REVEAL – prior evidence for new trials

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REVEAL – PrioR EVidencE for new triALs

Abstract

This guide is for clinical researchers who plan a new clinical trial and need to rapidly review the literature for prior trials in a systematic fashion. The results of this process can be used to (1) identify and characterise the knowledge gaps to justify a new trial (e.g., lack of evidence, concerns about research quality) and (2) inform the research question and methods of the new trial (e.g., outcome measurements, sample size calculation and practical conduct).

The guide follows a stepwise process with two main parts:

- **Part A describes a systematic search for and quality assessment of existing relevant systematic reviews on the topic of the planned trial.** If a relevant, high-quality and up-to-date systematic review of previous trials answers the planned research question, no further trial is necessary. If the systematic review concludes that more evidence on the planned research question is needed, the new trial can be convincingly justified, and the available evidence can be used to inform the protocol and conduct of the new trial. If there is no relevant, high-quality and up-to-date systematic review, the researcher must continue with Part B.
- **Part B describes a systematic search for and quality assessment of relevant clinical trials on the topic.** If there are no trials or only those that are methodologically compromised, or if too few previous trials exist to answer the planned research question, the new trial can again be convincingly justified.

This guide includes (1) a *detailed guidance document* (= the document that you are reading at the moment) listing for each step the essential and optional tasks with explanations and useful resources, and (2) a *structured report form* that takes researchers through the process step-by-step and provides a template to document all the relevant information needed to prepare respective sections of funding proposals or trial protocols for submission for ethics review. In addition, there is (3) a *worked example* with a completed report form and sample text for a funding proposal or a trial protocol.

Introduction

Before embarking on a new clinical trial, it is essential for researchers to assess the existing evidence landscape: Has this particular research question been previously addressed, and is there convincing existing evidence on this question? Reviewing the literature when planning a new clinical trial not only prevents unnecessary and unethical repetition but also provides a robust groundwork for subsequent research endeavours.

This guidance is for you if you are planning a clinical trial and you do not have the resources or skills to carry out a full systematic review (SR) to inform your planned trial.

This guidance helps you conduct a swift literature review. The results of your review will enable you to:

- Determine the necessity and relevance of initiating a new clinical trial.
- Enhance the background section of your trial protocol by highlighting any identified gaps in the current literature.
- Refine your trial's foundational elements, from specifying precise research questions and selecting outcomes and outcome measures to determining sample size and shaping the trial design.
- Reflect on insights gained from prior trials to optimise the execution of your new clinical trial.

How to use this guide

Begin with the report form – it guides you through the whole literature review process. Simply download ↓ it and start filling it in.

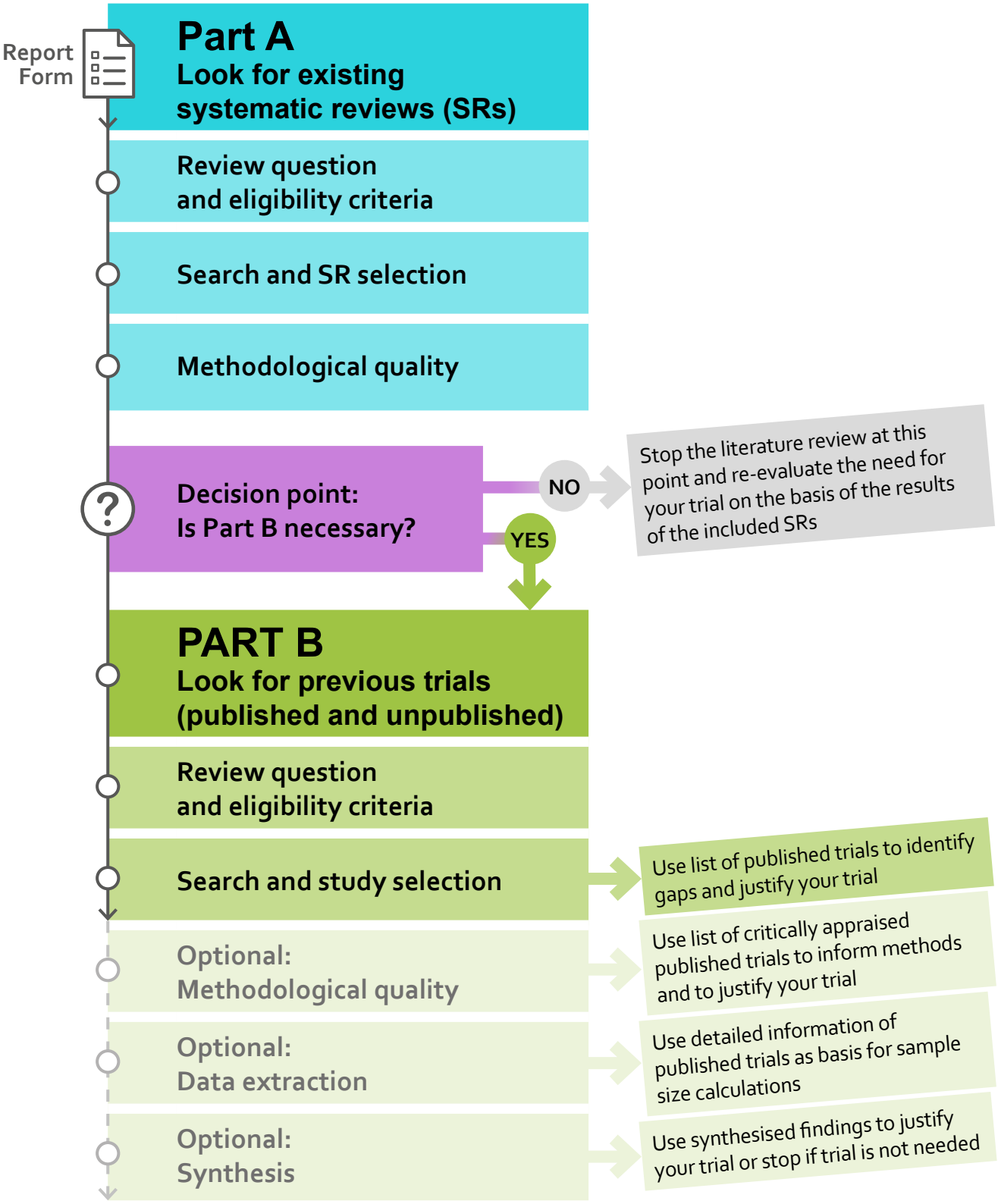
Both the guide and the report form are structured in the same way (see also the *figure* on the next page): In **Part A**, you will be searching for **published systematic reviews (SRs)** first. This is faster than first searching for primary studies, and if you find one or more well-conducted and up-to-date SRs on the topic of your planned trial, then you may not need **Part B** to search for **published, unpublished or ongoing primary studies**.

