



Leitfaden für die Erstellung von Projektskizzen zur „Richtlinie zur Förderung von Projekten zu klinischen Studien mit hoher Relevanz für die Patientenversorgung“

Modul 2:

Projektskizzen für systematische Übersichtsarbeiten zu klinischen Studien

Dieser Leitfaden stellt die Anforderungen für die Erstellung von beurteilungsfähigen Projektskizzen für systematische Übersichtsarbeiten dar. Er ergänzt die am 01. Juni 2026 im Bundesanzeiger veröffentlichte o. g. Förderrichtlinie (<https://www.gesundheitsforschung-bmfr.de/de/19250.php>). Er soll offene Fragen im Vorfeld der Einreichung klären.

Projektskizzen, die den Vorgaben der Förderrichtlinie und des folgenden Leitfadens nicht entsprechen, können ohne weitere Prüfung abgelehnt werden.

Es wird dringend empfohlen, zur Beratung mit dem DLR Projektträger Kontakt aufzunehmen.

Telefon: 0228-3821 2566; E-Mail: systematische-reviews@dlr.de

Bitte beachten Sie: für Modul 1 (explorative oder confirmatorische klinische Studien), Modul 3 (Patientenbeteiligung in der Konzeptphase) und Modul 4 (methodische Begleitforschungsprojekte) sind die Anforderungen an die jeweiligen Projektskizzen in separaten Leitfaden-Dokumenten beschrieben.

Inhaltliche Vorgaben für die Projektskizzen in Modul 2

Gefördert werden neuartige, methodisch und inhaltlich qualitativ hochwertige, **systematische Übersichtsarbeiten** zu klinischen Studien nach internationalen Standards. Darüber hinaus können auch methodisch und inhaltlich qualitativ hochwertige **Aktualisierungen bestehender systematischer Übersichtsarbeiten** zu klinischen Studien gefördert werden. Nicht gefördert werden Scoping Reviews und Realist Reviews. In jedem Fall muss die systematische Übersichtsarbeit beziehungsweise eine Aktualisierung eine hohe Relevanz für die klinische Praxis und für die betroffenen Patientinnen und Patienten haben.

Systematische Übersichtsarbeiten können in der Regel für einen Zeitraum von bis zu 24 Monaten gefördert werden.

Formale Vorgaben für die Projektskizzen in Modul 2

Im Sinne der Vergleichbarkeit aller eingereichten Projektskizzen sind die Formatvorgaben dieses Leitfadens verbindlich einzuhalten. Bitte verwenden Sie unbedingt die aktuelle Formatvorlage des DLR Projektträgers. Die darin vorgegebene Gliederung ist verbindlich:

https://projektraeger.dlr.de/media/gesundheit/GF/Template_systematic_review_2026.docx

Die Projektskizzen sind ausschließlich elektronisch als ein einzelnes pdf-Dokument einzureichen unter

<https://foerderportal.bund.de/easyonline/reflink.jsf?m=KG-REVIEWS&b=KG1SKIZZEN2026&t=SKI>

Es sind keine Papierversionen der Projektskizze sowie Papier- oder elektronische Versionen des von Easy-Online generierten „Projektblatt zur Skizze“ einzureichen.

Zusammenfassungen (deutsch/englisch)

Im Rahmen der elektronischen Einreichung sind **zwei Zusammenfassungen** der beantragten systematischen Übersichtsarbeit einzugeben – eine **deutsche allgemeinverständliche sowie eine englischsprachige allgemeinverständliche Zusammenfassung** (jeweils max. 2.000 Zeichen). Die Zusammenfassungen müssen klar und für ein breites Publikum leicht verständlich sein. Hoch wissenschaftliche bzw. wenig geläufige Begriffe sind zu vermeiden. Diese Zusammenfassungen können bei der Begutachtung der Projektskizze durch Patientenvertreterinnen und -vertreter genutzt werden. Deshalb sind hierin die Ziele, das Design, die erwarteten Ergebnisse und das Potenzial der Ergebnisse für die Umsetzung über das Forschungsfeld hinaus zusammenzufassen.

Allgemeine Hinweise

Nachfolgende Hinweise sind bei der Planung und Einreichung aller Projektskizzen zu beachten.

➤ **Wissenschaftliche Standards und Berichtsqualität**

Die Antragstellenden sind verpflichtet, nationale und internationale Standards zur Qualitätssicherung der klinischen Forschung einzuhalten. Hierzu sind bspw. die nachfolgenden Dokumente in der jeweils geltenden Fassung zu berücksichtigen:

- publizierte methodische Standards (z.B. von Cochrane und JBI¹),
- PRISMA- und GRIPP2-Statements (inkl. ggf. PRISMA-S und PRISMA-P),
- FAIR-Prinzipien.

Es wird empfohlen, die Arbeitshilfen der TMF (Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.) oder des Arbeitskreises Medizinischer Ethik-Kommissionen zu verwenden, z. B. zu Datenschutz oder Patienteneinwilligung.

➤ **Transparenz**

Vom BMFTR geförderte systematische Übersichtsarbeiten müssen bis spätestens drei Monate nach Beginn des Vorhabens in einem öffentlich zugänglichen **Register** eingetragen werden (z. B. in PROSPERO). Darüber hinaus ist das **Protokoll** der systematischen Übersichtsarbeit innerhalb von einem Jahr nach Vorhabenstart zu veröffentlichen.

