# Multi-stakeholder workshop on Real World Data (RWD) quality and Real World Evidence (RWE) use

**26-27 June 2023**
Hybrid meeting / EMA, Amsterdam

Building upon the experience of the submission of real-world evidence for regulatory purpose and the conclusions of previous activities around data standardisation, metadata, data quality and DARWIN EU®, this workshop aims to:

Day 1 – 26 June 2023:

- familiarise stakeholders with the approach used in drafting of considerations on Real-World Data linked to the EU Data Quality Framework
- discuss important challenges related to measuring and characterising data quality in the context of RWE generation

Day 2 – 27 June 2023

- discuss recent use of RWE including DARWIN EU® in the regulatory context, collect input from experts in the field and learn from existing experiences
- look back at the European Medicines Regulatory Network response to the COVID-19 pandemic and reflect on learnings and impact on the way we use RWE to address public health emergencies
- collect input from experts in the field and learn from existing experiences
- get multi-stakeholders' input to identify ways to enable further use and continue to establish the value of RWE in regulatory processes.

# Day 1 – Monday, 26 June 2023, 12:30 – 17:45 CEST

## 12:30 Joining and technical checks

## 13:00 Welcome and opening speech

**Welcome and opening remarks from the EMA** **10'**
*Peter Arlett (EMA BDSG Co-chair)*

**Opening remarks from the European Commission** **10'**
*Sara Rafael Almeida (EC)*

**Opening remarks from Heads of Medicines Agencies** **10'**
*Jesper Kjær (HMA BDSG Co-chair)*

## 13:30 Session 1: Development of the Data Quality Framework – status update and next steps

*Chair: Jesper Kjær (DKMA)*

**TEHDAS – Data quality framework**
**Presentation** **10'**
*Enrique Bernal-Delgado (TEHDAS)*

**Data Quality Framework published document** **20'**
**Presentation**
*Ana Cochino (EMA)*

**Questions & answers** **10'**

## 14:10 Session 2: Use cases: approach for assessing and improving Data Quality

*Chair: Peter Arlett (EMA)*

**RWD Data quality experience in Finland**
**Presentation** **10'**
*Piia Rannanheimo (FIMEA)*

**RWD Data quality experience in Denmark**
**Presentation** **10'**
*Signe Knudstrup, Kristian Holt Nielsen (Danish Health Data Authority)*

**RWD Data quality experience in France**
**Presentation** **10'**
*Emmanuel Bacry (Health Data Hub)*

**RWD Data quality experience by Industry**
**Presentation** **10'**
*Kelly Zou (Industry)*

**Questions & answers** **20'**

## 15:10 Coffee break

## 15:30 Session 3: Systems and processes underpinning Real-World Data

*Moderator: Jesper Kjær (DKMA)*

**Characterisation and maturity model consideration**
**Presentation** **15'**
*Ana Cochino (EMA)*

**Open discussion** **25'**

## 16:10 Session 4: Data Quality metrics for Real-World Data

*Moderator: Jesper Kjær (DKMA)*

**Data quality metrics in the context of DARWIN EU®**
**Presentation** **10'**
*Maxim Moinat (DARWIN EU® Coordination Centre)*

**Data Quality metrics for Real-World Data**
**Presentation** **15'**
*Katerina Deli (EMA)*

**Open discussion** **25'**

## 17:00 Session 5: Data Quality in the context of a regulatory/research question

*Chair: Peter Arlett (EMA)*

**Data Quality requirements and study design and analysis aspects**
**Presentation** **10'**
*Olaf Klungel (Universiteit Utrecht, MWP)*

**Data Quality in fit-for-purpose assessments**
**Presentation** **10'**
*Juan Jose Abellan (EMA)*

**Open discussion** **20'**

## 17:40 Closing remarks

**Wrap up** **5'**
*Jesper Kjær (DKMA)*

## Day 2 – Tuesday, 27 June 2023, 08:30 – 16:00 CEST

### 08:30 Joining and technical checks

### 09:00 Welcome and opening speech

**Welcome** **10'**
*Peter Arlett (EMA)*

### 09:10 Session 1: RWE in regulatory assessment and decision-making processes

*Chair: Michael Berntgen (EMA)*

**Regulator-led RWE studies – an EMA review of the experience gained**
**Presentation** **30'**
*Stefanie Prilla (EMA)*

**Use of RWE in medicines development and regulatory submissions – an industry perspective**
**Presentation** **20'**
*Álmath Spooner (Industry)*

