Special Communication | **Statistics and Research Methods**

Introducing the Library of Guidance for Health Scientists (LIGHTS)
A Living Database for Methods Guidance

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Abstract

IMPORTANCE Improving methodological quality is a priority in the health research community. Finding appropriate methods guidance can be challenging due to heterogeneous terminology, poor indexing in medical databases, and variation in formats. The Library of Guidance for Health Scientists (LIGHTS) is a new searchable database for methods guidance articles.

OBSERVATIONS Journal articles that aim to provide guidance for performing (including planning, design, conduct, analysis, and interpretation), reporting, and assessing the quality of health-related research involving humans or human populations (ie, excluding basic and animal research) are eligible for LIGHTS. A team of health researchers, information specialists, and methodologists continuously identifies and manually indexes eligible guidance documents. The search strategy includes focused searches of specific journals, specialized databases, and suggestions from researchers. A current limitation is that a keyword-based search of MEDLINE (and other general databases) and manual screening of records were not feasible because of the large number of hits (n = 915 523). As of September 20, 2022, LIGHTS included 1246 articles (336 reporting guidelines, 80 quality assessment tools, and 830 other methods guidance articles). The LIGHTS website provides a user-oriented search interface including filters for study type, specific methodological topic, research context, guidance type, and development process of the guidance. Automated matching of alternative methodological expressions (eg, enter *loss to follow-up* and find articles indexed with *missing data*) enhances search queries.

CONCLUSIONS AND RELEVANCE LIGHTS is a peer-supported initiative that is intended to increase access to and use of methods guidance relevant to health researchers, statisticians, methods consultants, methods developers, ethics boards, peer reviewers, journal editors, and funding bodies.

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Introduction

Systematic reviewers and meta-scientists often lament limitations in the methodological quality of health research. They frequently identify the need for better adherence to existing methods guidance,[1,2] improved methods guidance,[3,4] and stricter quality control through ethics committees,[5] funding agencies,[5,6] peer reviewers,[7] and journal editors.[4,6,8]

From the perspective of health researchers, however, finding appropriate and trustworthy methods guidance is not easy. Challenges include large variation in terminology,[9] lack of methodological index terms (**Box**), inconsistent use of index terms in MEDLINE,[9] and unstructured abstracts.[9] These challenges make it difficult for health researchers and information specialists to

perform precise and sensitive searches for methods guidance (eg, when performing a systematic review of methods guidance[10]) and hinder the dissemination and uptake of methods guidance.

One approach to increase the access to a specific body of literature is to create a specialized database. Successful examples include the database of the Enhancing the Quality and Transparency of Health Research (EQUATOR) network for reporting guidelines,[11] the Online Resource for Research in Clinical Trials (ORRCA) database for recruitment and retention research,[12] and the Core Outcome Measures in Effectiveness Trials (COMET) Initiative database for core outcome sets.[13] Such databases, if comprehensive, up-to-date, and easy to use, can render complex multidatabase searches unnecessary, save researchers time and resources, and increase both sensitivity and precision of systematic searches. In addition, specialized databases allow the use of content-specific indexing systems and search features. A database specifically for methods guidance was not available.

Herein, we introduce the Library of Guidance for Health Researchers (LIGHTS), a new searchable database for methods guidance in health research involving humans and human populations (ie, excluding basic and animal research). LIGHTS aims to improve the findability of methods guidance articles and revoke the burden of searching for methods guidance articles in MEDLINE, Embase, Google, and other general databases; to provide a comprehensive and up-to-date inventory of methods guidance; and, ultimately, to improve the uptake of methods guidance and the methodological quality of health research.

Methods

This Special Communication explains the development and maintenance of LIGHTS. Key methods include a diverse team of methodologists; explicit eligibility criteria for methods guidance; a regularly updated, multifaceted literature search; a process for eligibility assessment; a system for indexing the methods guidance; and a freely accessible online search portal (www.lights.science).[14]

Development Team

The development team consists of a core group including methods experts and information specialists (J.H., H.E., G.H.G., M.B., and S.S.) and an extended group of methodologically trained health researchers and students who work in a variety of areas of health research.[14] We do not involve patients or members of the public in formulating the research objectives, designing the review, interpreting the results, or drafting the manuscript.

