EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Regulatory Science: Are regulators leaders or followers?

15 December: European Medicines Agency, London, United Kingdom

Co-Chairs: Eric Abadie and Pat O'Mahony

Time	Item / Presentation title	Presenter, affiliation
09:00	Registration and coffee	
10:00	Welcome and Opening	
10:15	Modelling to support benefit-risk assessment: Will it enhance our capability and improve transparency?	Lawrence Phillips, on secondment to EMA from London School of Economics
10:45	Coffee Break	
11:15	Are regulators up to speed to address the challenges of biotechnological medicinal products?	Christian Schneider, chair of EMA CAT, Paul Ehrlich Institut, Germany
11:45	Addressing the Efficacy-Effectiveness Gap	Hans-Georg Eichler, European Medicines Agency
12:15	Lunch	
13:15	Health data to support medicines regulation: identifying the opportunities, improving the methods and building the capacity	Peter Arlett, European Medicines Agency
13:45	Detecting safety issues: will new scientific developments strengthen public health protection?	Miriam Sturkenboom, Erasmus Universiteit, The Netherlands
14:15	Coffee Break	
14:45	Novel Methodologies for Clinical Trials - do we still need to recruit patients?	Rob Hemmings, member of EMA CHMP, Medicines and Healthcare products Regulatory Agency, United Kingdom
15:15	Taking Stock (leading into discussion session)	Thomas Lönngren, European Medicines Agency
15:45	Interactive Session	
16:15	Thank you and Closing	Pat O'Mahony, chair of EMA Management Board, Irish Medicines Board, Ireland
16:30	End of conference	

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