



## VALIDATE Fellowship 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*. VALIDATE also aims to facilitate Continuing Professional Development (CPD) and career progression amongst its members.

VALIDATE is proud to partner with the Collaboration for Tuberculosis Vaccine Discovery ([CTVD](#)). CTVD is an international network of scientists and experts dedicated to fostering innovation, cooperation, and collaboration in the up-stream TB vaccine discovery, translational research and development space. CTVD serves as the Bill & Melinda Gates Foundation's major mechanism for enhancing collaboration in the field.

To support these aims, three VALIDATE Fellowships will be available in this 2021 grant call (with funding taken up in 2022-2023). The VALIDATE Fellowships will fund two years' independent scientific research, with the aim of producing initial/pilot data and a funding and experience track record that can be used by the Fellow to go on to obtain independent external funding and launch their career as a Principal Investigator and/or Group Leader.

The Fellow's proposed research must be scientifically excellent, and fall within the VALIDATE remit. **Please note that for this 2021 Fellowship 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.**

Applicants must:

1. Be an Associate member of VALIDATE, and/or a post-doctoral scientist working on research directly related to TB vaccine development nominated by a CTVD member
2. Be a low/middle income country (LMIC) member (to be considered 'LMIC' you must be a national of an LMIC and be based 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 are eligible.)
3. Not have received a prior VALIDATE Fellowship

The VALIDATE Fellowships cover costs for 24 months' salary and consumables for the Fellow, up to a total maximum of £100,000 (plus up to 15% indirect costs). Relevant training costs, or travel costs to visit essential collaborators may be included within the consumables budget. Fellows will become a member of the VALIDATE Network Management Board to gain Board experience.

Fellowships are via competitive application to the VALIDATE Network Management Board ([NMB](#)). Please submit your application form and associated documents **as one pdf document** by 4pm GMT on the closing date to the Network Management Team at [VALIDATE@ndm.ox.ac.uk](mailto:VALIDATE@ndm.ox.ac.uk).

All Fellows will be required to submit narrative and financial progress reports at 6, 12, 18 and 24 months. All awardees must agree to listing unpublished project data sets on the VALIDATE website to accelerate the progression towards development of efficacious vaccines.

We strongly advise you to get input and seek help/guidance from more experienced Senior Scientists in your institute to review, and help you improve, your application prior to your submission. Ensure your application is focused, has clear objectives that are achievable within the timeframe, and that your hypothesis and methods are scientifically rigorous. You may need Institution/finance approval sign off for your application so ensure you leave plenty of time to obtain this prior to the call deadline.

Please see the further details below about this award and how to apply. Do contact the VALIDATE Network Manager, Sam Vermaak (Samantha.Vermaak@ndm.ox.ac.uk), with any further queries.

## Details

### Funding eligibility

**Applicants:** Funding is for VALIDATE Associate and CTVD Early Career Researcher members only. Members based at academic institutes, governmental organisations, non-governmental organisations and in industry are all eligible.

**Activities supported:** all proposed research must be within the scope of the VALIDATE network and its remit (further information on this can be found on our [website](#)).

### Budget and timeframe

Maximum total budget is £115,000, consisting of:

Direct costs: must not exceed £100,000, plus

Indirect costs: must not exceed 15% of direct costs (maximum total £15,000)

Fellowships should run for 24 months.

### Eligible costs:

The direct costs should cover 24 month's salary for the Fellow plus consumables. As well as lab consumables, the consumables can include animal purchase & housing, sample shipment etc. A small amount of costs for training (e.g. tech transfer from another VALIDATE/CTVD laboratory) or travel costs for meetings with essential collaborators may be included in the consumables budget if relevant and justifiable. Costs stated must be reasonable, and travel must be via economy class only.

Up to 15% of the total direct budget may be added additionally for indirect costs (overheads).

VAT is allowable.

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.

Costs must be in Great British Pounds (GBP). Note that the awardee institute is responsible for any currency exchange alterations/fluctuations, so please consider this carefully in your budget. If this poses a problem for your institute then please get in touch with the VALIDATE team **ahead** of your application submission.

**Activities & costs not eligible:** research outside the VALIDATE objectives and remit; applications from Investigator or Affiliate members, or non-members, of VALIDATE/CTVD; 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 a) of your proposed research to the acceleration of vaccines against tuberculosis, and b) that the Fellowship would have on your career. Make sure you attach all the required supporting documents (listed in section 13 of the application form).

The application form and supporting documents must be submitted **as one pdf** by email by 4pm GMT on the closing date to the VALIDATE Management Team 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 UK-level 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 but are not limited to:

- 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 [MRC guidelines Research Involving Human Participants in Developing Societies](#) 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 <http://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/#ethics>.

In the case of social science research, VALIDATE recommends that award holders follow the [ESRC Framework for Research Ethics](#) 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 Fellowship 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 [MRC Regulatory Support Centre](#) has summarised these)
- follow the [MRC guidance detailed in Human Tissue and Biological Samples for Use in medical Research](#) (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 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](#) (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 [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'](#), (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 ([NMB](#)) 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 ([SAB](#)) have oversight of the NMB and the NMB review of Fellowship 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 Fellows will be sent award letters confirming the funds available within two weeks of the NMB decision. **Your Fellowship must start within one month of the date of the award letter, so it is advised that any contractual issues between partners are discussed prior to your Fellowship 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 contract for the awardee; projects must start within one month 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.

Fellows 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 Fellowship 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, 12, 18 and 24 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 four 25% tranches, on approval of each project report. 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 **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.

Fellows 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 Fellowships 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 Fellowship 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, CTVD and the Bill and Melinda Gates Foundation may choose to publish further details of awards, awardees, and information about successful projects. VALIDATE Fellows 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)