JDRF REQUESTS EXPRESSIONS OF INTEREST FOR:

THERAPEUTIC DEVELOPMENT AND CLINICAL TESTING OF IMMUNE THERAPIES FOR TYPE 1 DIABETES

PURPOSE

The purpose of this request for applications (RFA) is to facilitate translation of type 1 diabetes (T1D) research findings into viable immune therapeutic candidates. It is intended to support clinical studies that utilize novel approaches for testing single therapies or combinations that allow rapid evaluation of their potential for the treatment or prevention of T1D and late stage preclinical development of promising candidate therapies. It is JDRF's hope that projects successfully completed under this RFA will attract partners for large scale trials towards regulatory approval of therapeutic candidates.

BACKGROUND

Type 1 diabetes (T1D) is a chronic autoimmune disorder in which auto-reactive T cells mediate the destruction of insulin-producing pancreatic β-cells, leading to lifelong dependence on exogenous insulin. To date, there are no approved immune therapies for the prevention or treatment of T1D. Immune therapies that have shown promising results in T1D have included therapies that enhance the number and/or function of regulatory T cells (Treg) as well as those that disable or ablate auto-reactive effector T cells (Teff). To maximize efficacy and patient impact in T1D, a variety of therapies that directly or indirectly result in the incapacitation of Teff and/or enhancement of Tregs will be essential. To this end, continued pre-clinical development of new immune targeted product candidates is needed.

There are inherent challenges in translating findings from preclinical models to human T1D, especially with respect to the dose, route, and frequency of administration to result in clinically meaningful outcomes. These challenges make it difficult to compare candidate therapies head to head. There is therefore a need for innovative strategies for early clinical testing of therapeutic candidates as well as pre-clinical testing strategies that will lend confidence to their potential for efficacy in humans. This RFA seeks proposals both from non-profit and for-profit institutions involving innovative immune targeted product candidates that require pre-clinical development, as well as, clinical projects designed to test therapeutic candidates (alone or in combination) in innovative clinical studies in T1D.

OBJECTIVE/SCOPE

Examples of pertinent topics include, but are not limited to:

Preclinical Studies

- Leveraging effective strategies from other fields (e.g. oncology) to generate therapies to target the T1D immune system.
- Pre-clinical mechanistic and/or efficacy studies of candidate therapeutics in appropriate animal models (demonstration of effectiveness in 2+ models is desirable).
- Optimization of lead candidate molecules.
- IND-enabling studies of clinical candidates.

Clinical Studies

- Clinical trials to demonstrate safety and/or proof-of-mechanism of candidate immune therapies.
- Pilot combination trials intended to generate data to support larger, more advanced trials.
- Testing of therapies in a platform trial setting, including, studies intended to identify relevant immune pathways impacted by different candidate therapies in T1D (may be novel and/or repositioned therapies).

Projects involving preclinical studies must demonstrate a clear understanding of a preclinical development plan for their therapeutic, even if the funding solicited is for a component of such; this includes studies of safety and of plausible mechanism of action in a preclinical setting. Clinical projects must similarly articulate the positioning of their proposed study in the context of moving their therapeutic towards regulatory approval; access to cohorts/consortia and relevant mechanistic studies must therefore be shown.

Projects involving parties with complementary expertise are highly encouraged to submit to this RFA. This may include collaborations between pre-clinical and clinical groups, science groups with technology experts, including partnerships with external informatics teams, when appropriate, and public-private partnerships.

This RFA is not intended to support: projects not targeting pathways relevant to T1D, research on biomarker or assay development, knowledge generating studies around pathogenesis of T1D, or discovery studies without potential for near-term translation.

Applicants are encouraged to consult with JDRF Program Staff to discuss the responsiveness of their proposal to this RFA.

MECHANISM

The level of funding for individual projects will vary depending on the scope and overall objectives of a project, and EOIs from strong cross functional teams will be given highest priority. The level of funding may vary depending on the scope and overall objectives of the proposal. Budgets proposed should be commensurate with project scope. Pilot and feasibility studies may also be proposed.

Nonprofit organizations, public and private universities, colleges, hospitals, laboratories, units of state and local governments may apply under JDRF's **Strategic Research Agreement (SRA)** funding mechanisms. Under the terms of the SRA grant application, regular written reports will be required from the funded investigator with evidence of progress toward achieving research milestones as a basis for continued support.

For-profit entities may apply under JDRF's **Industry Discovery & Development Partnership (IDDP)** funding mechanism, which entails additional requirements including matching funds from the company. IDDP awards will be administered by contract agreements. Timelines for awards administered by contracts are typically longer than those listed at the end of this RFA, and will be determined ad hoc. Applicants interested in submitting an IDDP EOI in response to this RFA are required to contact JDRF program staff to discuss prior to submitting the EOI.

ELIGIBILITY

This RFA is open to academic investigators, biotechnology and pharmaceutical companies, or industry-academia partnerships, with preference given to collaborations between academic groups and commercial organizations.

Please note that additional information will be requested of applicants from for-profit entities or industry collaborations with academia if a full application is invited.

Applications may be submitted by domestic and foreign for profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. 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.

Please note that submissions from for-profit entities or collaborations involving for-profit entities will also be reviewed by the JDRF T1D Fund (http://www.jdrf.org/about/t1dfund/) in addition to JDRF Research.

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.

EXPRESSIONS OF INTEREST

Prospective applicants should submit an expression of interest, [2 pages maximum] on line via RMS360 (http://jdrf.smartsimple.us) to be considered for a full proposal request. The EOI template provided on the RMS360 website must be used to complete the application.

PROPOSAL

An approved Expression of Interest is required prior to submission of a full proposal. JDRF staff will contact applicants of successful EOIs regarding next steps.

SCIENTIFIC REVIEW CRITERIA

Expressions of Interest will be evaluated based on the following criteria:

- Significance
- Relevance
- Approach
- Innovation
- Investigator Experience
- Environment
- Commercial Feasibility: Is there a potential path to the marketplace?
- Therapeutic Strategy: Does project address unmet needs relative to existing alternatives/therapies?
- Development Potential: Is there a development path that enables the drug candidate to advance through preclinical and/or clinical development?
- Intellectual Property: Has the applicant secured intellectual property for the technology? If not, is it in the process of doing so?

PROJECTED DEADLINES

- RFA Release Date: .....May 14 2019
- EOI Deadline.....August 5, 2019
- Notification of EOI Outcome.....September 16, 2019
- Full Proposal Deadline.....October 31, 2019
- Response to Applicants (academic SRA)..... March 31, 2020
- Response to Applicants (IDDP).....June 30, 2020
- Earliest Anticipated Start Date (academic SRA).....May 1, 2020

CONTACTS

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RMS360 (http://jdrf.smartsimple.us)

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