

# Leitfaden für die Antragstellung im Rahmen der Förderinitiative: Innovative Therapieverfahren auf molekularer und zellulärer Basis

Im Rahmen der Fördermaßnahme 'Innovative Therapieverfahren auf molekularer und zellulärer Basis' stellt das BMBF Fördermittel zur Verfügung, die - abhängig vom Entwicklungsstand des Therapieansatzes - für Untersuchungen im Bereich der präklinischen Forschung ab dem proof of principle im Tiermodell bis einschließlich klinischer Studien der Phase II beantragt werden können.

Nachfolgender Leitfaden dient als **Leitlinie zur Antragstellung**.

Die Randbedingungen der Förderung sind in der Förderrichtlinie des BMBF (<http://www.gesundheitsforschung-bmbf.de/de/175.php>) niedergelegt. Gleichzeitig mit den Anträgen ist ein Datenblatt (Application Data Sheet) sowohl für das Consortium als auch für die Subprojects (<http://www.gesundheitsforschung-bmbf.de/de/1035.php>) auszufüllen und uns über das Internet zuzusenden. Das Application Data Sheet dient der Erfassung aller eingegangenen Anträge einschließlich der Zuordnung zu den Fachdisziplinen.

Bis zum **31.03.2006** können Anträge **in englischer Sprache** (DIN A4, 11 Punkt Arial, doppelseitig bedruckt) beim Projektträger Gesundheitsforschung für das BMBF, Heinrich-Konen-Str. 1, 53227 Bonn, (<http://www.pt-dlr.de/>), Tel. 0228/3821-234 oder -281 eingereicht werden.

Anträge sind entsprechend den Vorgaben dieses Leitfadens zu gliedern und an den Projektträger in **20-facher Ausfertigung plus einer ungebundenen Kopiervorlage sowie auf CD-ROM** vorzulegen.

**Anträge, die den Vorgaben des Leitfadens nicht entsprechen und bei denen keine elektronischen Daten (Application Data Sheet) vorliegen, können nicht berücksichtigt werden.**

Neben diesem Leitfaden gelten weiterhin die entsprechenden Merkblätter und Richtlinien des Förderers<sup>1</sup>, soweit in diesem Leitfaden nicht ausdrücklich andere Regelungen getroffen sind.

Weiterführende Links für die Antragstellung finden Sie auf den Internetseiten des Förderers. Die dort veröffentlichten Anforderungen / Informationen werden regelmäßig aktualisiert. Eine Durchsicht vor dem Verfassen des Antrags wird dringend empfohlen.

## Guideline for Grant Application

Please prepare your application in English (DIN A4, 11 point Arial). Make an entry under every heading/subheading subproject and send us 20 copies plus an unbound copy for reproduction.

### Note:

1) *Applications that fail to comply with these requirements will be considered incomplete and will*

*constitute grounds to reject the application outline without peer review.*

*2) Enterprises with commercial interests have to make sure that in case of funding financial credibility of the enterprise is secured for the applied funding period. In addition, the enterprise has to demonstrate that the own resources listed in the application will be secured for the entire funding period.*

# **I. Description of Consortium**

## **1. GENERAL INFORMATION ON THE CONSORTIUM:**

The description of the consortium should not exceed **5 pages maximum**.

### **1.1 Title of the consortium**

The title of the proposal (max. 140 characters) should be precise. In case of funding, this title will be quoted in the annual reports of the funding organisation. Please indicate an acronym (max. 40 characters) derived from the title of the proposal.

### **1.2 Coordinator of the consortium**

Name, address, telephone, fax, e-mail

### **1.3 Duration of project**

Please indicate the time period, for which funding is requested (up to 3 years), and the date, when funding should begin.

### **1.4 Summary**

Please give a summary of the main goals of the project (max. 1600 characters). The project summary serves two main purposes:

- i) It will inform the multidisciplinary review committee of the principal aims of the project.
- ii) If your project is funded the summary will be published on the internet through an electronic information system. (It should therefore be concise as well as comprehensible to a lay public). Please avoid abbreviations and include suitable key words to ease electronic search.

