DLR Projektträger

Bundesministerium
für Bildung
und Forschung

Leitfaden zur Antragstellung für die Fördermaßnahme „Translationsorientierte Verbundvorhaben im Bereich der seltenen Erkrankungen“

vom 25.03.2014

INHALTSVERZEICHNIS:

Einleitung

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

Der vorliegende Leitfaden stellt die Anforderungen für die Antragstellung detailliert dar und ergänzt die Förderrichtlinie des BMBF. Der Antrag besteht aus zwei Teilen:

a. Der Vorhabenübersicht (Kontaktdaten, Finanzdaten inklusive Begründungen für die beantragten Mittel, Kurzbeschreibungen), die über ein Internetformular vorgelegt werden;
b. Der Projektskizze als PDF-Dokument.

Beide Teile sind durch den Verbundkoordinator elektronisch über ein Internet-Portal einzureichen.

Beachten Sie bei der Einreichung Ihres Antrags folgende Hinweise:

1. Der Verbundkoordinierende stellt zur Antragstellung zunächst folgende Unterlagen als **EIN** PDF-Dokument zusammen:
   - die Projektskizze des Forschungsverbundes und der Teilprojekte nach den Vorgaben des Leitfadens (siehe S. 4ff.) (Format: DIN A4, 11 Punkt Arial, 1-zeilig) in **englischer Sprache**.
2. Das Einreichen der Projektskizze erfolgt durch den Verbundkoordinator über das dafür zur Verfügung stehende Internet-Portal: https://www.pt-it.de/ptoutline/application/FSE14
3. Zunächst werden die erbetenen Übersichtsangaben zum Vorhaben in das Internetformular eingetragen.
4. Nachdem alle Daten in die vorgegebenen Felder eingetragen sind, können diese über die Vorschaufunktion unter dem Menüpunkt „Kontrolle und Abgabe“ überprüft werden.
5. Anschließend kann unter dem Menüpunkt „Kontrolle und Abgabe“ die Projektskizze (s. Punkt 1) als PDF-Dokument hochgeladen werden. **HINWEIS:** Es kann nur ein einziges PDF Dokument hochgeladen werden. Mit dem Hochladen weiterer Dokumente werden automatisch alle früheren PDF-Dokumente überschrieben. **Die maximale Dateigröße für das PDF-Dokument ist 7 MB.**
6. Ebenfalls unter dem Menupunkt „Kontrolle und Abgabe“ werden abschließend beide Antragsteile verbindlich eingereicht („Button: Jetzt verbindlich einreichen“). Diese elektronische Version ist die Grundlage der Begutachtung.
7. Nach dem verbindlichen Einreichen des Antrags sind die im Internet verfügbaren Versionen der Vorhabenübersicht und der Projektskizze doppelseitig auszudrucken. Die Vorhabenübersicht darf nicht mehr den Aufdruck „Entwurf“ tragen.

Ihren Antrag (Angaben zur Vorhabenübersicht und Projektskizze) können Sie bis zum **21.05.2014, 17.00 Uhr** elektronisch einreichen. Die Vorlagefrist gilt nicht als Ausschlussfrist. Verspätet eingehende Projektskizzen können aber möglicherweise nicht mehr berücksichtigt werden. Bei verspäteter Einreichung wird dringend die vorherige Kontaktaufnahme mit dem zuständigen Projektträger empfohlen. Eine Vorlage per E-Mail oder Telefax ist nicht möglich.
Aus der Vorlage einer Projektskizze kann kein Rechtsanspruch auf Förderung abgeleitet werden.
Zusätzlich zu der Online-Version muss der **Antrag innerhalb einer Woche (Poststempel) in Papierform (s. Punkt 7) in 6-facher Kopienzahl** (doppelseitig bedruckt) sowie in einer ungebundenen Kopiervorlage eingereicht werden beim

Projektträger im DLR für das BMBF
Gesundheitsforschung
Stichwort „Seltene Erkrankungen“

Heinrich-Konen-Str. 1
53227 Bonn
Tel.: 0228-3821-1210, Fax: (-1257)
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Internet: www.gesundheitsforschung-bmbf.de

Eine Vorlage per Email oder Fax ist nicht möglich.

Mustervorlagen für die Projektskizze

Bitte erstellen Sie Ihre Projektskizze in englischer Sprache.
Die Projektskizze besteht aus den unten dargestellten sechs Teilen. Die Teile 1, 2 und 6 sind für alle Antragsteller verpflichtend. Die Teile 3, 4 und 5 müssen nur dann ausgefüllt werden, wenn entsprechende Studien innerhalb des Konsortiums geplant sind. Die maximal zulässige Seitenzahl für jeden Teil ist in Klammern angegeben. **Bitte nutzen sie unbedingt die für das jeweilige Teilprojekt passende Mustervorlage**, damit eine sachgerechte Bewertung auf Grundlage aller notwendigen Angaben erfolgen kann.

