Executive Summary

This workshop was the first of two workshops organised in the context of the Innovative Medicines Initiative (IMI) WEB-RADR project, which focuses on the evaluation of the use of mobile technologies in pharmacovigilance to Recognise Adverse Drug Reactions (RADR). The use of new technology is a great opportunity to empower patients to report and to provide reporters such as healthcare professionals, patients, consumers and carers with accurate, timely and up-to-date information on how to use medicines safely and effectively.

The project will develop a mobile app prototype in support of adverse drug reaction reporting and the provision of drug safety information to app users from medicines regulatory authorities. The mobile app will be subject to a user-based evaluation by focus groups based on a variety of stakeholders of different ages and medical backgrounds.

A second aspect of the project is to assess the usefulness of social media analytics. This includes gathering and aggregating unstructured information from social media with the aim to analyse and to detect potential safety issues related to medicines, which may not be identified through traditional methods in pharmacovigilance.

Whilst new technologies may provide powerful tools in adverse reaction reporting and the monitoring of the safety of medicines, challenges with regard to ethical principles, data protection safeguards, the accountability for data processing, the monitoring of the use of data and the need for enhancing data security and anonymity are also to be analysed. The aim is to develop a policy framework based on recommendations for potential future implementation and use of the WEB-RADR project deliverables.

The workshop provided a unique opportunity to exchange views and to discuss expectations with members of the European Medicines Agency’s Healthcare Professionals Working Party and the Patients’ and Consumers’ Working Party, the Pharmacovigilance Risk Assessment Committee and pharmacovigilance experts, representatives from Young People (Paediatric Committee) experts in the area of medical ethics and data protection and IMI WEB-RADR Consortium members. The outcome of the workshop will inform the WEB-RADR Consortium and the project deliverables.
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1. **Welcome and Objectives**

The workshop was hosted by the European Medicine Agency (EMA) as co-leader of work package (WP) 1 on governance and policy of the WEB-RADR project. Participants of the workshop included members of the EMA’s Healthcare Professionals Working Party, members of the EMA’s Patients’ and Consumers’ Working Party, members of the Pharmacovigilance Risk Assessment Committee (PRAC) and pharmacovigilance experts, members of the EudraVigilance Expert Working Group (EV-EWG), representatives from Young People (Paediatric Committee), experts in the area of medical ethics and data protection, a US FDA representative of the WEB-RADR Advisory Committee and IMI WEB-RADR Consortium members (see Annex 1 for participants list).

Peter Arlett, Head of Pharmacovigilance Department at the EMA, opened the workshop and welcomed the participants. He thanked everyone for engaging with the project and bringing their expertise and views to the meeting. He emphasised that the context of the project and the workshop was pharmacovigilance. He explained that the World Health Organization (WHO) has defined pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems. Fundamentally, pharmacovigilance is a public health function and the workshop aims to contribute to public health.

It was emphasised that pharmacovigilance is based on collecting data, analysing data, detecting new or changing safety issues with the aim to ultimately reducing harm from side effects so patients can benefit from their medicines. In the past 50 years, pharmacovigilance has relied predominantly on reports from healthcare professionals through spontaneous reporting systems. In the last 20 years the analysis of spontaneous reports has been further supplemented by epidemiological and observational studies with the aim to further analyse potential causal relationships of side effects and medicines as well as risk factors.

The WEB-RADR project is to explore new opportunities in the next phase of data collection and analysis in pharmacovigilance. Since 2012, by law all Member States have to have patient reporting schemes in place. Analysis in recent years have shown that patient reports have added significant value to pharmacovigilance, both in terms of number of reports but also in terms of quality thus providing often additional information on the impact of side effects rather than medical diagnosis only.

The use of mobile technology is a great opportunity to empower patients to report. There is also an excellent potential to provide reporters with accurate, timely and up-to-date information on how to use medicines safely and effectively. Mr Arlett also stressed that there are public health opportunities linked to social media although it is fair to say that there are many questions still to be addressed: can we detect adverse reactions faster? What are the best ways to protect personal data? Are there any ethical considerations to be taken into account?

The workshop was very much about listening to patients, healthcare professionals, data privacy and research experts as to how new technologies and the use of social media can
maximise opportunities to protect public health. The outcome of the WEB-RADR project should facilitate future policy development and establishing a regulatory framework that is based on best evidence as how to harness these new tools in pharmacovigilance.

Sabine Brosch (EMA) gave a short introduction to the Innovative Medicines Initiative (IMI). IMI is the world’s biggest public-private partnership (PPP) in the life sciences with the aim to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. The Joint Undertaking between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) supports collaborative research projects and building of networks between key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations and medicines regulators. EFPIA companies and other associated partners do not receive any EU funding, but contribute to the projects ‘in kind’, for example by donating their researchers’ time or providing access to research facilities or resources.

IMI WEB-RADR is a three-year research project, which was launched in September 2014. The workshop is the first of a series of two meetings, with a second workshop planned for the third quarter of 2016. The objectives were summarised as follows:

- Provide a detailed understanding of the motivations for the project and the research areas;
- Stipulate the research aspects and anticipated outcomes;
- Prepare a foundation for collaboration with consumers, patients, healthcare professionals and medicines regulators throughout the project;
- Understand stakeholders’ needs and concerns;
- Describe how and when consumers, patients and healthcare professionals will be consulted throughout the project and kept updated on progress.

In preparation of the workshop, WEB-RADR WP1 members launched a short survey to collect initial views from patients, consumers and healthcare professionals (see Annex 2). The results would be presented as part of session 5 and 6 of the workshop with the aim to facilitate the identification of specific interest areas as well as expectations as to what the project should accomplish and to ensure that ethical and personal data protection aspects would be identified upfront.

Andrew Cochrane¹ (Novartis) highlighted the importance of social media and the largely unexplored potential for contribution to the safety of medicines. The anticipated scope of the project is to include publicly² accessible social media such as Twitter with over 140 million

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¹ Replacing Dr. Dave Lewis (Novartis) IMI WEB-RADR project co-ordinator

² Regulatory Definitions for Pharmacovigilance in Social Media: Challenges and Recommendations for Consistency Version 3.0 Tufts Center for the Study of Drug Development (CSDD) Working Group on Social Media and Clinical Research Sub-team on Social Media and Pharmacovigilance: Nasiba Abdul-Karim, Robert Boland, Jethro Ekuta, Jeffrey Fetterman, Michael Ibara, Paulami Naik, Regina Ruben, Thomas Umrath, John van Stekelenborg, Dana Washburn and Tom Maneatis

Social media sites which are widely available for users to join, control content of and participate in. There could be a facilitator organization or IT company hosting the platform but they do not explicitly manage the format, content or design except compliance with posting rules. Public social media sites may require a username and password for identification or site revenue purposes but not for content protection purposes. Users of public social
users and Facebook with over 845 million users. Parallel threads of digital media include Electronic Health (eHealth) using information and communication technologies for the provision of health related services (e.g. diagnosis, monitoring treatment), Mobile Health (mHealth) using mobile communication systems for the provision of health related services, Digital health providing an intersection of the digital revolution with consumer healthcare, including genomics (use of gene chips to store a patient’s genetic identifiers and responses) and Telemedicine focusing on the delivery of healthcare at a distance using information and communication technologies for consumer healthcare.

