

|  |  |
| --- | --- |
| BMBF code: (For secretariat use only) |  |
| O:\OE-20\03_Leben\02_Öffentlichkeitsarbeit\Archiv_alte_Ordnerstruktur\BMBF_PT-DLR_Corporate Design\Logos\BMBF_4C_M_e.jpgResearch Networks for Health Innovations in Sub-Saharan Africa (RHISSA)  Full Proposal | |

***The entries in italics are to be seen as hints for the preparation of the application and must be deleted or replaced by the requested information before submission.*** ***The formatting of the application form must be retained.***

# General Information

*(Please refer to section 1 “General information” of the grant application guidelines.)*

| **Network Title** |  | | |
| --- | --- | --- | --- |
| **Network Acronym** | *max. 10 characters* | | |
| **Start Date** | *1st January 2023* | **End Date** | *31st December 2027*  *(Funding for max. 5 years)* |
| **African**  **Director** |  | | |
| **German**  **Co-Director** |  | | |

| **Abbreviations** *within the proposal in alphabetical order* | *AFRT, xxx; ROF, xxx; ZGR, xxx* |
| --- | --- |

**List of contents**

[1 General Information 1](#_Toc90478734)

[2 Information on the Applicants 3](#_Toc90478735)

[2.1 Network Partners 3](#_Toc90478736)

[*2.2* External Cooperating Partners *(not applying for funding)* 3](#_Toc90478737)

[3 Executive Overview 4](#_Toc90478738)

[3.1 General Information 4](#_Toc90478739)

[3.2 Project Summary 4](#_Toc90478740)

[3.3 Work Packages and Tasks 4](#_Toc90478741)

[3.4 Expected Impact at a Glance and Sustainability 4](#_Toc90478742)

[3.5 Risk Assessment and Contingency Plan 4](#_Toc90478743)

[*3.6* Related Applications *(if applicable)* 5](#_Toc90478744)

[3.7 Financial Overview 5](#_Toc90478745)

[4 Governance 5](#_Toc90478746)

[4.1 Roles and Responsibilities of the Director and Co-Director 5](#_Toc90478747)

[4.2 Roles and Responsibilities of the Network Partners 5](#_Toc90478748)

[4.3 Governance Structure, Project Coordination and Monitoring 6](#_Toc90478749)

[5 Overarching Work Package: Research 6](#_Toc90478750)

[5.1 Research Task 1: *“Title”* 6](#_Toc90478751)

[5.2 Research Task 2: *“Title”* 7](#_Toc90478752)

[5.3 to 5.x Research Tasks 3 to x: *“Title”* 9](#_Toc90478753)

[6 Overarching Work Package: Capacity Building 9](#_Toc90478754)

[6.1 Capacity Building and Strengthening 9](#_Toc90478755)

[6.2 Impact, Future Potential and Sustainability 9](#_Toc90478756)

[7 Overarching Work Package: Networking 9](#_Toc90478757)

[7.1 Network Strengthening 10](#_Toc90478758)

[7.2 Impact, Future Potential and Sustainability 10](#_Toc90478759)

[8 Overarching Work Package: Policy Engagement and Research Transfer 10](#_Toc90478760)

[8.1 Assessment of Current Health Policy Strategies, Gaps and Shortcomings 10](#_Toc90478761)

[8.2 Planned Milestones 10](#_Toc90478762)

[8.3 Impact, Future Potential and Sustainability 11](#_Toc90478763)

[9 Management and General Aspects 11](#_Toc90478764)

[9.1 Financial Management 11](#_Toc90478765)

[9.2 Data Management 11](#_Toc90478766)

[9.3 Ethics, Gender and Regulatory Issues 11](#_Toc90478767)

[10 Annexes 11](#_Toc90478768)

[10.1 Annex 1 11](#_Toc90478769)

[10.2 Annex 2 12](#_Toc90478770)

# Information on the Applicants

## Network Partners

*(Please refer to section 2.1 of the grant application guidelines.)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Partner No.** | **Institution (Acronym)** | **PI**  **Title(s)** | **PI**  **Surname** | **PI**  **First Name** | **Town** | **Country** | **Role in Network** | **CV attached?** |
| 1 | *Name of Institution (Acronym of Institution)* |  |  |  |  |  | Director |  |
| 2 |  |  |  |  |  |  | African PI |  |
| 3 |  |  |  |  |  |  | African PI |  |
| … |  |  |  |  |  |  | African PI |  |
| … |  |  |  |  |  |  | Co-Director |  |
| … |  |  |  |  |  |  | German PI |  |

