Catalyst Project Funding Guidance

A principal aim of the BactiVac Network is to accelerate the development and progression of vaccines against bacterial pathogens, particularly those that are of direct 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 £70,000** of funding and **EXCEPTIONALLY** we will consider projects up to a value of £100,000, for which a **strong justification for support** must be provided.

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, in particular involving **LMIC partners**, 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). Applications will be scored according to their scientific merit (60%, including quality of the project and research people & environment), facilitation of cross-network collaborations (20%, especially involving LMIC partners) and strategic impact for the Network (20%, including research impact and routes to further funding).

All projects in this round must start by no later than 01 November 2025, with funds available from 01 October 2025.

Applications should be made using the application form available on the website. Projects will need to align to one of the following (you will need to indicate which of these apply within your application):

1. Projects that focus on pathogens with outbreak potential (**see Appendix 1** for further scope details)
2. Projects that advance the ability to tackle the global challenge of antimicrobial resistance (AMR) through the development of vaccines to bacterial pathogens.

In addition to the points raised above, projects will be prioritised against the following criteria (equally weighted):

- Projects that target the exploratory to pre-clinical and clinical transitional bottlenecks
- The generation of novel partnerships between UK and LMIC partners (applications where the lead applicant is LMIC based are strongly encouraged in this round of catalyst funding)
- The generation of novel partnerships between UK and industry partners
- Projects that involve partnerships between diverse Network members, particularly those that include partners from LMICs and industry
- 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). BactiVac aims to fund a diversified portfolio of projects which catalyse research in bacterial vaccinology

All awardees will be required to submit narrative and financial reports at the project mid and end points (e.g. 3 and 6 months for a 6-month project). BactiVac will publish non-confidential information

relating to successful Projects on our website – please refer to our Privacy Policy.

All successful awards will be subject to the acceptance of our non-negotiable Terms and Conditions ***(* see footnote)*** – we would encourage all applicants to discuss these with the relevant departments in their institution at an early stage to avoid delays in award acceptance and initiation of the projects.

Please refer to our Frequently Asked Questions for further information. Queries regarding the application process should be sent to bactivac@contacts.bham.ac.uk.

Details

1. Funding eligibility

1.1. Applicants: Funding is available for BactiVac Network members only (membership is free - apply here). Proposals must include a minimum of two BactiVac Network members from different institutions, with one member of the partnership being based in the UK. Applications that are LMIC led and/or involve LMIC co-applicants, industry led and/or involve industry co-applicants, Early Career Researcher (ECR) led and/or involve ECR co-applicants are particularly encouraged. BactiVac is keen to receive applications for catalyst funding from members not funded in previous rounds of pump-priming awards. Applications should include a specified lead applicant with no more than 5 co-applicants. **Due to the funding regulations by which BactiVac must abide, please note that applicants from China (PRC) cannot be lead applicant (as our funding model is that all funds go via the lead applicant institution). Co-applicants from China (PRC) can be included on applications but as the Network is unable to provide any funding to China, such a co-applicant would not be eligible to apply for budget within the Application.**

1.2. **Value of grant:** each catalyst project award will typically be for a **maximum of £70,000 (100% full economic costing fEC)** of funding over a period of 6-months. **Exceptionally**, we will consider funding projects up to a value of £100,000 to a maximum of 12-months duration (100% fEC - this level of funding will require a strong case within the 'Resource Justification' section of the application form). Projects should be costed on a full economic cost (fEC) basis. Please note, BactiVac will award funding 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 (the list of LMIC countries is subject to change by the OECD).

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 but please note that (the list of LMIC countries is subject to change by the OECD).

1.4. **Scope/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). Projects will need to align to one of the following (you will need to indicate which of these apply within your application):

- Projects that focus on pathogens with outbreak potential (see Appendix 1 for further scope details)
- Projects that advance the ability to tackle the global challenge of antimicrobial resistance (AMR) through the development of vaccines to bacterial pathogens.

