***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

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# General information on the consortium

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

## 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.*

## 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.*

## 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.*

## 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.*

## 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.*

## 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*

## 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 |  |  |

# Detailed description of subprojects

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

## Subproject 1 - ACRONYM

|  |  |
| --- | --- |
| 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.*

### Local palliative reserach expertise

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

### 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.*

### 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.*

### 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.*

### 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.*

### 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.*

### 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*

### 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.*

### 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).*

### 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.*

### 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”.*

## Subproject 2 - ACRONYM

|  |  |
| --- | --- |
| 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.*

### Local palliative reserach expertise

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

### 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.*

### 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.*

### 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.*

### 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.*

### 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.*

### 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*

### 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.*

### 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).*

### 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.*

### 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”.*

## Subproject 3 - ACRONYM

|  |  |
| --- | --- |
| 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.*

### Local palliative reserach expertise

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

### 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.*

### 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.*

### 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.*

### 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.*

### 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.*

### 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*

### 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

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|  |  |  |
| --- | --- | --- |
| **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)

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*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);*

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* *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.*

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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”.*

# Attachments

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

## 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

## 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.*

## 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*