Agenda

Thursday 17 September, 09.30 – 19.00

Royal Institute of British Architects, 66 Portland Place, London W1B 1AD

09.00-09.30	**Registration**
09.30-09.45	**Welcome** Sir Alasdair Breckenridge CBE FRSE FMedSci
09.45-10.00	**Setting the scene: Realising the potential of real world evidence** Dr Massoud Toussi, Lead – Pharmacoepidemiology and Drug Safety, IMS Health
Session 1: Organisational perspectives on the acceptability of real world evidence In each of the following presentations, speakers will be asked to: • Summarise their organisation or sector's approach to using real world evidence • Outline the circumstances in which such evidence is considered acceptable and the opportunities, and • Consider some of the challenges to acceptability, and the ways that these are being tackled.	
10.00-10.15	**Medicines and Healthcare products Regulatory Agency** Dr June Raine CBE, Director of Vigilance and Risk Management of Medicines, MHRA
10.15-10.30	**European Medicines Agency** Dr Xavier Kurz, Head of Service, Monitoring and Incident Management, EMA
10.30-10.45	**US Food and Drug Administration** Dr Jonathan Jarow, Director – Office of Medical Policy, FDA
10.45-11.00	**Refreshment break**
11.00-11.15	**National Institute of health and Care Excellence** Professor Sarah Garner, Associate Director for Research and Development, NICE
11.15-11.30	**Association of the British Pharmaceutical Industry** Dr Virginia Acha, Executive Director – Research, Medical & Innovation, ABPI
11.30-11.45	**Innovative Medicines Initiative** Dr Pall Jonsson, Senior Scientific Adviser – IMI GetReal, NICE
11.45-12.30	**Discussion session: the acceptability challenge** • How might real world evidence contribute to regulatory and HTA decision-making? • What are the challenges associated with the acceptability of this evidence? • To what extent are these challenges being tackled and where are the opportunities?
12.30-13.15	**Lunch**
Session 2: Developing a common roadmap for change	
13.15-13.25	**Recap of the morning's discussion** Sir Alasdair Breckenridge CBE FRSE FMedSci
13.25-14.30	**Break-out session 1** Each group to discuss their aspirations for how real world evidence might be accepted and used in a regulatory context by 2020, and the key challenges that will need to be overcome to achieve this.
14.30-14.45	**Refreshment break**
14.45-15.40	**Break-out session 2** Each group to discuss practical steps that could be taken to remedy current challenges
15.40-16.55	**Feedback and discussion** To include development of a high-level action plan for change
16.55-17.00	**Conclusions and next steps** Sir Alasdair Breckenridge CBE FRSE FMedSci
17.00-19.00	**Drinks reception** Academy of Medical Sciences, 41 Portland Place (Fellow's room)