**SINGAPORE THERAPEUTICS DEVELOPMENT REVIEW**

**2023 (SEP) GRANT CALL FOR PILOT LETTER OF INTENT**

|  |
| --- |
| **Project Title:***(Please note that the project title should be non-confidential as it might be shared publicly if your project is awarded for funding)* |
|  |
| **Name of Lead Principal Investigator:** |
|  |
| **Institution(s)** (please list primary institution, followed by other affiliated institutions)**:** | **E-mail Address:** | **Telephone No.:** |
|  |  |  |
| **Appointment(s)** (please list primary appointment, followed by others)**:** | **Percentage FTE** (please submit a waiver request if total appointment time in public sector research institutions is <70%): |
|  |  |
| **Name of Clinical Co-Investigator/Collaborator (if applicable):***(Note: this is optional but strongly recommended)* |
|  |
| **Primary Institution:** | **E-mail Address:** | **Telephone No.:** |
|  |  |  |
| **Name of other Co-Investigator\* (if applicable):** |
|  |
| **Primary Institution:** | **E-mail Address:** | **Telephone No.:** |
|  |  |  |
| **Name of other Collaborator\* (if applicable):** |
|  |
| **Primary Institution:** | **E-mail Address:** | **Telephone No.:** |
|  |  |  |

*\* Add rows as required*

**Note to applicants:**

* Applicants are required to submit their LOI applications electronically *via* iGrants to the “Singapore Therapeutics Development Review 2023 (Sep) Pilot” between **11 September 2023 and 26 October 2023, 1700 hrs**.
* It is mandatory for all applications to be submitted and endorsed by the Host Institution's Innovation & Enterprise Office (IEO) and Director of Research (DOR) by **26 October 2023, 1700 hrs**.
* We will not entertain any late submissions, or submissions from individual applicants without endorsement from the Host Institution’s IEO or DOR. Applicants are strongly encouraged to approach their respective IEO representatives and DOR early to give sufficient time to gather input and endorsement.
* All sections should be completed. All text should be in single spacing Arial font, 10 pt.
* Applications should be submitted in **pdf** format.
* More details on the grant call can be found in the **Singapore Therapeutics Development Review 2023 (Sep) – Information Sheet**, which can be downloaded from <https://www.a-star.edu.sg/Research/funding-opportunities/stdr>

**Eligibility criteria:**

* Applicants are required to fulfill the following criteria at the point of application:

The Lead Principal Investigator (PI) should:

1. Hold at least a 0.7 FTE primary appointment in a Singapore publicly funded research or tertiary institution[[1]](#footnote-1);
2. Have the relevant scientific/technical background and necessary experience to direct the project being supported by the grant
* Post-doctoral researchers who wish to apply for STDR should submit a letter from their supervisor, as part of the application submission on iGrants, declaring that:
1. The supervisor supports the post-doctoral researcher's STDR application,
2. The contract of the post-doctoral researcher covers the entire STDR grant period, and
3. The grant body that is funding the post-doctoral researcher is agreeable to their application for STDR grants (if relevant).
* Exceptions to eligibility criteria will be considered on a case by case basis with the submission of a waiver request. Please write to the grant secretariat **before** the submission of your application, at least 7 days before the grant deadline on 26 October 2023, i.e. 19 October 2023.

**Contact details:**

For more information, please contact:

|  |
| --- |
| **STDR Secretariat:** |
| STDR\_Secretariat@hq.a-star.edu.sg  |
|  |

**On confidential information:**

Relevant privileged or confidential information should be disclosed if necessary, to convey a better understanding of the project. However, such information must be clearly marked in the proposal.

1. **project details**

For platform technology projects, please fill in section I based on your chosen lead product.

|  |
| --- |
| **Single asset/lead or Platform technology:** |
| **Single asset/lead:** | **[ ]**  | **Platform technology:** | **[ ]**  |
| **Stage of development** |
| **Target Validation** | **Hit Generation** | **Hit-to-Lead** | **Lead Optimisation** | **Preclinical** | **Others** |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
| **Primary Indication:** |
|  |
| **Target Class:** |
| *E.g. Class A GPCR* |
| **Target Name:** |
| *E.g. HRH1* |
| **Proposed Therapeutic Approach:** |
| **Chemical (Small molecule)** | **[ ]**  | **Antibody or antibody fragment** | **[ ]**  | **Cell therapy** | **[ ]**  |
| **Gene therapy (e.g. Nucleic acid therapeutics)** | **[ ]**  | **Peptide or protein** | **[ ]**  | **Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­\_** | **[ ]**  |

