EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

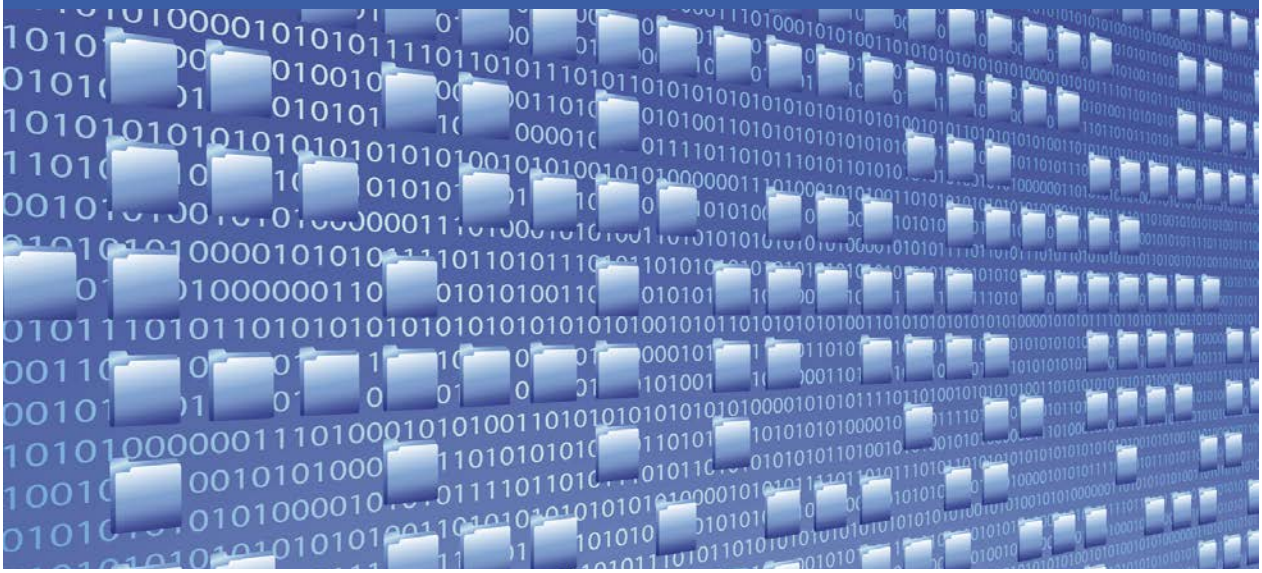
18 October 2016
EMA/439861/2016
Inspections, Human Medicines Pharmacovigilance & Committees Division

Patient Registries Workshop

28 October 2016

Meeting Room 2/A (2nd Floor)

European Medicines Agency, London, United Kingdom



30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Background and objectives

Through the Patient Registry Initiative launched in September 2015, the EMA aims to facilitate interactions between registry co-ordinators and potential users of registry data both at an early stage of the development, during the marketing authorisation evaluation procedure and post-authorisation. The initiative aims to optimise and facilitate, and thus increase, the use of existing disease registries in order to create more comprehensive, flexible and sustainable resources. In addition the initiative aims to map ongoing projects at national and international levels. Where no suitable disease registry exists the initiative aims to support the marketing authorisation holder (MAH) to create a new registry based on a standard methodological approach such as that created by the PARENT JA. This includes the application of standard core data elements and standardised protocols to ensure that the new registry has wider applicability.

This workshop is designed to bring together multiple stakeholders including registry owners, industry, HTA representatives and regulators to discuss the challenges and barriers to collaboration and identify specific solutions.

More specifically the workshop aims to:

- Identify the challenges faced by registries and industry when collaborating;
- Understand the technical challenges presented by disparate datasets;
- Identify concrete solutions to better facilitate relations to avoid duplication.

Outputs

A synopsis of the workshop will be published as a public report. Additionally the workshop will support the delivery of recommendations arising from the pilot phase of the EMA Initiative on Patient Registries due by the end of 2016.

