JDRF REQUESTS LETTERS OF INTENT FOR:
NO (TYPE) ONE LEFT BEHIND: EXPANDING ARTIFICIAL PANCREAS ADOPTION AND ACCESS AMONG TARGETED POPULATIONS

PURPOSE

JDRF is committed to expanding the reach of artificial pancreas (AP) systems and the benefits they can provide to people with type 1 diabetes (T1D) – of all ages and stages. While AP technology has evolved greatly over the last decade (one approved hybrid closed-loop system is currently available in several markets, and others are nearing the marketplace) much work remains to maximize adoption of and access to such systems among people with T1D. One focus area which can have a profound impact on expanding AP system usage in people with T1D is the generation of clinical evidence supporting the benefit of these devices – in terms of both biomedical and psychosocial outcomes – in targeted subpopulations which may have unique, unifying characteristics affecting AP effectiveness, safety, acceptance, and access. Demonstrating clinical success of AP systems in such populations may help improve adoption of and access to these devices. On the other hand, identification of safety, efficacy, and/or usability-related shortcomings may inform future development efforts and thereby also ultimately lead to increased adoption and access. JDRF challenges applicants to propose impactful clinical studies of AP technology (or, potentially, other non-clinical research) in targeted populations, providing novel, gap-filling evidence to advance our mission to expand the reach of life-improving AP technologies as widely as possible among people with T1D, at all ages and stages: “No (Type) One Left Behind.”

BACKGROUND

T1D is characterized by the loss of the body’s pancreatic beta cells which produce (among other things) insulin, a hormone that regulates blood glucose levels tightly in individuals without diabetes. With no endogenous insulin production, people with T1D rely on exogenous insulin. The delivery of this insulin, though, must be carefully regulated; too much insulin results in potentially acutely dangerous low glucose levels (hypoglycemia), while too little insulin can result in problematic high glucose levels (hyperglycemia) and/or a potentially dangerous condition known as diabetic ketoacidosis (DKA). In short, it is essential that a person with T1D is dosed the right amount of insulin at the right time. Moreover, even if a person with T1D were able to provide this degree of control, it would necessitate an unacceptably high burden of self-management.

AP devices [interchangeably, automated insulin delivery (AID) devices] are the most advanced device-based treatment option for people with T1D. These devices integrate three components to provide (at least partially) automated insulin delivery:

1) A continuous glucose monitor (CGM) which continuously measures glucose levels in the body,
2) An insulin pump, which has continuous access to the body to deliver insulin, and
3) An algorithm, which uses the information stream from the CGM and information about previously delivered insulin to calculate the optimal insulin infusion dose for the current conditions, and commands the insulin pump to deliver this calculated dose.

There is an ever-growing body of evidence demonstrating the ability of AP devices to both improve biomedical outcomes related to T1D (e.g., increasing time spent in a healthy glucose range while reducing exposure to hypo- and hyperglycemia) and simultaneously decrease the onerous responsibility of self-management. While adoption of and access to (e.g., via payer coverage) such systems is indeed growing, there still remains a large percentage of the population of people with T1D that are not using these systems. Roadblocks to uptake/adoption can include (but are not limited to) the following:

- Clinical studies often specifically exclude or under-represent certain populations, and therefore it is not well understood how AP systems can perform in such “under-studied” groups. Demonstrating the success of AP systems in these populations may drive adoption and/or increase prescriptions; on the

other hand, identification of problem areas (e.g., shortcomings in terms of safety, efficacy, and/or usability) is also valuable in that it may lead to better-informed future development efforts.

- Characteristics unique to certain populations – whether physical or behavioral – may limit their propensity to adopt AP systems. Elucidation of the root cause(s) of these barriers to adoption may inform future development efforts and thereby drive future adoption increases.
- Certain populations may be unaware or less aware of the existence of AP systems, or of their benefits. Studies scrutinizing such barriers may increase awareness of AP systems among both potential users and prescribers and lead to increased uptake.

As part of our mission to ensure the best treatment options are available to people with T1D of all ages and stages, JDRF invites applicants to propose impactful, novel, gap-filling clinical studies or other research initiatives investigating AP system use in targeted populations.

OBJECTIVES

Letters of intent are sought from academic or industry applicants to identify a population of individuals with T1D with unifying characteristics, until now under-studied and/or under-served, and investigate whether AP system use in such a population:

1) Is safe and can improve biomedical and psychosocial outcomes, and/or
2) Can be expanded or made more effective by identifying barriers in AP system design or implementation particular to the characteristics of the population, which may be addressed in future development efforts.

