**Application for an Epidemiological Study**

*Please prepare your application in English not exceeding 10 pages (DIN A4, Arial font size 11, line spacing 1.5, margins 2 cm). Signatures of the principal investigator and responsible biostatistician/data manager are mandatory (see appendix of part A).*

*The „Leitlinien und Empfehlungen zur Sicherung von Guter Epidemiologischer Praxis (GEP) von 2018“ must be considered.*

**B.x Subproject no. x**

|  |  |
| --- | --- |
| **Coordinator** | *Title, first and last name*  *Institution*  *Address*  *Telephone*  *E-Mail address* |
| **Title** |  |
| ***Biostatistician/data manager*** | Name, institution |
| **Condition/Topic** | *The medical condition being studied.* |
| **Objective(s)** |  |
| **Study Type** |  |
| **Target Population (key inclusion and exclusion criteria)** |  |
| **Main outcomes to be analysed** |  |
| **Statistical analysis** | *Anonymisation or pseudonymisation of data and statistical details* |
| **Sample Size** | *To be assessed for eligibility (n = …)*  *To be allocated to study (n = …)*  *Expected to be analysed (n = ….)* |
| **Duration** | *first study subject in to last study subject out*  *requested duration of funding (months)* |
| **Summary** | *(max. 500 symbols including space characters)* |
| **Participating Centres** |  |
| **External cooperation partners** | (optional, if applicable) |

1. Background and previous work

* 1. **Aim of the subproject**
* *Please describe the aims of the subproject and the research question(s) addressed as part of the research question of the network.*
* *What results are expected?*
* *Describe briefly the planned work packages, methodologies and technical approaches used in the subproject.*
  1. **Contribution to the network**
* *What is the contribution of this subproject to the One health approach of the network?*
* *Describe with whom and how you will work together within the network.*
  1. **Own previous work, resources and expertise**
* *Which own previous work and expertise is directly relevant for this subproject?*
* *Describe the necessary resources in place for accomplishing the subproject: infrastructure, capacities, specific expertise and previous achievements (e.g. methodologies, patient cohorts). If applicable, provide details on the type of biomaterial collections/patient cohorts and the concept for material acquisition and storage.*

2. Justification of design aspects

**2.1. Study Type**

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

*Describe and justify the population to be studied (inclusion/exclusion criteria). Include reflections on generalizability and representativeness.*

*What is the planned duration for the project? What are the long-term plans for sustainability and how will the financing be assured?*

**2.2. Data items to be analysed**

*Justify the data items chosen: Are there other projects that have utilized them before or guidelines proposing these data items? What is the planned follow-up for a single patient/subject? Discuss the relevance of the data items for the target population.*

**2.3. Gender aspects**

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

2.4. Methods against Bias

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

2.5. Data acquisition and storage

*How will the patients/subjects be elected and recruited for the project? How will the participating institutions be motivated for a timely and accurate data acquisition? Which instruments will be used to record the data? Are the instruments validated and reliable? Which standards will be used to classify diagnoses and stages of the diseases?*

*Describe the concept of data acquisition and storage. How will the personal responsible for data acquisition be trained?*

*Comment on the accessibility of data origins and on the possibilities to use or integrate already existing sources of data.*

**2.6. Biometric concept / Statistical analyses**

*What is the proposed strategy of statistical analysis? Which data items and variables will be included in the analyses? What are the intended recruitment rate and total number of patients/subjects necessary for these analyses? Which concrete statistical evaluations are planned at what time and which methods will be used? What is the assumed rate of loss due to follow up or missing/incomplete data? On what evidence are these assumptions based?*

**2.7. Feasibility of recruitment**

*What is the evidence that the intended recruitment rate and total number of patients/subjects for the project is achievable? Demonstrate conclusively the potential for recruiting the required number of suitable subjects (the best piece of evidence being pilot data collections and projects in a similar population/institution).*

**2.8. International collaborations**

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

**3. Ethical considerations**

*Comment on ethical considerations relating to the project (ethics votes, data protection, confidentiality, informed patient consent).*