In both Part A and B, we have defined **essential tasks** that you must carry out in your literature review. Additionally, we have added **optional tasks** that you can choose to do depending on your time and personnel resources. For each task we provide **further explanations** and **links to useful resources**.

Starting on page 7, you find a **navigation bar** at the bottom of each page. Click on it to move quickly from one part of the guide to another.

Disclaimer: The time to complete a swift literature review can vary substantially (several hours to several weeks) and depends on factors such as the topic of the research question, your knowledge and experience in systematic reviewing, and the available human resources, and support offered by your institution (e.g., library services, access to tools). Whatever your individual situation is, we strongly encourage you to follow the order of the listed essential tasks.

Overview of the swift literature review process



Task overview and navigation

Click on the step for further explanations

PART A	Look for existing systematic reviews (SRs)
Step A1: Review question	Conduct preliminary searches
	Structure review question using the population, intervention, comparator and outcome (PICO) framework
	Define the most important outcomes
Step A2: Eligibility criteria	Document inclusion and exclusion criteria for PICO elements
	Define additional elements in the eligibility criteria
Step A3: Search	Use findings from preliminary searches to design search strategy
	Develop the search strategy with input from an information specialist
	Use at least two information sources to identify SRs
	Document searches
Step A4: SR selection abstract level	Screen all identified titles/abstracts
	Refine eligibility criteria after screening 30–50 titles/abstracts
	Document the numbers of included and excluded titles/abstracts
Step A5: SR selection full-text level	Retrieve full texts of all potentially eligible titles/abstracts
	Screen all full texts and record the main reason for excluding a reference
	Document the number of included and excluded full-text articles (with reasons for exclusion)
How to proceed from here?	You found eligible SRs: proceed to **Step A6**
	You found no eligible SRs: proceed to **Part B**
Step A6: Methodological quality of eligible SRs	Assess the methodological quality of eligible SRs
Decision point: Is Part B necessary?	NO, you found at least one recent and good-quality SR → stop the literature review at this point and re-evaluate the need for your trial on the basis of the results of the included SRs
	YES, you found an outdated good-quality SR → proceed to **Part B** and update the existing SR
	YES, you found no recent and good-quality SR → proceed to **Part B**

Task overview and navigation

Click on the step for further explanations

PART B	Look for previous trials (published and unpublished)
Step B1: Review question and eligibility criteria	Check whether the review question and eligibility criteria are still valid
	Specify eligible design of previous trials
	For updates of good-quality SRs: restrict eligibility criteria regarding timeframe to after the SR's most recent search date
Step B2: Search	Use findings from preliminary searches to design search strategy
	Develop the search strategy with input from an information specialist
	Use at least two information sources to identify published trials
	Use ClinicalTrials.gov to identify ongoing or unpublished trials
	Document your searches
Step B3: Study selection abstract level	Screen all identified titles/abstracts
	Refine eligibility criteria after screening 30–50 titles/abstracts
	At minimum: search and screen the MEDLINE results directly in the platform (e.g., PubMed)
	At minimum: search and screen the ClinicalTrials.gov results directly in the platform
	Document the numbers of included and excluded titles/abstracts
Step B4: Study selection full-text level	Retrieve full texts of all potentially eligible titles/abstracts
	Screen all full texts and record the main reason for excluding a reference
	Review the whole entries of selected titles in Clinicaltrials.gov and record the main reason for excluding a reference
	Document the number of included and excluded full-text articles/trials register entries (with reasons for exclusion)
 **How to proceed from here?**	You found no ongoing, unpublished or published previous trials → stop the literature review and plan your trial
	You found no published but only ongoing or unpublished trials → stop the literature review and re-evaluate your plans for your trial
	You found eligible published trials → either 1) proceed to **Step B5**: Assess the risk of bias of eligible trials or 2) stop the literature review with a list of published trials

PART A
Look for existing systematic reviews (SRs)

STEP A1 Review question — Essential tasks

Conduct preliminary searches for existing SRs, trials, etc. to help define and refine your review question and eligibility criteria.

Preliminary searches are conducted during the preparation phase to get an idea of the available evidence on your topic.

For most people, this will mean 'Search as you usually do': Use information sources you are comfortable with (e.g., Google Scholar, PubMed) and browse through the results. You do not have to be systematic or comprehensive. It can be helpful to document the search terms you used.

Structure your review question using the population, intervention, comparator, outcome (PICO) framework.

The PICO framework works best for interventional research, but can also be applied to other types of questions (e.g., prognosis, diagnosis, aetiology).

For specific types of questions, you may need alternative frameworks (see resources for more information).