RESEARCH OUTCOMES

Researchers are charged with providing novel, gap-filling evidence, clinical or otherwise, to the scientific community and beyond on the use of AP systems in a targeted population, and/or identifying barriers in AP system design or implementation that preclude wider use among a population. In the latter case, researchers should also be able to make actionable recommendations for how to address these barriers for the benefit of future development efforts.

Examples of the types of factors that may unify a population include the following and combinations of the following, but are not limited to:

- Metabolic factors (e.g., duration of diabetes, puberty, level of physical fitness, obesity, hypoglycemia unawareness, frequent/severe hypoglycemia)
- Psychosocial characteristics (e.g., fear of hypoglycemia, distress/depression)
- Behavioral factors (e.g., meal bolus strategy, approach to sleep)
- Physical demographics (e.g., age, ethnicity)
- Contextual demographics (e.g., socioeconomics, residential setting)
- Other contextual factors [e.g., type of physician (endocrinologist vs. primary care provider)]
- Attitudes/prejudices (e.g., about medicine or technology)

In addition to these research outcomes, grantees will also be required to make data generated from JDRF funds openly accessible for the purposes of future research.

MECHANISM

In response to this announcement, proposals can be submitted to JDRF's **Strategic Research Agreement (SRA)** or **Industry Discovery and Development Program (IDDP)** grant mechanisms.

For more information on the Strategic Research Agreement mechanism, please refer to our website: http://grantcenter.jdrf.org/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements/

Each application may request up to $3,000,000 total (including up to 10% indirect costs), over a maximum of four years. JDRF may wish to work with prospective grantees to amend the scope of a proposal.

ELIGIBILITY

Letters of intent may be submitted by academic and non-academic domestic and foreign for-profit and non-profit organizations, public and private. Academic applicants must hold an M.D., D.M.D., D.V.M., Ph.D., or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility. Applications from for-profit entities or industry collaborations with academia may be submitted to this RFA; however, additional information will be requested from for-profit entities if a full application is invited.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

LETTER OF INTENT

Prospective applicants should submit an LOI online via RMS360 (http://jdrf.smartsimple.us) to be considered for a full proposal request. The LOI template provided on the RMS360 website must be used to complete the application. Applicants will be notified approximately eight weeks after the LOI deadline date if they have been approved to submit a full application.

Please see below for complete instructions. Letters of intent should use the template provided and include the following information:

- Background/rationale, published or preliminary data, hypotheses, specific aims, deliverables of project, collaborative framework if applicable
- Description of potential for project to provide important gap-filling evidence supporting increased adoption of and/or access to life-improving AP technologies, or generation of data to inform future development efforts which may ultimately increase adoption and access
- If applicable, critical analysis of other similar research or clinical studies that have been performed or are currently being planned or performed (see, e.g., clinicaltrials.gov), as well as a summary highlighting key differences between these efforts and the proposed effort
- Indication of whether research will include human subjects; if so a clinical synopsis is required
- Intellectual property or commercial efforts associated with the current application
- Estimated budget (total and yearly)

PROPOSAL

An approved LOI is required prior to submission of a full proposal. Upon notification of a request for a full proposal, the application must be completed using the templates provided on the RMS360 (http://jdrf.smartsimple.us). Proposal section templates in MS Word [**10 page maximum**] should be type-written, single-spaced and in typeface no smaller than 10-point font and have no more than six vertical lines per vertical inch. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications.

Note that all applications involving human subject research must include supplemental information to address subject safety, study design and investigational product information. More details can be found in the Human Subject Research Guidelines:
http://grantcenter.jdrf.org/wp-content/uploads/2012/12/JDRF_Scientific_Guidelines_final-Aug20151.pdf

DEADLINES

- **RFA release date** Wednesday, October 31, 2018
- **LOI deadline** Wednesday, December 5, 2018
- **Notice of invitation to full proposal** Wednesday, December 19, 2018
- **Proposal deadline** Wednesday, January 30, 2019
- **Response to applicants** August 2019
- **Earliest anticipated start date** October 2019

SUBMISSION INSTRUCTIONS

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

REVIEW CRITERIA

Applications will be evaluated based on JDRF's standard confidential award policy and according to the following criteria:

- Significance
- Relevance to T1D
- Plans for development/translation, if applicable
- Approach
- Innovation
- Investigator experience
- Environment

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If you have any grant-specific questions as you work within RMS360, please contact the administrative contact listed above.

For any **non-grant-specific** inquiries or issues, please contact SmartSimple Support Services via email support@smartsimple.com or phone (866) 239-0991. Support hours are Monday through Friday between 5:00am and 9:00pm US Eastern Standard Time.