Eligible costs include direct salaries (costed on a fEC basis, as described above), consumables, animal purchase & housing, sample shipment. Some travel costs for visits between collaborators are allowed if justifiable i.e. directly supporting the delivery of the project; costs stated must be reasonable and via economy class only, and a detailed breakdown of travel costs and purpose must be provided. 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**). Total duration of the project must not exceed 12 months. All projects must **start no later than 01 November 2025** (with funds available from 01 October 2025)**.**

1.5. **Activities not supported:** research outside the BactiVac objectives and remit; research that will not deliver outputs/outcomes that are primarily of benefit to LMICs; projects from non-members of BactiVac; PhD studentships; large equipment purchase (over £10,000); projects without collaboration between two or more institutions; Principal Investigator (PI) and co-applicant project supervision costs; workshops/training events that are not critical for the direct delivery of the research project.

2. Application process

This will be BactiVac's eleventh round of catalyst project funding (details of projects funded in previous rounds can be seen here). 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, how the research will deliver outputs/outcomes that will primarily be of benefit to LMICs, how the project is focussed on pathogens with outbreak potential ***or*** on addressing the global AMR challenge, and your future plans to secure follow-on funding to take your research forward. Make sure you attach all the required supporting documents (listed at the end of the application form). The requirement to complete the Due Diligence Questionnaire is mandatory. Please note that the Lead applicant's institution will be expected to have completed due diligence and export control checks on all co-applicants and evidence of this will need to be provided to BactiVac, if their project is approved for funding, before any milestone payments are released by the BactiVac.

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 their scientific merit (60%, including quality of the project and research people & environment), facilitation of cross- Network collaborations (20%, especially with LMIC partners - applications where the lead applicant is LMIC based, industry based and/or an early career researcher are strongly encouraged in this round of catalyst funding) and strategic impact for the Network (20%, including research impact and routes to further funding). A list of current 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 and will be retained in accordance with our Privacy Policy; 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. Funding in this round will be available from 01 October 2025 and all projects must start within 1 month of the proposed start date provided on the application form but **no later than the 01 November 2025. To comply with the strict timelines, it is advised that any contractual requirements/issues between partners are discussed prior to grant submission**. We would also strongly advise that the Lead applicant's institution conducts the required due diligence and export control checks on all co-applicants ahead of the NMOB funding decision meeting as evidence that this has taken place will need to be provided to BactiVac before any milestone payments are released by the Network.

Notifications of award will be made no later than **30 September 2025.**

All successful awards will be subject to the acceptance of our non-negotiable Terms and Conditions (**** see footnote)*** - we would encourage all applicants to discuss these with the relevant departments in their institution at an early stage to avoid delays in award acceptance and initiation of the project.

In addition, lead applicants will be expected to ensure appropriate due diligence and export control requirements have been considered regarding the project including all partners. Any risks identified should be managed in accordance with the **UKRI trusted research and innovation principles** including appropriate legal permissions and licenses obtained where required before project start.

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 an award letter contract together with the non-negotiable Terms and Conditions of Award (**** see footnote)*** for the awardee; projects may not start until this contract has been fully executed and milestone 1 has been met with provision of all relevant documentation, including evidence of the Lead applicant institution's due diligence and export control checks on all project co-applicants. Applicants are given 1 month to return the signed award letter and supply the requested documentation. Projects must start within 1 month of the proposed start date on the application, and no later than 1 November 2025, and the actual start date must be confirmed to the BactiVac admin team on bactivac@contacts.bham.ac.uk.

Before a project can start, as well as ensuring the Terms and Conditions of Award ***(*see footnote)*** have been brought to the attention of the relevant department within your institution, 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 in the application. Following confirmation of Award and receipt of the signed Award documentation, the lead applicant will be provided with details on the financial invoicing schedule and any further documentation required to set up the given institution for payments to be made. Whilst every effort is made to process this documentation as quickly as possible, applicants should be aware that the first instalment payment is unlikely to be received until after the project has commenced. Awardees are required to submit a short narrative and financial reports at the project mid and end points (e.g. 3 and 6 months for a 6-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), 30% on approval of the midpoint interim project report, 20% 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 and/or must be returned to 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 in accordance with our Privacy Policy.