Teil 1: Darstellung des Konsortiums (max. 12 Seiten inklusive Finanzplan)
Teil 2: Mustervorlage für ein Forschungsprojekt (max. 5 Seiten inklusive Finanzplan, bzw. max. 8 Seiten bei Studien mit Tierexperimenten)
Teil 3: Mustervorlage für eine klinische Studie (max. 12 Seiten inklusive Finanzplan)
Teil 4: Mustervorlage für eine epidemiologische Studie (Register-/Kohortenstudie) (max. 10 Seiten inklusive Finanzplan)
Teil 5: Mustervorlage für eine Biomaterialbank (max. 10 Seiten inklusive Finanzplan)
Teil 6: CVs aller Teilprojektleiter inkl. der wichtigsten Publikationen der letzten 5 Jahre (max. 1 Seite pro CV)

Für alle 6 Teile der Projektskizze ist folgendes Format zwingend einzuhalten:
DIN A4, 11 Punkt Arial, 1-zeilig, doppelseitig. Referenzen dürfen in kleinerer Schriftart verfasst werden, jedoch **nicht kleiner als 8 Punkt Arial**. Alle 6 Teile der Projektskizze sind in einem Dokument einzureichen.

Bitte nutzen Sie die vorgegebene Gliederung. Hierbei sind alle vorgegebenen Punkte zu adressieren. Die vorhandenen Eintragungen in kursiver Schrift sind als Hinweise für die Projektskizzenerstellung gedacht und sind vor Projektskizzeneinreichung zu löschen.

Neben diesem Leitfaden gelten weiterhin die entsprechenden Merkblätter und Richtlinien des BMBF, soweit in diesem Leitfaden nicht ausdrücklich andere Regelungen getroffen sind.
Weiterführende Links für die Antragstellung finden Sie auf den Internetseiten des BMBF[1]. Die dort veröffentlichten Anforderungen/Informationen werden regelmäßig aktualisiert. Eine Durchsicht dieser Informationen vor dem Einreichen eines förmlichen Antrages (zweite Verfahrensstufe nach Förderempfehlung) wird dringend empfohlen.

Wer sind die Ansprechpartner?

Es wird dringend empfohlen, zur Antragsberatung mit dem Projektträger Kontakt aufzunehmen. Weitere Informationen und Erläuterungen sind dort erhältlich. Kontaktpersonen sind:
Dr. Michaela Girgenrath (Tel.: 0228-3821-1775, E-Mail: michaela.girgenrath@dlr.de)
Dr. Ralph Schuster (Tel.: 0228-3821-1233, E-Mail: ralph.schuster@dlr.de)
Dr. Peter Buch (Tel.: 0228-3821-1129, E-Mail: peter.buch@dlr.de) und
Dr. Christiane Steinmüller (Tel.: 0228-3821-1133, E-Mail: christiane.steinmueller@dlr.de)

[1] *http://www.foerderportal.bund.de/*

Guidelines for Grant Application

1 Description of Consortium

1.1 GENERAL INFORMATION ON THE CONSORTIUM

APPLICANT / COORDINATING INVESTIGATOR	*In case of multiple applicants, the coordinating investigator of the consortium who will take responsibility for managing the entire consortium should be listed first.* • *First name, last name, academic title* • *Institution and department (complete name)* • *Postal address* • *Telephone* • *Fax* • *E-mail address*
TITLE	
ACRONYM	*The acronym for the consortium.*
CONDITION / TOPIC	*The exact medical condition / topic being addressed.*
OBJECTIVE(S)	*Which principal research questions are addressed? Clearly specify the primary goal of the project. Which (main) results are expected?*
KEYWORDS	*Maximum 5 keywords outlining the area of research.*
CONSORTIUM DURATION	*Indicated in months.*
SUMMARY	*Please provide a summary of the main goals and methodological approach of the project (max. 1600 characters, including spaces). 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.*
CONTINUATION OF CONSORTIUM FROM PREVIOUS FUNDING PERIOD?	☐ yes ☐ no *Comment, if applicable:*

Sub-project No.	Principal investigator	Institution	Title of Subproject	Function in the consortium
1	*Prof. xx*	*University of X..*	*Coordination unit of the consortium for research on fragile-X syndrome*	*Coordination, Monitoring, Processing of results*
2	*Dr. xy*	*University of Y….*	*Genotype-Phenotype correlations in patients with fragile-X syndrome*	*Analysis and description of genotype/phenotype correlations*

A1.2. RESULTS OF THE PREVIOUS FUNDING PERIOD

Only fill out if applicable

A1.2.1 SCIENTIFIC RESULTS

Describe briefly the highlights of scientific results achieved so far through the networking in the consortium. List all publications and patents directly resulting from the activities of the funded consortium. Here, only those publications are to be cited in which sponsoring through the BMBF in the context of the consortium has been mentioned univocally.

