



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2020
EMA/428155/2020

Agenda - Workshop on the draft guideline on registry-based studies

19 October 2020

12:30 – 17:00 (CET)

Virtual meeting



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Background

Many registry-based studies are performed to support regulatory decision-making in the pre- or post-authorisation setting. In order to address methodological aspects of studies conducted in registries to generate scientific evidence related to medicinal products, the [EMA Cross-Committee Task Force on Registries](#) has drafted a Guideline on registry-based studies.

The main objective of the draft Guideline is to provide recommendations on key methodological aspects of registry-based studies and the relevant legal basis and regulatory requirements for marketing authorisation applicants and holders. It is also relevant to patients and to those involved in the funding, creation and management of registries, those participating in the collection and analysis of registry data, and those planning to use the registry information and infrastructure to perform registry-based studies with a possible regulatory purpose.

The document defines a registry-based study as an investigation of a research question using the infrastructure of a new or existing registry for patient recruitment and data collection. A patient registry is defined as an organised system that collects data and information on a group of people defined by a particular disease, condition, exposure or health-related service, and that serves a pre-determined scientific, clinical and/or public health (policy) purpose.

An Annex of the draft Guideline reviews aspects of patient registries that regulators consider good practice for their use for regulatory purposes in general and more specifically registry-based studies.

The workshop will be broadcast live on EMA's website. You can follow the broadcast by clicking on the 'multimedia' tab on the event page on the day of the event. In addition to the online broadcast, there is limited capacity to participate in the virtual meeting room for people who wish to make verbal contributions to the meeting.

Objectives

- Respond to key questions and requests for clarification;
- Present stakeholders' perspectives on the usefulness of the Guideline for registry-based studies;
- Present recent experience on methodological aspects of registry-based studies.

Agenda

Item	Topic	Speaker	Time
1.	Connection to virtual room and technical checks	-	12.30
2.	- Welcome and introduction - Workshop objectives - Opening remarks	- Peter Arlett - Xavier Kurz - Peter Mol	12.45
SESSION 1: Overview of core recommendations of the draft Guideline and comments received Chair: Peter Mol			
3.	Overview of the main recommendations of the draft Guideline on registry-based studies	Xavier Kurz	13.00
4.	Summary of the comments received from stakeholders by October 9th, 2020	Valerie Strassmann	13.15
5.	Plenary discussion, Questions and Answers	All	13.30
BREAK – 14.00			
SESSION 2: Stakeholders' perspective on the use of the Guideline for registry-based studies Chair: Sabine Straus			
6.	- Regulator - Regulator - Registry holder - Pharmaceutical industry - Patients association	- Milena Stain - Marion Haberkamp - Eoin McGrath - Chris Chinn - Mariette Driessens	14.15
7.	Plenary discussion and summary	All	15.15
BREAK – 15.40			
SESSION 3: Recent experience on methodological aspects of registry-based studies Chair: Xavier Kurz			
8.	Experience of randomisation within a registry	Barbara Casadei	15.50
9.	Data quality and data verification in registries: results of a stakeholders' survey	Carla Jonker	16.05
10.	Collection of safety information linked to medicinal products through registries: results of a survey among registries listed in the ENCEPP Resources database	Kelly Plueschke	16.20
11.	Plenary discussion	All	16.35
12.	Summary of meeting and next steps	Peter Mol	16.50
End of meeting – 17.00			

Speakers in alphabetical order

Carla Jonker – Medicines Evaluation Board (MEB - NL)

Chris Chinn – Co-Chair of the EFPIA Integrated Evidence Generation and Use Working Group; Sanofi's Global Health Economic and Value Assessment group

Barbara Casadei - President of the European Society of Cardiology, EuroHeart Registry

Eoin McGrath – European Society for Blood and Marrow Transplantation (EBMT)

Kelly Plueschke – Data Analytics Workstream, EMA

Mariette Driessens – Patient Alliance for Rare and Genetic Diseases (VSOP); Patients Network for Medical Research and Health (EGAN)

Marion Haberkamp – Scientific Advice Working Party (SAWP) member; Federal Institute for Drugs and Medical Devices (BfArM – DE)

Milena Stein – EMA Committee for Medicinal products for Human use (CHMP) member; Bundesamt für Sicherheit im Gesundheitswesen (BASG - AT)

Peter Arlett – Head of Data Analytics and Methods task Force, EMA

Peter Mol – Co-Chair of the EMA Cross-Committee Task Force on Registries; Scientific Advice Working Party (SAWP) member; Medicines Evaluation Board (MEB – NL)

Sabine Straus – Chair of the EMA Pharmacovigilance and Risk Assessment Committee (PRAC); Medicines Evaluation Board (MEB - NL)

Valerie Strassmann – Data Analytics Workstream, EMA

Xavier Kurz – Co-Chair of the EMA Cross-Committee Task Force on Registries; Head of Data Analytics Workstream, EMA