*Add/Remove rows if applicable.*

*For each PI of the network partners listed above, you must add a short CV to Annex 1. The format for CVs is provided in the application guidelines.*

## External Cooperating Partners *(not applying for funding)*

*(Please refer to section 2.2 of the grant application guidelines.)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **External Partner No.** | **Institution (Acronym)** | **PI**  **Title(s)** | **PI**  **Surname** | **PI**  **First Name** | **Town** | **Country** | **Role in Network** |
| A | *Name of Institution (Acronym of Institution)* |  |  |  |  |  |  |
| B |  |  |  |  |  |  |  |

*Add more rows if needed.*

# Executive Overview

*(Please refer to section 3 of the grant application guidelines.)*

## General Information

|  |  |
| --- | --- |
| **SYNOPSIS** | |
| **Name of Director** |  |
| **Name of Co-Director** |  |
| **Network Title** | *Max. 140 characters* |
| **Network Acronym** | *Please enter the acronym of the project.* |
| **Participating Countries** |  |
| **Key Words** | *Max. 5 key words* |
| **Requested Total Funding** | *Requested funding for all partners for 5 years, including overhead costs/lump sum if applicable.* |

## Project Summary

*Please insert text.*

## Work Packages and Tasks

**WP Research**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description** | **Leading Institution Acronym** | **Participating Institution/s Acronym/s** | **Brief Goal** |
| 1. *Task* |  |  |  |
| 2. *Task* |  |  |  |
|  |  |  |  |

*Add more rows if needed.*

**WP Capacity Building**

Leading Institution *(if applicable)*:*Institution**Acronym*

Brief Goals for the entire network:*Please insert text.*

**WP Networking**

Leading Institution *(if applicable)*:*Institution**Acronym*

Brief Goals for the entire network:*Please insert text.*

**WP Policy Engagement and Research Transfer**

Leading Institution *(if applicable)*:*Institution**Acronym*

Brief Goals for the entire network:*Please insert text.*

## Expected Impact at a Glance and Sustainability

*Please insert text.*

## Risk Assessment and Contingency Plan

*Please insert text.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk & Barriers** | **Potential Impact on Project Success**  (L/M/H)[[1]](#footnote-2) | **Likelihood of Occurrence**  L/M/H | **Mitigation Plan**  for H/H, H/M, M/H and M/M |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

*Add/remove lines if needed.*

## Related Applications *(if applicable)*

*Please insert text.*

## Financial Overview

### Financial Breakdown per Partner

*Please insert the budget overview table from the excel sheet “Total” of Annex 2 here.*

### In-Kind and Cost-Share Contributions per Partner

|  |  |
| --- | --- |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1 and 2.2)* | |
| **In-kind**  (non-cash) |  |
| **Cost-share**  (cash/cash-equivalent) |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1 and 2.2)* | |
| **In-kind**  (non-cash) |  |
| **Cost-share**  (cash/cash-equivalent) |  |

*Add more rows and sections if needed.*

# Governance

*(Please refer to section 4 of the grant application guidelines.)*

## Roles and Responsibilities of the Director and Co-Director

*Please insert text.*

## Roles and Responsibilities of the Network Partners

|  |  |
| --- | --- |
| ***Partner No., Institution Acronym,*** *Town, Country, Name of PI/Director, Role in Consortium (from table in section 2.1 and 2.2)* | |
| Expertise and experience |  |
| Geographical coverage |  |
| Partner’s contribution to overall network (role & responsibility) |  |
| ***Partner No., Institution Acronym,*** *Town, Country, Name of PI/Director, Role in Consortium (from table in section 2.1 and 2.2)* | |
| Expertise and experience |  |
| Geographical coverage |  |
| Partner’s contribution to overall network (role & responsibility) |  |

*Please add (copy & paste) as many sections as needed.*

## Governance Structure, Project Coordination and Monitoring

*Please insert text and organisational chart.*

# Overarching Work Package: Research

*(**For each research task other than interventional clinical trials, provide the information in section 5.1 and copy and paste this entire blank section for additional tasks if needed. For interventional clinical trials, please provide the information in section 5.2 and duplicate it if necessary.)*

## Research Task 1: *“Title”*

*(Please refer to section 5.1 of the grant application guidelines.)*

### Summary

*Please insert text.*

### Task Leader and Contributing Scientists and Staff

|  |  |  |
| --- | --- | --- |
| **Task Leader** | | |
| **First Name, Surname** | **Partner Institution** | **Role/Responsibility** |
|  | *(Partner No., Institution Acronym from section 2.1 and 2.2)* |  |
| **Contributing Scientists and Staff** | | |
| **First Name, Surname** | **Partner Institution** | **Role/Responsibility** |
|  | *(Partner No., Institution Acronym from section 2.1 and 2.2)* |  |

