IMI WEB-RADR (recognising adverse reactions) project: goals and current activities

4 March 2015

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

Sabine Brosch (on behalf of the WEB-RADR Consortium)

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Project design

WP5 – Project Management and communication

MHRA (lead)
Novartis (EFPIA lead)

WP1 – Governance and policy
EMA (Public lead)
Sanofi (EFPIA lead)

WP2a – Social media platform
Epidemico (Public lead)
J&J (EFPIA lead)

WP3a – Mobile reporting platform
Epidemico (Public lead)
UCB (EFPIA lead)

WP2b – Analytics
UMC (Public lead)
J&J (EFPIA lead)

WP3b – User based evaluation
Uni of Groningen (Public lead)
Amgen (EFPIA lead)

WP4 – Scientific impact evaluation
University of Liverpool (Public lead)
Novartis (EFPIA lead)

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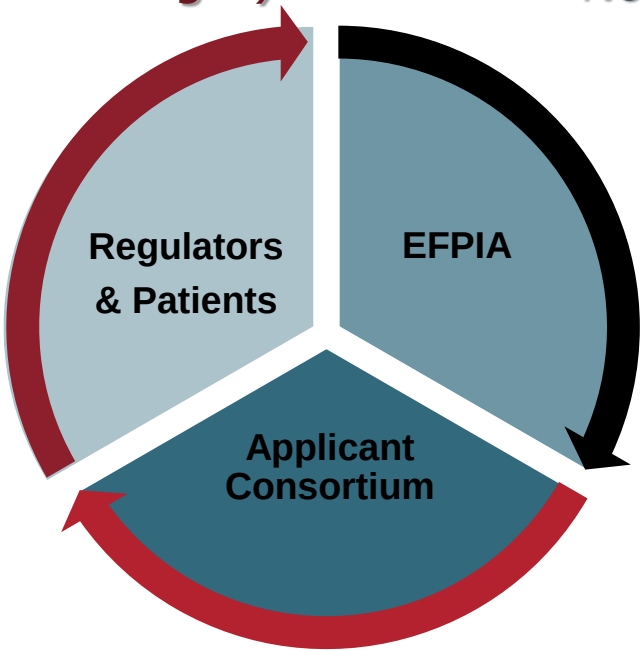
WEB-RADR Consortium structure

MHRA (Project Manager)
EMA
Halmed
Lareb
Eurordis



Novartis (Coordinator)
J&J (Deputy)
GlaxoSmithKline
Sanofi-Aventis
AstraZeneca
Amgen
UCB
Bayer

Universities of London, Liverpool & Utrecht
WHO (UMC), Epidemico and SRDC

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WP1 Policy development

- Goal: *Develop a policy framework on the use of mobile technologies and social media for the purpose of ADR reporting, safety monitoring and communication in the context of the EU pharmacovigilance legislation*
  - Use of mobile devices for easier, faster and more user-friendly reporting of ADRs
  - Social media to detect potential safety issues related to medicines
  - Use of mobile devices and social media as new mechanisms to communicate and interact with healthcare professionals and patients

- Ongoing activities:
  - Finalisation of report on 1st workshop organised in December 2014 with stakeholders (representatives of the PCWP, HCPWP, PRAC and EV-EWG); report to be published end of April 2015
  - Assessment of data privacy aspects with field experts
  - Review of current regulatory landscape (EU and non-EU)

WP2 Social Media Analytics

- *Goal: To provide access to classified social media data via a visualization platform for signal identification and/or confirmation*

- Expand on existing MedWatcher Social platform
  - Collect public social media posts describing possible ADRs in English and two other European languages
  - Remove noise from and effectively annotate social media data
  - Disseminate data in interactive dashboard while adhering to regulatory requirements
- Capture unique stream of intelligence for valuable insights not necessarily gathered from traditional drug safety data sources
- Leverage high volume of medical product discussions naturally occurring in online spaces
- Introduce the voice of the patient to the drug safety surveillance process

Current activities: Weekly TCs to develop methodology with field experts

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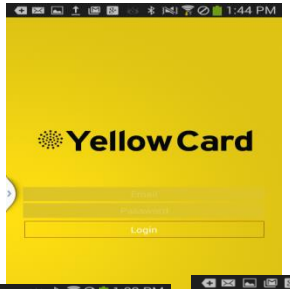
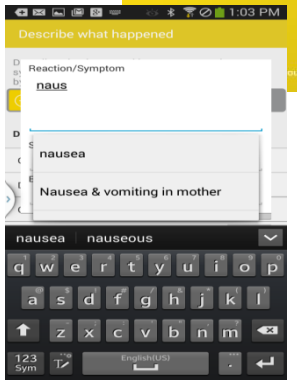
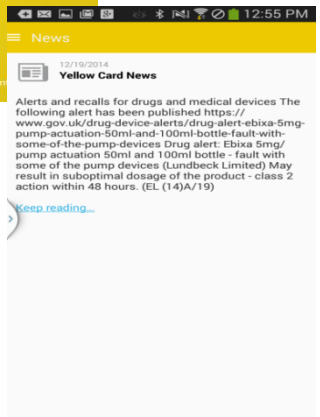
WP3 – Use of mobile technologies for ADR reporting and accessing safety information