1. **TYPE OF APPLICATION**
* **[ ]**  New STDR application – Please proceed to Section III.
* **[ ]**  Resubmission of previous STDR application(s) – Please complete the rest of Section II before proceeding to Section III.
1. **Details of previous STDR submission(s)**

Please provide your previous submission(s) and reviewer comments as annexes

|  |  |
| --- | --- |
| **Project title of previous submission** |  |
| **Date of previous submission** |  |
| **Please describe how you have addressed the reviewers’ comments in the current application** |  |

 \* Add rows as required for each previous submission

1. **LETTER OF INTENT**

In no more than **6 pages** (excluding images, tables and sections (a) and (k)-(m), single spacing, Arial font, 10 pt), describe the following sections in the research proposal.

1. **Please provide a non-confidential summary of your proposed research (max 250 words)**

*Provide an overall summary of the proposed research, including the target (if identified), evidence supporting therapeutic modulation of the target and the expected patient benefit.*

1. **Have you developed a platform technology (i.e. technology that can enable multiple applications or products)?**

**[ ]**  No – Proceed to fill out this application describing your application-specific product.

**[ ]**  Yes – If yes, please address parts (i) to (iii)

1. Describe the platform, how it enables drug development or production and its advantages

ii. Outline the opportunity matrix of possible therapies that can be developed using the platform.

iii. What specific application is your lead product in and why?

**Proceed to answer the questions in this application based on your chosen lead product.**

1. **Target Product Profile (TPP)**

Provide a preliminary TPP of the proposed therapeutic or product.

1. **Indication/Population (i.e. medical need)**

*Describe the target disease/indication or manifestation of a disease and/or population. What is the prevalence of the primary indication and addressable population, including secondary indications (if any)? Does this favour a specific subset of patients, or tackle a less explored pathway/a known pathway with a novel strategy?*

1. **Efficacy and potential adverse effects**

*What is its anticipated efficacy and potential adverse effects, particularly in comparison to the current standard of care? Why is it an improvement over the standard of care?*

1. **Mode of administration**

*What would be the dosing frequency and mode of administration?*

1. **Mechanism**
2. **Provide details of the molecule or mechanism being targeted (e.g. kinase, ion channel, receptor, protein-protein interaction etc.).**

**If you have a platform, please answer based on your chosen lead product.**

*Include information on where the target is expressed or present in healthy vs. diseased patients, and to which tissue and cellular compartment a therapeutic would be delivered (Is there any uncertainty regarding the mechanism of action?).*

*Please indicate structural information for target or ligand if any (Are there crystal structures or homology models? Has the target been screened previously? What is known about its native or synthetic ligands and their site of action?)*

1. **What evidence do you have that modulating the target would have a functional/therapeutic effect to the disease?**

*Please also describe the methods by which the target is validated as a driver of disease. These methods could include:*

* *RNA/protein expression data showing a correlation with the disease.*
* *Effect from target depletion/overexpression in vitro and in vivo (e.g. tissue specific KO animal models available.)*
* *Pharmacological modulation of target shown in cell-based assays and/or animal diseases models.*
* *Kaplan Meier patient survival data available correlating target expression and/or modulation.*
* *Human genetic linkage with disease through GWAS / SNP association.*
* *Clinical validation (of similar drugs; not applicable for first-in-class drugs.)*
* *Pharmacokinetics & toxicology assessment (maximum tolerated dose, drug-drug interactions, etc.)*
1. **Competitive Landscape**

*Why is this an attractive target or approach? Would this be a first in class approach? If not, what are the alternatives or competing technologies, and how is the proposed approach superior over existing technologies? Who else is working in the field? Elaborate on competitive landscape of your approach and differentiation between direct (same target, different compound) and indirect competition (different pathway, or different approach altogether e.g. surgery instead of drug treatment) for treating the disease.*

1. **Clinical Feasibility**

*Provide comments on the unmet need and clinical feasibility of the proposed approach, preferably from a clinical collaborator or partner. If there are no clinical collaborators, identify possible clinical collaborators that can help support the programme.*

1. **Research Proposal – Methods and approaches**

*Provide a summary of the hypotheses and methodologies, highlighting the novelty and originality of the concepts or approaches and the criticality of the experiment.*

*Provide a timeline of project milestones (Tables 1-2), indicative budget**[[2]](#footnote-2) (Table 3), expected outcomes (Table 4) and ethical considerations and containment (Table 5). Please use shading for the time points and add or delete rows as appropriate. Supporting data may be provided under section (l). The project should be separated into Phases 1 and 2 (each taking place not more than one year) with clear identification of go/no-go milestones at the end of Phase 1 that will determine whether Phase 2 funding can be unlocked.*