Die **Ergebnisse** der systematischen Übersichtsarbeit sind innerhalb von einem Jahr nach Abschluss des Vorhabens zu publizieren. Dies beinhaltet mindestens die Publikation der Ergebnisse auf einem wissenschaftlichen Kongress und in einer Fachzeitschrift. Die Veröffentlichung der Ergebnisse beinhaltet ebenfalls, dass die **Originaldaten** zur Nachnutzung zur Verfügung gestellt werden sollen. Wo immer möglich, sollten Forschungsdaten bereits während der Laufzeit von geförderten Projekten zugänglich gemacht werden.

Die Veröffentlichungen (Protokoll und Ergebnisse) sollen in einer wissenschaftlichen Fachzeitschrift so erfolgen, dass der Öffentlichkeit der unentgeltliche elektronische Zugriff (**Open Access**) auf den Beitrag möglich ist.

➤ **Aktive Beteiligung von Betroffenen und / oder relevanter Zielgruppen**

Um die Ausrichtung der geförderten systematischen Übersichtsarbeit am Bedarf der Patientinnen und Patienten sicherzustellen und ihre Relevanz, Anwendbarkeit und Praxisnähe zu erhöhen, soll

¹ <https://bi-global-wiki.refined.site/space/MANUAL>

die Perspektive einschlägiger Interessengruppen aus Gesundheitswesen und Gesellschaft, allen voran der Patientinnen und Patienten, auf allen relevanten Ebenen und Prozessen einbezogen werden. Dies reicht von der Formulierung der Forschungsfragestellungen über die aktive Beteiligung am Forschungsprozess bis hin zur Verbreitung von Forschungsergebnissen. In die Planung und Ausgestaltung der Forschung sollen explizit bereits erkrankte Menschen oder ihre Vertretungen, andere für das Forschungsvorhaben wichtige Akteure und Gruppen aus dem Gesundheitswesen und darüber hinaus – wo möglich und sinnvoll – weitere Bürgerinnen und Bürger aktiv einbezogen werden. Partizipation in der Forschung kann in verschiedenen Abstufungen erfolgen, von einer Beratung durch Patientinnen und Patienten bis hin zu einer Zusammenarbeit bei der Planung, Durchführung und Ergebnisverwertung des Projekts. Beispielsweise können Patientinnen und Patienten bzw. ihre Vertretungen in die Entscheidung darüber einbezogen werden, welche Vergleiche von Interesse sind und welche Studien sich für eine quantitative Zusammenfassung (via Metaanalysen) eignen.

Die folgenden, zum Teil internationalen Handreichungen, Leitfäden und Standards für Zielgruppenbeteiligung können wertvolle Hinweise liefern, wie die aktive Beteiligung von Patientinnen und Patienten gestaltet werden kann (keine abschließende Auswahl):

- Aktive Beteiligung von Patientinnen und Patienten in der Gesundheitsforschung – eine Heranführung für (klinisch) Forschende: <https://zenodo.org/record/7908077>
- Handreichung zur Patient*innenbeteiligung an klinischer Forschung (Jilani et al 2020): <http://dx.doi.org/10.26092/elib/229>
- INVOLVE, Briefing notes for researchers: <https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research>
- Hilfestellung der Rising Tide Foundation zur Patientenbeteiligung in der Planung von Forschungsprojekten: https://maps.risingtide-foundation.org/fileadmin/CCR/Program/2021_06_22_Patient_Involvement_for_Applicants_v1.5.pdf
- A Researcher's Guide to Patient and Public Involvement: <https://oxfordbrc.nihr.ac.uk/wp-content/uploads/2017/03/A-Researchers-Guide-to-PPI.pdf>
- Patientenbeteiligung im Rahmen von systematischen Übersichtsarbeiten: <https://www.cochrane.org/de/learn/courses-and-resources/getting-started-evidence/evidence-essentials/module-5-consumer-involvement-cochrane>

➤ Berücksichtigung von Geschlecht und weiteren Aspekten der Diversität

Menschen können z. B. je nach Geschlecht, Alter oder ethnischer Herkunft unterschiedlich von Erkrankungen betroffen sein, sowohl aus biologischen Gründen als auch wegen unterschiedlicher Verhaltensweisen und Zugängen zur Gesundheitsversorgung². Darüber hinaus können Therapien oder Medikamente unterschiedlich wirken. Daher sind Aspekte der Diversität, mindestens das Geschlecht, im Design der Übersichtsarbeit, der Zusammensetzung der Studienpopulationen in den Primärstudien, bei der Durchführung, Auswertung und Interpretation der Übersichtsarbeit sowie der Kommunikation von Ergebnissen angemessen zu berücksichtigen. Falls Aspekte der Diversität für ein Vorhaben als nicht relevant erachtet werden, ist dies zu begründen.