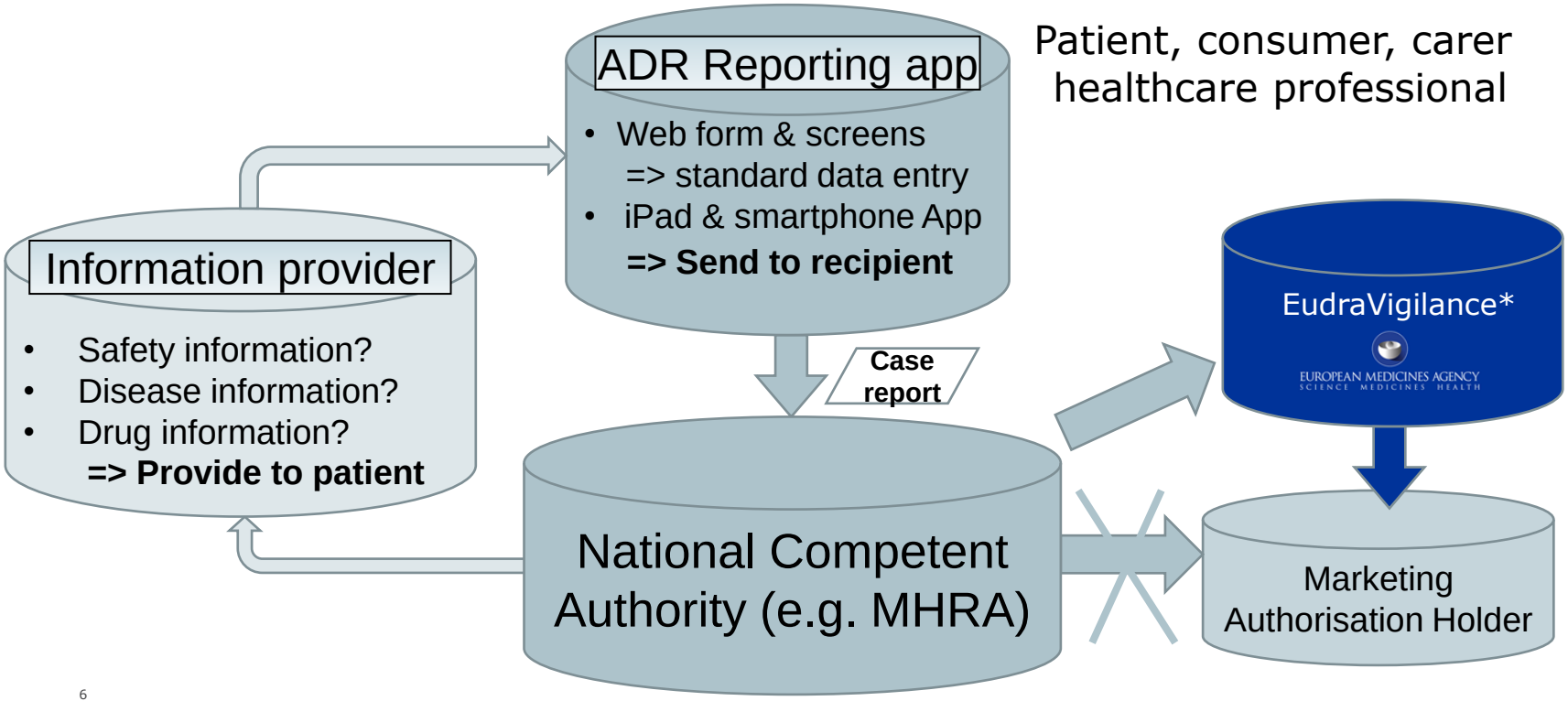
- *Goal*
  - *Facilitate reporting from health care providers and patients to the Health Authorities*
  - *Provide drug safety information to app users from national Competent Authorities*
- Ongoing activities
  - Selection of 3 pilot countries for mobile app reporting and alerting:
    - UK, Croatia, Netherlands
  - **UK Yellow Card app** in testing phase: Public launch **March 2015**
  - Croatia : November 2015, Netherlands, February 2016
  - Requirements development for the mobile app in 3 pilot countries and to allow adoption by additional Member States







WP3 – Use of mobile technologies for ADR reporting and accessing safety information



