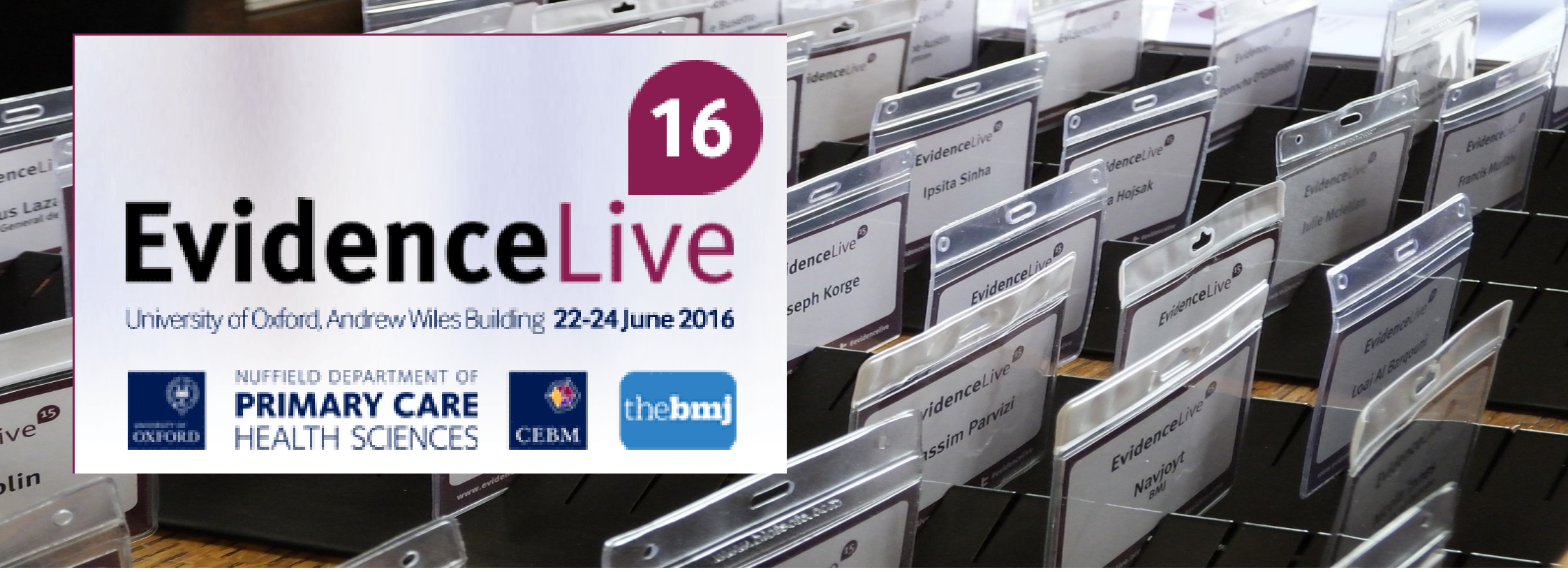

Regulatory Data Workshop
Tuesday June 21st 2016

Reflections and experience from the Tamiflu and Relenza Cochrane review
(The use of regulatory information for research synthesis)

Journal publications of randomised controlled trials ("literature") have so far formed the basis for evidence of the effects of pharmaceuticals and biologics. In the last decade, progressively accumulating evidence has shown that much of the literature is affected by reporting bias. This has evident implications for the reliability of any decision based on literature or its derivatives such as research synthesis. A recent survey has shown that only 10% of Cochrane reviews make serious efforts to search for and include unpublished material. Given the growing realisation that these form a potentially biased evidence base, we may need to develop explicit methods for including regulatory material in systematic reviews. But is it feasible or worthwhile?

In 2014, Tom Jefferson and Kamal Mahtani were amongst a group of authors that undertook the only Cochrane review based solely on unpublished on regulatory data. The review of Neuraminidase inhibitors for preventing and treating influenza was a seen as a major methodological development in the field of evidence-based medicine. The review challenged opinion across the regulatory, industrial and policy arenas, and has since been added as a landmark within the James Lind Library.

In this workshop Tom Jefferson and Kamal Mahtani will present and discuss some of these issues on the basis of experience of working with regulatory documents.

They will present the detailed rationale for use of regulatory documents, the types of documents, their availability and content, their inclusion in research synthesis and involve participants in the handling of each type of document. Participants will also get the opportunity to review some of the regulatory documents used the in Cochrane review as well as experience some of the data extraction methods used.

Registration Open

Participants are asked to bring their own laptop with pdf reading capability.
A wireless connection will be available.
All materials and refreshments are included in the course fee **£155**.
Numbers are capped to encourage small group learning .