It was explained that social media are the new internet based channel for social interaction. People create, share or exchange information, experiences and ideas in virtual communities and networks. The channel for interaction is provided by internet based applications accessible through computers and mobile devices. These applications allow the creation and exchange of user-generated content in the form of short messages, text, images, videos and documents. The users are able to view/share content from and with others in an interactive, often real-time digital environment. The information shared by public users is usually posted without prejudice, pre-screening or any validation/verification. Social media differ from traditional or industrial media in many ways, including quality, reach, frequency, usability, immediacy and permanence.

Pharmaceutical industry already has experience in using social media primarily for commercial purposes. This refers predominantly to distributing information about medicines to healthcare professionals and non-healthcare care professionals, diseases, and the treatment of diseases, company matters including announcements but also to listen to patient and professional conversations about marketed medicines. Some companies have extended the use of these platforms to include patient engagement, patient recruitment and retention within clinical trials. Data capture, collation, timely data mining and appropriate analysis can provide actionable intelligence to aid the protection of public health. The aim is to assess if this research can provide value to patients and consumers, healthcare professionals, regulators and the pharmaceutical industry.

Phil Tregunno (MHRA) gave an overview of the WEB-RADR consortium as well as the structure and deliverables of the WEB-RADR research project, which is organised in five work packages (WPs) as outlined in figure 1.
WEB-RADR will explore the potential value of social media and develop a mobile application (app) to facilitate adverse reaction reporting and communication on safety issues related to medicines by regulatory authorities. Links with other on-going research projects such as IMI PROTECT (WP5 on signal management) and SCOPE were also highlighted.
In terms of dissemination of the outcome of the WEB-RADR project, a dedicated website http://web-radr.eu/ was deployed which will be updated through the project. It is also anticipated that scientific papers will be disseminated through various fora, the EFPIA Pharmacovigilance Committee, University-based postgraduate education programmes or the EudraVigilance Expert Working Group.

2. **INTRODUCTORY STATEMENTS**

2.1. **Social media – opportunities and challenges for medicines regulatory authorities**

Dr. Robert Ball (FDA) gave an overview of the current process of collecting and evaluating individual case safety reports, highlighting that in 2013 the FDA received over a million adverse event reports to the FDA’s Adverse Event Reporting System (FAERS). FDA recently launched a social media data-mining project with the aim to evaluate the value of social media for the identification of potential adverse events. FDA, in collaboration with Epidemico, developed a digital data-mining platform with intakes from Twitter and Facebook public posts\(^3\). The posts were filtered to focus on those which mention both a product and an adverse event, consumer language was mapped to the Medical Dictionary for Regulatory Activities (MedDRA) and standard product names and product-event pairs were aggregated and analysed to identify potential safety signals. A website dashboard allowed users to search for products and events of interest, and to sign up for notifications when a safety signal was identified. The preliminary results from the project showed it was possible to identify adverse events in social media, but only a limited amount of information was available through some platforms (e.g. Twitter).

According to the FDA’s 2001 Draft Guidance on Postmarketing Reporting, adverse experience “information that is submitted to an applicant via the Internet (e.g., e-mail) should be reported to the FDA if the applicant has knowledge of the four basic elements for an individual case safety report (ICSR): patient identifier, product, event and reporter”.

For purposes of reporting by companies to FDA, adverse event reports from social media should be treated as spontaneous reports\(^4\). They are reviewed like any other spontaneous report acknowledging that there can be variability in the quality of the reports submitted.

Based on the experience with the collection of adverse events after the use of vaccines during the 2009 H1N1 influenza pandemic, FDA is also running a project entitled ‘Real-Time Application for Portable Interactive Devices (RAPID)’ with the aim to develop an efficient, real-time, bidirectional communication system for use in a Medical Counter Measures situation (e.g.

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\(^4\) Spontaneous reports are unsolicited communications from individuals (e.g., health care professional, consumer) to applicants that concern adverse experiences.
pandemic influenza) using mobile devices, such as smartphones. This involves the development of a mobile application and a system to receive and analyse reports.

FDA is exploring the value of social media mining for drug safety signal detection and developing tools to provide flexible mobile apps for adverse event reporting during public health emergencies. At present, for reporting purposes, adverse event information from social media should be treated as spontaneous reports. In future, for reporting purposes, it might be better to aggregate adverse event information from social media by source and report in summary fashion.

Questions and Answers (Q&As) based on the IMI WEB-RADR project introduction are summarised as follows:

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<td>EMA: Had FDA involved patients and healthcare professional organisations as part of their social media project?</td>
<td>FDA: They had not worked with patient groups or healthcare professionals directly in the social media or mobile app area. However, FDA has a large initiative on patient reported outcomes, which is focusing on clinical trial and product development. FDA started conversations with some interest groups but nothing formal had been established yet.</td>
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<td>EACPT: Did FDA see any changes in the reporting patterns?</td>
<td>FDA: this is a public project, the public in theory is aware but most likely this has no major influence on the results, but FDA is still evaluating the findings.</td>
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<td>Was the FDA project public knowledge, and if so, could this have influenced the patterns of data collected?</td>
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<td>GSK: Has FDA gained any insight about using social media to collect information on benefits and not only on risks?</td>
<td>FDA: There is an initiative to develop a benefit-risk framework focusing primarily on the premarketing drug development phase. There is lots of interest and discussion about how FDA might use real world data in the safety and benefit assessments. However this is still in an early discussion phase.</td>
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<td>UOL: What kind of feedback did FDA provide to reporters and have they looked at whether they got more positive responses from patients/consumers that received further input? It has been reported in literature that targeted feedback increases reporting.</td>
<td>FDA: The RAPID project is in its second year. The first year was dedicated to infrastructure development, the second year included the launch of pilot of testing with actual data. There is no experience at the moment to answer this question. RAPID focuses on public health emergency situations, any results may not apply to the broader aspects that</td>
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### Questions

**LAREB:** What influenced FDA’s decision to treat information from social media as spontaneous reports? Is FDA considering analysing these reports originating from social media differently?

**FDA:**

FDA’s regulations require companies to submit reports of adverse events after the use of the company’s drug if the report has the four basic elements for an individual case safety report (ICSR): patient identifier, product, event and reporter, without distinguishing the source of the report. Whether this is the best approach for reports from discussions online around drugs and adverse events, is unknown. It is likely that it would be more effective if companies who are using social media could summarise information on adverse reactions with their drugs, but this is still under evaluation and WEB-RADR may be able to inform decisions around this.

### 2.2. Digital media and research ethics

Daniel Sokol (12 Kings Bench Walk Chambers) gave an introduction to research ethics in the context of digital media. He explained three aspects of moral decision making: moral perception, moral reasoning and moral action. He continued by describing the following ethical issues: training/competence of researchers; consent and blurring of private and public; confidentiality and respect for privacy; incidental findings and risk of harm; storage of data; ethics approval and expertise of the committee; remuneration of participants; legal aspects. After the identification of ethical issues in a particular project, the next step would be moral reasoning based on the identification of the key issues and how to resolve them by balancing moral considerations and selecting the optimal option for implementation.

### 2.3. European data protection and digital media

Fabio Polverino (European Data Protection Supervisor office) gave an introduction to mHealth, a fast developing and largely unregulated environment, being the product of a convergence between healthcare and IT, impacting both the private and the public sectors. The drivers for
developing mHealth were emphasized as being better healthcare at lower cost, patient empowerment and easier and more immediate access to medical care online.

