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WEB-RADR

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Pharmacovigilance and Epidemiology

Innovative Medicines Initiative WEB-RADR Workshop Report: Mobile Technologies and Social Media as New Tools in Pharmacovigilance

19 October 2016, European Medicines Agency, London, UK

EXECUTIVE SUMMARY

This workshop was the second 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 has so far developed mobile app prototypes in three Member States to support adverse drug reaction reporting and the provision of drug safety information to app users from medicines regulatory authorities.

A second aspect of the project is to assess the usefulness of social media data for pharmacovigilance. The aim is to assess and identify if it may provide information which is not readily available through traditional methods in pharmacovigilance, and/or if it provides it any sooner.

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 have also been analysed.

The workshop provided a discussion platform for patients, health care professionals, medicines regulatory authorities and other experts to share their views and expectations and Participants included the European Medicines Agency's Healthcare Professionals Working Party and the Patients' and Consumers' Working Party, the Pharmacovigilance Risk Assessment Committee, pharmacovigilance and pharmacoepidemiology experts, representatives from Health Technology Assessment bodies, representatives from Young People (Paediatric Committee)

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experts in the area of medical ethics and data protection and IMI WEB-RADR Consortium members).

The workshop informed about developments and outputs from the project, dedicated breakout sessions allowed participants to focus on specific topics. These will inform the final deliverables of providing recommendations for policy and governance for mobile device and social media use for a pharmacovigilance landscape into the future.

WELCOME, OPENING REMARKS AND OBJECTIVES

Peter Arlett (EMA) welcomed all participants to the second WEB-RADR workshop and highlighted that the project should be seen in the context of an evolving pharmacovigilance system with more emphasis on a holistic lifecycle approach embracing the entire evidence hierarchy. Drivers for change are social, scientific and technological and because engagement of patients could be the biggest driver, tools such as social media and technology apps and devices have real potential to contribute to effective and safe use of medicines.

June Raine (MHRA) introduced the project structure and emphasised the value of the public private partnership. She outlined the objectives of the workshop 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. One of the essential activities within the workshop was a series of breakout groups to consider, discuss and debate how the outputs of WEB-RADR could be applied most effectively for the benefit of consumers, patients and carers as well as healthcare professionals.

SESSION 1- WEB-RADR: WHERE WE HAVE COME FROM AND WHAT WE HAVE ACHIEVED

Going mobile- experience so far with app based safety reporting

Linda Härmark (Lareb) gave an update on the three mobile apps launched in the UK, Netherlands and Croatia. For Adverse Drug Reaction (ADR) reporting the app can submit an ADR report to a national Competent Authority (NCA), provide a summary of submitted reports and save an ADR report to be submitted later. Initially the app was mainly intended to support reporting. As the project has evolved it became clear that the app has other utilities such as key features for communication. This included the ability to obtain generic safety news directly from NCAs, to save products to a 'watch list' to view news tailored to these products of interest, and to view statistical outputs of ADRs submitted to NCAs. She gave a demo of the news feeds and how to search for reports and information given on the number of downloads and reports submitted. In the Netherlands the app attracted a number of new reporters although no age difference was seen in reporting through the app versus traditional means.

A more detailed analysis is underway on the use of the app versus conventional reporting including assessment of completeness and clinical quality of reports. The design of the app has met the need for a fast and easy way to complete the report although the number of data elements compared to conventional forms is reduced, and therefore there may be less information for causality assessment. The numbers of downloads of the app are much higher than the submission of ADRs which may be due to the possibility for people to use the app more as a communication tool than for reporting.

Some questions were received on how the three apps differ; it was clarified that these are fundamentally the same but rebranded/translated. Concerns were raised that ADR data from the app may be shared via social media; it was clarified that the information is transferred directly from the app to the NCA and is not provided to any third party with national data protection requirements fully respected. It was explained that the social media analytics work stream was completely separated from the mobile app, which operates in the same way as 'traditional' spontaneous reporting systems.

