





VALIDATE Pump-Priming Grant Application Guidance

Summary

The VALIDATE Network aims to accelerate vaccine research and development for complex intracellular pathogens that cause diseases significant to low and middle-income countries (LMIC), with an initial focus on *Mycobacterium tuberculosis, Leishmania spp, Burkholderia pseudomallei* and *Mycobacterium leprae.*

Grants are available for pump-priming projects of up to £50,000 (plus up to 15% indirect costs) via competitive application to the Network Management Board (NMB). Projects should run for a maximum of 12 months and should lead to relevant and useful data for the field, or produce pilot data that will lead to a larger grant application to an external funder. Projects must be scientifically excellent, and fall within the VALIDATE remit.

Please note that for the 2022 pump-priming call, only research focused on tuberculosis vaccine development is eligible. Any aspect of research that will accelerate development of an efficacious TB vaccine is eligible, including biological, physical and social sciences, and humanities.

Awards are open to all VALIDATE and CTVD members, but projects must be led by a VALIDATE Associate or CTVD Early Career Researcher. All collaborators must be VALIDATE or CTVD members.

We particularly welcome projects including any of the following: new collaborations between VALIDATE and/or CTVD members, projects involving collaborators from more than one institute, projects including Early Career Researchers, projects led by and/or including LMIC partners, projects with industry involvement, cross-discipline research, projects promoting the One Health agenda, *in vivo* research, and translational research.

All awardees will be required to submit narrative and financial progress reports at 6 and 12 months. All awardees must agree to sharing unpublished and published project data set information on the VALIDATE shared data list to accelerate the progression towards development of efficacious vaccines for tuberculosis.

Please submit your application form and associated documents **as one pdf** by 4pm GMT on the closing date to the VALIDATE Network Manager, Samantha Vermaak, at <u>VALIDATE@ndm.ox.ac.uk</u>. All documents must be in English. Please see the further details below about this award and how to apply. Do contact Sam with any further queries.

Details

Funding eligibility

Applicants:

- Funding is for VALIDATE Network and/or CTVD members only.
- Projects must be led by a VALIDATE Associate member; or a post-doctoral scientist working on research directly related to TB vaccine development who is nominated by a CTVD member.

- The lead applicant must name a Senior Scientist who can support them as a mentor/sponsor (or co-applicant) with the planning, management and running of the project. This could be a Senior VALIDATE or CVTD member, your line manager or Head of Department. If you do not have someone relevant then please state this and VALIDATE and CTVD will help you find relevant support if your application is successful (this will not affect the review of your application).
- We strongly encourage all ECRs working on a project to be named co-applicants.
- Applications must include a letter of support from all co-applicant ECRs' Research Group Leader/Line Manager (to confirm they are happy for the ECR to take the time needed for the project if successful).
- Members based at academic institutes, governmental organisations, and non-governmental organisations are all eligible for funding and to lead/collaborate on a project.
- Members based in industry are eligible for funding and to be collaborators on a project, although they are not expected to be lead applicants.
- All applicants and co-applicants must be VALIDATE or CTVD members (for free VALIDATE membership apply <u>here</u>).

Value of grant and timeframe:

- Maximum total project budget is £57,500, consisting of:
 - o Direct costs: must not exceed £50,000, plus
 - Indirect costs (overheads): must not exceed 15% of direct costs (maximum total £7,500)
- Each institute's costs must be listed as separate budgets on the application form.
- Projects should run for a maximum of 12 months.

Eligible costs:

- All projects must be within the scope of the VALIDATE network and its remit (further information on this can be found on our <u>website</u>).
- Projects must be distinct from work previously funded by VALIDATE and/or CTVD.
- Research must contribute to knowledge that will accelerate the development of efficacious tuberculosis vaccines.
- Eligible costs include salaries, consumables, animal purchase & housing, sample shipment. Some travel costs for visits between collaborators are allowed if justifiable; costs stated must be reasonable and via economy class only.
- VAT is allowable.
- Costs must be in Great British Pounds (GBP).
- Please explain the costs your budget consists of, how you calculated your budget costs, and how these costs relate to your project, in the resource justification section of the application form.

Activities and costs not supported: research outside the VALIDATE objectives and remit; projects not focussed on TB research; projects from non-members of VALIDATE/CTVD; PhD/MSc/Undergraduate projects; equipment purchase.

Application process

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 tuberculosis. Make sure you attach all the required supporting documents (listed in section 12 of the application form). Any other appendices will not be accepted and will be excluded from your application. The application form and required supporting documents must be submitted **as a single pdf** by email by 4pm GMT on the closing date to the VALIDATE Network Manager at <u>VALIDATE@ndm.ox.ac.uk</u>. You will receive acknowledgement of your application within two working days.

Use of Human Samples or Data

VALIDATE expects all research involving human participants to be undertaken in accordance with UKlevel ethical behaviour (as VALIDATE HQ is UK-based), as well as international good practice and all local and national regulations and guidelines for where the research takes place. 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)
- Research involving human participants in developing societies presents specific ethical challenges and the <u>MRC guidelines Research Involving Human Participants in Developing Societies</u> must be followed
- 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.

