

# Developing a Child Health Trials Register: Benefits and Challenges



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## BACKGROUND AND OBJECTIVES

Trials registers were created in order to act as a repository for all trials for a specific review group. Considered to be a reliable pool of evidence, all review groups and fields are required to have one.

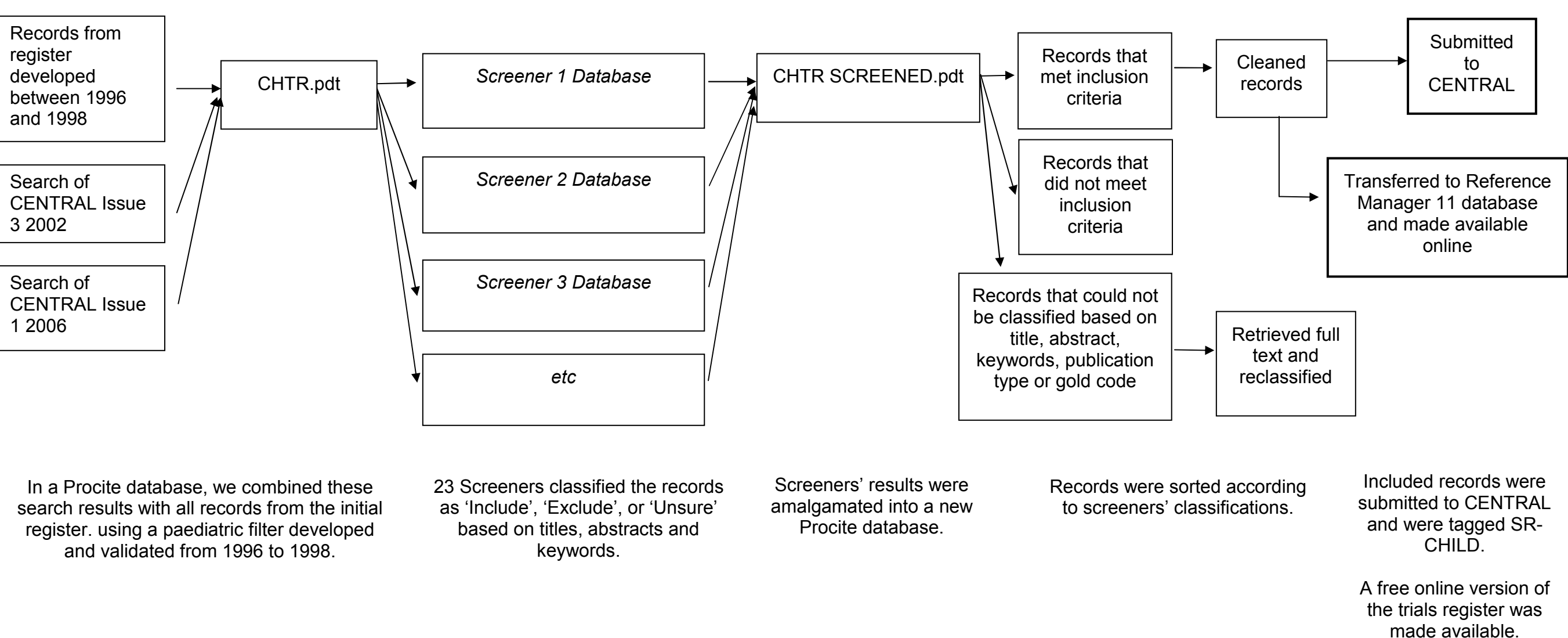
In 1996, members of the Child Health Field recognized the need for a comprehensive database of published, child-relevant clinical trials that could be used by paediatricians to inform their clinical practice and by researchers to identify knowledge gaps. An initial register was developed in 1998; the register was updated in 2002 and then again in 2006.

## METHODS

### Search

We searched CENTRAL Issue 3 2002 and Issue 1 2006 using a paediatric filter developed and validated from 1996 to 1998.

Figure: From screening to submission



### Inclusion Criteria

Screeners classified the records as 'Include', 'Exclude' or 'Unsure' based on **titles** and **abstracts**. Records were eligible for inclusion if: 1) the study was a randomized or controlled clinical trial as defined by the Cochrane Collaboration; and 2) outcomes were reported for children 0-18 years of age.