Eligibility Criteria

A document is eligible for LIGHTS if it satisfies all of the following criteria:

1. It is a peer-reviewed journal article (we may broaden this criterion in future versions of LIGHTS).
2. The document explicitly expresses the aim to provide guidance on a methodological topic. This could be stated in the journal section or article type (eg, *PLOS Medicine*'s "Guidelines and Guidance" or *Statistics in Medicine*'s "Tutorials in Biostatistics") or the article's title, abstract, or objective (typically provided in the abstract or at the end of the introduction). We accept any alternative expression for guidance (eg, guidelines, guide, step-by-step explanations, common mistakes and solutions, best practice statement, recommendations, tutorial, methodological framework, and other terms[9]).
3. The article is relevant for health-related research in humans and human populations as per judgment of the members of the LIGHTS team. We include guidance for any type of clinical or epidemiological research, including guidance for primary studies but also meta-analyses, health economics, implementation science, or clinical practice guidelines. We include methods guidance for any phases of a health research project, including planning, design, conduct, analysis, interpretation, and reporting but also postpublication considerations such as quality assessment and implementation.

Box. Selected Methodological Topics for Which MEDLINE Provides No Specific Index Terms

- Methods guidance
- Subgroup analysis
- Applicability
- Diagnostic test accuracy
- Meta-research
- Prognostic research
- Literature search
- Causal inference
- Directed acyclic graphs
- Random error
- Qualitative data analysis
- Sensitivity analysis
- Hypothesis tests
- Individual participant data
- Familywise error
- Blinding
- Missing data

Articles are excluded based on the following criteria:

1. The goal of the article is to propose a new method rather than recommend best research practice (those that suggest both a new method and best research practice may be eligible).
2. Guidance is focused on research content (eg, research priorities, interventions, or outcome variables) rather than research methods.
3. The article is a meta-study, simulation study, or other methodological study (unless they also explicitly state the aim to provide guidance).
4. The article is a methodological case study (eg, a "lessons learned" article in which primary researchers report on their experience with a specific methodology in a specific study).
5. The article is a research letter, editorial, or other type of commentary that does not contain original guidance (eg, for lack of a specific article type, editors may choose a commentary format for methods guidance).
6. The article illustrates the application of methods guidance to a specific study or medical area (eg, CONSORT applied to eHealth interventions[15]) without suggesting a modification.
7. The article describes a protocol for the development of methods guidance.

Literature Search

As of September 20, 2022, our search strategy consists of 5 sources (**Figure**):

1. A recent meta-study on methods guidance articles.[9] This search was limited to specific journals indexed in MEDLINE in 2020 and yielded 105 methods guidance articles.
2. General and methods-specific journals, sections, or article types designed specifically for methods guidance without time limit (**Table 1**).[16-25] Since MEDLINE does not include index terms for sections and article types of individual journals, we searched—manually or supported through web-scraping software[26]—sections denoting methods guidance on the websites of the journals.
3. Screening of databases specialized in methodological topics (Table 1).[11,12]
4. Screening of reference lists of reviews of the methods literature that included methods guidance (eg, statistical guidance on regression analysis[27]).
5. Suggestions from researchers in and outside our professional network.

A keyword-based search of MEDLINE and potentially other general databases was not feasible. In collaboration with an information specialist experienced in clinical research methods (H.E.), we have been working on a MEDLINE search strategy through the Ovid interface (eAppendix 1 in Supplement 1). Despite many iterations of systematic development (based on a seed sample of 1184 eligible methods guidance articles), the search yielded a very large number of records (915 523) that was not feasible to screen. The supplemental content shows the variant of the search that yielded the smallest number of records, included a time limit (2010 or later), and retrieved 77.8% of the seed

