BactiVac Catalyst Project Applications Guidance

Summary

A principal aim of the BactiVac Network is to accelerate the development and progression of vaccines against bacterial pathogens, particularly those that are of most relevance to low and middle-income countries (LMICs).

To achieve this aim we have funding available to support grants for pump-priming projects. These will typically be for a maximum of £50,000 of funding and usually run for 6 months and up to a maximum of 12 months. Exceptionally, we will consider projects up to a value of £100,000 over a 12 month period of funding as part of this initial funding call. Funding awarded will be at 80% fEC for academic institutions in the UK and at 100% fEC for other institutions. The purpose of these catalyst funds is to promote new collaborations and partnerships resulting in the preliminary data necessary to attract further, more substantial, funding leading to long-lasting and beneficial partnerships that grow bacterial vaccinology.

Membership of the BactiVac Network is a prerequisite when applying for these funds, with at least one member of the partnership being based in the UK (for free membership apply here). Projects will be awarded based on their scientific excellence via open calls announced through the BactiVac Network. Applications will be scored according to the scientific merit (50%), facilitation of cross-network collaborations (especially with LMIC and/or industry partners, 30%) and strategic impact for the Network (20%).

Applications should be made using the application form available on the website and, in addition to the points raised above, projects will be prioritised against the following criteria (equally weighted):

- The generation of novel partnerships between UK and LMIC partners
- The generation of novel partnerships between UK and industry partners (applications where the lead applicant is industry based are strongly encouraged in this initial round of catalyst funding)
- Projects that involve partnerships between diverse network members, particularly those that include partners from LMICs and industry
- Projects with a focus on the development of a vaccine against bacterial pathogens that are of interest/aligned to UK Health
- Projects that target the exploratory to pre-clinical and clinical transitional bottlenecks
- Projects that demonstrate a clear plan as to how the partnership will grow and be competitive for further funding – EXCEPTIONALLY, well-defined short-term projects will be considered
- Projects that demonstrate that research governance is already in place (e.g. collaboration agreements / intellectual property (IP) considerations).

All awardees will be required to submit narrative and financial reports at the project mid and end points (e.g. 6 and 12 months for a 12 month project).

Queries regarding the application process should be sent to bactivac@contacts.bham.ac.uk or by telephone on +44 121 414 6973.

Details

1. Funding eligibility

1.1. **Applicants:** Funding is available for BactiVac Network members only (for free membership apply here). Proposals must include a minimum of two BactiVac Network members from different institutes, with one member of the partnership being based in the UK.

1.2. **Value of grant:** each catalyst project award will typically be for a maximum of £50,000 of funding (over a 6-12 month period). Exceptionally, we will consider funding projects up to a value of £100,000 (over a 12 month period) as part of this initial funding call. Projects should be costed on a full economic cost (fEC) basis. Please note, BactiVac is funded by the UK's Medical Research Council (MRC) as part of the GCRF Networks in Vaccines Research and Development initiative. As per the MRC rules, funding will be awarded at 80% fEC for academic institutions based in the UK (with the remaining 20% of their project costs match funded by their institution) and at 100% fEC for all other institutions, including applicants based in industry and LMIC countries.

1.3. **LMIC funding:** to be considered 'LMIC' you must be based for your work in an LMIC country. A list of LMIC countries can be found here; all listed countries are eligible.

1.4. **Activities supported:** all projects must be within the scope of the BactiVac Network and its remit (further information on this can be found on our website). Eligible costs include salaries (costed on a fEC basis, as described above), consumables, animal purchase & housing, sample shipment. Some travel costs for visits between collaborators is allowed if justifiable; costs stated must be reasonable and via economy class only. VAT is allowable when applicable. Costs must be in Great British Pounds (GBP). Total project funding requested must not exceed the maximum value allowed (see **section 1.2**).

1.5. **Activities not supported:** research outside the BactiVac objectives and remit; projects from non-members of BactiVac; PhD studentships; large equipment purchase (over £10,000); projects without collaboration between two or more institutes; Principal Investigator (PI) project supervision costs.

2. Application process

There will be at least three catalyst project grant calls within the BactiVac funding period which runs until August 2021. Dates associated with these calls will be advertised on the BactiVac website.

