

# Diabetes Data Innovation Initiative

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## Funding Opportunity

### Purpose

The Leona M. and Harry B. Helmsley Charitable Trust (HCT) Type 1 Diabetes (T1D) Program is launching a Request for Proposals (RFP) to provide up to \$5 million USD for the development of innovative solutions that enable the use of diabetes data to ease the burden for people with T1D, their caregivers and healthcare providers.

### Background

HCT's T1D Program has made major investments in understanding the disease, developing better treatments, and improving care and access with the overall goal to ease the burden of living with T1D and improve health outcomes. T1D management requires hundreds of day-to-day, minute-to-minute decisions with a drug (insulin) that could be deadly if miscalculated. People with T1D, their caregivers, and healthcare providers are often overwhelmed by information on insulin dosing, blood glucose values, exercise, meals and other sources. However, if the data is aggregated and transformed into actionable knowledge, it could be used to adjust therapies and better manage daily activities, resulting in improved glucose control, quality of life and health outcomes.

New technologies (including, but not limited to, mobile platforms and applications, electronic medical records/electronic health records, embedded wireless sensors and communications, and big data analytics) could enable the integration of this data, identification of trends, personalized patient guidance and decision support for providers. Collectively, the solution would support people with T1D between doctor's visits and help healthcare providers better optimize treatment plans while making the most efficient and effective use of their time with patients.

### Objectives

Through this RFP, HCT is seeking to ease the burden of diabetes management by providing funding to programs that enable the use of diabetes data in innovative ways. This initiative is focused on intelligent patient guidance and provider clinical decision support technologies. Integration with consumer, patient and healthcare professional devices and platforms will likely be essential.

### Data sources could include but are not limited to:

- Blood glucose monitors
- Insulin pumps
- Continuous glucose monitors
- Traditional insulin pens
- Smart pens
- Fitness devices

- Health and medical apps and platforms (Apple Health, S-Health, etc.)
- Other (meals, heart monitors, Apple Watch, social media, etc.)

### **Target Population**

The solutions **must target people with T1D** and could also be used by:

- Caregivers
- Healthcare providers
- Nurses/Certified Diabetes Educators (CDE)
- Care coordinators (such as in an Accountable Care Organizations (ACO) or Patient-Centered Medical Home (PCMH) environment)
- B2B Enterprises (payers, pharmacy benefit manager (PBM), pharma, etc.)
- Other (researchers, not-for-profits, exchanges, advocacy organizations, etc.)

The proposed technology should be mindful of varying demographics including (but not limited to) numeracy, literacy, age, gender and socioeconomic status.

### **Validity**

- Approach should be based on clinical and behavioral scientific evidence or theory.
- Approaches for validating efficacy (pre or post market) are encouraged.

### **Usability**

- The user experience (of the technology and the end-to-end distribution process) must be appropriate for the specific user, be commensurate with generally accepted UI/UX/Human Factors design standards, and facilitate positive patient adoption, engagement, and retention.
- It is expected that newly developed technologies will embrace data interoperability and easily share data.

### **Scalable and Sustainable Distribution**

Applicants should specify how the market will be made aware of the technology and how it will be distributed (operationally and financially).

### **Funding Guidelines**

HCT will support one or more projects for a maximum of 24 months and up to \$5 million USD in total. The ability to identify parallel partial or matching funds in each project is desirable. Special consideration will be given to projects with a regulatory submission time of less than two years. Sequential launches (e.g. a roadmap of improved features and labeling over time) will be considered should they offer improved speed to market or other benefits.

### **Eligibility**

HCT seeks the best possible solutions to the Diabetes Data Innovation Initiative described in this request and welcomes applications from U.S.- and international-based nonprofit organizations (including institutions of higher education, public charities, hospitals and

government agencies); for-profit companies; and combinations of the aforementioned. Additionally, applicants who have developed proven solutions for other diseases and could leverage this experience to create a solution for T1D are encouraged to apply.

A sustainability plan and/or go-to-market model is required. Hence, a partnership with a private sector company is encouraged for those applicants who are not in the position to bring the technology to market. Applicants will need to articulate which partner entity would be submitting a regulatory filing, if necessary.

Applicants are required to publish applicable findings from the projects conducted with HCT funds; provided, however, that applicants may delay any such publication for a reasonable period in order to secure patents and copyrights.

### **Submission Process**

The HCT funding opportunity requires a two-step submission process:

#### **Letter of Inquiry (LOI)**

Applicants will be asked to submit a brief LOI describing their proposed project. This will include an executive summary, product description, distribution model, partnerships, contact information and proposed summary budget.

As part of the LOI stage, for-profit companies are required to acknowledge that they have reviewed and discussed the Overview of Grant Terms for Expenditure Responsibility with their legal counsel and, if awarded a grant, that they will segregate the grant funds from their for profit funds. If you are not able to comply with the Trust's terms, please do not apply for the funding.

#### **Full Proposals**

Based on submitted LOIs, selected applicants will be asked to submit a full proposal that will enable reviewers (external and/or internal) to fully evaluate the proposed project. Applicants should be prepared to provide a summary of relevant experience, expertise, capabilities, organizational background, project details, commercialization plan, a comprehensive line-item budget (with justification) and supporting documentation (e.g., most recent financial audit).

### **Timeline**

Funding Opportunity Release Date	June 1, 2015
LOI Submission Deadline	July 20, 2015
Selected Applicants Proceed to Full Proposal	August 2015
Full Proposal Submission Deadline	October 5, 2015
Anticipated Commencement of Selected Programs	First Quarter 2016

**Review & Selection Criteria**

HCT will select for funding those proposals where the application of funding support is assessed to have the greatest likelihood of uniquely achieving the objectives described above. Special consideration will be given to novel innovative approaches, particularly those that are likely to spark follow-on innovation to address the needs of those with T1D and/or projects with the aim of significantly accelerating product development through regulatory approval.

HCT will perform appropriate due diligence before an applicant is selected. International nonprofit organizations and both international and U.S.-based for-profit companies will be required to go through additional due diligence. Proposals and funded projects may be subject to review by a panel of research and industry experts (appropriate conflict of interest and confidentiality protections will be put in place).

**Contacts**

For program-related or technical questions about the funding opportunity, including questions of eligibility, please email: [t1dtechnology@helmsleytrust.org](mailto:t1dtechnology@helmsleytrust.org)

For assistance with the online application, email [grants@helmsleytrust.org](mailto:grants@helmsleytrust.org). Note: Any program-related questions sent to this email address will not be answered.

**Legal Disclaimer**

All funding decisions are made by Trustees of The Leona M. and Harry B. Helmsley Charitable Trust in its sole and absolute discretion, and any proposals not meeting the aforementioned criteria will not be considered. All submitted documentation will be handled and managed with reasonable care of confidentiality.