Resources:

University of Maryland, Framing a Research Question: https://lib.guides.umd.edu/SR/research_question

Evidence Based Library and Information Practice, Formulating the Evidence Based Practice Question: https://doi.org/10.18438/B8WS5N

Define the 3–5 most important outcomes.

Defining the most important outcomes may help ensure a feasible review process; focus on the most patient-relevant outcomes.

STEP A1 Review question — Optional tasks

Involve stakeholders (e.g., patients, clinicians) in determining the review question and PICO elements.

Involving stakeholders potentially enhances clinical or public relevance and applicability. Perspectives and expertise from outside the research team adds valuable understanding of the individual topic.

Search the COMET database for core outcome sets.

COMET provides core outcome measures in effectiveness trials. 'A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care'.

Resources:

COMET Initiative: https://www.comet-initiative.org/

STEP A2 Eligibility criteria — Essential tasks

Document your inclusion and exclusion criteria for the PICO elements of your review question.

Eligibility criteria (i.e., inclusion and exclusion criteria) add specific details to the PICO elements of your review question:

- e.g., population: age range, gender, disease stage/severity/duration
- e.g., intervention or comparison: the review question could state an entire drug class (e.g., serotonin-norepinephrine reuptake inhibitors), but in your eligibility criteria all drugs that are eligible are listed (e.g., Desvenlafaxine, Duloxetine, etc.)
- e.g., outcomes: specific outcome measures.

Detailed eligibility criteria are important because they will a) more accurately reflect the scope of the question, and b) help in making decisions during the literature screening process.

Eligibility criteria for SRs may be slightly different/broader than those for clinical trials (e.g., broader population).

Use the findings from your preliminary searches to help define your eligibility criteria.

Define any additional elements that are relevant for searching, study selection, data extraction or synthesis (e.g., eligible study designs, document types, languages, publication dates, full-text access).

Additional aspects may be important in deciding whether a SR is relevant for your literature review, e.g., the study designs the SR included, the publication date of the SR, etc.

STEP A3 Search — Essential tasks

Use the findings from your preliminary searches to design your search strategy (e.g., selection of search terms, relevant information sources).

Generally, you can base your search on two groups of search terms: a combination of a) alternative expressions for population AND b) alternative expressions for intervention. If the intervention is very new or the population is rare, you may need only one of these elements.

Searching for the comparator or outcomes is rarely appropriate: These elements are often less well reported in abstracts. Adding them to the search strategy might lead to missing relevant reviews.

Develop your search strategy with input from an information specialist (e.g., medical librarian).

Traditional systematic searches aim for the highest possible sensitivity: they aim to find all relevant publications and accept a large number of irrelevant documents in the search result as a trade-off. They often use many information sources, resulting in a large number of titles and abstracts to screen.

An information specialist can help you create searches with a higher specificity to find the majority of relevant studies but keep the number of hits manageable.

Resources:

Guidance for identifying SRs:

University of Tasmania, Systematic Reviews for Health: Finding Systematic Reviews: https://utas.libguides.com/SystematicReviews/Finding

JBI Manual for Evidence Synthesis, 10.2.6 Search Strategy for overviews of reviews (i.e., reviews of SRs): https://bit.ly/JBI-Manual

Use at least two information sources (including at least one bibliographic database, e.g., MEDLINE/PubMed) to identify SRs.

Systematic search sources can be separated into bibliographic databases (e.g., MEDLINE/PubMed, Epistemonikos, Cochrane Library) and additional sources (e.g., academic search engines, such as Google Scholar, or other supplementary search methods, such as checking the reference lists of included SRs). We recommend using at least one bibliographic database to ensure a high search sensitivity.

Some platforms (e.g., Epistemonikos, Cochrane Library) have reliable filter options for SRs. For other platforms/databases, you can use validated search filters to find SR: These are database-specific predefined search strategies whose performance has been tested (= validated).

Google Scholar usually retrieves a large number of records that are ordered by relevance. Because they cannot be easily exported in bulk, a pragmatic way to review them is to set Google Scholar to show 20 results per page and screen only the first page for every query. You can use the 'save' function to manually select references and export them into a reference management system.

Resources:

Find validated search filters, e.g., The ISSG Search Filter Resource: https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home

The University of Rhode Island: Exporting Citations from Google Scholar: https://uri.libguides.com/google/gscholexport

Document your searches.

A detailed documentation of search strategies is helpful for the search section of Part B but also for search updates, e.g., when you write the manuscript of your own trial results: Record the date and names of the databases/search engines used, and copy and paste the exact search strings you used in each database/search engine.

Also, document any filters or limits you applied to your search, e.g., selecting only the first 20 records for every Google Scholar search result.

STEP A3 Search — Optional tasks

Use a reference management software (e.g., EndNote, Zotero, Mendeley, Citavi) or a SR support platform to collect search results and document the data selection process.

When using several search sources, you must expect overlap in the search results. You can import all your search results from each source into the reference management software and deduplicate the results. Alternatively, some supportive review platforms (e.g., Rayyan, SR Accelerator) also include deduplication functions.

Resources:

Guidance for search result deduplication:
Universität Bern, Removing duplicate records: https://ilias.unibe.ch/goto_ilias3_unibe_cat_2297227.html

Platforms with deduplication tools:
Rayyan: https://www.rayyan.ai/
The Systematic Review Accelerator (SRA): https://sr-accelerator.com/
Deduklick: https://www.risklick.ch/products/deduklick/

STEP A4 SR selection | abstract level — Essential tasks

Screen all identified titles and/or abstracts using your eligibility criteria to decide whether the SRs may be relevant.

