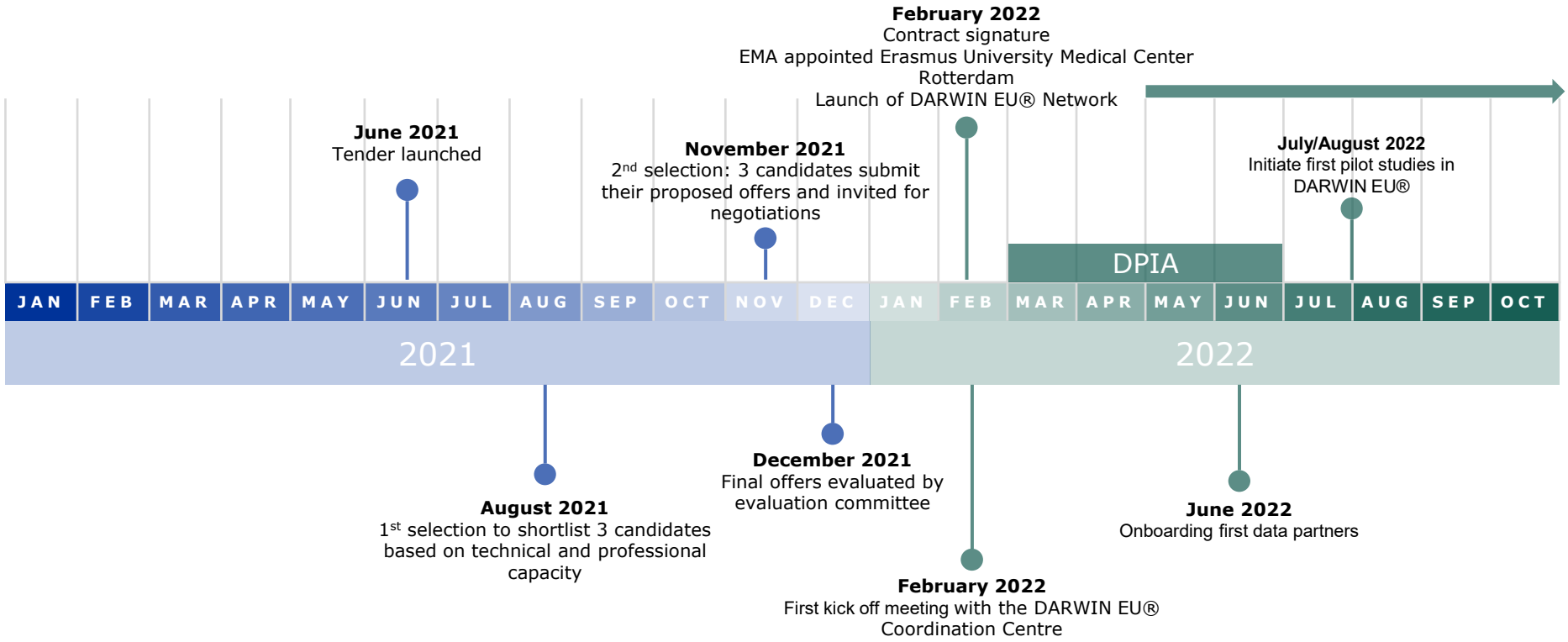
5.3 DARWIN EU®

PCWP/HCPWP joint meeting

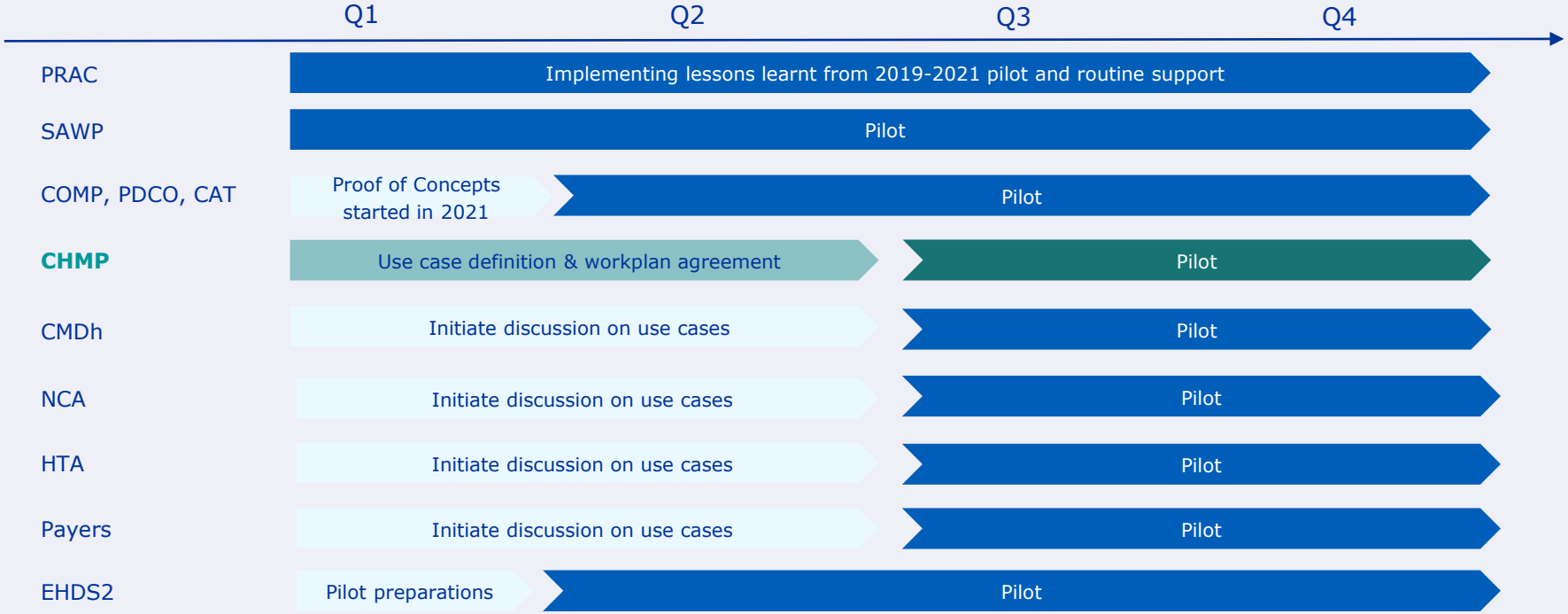
Presented by Andrej Segec, Aldo Maggioni, and Elizabeth Vroom on 2 June 2022
European Medicines Agency

