CURESEARCH CATAPULT

CureSearch Catapult Award:
Clinical Trial Awards in Pediatric Cancer

2019 Request for Applications

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2019 CureSearch Catapult Impact Fund Awards

Timeline (tentative dates)

Request for Applications Opens	June 3, 2019
Letter of Intent Deadline	July 19, 2019
LOI Notification/Full applications invited	September 3, 2019
Full Applications Due	October 15, 2019
Earliest Award Notification*	January 3, 2020

**Awards will be made on a rolling basis, pending availability of funds.*

CureSearch launched its Catapult Strategy to accelerate the development of novel, innovative, less-toxic treatments for children with cancer. For many reasons, new treatments are not being developed for children with cancer as quickly as they are for adults. The goal of the Catapult Award is to overcome barriers to pediatric cancer drug development by providing meaningful funding and expert scientific guidance in order to advance the development of promising oncology research out of the lab, into clinical trials and to regulatory approval, with the ultimate goal of improving clinical outcomes in childhood cancer patients and making new treatments widely available.

Program Description

The Catapult Award is currently soliciting proposals for its 2019 award cycle. CureSearch for Children's Cancer will review and fund projects advancing promising therapies for pediatric cancer into or further along in clinical development, and that show a strong potential for future approval and commercialization. Awards will be granted for 1-3 years, based on the needs of the project. The Catapult Award will provide funding support, as requested, up to $2.5M for the entire award period, for **"clinic-ready" projects** that fit the following parameters:

- **Phase 1 or Phase 2 pediatric clinical trials** that seek to test single or combination therapies for a pediatric cancer indication.
- Preference will be given to projects that address areas of high unmet need in pediatric oncology such as high-risk, relapsed, and metastatic disease and adolescent and young adult patient populations.

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- All pediatric clinical trial projects should be either IND-ready (that is, with sufficient data to support the submission and approval of an IND or IND-equivalent), available for clinical trial use under an existing, active IND (or IND-equivalent), or having already gained approval by the FDA or other competent regulatory authority for an adult indication, but having not been studied in pediatric oncology indications.
- For "first in human" clinical studies, all pre-clinical pharmacology and non-human safety and toxicology studies should be completed.
- CureSearch has a strong interest in **collaborative projects** that leverage existing regulatory guidelines or governmental programs that require or reward research in the development of new therapies for pediatric patients. **Collaborative projects between academia and industry are also strongly encouraged** (see eligibility below).

If an award is made, academic institutions will receive bi-annual grant payments over the project period. Awards to for-profit entities may be made in accordance with pre-determined milestones, or in the case of equity investments as a single investment as a portion of the capital raised by that company, or through an alternate schedule, depending on the project. For collaborative projects, payments will be made accordingly to the institution/entity of the principal investigator listed on the project.

Eligibility

Applications from academic scientists and physician researchers from non-profit research institutions or consortia in the US, EU, UK, Canada, China, India and Australia will be eligible. Priority will be given to academic researchers whose institutions own the intellectual property protecting the proposed research technology and who have licensed the technology through a spin-out company. Applications will also be considered from small, privately held, for-profit startup, biotechnology, or pharmaceutical companies in the US, EU, UK, Canada, India, China, or Australia seeking funding for the early stage clinical development of proprietary oncology drug technology.

Application and Review Process

Application and review will follow a two-stage process. Applicants must submit a "Letter of Intent" (LOI) (see application submission guidelines below) by stated deadline date. LOIs will be administratively reviewed by CureSearch Scientific Staff. LOIs will advance to review by the CureSearch Scientific Review Committee (SRC). Proposals will be evaluated in three criteria areas: scientific

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and clinical merit, probability of technical and regulatory success for clinical development, and commercialization potential. Promising high-potential LOI applicants will be invited to submit a full application for further review by the SRC, a representative from the CureSearch Industry Advisory Council, and the CureSearch Scientific Advisory Council.

Letter of Intent (LOI) submission guidelines:
All LOIs must be submitted in accordance with the requirements and instructions of this RFA. LOIs must be submitted via proposalCENTRAL at https://proposalcentral.com. Full application instructions will be provided to each applicant individually based on the initial LOI review.

To submit an LOI, you must establish a user account to submit a grant application. If you have a user account with proposalCENTRAL:

1. Log in to Proposal Central at https://proposalcentral.com.
2. To begin an LOI, select "Grant Opportunities".
3. In the drop-down menu in the upper left-hand corner, select "Filter by Grant Maker", then find "**CureSearch for Children's Cancer → CureSearch for Children's Cancer Catapult Impact Fund Award in Pediatric Cancer"**
4. Click the "apply now" link to create your LOI.
5. Complete all fields in the application and all templates that are provided. Upload all requested documents in PDF format. See the proposalCENTRAL FAQ section, for more information.