*Add more rows if needed.*

### State of the Art and Own Previous Work

*Please insert text.*

### Work Plan Including Milestones

*Please insert a Gantt chart.*

### Methods and Resources

*Please insert text.*

### Ethics, Quality Assurance and Safety and Data Handling

*Please insert text.*

### References

*Please insert text.*

## Research Task 2: *“Title”*

*(Please refer to section 5.2 of the grant application guidelines.)*

### Summary

*Please insert text.*

### List of Personnel Involved in the Trial

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial Sponsor:** | | | | |
| **Trial Management** | | | | |
| **#** | **First Name, Surname** | **Partner Institution** | **Responsibility/Role** | |
|  |  | *(Partner No., Institution Acronym from section 2.1 and 2.2)* |  | |
|  |  |  |  | |
| **Trial Statistician** *(It is mandatory that a trial statistician is included!)* | | | | |
| **#** | **First Name, Surname** | **Partner Institution** | | **Signature[[2]](#footnote-3)** |
|  |  | *(Partner No., Institution Acronym from section 2.1 and 2.2)* | |  |
| **Trial Supporting Facilities** | | | | |
| **#** | **First Name, Surname** | **Partner Institution** | **Responsibility/Role** | |
|  |  | *(Partner No., Institution Acronym from section 2.1 and 2.2)* |  | |
|  |  |  |  | |
| **Recruiting Centres** | | | | |
| **#** | **First Name, Surname** | **Partner Institution** | | **Expected No. of Patients** |
|  |  | *(Partner No., Institution Acronym from section 2.1 and 2.2)* | |  |
|  |  |  | |  |
| **Total Sum of Recruited Patients:** | | | |  |
| **Data Monitoring and Safety Board (DMSB)** | | | | |
| **#** | **First Name, Surname** | **Affiliation** | | |
|  |  |  | | |
|  |  |  | | |
|  |  |  | | |

### State of the Art and Own Previous Work

*Please insert text.*

### Study Synopsis

|  |  |
| --- | --- |
| **PRINCIPAL INVESTIGATOR** | *In case of multiple involved partners, the principal investigator/coordinating investigator of the trial who will assume responsibility for conducting the interventional clinical trial should be listed first.* |
| **TITLE OF STUDY** |  |
| **STUDY TYPE** | *e.g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/crossover* |
| **CONDITION** |  |
| **MEDICAL PROBLEM/ NEED FOR THE TRIAL** |  |
| **OBJECTIVE(S)** | *Which principal research questions are to be addressed? Specify clearly the primary hypothesis of the trial that determines sample size calculation.* |
| **INTERVENTION(S)** | Experimental intervention/index test:  Control intervention/reference test:  Duration of intervention per patient:  Follow-up per patient:  Experimental and/or control off label or on label: *refer to national African authorities or to WHO, FDA, EMEA or BFARM* |
| **KEY INCLUSION AND EXCLUSION CRITERIA** | Inclusion criteria:  Exclusion criteria: |
| **OUTCOME(S)** | Primary efficacy endpoint:  Key secondary endpoint(s):  Assessment of safety: |
| **STATISTICAL ANALYSIS** | Efficacy/test accuracy:  Description of the primary efficacy/test accuracy analysis and population:  Safety:  Secondary endpoints: |
| **SAMPLE SIZE** | To be assessed for eligibility (n):  To be allocated to trial (n):  To be analysed (n): |
| **TRIAL DURATION** | Time for preparation of the trial (months):  Recruitment period (months):  First patient in to last patient out (months):  Time for data clearance and analysis (months):  Duration of the entire trial (months): |
| **PARTICIPATING CENTERS** | To be involved (n):  Signed agreement to participate (n): |

*Add more rows if needed.*

*Please provide a chart indicating the Intervention Scheme/Trial Flow.*

### Justification of the Design Aspects

*Please insert text.*

### Work Plan Including Milestones

*Please insert a Gantt chart.*

### Ethics, Quality Assurance and Safety and Data Handling

|  |  |
| --- | --- |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1 and 2.2)* | |
| Ethical issue(s), ethical board |  |
| Quality assurance, monitoring, safety issues, stopping rules |  |
| Data collection, storage and handling |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1 and 2.2)* | |
| Ethical issue(s), ethical board |  |
| Quality assurance, monitoring, safety issues, stopping rules |  |
| Data collection, storage and handling |  |

