DLR Projektträger

Bundesministerium
für Bildung
und Forschung

Leitfaden für die Erstellung von Anträgen zur

„Richtlinie zur Förderung praxisverändernder klinischer Studien zur Prävention, Diagnose und Therapie von Krebserkrankungen“

im Rahmen der Nationalen Dekade gegen Krebs

https://www.gesundheitsforschung-bmbf.de/de/8498.php

Dieser Leitfaden dient als Hilfestellung zur Gestaltung eines Antrags für eine klinische Studie mit dem Ziel des Vergleiches und der Optimierung bereits bestehender präventiver, diagnostischer oder therapeutischer Interventionen in der krebsbezogenen Gesundheits- und Krankenversorgung.

Im Antrag soll die geplante Vergleichs- und Optimierungsstudie bereits so weitgehend beschrieben werden, dass eine gutachterliche Bewertung der besten Studienkonzepte im Hinblick auf Relevanz, Patientennutzen und Erfolgsaussichten möglich ist. Weiterhin müssen Angaben dazu gemacht werden, wie und unter Einbezug welcher Akteure und Interessengruppen die Vergleichs- und Optimierungsstudie im Zuge der Konzeptentwicklungsphase vorbereitet werden soll.

Der Leitfaden hebt hierzu einige Aspekte der Förderrichtlinie nochmals besonders hervor und erläutert diese.

1. Wen kann ich ansprechen?

Es wird empfohlen, zur Antragsberatung Kontakt mit dem DLR Projektträger Gesundheit aufzunehmen. Ansprechpartner sind:

Dr. Hubert Misslisch (hubert.misslisch@dlr.de); 0228 3821-1271),

Dr. Axel Aretz (axel.aretz@dlr.de); 0228 3821-1151),

sowie speziell in Sachen Partizipation (Beteiligung und Einbezug relevanter Interessengruppen):

Dr. Matthias von Witsch (matthias.vonwitsch@dlr.de); 0228 3821-1209).

2. Was wird gefördert?

Gegenstand der Förderung ist die Konzeptentwicklung und Durchführung wissenschaftsinitiierter, multizentrischer, prospektiver, kontrollierter klinischer Studien für die krebsbezogene Gesundheits- und Krankenversorgung. Ziel der Studien ist der Vergleich und die Optimierung bereits bestehender präventiver, diagnostischer oder therapeutischer Interventionen. Jede Studie muss eine konfirmatorische Zielsetzung aufweisen.

Die Studien sollen essentielle, praxisrelevante Fragen adressieren und ein hohes Potenzial zur Verbesserung der Versorgungspraxis aufweisen. Die Studien sollen auch auf eine messbare Verbesserung der Lebensqualität der Patientinnen und Patienten ausgerichtet sein. Sie sollen darauf abzielen, Empfehlungen und Leitlinien bzw. Standards für die Praxis entscheidend weiterzuentwickeln.

Die Förderung der Studien erfolgt in zwei Phasen:

2.1. Konzeptentwicklung

Zunächst wird eine Konzeptentwicklungsphase gefördert. Hier sollen wissenschaftliche Planungsarbeiten betrieben werden, welche die notwendigen Grundlagen für die Durchführung der darauffolgenden Realisierungsphase liefern. Diese Phase dient der wissenschaftlichen Entwicklung des Studienkonzepts unter aktivem Einbezug relevanter Interessengruppen, vor allem von Patientinnen und Patienten bzw. deren Vertretungen. In die Entwicklung des Studienkonzepts soll auch eine wissenschaftlich fundierte, umfassende, systematische Bewertung der Literatur und einschlägiger Studienregister zwecks Erhebung des aktuellen Standes der Forschung einfließen, die über das Maß der zur Antragstellung notwendigen Recherchen hinausgeht. Der Auf- bzw. Ausbau der Studiengruppe, die Verifizierung des Rekrutierungspotentials und die Entwicklung von Studiendesign und Methodik sind weitere wichtige Aspekte dieser Planungsarbeiten.

