Backing Up Your Statements
How To Perform Literature Searches To Prove Your Points

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Very often when I am reviewing a manuscript or a regulatory document, I will venture on a statement that I believe requires a reference. More often than not, the answer to my author query is “Everyone knows that . . .” or “The literature shows that . . .” I am reluctant to be argumentative, but I did not know that and would be interested in seeing the literature that shows that!

Whether an author is attempting to validate his/her work in the discussion section of a research paper or is preparing to write a comprehensive review article; or whether a sponsor is attempting to answer questions from a regulatory agency or set the stage for a new product or indication, caution is advised when glibly stating that “current published literature shows that . . .”

When I read this statement, I wonder: (1) Does the literature really show this? (2) Can the author prove it in an unbiased way? And (3) how robust is the “proof” (ie, how many published articles back up this statement)? Granted, some things are accepted at face value in science (eg, DNA and gravity), but for other statements, particularly ones that are favorable to an author’s or drug sponsor’s work, it is useful to back up the claims with valid literature references. I have discussed references in a previous article and will not repeat caveats on references, except to emphasize that comments concerning, for example, meeting abstracts, posters, and publications in languages one does not read are relevant to literature searches.

Main Points To Consider
The Basics of Literature Searches

If at all possible, and I would certainly encourage this approach for a document that will be used in support of a regulatory submission, a professional information specialist should be engaged. The author, however, must have a clear idea of the objective of the search and should give some thought to the selection of databases, years of inclusion of the databases, languages to include, and format (ie, meeting abstracts, original papers, review articles) before engaging the information specialist and should work with the specialist to refine the search strategy, if necessary. It must be noted, however, that PubMed is a free, online service that is excellent for literature searches for authors who are unable to engage a professional. A tutorial is available at http://www.nlm.nih.gov/bsd/disted/pubmed.html.

Process

After the search terms, databases, and date range have been defined and the information specialist or searcher provides a comprehensive list of the found articles in abstract form, the author’s first step is to review the output. Another search will possibly be needed to refine the search terms, databases, or date range. Any article that appears to meet the criteria should be read in full and summarized in a uniform manner (Table 1). Reading the abstract alone will not suffice because the abstract does not provide all...
A literature search was done by information specialists hired by or in the library of [Pharma Co: city, state]. The search was entitled “[add title of search].” The literature databases searched on [day month year] were [list databases (eg, MEDLINE [MEYY and ME95], CANCERLIT [CANC], EMBASE [EMYY and EM950], and EMBASE ALERT [EMBA])]. The publication date coverage was [give starting year] to [ending year], with no language restrictions. The patient population base included men and women [or children < 14 yr or adults > 60 years].
and EM95), and EMBASE ALERT (EMBA). The publication date coverage was 1989 to 2007, with no language restrictions. The patient population included men and women.

Seventy-two citations were found. The abstracts for all citations were read, and if the abstract was relevant, a full copy of the article was obtained. Fifty-eight articles were considered relevant; however, 43 articles were discovered to be laboratory and nonclinical studies, and these articles were not summarized. The remaining 15 articles were read, and the following information was abstracted: objective; patient population; glucose ranges; lipid range; and conclusion, as stated in the article.

Additionally, the reference sections of these articles were read, and four articles not appearing on the original search were identified.

**Take-Home Lesson**

A good literature search is invaluable to authors preparing comprehensive review articles and is necessary when attempting to convince regulatory agencies that published literature supports your submission. The hallmarks of a good literature search include the following:

- Documented databases, dates of search, and search terms;
- Careful selection of articles based on abstracts found;
- Accounting of all references found, vetted, and used, as well as accounting of references found outside the search; and
- Uniform abstraction or summation of all articles cited.

By using a few standardized processes, you will be able to confidently back up your statements that indeed “the literature does show” that your statements in a review article, original research article, or a regulatory submission are known to specific scientists, even if not to everyone.

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