Die folgenden, zum Teil internationalen Leitfäden und Standards können wertvolle Hinweise für die angemessene Berücksichtigung von Geschlechts- und Diversitätsaspekten in klinische Forschung liefern (keine abschließende Auswahl):

- Sex and Gender Equity in Research: Rationale for the SAGER Guidelines and Recommended Use: <https://doi.org/10.1186/s41073-016-0007-6>
- Sex and Gender Equity in Research Guidelines Checklist: <http://s.dlr.de/SAGER-checklist>

➤ Zuwendungsfähige Ausgaben

Gefördert werden in dieser Förderrichtlinie in der Regel Einzelvorhaben.

² Empfehlungen des Wissenschaftsrats zur Weiterentwicklung der Geschlechterforschung in Deutschland (2023), <https://doi.org/10.57674/9z3k-1y81>

Zuwendungsfähig ist der vorhabenbedingte Mehraufwand, wie Personal-, Sach- und Reisemittel. Falls keine individuellen Begründungen einen klaren Mehrbedarf für ein spezifisches Vorhaben verlangen, können folgende Positionen ohne weitere Erläuterungen im Antrag auf Zuwendung auf Ausgabenbasis bzw. Kostenbasis bzw. auf Zuweisung / für eine Verwaltungsvereinbarung (AZA(P) / AZK / AZV) beantragt werden:

Pos. 0812/0817/0822 (Personal)

- Stellen für Beschäftigte nach TVöD/TV-L E13 oder TV Ä1 (Stufe 2; NN-Personal) für bis zu 20 Vollzeit-Personenmonate.
- Beschäftigungsentgelte für Studentische Hilfskräfte für bis zu 480 Stunden.

Pos. 0835 (Vergabe von Aufträgen)

- Für Volltext-Übersetzungen von zu berücksichtigender Literatur bis zu 2.000 € inkl. ggf. anfallender MwSt.

Pos. 0841 (Sonstige allgemeine Verwaltungsausgaben)

- Als Aufwandsentschädigung von Patientenvertretungen, Angehörigen sowie von Vertreterinnen und Vertretern weiterer relevanter Zielgruppen bis zu 50 € pro Stunde und Person; für ein ganztägiges Meeting entspricht dies einer Vergütung von bis zu 400 € pro Person und Tag. Zusätzlich können pro o.g. Person bis zu 230 € pro Präsenztreffen zur Deckung von Ausgaben für Reisen zu o.g. Präsenztreffen ohne weitere Erläuterungen beantragt werden.
- Für Open-Access-Publikationen bis zu 6.000 €.
- Für die Beschaffung von Literatur, die nicht open-Access verfügbar ist bis zu 600 €.

Pos. 0844/0845 (Inlands- und Auslandsreisen)

- Für die Konferenzteilnahme einer Projektmitarbeiterin oder eines Projektmitarbeiters pro Konferenz im Inland bis zu 1.000 €, im Ausland bis zu 2.000 €. Soll die Konferenzteilnahme zusammen mit einer am Vorhaben beteiligten Patientenvertretung stattfinden, ist die pauschale Beantragung des o.g. Betrags für eine weitere Person ohne weitere Erläuterungen möglich; da es sich nicht um Projektmitarbeiterinnen und Projektmitarbeiter handelt, müssen diese Ausgaben in Pos. 0841 beantragt werden.
- Reisemittel für Projekttreffen bis zu 230 € pro Teilnehmerin / Teilnehmer und pro Tag.

Für den Fall, dass der Mittelbedarf größer ist bzw. über die o.g. Positionen hinausgeht, dann ist dies zwingend und jeweils individuell für die jeweils zusätzliche Position / zusätzlichen Mittel im Formantrag zu begründen. Ansonsten müssen keine Erläuterungen vorgelegt werden.

Entscheidungsverfahren in Modul 2

Für Projektskizzen zu systematischen Übersichtsarbeiten ist ein fachlicher Begutachtungsschritt vorgesehen. Einreichende sind zur Vorlage von in diesem Leitfaden spezifizierten **Projektskizzen** aufgefordert. Diese werden von einem unabhängigen, internationalen Begutachtungsgremium bewertet. In dem Fall, dass mehr geeignete Projektideen zur Förderung ausgewählt worden sind als Fördermittel zur Verfügung stehen, kann ein teilrandomisiertes Verfahren (Losverfahren) zum Einsatz kommen. Das teilrandomisierte Verfahren ist eine Bias-freie Lösung zur Entscheidungsfindung im breiten Mittelfeld, wenn eine weitere Ausdifferenzierung anhand wissenschaftlicher Kriterien schwer möglich ist.

Mustervorlage & Erläuterungen

Nachfolgend findet sich die Mustervorlage mit Erläuterungen für Projektskizzen für systematische Übersichtsarbeiten:

Mustervorlage & Erläuterungen für Projektskizzen für systematische Übersichtsarbeiten

Application for a Systematic Review

Make an entry under every heading/subheading. To ensure comparability of all submitted applications please prepare your application in English **not exceeding 13 pages for the headings 1. to 11.** (DIN A4, font size at least 11 point Arial, 10 point Arial for the synopsis and tables, and 9 point Arial for references, margins of at least 2 cm and single-spaced lines). Structure your application using the headings listed below. Only in case of a resubmission of this systematic review within this funding scheme, 14 pages are permitted including a response to previous reviewers' comments.

