



Leitfaden zur Antragstellung für den Förderschwerpunkt für seltene Erkrankungen

vom 02.10.2007

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Einleitung

Im Rahmen der Fördermaßnahme „Förderschwerpunkt für seltene Erkrankungen“ stellt das BMBF Fördermittel für den Aufbau und die Weiterentwicklung der nationalen Forschung in diesem Bereich zur Verfügung.

Anträge sind entsprechend den Vorgaben dieses Leitfadens zu gliedern. Die Rahmenbedingungen der Förderung für Verbünde für seltene Erkrankungen sind in der Förderrichtlinie des BMBF (<http://www.gesundheitsforschung-bmbf.de/de/1756.php>) niedergelegt. Gleichzeitig mit der **formlosen Vorhabensbeschreibung** sind **elektronische Datenblätter** (Application Data Sheets) sowohl für den Gesamtverbund als auch für die Teilprojekte auszufüllen. Die Datenblätter können über die o.g. Internet-Seite aufgerufen werden. Die elektronischen Datenblätter zur Antragstellung werden **ab 10. Dezember 2007** für Eintragungen im Internet freigeschaltet.

Vorhabensbeschreibungen für Verbundvorhaben (Format: DIN A4, einseitig, 11 Punkt Arial, doppelseitig bedruckt) können ab sofort **bis spätestens zum 12. Februar 2008** beim Projektträger Gesundheitsforschung für das BMBF, Heinrich-Konen-Str. 1, 53227 Bonn, (<http://www.pt-dlr.de/>), Tel. 0228/3821-210 oder -233 eingereicht werden. Mit Blick auf das internationale Begutachtungsverfahren wird die Einreichung der Vorhabensbeschreibungen **in englischer Sprache** dringend empfohlen.

Vorhabensbeschreibungen sind dem Projektträger **in fünfzehnfacher Papierversion** plus einer ungebundenen Kopiervorlage sowie als ein zusammenhängendes Dokument im PDF-Format auf CD-ROM vorzulegen.

Anträge, die den Vorgaben des Leitfadens nicht entsprechen, können für das weitere Verfahren nicht berücksichtigt werden.

Der Leitfaden umfasst zum einen ein Gliederungsschema für die Darstellung des Forschungsverbundes, zum anderen Gliederungsschemata für die unterschiedlichen Typen von Teilprojekten (A-C) und Biobanken als verbundübergreifenden Infrastrukturmaßnahmen (D), die jeweils bei Beantragung von entsprechenden Teilprojekten zu verwenden sind.

Guidelines for Grant Application

Click [here](#) for German version. Please prepare your application in English, **not exceeding 15 pages for description of the consortium, 7 pages for a research project description and 10 pages for a description of either a clinical trial (including a diagnostic study), a register/cohort study or a biobank project (format: DIN A4, single-spaced, Arial 11 points, two-sided print).**

Make sure to provide an entry under each heading/subheading. Signatures of the principal / coordinating investigators are mandatory and should be supplied in a separate letter of intent. For a clinical trial (including a diagnostic study), a register / cohort study or a biobank project, the additional signature of the responsible biostatistician / data manager is mandatory. Brief CVs for each principal investigator (max. 1 page each) should be added in an annex.

Note:

Applications that fail to comply with these requirements will be considered as not eligible and will be rejected without peer review.

Description of Consortium

1. GENERAL INFORMATION ON THE CONSORTIUM

APPLICANT / COORDINATING INVESTIGATOR	<i>In case of multiple applicants the coordinating investigator of the consortium who will take responsibility for managing the entire consortium should be listed first.</i> <ul style="list-style-type: none"> • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
TITLE	<i>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. An acronym is optional.</i>
CONDITION/TOPIC	<i>The exact medical condition / topic being addressed.</i>
OBJECTIVE(S)	<i>Which principal research questions are addressed? Clearly specify the primary goal of the project. Which (main) results are expected?</i>
KEYWORDS	<i>Maximum 5 keywords outlining the area of research.</i>
CONSORTIUM DURATION	<i>Indicated in months.</i>
SUMMARY	<i>Please provide 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 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 general public). Please avoid abbreviations.</i>
SUBPROJECTS	<i>List of subprojects in a table, for example see below:</i>

Subproject No.	Partner	Title of Subproject	Function within the Consortium	Contribution
1	University of X..	Coordination unit of the consortium for research on fragile-X syndrome	Coordination	Monitoring, evaluation and processing of results
2	University of Y....	Genotype-Phenotype correlations in patients with fragile-X syndrome ...	Clinical subproject partner	Analysis and description of genotype/phenotype correlations
..