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

Carrie Pierce (Epidemico) gave a summary of the social media monitoring platform, the steps in data acquisition and processing and the export and presentation on the dashboard. The data-sources used were Twitter and Facebook. It was clarified that public Facebook data is no longer available to the project at the individual post-level. The Facebook dataset used therefore covers March 2012 to October 2015. Additional data-sources are being investigated including data sets from patient forums (e.g., patient.co.uk, healthboards; dailystrength), Inspire online communities and Reddit.

Over 3 million public posts have been acquired so far, around 55% of these were removed (spam). 2% of these can be classified as 'proto- AEs' i.e. information which resembles potential adverse events. The reported terms in English, Spanish and French (the languages included in the scope of the project) are then mapped to the MedDRA coding dictionary. In addition, medicinal product labelling information can also be used to help train the "classifier", a tool to automatically identify text which could be for example; adverse events or indications. The challenges faced relating to social media include volatility of social media sources, large volumes of potentially irrelevant data, and the ability to combine speed of automated data collection with precision of human interpretation.

There are however equally important opportunities:

- obtaining better insight into how medicines are used in real life,
- partnering with online communities to gather data from collaborating patient groups,
- enhancing established pharmacovigilance tools by means of additional data sources, combining safety data from a variety of sources to identify new or underreported safety risks,
- providing more context by combining technology, e.g. a sentiment classifier with the AE classifier,
- exploring new technology in image and video analysis and understanding what matters most to patients.

It was confirmed that the analysis of content other than text may be looked at in the future but so far the focus is on natural language processing.

WEB-RADR – perspectives and expectations from patients

François Houÿez (EURORDIS) presented the patient perspectives for the project. A number of features had been identified in discussions with patients, which could be considered for inclusion for the app:

- A bar code scan to identify the product, its strength and batch number;

- An autocomplete feature for the product name;
- The name of manufacturer (e.g. useful for generic products using potential allergens in excipients);
- A voice recorder option to populate text fields;
- Ability to use other tools such as diagrams of the body to make completion of report easier;
- Ability to extract information if the user has medical record information on their phone;
- Ability to connect to other patients in their community;
- To retain information on e.g. disease history to avoid the need to complete a second ADR submission or links with additional health apps;
- Provision of more product specific updates and 'outcome of my report' (impact of my report in the pharmacovigilance system, and what happens next).

A survey with patients highlighted a wish to use mobile apps to be able to better understand their medical conditions and offer information on the choice of treatments. Provision of practical support such as care planning and facilitation of communication with healthcare professionals was also important.

As regards social media, it could be used to communicate how to manage side effects or improve quality of life. Regarding the behaviour of patients on social media it is likely they will be discussing more about quality of life whereas medical seriousness is more likely to be reported by healthcare professionals. It is not clear if patients will post on social media and report adverse reactions. Some signal detection aspects have also been discussed; use of recreational products, how lifestyle may influence ADRs, detection of supply issues and information on self-medication practices. Further research on how social media can be used for patients is needed. Aspects requiring further consideration are potential risks with un-validated or medically incorrect advice being given amongst patients on social media and the possibility to perform user acceptance of social media monitoring with respect to data protection and ethical principles.

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

Alessandro Spina (EMA) gave a summary of the assessment of the current legal framework. The landscape is complex in terms of data management and the interest in privacy aspects and data protection is high. The current legal framework is defined by Directive 95/46/EC, the e-Privacy Directive and further clarified based on the Opinions of the Article 29 Working Party (a working party of the national Data Protection Authorities (DPAs).

It was explained that because a post has been publically posted, from a data protection perspective, this does not give carte blanche for the use of the data; data protection and privacy should still be taken into account. Also pertinent to this project is that health data is subject to a special type of protection. The opinion of the Article 29 WP is that data generated by devices (irrespective of whether they are 'medical devices') can be considered health data 'if conclusions can be reasonably drawn about the health status of concerned person'.

Two corner-stones of data protection apply:

- Purpose limitation: Once purposes have been decided and clearly communicated to the individual, data can only be processed for compatible purposes;
- Data minimisation: Only data should be collected that is necessary for the specific purpose.

The "data controller" is a critical actor in determining the 'means and purposes of the processing operation'. The controller holds responsibilities regarding the concrete modalities in which data are processed (retention; security) and vis-à-vis the data subjects in terms of information about the processing, access rights and rectification.