Figure. Process for Article Search, Eligibility Assessment, and Indexing
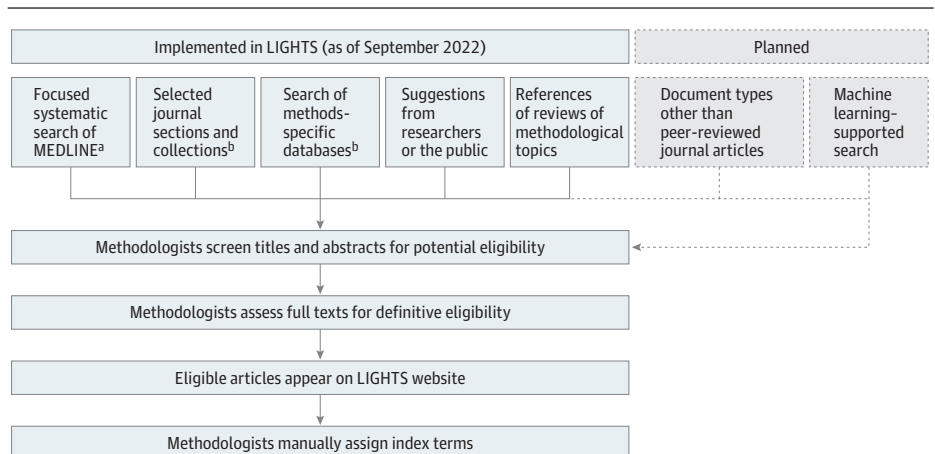
Abbreviation: LIGHTS indicates Library of Guidance for Health Scientists.

[a] See Hirt et al.[9]

[b] Table 1 provides a list of journal websites and databases that were screened.

sample. We tried other, more elaborate versions of the search strategy that retrieved a larger proportion of seed articles but at the cost of a substantial increase in the number of records because of unspecific search terms such as *key concepts*, *introduction to*, or *standards*.

Eligibility Assessment

Researchers of the core group apply the eligibility criteria to titles and, if available, abstracts of potentially eligible articles, resulting in a list of articles for full-text screening. Members of the extended group then select articles, preferably those matching their methodological expertise, and apply the eligibility criteria to the full text. To support the eligibility assessment, they collect a verbatim quotation expressing the article's aim to provide methods guidance. This quotation appears in LIGHTS as a subtitle. A second methodologist double-checks the full-text eligibility assessment, discusses disagreements, and, if necessary, approaches a third team member for arbitration. An instruction manual provides detailed explanations for the eligibility assessment (eAppendix 2 in Supplement 1).

Indexing Process

The systematic indexing of guidance articles serves 2 purposes: to group together guidance articles on the same topic and to facilitate a synonym search by linking together alternative expressions for the same methodological concept. Using a shared spreadsheet, researchers assign to each included guidance document 1 or more index terms for each of the following 5 categories:

1. Study type (eg, randomized controlled trial, case-control study, scoping review)
2. Methodological topic (eg, missing data, causal inference, patient-reported outcomes)
3. Medical context (eg, neurology, public health, infectious diseases)
4. Guidance type (eg, guidance for study planning, analysis, or reporting)
5. Guidance development process (eg, consensus study, meta-research, user testing)

We collect and organize the index terms in a controlled vocabulary[28] that we curate in a separate spreadsheet. We arrange the index terms in a hierarchical structure and, for each index term, record alternative terms (abbreviations, variations, synonyms, and opposites), the preferred term (ie, the term we use for indexing if ≥2 alternative terms are available), related terms, and clarifying comments following established standards for taxonomy data.[29] We plan to develop the emerging vocabulary into a separate resource (eg, for information specialists who are designing a search strategy for a systematic review of a methodological topic[10]) and make it accessible through the LIGHTS website.

Table 1. Methods-Specific Journal Sections, Article Types, Article Series, and Databases Screened for Methods Guidance

Resource	Type of resource	No. of records[a]
BMJ research methods & reporting[16]	Article type	78
PLoS Med guidelines and guidance[17]	Article type	63
Wiley Online Library Statistics in Medicine tutorials in biostatistics[18]	Article type	133
JAMA User's Guide to the Medical Literature[19]	Collection	45
Ann Intern Med research and reporting methods[20]	Article type	89
BMJ statistics notes[21]	Series	68
PLoS ten simple rules[22]	Series	102
STRATOS initiative[23]	Guidance development group	40
J Clin Epidemiol GRADE guidance[24]	Guidance development group	33
EQUATOR Network library for health research reporting[11]	Collection of reporting guidelines	527
ORRCA[12]	Collection of articles related to recruitment and retention	6012
TRIAL FORGE[25]	Guidance development group	3

Abbreviations: EQUATOR, Enhancing the Quality and Transparency of Health Research; GRADE, Grading of Recommendations Assessment, Development and Evaluation; ORRCA, Online Resource for Research in Clinical Trials; STRATOS, Strengthening Analytical Thinking for Observational Studies.