2. OBJECTIVES, RELEVANCE, EXPERTISE AND INNOVATION

2.1 OBJECTIVES, OVERALL CONCEPT AND RELEVANCE OF THE CONSORTIUM

Describe the planned research priorities with respect to the current state-of-the-art, outlining a clearly defined thematic focus. What is the prevalence and medical relevance of the chosen disease (group)? How many patients can be reached within the planned collaboration? Which medical problem is addressed? Which results are expected?

2.2 EXISTING INFRASTRUCTURE AND PREVIOUS ACHIEVEMENTS

Describe the quality and scope of existing national and international networking in disease-oriented research addressed by this call as well as existing infrastructure and previous achievements relevant for the application, e.g. developed methods, biobanks, well-characterized patient cohorts, databases, service components.

In case of the existing networks for rare diseases, please also describe briefly the achievements resulting from the ongoing network collaboration (including publications).

Additionally, please list ongoing projects related to the present topic, indicating funding sources and possible overlaps and synergies with the proposed consortium.

2.3 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 disease?

3. STRUCTURE OF THE PLANNED COOPERATION

3.1 COOPERATION, COORDINATION AND COMMUNICATION

Which coordination structure is available or 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 existing or planned measures of coordination and communication as well as structures of internal and external controlling. A diagram depicting the coordination structure may be useful. Please also describe what kind of procedures are planned to ensure extensive information of patients and medical professionals about the results of the planned research and best practices in diagnosis, treatment and care.

3.2 QUALITY ASSURANCE, STANDARDIZATION, EXCHANGES

Explain planned measures for quality assurance as well as for standardization and exchange of procedures, samples and data within the consortium.

3.3 ADDED VALUE

Comment on the synergistic effects of interaction within the consortium. For the collaboration with groups outside of the consortium (associated groups) that are essential for the implementation of the work program, please describe nature and content of the intended collaboration. Please also describe potential themes for networking with other consortia.

3.4 TIMEFRAME / MILESTONES

In which time-frame will major workpackages be achieved? What kind of milestones are planned?

3.5 FINANCIAL SUMMARY

Financial Plan

Title of the consortium: "....."

Subproject number and short title	Personnel		Consumables €	Equipment €	Commissions €	Travel €	Other €	Total of BMBF funds applied €	Co-financing by industry or others €
	Number of Sci, Grad, Eng, T, O*	€							
TOTAL CONSORTIUM	-								

(Insert lines according to space required.)

**Sci = Scientist, Grad = Graduate student, Eng = Engineer, T = Technician, O = Other*

To calculate: Sci ≅ 60.000,- €/year, Grad ≅ 30.000,- €/year, Eng ≅ 50.000,- €/year, T ≅ 40.000,- €/year,

For industrial partners, please note: insert not total project costs, but BMBF share only.

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

The following outline shall be used for the description of regular **research projects**. In case you want to apply for funding of a **clinical trial** (including a diagnostic study), a **register/cohort study** or a **biobank**, please proceed to part B, C or D of this guideline. If funds for other central projects such as coordination or service components are applied for, please use the general subproject scheme (part A) and, if necessary, modify it accordingly.

A. Description of Research Project

The description of each research project must not exceed 7 pages (format: DIN A4, single-spaced, Arial 11 points, two-sided print).

1. GENERAL INFORMATION ON THE RESEARCH PROJECT

PRINCIPLE INVESTIGATOR AND CO-INVESTIGATORS OF THE SUBPROJECT	Name and contact details <ul style="list-style-type: none"> • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
TITLE OF SUBPROJECT	<i>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.</i>
CONDITION/TOPIC	<i>The exact medical condition / topic being examined .</i>
OBJECTIVE(S)	<i>Which principal research questions are addressed? Clearly specify the primary goal of the project. Which (main) results are expected?</i>
KEYWORDS	<i>Maximum 5 keywords outlining the area of research.</i>
DURATION OF SUBPROJECT	<i>Indicated in months. Please quote i) the time period for which funding is requested (max. 3 years) and ii), the date when funding should begin.</i>
SUMMARY	<i>Please provide a summary of the main goals and the 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.</i>

2. SPECIFIC INFORMATION ON THE RESEARCH PROJECT

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

Describe the international state-of-the-art and your own previous work in the research field. List 5 of your most relevant publications of the past 5 years and the relevant patents over the last 5 years, both with respect to your proposal.