Fabio Polverino further explored the definition of ‘health data’ and the question, if this included lifestyle/well-being information. He highlighted the challenges with regard to the social and private costs of failing to deploy proper data protection safeguards, the accountability for data processing, the monitoring of the use of big data and the need for enhancing data security and anonymity.

By 2017, 3.4 billion people are expected to own a smartphone. 23% have used mHealth solutions, 77% never used a phone for health issues and 67% want to do «nothing at all» on the phone for their health. The way forward therefore requires effective data protection thus leading to improved users' confidence, greater development of mHealth and social and private benefits.

mHealth requires efficient allocation of responsibility among multiple players involved (app designers, app stores, third parties) but also requires identification of data controllers in charge of processing data. The latter can be complicated by the fact that there might be multiple processing steps and thus multiple controllers, which need to be identified.

There is also the need to understand the trends in mHealth, namely multiple purposes and data maximisation but also data transfer and remote processing. From an ethical perspective, individuals should be empowered, not only in healthcare, but also with respect to their personal life. Empowerment means transparency and awareness in the first place but also retaining control over one’s own personal data at any time.

In summary, data protection tools provide the way forward. This is by providing clear information and transparency (let people know!), clear definition of the purpose (many purposes, but one thing at a time!), minimising the data focusing on the data that are really needed (use only the data you need!), apply privacy by design and by default (care for users and customers!) and ensuring data security (avoid data leaks!).

Questions and Answers (Q&As) based on the ethical and data privacy issues are summarised as follows:

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<tr>
<td>EMA: In other projects there has been some resistance to implementing Privacy Enhancing Technologies (PETs) due to their complexity. Is the EDPS aware of initiatives at the level of Standard Development Organisations to further improve the PETs?</td>
<td>EDPS: The landscape of mHealth proves to be complex due to the presence of various operators and players in the market place. Regarding mobile apps, there are the mobile application designers, the mobile owners or editors, the application stores and the advertisers or healthcare providers. Each of them is involved in the processing of personal data and might not be necessarily be a data</td>
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### Questions

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<tr>
<td>protection expert. There is a need to provide guidance on data protection to make business viable and compliant with the legislation. There are various initiatives from public bodies and organisations setting standards such as the European Network And Information Security Agency (ENISA) - an agency offering guidance on data protection compliance to application developers and designers.</td>
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### 3. USE OF MOBILE TECHNOLOGIES FOR ADVERSE DRUG REACTION (ADR) REPORTING AND ACCESSING SAFETY INFORMATION: EVALUATION OF PATIENTS’ AND HEALTHCARE PROFESSIONALS’ NEEDS AND CONCERNS

#### 3.1. *Introduction to research topic and anticipated deliverables*

Carrie Pierce (Epidemico) and Stephanie Bodin-Parssinen (UCB) gave an overview of the planned development of a mobile app in support of adverse drug reaction reporting and the provision of drug safety information to app users from medicines regulatory authorities. The app development will be based on the ‘medwatcher’ prototype app tested by FDA for the purpose of medical devices in 2010. The objectives of the app are to provide a simple method for patients and healthcare professionals to report adverse drug reactions, to receive drug safety alerts, to promote drug safety by increasing transparency around adverse drug reactions and to receive high-quality adverse drug reaction submissions as a result of conscientious app design and user feedback.

The ‘medwatcher’ app will serve as a starting point and be adapted for the purpose of the WEB-RADR project and the European needs. It is planned to launch a customised ‘Yellow card’ app in the UK first, followed by a deployment in Croatia and the Netherlands.

Carrie Pierce outlined the key features of the app. It has an icon-based menu and users can add products of interest to a “watch list”, which generates a news feed which alerts users about drug safety information from regulatory authorities. Potential future enhancements under discussion include the possibility to submit images (e.g. skin reactions) or scan bar codes. Although the project initially focuses on the delivery of an app for three European countries, the project aims to develop a generic mobile app, which can be customised by other medicines regulatory authorities in EEA Member States according to their local requirements.

Peter Mol (UMCG) outlined the scope of WP 3b, which focuses on the user-based evaluation and will complement work from work package 4. He informed that the goal is to target a variety of stakeholders of different ages and backgrounds. The aim is to establish focus groups to understand and assess stakeholder needs and to adapt the app to their specific needs. This
will include adolescents, orphan disease patients, elderly patients, patients with type 2 diabetes and an industry group. The countries involved will be France, the Netherlands, Sweden and the United Kingdom with four to nine participants in each group.

Raphael Van Eemeren (Amgen) described the initial results from the stakeholder survey conducted in preparation of the WEB-RADR workshop. 75% of responses came from patients and patient associations. Although only 50% of those who responded had ever reported an adverse reaction, initial feedback suggests that a key factor to motivate reporting is improved information provision. This is a critical area for the project to evaluate to balance the customisation of effective communication with the need to keep the amount and type of information proportional.

Peter Møl further explained that as part of the project a quantitative survey will be conducted (electronically or postal). The survey will be based on a study population of 100 users and will be translated in French, Dutch and Swedish. It is intended to send two reminders as applicable but no remuneration of interviewees is planned. Usability testing will be performed to assess satisfaction with the mobile app including the two-way risk communication functionalities.

Questions and Answers (Q&As) based on the mobile app and the stakeholder evaluation are summarised as follows:

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<tr>
<td>EMA: Is the mobile app research being performed in parallel with the release of the app and will design improvements be based on the results from this?</td>
<td>UMCG: Yes, the research is being performed in parallel and the outcome should facilitate an app development, which will support the interaction with patients and healthcare professionals.</td>
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<tr>
<td>EURORDIS: What happens in terms of governance and maintenance if the app developer is acquired by a third party?</td>
<td>Epidemico: This will be dealt with as part of contractual arrangements and addressed by the WEB-RADR Steering Committee (See DP001).</td>
</tr>
<tr>
<td>EDPS: With the current system, information is filtered by a pharmacovigilance specialist at the receiver’s end. Who will filter the information with the app? When this information is shared, will result this in situations like customer feedback?</td>
<td>Epidemico – The filter/review will be in place at the level of the medicines regulatory authority, who will receive the reports in the same way as via other reporting methods. No promotional customer feedback is intended to be implemented. MHRA: Data presentation is an important aspect but equally important is the assessment and communication of assessment outcomes as being done by publication of PRAC outcomes.</td>
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</table>
3.2. A patient perspective – use of mobile applications for adverse reaction reporting

Francois Houyez (EURORDIS) gave a patients’ perspective on the use of mobile apps for communicating information about the safety of medicines. There are many examples of where information from patients has been invaluable in early identification of rare side effects. This is particularly seen in patients, who are informed and engaged in discussions around their health and their medicines. It is exactly this wealth of knowledge and insight which WEB-RADR seeks to harness. Although most Member States now have on-line reporting forms in addition to traditional reporting methods such as paper, there is still a need to improve communication and awareness of adverse reaction reporting. WEB-RADR promises to create a very usable tool, with possibilities to broaden the function of the app to include aspects of lifestyle of the patient (such as use of herbals or recreational drugs), the impact on quality of life and to provide information on aspects such as falsified medicines, shortages and recalls and how best to communicate with the patient. The workshop recognised the importance of presentation of information to patients and healthcare professionals including the conveying messages on outcomes of safety assessments. The mobile app could be further enhanced by providing functionalities such as detection of fake drugs, medicines expiration alerts, personal drugs management, online consultation or alerts of product shortages and where to obtain the medicine.

