JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

Australian Type 1 Diabetes Clinical Research Network

JDRF Australia

Request for Applications: Australian T1D Clinical Research Network Clinical Trial Collaborative – Immunotherapy

Applications Open	Monday	17 Aug 2020
RFA Webinar 1^ - Introduction to RFA	12-1pm Tuesday	1 Sep 2020
RFA Webinar 2^ - Q&A	2-3pm Thursday	22 Oct 2020
Collaborative Application and Associated Clinical Trial Proposal Deadline* †	Thursday	26 Nov 2020
Invitation for Additional Information for Clinical Trial Proposals	Monday	21 Dec 2020
Clinical Trial Proposal Additional Information Deadline* †	Thursday	25 Feb 2021
Notification to Awardees	Thursday	22 April 2021

^ Subject to change; please email JDRF to express your interest in attending

* Applicants must note that the Research Office of each Administering Organisation is required to certify to JDRF all "full submission" applications in RMS360 and may have an internal closing time which precedes this deadline

† Deadlines are at 11:59 pm AEST/AEDT

Click here to apply

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1 Background

Australian T1D researchers specialising in the immunotherapy field have a strong international track record and are at the forefront of international research. However, fragmentation of resources and lack of long-term funding hinders efficient study development and optimised translation of research outcomes.[1]

The vision of the JDRF Immunotherapies Program aims to halt the progression of and ultimately achieve a cure for T1D through the development of disease-modifying therapies that induce desirable and lasting changes to the immune system. To achieve this vision, JDRF will facilitate Australian researchers in establishing one national T1D Clinical Research Network (CRN) Clinical Trial Collaborative to promote Immunotherapy research and provide funding to support this initiative for up to four years. In addition, JDRF will in the first instance provide additional funding to enable participation of the Collaborative in international immunotherapy trials testing disease modifying therapies, and then in later years may support investigator-initiated immunotherapy trials.

Ideally, the Collaborative should build on existing infrastructure and expertise to optimise the current network of immunotherapy researchers to form one national, multidisciplinary platform of institutions focusing on excellence in Immunotherapy research aligned with JDRF's mission and research priority areas.

The mission of the Collaborative will be to function as a highly interconnected and sustainable platform to enable the conduct of global, multidisciplinary, large-scale T1D trials in the area of immunotherapy thereby accelerating knowledge translation and patient benefit. A national platform working cohesively on T1D projects focused on immunotherapy will strengthen Australia's research capacity by building on existing initiatives and infrastructure, ultimately to procure leveraged competitive funding, securing the long-term global sustainability of the Collaborative as an internationally recognised Australian T1D immunotherapy research platform. A collaborative network of Australian research sites would also consolidate and expand existing expertise and human resources and nurture emerging talent to develop a uniform approach to research and allow novel therapies to be tested in the Australian healthcare setting, accelerating access to therapies that prove effective.

To successfully establish the Collaborative, a detailed understanding of the regulatory framework will be required. The Collaborative must have in place a clearly defined set of goals and an established governance model. In addition, it is expected that the Collaborative will provide an exceptional environment for training of basic and clinical researchers in T1D and facilitate access to resource sharing and enhance knowledge of the wider T1D research community.

[1] The Australian T1D Research Resource Map

2 General Operating Principles of the Collaborative

The Collaborative will be founded on the following operating principles, which underpin the delivery of the program objectives and forms part of the selection criteria (section 11).

1. Patient focused: To be successful the Collaborative must have a strong T1D program that is aligned to the vision and implementation of JDRF's mission. The primary goal should be on patient benefit which underscores all the activities of JDRF including education and engagement of the T1D patient community, including those in rural and regional Australia, in research and trials ultimately making therapies and technologies more accessible to improve patient outcomes

2. Collaboration: A strong multidisciplinary collaborative framework will be integral to connect Australian institutions nationally and globally, thereby building interdisciplinary expertise of international standards and recognition. The Collaborative will nurture partnerships between researchers, institutes, industry and funders to benefit from existing expertise and resources and leverage prior investments in Australia by JDRF and other funders

3. Innovation: The Collaborative will have an innovative approach to developing an international standing in the advancement of T1D knowledge, research, training, policy and practice

4. Building Australia's talent: The Collaborative will build Australia's talent and human capital by facilitating robust training and career prospects to attract and retain talents of the highest quality to T1D research. The Collaborative will allow Australian researchers opportunities to work over long periods of time and must be able to provide adequate support staff to achieve the desired activities

