REQUEST FOR PROPOSALS:

OPEN-PROTOCOL AUTOMATED INSULIN DELIVERY SYSTEM INITIATIVE

PURPOSE

JDRF is launching an initiative to accelerate the development of "open-protocol" automated insulin delivery (artificial pancreas) systems. JDRF is soliciting proposals from insulin pump manufacturers and continuous glucose monitor (CGM) manufacturers that will enable seamless, secure connectivity with other devices (e.g., by using Bluetooth technology). JDRF remains committed to supporting the traditional, proprietary commercial development of artificial pancreas systems; in parallel, JDRF will launch efforts in the United States and globally to partner with regulators and legal experts to establish predictable approval pathways for systems that allow for secure, open-protocol-based control through commercially developed devices and software.

BACKGROUND

For more than a decade, JDRF has played a leadership role in accelerating the development and commercialization of artificial pancreas (AP) systems that automate insulin delivery, defining a roadmap for increasingly sophisticated systems that would, with each generation, improve outcomes and reduce burden for people with T1D. Now, the first commercial system, which has been shown to provide significant benefit to people with diabetes, is on the market, and others are in development.

At the same time, a thriving community of users has rallied behind a patient-driven ecosystem, using do-it-yourself (DIY) approaches. In such systems, continuous glucose monitors and insulin pumps are reverse-engineered, allowing open-protocol efforts such as Nightscout, OpenAPS and Loop to display data in innovative ways and even to control automated insulin delivery. This DIY movement has grown rapidly, and JDRF believes that in order to support innovation and enable T1D families to use this approach safely, we must forge pathways to make devices compatible and enable open-protocol systems.

This new initiative will explore ways to overcome potential challenges in the use and adoption of open-protocol systems, most notably helping to establish clear financial, regulatory and legal frameworks. JDRF will enlist various experts and allies as part of this initiative, which will be led by JDRF Research Director Daniel Finan, Ph.D., under the direction of Chief Mission Officer Aaron Kowalski, Ph.D.

OBJECTIVES

JDRF will support the development of insulin pump systems and CGM systems that allow for control via secure, openly published communication protocols by third-party cell-phone based applications (apps) and/or other devices. This development will allow individuals or third-party developers to communicate with the insulin pump and CGM via secure, well-documented, and verified communication protocols.

Examples include, but are not limited to:

- An insulin pump, able to be controlled (i.e., its insulin delivery manipulated) via a secure wireless protocol (e.g., Bluetooth LE or similar protocol)
- A CGM, able to interface via a secure wireless protocol
- A cell phone-based application (app) with the ability to communicate with an insulin pump and CGM via a secure wireless protocol
- A specialized, separate device with the ability to communicate with an insulin pump and CGM via a secure wireless protocol; in this approach, the separate device will also need to communicate with a cell phone-based app or otherwise be able to control the insulin delivery of the insulin pump
- Other innovative solutions will be considered

OTHER SPECIFICATIONS

The device itself need not have a built-in algorithm, nor even a built in user interface.

The insulin pump must have robust failsafe capabilities. That is, if it becomes separated from its external controller (cell phone or other device), it does not fail (e.g., it reverts to basal insulin delivery).

The device must have an interface enabling it to be suspended by the user when the external controller is not available.

The device must support reservoir-based delivery of at least one drug using commonly available reservoirs and infusion-site connectors.

The device must allow for secure, authenticated control and programming by do-it-yourself (DIY) developers without restrictions on who may control the device, i.e., the communication protocol may not be limited to only entities that have executed business partnerships.

The device must be intended for sale and distribution. The indication for use of the device will be to the effect of: a controllable infusion pump intended for use with an approved, external controller.

Limitation on Liability. JDRF will work with applicant to develop a liability limitation framework that accounts for the fact that the external controller will be responsible for insulin delivery decisions.

Regulatory Pathway. JDRF will work in parallel with the applicant and U.S. and international regulators to establish a regulatory pathway.

MECHANISM

JDRF will solicit letters of intent (LOIs) and those proposals selected for full application will require a more detailed development plan. Applications would be funded under either the Strategic Research Agreement mechanism[1] or the Industry Discovery and Development Partnerships mechanism[2].

ELIGIBILITY

[1] http://grantcenter.jdrf.org/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements/

[2] http://grantcenter.jdrf.org/industry-partnerships/

Applications may be submitted by for-profit entities as well as nonprofit organizations, public and private universities, colleges, hospitals, laboratories, and units of state and local governments.

DEADLINES

- RFP Release Date:.....Wednesday, October 18th, 2017
- LOI Deadline: .....Wednesday, December 6th, 2017
- Full Proposal Notification: .....Wednesday, December 20th, 2017
- Full Proposal Submission Deadline: .....Wednesday, January 31st, 2018
- Response to Applicants Date:.....June 2018
- Anticipated Earliest Start Date: .....July 2018

SUBMISSION INSTRUCTIONS

Applicants should register and submit their completed LOI in RMS360 (http://jdrf.smartsimple.us).

Applicants are strongly advised to discuss their proposed project with the JDRF Artificial Pancreas Lead, Dr. Daniel Finan (dfinan@jdrf.org), before submitting.

REVIEW CRITERIA

JDRF will review and select LOIs to be developed into full proposals based on their differentiation and perceived reduction in burden and improved ease of use for people with diabetes.

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