Programme details

Friday, 28 October 2016

09:00 Welcome and introduction

Noël Wathion, Deputy Executive Director, EMA

09:10 – 11:00 Session 1: Setting the scene
Challenges and Opportunities for Collaboration

Session Chair: Peter Arlett, EMA

09.10-09.30 ***Challenges and Opportunities for Collaboration***
European Society for Blood and Marrow Transplantation (EBMT)
Jürgen Kuball, Head of Department, Hematology, University Medical Centre, Utrecht, The Netherlands

09.30-09.50 ***Ensuring sustainability***
Jim Green, President of the International Niemann-Pick Disease Registry, UK

09.50-10.05 ***Product versus disease registry – what drives the choice?***
Jonathan Appleby, Chief Scientific Officer, Rare Diseases Gene Therapy, GlaxoSmithKline, UK

10.05-10.20 ***The Health Technology Assessment perspective***
François Meyer, Director, International Affairs, Haute Autorité de la Santé, France and EUnetHTA

10.20-10.30 ***A Regulator's perspective***
Nils Feltelius, Member of the Rheumatology-Immunology Working Party (RIWP), Senior Expert and Clinical Assessor, Medical Products Agency, Sweden

10.30-11.00 ***Questions and panel discussion***

Panel Moderators:

Sabine Straus, Pharmacovigilance and Risk Management Committee (PRAC) member, staff member at the Medicines Evaluation Board, The Netherlands and Associate Professor at the Erasmus Medical Centre, Department of Medical Informatics, Rotterdam

Peter Mol, Vice-Chair, Scientific Advice Working Party (SAWP), Principal Clinical Assessor, Medicines Evaluation Board, The Netherlands

11:00 - 11:20 Coffee break

11:20 – 13:00 Session 2: Success factors for international collaborations

Session Chair: Alison Cave, EMA

11.20-11.40 ***Standardisation of cancer registries data collection and validation at European level***

Carmen Martos – Joint Research Centre (JRC), ISPRA, Italy

11.40-12.00 ***The Pharmachild project: the PRINTO pharmacovigilance registry***

Nicola Ruperto, Pharmachild project, Genoa, Italy

12.00-12.30 ***Case Study:***

Challenges of comparator groups and the role of disease registries in medicines development

12.00-12.15 **Jamie Geier**, Senior Director of Epidemiology, Pfizer Inc., USA

12.15-12.30 **Kimme Hyrich,** Principal Investigator of BSRBR-RA registry**,** Professor of Epidemiology, University of Manchester, UK

12.30-13.00 ***Questions and panel discussion***

Panel Moderators:

Tomas Salmonson, Chair, Committee for Medicinal Products for Human Use (CHMP), Senior Scientific Advisor, Medical Products Agency, Sweden

Jan Span, Member of the Cross-Committee Task Force on Registries and Senior Clinical Assessor, Medicines Evaluation Board, The Netherlands

13:00 – 14:00 Lunch break

14:00 – 15:45 Session 3: Possible solutions

Session Chair: Xavier Kurz, EMA

14.00-14.20 ***Is the answer active data extraction from hospital records?***

Fergus Caskey – Medical Director, UK Renal Registry

14.20-15.05 ***Integration of data across multiple data sources***

14.20-14:35 **Jan Hillert**, Group Leader, Neurogenetics, Multiple Sclerosis, Karolinska Institute, Sweden

14.35-14.50 **Metka Zaletel,** PARENT Joint Action**,** Head of Health Data Centre, National Institute of Public Health, Slovenia

14.50-15.05 **Johan van Bussel**, Head of healthdata.be, Scientific Institute of Public Health, Brussels, Belgium

15.05-15.25 ***Designing integrated platforms for rare diseases research***

Emma Heslop, Project Manager, RD CONNECT, UK

15.25-15.50	***Questions and panel discussion***
	Panel Moderators:
	Martin Van Der Graaff, Secretary Scientific Advisory Board, Sector Healthcare, National Healthcare Institute, The Netherlands
	June Raine Chair, Pharmacovigilance and Risk Assessment Committee (PRAC), Director of Vigilance and Risk Management of Medicines Division, MHRA, UK
15:50 – 16:00	**Closing remarks**
	Fergus Sweeney, Head of Division, Inspections and Human Medicines Pharmacovigilance, EMA