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, as well as updates with regard to information provided within the interim and final reports. All information will be used in accordance with our Privacy Policy, which also includes details of our document retention policy.

Any publications, outputs or downstream funding must appropriately acknowledge the catalyst funds awarded through BactiVac, in accordance with the Terms and Conditions of Award.

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, in accordance with our Privacy Policy.

BactiVac's core funding comes from the Medical Research Council (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.

All procedures must adhere to UKRIs policy on the use of animals in research, which requires work conducted to achieve equivalent welfare standards to work in the UK (https://www.ukri.org/wp-

content/uploads/2024/07/UKRI-110724-PolicyOnResearchAndInnovationInvolvingAnimalsMay2024.pdf).

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 appropriate local and national regulations and safeguarding.

12.Useful Resources

- BactiVac Catalyst Project Funding Application Guidance Document
- BactiVac Catalyst Project Funding Due Diligence Questionnaire
- BactiVac Catalyst Project Funding –Frequently Asked Questions
- BactiVac Privacy Policy
- BactiVac Terms and Conditions of Award
- List of LMIC countries *(all countries listed count as LMIC) -this list is subject to update by the OECD*
- UK Government information on Overseas Development Agency (ODA) strategic objectives

**** Please note revisions may occur prior to Award***

Appendix 1: Further details of scope <u>for projects that focus on pathogens with outbreak potential</u>

Applications should focus on one or more **bacterial pathogens with known outbreak potential**. Examples of these are listed below, although projects examining other pathogens may be supported depending on the justification provided:

- *Legionella pneumophila* (Legionnaire's Disease)
- *Mycoplasma pneumoniae*
- *Bordetella pertussis* (Whooping cough)
- *Burkholderia pseudomallei* (Melioidosis)
- *Corynebacterium diphtheriae* (Diphtheria)
- *Shigella dysenteriae* type 1
- *Campylobacter*
- *Brucella* spp (Brucellosis)
- *Listeria monocytogenes* (Listeriosis)
- *Coxiella burnetii* (Q fever)
- Scrub typhus
- *Bacillus anthracis* (Anthrax)
- *Francisella tularensis* (Tularemia)
- *Yersinia pestis* (Plague)

Or an, as yet, unknown bacterial 'Pathogen X', with outbreak potential.

Within the above remit of bacterial pathogens with outbreak potential, the following types of projects will be considered:

1. Specific vaccine development projects
2. Vaccine Technology Platform studies:
    a. Comparative Technology Platform studies
    b. Conjugation/bioconjugation/synthetic conjugates
    c. mRNA/viral vectors
    d. OMV
    e. Protein/adjuvant formulations.
3. Adjuvant platforms & routes of delivery:
    a. Adjuvant exploratory studies
    b. Vaccination route comparisons – parenteral/mucosal immunity.
4. Immunoassays:
    a. Diagnostics aimed at supporting vaccine clinical trials
    b. Correlates of protection, DIVA (Differentiating Infected from Vaccinated Animals)
    c. Harmonization & standardization of immunoassays for clinical trials
    d. Development of International Standards.
5. Models:
    a. Animal models of bacterial outbreak infections
    b. Human challenge models of bacterial outbreak infection.
6. One Health:
    a. Zoonotic diseases focusing on pathogens that cross the animal/human species boundary and are pathogenic to humans

   b. Collaborations between veterinary and human vaccinologists.

7. Regulation:
   a. Regulation targeted at rapid global advancement of bacterial outbreak vaccines
   b. Building on experience from regulation related to viral outbreak pathogens.

8. Manufacturing:
   a. Approaches to enable rapid manufacturing and scale-up of vaccines targeting bacterial outbreak pathogens.
   b. Approaches that address bacterial outbreak responses.