BEAUFTRAGT VOM

Bundesministerium für Bildung und Forschung

DLR Projektträger

Leitfaden für die Erstellung von Anträgen für die beschränkte Bekanntmachung zur Förderung von „Forschung in der Palliativversorgung – Weiterförderung erfolgreicher Verbundprojekte“ vom 25.07.2019

Dieser Leitfaden stellt die Anforderungen für die Erstellung eines Anschlussantrags dar. Er ergänzt die o. g. Bekanntmachung und soll offene Fragen im Vorfeld der Einreichung klären. Es wird empfohlen, zur Beratung Kontakt mit dem DLR Projektträger aufzunehmen. Weitere Informationen und Erläuterungen sind dort erhältlich.

Ansprechpersonen sind:

Für Statusbericht und Vorhabenbeschreibung:

Dr. Marijke Looman, Telefon: 0228 3821-1611, E-Mail: marijke.looman@dlr.de
Dr. Vera Mönter-Telgen, Telefon: 0228 3821-1717, E-Mail: vera.moenter@dlr.de

Für Formanträge (AZA/AZAP/AZV oder AZK):

Sylvia Rubröder, Telefon: 0228 3821-1162, E-Mail: sylvia.rubroeder@dlr.de

Allgemeine Informationen

Gefördert werden ausschließlich Anschlussvorhaben erfolgreicher Verbundprojekte der bisherigen Fördermaßnahme des BMBF zur Forschung in der Palliativversorgung – Versorgungsforschung und klinische Studien (Förderbekanntmachung vom 10. Dezember 2015). In diesem Rahmen werden bislang die beiden folgenden Forschungsverbünde gefördert:

- PiCarDi - Palliative Care und hospizliche Begleitung von Menschen mit geistiger und schwerer Behinderung,
- SedPall - Aktuelle Praxis der Sedierung in der Spezialisierten Palliativversorgung in Deutschland.

Entscheidungsverfahren

Für die Vorhabenbeschreibung und den Statusbericht ist ein fachlicher Begutachtungsschritt vorgesehen. Sie werden unter Hinzuziehung eines unabhängigen, internationalen Begutachtungsgremiums bewertet. Mit Blick auf das internationale Begutachtungsverfahren wird die Einreichung der Vorhabenbeschreibung und des Statusberichts in englischer Sprache empfohlen.

Formale Vorgaben für Förderanträge

Es ist ein vollständiger Verbundantrag vorzulegen (max. 36 Monate Laufzeit). Dieser besteht aus (s. hierzu auch Hinweise und Checkliste zur Formantragstellung):

- förmliche Förderanträge auf Zuwendung (AZA/AZAP/AZV oder AZK) der Verbundpartner
- Anlagen zum Antrag der Verbundkoordination:
  - Statusbericht des Verbunds über die zurückliegende Förderphase (wie empfohlen in englischer Sprache),
  - Vorhabenbeschreibung des Verbunds für die zweite Förderphase (wie empfohlen in englischer Sprache).

Der Umfang von Statusbericht und Vorhabenbeschreibung darf insgesamt 70 Seiten [DIN-A4-Format, 1,5-zeilig (1-zeilig für die Synopse), Arial 11 Punkt (Arial 10 Punkt in der Synopse und in vorgegebenen Tabellen), 1-seitig, Randbreite 2 cm] zzgl. Anlagen nicht überschreiten.

Die Vorhabenbeschreibung und der Statusbericht sind in Abstimmung aller Beteiligten durch die/n vorgesehene/n Verbundkoordinator/in als Vorhabenbeschreibung des Verbunds bzw. Statusbericht des Verbunds vorzulegen. Aus der Vorhabenbeschreibung und dem Statusbericht müssen die Beiträge der einzelnen Verbundpartner eindeutig hervorgehen.

Die Unterlagen müssen selbsterklärend und aussagekräftig sein sowie alle Informationen beinhalten, die für eine sachgerechte Bewertung erforderlich sind. Sie müssen ohne weitere Informationen/Recherchen bzw. ohne Lektüre der zitierten Literatur eine Beurteilung zulassen. Als Anlagen sind ausschließlich die in den Mustervorlagen (Templates) aufgeführten Dokumente zugelassen.

- Eine deutschsprachige Vorhabenbeschreibung mit Verwertungsplan gemäß den Richtlinien für Zuwendungsanträge auf Ausgabenbasis bzw. Kostenbasis des BMBF ist im Falle einer positiven Bewertung von Statusbericht und Vorhabenbeschreibung des Verbundes nachzureichen.

Die Formanträge der Verbundpartner sind elektronisch über das Internetportal von easy-Online zu erstellen.

Link: https://foerderportal.bund.de/easyonline/reflink.jsf?m=GY-VERSORGUNG&b=PALLIATIVANSCHLUSS

Die verbindliche Einreichung der Formanträge soll bis spätestens zum 01.10.2019 für den Verbund PiCarDi bzw. zum 02.03.2020 für den Verbund SedPall elektronisch erfolgt sein. Zusätzlich ist die umgehende Vorlage der rechtsverbindlich unterschriebenen Formanträge auf dem Postweg erforderlich.

Entscheidend für die Fristwahrung sind die auf elektronischem Wege über das Internet-Portal easy-Online verbindlich eingereichte Förderanträge der Verbundpartner mit allen ergänzenden Informationen. Die Vorlagefrist gilt nicht als Ausschlussfrist. Verspätet eingegangene Anträge können aber möglicherweise nicht mehr berücksichtigt werden. Bei verspäteter Einreichung wird dringend die vorherige Kontaktaufnahme mit dem Projektträger empfohlen. Aus der Vorlage der Anträge kann kein Rechtsanspruch auf Förderung abgeleitet werden. Eine Vorlage per E-Mail oder FAX ist nicht möglich.

Adresse für postalische Einreichung:
DLR Projektträger Gesundheit
Kennwort „Palliativversorgung“
Heinrich-Konen-Str. 1
53227 Bonn.