Anonymisation and pseudonymisation are important tools to apply. Irreversibly preventing identification, having regard to all the means 'likely reasonably to be used' to be applied for identification is anonymisation. Pseudonymisation is a security measure, not a way to totally anonymise data taking into account that the 'key' for re-identification is retained. There is some ambiguity of the term 'de-identification'. In any case there is a strong need for transparency of the methodology used to de-identify datasets.

Nicola Orlandi (Novartis) continued to cover the aspects of consent, which is generally used as the main legal basis for processing personal data. Consent must be explicit and users must be able to withdraw their consent using accessible and easy to understand mechanisms, including e.g. choosing to delete their personal data (locally or remotely, or both), or e.g. by choosing to uninstall an app. Social media needs to be considered separately. It is acknowledged that listening through social media could lead to collection of personal data besides health data, which may impact on privacy principles. The Article 29 WP recommends that social media providers should make available adequate warnings to users about the privacy risks to themselves and to others once they upload information on a social network. The social network requires the data subject's free, informed and specific consent, which shall be obtained prior the creation of the user's profile and before the data start to be processed. Sensitive personal data may only be published on the Internet with i) the explicit consent from the data subject or if ii) the data subject has made the data manifestly public himself.

However, when it comes to collection of this data, the lack of direct contact with the data subject means that other legal provisions than consent should be considered for processing: Legitimate interests pursued by data controllers or, with reference namely to health data, clearly made public by the individual.
In this case the data controller(s) should proactively adopt measures to give to the individual control over processing of their data, meaning adequate and intelligible information about the processing and the purpose (incl. right to object to the processing).

It is also important to highlight that the current legislation dates back to 1995 when the internet was still an esoteric concept. The new General Data Protection Regulation (GDPR), Regulation (EU) 679/2016 is approved and will enter into force in May 2018. Its aim is to reach harmonisation within EU countries but there are still areas where Member States may maintain or introduce more specific provisions: data concerning health is one of them. It introduces new definitions and conditions for the lawfulness of processing, for consent and processing of special data (including health related data) as well as for further processing and compatible use of data, which has already been collected.

Further defined are the features of privacy by design and default. Privacy by design refers to the process of 'implementing technical and organisational measures appropriate to the processing activity being carried out and its objectives, such as data minimisation and pseudonymisation, in such a way that the processing will protect the rights of data subjects'.

Privacy by default refers to the process of 'implementing appropriate measures for ensuring that, by default, only personal data, which are necessary for each specific purpose of the processing are processed'.
In addition to explicit consent and to data manifestly made public by the data subject, Art. 9-2(i) (special data) provides a condition for processing special data such as the processing of health data necessary for reasons of public interest in the area of public health such as ensuring high standards of quality and safety of health care.

Art. 89 relates to processing data for the purpose of scientific research with adequate safeguard measures (incl. pseudonymisation). These articles may provide adequate legal grounds for processing of health data such as that conducted within WEB-RADR providing appropriate controls and safeguards are in place.

SESSION 2- HOW TO OPTIMISE WEB-RADR DELIVERABLES

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

Peter Mol (UMCG) presented initial results of studies conducted on how the use of apps can be optimised.

A qualitative study was performed based on the 'Unified Theory of Acceptance and Use of Technology model (UTAUT)' [1] to look at barriers and facilitators. The model was used to pose questions such as who will use the technology and what features does the technology need. Issues such as how the technology may affect doctor-patient relationships, interaction with regulators, layout, language used and data protection aspects were highlighted.

There was feedback that an app should only have one feature where others wanted it to be multi-faceted. Another survey also looked at risk communication by NCAs and the information used to keep up to date. Mobile phone apps did not score highly as being useful as medical reference, the Summary of Product Characteristics (SmPC) was used more frequently. A quantitative survey was also launched in seven European languages. 388 healthcare professionals (HCP) and 621 patients responded, with a similar result in both groups being interested in apps to report ADRs and to receive information. An app with a two-way communication would be appreciated the most. A dominating aspect was the potential speed and ease for reporting through apps. Patients favoured feedback when they are reporting ADRs in the form of reassurance on the nature of the ADRs whereas HCPs preferred receipt of information, such as how to alleviate symptoms.
Both HCPs and patients were interested in information on drug interactions, new indications were also of interest especially for HCPs. It was revealed that patients would not be very interested in using the app to 'chat' with other patients about their experience although they would be a little more interested in a passive engagement to listen to what others say.