Complete the application form as directed on the form itself, adhering to the word limit where stated. Ensure you complete all sections, and make clear the importance and impact of your project to the acceleration of vaccines against bacterial pathogens. Make sure you attach all the required supporting documents (listed at the end of the application form).

The application form and supporting documents must be submitted by email by the closing date to the BactiVac Admin Team at bactivac@contacts.bham.ac.uk. You will receive acknowledgement of your application within two working days.

3. Application Review

All applications received in the funding round will go to the BactiVac Network Management Oversight Board (NMOB) for competitive assessment. NMOB members will review and score applications using a standard template. Applications will be scored according to the scientific

merit (50%), facilitation of cross-network collaborations (especially with LMIC and/or industry partners, 30%) and strategic impact for the network (20%). A list of NMOB members is available here. NMOB members do not input into discussions about an application where they have a conflict of interest (see below for details on conflicts of interest). Following review of all applications, a ranked list will be used to select applications for funding. Quorum for the review meeting is the NMOB Chair plus 5; the NMOB Chair will accept written reviews from members who cannot attend the meeting.

All information submitted is held in strictest confidence; all NMOB members have signed a confidentiality agreement as a requirement of their Board participation.

4. Conflict of Interest

Examples of a conflict of interest include NMOB members that are:

- Employed by the same institution as the applicant(s)
- Actively involved in research collaborations with the applicants(s)
- Working closely with the applicant(s), for example as a co-author or PhD Supervisor, or has worked closely in the last 4 years
- Holding a current position on the governing body of or an honorary position within the institution(s) of the applicant(s)
- In receipt of personal remuneration in excess of £5,000 per annum from the applicant's organisation
- Personal/family relationship with the applicant(s).

5. Notification of Review Results

Successful projects will be sent award letters confirming the funds available within 3 weeks of the NMOB decision. Projects must start within 3 months of the date of the award letter, so it is advised that any contractual issues between partners are discussed prior to grant submission.

Unsuccessful applicants will be informed as soon as possible and the BactiVac Admin Team may pass on specific feedback if available.

6. Post-award Administration

The University of Birmingham will issue a simple award letter contract for the awardee; projects may not start until this contract has been fully executed. Projects must start within 3 months of the date on the award letter and the actual start date must be confirmed to the BactiVac Admin team on bactivac@contacts.bham.ac.uk.

Before a project can start, applicants must consider whether a collaboration agreement is required for the project. If required, collaboration agreements must be in place before the project starts. As stated in the criteria listed in the summary section above, projects which already have these in place will be looked at favourably during the review process.

Funds must be spent as detailed on the application. Awardees are required to submit a short narrative and financial reports at the project mid and end points (e.g. 6 and 12 months for a 12 month project). These reports must be submitted to the BactiVac Admin Team before the grant funds will be released. Payment will usually be made as follows: 50% at project initiation (once the actual project start date has been confirmed to us), 40% on approval of the midpoint project report, 10% on approval of the end of project report. Payment will be for actual expenditure up to the value agreed in the original award letter. Funding will be awarded at 80% fEC for academic institutions based in the UK (with the

remaining 20% of their project costs match funded by their institution) and at 100% fEC for all other institutions, including applicants based in industry and LMIC countries.

BactiVac does not require receipts to be submitted but these **must** be kept by the host institution as they may be required for future audits. The awardee's host institution must follow their standard procedures for financial accounts. Any underspend on grants will be retained by BactiVac.

Awardees are encouraged to submit their project's results for publication in a peer-reviewed journal, or as a case-study. A non-confidential brief lay summary of the project's outcomes, taken from the final report, will be published on the BactiVac website and in other publicity.

7. Publicising outputs and Data Protection

Successful catalyst projects will be listed on the BactiVac website and in other promotional literature, with a non-confidential abstract outlining the work proposed. Any publications, outputs or downstream funding must acknowledge the catalyst funds awarded through BactiVac as follows:

"This work was supported by the Bacterial Vaccines (BactiVac) Network funded by the GCRF Networks in Vaccines Research and Development which was co-funded by the MRC and BBSRC."

