Searching Trials Registers such as ClinicalTrials.Gov and the World Health Organization Portal (ICTRP) and Regulatory Agency Sources to Identify Clinical Trials for Systematic Reviews and Other Clinical and Research Questions.

Since the launch of ClinicalTrials.gov in 2000, as a result of US legislation calling for better access to information about clinical trials, there has been increasing awareness amongst health care librarians and other information specialists of the importance of being able to identify clinical trials and their results. Further legislation required the submission of 'basic results' for certain clinical trials and led to the scope of ClinicalTrials.gov being expanded in 2008 to include study results posted by the investigators, irrespective of whether those results had been published. ClinicalTrials.gov, is, therefore, an increasingly rich source of results of trials to include in systematic reviews and, for example for Cochrane Reviews, is now recognized as a mandatory source to search.

This interest has intensified as a result of the Comparative Effectiveness Research agenda worldwide and it is now recognized that, for questions regarding the clinical effectiveness of treatments, the most appropriate and reliable evidence will generally be derived from the results of clinical trials.

The WHO International Clinical Trials Registers Portal enables users to search simultaneously across a range of clinical trials registers, including ClinicalTrials.gov. Recent research, however, has shown that for optimal retrieval it is essential to search both sources separately.

This course will address the most effective way to search these resources, given the different interfaces available and how these differences impact not only on retrieval but also on associated aspects such as managing the search results. One aspect of the course will be the presentation of recent research evidence on the use of clinical trial registers to identify trial evidence for systematic reviews and meta-analyses, and on the relative retrieval of trials from ClinicalTrials.gov and the WHO Portal.

In addition to ClinicalTrials.gov and the WHO Portal, there is a wide variety of national and international registers together with registers from a number of drug companies and other organizations. The course will also cover information available through regulatory agency sources such as those provided by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The course will provide opportunities to learn new techniques, to discuss best approaches, to share insights and to assess variations in current best practice. The course will consist of short presentations, small group and plenary discussion and hand-on exercises.

TIMETABLE

Trainers: Julie Glanville, York Health Economics Consortium, York, UK
Carol Lefebvre, Lefebvre Associates Ltd, Oxford, UK

Day 1

9.15	Welcome and introduction to the workshop (Carol)
9.30	Discussion: Why do we need to know about ongoing research? (Julie)
10.00	Presentation: What are trials registers? Background and brief history (Carol)
10.45	Coffee
11.00	Presentation and group discussion: Key trials and trials results registers (Carol)
11.30	Finding clinical trials, research registers and research results (presenters' website) (Julie)
11.45	Hands-on exercise: exploring the trials search website
12.45	Lunch
13.45	Presentation: Search issues in key trials registers (Julie)
14.30	Hands-on exercise and feedback: ClinicalTrials.gov and the WHO Portal (ICTRP) (Julie)
15.15	Coffee
15.30	Discussion of the exercise
15.45	Presentation: Critiquing searches of trials registers (Carol) • How does PRESS help us to critique trials register searches?
16.15	Discussion and questions (Carol and Julie)
16.45	Close

Day 2

9.15	Welcome and introduction to the second day (Carol)
9.30	Presentation: other research registers (Julie) • Trials are not only accessible via trials registers • We want to know about other types of research as well as trials
10.15	Exercise: searching other research registers (Julie)
10.45	Coffee
11.00	Presentation: Obtaining trial information from regulatory agencies: the (US) FDA and (European) EMA (Carol)
11.30	Exercise: identifying information from regulatory agencies (Carol)
12.30	Questions
12.45	Lunch
13.45	Presentation: new trial access initiatives (AllTrials and OpenTrials) (Julie)
14.15	Hands-on exercise: AllTrials and OpenTrials (Julie)
15.00	Coffee
15.15	Presentation: Record management issues: downloading results (Julie)
15.45	Record management issues: documenting and reporting searches (Carol)
16.15	Discussion and final questions (Carol and Julie)
16.45	Close