*Table 1: Phase 1 Proposed Milestones and Timeline*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase 1 Project Milestones/Deliverables***Applicants need not use the full year, and are encouraged to accelerate the project where reasonable.* | **Q1** | **Q2** | **Q3** | **Q4** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Go/No-Go milestones:** |

*Table 2: Phase 2 Proposed Milestones and Timeline*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase 2 Project Milestones/Deliverables***Applicants need not use the full year, and are encouraged to accelerate the project where reasonable.* | **Q1** | **Q2** | **Q3** | **Q4** |
|  |  |  |  |  |
|  |  |  |  |  |
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*Table 3: Indicative budget2*

|  |  |
| --- | --- |
| **Category** | **Budget** |
| **Phase 1** | **Phase 2** |
|  | ***Direct costs*** |
| **Manpower** |  |  |
| **Equipment** |  |  |
| **Other Operating Expenses** |  |  |
| **Overseas Travel** |  |  |
| **Direct Costs (Total)** |  |  |
|  | ***Indirect costs*** |
| **Indirect Costs (30% of direct costs)** |  |  |
|  | ***Total (direct + indirect costs)*** |
| **Budget for each Phase** |  |   |
| **Total budget (Phase 1 +2):** |  |

*Table 4: Expected Outcomes*

|  |
| --- |
| **EXPECTED OUTCOMES***Please indicate your realistic expectations on the outcomes of this grant. Please state ‘NA’ where indicator is not applicable.* |
| Performance Indicators | Indicate number/ value |
| Capability Indicators | Developing long term R&D capability | Invention disclosures |       |
| Proof-of-concept studies in man |       |
| Kick-start clinical treatments/therapeutics |       |
| Patents filed |       |
| Patents granted |       |
| Patents commercialised |       |
| Papers published in international journals (To state impact factor) |       |
| Presentations at international conferences |       |
| Awards for research at national and international level |       |
| Industry Relevance Indicators | R&D collaboration | R&D projects with industry cash funding |       |
| Industry dollars received or in-kind contributions for Project |       |
| Outcomes | Revenue from royalties and licensing agreements |       |
| Spin-off companies registered |       |
| Licences |       |
| Follow-on funding from another translational grant agency |       |
| Follow-on funding from venture capitalists |       |
| New products or processes commercialised |       |

*Table 5: Ethical Considerations and Containment*

|  |
| --- |
| **ETHICAL CONSIDERATIONS AND CONTAINMENT** *Fund disbursement is subjected to ethics approval if the project involves any of the below.* |
| *Please check the box Yes or No if programme involves any of the following:* | Please declare the participating institutions where study requiring ethics approval is conducted: |
| a) | Human Subject | [ ]  Yes [ ]  No |       |
| b) | Use of Human Material/Animal Tissues or Cells from Primary Donors (i.e. subject/volunteers recruited for project) | [ ]  Yes [ ]  No |       |
| c) | Use of Commercially Available Human Material/Animal Tissues or Cells | [ ]  Yes [ ]  No |       |
| d) | Animal Experimentation | [ ]  Yes [ ]  No |       |
| e) | Requirement for Containment | [ ]  Yes [ ]  No |       |
| f) | Multi-centre trial(s) | [ ]  Yes [ ]  No |       |
| A copy of the ethics approval is attached | [ ]  Yes [ ]  No |       |

1. **Intellectual Property (IP)**

*Describe your IP in this area and any other prior art. What is the funding source behind any background IP, and are there any obligations? State if the background IP is co-owned. Highlight any potential encumbrances or issues with Freedom to Operate (FTO)/competitor patents, or with pre-existing background IP that is not generated in Singapore or already licensed to other companies. Is there potential for new IP to be developed in Singapore with the grant funding?*

1. **Plans for Commercialisation**
2. **Commercialisation Roadmap**

*What is your commercialisation strategy (e.g. spin-offs, out-licensing, co-development with industry partners)? Identify the critical path of work, points of go/no-go decisions, and important value inflection points that would help demonstrate progress in success and reduction of uncertainty. Please describe your roadmap in the context of a timeline and specific potential partners, for example: out-licensing, the formation of new commercial enterprises, co-development with industry funding.*

1. **Discussions with strategic partners, if available**

*Who are the strategic partners (e.g. national platforms, pharma companies, investors) you have identified, and have you approached them? Which commercialisation partners and/or investors have you initiated discussions with? Please provide any letters of endorsement or feedback from potential investors or commercialisation partners, if available. If discussions have been initiated, please provide details in Table 6 on the organisation(s) involved, when the discussion took place and what feedback was provided.*

