8 December 2014
EMA/657669/2014

DRAFT Agenda – Innovative Medicines Initiative WEB-RADR Workshop: mobile technologies and social media as new tools in pharmacovigilance

10 December, 09.00-17.00, European Medicines Agency, London, room 3F (by invitation only)

Item	Agenda	Name	Timing
0.	**Registration**		08.15 – 09.00
1.	**Welcome**	Peter Arlett (EMA)	09.00 – 09.05
2.	**Objectives of the workshop**	Sabine Brosch (EMA)	09:05 – 09:15
3.	**IMI WEB-RADR (recognising adverse reactions) project: public-private partnership, goals, objectives and deliverables** *Project overview*	*Mick Foy (MHRA)* *Andrew Cochrane (Novartis)*	09:15 - 09:30
4.	**Introductory statements**	Moderator: Sabine Brosch (EMA)	09:30 - 10:20
a.	*Social media – opportunities and challenges for medicines regulatory authorities*	*Robert Ball (FDA, US)*	09:30 – 09:50
b.	*Digital media and research ethics*	*Daniel K. Sokol (UK)*	09:50 – 10:00
c.	*European Data Protection and digital media*	*Fabio Polverino, European Data Protection Supervisor (EDPS) office*	10:00 - 10:10
d.	*Questions and Answers*	*All*	10:10-10:20
Coffee break			10:20 -10:40

Item	Agenda	Name	Timing
5.	**Use of mobile technologies for adverse drug reaction (ADR) reporting and accessing safety information: evaluation of patients' and healthcare professionals' needs and concerns**	Moderator: Peter Arlett (EMA)	10:40 - 12:00
a.	*Introduction to research topic and anticipated deliverables including Q&As*	*Peter Mol (UMCG) and Raphael Van Eemeren (Amgen), Nabarun Dasgupta (Epidemico), Stephanie Bodin-Parssinen (UCB)*	10:40 –11:00
b.	*A patient perspective – use of mobile applications for adverse reaction reporting*	*Francois Houyez (EURODIS)*	11:00-11:10
c.	*Experience of use of apps and social from a Healthcare professional perspective*	*Adamos Hadjipanayis (European academy of paediatrics)* *and* *Donald Singer (European association for clinical pharmacology and therapeutics)*	11:10-11:15 11:15-11:20
d.	*Summary of survey results and collective comments from the Agency's stakeholders*	*Peter Mol (UMCG) and Raphael Van Eemeren (Amgen), Nabarun Dasgupta (Epidemico), Stephanie Bodin-Parssinen (UCB)* *And further feedback from representatives of the Healthcare Professionals Working Party, Patients and Consumers Working Party, PRAC[1] and the EV-EWG*	11:20 -11:40
e.	*Panel discussion*	*All incl. Robert Ball (FDA, US)*	11:40-12:00
Lunch			12:00 - 12:45

[1] Pharmacovigilance Risk Assessment Committee

Item	Agenda	Name	Timing
6.	**Analysis of social media comments for pharmacovigilance purposes**	Moderator: Almath Spooner (PRAC vice chair, HPRA)	12:45 –14:15
a.	*Introduction to research topic and anticipated deliverables including Q&As*	*John van Stekelenborg (JPNV and Carrie Pierce (Epidemico)*	12:45 - 13:15
b.	*Summary of survey results and collective comments from the Agency's stakeholders*	*John van Stekelenborg (JPNV) and further feedback from representatives of the Healthcare Professionals Working Party, Patients and Consumers Working Party, PRAC and the EV-EWG*	13:15 - 13:50
c.	*Panel discussion*	*All incl. Robert Ball (FDA), Nabarun Dasgupta (Epidemico)*	13:50 - 14:15
Coffee break			14:15 - 14:35
7.	**Digital media - personal data protection and ethical considerations - recommendations for future policy development**	Moderator: Alessandro Spina (EMA Data Protection officer)	14:35 - 16:30
a.	*Introduction to research topic and anticipated deliverables followed by Q&As*	*Sabine Brosch (EMA)and Victoria Newbould (EMA)*	14:35 - 14:50
b.	*Summary of survey of current regulatory requirements and practices*	*Anne-Marie De-Ferran (Sanofi) and Susana Goncalves (Novartis)*	14:50 - 15:20
c.	*Ethical considerations and digital media*	*Daniel K Sokol (UK)*	15:20 -15:40
d.	*EU data protection and digital media*	*Fabio Polverino (EDPS office)*	15:40 - 16:10
e.	*Panel discussion*	*incl. Robert Ball (FDA, US), Mickaël TOME (CNIL, FR), Daniel K. Sokol (UK), Anne Bahr (Sanofi), Nicola Orlandi (Novartis)*	16:10 - 16:30

Item	Agenda	Name	Timing
8.	**Evaluation of added value of mobile apps and social media to existing pharmacovigilance tools**	Moderator: Almath Spooner (PRAC vice chair, HPRA)	16:30 - 16:50
a.	*Introduction to research topic and anticipated deliverables followed by Q&As*	*Munir Pirmohamed (ULIV) and Andy Cochrane (Novartis)*	16:30 - 16:50
9.	Closing statement and goodbye	Sabine Brosch (EMA)	16:50 –17:00