Your uploaded PDF document has to comprise the application itself and all appendices in one pdf document. Do not submit any other documents / attachments.

1. SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	<i>Name, address, telephone, e-mail</i> <i>In case of multiple applicants, the principal investigator / coordinating investigator of the project who will assume responsibility should be listed first</i>
TITLE OF REVIEW	<i>The title of the review should be as precise as possible.</i>
ACRONYM OF REVIEW	<i>Please provide a brief acronym.</i>
CONDITION	<i>The medical condition being studied (e.g. asthma, myocardial infarction, depression)</i>
OBJECTIVE(S)	<i>Which research questions are to be addressed? Does the proposal aim at methodological progress in the field of reviews?</i>
TYPE OF REVIEW	<i>Key words only (e.g. IPD-analysis, network meta-analysis, "classic" systematic review, living systematic review, update of an existing systematic review).</i>
STUDY SELECTION	<i>Specify key selection criteria. Define and prioritize data items for outcomes. For reviews on diagnostic test accuracy, index test and reference standard should appear in this section.</i> <u>Population (of patients):</u> <u>Intervention:</u> <u>Comparator(s):</u> <u>Outcomes:</u> <u>Design of primary studies:</u> <u>Other report characteristics:</u>
INFORMATION SOURCES AND SEARCH STRATEGIES	<i>Describe the search strategy to identify relevant research, i.e. specify databases and other sources to be searched.</i>
QUALITY ASSESSMENT	<i>Describe the strategies to assess the quality of primary studies (methodological quality, systematic error, validity, generalisability, applicability).</i>

DATA EXTRACTION	<i>Specify extraction process and detail quality assessment of extracted data.</i>
DATA SYNTHESIS	<i>Specify strategy for data synthesis (effect measures) and presentation of results (forest plots) taking into account possible heterogeneity, risk of bias and subgroup analysis.</i>
SAMPLE SIZE	<i>Estimate the number of eligible primary studies (and individual patient data, if applicable) to be included.</i>
DURATION	<i>Requested duration of funding (usually a maximum of 24 months)</i>
CONFLICT OF INTEREST	<i>Report any potential sources of conflict of interest of the applicants and cooperating experts</i>
PREVIOUS BMFTR SUBMISSION NUMBER	<i>If application is a resubmission in this funding line, please fill in the previous application number.</i>

2. RESPONSE TO REVIEWERS' COMMENTS ON A PREVIOUS VERSION OF THIS SYSTEMATIC REVIEW

Only for a resubmission of this systematic review within this funding scheme:

Please summarize in English the assessment of your previous application with the major recommendations given. Please respond with a short point-by-point reply separately to each recommendation citing the adjacent expert comment. Where necessary, refer to changes made in this outline application.

If the systematic review is not a resubmission, you may delete this paragraph including the heading.

3. RELEVANCE

3.1 MEDICAL PROBLEM

Which medical problem is to be addressed? Which main research questions are to be addressed? Please justify the relevance of the medical problem and the choice of the research questions.

3.2 PREVALENCE, INCIDENCE, MORTALITY

Please state the prevalence, e.g. per 100.000 residents, incidence, e.g. per 100.000 residents per year and mortality (case fatality rate) of the addressed disease, according to most reliable data.

3.3 BURDEN OF DISEASE

Please provide suitable indicators to describe the burden of disease, e.g. DALYs (disability-adjusted life years). Please provide information on the socioeconomical burden of disease.

3.4 OBJECTIVES / NEED FOR THE SYSTEMATIC REVIEW

What are the objectives/goals of this systematic review?

How significant is the systematic review in terms of its potential impact of relieving the burden of disease and/or burden of treatment (e.g. dose reduction, avoiding adverse effects) and/or improving quality of life? The different aspects of relevance for routine medical care for individual patients on the one hand and the relevance for the German healthcare system on the other hand should be explained.

Which therapy options are available for treatment of the disease? How can the systematic review influence evidence-based treatment decisions in clinical practice in Germany? How significant is

the review for planning of further clinical research? Does the review contribute to methodological progress in the field of systematic reviews?

3.5 EVIDENCE

Set your review into perspective by describing all evidence considered before undertaking the systematic review, enabling readers to understand the implications of the review in the context of previously available and comparable research. Briefly report the sources searched (e.g., databases, journal or book reference lists, registries), the exact search time frame (including start and end dates), search terms used, and inclusion and exclusion criteria, ensuring that the search is not restricted to English-language publications.

State how many / which relevant reviews were identified. Describe whether similar systematic reviews are currently being conducted by other research groups and summarize relevant research already conducted by your group or others. In addition, report the quality (risk of bias) of the identified evidence and, where appropriate, provide pooled estimates derived from meta-analysis. Existing systematic reviews should also be assessed using a standardized quality appraisal method; describe the outcome of this assessment and discuss whether the quality of existing reviews is acceptable or whether important limitations remain.

If helpful, existing systematic reviews and meta-analyses identified can be listed in a table.

