Description: (1) Overview of data standardization methods used in common data models (Patrick Ryan, 20 min)

(2) Overview of methods applied to combine data, results from a systematic review of the CARING consortium (Morten Anderson, 20 min)

(3) Perspectives from ongoing initiatives (10 min each)

(a) EU – Martijn Schuemie
(b) US – Kevin Haynes
(c) Asia – Kenneth Man

(4) Open panel discussion – all panelists (chaired by Marie L De Bruin, 20 min)

In this workshop, we will present experiences of implementing a common data model, and engage the audience in an open discussion about the expectations and challenges for standardizing data for collaborative network–based analyses.

676. Comparisons in Pharmacoepidemiology: New Challenges and Limitations of Current Approaches

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Background: Undertaking robust comparisons in pharmacoepidemiological (PE) and comparative effectiveness (CE) studies are a major challenge. In these designs certain subject characteristics may influence the probability of exposure and the researcher cannot control allocation to treatment or the conditions under which treatment is given. Hence there is the potential for non-random selection into a cohort, and if appropriate, the comparator group(s). Methodological advances in statistical analyses allow exploration of observed (and unobserved) characteristics affecting selection, but have their limitations. Problems with comparisons have become more difficult with the widespread application of clinical guidelines (national/regional), pharmacoeconomic policies and policies for reimbursement, all of which determine treatment choices thus introducing selection biases which are beyond the capabilities of existing methods to handle.

Objectives: To explore current challenges to the design of postmarketing studies of medicines for which there are significant external influences governing use and discuss possible solutions.

Description: There will be a series of four didactic presentations from pharmacoepidemiologists covering the challenges of study designs where inference regarding differences between new and existing agents is of interest, as well as proposing approaches to handle the problems using real world-examples. The session will also include a substantial time for panel discussion.

The session will feature the following topics and presenters (shown by initials)

(1) How guidelines and other external factors e.g. pharmacoeconomic policies limit (and sometimes prohibit) the use of comparators in PE studies with examples of approaches to handle these challenges (SAWS)
(2) Pragmatic Trials and Propensity Matching: Methods to minimise the confounding problems of observational research (TVS)
(3) Lessons from Social Science: The contextual comparator to characterise adoption vs counterfactual comparator to compare risks (DL)
(4) Using guidelines to identify a prognostically comparable untreated comparator group (OK).

677. How to Bridge the Gap between Requirements of Regulatory and Health Technology Assessment Authorities for Post Authorization Studies? Examples from Europe and Asia

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Background: Health technology assessment (HTA) authorities generally explore additional characteristics of medicines and complete the efficacy and safety assessment carried out by regulatory authorities. This pattern is changing and the overlap between the requirements of regulatory and HTA bodies is growing. As an example, the introduction of post authorization efficacy studies (PAES) on top of post authorization safety studies (PASS) in the European regulatory guidelines presents methodological and logistic challenges for addressing both objectives in post authorisation studies.

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