* Simplified ADR reporting-post EV audit

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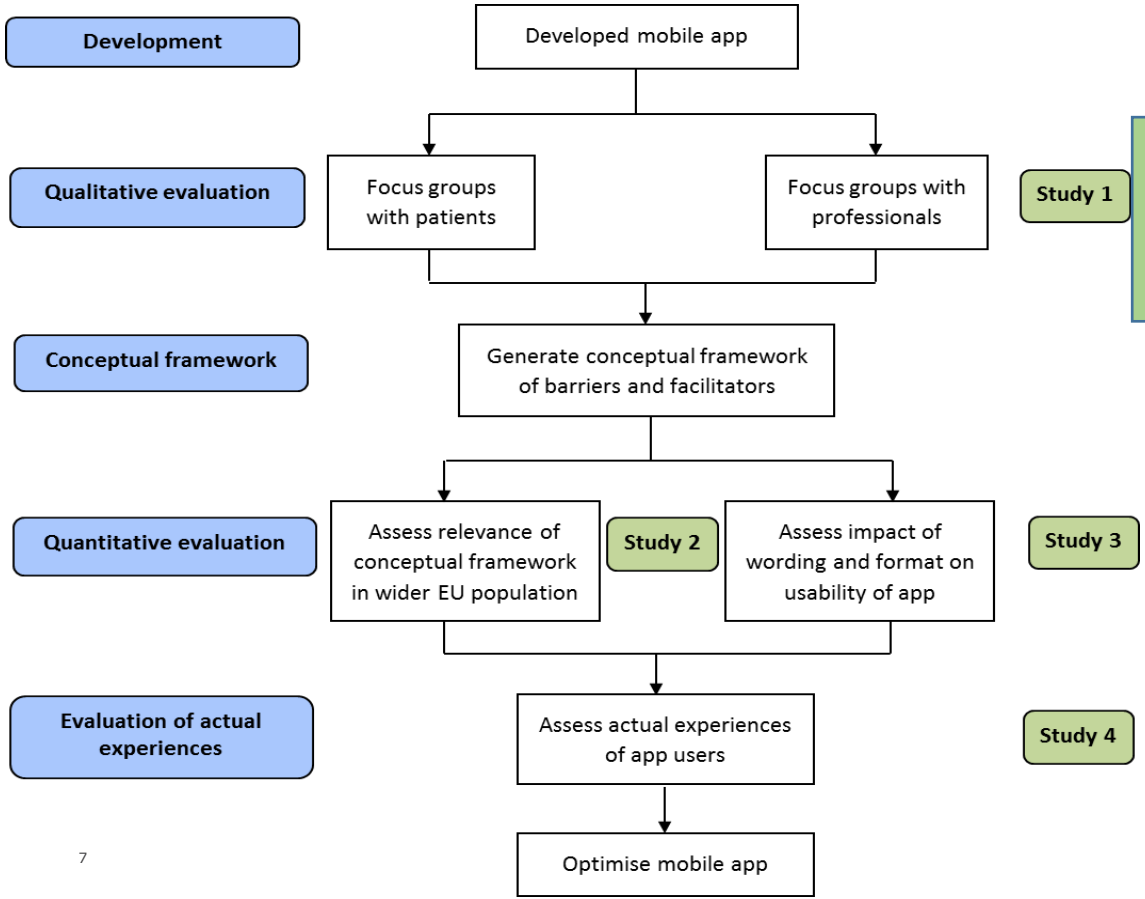
WP3 – Use of mobile technologies for ADR reporting and accessing safety information



Study 1 – Explore

- needs and preferences for a mobile app on two-way risk communication
- perspectives on such a mobile app prototype

Focus Groups

Country	Patients	Healthcare professionals
Spain	- Rare disease - Caregivers	Relevant healthcare professionals
France	Rare disease	
UK	Adolescents	Pediatricians
Sweden		Pharmacovigilance experts
Netherlands	Type 2 diabetes	- GPs - Pharmacists - Internists

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WP4: Evaluation of added value of mobile apps and social media to traditional pharmacovigilance

- *Goal: evaluation of use of mobile apps and social media and whether they provide new insights over and above that produced by traditional pharmacovigilance methods*
- Ongoing activities
  - Two protocols for the work to be undertaken in WP4 are being finalized – one will focus on mobile apps and the other on social media
  - WP4 has to rely on WP2 and WP3 to generate data to undertake evaluation, and thus outputs will be towards the end of the project
  - The pathway by which data on social media will flow from WP2 to WP4 has been agreed
  - A review article on how social media has been used in pharmacovigilance is being prepared

External Communications

- Project web created: http://web-radr.eu

- Active dissemination of tools and scientific outcomes
  - SCOPE/ EMA and EU Regulatory Network
  - Scientific publications

- Communications via participating consortium members and EFPIA partners at selected fora
  - Drug Information Association
  - EFPIA Pharmacovigilance Committee
  - University-based postgraduate education (PhV, EU2P, etc.)
  - EudraVigilance Expert Working Group

Summary

- Traditional ADR reporting and signal management methods are changing
- New technologies offer new possibilities for pharmacovigilance
- WEB-RADR seeks to investigate, develop tools and recommend policy
- We keep you informed

Thank you for your attention

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