DOI or Web Link to Trial Publication	First Author	Title	Year	Assessment of Quality (Good, average, poor)	Relevance to current systematic review

Why do you think the proposed systematic review is needed? What will it add to the existing systematic reviews? What is the novel aspect of the proposed systematic review in comparison to already existing reviews? For a review update, please state the present need (e.g., novel publications of clinical trials). What additional benefits or advantages would the systematic review in your field of interest offer compared to existing ones? What are the chances of the proposed review to lead to either new or more robust conclusions? What is the relevance of the results?

4. PATIENT AND TARGET GROUP INVOLVEMENT PLAN

Please use only the table below to describe how affected patients and other relevant target groups (e.g. (caring) relatives, users and / or providers of medical services) are / were involved in the different phases of the research process. How will / were patients and other relevant target groups (be) involved in identifying research needs, the planning, conduct of the systematic review, and in the exploitation of systematic review results?^{3,4} **Patient involvement is mandatory wherever feasible.**

Who? Which patients, patient representative(s), patients' self-help group(s), patient advocacy group(s) or other relevant target groups were / will be involved? Who is planned to be engaged in dissemination of the results?

How? How have patient representative(s), patients' self-help group(s), patient advocacy group(s) or other relevant target groups been involved in the planning of the review? How did you assess the relevance of your research question for patients? How were the patients' needs, goals, concerns and preferences considered? How will patient representative(s), patients' self-help group(s), patient advocacy groups or other relevant target groups be engaged during the conduct

³ s. auch eine Einführung von INVOLVE zugehörig zum Britischen National Institute for Health Research, NHS „Briefing note for Researchers“: <http://s.dlr.de/INVOLVE-briefing-notes>

⁴ Consider GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research” for reporting of patient and public involvement. <https://www.equator-network.org/reporting-guidelines/gripp2-reporting-checklists-tools-to-improve-reporting-of-patient-and-public-involvement-in-research/>

of the review and dissemination of results? How will involvement be supported, resourced and funded?

Patient and target group involvement can be implemented in different stages of the review and to a different extent.

Phase of the Research Process	How is / was / were relevant group(s) involved?
Identification of research needs	
Planning of the systematic review / Preparation of this proposal	
Conduct of the systematic review	
Exploitation and dissemination of results of the systematic review	

5. STRATEGIES FOR DATA SHARING AND DISSEMINATION OF RESULTS

Please describe the measures being taken (e.g. through CC licences) to ensure the management, maintenance and long-term accessibility of your data with a view to its future reuse (including by third parties, whilst taking into account data protection regulations and copyright-protected data). Please use existing standards and data repositories where appropriate.

What will be your strategies for the dissemination of results? Indicate how the expected results of the systematic review will be used; discuss dissemination of results, especially beyond regular journal publication, describe intended measures, detail potential economic impact and relevance for patients' decision making.

6. JUSTIFICATION OF DESIGN ASPECTS

6.1 POPULATION

Justify the population of patients to be studied. Include reflections on generalisability and representativeness. In case of an individual patient data meta-analysis please justify feasibility of individual patient data acquisition in detail.

6.2 INTERVENTION(S)

Justify the intervention(s) to be studied. Describe the intervention(s) as exactly as possible. Address important potential adverse effects of the intervention(s).

6.3 COMPARATOR(S)

Justify the choice of comparator(s) being used by primary studies. Which evidence establishes the appropriateness of the chosen comparator(s)? Describe the control interventions as exactly as possible.

6.4 OUTCOMES

Justify the outcomes chosen: Are there other reviews that have utilized them? Are there any guidelines proposing them? Are they relevant for patients? Discuss the clinical relevance of the outcomes for the target population. Have they been validated? Define the timing of outcome measurements.

6.5 DESIGN OF PRIMARY STUDIES

Justify the design of the primary studies to be included/ excluded. Are there any restrictions, e.g. a minimal time of follow-up?

6.6 INFORMATION SOURCES AND SEARCH STRATEGIES

Note: While section 3.5 includes the description of search results with respect to existing systematic reviews / evidence, this and the following sections focus on the search for primary studies which are the basis for the planned systematic review.

Justify the search strategies to identify relevant primary studies: Are all relevant bibliographic databases considered? What other sources will be searched (e.g. hand searches of reference lists of existing relevant systematic reviews or specific journals, citation indices, trial registries, pre-print repositories, grey literature databases? Will authors, sponsors or other experts be contacted? Present a full electronic search strategy for one bibliographic database, including any limits used, such that it could be repeated in the respective mandatory appendix. Describe whether during the preparation of this application, an information retrieval specialist and/or medical librarian was involved (which is strongly recommended).

6.7 STUDY SELECTION

How many eligible primary studies are expected to be included? How did you determine this number (please cite published data and critically evaluate it)? Were all identified studies/systematic reviews checked to ensure they were published in a reputable peer-reviewed journal? Describe the number and expertise of the reviewers for study selection.

In the following table, give an overview of the most relevant studies in the field of this application as examples of studies from your prior search and explain their relevance to the systematic review.

Clinical trials to be included / excluded in/from the systematic review

DOI or Web Link to Trial Publication	First Author	Title	Year	Relevance to current systematic review

For individual patient data analysis (IPD) additionally state the expected number of study participants. How many PIs from primary studies have confirmed their cooperation (Please provide letters of intent, if possible in the respective appendix.)? How representative are the data of these studies for the results of all eligible trials?

