Translational Award Outline Application Guidelines

How to apply:

Translational Award applicants must first submit an outline application. The purpose of the outline application is to ascertain whether the project aims, rationale and deliverability are appropriate.

Successful applicants will be invited to submit a full application.

Completing the outline application form:

The outline application form must be completed in partnership with your institution's Technology Transfer Office (TTO). We require a contact at your institution's TTO, who will contribute to the outline application.

- We expect the principal investigator to take the lead on defining the unmet need that the project seeks to address and the proposed solution for this need, the project's rationale and the project plan.

- We normally expect the TTO to take the lead on assessing the competitive landscape and intellectual property strategy for the project. The TTO should provide support to successful applicants in managing and exploiting intellectual property (IP) generated from the Translational Award. The award is competitive, so TTOs should only put forward projects with clear translational potential and well-thought out commercialisation strategies.

General points:

- Please complete the form in 11 point Arial font.
- Send the application as a pdf attachment to researchtranslation@bhf.org.uk. Please title the email: Preliminary_[Your surname]_[Project title].

Section 1: Project Summary

1.1 Title (20 words maximum).

1.2 Abstract (100 words maximum): state the unmet need, your proposed technology, the rationale for why your proposed technology is likely to meet the unmet need and your development plan.

1.3 Key differentiator (20 words maximum): summarise the key uniqueness or advantage of your project.

1.4 Conflicted reviewers: where appropriate, give names of reviewers, with justification, who you feel are unsuitable to review your application due to conflicts of interest.

Section 2: Contact Details

2.1 Principal Investigator: the individual who will take responsibility for the overall leadership and management of the project. S/he should work in an established research institution in the UK.

2.2 Co-applicant: an individual who works in an established research institution and who will make a significant contribution to the planning and/or delivery of the proposed work but not on a contracted/out-sourced basis.

2.3 Collaborator, academic: an individual who will supply technical advice or reagents but will not be involved in the day-to-day execution of the project. Outsourcing: parties who are undertaking work on a contracted/out-sourced basis e.g. contract research organisations (CROs).

Please contact a member of the Translational Research team (researchtranslation@bhf.org.uk) for advice about appropriate CRO contacts and further information about CROs, if needed.

2.4 Host Institute Technology Transfer Office Contact: a representative from the TTO who will manage the project and have an active role in maintaining and exploiting IP generated from a successful application.

Section 3: Project Details (3 pages maximum)

Points to consider:

3.1 Background:

- What is the clinical or product development need you are seeking to address? Please keep this section brief.
- What is your proposed technology and who is the target population?
- What are the competing solutions and their stages of development?
- What is the competitive advantage of your proposed technology?

3.2 Current status:

- Provide key points of validation and experimental evidence produced to date that provides the rationale for your proposed solution.
- Current IP status: please give details of any existing IP, including patents or patent applications.
- Anticipated IP: what is the IP strategy for further development agreed with your TTO? What new types of IP may arise during the project?
- Does the project have freedom to operate or are there any legal agreements with commercial, academic or other organisations that could present a freedom to operate problem in the future?
- Describe the nature of any patent searches or IP assessments made to date. How extensive have these been?

3.3 Proposed project plan:

- Structure the plan by milestone(s), including:

    - The overall estimated timeline for each milestone.
    - Details of key experiments / work to be done, including estimated timelines.
    - Estimated costs, indicating any outsourced costs or quotes e.g. from CROs.
    - Milestone end points or deliverables that will be used to determine whether the milestone has been met successfully. Refer to the 'Tips for Milestones' for further advice on milestone design.
    - How the project will be managed.
- De-risking the technology: explain how and why this Award will be sufficient to advance the technology to a state where follow-on investors would be interested.
- Next steps: assuming successful completion of all milestones, what would be the next steps to ensure progression of your technology?
- Longer term objectives: what is the proposed strategy for commercial uptake or clinical adoption? To what extent has this strategy been explored e.g. regulatory requirements, IP management, any commercial barriers, and potential partnerships? Describe your envisaged final commercial product and how it would be used in a clinical setting.

Tips for Milestones:

- A milestone is a key decision point within a project and can be either scientific or commercial e.g. completion of a specified set of experiments or a successful patent application.
- Milestones are designed to ensure that the project remains focused on well-defined goals and only continues if it is successful. Thus, for each milestone, all end points must be met for the project to progress.
- Milestones must be:
    - **Specific and Measurable**: include precise and quantifiable end points such as target value range and acceptable (cut-off) values e.g. 'Medicinal chemistry optimisation will produce a compound analog with EC_{50} <10 nM and LD_{50}> 5-fold above EC_{50}', and NOT 'Medicinal chemistry optimisation will produce compound analogs with improved potency and reduced toxicity.'
    - **Achievable**: objectives must be realistic in terms of feasibility and have timelines with deadlines.
    - **Relevant**: the targets you set for each milestone should reflect key decision points that will determine the project's progression. The end points at each milestone should be designed appropriately so that a clear decision can be made as to whether the project should progress or not. Rationale should be provided for the choices of *in vitro* and/or *in vivo* models, parameters to be tested and target quantitative values that will define each milestone(s).
    - **Time-framed**