### **1.5 Plan for the exploitation of results**

Please indicate how the expected results of the project will be used. Describe how the results of the research will either be disseminated to potential users or how they will be commercialized. Explain the potential clinical or commercial impact of the results.

## **2. Innovation and Relevance of the Project**

### **2.1 Medical problem**

What is the medical problem? What is the medical need to be addressed? (e.g. burden of the disease, prevalence, incidence, reasons for the project)?

### **2.2 Hypothesis**

What is the hypothesis to prove? Which results are expected?

### **2.3 Novel aspect**

What is the novel aspect of the proposed therapy?

## 2.4 Evidence

How has the evidence been assessed? (e.g. recent research, pilot studies, review of publications, ongoing related studies). Which were the major findings?

## 3. Description of the consortium

### 3.1 Summary of consortium structure

**Example:**

Subproject No.	Partner	Titel of Subproject	Function in the consortium	Contribution
1	xyz GmbH	Identification of pharmacogenetic polymorphisms by high-throughput screening	Coordination	Monitoring, evaluation and processing of results
2	University of...	Significance of CYP2C9 polymorphism for oral anti-diabetica	Preclinical partner	Establishing pharmacogenetic assays

### 3.2 Cooperation

What structure is available, respectively will be implemented for an efficient cooperation within the consortium. How will the consortium be managed? What are the contributions of the individual partners?

### 3.3 Timeframe / milestones

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

### 3.4 Summary of financial plan for all subprojects

**Example:**

Subproject No.	Partner	Total costs of project	Applied BMBF Funds	Co-financed by industry or other sources
1	xyz GmbH	500.000 €	250.000 €	250.000 €
2	University of...	300.000 €	300.000 €	0

## II. Description of Individual Subprojects

### A. PRECLINICAL RESEARCH PROJECT

The following outline is relevant for *preclinical research projects* only.

In case you want to apply for funding of a *clinical trial*, please proceed to outline II B.

The description of each preclinical research project should not exceed 7 pages maximum.

### **1.1 Title of the subproject**

The title of the subproject (max. 140 characters) should be precise. In case of funding this title will be quoted in the annual reports of the funding organisation. Please indicate an acronym (max. 40 characters) derived from the title of the subproject.

### **1.2 Principal investigator of the subproject**

Name, address, telephone, fax, e-mail

### **1.3 Scientific discipline and previous work**

Please name your discipline and your special field of work. Describe the major findings of your previous work. Give 5 of your most relevant publications of the past 3 years.

### **1.4 Scheduled duration**

Please quote

- the time period for which funding is requested (max. 3 years).
- the date when funding should begin

### **1.5 Summary**

Please give a summary of the main goals of the subproject (max. 1200 characters). The summary serves two main purposes:

- i) It will inform the multidisciplinary review committee of the principal aims of the subproject.
- ii) If your subproject 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 and include suitable key words to ease electronic search.

## **2. INNOVATION AND RELEVANCE OF THE SUBPROJECT**

### **2.1 Hypothesis / Research Goal**

What is the hypothesis to be tested? What is the aim of the study? What results are expected?

### **2.2 Novel aspect and future impact**

What is the novel aspect of the proposed therapy? What is the relevance of the subproject in the context of the consortium? Specify the impact of the results on clinical practise, understanding of the disease or disease intervention.

### **2.3 Methods**

Please describe briefly the methods you intend to apply.

### **2.4 Working plan including milestones**

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

### **2.5 Compliance with GLP**

If an approval of the novel therapy is intended, please indicate how the preclinical research will be conducted in compliance with the requirements of GLP (good laboratory practice) standards.

### **2.6 Financial Plan**

Please structure the financial plan by completing the table financial plan for subproject No... as outlined in the appendix.

## **2.7 Co-financing**

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

## **2.8 Other funding**

In case you have already submitted parts of the same request to other institutions or the BMBF, please mention this here. Indicate other sources which will provide funds, free services or consumables.

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.

## **2.9 Plan for exploitation of the results**

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

## **B. CLINICAL TRIAL PROJECT**

**The following outline is relevant for subprojects with focus on *clinical trials* only. Signatures of principal investigator and responsible biostatistician are mandatory.**

The description of each clinical research project should not exceed 7 pages maximum, not including the clinical trial protocol.

