



Deutsche Krebshilfe

Gegründet von Dr. Mildred Scheel

Förderungsschwerpunktprogramm

Therapiestudien bei Patienten im höheren Lebensalter bzw. bei Patienten mit Ko-Morbiditäten und/oder Einschränkungen von Organfunktionen und/oder schlechtem Allgemeinzustand ('medically non-fit').

Leitfaden für das Kurzprotokoll (Outline Trials Application for the Funding of a Clinical Trial)

Version vom 20.03.2007

Bitte reichen Sie zunächst eine maximal 10-seitige Antragsskizze (10 Exemplare, in englischer Sprache) ein, die nach den Vorgaben dieses Leitfadens zu erstellen ist. Die Skizzen sind bis zum **31.07.2007**, 12:00 Uhr bei der Geschäftsstelle der Deutschen Krebshilfe einzureichen. Verspätet eingehende Skizzen können nicht berücksichtigt werden. Antragsskizzen, die den Vorgaben dieses Leitfadens nicht entsprechen, können ebenfalls nicht berücksichtigt werden.

Die Antragsskizze ist in englischer Sprache abzufassen. Bitte übernehmen Sie alle Ordnungsnummer und die dazugehörigen Überschriften aus diesem Leitfaden. Punkte, die für Sie nicht zutreffen, kennzeichnen Sie mit 'entfällt' ('does not apply'; gegebenenfalls mit Begründung). Bitte schicken Sie uns die Angaben zu den Antragstellern und die Zusammenfassung zusätzlich, sowohl in Englisch als auch in Deutsch, als Word-Dokument per E-Mail (FA-Therapiestudien@krebshilfe.de).

1. GENERAL INFORMATION

1.1 STUDY SYNOPSIS

Applicant/Coordinating Investigator	<ul style="list-style-type: none"> - Last name, first name, academic title, date of birth, - Institution and department, - Postal address, - Telephone, fax, e-mail address. <p>In case of multiple applicants the principal investigator/coordinating investigator of the trial who will assume responsibility for conducting the clinical trial, should be listed first.</p>
Title of the study	The title of the trial (not exceeding 140 characters) should be as precise as possible. In case of funding this title shall be quoted in the annual reports of the funding organisations. Acronym is optional.
Short title of the trial	
According to AMG	Is the clinical trial a trial according to §§40-42a of the German Medicine Act (AMG).
Objective(s)	Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.
Intervention(s)	<p>Description of the experimental and the control treatments or interventions as well as dose and mode of application.</p> <ul style="list-style-type: none"> - Experimental intervention. - Control intervention. - Duration of intervention per patient.
Key inclusion and exclusion criteria	<ul style="list-style-type: none"> - Key inclusion criteria. - Key exclusion criteria.
Outcome(s)	<ul style="list-style-type: none"> - Primary efficacy endpoint. - Key secondary endpoint(s). - Assessment of safety.
Duration of treatment an follow-up	<ul style="list-style-type: none"> - Duration of treatment per patient. - Follow-up per patient.
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	<ul style="list-style-type: none"> - Efficacy. - Description of the primary efficacy analysis and population. - Safety. - Secondary endpoints.
Sample size	<ul style="list-style-type: none"> - To be assessed for eligibility (n = ...). - To be allocated to trial (n = ...). - To be analysed (n=...).
Trial Duration	- Duration of the entire trial (First patient in to last patient out).
Participating centres	How many centres will be involved?

1.2 SUMMARY

Give a short summary of the main aspects of the project. The project summary serves to inform the committees, which make the decision on your grant, of the principal aspects e.g. goals, design, subjects, expected outcome of your project.

1.3 INTERVENTION SCHEME / TRIAL FLOW

Describe the intervention scheme and give a schematic diagram (flow chart) of design, procedures and stages.

2. THE MEDICAL PROBLEM

Which oncological problem is to be addressed? What is the novel aspect of the proposed trial? Which principal research questions are to be addressed?

Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.

Evidence: Set your trial into perspective. Which trials have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and/or feasibility studies, relevant previous/ongoing trials

3. JUSTIFICATION OF DESIGN ASPECTS

3.1 CONTROL(S) / COMPARISON(S)

Justify the choice of control(s)/comparison(s): Is placebo acceptable? Which trials have established efficacy and safety of the chosen control regimen?

3.2 INCLUSION / EXCLUSION CRITERIA

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

3.3 OUTCOME MEASURES

Justify the endpoints chosen: Are there other trials 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?

3.4 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 trial groups?

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).

3.5 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.

3.6 FEASIBILITY OF RECRUITMENT

What is the evidence that the intended recruitment rate is achievable? Describe from what data you assessed the potential for recruiting the required number of suitable subjects.

4. STATISTICAL ANALYSIS

What is the proposed strategy of statistical analysis? What is the strategy for analysing the primary outcome? If interim analyses are planned, please specify. Are there any subgroup analyses?

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. FINANCIAL SUMMARY

Please give a rough estimation of the costs expected for the recruiting and the follow up (e. g. Clinical Project Management, Trial Design and Preparation, Statistical Planning, Protocol, Case Report Form (CRF), Informed Consent, CRF printing, Data management, IT, Biometry, on-site Monitoring, Data Monitoring and Safety Committee, Travel costs for Trial Committees, Meetings, Reference Centres, Materials, Insurance).

Please indicate any co-financing of the trial by industry and/or other third parties (e. g. trial drugs).