**4. Project management**

**4.1. Major participants**

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

*Please indicate roles of major participants.*

**4.2. Project supporting facilities**

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

**4.3. Quality assurance**

*Describe and justify the concept for quality assurance. How is the data integrity and plausibility controlled? Describe the actual organisational and technical measures for quality assurance and quality control (e.g. second control of data which cannot be controlled by plausibility tests, coding of data, second control of coding, documentation of data corrections). How and when will they be implemented? Are these e.g. outlined in a special quality manual (“Operationshandbuch”)? Comment on the usefulness of feedback strategies concerning data quality.*

*Which indicators are used to measure and quantify the quality of the register concerning e.g.:*

* *structures (e.g. indicators measuring data plausibility)*
* *processes (e.g. indicators measuring the organisation of data acquisition)*
* *results (e.g. indicators measuring correctness, completeness, representativeness and accuracy).*

*Comment on the necessity of an external quality assurance/monitoring.*

**4.4. Data safety concept***How will the existing legal requirements for data safety be met? Describe the data safety concept applied and the planned data flow (diagram). If applicable, provide positive vote of the data security organisation in charge. Depending on the type of project, is anonymisation or pseudonymisation of data planned? Comment on the following aspects of the data safety concept, if applicable:*

* *Technical and organisational instruments*
* *Central patients list (localisation)*
* *Identification data*
* *Pseudonymisation and de-pseudonymisation (localisation)*
* *Informed patient consent*
* *Patient right of access to personal data*
* *Storage time of data*
* *Workflow for quality assurance*
* *Safety of data transmission and documentation*
* *Policy document including all legal regulations and agreements*

4.5. References

*Please list key references here (max. 5, font size not less than 6 pt).*

4.6. Timeframe / Milestones

*Please provide a proposal of milestones reflecting planning, recruitment status and data clearing/analysis progress. Include a diagram showing stages and milestones. Comment on the possibility of sustainable establishment of the project after funding, if applicable.*

4.7. Financial details of the study

**4.7.1. Co-financing by industry and/or other third parties**

Co-financing by industry or other third parties is possible if

* the independence of investigators is ensured and
* terms and conditions of the financial commitment are disclosed.

If co-financing is intended the application should briefly describe the type and volume of the intended co-financing, indicating the respective company or other third party.

Details are to be specified:

* Describe the type and volume of support (including any services or consumables provided free of charge).
* Indicate the amount of support to be provided and assure in writing that the third party will render these services, stating their terms and conditions, if any.
* Assure that the coordinating investigator is independent, in particular with regard to the analysis of the project and the publication of its results. A statement giving such assurances will be demanded after the review process is finished.

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

4.7.2. Financial summary

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Organizational Segment** | **Institution/ Participant/ Trial Site** | **Qualification and Task of staff/**  **No. of items/ Kind of equipment/ Explanation** | **Salary group** | **Total months** | **Total (€)** | **Justification** |
| 1 | **Scientific Management** |  |  |  |  |  |  |
| 2 | **Organisational Management** |  |  |  |  |  |  |
| 3 | **Data (Security) Management** |  |  |  |  |  |  |
| 4 | **Statistical data analysis** |  |  |  |  |  |  |
| 5 | **Quality assurance** |  |  |  |  |  |  |
| 6 | **Meetings/ Travel** |  | *No. of attendees ; No. of meetings (€ / person)* |  |  |  |  |
| 7 | **Case payment** |  | *Assays/examinations per patient; hours of staff per patient; €/patient x No. of patients* |  |  |  |  |
| 8 | **Documentation payment** |  | *documentation per subject/patient*  *hours of staff per subject/patient  € / patient x No. of patients* |  |  |  |  |
| 9 | **Materials** |  | *Consumables* |  |  |  |  |
| 10 | **Equipment** |  |  |  |  |  |  |
| 11 | ***Other*** |  |  |  |  |  |  |
| **TOTAL**  Total Budget:  Institutional Overhead: *e.g., “Projektpauschale” for Universities and University clinics; give amounts in €*  Requested Budget (sum):  Co-Financing applicable? *Yes / No (e.g., by industry or other funding sources)* € | | | | | | | |

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