In case of a proposal from an existing network for rare diseases, please also explain the achievements resulting from the ongoing network collaboration (including publications).

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 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, which will be entirely delegated to other groups, please provide a confirmatory letter of collaboration.

2.4 RESOURCES

Does the project involve utilization of (characterized) biomaterial banks or collections, patient registers or cohorts (cf. 3.3 description of consortium)? If yes, please specify the nature of the respective infrastructure and how access to the resources is granted and organised. Are potential co-founders informed? If yes, how? How is the co-authorship regulated?

2.5 WORK PLAN INCLUDING MILESTONES

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

2.6 NETWORKING

What is the special contribution of the individual subproject to the overall goals of the consortium? How does the subproject 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 AND JUSTIFICATION OF REQUESTED BUDGET

Please structure your information about the financial plan by completing the table "Financial plan for subproject" as outlined in the table below and justify the requested budget in relation to the work plan.

Please indicate any co-financing 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 source.

Additionally, please list ongoing projects related to the present topic, indicating funding sources and possible overlaps with the project proposal.

Financial plan for subproject no. ...									
Title of subproject: "....."									
Personnel			Consumables €	Equipment €	Commissions €	Travel €	Other €	Total of BMBF funds applied €	Co-financing by industry or others €
Number of Sci, Grad, Eng, T, O*	TvöD/ TvÄ/ BAT	€							

*Sci = Scientist, Grad = Graduate student, Eng = Engineer, T = Technician, O = Other

To calculate: Sci \cong 60.000,- €/year, Grad \cong 30.000,- €/year, Eng \cong 50.000,- €/year, T \cong 40.000,- €/year, For industrial partners, please note: insert not total project costs, but BMBF share only.

3. REFERENCES

Publication listing according to numerical appearance in the text.

B. Description of Clinical Trial

The description of an 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, 11 point Arial). Structure your application using the headings listed below. **Signatures of principal / coordinating investigator and responsible biostatistician are mandatory.**

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

1. STUDY SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	<p><i>Name and contact details</i></p> <p><i>In case of multiple applicants the principal investigator / coordinating investigator¹ of the trial who will assume responsibility for conducting the clinical trial, should be listed first.</i></p> <ul style="list-style-type: none"> • <i>First name, last name, academic title</i> • <i>Employment status</i> • <i>Institution and department (complete name)</i> • <i>Postal address</i> • <i>Telephone</i> • <i>Fax</i> • <i>E-mail address</i>
TITLE OF STUDY	<i>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.</i>
CONDITION/TOPIC	<i>The exact medical condition / topic being studied.</i>
OBJECTIVE(S)	<i>Which principal research questions will be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.</i>
INTERVENTION(S)	<p><i>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.</i></p> <p><u>Experimental intervention:</u></p> <p><u>Control intervention:</u></p> <p><u>Duration of intervention per patient/subject:</u></p>
KEY INCLUSION AND EXCLUSION CRITERIA	<p><u>Key inclusion criteria:</u></p> <p><u>Key exclusion criteria:</u></p>

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 multicentre trial."

OUTCOME(S)	<u>Primary efficacy endpoint:</u> <u>Key secondary endpoint(s):</u> <u>Assessment of safety:</u>
STUDY TYPE	<i>E.g. randomized / non-randomized, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over</i>
STATISTICAL ANALYSIS	<u>Efficacy:</u> <u>Description of the primary analysis and population</u> <u>Safety:</u> <u>Secondary endpoints:</u>
SAMPLE SIZE	<u>To be assessed for eligibility (n = ...)</u> <u>To be allocated to trial (n = ...)</u> <u>To be analysed (n = ...)</u>
TRIAL DURATION	<u>First patient/subject in to last patient/subject out:</u> <u>Duration of the entire trial:</u>
SUMMARY	Please provide 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 CENTRES	<i>How many centres will be involved?</i> <i>How many centres have signed an agreement to participate?</i>

2. AIM OF THE CLINICAL TRIAL

2.1 MEDICAL PROBLEM

Which medical problem will be addressed? What is the novel aspect of the proposed trial? Which principal research questions will be addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.