Questions and Answers (Q&As) based on the mobile app from a patient’s perspective are summarised as follows:

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<tr>
<td>PRAC representative: Is it planned that the app also provides access to health records stored on the mobile device of the user? If so, how will it be ensured that these records are kept up to date?</td>
<td>EURORDIS: The use of health records in the app is a theoretical discussion at present but most patients known by EURORDIS do keep their records up to date in a real time manner and these possibilities are of interest for consideration medium to long term.</td>
</tr>
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3.3. Experience of use of apps and social from a healthcare professional perspective

Dr Adamos Hadjipanayis (European academy of Paediatrics) presented his perspective as a healthcare professional on the use of mobile apps. Mobile device use has now overtaken the use of desktops for internet access, with future use predicted to continue to rise. A study in Cyprus on the use of smartphones was undertaken with paediatricians. 71% of the paediatricians surveyed had a smartphone and 40% of these use medical apps mainly for the purpose of diagnostic tools, clinical or drug and coding reference. Professor Donald Singer (European Association for clinical pharmacology and Therapeutics - EACPT) added to the healthcare professional perspective by sharing experience of a project in Rwanda during 2014. There had been policy efforts on pharmacovigilance in Rwanda, supported by advice from the
WHO, on strategy and reporting tools however there was little tradition of informing patients about pharmacovigilance in Rwanda and healthcare professionals themselves had limited knowledge of how and what to report. Pharmacovigilance is a particular challenge in low resource settings as there are many factors involved, including co-morbidity, use of high risk medicines and traditional medicines, and problems with counterfeit, falsified and sub-standard products. Reporting had been very low – only around one report per major referral hospital in the year prior to the project. The project piloted online reporting tools and trained hospital medical and pharmacy staff in all district and national referral hospitals on pharmacovigilance leading to much improved reporting at the local and national level. This subsequently led to improved implementation of pharmacovigilance, supported by availability of mobile-compatible online reporting tools, initially for healthcare professionals. During an 8 week pilot phase from September to November 2014, there were 46 reports of serious adverse drug reactions from 3 referral hospitals, including 7 reports attributed to use of traditional medicines. This project highlights the potential benefits of e-health involving mobile technology in countries with high usage of smartphones. EMA commented that the issue of counterfeit medicines is less of an issue in European systems but is of high relevance for African healthcare systems where counterfeit products more commonly reach and cause harm to patients. EACPT noted that there are likely to be increasing issues with counterfeit products also in Europe with the rise in use of internet pharmacies. The app could ask simple questions about where the medicine is from to help to identify sources of medicines associated with problems.

Questions and Answers (Q&As) based on the mobile app from a healthcare professional perspective are summarised as follows:

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<tr>
<td>Which data collected through the mobile app are being released in each country?</td>
<td>MHRA: Each individual Member State will decide on how to utilise the 'app package' once available as implementation of the app will need to be based on national rules.</td>
</tr>
<tr>
<td>Could mobile devices be used to 'provide training' how to use medicines safely?</td>
<td>The particulars are outside the scope of WEB-RADR but general aspects of communication with stakeholders are addressed in the project.</td>
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4. ANALYSIS OF SOCIAL MEDIA COMMENTS FOR PHARMACOVIGILANCE PURPOSES

4.1. *Introduction to research topic and anticipated deliverables*

John van Stekelenborg (JPNV) introduced the aims of work package 2b focusing on social media analytics. The goal is to assess how to harvest information from social media and turn it into something useful for pharmacovigilance purposes. The work would be split into three main
areas; identification of suspected drug-related events, record linkage (i.e. how to handle "duplicates") and signal detection. It is well recognised that "Big Data" is unstructured and is of variable quality and value. This poses challenges for analysis and capture of information, but the real strength being that it is present in very large volumes.

Carrie Pierce (Epidemico) gave a demo of the social media platform to leverage social media data in order to contextualize and supplement traditional pharmacovigilance data. The strength is that patients discuss aspects of their health including their experience with medicines they are taking in an unmodified and rich way in social media and can provide a unique insight into their experiences. The data is collected through an Application Programming Interface (API) such as Marketplace Web Services, which acquire public posts such as Facebook, Twitter and open patient forums. Firstly the project aims to screen for medicinal product names based on a product list for the purposes of the project. A Natural Language Processing (NLP) machine learning algorithm is continuously trained to recognise relevant language in conjunction with a further human curation step to increase precision.

4.2. Summary of survey results and collective comments from the Agency’s stakeholders

John van Stekelenborg (JPNV) described the results of the survey performed in preparation of the workshop. It was noted that the respondents were of a very specific demographic taking into account their knowledge of pharmacovigilance and the results therefore may not reflect opinions which are later characterised through the focus groups of work package 3b and 4. He informed that unsurprisingly the highest usage of social media was identified as being Facebook and Twitter. Due to the nature of the respondents’ activities, Linkedin was also very popular for professional networking, closely followed by patient forums where more than 50% are likely to discuss their experience with medical treatments and medicines.

The respondents of the survey were highly engaged with social media although they are still reluctant to share e.g. images of their disease or adverse reactions. The survey also showed that 75% of the survey participants feel there is value to monitoring social media for the purpose of pharmacovigilance. This activity could offer some real benefits in detecting adverse effects of a different nature to those reported through traditional routes earlier, faster, in a simple and cost effective manner and enable the patient voice to be heard.

The survey also revealed that there is still scepticism about the reliability of the information; the analytical sub team of WP3b need to address and evaluate concerns raised in the survey over accuracy of data in social media and the fact that it is not evidence based and may have a negative influence on usage of medicines by fuelling myths and promotion of incorrect or even fraudulent information.

Discussions on data ownership and the further consideration around publically available data and fundamental rights to personal data protection also took place. Pain Alliance Europe raised concerns over who owns the data and if the project is giving Facebook the authority to publish personal data. Fabio Polverino (EDPS office) was clear that we are all owners of our data and if anyone wishes to use the data, we must be asked what it is to be used for and if anyone else will be involved. Fundamentally, the patient must be at the centre of the discipline.
Alessandro Spina (EMA Data Protection Officer) stressed that just because something happens in public does not mean that it is a public fact. This is a fundamental principle of data privacy that even if someone is sharing an experience in public, does not mean the information can be used freely by anyone.

Sanofi raised concerns on the difficulty of removing hoax information possibly also form competitor companies. This information may look very real and can become potentially very damaging to the reputation of a medicinal product if the hoax ‘goes viral’.

