REQUEST FOR EXPRESSIONS OF INTEREST (EOI):

# IMPROVED LONGEVITY FOR SUB-CUTANEOUS INSULIN INFUSION

## PURPOSE

JDRF is launching an initiative to overcome challenges for increased longevity for delivery of insulin via sub-cutaneous infusion. Components include infusion sets and cannula used in patch pumps. Based on these EOIs, potential applications will be subsequently invited to be developed and submitted as full proposals.

## BACKGROUND

In 2006, JDRF launched its Artificial Pancreas Project to accelerate the development of commercially available closed-loop systems. Since then, significant progress has been made in developing and testing algorithmic approaches to automate insulin delivery, and clinical studies have progressed to the outpatient pilot setting. More recently, JDRF and the Helmsley Charitable trust has funded work to improve the reliability of infusion sets.

However, all current insulin infusion sets/devices cleared in the US are only indicated for 72 hours of continuous wear. Although some people are able to wear an infusion set for longer than the recommended 3 day, other people experience infusion set failure after only 1 day. The reasons for this disparity are currently unknown.

JDRF is committed to accelerating the development of artificial pancreas systems, which is a combined Continuous Glucose Monitor (CGM), algorithm and insulin delivery system to provide automated insulin delivery. One challenge for adoption of these systems is the requirement for two external sites for insulin infusion and CGM. At present, CGMs are transitioning to 14 day wear duration from 7 days, adding to user burden due to discrepant timing of site change and limiting the potential for combined infusion and CGM sites.

Hence, JDRF desires to reduce the burden for people with T1D of managing infusion sites, and facilitate more user-friendly artificial pancreas configurations, by extending the duration of infusion sets to match CGM wear durations.

## OBJECTIVES

In this call, JDRF intends to fund innovative approaches to identifying the fundamental mechanism of failure and/or provide mitigations to known failure modes when delivering insulin via sub-cutaneous cannula. The immediate aim is to increase the reliability of insulin infusion, with an ultimate aim to extend the wear duration of infusion sets and patch pumps to match the wear duration of CGMs, for the majority of people with T1D.

The objective of this initiative is to identify common mechanisms of failure, or demonstrate effective mitigation of known failure mechanisms, in continuous sub-cutaneous insulin infusion.

**Examples of mechanisms of failure discovery may include, but are not limited to:**

- ECM or other protein deposition
- Inflammation and wound healing process
- Fibrosis

- Tissue Granulation

**Examples of mitigations for known failure modes may include:**

- Drug eluting materials
- Cannula Coatings or Surface treatments
- Insulin Excipients

Discovery proposals must have a clear pathway to commercial viability, and particular emphasis will be given to novel mechanisms of mitigation. Evaluations of proposed mitigations will require preliminary evidence of an underlying mechanism to be addressed.

## MECHANISM

Successful EOIs from for profit entities would be invited under our Industry Development and Discovery Program mechanism[1]. Applications from nonprofit organizations, public and private universities, colleges, hospitals, laboratories, units of state and local governments would be invited under our Strategic Research Agreement mechanism[2]. Projects should request costs commensurate with activities proposed for milestone-based funding of up to 2 years. Indirect costs may not exceed 10% of the direct costs. The level of funding will vary depending on the scope and overall objectives of the proposal.

## ELIGIBILITY

Applications may be submitted by for-profit entities as well as nonprofit organizations, public and private universities, colleges, hospitals, laboratories, units of state, and local governments. There are no citizenship requirements.

## EXPRESSION OF INTEREST

An approved EOI is required prior to submission of a full proposal. Each EOI should comprise a single project. The EOI should include the following information at the least:

- Title, lead investigator, brief description and specific aims
- Background /Rationale and Specific Aims of overall project
- Table of clinical cohorts and studies to be included
- Overview of hypotheses, goals, deliverables and any collaborative framework
- Brief overview of any supporting data
- Expected deliverables and impact of the proposed work
- Intellectual Property or commercial efforts associated with the application
- Total budget / budget by year
- Biosketches for all Principal Investigators

[1] http://jdrf.org/grant-center/industry-partnerships/#description

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

## DEADLINES

- **EOI Release Date:** ..... Aug 10th, 2015
- **EOI Submission Deadline:** ..... Sep 22th, 2015
- **Request for Full Proposal Notification:** Oct 21th, 2015
- **Full Proposal Submission Deadline:** .... Dec 1st, 2015
- **Response to Applicants Date:** ..... March 2016
- **Anticipated Start Date:** ..... April 1, 2016

## SUBMISSION INSTRUCTIONS

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

**As a courtesy, please email the scientific contact, Vincent Crabtree (vcrabtree@jdrf.org) to inform us of your intention to submit an EOI.**

## REVIEW CRITERIA

JDRF will review and select EOIs to be developed into full proposals, with the aim of identifying critical mechanisms of failure or evaluating novel mitigations.

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