[a] As of June 27, 2022.

A second team member double-checks the indexing. The 2 team members discuss disagreements and, if necessary, approach a third team member for arbitration. The instruction manual provides detailed explanations for the indexing process (eAppendix 2 in Supplement 1).

Results

As of September 20, 2022, LIGHTS (www.lights.science) included 1246 articles (336 reporting guidelines, 80 quality assessment tools, and 830 other methods guidance articles). Between August 1 and 31, 2022, the median number of unique visitors per day was 444 (range, 105-731).

The search interface provides 5 search facets corresponding to categories we use for indexing. Three additional search facets are based on the following metadata that we retrieved from the publisher's website, MEDLINE, or another bibliographic source: date of publication, authors (all authors), and journal. **Table 2** shows the most frequent categories for each of the 8 search facets as of September 20, 2022. The search features include automated synonym mapping. For instance, if users enter *loss to follow-up* (one of several alternative terms for missing data), LIGHTS will also show all guidance articles indexed with *missing data*, irrespective of whether the article's title, abstract, or keywords include the term *loss to follow-up*.

Discussion

LIGHTS is a new open-access database curated by researchers working in different areas of health research that is optimized for health researchers, including those concerned with assessing the quality of study proposals and reports, developers of methods guidance, and learners and educators in health research. We are planning to update LIGHTS every 6 months.

LIGHTS as a Resource

For Health Researchers

LIGHTS offers guidance for investigators at any stage of a study. In early stages, guidance for clarifying the need for new studies may be particularly useful (eg, for deciding whether a new systematic review is needed[30]), as well as guidance on methodological concepts (eg, Prognosis Research Strategy [PROGRESS] framework for prognostic research[31]), types of adaptive trial designs,[32,33] guidance for specific design considerations (eg, Difference Elicitation in Trials [DELTA^2] guidance for sample size calculation[34]), and reporting guidelines that often provide a well-structured overview of the key steps of a study (eg, a randomized clinical trial[35] or a systematic review[36]). Over the course of a study, other types of guidance may become relevant, including guidance on trial process organization (eg, patient recruitment[37] or data collection[37]), specific analytic issues (eg, handling missing data[38]), presenting results (eg, creating figures[39]), interpreting the strength on evidence (eg, regarding a prognostic factor[40,41]), and structuring study reports (eg, of a randomized clinical trial[35] or a systematic review[36]).

For Assessors of Study Quality

Funding agencies, ethics committees, journal editors, peer reviewers, systematic reviewers, meta-researchers, and others who assess the quality of health research can use LIGHTS to identify suitable quality assessment tools (eg, to assess risk of bias in a randomized clinical trial[42] or the credibility of a subgroup claim made in a meta-analysis[41]). LIGHTS includes quality assessment instruments for various types of studies.

For Developers of Methods Guidance

Developers of methods guidance can use LIGHTS to identify previous methods guidance. Reviewing previous guidance helps avoid unnecessary duplication (eg, we are aware of >30 checklists for

assessing the credibility of subgroup analyses[43]). In addition, review of previous guidance can identify experts in methodological areas, for example, to form an expert panel for a consensus study. Finally, LIGHTS provides a platform to disseminate newly developed methods guidance. Future

Table 2. Content of LIGHTS and 4 Most Frequent Categories of Each Search Facet

Search facet by most frequent categories[a]	Frequency, No. (%) (N = 1246)
Study type	
Nonspecific	293 (24)
Randomized controlled trials	206 (17)
Observational studies	128 (10)
Systematic reviews	98 (8)
Methodological topic (other than study type)[b]	
Nonspecific	364 (29)
Bias and confounding	44 (4)
Certainty in evidence	38 (3)
Heterogeneity of effects	27 (2)
Guidance type[b]	
Conduct (broad)	534 (43)
Reporting	336 (27)
Conceptual overview (broad)	200 (16)
Analysis	123 (10)
Development process[b]	
Not reported	447 (36)
Stakeholder involvement	237 (19)
Consensus process	216 (17)
Systematic review of methodological literature	152 (12)
Medical context[b]	
Nonspecific	648 (52)
Psychiatry or psychology	28 (2)
Oncology	24 (2)
Surgery	19 (2)
Publication date	
2020s	316 (25)
2010s	726 (58)
2000s	124 (10)
1990s	45 (4)
Author[c]	
Altman D	107 (9)
Guyatt G	82 (7)
Moher D	64 (5)
Schünemann H	61 (5)
Journal[c]	
BMJ	182 (15)
J Clin Epidemiol	161 (13)
Stat Med	135 (11)
Ann Intern Med	50 (4)

