JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

Australian Type 1 Diabetes Clinical Research Network

Request for Applications (RFA) - Trials

Expression of Interest (EOI)

Click Here to Apply

January 2024

Funder	JDRF Australia
Funding category	Clinical Trials (CTs)
Funding field	New therapies for the treatment of Type 1 Diabetes (T1D),
Budget	As per proposed budget, subject to review and funding availability
Submission deadline	Applications can be submitted any time of the year. Funding decisions will be announced twice a year in April and December.

Contents

About JDRF

JDRF leads the global fight against type 1 diabetes (T1D) by funding research to improve lives and find cures for those with the disease and find cures.

Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. We connect the leading individuals in every discipline, industry, and organisation with a single focus of eradicating T1D. With over 50 years of investment in the best researchers, we support an innovative pipeline of research from the earliest stages through to clinical trials of new treatments, devices, and therapies. Alongside this, we advocate for greater access or financial support so that everyone living with T1D can access life-changing new therapies.

Type 1 Diabetes Clinical Research Network (T1DCRN) in Australia and New Zealand

The Australian Type 1 Diabetes Clinical Research Network (T1DCRN) is a national framework that supports the most promising T1D research and clinical trials. To date, T1DCRN initiatives have supported more than 300 researchers across 70 institutions, connecting approximately 2,500 Australians with the latest research, treatments, and technologies. The sharp focus on patient benefit is a unique dimension of the T1DCRN and this patient-centric approach provides a platform to accelerate therapies and amplify research impact. To fulfil its mission, in the next three years the T1DCRN aims to build on prior achievements and increase the impact of T1D research via expansion of its scientific priorities. These new research directions will bring new talent, knowledge, and collaborations across relevant disciplines to the field of T1D to address critical research questions pertaining to T1D risk and heterogeneity. This new phase of the T1DCRN aims to:

- Increase the volume and impact of Australian T1D clinical research, while investing in large-scale prevention and screening initiatives.
- Support “bench to bedside” research and ensure researchers have the required supporting tools and policy environment.
- Nurture current and future research leaders in T1D while attracting bright new talents.

The program has a track record of successful implementation of major collaborative programs (Figure 1). Through identification of gaps and needs, diverse consultations, and establishment of partnerships, the T1DCRN strategically supports national translational programs that address prevention, early diagnosis, new therapies and capacity building. With the overarching goals of identifying individuals at risk of T1D to prevent the onset of clinical diabetes, providing clinical trial and data capture platforms, and accelerating the pace of translation by embedding outcomes into clinical care, the T1DCRN funds:

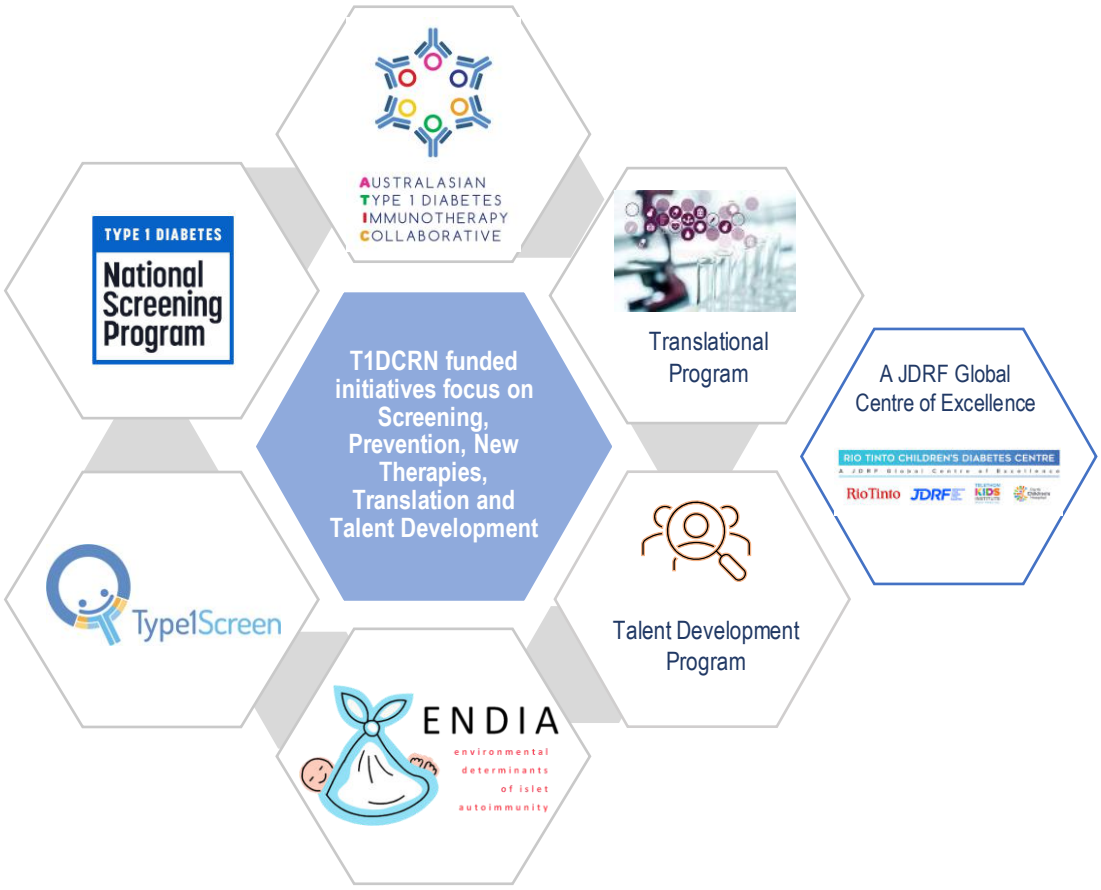

Figure 1. JDRF programs have been strategically implemented to provide the infrastructure and expertise needed to interconnect for optimal and faster outcomes.

- The Environmental Determinants of Islet Autoimmunity Study (ENDIA) - an Australian prospective pregnancy cohort study investigating the environmental triggers responsible for the autoimmune process that leads to T1D.
- Type1Screen (T1S) - a program which offers autoantibody testing to individuals over two years who have a relative with T1D or have had a previous positive antibody test to determine if they are at risk of developing T1D.
- Type 1 Diabetes National Screening Program, a General Population Screening pilot (GPS) - its objective is to determine the feasibility and acceptability of autoantibody screening in Australia. This will enable identification of those in the population who are likely to benefit from taking part in clinical trials involving preventative therapies.
- Australasian T1D Immunotherapy Collaborative (ATIC) - a highly interconnected consortium run by leading Australian immunologists and endocrinologists. It represents a platform that has the capacity to facilitate the conduct of clinical trials according to international standards, thereby strengthening Australia's reputation as a preferred site.
- Translational and Talent Development Programs – designed to identify promising research ideas and invest in a sustainable and impactful way that will facilitate scientific discoveries towards translation and commercialisation to significantly impact clinical care and the lives of people living with T1D.

- Through JDRF, philanthropic funding has also established The Rio Tinto Children's Diabetes Centre - a JDRF Global Centre of Excellence (CoE) that aims to improve the lives of children and young adults living with diabetes by bringing together research, education and clinical care. The mission of the CoE is to undertake research that is translated into effective clinical management, ensuring patients receive the best evidence-based care available.

Together, these platforms and networks offer a wealth of readily available data, experience and knowledge which can be leveraged for patient benefit.

Objective and scope of the RFA

T1D is a progressive, life-long condition. Ongoing research efforts for the prevention and treatment of T1D have focused on therapies that aim to preserve beta cell health or/and delay the destruction of functional beta cell mass, with the goal of restoring glycaemic control and eliminating the need for exogenous insulin. These therapies can be broadly categorised into three groups.

1. Disease modifying therapies (DMTs), which can impact various stages of T1D by preventing insulin dependence in those at risk for developing T1D (Stages 1 and 2), maintaining or increasing insulin production in those recently diagnosed or living with established T1D (Stage 3) and restoring insulin independence in these populations (Stage 3).
2. Cell therapies, which by replacing or regenerating the destroyed beta cells, enable the body to produce its insulin again, potentially reducing the need to inject insulin.
3. Adjunctive therapies, which in combination with insulin, help improve glucose control, potentially slowing progression of T1D.

The **objective** of this RFA is to support clinical trials that are key to advancing the field and have the potential to prevent, delay and treat T1D.

