

# Search manual: Results publications

Thank you for contributing to the systematic search for results publications of Nordic clinical trials! Please read this manual before starting.

## TL;DR

- For each trial, we search for eligible results publications in 3 steps: (1) check the registration for links, (2) Google search with trial ID(s), (3) Google search with other registry terms.
- We go through steps 1-2 for each trial and extract all matching publications.\* If none is found by step 2, we go through step 3.
- Extractions are made in an online [extraction form](#). Use the form once for each potentially eligible results publication.\* Don't keep several forms open at once.
- Everyone starts with 10 "[training trials](#)". After finishing those (without major discrepancies), you'll receive a personal sheet with trials to extract.

\* We extract every matching publication with a unique URL (and unique DOI or no DOI), to a maximum of 8 publications.

## Newest changes

- See [Q&A](#): What do I do if ... I found a duplicate? ...I've made a mistake in the submitted form? ... I can't access a full-text publication?

## Materials you need

- Your trial sheet (a link to a Google spreadsheet will be emailed to you). However, you'll first start with the 10 [training trials](#).
- [Q&A section](#) of this document.
- [Protocol](#) for an overview of the project.
- The link to the [extraction form](#)
- The Slack channel to request any full-text publications you can't access (Please try first to access articles via unpaywall and/or Google Scholar).

**Are you entirely new to clinical trials and trial registries?** Then you'll have to do a bit of reading before starting to get yourself familiar with the topic! The search manual assumes you have some knowledge about clinical trial terms and about the trial registries, so it's your responsibility to get up to speed to make sure you understand the concepts (for example what's meant by intervention studies, observational studies, randomization, masking/blinding, indication/population, intervention/treatment, comparator, and outcome measures).

Example readings:

- How to read a study record at ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/help/how-read-study>
- How to read a study record at the EU Clinical Trials Register (EUCTR), see p.6 "Search results explained":  
[https://www.clinicaltrialsregister.eu/doc/How\\_to\\_Search\\_EU\\_CTR.pdf](https://www.clinicaltrialsregister.eu/doc/How_to_Search_EU_CTR.pdf)
- Glossary of clinical trial terms: <https://clinicaltrials.gov/ct2/about-studies/glossary>
- Clinical trial terminology crash-course (before you dive into the glossary)  
<https://www.news-medical.net/life-sciences/A-Guide-to-Understanding-Clinical-Trial-Terminology.aspx>

We also recommend that you click around in a trial registration at ClinicalTrials.gov and at the EUCTR to get familiar with the websites.

## Online form general instructions

We use an online Google form. Please make sure you have a stable internet connection.

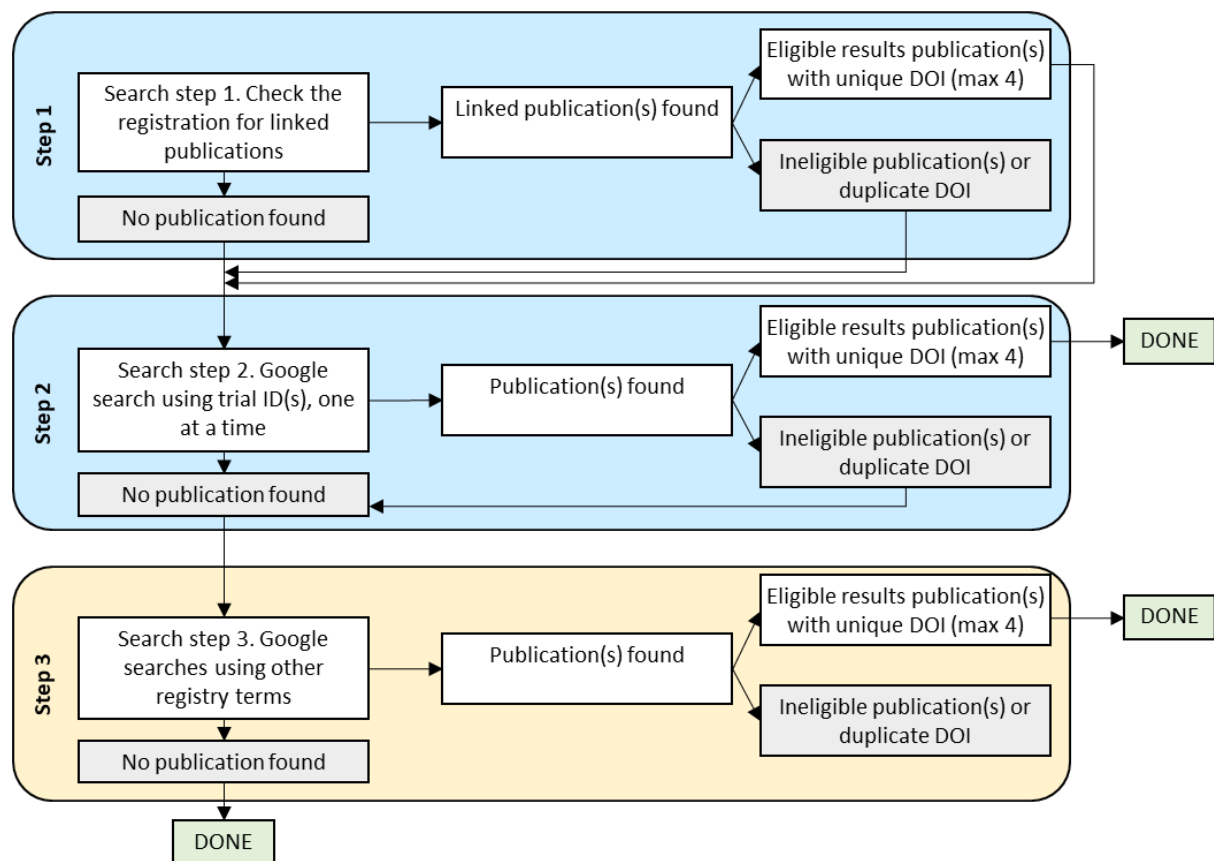
This is the link to the online form: [extraction form](#)

