International **regulators summit on real-world evidence**
EU BD stakeholder implementation forum	**Multi stakeholder forum Big Data - Dec. 2021**	Stakeholder forum
Veterinary recommendations	**Workshop on the** Veterinary **Data Strategy**	**International** cooperation **forum** and the **Vet Data Hub** established

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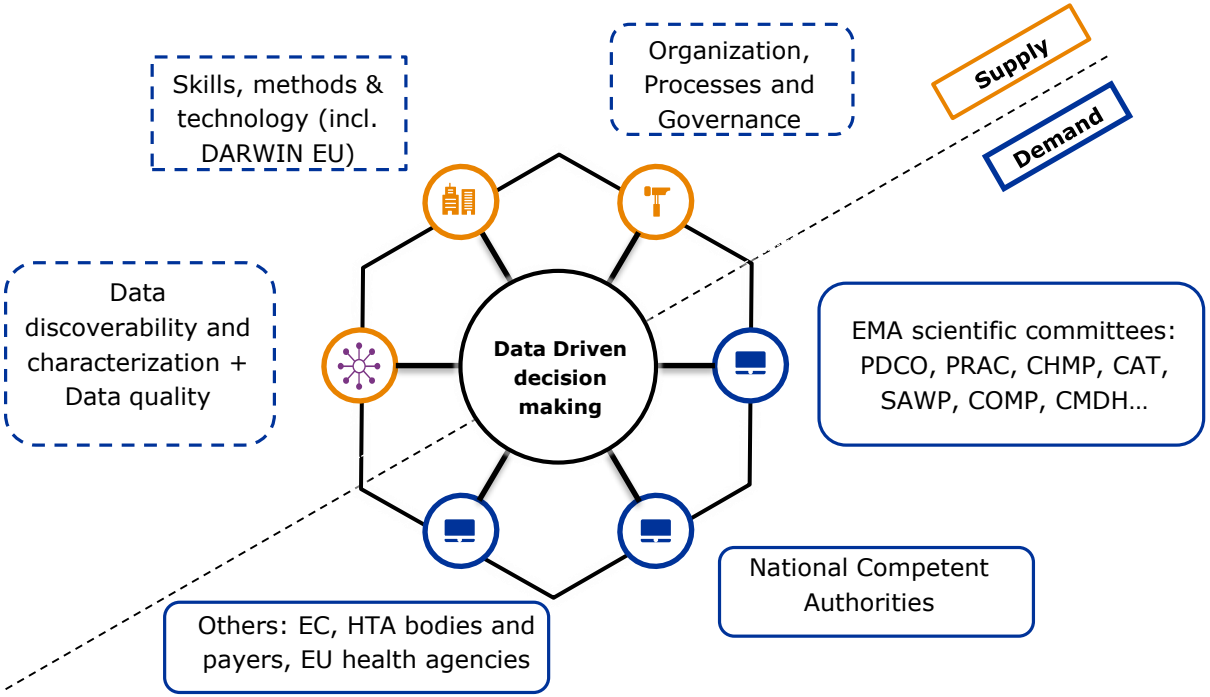
Deep dive on 'RWE' priority recommendations



Vision to enable the generation and use of RWE in decision-making

Coming in 2022: DARWIN EU®

DARWIN EU is a federated network of data, expertise and services

Status:
- Coordination centre appointment expected early 2022
- First pilot/studies from 2022