Abbreviation: LIGHTS indicates Library of Guidance for Health Scientists.

[a] As of September 20, 2022.

[b] Based on manual indexing.

[c] Based on metadata, for example, from the publisher website or MEDLINE/PubMed.

features could include a registry for planned guidance development projects and feedback measures such as access statistics and user ratings.

For Health Research Learners and Educators

LIGHTS includes guidance for users at various levels of familiarity with a methods topic ranging from introductions to expert level. Many guidance documents start with conceptual overviews often written by leading experts, sometimes supported by systematic reviews and consensus panels, and may therefore provide excellent introductions on a given methodological topic.[31,44] Another guidance format that may be useful for learners is "challenges and solutions."[45,46] Those articles, ideally informed by meta-research, can direct learners and educators to the most relevant methodological issues. Another group of users who may appreciate the varying levels of difficulty are methods consultants who are looking for methods guidance that matches their client's level of understanding.

Relationship of LIGHTS With Other Databases

The EQUATOR network provides a searchable library for reporting guidelines.[11] Many reporting guidelines qualify for inclusion in LIGHTS. What may seem unnecessary overlap has a number of advantages. First, often a specific study design (eg, randomized clinical trial[35]) defines the scope of a reporting guideline. We anticipate that users of LIGHTS will appreciate finding both reporting and nonreporting guidance on the same topic in a common database. Second, reporting guidelines often include consensus-based definitions and terminologies that help us calibrate our controlled vocabulary. Third, reporting guidelines, although designed primarily to support the writing of manuscripts, often provide a reasonable step-by-step structure for those who are planning research projects. Fourth, including reporting guidelines in LIGHTS can help promote their dissemination because LIGHTS may be attracting a broader audience (in particular those who are in an early stage of a research project).

There is little overlap of LIGHTS with other methods-specific databases (Table 1). For instance, the ORRCA database for recruitment and retention research includes more than 6000 articles, but only 20 currently qualify as methods guidance eligible for LIGHTS. This small proportion illustrates the potential value of LIGHTS: most methods articles do not aim to provide guidance.

Other methods-specific databases can serve as models for LIGHTS. For instance, the COMET database is based on a machine learning–supported search process.[47] We are currently developing a similar approach for LIGHTS. SAGE research methods—a website primarily for guidance books available from SAGE Publishing, therefore not overlapping with LIGHTS—provide a tool termed a *methods map*[48] through which users can browse the vocabulary used for indexing books. Similarly, we are planning to provide access to the vocabulary of LIGHTS.

Limitations

The main limitation of LIGHTS is that, for reasons of feasibility, it is currently not based on a systematic search of MEDLINE, Embase, and potentially other general databases. Machine learning—specifically learn-to-rank models—may provide a solution to facilitate the screening of the very large data sets produced by keyword-based searches for methods guidance articles.[47]

We restricted our focus to journal articles to avoid increasing the complexity of this project. We have plans for gradually broadening the inclusion criteria. For instance, we are considering including guidance documents provided by regulatory authorities such as the US Food and Drug Administration[49] and the European Medicines Agency.[50] We excluded textbooks because they are organized in other catalogs and are typically much broader in scope than journal articles. Individual book chapters, while sometimes comparable in scope, are difficult to search and would have greatly complicated our search process.

Users of LIGHTS will often find multiple guidance documents for a given research task. Deciding which guidance documents are most appropriate can be a challenge. Although the search facets in

LIGHTS offer potential directions (eg, users may prefer guidance based on a systematic development process or those developed by prominent authors), formal quality criteria for methods guidance are currently not available. To inform the development of such criteria, more research is needed to better understand when a guidance document can be considered more or less appropriate.