### **1.1 Title of trial**

The title of the trial (max. 140 characters) should be precise. In case of funding this title will be quoted in the annual reports of the funding organisations.

Please indicate an acronym (max. 40 characters) derived from the title of the trial.

### **1.2 Principal investigator of the clinical trial**

Name, address, telephone, fax, e-mail

### **1.3 Scientific discipline and field of work**

Please name your discipline (e.g. internal medicine, surgery) and your special field of work (such as cardiology, experimental accident surgery), so the project can be categorized with regard to its main intention. Describe the major findings of your previous work. Give 5 of your most relevant publications of the past 3 years.

### **1.4 Scheduled duration**

Please quote

- the time period for which funding is requested (max. 3 years)
- the date when funding should begin

### **1.5 Summary**

Please give a summary of the main goals of the clinical trial (max 1000 characters). The summary serves two main purposes:

- i) It will inform the multidisciplinary review committee of the principal aims of your trial.
- ii) If your trial 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 and include suitable key words to ease electronic search.

## **2. Innovation and Relevance of the Trial**

### **2.1 Medical problem**

What is the medical problem? What is the medical need to be addressed? (e.g. burden of the disease, reasons for the study, prevalence, incidence)?

### **2.2 Hypothesis / Research Goal**

What is the hypothesis to be tested? What is the aim of the trial? What results are expected?

### **2.3 Novel aspect and future impact**

What is the novel aspect of the proposed therapy? What is the relevance of the subproject in the context of the consortium? Specify the impact of the results on clinical practise, understanding of the disease or disease intervention.

### **2.4 Evidence**

How has the evidence been assessed (systematic reviews, pilot studies, ongoing related trials)? Which were the most significant findings?

### **2.5 Plan for exploitation of results**

The exploitation plan should indicate how the expected results of the trial will be used and the steps necessary for their implementation.

## **3. Design of the Trial**

### **3.1 Trial design**

### **3.2 Trial interventions**

What are the planned trial interventions? (experimental and control)

### **3.3 Inclusion / exclusion criteria**

### **3.4 Duration**

What is the planned duration of the whole trial? Specify recruitment, treatment, follow-up, and analysis periods.

### **3.5 Outcome measures**

What are the proposed outcome measures? (primary and secondary outcome)

### **3.6 Methods against bias**

What are the proposed methods against bias? (e.g. randomization method, blinding)

### **3.7 Power calculations**

How is the power calculations justified?

### **3.8 Numbers of participants**

What are the planned numbers of participants in different stages of the trial?

To be assessed for eligibility (n = ...)  
To be allocated to trial (n = ...)  
To be analysed (n = ...)

How is the recruitment of the participants required within the time frame justified?

### 3.9 Trial sites

How many trial sites will participate?

### 3.10 Analyses

What is the proposed type and frequency of analyses? Are there any planned subgroup or interim analyses?

## 4. Ethical Considerations

### 4.1 Risks for participants

What are the risks for the safety of participants involved in the trial?  
Discuss briefly the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant / population concerned.

## 5. Trial Management and Expertise

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

#	Name	Affiliation	Responsibility / Role	Signature
			<i>Principal/Coordinating Investigator</i>	
			.....	

### 5.1 Trials expertise

Please indicate trials expertise of above-mentioned persons by citing relevant publications and/or specifying major role in ongoing trial(s) (to be identified); (max. 5 publications of the last 5 years).

### 5.2 Trial-supporting facilities

Which trial-specific facilities and other resources are available for conducting the trial? What are the proposed measures for quality assurance? Please comment on the planned supervision of the trial.

## 6. Financial Plan

**Funds can only be granted for research activities. Do not include patient care costs.**

### 6.1 Financial Plan for Subproject

Please structure the financial plan by completing the table financial plan for subproject No. as outlined in the appendix.

## 6.2 Co-financing

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

## 7. DECLARATIONS

### 7.1 Sponsors declaration

The medical institution receiving the funds by BMBF has the responsibility to ensure that the clinical trial is conducted according to the highest standards regarding the safety of subjects and the quality of data. It is expected that the persons responsible in the respective institution are aware of the trial run through their department(s) and must ensure to provide the principal / coordinating investigator with support required. Any problems associated with the trial should be jointly resolved by the institution and the principal / coordinating investigator without delay.