The **goal** of this RFA is to build capacity and increase the number of clinical trials into novel therapies for T1D via a dual approach: by enabling Australia's participation in international trials and by supporting the most promising local clinical trials.

This RFA will assist JDRF to identify and support the conduct of nationally and globally collaborative clinical trials in T1D. More specifically, the RFA will aim to:

- Provide Australian individuals at risk or/and living with T1D with increased opportunities to access novel therapies.
- Provide an avenue for Australian researchers to conduct first in man studies, hence expediting translation of newly identified therapies into treatment choices for T1D patients and individuals at risk.
- Foster international and national collaborative trials between health care professionals and industry thus increasing the number of clinical trials on offer as part of clinical care approaches.

Priority areas

JDRF are seeking Expressions of Interest (EOI) for clinical trial proposals with the focus on testing new, as well as generic or proprietary treatments to prevent the onset, progression, and/or offer better treatment options for T1D.

Proposed clinical trials may focus on testing singular and combination therapies to increase their efficacy, including combining new T1D therapies with multiple repurposed therapies, testing treatments that are beneficial to a specific group of T1D patients or treatments that are effective to the entire patient population living with T1D.

EOIs can be submitted by both non-profit and for-profit institutions for funding to enable therapeutic candidates (alone or in combination) for testing at Australian clinical trial sites. Specifically, we are seeking EOIs on clinical trials focusing on:

- Targeted therapies aimed at altering the immune system to prevent destruction of insulin-producing β cells (i.e., antigen-specific therapies that provide a targeted approach towards inducing peripheral immune tolerance without leading to systemic immune inhibition and associated complications).
- Approaches directed at other T1D autoimmunity induced pathologies such as inflammation.
- Testing small-molecules or/and monoclonal antibodies with established efficacy and safety profiles in other diseases, designed to specifically inhibit molecular pathways leading to the onset of autoimmunity.
- Combination of two or more immune therapies or combination of immune therapies with β cell survival therapies.
- Combination of immune and β cell regeneration therapies.
- Therapeutic agents other than insulin aimed at improving glycaemic control, reduce insulin requirement.
- Secondary mechanistic studies embedded within the clinical trial design are allowed.

Cost effectiveness, speed and innovative trial design are all priorities of JDRF. Collaborative national and international proposals and trials that bring leveraged investment to the T1DCRN will be prioritised.

Exclusion criteria

EOIs will also be excluded from further consideration if at any time during the assessment process JDRF or the review panel determines a proposal or parts of it to:

i. Purely laboratory-based research studies that are not part of mechanistic studies linked to a proposed clinical trial or observational cohort studies are excluded from this call.
ii. Duplicate (as opposed to expanding) a current or planned trial (either in Australia or overseas).
iii. Lack sufficient multidisciplinary and cross-institutional collaboration or national representation.
iv. Lack a clearly articulated hypothesis and clear impact.

Eligibility

EOIs submitted in response to this RFA must demonstrate they meet the following eligibility criteria:

- Alignment with JDRF T1D clinical trial priority areas (see above).
- Relevance of the trial to the goals and objectives of this RFA.
- Cost effectiveness.

All Australian based investigators and respective institutions are eligible to apply.

Principal Investigators (PIs) and Co-PIs (Co-Principal Investigators) must hold a Ph.D., an M.D., or an equivalent academic degree.

PIs must be affiliated with an Australian university, hospital, research institute, or other comparable institutions which may include a for-profit entity. Collaborations with PIs from international institutions are encouraged.

Internationally based investigators are also eligible to participate in funded trials, provided a collaboration with an Australian administering institution is demonstrated.

Funding

JDRF may fund one or more clinical trials annually depending on funding availability:

- Partnerships between industry and academia will be prioritised. It is expected that adequate information outlining the roles and responsibilities of the industry partner and contractual nature of the collaboration, including but not limited to aspects such as data ownership, commercialisation, data access and intellectual property, is provided.
- Investigator-initiated trials that are an extension of work previously or currently supported by JDRF or newly developed clinical trial proposals are invited.
- Evidence of institutional commitment in the form of matched institutional or industry funding and resources is highly desirable and will be favourably regarded in the review process.

Please note that grants awarded by JDRF Australia through the T1DCRN are listed on the Australian Competitive Grants Register. As such, Australian institutions may recover indirect costs through Research Block Grants funding. JDRF Australia will not provide funding for indirect costs, including basic facilities and equipment, organisational overheads and/or infrastructure costs. These must not be included in the budget request.

