Bundesministerium
für Bildung
und Forschung

Leitfaden für die Antragstellung
im Rahmen der BMBF-Bekanntmachung für die Förderung
von Forschungsverbünden zur „Gesundheit im Alter“
Stand: 19.09.2006

Im Rahmen der Fördermaßnahme **„Gesundheit im Alter“** stellt das BMBF Fördermittel für inter- und multidisziplinäre Forschungsverbünde, die Fragestellungen zur Gesundheit im Alter aufgreifen, zur Verfügung. Dabei sollen insbesondere die übergeordneten Themenbereichen Ko- und Multimorbidität bei älteren Menschen sowie Stärkung der gesundheitlichen Ressourcen und der Autonomie im Alter bearbeitet werden. Der nachfolgende Leitfaden erläutert die Vorgaben zur Antragstellung. Die Randbedingungen der Förderung sind in der Förderrichtlinie des BMBF niedergelegt (http://www.gesundheitsforschung-bmbf.de/de/1381.php). **Eine Durchsicht dieser Richtlinien vor dem Verfassen des Antrags wird dringend empfohlen.**

Beim Projektträger des BMBF im DLR –Gesundheitsforschung, Heinrich-Konen-Str. 1, 53227 Bonn, (http://www.pt-dlr.de/) sind hierzu **formlose Vorhabenbeschreibungen** (Format: DIN A4, 1-zeilig, 11 Punkt Arial, doppelseitig bedruckt)

bis zum 03. Januar 2007

über den jeweils vorgesehenen Verbundkoordinator auf dem Postweg einzureichen. Eine Vorlage per „electronic mail“ oder Telefax ist nicht möglich. Im Hinblick auf die internationale Begutachtung ist, die Vorhabenbeschreibung **in englischer Sprache** zu verfassen und diese in **20-facher Ausfertigung** mit einer ungebundenen Kopiervorlage sowie im pdf-Format auf CD-ROM vorzulegen.

Die Vorhabenbeschreibungen sind entsprechend den Vorgaben dieses Leitfadens zu gliedern. Anträge, die den Vorgaben des Leitfadens nicht entsprechen, können ggf. bei der Begutachtung und Förderung nicht berücksichtigt werden.

Ansprechpartner beim Projektträger:
Dr. Wolfgang Ballensiefen Tel. 0228 3821-144
Dr. Martin Barth, Tel. 0228 3821-250

Guideline for Grant Application

Please prepare your application in English **not exceeding 10 pages for the consortium and 10 pages for each subproject proposal**.

Provide an entry under every heading and subheading. Signatures of principal / coordinating investigator are mandatory.

Note: *Applications that fail to comply with these requirements might be considered as not eligible and could be rejected without peer review.*

Description of Consortium

1. GENERAL INFORMATION ON THE CONSORTIUM

APPLICANT / COORDINATING INVESTIGATOR	Name, address, telephone, fax, E-Mail In case of multiple applicants the principal investigator / coordinating investigator of the project who will take responsibility for conducting the entire project should be listed first. • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
TITLE	*The title of the project (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 organisation. Acronym is optional.*
CONDITION/TOPIC	*The exact medical condition or topic being addressed.*
OBJECTIVE(S)	*Which principal research questions are to be addressed? Specify clearly the primary goal of the project. Which results are expected?*
KEY WORDS	*Maximum 6*
PROJECT DURATION	*In months*
SUMMARY	*Please give a summary of the main goals and methodological approach of the project (max. **1600 characters**). The project summary serves two main purposes: i) It will inform the multidisciplinary review committee of the principal aims of the subproject. ii) If your project is funded the summary will be published on the internet through an electronic information system. (It should therefore be concise as well as comprehensible to a lay public). Please avoid abbreviations.*

PARTICIPATING PARTNERS	*Example:*

Subproject No.	Partner	Titel of Sub-project	Function in the consortium	Contribution
1	*University of X..*		*Coordination*	
2	*University of Y….*		*Preclinical partner*	
..	*…*	*…*	*…*	*…*

2. OBJECTIVES, INNOVATION AND RELEVANCE

2.1 OBJECTIVES AND OVERALL CONCEPT OF THE CONSORTIUM

They should contain a description of the planned research priorities with respect to the current state of the art. Give a clearly defined thematic focus. Which problem is to be addressed? Which results are expected?