6.8 QUALITY ASSESSMENT AND DATA EXTRACTION

Justify the data extraction strategies. Describe the strategies and tools used for data extraction and risk of bias assessment. Detail consequences possibly arising from quality assessment. Describe the number and expertise of assessors for data extraction.

7. DATA SYNTHESIS

A biometrician with proven expertise and experience in carrying out the planned analyses should be involved in the data synthesis. What is the proposed strategy of information synthesis? Justify the choice of methods used (e.g. rationale for considering or conducting network meta-analysis). Will the calculation of a summary measure be justified? If yes, specify effect measures and statistical models. Describe how to investigate heterogeneity/ homogeneity and risk of bias based on the expected number of primary studies (sample size of your review). For network meta-analyses provide a diagram illustrating the network. Are there any planned subgroup or sensitivity analyses? Describe how the certainty/trustworthiness of the body of evidence will be assessed (with e.g. GRADE).

8. WORK PACKAGES AND TIMES PLAN

Describe in detail the main aims and the work plan for the systematic review. Which milestones and project deliverables must be achieved during the funding period? How will this be achieved? Provide a time frame and an overview of milestones for the work in the systematic review. Please describe the estimated time plan considering above mentioned work packages.

9. EXPERTISE

Please indicate persons responsible for the review. Please note that each listed area of expertise must be assigned to a qualified person.

#	Name	Affiliation	Role
			Principle Investigator (if the principle investigator is not one of the persons below)
			Clinical expertise
			Biometrical expertise
			Information retrieval specialist /medical librarian
			Prior formal training in systematic review methods and/or experience in conduction a systematic review
			Patient Representative / Organisation
		

Ensure that the team of participating investigators has the necessary range of disciplines and expertise to carry out the systematic review (i.e., if applicable: network meta-analysis, diagnostic test accuracy review). It is mandatory for the review team to have a diverse range of experience in order to foster collaboration between younger and more experienced reviewers, with the aim of ensuring quality in the future and promoting the development of the next generation. Shortly describe, whether this is the case.

10. REFERENCES

For your references please use the Vancouver style (the full title of the publication must be displayed; please find further information here: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

For the references, 9 point Arial can be used.

11. FINANCIAL PLAN

Please detail and justify (in the table) the costs expected for the entire duration of the systematic review.

Please consider the details on eligible items (see the section "Zuwendungsfähige Ausgaben" of the application guideline), especially with regard to the requested scope and the required explanations for each item. IMPORTANT: please make sure that the finances applied for here match the finances applied for in the formal application in the electronic application system easy-Online.

Item *	Man Months (Full Time Equivalents)	Description / Justification	Amount requested (€)
Personnel	-		
Scientific			
Non-Scientific			
Other			

Contracts***	-		
Publication **	-		
Travel Expenses	-		
Other Expenses	-		
TOTAL (without overhead / „Projektpauschale“)			

* Please note: Standard equipment available at the institution cannot be funded.

** According to BMFTR guidelines, where possible, open access publication should be used.

***In cases where subcontracts are foreseen, applicants should assess on a case-by-case basis whether value added tax must be considered and include this in their calculations. The addition of value added tax after the evaluation of the proposal is impossible. Thus, it is advisable to carefully plan subcontracts and requested funds for those in this proposal. Further, applicants should detail why a subcontract is necessary and tasks cannot be fulfilled by the applicant himself.

Please note: The application, up to this point, is not allowed to exceed 13 pages (resubmission: 14 pages).

APPENDICES

Your uploaded one PDF document has to comprise the application itself and all appendices.

Mandatory appendices:

- Appendix 1: List of Abbreviations, max. ½ page
- Appendix 2: Lay Summary for Patient Representatives Reviewers, max. 2 pages
- Appendix 3: Search Strategy
- Appendix 4: CVs of Major Participants, max. 4 CVs, max. 2 pages per CV

Optional appendices:

- Appendix 5: Letter(s) of Support for Patient and Target Group Involvement
- Appendix 6: If individual patient data (IPD) analysis is planned: Letters of Support for primary data

Do not submit any other appendices (e.g., letter of intent / letter of support by other parties).

APPENDIX 1: LIST OF ABBREVIATIONS (mandatory, max. ½ page)

Please provide a list of abbreviations used. However, use abbreviations only moderately. Nevertheless, all abbreviations must be introduced at first use.

APPENDIX 2: SUMMARY FOR PATIENT REPRESENTATIVES REVIEWERS (mandatory, max 2 pages)

Patient reviewers will assess the relevance, patient engagement in the project and feasibility of the proposal. Their assessment is considered in the overall assessment of the proposal. Please answer the questions shortly and concise, write in Layman's terms⁵. **It is highly recommended to co-write this part with a lay person or seek the opinion of a layperson regarding your written texts in this section.**

This part of the application will be evaluated by patient representative reviewers on the basis of:

- The readability of the information you provide with this form. Please put emphasis on a lay and comprehensive writing.
- The importance of the described systematic review for patients

Make sure that the core aspects of this proposal become clear from this summary alone, without having read the main application and other appendices.

Please use abbreviations only moderately and do only use common abbreviations. Nevertheless, all abbreviations must be introduced at first use.

