EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ad-Hoc Focus Group on RWD & RWE

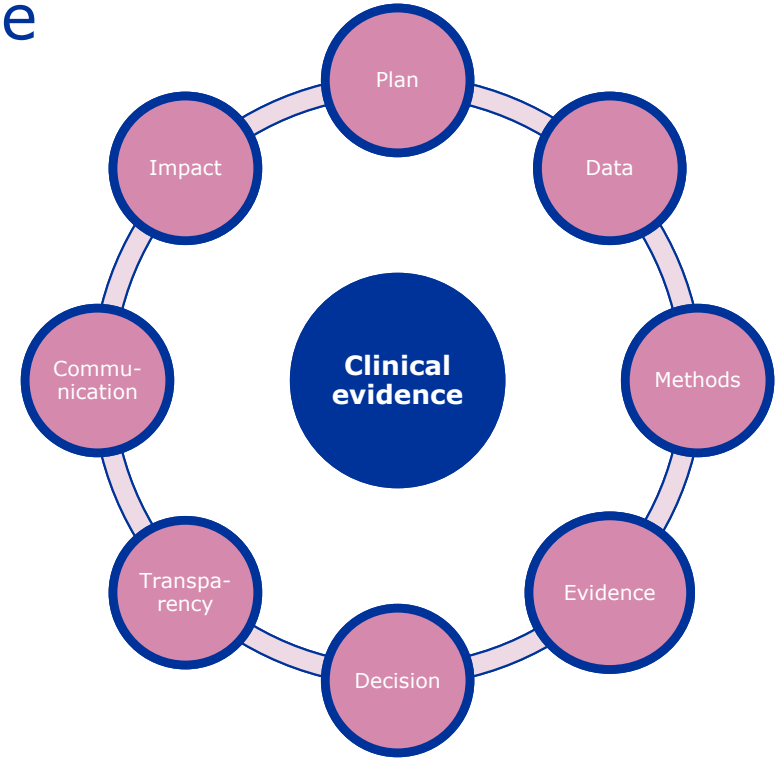
Background, Objectives & Working Methods
04 July 2024

Patrice Verpillat
Real-World Evidence Workstream
Task Force Data Analytics & Methods

An agency of the European Union

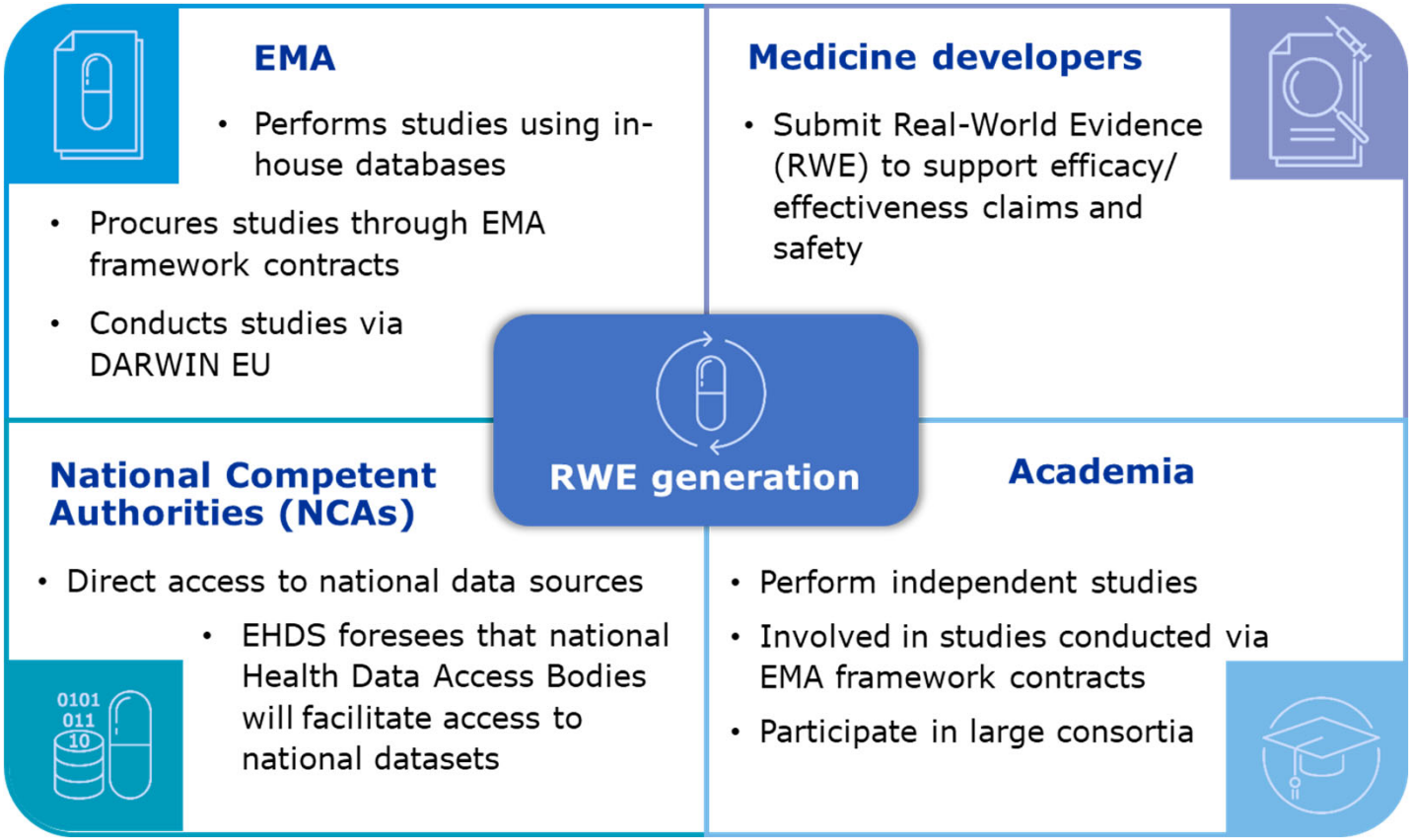
RWD and RWE play a crucial role in bridging the gap between clinical research and practice

