

Tres Cantos Open Lab Foundation

Project Review and Approval Process

MARCH 2016

| Step | Details |
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| <p>Submission of proposals</p> <p><i>See appendix D for a general submission flow chart</i></p> | <ul style="list-style-type: none"> • Open Lab proposals can be submitted any time (rolling call) via the Tres Cantos Open Lab Foundation website (www.openlabfoundation.org) or directed to the GSK Sponsor, if already identified. • Proposals are of a standard format. If funding is required for the project then the request should follow the Foundation's funding guidelines (Appendix A) and the mobility requirement for the open lab researcher if already identified (Appendix B) • For applications through the website, a GSK Sponsor may be assigned by the Open Lab Manager. This Sponsor may meet with the potential collaborator to discuss the opportunity and assess initial fit against the selection criteria (i.e. the founding principles of the Foundation and the Open Lab strategy - Appendix C) |
| <p>Preliminary evaluation of proposals</p> | <ul style="list-style-type: none"> • All the proposals are reviewed by an Open Lab Review team composed of biology, pharmacology, medchem and open lab managers to ensure implementation feasibility and assess fit against the selection criteria. Key questions considered at this review are: <ul style="list-style-type: none"> - Does the project fit with the strategy and objectives of the Foundation? - What is the added value of the project operating within the open lab concept? - What is the GSK capacity to support the project in the Tres Cantos site (GSK DDW)? - Does the third party institution agree to the stated IP principles? - Are the funding requirements clear? - Input by a particular Governing Board member, may be obtained ahead of or after this review • Open Lab Review Team decisions may be: <ol style="list-style-type: none"> (1) Progressed to the Governing Board meeting evaluation as it stands (2) Progressed to the Governing Board meeting with some changes - the GSK Sponsor contacts the potential collaborator to discuss and implement these changes into the final proposal to the Governing Board. (3) Rejected - the submitter is informed of the outcome by either the GSK Sponsor (if there is one assigned) or by the Open Lab Manager. The possibility of re-submission, changing the proposal to fulfil Open Lab Review recommendations, is always open. |
| <p>Governing Board Review and Foundation endorsement</p> | <ul style="list-style-type: none"> • Regularly the Board meets to perform a high level review of the proposals to ensure overall quality of the science, portfolio and project selection • The Board makes recommendations to the Trustees • The Trustees approve or reject the proposals • The submitters are informed of the outcome in writing by e-mail (unless an original document is specifically requested in the application form) . |

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| Project set up | <input type="checkbox"/> The Home Institution accepts the Terms and Conditions of the Grants; then the Home and the Host Institution sign an Agreement to regulate the collaboration |
| | <p>terms. The Open Lab researcher adheres to this Agreement.</p> <input type="checkbox"/> The contractual/working permits, EHS, etc. procedures for the Open Lab researcher are fulfilled, and logistics organized. |
| Ongoing review | <input type="checkbox"/> The Project Leader and Mentor assigned to the project coordinate with the Principal Investigator at the Home Institution to give the project and the Open Lab researcher all the necessary scientific and technological support. |
| | <input type="checkbox"/> Projects are progressed in accordance with the agreed Work Plan. Each quarter, a progress report (milestones) is produced by the Open Lab researcher and issued to the Trustees and the Governing Board. |
| | <input type="checkbox"/> Assuming the project is on track then eligible project costs are reimbursed to the collaborating institute up to the maximum funding awarded. . Deviations should be flagged and if these are not resolved then they will be brought to the attention of the Trustees. |
| Closure | <input type="checkbox"/> Once the funded Open Lab project is complete, the Open Lab Foundation expects that the participant investigator leads and develops a strategy to progress the project in case of successful results. |

Appendix A – Guidance on Costs

General Funding rules:

- Funding, as approved by the Trustees of the Foundation, will cover personnel costs, travel costs, and accommodation expenses of visiting scientists during their stay in the GSK facilities. Other spends such as lab consumables, conference fees, attendance to meetings, etc. can be covered according to the project needs.
- In general, the Foundation has adopted a policy of zero overhead. Any exceptions to this policy will have to be justified for approval by the Trustees at the Governing Board review.
- Project funding is granted contingent on achieving key milestones.
- Typically, the Foundation expects that the project duration will range from minimum 4 months to maximum 24 months
- In general, it is anticipated that at least 50% of the project duration will occur in the facilities of the GSK DDW in Tres Cantos, Spain. Project activities running for up to half of the project duration may be conducted at the home institution, according to the capacities and/or expertise available at each site.
- Funding will be approved and transferred in GBP. Exchange rates differences are not eligible project costs.