Patients were interested to receive information on medicines which they use, HCPs would like broader information on all marketed products not only the ones they prescribe. Patients were a little more concerned with security aspects, around half opted for entering a password every time as opposed to an automatic login, but two-thirds of HCPs opted for the automatic login.

A question was raised that there may be some cultural differences in Eastern European countries where there was no response to the survey. In general results were consistent across countries, however it could be further investigated.

Where do social media add value for pharmacovigilance?

Simon Maskell, (University of Liverpool) presented the perspective from the analysis of the usefulness of social media data for pharmacovigilance which relies on quality and quantity of reports. There is an opportunity for social media to separate these concepts and provide information in different ways.

[1] Venkatesh, MIS Quarterly 2003:27(3);425-478

Despite the perception of social media as a new data source being huge, when comparing the quantity of ADRs in Twitter to that from traditional means, Twitter produces far less reports. This can be further stratified into types of MedDRA Preferred Terms (PTs) which are more represented in Twitter than others. The process is ongoing to identify which are these PTs but so far examples of those reported frequently in social media include dependence and tolerance issues. There is far less information on off-label use or product quality issues. There are also 'data rich' and 'data poor' drugs in social media, e.g. vardenafil has more posts on Twitter than there are ISCRs in Vigibase.

The results so far show that social media data do not provide any more information in terms of quality especially due to the character length restrictions in Twitter. This may be different when looking at patient fora, but there is also an additional consideration in that there is a possibility to look retrospectively and prospectively at other posts from a certain twitter user. Other information may be available in these posts which may be combined. The possibility to look longitudinally may be of particular value for events in pregnancy. Further potential utilities include provision of a denominator of particular events without an association with a drug. Sentiment analysis could be performed following label changes. Work is ongoing to maximise the 'yield' from social media, and to assess if the information translates to signals being detected earlier.

A question was raised on 'off label use' as this is unlikely to be picked up in social media itself. It was clarified that off label use could be picked up through knowledge of product use and in the context of the approved indications.

Meeting expectations from patients and healthcare professionals

John Van Stekelenborg (JNJ) presented on meeting expectations of patients and healthcare professionals and how the regulatory framework could provide support.

Areas which could be included in the expectations can be divided in five areas:

i. Reporting and Communication

- Providing tools to report adverse reactions;
- Sharing experiences and practices: communities of patients or HCPs;
- Two-way communication: risk communication; information sharing.

ii. Routine pharmacovigilance

- Adverse reaction collection 'machine';
- Alleviating underreporting in spontaneous systems or correcting reporting biases;
- Finding rare events not often reported through spontaneous reporting;
- Finding medical side effects earlier than in other systems across a broad spectrum.

iii. "Niche" pharmacovigilance

- Finding new information in niche areas underrepresented in current monitoring systems e.g. exposure during pregnancy/ abuse/ misuse/ early monitoring of new products.

iv. Adjunct for pharmacovigilance

- Use for strengthening of hypotheses emerging from other systems;
- Providing additional insight into safety issues identified through other means.

v. Quality of life issues

- Finding areas of patient and HCP concern that are not necessarily medically important, but that affect quality-of-life e.g. sleeplessness, stress.

Ideally, good regulations should encourage innovation and entrepreneurism, promote and safeguard patients and public health, protect privacy, encourage fairness and help focus resources on the right priorities. There is likely to be competing priorities between all these areas and therefore a balance must be found to optimise expectations from regulators and meeting regulatory obligations by healthcare professionals. .

In particular, there needs to be clarity on MAHs' obligations vis-à-vis social media in regards to monitoring and reporting obligations. This includes status of cases and signals identified in social media including privacy issues. There should be optimal use of resources taking into account the quality and value of the various PHV data sources based on demonstrated benefits for the safe use of medicines and the protection of public health.

