**CCHMC Innovation Fund/Adare Repurposing Innovation Award**

 **Request for Proposals (RFP)**

*Two funding streams are available via the Innovation Fund:*

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:** The Applicants with proposals that repurpose a currently marketed product or known drug for a new indication are eligible. Adare is interested in proposals that either optimize 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.)

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.)

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| 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
* Algorithmic diagnostics as opposed to single biomarker associations
* Target validation
 | 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)
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**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, 2018 and end June 30, 2019. 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, 2019, and further work is needed.

**Funding Categories.** Applications will be categorized into the areas listed below. The proposal Selection Committee expects to make at least one award in each area, provided there are worthy proposals:

* Biologic, Cell & Tissue Therapies
* Diagnostics and Medical Devices
* Digital Health and Care Delivery
* Small Molecule Therapies
* Drug Repurposing or Optimization (**Adare**)

**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 the Innovation Ventures for consideration in the program.
* Applicants must be up to date with or able to obtain IRB or IACUC approval for work proposed, if applicable.

**The Application Process**

Guidelines for submission of the Letter of Intent (LOI)

* File an [invention disclosure](https://mcinteumprd1.chmccorp.cchmc.org/InteumWeb/inventorportal/login.aspx) with CCIV prior to LOI submission.
* Review the evaluation criteria.
* Complete LOI template.
* Email the completed LOI to Ginny Van Horne at Virginia.vanhorne@cchmc.org **by 2:00 p.m. on February 6, 2018.**

The Innovation Ventures office 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, and well-described value propositions.

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 during a review panel meeting in mid-May 2018 (see Key Dates section for specifics).

Guidelines for submission of Full Proposal

* Proposals can range from 5-8 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 **places a strong emphasis on the commercial potential** of the proposed project. Applicants are encouraged to contact Ginny Van Horne with questions.
* Inclusion of letters of support in the proposal from appropriate stakeholders (e.g., strategic partners, customers, and/or investors) is optional.

**Publications/Reporting**

* Publications arising from an award funded by the Innovation Fund are required to acknowledge the CCHMC Innovation Fund as the source of funding.
* Awardees will be required to submit a final report (no more than 3 pages). PIs that do not submit timely reports will not be eligible to apply for year 2 funding.

**2018 Key Dates:**

* **January 3:** Request for Proposals (RFP) released.
* **February 6, (2:00 p.m.):** Deadline for receipt of Letters of Intent (LOIs).
* **Week of February 19 or 26:** For those who applied to the Adare opportunity, Adare may convene brief telephone calls with PIs to gain further clarity on projects proposed.
* **February 23:**  Top-rated applicants invited to submit proposals.
	+ **Adare applicants notified by March 5**
* **April 3, (noon):** Deadline for receipt of full proposals.
* **Week of April 30 or May 7:** For those who submitted a full application to the Adare opportunity, Adare may conduct a 30-minute phone call with PIs for a question and answer session.
* **Mid-May:** Selected PIs to present their proposals to reviewer panel (not applicable to those PIs who submitted projects for consideration by Adare).
	+ PI presentation limited to 3-5 minutes
	+ Reviewers will ask PIs questions for up to 20 minutes
* **Mid-May Mandatory PI Presentation Dates** **for Selected PIs:**
	+ May 15 – Digital Health & Care Delivery presentations
	+ May 16 – Biologic Cell & Tissue Therapies presentations
	+ May 18 – Small Molecule Therapies presentations
	+ May 22 – Diagnostics & Medical Devices presentations
* **Mid-June:** Applicants notified of funding decisions.
* **Mid-to-late June:** Kick-off meetings with PIs, business managers and Innovation Ventures staff.
* **July 1 (FY 19):** Funds disbursed.

**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.

Evaluation Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications. Using the below 6 review criteria, reviewers will evaluate the proposals. Criterion will be rated as Yes/No. Applicants must successfully address all criteria in their applications.

Criterion 1: 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).

Criterion 2: 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?”

Criterion 3: 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? [Metric: IP status]

Criterion 4: 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? [Metric: preliminary data supporting feasibility]

Criterion 5: 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. [Metrics: size of market; letters of interest from outside entities]

Criterion 6: Mission impact/intangibles. Does the proposed project have a positive outcome on improving the health of children? [Metric: potential outcomes]

**Innovation Fund Reviewers**

Each review panel will be comprised of an Innovation Ventures portfolio manager, two CCHMC scientists, two CCHMC clinicians, two experts from industry, two investors, and two entrepreneurs. Andrew Wooten, Innovation Ventures VP will participate on each panel. (Adare applications will be reviewed by Adare scientists and staff.) We are in the process of securing reviewers. Additional names will be added to the list below.

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| Biologic, Cell & Tissue TherapiesCTC: David Wang, Andrew WootenRobert Beech, CincyTechShin Fuse, MPMMichael HelmrathHootan Khatami, SucampoDoug MillayCatherine Pearce, CinRxJan Rosenbaum, AirwayJohn Rice, CincyTechTim Schroeder, CTIPranav ShivakumarLou Tartaglia, 5am Ventures | Diagnostics and Medical DevicesCTC: Jon Brophy, Andrew WootenJim Adox, Venture InvestorsMatt BatieRyan Bledsoe, Relievant MedsystemBrian ColeyHalima MoncrieffeJosh Nichols, CincyTechDan von AllmenHector Wong |
| Digital Health and Care DeliveryCTC: Matt Wortman, Andrew WootenJudith DexheimerKevin DufendachOlivier Fischer, Transmissions, IncStuart GoldsteinCharlie Key, LosantEric KirkendallBryan TowneHarsh Patel, Venture WireframeMike Venerable, CincyTechDon Wright, Greystone | Small Molecule TherapiesCTC: Karen Lammers, Andrew WootenJoe Gardner, AerpioSatish MadalaBrian Meltzer, AdareMike Myers, Eli LillyJohn PerentesisJohn Rice, CincyTechJan Rosenbaum, AirwayBill SeibelArmen Shanafelt, Lilly VenturesRay Takigiku, BexionLou Tartaglia, 5Am ventures |