2.2 Realisierung

In der anschließenden, ebenfalls partizipativ gestalteten Realisierungsphase erfolgt die Umsetzung und Ergebnisverwertung der konfirmatorischen, multizentrischen Vergleichs- und Optimierungsstudie.

Falls notwendig und zielführend kann der eigentlichen Realisierungsphase noch eine Pilot-, bzw. Machbarkeitsstudie vorgeschaltet werden, die der weiteren Vorbereitung dieser Studie dient. Mögliche Ziele der Machbarkeitsstudie können z. B. die Operationalisierung der pati-

entenrelevanten Endpunkte, die Erprobung von patientenrelevanten Therapieregimen unter Berücksichtigung ihrer Machbarkeit und Akzeptanz, eine Nutzenabschätzung der neuen Therapie, eine Dosisfindung und/oder eine Abschätzung des Nutzen-Risiko-Verhältnisses sein. Auch hierbei sind alle relevanten Interessengruppen bzw. ihre Vertretungen einzubinden. Gegen Ende der Machbarkeitsstudie ist ein Bericht sowie ggf. ein modifizierter Antrag zur weiteren Realisierung der Studie vorzulegen.

3. Wie wird gefördert?

Zunächst wird eine Zuwendung für eine in der Regel bis zu sieben-monatigen Konzeptentwicklungsphase gewährt.

Mit Ende dieser vorbereitenden ersten Phase ist aufbauend auf den Erkenntnissen der erfolgten Planungsarbeiten ein detaillierter Antrag zur Realisierung der eigentlichen, in der Regel bis zu acht-jährigen Vergleichs- und Optimierungsstudie vorzulegen.

Falls notwendig und zielführend kann der eigentlichen Realisierungsphase eine Machbarkeitsstudie vorgeschaltet werden, die der weiteren Vorbereitung dieser Studie dient. Mögliche Ziele der Machbarkeitsstudie können z. B. die Operationalisierung der patientenrelevanten Endpunkte, die Erprobung von patientenrelevanten Therapieregimen unter Berücksichtigung ihrer Machbarkeit und Akzeptanz, eine Nutzenabschätzung der neuen Therapie, eine Dosisfindung und/oder eine Abschätzung des Nutzen-Risiko-Verhältnisses sein. Auch hierbei sind alle relevanten Interessengruppen bzw. ihre Vertretungen einzubinden.

Nach Abschluss der Konzeptentwicklungsphase wird gesondert zu den weiteren Antrags- und Förderschritten aufgefordert.

Bedingung für die Fortsetzung der Finanzierung in den einzelnen Förderphasen ist jeweils ein erneuter Bewertungsschritt.

Die „Grundsätze und Verantwortlichkeiten bei der Durchführung klinischer Studien“ des BMBF sind verpflichtend zu beachten:
http://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/GF/Grundsaetze_Verantwortlichkeiten_Klinische_Studien.pdf.

Partizipation

Partizipative Ansätze sind in der Planung, Durchführung und bei der Verwertung der Ergebnisse des Vorhabens umzusetzen. In besonderen Ausnahmefällen, in denen eine Einbindung nicht oder nicht in allen o. g. Projektabschritten möglich ist, sind die Gründe hierfür zu benennen. Wir verweisen in diesem Zusammenhang auf Hinweise von INVOLVE, einer Organisation, die sich im Auftrag des National Institute for Health Research in Großbritannien intensiv mit der Einbindung von Öffentlichkeit und Patientinnen bzw. Patienten in die Forschung befasst („Briefing Notes for Researchers“; http://www.invo.org.uk/resource-centre/resource-for-researchers/).

4. Wie werden die Fördermittel beantragt?

Die Anträge für Konzeptentwicklungsphasen müssen elektronisch über das Internet-Portal „easy-Online“ (https://foerderportal.bund.de/easyonline/reflink.jsf?m=KD-KREBSDEKADE&b=KD-OPTSTUDIEN2019) beim DLR Projektträger eingereicht werden, und zwar spätestens bis zum

13. Mai 2019.

Entscheidend für die Fristwahrung ist der auf elektronischem Wege im Internet-Portal verbindlich eingereichte Antrag. Eine Vorlage per E-Mail oder FAX ist nicht möglich.