Every potentially eligible results publication is extracted using the same link consecutively. Use the form once for each potentially eligible publication.

**Important:** Make sure to only have 1 version of the form open at any time, since otherwise you may overwrite your answers. Don't try to fill in information for several publications at the same time by having several forms open.

**Tip:** Don't put the form in a tab among others; instead, use a separate browser window.

## Overview of search process



Go through steps 1-2 for all trials.

Continue with step 3 only if no eligible results publication has been found during steps 1-2. (See Box 1 for what we mean by results publication.)

At each step, extract every eligible results publication (max 4 per step), except those with the same URL or same DOI as one previously extracted for the same trial. Those we don't extract again. However, if an article appears for example in the shape of a preprint *and* a journal publication, even with the same text, we extract both.\*

**Tip:** Your trial sheet gives you the trial registration URL and trial ID. You'll need these for the searches.

**Tip 2:** What is a DOI? <https://apastyle.apa.org/learn/faqs/what-is-doi> .

\* Why both? Across all trials, we want to make sure we extract the earliest one (so we don't stop after finding the journal publication).

Comment: If you have participated in previous trial reporting projects, the process may differ. Here, you simply report all publications you find (after assessing unique URL, unique DOI, and eligibility). You don't need to select which publication is the earliest among several (that's done automatically by CA afterwards).

## Detailed search steps

**1) Check the registry website** to identify results publications linked in the registration.

Comments: The URL to the trial registration is in the trial sheet for you to click. Look through the registration for links to results publications. Not all links lead to eligible results publications.

Tip: At ClinicalTrials.gov, results publications are listed at the bottom of the record.

**2) Google search using the main trial ID** (EudraCT number for EUCTR trials; NCT ID for ClinicalTrials.gov trials), then other trial ID(s) if present, one at a time. The first page (or minimum 10 first hits) will be screened.

Comments: The main trial ID is in the trial sheet for you to copy. Other trial IDs can (sometimes, but not always) be found in the registration. If the Google hit does not seem relevant based on its title, you don't need to click to verify.

**3) Google search using two combinations of terms from the registry, e.g., title, principal investigator name, intervention/treatment, disease/symptoms, or other.** Use combinations that you believe are specific enough to yield a valid match. The first page (or minimum 10 first hits) will be screened for each combination.

Comments: If the Google hit does not seem relevant based on its title, you don't need to click to verify.

## When you find a potential hit

First, check so that the publication doesn't have the same URL or DOI as one you have previously extracted for this trial.

Then, assess whether the article is an eligible results publication according to the eligibility criteria in the protocol (Box 1).

If the article is a full match or a "near" match (meaning that all criteria 2a-2e are matching except one), proceed to fill out the form. It contains questions on publication info, eligibility, and a few items to extract.

We accept *either* peer-reviewed publications *or* any article that calls itself a preprint (the preprint status has to be explicit, either in the article or on the platform). For an article that isn't a preprint, if you're unsure whether it's peer-reviewed, you could start with searching for the journal's name in this [Journals & Newspapers listing](#). If a publication comes just short of the 500-word limit or you can't find out whether it's peer-reviewed, contact us.

**Note.** When extracting publication dates, please look for the *earliest* date available. This is usually the date of the electronic publication (epub date). If only month and year are given, enter the first day of the month.

