Innovative Medicines Initiative
WEB-Recognising Adverse Drug Reactions 2
Webinar 1: WEB-RADR 2 technology and innovation
Question and Answer

Theme: Technology development and mobile application overview

Q: Could an organisation - say a hospital trust's Medical Safety Officer (MSO) - see all the reports submitted by that Trust using the app?
A: The Vigilance Hub is accessed via credentials provided by platform managers, typically the MHRA, or by organisation leads, leads at a specific organisation. As such, there is no limitation on access from a technical aspect. However, through GDPR, we must be explicit on the use of any data and who has subsequent access to this, and this would need to be considered carefully to ensure we met our legal requirements. We are very happy to explore the ways in which we can use the hub to engage stakeholders further.

Q: Can the industry use the platform to submit XML E2B files to Regulators?
A: The technology to 'load' a pre-existing xml is available within the Vigilance Hub, however this is not currently surfaced for a user of the App. This would be possible to implement as an enhancement and we'd be happy to discuss with interested partners.

Q: How many reports have been made since the beginning with Med Safety and WEB-RADR applications, by number and by country?
A: We are working to have current reporting numbers for all Med Safety and WEB-RADR applications. As of October 2019, the data gathered is as follows:

Country	Launch date	Number of total downloads (up to 29 Oct 2019)	Number of ADR reports via Med Safety App
Burkina Faso	16.06.2017	Since launch: approx. 1,525	Approx. 50 since the launch as of November 2019
Zambia	29.06.2017	Since launch: approx. 900	Approx. 20 in 2017 and 2018
Armenia	07.05.2019	Since launch: 1,054	16 during 07 May 2019-07 May 2020
Ghana	28.06.2019	Since launch: 1,228	87 (9/87 reports (10.3%) malaria medicines) as of October 2019
Ethiopia	23.09.2019	Since launch: 197	Not yet received as of November 2019

Q: Has the increase in reporting in Burkina Faso (and other developing countries) been just as a result of direct patient use or has it helped to increase Marketing Authorisation Holder (MAH) engagement and efforts to meet regulatory compliance too?
A: The success of the Burkina Faso App is a testament to their launch event and ongoing work to encourage usage of the App locally. Whilst the App has not been targeted to increase MAH compliance, a national focus on pharmacovigilance will support the wider regulatory field.

Q: Where are the data from the filled in report for side effects stored? In the country of origin or in another country (centrally for all countries)?
A: The data collected from reporters on their suspected side effects is stored in an EU based Amazon Web Services server; this enables App users to access their reports within the App. It is possible to amend this for different platforms though this affects the cost of the delivery. Data is subsequently sent to a database of choice for local processing, for example VigiFlow.

Q: How much does it cost for a national PV centre to request for a WEB-RADR country Med Safety system? What is the application process?
A: As of January 2021, the cost for the Med Safety App roll out includes a one-off development cost of 4,000 GBP and an annual maintenance cost of 2,120 GBP. To express your interest in adopting the App, please contact WEB-RADR@mhra.gov.uk. Discussions will then be initiated with WHO, UMC, MHRA and the adopting country.

Q: As a way of supporting public health programs, is there a plan to enhance the app to support collecting data from active drug safety monitoring programs?
A: Yes; now that we have the new report configuration capability we can already build a range of different forms, which can include active drug safety monitoring programs.

Q: How do we access the specific details for API integration for a digital platform to the Yellow Card system in the UK?
A: We have developed guidance materials to support API access, and whilst we are looking to enhance these even further, these are available now. Please contact us at WEB-RADR@mhra.gov.uk to request these documents.

Q: Would the new WEB-RADR App be able to support risk minimisation in a specific Public Health Programs (e.g. providing guidance to patients on the proper use of a specific product (e.g. anti TB or anti Malaria program). If so, would the new WEB-RADR App be able to support providing individualised advice e.g. vs age or body weight?
A: Within the Vigilance Hub, we have a tile called resources which can host guidance documents. Whilst this is not currently surfaced within the Apps, this would be functionality that we could display there however the News functionality could be used for this purpose. In the future we would like to be able to provide tailored information to patients although we are not expecting to provide tailored clinical advice through the app.

Q: Are there plans to include the use of graphics and pictures within the app?
A: Yes. Development work is underway for both of these areas and will be available as part of the work to deliver E2B R3 standards. We hope the functionality will be available in the Apps later this year

Theme: Industry case study: AbbVie e-PV mobile application

Q: How would you define whether the app provides similar quality reports to traditional methods? Are there specific 'quality markers' that you consider when comparing data from the two methods?

A: The Clinical Documentation tool (ClinDoc) will be used to assess the level of relevant clinical information present in each report. In addition, each report will also be assessed using vigiGrade to provide an assessment of completeness. Both methods are detailed in the literature

Q: Are you going to audit this PSP to verify is safety reporting was done properly?

A: Yes. Any PSP service provider must be subject to regular audit and ongoing compliance monitoring by the marketing authorisation holder to ensure full and correct safety reporting to the MAH.

Q: Did you implement MedDRA for coding AEs?

A: MedDRA was not used in this instance of the WEB-RADR APP but it is available. The reason is that we do not ask PSP service providers to MedDRA code when reporting AEs and instead we ask them to report AE terms using the verbatim terms. This is an option that should be explored based on each situation/reporter that the APP is considered for use.

Q: Did you implement off-line use?

A: No. However, if users of the APP are likely to be in areas where access to the internet is unreliable it would be recommended to utilize the off-line version.

Q: How does the e-PV industry app differ to the regulator apps?

A: Each company that explores the use of WEB-RADR APP would define the data fields they wish to have included in the APP. For AbbVie, we determined the fields and terminology that best matched our internal systems and reporting forms, however the flexibility is significant; feedback from MHRA is that e-PV contained more data fields than Regulator versions of the APP.

Q: What was the rational not to use E2BR3 as communication protocol?

A: This is solely based on our internal reporting system we linked e-PV to, in which a flexi-XML format is used.

Theme: Application Programming Interfaces within the Danish healthcare setting

Q: There are a lot of free-text fields in the application shown, what is your experience regarding data quality?

A: The new WEB-RADR REST service is not yet in production but from the existing EHR webservice and the similar e-form to report ADRs, we have good experiences with free text fields implemented from the E2B standard. From the case summary (narrative) text field, we most often receive relevant information that improves the quality of the case. Other free text fields in the medical history and test result parts of the case will improve, when it is made possible to map directly from clinical terminologies (used in EHR systems) to MedDRA. In Denmark, ADR reports are written in Danish, and it will require manual coding and translation from Danish to MedDRA until new tools for this are ready and implemented.