Allgemeine Hinweise

Die nachfolgenden Hinweise sind bei der Planung und Einreichung zu beachten.

Merkblätter und Richtlinien des BMBF

Neben der Förderrichtlinie gelten weiterhin die entsprechenden Merkblätter und Richtlinien des BMBF, soweit in der Förderrichtlinie 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.

Wissenschaftliche Standards und Arbeitshilfen

Die Antragsteller sind verpflichtet, die die nationalen und internationalen Standards zur Qualitätssicherung der Forschung einzuhalten. Hierzu sind insbesondere die nachfolgenden Dokumente in der jeweils geltenden Fassung zu berücksichtigen (die Aufzählung ist nicht abschließend):

- Deklaration von Helsinki
- ICH-Leitlinie zur Guten Klinischen Praxis (GCP)
- Memorandum zur Sicherung der guten wissenschaftlichen Praxis (DFG)

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

- Richtlinien des CIOMS (Council for International Organization of Medical Sciences) und der WHO (World Health Organization): "International Ethical Guidelines for Biomedical Research Involving Human Subjects"
- CONSORT Statement (Consolidated Statement of Reporting Trials)
- Leitfaden des Medical Research Council (MRC): „Developing and evaluating complex interventions - new guidance”
- Gute Praxis Sekundärdatenanalyse (GPS): Leitlinien und Empfehlungen

Mustervorlagen (Templates) und Erläuterungen

Bitte verwenden Sie die beiliegenden **verbindlichen Gliederungsvorlagen** für den Statusbericht und die Vorhabenbeschreibung des Verbunds. Die vorhandenen *Eintragungen in kursiver Schrift geben Hinweise auf die Art der geforderten Informationen*. Sie sollen gelöscht werden.

Mustervorlage status report

Mustervorlage full proposal

Mustervorlage ressourcenbezogener Arbeitsplan

Hinweise und Checkliste zur Formantragstellung

Statusbericht

Bitte machen Sie zu jeder Überschrift und Unter-Überschrift entsprechende Angaben. Wenn eine Überschrift auf Sie nicht zutrifft, trage Sie n.a. (not applicable) ein. Statusbericht und Vorhabenbeschreibung sollen insgesamt nicht mehr als bis zu 70 Seiten zzgl. Anhänge umfassen. Querverweise / Referenzen vom Statusbericht zur Vorhabenbeschreibung und vice versa sind möglich.

Wir schlagen vor, für den Statusbericht bis zu 15 Seiten zu nutzen.

Bitte löschen Sie die Hinweise in kursiver Schrift.

[insert here: PiCarDi or SedPall *]*

Status report on achievements in the 1st funding phase

A. Status report

A.1. Synopsis – summary

Coordinating Investigator	*Name, Institution / department*
Title and acronym	*In English* *In German*
Keywords	*Max. 5 keywords*
Summary	*Short description of thematic focus, research question, initial objectives of the consortium and achivements reached (e.g. preliminary results concerning primary and secondary patient-relevant outcomes of the study).*
Recruitment, data collection	*Target and study population, sample size, recruitment* *Have you faced major problems/delay concerning recruitment and/or data collection?*
Methods	*Description of methodological approaches (data collection, data analysis…)*
Collaboration partners incl. patient involvement	*Enumeration of involved collaboration partners and their tasks (e.g. recruitment, allocation of data / methods.)*

For this table 10 point Arial, single-line may be used. Please do not exceed 1 page.

A.2. Subprojects – division of responsibilities

Sub-project	Partner	Title subproject (Acronym)	Contribution to the project
1	*University of X..*		*responsibility for workpakeges x, y, z*
2	*University of Y….*		*responsibility for workpakeges x, y, z*
3	*…*	*…*	*…*

For this table 10 point Arial, single-line may be used.

Please report shortly on the collaboration between the funded partners.

A.3. Preliminary results

Please describe relevant developments and preliminary results.

Challenges and changes

If applicable, comment on delays and/or modifications of the study design. Have you faced challenges (e.g. recruitment data and personal) due to which you had to change your study design?

A.4. Collaboration

How are patients and or their organisations involved in the project? What ist their contribution to the project results?

Report on interdisciplinary, multiprofessional und international collaboration realised so far.

A.5. Dissemination

Which activities for the dissemination of preliminary results have been realised so far?

A.6. Work plan

Describe the initially planned working operations of the consortium with all subprojects and the time frame (Gantt-Chart with milestones). Indicate delays and/or modifications and describe them in the text. You can refere to section A3.

Workpakages (WP)	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WP 1 - xyz				~~M1~~		**M1**						
WP n - xyz												
WP n - xyz												
WP n - xyz												

Explanation

Initial plans		~~Mn~~
Revised plans		**Mn**

Milestone	Comment
M1 xyz	
M2 xyz	
M3 xyz	

For this table 10 point Arial, single-line may be used.

B. Attachments

B.1. Literature

Please list publications you have quoted within your status report. References should be listed according to their numerical appearance in the text.

B.2. Publications

Relevant scientific publications of the consortium and the subprojects can be attached ore linked. Relevant public relation documents of the consortium and the sub projects can be attached or linked (e.g. homepage, press release, newsletter, information for practitioners etc.).

Vorhabenbeschreibung

Bitte machen Sie zu jeder Überschrift und Unter-Überschrift entsprechende Angaben. Wenn eine Überschrift auf Sie nicht zutrifft, tragen Sie n.a. (not applicable) ein. Statusbericht und Vorhabenbeschreibung dürfen insgesamt nicht mehr als 70 Seiten zzgl. Anlagen umfassen. Querverweise/Referenzen vom Statusbericht zur Vorhabenbeschreibung und vice versa sind möglich.

Wir schlagen vor, für die Beschreibung des Verbundes bis zu 10 Seiten zu nutzen und für die Beschreibung der Teilprojekte jeweils bis zu 15 Seiten.

Bitte löschen Sie die in kursiver Schrift verfassten Hinweise.