*Add more rows and sections if needed.*

### References

*Please insert text.*

## to 5.x Research Tasks 3 to x: *“Title”*

*(Please copy and paste additional forms, either from section 5.1 or 5.2.)*

# Overarching Work Package: Capacity Building

*(Please refer to section 6 of the grant application guidelines.)*

## Capacity Building and Strengthening

|  |  |  |
| --- | --- | --- |
| **WP Leader: *Name, Institution Acronym*** *(if applicable; from table in section 2.1)* | | |
| **Capacity Tasks** | **Milestones**  to ensure capacity building and strengthening | **Milestone Year** |
| ***Partner No., Institution Acronym****, Country**(from table in section 2.1)* | |  |
| 1. |  |  |
| 2. |  |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |  |
| 1. |  |  |
| 2. |  |  |

*Add more rows and sections if needed.*

## Impact, Future Potential and Sustainability

*Please insert text.*

# Overarching Work Package: Networking

*(Please refer to section 7 of the grant application guidelines.)*

## Network Strengthening

|  |  |  |
| --- | --- | --- |
| **WP Leader: *Name, Institution acronym*** *(if applicable; from table in section 2.1)* | | |
| **Networking Tasks** | **Milestones**  to create/strengthen linkages, networks and collaborations | **Milestone Year** |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |  |
| 1. |  |  |
| 2. |  |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |  |
| 1. |  |  |
| 2. |  |  |

*Add more rows and sections if needed.*

## Impact, Future Potential and Sustainability

*Please insert text.*

# Overarching Work Package: Policy Engagement and Research Transfer

*(Please refer to section 8 of the grant application guidelines.)*

## Assessment of Current Health Policy Strategies, Gaps and Shortcomings

*Please insert text.*

**Current Relevant Policymakers and Stakeholders**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Current Policymakers and Stakeholders** | | | | |
| **First Name, Surname** | **Institution** | **Contact Details** | **Involvement in the Network** | **Other/please specify** |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | | | | |
|  |  |  |  |  |
|  |  |  |  |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | | | | |
|  |  |  |  |  |

*Add/remove lines/rows as needed.*

## Planned Milestones

|  |  |  |
| --- | --- | --- |
| **WP Leader: *Name, Institution acronym*** *(if applicable; from table in section 2.1)* | | |
| **Policy and Transfer Tasks** | **Milestones**  to strengthen policy engagement and research transfer | **Milestone Year** |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |  |
| 1. |  |  |
| 2. |  |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |  |
| 1. |  |  |
| 2. |  |  |

*Add more rows and sections if needed.*

## Impact, Future Potential and Sustainability

*Please insert text.*

# Management and General Aspects

*(Please, refer to section 9 of the grant application guidelines.)*

## Financial Management

*(African Partners only)*

|  |  |
| --- | --- |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |
| Accounting |  |
| Contract award procedure for supplies and services |  |
| Internal and external control systems |  |
| Previous grant experience |  |
| ***Partner No., Institution Acronym,*** *Country**(from table in section 2.1)* | |
| Accounting |  |
| Contract award procedure for supplies and services |  |
| Internal and external control systems |  |
| Previous grant experience |  |

*Please add (copy & paste) as many sections as needed.*

## Data Management

*Please insert text.*

## Ethics, Gender and Regulatory Issues

*Please insert text.*

*Attach the signature sheet at the end of the full proposal and upload it as one PDF file.*

# Annexes

*(Please refer to section 10 of the grant application guidelines.)*

## Annex 1

*(One PDF file,* ***mandatory****)*

|  |  |
| --- | --- |
| **Files** | **Attached?** |
| a. Signed Draft Declaration of Collaboration |  |
| b. Letters of Support (LoS) of all Partner Institutions |  |
| c. Written Support of relevant Institutions/Authorities/External Partners indicating Type and Duration of the Support and/or Role in the Consortium |  |
| d. CVs of Director, Co-Director and other Principal Investigators |  |
| e. Declaration on Anti-Corruption |  |
| f. Declaration on Environmental Awareness and Equality |  |

## Annex 2

*(One Excel file,* ***mandatory****)*

|  |  |
| --- | --- |
| **File** | **Attached?** |
| Budget estimation |  |

1. Low, Medium, High [↑](#footnote-ref-2)
2. Signatures may be collected and submitted separately from application form [↑](#footnote-ref-3)