For a small number of guidance documents, users will find different versions such as the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guidelines from 2009 and 2020[36] or the Cochrane risk of bias tool, versions 1.0 and 2.0.[42] For now, we suggest keeping both updated guidance and previous versions, assuming that users of LIGHTS will naturally prefer the most recent version. If the number of updated guidance documents in LIGHTS increase—most guidance articles are one-time initiatives—we will develop a system for labeling different versions.

Future Directions

We conceptualized LIGHTS as a living resource and will implement improvements depending on available funding and suggestions from users. Our current plans include studying the suitability of machine learning to support the search for eligible methods guidance, developing a user interface for our controlled vocabulary, and including nonjournal articles (eg, methods guidance published by the US Food and Drug Administration[49] or European Medicines Agency).[50]

As an area for future research, we suggest the development of formal guidance both for developing and reporting methods guidance. Such guidance would include recommendations for reviewing the methodological literature specifically to inform method guidance, for selecting and involving key stakeholders in the guidance development process, and for presenting methods guidance that optimizes researcher-friendliness and findability (eg, label it as "methods guidance" and provide a clear objective in a structured abstract.[9]

Conclusions

LIGHTS is a new peer-supported initiative and a publicly available database that may increase access to and promote the use of existing methods guidance and inform the development of future guidance. LIGHTS is intended to support health researchers in making methodological choices, support research evaluators in identifying methodological standards or quality assessment tools, help developers of methods guidance identify existing guidance, and serve as a resource for health research students, science educators, and methods consultants.

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REFERENCES

1. Lohner S, Gryaznov D, von Niederhäusern B, et al. Reporting quality of trial protocols improved for non-regulated interventions but not regulated interventions: a repeated cross-sectional study. *J Clin Epidemiol*. 2021;139:340-349. doi:10.1016/j.jclinepi.2021.05.011

2. Arnup SJ, Forbes AB, Kahan BC, Morgan KE, McKenzie JE. The quality of reporting in cluster randomised crossover trials: proposal for reporting items and an assessment of reporting quality. *Trials*. 2016;17(1):575. doi:10.1186/s13063-016-1685-6

3. Carrasco-Labra A, Devji T, Qasim A, et al. Serious reporting deficiencies exist in minimal important difference studies: current state and suggestions for improvement. *J Clin Epidemiol*. 2022;150:25-32. doi:10.1016/j.jclinepi.2022.06.010

4. Hardwicke TE, Salholz-Hillel M, Malički M, Szűcs D, Bendixen T, Ioannidis JPA. Statistical guidance to authors at top-ranked journals across scientific disciplines. *Am Stat*. Published online December 1, 2022. doi:10.1080/00031305.2022.2143897

5. Pirosca S, Shiely F, Clarke M, Treweek S. Tolerating bad health research: the continuing scandal. *Trials*. 2022;23 (1):458. doi:10.1186/s13063-022-06415-5

6. Page MJ, Altman DG, McKenzie JE, et al. Flaws in the application and interpretation of statistical analyses in systematic reviews of therapeutic interventions were common: a cross-sectional analysis. *J Clin Epidemiol*. 2018; 95:7-18. doi:10.1016/j.jclinepi.2017.11.022

7. Chauvin A, Ravaud P, Baron G, Barnes C, Boutron I. The most important tasks for peer reviewers evaluating a randomized controlled trial are not congruent with the tasks most often requested by journal editors. *BMC Med*. 2015;13:158. doi:10.1186/s12916-015-0395-3

8. Agarwal A, Johnston BC, Vernooij RWM, et al. Authors seldom report the most patient-important outcomes and absolute effect measures in systematic review abstracts. *J Clin Epidemiol*. 2017;81:3-12. doi:10.1016/j.jclinepi.2016.08.004

9. Hirt J, Ewald H, Lawson DO, Hemkens LG, Briel M, Schandelmaier S. A systematic survey of methods guidance suggests areas for improvement regarding access, development, and transparency. *J Clin Epidemiol*. 2022;149: 217-226. doi:10.1016/j.jclinepi.2022.05.005