## Box 1. Eligibility criteria for results publications

### **Results publications**

We will include **results publications** that correspond to both the following criteria 1-2:

1. Is a peer-reviewed scientific publication or preprint with >500 words. Doctoral theses, congress abstracts, or other summaries are not counted as results publications unless fulfilling these criteria. Reviews not reporting primary data are not included.
2. Is matched to an eligible clinical trial on all criteria a-e. If there is a “near” match, meaning that all criteria (a-e) match except one, eligibility needs to be discussed with a second reviewer for consensus.
  - a. Study design (intervention model, randomization, masking)
  - b. Indication/population
  - c. Intervention/treatment
  - d. Comparator (if applicable)
  - e. The publication’s primary outcome measure needs to be listed as an outcome measure in the registration (whether as primary or not). If the publication has several primary outcome measures, the rule applies for at least one of them. If the publication has no primary outcome measure assigned, the rule applies to the first outcome measure mentioned.

Publications will be counted regardless of whether actual enrollment matches planned enrollment since this is often subject to change (e.g., (44)). Publications that report *preliminary* analyses for at least one predefined outcome will be counted. Also publications reporting *interim results* or *fewer study arms* are counted (given that the overall study aim is still the same). Publications with reports of several trials combined (without disaggregating between trials) are not included.

In both the EUCTR and ClinicalTrials.gov, there are fields to specify primary outcome(s), but changes to outcomes are common (45). This project aims to follow up any reporting (and not discrepancies between registrations and publications).

Please note: regarding 2b (indication/population), we have chosen to ignore whether the enrollment matches (the number of enrolled persons)..

## Extraction form step by step

### 1. Extractor.

Choose your name in the drop-down list or “Other” to fill out your name if it’s not there (but it should be).

2. Trial ID.

Can be found in the trial sheet. It's a NCT ID or a EudraCT number. Please take care to avoid typos.

3. Did you find any potentially eligible results publication? If you're in doubt, click Yes and continue to the next section.

4. Link to article. Use a link that includes the DOI if there is such a link. Even if you're unsure of the eligibility, please include the link (and answer the questions as appropriate below). (Note: If this publication shares the exact same URL as for another publication that you've previously extracted for this trial, then don't extract it again.)

If you're at the publisher's site, you can page-search (on Windows computers, Ctrl+F) for "DOI" to find the article's own DOI. Often, you'll find a hyperlink constructed to include the DOI (which leads back to the publisher's site). That one is meant to be permanent and that's why we want it extracted, if possible.

5. Article DOI (always starting with "10") If none is available, enter "NA".

6. Is there a PubMed ID (PMID)? This is an 8-digit number.

You can either site-search for PMID, PubMed ID, or keep a tab open for PubMed and enter the publication's DOI there to find the PMID (if it exists).

7. Where/how did you find this article? "Other" can be for example if you found it as a cross-reference in another article.

Enter at which search step you found the article: Linked at the registration, through the systematic Google search (steps 2-3 are both referred to by this), or specify other way.

8. What type of results publication is this?

Journal publication, preprint, or other. See eligibility criteria.

9. Is the publication matched to the registration on these criteria? Check the boxes that match. (We only extract publications that potentially match on all criteria, or, all criteria except one). For "comparator": leave that box unchecked only if this criterion is applicable and it doesn't match.

**This is the most complex and time-consuming step.** It will help a lot if you first get yourself familiar with clinical trial terms and the trial registries! See section "Materials you need" above.

You need to look at each criterion and compare the information in the registration with the information in the results publication.

The text doesn't need to be exactly the same. We're not intending to exclude publications because they weren't well-written. We're not assessing the quality of the trial's reporting. We're simply looking to find publications that match the trial (in a reasonably unambiguous way) and that report its results.

Some publications linked in the trial registry are not actually results publications for the trial. For example, it can be a publication that validates a method used in the trial, or a descriptive analysis. We don't want to include those.

When looking at the criteria, you can for example ask yourself these questions:

- Was the study design the same? (Tip: "single-arm" trials are exactly what they're named, a single group, so they generally don't have a control group and therefore can't be randomized or blinded).
- Does the trial include the same type of persons (population) or disease (indication)? Here, you may need to look at eligibility criteria as well as settings. Note that you're not meant to exclude any results publication because the number of participants is different.
- Was the same comparator used? Not all trial designs involve a comparator, that's why we write "if applicable". Here, we assume that you have background knowledge on clinical trial comparators. Broadly and simply speaking, comparator categories are active comparators (another treatment), standard of care, or placebo.
- What's the primary outcome in the publication? Is that outcome listed in the registration?