Panel discussion

A panel discussion including Carrie Pierce (Epidemico), François Houÿez (EURORDIS), Donald Singer (European Association for Clinical Pharmacology and Therapeutics), Jamie Wilkinson (Pharmaceutical Group of the European Union) and Bob Ball (FDA) gave rise to discussions on how to analyse data when there is a user with several profiles with different names and perhaps communicating in different social media; it was explained that methods are applied as part of the project to identify duplicates based on the similarity of the text.

Aspects of data protection were raised - especially concerning the fact that a large majority of users do not read the terms of use of the social network site; it can be argued that they have not truly consented. This is a big challenge and it is important to enhance trust and to provide a good model for data protection to enhance business value. Proactive transparency about processing of data was stressed as a critical feature.

Bob Ball from the FDA explained that there is a similar project ongoing in the U.S called RAPID (Real Time Application for Portable Interactive Devices)- with a slightly narrower focus looking at adverse events from medicines used in response to public health emergencies, and a collaboration for research with patient reported data from 'patientslikeme' is also underway. Previous work with Epidemico on signal detection did not find social media to be better or faster than traditional methods but it could have potential in certain niche areas.

Feedback from breakout sessions 1-4

1. Patients and healthcare professionals – what do we want as WEB-RADR outputs?

François Houÿez (EURORDIS) reported on the discussions from breakout session 1. It is considered that the app is fast and easy to use. It has potential for clinical hospital pharmacists. It should also be investigated if the app can be used in those countries with reporting obligations for HCP. A potential concern with the app was that its speed of use could facilitate a more impulsive or angry type of reporting. It was also discussed whether a HCP should receive a copy of an ADR report a patient submits. This would only be possible if the patient had provided the contact details of the HCP. It was also discussed, what and when a HCP should be expected to follow-up on such report; is there a duty of care upon the HCP to act or is there a joint responsibility with the NCA?

Taking into account that paper reports or reports submitted through web-forms are usually not sent as copy to the patient's HCP, the app should operate on the same principles. Regarding two-way communication, although generally seen as a positive aspect, a potential detrimental effect from providing information to the patient could mean that they are falsely reassured and do not seek medical advice when it is needed. A potential for linking ADR reports with health records was raised.

Acknowledging that not everyone may use the app for reporting, it would be positive to offer an additional alternative to traditional routes.
Promotion of the app (as is safety reporting in general) was seen as an important factor supported by an effective communication campaign. Ideally this should be systematically communicated to patients perhaps through the pharmacist. Another point raised was the usefulness of the app to communicate with patients and HCPs on shortages or withdrawn products, although there may also be an argument that communicating shortages actually compound the problem due to stock piling.

Security of the app was raised as a key subject. Whilst this is true, it may be more of a perceptual concern as it has been mooted that an app is actually more secure than the traditional reporting mechanisms where sensitive data is written for example onto paper forms which could, in theory be intercepted.

A point was introduced about the extreme caution which must be exercised for HCPs to communicate with patients via social media. There had been a previous concern around HCPs communicating with their patients via 'WhatsApp'. Since the platform has been bought by Facebook, the automatic integration of data means there were suggestions for the patient to connect to other patients in the contact list of the HCP, and given the sensitivity of this special category of data, this was considered a serious data breach. The world medical association[2] responded with a communication to HCPs and a set of recommendations in order to protect patient's data in this regard.

There are still some differences in opinions on the utility of the app for reporting. Is it likely that patients will proactively download an app on the off-chance that they suffer an adverse reaction? Or are there certain groups of patients perhaps those with rare diseases who would find the reporting app useful. Alternatively it could be more of a communication tool for patients and a reporting tool for HCP. There had also been some perceptions from HCPs that using a mobile phone in the course of one's clinical duties may have negative connotations in terms of professional respectability. There are other implications for the communication aspects in that this could be potentially resource heavy and any two-way communication strategy would need to be done in a focused way.

