FIVE KEY STEPS FOR YOUR LITERATURE REVIEW

1 Develop a P.I.C.O Table

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Once you have a research question, use a PICO table to guide the literature review. You will need a PICO table for each indication of your device.

P	I	C	O
Patient, population	**Intervention**	**Comparison**	**Outcomes**
What are the characteristics of the patients or population? What is the disease or condition?	What do you want to do with these patients (e.g., treatment)	What is the alternative to the intervention?	What are the clinically relevant safety and performance outcomes?

Hint: Use indication and intended treatment group to guide you

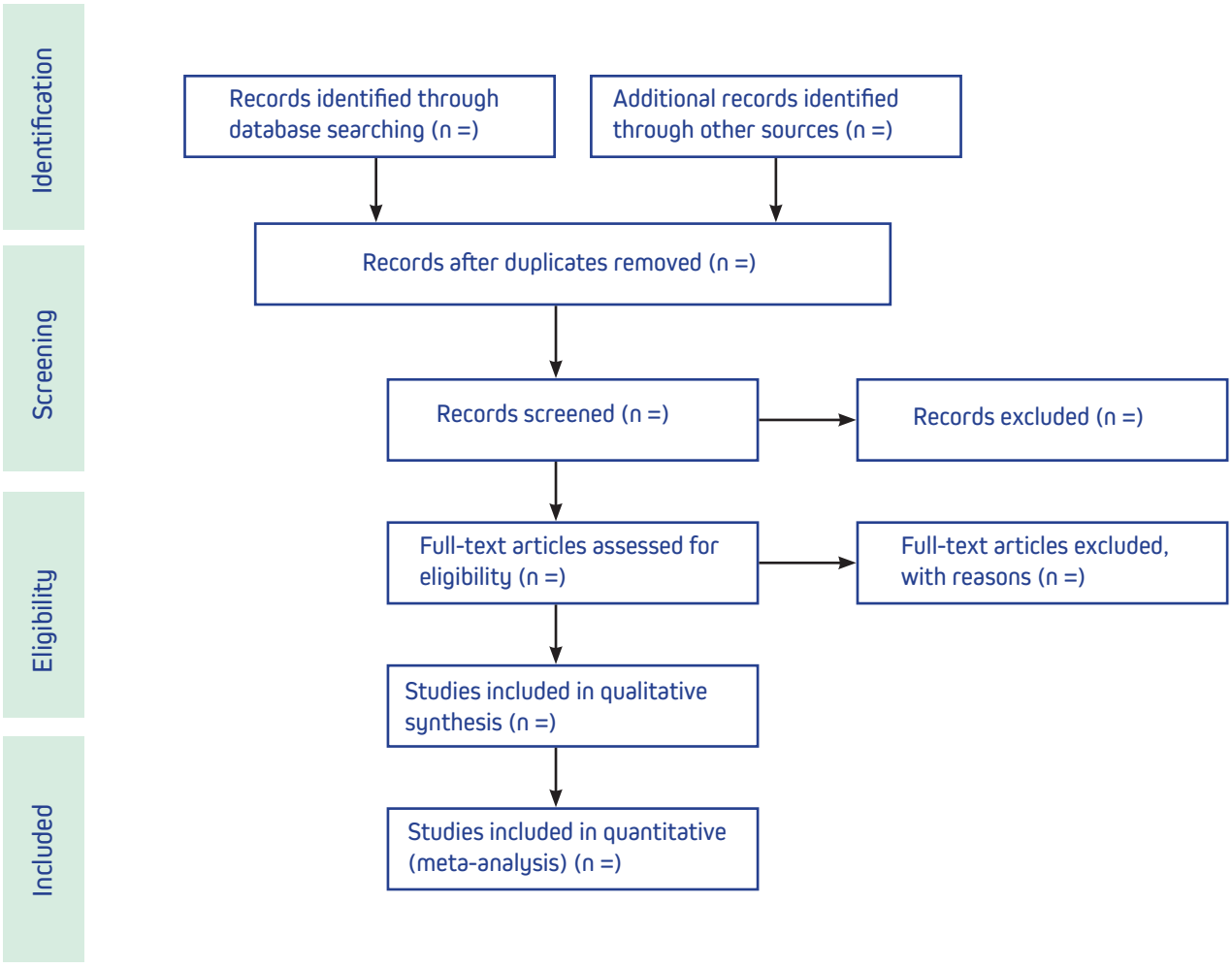
2 Develop a Search Strategy

- Use your PICO table to help generate search terms
- If possible, engage a librarian (for more information visit https://www.mlanet.org/)
- Use synonyms, singular/plural forms, verbal forms, adjectives, different spellings
- Be aware of classification terms used by databases
- Consider using Boolean search operators to broaden or narrow your search: 'AND', 'OR', 'NOT'
- Consider using more than one database (e.g., Medline & Embase)
- Visit PubMed for a tutorial on conducting a search!

(https://www.nlm.nih.gov/bsd/disted/pubmedtutorial/020_010.html)

3 Produce a PRISMA Flow Chart

The flow chart depicts the flow of information through the different phases of a literature review.



Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

A PRISMA flow chart maps out the number of records identified, included and excluded, and the reasons for exclusions.

To develop a PRISMA flow chart you will need to:

- Screen your articles against predetermined exclusion criteria
- Record the reason for exclusion when a study is excluded
- For more information visit www.prisma-statement.org

Common exclusion criteria include:

- Not device of interest
- Non-clinical study
- No safety or performance data
- Review article with no original data
- Non-English
- Out of date range
- Non peer reviewed article
- Conference abstract
- Duplicate articles

4 Appraise and weight your clinical studies

Evaluators should appraise each individual article in terms of its contribution to the evaluation of the clinical performance and safety of the device.

- Uncertainty arises from two sources:
  - the methodological quality of the data
  - relevance of the data to the evaluation of the device

- Consider using the Appraisal Criteria for Suitability table and the Appraisal Criteria for Data Contribution Tables from MEEDEV 2.7,1 Rev. 3 Appendix D – A Possible Method of Appraisal (end page)

- Also consider stratifying the studies according to their study design. Consider using the Oxford Centre for Evidence-Based Medicine (OCEBM)'s guidance for establishing level of evidence (https://www.cebm.net/2016/05/ocebm-levels-of-evidence/)

5 Extract safety and/or performance outcome data

Make sure to extract PICO data

- Goal is to demonstrate compliance with each of the Essential Requirements pertaining to the clinical performance and safety of the device
- Any residual risks will need to be further evaluated

Consider using the Appraisal Criteria for Suitability and Data Contribution

Sample Appraisal Criteria for Suitability

Suitability Criteria	Description		Grading System
Appropriate device	Were the data generated from the device in question?	D1 D2 D3	Actual device Comparable device Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1 A2 A3	Same use Minor deviation Major deviation
Appropriate patient group	Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1 P2 P3	Applicable Limited Different population
Acceptable report/ data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 R2 R3	High quality Minor deficiencies Insufficient information

Sample Appraisal Criteria for Data Contribution

Data Contribution Criteria	Description		Grading System
Data source type	Was the design of the study appropriate?	T1 T2	Yes No
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1 O2	Yes No
Follow up	Is the duration of follow-up long enough to assess duration of treatment effects and identify complications?	F1 F2	Yes No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1 S2	Yes No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 C2	Yes No

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Prisma Flow Chart

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