17 Oct 2016

Innovative Medicines Initiative WEB-RADR project: mobile technologies and social media as new tools in pharmacovigilance Workshop Programme

19 October, 09.00-17.00, room 2A (By invitation only)

European Medicines Agency, London, United Kingdom

Introduction

IMI's WEB-RADR Project is organising its second workshop to discuss the use of mobile technologies and social media as new tools to generate evidence for the monitoring of the safety of medicines.

WEB-RADR has set itself the goal of delivering a mobile app for both healthcare professionals and the public to report suspected adverse reactions to the national medicines regulatory authority, with the aim of facilitating the identification of potential safety concerns associated with the use of medicines in a fast and easy way. The future use of the app as a platform to provide accurate and timely information on medicines to consumers, patients, carers and clinicians is also being investigated.

After two years' work WEB-RADR has delivered fully operational apps via the MHRA in the UK, Lareb in the Netherlands and Halmed in Croatia. Each one of the apps supports the reporting of suspected adverse reactions by patients and healthcare professionals. The information provided is imported directly into the safety systems operated by the national medicines regulatory authority. The apps also provide information on previously reported safety concerns.

Another goal is the development of text mining and analysis tools of publicly available data on social media sites to complement existing methods of safety signal detection for medicines. The WEB-RADR team has designed, constructed, tested and deployed a dashboard for the monitoring of the use of medicines as well as potential adverse reactions reported via social media.

This work should benefit patients and healthcare professionals as well as organisations concerned with patient safety including medicines regulatory authorities, marketing authorisation holders and researchers.

The aim of the workshop is to engage with consumers, patients, healthcare professionals and medicines regulatory authorities to discuss latest developments and to obtain input and feedback to maximise the utility and benefits of the project deliverables.

Welcome to participants

On behalf of the IMI WEB-RADR project consortium and the programme committee, we are pleased to welcome you to this second workshop on the use of mobile technologies and social media as new tools in pharmacovigilance.

The use of innovative technology and data sources provides a unique opportunity for organisations responsible for drug safety to detect potential safety issues related to medicines, which may not be detected through traditional methods in pharmacovigilance. The quantity and near instantaneous nature of publicly available social media data raises the potential for real-time monitoring of adverse reactions and expedited signal detection. The WEB-RADR research therefore provides an insight in a new potential data source for studying everyday behaviours/practices and outcomes. Furthermore, the use of mobile apps is a great opportunity to empower consumers, patients and healthcare professionals to report suspected adverse reactions to medicines in a fast and easy way, providing important information on the safety of medicines.

In December 2014, the project held a first workshop which heard consumers, patients, healthcare professionals, data privacy and research experts on their views and expectations to maximise opportunities to protect public health but also to discuss ethical and data privacy concerns.

Our main objective is to maximise the utility and benefit of the project to improve public health. The early deliverables in the form of the apps and the social media dashboard have been deployed. The time is right to place a particular emphasis on the development of options for recommendations that can inform the development of future guidance on the pharmacovigilance of social media. One of the essential activities within the workshop is a series of breakout groups to consider, discuss and debate how the outputs of WEB-RADR can be applied most effectively for the benefit of consumers, patients, carers as well as healthcare professionals.

Therefore, the specific aim of this second workshop is to inform about developments and outputs from the project and to provide a platform for patients, health care professionals, medicines regulatory authorities and other experts to share their views and expectations, and agree on next steps to maximise outputs of WEB-RADR in strengthening pharmacovigilance.

We look forward to meeting you in London and to your input.

Yours sincerely,

June Raine and Peter Arlett

Objectives

The objectives of this workshop are to discuss and explore with consumers, patients, healthcare professionals, representatives of medicines regulatory authorities and other domain experts:

- How to raise awareness and engagement of consumers, patients and healthcare professionals in the reporting of adverse reactions using mobile apps;
- Factors that could facilitate the uptake of the mobile app by consumers, patients as well as healthcare professionals;
- Opportunities to use the mobile app to provide timely and accurate information to consumers, patients and clinicians;
- How adverse reactions and other safety issues could be detected by optimising technology;
- Areas where public social media data might prove useful as real world evidence for safety monitoring of medicines;
- How to deal with these new data sources from a regulatory perspective;
- Criteria for the long-term sustainability of the app and the roll-out across the EU and possibly beyond.