[insert here: Name of the network*]*
Full proposal
for
2nd funding phase

A. General information on the consortium

Please provide a description of the consortium (approx. 10 pages).

A.1 Synopsis

Coordinating Investigator consortium	*Name, Institution / department (complete name)*
Principal Investigators subprojects	*Name, Institution / department (complete name)* *Name, Institution / department (complete name)* *Name, Institution / department (complete name)*
Title and acronym	*In English (max. 140 characters)* *In German (max. 140 characters)*
Keywords	*Max. 5 keywords*
Objective(s)	*Which main research questions are addressed? Specify the primary goal of the project. Which main results are expected?*
Recruitment, data collection	*Target and study population, sample size, recruitment*
Methods	*Description of methodological approaches (data collection, data analysis…)*
Collaboration partners incl. patient involvement	*Enumeration of involved collaboration partners and their tasks (e.g. recruitment, allocation of data / methods.)*
Funds applied for and duration	*Xxx Euro, xxx months (max 36 months)*

For this table 10 point Arial, single-line may be used. Please do not exceed 1 page.

A.2 Partners applying for funding

Sub-project	Partner	Title subproject (Acronym)	Contribution to the project
1	*University of X..*		*responsibility for workpakeges x, y, z*
2	*University of Y….*		*responsibility for workpakeges x, y, z*
3	*…*	*…*	*…*

For this table 10 point Arial, single-line may be used.

A.3 Relevance and aims

Which issues in German palliative care are addressed in your consortium and in the subprojects?

Briefly explain the current state of German palliative care and the relevance of the study.

Which main research questions will be addressed by the consortium?

What are novel aspects of the proposed consortium and the subprojects?
Which results are expected? How will the results of the consortium benefit palliative care presumably?

Details on the subprojects should be given in section B.

A.4 Structure of the planed consortium

Describe the local structure and the implementation of the project.
Illustrate your concepts for an efficient cooperation within the consortium. How will the consortium be managed? What kind of contributions do you expect from individual partners?
Describe measures of coordination and communication as well as structures of internal and external controlling and quality assurance planned or already in place.

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

A.5 Dissemination and implementation

Explicate your strategies for dissemination of results among the scientific community, the public and actors involved (e.g. sickness funds, professional societies, general practitioners).
Please state achievable goals regarding the translation and transfer of results of the consortium to palliative care. How will actors, e.g. from health care and nursing care, be engaged during the project and how are the results implemented after the end of the project?
Outline strategies and measures to disseminate and implement the results within the German health care system.
You may give mor details in section B if the subprojects pursue distinct plans for dissemination and implementation.

A.6 Workplan

Describe the intended working operations (work pakages (WP)) with milestones (M) and the time frame for the consortium and all subprojects. More details can be given in section B.
Additionally, fill in a Gantt-Chart. More details can be given in section B.

Workpakages (WP)	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WP 1 - xyz				**M1**								
WP n - xyz							**Mn**					
WP n - xyz												
WP n - xyz												

M1: *Milestone xyz …*

Mn: *Milestone xyz*

A.7 Financial summary

subproject No.	**Partner**	**Total project costs**	**Funds applied for (including overhead / lump sum)**
1	University of X		
2	University of Y		
3			
	Total amount all partners		

B. Detailed description of subprojects

Please provide a description of each subproject (approx. 15 pages each).

B.1 Subproject 1 - ACRONYM

B.1.1 Synopsis	
Principal investigator	*Name, Institution / department*
Title and acronym of the subproject	*In English* *In German*
2nd phase/new project?	*Did you start the project in the 1st fundig phase and do you apply for a 2nd phase? or* *Do you apply for a new research project beginning with the start of the 2nd funding phase?*
Objective(s)	*Which main research questions are addressed? Specify the primary goal of the project. Which (main) results are expected (e.g. primary and secondary patient-relevant outcomes of the study)?*
Study type	*E.g. analysis of secondary data, prospective or retrospective study, controlled study*
Methods	*Description of methodological approaches (data collection, statistical analysis…)*
Target and study population, sample size	*Describe the population which will be in focus of the study, selection of study population, comment on estimated sample size and your recruitment strategy.*
Intervention(s)	*If you carry out an interventional study, briefly describe of the experimental and control intervention(s).*
Collaboration partners including patients involvement	*Enumeration of involved collaboration partners and their tasks (e.g. recruitment, allocation of data / methods.)*
Funding applied for and duration	*Summe der beantragten Mittel, welche auf das Teilprojekt entfallen inklusive Projektpauschale* *Xxxx* EUR, *xxx* months *(max 36 months)*

For this table 10 point Arial, single-line may be used. Please do not exceed 1 page.

B.1.2 Local palliative reserach expertise

Briefly comment on the scientific palliative research expertise on-site (e.g. research profile and research activities at the institution).

B.1.3 Relevance and aims

Which main research questions will be addressed in the subproject? Please rank the research questions according to importance, indicating major and minor hypotheses of the study.

What are novel aspects of the proposed study?

Which results are expected? Explain how the results oft he subproject benefit palliative care presumably?

Place your study in the context of the national and international state of the art. Discuss the relevance of international studies for German palliative care research. Compare to similar studies. Refer to relevant systematic review(s) and/or (own) pilot studies, feasibility studies, or relevant previous / current trials ore studies.

B.1.4 Study design

Explain the study design chosen.
State why you chose your approach(es) as opposed to others.
Describe the experimental and control interventions.

collaboration

Describe the interdisciplinary, multiprofessional and international collaboration in your subproject.
Explain how your collaborations contribute to study's aims and innovation.
Please describe your participatory research approaches. Explain how patients and other relevant parties (for instance relatives or representatives) will be involved.

