

REQUEST FOR LETTERS OF INTENT (LOI):

EXPLORATORY CLINICAL TRIALS FOR DIABETIC RETINOPATHY:

PURPOSE

JDRF is committed to facilitating the translation of therapies for diabetic retinopathy to individuals with Type 1 Diabetes (T1D). To this end, JDRF is soliciting letters of intent for clinical trials of novel therapies for non-proliferative (NPDR), or proliferative retinopathy (PDR).

BACKGROUND

Diabetic retinopathy is a sight-threatening complication of diabetes and the largest cause of blindness in the US. Despite recent advances in the treatment of diabetic macular edema, there remains a large unmet clinical need to prevent or reverse vision loss via the treatment of NPDR and PDR.

OBJECTIVES

Letters of intent are sought from investigators with for innovative approaches to arrest or reverse NPDR or to resolve PDR. Exploratory and initial proof of concept clinical trials which could provide a strong scientific rationale for larger or pivotal studies will be given highest priority. Clinical trials must include subjects with T1D; however trials will be considered which also propose enrollment of those with Type 2 Diabetes (T2D). Proof of concept clinical studies may propose use of approved or investigational products based on an excellent scientific rationale. JDRF is particularly interested in clinical trials which propose novel means of subject stratification based on estimated risk of progression of NPDR.

Endpoints of interest include:

- Change in ETDRS scale; prevention of progression or improvement
- Visual acuity
- Other well-justified measures of visual function
- Progression to proliferative diabetic retinopathy
- Vision-related quality of life scores

Clinical trials of up to 36 months duration will be considered. Investigators proposing trials exceeding this duration should contact Dr Helen Nickerson to assess whether submission is possible.

MECHANISM

Accepted letters of intent from academic groups would be submitted as Clinical Strategic Research Agreements (<http://jdrf.org/grant-center/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements>). Letters of intent from industry groups would be invited to submit applications to the JDRF Industry Partnership program <http://jdrf.org/grant-center/industry-partnerships/>

Under exceptional circumstances, proposals which also include preclinical studies may be considered if needed to obtain regulatory approval to move forward with the proposed clinical trial. Please contact Dr Helen Nickerson to discuss studies in this area.

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.

LETTER OF INTENT

An approved LOI is mandatory prior to submission of a full proposal. Please see below for complete instructions.

DEADLINES

- Request for LOI Release Date:.....April 21st 2014
- LOI Submission Deadline.....June 20th 2014
- LOI Notification:July 2014
- Full Application Deadline:September 16th 2014
- Response to Applicants Date:January 2015
- Earliest Anticipated Start Date:February 2015

SUBMISSION INSTRUCTIONS


Applicants should register and submit their completed LOI in RMS360 (<http://jdrf.smartsimple.us>). The deadline to submit a completed LOI is June 20, 2014.

REVIEW CRITERIA

JDRF will review and select LOIs to be developed into full proposals. Please direct queries about the suitability of your proposal to the scientific contact below.


SCIENTIFIC CONTACTS

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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.