2.2 EVIDENCE

Set your clinical trial into perspective. Which trials have previously been conducted, either by you or by others? What is the relevance of their results, overall and concerning your planned clinical trial? 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 performed, provide 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 CLINICAL 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 the individual patient and society/science benefit from the trial?

2.4 STRATEGIES FOR THE EXPLOITATION OF RESULTS

What will be your strategies for the dissemination of results? How will the expected results of the clinical trial be used; specify dissemination of results beyond publication in scientific journals; detail potential economic impact.

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

2.5 ADDED VALUE

Comment on the interaction between the planned clinical trial and the other subprojects within the consortium.

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? Provide 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 chosen endpoint(s): are there other clinical trials that have utilized the same endpoint(s). Are there any guidelines proposing this/these endpoint(s)? 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

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 provide 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; provide 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)?

Pilot study

Has any pilot study been carried out using the same design?

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 clinical trial protocol. Please detail the power of the German component of the trial, on its own as well 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

Provide a description of ethical considerations relating to the clinical 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 (*indicate responsibilities / roles of major participants*)

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

Please indicate clinical trial expertise of **all** major participants by citing relevant publications and/or specifying their responsibility / 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 clinical trial.

Who is responsible for statistics? Professional background/expertise³ should be given. Though not mandatory, certification is highly desirable.

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

6.2 CLINICAL TRIAL SUPPORTING FACILITIES

³ For example, GMDS certificate, <http://www.gmds.de/texte/zertifikate-weiteres.html>; see also: ICH guidance E9 "Statistical Principles of Clinical Trials"

Which trial-specific facilities and other resources are available for conducting the clinical 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); provide name and affiliation of independent DMSC members.

Arrangements for the management of the clinical trials will vary according to the nature of the trial proposed. However, all trials should include an element of expert advice and monitoring, which is entirely independent of the principal / coordinating investigator and the medical institution involved. This will normally be fulfilled by 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 clinical trial. Thus, the arrangements for supervision should be detailed and justified. The role of these committees may comprise the monitoring and supervision of the progress of the trial (including safety data and critical efficacy endpoints at intervals); reviewing relevant information from other sources, ensuring adherence to protocol; considering interim analyses; advising whether to continue, modify, or stop a trial; and providing the funding organisations with relevant information and advice.

Applicants should submit their proposed arrangement for supervision of the clinical trial and a suggested **membership and affiliation** for the committee(s). A minimum of 3 DMSC members should be named.

7. REFERENCES

Publication listing according to numerical appearance in the text.

8. TIMELINE / MILESTONES

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

9. FINANCIAL DETAILS OF THE STUDY

9.1 FINANCIAL SUMMARY

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

The overall expenditure should be summarized in the table below. Please provide both person months and 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/ TvÄ/ BAT	Total months	Total years	Total (€)	Year 1 (m/€)	Year 2 (m/€)	Year 3 (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 € / person								
7	Meetings/ Travel	no of attendees	no of meetings @ x € / person								
8	Case payment		examinations per subject/patient hours of staff per subject/patient € / patient x no of patients								
9	Reference centres		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 effort indicated in months; € = expenditures indicated in Euro

9.2 EQUIPMENT

Please list larger instruments available for the conductance of the clinical trial. In case you apply for instruments which are already available at your institution but cannot be used for the clinical trial please provide detailed information.

Application of instruments

Please list all requested instruments with price information.

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

Co-financing by industry and/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.

- 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 received; please contact the funding organisations first! Appropriate agreements on intellectual property, confidentiality, publication of results, property rights should be concluded between all those partners that are playing a leading part in the conduct of the clinical trial.

Agreement with manufacturer on variation of authorisation

If the clinical 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 (Federal Institute for Drugs and Medical Devices) if the trial result is favourable.

Please be aware of the legal provisions relevant for cooperations between industry, medical institutions and their staff.⁴

9.4 OTHER FUNDING

In case you have already submitted the same request for financial support or parts hereof to other institutions, please provide this information. 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".