A1.2.2 STRUCTURAL DEVELOPMENT

Describe briefly: achievements in management infrastructure, organisational support, quality assurance; achievements of networking, e.g. methods developed, biobanks, well-characterized patient cohorts, databases, high throughput sequencing or other relevant research platforms / service components; added value of the cooperation so far; other national and international collaborations of the consortium; dissemination of results and public relations work.

1.2. OBJECTIVES, RELEVANCE, EXPERTISE AND INNOVATION

1.2.1 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? What strategies will be used to ensure translation of the results?

1.2.2 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, high throughput sequencing or other relevant research platforms / service components.

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

1.2.3 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?

1.3. STRUCTURE OF THE PLANNED COOPERATION

1.3.1 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.

1.3.2 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.

1.3.3 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.

1.3.4 INVOLVEMENT OF PATIENT SUPPORT GROUPS

Please comment on the involvement of relevant patient support groups in the work of the consortium.

1.3.5 TIMEFRAME / MILESTONES

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

1.3.6 REFERENCES

Please list key references here in numerical order (max. 50 references, font size not less than 8 pt).

1.3.7 FINANCIAL SUMMARY

Please provide a brief financial summary here, showing the overall financial structure of the consortium. Please make sure that all overhead costs (e.g., “Projektpauschale” for universities and university clinics) are properly considered. Inclusion of overhead costs must be clearly visible here. In addition, do also consider the added value tax (Mehrwertsteuer) for commissions if applicable.

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*
Other costs: eg. animal costs etc.
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), an* ***epidemiological*** *(****registry/cohort) study*** *or a* ***biobank****, please proceed to part 3, 4 or 5 of this guideline. If funds for other central projects such as coordination or service components are applied for, please use the general research project scheme (part 2) and, if necessary, modify it accordingly.*

2. Description of Research Project

The description of each research project must not exceed 5 pages including financial plan (format: DIN A4, single-spaced, Arial 11 points). Three additional pages are allowed for the description of further details in case of a study involving animals.

2.1. GENERAL INFORMATION ON THE RESEARCH PROJECT

PRINCIPLE INVESTIGATOR AND CO-INVESTIGATORS OF THE SUBPROJECT	*Name and contact details* • *First name, last name, academic title* • *Institution and department (complete name)* • *Postal address* • *Telephone* • *Fax* • *E-mail address*
TITLE OF SUBPROJECT	*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.*
CONDITION / TOPIC	*The exact medical condition / topic being examined.*
INVOLVEMENT OF ANIMALS	☐ yes ☐ no
OBJECTIVE(S)	*Which principal research questions are addressed? Clearly specify the primary goal of the project. Which (main) results are expected?*
KEYWORDS	*Maximum 5 keywords outlining the area of research.*
DURATION OF SUBPROJECT	*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.*
SUMMARY	*Please provide a summary of the main goals and the methodological approach of the project (max. 1600 characters, including spaces). 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.*
CONTINUATION OF PROJECT FROM PREVIOUS FUNDING PERIOD	☐ yes ☐ no *Comment, if applicable:*

A2.2. RESULTS OF THE PREVIOUS FUNDING PERIOD

Only fill out if applicable

A2.2.1. ORIGINAL AIMS OF THE PROJECT
Describe the original aims at the starting point of your project.

A2.2.2. SCIENTIFIC RESULTS
Describe the scientific highlights so far of your project. Compare the obtained results with the schedule and milestones envisaged in the initial proposal.

A2.2.3. RELEVANT PUBLICATIONS AND PATENTS
List all publications directly resulting from the activities of the funded project (here, only those publications are to be cited in which sponsoring through the BMBF in the context of the competence network has been mentioned univocally). Indicate if a publication represents the joint activities of two or more consortium groups. Describe additional dissemination and exploitation of results.

A2.2.4. NETWORKING
Provide a summary how you have contributed to networking. Focus (i) on the use of the consortium structure by the project and (ii) on the special contributions of the project to the overall aims of the consortium.

2.2. SPECIFIC INFORMATION ON THE RESEARCH PROJECT

2.2.1 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.

2.2.2 AIMS
What is the hypothesis to be tested? What is the aim/purpose of the subproject? Which are the novel aspects of the subproject? What results are expected? How will the results contribute to better health care

2.2.3 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.