Double screening was applied to a sample of the records to calculate interrater agreement. Decision rules were developed and applied to records classified as 'Unsure'. These rules allowed screeners to use three additional fields to determine a record's eligibility for inclusion: **subject headings**, **Medline publication type**, and the **study design or gold code** assigned by trials search coordinators. We also developed strict criteria around pregnancy studies and specified exact age ranges for mixed children and adult studies.

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We retrieved full text for studies that could not be classified based on these decision rules.

## RESULTS

There were 26,638 records in the original register. Our searches of CENTRAL retrieved an additional 64,987 records. These were classified as: include (n= 44,484); exclude (n=19,678); and unsure (n=27,463) (numbers include duplicates). We ended up with an extremely high number of records in the 'Unsure' category and were required to apply more stringent decision rules in order to reduce these numbers. Once decision rules were applied, the numbers in this category were reduced to 2,805 records for which we retrieved full text. There are currently 30,151 unique records in the register. These have been tagged 'SR-CHILD' in CENTRAL. They are also available online at: <http://www.chtr.med.ualberta.ca>.

Table: New decision rules to apply to 'Unsure' records

Pregnancy Studies		
INCLUDE	EXCLUDE	UNSURE
HIV transmission	Secondary or tertiary outcome on neonate	
Nutritional Supplements		
Breastfeeding		
Adolescent Studies — where age ranges are stated in the title or abstract		
INCLUDE	EXCLUDE	UNSURE
Age 13-21	Age 18-21	
Age 14-21	Age 13-22	
Age 15-21	Age 14-22	
Age 16-21	Age 15-22	
Age 17-21	Age 16-22	
	Age 17-22	
	Age 18-22	
Adolescent Studies — MeSH terms include 'Adolescent' and 'Adult' but NOT 'Child' or 'Infant' and the title and abstract contain the following text :		
INCLUDE	EXCLUDE	UNSURE
'teen', 'adolescent', 'juvenile', 'youth'	'adults', 'men', 'women'	'young adults'
	no terms indicating age	