2. Regulatory questions – what are the options?

John Van Stekelenborg (JNJ) gave feed-back on regulatory questions raised by pharmaceutical industry. This breakout session focused on six key questions from a list of 75 submitted by EFPIA:

- What should be the definition of 'sponsorship' or 'under MAH control'?
- What obligations should there be for MAHs to screen social media (whether sponsored by them or not) sites for ICSR collection?
- What obligations should there be for MAHs to screen social media sites (whether sponsored by them or not) for signal detection purposes?
- Should the receipt of 'de-identified' data (i.e. where reporter name/e-mail /twitter name etc. has been stripped out by 3rd party) remove obligations to;
    a) collect
    b) report ICSRs from social media
    c) attempt follow-up?

- What obligations should MAHs have for screening/active listening to (sponsored and non-sponsored) social media posts that are not in English/non-EU languages?
- Should the purpose for looking at social media make a difference for pharmacovigilance obligations i.e. whether looking at pharmacovigilance purposes (signal detection) or market research?

A set of options and corresponding pros and cons were discussed for each question taking into account that guidance is already provided for many aspects in the Good Pharmacovigilance Practice modules in the EEA and US FDA guidance.
From the discussions it was largely considered that there is little benefit to report ICSRs that result from the screening of social media sites (especially those which are not company sponsored).

The requirements could be seen as analogous to those of secondary use of data with no direct contact with patients or healthcare professionals. Results from the work carried out as part of work package 4 will provide important input in the finalization of regulatory recommendations. It is likely that the social media utility will proof beneficial mainly for niche areas. It could also be tailored to the safety profile of a product or to be used as a source to answer specific regulatory questions where an aggregate review could be required.

In regards to the discussion around languages, there were various proposals ranging from monitoring all languages to monitoring all languages where the product is approved for company sponsored sites. For non-sponsored sites monitoring could be conducted where there is a risk identified in the risk management plan.

It was discussed that in general the obligations should focus on collection and assessment of aggregated social media data rather than individual case reporting. In accordance with current GVP Module VI requirements any new safety information, which may impact on the risk-benefit profile of a medicinal product, should be notified immediately to the competent authorities in Member States where the medicinal product is authorised and to the Agency. Safety information should be collated as part of the pharmacovigilance system established at Member State level. There should be no requirement to follow up individual cases as this could pose ethical and data protection issues. Any findings that impact on the safety of medicines should be discussed in the relevant sections of the concerned periodic safety update report and analysed as regards their overall impact on the medicinal product risk- benefit profile.

3. How could social media monitoring support signal detection?

Dave Lewis (Novartis) provided feedback from the breakout session on signal detection. It was widely acknowledged that there is a great deal of noise in social media data, and no example of a signal found through social media could be identified within the representatives of the group. There were some differing views on whether social media should only be considered as a support to signal detection or whether it has potential for de-novo signal detection or assessment and whether the evidence on its utility is required before making these decisions. Alternatively it could be seen as one of a range of tools.

There were many synergies with the discussions in session 2 for areas to focus on. New medicines were identified as an area to concentrate on, also for identified risks in the Risk Management Plan, clusters and patterns including geographical patterns and product quality defects. It can also be seen as an adjunct to traditional methods. There was also a strong recommendation from the group to look in more detail at patient fora as part of the project, and findings from another IMI project; Get-real have shown much higher quality data from forums. Areas for further research include abuse/misuse, longitudinal data for pregnancy outcomes or long latency ADRs, rare and severe events, quality of life, patient tolerability and potentially other aspects such as incorrect use of medicines such as cutting tablets in half for financial reasons. The possibility of hoax posts or unreliable data is acknowledged but a

pragmatic approach should be taken. A point was also raised about groups of HCPs sharing information on use of medicines through chat groups such as WhatsApp, and if there is a potential for regulators to 'join' these groups. There is a potential to use the app for active surveillance of issues listed in the RMP and to proactively ask patients to report on those topics. The need to re-validate on a constant basis was also recognised as social media and the digital world evolve quickly. There may be some caution from a resource perspective and a scientific one in using social media for signal detection although there should be a possibility to adopt a new strategy if and when evidence becomes stronger for where there is an opportunity to detect signals earlier.