Gender issues

Please identify and explain how gender issues are addressed in your research. Define gender differences and inequalities, for instance with respect to accessibility or utilization of health care services.

targets / study population

The inclusion and exclusion criteria should make up the eligibility criteria that rule in or out the participants in a research study. Please specify the target population. The inclusion and exclusion criteria must be comparable to standard care or treatment-as-usual condition (external validity). Comment on the sample size calculation and sample size justification. Reflect upon possible generalisations.

endpoints

Explain the patient-relevant endpoints chosen. Can you name other trials that utilized these endpoints? Are there any guidelines proposing these endpoints?
Please discuss the clinical relevance and validation of endpoints for the target population.

field access and feasibility

Please explain the sample size determination. Please explain your strategy for the recruitment of sufficient patients-numbers. Please demonstrate the likelihood for recruiting the required number of

suitable subjects (for instance through pilot studies and preceding trials) and comment on the methodical approach and sample issues. Comment on your strategies to overcome barriers to access to health care institutions and patients.

data collection

Describe your methods and instruments for data collection. State why you chose your approach(es) as opposed to others. How do you record and document the data? Are the instruments validated and reliable?
If you plan to use existing data: Define the datasets to be used. Specify the type of da- taset, e.g. routine data from sickness funds. Comment on the quality of the existing data. Which characteristics / items of the existing data will be used for this study? How generalizable are the expected results derived from this dataset?
Please describe strategies to reduce the influence of implicit bias. Please comment on anticipated non-response and missing data as well.

data analysis

Illustrate your methods of data analysis and state why you chose your approach(es) as opposed to others. Explain your selection of research methods and describe the stages of data analysis.
Explain the statistical analysis in terms of data items and variables. What are the independent and dependent variables?
Please provide examples of statistical models and assumptions that will be used.

quality assurance and safety

Describe the measures for quality assurance and quality control with respect to organisational and technical implementation.
Comment on the necessity of an external quality assurance / monitoring of the study / expert advice (entirely independent of the coordinating investigator and the institution(s) involved, e.g. scientific advisory board/trial steering committee).
The registration in a national or an international study registry has to be confirmed at the beginning of the study.
The study protocol has to be published at the beginning of the study preferably in a scientific journal. All results of the study (also negative ones) have to be published in scientific journals.

B.1.5 Dissemination and implementation

Explicate your strategies for dissemination of results among the scientific community, the public and actors involved (e.g. sickness funds, professional societies, general practitioners).

Please state achievable goals regarding the translation and transfer of results of your subproject to palliative care. How will actors, e.g. from health care and nursing care, be engaged during the project and how are the results implemented after the end of the project?
Outline strategies and measures to disseminate and implement the results within the German health care system.
You may refer to section A if the subprojects pursue a common plan for dissemination and implementation.

B.1.6 Ethical and legal considerations

Comment on ethical and legal considerations related to the study and discuss briefly whether they are adequate and justified (e. g. assessment of risks and benefits, care and protection for research participants, protection of research participants' confidentiality, data protection, informed consent process).
Identify patients' needs, perspectives, and preferences. Explain the involvement of patient-representatives / patient advocacy groups.
A final version of the study protocol and a statement by the ethics committee will be required by the funding organisation before the conduction of the study.

B.1.7 Study participants

Please list of major participants and indicate tasks / responsibilities, including people responsible for design, management and analysis of the study. Describe the professional background and expertise of all participants. Cite relevant publications and/or specify their major role in ongoing comparable studies.

name	affiliation *(only institution and city)*	responsibility / task
		Principal investigator
		…
		…
		Responsible for study statistics / qualitative methods
		Responsible for quality assurance/data management
		Recruiting centres (e.g. hospitals, nursing homes, network of health care providers)
		Trial-supporting facilities/ institutions (e.g. sickness funds)
		Support and advocacy organisations of patients

For this table 10 point Arial, single-line may be used. Responsibilities indicated are examples. Lines can be changed/deleted.

B.1.8 Work plan

Describe the intended working operations (work pakages (WP)) with milestones (M) and the time frame for the subproject in detail, additianialy fill in a Gantt-Chart. If the Gantt-Chart given in section A is sufficiently detailed refere to section A.

Workpakages (WP)	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WP 1 - xyz				**M1**								
WP n - xyz							**Mn**					
WP n - xyz												
WP n - xyz												

M1: *Milestone xyz …*

Mn: *Milestone xyz*

B.1.9 Personel applied for

How many human resources do you need for the research project?

position	**PM***	**tasks**
Senior researcher**		
Researcher		
PhD student		
Study nurse		
Documentalist		
Other Student assistant	(hours)	

*PM = personal month, sum for 3 years
** has to be justified thru special responsibility
For this table 10 point Arial, single-line may be used. Positions indicated are examples. Lines can be changed/deleted.

B.1.10 Financial plan

Total costs for the subproject have to be assigned in the table below.

Costs for basic equipment as well as service deliveries are not applicable for funding.

Funds applied for have to be justified according to the work plan.

Position	**Person months**	**Sum EURO**
Personnel		
Scientific		
Non-scientific		
Other	(hours)	
Subcontracts		
Consumables		
Case payment		
Equipment*		
Travel costs		
sum		
Overhead / lump sum (if applicable)		
Total amount		

* Equipment (can only be funded when it is not included in the basic equipment, or when existing equipment is not available for the project)

Please state what is included in the position and comment if necessary on:
Personnel (responsibilities); Justify the level of the position, the time necessary to achieve tasks, you can refer to the table personel above;
Subcontracts (why are they necessary? For which work packages?);
Consumables (brief statement regarding the items needed, including case payment);
Case payment (calculate assays/examinations per patient, hours of staff per patient: €/patient x no. of patients);
Travel costs (list of intended journeys);
Equipment (can only be funded if it is not included in the basic equipment, or when existing equipment is not available for the project).

B.1.11 Co-Financing by industry and / or other third parties

Co-financing by industry, health insurances 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 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, e.g. travelling costs).*
- *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 study and the publication of its results. A statement giving such assurances will be demanded after the review process is finished.*

If approval of funding of the second phase is made, appropriate agreements on intellectual property rights, confidentiality and publication of results are to be concluded between all those playing a leading part in the conduct of the study.
Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.

B.1.12 Other funding

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

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".