10. Gentles SJ, Charles C, Nicholas DB, Ploeg J, McKibbon KA. Reviewing the research methods literature: principles and strategies illustrated by a systematic overview of sampling in qualitative research. *Syst Rev*. 2016;5 (1):172. doi:10.1186/s13643-016-0343-0

11. The EQUATOR Network. Enhancing the Quality and Transparency of Health Research. Library for health research reporting. Accessed September 13, 2021. https://www.equator-network.org/

12. ORRCA. Online Resource for Research in Clinical Trials. Welcome to ORRCA. Accessed January 22, 2020. https://www.orrca.org.uk/Home/Index/

13. COMET. Core Outcome Measures in Effectiveness Trials Initiative. Accessed July 3, 2019. https://www.comet-initiative.org/

14. LIGHTS. Library of Guidance for Health Scientists. 2022. Accessed August 9, 2022. https://lights.science

15. Baker TB, Gustafson DH, Shaw B, et al. Relevance of CONSORT reporting criteria for research on eHealth interventions. *Patient Educ Couns*. 2010;81(suppl):S77-S86. doi:10.1016/j.pec.2010.07.040

16. *BMJ*. Research methods & reporting. Accessed June 27, 2022. https://www.bmj.com/research/research-methods-and-reporting

17. *PLOS Med*. Guidelines and guidance. Accessed June 27, 2022. https://journals.plos.org/plosmedicine/search?filterJournals=PLoSMedicine&filterArticleTypes=Guidelines%20and%20Guidance&q=%22Guidelines%20and%20Guidance%22&page=1&utm_content=b&utm_campaign=ENG-467

18. Wiley Online Library, Statistics in Medicine. Tutorials in biostatistics. Accessed August 1, 2022. https://onlinelibrary.wiley.com/page/journal/10970258/homepage/tutorials.htm

19. *JAMA*. Users' Guide to the Medical Literature. Accessed March 8, 2022. https://pubmed.ncbi.nlm.nih.gov/?term=user*%5Bti%5D+Guide*%5Bti%5D+AND+%22medical+literature%22+AND+JAMA&show_snippets=off&size=100

20. *Ann Intern Med*. Research and reporting methods. Accessed June 28, 2022. https://www.acpjournals.org/action/doSearch?ConceptID=508329

21. *BMJ*. Statistics notes. Accessed June 27, 2022. https://www.bmj.com/specialties/statistics-notes

22. *PLOS*. Ten simple rules. April 22, 2020. Accessed June 27, 2022. https://collections.plos.org/collection/ten-simple-rules/

23. STRATOS (Strengthening Analytical Thinking for Observational Studies) initiative. Accessed September 13, 2021. https://www.stratos-initiative.org/

24. *J Clin Epidemiol*. GRADE series. Updated September 24, 2020. Accessed June 27, 2022. https://www.jclinepi.com/content/jce-GRADE-Series

25. Trial Forge. A systematic approach to making trials more efficient. 2015. Accessed January 22, 2020. https://www.trialforge.org/

26. ParseHub. Accessed June 27, 2022. https://www.parsehub.com/

27. Wallisch C, Bach P, Hafermann L, et al; Topic Group 2 of the STRATOS Initiative. Review of guidance papers on regression modeling in statistical series of medical journals. *PLoS One*. 2022;17(1):e0262918. doi:10.1371/journal.pone.0262918

28. Hedden H. *The Accidental Taxonomist*. Information Today, Inc; 2022.

29. W3C Sematic Web. SKOS Simple Knowledge Organization System—home page. Updated December 13, 2012. Accessed July 12, 2022. https://www.w3.org/2004/02/skos/

30. Tugwell P, Welch VA, Karunananthan S, et al. When to replicate systematic reviews of interventions: consensus checklist. *BMJ*. 2020;370:m2864. doi:10.1136/bmj.m2864

31. Hemingway H, Croft P, Perel P, et al; PROGRESS Group. Prognosis research strategy (PROGRESS) 1: a framework for researching clinical outcomes. *BMJ*. 2013;346:e5595. doi:10.1136/bmj.e5595

32. Janiaud P, Serghiou S, Ioannidis JPA. New clinical trial designs in the era of precision medicine: an overview of definitions, strengths, weaknesses, and current use in oncology. *Cancer Treat Rev*. 2019;73:20-30. doi:10.1016/j.ctrv.2018.12.003

