Johnson & Johnson Corporate Office of Science and Technology (COSAT) – University of Pittsburgh (Pitt)

TRANSLATIONAL INNOVATION PARTNERSHIP PROGRAM (TIPP)
COSAT – Pitt TIPP

Request for Proposals

Program:
For the first time, the University of Pittsburgh has partnered with Johnson & Johnson Corporate Office of Science and Technology (COSAT) to establish the Translational Innovation Partnership Program to improve the development speed and relevance of early stage Pitt technologies with potential to benefit patients and the healthcare system. Research areas for the Program may include therapeutics, therapeutic / diagnostic pairs, or platform technologies with applications in one or more of the following fields:

- Immunology, including diseases with an immune or inflammatory basis
- Oncology
- Cardiovascular Disease
- Metabolic Disease
- Neuroscience
- Virology
- Vaccines

This program is a co-managed fund which has been financially supported by COSAT, the University of Pittsburgh and the University of Pittsburgh Medical Center (UPMC). Projects will be selected by a committee with representative(s) from each of these parties.

The goal of this program is to answer critical questions along the development and commercialization pathway of promising technologies, in order to de-risk the opportunities so that they are more attractive to industry.

Eligibility Criteria:
Supported projects will have defined characteristics. They will:

- Arise from research and intellectual property developed at the University of Pittsburgh
- Be at a stage where carefully designed projects with defined milestones can provide preclinical or clinical proof of concept, or otherwise significantly de-risk a product concept.
- Involve new therapeutics (small molecules, biologics, vaccines), therapeutic / diagnostic pairs (but not stand-alone diagnostics), or platform technologies
- Be of high scientific merit and high potential impact
- Address healthcare needs in one or more of the following therapeutic areas: Immunology, Oncology, Cardiovascular, Metabolic Disease, Neuroscience, Virology and Vaccines.
- Be developed by Pitt investigators with established credentials and expertise, and only within the United States

Award Period
Projects are expected to be between 12 and 18 months in duration. Anticipated award date July 9th 2012

Budget Information
Four $100,000 awards will be funded. This amount includes indirects. Indirect rate is to be determined but will be less than or equal to 28.25%. Johnson & Johnson may provide additional in-kind resources to support project awardees. These will be discussed on an as-needed basis.

Submission Guidelines:
Proposal submission and selection is a two-stage process. Step 1 is to submit a written one-page Letter of Intent (LOI) proposal. Selected projects will then be invited to submit a written Full Proposal in Step 2.

Written Format: 1 inch page margins, Font: Times New Roman, at least 11 point size. Line break between paragraphs.
Step 1: LOI Submission

Deadline: no later than 8:00 a.m. Monday April 9th 2012- One-page Letter of Intent (LOI) proposals due via e-mail submission at upddi1@pitt.edu. LOIs will be accepted online starting Tuesday March 13th. You will be sent an e-mail confirming our receipt of your LOI.

Body of the LOI:
The LOI narrative must include:
1. The unmet or poorly met clinical need. This should include some metrics, such as the number of patients affected annually, health care expenditures for treatment and/or diagnosis, and likely future trend of the problem.
2. The proposed solution including status and timeline to clinical testing. This needs to be as focused as possible on the development of a product or technology solution to the identified problem, i.e. "translational" as opposed to "academic" (which is defined as adding to the general body of knowledge, but not product specific). Examples of translational projects include (but are not limited too): drug candidate optimization using medicinal chemistry (small molecule) or protein engineering (biologic); formulation development; animal pharmacology or toxicology studies; in vitro human translational studies; phase 0 clinical trials.
3. Concise summary of preliminary data, such as published articles, if any, which support that the proposed solution would actually work and that there would be a future clinical demand for it.
4. Specific Milestones that must be reached to derisk the technology solution and add value to the program.
5. An estimate of the direct R&D costs for personnel, minor equipment and supplies (do not add in the university overhead at this point). Please summarize previous work and grants received for this solution
6. The Intellectual Property status including Invention Disclosures, Patent Applications, IP Ownership; Material Transfer Agreements, Sponsored Research Agreements, or Gift Agreements related to this project; Patents awarded and/or technologies licensed, related to your proposed technology, including third party IP.

