

Funding for the development of products for the prevention, diagnosis and treatment of neglected and poverty related diseases

14 July 2011

Guidelines for applicants

Please structure your application for funding as indicated below, answer all questions and keep in mind the selection criteria mentioned in the Annex.

1. Contact

1.1 Name and contact details of CEO

1.1 Name and contact details of main contact person

1.3 Name and contact details of person responsible for administration and finance

1.4 Internet address

2. The product (no more than 2 pages)

2.1 For what product are you requesting funding? (target groups, product features)

2.2 Why is the product needed in (which) developing countries, and how will it fill an existing gap?

2.3 How will the product contribute to the alleviation of poverty and the achievement of Millennium Development Goals (MDGs) 4 and 5?

2.4 What is the expected impact of the proposed product?

3. Product development partnership (PDP) activities (no more than 3 pages)

3.1 Purpose of the organisation (vision, mission and goal)

3.2 History of the PDP (track record):

- Cooperation within the PDP
- Scientific presentations
- Management capacity

- Perspectives on development policy
- What are your main achievements to date, and how do you justify the funding received to date? Please list the achievements in all areas of your work and describe how they correlate with the performance measurement framework used.
- Financial performance of the PDP (balance sheets, annual financial statements of the last 3 years, from all partners if possible)

3.3 What problems does the PDP address?

3.4 How does the PDP address the problems? What are your main problem solving strategies and activities?

3.5 What are the expected outputs and outcomes?

Please present your main (3-5) areas of activity for the next year and for the next 5 years.

Please state your primary outputs and outcomes and expected milestones for the next 5 years.

Please explain how your organisation measures its performance against the expected outputs and outcomes.

Please append a description of the basic structure of any performance analysis (including key milestones) used by the PDP.

Have other funders accepted the basic structure of the performance measurement and the key milestones?

3.6 Outline how you manage your portfolio.

Please include key decision points and milestones used to assess whether a project should remain in the portfolio. Also, please note who is involved in decision making, both on an individual project level and in terms of a strategic portfolio review. Please state how you handle conflicts of interest.

3.8 Who are the main beneficiaries of your work?

3.9 Describe your implementation strategy (support in the registration and prequalification) for market access.

4. Organisation (no more than 3 pages)

4.1 How is the PDP organised?

Please provide an organigram of the PDP and a description of the reporting and accountability rules for staff, management, boards and stakeholders.

Please append the terms of reference for your board and the (scientific) advisory committee.

Please state the current staffing level and specify the levels of qualifications of the management and staff.

Are there any significant gaps in current staffing levels that prevent you from delivering on your mandate? If so, what measures are you taking to close these gaps?

4.2 What are your mechanisms for due diligence (e.g. for costing and pricing) and what budget do you allocate for due diligence in order to improve the exchange of information in negotiations with the most important partners?

4.3 Please specify any interactions with other ministerial departments of the German Government.

5. Cooperating with actors/stakeholders (no more than 2 pages)

5.1 How do you work with the following institutions and persons, and how do they influence your work? (Duration and terms and conditions of cooperation)

- Partners in developing countries (political decision makers and researchers)
- Research and academic institutions in industrialised countries
- Industry - outline your strategy for negotiation on intellectual property issues and how this influences your partnerships. Are you generally able to follow principles of equitable licensing? If not, please justify/explain.
- Civil society
- Others (please note any other major stakeholder groups that you work with – e.g. international initiatives, such as Roll Back Malaria or other PDPs)
- Employees
- Management

5.2 Are any of your resources being used by others if not fully used by you (i.e. how is capacity being shared)? Are there plans for future use of research infrastructure after your planned trials? Do you use resources of others (e.g. laboratory facilities, clinical trial sites etc.)?

6. Evaluation of the PDP (no more than 3 pages)

6.1 Internal evaluation

How do you evaluate progress of your PDP?

Please describe your monitoring and evaluation plan.

Describe how you act upon conclusions and recommendations from internal evaluations.

6.2 How will indicators of performance measurement provide the basis for judging success?

6.3 Have you had any external evaluations (summarise only and append details if needed. Do not send copies of evaluations). If yes, how did you act upon the conclusions and recommendations?

6.4 Are there any plans for external evaluations in the next five years?

6.5 What are the mechanisms for quality management and quality control (e.g. in clinical trials, ethics, publication of results)?

7. The PDP in the wider development context (no more than 2 pages)

7.1 Economic aspects

What is the economic impact of the disease to be controlled by the proposed product?

What is the potential economic impact of the work of the PDP on growth and poverty in partner countries?

7.2 Social aspects

What impact does the PDP currently have on poor people?

What impact is the PDP expected to have in the future?

Which groups of poor people will benefit and how?

How does the PDP address aspects of gender, different age groups, vulnerable groups and hard to reach groups?

7.3 Considerations concerning the scientific community in developing countries

How can researchers in developing countries benefit from the work of the PDP?

7.4 Capacity building

Is capacity building part of your strategy? Please outline the development of infrastructure and human resources, transfer of knowledge (e.g. results from clinical studies that are potentially useful to the local health authorities) as well as technology transfer.

7.5 Local production

Who are your manufacturing partners in developing countries?

7.6 What will change as a result of the work of the PDP? And how will this contribute to the alleviation of poverty and, specifically, to the achievement of Millennium Development Goals (MDGs) 4 and 5?

7.7 Ethical issues

What ethical issues do you encounter and how do you address them?

7.8 Environmental considerations

What is the environmental impact of your work?

How do you manage potential environmental risks?

Are there any positive environmental impacts that could be built on and enhanced?

8. Risks (no more than 2 pages)

- 8.1 Do you carry out regular risk assessments? If so, please provide details.
- 8.2 Please specify up to 5 major risks which you have identified in your risk analyses.
- 8.3 How do you capture and manage risks, and how do you identify new risks?
- 8.4 What good practice principles or benchmarks do you use to manage risk?
- 8.5 How do you collaborate with partners in the identification, assessment and management of risk? How are risks shared between the PDP and its partners?
- 8.6 How do you deal with conflicts of interest?

9. Funding the PDP (no more than 6 pages)

9.1. Current funding (no more than 2 pages)

9.1.1 What are other donors' /partners' financial and/or non-financial contributions?

Please append a list of donors/partners including details of funding and a brief description of in-kind contributions provided by them. Please identify approved funding and projected funding commitments for the next five years.

9.1.2 What are your accounting and audit arrangements?

9.2 Financial planning (no more than 4 pages)

9.2.1 Please give an overview of your financial planning and append details, if required, in the annex. Please include:

Budget projections (scenarios: low, medium, high) for the next five years and summarise the major assumptions underlying each of the projections;

If available, budget projections for any periods of more than five years;

Budget projections should be broken down by type of expenditure (e.g. basic research, pre-clinical development, production process development, clinical trials, clinical trial capacity development, advocacy, legal and registration fees, etc.)

9.2.2 What, where and how large are the main funding gaps for your proposed work plan?

9.2.3 What difference will BMBF funding make?

10. Technical Annex (no more than 10 pages)

Please add a technical annex of up to 10 pages on the scientific basis of your proposed product and progress made to date. This annex will be given to an international expert council for peer review and should be written for a specialist readership. You should append up to five references.

The annex should include a brief but realistic assessment of the progress of other programmes pursuing the same goals. The peer reviewers will give a judgement on whether

the PDP's estimates of scientific success are realistic, on the likely impact of the product on public health and a comparison with other approaches to the same problem.