1. THE MEDICAL PROBLEM AND RELEVANCE

What is the medical problem / principal research question that is addressed in the planned systematic review? How is this research important or relevant to patients and/or other relevant target groups (e.g. (caring) relatives, users or providers of medical services)?

What is the significance and relevance of the review regarding relieving the burden of disease and/or burden of treatment (e.g. dose reduction, avoiding adverse effects), improving quality of life, routine medical care for individual patients, and the German healthcare system? Is there any

⁵ If you are uncertain how to explain complex research to a lay person, please consult the following resources:

<http://www.plainenglish.co.uk/files/howto.pdf>

<https://hso.research.uiowa.edu/medical-terms-lay-language>

<https://www.elsevier.com/connect/authors-update/in-a-nutshell-how-to-write-a-lay-summary>

evidence (e.g. from a priority setting partnership) that the proposed review addresses a research question of high relevance for the affected patients and/or other relevant target groups? What evidence already exists (e.g. systematic reviews, meta-analyses, clinical trials), are similar reviews ongoing, and what is the quality (risk of bias) and limitation of existing evidence?

Which therapy options are available for treatment of the disease, how can the review influence evidence-based treatment decisions in clinical practice in Germany, and what is the relevance of the results for further clinical research and methodological progress? What will happen after the review has been executed? What will be the next steps if the research turns out to be successful?

2. PATIENT AND TARGET GROUP INVOLVEMENT

How are affected patients and other relevant target groups involved in the different phases of the research process? Please fill in this table and do not add additional text.

Phase	How are affected patients and other relevant target groups involved?
Identification of re-search needs	
Planning of the systematic review/ Preparation of this proposal	
Conduct of the systematic review	
Exploitation and dissemination of results of the systematic review	

3. DESIGN ASPECTS

Describe your hypotheses and assumptions you will test. Justify / describe the intervention(s) to be studied. Justify the choice of comparator(s) being used by primary studies. Which evidence establishes the appropriateness of the chosen comparator(s)? Describe the control interventions. Justify the outcomes chosen. Justify the design of the primary studies to be included/ excluded.

4. EXPERTISE

Who will be part of the research team for this systematic review, what is their respective expertise and what are their roles?

5. TIME AND WORK PLAN

Provide a time frame and an overview of milestones for the work in the systematic review project.

6. FINANCIAL PLAN

Give a narrative overview of the planned financial budget.

APPENDIX 3: SEARCH STRATEGY (mandatory)

To substantiate the evidence presented in Section 6.6 (search strategies for primary studies), please present the full search strategy to find primary studies for one electronic database (e.g.

MEDLINE, the Cochrane library or clinicaltrials.gov) including any limits used, such that it could be repeated. Indicate filters used. Only present the strategy for one database.

Present the search strategy only, do not provide further explanations. The narrative of the results is to be presented under Section 6.7 (study selection). Guidance concerning search techniques can be found here: <https://www.cochrane.de/literaturrecherche>.

Example for a full search strategy in MEDLINE (conducted to identify randomized controlled, blinded trials of antipsychotic drugs in treatment resistant patients with schizophrenia):

Search strategy for Medline (30th June 2013)

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1  exp Schizophrenia/ (86112)
2  exp Psychotic Disorders/ (38267)
3  schizo$.mp. (127884)
4  or/1-3 (153641)
5  ("treatment resist$" or "therapy resist$" or "drug resist$" or "chemical resist" or "treatment refract$" or "treatment fail$" or nonre-
spon$" or non-respon$" or "non respon$" or "not respon$" or "no respon$" or "partial respon$" or "partially respon$" or "incomplete
respon$" or "incompletely respon$" or unrespon$" or "failed to respond" or "failed to improve" or "failure to respon$" or "failure to
improve" or "failed medication$" or refractory or resistant or (inadequate$ adj3 respon$)).mp. (621509)
6  exp Drug Resistance/ (253660)
7  5 or 6 (667475)
8  exp Antipsychotic Agents/ (122182)
9  antipsychoti$.mp. (50055)
10 neurolept$.mp. (20926)
11 benperidol/ or chlorpromazine/ or chlorprothixene/ or clopenthixol/ or Clopenthixol/ or clozapine/ or droperidol/ or flupenthixol/
or fluphenazine/ or fluspirilene/ or haloperidol/ or iloperidone/ or loxapine/ or mesoridazine/ or Methotrimeprazine/ or molindone/ or
olanzapine/ or Penfluridol/ or Perazine/ or perphenazine/ or pimozide/ or prochlorperazine/ or promazine/ or promethazine/ or queti-
apine/ or Reserpine/ or risperidone/ or sulpiride/ or thioridazine/ or thiothixene/ or trifluoperazine/ or Trifluperidol/ or triflupromazine/
or Verapilide/ or Tiapride Hydrochloride/ (69795)
12 (acetophenazine or amisulpride or aripiprazole or asenapine or benperidol or bromperidol or butaperazine or carpipramine or
chlorproethazine or chlorpromazine or chlorprothixene or clocapramine or clopenthixol or clozapine or cyamemazine or dixyrazine
or droperidol or fluansone or fluphenazine or flupenthixol or fluphenazine or fluspirilene or haloperidol or iloperidone or levome-
promazine or levosulpiride or loxapine or lurasidone or melperone or mesoridazine or molindone or moperone or mosapramine or
olanzapine or oxyperitine or paliperidone or penfluridol or perazine or pericyazine or perphenazine or pimozide or pipamperone or
pipothiazine or prochlorperazine or promazine or promethazine or prothipendyl or quetiapine or remoxipiride or reserpine or risperi-
done or sertindole or stelazine or sulpiride or sultopride or thiopropazate or thioproperazine or thioridazine or thiothixene or tiapride
or trifluoperazine or trifluperidol or triflupromazine or verapilide or ziprasidone or zotepine or zuclopenthixol).mp. (93792)
13 or/8-12 (149852)
14 4 and 7 and 13 (3026)
15 exp clinical trial/ (785982)
16 exp randomized controlled trials/ (102420)
17 exp cross-over studies/ (35635)
18 randomized controlled trial.pt. (384946)
19 clinical trial.pt. (501097)
20 controlled clinical trial.pt. (89142)
21 (clinic$ adj2 trial).mp. (597724)
22 (random$ adj5 control$ adj5 trial$).mp. (507275)
23 (crossover or cross-over).mp. (66025)
24 ((singl$ or double$ or trebl$ or tripl$) adj (blind$ or mask$)).mp. (179088)
25 randomi$.mp. (582908)
26 (random$ adj5 (assign$ or allocat$ or assort$ or reciev$)).mp. (165555)
27 or/15-26 (1088679)
28 14 and 27 (1048)