*For experiments with the use of animals please describe the character of your approach e.g. "explorative" if you aim at generating pathophysiological theories of diseases or "confirmatory" if you aim to demonstrate strong and reproducible treatment effects in animal models. Detailed information about the relevance to human biology, the study design and analysis **is mandatory**. This information should be given in accordance to the suggestions of the ARRIVE Guidelines[2].*

- *Nature of the ethical review permissions (licences, guidelines)*
- *Study design (number of experimental control groups, steps to minimise the effects of subjective bias)*
- *Experimental procedures (details of procedures concerning drug delivery, anaesthesia/analgesia, surgery, e.g. How, When, Where and Why)*

[2] *The ARRIVE Guidelines: Animal Research: Reporting of In Vivo Experiments. Originally published in PLOS Biology, June 2010*

- *Experimental animals (details of the animals e.g. species, strain, sex, developmental stage, age, weight, source of the animals, genetic modification status, etc.)*
- *Housing and husbandry (housing type, husbandry conditions)*
- *Sample size (total number of animals in each experiment and experimental group, sample size calculation)*
- *Allocating animals to experimental groups (details of allocation including randomisation or matching, order of treatment and assessment)*
- *Experimental outcomes (definition of assessed primary and secondary outcomes)*
- *Description of statistical methods*

Please note that 3 additional pages are allowed for the description of the animal experiments.

2.2.4 RESOURCES

Does the project involve utilization of (characterized) biomaterial banks or collections, patient registers or cohorts, high throughput sequencing or other relevant research platforms? 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?

2.2.5 WORK PLAN INCLUDING MILESTONES

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

2.2.6 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?

2.2.7 POTENTIAL HEALTH IMPACT, EXPLOITATION AND DISSEMINATION STRATEGIES

Please indicate how the expected results of the subproject will be used. What is the potential health impact of the expected results? How will translation be facilitated? What are the steps necessary to bring the results to practice? Describe the proposed arrangements for disseminating the results of the research to potential users.

2.2.8 REFERENCES

Please list key references here in numerical order (font size not less than 8 pt).

2.2.9 FINANCIAL SUMMARY

[1]Please make sure that all overhead costs (e.g. “Projektpauschale” for universities and university clinics) are properly considered. Inclusion of overhead costs must be clearly visible here.
[2]In addition, do also consider the added value tax (Mehrwertsteuer) for commissions if applicable.

Personnel			
Position / Salary Group	Total Budget	Duration (months)	Tasks / Justification

Other resources		
Type	Total Budget	Specification / Justification
Consumables		
Equipment		
Commissions[2]		
Travel		
Other (e.g. animal costs)		

Summary	
Total Budget:	
Institutional Overhead[1]:	
Requested Budget (sum):	
Co-Financing applicable?	Yes / No *(e.g., by industry or other funding sources)*

3. Description of Clinical Trial

*Please prepare your application in English **not exceeding 12 pages per trial** for the headings 3.1 to 3.9, including references and financial plan (*DIN A4, 11 point Arial, single-spaced, publication listings in numerical order*). Make an entry under every heading. Signatures of **principal investigator** and responsible **biostatistician** are mandatory.*

• **Applicant / Coordinating Investigator**	*In case of multiple applicants the principal investigator / coordinating investigator*[3] *of the trial who will assume responsibility for conducting the clinical trial, should be listed first.* *Title, first and last name* *Institution* *Address* *Telephone and Fax* • *E-Mail address*
• **Title of study**	
• **Condition**	• *The medical condition being studied*
• **Objective(s)**	*Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.*
• **Intervention(S)**	• *Description of the experimental and the control treatments or interventions as well as dose and mode of application. For diagnostic tests or procedures the index test and the reference procedure (gold-standard) should be described.* • Experimental intervention / index test: • Control intervention / reference test: • Duration of intervention per patient: • Follow-up per patient: • Experimental and/or control off label or on label in Germany: *if applicable*
• **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*

[3] "Investigator" as defined in the harmonised "Guideline for Good Clinical Practice" of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH GCP) (http://www.ema.europa.eu/pdfs/human/ich/013595en.pdf) . This definition should be used accordingly for non-drug trials/studies: *(1.34 Investigator)"A person responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator."* (*1.19 Coordinating investigator) "An investigator assigned the responsibility for the coordination of investigators at different centres participating in a metacentre trial.*"

	group/cross-over , prognostic, diagnostic
• **Statistical analysis**	• Efficacy / test accuracy: • Description of the primary efficacy / test accuracy 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**	Time for preparation of the trial (months): First patient in to last patient out (months): Duration of the entire trial (months): Recruitment period (months):
• **Participating centers**	*How many centres will be involved?* (n) • Signed agreement to participate (n)*: How many centres have signed an agreement to participate? Full list under 5.3.10.*

A.3.1. RESULTS OF THE PREVIOUS FUNDING PERIOD

Only fill out if applicable

A3.1.1. ORIGINAL AIMS OF THE PROJECT

Describe the original aims at the starting point of your project.