* If you have difficulties registering, logging in, or creating your application, contact proposalCENTRAL Customer Support: Phone (800) 875-2562 or email pcsupport@altum.com.

Letter of Intent Template
Download the Template from proposalCENTRAL and fill in the following sections. The LOI Narrative (Section B) is limited to 5 pages and should be prepared as a word document (converted to pdf for upload). Cited Publications and LOI supporting documents (i.e. Biosketch, Letters of Collaboration/Support) are not included in this page number limit.

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Document format:

Please adhere to the following formatting requirements:

- PDF file format
- Font size: 11 point
- Font Type: Times New Roman or Arial
- Page Size: No larger than 8.5 inches x 11.0 inches
- Margins: 0.5 inch in all directions
- The complete LOI narrative (section B, below) **must not exceed 5 pages** in length.

A. Applicant and Project information

1. Title of Research Proposal
2. Principal Investigator, Co-investigators
3. Institution and/or Company
4. Stage of study
   Clinical Trial
   i. Phase 1(1a/1b)
   ii. Phase 2 (2a/2b)
5. Agent(s) or technology being tested
6. Technology intellectual property status

B. Project Plan/Study Design and Rationale (5 page limit)

1. Rationale and background
2. Preliminary studies (summary of key preclinical or pre-IND/IND-enabling studies, include figures if necessary)
3. Study hypothesis and aims
4. Study design and milestones
5. Patient eligibility criteria, accrual estimates and clinical endpoints, if appropriate
6. Pediatric safety considerations/therapeutic index
7. Path to clinical testing in pediatric oncology patients

C. Significance and Innovation (1 page limit)

Describe how the proposed technology or therapeutic fulfills an unmet medical need, benefits the pediatric patient population, how the proposed

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agent is superior to existing therapies and how the technology and/or approach is innovative.

D. Intellectual Property and Commercialization (1 page limit)

This section should include:

1. Current and anticipated intellectual property
2. Commercialization plan

Describe how the proposed technology or therapeutic will be commercialized. This includes a description of intellectual property, future markets, partners, investors, resources, milestones etc. that will be needed to commercialize the subject technology or therapy.

E. Supporting documentation (not included in page limit)

Please include, if available, any of the following supporting documentation (under CDA/NDA):

- Documentation of regulatory interactions (e.g. pre-IND meeting minutes, IND clearance/complete response letters, briefing documents)
- Clinical trial concepts/synopses or protocols

F. Cited Publications (not included in page limit)

G. Appendix documents (not included in page limit)

• Budget template – the budget should reasonably reflect the direct costs needed to carry out the project and should not exceed $2.5M in total costs over the entire project period. The budget should be as evenly distributed across the requested years of support as possible. 10% indirect costs (for academic institutions) are included in the $2.5M budget total. For example, if $1M are requested, the payment would be $900,000 direct + $100,000 indirect.
• Budget justification
• NIH Biographical sketch for all key personnel
• Letter(s) of collaboration from co-investigators/collaborators
• Letter of support from commercial partner, if appropriate
• IACUC and IRB approval letters, if appropriate

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Catapult Impact Fund Award Review Criteria

All LOI applications will be reviewed for the following components by the SRC:

- Relevance to improving clinical outcomes in childhood cancer patients (e.g. survival, acute toxicity, late effects).
- Innovative biological or pharmaceutical approach
- Compelling scientific hypothesis
- Supporting preliminary data demonstrating clinical and drug development feasibility and likelihood of clinical efficacy
- A clinical development plan with achievable milestones that, if successful, will increase the likelihood of technology commercialization
- Expertise and environment of preclinical and clinical research teams
- Ability to define and meet regulatory requirements
- Availability/accessibility of research agent or technology
- Strong intellectual property position
- For academic institutions, a documented track record of out-licensing technology to pharma and/or successfully spinning out start-up companies
- A viable product commercialization pathway that includes application in pediatric cancer patients

FULL APPLICATION SUBMISSION

Only applicants with LOIs deemed most meritorious and aligned with Program's goals will be invited to submit full applications. Full applications will require additional information from the applicant including, but not limited to:

- Written response to reviewer questions and concerns
- IND submission packet and documentation of relevant IND (or IND-equivalent) enabling studies (non-clinical pharmacology studies,

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summaries of relevant CMC data/strategy, clinical trial protocols, pre-clinical data that includes proof of biology/mechanism and evidence of tumor efficacy in relevant preclinical models)
• Documentation from regulatory interactions (e.g. minutes, correspondence, briefing documents, presentations)
• Information on any regulatory incentives granted by FDA (or other competent regulatory authority) or under review (ie, orphan drug status, pediatric priority review voucher status)
• Business/commercialization plan
• Correlative Science: Aims and Resources needed
• Revised Budget Estimate
• (Cell therapy) Production Process
• (Personalized vaccine) Selection and Production Process
• (Checkpoints) Biomarkers + Adverse Events Monitoring
• Contractors, CROs agreements/quotes/letters
• Track-record of valorization/commercialization