Ein vollständiger Antrag umfasst

- den sogenannten Formantrag AZA/AZAP bzw. AZK,
  als separates PDF-Dokument eine **deutschsprachige** Vorhabenbeschreibung ausschließlich für die Konzeptentwicklungsphase mit Arbeitsplan, Meilensteinplanung und Finanzierungsplan des Vorhabens, sowie einem Verwertungsplan mit Darstellung der Notwendigkeit der Zuwendung[1],

- ebenfalls als separates PDF-Dokument eine begutachtungsfähige, **englischsprachige** Beschreibung der Studie einschließlich der Konzeptentwicklungsphase (siehe untenstehendes Muster).

Die begutachtungsfähige, englischsprachige Beschreibung muss den **Vorgaben und der Formatierung** der Mustervorlage entsprechen (siehe Punkt 6.).

5. Was geschieht nach der Einreichung des Antrags?

Die englischsprachigen Beschreibungen werden von einem unabhängigen, interdisziplinär und international besetzten Begutachtungsgremium bewertet.

Auf der Grundlage dieser Bewertung werden die für eine Förderung in der Konzeptentwicklungsphase geeigneten Projekte ausgewählt. Die Antragstellenden werden über das Ergebnis schriftlich informiert.

Für die ausgewählten Projektideen werden dann zunächst Zuwendungen für Konzeptentwicklungsphasen gewährt.

Zu den weiteren Förderschritten siehe Punkt 3.

6. Mustervorlage für die begutachtungsfähige, englischsprachige Beschreibung

Die unten dargestellte Mustervorlage kann unter http://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/GF/Word_Vorlage_Leitfaden_Studien_Krebs_2019.docx auch als editierbare MS-Word-Datei heruntergeladen werden.

[1] AZAP: https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=1750
AZK: https://foerderportal.bund.de/easy/module/easy_formulare/download.php?datei=1752

Clinical Study - Comparison and Optimization of Interventions in Prevention, Diagnosis and Treatment of Cancer

This application consists of two parts:

- Part A: Description of the envisaged realization-phase (max. 7,5 pages; 2 extra pages may be added if an additional pilot study is deemed necessary for preparation. Please refer to Nr. 12 of Part A)
- Part B: Detailed description of the proposed concept-development-phase (max. 3,5 pages)

To ensure comparability of all submitted applications please prepare your application in English, using the template below, and **not exceeding 11 pages in total** (2 extra pages may be added if an additional pilot study is deemed necessary for preparation. Please refer to Nr. 12 of Part A) (General requirements are: DIN A4, at least 10 point Arial and 9 point Arial for the synopsis and references, margins of at least 2 cm, single-spaced lines). The number of pages includes cited literature.

Please delete all explanatory texts from the template (headlines must remain in place!) and insert your information.

Signatures of the applicant and major participants (e. g. biometrician) are mandatory in parts A and B.

Part A: Description of the envisaged realization-phase (max. 7,5 pages)

LAY SUMMARY PART A (ENVISAGED STUDY)

Please provide a brief summary of the envisaged study including the relevance for patients, their families and carers. Summarize the objectives, design, expected outcomes and potential of the findings to translate beyond the research setting.

Please note: The lay summary needs to be written as a plain English summary, such that it is clear, easy to understand, and is easily accessible to a broad lay audience. Avoid the use of highly technical terms. This summary will be used for support of lay persons involved in the review of these proposals. It may be used later on when providing information to the public concerning the variety of research funded within this call. The word limit is **300 words**.