Epidemico explained there are methods to remove profanity. Experience will be gained from a parallel project in developing a sentiment reading algorithm, the analytics package will also provide information to look into this to establish a baseline metric on reliability as there are examples of where misinformation can cause real public health issues, such as public health scares over vaccine safety.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Answers</th>
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<tr>
<td>European federation of asthma and allergy association (EFA): How can engagement with patients in closed fora be further improved? This poses particular problems where advice is often provided to patients and carers on their disease/treatment in a non-regulated manner. EFA have seen many examples of patients/carers asking for advice through closed fora</td>
<td>Epidemico informed that for the purpose of this project the focus would be on public fora but the communication aspect is certainly an important one especially for medicines regulatory authorities</td>
</tr>
<tr>
<td>EURORDIS: Who will be given access to the Medwatcher dashboards as patient representatives from EURORDIS are keen to be able to access the dashboards</td>
<td>MHRA explained that sustainability will be looked at in year 2 when results are available on the applicability and use of the tools. This will drive how and who the dashboards should be made available to. Also decisions on whether to combine data from social media into the routine data set will be made, which will be evidence driven</td>
</tr>
<tr>
<td>The European society of oncology pharmacists (ESOP) highlighted that they are involved in training patients to use their medications in a safe way and wondered how mobile devices could facilitate this?</td>
<td>It was clarified that this is not within the scope of the project. An app, which manages patient’s medications could turn into a device itself and would need to comply with legislation on medical devices. This aspect however is important to bear in mind both as part of the WEB-RADR project and outside especially in the context of improving communications between healthcare professionals, medicines regulators and patients</td>
</tr>
</tbody>
</table>
5. DIGITAL MEDIA – PERSONAL DATA PROTECTION AND ETHICAL CONSIDERATIONS – RECOMMENDATIONS FOR FUTURE POLICY DEVELOPMENT

5.1. Introduction to research topic and anticipated deliverables

Alessandro Spina (EMA) opened the session on data protection and ethical considerations. He emphasised that challenges from a legal perspective should not be considered as barriers to the project and the potential for the benefit it holds.

Sabine Brosch (EMA) informed the workshop participants about the role of WP1 in supporting the assessment of stakeholder needs, expectations as well as challenges in relation to ethical and data protection related aspects throughout the project. A review of the legal, regulatory and personal data protection requirements as well as ethical aspects in the context of the new pharmacovigilance tools will be conducted. Based on evidence and experience gathered from the other work packages, the ultimate objective for WP 1 is to elaborate a policy framework with recommendations towards future utilisation of the new WEB-RADR technologies and methods in the EU.

5.2. Summary of survey of current regulatory requirements and practices

Anne-Marie De-Ferran (Sanofi) presented an overview of existing policy documents on social media monitoring in the context of pharmacovigilance. Good Pharmacovigilance Practices (GVP) especially Modules VI and IX require that MAHs screen digital media for which they are responsible for adverse reactions and any information which may constitute a safety signal. It also provides guidance on what should be considered as company sponsored digital media.

Sanofi and Novartis performed a survey of 180 countries to gather information on policies, guidance and regulations on social media monitoring. The response rate was a 100%. The survey revealed that 79% of the surveyed countries have no such policies, and most of those who do have similar provisions as set out in GVP. A smaller number of countries within the EEA have policies, which exceed the guidance in GVP, namely UK, Sweden, France and Italy. Turkey, USA and Korea have also further guidance developed. The outcome of the survey will inform the development of a future policy framework on the use of social media in the EEA.

5.3. Ethical considerations and digital media

Daniel Sokol (UK) further elaborated on the ethical considerations in research particularly for internet based research. The principle constraint to research is compliance with the law; ethical considerations fall under this umbrella. Consent is a dominant feature in research ethics, the prevailing principle being that of respect for autonomy, namely allowing persons to make decisions based on their own beliefs and values. Consent can only be considered valid if
it satisfies the criteria of adequate information, competence of the subject in making a particular decision and that the subject has done so on a voluntary basis without any coercion.

In the context of WEB-RADR, information could be provided in the form of a disclaimer although consideration should be given to the content and how prominently this is displayed. How adequate the information is will be also be driven by the expectations of the individual creating the post. Some work packages in the project are able to provide a higher quality consent such as in work package 3b where there will be direct contact with the study participants as a natural person in the way traditional clinical research may be conducted but it is harder to ascertain whether a 'virtual subject' has consented or not when analysing Big Data. There may be some questions about competence and capacity of the subjects even in the studies with direct contact. Some of the groups include patients who are suffering from an illness, which may affect their capacity to consent; this is an unknown quantity with the virtual subjects. Decisions on the need for consent also need to be taken in the wider setting of the risk for harm versus the potential benefits of the research. The declaration of Helsinki principles should apply for all medical research; 'Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.'

There are differences between privacy and confidentiality. There is a general obligation for all to respect others privacy. This relates to who may enter into what space and how information is permitted to be accessed. There should be an understanding between parties that if one has shared information they consider to be confidential or secret and the other party agreed, they will not reveal it to anyone who is not authorised to receive it. This is not necessarily applicable to Twitter posts for example.

There are risks in guaranteeing absolute confidentiality; this may not be possible if information should be disclosed in the best interests of other parties, and intervention may be required if there is any potential for harm in not doing so. There are risks for this particular project if it is perceived that online data is not secure; there will be a reduction in willingness to share information leading potentially to harm for online communities and research in general.

The presentation was concluded with the suggestion to use a checklist such as published by the Association of Internet Researchers to identify any issues in the first stage of the moral analysis. It is likely that unforeseen ethical issues will arise in such a large project as this, but that there should be a process in place to allow issues arising to be resolved in a transparent, ethically and legally defensible manner.

5.4. EU data protection and digital media

Fabio Polverino (EDPS) further elaborated on the opportunities and challenges related to digital media and mHealth. Ensuring individual rights to data privacy and data protection is important not only to those individuals involved but also to the mHealth industry thus preserving confidence and trust in their products.

It was stressed that there are public health benefits of projects such as these for which data protection law does not seek to jeopardise, instead to strengthen the public health by ensuring the successful optimization of use of data on a large scale applicable to populations, within the
constraints/boundaries of the law and safeguarding individual rights in an ethically rigorous manner.

A major challenge lies in defining what constitutes health data especially in relation to data protection. Medical symptoms for example clearly are health data but it needs to be further defined if life style information such as diet and exercise patterns should also be included. Critical to the protection of personal data is the identification of the data controller(s); this assessment is complex in the area of mHealth (and possibly in relation to the WEB-RADR project) as there are multiple processes and multiple controllers, which need to be identified at various stages. An ethically sound principle pertaining to this project is to empower patients and consumers. This means that patients and consumers should be retaining control of their own data at any time. Furthermore, transparency and awareness of data processing are required from the outset. Data transfers and remote processing may be occurring in big data and mHealth. This may pose challenges especially if data is processed outside the EEA. To be successful, there need to be best use of data protection tools. This includes making sure there is clear and transparent information about the use of the data, purpose limitation, data minimization, privacy and security measures.

The legal tools available include the data protection Directive 95/46/EC and the e-privacy Directive 2002/58/EC as well as the European Commission proposal for a new General Data Protection Regulation (GDPR)\(^6\), which has not been adopted yet. However the regulation already provides an overview of strategies for data protection compliance. Several measures foreseen in the GDPR will allow keeping with the pace of the evolution of mHealth. Policy development will have to enhance the implementation aspects thus fostering accountability and enhance compliance with data protection rules, promote data security and PETs, empowering of individuals on data protection aspects and encouraging the use of “Big Data” with applicable judgment.

BEUC asked how social media can inform users that their data may be used for research and how consent may be sought through these media. Mr Polverino recognised that it is very difficult to provide information to individuals through a social media framework although there are ways to reach out to the community and indicate that personal data may be used perhaps by seeking assistance from the site operator. The sites can have disclaimers and links to policies to raise awareness amongst the public. John van Stekelenborg asked about Facebook policies and information sharing. Previously there was a default opt-in for data sharing but newcomers to Facebook have an opt-in to make the post publically accessible. The opt-in is very general in that data may be used but is not clear, which data and for what purpose they would be used and if this constitutes consent. Daniel Sokol commented that consent should be seen as a continuum of very high quality rather than consent of low quality in the framework of social media.