A3.1.2. SCIENTIFIC RESULTS

Describe the scientific highlights so far of your project. Compare the obtained results with the schedule and milestones envisaged in the initial proposal.

A3.1.3. RELEVANT PUBLICATIONS AND PATENTS

List all publications directly resulting from the activities of the funded project (here, only those publications are to be cited in which sponsoring through the BMBF in the context of the competence network has been mentioned univocally). Indicate if a publication represents the joint activities of two or more consortium groups. Describe additional dissemination and exploitation of results.

A3.1.4. NETWORKING

Provide a summary how you have contributed to networking. Focus (i) on the use of the consortium structure by the project and (ii) on the special contributions of the project to the overall aims of the consortium.

3.1 Summary of the trial

3.1.1 Main aspects of the trial

Give a summary of the main aspects of the project; it should not exceed 15 lines (max. 1600 characters incl. blanks). The project summary serves two main goals: It will inform the multidisciplinary committees which make the final decision on your grant of the principal aspects e.g. goals, design, subjects, expected outcome of your project.

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. Electronic search will be eased if you avoid abbreviations and include suitable key words.

3.1.2 Intervention Scheme / Trial Flow

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

3.1.3 Frequency and scope of study visits

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

3.2 The medical problem

3.2.1 Evidence

Set your trial into perspective; substantiate your starting hypothesis. What is the rationale for the intervention? Which trials have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s)[4] and/or (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. State what your study adds to the totality of evidence when your study is added to previous work. Include a description of how you searched for the evidence (databases, search terms, limits) and how you assessed its quality — i.e., how you selected and how you combined the evidence. Note that missing evidence precludes funding.[5]

3.2.2 The need for a trial

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

3.2.3 Strategies for data handling and the dissemination of results

Describe what measures will be implemented to ensure the data management, curation and long-term preservation for future reuse. Please regard existing standards and data repositories where appropriate. 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.

3.3 Justification of design aspects

3.3.1 Control(s) / comparator(s)

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

3.3.2 Dose, mode and scheme of intervention

Justify the dose, the mode and the scheme of the intervention. How does the intervention compare to other interventions for the same condition? For diagnostic trials: What is the rationale for the units, cut off and/or categories?

3.3.3 Additional treatments

Please describe the medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial, if applicable.

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[4] Eine Definition für einen systematischen Review finden Sie unter Oxman, AD (1994). Checklists for review articles, BMJ; 309; 648-651.

[5] vgl. hierzu Clark S and Horton R (2010). Putting research into context – revisited; The Lancet; 376(9734); 10-11

3.3.4 Inclusion/exclusion criteria

Justify the population to be studied, include reflections on generalisability and representativeness, specifically with regard to gender and age.

3.3.5 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.

3.3.6 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?

3.3.7 Methods against bias

Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating participants to trial groups? Will trial site effects be considered in randomisation?
Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome).
For diagnostic trials: what is the training and expertise of persons executing and reading the index tests and the reference standards.

3.3.8 Proposed sample size/power calculations

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

3.3.9 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?

3.3.10 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 trials 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.

3.3.11 Stopping rules

Please specify the "stopping rules" or "discontinuation criteria" a) for the individual patient and b) for the whole trial. Please specify rules for closing participating centers, which fail to include the estimated number of patients.

3.4 Statistical Analyses

What is the proposed strategy of statistical analysis? If multiple hypotheses are foreseen for confirmatory testing what is the procedure to ensure Type I error control and what will be the primary data analysis set (e.g. ITT-population in case of superiority RCT). What is the strategy for analysing the primary outcome? If applicable, how will multiple primary end points be analysed statistically? If interim analyses are planned, please specify. Are there any subgroup analyses? How will missing data and subjects withdrawn from the trial be handled statistically? What are the methods for calculating test reproducibility in diagnostic trials? In case of an unchanged overall outcome, how will you investigate any processes of change (secondary outcomes)? Make sure that a negative result still allows a valid statistical conclusion.

3.5 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).