Consent for co-funding

JDRF actively seeks co-funding opportunities with other funding bodies. With consent from the applicant, JDRF Australia may share the application and information pertaining to the assessment with other relevant parties. Refusal of the applicant to share the application will not influence funding decisions made by JDRF Australia.

Selection process and criteria

EOIs will be reviewed based on strength of scientific rationale, appropriateness of patient population, adequacy of study design, investigational agent availability and budget. The top ranked EOIs will be shortlisted, PIs will be notified of the outcome via e-mail and will be invited to submit a full proposal.

The review process of the full-length applications will be tailored based on the trial status and site location:

- Where a clinical trial is an already approved international trial that lists Australia as a new site, JDRF may ask for ranking, critiques, and recommendations. This information will be taken into consideration during JDRFs review.
- Proposals which have not been scientifically reviewed will be subjected to expert review against the following criteria:

Appropriateness (25%)

- Clear indication of the trial being built upon ethical principles (i.e., informed consent, first do not harm and beneficial outcomes that outweigh the risks for all participants).
- Adequate supporting evidence of how the proposed intervention might work and its underpinning mechanisms.
- Clarity of the research question in terms of the targeted population, intervention, comparator, and outcomes.
- Whether the study design is fit for the research question.

Significance of research outcomes (30%)

- If the aims of the application are achieved, how will this lead to changes in the health system?
- What will the impact of the results be on the T1D community?
- Does this research have the potential to further build clinical capacity to increase national and international collaboration, especially collaboration within other major JDRF funded programs?

Feasibility (25%)

- Whether the feasibility assessment provided by the investigative team is indicative of successful recruitment and completion of the trial.
- The scientific environment in which the trial will be conducted is adequate (the proposed trial takes advantage of unique features of the research environment or employs useful collaborative arrangements).
- Are all significant risks identified and appropriate mitigation steps outlined?

Stakeholder engagement (20%)

- Is there adequate national representation in the investigative team and is the proposed work aligned with the expertise of the investigator(s) and other researchers?
- Are all relevant stakeholders identified, and subsequently engaged at the appropriate stages of the proposed trial?
- Are other JDRF initiatives, such as ADDN, T1S, and CoE effectively engaged?

Note: All trials that are to be conducted under the ATIC umbrella must undergo pre-selection processes described within its Clinical Trial Prioritisation Framework.

Publications, Data and Biological Sample Sharing

The T1DCRN is committed to the timely publication and dissemination of all information and materials developed under T1DCRN funding. Additionally, the T1DCRN is committed to the sharing of bio-samples with the wider research community. The recipient of this award must agree to this principle and must take reasonable steps in order to make available all generated project materials for publication and wider dissemination as well as facilitate availability of collected bio-samples as described in JDRF Australia's Policy on Data and Biosample Sharing.

Sharing of data and bio-samples must be supported by clear policies and guidelines, as well as mechanisms to satisfy this requirement. The Funding Agreement between the administering institution and JDRF will comprise a Data Sharing Plan which must be completed by the Lead Principal Investigator(s) for each clinical trial proposal.

Progress reports will be required as outlined in the Funding Agreement. In line with the Australian Government funding agreement for the Initiative, recipients may be required to participate in a Review by the Government at any time as required.

Submission Instructions

EOIs for Clinical Trials must be submitted directly to JDRF using the online grants management system RMS360 (http://jdrf.smartsimple.us). Applications must be completed using templates provided in RMS360 and all asterisked fields in RMS360 must be completed.

Shortlisted EOIs will be required to submit a full proposal. JDRF staff will contact applicants of successful EOIs regarding next steps.
Information submitted as part of the application is collected and stored in accordance with the JDRF Privacy Policy.

All parties involved in or associated with an application must declare at the date of submission any Conflict of Interest that exists or is likely to arise in relation to any aspect of the application. Refer to JDRF Australia's Network Conflict of Interest policy for further information.

EOI Submission Checklist

Primary information is to be provided as follows:

1. Research Plan *(maximum 4 pages; use template)*
2. Bio-sketches - use NIH (National Institutes of Health or JDRF template)

Contact Details

For inquiries relating to the alignment of your proposal to this RFA and submission requirements please consult:

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