5. Data and Resource Sharing: With the intention of creating a long-term research legacy, the Collaborative will consolidate and capture valuable research information and invest in secondary analysis of outcome data which will be generated for sharing with entities external to the Collaborative

6. Productivity and Impact Driven: The Collaborative will be a dynamic entity with a strong focus on productivity where new projects will be directed by progress towards objectives, thereby maximising the potential for impact on the wider community including patients, education institutes, hospitals, health care professionals, governments, industry and the private and not-for-profit sector

3 Purpose of this RFA

The purpose of this RFA is to invite Australian T1D researchers with a strong international track record in immunotherapy to submit one application describing the formation of a highly collaborative approach towards consolidating current infrastructure and expanding capacity in performing clinical research in immune therapies via a singular, national platform and its proposed budget. The aim of the Collaborative is to achieve a sustainable research ecosystem whereby infrastructure and resources are shared between Collaborative sites to accelerate world-class immunotherapy research in Australia.

This RFA compromises two broad components:

- Applications describing the formation of a collaborative and support of current activities
- Request for Clinical Trial Proposals for the participation of Australian Collaborative sites in international immune therapy trials

In line with the vision of the JDRF Immunotherapies Program, this RFA is soliciting the inclusion of up to five associated clinical trial proposals requesting funding to enable the participation of Collaborative sites in existing or pending international, large scale, multicentre immunotherapy trials, biomarker validation studies and clinical work that is key to advancing the immunotherapy field.

JDRF will provide funding for up to four years for the establishment and ongoing support of current clinical trials, screening and core activities of the Collaborative. In addition, JDRF may provide funding for the conduct of international immune therapy trials throughout this period. Furthermore, to ensure that infrastructure is utilised and further opportunities to build capacity are provided, JDRF may accept Letters of Intent (LOI's) for investigator-initiated trials in the later stages of the funding period (subject to available funding).

It is highly encouraged that all applications focus on collaborative efforts utilising existing initiatives involving T1D populations (e.g. ENDIA, ADDN, Type1Screen). It is envisioned that this funding opportunity will consolidate and strengthen excellence in immunotherapies research in Australia alongside research infrastructure that has been developed as result of prior initiatives.

4 Goals and Objectives of the Collaborative

In line with the T1DCRN, the overarching goal of the Collaborative is to positively impact the lives of people with T1D in Australia through the support and promotion of clinical research, focussing on at-risk populations, new onset populations and individuals with established T1D. This will be achieved by bringing together domestic and international experts in T1D and immunotherapy research to facilitate efficient and effective delivery and adoption of clinical research in Australia and invest in and build long-term research

capacity. Additionally, the Collaborative should aim to forge significant global partnerships to leverage existing domestic and international expertise in T1D research and address urgent gaps in research priorities, ultimately to accelerate access to novel therapies for Australian patients with T1D.

Through these areas of focus the Collaborative will:

1. Engage the international T1D research community in Australian research and enhance Australia's position as a world leader in T1D in immunotherapy research
2. Build a platform where diverse expertise across sectors in health interacts with emerging talent and attracts international research to Australia
3. Strengthen and expand the skill set, knowledge base and capacity, and reduce duplication in Australian T1D Immunotherapy research
4. Enable research excellence by setting clear expectations, roles and responsibilities for all participating sites
5. Support the progression of game-changing immunotherapies by conducting clinical trials in T1D that will deliver improved patient outcomes and quality of life
6. Build human capacity and talent by the inclusion of both early-mid career researchers (EMCR) and established researchers in the leadership group to provide opportunity for EMCR to develop their leadership experience under the mentorship of more senior researchers

5 Eligibility

5.1 Applicants

Investigators and institutions based in Australia are eligible to respond to this RFA. Applications must be made by a team of Principal Investigator/s holding an MBBS., PhD, or equivalent academic degree and hold a position at a university, hospital or research institute.

Industry collaborations are permitted and highly encouraged within the Collaborative provided adequate information is provided outlining the roles and responsibilities of the industry member and contractual nature of the collaboration, including but not limited to aspects such as licencing and intellectual property.

If you are unclear on your eligibility, please seek clarification from the Program Contacts (Section 15).

5.2 Alignment with RFA Objectives

All Collaborative Applications and Associated Clinical Trial Proposals will be eligible if they meet the initiative's goals and objectives (section 4).

