

There are three specific categories of grey literature that we search: Regulatory Information, Trial Registries, Abstracts and Conferences. On the tracking worksheet (at the end of this document) please find listed all the sources the SRC routinely searches (bulleted titles) for its own reports, others listed serve as reminders that they are available if further research is needed or if somebody asks for suggestions of additional places to locate grey literature.

### **Regulatory Materials:**

**FDA** - this is the bulk of the work for grey literature searching. Both from a searching perspective as well as the amount of material to be reviewed by the EPCs, it is also the source that we're most likely to find otherwise unpublished clinical trials that are relevant to the systematic review. The [Drugs@FDA](#) is THE website. Unfortunately, the only way to search this site is to search specifically by a drug name. This is why it is important to get a specific drug list from the EPC's - drug categories such as "beta blockers" is not useful. If the report is an update, use the advanced search options so you can limit the search by date. Unfortunately, this is the extent of the search capability of Drugs@FDA, specific drug name and date.

Once you search by the specific drug name, you will get a long list of related drugs. As you click on each name, there may be one or more levels of lists. Keep clicking through all list levels looking for a page which has a link that says "**Approval History, Letters, Reviews, and Related Documents**". Once on this page you will be looking for a link that says "**Review**". This may open an html page or a pdf document. Look for either a "**Medical Review**" or a "**Statistical Review**" (labeled as such on the html page, or you'll see it by reviewing the table of contents of the pdf documents). Unfortunately, the reports are variable and you kind of have to poke around to see what's going on. Because of the multiple levels of lists that you will have to go through, keeping track by carefully going through each level is about the only way to make it work. The changing colors of the visited links will help you keep your place. While it is tempting to try to speed the work up by opening up multiple tabs, I have found that this does not always work. Trying to open too many tabs from the search often crashes the site & because the pages look nearly identical it can be hard to keep your place (for instance, if a page opens up and is empty, the link color still changes to "visited" and it can become hopelessly confusing!). *Patently clicking through all the list levels is unfortunately the only way to find the reviews.* It's more "targeted browsing" than it is searching. *Rose's tip: the best way to get through this is to listen to music or podcasts while doing it.*

Depending on the how long the list of drugs is and the number of FDA entries for each drug, this part of the search can take an enormous amount of time. *Recommendation: do it first, everything else goes much more quickly.*

**Devices@FDA** - sometimes the interventions aren't drugs, but devices. You can search for regulatory information at [Devices @FDA](#). You can really only **search by specific device name and date**. You're searching for a document called **510(k) summary -- it can be found by clicking on the link (usually with some sort number) in the column named "device or consumer information/instructions."**

**Health Canada**, in addition to searching for US regulatory information, we search the [Canadian regulatory information](#). You can search by product name and active ingredient. I usually search both, if find stuff with the first search I don't bother to search the second, but if the first search doesn't turn anything up, I'll search the second category. In the Canadian database we're looking for documents called **Product Monographs, you can see if there is going to be a Product Monograph for each record**

**by looking at the column labeled "PM" if it says "yes" then click on the link in the "DIN" column to get to page where you can download the pdf.** A couple of things to note:

- While there appears to be a specific URL for the page that the pdf is on, this URL usually "expires". Meaning that while I'm doing the searching if I double check, the URL appears to bring you right to the page. But a couple of days later if you try, it just takes you to an error page. Since these URLs expire before they can be of any use to the EPCs and usually end up confusing them, I just stopped including them
- Also, it is usually the case that if there are multiple listings for a single drug by the same company, they all link to the same Product Monographs. I usually just look at the first one, especially if the list is long. However, you may want to double check this for yourself.

**Authorized Medicines for EU**, in addition to the US and Canada, we also look for [EU regulatory informtion](#) . Try a keyword search under "name". In general you're much less likely to find material here than the other two sites, but we check it just to be thorough. If you get a hit, **click on the link which is the name of the drug and click on the tab named "Assessment history."** We are specifically only looking for the PDF titled Scientific Discussion. Like the FDA's statistical and medical reviews, these are the only documents which may contain otherwise unpublished clinical trials of these drugs.

#### **On to Clinical Trials:**

**ClinicalTrials.gov** is the main site we use to identify clinical trials. While the searches for regulatory information hinged on using specific drugs/devices from a list, the searches for the clinical trials can be more traditionally subject based. *Rose's tip: since the databases we're searching are so small compared to the bibliographic databases, the search strategies can usually be quite simple. With ClinicalTrials.gov rely on the advance search screen, and utilize the condition and intervention fields heavily.* The system does automatic term matching, uses MeSH, and sometimes the age group and gender limits will be useful. Because completed studies are the only ones that are of interest to the reviewers (not yet completed studies don't have data that can be used) limit the search to completed studies.

