

建议考虑的文献检索和筛选要素

Recommended literature retrieval and screen factors

一、 检索数据库

retrieval database

注册申请人需根据申报产品的具体情况（如设计特征、适用范围等）选择检索数据库，并在方案中论述选择的理由。数据库的选择应具有全面性，可考虑的数据库类型举例如下。

Registration applicant shall select retrieval database according to specific circumstance(such as design characteristic, scope of application and so on) of the product under approval, and shall discuss the selection reason in the scheme. Selection of database shall be comprehensive, recommended databases as follow:

1.科学数据库：如美国《医学索引》（Medline）、荷兰《医学文摘》（EM）、中国期刊全文数据库等。

Science databases: such as America Medline, Netherlands EM, the China Journal Full-text Database and so on.

2.临床试验数据库：如科克伦对照试验注册中心（CENTRAL）、临床试验注册资料库（ClinicalTrials.gov）等。

Clinical trial databases: such as Cochrane controlled trial registration center (CENTRAL), ClinicalTrials.gov and so on.

3.系统评价数据库：如科克伦（Cochrane）图书馆等。

System assessment databases: such as Cochrane library and so on

4.专业数据库：如诊断测试索引数据库（MEDION）、骨关节登记数据库等。

Special databases: such as MEDION, Bone joint registration database and so on.

二、 检索途径、检索词、检索词的逻辑关系

Retrieval approach, Search words, logical relationship among the search words

为全面、准确的检索出申报产品的临床文献，应综合考虑检索途径的选择、检索词的选择和各检索词间逻辑关系的配置，制定科学的检索策略。常见的检索途径包括主题词检索、关键词检索、摘要检索、全文检索等。检索词应与选择的检索途径相适应，考虑因素如

产品的通用名称、商品名称、生产企业、基本原理、结构组成、制造材料、设计特征、关键技术、适用范围等。进行检索词逻辑组配时，应正确地选用逻辑算符来表达检索词之间的逻辑关系，如逻辑或（OR）扩大检索范围，逻辑与（AND）缩小检索范围。应在检索方案中论述检索途径、检索词、检索词逻辑关系的确定理由。

In order to retrieve clinical literatures of product under approval fully and accurately, shall consider selection of retrieval approach, search words, the configuration of logical relationship among the search words comprehensively, make scientific search strategy. Common retrieval approaches include subject terms retrieval, keyword search, abstract retrieval, full text retrieval and so on. Search words should be adapt to the retrieval approaches, factors to consider include product's common name, trade name, manufacturer, basic principle, structural composition, manufacturing materials, design characteristic, key technology, application and so on. Retrieval word logic coordination, should select logical operators properly to express the logical relationship among the retrieval words, such as logic OR expands the retrieval range, logic AND reduces the retrieval range. Should discuss reason to determine retrieval approach, Search words, logical relationship among the search words.

三、 文献筛选流程和筛选标准

literature screening process and screening criteria

对于检出文献的筛选，建议按照图 1 设定的步骤进行。注册申请人根据文献的题名和摘要，筛选出可能符合要求的文献；根据文献全文，筛选出纳入分析的文献；根据全文仍不能确定是否纳入分析的文献，需与作者联系以做出判断。

Suggest conduct “Screening of the detection literature” according to procedures set in figure 1. Registration applicant screen out possible satisfactorable literature according to title and abstract of the literature. Screen out incorporated literature according to full text of the literature. If can not make sure whether bring into analysis or not according to full text, shall contact with the author to make judgement.

文献的筛选标准，即文献的纳入和排除标准，应明确、具有可操作性。

Screening criteria of literature is incorporate and exclusion criteria of literature, should be specific and have operability.



四、 文献检索和筛选结果的输出

output of literature retrieval and screening result

文献检索和筛选结果的输出形式包括题名、摘要及全文。经筛选纳入临床评价的文献应提供全文。Output form of literature retrieval and screening result include title, abstract and full text. The full text shall be provided if the literature is selected as clinical evaluation.