The awarding of funds is therefore linked to the condition that the medical institution employing the principal / coordinating investigator assumes full responsibility and all functions and obligations of the sponsor as listed in chapter 5 of 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)<sup>2</sup>, notwithstanding the fact that the funding organisation provides additional external funds. In particular, appropriate agreements should be concluded with the parties conducting the trial in order to ensure that the responsibility referred to above can be exercised. A corresponding declaration has to be submitted comprising the assurance that

1. the trial will be conducted in accordance with the principles of ICH GCP and
2. the medical institution will assume the sponsor's responsibilities in accordance with chapter 5 of ICH GCP.

The text of the sponsor's declaration is available on the funding organisation's web sites ([http://www.gesundheitsforschung-bmbf.de/\\_media/Sponsorerklaerung\\_Klinische-Studien.pdf](http://www.gesundheitsforschung-bmbf.de/_media/Sponsorerklaerung_Klinische-Studien.pdf)). Please use this text for your declaration, which must be duly signed by a representative of the medical institution and the principal / coordinating investigator. The sponsors declaration should be joined to the application.

### 7.2 Staff and institutions general contribution

Please indicate name, academic titles and employment grade of participating scientists and PhD-students as well as the number of technical employees who will be working on the project. Please list separately the persons paid by the institutions basic funding and those paid from other grants (including fellowships).

Please state the annual fund for consumables which comes from the institutions budget or any other sources (please list separately) to pay for the research for which your project is part of. Use estimates where applicable.

### 7.3 Other funding

In case you have already submitted the same request for financial support or parts hereof to other institutions or the BMBF, please mention this here. Indicate other sources 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".

## **TRIAL PROTOCOL**

Please attach, **as a separate document**, the trial protocol which should be in accordance with ICH GCP (cf. chapter 6 of ICH GCP, Clinical Trial Protocol and Protocol Amendment(s)). The topics laid down there may be adjusted slightly to reflect the needs of non-drug trials.

A protocol for an interventional trial should be written in accordance with the structure given below<sup>3</sup>. You should provide information on **all** of the items listed. Further items may be added if necessary. For any requirement listed below deemed not applicable, relevant or appropriate, a clear statement justifying the omission of the information specified shall be provided on each occasion. Applications that fail to comply with these requirements will be considered incomplete and will constitute grounds to reject the application without peer review.

The protocol should be preceded by a

- table of contents including a list of supplements and
- a protocol summary (a template can be found on the funding organisations web site)

### **3.1 General Information**

3.1.1 Protocol title, protocol identifying number and date

3.1.2 Name and address of the sponsor<sup>4</sup>, biostatistician, and monitor

3.1.3 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor

3.1.4 Name, title, address and telephone number(s) of the sponsors medical expert for the trial<sup>5</sup>

3.1.5 Name and title of the investigator(s) who is(are) responsible for conducting the trial, and the address(es) and telephone number(s) of the trial site(s)<sup>6</sup>

3.1.6 Name, title, address and telephone number(s) of the qualified physician, who is responsible for all trial site-related medical decisions (if other than investigator)

3.1.7 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical departments and/or institutions involved in the trial

### **3.2 Background information**

3.2.1 Name and description of the investigational product(s) and/or the medicinal product and/or the method to be studied

3.2.2 Summary of findings from preclinical studies and previous clinical trials/ studies/clinical standards

3.2.3 Risks and benefits, if any, to human subjects

3.2.4 Description of and justification for the route of administration / method / intervention

3.2.5 A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s)

3.2.6 Description of the population to be studied

3.2.7 References to literature and data that are relevant to the trial and that provide background for the trial.

### **3.3 Trial objectives and purpose**

A detailed description of the objectives and the purpose of the trial (medical problem / clinical need, clinical relevance, hypotheses, concrete objective, novelty, evaluation of available evidence including a systematic, reproducible literature search)

### **3.4 Trial design**

3.4.1 Primary and secondary endpoints

3.4.2 A description of the type / design of the trial to be conducted and a schematic diagram of trial design, procedures and stages