There are several options to choose from for screening your search results from a database:

- Review the titles/abstracts directly online (e.g., collect them directly in PubMed)
- Download a csv/Excel file with the search results and document which references you included.
- Download the search results (e.g., as a RIS file); import it into a reference management software (e.g., Endnote, Zotero) to select eligible studies there.
- Upload the search results into supportive screening software (e.g., Rayyan, Covidence).

Supportive screening software can save resources through keyword highlighting, tagging functions and ranking the most relevant records with the use of artificial intelligence systems that aim to recognise prior inclusion or exclusion decisions.

Resources:

Examples for screening software:
Rayyan: https://www.rayyan.ai/
Covidence: https://www.covidence.org/
DistillerSR: https://www.distillersr.com/products/distillersr-systematic-review-software
Eppi Reviewer: https://eppi.ioe.ac.uk/cms/Default.aspx?tabid=2914

Refine eligibility criteria after screening a first batch (e.g., 30–50 abstracts) and add further details for clarity, if necessary.

Often, during the study selection process, additional questions arise regarding the eligibility criteria details. Therefore, it is helpful to refine your eligibility criteria at the start of the screening process, after you screen a first batch. Refining can mean adding more detail for clarity or adding illustrative examples to make screening decisions easier.

Document the number of included and excluded abstracts using the PRISMA flowchart in the report form.

At the title/abstract level, it is not necessary to document the reasons for exclusion; it is enough to document the number of included and excluded abstracts.

STEP A5 SR selection | full-text level — Essential tasks

Retrieve the full texts of all potentially relevant abstracts.

There are several ways to retrieve the full texts of your potentially eligible references:

- Reference management software and screening software often provide a service to automatically retrieve full-text PDFs.
- Search using the DOI: you will be able to retrieve all open-access articles and those available to you through your institution.
- Search on Google Scholar: if the PDF is available to you, you will see a direct link.
- Check ResearchGate: authors often provide a download option of their article, or you can request a copy from the authors.
- Contact the corresponding author and ask for the full text.
- Ask a friend who works at another institution; they may have access to other publishers.

Screen all full texts using your eligibility criteria from Step A2 to decide whether the SR is included and record the main reason for excluding a reference.

Reasons for excluding a full-text reference should be documented. The easiest way is to align the exclusion reasons with your eligibility criteria and number the exclusion reasons accordingly (e.g., X1_ineligible population).

Document the number of included and excluded full-text articles using the PRISMA flowchart in the report form and include the reasons for excluding for each full-text reference.

Screening software automatically keeps track of screening decisions and reasons for exclusion.

STEP A4+5 — SR selection | abstract and full-text level — Optional tasks

Involve a second researcher (or more) and choose one of the following options:

- Mark unclear abstracts/full texts and discuss uncertain screening decisions with them.
- Use them to cross-check a subset of references: either a subset of abstracts/full texts (e.g., random 25%) or all excluded abstracts/full texts.
- Use them to screen all abstracts/full texts independently and discuss conflicting screening decisions.

Involving more researchers enhances the rigour and reliability of the review process, aiming at more accurate inclusion and exclusion of studies, reducing the risk of missing relevant studies. Different researchers may also bring varied expertise and perspectives into the research process.

If two or more researchers are involved:

- Conduct a screening pilot exercise with 30–50 abstracts (or 10% of retrieved records) and discuss uncertainties.
- Conduct a screening pilot exercise with 5–10 full texts (or 10%) and discuss uncertainties.

Screening pilot exercise: choose some records (e.g., 30–50 abstracts and 5–10 full texts), screen them independently and, afterwards, compare conflicting decisions. Justify the reasons for including versus excluding certain references and find consensus among the team. If the conflicts resulted from unclear eligibility criteria, consider refining the criteria. The aim of the pilot exercise is to get all involved researchers on the same page and discuss unclarities in the eligibility criteria.

How to proceed from here?

If you found **eligible SRs** after screening abstracts and full texts → proceed to **Step A6**.

If you found **no eligible SRs** after screening abstracts and full texts → proceed to **Part B**.

STEP A6 Methodological quality of eligible SRs — Essential tasks

Assess the quality of eligible SRs using a practical quality assessment tool (e.g., "fast and frugal" decision tree).

Only assess the quality of SRs that answer your review question. If you found many eligible SRs, only assess the quality of those most recent.

The "fast and frugal" decision tree allows an accelerated critical appraisal that is based on AMSTAR 2, a validated critical appraisal tool for SRs. However, if a more detailed appraisal is needed, you should consider using the full AMSTAR 2 assessment.

Resources:

"Fast and frugal" decision tree for the rapid critical appraisal of SRs: https://doi.org/10.1101/2023.03.20.23287481

AMSTAR 2: https://amstar.ca/Amstar_Checklist.php

STEP A6 Methodological quality — Optional tasks

Involve a second researcher (or more) and choose one of the following options:

- Use them to verify assessment of quality appraisal decisions.
- Use them to do the quality assessment of SRs independently.

If you involve a second researcher to verify your assessment decisions, highlight relevant paragraphs in the texts so that they can find the relevant content more easily.

Decision point – Is Part B necessary?

NO, if you found **at least one recent and good-quality SR** that addressed your review question → stop the literature review at this point and re-evaluate the need for your trial or use the SR to inform your trial.

Whether a SR can be considered 'recent' depends on the topic under investigation. In a fast-changing field, a SR with a search date of 2 years ago may be already out of date. In a field where developments are slower, a SR with a search date of, e.g., 5 years ago maybe still be usable. In any case, we recommend consulting an expert in the field to judge whether the SR is outdated.

Finding a recent and good-quality SR that addressed your review question is an indicator for sufficient evidence in the field. Therefore, your planned trial may not be necessary in its current form. Consider **modifying the research question of your trial if you are to proceed with it.**

YES, if you found an **outdated good-quality SR** that addressed your review question → proceed to **Part B** and update the existing SR.

