DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Clinical Research:

DZHK-associate Clinical Studies, Registries, or Cohort Studies

(without DZHK financing)

- Application preparation instructions for application template -

General

Preparing your application

Please prepare your application in English not exceeding a maximum of 10 pages in length for the given headlines 1.-9. It contains a synopsis of the study protocol, an abstract ('summary'), at least one page concerning the scientific aims of the study, information about statistics, ethics, financial aspects, and the study management. The scientific matching is asked for as well as a short explanation about the association's advantages for the DZHK and a description of the expectations on the DZHK (half a page). Structure your application using the headings listed below. Make an entry under every heading. Do not erase any heading, rather answer 'not applicable'. Applications that do not meet the guideline will not be considered.

Note

Studies that apply for DZHK-association may be submitted any time.

Submission

Via email: → Please submit one signed PDF file to clinicalstudies@dzhk.de

1. Study synopsis

a) Applicant/ Coordinating investigator	In case of multiple applicants the principal investigator/coordinating investigator[1] of the trial who will assume responsibility for conducting the clinical trial, should be listed first. • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • E-mail address
c) Title of 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. Please provide an acronym*
d) Medical condition	*The medical condition being studied (e.g. asthma, myocardial infarction, depression).*
e) Objective(s)	*Which principal research questions are to be addressed? Specify clearly the primary hypothesis of the trial that determines sample size calculation. Name any secondary hypotheses.*
f) Intervention(s)	*Description of the experimental and the control treatments or interventions as well as dose and mode of application. For diagnostic tests or procedures the index test and the reference procedure (gold-standard) should be described.* Experimental intervention / index test: Control intervention / reference test: Follow-up per patient: Duration of intervention per patient: Experimental and/or control off label or on label in Germany: *if applicable*
i) Study type	*e.g randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/cross-over, prognostic, diagnostic*
m) Participating centres	To be involved (n): *How many centres will be involved?* Signed agreement to participate (n)*: How many centres have signed an agreement to participate? Full list under 6.2.*

[1] "Investigator" as defined in the harmonised "Guideline for Good Clinical Practice" of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH GCP) (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf). This definition should be used accordingly for non-drug trials/studies: *(1.34 Investigator) "A person responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator."* (*1.19 Coordinating investigator) "An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial."*

1.1 Summary

Give a summary of the main aspects of the project; it should not exceed 15 lines (max. 1600 characters incl. blanks) and include information on the principal aspects e.g. goals, design, subjects, expected outcome of your project.

It should be concise as well as comprehensible to a lay public. In case of DZHK-association this summary may be used for display on the DZHK-Internet. Electronic search will be eased if you avoid abbreviations and include suitable key words.

1.2 Key words

1.3 Intervention Scheme / Trial Flow

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

1.4 Frequency and Scope of study Visits

What is the proposed frequency and scope of study visits and, if applicable, the duration of post-trial follow-up? Please give a schematic diagram additionally.

2. Scientific aim(s) of the trial - the Medical problem

Which medical 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.

2.1 Evidence

Set your trial into perspective; substantiate your starting hypothesis. What is the rationale for the intervention? 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 (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. State what your study adds to the totality of evidence when your study is added to previous work. Include a description of how you searched for the evidence (databases, search terms, limits) and how you assessed its quality — i.e., how you selected and how you combined the evidence.

2.2 The need for a trial

What impact will the results have on clinical practice or understanding of the proposed intervention or underlying disease? Why is a trial needed now?
How will a) the individual patient and b) society/science benefit from the trial?

Detail potential economic impact.

3. Scientific aim(s) of the trial – justification of design aspects

Please do provide justifications in addition to listing the respective parameters.

3.1 Control(s)/comparator(s)

Justify the choice of control(s)/comparison(s): Is placebo acceptable? Is there a gold standard? Which trials establish efficacy and safety of the chosen control regimen? For diagnostic trials: What is the rationale for the units, cut off and/or categories?

3.2 Inclusion and exclusion criteria

Justify the population to be studied and 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? Will trial site effects be considered in randomisation?
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).
For diagnostic trials: what is the training and expertise of persons executing and reading the index tests and the reference standards.

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 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 trial is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the trial 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.

3.6 Feasibility of recruitment

What is the evidence that the intended recruitment rate is achievable (e.g. pilot study)? Describe the data from which you have assessed the potential for recruiting the required number of suitable subjects.

4. Statistical Analyses

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? What are the methods for calculating test reproducibility in diagnostic trials?

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. Trial management

6.1 Key participants

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

Trial Sponsor				
Key participants				
#	**Name**	**Affiliation**	**Responsibility/Role**	**Signature**
1			Principal/Coordinating Investigator	
2			Trial statistician[2]*	

pls. take care to allow for at least 14 days for the statistician to consider statistics of the trial

6.2 Supporting facilities

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

Trial Supporting facilities *(central laboratories, pharmacies etc.)*			
#	Name	Affiliation	Responsibility/Role
Recruiting centres *(please provide signatures on declaration of commitment)*			
#	Name	Affiliation *(only institution and city, no complete address)*	Expected no. of patients recruited for the complete trial
		Total sum of recruited patients	Σ =

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

7. Financing

7.1 Financial summary

Indicate total duration of the trial, the period of time for which the project is funded and when funding begins. Please give a rough estimate of the costs expected for the total duration of the trial:

Item	**Total funding period (€)**
Administrative/organisational trial management (incl. quality management, data management, travel costs, fees and insurance, etc.)	
Case payments	
Materials (e.g. trial drug, etc.)	
Other: *please specify*	
TOTAL	

7.2 Outline of cost coverage

Name all funding sources and amount of money acquired. Is the trial co-financed by a company?

7.3 Is the trial drug or the therapeutic, diagnostic or prognostic test procedure that is object of this trial under patent protection?

☐ Yes, until DATE

☐ No

7.4 Commercial interest

Please describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists. **Please note that proposals for trials whose outcomes are of direct commercial interest to a company are not eligible for DZHK funding.**

8. Match of DZHK and trial aims

8.1 Matching of scientific aim(s)

Please describe briefly how your trials aim(s) match with the DZHK aims outlined in §2 of DZHK statutes (Vereinssatzung).

8.2 Advantages linked to the trials DZHK association for the DZHK

Please outline why the DZHK should be associated with your trial from the DZHKs perspective.

8.3 Expectations related to DZHK-association of the trial

Please indicate your expectations from the DZHK in regard of the DZHK-association commitment.

8.4 Suggestions for merging the trial into DZHK infrastructure

Please provide your plan of how to fit your trial into the DZHK scientific infrastructure, e.g. do you plan to use the DZHK central data management (ZDM), to submit your data to the DZHK Use & Access policy, to apply DZHK-SOPs, etc..

9. Bibliography

Publication list in the order of appearance in the text. Please list only publications you cited. Please highlight your own project-relevant publications.

PLEASE DO NOT EXCEED A MAXIMUM OF 10 PAGES UP TO THIS POINT.