2.2 NOVEL ASPECT AND FUTURE IMPACT

What is the novel aspect of the proposed investigations? Which impact will the results have on clinical practice (e.g. prevention, diagnosis, therapy) or understanding of the addressed problem?

3. STRUCTURE OF THE PLANNED COOPERATION

3.1 COOPERATION, COORDINATION AND COMMUNICATION

Which structure is available, respectively will be implemented for an efficient cooperation within the consortium? How will the consortium be managed? What are the contributions of the individual partners? Describe measures of coordination and communication as well as structures of internal and external controlling and quality assurance planned or already in place.

3.2 ADDED VALUE

Comment on the synergistic effects of interaction within the consortium and potential for networking with other consortia as well as perspectives for the improvement of such structures.

3.3 TIMEFRAME / MILESTONES

In which time-frame major work-packages will be achieved; what milestones are planned?

3.4 FINANCIAL SUMMARY

Example:

Subproject No.	**Partner**	**Total costs of project**	**Applied BMBF Funds**	**Co-financed by industry or other sources** (if applicable)

1	*xyz GmbH*	*500.000 €*	*250.000 €*	*250.000 €*
2	*University of…*	*300.000 €*	*300.000 €*	*0*
…	*….*	*……*	*……*	*…..*

Description of subprojects **(N° XY, refer to main list)**

*The following outline is generally relevant for research projects. In case you want to apply for funding of a **clinical trial** (including a diagnostic study) or a* **cohort study**, *please proceed to the respective outlines in part **B** or **C** of this guideline.*

A. RESEARCH PROJECT

The description of each research project should not exceed 10 pages maximum.

1. GENERAL INFORMATION ON THE SUBPROJECT

PRINCIPLE INVESTIGATOR AND CO-INVESTIGATORS OF THE SUBPROJECT	Name, address, telephone, fax, E-Mail • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
TITLE	*The **title** of the project (not exceeding **140 characters**) should be precise. In case of funding this title shall be quoted in the annual reports of the funding organisation. **Acronym** (max **40. characters**) is optional.*
OBJECTIVE(S)	*Which principal research questions are to be addressed? Specify clearly the primary goal of the project. Which results are expected?*
KEY WORDS	*Maximum 5*
SCHEDULED DURATION WITHIN ENTIRE PROJECT	*In months. Please quote i) the time period for which funding is requested (max. 3 years) and ii), the date when funding should begin.*
SUMMARY	*Please give a **summary** of the main goals and the methodological approach of the project (max. **1200 characters**). The project summary serves two main purposes: i) It will inform the multidisciplinary review committee of the principal aims of the subproject. ii) If your project is funded the summary will be published on the internet through an electronic information system. (It should therefore be concise as well as comprehensible to a lay public). Please avoid abbreviations.*

2. DESCRIPTION OF THE SUBPROJECT

2.1 STATE-OF-THE-ART AND OWN PREVIOUS WORK

Describe the international state-of-the-art and your own previous work in the field. Give 5 of your most relevant publications of the past 3 years

2.2 AIMS

What is the hypothesis to be tested? What is the aim/purpose of the subproject? What results are expected? Which are the novel aspects of the subproject?

2.3 METHODS

Please describe briefly the key methods used in the proposed project. Indicate which methods are established in your group and which methods will be established through collaborations. For subtasks entirely delegated to other groups please provide a letter of collaboration.

2.4 RESOURCES

Does the project involve utilization of (characterized) biomaterial banks or collections, patient registers or cohorts? If yes, please specify the nature of the respective infrastructure and how access is granted and organised. Are potential co-founders informed? If yes, how were they informed? How is the co-authorship regulated?

2.5 WORKING PLAN INCLUDING MILESTONES

Please describe the work-packages, the milestones you plan to achieve and the necessary time-frame.

2.6 NETWORKING

What is the special contribution of the project to the goals of the consortium? How does the project benefit from the consortium?