*Table 6: Significant milestones in discussions with strategic partners*

|  |  |  |
| --- | --- | --- |
| **Significant milestones** | **Tick if relevant** | **Details of discussion** *(e.g. who and/or which organisation, when the discussion took place, what feedback was provided, conditions of the collaboration (if any), deadline for a signed agreement (if in discussion))* |
| Have not started engagements with potential partners | **[ ]**  |  |
| Presented concept/proposal to potential partner or commercial entity  | **[ ]**  |  |
| Partner or commercial entity has agreed to collaborate | **[ ]**  |  |
| Signed agreement (e.g. RCA, LOI, term sheet) with partner or commercial entity | **[ ]**  |  |

1. **Regulatory pathways and potential barriers**

*Is there a regulatory pathway and how will your work address regulatory requirements? Are there any potential obstacles or barriers to commercialisation?*

1. **Funding streams**

*Please highlight prior funding streams (sources, values, scope of project, outcomes) in Table 7, including any grants applied in which the outcome is pending. Highlight if there is any potential overlap of the above funding with this application. Note that double-dipping is strictly prohibited. For any overlap, please explain how it would be managed.*

*Please include anticipated funding requirements (sources and values) subsequent to the lifetime of this project in Table 8.*

*Table 7: Prior funding streams relevant to project*

|  |  |
| --- | --- |
| **Title of Research**  |  |
| **Scope of Project** |  |
| **Details of Funding (Application ID, Source of funding, Amount, Support period (years))** |  |
| **Outcome of Project** |  |

 *\* Add rows as required for each funding stream*

*Table 8: Anticipated funding subsequent to STDR project*

|  |  |
| --- | --- |
| **Source of Support**  |  |
| **Anticipated Value** |  |
| **Anticipated Scope** |  |

 *\* Add rows as required for each funding stream*

1. **References**

*List the references in the order cited in this proposal. Please attach 2 to 5 key references as PDF files (e.g. related publications) in your submission and indicate in the list which references were attached. If your files exceed the size limit, please try to compress the files.*

1. **Supporting data, if any**
2. **Curriculum Vitae of Lead Principal Investigator**

*Please use the format below and indicate NA if the required information is not applicable. Limit the CV to 3 pages*.

|  |  |  |
| --- | --- | --- |
| Name:        | Title:       |  |
| Email:       | Contact No:       | Fax:       |
| Current Position(s) (provide full details, e.g. joint appointments, other academic appointments including those outside of Singapore) |
| Percentage of time spent in Singapore every year:       |
| Employment History |
| Academic qualifications (Indicate degree title, award year and institution name) |
| Research interests |
| Publications in last 5 years (include only publications of direct relevance to study, stating impact factors)  |
| Patents held (related or unrelated to study) |
| Scientific Awards |
| Half page summary of research outcomes from all previous grants [eg. publications (full papers only for past 5 years and highlight papers relevant to study), patents, awards, etc] |

1. **UNDERTAKING**
2. **UNDERTAKING BY LEAD Principal Investigator and all Co-Investigator(s) & Collaborator(s)**

**In signing the Letter of Intent, the Lead Principal Investigator and all Co-Investigator(s) & Collaborator(s) undertake(s), on any Grant Award, to:**

* Declare that all information is accurate and true.
* Ensure that approval from the funding agency has been obtained before engaging in any commercial activity that will exploit the finds of the research funded by the funding agency
* Read, support and agree to this proposal being carried out in the Institution(s)
* Be actively engaged in the execution of the research and ensure that the study complies with all laws, rules and regulations pertaining to animal and human ethics, including the Singapore Good Clinical Practice Guidelines
* Not send similar versions or part(s) of this proposal to other agencies for funding.
* For Biomedical Science proposal, submit supporting documents of ethics approval obtained from the relevant Institutional Review Board (IRB) and Animal Ethics Committee for studies involving human subjects/human tissues or cells, and animal/animal tissues or cells respectively.
* Ensure that all necessary licenses and approvals have been obtained or are being sought
* Ensure that funding agency is acknowledged in all publications.
* Ensure that all publications arising from the research is deposited in the Institution’s open access repository (or any other institutional/subject open access repository), in accordance to the Institution’s open access policy.
* Ensure that the requested equipment/resources are not funded by another agency or research proposal.
* Ensure that there is a reasonable effort in accessing available equipment/resources within the Institution(s) or elsewhere within Singapore.
* Ensure that there is no financial conflict of interest
* Adhere to the funding agency's Grants Terms & Conditions (T&Cs) and Funding Guidelines, as well as all other applicable guidelines, policies and procedures adopted by the funding agency, which may be amended or varied from time to time;
* Comply with the provisions of any relevant laws of the Republic of Singapore, statutes, regulations, by-laws, rules, guidelines and requirements applicable to it; and
* Agree to hold primary responsibility for the responsible conduct of research, and shall abide and comply with the ethical, legal and professional standards relevant to research, in accordance to the research integrity policy of the Institution(s).