Unfortunately, the drop down menu in the advanced search screen for "recruitment" doesn't quite get you to that granularity. *Rose's tip: here's the work around - develop your search using the advanced search screen, then select "closed studies" from the "recruitment" drop down menu.* Your results will not contain completed studies, but also studies that have been closed to recruitment for other reasons. At this point click on the "refine search" tab to the right you'll see a link called "expert search" click on it and you'll see a command line version of the search.

Replace this section: ( **NOT ( "Recruiting" OR "Not yet recruiting" OR "Available" ) ) [SUMMARY-STATUS]** with ( **Completed**) [SUMMARY-STATUS] and re-run the search.

You've now limited it to completed searches. Keep a copy of the search strategies used while looking for clinical trials and conference abstracts, the expression of the search in the expert search screen is what we use for clinical trials. It can be copied and pasted directly into the quick search box of ClinicalTrials.gov to re-run the search at any time.

In addition to ClinicalTrials.gov, there are some other trial registries that we also look at additional clinical trial registries

[Current Controlled Trials Meta registry](#) - Select all the trials except for ClinicalTrials.gov. Under "Results Order" select "Alphabetic" from the drop down menu - there are lots of duplicates when searching the meta-registry and having them listed alphabetically makes it easier to identify them. Then do a simple search in the search box. In the results list you can see whether or not the "status" is "completed", again researchers are only interested in completed studies, but there is no way to limit the search by status. I usually open a new tab with each completed trial. In the search documentation use the trial registry number as the author, and if available use the scientific title as the title, and copy the URL. Since there isn't an abstract the way there is with ClinicalTrials.gov records copy and paste the entire content of the web record. It's kind of messy, but it's the best way to get enough information into the documentation so that the researchers can decide if the study would be included or excluded.

[Clinical Study Results](#) - this is a website from PhRMA. One reason to search this trial registry is that it sometimes contains actual protocols for trial. Protocols aren't available from other trial registries so it's a good source to search, even if you don't usually find much. You can search by "drug name" if you have a drug list or use the indication "keyword field" Once you are looking at the results list you can **ignore any results that have a "unique ID" that starts with "NCT" these are trials that are already registered in ClinicalTrials.gov.**

[WHO International Clinical Trials Registry Platform Search Portal](#), is another meta-registry with a lot of international content. On the advanced search page you can specify condition and intervention. As we are usually **only looking for completed trials, the closest we can come with the search is to change "recruitment status" from "Recruiting" to "ALL". Once you get the results page you can "sort by" "Trial ID" that way all the results from ClinicalTrials.gov (starting with NCT) and from Current Controlled Trials (starting with IRCTN) can be skipped over.** Then scan the results for records that indicate "not recruiting" in the "recruitment status" column – for ease, just open each trial in a new tab. Now you'll need to review the "recruitment status" again. Look only for trials that are "completed" some others may not be recruiting because they are "not yet recruiting" or other reasons. For any new trial that is in fact completed in your documentation use the MainID as the author, the scientific title as the title, the URL and then copying and pasting the entire content into the abstract field. Again, it's a little messy but gets the information into your documentation where it can be easily reviewed for inclusion and exclusion criteria.

## Conference Papers and Abstracts

**CSA Conference Papers Index** - (Hopefully available to you via your institution's library)  
It's a pretty straightforward interface, so no special search tips!

**Scopus** – (Again hopefully your institution's library has a subscription to this or its competitor Thomson Reuter's **Web of Science**)

Again the searching is pretty straightforward (in this case, keyword only, no subject terms). In order to limit to conference papers and abstracts, at the results page you'll see a number of categories to "refine results" as well as a link to "add categories". Click on that link and add "document type" then click "conference paper" and "limit to".

<b>Topic:</b>		
<b>Regulatory Info:</b> <ul style="list-style-type: none"> <li>• Drugs@FDA</li> <li>• Devices@FDA</li> <li>• Health Canada</li> <li>• Authorized Medicines for EU</li> </ul> <p>CDER Archives Dockets Management Drug Information Portal MedWatch</p>	<b>Trial Registries:</b> <ul style="list-style-type: none"> <li>• ClinicalTrials.gov</li> <li>• Current Controlled Trials</li> <li>• Clinical Study Results</li> <li>• WHO Clinical Trials</li> </ul> <p>Center Watch IFPMC Clinical Trial Results Portal GlaxoSmithKline Results</p>	<b>Abstracts and Conferences</b> <ul style="list-style-type: none"> <li>• Conference Papers Index</li> <li>• Scopus</li> </ul> <p>BMC Meetings NLM Gateway - meetings Papers and Proceedings First Suggestions (DIRLINE)</p>
<b>[Gov Docs]</b> <ul style="list-style-type: none"> <li>• RePORTER</li> <li>• HSRPROJ</li> <li>• AHRQ GOLD</li> </ul>	<b>[Misc.]</b> <ul style="list-style-type: none"> <li>• NY Academy of Medicine</li> <li>• OpenSIGLE</li> <li>• OAlster</li> <li>• Other</li> </ul>	

From Robin Paynter at the Oregon Health & Science University