

# *Prior Art and Its Use in Safety Assessment Process*

The appropriate starting place for the safety assessment of any new chemical entity, particularly a potential new drug, is to first determine what is already known about the molecule, its structural and therapeutics class analogues (pharmacological analogues being agents with assumed similar pharmacological mechanisms), and the disease one seeks to treat. Such a determination requires the fullest possible access and review of the available literature. Here we try to at least overview the range of approaches to gathering such data (Table 1). In using this information, one must keep in mind that there is both an initial requirement to build a data file or database and a continuing need to update such a database on a regular basis, serving as part of the project record. Updating a database requires not merely adding to what is already there but also discarding out-of-date (i.e., now known to be incorrect) information and reviewing the entire structure for connections and organization.

Such data are first used in selecting which possible compounds should be carried forward in development as a possible new drug [as illustrated in Figure 1 and explored in detail in Gad (2005)].

## **1 CLAIMS**

Claims are what is said in labeling and advertising and may be either of a positive (therapeutic or beneficial) or negative (lack of an adverse effect)