STUDY SYNOPSIS

APPLICANT/COORDINATING INVESTIGATOR	Name, address, telephone, e-mail *In case of multiple applicants the principal investigator/coordinating investigator[2] of the study who will assume responsibility for conducting the clinical study, should be listed first.*

[2] Zur Definition des "Investigator" siehe “Guideline for Good Clinical Practice” der International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH GCP) (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf).
1.34 Investigator: “A person responsible for the conduct of a clinical study at a study site. If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be

TITLE OF STUDY	*Descriptive title identifying the study design, population, and interventions to be compared. In case of funding this title shall be quoted in the annual reports of the BMBF. Acronym is optional.*
CANCER ENTITY(IES)	*The type(s) of cancer being studied*
OBJECTIVE(S)	*Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the study that determines sample size calculation.*
INTERVENTIONS	*Description of the interventions (preventive, diagnostic, or therapeutic) to be compared and/or optimized as well as dose and mode of application, if applicable.* Experimental interventions: Control intervention: Duration of intervention per patient: Follow-up per patient:
KEY INCLUSION AND EXCLUSION CRITERIA	Key inclusion criteria: Key exclusion criteria:
OUTCOME(S)	Primary endpoint: Key secondary endpoint(s): Assessment of safety:
STUDY TYPE	*e.g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/cross-over*
STATISTICAL ANALYSIS	Primary endpoint analysis and population: Safety: *Please describe the strategy for assessment of safety issues in the study. Which are relevant safety variables?* Secondary endpoint analysis:
SAMPLE SIZE	To be assessed for eligibility (n = …) To be allocated to study (n = …) To be analysed (n = …)
STUDY DURATION	Time for preparation of the study (months): Recruitment period (months): First patient in to last patient out (months): Time for data clearance and analysis (months): Duration of the entire study (months):
PARTICIPATING CENTERS	To be involved (n): *How many centers will be involved? Please also list the cities.*
PREVIOUS BMBF PROJECT NUMBER	*If applicable, the BMBF code number of the latest application or of any previous application(s) for project-funding relevant to this study.*
SUBMISSION OF PROPOSAL ELSEWHERE / OTHER FUNDING	*Please state, if the same or a similar version of this proposal has been submitted in another funding programme, or if you receive any other funding for parts of the study proposed here.*

called the principal investigator." 1.19 Coordinating investigator: "An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicenter study." Diese Definition sollte auch für nicht-pharmakologische Studien verwendet werden.

1. RELEVANCE

Which (medical) problem with regard to cancer is addressed? Which principal research questions are addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.

1.1 PREVALENCE, INCIDENCE, MORTALITY OF THE CANCER ENTITY (ENTITIES)

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 disease, according to most reliable data.

1.2 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 socio-economical burden of disease.

1.3 IMPROVEMENT OF PREVENTION / DIAGNOSIS/THERAPY/IMPACT OF THE STUDY

Novelty: Which options are available for prevention/diagnosis/therapy? What is the novel aspect of the proposed study? Which existing paradigms are challenged by the study?

Clinical impact: Provide information on the possible impact on the delivery of health care and on clinical practice. Which evidence gap is to be closed?

Patient benefit: Describe the possible clinical and quality-of-life benefit(s) for the patients. Include the patient's perspective. Detail the potential impact on relieving the burden of disease and/or treatment (e.g. dose reduction, avoiding adverse effects, shortening futile treatment times).

Socioeconomic impact: Reflect on the socioeconomic impact of the study.

1.4 PATIENT INVOLVEMENT

Please describe how involvement of patients will be implemented in the planning, conduction and exploitation of results of the study[3]. Please note: Patient involvement is mandatory wherever feasible and constructive.

Who? Which patients, patient representative(s), patients' self-help group(s) or patient advocacy group(s) are to be involved in the planning of the study? Who is planned to be involved during the conduction of the ongoing study? Who is planned to be engaged in dissemination of the results?

How? How will patient representative(s), patients' self-help group(s) or patient advocacy group(s) be involved in the planning of the study? How will the patients' needs, goals, concerns and preferences be considered? How will patient representative(s), patients' self-help group(s) or patient advocacy groups be engaged during the conduction of the study and dissemination of results?

When? When will patients, patient representative(s), patients' self-help group(s) or patient advocacy group(s) be involved in e. g. developing the main question, developing the study design, defining endpoints, accompanying the ongoing study, communicating study results?