We declare that the facts stated in this application and the accompanying information are true. This is an original and latest version of the proposal. We also declare that no other versions of this proposal (or parts thereof) with similar objectives, scope, deliverables or outcomes have been or will be submitted to any other funding bodies.

**Lead Principal Investigator:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  |  |  |  |  |
|  |  |  |  |  |  |
| Designation: |  |  | Institution: |  |  |
|  |  |  |  |  |  |
| Signature\*: |  |  | Date: |  |  |
|  |  |  |  |  |  |

*\* Electronic signatures are acceptable*

**Co-Investigator(s) or Collaborator(s) (if applicable):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  |  |  |  |  |
|  |  |  |  |  |  |
| Designation: |  |  | Institution: |  |  |
|  |  |  |  |  |  |
| Signature\*: |  |  | Date: |  |  |
|  |  |  |  |  |  |

*\* Electronic signatures are acceptable*

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| --- | --- | --- | --- | --- | --- |
| Name: |  |  |  |  |  |
|  |  |  |  |  |  |
| Designation: |  |  | Institution: |  |  |
|  |  |  |  |  |  |
| Signature\*: |  |  | Date: |  |  |
|  |  |  |  |  |  |

*\* Electronic signatures are acceptable*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  |  |  |  |  |
|  |  |  |  |  |  |
| Designation: |  |  | Institution: |  |  |
|  |  |  |  |  |  |
| Signature\*: |  |  | Date: |  |  |
|  |  |  |  |  |  |

*\* Electronic signatures are acceptable*

1. **ENDORSEMENT BY INNOVATION & ENTERPRISE OFFICE(s) (IEO)**

To be completed by the Innovation & Enterprise Office(s) (IEO) (or equivalent) of the institution(s) of the Lead Principal Investigator (PI).

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| --- |
| **Specific Comments (if any)**:  |
|  |

**The Lead PI’s Institution Innovation & Enterprise Office (IEO) supports this proposal.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  |  | E-mail: |  |  |
|  |  |  |  |  |  |
| Designation: |  |  | Institution: |  |  |
|  |  |  |  |  |  |
| Signature\*: |  |  | Date: |  |  |
|  |  |  |  |  |  |

*\* Electronic signatures are acceptable*

1. **UNDERTAKING BY head of LEAD institution**

To be completed by the Director of Research (or equivalent) of the institution:

|  |
| --- |
| **Specific Comments (if any)**:  |
|  |

**In signing the LOI Application, the Host Institution undertakes to:**

* Confirm the accuracy and completeness of the information submitted.
* Ensure that the applicant is independently salaried by the institution for the entire period of the grant.
* Ensure that the budget is appropriate and reasonable (e.g., no double funding/excessive purchase of equipment), and is aligned with the Host Institution’s HR and other policies.
* Ensure that the proposed research will be conducted in the Host Institution.
* Provide adequate resources to the applicant for the entire grant period (e.g., lab spaces, mentorship and career development support).
* Ensure that the funds provided are used for appropriate purposes.
* Ensure that the study complies with all laws, rules and regulations pertaining to national and the institution’s research operating procedures and guidelines.

**The Institution supports this proposal.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  |  |  |  |  |
|  |  |  |  |  |  |
| Designation: |  |  | Institution: |  |  |
|  |  |  |  |  |  |
| Signature\*: |  |  | Date: |  |  |
|  |  |  |  |  |  |

*\* Electronic signatures are acceptable*

1. For joint appointees, total appointment time in Singapore publicly funded research or tertiary institutions should be at least 0.7FTE. [↑](#footnote-ref-1)
2. Up to S$330K (including 30% indirect costs of ~S$80K) may be awarded for Pilot Phase 1. Projects will be assessed by panel review towards the end of Phase 1 to determine eligibility to receive Phase 2 funding, which is an additional budget of up to S$500K (including 30% indirect costs of ~S$115K).  [↑](#footnote-ref-2)