2.7 DISSEMINATION AND EXPLOITATION STRATEGIES

Please indicate how the expected results of the subproject will be used. Describe the proposed arrangements for disseminating the results of the research to potential users.

2.8 FINANCIAL PLAN

Please structure the financial plan by completing the table “financial plan for subproject No...” as outlined in the table below.

2.9 CO-FINANCING

Please indicate any co-financing of the studies by industry or other sources.

Co-financing by industry or other third parties is possible if

- the independence of investigators is ensured and
- terms and conditions of the financial commitment are disclosed.

If co-financing is intended the application should briefly describe the type and volume of the intended co-financing, indicating the respective company or other third party.

3. ETHICAL CONSIDERATIONS

Comment on ethical considerations relating to the project (confidentiality, informed patient consent, consent of disoriented patients, care and protection for research participants, assessment of risks and benefits etc.).

Appendix: Financial Plan for Subproject No. …

Type of expenditure	**1st year** (months)	**2nd year** (months)	**3rd year** (months)	**1st year** (EUR)	**2nd year** (EUR)	**3rd year** (EUR)	**Total of BMBF funds applied (EUR)**	**Co-financed by industry or others (EUR)**
PERSONNEL								
Scientist*	*6*	*12*	*12*	*22.698*	*45.398*	*45.398*	*113.494*	*0*
Graduate student*	*12*	*12*	*12*	*22.698*	*22.698*	*22.698*	*68.094*	*0*
Technician*		*12*	*12*		*33.564*	*33.564*	*67.128*	*0*
Engineer*	*12*	*12*		*39.336*	*39.336*		*78.672*	*0*
Others*								
CONSUMABLES								
EQUIPMENT (to specify**)**								
COMMISSIONS (to specify)								
TRAVEL								
OTHER (to specify)								
TOTAL of BMBF funds applied								
TOTAL of co-financed by other sources								

* Please use global employment rates of the BMBF for calculating the salaries (Insert lines according to space required)

B. CLINICAL TRIAL PROJECT

The following outline is only relevant for subprojects with focus on clinical trials.

Application for the Funding of a Clinical Trial

*The application for a clinical trial should **not exceed 10 pages for the headings 1. to 8.**, including a maximum of 1 page of references (DIN A4, at least 10 point Arial). Structure your application using the headings listed below. Make an entry under every heading. For the information of the reviewers, refer to the respective chapter in the trial protocol for further details if necessary.* ***Signatures of principal / coordinating investigator and responsible biostatistician are mandatory. Submit application, appendix, and the trial protocol according to GCP.***

Note: *Applications that fail to comply with these requirements will be considered incomplete and might be rejected without peer review.*

1. STUDY SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	Name, address, telephone, fax, E-Mail 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 • Employment status • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
TITLE OF STUDY	*The title of the study (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.*
CONDITION/TOPIC	*The medical condition being studied (e.g. Parkinson, depression, asthma).*
OBJECTIVE(S)	*Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.*

[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.emea.eu.int). 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 multicenter trial.*"

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 experimental test and the gold-standard or reference procedure should be described.* Experimental intervention: Control intervention: Duration of intervention per patient/subject:
KEY INCLUSION AND EXCLUSION CRITERIA	Key inclusion criteria: Key exclusion criteria:
OUTCOME(S)	Primary efficacy 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	Efficacy: Description of the primary analysis and population Safety: Secondary endpoints:
SAMPLE SIZE	To be assessed for eligibility (n = …) To be allocated to trial (n = …) To be analysed (n = …)
TRIAL DURATION	First patient/subject in to last patient/subject out: Duration of the entire trial:
SUMMARY	Please give a summary of the main aspects of the project (max. **1600 characters**). The project summary serves two main purposes: i) It will inform the multidisciplinary review committee of the principal aspects e.g. goals, design, subjects, expected outcome of your project. ii) If your project is funded the summary will be published on the internet through an electronic information system. (It should therefore be concise as well as comprehensible to a lay public). Please avoid abbreviations.
PARTICIPATING CENTERS	*How many centres will be involved?* *How many centres have signed an agreement to participate? To be detailed in the trial protocol*

2. AIM OF THE TRIAL

2.1 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.