Mickaël Tome (CNIL) pointed out that the project is looking at sensitive personal data and therefore some guarantees should be provided by data controllers. The analysis of social

\(^6\) Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) COM (2012) 11, final.
media for pharmacovigilance purposes should be put in perspective with the broader issue of the re-use of personal data published on the internet and associated requirements in terms of loyalty, transparency, necessity and proportionality. Although no specific recommendation has yet been issued on the data protection aspects of the use of mobile technologies for pharmacovigilance purposes, the CNIL has engaged in discussions with actors in the sector of eHealth and mHealth and concerns voiced on the status of the data (health vs lifestyle/well-being), how this data is processed and stored and also the ethical aspects of the use of such data.

Anne Bahr (Sanofi) commented on the fact that consent is one legal ground for processing of personal data, if there is no consent it should be investigated which legal ground this can be done within. With regards to the definition of health data, it should be related to the purpose of use of the data. If the purpose is for health, the data should be considered health data not well-being data but it could be different if the purpose is different even though the data is the same. A code of conduct for secondary use of health data has been developed in other IMI projects.

Nicola Orlandi (Novartis) explained that the project is addressing a very important issue and that this is a good exercise in bringing together a multidisciplinary team to deliver data privacy by default and design to give real benefits to patients. Regarding social media it should be considered that the data may not have come from the patient themselves and therefore the aspect of consent is even more complex.

Pain alliance Europe (PAE) would like to encourage that lifestyle data is considered as part of health data. Lifestyle is very important to consider and can contribute to the use of drugs. Secondly they are still unsure if the question has been answered as to who owns the data.

Sanofi agreed that lifestyle should be part of health data. It was also emphasised that WEB-RADR is a European project although the social media being analysed can be international and therefore may not subject to European data privacy law. Privacy and personal data protection should be considered as two different things. In the US there are business data and personal data. Business data can be personal but it is not considered private and is not protected by law. How do we know if a patient is posting from US or UK, if we are e.g. looking at English speaking fora? How do we manage the difference in understanding of personal data?

EMA confirmed that although geographical processing of data is important, for the purpose of this project the data controller is subject to European data protection law, regardless of where the data of the data subjects are collected. Regarding data being classified as health data when it is not apparent, trends seen in case law of the European Court of Justice show that the definition of the nature of the data is less relevant for the purpose of assessing the sensitive nature of the information that the data may infer to. Therefore, the idea to apply different standards to different classifications of data because they do not appear to be sensitive data is unwise. CNIL added to this in the context of on-going discussions on the ‘quantified self’

where there are many cases of where the analyst may think they are not in the presence of health data when it transpires that they actually are.

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7 Kelvin Kelly, founder of wired, established the platform quantifiedself.com with journalist Gary Wolf, and introduced the concept to a broader audience
In response to questions on who is the data controller or the data subject, Mr Polverino clarified that the data subject is the natural person, who can be identified for example through data such as a name. The data controller may keep information on the data subject for a specific purpose but there may be more than one data controller if the information is used in different ways. The data subject has the rights to the data and the data controller (who defines the means and the purposes of the processing) has an obligation to fulfil to the data subject. For WEB-RADR, the social media platform is the data controller and even though the terms and conditions may have reference to how the information is processed, there may be other controllers and it is not the usual bilateral relationship as it involves a number of entities processing personal data (albeit in a legitimate way).

In summary, WP1 is tasked with cutting through complexity in balancing the drive to support pharmacovigilance whilst navigating through some challenging landscapes; EU law, general data protection legislation which is itself evolving, development of an app for reporting and secondary use of social media data. Some guiding principles should however be applied upfront: not to use more data than necessary, to keep personal data limited for the purpose and to keep it secure. Epidemico emphasised that they are operating as an EU company will work in full compliance with EU data protection law with a strong commitment to transparency as regards their processes for personal data anonymisation. It was concluded that although complex, it is possible that the project can work in the interest of public health whilst being in compliance with legal and ethical considerations.

6. EVALUATION OF ADDED VALUE OF MOBILE APPS AND SOCIAL MEDIA TO EXISTING PHARMACOVIGILANCE TOOLS

6.1. Introduction to research topic and anticipated deliverables

Prof Munir Pirmohamed (University of Liverpool) informed that WP 4 is looking at the evaluation of the WEB-RADR project deliverables in close collaboration with the other work packages, particularly WP1. Conclusions from the evaluation efforts will drive the policy decisions in an evidence based manner.

The key questions to be addressed as part of WP4 include:

- What new insights can social media bring?
- How can social media knowledge be verified or validated scientifically?
- Does the new information complement or contradict existing knowledge?
- How can the process of deriving the new insights be efficient and effective?
- Are there disease areas or drugs where these new insights are more applicable?
- How can the insights be meaningful but not intrusive?

Prof Pirmohamed explained that their work would compare app based adverse reaction reporting to other electronic or paper based reporting mechanisms. Social media will be evaluated in terms of whether it can be used to detect new safety signals, and whether the data are reliable. A range of different types of products would be chosen for the social media
monitoring for the purposes of the research. Any differences in types of reactions reporting, for example if there are reports of events described in an objective fashion such as a bleed as opposed to more subjective descriptions such as suicidal ideations would need to be further analysed.

It is acknowledged that any findings occurring during the course of the project must be dealt with in accordance with current legal requirements. Other caveats such as ensuring that the doctor-patient relationship is always respected and avoiding misinformation from false or spurious data would need to be adequately addressed.

Technology will evolve as the project moves on and the evaluation resulting in recommendations must evolve in tandem. Dialogues would need to be established to encourage participation of patients and consumers to identify which content will promote interaction and how best to make use of innovative strategies to leverage information and drive online influence. In conclusion, patients are increasingly aware of online information and the WEB-RADR project must demonstrate real advantages and benefits to patients.

7. FURTHER REFERENCES

- WEB-RADR website
- European Data Protection Supervisor Opinion 1/2015 Mobile heath reconciling technological innovation with data protection 21 May 2015

8. WORKSHOP DISCUSSION POINTS TO INFORM THE WEB-RADR PROJECT

Discussion points, which will be followed-up as part of the WEB-RADR project are summarised below:

<table>
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<tr>
<th>Discussion Point Identifier (DPI)</th>
<th>Discussion Point (DP)</th>
<th>Description</th>
<th>Discussion</th>
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<tbody>
<tr>
<td>DP001</td>
<td>App maintenance</td>
<td>What happens in terms of governance and maintenance of the app?</td>
<td>Maintenance of the WEB-RADR mobile app following completion of the project will need to be addressed before project closure</td>
</tr>
<tr>
<td>DP002</td>
<td>App design</td>
<td>How can data be structured to be most useful, bearing in mind for instance FDA’s Sentinel Common Data</td>
<td>The app design is led under WP3a and future enhancements will be based on the user based evaluation how new data</td>
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<td>Discussion Point Identifier (DPI)</td>
<td>Discussion Point (DP)</td>
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<td>Discussion</td>
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<td></td>
<td>Model?</td>
<td>types such as voice recording and images can be analysed in an automated fashion and considering the importance of being able to ask questions about the medicines history of a patient including over the counter (OTC) medicines</td>
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<tr>
<td>DP003</td>
<td>Engagement with social media communities.</td>
<td>How to engage with patients in closed fora?</td>
<td>It is planned that the scope of the WEB-RADR project would focus on public fora. Engagement with patients in closed fora would need to be further elaborated</td>
</tr>
<tr>
<td>DP004</td>
<td>Ensuring confidence in the WEB-RADR project and social media</td>
<td>Loss of trust in certain platforms may lead to a decline of use of those platforms in general and also cause a negative perception of the WEB-RADR project</td>
<td>Loss of trust in certain platforms is an issue facing internet research in general. WP2a will closely assess latest developments and the impact of their research. Perceptions specific to WEB-RADR are to be managed through the project</td>
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<tr>
<td>DP005</td>
<td>Access to data collected through the WEB-RADR project</td>
<td>Who will have access to the social media data collected and the dashboards created for the analysis?</td>
<td>The applicability and use of the tools including data collected will be addressed in the context of the project sustainability</td>
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<tr>
<td>DP006</td>
<td>Signal detection</td>
<td>Decisions on how to use</td>
<td>The integration of social</td>
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<td>Discussion Point Identifier (DPI)</td>
<td>Discussion Point (DP)</td>
<td>Description</td>
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<td>information from social media in the context of existing data sets and considerations for signal detection</td>
<td>media data in the current signal management processes will depend on the outcome of the research. This is to be considered in WP2b once results are available and will also feed into WP1. Policy will be evidence driven</td>
</tr>
<tr>
<td>DP007</td>
<td>Languages</td>
<td>Gaining experience with the use of EU languages other than English</td>
<td>WEB-RADR will include two additional languages (French and Spanish) with the aim to inform about language specific challenges</td>
</tr>
<tr>
<td>DP008</td>
<td>Data integrity and provenance</td>
<td>Concerns over malevolent posts/hoaxes and the impact on the reliability of the data collected</td>
<td>WEB-RADR will inform about the potential risks of malevolent posts or hoaxes once the results have been evaluated. In parallel, a sentiment reading algorithm will be applied to facilitate the assessment</td>
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<tr>
<td>DP009</td>
<td>Data ownership</td>
<td>Data ownership of publically available data and fundamental rights to personal data protection</td>
<td>Data privacy aspects to be further evaluated in WP1</td>
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<tr>
<td>DP010</td>
<td>Informed consent</td>
<td>How to obtain consent through social media</td>
<td>To perform an analysis of default and design privacy settings in the platforms used in the project and to further elaborate consent as an</td>
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<td>Discussion Point Identifier (DPI)</td>
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<tr>
<td>DP011</td>
<td>Definitions</td>
<td>Definition of health data and lifestyle/well-being data</td>
<td>Definitions awaited from the GDPR, project definitions to be based on the EDPS opinion on mHealth</td>
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<tr>
<td>DP012</td>
<td>Data processing</td>
<td>Processing of personal data and consent</td>
<td>Data privacy experts will further analyse this aspect as part of WP1</td>
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<tr>
<td>DP013</td>
<td>Data controller</td>
<td>Data controllers for mobile app and social media analytics</td>
<td>To be further elaborated</td>
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<tr>
<td>DP014</td>
<td>Ethical aspects</td>
<td>Use a checklist such as published by the Association of Internet Researchers to identify any issues in the first stage of the moral analysis</td>
<td>To be considered as part of the review of literature on ethics in WP1</td>
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### Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<td>API</td>
<td>Application Programming Interfaces</td>
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<td>EMA</td>
<td>European Medicine Agency</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>EV-EWG</td>
<td>EudraVigilance Expert Working Group</td>
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<td>EACPT</td>
<td>European Association for Clinical Pharmacology and Therapeutics</td>
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<td>EDPS</td>
<td>European Data Protection Supervisor</td>
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<td>EURORDIS</td>
<td>European Organisation for Rare Diseases</td>
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<td>FDA-US</td>
<td>US Food and Drug Administration</td>
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<td>GDPR</td>
<td>General Data Protection Regulation</td>
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<td>GSK</td>
<td>GlaxoSmithKline</td>
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<td>GVP</td>
<td>Good Pharmacovigilance Practice</td>
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<td>HALMED</td>
<td>Croatian Agency for Medicinal Products and Medicinal Devices</td>
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<td>ICSR</td>
<td>Individual Case Safety Report</td>
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<td>IMI</td>
<td>Innovative Medicine Initiative</td>
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<td>JPNV</td>
<td>Janssen Pharmaceutica NV</td>
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<tr>
<td>MHRA-UK</td>
<td>Medicine and Healthcare Products Regulatory Agency</td>
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<td>NLP</td>
<td>Natural Language Processing</td>
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<td>PET</td>
<td>Privacy-enhancing technology</td>
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<td>RAPID</td>
<td>Real-Time Application for Portable Interactive Devices</td>
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<td>SME</td>
<td>Small and Medium-sized Enterprise</td>
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<td>UMCG</td>
<td>University Medical Centre Groningen</td>
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<td>WP</td>
<td>Work Package</td>
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<td>WEB-RADR</td>
<td>Recognising Adverse Drug Reactions</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>Alastair Sutcliffe</td>
<td>Institute of Child Health, University College London (UCL)</td>
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<td>Alastair Fowkes</td>
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<td>Alessandro Spina</td>
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<td>Almath Spooner</td>
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<td>Ancel-la Santos Quintano</td>
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<td>Daniel Sokol</td>
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<td>David Haerry</td>
<td>European Aids Clinical Society (EACS)</td>
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<td>Diane Farkas</td>
<td>Sanofi</td>
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<td>Erzsébet Podmaniczky</td>
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<td>Fabio Polverino</td>
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<td>Munir Pirmohamed</td>
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<td>Magnus Wallberg</td>
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<td>Zindrou Zoi</td>
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Annex 2 – Workshop Survey Results

General demographics

64 responses

- Please select your gender (optional)
  - Female
  - Male

- Select your stakeholder type
  - Healthcare professional
  - Non healthcare professional

General demographics

- Healthcare professional type
  - Physician
  - Pharmacist
  - Nurse
  - Other (please specify)

- Non healthcare professional type
  - Patient
  - Consumer
  - Carer
  - Other
ADR reporting

Have you ever reported an adverse drug reaction?

- Yes
- No

To whom did you report?

- National relevant regulatory authority
- A pharmacist
- A physician
- A company representative
- Other

What methods would/do you use to submit ADR reports?

- Verbal during visit
- Paper
- Phone
- Email
- Fax
- ADR website
- Company website
- Other website
- Other

In your opinion, what are the barriers to ADR reporting?

- Insufficiency of means to report
- Insecure means to report
- Unsecure website or report
- Not enough desire to report
- Not enough knowledge about the barriers over the reports
- Other
Features for app

Would additional features make the use of an app for ADR reporting more attractive to you?

- No
- Yes

Use of social networking sites

Do you use social networking sites such as Facebook, Twitter, other blogs, patient forums?

- No 23%
- Yes 77%

Which social networking sites do members of your organization use to communicate about health issues?