[3] s. auch eine Einführung von INVOLVE zugehörig zum Britischen National Institute for Health Research, NHS „Briefing note for Researchers": http://www.invo.org.uk/resource-centre/resource-for-researchers/

Is engagement at specific time points or continuous engagement (including feedback loops) planned?

Patient involvement can be implemented in different stages of the study and to a different extent. Please justify why your concept is adequate for the planned study.

2. EVIDENCE

Set your study into perspective. This section should detail the background of the starting hypotheses of the study.

Prove that the envisaged study has not been conducted previously. Provide the evidence for the efficacy of the established interventions to be compared/optimized, and for the feasibility of the proposed comparison. Please describe how you searched for the evidence. Indicate the electronic databases searched (e. g. MEDLINE, Cochrane Central, the Cochrane library, clinicalstudys.gov, Deutsches Register Klinischer Studien (DRKS) or International Clinical Trials Search Portal (ICTRP)). Provide a narrative summary: Which studies have been conducted either by you or by others to substantiate your study-hypothesis? What is the relevance of their results? Give references to any relevant systematic review(s)[4] and/or pilot studies, feasibility studies, relevant previous/ongoing studies, case reports/series. State what your study adds to the existing body of evidence.

3. JUSTIFICATION OF DESIGN ASPECTS

Please provide justifications and do not list the respective information only.

3.1 CONTROL(S) / COMPARATOR(S)

Justify the choice of control(s) / comparison(s): Is placebo necessary as a third arm?

3.2 INCLUSION / EXCLUSION CRITERIA

Justify the population to be studied, include reflections on generalisability and representativeness.

3.3 INTERVENTIONS

Justify the choice of the interventions planned for the study. Illustrate your intervention scheme graphically in the appendix. Please consider following the TIDieR checklist and guide for describing the interventions.[5]

3.4 OUTCOME MEASURES

Justify the envisaged endpoints: Are the endpoints relevant for the patients? Are there other studies that have utilized this endpoint? Are there any guidelines proposing this endpoint/these endpoints? Discuss the clinical relevance of the outcome measures for the target population. Have the measures been validated?

3.5 METHODS AGAINST BIAS

Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating participants to study groups? Will study-site effects be considered in randomization?

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[4] Eine Definition für einen systematischen Review finden Sie unter Cook DJ, Mulrow CD, Haynes RB. Systematic Reviews: Synthesis of Best Evidence for Clinical Decisions. Ann Intern Med 1997; 126 (5): 376-380

[5] Hoffmann T, Glasziou P, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687

Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e. g. blinded assessment of outcome).

3.6 PROPOSED SAMPLE SIZE/POWER CALCULATIONS

What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians, the software used for sample size calculation etc., as appropriate. Justify the size of difference that the study is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the study is powered to exclude. It is important that the sample size calculations take into account anticipated rates of non-compliance and losses to follow up.

If the proposed sample size is not based on statistical calculation, please justify why another approach has been chosen and why the proposed sample size will be adequate to answer the objective of the study.

3.7 FEASIBILITY OF RECRUITMENT

What is the evidence that the intended recruitment rate is achievable (e. g. pilot study)? Describe from what data you assessed the potential for recruiting the required number of suitable subjects. Comment on the prevalence of the disease, the access to patients and their willingness to be randomized in a study.

4. STATISTICAL ANALYSIS

What is the strategy behind the statistical analysis? What is the strategy for analysing the primary outcome? If interim or subgroup analyses are planned, please specify.

5. ETHICAL CONSIDERATIONS

Discuss briefly the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.

6. STRATEGIES FOR DATA HANDLING

Describe briefly what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your data (also by third parties, taking into account privacy rules and proprietary data). Also mention at which stage data sharing will be ensured. Please use existing standards and data repositories where appropriate. Further information can be found under:
http://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/guidelines_research_data.pdf.

7. STUDY MANAGEMENT

7.1 MAJOR PARTICIPANTS

Please indicate persons responsible for design, management and analysis of the study.