Update the SR: take the identified SR as a source of studies and supplement it with a search for recent studies not covered by the outdated SR.

YES, if you found **no recent and good-quality SR** → proceed to **Part B**.

If you did not find any SR or found only outdated or low-quality SRs on your review question, you should look for previous trials to discern whether your trial is needed.

PART B
Look for previous trials (published and unpublished)

If you found an outdated SR on your review question or a SR that is on a similar topic but does not answer your review question, you can use the information from these SRs to inform your search for previous trials: e.g., to update an outdated SR, to choose relevant information sources or to specify eligible outcome measures.

STEP B1 Review question and eligibility criteria

Essential tasks

Check whether your review question and eligibility criteria from Part A are still valid and modify as necessary.

Eligibility criteria for SRs may be slightly different/broader than those for previous trials (e.g., broader population); therefore, it is important to check your criteria again at this stage and make changes as needed.

If in Part A, you identified outdated or low-quality SRs. You can still use these reviews to plan Part B, e.g., by specifying eligible population sub-groups, outcomes or outcome measures or study designs.

If you made major modifications, get feedback on the new versions of your review question and eligibility criteria, e.g., from another researcher, an experienced systematic reviewer or a clinical expert.

Specify the eligible design of previous trials (published and ongoing or unpublished).

Depending on your review question and your planned trial, you may, e.g., search for randomised controlled trials (RCTs) and exclude other study designs.

If you conduct an update of a good-quality SR that assessed your review question, restrict the eligibility for included published trials to those published after the SR's most recent search date.

If the good-quality SR searched the literature up until, e.g., 15 June 2022, then allow some overlap and set the search limits to start from June 2022 up to present.

STEP B2 Search

Essential tasks

Use the findings from your preliminary searches and Part A to design your search strategies for published and unpublished trials (e.g., selection of search term, relevant information sources).

Generally, you can use the same elements (e.g., population and intervention) as identified in **Step A3**. However, the information sources, search terms and study design filters may differ.

Develop your search strategies with input from an information specialist (e.g., medical librarian).

Search strategies to identify SRs are often broader than those aimed at identifying clinical trials. Therefore, it is likely that you will have to revise the search strategy you used for Part A to be more specific. Additionally, the bibliographic databases used for finding published trials use more sophisticated search functions than trials registers to find study protocols of ongoing trials: You must adapt your search strategy to the interface you use.

Resources:

Rapid reviews methods series: Guidance on literature search: https://doi.org/10.1136/bmjebm-2022-112079

Use at least two information sources to identify published trials:

1. Search in the bibliographic database MEDLINE (e.g., via PubMed).

2. Use one additional information source (e.g., Google Scholar, checking reference lists).

In most cases, MEDLINE (e.g., searched via PubMed) will contain the majority of relevant medical studies. Additional searches will help in finding studies not in found by the search strategy or not available in MEDLINE.

Additional information sources:

- Use search engines, e.g., Google Scholar.
- Screen references of SRs found in Part A.
- Screen references of included trials.

Use ClinicalTrials.gov to identify ongoing or unpublished trials.

ClinicalTrials.gov is a US-based trials register widely used by international researchers. It mainly contains trial protocols but, in some cases, also results data. Searching it gives you an overview of ongoing research and completed but not (yet) published research.

Trials registers generally have very limited search functionalities, so searches must be simpler and broader than bibliographic database searches. Your search strategy should contain no more than two concepts (e.g., intervention, population) and only the most important search terms.

Resources:

Guidance for the systematic identification of ongoing or unpublished studies ('Searching clinical trials registers: guide for systematic reviewers'): https://doi.org/10.1136/bmj-2021-068791

Document your searches in bibliographic databases, trials registers and additional information sources.

Document your search steps while you conduct the searches, including:

- Names of all information sources used (e.g., databases, registers, search engines, reference list checking, etc.)
- Search dates for each information source
- Full search strategies for all databases, registers and websites, including any filters and limits used (e.g., study design filters, language and date limits, only exporting the first page of search engine results)
- Trials registers and websites: at minimum document the search terms and procedure that you employed (i.e. if you used combined searching and screening or if you used a reference management software).

STEP B2 Search — Optional tasks

Search two or more bibliographic databases and deduplicate the results before screening.

Using more than one database will increase the sensitivity of the search. Appropriate information sources depend on the topic, but also the relevant study designs.

If you are looking only for RCTs, the Cochrane Central Register of Controlled Trials (CENTRAL) is an appropriate second database in addition to MEDLINE/PubMed.

If you use a database other than CENTRAL, you can use validated search filters to find published trials, in particular if you are only interested in RCTs. If using filters built into search interfaces, you should understand how they function: depending on the database's default settings, not all the studies you are interested in may be found.

When using several search sources, you must expect overlap in the search results. You can import all your search results from each source and deduplicate the results. Alternatively, some supportive platforms (e.g., Rayyan, SR Accelerator) also include deduplication functions.

Resources:

Find information about databases for systematic searching: https://www.searchsmart.org/

Find validated search filters, e.g., The ISSG Search Filter Resource: https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home You can browse by study design, but you should also check the 'Filters within database interfaces and machine learning classifiers' section.

Guidance for search result deduplication:
Universität Bern, Removing duplicate record: https://ilias.unibe.ch/goto_ilias3_unibe_cat_2297227.html

Platforms with deduplication tools:
Rayyan: https://www.rayyan.ai/
The Systematic Review Accelerator (SRA): https://sr-accelerator.com/
Deduklick: https://www.risklick.ch/products/deduklick/

Use additional trials registers to identify ongoing or unpublished trials.

