



CALL FOR EXPRESSIONS OF INTEREST

May, 2006

Closing date: 5 June, 2006

**DVDC is a joint initiative of Australia's
National Health and Medical Research Council
and the
Juvenile Diabetes Research Foundation International**



Australian Government

National Health and Medical Research Council



dedicated to finding a cure

Diabetes Vaccine Development Centre

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BACKGROUND

DVDC (Diabetes Vaccine Development Centre) is a joint initiative of the Australian Government, through the National Health and Medical Research Council (NHMRC) and the New York-based Juvenile Diabetes Research Foundation International (JDRF). Based in Melbourne, Australia, DVDC is global in its outlook and strategy.

Following a recent review of its activities, DVDC's Board has broadened the acceptance criteria for projects within its scope. In addition to studies ready for clinical development, DVDC is now also interested in supporting focused, relevant pre-clinical studies. In this context, DVDC seeks to work closely with principal investigators leading such projects to facilitate the translational research required for subsequent early-stage product development.

OVERVIEW OF DVDC

DVDC's mission is: *to accelerate the development of one or more immunotherapeutic products that will prevent or delay the progress of type 1 diabetes, aiming to have clinical proof of concept in 3 – 5 years, with the studies conducted to a standard acceptable to an industrial partner.*

DVDC operates as a virtual company to bring together the crucial components of the vaccine/immunotherapeutic development process, up to and including clinical proof-of-concept studies. DVDC funds, supports and facilitates the activities of groups with different approaches to the development of immunotherapeutic treatments for type 1 diabetes. Although based in Australia and physically located within The University of Melbourne (which acts as its sponsoring administering institution), DVDC seeks to support promising therapeutic candidates worldwide.

Details of the strategic framework within which DVDC operates are available at:
www.dvdc.org.au

While DVDC will accept applications at any time during the year, it will generally announce two calls for Expressions of Interest each year. This call is for May, 2006 with an anticipated project commencement date of late 2006 for those projects identified as being of priority for DVDC support.

DVDC FUNDING

DVDC has committed some of its funds to several exciting, leading edge proposals as a result of previous calls for Expressions of Interest (EoIs). From its uncommitted funds, DVDC has the ability to support selected new initiatives aimed at the development of new candidate immunotherapeutic products.

DVDC invites submissions of short proposals (not more than 5 pages) from organisations worldwide defining their proposed product and outlining their proposed project plan, while explaining how it fits the mission of DVDC and serves the field of Type 1 Diabetes. All information sent to DVDC will be kept strictly confidential.

DVDC reserves the right to remove from further consideration Expressions of Interest for projects that are too early in development and thus without prospect for defining a specific product candidate. As an indication, to be considered the project needs to revolve around a clearly defined product description and be perceived as no further than 2 years from having commenced clinical studies. DVDC will consider those projects where some further preclinical studies are required to gather data that are regarded as an essential requirement to progress to the clinic or to the development of a product to 'a standard acceptable to an industrial partner'.

DVDC is interested in receiving EoIs from researchers who have serious plans to test a diabetes immunotherapy in the clinic. DVDC can support early stages of testing, including GMP manufacture, small scale fill and finish, and toxicology testing.

Subsequent to initial review, applicants invited to submit a full application will be provided with a written assessment from DVDC's peer review process and will have an opportunity to respond. DVDC will offer to work collaboratively with principal investigators to facilitate their product development plans and thereby best advance the project to the clinic.

ASSESSMENT CRITERIA

Submissions will be assessed according to the following criteria, listed roughly in descending order of significance:

- 1) Likelihood of a candidate immunotherapeutic generating clinical data within 3-5 years.
- 2) Suitability of the product to be developed commercially. In this context the following issues are of importance:
 - Solid evidence of efficacy in relevant animal models (preferably more than one)
 - Data from studies providing sound rationale for mechanism of action
 - Safety profile acceptable for clinical development
 - Clearly defined intellectual property situation
 - Innovative approach
 - Likely cost of production with clear indication of currency used
 - Proposed arrangements for ethical clearances
 - Expertise and experience of personnel involved.

- 3) Clearly defined product description.
- 4) Current (if any) and proposed funding support for the project. DVDC funding can be for a variable duration and will be performance- and milestone-based. (Note: DVDC has limited funds and will look more favourably on projects where co-funding arrangements are proposed.)

TIMETABLE

Invitation to organisations worldwide to submit 5 page (maximum) expressions of interest (EOIs)	Mid May, 2006
Closing date for submission of EOIs	5 June, 2006
EOIs reviewed by DVDC Board members	14 June, 2006
Full applications may be invited	
Closing date for full applications	31 July, 2006
Full applications reviewed by DVDC external review panel	
DVDC internal review process and applicants may be invited for interview by DVDC Board members	13 September, 2006
Applicants advised of outcome	Late September, 2006

SUBMISSION OF EXPRESSIONS OF INTEREST AND QUERIES

Organisations with a project that has the potential to meet DVDC's mission are encouraged to discuss their project informally and confidentially with Dr David O. Irving, Chief Executive Officer (+61 3 8344 0753, email: dirving@dvdc.org.au), prior to submitting an Expression of Interest.

Expressions of Interest, preferably by email in PDF format, should be directed to:

Ms Mary Joy Gleeson
 Centre Liaison Manager
 Diabetes Vaccine Development Centre
 School of Population Health
 University of Melbourne 3010
 AUSTRALIA

Telephone: +61 3 8344 0752
 Fax: +61 3 9348 1827
 E-mail: mjgleeson@dvdc.org.au

CURRENT PROJECTS BEING SUPPORTED BY DVDC

Title:

A randomized, double-blind, placebo-controlled trial of intranasal insulin in children and young adults at risk of Type 1 Diabetes: Intranasal Insulin Trial II (INIT II)

Principal Investigators:

Professor Len Harrison
Department of Clinical Immunology and Allergy,
Royal Melbourne Hospital, AUSTRALIA

Associate Professor Peter Colman
Department of Diabetes and Endocrinology,
Royal Melbourne Hospital, AUSTRALIA

Study Objectives:

To determine whether intranasal administration of insulin to children and young adults at risk of type 1 diabetes will:

- (i) reduce their rate of development of diabetes;
- (ii) prevent expected loss of pancreatic β -cell function;
- (iii) improve insulin action;
- (iv) stimulate immune responses consistent with the induction of immune tolerance to insulin.

Title:

Islet autoantigen-derived peptides eluted from human HLA class II molecules as vaccines for the immunotherapy of type 1 diabetes: a safety and proof of concept study in man.

Principal Investigators:

Dr Colin Dayan
Consultant Senior Lecturer,
Clinical Research Unit,
University of Bristol, UK

Dr Mark Peakman
Reader in Immunology,
King's College London, UK

Study Objectives:

To determine whether intradermal administration of a soluble peptide sequence:

- (i) is safe particularly in terms of hypersensitivity reactions over a wide dose range;
- (ii) can induce a regulated immune response.