Note that GSK will be providing in-kind contributions to the project, including, but not limited to:

- Use of premises (space), associated site costs and shared service support
- Lab supplies
- Pre-clinical development services (in vivo studies, Chem Dev, Pharm Dev)
- Compound screening
- Access to full compound collection as appropriate for project needs
- Access and support from a “GSK mentor” throughout the duration of the project □ Support from other scientists as project needs.

Specific funding rules:

- *Personnel costs:* Scientists’ salary will be calculated deducting all employer costs (social security contributions, life insurance if provided, canteen, etc) from the personnel costs awarded. The maximum funding per category has been set taking the FP7-Marie Curie funded personnel costs as a reference. The maximum costs funded are:

Technician: £37.696/year Degree: £41.165/year

PhD (<10 years post doctoral experience): £50.870/year PhD

(>10 years post doctoral experience): £76.087/year □

Operational costs: In consonance with its charity status, the Open lab Foundation adopts a zero overheads policy.

Notwithstanding, there are some administration and operational costs that are considered for funding:

- Shipment of materials and courier
- Researcher's visa expenses: medical checkups, Consulate administrative fees, local trips to get the visa, and others.
- Recruitment expenses: all those expenses regarding the recruitment of the scientists (advertising, contracting, etc)

Any other type of operational costs to be budgeted will be clearly detailed in the budget submission form.

- *Travel costs:* The maximum number of trips from the Home Institution to the Tres Cantos Open Lab covered for funding are:
 - Project duration up to 7 months: one round trip for each of the visiting scientists and leader investigators.
 - Project duration over 7 months: two round trips for each of the visiting scientists and leader investigators.

Reference for short-haul flights (within Europe) is £300 and for long-haul flights (outside Europe) is £1.000.

Reference for on-travel subsistence costs is £130/day.

- *Accommodation:* Accommodation during the scientists' stay in GSK DDW does not need to be budgeted in the proposal. Accommodation will be available from day of arrival and directly paid (rent and utilities) by the TCOLF external supplier Relocations España, provided that the scientist relocates to one of the flats administered in Tres Cantos. Accommodation at the home institution location, if needed, is not eligible for TCOLF funding.

□ **Appendix B – Open Lab Researcher eligibility rules**

- *Mobility:*
 - As a general rule researchers must not have resided or carried out their main activity (work, studies, etc) in Spain for more than 12 months in the 3 years immediately prior to the open lab application date. Compulsory national service and/or short stays such as holidays are not taken into account.
 - For Spanish academic and research Institutions the above rule will only be applicable if the Open Lab researcher is to be recruited for the project. Researchers already working for the Institution at the time of the original open lab application are exempted from complying with the mobility rule.
- Former Open Lab researchers are not eligible for that position (whether with the same or with a different home institution).

Appendix C - Open Lab Strategy and Founding Principles of the Foundation

Founding Principles

- To be a 'not for profit' entity funding research into medicines for diseases of the developing world
- Diseases of interest are Malaria, Tuberculosis, and Kinetoplastids Diseases (Leishmaniosis, Chagas and Sleeping Sickness)
- Funds are to be used to support activities within, or in collaboration with, the GSK open laboratory at Tres Cantos, Spain.

Open Lab Strategy

□ *Scope of the proposals*

The Tres Cantos Open Lab Foundation wishes to receive innovative proposals that will advance discovery or development of therapies for Malaria, Tuberculosis and Kinetoplastid diseases (Leishmaniosis, Chagas and Sleeping Sickness). The following aspects of drug discovery for these therapeutic areas are of particular interest, but proposals addressing other aspects are very welcome:

- Dissection of pathogen or host immunological pathways in order to identify potential therapeutic targets.
- Physiologically relevant models of disease that may be amenable to screening or prioritization of chemical entities.
- New chemical entities that target pathogen replication, transmission or human pathology.

□ *Technical Requirements*

- Be relevant to accelerating the discovery or development of therapeutic approaches for Malaria, Tuberculosis, Leishmaniosis, Chagas and Sleeping Sickness.
- Be feasible to be conducted at the home and the host institutions from the technological point of view.
- Be innovative in tackling one unmet goal in the concerned disease (e.g. malaria transmission blocking, radical cure of malaria infections caused by *P. vivax*, shorter treatment for MDR (multi drug resistant)-TB, a good and predictive physiological model of the disease for screen, new and better drugs to treat any of the kinetoplastid diseases, etc)

□ *Intellectual Property*

Grantees are committed to allocate IP arising from TCOLF supported projects to WIPO Re:Search, a "patent pool" for open innovation in neglected diseases, including Malaria and Tuberculosis, so that IP output is made available royalty free for research and marketing of drugs against neglected diseases in the least developed countries:

http://www.wipo.int/export/sites/www/research/docs/guiding_principles.pdf.

Appendix D – Submission Workflow