#	Name	Affiliation	Responsibility/Role	Signature
			Principal/Coordinating Investigator	
			Study Statistician [6]	

7.2 STUDY EXPERTISE

Please indicate study expertise of all above-mentioned participants by citing relevant publications and/or specifying major role in ongoing study(ies) (to be identified; max. 5 publications of the last 5 years per person). Ensure that the team of investigators has the necessary expertise to carry out the study.

7.3 STUDY-SUPPORTING FACILITIES

Which study-specific facilities and other resources are available for conducting the study?

8. EXPLOITATION / DISSEMINATION OF RESULTS

How can results be transferred to the health care system? Briefly describe the key steps of your strategy. Briefly comment on the skills and expertise of the members of the management team with regard to exploitation. Are there plans for involvement of other experts? Briefly discuss the regulatory aspects of the envisaged study. Are there plans to involve regulatory experts/authorities in the planning and conduction of the study? Briefly comment on the freedom to operate in respect to patent and exploitation strategy, if applicable.

9. FINANCIAL SUMMARY

Please give a rough estimation of the costs expected for the total duration of the study.

Item	Costs (€)
Clinical Project Management	
Project Management: (e.g. Statistical Planning, Protocol, Case Report Form (CRF), Informed Consent, CRF printing)	
Case Payment	
Data Management (e.g. Database Set-up and Validation Data Entry, Coding, Query Management)	
Biostatistics	
Quality Assurance (e.g. Pre-Study Visits, On-Site Monitoring, Data Monitoring and Safety Committee)	
Travel (e.g. Study Committees, Meetings)	
Materials	
Study Drug	
Fees, Insurance	
Other	
TOTAL	

[6] Assure that the biostatistician has the expertise to carry out clinical studies, e.g.: GMDS certificate (http://www.gmds.de/organisation/zertifikate/zertifikate.php), ICH guidance E9 *"Statistical Principles of Clinical Trials".*

Co-financing of the study by a company:

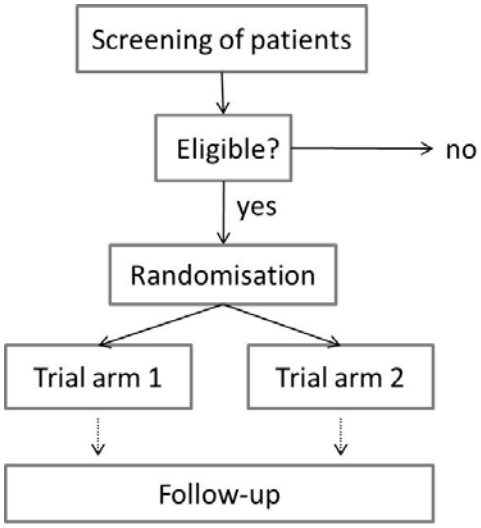
For pharmacological interventions: study drug under patent protection
☐ no; ☐ yes, until date:

Commercial interest: Describe any potential commercial interest of a company in the results of the study or explain why no such interest exists. Note that direct substantial commercial interest of a single company in the results of the study precludes funding.

10. INTERVENTION SCHEME / STUDY FLOW

Provide a schematic diagram of the study flow including interventions and procedures in order to complement the information given in the respective sections above. DO NOT provide a visit schedule, procedure table, time table etc. or any other further explanations. Only abbreviations can be listed in a legend.

Basic example for a schematic diagram of the study design:



11. REFERENCES

For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

12. NECESSITY AND REQUESTED FUNDING OF A PILOT STUDY ("MACH BARKEITSSTUDIE")

Judging from the time-point of submission of the proposal for the concept development phase, will it be necessary to conduct further preparatory steps within a pilot study before the actual realization phase of the clinical study can be initiated?

please tick:
yes □ no □

If “yes”, please elaborate here which further steps of preparation are envisaged for the pilot or feasibility study, and why they cannot be accomplished within the concept development phase.

If “yes”, two extra pages may be added to the page-limit for this part.

Possible aims of a pilot or feasibility study are e.g. the operationalization of patient-relevant end-points, testing of patient-relevant therapy regimens with regard to their practicability and acceptance, further work regarding the feasibility of recruiting the required number of suitable subjects, cost-benefit- or risk-benefit- analyses, or dose-adjustments.