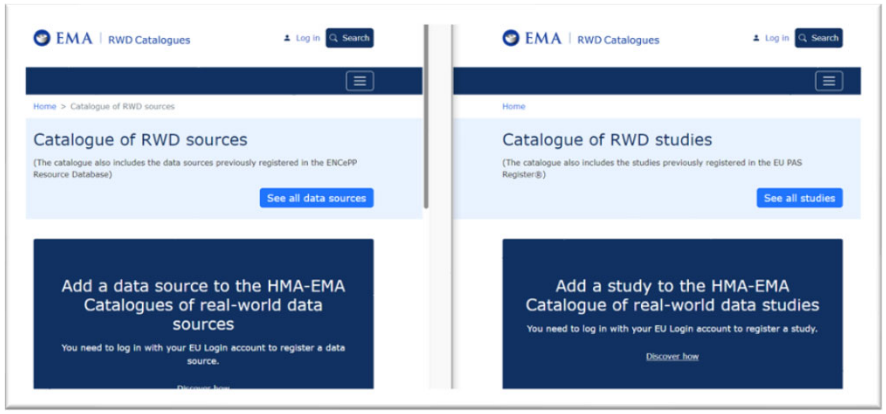
- Evidence generation is planned and guided by **purpose**, data, knowledge and expertise
- Research question drives evidence choice and embraces spectrum of data and methods
- **Clinical trials remain core but are bigger, better and faster**
- **Real world evidence is enabled, and its value is established**
- The patient voice guides every step of the way
- Healthcare systems are supported in their choices
- High levels of transparency underpin societal trust



At the core of a successful MA dossier is excellent clinical evidence

Who delivers RWE for regulatory purpose in the EU?





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15 April 2024
EMA/150527/2024
Committee for Human Medicine Products/Methodology Working Party (CHMP/MWP)

Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence.

Draft

Draft agreed by Methodology Working Party (MWP)	October 2023
Adopted by CHMP PROM for release for consultation	15 April 2024
Start of public consultation	<DD Month YYYY>
End of consultation (deadline for comments)	<DD Month YYYY>
Agreed by Methodology Working Party (MWP)	<Month YYYY>
Adopted by CHMP PROM	<DD Month YYYY>

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	Non-interventional study, real-world data, real-world evidence, feasibility assessment, bias, confounding, data quality

Willingness to intensified dialogue and continued collaboration on RWD/RWE

Overall objective of the proposed Ad-Hoc Focus Group

Share knowledge and experience with use of RWD and generation of RWE to advance integration of relevant and reliable RWE in regulatory decision making

Specific objectives

To **exchange views on RWD and RWE key concepts, discuss priorities and possible approaches, explore possible solutions** for enhancing the use of excellent evidence generated by the analysis of RWD into regulatory decision making

- The Focus Group should particularly discuss any relevant topics related to design of studies using RWD (e.g., data quality, fit-for-purpose data, feasibility assessment, place for innovative designs and/or methods…), interpretation and reporting of results (e.g., impact and interpretation of heterogeneity in multi-database studies…), and good science principles to be applied to any study using RWD (e.g., transparency, fit-for-purpose evidence…)
- The Focus Group could also identify RWD/RWE areas for multi-stakeholder approach needs, if relevant

Expected outcomes

- **Share views** on important concepts such as what is RWD and generated RWE, including "fit-for-purpose"
- **Reflect** on the application of the Data Quality Framework and use of the HMA-EMA RWD catalogues, and discuss ways for improvement if needed
- **Agree** on key elements to be assessed at the feasibility step of any study using RWD
- **Share experience** with novel/ innovative designs and methodologies
- …

Working Method

Focus Group set-up now

Meetings will take place every 3 to 4 months (first meeting expected in Sep – TBC)

Call for topics to be sent 1 month before the planned meeting date

5 to 6 industry stakeholders experts participating per Focus Group meeting

(*Note*: Call for industry expects nominations with specific expert profile description (mostly be methodologists to fit the scientific/ technical discussions) will be sent by EMA to relevant EU Trade Associations)

We are committed to realize the full potential of RWE in regulatory decision making and we do recognize that the best science is advanced through dialogue, collaboration and trusted partnership

Any questions?

Further information

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

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