**Searching Regulatory Databases (European Medicines Agency (EMA) and US Food and Drugs Administration (FDA)) for Cochrane Reviews**

**Background**

In a recent editorial on the Cochrane Library[[1]](#footnote-1) Jeppe Schroll and Lisa Bero suggested “that searching regulatory data from the EMA and the FDA should be part of any Cochrane Review of drug interventions”. This recommendation was based on research showing “that including unpublished data from regulatory agencies changed the results of the original meta-analysis”[[2]](#footnote-2). This work came out of a project funded by Cochrane under the Methods Innovation Funding initiative entitled: Searching for unpublished trials using trials registers and trials web sites and obtaining unpublished trial data and corresponding trial protocols from regulatory agencies.[[3]](#footnote-3) Other outputs from this project include[[4]](#footnote-4)

**Implications?**

When should TSCs consider searching these sources for Cochrane reviews? Don’t panic! Searching regulatory databases should only be considered if all the following circumstances apply:

* If the drug/device is newly approved by EMA or FDA (last 5 years) or is utilised for a new indication (last 5 years)
* If the drug/device has been approved for use for the condition in question
* When the drug/device is compared to placebo for the comparisons in the review; although searches for reviews of other drug comparisons might also yield results

Searching the databases under the above conditions could provide useful study level data on drug efficacy. These sources are difficult to search and the search interfaces change regularly. The data can be difficult to analyse, therefore TSCs should discuss with their author teams whether the above circumstances apply to the review question, and whether to search these sources.

In recognition of the complexities around this area, Cochrane has recently funded a project , under the Cochrane Methods Innovation Funding (MIF) Call for 2015-2018 entitled:

Interim guidance on the inclusion of Clinical Study Reports and other regulatory documents in Cochrane Reviews.

Lead investigators: Tom Jefferson and Carl Heneghan (supported by the Information Retrieval, Bias, Adverse Effects, and Individual Participant Data Methods Groups).

The aim of the project is to draft interim guidance for Cochrane authors on how to decide whether to include CSRs and other regulatory documents in a Cochrane Review.

Further guidance on how to include CSRs and other regulatory documents in a Cochrane Review is the subject of a follow-up application.

Do you have any experience searching these sources or any tips you can share? If so, we would love to hear from you.

 Further reading[[5]](#footnote-5)

1. Jeppe Schroll, Lisa Bero. Regulatory agencies hold the key to improving Cochrane Reviews of drugs[editorial]. Cochrane Database of Systematic Reviews 2015;(4): 10.1002/14651858.ED000098 [↑](#footnote-ref-1)
2. Hart B, Lundh A, Bero L. Effect of reporting bias on meta-analyses of drug trials: reanalysis of meta-analyses. BMJ 2012;344:d7202. dx.doi.org/10.1136/bmj.d7202 [↑](#footnote-ref-2)
3. This project was led by Lisa Bero (the San Francisco Branch of the United States Cochrane Center), in collaboration with the Nordic Cochrane Centre, the Cochrane Acute Respiratory Infections Group, the Cochrane Information Retrieval Methods Group and York Health Economics Consortium. [↑](#footnote-ref-3)
4. Arber M, Cikalo M, Glanville J, Lefebvre C, Varley D, Wood H. Annotated bibliography of published studies addressing searching for unpublished studies and obtaining access to unpublished data. York: York Health Economics Consortium; 2013.

<http://irm.cochrane.org/sites/irm.cochrane.org/files/uploads/Annotatedbibliographtifyingunpublishedstudies.pdf>; Schroll, JB, Bero, L, Gotzsche, P. Searching for unpublished data for Cochrane reviews: Cross sectional study. BMJ 2013;346:f2231; Wolfe, N, Gotzsche, PC and Bero, L.  Strategies for obtaining unpublished drug trial data:  A qualitative interview study.  Systematic Reviews. 2013; 2:31. <http://www.systematicreviewsjournal.com/content/2/1/31> [↑](#footnote-ref-4)
5. Chan AW. Out of sight but not out of mind: how to search for unpublished clinical trial evidence. BMJ. 2012 Jan 3;344:d8013. doi: 10.1136/bmj.d8013.http://www.ncbi.nlm.nih.gov/pubmed/22214892 [↑](#footnote-ref-5)