2.2 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)[2] and/or (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/ series. If you believe that no relevant previous trials have been done, give details of your search strategy for existing information. This should both detail the background of the starting hypotheses **and** the feasibility of the trial.

2.3 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?

2.4 STRATEGIES FOR THE EXPLOITATION OF RESULTS

What will be your strategies for the dissemination of results? Indicate how the expected results of the trial will be used; discuss dissemination of results, especially beyond regular journal publication, describe intended measures, detail potential economic impact.

2.5 ADDED VALUE

Comment on the interaction within the consortium and other potential roles within the network.

3. JUSTIFICATION OF DESIGN ASPECTS

3.1 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? Give a schematic diagram (flow chart) of design, procedures and stages.

3.2 CONTROL(S)/COMPARATOR(S)

Justify the choice of control(s)/comparison(s): Which trials establish efficacy and safety of the chosen control regimen?

3.3 INCLUSION/EXCLUSION CRITERIA

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

3.4 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? Justify appropriateness and limitations of composite endpoints, if applicable.

Determination of primary and secondary measures

How will primary and secondary endpoints be derived from actual measurements, e.g. how is the figure used in the statistical test calculated from the variables initially measured in the subjects?

3.5 METHODS AGAINST BIAS

[2] For definition of a systematic review, see Oxman, AD (1994). Checklists for review articles see BMJ; 309; 648-51.

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).

3.6 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, 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.

Compliance / Rate of loss to follow up

Provide details for assumptions on compliance issues. On what evidence are the compliance figures based?

What is the assumed rate of loss to follow up? On what evidence is the loss to follow up rate based? How will losses to follow up or non-compliance be handled in the statistical analysis?

3.7 FEASIBILITY OF RECRUITMENT

What is the evidence that the intended recruitment rate is achievable (e.g. pilot study)?

a) Pilot study

Has any pilot study been carried out using this design?

b) Achievability of recruitment rate

What is the evidence that the intended recruitment rate is achievable? Demonstrate conclusively the potential for recruiting the required number of suitable subjects (the best piece of evidence being pilot studies and preceding studies in a similar population/same institutions). How did you assess that you can recruit the necessary number of patients in each participating centre? Show justification of numbers of eligible patients per trial site in a table. The recruitment plan should show the projected recruitment including the criteria for the selection of trial sites.

International collaborations

If the proposed trial includes non–German centres or collaboration with organisations in other countries please give full details of funding arrangements agreed or under consideration in the trial protocol. Please detail the power of the German component of the trial, as well on its own as part of the international study.

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?

5. ETHICAL CONSIDERATIONS

Give a description of ethical considerations relating to the trial (assessment of risks and benefits, care and protection for research participants, protection of research participants' confidentiality, informed consent process).

6. TRIAL MANAGEMENT

6.1 MAJOR PARTICIPANTS *(please indicate roles of major participants)*

#	Name	Affiliation	Responsibility / Role	Signature
			Principal/Coordinating Investigator	
			…	
			….	

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

Professional backgrounds/expertise should be detailed in an appendix to the trial protocol (refer to the respective chapter in the trial protocol).

Who is responsible for statistics? Professional background/expertise[3] should be given. Though not mandatory, certification is highly desirable.

#	Name	Affiliation	Responsibility/Role	Signature
			Trial Statistician / Responsible for Statistics	

6.2 TRIAL-SUPPORTING FACILITIES

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

6.3 QUALITY ASSURANCE/MONITORING

What are the proposed measures for quality assurance? Describe and justify the monitoring strategy (percentage of source data verification, number of items to be monitored, number of monitor visits per trial site).

6.4 SAFETY

Please comment on the planned supervision of the trial (DMSC); give name and affiliation of independent DMSC members.