A good resource for our expectations can be found at <u>http://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/#ethics.</u>

In the case of social science research, VALIDATE recommends that award holders follow the <u>ESRC</u> <u>Framework for Research Ethics</u> which highlights the responsibility of the research organisation for ensuring that the research is subject to appropriate ethics review.

All projects should assess and mitigate the impacts of study participation on study volunteers/patients (e.g. potential for stigma, violence etc) in the application.

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, e.g. the Human Tissue Act 2004
- follow the relevant standards and Codes of Practice issued by the Human Tissue Authority (HTA) (the <u>MRC Regulatory Support Centre</u> has summarised these)
- follow the <u>MRC guidance detailed in Human Tissue and Biological Samples for Use in medical</u> <u>Research</u> (2014).

All legal requirements for the import/export of biological materials must be adhered to.

Use of Animals

VALIDATE 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 (or local equivalent; whichever is more stringent).

For research in the UK, the provisions of the Animals (Scientific Procedures) Act 1986 must be observed (with equivalent local and international guidelines followed by those working outside the UK). All VALIDATE awards are made on the absolute condition that no work which is controlled by the Act will begin until the necessary licences have been obtained from the Home Office (or equivalent

VALIDATE Pump-priming grant application guidance document v5.0

body if work is outside the UK). Any recommendations arising from the VALIDATE review process with regards to animal use must be followed. When animals are purchased from commercial suppliers, incountry suppliers should be used wherever possible, to minimise the risk of suffering during transport.

All research involving non-human primates must comply with the <u>NC3Rs Guidelines: Primate</u> accommodation, care and use (or local equivalent; whichever is more stringent).

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 <u>Scientific</u> <u>Advisory Committee on Genetic Modification (Contained Use) guidance</u>.

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 <u>Infection at work: controlling the risk</u>, <u>Biological Agents: the principles, design and operation of containment in a level 4 facility</u> and <u>Biological agents: Managing the risks in laboratories and healthcare premises</u>, (or equivalent local guideline; whichever is more stringent) as well as local national regulations.

Application Review

All applications received in the funding round go to the VALIDATE Network Management Board (<u>NMB</u>) for competitive assessment. NMB members review and score applications using a standard template. NMB members will not participate in 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 is used to select applications for funding. Quorum for the review meeting is the NMB Chair plus 5; the NMB Chair will accept written reviews from members who cannot attend the meeting.

The VALIDATE Scientific Advisory Board (<u>SAB</u>) have oversight of the NMB and the NMB review of funding applications to ensure transparency, fairness and consistency. All information submitted is held in strictest confidence; all NMB and SAB members have signed a confidentiality agreement as a requirement of their Board participation.

Notification of Review Results

Successful projects will be sent award letters confirming the funds available within two weeks of the NMB decision. Projects must start within two 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 promptly and the Network Manager may pass on specific feedback if available.

Post-award Administration

The University of Oxford will issue a simple award letter, followed by a short contract for the awardee; projects must start within two months of the date on the initial award letter. Projects may not start until the fully executed contract is in place with University of Oxford; the actual start date must be confirmed to the Network Manager.

Project leaders must consider whether a collaboration agreement is required for the project. If required, collaboration agreements must be put in place before the research starts. These agreements

must not delay the completion of the project so we strongly advise you start collaboration agreement discussions and drafting promptly.

Funds must be spent as detailed on the application. Awardees are required to submit narrative and financial progress reports at 6 and 12 months into the project. These reports must be submitted to the Network Manager before the grant funds will be released. Payment is usually made in arrears to the awardee's Institute in two 50% tranches, on approval of the 6 and 12 month progress reports. Payment will be for actual expenditure up to the value agreed in the original award letter.

VALIDATE does not require receipts to be submitted but these <u>must</u> be kept by the host institution as they may be required for future audits. The grantee's host institution must follow their standard procedures for financial accounts.

Any underspend on grants will be retained by VALIDATE.

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 summary of the project's outcomes, taken from the final report, will be published on the VALIDATE website and in other publicity. A data set list of all data from funded projects must be sent to the VALIDATE Network Manager within six months of the end of the project, to be added to VALIDATE's shared data list to aid the progression towards development of efficacious vaccines for these pathogens.

Publicity and Data Protection

Successful pump-priming projects will be listed on the VALIDATE website and in other publicity, with a non-confidential abstract outlining the work proposed. Copies of applications will be made available to the VALIDATE NMB and SAB (and may be made available to CTVD and BMGF as our funders), who will use information provided for reviewing the proposal and post-award administration. VALIDATE, CTVD and the Bill and Melinda Gates Foundation may choose to publish further details of awards, awardees, and information about successful projects. VALIDATE projects are required to present their work at the VALIDATE Annual Meetings.

Conflict of Interest

Examples of a conflict of interest include:

- Employed by the same department in the same institution as the applicant(s)
- Close active collaboration impacting on the application being reviewed
- Holding a current position on the governing body of the applicant(s) organisation
- Personal/family relationship with the applicant(s)