3.6 Quality assurance and safety

3.6.1 Quality assurance / monitoring

What are the proposed measures for quality assurance?
Which institution will perform the monitoring? Which SOPs will be utilized? Describe and justify the monitoring strategy (percentage of source data verification, number of monitor visits per trial site).
Please note: The funding agencies will insist on the conduct of pre-trial visits before trial starts in each recruiting centre by independent bodies. Please make sure to include these as a milestone into the time plan and into the budget. The results of these visits should be documented. Note that insufficient results of pre-study visits may lead to discontinuation of funding.

3.6.2 Safety

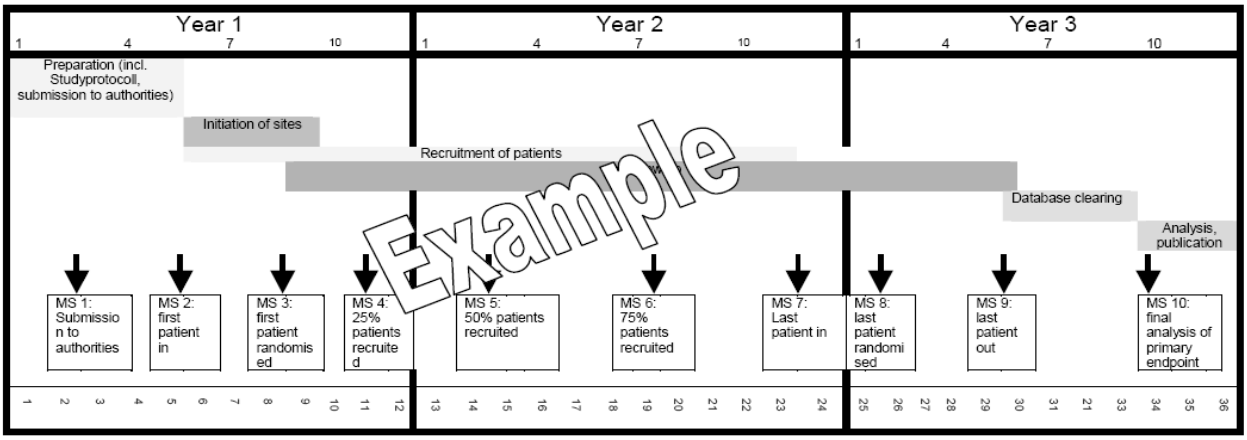
Please comment on the planned supervision of the trial (DSMB); give name and affiliation of independent DSMB members.
Arrangements for the management of the trials will vary according to the nature of the study proposed. However, all should include an element of expert advice and monitoring, that is entirely 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 (DSMB).
It is recognised that these arrangements may not always be appropriate and the committees needed may vary according to the nature of the study. 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** for the committee(s). A minimum of 3 members should be named. List under 3.10.*

3.7 References

Please list the most important references in numerical order (max. 20, font size not less than 8 pt) here.

3.8 Trial timeline flow

As funding will critically depend on the study progression according to milestones, please provide a diagram reflecting preparation, initiation of centres, recruitment, follow-up and data cleaning/analysis. An example of such a diagram is given below. As payments by the funding organizations will be made in instalments, please indicate funds needed at respective milestones.



3.9 Financial details of the trial

3.9.1 Commercial interest

Please justify, why this trial should be funded by a public funding agency and describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists. Note that direct commercial interest of a company in the results of the trial precludes funding.

3.9.2 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.

- *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.*

3.9.3 Financial summary

The overall expenditure should be summarized in the table below (maximum 1 page). Indicate amounts in € in the column "Total (€)".Please provide man months for staff and € for all other expenditures. Please make sure that all overhead costs (e.g. "Projektpauschale" for universities and university clinics) are properly considered. Inclusion of overhead costs must be clearly

visible here. In addition, do also consider the added value tax (Mehrwertsteuer) for commissions if applicable.

	Organizational Segment	Institution/ Participant/ Trial Site	Qualification and Task of staff/ No. of items/ Kind of equipment/ Explanation	Salary group	Total months	Total (€)	Justification
1	**Clinical project management**						
2	**Project management**						
3	**Data Management**						
4	**Biometry**						
5	**Quality Assurance/ Monitoring**		*number of visits per site* *mean number of days per visit* *monitoring costs per day* *total No. of visits x € each*				
6	**Trial committees**		*No. of DSMB members ; No. of meetings x €/p*				
7	**Meetings/ Travel**		*No. of attendees ; No. of meetings x €/p* *travel costs monitoring*				
8	**Case payment**		*assays/examinations per patient; hours of staff per 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

Total Budget:
Institutional Overhead: *e.g., "Projektpauschale" for universities and university clinics; give amounts in €*
Requested Budget (sum):
Co-Financing applicable? *Yes / No (e.g., by industry or other funding sources) €*

months = staff indicated in months where applicable; € = other expenditures indicated in Euro where applicable; /p = per person

3.10 List of participants involved in the trial

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

Other participating groups / bodies *(e.g. steering committee in international trials)*			
#	Name	Affiliation	Responsibility/Role
Review of trial protocol *(who will review and finalize the protocol? Please refer to numbers above and/or include others)*			
#	Name	Affiliation *(only institution and city, no complete address)*	

3.11 Declarations of commitment of participating centres

Please use the template provided to declare the commitment of each participating centre (including the centre of the principal investigator). The template is to be signed personally by the investigator at the respective site.