**Some trials have complex designs.** If you're dealing with a non-standard trial design (e.g., many arms) and the protocol and this search manual don't give you enough answers to assess the eligibility of a results publication, reach out to us for guidance.

10. Comments? If this was a "near match" (matched on all criteria except one) or if you were unsure about any criterion, please leave your comments here.

Take this opportunity to leave comments if you want to discuss or explain anything.

11. What trial registration numbers were noted in the article? Select all that apply. These are typically found in the abstract, methods section, or at the end of the article. You can page-search for "NCT" to find NCT IDs, and for "regist" to find sentences saying for example "this trial was registered at xxxx" or "trial registration: xxxx". But there's no good way to page-search for EudraCT numbers, so you need to look for those.

12. If you found another trial registration number than EudraCT number or NCT ID, enter it here (even if you're unsure). Separate several numbers with a semicolon.

13. You'll then be asked either to fill out the PMID (if you clicked that one exists) or to fill out the publication date (we enter that manually for publications without PMID).

14. Final comments. Any comments on the extraction can be entered here. Don't miss to click "submit"!

*Take the opportunity to leave comments*, especially if you're filling out that no potentially eligible publications were found at any step. Were there any linked publications in the registry that turned out to be ineligible? For example: "there was a publication linked in the registry, <LINK to publication>, that didn't report on an outcome for the trial".

## Q&A - Identification of results publications

### **I found a trial that is double-registered, both at ClinicalTrials.gov and in the EUCTR. Should I extract it again?**

Yes, please complete the search for the other registry as well, following our algorithm: (1) check for results publications linked at the registration, (2) search Google with the registry ID, and so forth.

Explanation: The issue is that cross-registered trials usually don't have links to results publications in *both* their registrations, but only one. For example, they may have linked publications at CT.gov, but not in the EUCTR. That's why we want to make sure we look in both places. Also, we want to make sure to Google search using both trial IDs (NCT ID and EudraCT ID) and this may not have been done in the first search, if the cross-registered ID wasn't mentioned in that registration. We expect <10% cross-registered trials in total.

### **Will the comments be publicly shared?**

No, the final dataset that we share will not contain the comments made during extraction (these are primarily meant to help you during the discrepancy discussions with your paired reviewer).

### **What do I do if I've made a mistake in the form I submitted, can I change this?**

To communicate any corrections that need to be made, these are the two options:

1) In your trial sheet, there is now a comments column. You can use that to enter any corrections to be made (make sure to be very specific).

2) Or, use this [edit request log](#) to describe the error and we (CA) will correct it in the form's data collection sheet.

Please use those two options instead of email, so that we can keep close track of data management related points.

### **What to do if I can't access a full-text publication?**

Use the Slack channel to request any full-text publications you can't access (Please try first to access articles via unpaywall and/or Google Scholar).

### **For EUCTR trials, do we extract summary results from the registry?**

No, in this round of searches we only care about "*results publications*" (journal publications, preprints, or other) that are outside the registry. The reason that we look in the registration is to find external links.

So, "summary results" in the trial registry are not what we're extracting here. Unsure of what summary results are? Please see the protocol :-)

### **If there are articles linked in the registry that aren't eligible, do I need to fill out the form to report that?**

No, the form should only be filled out for each eligible article (and articles you're unsure of, that are potentially eligible). Ineligible articles are not documented. The form is also used if you find no publication at all, having completed all three search steps.

### **If I want to make comments to my extractions, where do I enter them?**



Please enter any comments at the very end of the form in the designated comments question. Don't leave comments in other fields.

**If I find no publication at all (after step 3), how do I report this?**

Use the same online form as when you report publications found.

**I found an error in the form, where do I report this?**

Please let me know, [caxfors@stanford.edu](mailto:caxfors@stanford.edu)

**I accidentally closed a window while extracting.**

If the window is *accidentally closed* while working, you can access it again with the same link you used to open it. The form should then let you continue where you left off. This only works with 1 unsubmitted form open at a time!

**I'm halfway through a form and want to continue later. What do I do?**

If you put your computer on sleeping mode and keep the browser open, you can just continue later. The same happens if you lose internet connection.

If you want to shut down the system and continue at a later time:

- (1) click through the sections until you reach "submit", and send it in, half-empty.
- (2) Immediately, a page shows with a link that says "Edit your answers". Save that link somewhere.
- (3) Use that saved link to access the form where you left it off. The same procedure can be repeated.

**I'm unsure of the clinical trial terms used in the eligibility criteria.**

For definitions see <https://clinicaltrials.gov/ct2/about-studies/glossary>. Don't hesitate to ask me if you have questions: [caxfors@stanford.edu](mailto:caxfors@stanford.edu).