3.4.3 A description of the measures and procedures taken to minimize / avoid bias (randomization / blinding)

3.4.4 A description of the trial treatment(s), the investigational product(s) and the procedures and methods to be studied

3.4.5 The expected duration of subject participation and a description of the sequence and duration of all trial stages, including follow-up

3.4.6 A description of the stopping rules or discontinuation criteria

3.4.7 Accountability procedures for the investigational product(s) and comparator(s)

3.4.8 Maintenance of trial treatment randomization codes and procedures for unblinding

3.4.9 The identification of any data to be recorded directly on the case report form

3.4.10 Terms and conditions for amendments to the protocol

### **3.5 Selection and withdrawal of subjects**

3.5.1 Subject inclusion criteria

3.5.2 Subject exclusion criteria

3.5.3 Criteria for the withdrawal of subjects (procedures specifying when and how to withdraw subjects from the trial. Data to be collected for withdrawn subjects, replacement of subjects, follow-up for subjects withdrawn from treatment).

### **3.6 Treatment of subjects**

3.6.1 A clear and complete description of the trial and reference methods, the standardisation strategies, and the follow-up period(s) (in the case of drug trials, also indication of the mode(s)

of administration, packaging and labelling of the investigational product(s) in accordance with Good Manufacturing Practice (GMP)

3.6.2 Medication(s) / treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial

3.6.3 Procedure for monitoring subject compliance

### **3.7 Assessment of efficacy**

3.7.1 Specification of the efficacy parameters and justification for their clinical relevance

3.7.2 Methods and timing for assessing, recording and analysing of efficacy parameters

### **3.8 Assessment of safety**

3.8.1 Specification of safety parameters

3.8.2 Methods and timing for assessing, recording and analysing safety parameters

3.8.3 Procedure for eliciting reports of and for recording and reporting adverse events

3.8.4 Type and duration of the follow-up of subjects after adverse events

### **3.9 Statistics**

3.9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis(es)

3.9.2 The number of subjects planned to be enrolled; reason for choice of sample size, including reflections on the level of significance, the power of the trial and clinical justification

3.9.3 A demonstration of the potential for recruiting the required number of suitable subjects within the intended period.

3.9.4 Criteria for the termination of the trial

3.9.5 Rules for accounting for missing, unused and spurious data

3.9.6 Procedures for reporting any deviation(s) from the original statistical plan

3.9.7 Selection of subjects whose data are to be included in the analysis (e.g. intention-to-treat, per protocol)

### **3.10 Direct access to source data / documents**

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator / institution / patient will permit trial-related monitoring, audits, reviews by the independent ethics committee, and regulatory inspections, providing direct access to source data / documents.

### **3.11 Quality control and quality assurance**

e.g. standardisation, extent and nature of monitoring, audits.

### **3.12 Ethics**

Description of ethical considerations relating to the trial (assessment of risks and benefits, care and protection of research participants, protection of research participants confidentiality, informed consent process)

### **3.13 Data handling and record keeping**

E.g. documentation of trial data, data management, queries, archiving.

### **3.14 Insurance**

A description of the arrangements for insurance coverage for research participants, if applicable

### **3.15 Publication policy**

The publication policy should preferably be stated in supplement 3.16.11.

### **3.16 Supplements<sup>7</sup>**

*In addition to the supplements listed below, further supplements may be attached, if necessary.*

#### **3.16.1 Signature sheet**

*carrying the signatures of the coordinating investigator, the principal investigators and the responsible biostatistician, including a statement that the clinical trial will be conducted in compliance with the protocol and GCP*

#### **3.16.2 List of investigators**

*(name, title, address, and telephone number(s) and addresses and telephone numbers of the trial sites unless listed under 3.1.5. above)*

#### **3.16.3 Expertise of those responsible for the trial**

*Conduct of the trial*

*Please submit tabular scientific CVs for academic staff members playing a leading role in the trial. The CVs should indicate their expertise (education, training, and experience) regarding clinical trials.*

*Publications*

*Please join a list of relevant publications by the principal / coordinating investigator that have appeared during the last five years (only the results of clinical trials). Please indicate which publications are in print, accepted by & or submitted to &.*