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APPENDIX 4: CVS OF MAJOR PARTICIPANTS (mandatory, max. 4 CVs, max. 2 pages per CV)

Given the template, include tabular CVs from the principal investigator plus a maximum of three other major participants from the team given in the table in Section 9.

Personal Data

Name	
Current institution/affiliation	
Current position	
Optional: Identifiers/ORCID	

Employment / for Patients: (voluntary) engagement

Role	Organisation / Institution	Duration
<i>For example: Assistant professor</i>	Please provide a tabular list of stages of your professional career (most recent at the beginning). <i>For example: University Hospital Healthy Patient, Department for Gesundheit, Bonn, DE</i>	<i>01.2018 – 03.2023</i>

Education

Degree	Organisation	Duration
<i>For example: PhD/ Dr.med. (Ophthalmology)</i>	Please provide a tabular list of stages of your academic career (most recent at the beginning). Please state the respective time period for each stage/position. <i>For example: University of Greatness, Bonn, DE</i>	<i>01.2015 – 02.2019</i>

Further education / supplementary career information (optional, free text field)

Here, you may enter further career stages or information relevant to your project application, if you feel that this information may be relevant to the appropriate review and evaluation of your academic achievements. For example, you may voluntarily enter supplementary information relating to your career or special personal circumstances (e.g. periods of absence due to childcare responsibilities, maternity leave, caring for relatives/career delays due to “first generation academic”, compulsory or voluntary services, language acquisition, migration or integration phases).

Major achievement (optional, free text field)

You may describe one of your major achievements from your career. This could include your most important scientific contribution to date and do not have to be directly related to your current application. Please do not state any proxy indicators such as your h-index, citation metrics etc. Your achievement might for example be related to knowledge gain and innovation, patents, software, patient and public involvement activities, support and/or development of young career researchers or colleagues or the impact of your achievement/activities on the society or on standing policies.

List of relevant systematic review publications

Year	Topic	Registration of the Review	Published protocol	Role in the Project
	<i>Please give the topic here (e.g., therapy X in disease Y). The full title is not required here.</i>	<i>if the review was registered, please give the DOI number OR web link here.</i>	<i>if the review protocol was published, please give the DOI number OR web link here</i>	<i>e.g. Content Expert/Review Author, Biostatistician, Data Search Expert...</i>

List of other relevant publications

Year	Topic	Publication	Role in the Project
	<i>Please give the topic here (e.g., improvement of statistical method X). The full title is not required here.</i>	<i>please give the DOI number OR web link here.</i>	<i>e.g. Content Expert/Review Author, Biostatistician, Data Search Expert...</i>

APPENDIX 5: LETTER(S) OF SUPPORT FOR PATIENT AND TARGET GROUP INVOLVEMENT (optional / desired)

Provide (a) letter(s) of support of (the) patient representative(s), patients' self-help group(s), patient advocacy group(s) involved in the review. This means that scientific project leaders should NOT include letters of support by other scientific/medical/clinical project partners!

The letter(s) of support should clearly indicate which kind of support is intended and why this research question is relevant for them. If the letter of support is written in German, an English translation should be provided.

Include the letters only, do not provide further explanations. The narrative of patient representatives and target group involvement is to be presented under Section 4.

APPENDIX 6: INDIVIDUAL PATIENT DATA (IPD) META-ANALYSIS (optional / desired if IPD is planned)

If you plan to conduct a meta-analysis based on individual patient data (IPD), please additionally include letters of support of principal investigators from primary studies wherever possible. These letters should be written in English and should provide a clear and detailed statement on which type of data of how many study participants will be provided.

Include the letters only, do not provide further explanations. The narrative of patient representatives and target group involvement is to be presented under Section 4.