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>)

C. Description of Register / 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, 11 point Arial, single-spaced, references in numerical order). Structure your application using the headings listed below. Make an entry under each 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	<p><i>Name and contact details</i></p> <p><i>In case of multiple applicants the principal investigator / coordinating investigator should be listed first.</i></p> <ul style="list-style-type: none"> • <i>First name, last name, academic title</i> • <i>Employment status</i> • <i>Institution and department (complete name)</i> • <i>Postal address</i> • <i>Telephone</i> • <i>Fax</i> • <i>E-mail address</i>
TITLE OF PROJECT	<i>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.</i>
CONDITION/TOPIC	<i>The exact medical condition / topic being studied.</i>
OBJECTIVE(S)	<i>Which principal research questions will be addressed? Specify clearly the primary goal of the project. Which results are expected?</i>
KEYWORDS	<i>Maximum 6</i>
TYPE OF PROJECT	
PROBANDS (KEY INCLUSION AND EXCLUSION CRITERIA)	
MAIN OUTCOMES TO BE ANALYSED	
STATISTICAL ANALYSIS	<p><i>Strategy:</i></p> <p><i>Anonymisation or pseudonymisation of data:</i></p>
SIZE AND DURATION OF REGISTER/STUDY	
SUMMARY	<i>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.</i>
PARTICIPATING CENTRES	

2. AIM OF THE PROJECT

2.1 MEDICAL PROBLEM

Which medical problem will be addressed? Which principal research questions/hypotheses will 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. Provide references to relevant publications and running comparable projects. What are the novel aspects 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 the individual patient and society/science benefit from the register/study?

2.4 STRATEGIES FOR THE EXPLOITATION/DISSEMINATION OF RESULTS

What will be your strategies for the dissemination of results? How will the expected results of the clinical trial be used; specify dissemination of results beyond publication in scientific journals; detail potential economic impact. If applicable, how is the scientific community informed about the availability of data?

2.5 ADDED VALUE

Comment on the interaction between the planned project and the other subprojects within the consortium.

3. JUSTIFICATION OF DESIGN ASPECTS

3.4 TYPE OF PROJECT

Is it a clinical/epidemiological register or a cohort study?

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

In case of a clinical register/ cohort 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). 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 provide full details of the 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 major participants by citing own relevant publications and/or specifying their responsibility / 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 will the data integrity and data plausibility be 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, 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 register, 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 pseudonymisation 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 depseudonymisation (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 / MILESTONES

As funding by BMBF will critically depend on the progress according to the proposed milestones, please provide important milestones reflecting planning, recruitment status and data clearing/analysis progress. Include a diagram, which illustrates the clinical trial stages and the 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 the total duration of the project, the period of time for which funding is requested, and when the funding should begin.

The overall expenditure should be summarized in the table below. Please, provide both person months and 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/ TvÄ/ BAT	Total months	Total years	Total (€)	Year 1 (m/€)	Year 2 (m/€)	Year 3 (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 € / person								
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 effort indicated in months; € = expenditures indicated in Euro

8.2 EQUIPMENT

In case you apply for instruments which are already available at your institution but cannot be used for the clinical trial please provide detailed information.

Please list all requested instruments with price information.

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

Co-financing by industry and/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 don't make any agreements before notion of award has been received; 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.

Please be aware of the legal provisions relevant for cooperations 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 provide this information. 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".

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>)

E. Description of Biomaterial Bank

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, 11 point Arial, single-spaced, publication listings in numerical order). Structure your application using the headings listed below. Make an entry under each heading (fill in "n.a." if not applicable) under every heading. Signatures of principal / coordinating investigator and responsible biostatistician/data manager are mandatory.