Programme Committee

June Raine	Chair of the Pharmacovigilance Risk Assessment Committee (PRAC) Medicines and Healthcare products Regulatory Agency (MHRA)
Mick Foy	Medicines and Healthcare products Regulatory Agency (MHRA)
Phil Tregunno	Medicines and Healthcare products Regulatory Agency, (MHRA)
Sabine Brosch	European Medicines Agency, EMA
Victoria Newbould	European Medicines Agency, EMA
Alessandro Spina	European Medicines Agency, EMA
Simon Maskell	University of Liverpool
Peter Mol	University Medical Centre Groningen (UMCG)
Dave Lewis	Novartis
John van Stekelenborg	Janssen Pharmaceutical companies of Johnson and Johnson
Anne-Marie De-Ferran	Sanofi
Raphael Van Eemeren	Amgen

Programme details

Wednesday, 19 October 2016

08.15 Registration

Go to reception on the ground floor to register and receive your badge. Then join delegates in room 2A.

08.45 Welcome and opening

Opening remarks

Peter Arlett

European Medicines Agency (EMA)

Introduction and objectives of the workshop

June Raine (PRAC chair), (MHRA)

09.00 Session 1

WEB-RADR: where we have come from and what we have achieved

Moderators: Mick Foy (MHRA) and Norbert Paeschke (PRAC nominated representative), Bundesinstitut für Arzneimittel und Medizinprodukterodukte (BfArM)

- ***Going mobile- experience so far with app based safety reporting***

  Linda Harmark (Lareb)

- ***Social media for safety monitoring – what we have learned so far***

  Carrie Pierce (Epidemico)

- ***WEB-RADR – perspectives and expectations from patients***

  Francois Houyez (EURORDIS)

- ***Data protection aspects relevant to WEB-RADR-summary of assessment***

  Alessandro Spina (EMA) and Nicola Orlandi (Novartis)

10.30 Coffee

11:00 Session 2

How to optimise WEB-RADR deliverables

Moderators: June Raine (PRAC chair) and Peter Arlett (EMA)

- ***Where and how can the use of mobile apps be optimised?***

  Peter Mol (UMCG)

- ***Where does social media add value for pharmacovigilance***

  Simon Maskell, University of Liverpool

- ***Meeting expectations from patients and healthcare professionals***

  John Van Stekelenborg (JNJ)

Panel discussion including Carrie Pierce (Epidemico), Francois Houyez (EURORDIS), Donald Singer (European Association for Clinical Pharmacology and Therapeutics), Jamie Wilkinson (Pharmaceutical Group of the European Union) and Bob Ball (FDA)

12.30 Lunch

13.30 Breakout sessions

- **1. Patients and healthcare professionals – what do we want as WEB-RADR outputs?** — **Room 2A**

  Facilitator: Francois Houyez (EURORDIS)

  Rapporteur: Anne Marie de Ferran (Sanofi)

- **2. Regulatory questions – what are the options?** — **Room 2J**

  Facilitator: Peter Mol (UMCG)

  Rapporteur: John Van Stekelenborg (JNJ)

- **3. How could social media monitoring support signal detection?** — **Room 2C**

  Facilitator: Phil Tregunno (MHRA)

  Rapporteur: Dave Lewis (Novartis)

- **4. How to ensure future maintenance and sustainability of WEB-RADR?** — **Room 2G**

  Facilitator: Mick Foy (MHRA)

  Rapporteur: Carrie Pierce (Epidemico)

15.00 Coffee

15.30 Feedback session

Moderators: Peter Arlett (EMA) and Bob Ball (U.S FDA)

- ***Feedback from breakout sessions 1-4***

  Facilitators

16:30 Next steps for stakeholder engagement and closing remarks

Moderators: June Raine (MHRA) and Peter Arlett (EMA)

- ***Moving forward for stakeholder engagement and project deliverables***

  Peter Arlett (EMA)

- ***Wrap up and overall conclusions***

  June Raine (PRAC chair)

17:00 End of workshop

WEB-RADR