33. Superchi C, Brion Bouvier F, Gerardi C, et al; PERMIT Group. Study designs for clinical trials applied to personalised medicine: a scoping review. *BMJ Open*. 2022;12(5):e052926. doi:10.1136/bmjopen-2021-052926

34. Cook JA, Julious SA, Sones W, et al. DELTA^2 guidance on choosing the target difference and undertaking and reporting the sample size calculation for a randomised controlled trial. *Trials*. 2018;19(1):606. doi:10.1186/s13063-018-2884-0

35. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *PLoS Med*. 2010;7(3):e1000251. doi:10.1371/journal.pmed.1000251

36. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *J Clin Epidemiol*. 2021;134(3):178-189. doi:10.1016/j.jclinepi.2021.03.001

37. Huang GD, Bull J, Johnston McKee K, Mahon E, Harper B, Roberts JN; CTTI Recruitment Project Team. Clinical trials recruitment planning: a proposed framework from the Clinical Trials Transformation Initiative. *Contemp Clin Trials*. 2018;66:74-79. doi:10.1016/j.cct.2018.01.003

38. Cro S, Morris TP, Kenward MG, Carpenter JR. Sensitivity analysis for clinical trials with missing continuous outcome data using controlled multiple imputation: a practical guide. *Stat Med*. 2020;39(21):2815-2842. doi:10.1002/sim.8569

39. Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M; PRO Data Presentation Delphi Panel. Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. *Qual Life Res*. 2019;28(2):345-356. doi:10.1007/s11136-018-2020-3

40. Foroutan F, Guyatt G, Zuk V, et al. GRADE Guidelines 28: use of GRADE for the assessment of evidence about prognostic factors: rating certainty in identification of groups of patients with different absolute risks. *J Clin Epidemiol*. 2020;121:62-70. doi:10.1016/j.jclinepi.2019.12.023

41. Schandelmaier S, Briel M, Varadhan R, et al. Development of the Instrument to Assess the Credibility of Effect Modification Analyses (ICEMAN) in randomized controlled trials and meta-analyses. *CMAJ*. 2020;192(32):E901-E906. doi:10.1503/cmaj.200077

42. Sterne JAC, Savović J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019;366:l4898. doi:10.1136/bmj.l4898

43. Schandelmaier S, Chang Y, Devasenapathy N, et al. A systematic survey identified 36 criteria for assessing effect modification claims in randomized trials or meta-analyses. *J Clin Epidemiol*. 2019;113:159-167. doi:10.1016/j.jclinepi.2019.05.014

44. Fisher DJ, Carpenter JR, Morris TP, Freeman SC, Tierney JF. Meta-analytical methods to identify who benefits most from treatments: daft, deluded, or deft approach? *BMJ*. 2017;356:j573. doi:10.1136/bmj.j573

45. Sterne JAC, White IR, Carlin JB, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ*. 2009;338:b2393. doi:10.1136/bmj.b2393

46. Cipriani A, Higgins JPT, Geddes JR, Salanti G. Conceptual and technical challenges in network meta-analysis. *Ann Intern Med*. 2013;159(2):130-137. doi:10.7326/0003-4819-159-2-201307160-00008

47. Norman CR, Gargon E, Leeflang MMG, Névéol A, Williamson PR. Evaluation of an automatic article selection method for timelier updates of the Comet Core Outcome Set database. *Database (Oxford)*. 2019;2019:baz109. doi:10.1093/database/baz109

48. SAGE research methods. Accessed September 27, 2021. https://methods.sagepub.com/

49. US Food and Drug Administration, Office of the Commissioner. Search for FDA guidance documents. Accessed September 27, 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents

50. European Medicines Agency. Scientific guidelines. 2018. Accessed September 27, 2021. https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines

SUPPLEMENT 1.
eAppendix 1. Ovid MEDLINE Search Strategy (Not Part of the Current Search Process of LIGHTS), Yielding 915 523 Records on May 6, 2022, Covering 921 (77.8%) of a Sample of 1184 Seed Articles

eAppendix 2. Instructions for Team Members of LIGHTS Working Group for Full-Text Eligibility Assessment, Indexing, and Taxonomy Development for LIGHTS

SUPPLEMENT 2.
Data Sharing Statement