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

1. SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	<p><i>Name and contact details</i></p> <p><i>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.</i></p> <ul style="list-style-type: none"> • <i>First name, last name, academic title</i> • <i>Institution and department (complete name)</i> • <i>Postal address</i> • <i>Telephone</i> • <i>Fax</i> • <i>E-mail address</i>
TITLE	<i>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.</i>
CONDITION/TOPIC	<i>The medical condition / topic being studied</i>
OBJECTIVE(S)	<i>Please specify the relation of the project within the network or to other subprojects. Comment on the correlation/connection to the entire consortial research.</i>
KEYWORDS	<i>Maximum 5</i>
PROJECT DURATION	<i>In months</i>
SUMMARY	<i>Please provide 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.</i>
PARTICIPATING CENTRES	

2. AIM OF THE PROJECT

Which medical area/disease entity will be addressed? Does the biomaterial bank relate to a specific disease(s)? What are the novel aspects that will be studied by the proposed biomaterial bank itself or within the network and/or subprojects? Which principal research questions/hypotheses to be addressed, if applicable in cooperation with subprojects? Bring them into order indicating major and minor motivations / starting hypotheses of the investigation(s) planned.

2.1 EVIDENCE

Set your biomaterial bank (BMB) into perspective. Do related (systematic) collections exist? In which context were these collections sampled (basic and/or clinical research, treatment context)? Have relevant results been drawn? Give references to any relevant (systematic) BMB(s) and/or (own) publications, if applicable. What are the novel aspects of the planned BMB?

2.2 THE NEED FOR A BIOMATERIAL BANK

What impact will potential results provide for the clinical practice or understanding the disease? Why is a (systematic) collection necessary? How will the society/science benefit from the BMB?

2.3 STRATEGIES FOR THE EXPLOITATION/DISSEMINATION OF RESULTS AND MATERIALS

What will be your strategies for the dissemination of results? Indicate how the expected results of the BMB will be used; discuss dissemination of results, especially beyond publication in scientific journals; describe potential sustainability measures (i.e. open to scientific community or non-academic research). If applicable, how is the scientific community in general informed about the availability of samples?

2.4 ADDED VALUE

Comment on the interaction between the planned project and the other subprojects within the network.

3. ORGANISATION AND BREADTH OF INTENDED BIOMATERIAL BANK

3.1 TYPE OF BIOMATERIAL BANK

What organisational model does apply to your intended BMB? Is the BMB itself performing research? Is the purpose of the BMB exclusively the collection and distribution of biomaterials and data without own research projects? Will the BMB project provide services (RNA/DNA extraction, immunohistology/TMA, PCR, Affymetrix Chips, etc) on assignment of other projects in the consortium?

- Centralised collection (multiple providers, primary storage in one place and limited access for third parties) or
- Decentralized collection (multiple providers, primary storage in one place, broad access for and investigations by third parties different from the holder) or
- Decentralized collection of cooperative nature (storage and/or investigation of collected materials primarily decentral)

What biological material is intended to be sampled (nature [tissue or sample type] and numbers)?

Comment on the primary goal of the material collection:

- Is the material primarily stored for routine diagnostic or therapeutic purposes and can additionally be used for research questions? If applicable, in which amount yet? Is the treatment context embedded in a clinical study (purpose commitment)? If applicable, in which amount yet?
- Is the material only sampled and stored for research question(s)?

What is the planned duration for the BMB?

3.2 POPULATION TO BE STUDIED

Describe and justify the (patient) population to be studied (inclusion/exclusion criteria). Include reflections on generalisability.

3.3 DATA AND MATERIAL ACQUISITION AND STORAGE

Describe the concept of data and material acquisition and storage.

- Which data are intended to be sampled and stored (data of patient, data of the sample(s), data of sample analysis)?
- If applicable, describe obtained numbers and comment on data protection.
- Does or will the database contain clinical, genetic or pathological information?
- Who does or will provide that input and where?
- Who is responsible for update and maintenance of the database?
- Which instruments will be used to record the data? Are the instruments validated and reliable?
- How will the personal responsible for data acquisition be trained?
- How will the patients be selected and recruited for the BMB?
- Which standards will be used to classify diagnoses and stages of the disease(s)?
- Comment on the potential accessibility of related resources (if applicable, cf. 2.1) and on the possibilities to use or integrate already existing sources or data.

3.4 FEASIBILITY OF COMPREHENSIVE SAMPLING

What is the evidence that the intended recruitment rate and total number of samples/patients for the BMB is achievable? In case of existing (systematic) collections, which publications of the last 2 years are based on this material bank?

3.5 INTERNATIONAL COLLABORATIONS

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

4. ETHICAL CONSIDERATIONS

Specify the ethical considerations relating to the BMB (informed patient consent, purpose commitment declaration, interest in property, personal rights). Do you/did you ask for permission to use the clinical/genetic/pathological data for research purposes? If possible, provide a "Letter of Intent" from respective partners/institutions.