- Crowdspan
- Disease awareness
- Facebook
- Flickr
- Google+
- HHS
- Interact
- LinkedIn
- MySpace
- Patient Forums
- Patients Live
- Reddit
- Plurk
- Panser
- Twitter
- Tumblr
- VNC
- Yahoo!
- YouTube
- Other (please specify)
Use of social networking sites

Approximately how long have you been using social networking sites?
- Over a year: 95%
- More than six months: 4%

How frequently do you visit social networking sites?
- Everyday: 76%
- Twice a week: 16%
- Once a week: 4%
- Once a month: 2%
- Less than once a month: 0%

For which purposes do you use social media?
- News
- Personal networking
- Professional networking
- Educational purposes
- Exchanging/share info for similar experiences
- Information on conditions
- Information on diseases
Use of social networking sites

Which forums on social networking sites do you use, which could be also of interest to the WEB-RADR project?

- Instagram
- Rare Connect - part of Eurordis website Health Unlocked
- Linkedin
- Facebook group for LHON
- Forums created in the frame of clinical trials, for the trial’s participants
- Facebook
- Twitter
- Pinterest
- ISAL Foundation website; SIP website
- SuomenKipury Facebook. Discussion forum by Suomen Kipury (Finnish Pain association)
- GaucherDisease@yahoogroups.com
- nhs networks
- HealthUnlocked
- #bcsm #hcsmeu #bcsm #doctors2.0 #oncology
Use of social media

- How reliable do you think the information shared on social networking sites is?
  - Very: 5%
  - Fairly: 25%
  - Not very: 34%
  - Unreliable: 14%
  - Other: 15%
  - Don’t know: 7%

- Do you see benefits in the analysis of public domain social media conversation data for the monitoring of the safe use of medicines?
  - Yes: 74%
  - No: 26%

Benefits of social media

**Simplicity and availability**
- Simple method for gathering information trusting that they are true. Possibility of extended, public actions on ADRs reporting, continuous education and medicine use and direct information how medicines are used.
- However imperfect it is better than nothing, which for many people is the alternative.
- The reporting of eventual adverse effects, strategies to overcome some difficulties caused by some medicines, disclosure of eventual problems with medicines.
- Raising Awareness; Cheap way of inventory of problems; Good post surveillance tool.
- Patients often discuss effect (or feeling) of using a drug - sometimes we describe symptoms/reactions between us where there are not scientific evidence and therefore doctors most likely will not recognize - but after years of us saying "it" they will... so patients are ahead.
- Having access to information on medicines on sites which are recommended by pharmacists or doctors.
- Capture of information more quickly.
- Useful to get an idea of patient concerns about side effects etc.
- Qualitative content can generate items for systematic quantitative research.
Benefits of social media

Broadness

- There are many Facebook groups about allergies and asthma in Sweden and they are often asking after good medicine and treatments and I think this would be a great forum for this.
- It may identify serious health issues quickly. It may facilitate help and assistance quicker. It may identify areas of the country or certain countries where there are a number of similar ADR and may indicate counterfeit medicines usage or other problems with quality issues for medication i.e. contamination.
- A new ADR may be found from these comments.
- Collect and analyse the collective knowledge patients have.
- Many users - useful and trustful to me too is the drug used in my country too - allowed and unity for medicine market.
- Analysing information increases patient’s safety. Collecting data on marketed therapeutic products and sharing this data with patients allows patients to make more informed decisions and reduce risks.
- Assess to more feedback from a broader patient population.
- One gets real life info on medicines taken at the prescribed times, dosage, feeling of patients and important others towards the medication, comparison with other medicines taken, discussion about quality of life with that medicine...
- Trends in satisfaction or dissatisfaction would be picked up & addressed.

Benefits of social media

Personal/confidence/awareness

- Express personal opinions.
- People may be more likely to talk about it within forums but not report it.
- While not reliable, it can provide some interesting information about trends and patterns and also perhaps detect early signs some potential adverse use of medicines.
- Yes, because you get access to raw data of people sharing with friends.
- Sharing experience on treatment - diagnosis; adverse effect; notice on patient problems.
- Raising awareness of the participants.
- Could alert to adverse affects which are not formally reported.
Benefits of social media

Other
- Side effects
- Anecdotes, stories
- Good inputs for the research specially for rare diseases
- Recently via patient communities/platforms and Facebook groups information surfaced that there might be a problem (not sure yet what the problem is, information pending) with one of the thyroid hormones after a change from glass jar to blister. There were too many patients reporting adverse reactions to the change, who via SoMe were made aware to report to the authorities and the patient organisation. Although to my opinion it took too long for authorities and the producer to take action, the problem seems to have been identified now almost half a year after the first reports. We are awaiting news very soon. So yes, SoMe, patient platforms, SoMe Facebook groups etc. can certainly be the first identification of a potentially problem with drugs.

Disadvantages of social media

Accuracy/evidence
- I am not sure how this could be evaluated from accuracy
- Social media too often lacks evidence based information, can merely be opinion. They also can tend to fuel myths and wrong information.
- Lack of understanding, knowledge and critical analysis of the general public of ADRs

Validation/reliability
- Non-professionals may use medical terminology without being sure of what this means, searching for keywords may mean duplicate 'reports' across social media platforms for one person
- I doubt the reliability of information. Can any information gathered be considered representative of a group of patients?
- Open to abuse and false reporting—no peer review
- Unreliable

Trustworthiness
- Lack of trust
- I trust only official information that comes from hospitals
Use of social media

Do you have concerns regarding the analysis of public domain social media conversation data, e.g., how many posts mention adverse drug reactions?

- No: 44%
- Yes: 56%

Use of social media

If a medicines regulatory authority wanted to contact you regarding a public post about an ADR on a social networking site, how would you prefer to be contacted?

- Email: 62%
- Phone: 5%
- Private direct message: 15%
- Reply public post in social media: 4%
- Through my doctor: 9%
- I would not feel comfortable being contacted: 7%
Use of social media

Which of the following areas do you think should be included in the analysis of public social media data?

- Adverse reactions related to medicines: 86.8%
- Quality detects of medicines including delivery devices: 71.2%
- Deviations from recommended use e.g. off-label use (including unexpected benefits), misuse, abuse, overdose or medication errors: 71.2%
- Pregnancy exposure regardless of adverse reactions: 51.9%

Medicinal products of interest for social media monitoring

As part of the WEB-RADR project, which types of medicinal products would you be most interested in monitoring in social media data? (You may select more than one option)

- Medicinal products subject to additional monitoring (marked with an inverted black symbol): 61.8%
- A specific class of medicinal products: 71.2%
- Other: 23.1%
Medicinal products of interest for social media monitoring

- Population-oriented
- In my role in paediatrics - products in this category
- Orphan drugs

- Safety profile-oriented
- Medicines marked with a black triangle for the beginning, then cancer and cardio-diseases

- Therapy-area oriented
- Medicines marked with a black triangle for the beginning, then cancer and cardio-diseases
- Oncological medicines
- Opioids - cannabinoids - analgesic drugs
- Vaccines
- Oncology medicines, as their AEs in real life are important to monitor

Medicinal products of interest for social media monitoring

- Usage-oriented
- Rarely used drugs
- Biologics, biosimilars, advanced therapeutic medicinal products, orphan products
- All new products
- Drugs not specifically approved but prescribed

- External reference-oriented
- I only trust those which are mentioned on www.CBIP.be