B.2 Subproject 2 - ACRONYM

B.2.1 Synopsis	
Principal investigator	*Name, Institution / department*
Title and acronym of the subproject	*In English* *In German*
2nd phase/new project?	*Did you start the project in the 1st fundig phase and do you apply for a 2nd phase?* *or* *Do you apply for a new research project beginning with the start of the 2nd funding phase?*
Objective(s)	*Which main research questions are addressed? Specify the primary goal of the project. Which (main) results are expected (e.g. primary and secondary patient-relevant outcomes of the study)?*
Study type	*E.g. analysis of secondary data, prospective or retrospective study, controlled study*
Methods	*Description of methodological approaches (data collection, statistical analysis…)*
Target and study population, sample size	*Describe the population which will be in focus of the study, selection of study population, comment on estimated sample size and your recruitment strategy.*
Intervention(s)	*If you carry out an interventional study, briefly describe of the experimental and control intervention(s).*
Collaboration partners including patients involvement	*Enumeration of involved collaboration partners and their tasks (e.g. recruitment, allocation of data / methods.)*
Funding applied for and duration	*Summe der beantragten Mittel, welche auf das Teilprojekt entfallen inklusive Projektpauschale* *Xxxx* EUR, *xxx* months *(max 36 months)*

For this table 10 point Arial, single-line may be used. Please do not exceed 1 page.

B.2.2 Local palliative reserach expertise

Briefly comment on the scientific palliative research expertise on-site (e.g. research profile and research activities at the institution).

B.2.3 Relevance and aims

Which main research questions will be addressed in the subproject? Please rank the research questions according to importance, indicating major and minor hypotheses of the study.

What are novel aspects of the proposed study?

Which results are expected? Explain how the results oft he subproject benefit palliative care presumably?

Place your study in the context of the national and international state of the art. Discuss the relevance of international studies for German palliative care research. Compare to similar studies.

Refer to relevant systematic review(s) and/or (own) pilot studies, feasibility studies, or relevant previous / current trials ore studies.

B.2.4 Study design

Explain the study design chosen.
State why you chose your approach(es) as opposed to others.
Describe the experimental and control interventions.

collaboration

Describe the interdisciplinary, multiprofessional and international collaboration in your subproject.
Explain how your collaborations contribute to study's aims and innovation.
Please describe your participatory research approaches. Explain how patients and other relevant parties (for instance relatives or representatives) will be involved.

Gender issues

Please identify and explain how gender issues are addressed in your research. Define gender differences and inequalities, for instance with respect to accessibility or utilization of health care services.

targets / study population

The inclusion and exclusion criteria should make up the eligibility criteria that rule in or out the participants in a research study. Please specify the target population. The inclusion and exclusion criteria must be comparable to standard care or treatment-as-usual condition (external validity). Comment on the sample size calculation and sample size justification. Reflect upon possible generalisations.

endpoints

Explain the patient-relevant endpoints chosen. Can you name other trials that utilized these endpoints? Are there any guidelines proposing these endpoints?
Please discuss the clinical relevance and validation of endpoints for the target population.

field access and feasibility

Please explain the sample size determination. Please explain your strategy for the recruitment of sufficient patients-numbers. Please demonstrate the likelihood for recruiting the required number of suitable subjects (for instance through pilot studies and preceding trials) and comment on the

methodical approach and sample issues. Comment on your strategies to overcome barriers to access to health care institutions and patients.

data collection

Describe your methods and instruments for data collection. State why you chose your approach(es) as opposed to others. How do you record and document the data? Are the instruments validated and reliable?
If you plan to use existing data: Define the datasets to be used. Specify the type of da- taset, e.g. routine data from sickness funds. Comment on the quality of the existing data. Which characteristics / items of the existing data will be used for this study? How generalizable are the expected results derived from this dataset?
Please describe strategies to reduce the influence of implicit bias. Please comment on anticipated non-response and missing data as well.

data analysis

Illustrate your methods of data analysis and state why you chose your approach(es) as opposed to others. Explain your selection of research methods and describe the stages of data analysis. Explain the statistical analysis in terms of data items and variables. What are the independent and dependent variables?
Please provide examples of statistical models and assumptions that will be used.

quality assurance and safety

Describe the measures for quality assurance and quality control with respect to organisational and technical implementation.
Comment on the necessity of an external quality assurance / monitoring of the study / expert advice (entirely independent of the coordinating investigator and the institution(s) involved, e.g. scientific advisory board/trial steering committee).
The registration in a national or an international study registry has to be confirmed at the beginning of the study.
The study protocol has to be published at the beginning of the study preferably in a scientific journal. All results of the study (also negative ones) have to be published in scientific journals.

B.2.5 Dissemination and implementation

Explicate your strategies for dissemination of results among the scientific community, the public and actors involved (e.g. sickness funds, professional societies, general practitioners).

Please state achievable goals regarding the translation and transfer of results of your subproject to palliative care. How will actors, e.g. from health care and nursing care, be engaged during the project and how are the results implemented after the end of the project?
Outline strategies and measures to disseminate and implement the results within the German health care system.
You may refer to section A if the subprojects pursue a common plan for dissemination and implementation.

B.2.6 Ethical and legal considerations

Comment on ethical and legal considerations related to the study and discuss briefly whether they are adequate and justified (e. g. assessment of risks and benefits, care and protection for research participants, protection of research participants' confidentiality, data protection, informed consent process).
Identify patients' needs, perspectives, and preferences. Explain the involvement of patient-representatives / patient advocacy groups.
A final version of the study protocol and a statement by the ethics committee will be required by the funding organisation before the conduction of the study.

B.2.7 Study participants

Please list of major participants and indicate tasks / responsibilities, including people responsible for design, management and analysis of the study. Describe the professional background and expertise of all participants. Cite relevant publications and/or specify their major role in ongoing comparable studies.

name	affiliation (only institution and city)	responsibility / task
		Principal investigator
		…
		…
		Responsible for study statistics / qualitative methods
		Responsible for quality assurance/data management
		Recruiting centres (e.g. hospitals, nursing homes, network of health care providers)
		Trial-supporting facilities/ institutions (e.g. sickness funds)
		Support and advocacy organisations of patients

For this table 10 point Arial, single-line may be used. Responsibilities indicated are examples. Lines can be changed/deleted.