Arrangements for the management of the trials will vary according to the nature of the trial proposed. However, all should include an element of expert advice and monitoring, that is entirely

[3] *e.g.* GMDS certificate, http://www.gmds.de/texte/zertifikate-weiteres.html; see also: ICH guidance E9 "Statistical Principles of Clinical Trials"

independent of the principal/coordinating investigator and the medical institution involved. This will normally take the form of a scientific advisory board/trial steering committee (TSC) and/or an independent data monitoring and safety committee (DMSC).

It is recognised that these arrangements may not always be appropriate and the committees needed may vary according to the nature of the trial. Thus, the arrangements for supervision should be detailed and justified. The role of these committees can comprise to monitor and supervise the progress of the trial (including the safety data and the critical efficacy endpoints at intervals), to review relevant information from other sources, to ensure adherence to protocol, to consider interim analyses, to advise whether to continue, modify, or stop a trial, and provide the funding organisations with information and advice.

*Applicants should submit their proposed arrangements for overseeing of the trial and a suggested **membership and affiliations** for the committee(s) (name, title, address and telephone number should be given in the trial protocol). A minimum of 3 members should be named.*

7. REFERENCES

Publication listing according to numerical appearance in the text.

8. TRIAL TIMELINE FLOW / MILESTONES

As funding by BMBF will critically depend on the trial progression according to milestones, please provide a proposal of milestones reflecting planning, recruitment status and data clearing/analysis progress. Include a diagram showing trial stages and milestones.

9. FINANCIAL DETAILS OF THE STUDY

9.1 FINANCIAL SUMMARY

Indicate total duration of the trial, the period of time for which funding is requested, and when funding should begin.

The overall expenditure should be summarized in the table below. Please, provide both man months and € for employment costs and state the requested funds separately for each year of the trial. Funds can only be granted for research activities. Do not include patient care costs.

	Organizational Segment	Institution/ Participant/ Trial Site	No of items/ Kind of equipment/ Explanation	Qualification of staff	TVöD/ BAT	Total months	Total	Total (€)	y1 (m/€)	y2 (m/€)	y3 (m/€)	y… (m/€)
1	**Clinical project management**											
2	**Project management**											
3	**Data Management**											
4	**Biometry**											
5	**Monitoring**		number of visits per site number of days per visit monitoring costs per day total no of visits @ x € each									
6	**Trial committees**	no of DMSC members	no of meetings @ x € / p									
7	**Meetings / Travel**	no of attendees	no of meetings @ x € / p									
8	**Case payment**		examinations per subject/patient hours of staff per subject/patient € / patient x no of patients									
9	**Reference centers**		no of samples@ x €									
10	**Materials**		consumables									
			trial manuals, files, forms									
11	**Trial drug**		€ / patient									
12	**Insurance**		€/ patient									

13	**Fees**											
14	**Equipment**											
15	***Other***											
	TOTAL							€	€	€	€	€

m = staff indicated in months; € = other expenditures indicated in Euro; ./p = per person

9.2 EQUIPMENT

Please list larger instruments available to you for the trial. In case you apply for instruments which are available where you work, but which are not at the project's disposal, please give detailed information.

Application of instrumentation

Please list all requested instrumentation with price information.

9.3 CO-FINANCING BY INDUSTRY AND/OR OTHER THIRD PARTIES

Co-financing by industry or other third parties is possible if

- the independence of investigators is ensured and
- terms and conditions of the financial commitment are disclosed.

If co-financing is intended the application should briefly describe the type and volume of the intended co-financing, indicating the respective company or other third party.

Details are to be specified in the trial protocol:

- Describe the type and volume of support (including any services or consumables provided free of charge, e.g. drugs for the trial).
- Indicate the amount of support to be provided and assure in writing that the third party will render these services, stating their terms and conditions, if any.
- Assure that the coordinating investigator is independent, in particular with regard to the analysis of the trial and the publication of its results. A statement giving such assurances will be demanded by the funding organizations after the review process is finished.

Please don't make any agreements before notion of award has been made; please contact the funding organisations first! Appropriate agreements on intellectual property, confidentiality, publication of results, property rights should be concluded between all those playing a leading part in the conduct of the trial.