EU Medicines Regulatory Network

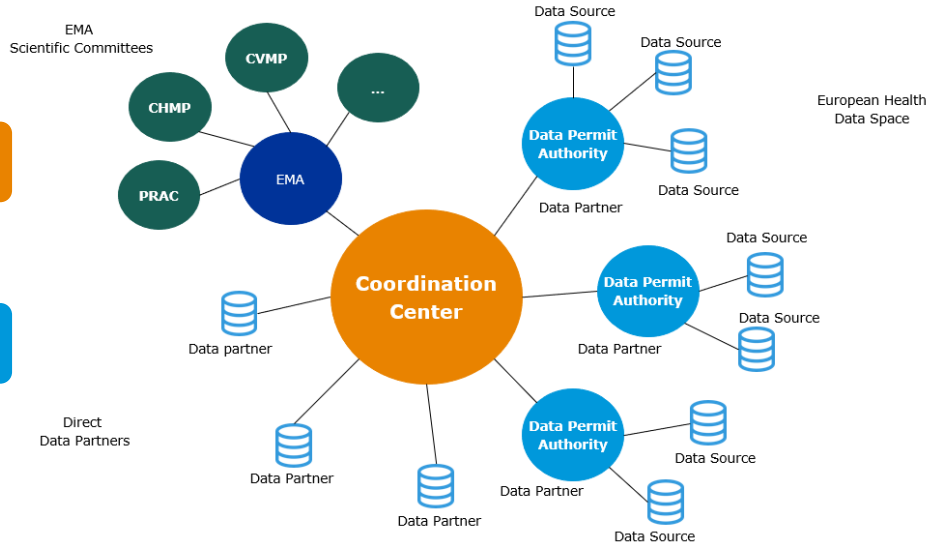
- **EMA** - provides leadership, setting standards, contracting studies, **overseeing**
- **European Medicines Regulatory Network -** including EMA scientific committees and working parties, national competent authorities (NCAs) and the European Commission: **request studies** via EMA

The Coordination Centre

- **Establishes** and **maintains the network** (including onboard/maintain data sources), manage the **execution of scientific studies**

Data Partners, incl. Data Permit Authorities

- **Partners** who have access to data, or who may request analyses in a data source and provide results to the Coordination Centre
- This includes **Data Permit Authorities** (DPAs), already existing or to be created as part for the European Health Data Space (EHDS)



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Complementary activities – Methodologies and capabilities

- Refine methodologies for the use of RWE:
  - Call published for the Horizon Europe Cluster 1 Health, submission from Oct. 21 to Apr 22 (HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment)
  - Evaluation of the impact of RWE in the decision-making process and to promote the provision of recommendations for best practice
- Big Data learning initiative workshop 30 November 2021:
  - track and learn from relevant Big Data applications through the product life-cycle and feed learnings to reflection papers and guidance.
- Developing training Data Science, Pharmacoepidemiology and Biostatistics
  - Curriculum agreed in 2021 and delivery and roll-out planned for 2022
- Creation of a Methodology Working Party with dedicated expertise in RWE

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Complementary activities – Transparency, data quality and pilots

- Increase access to the adequate data sources and expertise
- Increase data quality
  - 1st version of EU Data Quality Framework for big data used in the regulatory decision-making process is expected in 2022.
- Refine use cases and create processes together with committees
  - Pilots with committees have progressed to prepare for the future operating model with DARWIN EU and generation of RWE: see next slide

