CCHMC Innovation Fund/Adare Repurposing Innovation Award
Request for Proposals (RFP)

Two funding streams are available:

(1) CCHMC Innovation Fund (internal funding): Awarded annually, the Innovation Fund provides up to $100,000 in total direct funding, for one-year, to an innovator (or innovation team) at Cincinnati Children’s to advance the development of technologies toward the commercial market. This award is intended to add value to the technology to increase the probability of licensing to an established company or start-up. Priority will be given to technologies that show a strong probability of return on investment. **Grant funds are to be used to enable product development and commercialization.**

(2) Adare Pharmaceuticals™ Drug Optimization and Repurposing Innovation Fund: Applicants with proposals that repurpose a currently marketed product, therapeutic or known drug for a new indication are eligible. Adare is interested in proposals that either optimize (e.g., a delivery route, onset of action and/or length of efficacy) or repurpose a known drug for a new indication. Specifically, Adare is interested in studying known therapeutics that could benefit from improved efficacy, improved adverse event/tolerability profiles, improved pharmacokinetic/pharmacodynamic relationships or be developed for an entirely new purpose. Therapeutics must be available for optimizing or repurposing with no more than 5 years of patent exclusivity remaining. **Following completion of the funded research program, Adare will have an exclusive option to enter into a licensing agreement for these projects/intellectual property.** Adare offers up to $200,000 in funding over two, one-year installments. (Year 2 funding is contingent upon the successful completion of milestones.) Please contact Ginny Van Horne directly for instructions.

CCHMC Innovation Fund Application Process: The application process begins by submitting a one-page Letter of Intent (LOI) and invention disclosure form. Selected applicants will be invited to submit a full proposal and will be expected to briefly present their project (i.e., 3-5 minutes) to reviewers as well as answer questions. (Please reference Key Dates section for specifics.)

| Funds are to be used to enable product development and commercialization. Examples include: |
| • Prototype development |
| • Human clinical data |
| • Pre-clinical data |
| • PK/PD |
| • Formulations |
| • Drug delivery systems/platform development |
| • Large animal studies |
| • Other advanced pre-commercial research |

| Funds cannot be used for: |
| • Published Content (e.g., guidelines, best practices, training manuals) |
| • Core services (e.g., drug discovery core) |
| • Basic science (this is considered too far from the clinic, hence, limited commercial potential at this stage) |
| • Travel |
Algorithmic diagnostics as opposed to single biomarker associations
Target validation

Budget/Funding Cycle

Budget cannot exceed $100,000.00 total costs. Please only request funds required to complete project. Funds cannot be used for travel. No more than 15% of the total project budget can be allocated toward PI(s) salaries.

Projects will begin July 1, 2019 and end June 30, 2020. With adequate progress, the possibility of renewal for a second $100,000 in total direct funding and an additional 12 months will be considered, assuming mutually agreed upon milestones and deliverables have been met by June 30, 2020, and further work is needed.

At the end of the funding period, awardees will be required to submit a final report.

Proposal Categories

- Biologic, Cell & Tissue Therapies
- Diagnostics
- Digital Health and Care Delivery
- Medical Devices
- Small Molecule Therapies
- Drug Repurposing or Optimization (Adare) – Do not submit LOI; Contact Ginny Van Horne directly if interested in this opportunity.

Eligibility

- The application must be submitted by a Cincinnati Children’s employee, who is the primary innovator on the project.
- An invention disclosure must be submitted to Innovation Ventures for consideration in the program. If the technology proposed references an existing disclosure, please reference the Technology ID number in your submission email.
- Applicants must be up to date with or able to obtain IRB or IACUC approval for work proposed, if applicable.

The Proposal Process

LOI Submission Guidelines:

- File an invention disclosure with Innovation Ventures prior to LOI submission. If the technology proposed references an existing disclosure, please reference the Technology ID number in your submission email.
- Review the evaluation criteria.
- If you are interested in the Adare opportunity, please contact Ginny Van Horne directly for separate instructions.
- Complete Innovation Fund LOI cover page template.
- Email the completed LOI to Ginny Van Horne by 1:00 p.m. on February 5, 2019.

Innovation Ventures staff will review and screen LOIs received. As needed, Innovation Ventures staff will engage subject matter experts in the LOI review. LOIs will be examined for:
• Clarity and credibility
• Strength of intellectual property (IP)
• Market need (i.e., what is the ultimate product that will provide a distinct IP or market position; how is the proposed project distinct from what currently exists in the market; who is the customer for this project; what is the specific patient population impacted by the project)
• Clear research methods
• Programmatic fit and balance
• Qualifications of the project team
• Well-described value propositions.