4. How to ensure future maintenance and sustainability of WEB-RADR?

Carrie Pierce (Epidemico) summarised the discussion in the breakout session looking at maintenance and sustainability where the aims were to discuss plans and criteria for the long-term sustainability of technology outputs for both the social media analysis platform and the mobile app and to identify key questions. The main themes were maintenance of the tools developed, plans to roll out to additional users or territories and enhancement of the tools already developed. It was agreed that this largely depends on the research findings and the subsequent regulatory recommendations if and how social media and mobile devices should be used. Discussion for the app included how broad the applicability is (at least in terms of geography and use by various stakeholders), bearing in mind the variable results that have been achieved across Europe. The Application Programming Interfaces (APIs) that support the existing app could be made available to other technology developers, for instance enabling them to embed regulatory new feeds or ADR reporting functionality into their own apps. It will be important to increase the awareness of the app and possibly MAHs could play a role by promoting it in patient information leaflets. For the social media dashboard, the maintenance aspects are more complex as the nature of the data changes, the software will need to be maintained as well.

Various models need to be considered for sustainability; one being a potential maintenance organisation. This would require an independent management structure and be a not-for-profit arrangement. Integration of the app APIs described above into other systems (clinical, other apps, website, patient support group, electronic health records) was also agreed to be a key component of sustainability. There may also be opportunity to exploit the data processing components of the social media dashboard. An aspect for additional thought is the scope of the sustainability and whether this includes the data itself as well as the software. All of these aspects will be further looked at when developing the sustainability plan.

Next steps for stakeholder engagement and closing remarks

June Raine (MHRA) and Peter Arlett (EMA) concluded by thanking all participants to the workshop. With a clearer idea of where project is across all work package deliverables, there should be a focus on the purposes and to clearly target those who use medicines. It was also recognized that future planning needs to be around the research. It is recognized that the challenges around the legal framework, including the forthcoming GDPR is of great importance. There must be a focus on increased transparency on how data protection is dealt with in order to promote confidence in the outputs of the project. Colm Carol gave the IMI perspective and highlighted that the project is progressing impressively with many achievements to date. This puts the project in good shape to refine what to do in the final year, considering the impact and key considerations for sustainability. He explained that the WEB-RADR was launched under the FP7 framework. IMI has now progressed to Horizon 2020 where there is a particular project on big data for better outcomes looking in broader terms of data and real world evidence of which social media is a part of.

Annex 1: Workshop participants

Name	Organisation
Faiza Afzal	UCL Institute of Child Health (UCL ICH)
Christel Al Hashmy	European Medicines Agency (EMA)
Peter Arlett	European Medicines Agency (EMA)
Ayesha Bailey	Amgen Ltd.
Robert Ball	Food and Drug Administration (FDA)
Nathalie Bere	European Medicines Agency (EMA)
Sabine Brosch	European Medicines Agency (EMA)
Cristina Cabrita	Portuguese Association for Consumer Protection (DECO)
Nenad Čajko	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
Rob Camp	European Patients' Academy (EUPATI)
Lucia Caporuscio	European Medicines Agency (EMA)
Colm Carroll	Innovative Medicines Initiative (IMI)
Giulio MariaCorbelli	European AIDS Treatment Group (EATG)
Viorica Cursaru	Myeloma Euronet (MER)
Lucia D'Apote	European Medicines Agency (EMA)
Sieta de Vries	University of Groningen
Anne-Marie De-Ferran	Sanofi
Jürgen Dietrich	BAYER AG
William Dixon	The University of Manchester
Isaura Duarte	European Medicines Agency (EMA)
Vicki Edwards	AbbVie Ltd
Monica Ensini	European Medicines Agency (EMA)
Michael Evans-Brown	European Monitoring Centre on Drugs and Drug Addiction (EMCDDA)
Julianna Fogd	European Medicines Agency (EMA)
Mick Foy	Medicines and Healthcare Products Regulatory Agency (MHRA)
Sara Gama	Novartis
Georgy Genov	European Medicines Agency (EMA)
Susana Goncalves	Novartis
Raquel Gopa	European Medicines Agency (EMA)
Margarida Guimarães	Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)
Adamos Hadjipanayis	European Academy of Paediatrics (EAP)
David Hans-Ulrich Haerry	European AIDS Treatment Group (EATG)
Linda Härmark	Netherlands Pharmacovigilance Centre (Lareb)
Judy Harrison	MedDRA Maintenance and Support Services Organization (MedDRA MSSO)
André Herchuelz	Standing Committee of European Doctors (CPME)
Steve Hobbiger	GlaxoSmithKline (GSK)
François Houÿez	European Organisation for Rare Diseases (EURORDIS)
Rasa Judickiene	European Medicines Agency (EMA)
Rachel Kalf	The National Health Care Institute (ZIN)
Agnes Kant	Netherlands Pharmacovigilance Centre (Lareb)
Xavier Kurz	European Medicines Agency (EMA)
Carmen Lasheras Ruiz	European Organisation for Rare Diseases (EURORDIS)