Copies of applications will be made available to the BactiVac NMOB who will use information provided for reviewing the proposal and post-award administration. BactiVac may choose to publish further non-confidential details of awards, awardees, and information about successful projects.

All funding comes from the MRC, so to meet the Research Councils' obligations for public accountability and the dissemination of information, non-confidential details of awards may also be made available on the Research Councils' websites and other publicly available databases, and in reports, documents and mailing lists. The MRC will use this information for research related activities, including but not limited to, statistical analysis in relation to the evaluation of MRC funding, study of trends and policy and strategy studies. Recipients of catalyst awards may be required to attend and contribute to MRC events within relevant areas at the request of the MRC.

8. Use of Human Samples or Data

BactiVac expects all research involving human participants to be undertaken in accordance with MRC policies and guidance available from http://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/#ethics. These include:

- Good Research Practice (2012);
- Medical research involving adults who cannot consent (2007);
- Medical Research Involving Children (2004);
- Human Tissue and Biological Samples for Use in Research (2014);
- Personal Information in Medical Research (2000).

Independent Research Ethics Committee approval is required for research that involves human participants (whether patients or healthy volunteers) or records. Such approval is also required for certain studies of human tissues.

In the case of social science research, BactiVac recommends that award holders follow the ESRC Framework for Research Ethics (revised 2015) which highlights the responsibility of the research organisation for ensuring that the research is subject to appropriate ethics review.

Research involving human participants in developing societies presents specific ethical challenges and the MRC guidelines Research Involving Human Participants in Developing Societies must be followed.

Award holders whose research involves the removal, use or storage of human tissue as specified in the relevant legislation must:

- comply with the appropriate legislation, i.e. the Human Tissue Act 2004 and/or the Human Tissue (Scotland) Act 2006
- follow the relevant standards and Codes of Practice issued by the Human Tissue Authority (HTA) (the MRC Regulatory Support Centre has summarised these)
- follow the MRC guidance detailed in Human Tissue and Biological Samples for Use in medical Research (2014).

For research taking place outside the UK, in addition to UK guidelines local national guidelines and international best practice must be followed. All legal requirements for the import/export of biological materials must be adhered to.

9. Use of Animals

BactiVac supports the principles of the 3Rs (Replacement, Reduction and Refinement). Award holders are expected to abide by the core principles set out in the cross-funder guidance 'Responsibility in the use of animals in bioscience research: Expectations of the major research councils and charitable funding bodies' and GC2 of the RCUK Terms and Conditions.

The standards and principles of the Animals (Scientific Procedures) Act 1986 must be observed. All BactiVac awards are made on the absolute condition that no work that is controlled by the Act will begin until the necessary licences have been obtained from the Home Office (or equivalent body if work is outside the UK). When animals are purchased from commercial suppliers, in-country suppliers should be used wherever possible, to minimise the risk of suffering during transport.

All research involving non-human primates must comply with the NC3Rs Guidelines: Primate accommodation, care and use.

10.Genetically Modified Organisms (GMO)

National regulations and international best practice must be followed. Researchers who carry out genetic modification should be familiar with the legislative requirements and with the Scientific Advisory Committee on Genetic Modification (Contained Use) guidance.

11.Dangerous Pathogens

Research organisations accommodating projects involving the use of dangerous pathogens must comply with the safeguards recommended by the UK Advisory Committee on Dangerous Pathogens in their guidance 'Infection at work: controlling the risk', 'Biological Agents: the principles, design and operation of containment in a level 4 facility' and 'Biological agents: Managing the risks in laboratories and healthcare premises', as well as local national regulations.

12.Useful Resources

UK Government information on Overseas Development Agency (ODA) strategic objectives:

https://www.gov.uk/government/collections/official-development-assistance-oda--2

Further information on the 'Accelerating innovative healthcare and medicines' challenge identified as part of the UK government's investment in the areas of advanced therapies, medicines and vaccines development and manufacturing:

https://www.gov.uk/government/collections/industrial-strategy-challenge-fund-joint-research-and-innovation

List of LMIC countries (all listed countries count as LMIC):

http://www.oecd.org/dac/stats/documentupload/DAC%20List%20of%20ODA%20Recipients%202014%20final.pdf