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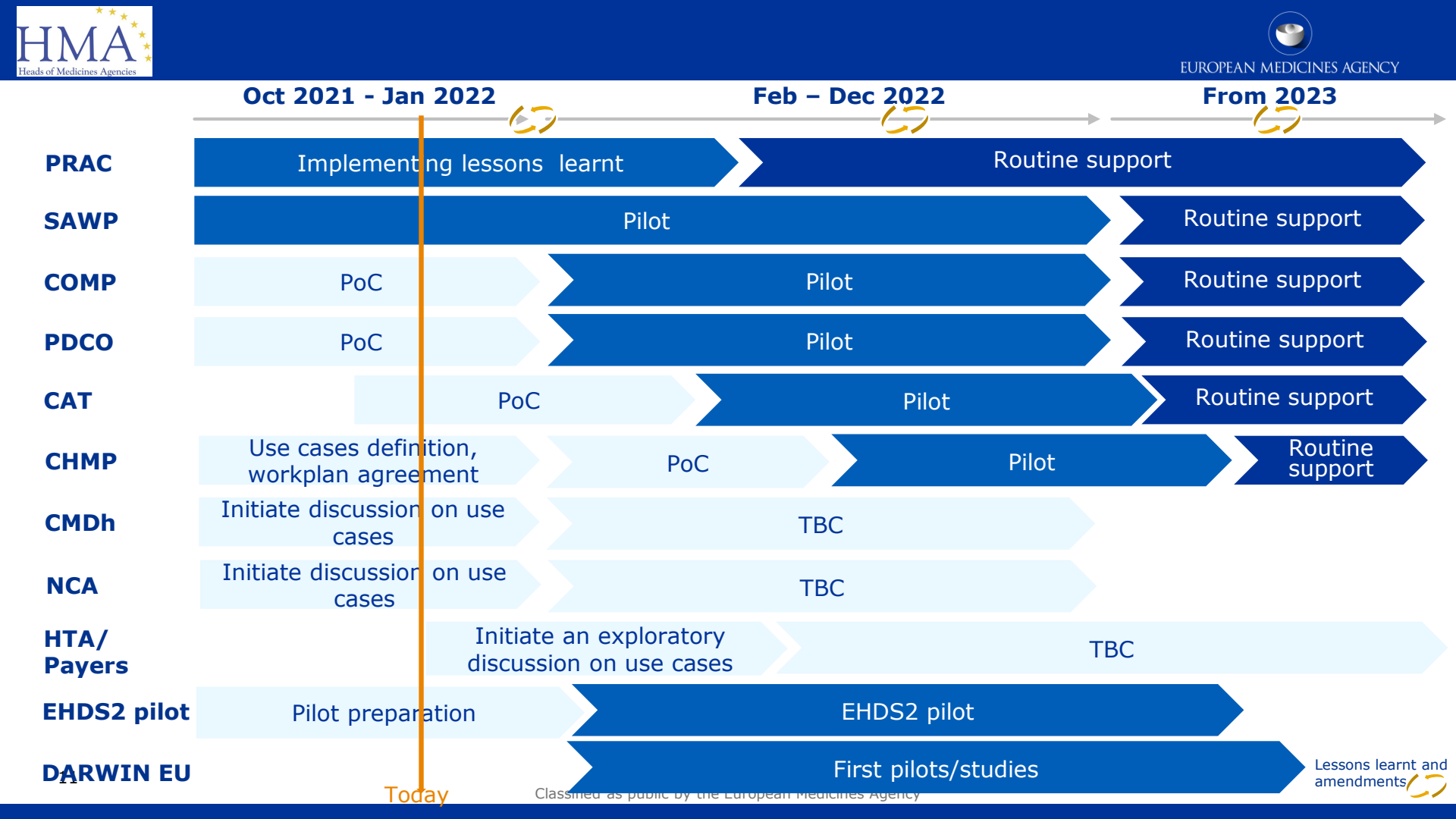

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Future collaborations in 2022

DARWIN EU	**ENCePP consulted on key aspects of data, methods and governance**
Data quality & representativeness	**ENCePP to be consulted on EU data quality framework (e.g. workshops participation, survey…)**
Data discoverability	**ENCePP to be consulted on metadata and catalogue of studies (e.g. workshops participation, survey…)**
EU Network skills	**possible outreach to ENCePP and academia on Big data curriculum**
EU Network processes	**ENCePP to be informed on RWE pilots/studies**
Network capability to analyse	**ENCePP to be informed pilot on raw data analysis**
Delivery of expert advice	**ENCePP to be informed/consulted on Registries guidance and Roadmap for RWE guidance**
Governance framework	**Q&A on data protection will be shared with ENCePP**
International initiatives	**ENCePP possible opportunities on roadmap on international collaboration on RWE**
EU BD stakeholder implementation forum	**ENCePP is invited to each Multi stakeholder forum Big Data**
Veterinary recommendations	

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Conclusion

- Progress on implementation of the Big Data recommendations continued in 2021 and plans for 2022 will enable to provide stakeholders with tangible deliverables.
- Implementation will require strong engagement and collaboration with stakeholders in 2022.

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Big Data Task Force final report December 2019

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Thank you

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