Further examples of trials registers:

- WHO International Clinical Trials Registry Platform (ICTRP) https://www.who.int/clinical-trials-registry-platform: Meta-registry that collects data from many national trials registers
- National trials registers, e.g., Australian New Zealand Clinical Trials Registry (https://www.anzctr.org.au), Swiss National Clinical Trials Portal (https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial).

Export the search results in bulk and screen them separately from the search.

Search results from trials registers can usually be exported as tables or lists, but importing into reference management software and/or screening platforms may require additional steps. For a small search result, this may not be efficient.

Consider using Excel for screening the results of trials registers instead of other screening platforms where importing is required.

STEP B3 | Study selection | abstract level — Essential tasks

Screen all identified titles/abstracts using your eligibility criteria from Step B1 to decide whether the published trials are relevant:

- **Results from the search in bibliographic databases (e.g., MEDLINE/PubMed)**
- **Results from the search from additional information sources (e.g., Google Scholar, references of SRs found in Part A).**

There are several options to choose from for screening your search results from a database:

- Review the titles/abstracts directly online (e.g., collect them directly in PubMed).
- Download a csv/Excel file with the search result and document which references you included.
- Download the search result (e.g., as a RIS file); import it into a reference manager (e.g., Endnote, Zotero) to select eligible studies there.
- Upload the search results into supportive screening software (e.g., Rayyan, Covidence; see Step B3 | optional tasks).

Refine eligibility criteria after screening a first batch (e.g., 30–50 abstracts), and add further details for clarity, if necessary.

Often, during the study selection process, additional questions arise regarding the eligibility criteria details. Therefore, it is helpful to refine your eligibility criteria at the start of the screening process, after you screen a first batch. Refining can mean adding more detail for clarity or adding illustrative examples to make screening decisions easier.

At minimum, search and screen the MEDLINE results and search engines directly in the platform (e.g., PubMed), i.e., through combined searching and screening, usually done by one person.

If you only search a single bibliographic database, you can screen the results directly on the platform you searched (e.g., PubMed). Read the abstracts in the results window and collect those that seem relevant in a marked list/Clipboard. Do not forget to document the number of initial retrieved records and the number of records you selected for full-text retrieval.

Screening of additional search sources depends on the method used: academic search engines usually have marked list and export functions; reference lists of publications can be checked manually in the full text or exported from a citation index.

If you search more than one information source that has an option for bulk exporting the search results, or if you work with a second screener, you should use a reference management software or a SR support platform (see Step B3 | optional tasks).

At minimum, search and screen the ClinicalTrials.gov results directly in the platform, i.e., through combined searching and screening, usually done by one person.

Combining searching and screening usually involves a more 'Google-like' approach, which may be iterative:

- Type 1–2 simple search terms into the search field.
- Screen all identified records in the search results.
- Save any relevant studies, followed by another round of searching and screening if necessary.

Search results in trial registries, like ClinicalTrials.gov, are different from bibliographic databases, such as MEDLINE/ PubMed: there is no abstract and no full text in PDF format.

The search results page of ClinicalTrials.gov shows information about the study title, interventions and conditions. Use this information to screen for relevant trials within the register. In the first step of literature selection, screen the titles and in the second step, screen the complete entry.

Do not forget to document the number of initial retrieved records and the number of full records you screened.

If you search more than one trials register or work with a second screener, you should export the search results as a table or list or into a reference management software (see **Step B3** | optional tasks).

Document the number of included and excluded titles/abstracts using the PRISMA flowchart in the report form.

Document the total number of abstracts from MEDLINE/PubMed and titles from Clinicaltrials.gov that you screened and the number of included and excluded titles/abstracts.

At the title/abstract level, it is not necessary to document the reasons for exclusion; it is enough to document the number of included and excluded titles/abstracts.

STEP B4 Study selection | full-text level — Essential tasks

Retrieve the full texts of all potentially relevant abstracts of published trials.

There are several ways to retrieve full texts of your potentially eligible references:

- Reference management software and screening software often provide a service to automatically retrieve full-text PDFs (of open-access articles).
- Search using the DOI: you will be able to retrieve all open-access articles and those available to you through your institution.
- Search on Google Scholar: if the PDF is available to you, you will see a direct link.
- Check on ResearchGate: authors often provide a download option of their article, or you can request a copy from the authors.
- Contact the corresponding author and ask for the full text.
- Ask a friend who works at another institution; they may have access to other publishers.

Screen all full texts using your eligibility criteria to decide whether to include the published trial. Record the main reason for excluding a reference.

Reasons for excluding a full-text reference should be documented. The easiest way is to align the exclusion reasons with your eligibility criteria and number the exclusion reasons accordingly (e.g., X1_ineligible population).

Review the whole entries of selected titles in Clinicaltrials.gov and decide whether the ongoing or unpublished trial is included. Record the main reason for excluding a reference.

Use the same reasons for excluding an ongoing or unpublished trial as for full texts of published trials. If further exclusion reasons are required, add them at this stage.

Document the number of included and excluded full-text articles/trials register entries using the PRISMA flowchart in the report form and include the reasons for excluding for each full-text reference.

Screening software automatically keeps track of screening decisions and reasons for exclusion.

STEP B3+4 Study selection | abstract and full-text level — Optional tasks

Screen the results from two or more bibliographic databases using supportive screening software (e.g., Rayyan, Covidence).

If you use two or more bibliographic databases in your search, you should merge and deduplicate the results in a reference management software. Alternatively, some supportive screening software can also automate deduplication (see Step A3 | optional tasks).

Supportive software can save resources through keyword highlighting, tagging functions and ranking the most relevant records with the use of artificial intelligence systems that aim to recognise prior inclusion or exclusion decisions.