B.2.8 Work plan

Describe the intended working operations (work pakages (WP)) with milestones (M) and the time frame for the subproject in detail, additianialy fill in a Gantt-Chart. If the Gantt-Chart given in section A is sufficiently detailed refere to section A.

Workpakages (WP)	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WP 1 - xyz				**M1**								
WP n - xyz							**Mn**					
WP n - xyz												
WP n - xyz												

M1: *Milestone xyz …*

Mn: *Milestone xyz*

B.2.9 Personel applied for

How many human resources do you need for the research project?

position	**PM***	**tasks**
Senior researcher**		
Researcher		
PhD student		
Study nurse		
Documentalist		
Other Student assistant	(hours)	

*PM = personal month, sum for 3 years
** has to be justified thru special responsibility
For this table 10 point Arial, single-line may be used. Positions indicated are examples. Lines can be changed/deleted.

B.2.10 Financial plan

Total costs for the subproject have to be assigned in the table below.

Costs for basic equipment as well as service deliveries are not applicable for funding.

Funds applied for have to be justified according to the work plan.

Position	**Person months**	**Sum EURO**
Personnel		
Scientific		
Non-scientific		
Other	(hours)	
Subcontracts		
Consumables		
Case payment		
Equipment*		
Travel costs		
sum		
Overhead / lump sum (if applicable)		
Total amount		

* Equipment (can only be funded when it is not included in the basic equipment, or when existing equipment is not available for the project)

Please state what is included in the position and comment if necessary on:
Personnel (responsibilities); Justify the level of the position, the time necessary to achieve tasks, you can refer to the table personel above;
Subcontracts (why are they necessary? For which work packages?);
Consumables (brief statement regarding the items needed, including case payment);
Case payment (calculate assays/examinations per patient, hours of staff per patient: €/patient x no. of patients);
Travel costs (list of intended journeys);
Equipment (can only be funded if it is not included in the basic equipment, or when existing equipment is not available for the project).

B.2.11 Co-Financing by industry and / or other third parties

Co-financing by industry, health insurances 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 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, e.g. travelling costs).*
- *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 study and the publication of its results. A statement giving such assurances will be demanded after the review process is finished.*

If approval of funding of the second phase is made, appropriate agreements on intellectual property rights, confidentiality and publication of results are to be concluded between all those playing a leading part in the conduct of the study.
Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.

B.2.12 Other funding

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

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".

B.3 Subproject 3 - ACRONYM

B.3.1 Synopsis	
Principal investigator	*Name, Institution / department*
Title and acronym of the subproject	*In English* *In German*
2nd phase/new project?	*Did you start the project in the 1st fundig phase and do you apply for a 2nd phase?* *or* *Do you apply for a new research project beginning with the start of the 2nd funding phase?*
Objective(s)	*Which main research questions are addressed? Specify the primary goal of the project. Which (main) results are expected (e.g. primary and secondary patient-relevant outcomes of the study)?*
Study type	*E.g. analysis of secondary data, prospective or retrospective study, controlled study*
Methods	*Description of methodological approaches (data collection, statistical analysis…)*
Target and study population, sample size	*Describe the population which will be in focus of the study, selection of study population, comment on estimated sample size and your recruitment strategy.*
Intervention(s)	*If you carry out an interventional study, briefly describe of the experimental and control intervention(s).*
Collaboration partners including patients involvement	*Enumeration of involved collaboration partners and their tasks (e.g. recruitment, allocation of data / methods.)*
Funding applied for and duration	*Summe der beantragten Mittel, welche auf das Teilprojekt entfallen inklusive Projektpauschale* *Xxxx* EUR, *xxx* months *(max 36 months)*

For this table 10 point Arial, single-line may be used. Please do not exceed 1 page.

B.3.2 Local palliative reserach expertise

Briefly comment on the scientific palliative research expertise on-site (e.g. research profile and research activities at the institution).

B.3.3 Relevance and aims

Which main research questions will be addressed in the subproject? Please rank the research questions according to importance, indicating major and minor hypotheses of the study.

What are novel aspects of the proposed study?

Which results are expected? Explain how the results oft he subproject benefit palliative care presumably?

Place your study in the context of the national and international state of the art. Discuss the relevance of international studies for German palliative care research. Compare to similar studies.

Refer to relevant systematic review(s) and/or (own) pilot studies, feasibility studies, or relevant previous / current trials ore studies.

B.3.4 Study design

Explain the study design chosen.
State why you chose your approach(es) as opposed to others.
Describe the experimental and control interventions.

collaboration

Describe the interdisciplinary, multiprofessional and international collaboration in your subproject.
Explain how your collaborations contribute to study's aims and innovation.
Please describe your participatory research approaches. Explain how patients and other relevant parties (for instance relatives or representatives) will be involved.

Gender issues

Please identify and explain how gender issues are addressed in your research. Define gender differences and inequalities, for instance with respect to accessibility or utilization of health care services.

targets / study population

The inclusion and exclusion criteria should make up the eligibility criteria that rule in or out the participants in a research study. Please specify the target population. The inclusion and exclusion criteria must be comparable to standard care or treatment-as-usual condition (external validity). Comment on the sample size calculation and sample size justification. Reflect upon possible generalisations.

endpoints

Explain the patient-relevant endpoints chosen. Can you name other trials that utilized these endpoints? Are there any guidelines proposing these endpoints?
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field access and feasibility

Please explain the sample size determination. Please explain your strategy for the recruitment of sufficient patients-numbers. Please demonstrate the likelihood for recruiting the required number of suitable subjects (for instance through pilot studies and preceding trials) and comment on the

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		…
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	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WP 1 - xyz				**M1**								
WP n - xyz							**Mn**					
WP n - xyz												
WP n - xyz												

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Mn: *Milestone xyz*

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Documentalist		
Other Student assistant	(hours)	

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Subcontracts		
Consumables		
Case payment		
Equipment*		
Travel costs		
sum		
Overhead / lump sum (if applicable)		
Total amount		

* Equipment (can only be funded when it is not included in the basic equipment, or when existing equipment is not available for the project)

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- *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 study and the publication of its results. A statement giving such assurances will be demanded after the review process is finished.*

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B.3.12 Other funding

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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".