Name	Organisation
David Lewis	Novartis
Amr Makady	The National Health Care Institute (ZIN)
Simon Maskell	University of Liverpool
Peter Mol	College ter Beoordeling van Geneesmiddelen (CBG)
Sebastian Monzon	European Medicines Agency (EMA)
Daniel Morales	European Medicines Agency (EMA)
Valerie Muldoon	European Medicines Agency (EMA)
Victoria Newbould	European Medicines Agency (EMA)
Sheila O'Brien	Amgen Ltd
Mikaela Odemyr	European Federation of Allergy and Airways Diseases Patients Associations (EFA)
Imran Omar	European Association of Urology (EAU)
Nicola Orlandi	Novartis
Norbert Paeschke	Federal Institute for drugs and Medical Devices (BfArM)
Laura Patten	European Medicines Agency (EMA)
Carrie Pierce	Epidemico
Phillip Pierce	Johnson & Johnson
Jennifer Preston	NIHR Alder Hey Clinical Research Facility (NIHR Alder Hey CRF)
Isabel Proaño	European Federation of Allergy and Airways Diseases Patients Associations (EFA) VIA TC
Alicia Ptaszynska-Neophytou	Medicines and Healthcare Products Regulatory Agency (MHRA)
Anna Radecka	Medicines and Healthcare Products Regulatory Agency (MHRA)
June Raine	Medicines and Healthcare Products Regulatory Agency (MHRA)
Ghosh Rajesh	Novartis
Ioana Ratescu	European Medicines Agency (EMA)
Patrick Revelle	MedDRA Maintenance and Support Services Organization (MedDRA MSSO)
Cristina Sandu	European Medicines Agency (EMA)
Joseph Savirimuthu	University of Liverpool
Roumen Sedefov	European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
Sunayana Shah	The Association of the British Pharmaceutical Industry (ABPI)
Ivana Silva	European Medicines Agency (EMA)
Donald RJ Singer	European Association for Clinical Pharmacology and Therapeutics (EACPT)
Richard Sloane	The University of Liverpool
Daniel Sokol	12 Kings Bench Walk Chambers (12kbw)
Alessandro Spina	European Medicines Agency (EMA)
Edward Suggate	Johnson & Johnson
András Süle	European Association of Hospital Pharmacists (EAHP)
Alastair Sutcliffe	UCL Institute of Child Health (UCL ICH)
Rafal Swierzewski	European Cancer Patient Coalition (ECPC)
Mickaël Tome	National Commission for Data Protection (CNPD)
Phil Tregunno	Medicines and Healthcare Products Regulatory Agency (MHRA)
Raphael Van Eemeren	Amgen Ltd
Joop Van Griensven	Pain Alliance Europe(PAE)
Anja van Haren	Medicines Evaluation Board (MEB)
John van Stekelenborg	Johnson & Johnson
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Name	Organisation
Magnus Wallberg	Uppsala Monitoring Centre (WHO UMC)
Jamie Wilkinson	Pharmaceutical Group of the European Union (PGEU)
Gabriela Wirsching	Bayer Pharma AG
Antoni Wisniewski	AstraZeneca
Lisa Wong	UCL Institute of Child Health (UCL ICH)
Zoe Zindrou	European Multiple Sclerosis Platform (EMSP)

Annex 2 - 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