Agreement with manufacturer on variation of authorisation:

If the trial is aimed at extending the indication of a drug, modifying its mode of administration/preparation or dosage, or target population, the manufacturer of the drug must assure in writing that he will undertake to apply for a variation of the authorisation at the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM, Federal Institute for Drugs and Medical Devices) if the trial result is favourable. A corresponding statement should be joined to the protocol.

Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.[4]

[4] Detailed information can be found in particular in the "Gemeinsamer Standpunkt zur strafrechtlichen Bewertung der Zusammenarbeit zwischen Industrie, medizinischen Einrichtungen und deren Mitarbeitern" (Common position concerning the consideration of cooperation between industry, medical institutions and their staff from the aspect of criminal law) published by the Verband forschender Arzneimittelhersteller (Association of Research-Based Pharmaceutical Companies) (http://www.vfa.de/de/vfa/gemeinsamerstandpunkt.html)

9.4 OTHER FUNDING

In case you have already submitted the same request for financial support or parts hereof to other institutions, please mention this here. Indicate those third parties which will provide funds, free services or consumables such as trial medication.

If this is not the case please declare:

"A request for funding this project has not been submitted to any other addressee. In case I submit such a request I will inform the Federal Ministry of Education and Research immediately".

10. STUDY PROTOCOL IN ACCORDANCE WITH ICH GCP

Append the trial protocol in English in accordance with ICH GCP (cf. chapter 6 of ICH GCP, “Clinical Trial Protocol and Protocol Amendment(s)”). The topics laid down there may be adjusted slightly to reflect the needs of non-drug studies.

Should you consider any requirement not applicable, relevant or appropriate, a clear statement justifying the omission of the information specified shall be provided on each occasion?

The final version of the protocol has to be submitted to the funding organization together with the statement by the ethics committee after the review process, but prior to any notion of award.

Note: Any potential conflicts of must be disclosed in the study protocol. The rules set forth in the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals" have to be observed by analogy (www.thelancet.com).

C. COHORT STUDY

The following outline is only relevant for subprojects with focus on cohort studies.

Application for the Funding of a Cohort Study

Please prepare your application in English **not exceeding 10 pages for the headings 1. to 7.**, including a maximum of 1 page of references (DIN A4, at least 10 point Arial, references in numerical order). Structure your application using the headings listed below. Make an entry under every heading (fill in n.a. if not applicable). Signatures of principal / coordinating investigator and responsible biostatistician/data manager are mandatory.

Note: Applications that fail to comply with these requirements will be considered incomplete and will be rejected without peer review.

1. SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	Name, address, telephone, fax, E-Mail In case of multiple applicants the principal investigator / coordinating investigator should be listed first. • First name, last name, academic title • Employment status • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
TITLE	*The **title** of the project (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.*
CONDITION/TOPIC	*The medical condition being studied (e.g. Parkinson, depression, asthma).*
OBJECTIVE(S)	*Which principal research questions are to be addressed? Specify clearly the primary goal of the project. Which results are expected?*
KEY WORDS	*Maximum 5*
TYPE OF PROJECT	
PROBANDES (KEY INCLUSION AND EXCLUSION CRITERIA)	
MAIN OUTCOMES TO BE ANALYSED	
STATISTICAL ANALYSIS	*Strategy:*

	Anonymisation or Pseudonymisation of data:
SIZE AND DURATION OF STUDY	
SUMMARY	*Please give a **summary** of the main goals of the project (max. **1600 characters**). The project summary serves two main purposes: i) It will inform the multidisciplinary review committee of the principal aims of the project. ii) If your project is funded the summary will be published on the internet through an electronic information system. (It should therefore be concise as well as comprehensible to a lay public). Please avoid abbreviations.*
PARTICIPATING CENTERS	

2. AIM OF THE PROJECT

2.1 MEDICAL PROBLEM

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

2.2 EVIDENCE

Set your project into perspective. Give references to relevant publications and running comparable projects. What is the novel aspect that will be studied by the proposed project?

2.3 THE NEED FOR THE PROJECT

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

2.4 STRATEGIES FOR THE EXPLOITATION/DISSEMINATION OF RESULTS

Indicate how the expected results of the project will be used; discuss dissemination of results, especially beyond regular journal publication, describe intended measures, detail potential economic impact. If applicable, how is the scientific community informed of the availability of data?