Table of contents

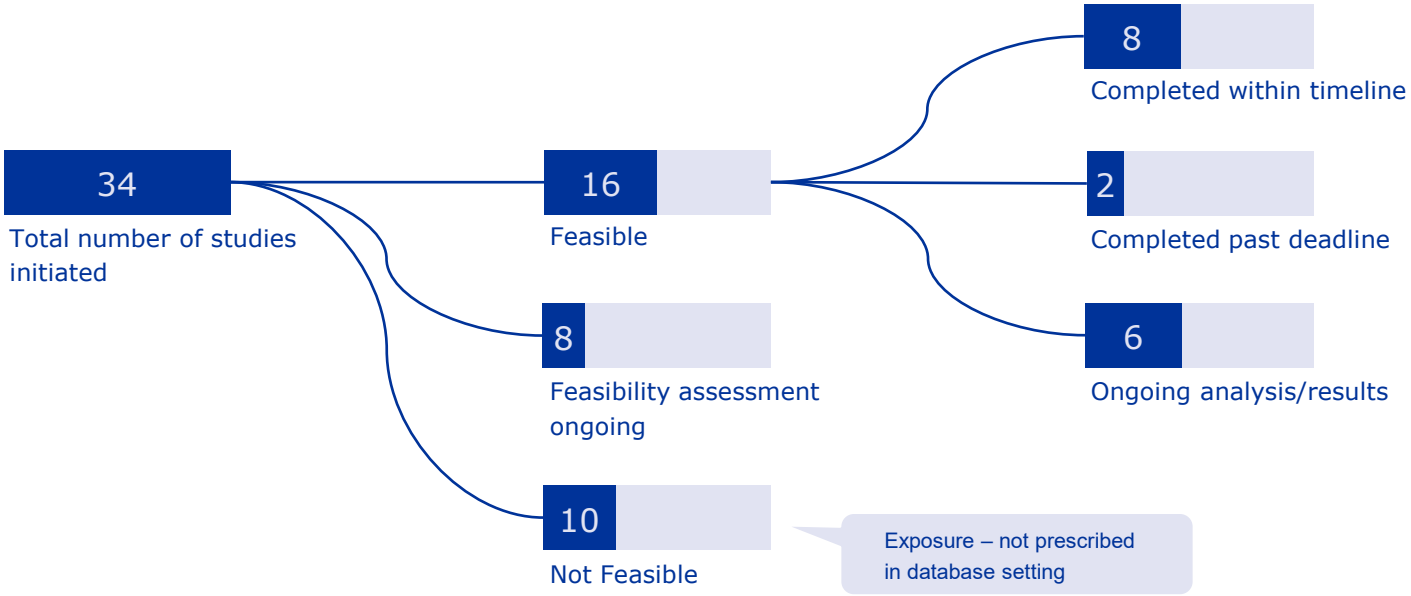
DARWIN EU® timeline



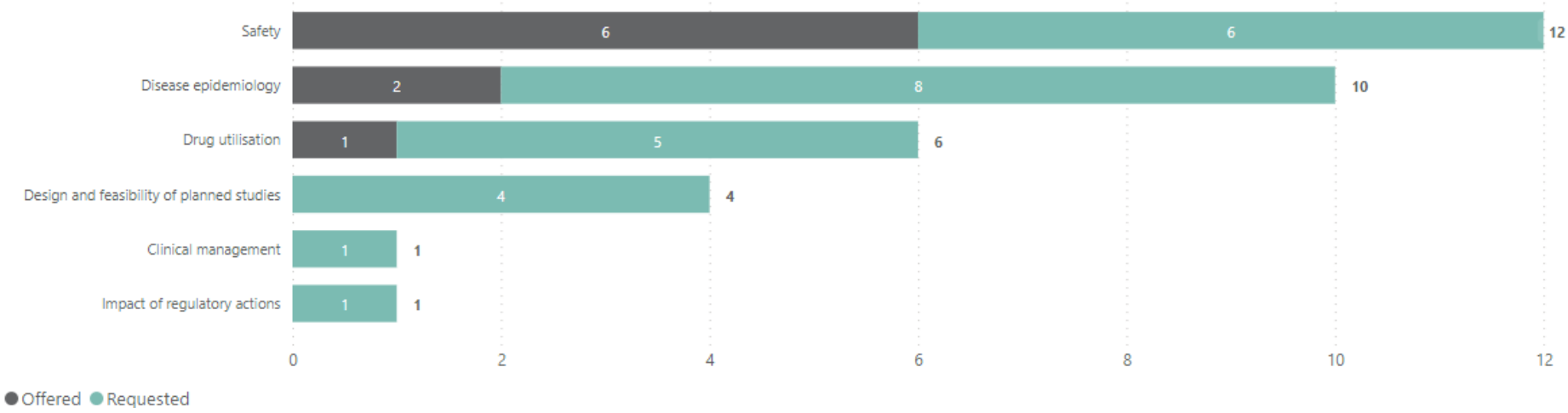
Looking at 2022 | Integration of RWE



Ongoing and finalised studies | October ’21 – May ‘22



Ongoing and finalised studies | October ’21 – May ‘22



CHMP Pilot

Objectives	○ Inform of the RWE initiatives at EMA ○ Practical aspects of the RWE pilots with CHMP
Timeline	○ CHMP pilot outline to be circulated by EMA for comments (2 week consultation) ○ Pilot to be initiated in June/July 2022 and to run for 12-18 months with a mid-pilot evaluation report
Possible use cases	○ Supporting the planning and validity of applicant studies ○ Understanding clinical context ○ Investigating associations and impact

Criteria for prioritisation

At least 10 new data partners per year from Year 1 to Year 4

- Continuous data collection with at least yearly update and ideal lag time between data capture and data availability of 6 months or less
- Health outcomes and medicines prescribed identifiable and linked to individual patients
- Well-defined underlying population with entry and exit dates; data sources in which patients can be registered with different identifiers to be clearly identified
- Care setting appropriate for research questions and not adequately represented by other databases (e.g. primary and specialist care, inpatient hospital care, data source measuring indication, dose and duration)
- Geographical spread: covers EU country not adequately represented by other data sources
- Proven track record for collaborative studies
- Conversion into common data model with appropriate validation/testing
- *Adequate and transparent governance allowing peer-review of quality management processes*
- *Adequate infrastructure allowing secure transfer of results.*

Primary Criteria

Supported by DARWIN EU Advisory Board

Criteria for prioritisation

At least 10 new data partners per year from Year 1 to Year 4

Non-EU data source, if it may significantly contribute to research questions raised by EMA Committees

Database which provides linkage and continuous follow up between primary and secondary care

