



JDRF Seeks Expression of Interest for Projects that will Culminate in the Delivery of a PMA Application to the FDA for a Product that Provides Automated Glucose Regulation in Type 1 Diabetes.

Background and Purpose of Request

The JDRF is committed to translation of research findings into clinical results.

The JDRF has launched an initiative to support research that will accelerate access to promising continuous glucose sensing and insulin delivery technologies that improve diabetes outcomes. These studies include a large randomized controlled trial examining the effectiveness of continuous glucose sensors in people with type 1 diabetes. They also include a number of feasibility studies that are testing a number of control algorithms and systems in partially or fully closed-loop prototype systems in a controlled environment. Furthermore, the JDRF has partnered with the Food and Drug Administration (FDA) to more clearly define the pathway from these clinical research center (CRC)-based studies to “real world” ambulatory studies in the near future.

JDRF is soliciting expressions of interest to co-fund the development of a system that will provide optimal automated glucose regulation in a “closed-loop” or semi closed-loop fashion and to make this a reality for people with type 1 diabetes in an accelerated fashion.

Specific Goals of Request

To Design, Build, Deliver Closed-loop Hardware

This request for proposals aims to accelerate the progress towards a mechanical system that will be submitted to the FDA for regulatory approval and then made available to patients with diabetes.

Proposals should focus on this system (the deliverable) and provide a clearly described plan including specific interim milestones culminating in the deliverable. The deliverable would:

- Be developed to a level of FDA “approvability”, including all preliminary validation by the FDA that is needed to support the feasibility research that will lead to such a submission
- Be amenable to easy use in “real world” situations
- May include a combination of insulin pump delivery, with or without delivery of other hormones/molecules controlling glucose: a continuous glucose sensor, an intermediate “platform” and/or other innovative mechanical approaches to achieve the objective of safe automated insulin delivery
- Would provide in “real world” multi-center randomized controlled trials indisputable improvement in glycemic control with the utmost safety
- May be a closed or open platform
 - That is the deliverable may be a fully integrated system – pump, sensor, algorithm/controller all in one integrated package - or it may be a solution that takes advantage of an open “plug and play” approach that allows for communication between multiple sensors and pumps

Proposals may integrate the current capabilities of the JDRF Artificial Pancreas Project Consortium such as:

- A clinical network that can/will test prototype devices in human clinical trials
- A network of control algorithm developers
- Regulatory support

Expressions of intent should be no more than 2 pages in length including, where applicable, the following information:

- Name, title and contact information for the point of contact/principal
- Brief details of approach proposed, including rationale and description of proposed tools to be utilized and potential collaborative efforts
- Brief details of endpoints proposed, with emphasis on key milestones on a specific timeframe
- Total estimated budget and project duration

Inquiries in this area should be referred to Aaron Kowalski Ph.D., email: akowalski@jdrf.org, tel: 212-479-7512. Expressions of interest should be submitted by email attachment to Dr Kowalski by October 1st 2007.