Name of investigator:
Institution:

Information on the clinical trial

Trial title:	
Inclusion criteria:	
Exclusion criteria:	
recruitment period (months):	

Strategy for the determination of recruitment figures

How many patients with the condition specified above have you seen in your institution during the last 12 months?	
How many of these patients would fulfil the inclusion criteria of the above mentioned trial?	
How many of these patients would approximately agree to participate in the above named clinical trial per year?	
How many patients will approximately be recruited during the entire trial?	

Which source did you use for the estimation of potential participants in the above named clinical trial?

☐ Individual estimation
☐ Hospital data management system
☐ Patient registry
☐ Others

If others: please specify

Are there any other ongoing clinical trials/ projects competing for the same patients? ☐ yes ☐ no

If yes: How will this affect recruitment for the above-named clinical trial?

Commitment to participate

I hereby agree to participate in the above-named clinical trial and support the trial by recruiting patients.

_____
Date/ Signature

Conflicts of Interest

I hereby declare that I have no conflict of private, economical or financial interests with regard to the above mentioned clinical trial and the investigational drugs that will be used.

_____
Date/ Signature

C. Description of an Epidemiological Study

*Please prepare your application in English **not exceeding 10 pages**, including references and financial plan (*DIN A4, 11 point Arial, single-spaced, publication listings in numerical order*). Signatures of **principal investigator** and responsible **biostatistician/data manager** are mandatory.*

Coordinator	*Title, first and last name* *Institution* *Address* *Telephone and Fax* *E-Mail address*
Title	
Condition/Topic	*The medical condition being studied.*
Objective(s)	
Type of project	
Probands (key inclusion and exclusion criteria)	
Main outcomes to be analysed	
Statistical analysis	*Anonymisation or pseudonymisation of data and statistical details*
Size and duration of Register/Cohort	
Summary	*(max. 500 symbols including space characters)*
Participating centers	
External cooperation partners	**(optional, if applicable)**

A.4.1. RESULTS OF THE PREVIOUS FUNDING PERIOD

Only fill out if applicable

A4.1.1. ORIGINAL AIMS OF THE PROJECT

Describe the original aims at the starting point of your project.

A4.1.2. SCIENTIFIC RESULTS

Describe the scientific highlights so far of your project. Compare the obtained results with the schedule and milestones envisaged in the initial proposal.

A4.1.3. RELEVANT PUBLICATIONS AND PATENTS

List all publications directly resulting from the activities of the funded project (here, only those publications are to be cited in which sponsoring through the BMBF in the context of the competence network has been mentioned univocally). Indicate if a publication represents the joint activities of two or more consortium groups. Describe additional dissemination and exploitation of results.

A4.1.4. NETWORKING
Provide a summary how you have contributed to networking. Focus (i) on the use of the consortium structure by the project and (ii) on the special contributions of the project to the overall aims of the consortium.

4.1 Background and previous work

4.1.1. Background
Provide an overview about the background for the research question. Describe how the planned register/cohort is different from other existing or planned national or international registers/cohorts.

4.1.2. Own previous work
Describe your previous work in the field and list all publications directly relevant for the planned project.

4.1.3 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.

4.1.4. 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?

4.1.5. 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 register/study?

4.2 Justification of design aspects

4.2.1. Type of project
Is it a clinical/epidemiological register or 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? What are the long term plans for sustainability and how will the financing be assured?

4.2.2. 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.

4.2.3 Gender aspects
Are gender specific aspects adequately addressed? Does the methodology ensure that possible sex- and gender differences will be investigated? Have possibly differential outcomes and impact of the research on women and men be considered? Are questionnaires, surveys etc. designed to unravel potentially relevant sex- and gender differences? Is there a gender balance in the project consortium and team?

4.2.4. Methods against Bias

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

4.2.5. 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.

4.2.6. 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?

4.2.7. 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).

4.2.8. 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.

4.3 ETHICAL CONSIDERATIONS

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

4.4 PROJECT MANAGEMENT

4.4.1. Major participants

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

Please indicate roles of major participants

4.4.2. Project supporting facilities

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

4.4.3. 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, 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.