C. Attachments

Refer to the page number of the attachment as "C-1", "C-2" etc. in the proposal above.

C.1 References

Please list publications you have quoted within your application. References should be listed according to their numerical appearance in the text. Those references given in connection with the research profile of a person or institution should be listed with the CVs in section C2.

Consortium – ACRONYM

Subproject 1 – ACRONYM

Subproject 2 – ACRONYM

Subproject 3- ACRONYM

C.2 Curriculum vitae

Include tabular scientific CVs for academic staff members playing a leading role and further relevant persons in the consortium and the subprojects as indicated in the project outline above. Publications as reference for expertise have to be attached to the CV.

C.3 Declaration of commitments

Each partner holding key competences relevant for the consortium or one of the subprojects needs to provide a declaration of commitment.

***Participating/recruiting centres** must declare their commitment on a **separate sheet including their signatures** (if an umbrella organisation or a network of several recruiting centres is involved, it is sufficient if the authorised representative of the organisation or the network, signs the sheet). Following details are needed, if applicable:*

a) Name of investigator
b) Institution
c) Trial name
d) Trial duration
e) Inclusion/exclusion criteria
f) Strategy for the determination of recruitment figures at the recruiting centre
g) Number of patients expected to be recruited for the trial under the above mentioned criteria
h) Detailed description of the working package conducted by each/the participating centre(s)
i) Conflict of interest
j) Signature

*If **data from health insurances or other institutions** such as German Pension Fund are used for the study, the access to data needs to be clarified and documented on a separate sheet including signature (if an umbrella organisation or a network of several recruiting centres is involved, it is sufficient if the authorised representative of the organisation or the network, signs the sheet). Following details are needed, if applicable:*

a) Contact person
b) Institution
c) Study name
d) Data provided (inclusion/ exclusion criteria, number of patients)
e) Data protection
f) Conflict of interest
g) Signature

Hinweise zum ressourcenbezogenen Arbeitsplan

- **Vorlage mit dem Formantrag** (AZA(P)/ AZK) für die Bewilligung, dabei müssen die Ansätze je Stelle und Arbeitspaket (AP) mit den Angaben im AZA(P)/ AZK und den Finanzierungsplänen übereinstimmen!
- **Personalausgaben/ -kosten** ergeben sich aus der Berechnung im AZA(P)/ AZK. Hier erfolgt lediglich Angabe von Personalmonaten (PM) bei AZA(P) bzw. produktiven Stunden bei AZK.
- **AZA:** Die Laufzeit ist farbig zu markieren, beim Personal sind je Monat der Anteil an PM anzugeben. In Kumulation der Arbeitspakete ist je Einzelmonat max. Wert für Anzahl der Stellen möglich, z.B. 1x Vollzeit => max. 1,00, bei Teilzeit-Stellen entsprechend anteilig.
- **AZK:** Die Laufzeit ist farbig zu markieren, beim Personal sind je Monat die **produktiven Stunden** anzugeben (*1 PM/ MM/ FTE = ca. 142 produktive Stunden max. bei einer 40-Stunden-Woche).* Eine erheblich abweichende Kalkulation ist zu erläutern!
- Zwischen- und Gesamtsummen werden über Formeln automatisch ermittelt!

Zeit/ Arbeitspakete	20XX													20XX													20XX													20XX												
	Quartal 1			Quartal 2			Quartal 3			Quartal 4			PM	Quartal 1			Quartal 2			Quartal 3			Quartal 4			PM	Quartal 1			Quartal 2			Quartal 3			Quartal 4			PM	Quartal 1			Quartal 2			Quartal 3			Quartal 4			PM
	1	2	3	4	5	6	7	8	9	10	11	12		1	2	3	4	5	6	7	8	9	10	11	12		1	2	3	4	5	6	7	8	9	10	11	12		1	2	3	4	5	6	7	8	9	10	11	12	
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Hinweise und Checkliste zur Formantragstellung

Das elektronische Online-Antragssystem **easy-Online** finden Sie unter https://foerderportal.bund.de/easyonline. Der direkte Link zu Ihrer Fördermaßnahme lautet https://foerderportal.bund.de/easyonline/reflink.jsf?m=GY-VERSORGUNG&b=PALLIATIVANSCHLUSS.

Bitte beachten Sie bei der Erstellung der Formanträge folgende Dokumente:

- Richtlinien für Zuwendungsanträge auf Ausgabenbasis (AZA) oder
- Richtlinien für Zuwendungsanträge auf Kostenbasis von Unternehmen der gewerblichen Wirtschaft (AZK) und
- Merkblatt Vorkalkulation für Zuwendungen - Kostenbasis - (AZK 4).

Die Dokumente finden Sie im **Formularschrank des BMBF**:
https://foerderportal.bund.de/easy/easy_index.php?auswahl=easy_formulare&formularschrank=bmbf&menue=block

Die folgenden Erläuterungen sollen Ihnen die Formantragstellung erleichtern. Sie ergänzen die oben genannten Richtlinien. Die Lektüre der Richtlinien ist für die Antragstellung unerlässlich.