Resources:

Examples for screening software:
Rayyan: https://www.rayyan.ai/
Covidence: https://www.covidence.org
DistillerSR: https://www.distillersr.com/products/distillersr-systematic-review-software
Eppi Reviewer: https://eppi.ioe.ac.uk/cms/Default.aspx?tabid=2914

Involve a second researcher (or more) and choose one of the following options:

- Mark unclear abstracts/full texts and discuss uncertain screening decisions with them.
- Use them to cross-check a subset of references: either a subset of abstracts/full texts (e.g., random 25%) or all excluded abstracts/full texts.
- Use them to screen all abstracts/full texts independently and discuss conflicting screening decisions.

Involving more researchers enhances the rigour and reliability of the review process, aiming at more accurate inclusion and exclusion of studies, reducing the risk of missing relevant studies. Different researchers may also bring varied expertise and perspectives into the research process.

If two or more researchers are involved:

- Conduct a screening pilot exercise with 30–50 abstracts (or 10% of retrieved records) and discuss uncertainties.
- Conduct a screening pilot exercise with 5–10 full texts (or 10%) and discuss uncertainties.

Screening pilot exercise: choose some records (e.g., 30–50 abstracts and 5–10 full texts), screen them independently and, afterwards, compare conflicting decisions. Justify the reasons for including versus excluding certain references and find consensus among the team. If the conflicts resulted from unclear eligibility criteria, consider refining the criteria. The aim of the pilot exercise is to get all involved researchers on the same page and discuss unclarities in the eligibility criteria.

How to proceed from here?

If you found **no ongoing, unpublished or published trials** that fulfil your eligibility criteria → Stop the literature review and go on with planning your own trial: Use the fact that there are no similar published triasl available as justification for your trial.

Report the results from your literature review in the study protocol of your own clinical trial.

If you found **no published, but only ongoing or unpublished trials** that fulfil your eligibility criteria → Stop the literature review and check the content and methodological aspects of the ongoing or unpublished trials to decide whether your planned trial should be modified to close an evidence gap.

Consult with your team or supervisor to determine whether the included ongoing or unpublished studies affect the decision to carry out your clinical trial or the methodological approach of your clinical trial.

If you move forward with your clinical trial: Report the results from your literature review in the study protocol of your clinical trial.

If you found **eligible published trials** similar to the clinical trial you are planning:

→ **Option 1**: proceed to **Step B5** : Assess the RoB of eligible trials.

→ **Option 2** (with no further time and other resources): stop the literature review with a **list of published trials** (without methodological quality assessment, data extraction or synthesis) and **re-evaluate the need** for your trial.

Consult with your team or supervisor to determine whether the included published trials affect the decision to carry out your clinical trial or the methodological approach of your clinical trial. Consider **modifying the research question of your trial if you are to proceed with it**.

If you move forward with your clinical trial: Report the results from your literature review in the study protocol of your clinical trial.

STEP B5 Methodological quality/Risk of Bias (RoB) Optional tasks

Assess the RoB of the included published trials using a validated and study design-specific assessment tool (e.g., RoB 2 Tool for RCTs).

Use RoB ratings in SRs: If your included published trials are also part of the well-conducted SRs that you found, use the RoB assessments from the existing SR.

Study design-specific assessments means that the appropriate tool must be chosen for the type of study design. An RCT could be assessed by the RoB 2 Tool, while non-randomised studies must be assessed by other tools (e.g., ROBINS-I).

If you included a high number of published trials: Consider doing RoB assessments only for a subset (e.g., the 3–5 most recent or largest trials, or those with the highest relevance to your review question).

Assessing the potential risk of bias of included studies is always beneficial: Although it is complex, the guiding questions in the RoB 2 tool will help you gain an in-depth understanding of important steps you must consider when planning your own new clinical trial, which aims to be at the lowest RoB possible.

Resources:

RoB 2 Tool for RCTs: https://www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2

ROBINS-I for observational studies (e.g., cohort studies): https://www.riskofbias.info/welcome/home/current-version-of-robins-i

If your resources permit, involve a second researcher (or more) and choose one of the following options:

- Use them to verify a subset of RoB ratings (e.g., random 25%).
- Use them to verify all RoB ratings and resolve conflicts by discussion.
- Use them to assess the RoB independently for all included studies and discuss conflicting assessments.

Involving more researchers enhances the reliability and may reduce bias in the critical appraisal of studies. Subjective judgement may influence a single reviewer's assessment. By involving a second researcher, different perspectives are considered and bias in judgement can be mitigated.

If you involve a second researcher to verify your assessment decisions, highlight relevant paragraphs in the texts so that they can find the relevant content more easily.

How to proceed from here?

If you found **only high RoB trials** that answer your review question → Stop the literature review and proceed with planning your own trial: use the fact that there are only high risk of bias studies to justify your trial.

Report the results from your literature review in the study protocol of your own clinical trial.

If you found **trials with varying RoB ratings**

→ **Option 1**: proceed to **Step B6**: Data extraction.

→ **Option 2** (with no further time and other resources): stop the literature review with **a list of critically appraised published trials** (without data extraction or synthesis) **and re-evaluate the need** for your trial.

If you decide, based on the results from your literature review, that your trial is needed, report the results from your literature review in the study protocol of your clinical trial. You can use the list of critically appraised published trials to identify gaps in the literature and to justify your trial.

If you found **only low RoB trials**

→ **Option 1**: proceed to **Step B6**: Data extraction.

→ **Option 2** (with no further time and other resources): stop the literature review with **a list of critically appraised published trials** (without data extraction or synthesis) **and re-evaluate the need** for your trial.

Finding low RoB studies that addressed your review question is an indicator for sufficient evidence in the field. Therefore, your planned trial may not be necessary in its current form. Consider **modifying the research question of your trial if you are to proceed with it.**

STEP B6 Data extraction

Optional tasks

Prepare a data extraction table with the items of interest.