2.5 ADDED VALUE

Comment on the interaction within the consortium and other potential roles within the network.

3. JUSTIFICATION OF DESIGN ASPECTS

3.4 TYPE OF PROJECT

Is it a clinical/epidemiological cohort study?

In case of an epidemiological cohort study: Is the project population-based? Which degree of completeness will be achieved? Which region will be covered?

In case of a clinical study: Which institutions of the health care system will contribute to the project (number of private practices, regional and university hospitals, regions covered, completeness of patients recorded by the institutions)?

Describe and justify the population to be studied (inclusion/exclusion criteria). Please include reflections on generalisability and representativeness.

What is the planned duration for the project?

3.2 DATA ITEMS TO BE ANALYSED

Justify the data items chosen: Are there other projects that have utilized them before or guidelines proposing these data items? What is the planned follow-up for a single patient? Discuss the relevance of the data items for the target population. Are gender specific aspects adequately addressed?

3.3 METHODS AGAINST BIAS

What measures against bias due to selection or confounding will be implemented? Which additional information will be documented to for confounding? Please comment on anticipated non-response and missing data.

3.4 DATA ACQUISITION AND STORAGE

How will the patients be elected and recruited for the project? How will the participating institutions be motivated for a timely and accurate data acquisition? Which instruments will be used to record the data? Are the instruments validated and reliable? Which standards will be used to classify diagnoses and stages of the diseases?

Describe the concept of data acquisition and storage. How will the personal responsible for data acquisition be trained?

Comment on the accessibility of data origins and on the possibilities to use or integrate already existing sources of data.

3.5 BIOMETRIC CONCEPT / STATISTICAL ANALYSES

What is the proposed strategy of statistical analysis? Which data items and variables will be included in the analyses? What are the intended recruitment rate and total number of patients necessary for these analyses? Which concrete statistical evaluations are planned at what time and which methods will be used? What is the assumed rate of loss due to follow up or missing/incomplete data? On what evidence are these assumptions based?

3.6 FEASIBILITY OF RECRUITMENT

What is the evidence that the intended recruitment rate and total number of patients for the project is achievable? Demonstrate conclusively the potential for recruiting the required number of suitable subjects (the best piece of evidence being pilot data collections and projects in a similar population/institution).

3.7 International collaborations

If the proposed project includes non-German centres or collaboration with organisations in other countries please give full details of funding arrangements agreed or under consideration.

4. ETHICAL CONSIDERATIONS

Comment on ethical considerations relating to the project (confidentiality, informed patient consent).

5. PROJECT MANAGEMENT

5.1 MAJOR PARTICIPANTS *(please indicate roles of major participants)*

#	Name	Affiliation	Responsibility / Role	Signature
			Principal/Coordinating Investigator	
			…	
			….	
			Responsible for Statistics	
			Responsible for Quality Assurance/Data Management	

Please indicate the expertise of all above-mentioned participants by citing own relevant publications and/or specifying major role in ongoing comparable research projects (list max. 5 publications of the last 5 years per person). Give the professional background of all participants.

5.2 PROJECT-SUPPORTING FACILITIES

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

5.3 QUALITY ASSURANCE

Describe and justify the concept for quality assurance. How is the data integrity and plausibility controlled? Describe the actual organisational and technical measures for quality assurance and quality control (e.g. second control of data which cannot be controlled by plausibility tests, coding of data, second control of coding and documentation of data corrections). How and when will they be implemented? Are these e.g. outlined in a special quality manual ("Operationshandbuch")? Comment on the usefulness of feedback strategies concerning data quality.

Which indicators are used to measure and quantify the quality of the study concerning e.g:

- structures (e.g. indicators measuring data plausibility)
- processes (e.g indicators measuring the organisation of data acquisition)
- results (e.g. indicators measuring correctness, completeness, representativeness and accuracy).

Comment on the necessity of an external quality assurance/monitoring.