**Use of RWE in medicines development and regulatory submissions – a regulator's perspective**
**Presentation** **20'**
*Carla Torre (University of Lisbon, CHMP & MWP)*

**Presentation of the results of the pre-workshop survey**
**Presentation** **10'**
*Stefanie Prilla (EMA)*

**Panel discussion/Questions & answers** **30'**
*(with Jorge Batista (PGEU) to join the panel discussion)*

### 11:00 Coffee break

### 11:20 Session 2: DARWIN EU® where we are in the Phase 2 of its implementation

*Chair: Jesper Kjær (DKMA)*

**DARWIN EU®: where we are in the Phase 2 of its implementation**
**Presentation** **10'**
*Andrej Segec (EMA)*

**DARWIN EU® to support HTA and payers' research RWE needs**
**Presentation** **10'**
*Juan Jose Abellan (EMA)*

**DARWIN EU® to support EHDS2 pilot**
**Presentation** **10'**
*Mario Jendrossek (Health Data Hub)*

**DARWIN EU® in the context of infectious diseases and health emergencies**
**Presentation** **10'**
*Erika Duffell (ECDC)*

**Panel discussion/Questions & answers** **30'**
*(with Katia Verhamme (Erasmus MC, DARWIN EU® Coordination centre) to join the panel discussion)*

## 12:30 Lunch

## 13:35 Session 3: Opportunities and challenges related to the use of registries

*Chair: Peter Mol (SAWP)*

**Example of use of registry data to support regulatory decision making**
**Presentation** **15'**
*Patricia McGettigan (PRAC)*

**Example of use of registry data to support regulatory decision making**
**Presentation** **15'**
*Pamela Dobay, Meritxell Sabidó (Industry)*

**Example of use of registry data in a randomised clinical trial context**
**Presentation** **15'**
*Lars Wallentin (ESC)*

**EMA guideline on registry-based studies: results of a survey**
**Presentation** **10'**
*Kelly Plueschke (EMA)*

**Panel discussion/Questions & answers** **30'**
*(with Mencía de Lemus (CAT) to join the panel discussion)*

## 15:00 Session 4: Using RWE to address public health emergencies – learnings and a view to the future

*Chair: Marco Cavaleri (EMA)*

**Measuring vaccine performance under emergency situations: case studies and learnings for RWE generation**
**Presentation** **10'**
*Mathijs Goossens (EMA)*

***Adapting traditional pharmacoepidemiology methods to new challenges*** **5'**
*Olaf Klungel (Universiteit Utrecht, MWP)*

***PRAC perspective*** **5'**
*Jean-Michel Dogné (PRAC)*

***Industry perspective*** **5'**
*Nicolas Praet (Industry)*

**Panel discussion/Questions & answers** **30'**

## 15:55 Closing remarks Day 2

**Wrap up** **5'**

*Peter Arlett (EMA) & Jesper Kjær (DKMA)*

*Data protection note*

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## Abbreviations

BDSG - Big Data Steering Group
CAT - Committee for Advanced Therapies
CHMP - Committee for Medicinal Products for Human Use
DKMA – Danish Medicines Agency
EC – European Commission
ECDC - European Centre for Disease Prevention and Control
EMA – European Medicines Agency
ESC - European Society of Cardiology
FIMEA - The Finnish Medicines Agency
HMA - Heads of Medicines Agencies
MWP - Methodology Working Party
PGEU - The Pharmaceutical Group of the European Union
PRAC - Pharmacovigilance Risk Assessment Committee
SAWP - Scientific Advice Working Party
TEHDAS - Towards the European Health Data Space