I. Checkliste zum Formantrag

Erforderliche Unterlagen:	**Prüfen: √**
Druckexemplar rechtsverbindlich unterschrieben	☐
Vorhabentitel (AZA/AZAP/AZK, Seite 1) in **deutscher Sprache**	☐
Erläuterungen zum Finanzierungsplan in easy AZA/AZAP/AZK oder als separate Datei in deutscher Sprache	☐
Vorlage personenbezogener Daten bei Beantragung von namentlich bereits bekanntem Personal	☐
Deutsche Vorhabenbeschreibung mit Verwertungsplan gemäß der Gliederung zu AZA/AZAP/AZK, Seite 9 in den "Richtlinien für Zuwendungsanträge auf Ausgabenbasis" bzw. „Richtlinien für Zuwendungsanträge auf Kostenbasis von Unternehmen der gewerblichen Wirtschaft (AZK)“ ***(wird in diesem Einzelfall nachgefordert)***	☐
Ressourcenbezogener Arbeitsplan	☐
Optionale Unterlagen:	**Prüfen: √**
Dienstwegexemplar* über das zuständige Landesministerium (gilt nur für Hochschulen)	☐
Bestätigung über den Abschluss der Kooperationsvereinbarung für Verbundprojekte	☐
Angebote (Geräte, Auftragsvergaben)	☐
Stellungnahme zur Umsetzung der Auflagen/Empfehlungen aus der Begutachtung	☐
Finanzierungszusage/n	☐
Bonitätsunterlagen *(evtl. näher ausführen)*	☐
KMU-Erklärung	☐

*nicht erforderlich in: Baden-Württemberg, Bayern, Berlin, Brandenburg, Bremen, Hessen, Niedersachsen, Nordrhein-Westfalen, Rheinland-Pfalz. Sonderregelung Saarland: Dienstwegverzicht nur für die Universität des Saarlandes, jedoch nur, wenn der Antrag über die Grundausstattung hinaus keine weitere finanzielle Eigenbeteiligung der Universität vorsieht - also nur bei Vollfinanzierung der zusätzlichen Ausgaben, Sonderregelung Schleswig-Holstein: Dienstwegverzicht bei **Fach**hochschulen.

II. Allgemeine Hinweise

Deutsche Vorhabenbeschreibung

Die deutsche Vorhabenbeschreibung ist Teil Ihres Formantrags und gemäß der Gliederung zu AZA/AZAP/AZK, Seite 8-10 bzw. Seite 4-6 in den Richtlinien für Zuwendungsanträge auf Ausgaben- bzw. Kostenbasis zu erstellen. Sie stellt eine Zusammenfassung Ihres Forschungsvorhabens dar. Bitte nehmen Sie – in einer für Laien verständlichen Sprache – zu jedem der in der Gliederung aufgeführten Punkte Stellung.

Für Verbundvorhaben muss zusätzlich eine kurze zusammenfassende Vorhabenbeschreibung des gesamten Verbundes in deutscher Sprache beigefügt werden. Aus der Beschreibung muss die arbeitsteilige Zusammenarbeit der Verbundpartner eindeutig hervorgehen. Zudem ist ein gemeinsamer Verwertungsplan für den Verbund vorzulegen. Wenn die Verwertung im Verbund nur gemeinsam erfolgen kann, ist es ausreichend, ausschließlich einen gemeinsamen Verwertungsplan für den Gesamtverbund vorzulegen. In diesem müssen ggf. teilprojektspezifische Verwertungsabsichten gesondert ausgewiesen werden. Andernfalls sind neben einem Verwertungsplan für den Verbund auch Verwertungspläne für jede Zuwendung erforderlich.

Kurzfassung der Vorhabensbeschreibung

Die Kurzfassung der Vorhabenbeschreibung auf AZA/AZAP/AZK, Seite 5 wird im Internet veröffentlicht unter http://www.gesundheitsforschung-bmbf.de/de/Gefoerderte%20Projekte.php. Die Kurzfassung sollte für Laien verständlich das Projekt beschreiben. Verwenden Sie keine Abkürzungen, Aufzählungen oder Fachwörter, sondern ausschließlich geläufige Begriffe. Bitte fügen Sie eine englische Übersetzung dieses Textes bei.

Sollten Sie mit der Veröffentlichung der Kurzfassung nicht einverstanden sein, legen Sie uns bitte einen veröffentlichungsfähigen Text gleichen Umfangs bei.

III. Weitere Hinweise zu Positionen des Finanzgerüsts

Bitte beachten Sie, dass nur Ausgaben/ Kosten zuwendungsfähig sind, die ausschließlich zur Durchführung des geplanten Vorhabens verwendet werden. Unabhängig davon können Hochschulen und Universitätskliniken eine Projektpauschale erhalten.

Personal

Für jede der beantragten Stellen ist in den Erläuterungen eine kurze Aufgabenbeschreibung unter Hinweis auf die geplanten Vorhabensarbeiten zu erstellen. Die erforderliche Qualifikation (Stellenbeschreibung) und die notwendige Personalkapazität müssen nachvollziehbar dargestellt werden. Bei personenbezogenen Berechnungen sind die zugrundeliegenden Daten beizufügen.

Für jede beantragte Hilfskraft-Stelle werden eine Aufgabenbeschreibung und die Berechnungsgrundlage für das vorgesehene Beschäftigungsentgelt benötigt. Bitte geben Sie dazu die Anzahl der Arbeitsstunden und den Stundensatz mit Ausweisung des Arbeitgeberanteils an. Sollten für Sie die Richtlinien der Tarifgemeinschaft deutscher Länder

über die Arbeitsbedingungen der wissenschaftlichen und studentischen Hilfskräfte gelten, sind die entsprechenden Vergütungshöchstsätze zu berücksichtigen.

Verbrauchsmaterialien

Bitte erstellen Sie eine kurz begründete, summarische Zusammenstellung der Verbrauchsmaterialien. Aus dieser muss auch die Berechnungsgrundlage der einzelnen Posten hervorgehen.

Patente

Mittel für die Anmeldung eines Patentes, die während der Laufzeit initiiert wurden, sowie Mittel für die Aufrechterhaltung eines Patents mit entscheidender Bedeutung für das Vorhaben können in der Regel mit bis zu 10.000 Euro gefördert werden. Bei Unternehmen der gewerblichen Wirtschaft gilt dies nur für KMU.