IP / Royalty Sharing
The recipient of this Award or his/her institution shall own any invention. However, the recipient shall promptly notify CureSearch of any invention and associated patent filing resulting from the research. If the recipient or his/her institution grants any right to the invention to a third party for commercial application and receives any amounts from the invention, CureSearch shall be entitled to receive a share calculated by multiplying the amounts received by a fraction , the numerator of which is the amount of the Award, and the denominator of which is the direct cost incurred by the recipient and his/her institution in developing the invention, except in no event shall the CureSearch share of any such amount received that exceeds 30%. CureSearch will use any share it receives to to replenish the Catapult fund for re-investment in disease modifying therapies, including by awarding additional Catapult grants. CureSearch is not looking to make money, but rather to sustain a philanthropic fund of dollars to strategically advance better, less toxic, children's cancer treatments well into the future.

Monitoring and Reporting
Project milestones will be established as part of the investment agreement specific to each funded project. Routine reporting on those metrics is required under the agreement. Progress reports must be submitted every six months to researchgrants@curesearch.org. Progress report guidelines and templates will be provided at the time of the award. Continued funding is dependent on meeting

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agreed-upon milestones. Of note, if new information learned through the study changes future milestones, a revised milestone agreement should be provided to CureSearch for approval. Delayed or lack of progress may result in suspension of future funding.

CONFIDENTIALITY

CureSearch treats all LOIs, full applications and associated research information (collectively, the "Confidential Information") in confidence using no less than reasonable care in protecting such Confidential Information from disclosure to third parties who do not participate in the grant review process and CureSearch assessments. All Confidential Information will be used by CureSearch and its scientific reviewers only internally for the purposes of reviews and assessments, and will be shared only in accordance with its sharing policy stated herein.

CONFLICTS OF INTEREST

Principal investigators, co-investigators, sub-contractors or collaborators submitting applications to the RFA will be excluded from serving on the Scientific Review Committee. However, non-applicants who are invited to serve on the SRC may still have a conflict of interest if 1) the application is from the reviewer's own institution regardless of whether the reviewer has had any involvement in preparing the application, 2) the reviewer, his/her immediate family, or close professional associate(s) has a financial interest or vested interest in the outcome of the proposed research, or 3) the reviewer has been involved in discussions regarding the application, is a provider of services, cell lines, reagents or other materials, or writer of a letter of support for the applicant. When a conflict of interest is deemed to be present, the reviewer will be ineligible to review the proposal and be asked to recuse themselves from the deliberations.

REQUIREMENTS FOR AWARDEES

- Subject to confidentiality considerations, It is required that the results of the research, regardless of study success, will be published as rapidly as possible in a peer-reviewed scientific journal. Publications should be consistent with high standards of scientific excellence and rigor and include acknowledgement of the funding provided by CureSearch for Children's Cancer.

- Progress Reports for CureSearch are due every six months. Progress report

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forms and instructions will be provided by CureSearch at the time of the award and reminders will be provided two months prior to due dates.

- Principal investigators are required to attend the annual CureSearch Summit to be held during the first quarter of eah year. Grantees will report on the progress of their projects, exchange information with other investigators, industry and other stakeholders, explore possible collaborative efforts, and identify strategies/resources to advance projects towards clinical application and commercialization.

- Principal investigators will work closely with CureSearch to translate complex science, findings and outcomes for donors and constituents. This will be done by conducting interviews for videos, podcasts, webinars, newsletters and/or other written updates.

- Principle investigators are expected to participate in CureSearch volunteer leadership activities, including yearly scientific review and the IMPACT series.

- Grantees are expected to account for the monies expended under the Award; any monies spent either not in accordance with the approved research project or prior to pre-approval of any material change in the project are subject to repayment and may be cause for immediate termination of funding by CureSearch.

- Grantees are expected to meet scheduled milestones and submit deliverables on time. Failure to meet milestones, furnish scheduled deliverables, including the aforementioned reports or to comply with the terms of the grant may serve as a base for termination of funding by CureSearch.

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QUESTIONS?

Contact information for all inquiries about application submission is provided below.

Type of Inquiry	Contact
All programmatic inquires (including questions related to eligibility, application requirements, etc.)	**CureSearch** Email: researchgrants@curesearch.org Phone: +1-240-235-2215
All technical inquiries related to the online application system, proposalCENTRAL	**Proposal Central** Email: pcsupport@altum.com Phone: 1-800-875-2562

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