*Please enclose those publications (not more than three) which are important for evaluating the application.*

#### **3.16.4 Supporting infrastructure of the medical institution(s)**

*To support the successful conduct of the clinical trial at the highest possible standard, the funding organisations expect appropriate participation by the institution(s). Please indicate the resources available at your medical institution:*

- existing trial-specific supporting facilities, if any*
- previous experience with the conduct of clinical trials in accordance with GCP*
- possibilities for the training of trial staff*
- opportunities for earning a doctorate or qualifying as a professor on the basis of scientific achievements gained in clinical trials*
- consideration of scientific achievements accomplished in conducting clinical trials in the performance-related allocation of research resources*

*trial-specific information technologies*

#### **3.16.5 Advisory Boards**

*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 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 study. Thus, the arrangements for supervision should be detailed and justified in the proposal. 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) (name, title, address and telephone number). A minimum of 3 members should be named; the funding organisations will decide on final membership.*

#### **3.16.6 Opinion from the Ethics Committee**

*A favourable opinion from the appropriate ethics committee should be joined to the application. All support is contingent on approval being obtained from the relevant ethics committee.*

#### **3.16.7 Allocation of responsibilities**

*The applicant(s) should define, establish, and allocate all trial-related duties and functions.*

### **3.16.8 Recruitment plan**

*For each trial site, the recruitment plan should show the projected recruitment.*

### **3.16.9 Criteria for the selection of trial sites**

#### **3.16.10 Conflicts of interest**

*Any potential conflicts of must be disclosed. The rules set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals" have to be observed by analogy (<http://www.thelancet.com/>)*

*All applicants must disclose any financial and/or personal relationships with other persons and organisations which might impair the independence of their work. Conflicts of interest may arise from financial relationships with industry (for example, through employment, consultancies, stock ownership, honoraria, expert testimony). Applicants must detail potential bias on a separate sheet and should also disclose the conflicts of interest to all trial participants.*

*The lack of conflicts of interest should be expressly confirmed on a separate sheet to be signed by each applicant and/or principal investigator.*

#### **3.16.11 Agreements on intellectual property, confidentiality, publication of results, property rights**

*Appropriate agreements should be concluded between all those playing a leading part in the conduct of the trial.*

Agreement with manufacturer on variation of authorisation

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

#### **3.16.12 Co-financing by industry and / or other sources**

Co-financing by industry or other sources is possible if the independence of investigators is ensured and the terms and conditions of the financial commitment are disclosed. If co-financing is intended, the following information should be provided:

- The application should describe the type and volume of the intended co-financing, indicating the respective company or other sources (name, address, contact with telephone number and e-mail address).

- Those co-financing must describe the type and volume of support (including any services or consumables provided free of charge, e.g. drugs for the trial). They must indicate the amount of support to be provided and must assure in writing that they will render these services, stating their terms and conditions, if any. They must also 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 should be joined to the protocol.

Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.<sup>8</sup>

<sup>[1]</sup>,BMBF/ Projektträger: Richtlinien für die Zuwendungsanträge auf Ausgabenbasis (AZA) des BMBF. (<http://www.gesundheitsforschung-bmbf.de/de/196.php>). Für die wissenschaftliche Begutachtung ist in jedem Fall zunächst ein Antrag nach dem vorliegenden Leitfaden einzureichen.

<sup>[2]</sup> ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6 / International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH E6, 1 May 1996)

<sup>[3]</sup> The terms utilized are those used in ICH GCP to avoid any unclear definitions. These terms should be used analogously, where necessary.

<sup>[4]</sup> The sponsor usually is the medical institution of the principal and/or coordinating investigator.

<sup>[5]</sup> Usually not applicable in the case of investigator-initiated trials

<sup>[6]</sup> In the case of larger, multicenter trials, the investigators/trial sites should be listed in a separate appendix.

<sup>[7]</sup> Explanatory notes are printed in italics.

<sup>[8]</sup> 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/vfar/gemeinsamerstandpunkt.html>).

**Appendix: Financial Plan for Subproject No. ...**

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

\* Please use global employment rates of the BMBF for calculating the salaries

(Insert lines according to space required)