5.4 DATA SAFETY CONCEPT

How will the existing legal requirements for data safety be met? Describe the data safety concept applied and the planned data flow (diagram). If applicable, provide positive vote of the data security organisation in charge. Depending on the type of project, is anonymisation or pseudo-

nymisation of data planned? Comment on the following aspects of the data safety concept, if applicable:

- Technical and organisational instruments
- Central patients list (localisation)
- Identification data
- Pseudonymisation and depseudonymsation (localisation)
- Informed patient consent
- Patient right of access to personal data
- Storage time of data
- Workflow for quality assurance
- Safety of data transmission and documentation
- Policy document including all legal regulations and agreements

6. REFERENCES

Publication listing according to numerical appearance in the text.

7. TIMELINE FLOW / MILESTONES

As funding by BMBF will critically depend on the progress according to milestones, please provide a proposal of milestones reflecting planning, recruitment status and data clearing/analysis progress. Include a diagram showing stages and milestones. Comment on the possibility of sustainable establishment of the project after BMBF funding, if applicable.

8. FINANCIAL DETAILS OF THE STUDY

8.1 FINANCIAL SUMMARY

Indicate total duration of the project, the period of time for which funding is requested, and when funding should begin.

The overall expenditure should be summarized in the table below. Please, provide both person-months and € for employment costs and state the requested funds separately for each year of the project.

	Organizational Segment	Institution/ Participant/ Trial Site	No of items/ Kind of equipment/ Explanation	Qualification of staff	TVöD/ BAT	Total months	Total	Total (€)	y1 (m/€)	y2 (m/€)	y3 (m/€)	y… (m/€)
1	**Scientific Management**											
2	**Organisational Management**											
3	**Data (Security) Management**											
4	**Statistical data analysis**											
5	**Quality assurance**											
7	**Meetings / Travel**	no of attendees	no of meetings @ x € / p									
8	**Documentation payment**		documentation per subject/patient hours of staff per subject/patient € / patient x no of patients									
10	**Materials**		Consumables									
			trial manuals, files, forms									
14	**Equipment**											
15	***Other***											
	TOTAL							€	€	€	€	€

m = staff indicated in months; € = other expenditures indicated in Euro; ./p = per person

8.2 EQUIPMENT

In case you apply for instruments which are available where you work, but which are not at the project's disposal, please give detailed information. Please list all requested instrumentation with price information.

8.3 CO-FINANCING BY INDUSTRY AND/OR OTHER THIRD PARTIES

Co-financing by industry or other third parties is possible if

- the independence of investigators is ensured and
- terms and conditions of the financial commitment are disclosed.

If co-financing is intended the application should briefly describe the type and volume of the intended co-financing, indicating the respective company or other third party.

Details are to be specified:

- Describe the type and volume of support (including any services or consumables provided free of charge).
- Indicate the amount of support to be provided and assure in writing that the third party will render these services, stating their terms and conditions, if any.
- Assure that the coordinating investigator is independent, in particular with regard to the analysis of the project and the publication of its results. A statement giving such assurances will be demanded by the funding organizations after the review process is finished.

Please do not make any agreements before notion of award has been made; please contact the funding organisation first! Appropriate agreements on intellectual property, confidentiality, publication of results, property rights should be concluded between all those playing a leading part in the conduct of the project.

Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.[5]

8.4 OTHER FUNDING

In case you have already submitted the same request for financial support or parts hereof to other institutions, please mention this here. Indicate those third parties which will provide funds, free services or consumables for the project.

If this is not the case please declare:

"A request for funding this project has not been submitted to any other addressee. In case I submit such a request I will inform the Federal Ministry of Education and Research immediately".

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[5] Detailed information can be found in particular in the "Gemeinsamer Standpunkt zur strafrechtlichen Bewertung der Zusammenarbeit zwischen Industrie, medizinischen Einrichtungen und deren Mitarbeitern" (Common position concerning the consideration of cooperation between industry, medical institutions and their staff from the aspect of criminal law) published by the Verband forschender Arzneimittelhersteller (Association of Research-Based Pharmaceutical Companies) (http://www.vfa.de/de/vfa/gemeinsamerstandpunkt.html)