Figure: Flow of records through the selection process

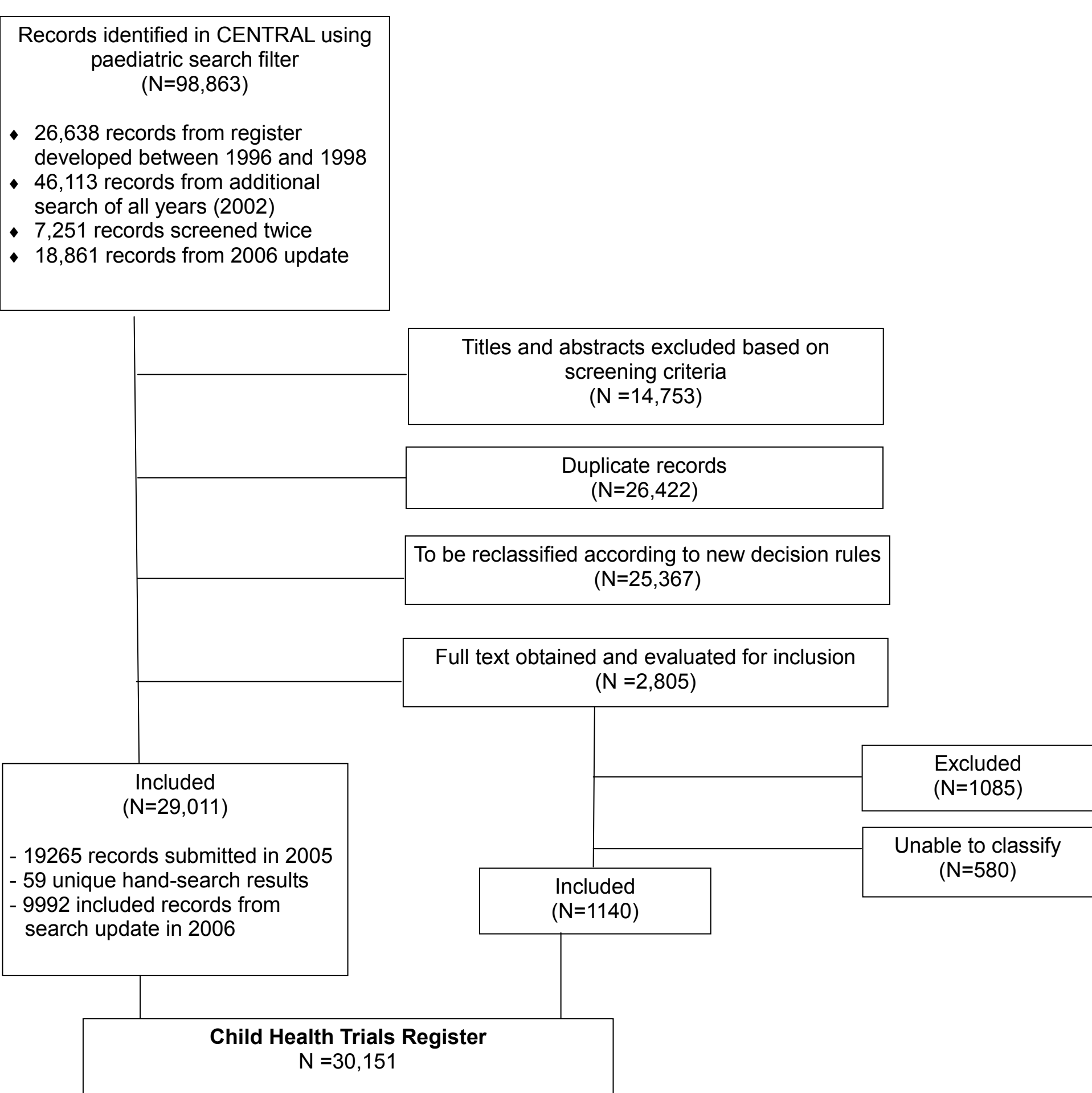


Table: Benefits and Challenges

Benefits	
<ul style="list-style-type: none"><li>One-stop resource for paediatricians and child health researchers</li><li>Resource for epidemiologic research on paediatric trials</li><li>Comprehensive base of high quality, primary studies for systematic reviewers</li><li>Contains records from MEDLINE, EMBASE, PysclINFO, ERIC, as well as hand-searching results</li></ul>	
Challenges	Solutions
Estimating required resources	Need to assess staff requirements, skill level, software, maintenance costs, software development costs, copyright permissions and time requirements
Started with overly stringent screening criteria—Screening using title and abstract only resulted in over 20,000 records in the 'Unsure' category.	Allowed screeners to use three additional fields: keywords, publication type and gold code. This reduced the number of records in the 'Unsure' category to 1860.
Unclear inclusion criteria for pregnancy and adolescent studies	Developed decision rules for age cut-offs and subject areas (See table 'New decision rules to apply to 'Unsure' records')
Large number of unclear or incorrect records downloaded from CENTRAL	Manually went through all records to clean up or correct authors, journal titles, dates, conference proceedings
Maintenance — There are thousands of new records to review each year. as well as retrieving full text and cleaning records	Currently investigating potential sources of funding to support these activities
Bibliographic Software with online searching ability	Used an inexpensive software - Reference Manager 11
Ensuring usability — Poor search engine in Reference Manager 11, promoting the register	Process to be developed to identify and address end-users' needs
Estimating overall costs	Need to look at the amount of funding for all required resources—not just staff
Cost of copyright permission — we were unable to display the abstracts for the majority of our records as well as the keywords for our EMBASE records	<ul style="list-style-type: none"><li>Removed abstracts from all records</li><li>Linked records originating from PubMed to the abstract on the PubMed site using its PubMed ID or provided a URL to free full text where available</li><li>For EMBASE records we removed keywords in addition to abstracts</li></ul>

## RECOMMENDATIONS

- Plan thoroughly for all resources at the outset of the project. Be sure to include a long term maintenance plan.
- Funding should include staff costs, software (bibliographic software for all staff, web server), software development costs, copyright permission fees, and maintenance costs.
- Anticipate that screening, record cleaning, and tracking references throughout the entire process will take a great deal of time
- If you plan to make your register freely available online:
  - seek additional funding to support software development costs, web server costs, and copyright permission fees;
  - contact database vendors in advance to find out price estimates of displaying abstracts and keywords.

The many advantages of developing a trials register must be weighed with the extensive resources required. Further work is planned to update the register, regularly incorporate hand search results, revise and validate the search filter, and test the register for comprehensiveness. Our experience will inform future updates as well as the development of other specialized registers.