Please note that involvement of patients and other stakeholders will be mandatory wherever feasible and constructive also in pilot or feasibility studies.
(After conduction of the concept development phase, pilot or feasibility studies preceding the actual clinical studies may be proposed where deemed necessary.)

FINANCIAL ESTIMATE FOR THE PILOT STUDY

Please give a rough estimation of the costs expected for the total duration of the study.

Duration of pilot study:

Item	**Costs (€)**
Clinical Project Management	
Project Management: (e.g. Statistical Planning, Protocol, Case Report Form (CRF), Informed Consent, CRF printing)	
Case Payment	
Data Management (e.g. Database Set-up and Validation Data Entry, Coding, Query Management)	
Biostatistics	
Quality Assurance (e.g. Pre-Study Visits, On-Site Monitoring, Data Monitoring and Safety Committee)	
Travel (e.g. Study Committees, Meetings)	
Materials	
Study Drug	
Fees, Insurance	
Other	
TOTAL	

Co-financing of the study by a company:

For pharmacological interventions: study drug under patent protection
☐ no; ☐ yes, until date:

Commercial interest: Describe any potential commercial interest of a company in the results of the study or explain why no such interest exists. Note that direct substantial commercial interest of a single company in the results of the study precludes funding.

Part B: Detailed description of the proposed concept-development-phase (max. 3,5 pages)

LAY SUMMARY PART B (CONCEPT DEVELOPMENT PHASE)

Please provide a brief summary of the proposed concept development phase. Highlight the added value of the concept development phase for preparation of the envisaged study described in Part A. Summarize the additional preparatory steps planned. Briefly sketch which relevant stakeholders you are planning to involve, and for what reason.

Please note: The lay summary needs to be written as a plain English summary, such that it is clear, easy to understand, and is easily accessible to a broad lay audience. Avoid the use of highly technical terms. This summary will be used for support of lay persons involved in the review of these proposals. It may be used later on when providing information to the public concerning the variety of research funded within this call. The word limit is **300 words**.

APPLICANT/COORDINATING INVESTIGATOR

Provide the name, affiliation and contact data of the principal investigator/coordinating investigator who will assume responsibility for conducting the concept development phase.

MAJOR PARTICIPANTS

Please indicate the major participants supporting the principal investigator.

#	Name	Affiliation	Responsibility/Role	Signature

AIMS AND WORK PLAN (MAX. DURATION: 7 MONTHS)

Describe in detail the main aims and the work plan for the concept development phase.

Where do you currently stand regarding the preparation of the envisaged clinical study? What needs to be achieved in order to provide a solid basis for initiation of the clinical study? Which aspects of the envisaged clinical study must be developed further? How will the work in the concept development phase contribute to the preparation and initiation of the realization phase of the envisaged clinical study? Which concrete milestones must be achieved during the concept development phase? How will these be reached? Provide a time frame and an overview of milestones for the work in the concept development phase.

INVOLVEMENT OF PATIENTS AND OTHER RELEVANT STAKEHOLDERS

Please describe how patients and other relevant stakeholders (e. g. clinicians, health care personnel, regulators, etc.) will be involved in the concept development phase.

Please note: Patient involvement is mandatory wherever feasible and constructive.

Who will be involved?

What roles will the involved persons/organisations play? What are the main features of the envisaged clinical study that will be influenced by the involved persons (e. g. developing the main question, developing the study design, defining endpoints, feasibility of recruitment, exploitation of study-results, etc.).

How/by which means and when will patients and other relevant stakeholders be involved? How will especially the patients' needs, goals, concerns and preferences be considered?

Please justify why your concept for involvement is adequate for the concept development phase.

REQUESTED FUNDING FOR THE CONCEPT DEVELOPMENT PHASE

	PM	Description/Justification	Amount requested (€)
Personnel	x		
Scientific			
Non-scientific			
Other			
Contracts	x		
Travel Expenses	x		
Other Expenses			
Total	**x**		

PM = person months

(if more than one partner is to receive funding, please add additional charts)

Total amount of funding (for all partners):