The data extraction table (often called data extraction form) may group the data to extract according to the PICO format.

Extract only data for the most important outcomes and characteristics (PICO elements).

Often the following data items are extracted: study characteristics (date of conduct, study design, setting, patient population, intervention, comparator) and outcome data (outcomes measured, relevant results and subgroup results), along with identifying details for each trial (publication reference or study identifier).

If your included previous trials were included in the well-conducted SRs that you found, consider extracting the results/summaries directly from the existing SR instead of from the reports of the published studies.

If your resources permit, involve a second researcher (or more):

- Conduct a pilot exercise with a small number of studies (1–3 studies) to test and refine the data extraction form.

Choose one of the following options:

- Use them to check data extractions of a subset of studies (e.g., random 25%).
- Use them to check data extractions of all studies to further minimise bias if resources permit.

If you involve a second researcher who will check your data extractions, highlight relevant paragraphs in the texts so that they can find relevant content more easily.

Consider using data extraction software. This could help provide examples for each item of interest, decrease the level of unnecessary extracted details and allow a consistent extraction among the team members.

You could also use a spreadsheet and share it through a platform (e.g., MS Teams or Google Documents) so that everyone can edit it at the same time.

Resources:

Software to screen and extract data:

Covidence: https://www.covidence.org/
DistillerSR: https://www.distillersr.com/products/distillersr-systematic-review-software
Eppi Reviewer: https://eppi.ioe.ac.uk/cms/Default.aspx?tabid=2914

Software that aims to semi-automate data extraction:

Dextr: https://www.niehs.nih.gov/research/atniehs/labs/iha/dextr
RobotReviewer: https://www.robotreviewer.net/

How to proceed from here?

→ **Option 1**: proceed to **Step B7**: Synthesis

→ **Option 2**: (with no further time and other resources): stop the literature review with the **data extractions of included published trials** (without synthesis).

Report the results from your literature review in the study protocol of your clinical trial. You can use the detailed information that you extracted from the studies. e.g., as a basis for sample size calculations or to inform decisions on methodological aspects of your own clinical trial.

STEP B7 Synthesis — Optional tasks

Synthesise the results of eligible trials narratively and present the result in tables.

Presenting relevant data into tables makes it easier to identify similarities and differences between the included trials, providing a clearer overview of 'what is known' and 'what remains unclear or missing' regarding the topic of interest. It will also facilitate the narrative synthesis of the results.

Structure the synthesis in a way that is most useful to highlight the gaps in the evidence base, i.e., by outcome, by interventions or by comparisons (if you have multiple comparisons).

Resources:

The Synthesis Without Meta-analysis (SWiM) guideline provides further information on narrative synthesis: https://swim.sphsu.gla.ac.uk/

If the data and your resources permit, consider performing a meta-analysis (MA) to synthesize the results of eligible trials quantitatively:

- Involve a researcher with statistical training in MA (e.g., statistician) to plan and conduct the MA, and decide which data and outcomes are appropriate.
- Use the findings from your MA to best inform the sample size calculation for your new clinical trial.

Establish whether MA is a valid option for all outcomes of interest, regarding the type of data (continuous versus dichotomous data), identified trials (population and study characteristics), and significance for your future steps. You can also choose the most relevant outcomes for your topic.

Resources:

Chapter on conducting MA in the Cochrane Handbook: https://training.cochrane.org/handbook/current/chapter-10

Software to conduct the MA: e.g., STATA, R, SAS, RevMan.

Assess the certainty of evidence for the most important outcomes, e.g., by using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

- Involve a researcher with GRADE-training to assess the certainty of evidence.
- If possible, involve a second researcher to verify the correctness and plausibility of all ratings.

The overall strength of evidence for an effect can be graded. This approach enables the consideration of factors beyond study design and how they may influence recommendations for both practice and research. Assessing the certainty of evidence will help you to identify critical or important outcomes lacking sufficient data for conclusive judgments.

Resources:

Check the GRADEpro website for additional information related to certainty of evidence assessment: https://www.gradepro.org/

GRADE Training material: https://training.cochrane.org/introduction-grade

Assess the applicability of included trials' results and the purpose (pragmatic vs. explanatory) of your planned trial using the PRagmatic-Explanatory Continuum Indicator Summary (PRECIS-2) tool.

An assessment of the purpose of previous trials can help you to better define the existing evidence gap.

The assessment of the purpose of your planned trial will help you to make design choices concordant with your trial's purpose.

Resources:

Information on PRECIS-2: https://www.precis-2.org/

How to proceed from here?

If you found **sufficient evidence** of high quality that answers your review question

→**Re-evaluate the need for your trial**.

Finding sufficient evidence that addressed your review question means that your planned trial may not be necessary in its current form. Consider **modifying the research question of your trial if you are to proceed with it**.

If you found **insufficient evidence**

→**Start your own clinical trial** and justify it using the fact that there is insufficient evidence available.

Report the methods and results from your literature review in the study protocol of your own clinical trial:

- Mention that you conducted a literature review using this guidance (and cite the guidance) and briefly describe the methods of your literature review.
- Report the synthesis of the results of the included trials to characterise the knowledge gap regarding your review question and to provide justification for your own clinical trial.
- Highlight your trial purpose, its relevance and its novelty; include a brief description of your search strategy and the characteristics of the included trials (e.g., number of included trials, their methods and results, limitations of included trials, including the RoB if assessed).

Optional:

Add the completed report form with all documentations as an appendix to the study protocol for your planned trial or to a proposal.

Publish the findings of your literature review as a separate piece of research (e.g., in a preprint repository, peer-reviewed journal).

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