

WHAT IS WEB-RADR?

Now used by over one billion people globally, social media websites and mobile phone apps enable and encourage users to create, share, and exchange information and experiences instantly. The MHRA is the coordinator and managing entity of an innovative three-year project that seeks to utilise the powers of these new technologies and modes of communication for pharmacovigilance purposes. WEB-RADR arose in response to the Innovative Medicines Initiative's (IMI) ninth call for projects, "Leveraging Emerging Technology for Pharmacovigilance". It is led by a consortium of world-leading experts from regulatory agencies, academia, and industry.

OUR CONSORTIUM

- Amgen
- AstraZeneca
- Bayer
- Croatian Agency for Medicinal Products and Medical Devices (HALMED)
- Epidemico
- European Medicines Agency (EMA)
- European Organisation for Rare Diseases (EURORDIS)
- Janssen Pharmaceutica
- Lareb
- MHRA
- Novartis Pharma
- Sanofi-Aventis R&D
- Software Research & Development Consultancy (SRDC)
- UCB Pharma
- University College London
- University of Liverpool
- University Medical Centre Groningen (UMCG)
- Uppsala Monitoring Centre (UMC)

All participating bodies are represented on the Consortium Assembly.

WE HAVE

2
MAIN
AIMS

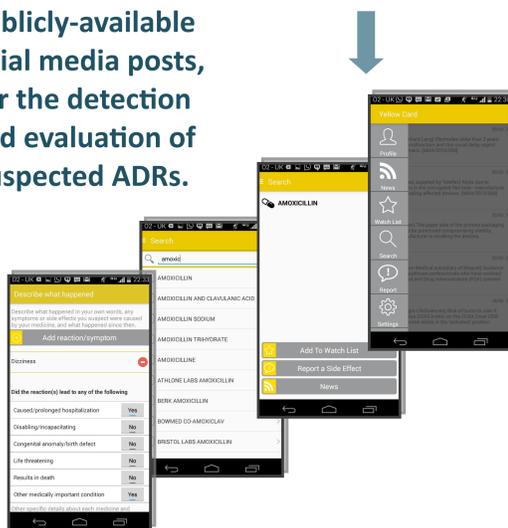


A mobile app for HCP and patient ADR reporting. The app will also communicate the latest safety information to users.



Data-mining techniques for publicly-available social media posts, for the detection and evaluation of suspected ADRs.

The app is now in test mode in the UK



ABOUT IMI

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative, and supports collaborative research projects for pharmaceutical innovation in Europe. IMI is a joint undertaking between the EU and the pharmaceutical industry association EFPIA.

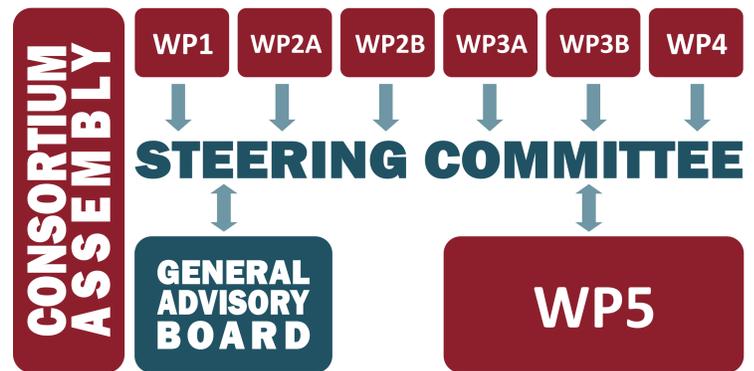
www.web-radr.eu
email: web-radr@mhra.gsi.gov.uk

Follow us @webradr

OUR STRUCTURE

WE ARE IN
MONTH

7
OF
36



OUR WORK PACKAGES

MANAGEMENT & COMMUNICATION | WP5 | LED BY MHRA

WP5 coordinates the project, with overall responsibility for establishing and maintaining effective administrative, financial, and managerial processes. It is responsible for internal and external communications, ensuring WEB-RADR's progress and outputs are disseminated to all stakeholders, including the public.

GOVERNANCE & POLICY | WP1 | LED BY EMA

WP1 is developing a policy framework on the use of mobile devices and social media data for pharmacovigilance purposes. It will ensure compliance of WEB-RADR deliverables with EU law and GVP modules.

SOCIAL MEDIA | WP2A | LED BY EPIDEMICO

WP2A will provide access to classified social media data via a visualisation platform for signal identification and confirmation. The WP2A team will expand the platform to include two non-English European languages.

ANALYTICS | WP2B | LED BY UMC

WP2B is developing and linking new and existing analytical tools for the analysis of social media content. It will improve the quality and relevance of data extracted from social media sources. WP2B focuses on suspected ADR identification, record linkage of duplicate reports, and signal detection.

MOBILE REPORTING PLATFORM | WP3A | LED BY EPIDEMICO

WP3A is developing a mobile phone app for the public and HCPs. The app will alert users about new safety warnings, and users will be able to report suspected ADRs via a user-friendly form. The app will be able to accommodate additional languages.

USER-BASED EVALUATION | WP3B | LED BY UMC

WP3B will evaluate the usability of the WP3A app, as well as reasons why patients and HCPs may or may not use a mobile app to report ADRs and access safety information. It will test different prototypes of the WP3A app, assessing usability, accessibility, and issues of health literacy. WP3A findings will enable continuous improvement of the WP3A app.

SCIENTIFIC IMPACT EVALUATION | WP4 | LED BY UNIVERSITY OF LIVERPOOL

WP4 will examine whether or not novel media tools, such as apps and social media, add value to existing pharmacovigilance methodologies. It will assess where social media sits within the hierarchy of evidence in signal detection. WP4 will also evaluate the use and quality of data generated via the WP3A app.