5. BIOMATERIAL BANK OPERATORSHIP AND MANAGEMENT

5.1 OWNERSHIP

Who will be the operator of the BMB? What will be the legal form of the BMB? Where is the ownership defined?

- Is the acquisition of ownership intended or the concession of life estate (w/o acquisition of ownership) on the samples? If any of these, by what means can the different regulations be met?

According to your organisational model, what measures are intended to support potential long-term usage?

- How is access to the BMB organised? Are potential co-founders informed? If yes, how?
- How is the co-authorship regulated?
- How are formal aspects, e.g. ethical review and/or rationing with scarce material taken into account? If applicable, how many material/data applications did you receive in the last 2 years? If applicable, how were/are material/data applications reviewed (e.g. independent board?)

- Do scientists pay for samples? (how much)? Is there a fee difference between internal and external usage?

5.2 MAJOR PARTICIPANTS (please indicate roles of major participants according to your organisational model)

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

Who is responsible for statistics? Professional background/expertise should be given.

#	Name	Affiliation	Responsibility/Role	Signature
			Responsible for Statistics	

Who is responsible for quality assurance and the data documentation?

#	Name	Affiliation	Responsibility/Role	Signature
			Responsible for Data Assurance	

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

5.3 BIOMATERIAL BANK SUPPORTING FACILITIES

Which BMB-specific facilities and other resources are available for conducting the systematic collection?

5.4 QUALITY ASSURANCE

Describe and justify the concept for quality assurance. Describe the actual organisational and technical measures for quality assurance and quality control (coding of data, second control of coding, documentation of data corrections). Are GLP guidelines implemented? Have quality procedures (Standard operation procedures, SOPs) been developed? Are they formulated in specific manuals?

5.5 DATA PROTECTION CONCEPT

How will the existing legal requirements for data protection be met? Describe the data protection concept applied and the planned data and work flow (diagrams). If applicable, provide positive votes of the data protection organisation in charge. Depending on organisational model and purpose of the BMB, is anonymisation of data applicable? Comment on the following aspects of the data protection concept:

- Technical and organisational instruments
- Central patients list (localisation)
- Patient identification data
- Pseudonymisation and de-pseudonymisation (localisation, where does this process take place)
- Informed patient consent
- Right of withdrawal

- Purpose commitment declaration
- Storage time of data
- Workflow for quality assurance
- Safety of data transmission and documentation
- Criteria of material dissemination
- Policy document including all legal regulations and agreements

6. REFERENCES

Publication listing according to numerical appearance in the text.

7. TIMELINE / MILESTONES

As funding by BMBF will critically depend on the progress according to milestones, please provide major milestones reflecting planning, recruitment status and data clearing/analysis progress. Include a diagram, which illustrates the clinical trial stages and the milestones. Comment on the possibility of sustainable establishment of the biomaterial bank after BMBF funding.

8. FINANCIAL DETAILS OF THE STUDY

8.1 FINANCIAL SUMMARY

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

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

	Organizational Segment	Institution/ Participant/	No of items/ Kind of equipment/ Explanation	Qualification of staff	TVöD/ TvÄ/ BAT	Total months	Total years	Total (€)	Year 1 (m/€)	Year 2 (m/€)	Year 3 (m/€)
1	Scientific BMB Management										
2	Organisational BMB Management										
3	Data (Security) Management										
4	Statistical data analysis										
5	Quality assurance										
6	Meetings/ Travel	no of attendees	no of meetings x € / person								
7	Documentation payment		documentation per sample/patient hours of staff per sample/patient € / patient x no of patients								
8	Materials		Consumables, laboratory expenses								
9	Equipment										
10	Other										
TOTAL								€	€	€	€

m = staff effort indicated in months; € = expenditures indicated in Euro

8.2 EQUIPMENT

In case you apply for instruments which are already available at your institution but cannot be used for the clinical trial please provide 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 and/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 BMB 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 a formal notion of award has been received; 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 BMB.

Please be aware of the legal provisions relevant for cooperations between industry, medical institutions and their staff.⁶

8.4 OTHER FUNDING

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

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".

⁶ 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>)