Selected applicants will be invited to submit a full proposal and will be expected to briefly present their project to reviewers as well as answer questions during a review panel meeting in late May 2019 (see Key Dates section for specifics).

Proposal Submission Guidelines – Due by Noon, April 8, 2019
• Proposals cannot exceed 8 pages, single spaced, one-inch margins, using an 11-point font or larger. Please see Full Proposal Template and Instructions for additional information. The proposal evaluation and selection process place a strong emphasis on the commercial potential of the proposed project.
• Please hyperlink publications and resources, when possible.
• Limit proposed aims to ½ - ¾ page. If your project is selected for funding, Innovation Ventures – with input from experts – may adjust aims to align with a commercial perspective.
• Inclusion of letters of support in the proposal from appropriate stakeholders (e.g., strategic partners, customers, and/or investors) is optional.
• Do not attach biosketches.
• Save the proposal as a Word or PDF document. Instructions on proposal submission will be conveyed to invited applicants via email by late March.

2019 Key Dates for CCHMC Innovation Fund:
• January 2: RFP released.
• February 5, (1:00 p.m.): Deadline for receipt of Letters of Intent (LOIs).
• February 28: Top-rated applicants invited to submit proposals.
• April 8, (noon): Deadline for receipt of full proposals. Applicants will receive feedback by May 13.
• Mandatory PI Presentation Dates for Selected PIs: Selected PIs to present to reviewer panel. Presentation is limited to 5 minutes followed by Q&A with reviewers. No slides permitted.*
  o May 22 – Small Molecule Therapies
  o May 23 – Digital Health & Care Delivery*
  o May 30 – Biologic Cell & Tissue Therapies
  o May 30 (morning) – Diagnostics
  o May 30 (1:30-4:30 p.m.) – Medical Device
• Late June: Applicants notified of funding decisions.
• Early July: Kick-off meetings with PIs, business managers and Innovation Ventures staff.

*Digital applicants may have the option to briefly demo their product within the time limit.

2019 Key Dates for Adare
• January 2: RFP released.
• March 13: Applicants to present projects to Adare staff.
• April 17: Applicants notified about next steps.

Innovation Fund Evaluation Process
Innovation Ventures staff and subject matter experts will conduct the initial review and validation of proposals. Reviewers will read proposals prior to in-person sessions with PIs. Final scoring will take place after PI presentations.

Innovation Fund Evaluation Criteria
Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications. Reviewers will evaluate the proposals using the criteria below. Criterion will be rated as Yes/No. Applicants must successfully address all criteria in their applications.

• Significance/clinical impact. If successfully completed, what will be the research outcome impact? That is, will it address a significant unmet clinical need? Address an under-met clinical need? Better address a need that is currently met? Or, not address an existing need? Application should clearly elaborate the clinical unmet need (i.e., the problem), the product/service, and how the product/service will address the clinical needs (solution).
• Novelty of idea/approach. If successfully completed, how will the clinical product be characterized? That is, will it be characterized as revolutionary? Evolutionary? “Me Too?”
• Intellectual property. What is the status of Intellectual Property (IP) for this proposal? Do patents already exist (issued patent)? Have patents been filed (patent application)? Have invention disclosures been submitted? Is there no IP activity as of yet? Is the project not likely to be patentable? If not patentable, might other proprietary protection be possible? Degree to which the IP is protected and will protect the expected business model of a start-up company?
• Feasibility. Is the science based on solid principles? Is the proposed research plan a sound approach for establishing technical and commercial feasibility? Is the research plan appropriate? Are the timeline and milestones proposed feasible? Can project be validated within its first year? Is there a commercially reasonable path to market entry of first product?
• Commercial potential. Does the proposed research envision a commercial product? What is the expected timeframe for the product to reach the market (in years)? What is the specific patient population impacted by the technology? Who is the customer (client) for this technology? What is the ultimate product that will provide a distinct intellectual property position? What is the product that will result in a unique IP position? How is the proposed technology distinct from what exists in the current and future marketplace? What is the commercialization stage? In addition to answering the above questions, each project will be screened against the following criteria: clinical/regulatory/reimbursement, market profile, and exit package profile/landscape.
• Mission impact/intangibles. Does the proposed project have a positive outcome on improving the health of children?

Innovation Fund Reviewers
Each review panel will be comprised of an Innovation Ventures portfolio manager, CCHMC scientists, CCHMC clinicians, experts from industry, investors, and entrepreneurs. Andrew Wooten, Innovation Ventures VP, will participate on each panel.

Questions? Contact Ginny Van Horne at 803-1175 or virginia.vanhorne@cchmc.org