Database with mother/child linkage

Information on dispensed medicines

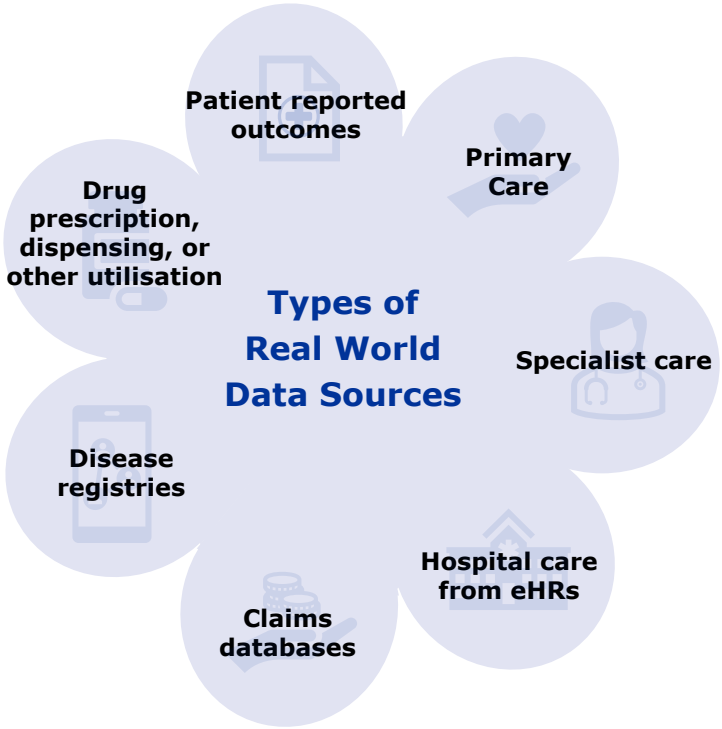
Large sample size (i.e. number of active patients)

Databases not converted or partially converted into OMOP data model with potential for significant contribution to research questions raised by EMA Committees

Secondary Criteria

Supported by DARWIN EU Advisory Board

Onboarding of data partners and first studies



- Initially 10 partners to be onboarded
- First pilot studies in 2022 for a number of use cases across the medicinal product lifecycle
- By 2025, > 100 studies per year will be conducted

Data Protection Impact Assessment & Data Use Agreement

DP by design

Federated model: data stays local

Robust DP safeguards

In accordance with Article 39 of Regulation (EU) 2018/1725, EMA is performing a Data Protection Impact Assessment (DPIA) prior to the initiation of the processing activities → expected for June 2022

- A **preliminary DPIA** was conducted in 2021 in preparation of the procurement of the DARWIN EU® Coordination Center (CC) services

Aim is to assess all personal data processing activities to be performed by CC to

- Describe the nature, scope, context and purposes of the personal data processing;
- Assess the necessity and proportionality of the personal data processing;
- Identify and assess risks to individuals & any additional measures to mitigate those risks.

Review data use agreement (DUA) template with data partners which will set out data protection roles and responsibilities

Next steps for DARWIN EU®

- Finalising DPIA (June 2022)
- Completing Milestone 1 (T0+3M) – reviewing and accepting deliverables
- Agreement on data use agreement template, study templates
- Selection of Y1 data partners and onboarding
- Start of first pilot studies, realising first benefits for the network and stakeholders
- Future data partner calls anticipated

More Information

Data Analysis and Real World Interrogation Network (DARWIN EU) | European Medicines Agency (europa.eu)

DARWIN EU® webinar recording

Coordination Centre website – coming soon in 2022!

For regular updates on DARWIN EU® Subscribe to the Big Data Highlights newsletter by sending an email to: bigdata@ema.europa.eu


BIG DATA
HIGHLIGHTS
Quarterly update on implementation activities of the HMA-EMA Big Data Steering Group workplan
An agency of the European Union

Editorial

Patients' perspective on real-world evidence in regulatory decision making

INSIDE THIS ISSUE
Editorial 1
Featured topics 3
Getting involved 6
List of acronyms 7

Marilena Vrana
Manager Patients and Research, European Heart Network

Digitalisation has increasingly been embedded in our everyday life. Digital technologies have begun to change the practice of medicine, hence research and innovation. The availability of a broad scope of tools, whether electronic health records, mobile-health tools, wearables, registries or others, have increased tremendously the generation of health data.

Digitalisation is steering medicine to bottom-up data management that involves real-time data extraction and analysis of various data sources. This offers the opportunity to improve the generation of evidence, including the design, speed and efficacy of randomised controlled trials for the development of new medicines without compromising patient safety.

Patients are generally supportive of sharing their data for research.

They perceive that data sharing could lead to innovative medicines that meet their real needs and improve health outcomes, and most notably their quality of life. Public and patient motivations and willingness to share data relate to their perception of contributing to the 'common good'. Nonetheless, they expect transparency and require reassurance and mechanisms to mitigate risks so that their health data will be protected.

Meaningful patient involvement in both research for novel products and in medicines regulatory processes is key factor for trust in future innovations. Patient needs and expected outcomes are key to factor-in from the outset to ensure relevance, value, efficacy and adherence. Robust collection of high-quality data coming from patient reported outcomes is increasingly important to better evaluate the added value of a medicine.

BIG DATA
HIGHLIGHTS
Issue 2 – May 2022
Page 2

Any questions?

Further information

Data Analysis and Real World Interrogation Network (DARWIN EU) | European Medicines Agency (europa.eu)

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**