

REQUEST FOR EXPRESSIONS OF INTEREST (EOI):

FAULT DETECTION ALGORITHMS FOR RISK MITIGATION IN ARTIFICIAL PANCREAS SYSTEMS

PURPOSE

JDRF is launching an initiative to accelerate the development of algorithm-based approaches to detect and mitigate failure events in the components of artificial pancreas systems. These components include continuous glucose monitors, pumps and infusion sets. JDRF is soliciting Expressions of Interest (EOIs). 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. To achieve improved control and ultimately euglycemia, it is critically important that these systems not only maintain blood glucose within the target range but also mitigate the risk of system-based errors that would lead to unneeded dosing of insulin and hypoglycemia. In this call, JDRF intends to fund innovative approaches to detect such events that could occur through failure in hardware, software, mechanics or electronics, or a combination of the above and could be readily incorporated into future commercial artificial pancreas systems.

OBJECTIVES

The objective of this initiative is to identify algorithmic approaches that mitigate system errors and ensure reliability and efficacy of artificial pancreas systems.

Examples of pertinent risks for algorithm-based detection/mitigation include:

- Glucose sensor failures - degradation, dropouts, dislodgement
- Bumpless transfer during sensor recalibration and new sensor insertions (changing between auto and manual)
- Insulin pump or infusion set failures - occlusions, dislodgement
- Software crashes/failure
- Wireless communication interruption or failure
- Data corruption
- Unexpected user actions (eg. calibration error, miscalculated insulin delivery)

MECHANISM

Projects may request a maximum of \$1,000,000 USD of milestone-based funding for up to 2 years. Since the nature and scope of research supported by this initiative may vary, the budget and length of awards may vary. Indirect costs may not exceed 10% of the direct costs.

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. Please see below for complete instructions.

DEADLINES

- Request for EOI Release Date:.....November 20, 2012
- EOI Submission Deadline:.....January 2, 2013
- EOI Notification:January 2013
- Application Receipt Date:February 28, 2013
- Response to Applicants Date:.....June 2013
- Earliest Anticipated Start Date:July 2013

SUBMISSION INSTRUCTIONS

Applicants must register as an applicant and submit both their EOI and application using the templates available at JDRF's on-line application system [proposalCENTRAL](https://proposalcentral.altum.com/) (<https://proposalcentral.altum.com/>).

As a courtesy, please email the scientific contact, Marlon Pragnell (mpragnell@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 significantly accelerating product development through regulatory approval.

SCIENTIFIC CONTACT

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PROPOSAL CENTRAL

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☎ (301) 916-4557 ext. 227, or toll-free in the US, (800) 875-2562 ext. 227

Assistance can be obtained Monday through Friday between 8:30am and 5pm U.S. Eastern Time