A project selection committee will evaluate the LOI proposals. Proposals with the highest ranking will be invited to submit a Full Proposal. Investigators will be notified with the result of the LOI proposal review on or before May 7th 2012. It is possible that the Program Director may contact you after submission to clarify and discuss your LOI proposal. Please feel free to contact the Program Director to discuss your idea prior to submission of your LOI.

LOI submissions not invited to submit a Full Proposal will be provided specific feedback on areas and items to address for future translational success.

Step 2: Full Proposal Submission

Deadline: 8:00 a.m. June 4th 2012: Full proposals must be submitted via e-mail to upddi1@pitt.edu

These Full Proposals will be thoroughly reviewed and evaluated by the Project Selection Committee and the Office of Technology Management. All Full Proposals will be provided feedback on areas and items to address for future translational success. Awardees will be notified by July 9th 2012.

Full Proposals consist of a cover page, the body of proposal, budget, and a brief biography of PIs. The body of proposal must not exceed five pages of narrative.

Cover Page:
The cover page must contain the project title, contact information of all PIs, Non-confidential abstract, description and keywords for the Project, and the approval/signature of the department chairs of all Co-PI’s. The cover page form will be e-mailed to you after you are invited to submit a full application

Body of Proposal:
The Full Proposal should be modeled from the LOI proposal and must include a complete discussion of:
1. The clinical relevancy and market need for the proposed research. The unmet or poorly met clinical need or disease.
2. The market metrics for your proposed product/therapy, such as the number of patients likely affected by your product, health care/societal expenditures for your clinical problem, etc.
3. The current approaches for assessment or treatment of your chosen clinical problem, the known shortcomings of those approaches.
4. Your envisioned future health care industry product and the advantages it would have compared to the current approaches.
5. Potential limitations and challenges and proposed approaches to address them
6. Milestones and the research plan for their achievement, including their significance to the translational outcome and time line for completion
7. Intellectual property status, strategy and future plan including Invention Disclosures, patent applications filed, Material Transfer Agreements, Sponsored Research Agreements, or Gift Agreements related to this project; IP ownership, patents awarded and/or technologies licensed, and third party existing IP related to your proposed technology.
8. Applications or approvals for animal and/or human testing (if needed).

Budget:
Prepare a detailed research budget including all of the direct costs for personnel, materials, supplies and equipment that will be needed to meet your stated research goals (You must use the budget format that will be provided).

Major capital expenditures are not permitted. Minor equipment items specifically needed for conductance of the research plan of less than $5,000 per item are acceptable. Funds may be used for salary support of post-doctoral fellows, technicians, graduate students and other research staff, research materials and supplies but may not be used for administrative support, construction, renovation or for tuition. Operating supplies, minor equipment items, commercialization/translational analyses such as IP, market, regulatory and reimbursement, imaging time and travel directly associated with the research activity are examples of eligible budget items. Grant budgets are expected to be in the $100,000 range including indirect costs.

Biographies:
Please submit a brief (250 word) biography for each PI.

Duration:
Grants will be awarded for a 12 to 18 month period.

Post Award:
All award recipients will be required to submit progress reports. Depending on the nature of the funded application, this report may be required quarterly OR after the completion of each project milestone. Awardees may be required to meet with the Project Director quarterly to review project status. Guidelines for the report will be given to each awardee.

Awardees will also be expected to promptly disclose all potential inventions that may result from this funding to the Office of Technology Management at the following website https://disclosures.tt.pitt.edu/UREF1304921613346628796/WD1_Login/.

Questions:
For questions regarding the Translational Innovation Partnership Program, or preparation of Proposals, please contact:

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