

## 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*. The Network's priorities lie in cross-pathogen, cross-discipline, cross-species and cross-continent research, with the aim of making step-change progress towards efficacious vaccines targeting these pathogens.

Grants are available for pump-priming projects of up to £50,000 (at 100% FEC), 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.

**This is the final planned pump-priming call for VALIDATE, and the VALIDATE NMB strongly encourage collaborative projects led by and/or involving LMIC researchers.** In addition, we particularly welcome projects including any of the following: new collaborations between VALIDATE members, projects led by and/or including Early Career Researchers, projects with industry involvement, cross-pathogen research, cross-discipline research, projects promoting the One Health agenda, *in vivo* research, and translational research.

Awards are open to all VALIDATE Investigators and Associates, but projects must have at least one Investigator involved. Projects must include VALIDATE members (Investigator or Associate) from at least two different Institutes and all collaborators must be VALIDATE members.

All awardees will be required to submit narrative and financial reports at 6 and 12 months. All awardees must agree to sharing unpublished project data via the VALIDATE portal (a secure area only accessible to Network members who have signed the VALIDATE CDA) to accelerate the progression towards development of efficacious vaccines for these pathogens.

Please submit your application form and associated documents **as one pdf** by 4pm on the closing date to the Network Manager, Samantha Vermaak, at [VALIDATE@ndm.ox.ac.uk](mailto:VALIDATE@ndm.ox.ac.uk). 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 Investigators and Associates only.
- Projects must include a minimum of two Network members (Investigator or Associate) from different institutes.

- Projects led by an Associate (which is encouraged) must include at least one Network Investigator collaborator who will give them support and guidance in managing the project.
- We strongly encourage ECRs working on a project to be named co-applicants.
- One collaborator on the project must be based at a UK institute (they do not have to receive monetary funding but must contribute meaningfully to the project).
- Applications including Associates must include a letter of support from their Research Group Leader/Line Manager (to confirm they are happy for the Associate to take the time needed for the project if successful).
- Investigators/Associates based at academic institutes, governmental organisations, non-governmental organisations and industry are all eligible. [Non-LMIC organisations and all industry partners are funded at 80% and expected to provide 20% matched funding.]
- All partners must be VALIDATE members (for free membership apply [here](#)).

#### **Value of grant:**

- Project budgets can be up to £50,000 (at 100% FEC).
- Each institute's costs must be listed as separate budgets on the application form.
- VALIDATE is funded by the UK's Medical Research Council (MRC). As per the MRC rules:
  - non-LMIC applicants and all industry partners will be awarded 80% of costs and will be expected to have matched funding for the remaining 20% of their project costs
  - [LMIC](#) applicants will be awarded 100% of project costs

- **NB** overseas units associated with a UK University where the administering Centre is based within a UK Research Organisation, are classified as being UK-based and will be funded at 80% FEC. I.e. if the costs are charged directly by the LMIC organisation, these can be paid at 100% FEC; but if the costs are charged by the UK Partnering institution, then these costs are paid at 80% FEC.

This reduced amount acknowledges that the underpinning research infrastructure is already supported through core awards from either MRC or Wellcome. Affected institutes are: MRC Unit The Gambia at LSHTM, MRC/UVRI & LSHTM Uganda Research Unit, KEMRI-Wellcome Trust Research Programme, Malawi-Liverpool-Wellcome Trust Clinical Research Programme, The Africa Health Research Institute South Africa, Mahidol Oxford Tropical Medicine Research Unit in Thailand and Laos, and The Oxford University Clinical Research Unit in Vietnam.

**LMIC funding:** to be considered 'LMIC' you must be a national of an LMIC country and still be based for your work in an LMIC country (although your nationality and current residency do not have to be for the same LMIC). A list of LMIC countries can be found [here](#); all listed countries (in any column) are eligible.

#### **Activities supported:**

- All projects must be within the scope of the VALIDATE network and its remit (further information on this can be found on our [website](#)).
- VALIDATE will only fund research on our four focus pathogens.
- Eligible costs include salaries (at full economic costing [FEC]), 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).
- Total project cost (including matched funding) must not exceed £50,000.

**Activities not supported:** research outside the VALIDATE objectives and remit; projects from Affiliate members or non-members of VALIDATE; PhD/MSc/Undergraduate projects; equipment purchase; projects without collaboration between two or more institutes; projects without a UK-based collaborator.

**Indirect costs:**

- UK institutes may include FEC on salaries (including estates charges for research staff) but no other indirect costs are eligible (i.e you cannot charge a flat 20% indirects cost on the project, for example).
- Non-UK non-LMIC institutes may charge indirects equivalent to UK FEC on salaries.
- LMIC institutes (other than those associated to a UK institute) may charge either the equivalent of FEC on salaries, **or** up to 20% indirects on non-FEC salary costs, as a contribution to the institute's infrastructure costs. Other indirects are not eligible.

## **Application process**

This is the final pump-priming grant call planned for the MRC-funded period of VALIDATE.

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 VALIDATE target pathogens. Make sure you attach all the required supporting documents (listed in section 13 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 on the closing date to the VALIDATE Network Manager at [VALIDATE@ndm.ox.ac.uk](mailto:VALIDATE@ndm.ox.ac.uk). 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 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, VALIDATE 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.

## 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](#).

The provisions of the Animals (Scientific Procedures) Act 1986 must be observed. 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 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, 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](#).

## 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](#).

## 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.

## Application Review

All applications received in the funding round go to the VALIDATE Network Management Board ([NMB](#)) for competitive assessment. NMB members review and score applications using a standard template. NMB 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 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 ([SAB](#)) 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 2 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 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 project reports. Payment will be for actual expenditure up to the value agreed in the original award letter. LMIC applicants will be awarded 100% of project costs; non-LMIC applicants will be awarded 80% of costs and will be expected to have matched funding at their Institute for the remaining 20% of their project costs.

VALIDATE 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 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. All data from funded projects must be uploaded to the VALIDATE data portal within a timely fashion, and all data within six months of the end of the project 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 who will use information provided for reviewing the proposal and post-award administration. VALIDATE 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.

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 pump-priming awards may be required to attend and contribute to MRC events within relevant areas at the request of the MRC.

## **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)

## **Useful Resources**

UK Government information on ODA strategic objectives:

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

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

[http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/DAC\\_List\\_ODA\\_Recipients2018to2020\\_flows\\_En.pdf](http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/DAC_List_ODA_Recipients2018to2020_flows_En.pdf)