4.4.4. 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*

4.5 References

Please list key references here in numerical order (max. 20, font size not less than 8 pt).

4.6 Time flow / 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 funding, if applicable.

4.7 Financial details of the study

4.7.1. 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 after the review process is finished.*

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

4.7.2. Financial summary

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. Please make sure that all overhead costs (e.g. "Projektpauschale" for universities and university clinics) are properly considered. Inclusion of overhead costs must be clearly visible here. In addition, do also consider the added value tax (Mehrwertsteuer) for commissions if applicable.

	Organizational Segment	Institution/ Participant/ Trial Site	Qualification and Task of staff/ No. of items/ Kind of equipment/ Explanation	Salary group	Total months	Total (€)	Justification
1	**Scientific Management**						
2	**Organisational Management**						
3	**Data (Security) Management**						
4	**Statistical data analysis**						
5	**Quality assurance**						
6	**Meetings/ Travel**		*No. of attendees ; No. of meetings (€ / person)*				
7	**Case payment**		*Assays/examinations per patient; hours of staff per patient; €/patient x No. of patients*				
8	**Documentation payment**		*documentation per subject/patient* *hours of staff per subject/patient* *€ / patient x No. of patients*				
9	**Materials**		*Consumables*				
10	**Equipment**						
11	***Other***						

TOTAL

Total Budget:
Institutional Overhead: *e.g., "Projektpauschale" for universities and university clinics; give amounts in €*
Requested Budget (sum):
Co-Financing applicable? *Yes / No (e.g., by industry or other funding sources)* €

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

5. Description of Biomaterial Bank

Please prepare your application in English **not exceeding 10 pages for the headings 1 to 8**, including financial plan and 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). Signatures of principal / coordinating investigator and responsible biostatistician/data manager are mandatory.

5.1. SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	*Name and contact details* *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 medical condition / topic being studied*
OBJECTIVE(S)	*Please specify the relation of the project within the network or to other subprojects. Comment on the correlation/connection to the entire consortial research.*
KEYWORDS	*Maximum 5*
PROJECT DURATION	*In months*
SUMMARY	*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.*
PARTICIPATING CENTRES	

A5.2. RESULTS OF THE FIRST FUNDING PERIOD

Only fill out if applicable

A5.2.1. ORIGINAL AIMS OF THE PROJECT

Describe the original aims at the starting point of your project.

A5.2.2. SCIENTIFIC RESULTS

Describe the scientific highlights so far of your project. Compare the obtained results with the schedule and milestones envisaged in the initial proposal.

A5.2.3. RELEVANT PUBLICATIONS AND PATENTS
List all publications directly resulting from the activities of the funded project (here, only those publications are to be cited in which sponsoring through the BMBF in the context of the competence network has been mentioned univocally). Indicate if a publication represents the joint activities of two or more consortium groups. Describe additional dissemination and exploitation of results.

A5.2.4. NETWORKING
Provide a summary how you have contributed to networking. Focus (i) on the use of the consortium structure by the project and (ii) on the special contributions of the project to the overall aims of the consortium.

5.2. 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.

5.2.1 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?

5.2.2 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?

5.2.3 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?

5.2.4 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

5.3.1 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?

5.3.2 POPULATION TO BE STUDIED

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

5.3.3 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.

5.3.4 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?

5.3.5 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.

5.4 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.

5.5. BIOMATERIAL BANK OPERATORSHIP AND MANAGEMENT

5.5.1 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 scare 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?

5.5.2 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).

5.5.3 BIOMATERIAL BANK SUPPORTING FACILITIES

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

5.5.4 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?

5.5.5 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-pseudonymsation (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*

5.6. REFERENCES

Publication listing according to numerical appearance in the text.

5.7. 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.

5.8. FINANCIAL DETAILS OF THE STUDY

5.8.1 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.

5.8.2 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 cooperation between industry, medical institutions and their staff.[6]

5.8.3 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".

5.8.4 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. Please make sure that all overhead costs (e.g. "Projektpauschale" for universities and university clinics) are properly considered. Inclusion of overhead costs must be clearly visible here. In addition, do also consider the added value tax (Mehrwertsteuer) for commissions if applicable.

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[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)

	Organizational Segment	Institution/ Participant/	Qualification and task of staff No of items/ Kind of equipment/ Explanation	Salary group	Total months	Total (€)	Justification
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	**Overhead**						
10	**Other**						

TOTAL

Total Budget:

Institutional Overhead: *e.g., "Projektpauschale" for universities and university clinics; give amounts in €*

Requested Budget (sum):

Co-Financing applicable? *Yes / No (e.g., by industry or other funding sources)* €

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