5.3 Overlap of Research

The objectives of this RFA and the T1DCRN emphasise commitment to encouraging multidisciplinary collaboration and funding of projects that will present the greatest benefit to the T1D community. After the initial review, if more than one application is received investigators may be invited to combine their application into one single full submission in line with the purpose of this RFA (section 3).

In submitting an application in response to this RFA, you are consenting to information about your application being shared with other applicants for this purpose if appropriate and acknowledge that you may be asked to combine your application with another applicant. Consent to share information about an application is included in the Collaborative Proposal template. You will be informed about this prior to JDRF sharing any information and given the opportunity to withdraw your application if desired.

5.4 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 of the application with other funding bodies that are specifically interested in supporting the research generated through T1DCRN. Consent to disclose the details of the application is included in the Collaborative Proposal template. Refusal of the applicant to consent will not influence funding decisions made by JDRF Australia.

6 Exclusion Criteria

The application will 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:

1. Duplicates a current or planned project (either in Australia or overseas)
2. Lacks sufficient multidisciplinary and cross-institutional collaboration or involves a single site
3. Fails to include diversity of expertise form disciplines outside of T1D
4. Has an absence of a clearly articulated vision and steps to progress the establishment of the Collaborative towards achieving a sustainable platform
5. Contains harmful or high-risk elements that are inadequately managed or would be unlikely to lead to viable approaches to treating, preventing or curing T1D due to the harm-benefit ratio

6. Fails to include and engage currently operating immunotherapy trials, and T1D networks and datasets

7 Funding

JDRF will fund one National collaborative platform and in addition may fund the participation of Collaborative sites in clinical trials involving immune therapies. Funding of up to $600,000 per year over four years will be provided towards the establishment, support and ongoing activities involved in the conduct of clinical trials, which should include screening, and current ongoing clinical and core research activities. The final budget for the platform will be negotiated prior to the commencement of the initiative and may be renegotiated as the scope and nature of activities may change over time. Continuation of funding will be subject to availability of funds and satisfactory progress throughout the life of the award.

Furthermore, JDRF will consider Clinical Trial Proposals for participation in new international immunotherapy trials by the Collaborative whereby additional funding may be provided to enable the collaborative to participate in existing international immunotherapy trials. Further to this initial funding, JDRF may release an open call for LOIs seeking funding for investigator-initiated trials at a later stage in the initiative (subject to available funding).

Evidence of institutional commitment in the form of matched institutional or industry funding and resources is highly desirable and will be marked favourably in the review process.

Grants awarded by JDRF Australia through the T1DCRN are listed on the Australian Competitive Grants Register. As such, indirect costs can be recovered 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.

8 Application: Clinical Trial Collaborative - Immunotherapy

The proposed Collaborative may include smaller sites with limited resources and/or research experience, basic science facilities with specialised expertise and/or resources (potentially outside of T1D research), industry and larger established sites with a proven track record in leading multicentre T1D clinical trials. JDRF strongly encourages the Collaborative to include regional and remote sites with access to target populations.

It is expected that all Collaborative members will be full participants in the development and implementation of Clinical Trials and that more established Clinical sites will provide assistance and training to less experienced sites to build their capacity.

JDRF will conduct two webinars shortly after the release of the RFA. The first of these webinars will be to facilitate networking and clarify the expectations of the Collaborative and associated clinical trials, eligibility criteria and application process. The second

webinar will be to conduct a subsequent question and answer session regarding aspects of the application process, requirements of the application or clarification of any other aspects of the RFA. If you wish to attend either of these webinars please email JDRF to express your interest in doing so. Webinars will be recorded and placed on the JDRF website if you are unable to attend.

The following information must be addressed in the application:

1. Proposal Synopsis^: A summary outlining the objectives of the Collaborative, rationale for each objective, long term goals, key outcomes and deliverables, and overall significance to T1D care and JDRF's priorities. The synopsis should be no longer than three pages

2. Collaborative Proposal^: Provides details of principal investigators and support personnel at each site. The experience and expertise of each site in conducting T1D research or providing critical services, facilities, and access to target populations including existing T1D networks should be addressed

3. Operational Plan^: A detailed outline of the objectives and strategy of the Collaborative including details of proposed infrastructure and expertise that will enable the success of the Collaborative. The following aspects including, but not limited to the following should be included:

    - Proposed governance framework and organisational chart
    - Planned integration of prior expertise and infrastructure
    - Trial implementation, analysis and reporting processes
    - Communication strategies
    - Knowledge exchange platforms including a framework of how research outcomes will be translated to better clinical outcomes or change in policy and practice for individuals with T1D
    - Proposed methods of assigning the role of sponsor for JDRF funded trials

4. Collaborative Proposal Budget^: A detailed annual, itemised budget for the establishment and ongoing support of the Collaborative. Budget detailing core expenses (key personnel costs, administrative costs, general equipment and supply costs etc.), education and training, and securing research team members (such as Emerging Investigators or Research Coordinators and Clinical Trial Nurses) must be itemised separately for the proposed Collaborative site. Budget must include screening, and current clinical and core research activities.

5. Budget Justification^: A narrative explanation of the proposed budget validating the importance of the requested funds and proposed outcome

6. Collaboration and Engagement Plan^: Details how the Collaborative will foster strategic alliances and collaboration with researchers, industry, Governments, clinical networks and other Australian and international stakeholders to facilitate exchange of ideas and adoption of new global initiatives. The plan should emphasize the strength of the team in the inclusion of a broad spectrum of well-connected experts, ensuring expertise outside Australia and evidence of committed and integrated global engagement. The following aspects including, but not limited to the following should be included:

    - Proposed roles and responsibilities of each site within the Collaborative
    - Details of consolidation of screening infrastructure and/or collaboration with T1D clinical networks (e.g. TrialNet, ENDIA, Type 1 Screen, EXTEND) if applicable

7. Talent and Human Capacity Building Plan^: The proposed methods concerning how the Collaborative will warrant inclusion, retention and career growth of early-mid career researchers, established researchers and supporting staff members

8. Data and Biosample Sharing Plan^: A comprehensive outline of how data and other resources developed within the Collaborative will be shared and made available to the broader community within a reasonable timeframe

9. Bio-sketch^: Biographical sketches for all named PI and co-PI should be provided. Applicants must have extensive experience and current ability to lead investigations and/or in performing clinical research and trials in T1D

10. Letters of support: Applications must include a letter of support from each proposed site. In providing and signing these letters, the organisations are certifying their support of and researcher participation in the Collaborative. These letters of support must be on official letterhead and signed by a senior representative of the organisation

    ^Please use template provided in RMS360

9 Associated Clinical Trial Proposals

Clinical Trial proposals must focus on JDRFs priority areas and in the first instance involve the participation of Collaborative sites in an existing international immune therapy trial, biomarker validation study, or other key clinical work paramount to advancing the immunotherapy field. A particular emphasis will be placed on collaboration amongst sites and the international research community during the review process.

Basic scientific studies will be considered for Clinical Trial Proposals, provided the proposal is auxiliary to a clinical trial and includes a detailed translation plan outlining the trajectory from “bench to bedside”. Investigator-initiated proposals may be considered at a later stage of this initiative via the subsequent release of an open call for LOIs.

A maximum of five Clinical Trial Proposals seeking finding to enable the participation of Australian Collaborative sites in an existing or planned international immunotherapy trial may be submitted together with the application. Each Clinical Trial Proposal must be scientifically distinct, should address one or more of the subject areas detailed in JDRF's Immunotherapies Program.

All applications must include the following documents uploaded into RMS360:

1. Clinical Trial Proposal^: The following information should be included. The proposal should be no more than three pages
    - Title of application
    - Rationale
    - Significance
    - Research team and environment
    - Provision of external support
    - References
    - Consideration for co-funding
2. Clinical Trial Proposal Budget^: An indicative budget for each grant period only. A more detailed budget and justification will be requested if additional detail is invited
3. Clinical Trial Feasibility Assessment^: An outline of the capability and experience of each proposed site in managing clinical trials and providing critical expertise, resources and facilities and ability to translate clinical findings into the Australian setting

^Please use template provided in RMS360

10 Review Process

Ideally JDRF would like to receive one application describing a single national Collaborative platform and up to five Associated Clinical Trial Proposals. In the first instance JDRF will determine whether the Collaborative application and associated Clinical Trial Proposals satisfy the eligibility criteria (section 5) and will then assess the application according to the collaborative approach and selection criteria (section 11). Clinical Trial Proposals will be ranked in order of scientific merit, feasibility of implementation and may be funded according to the available budget and according to the relevance to the mission of the T1DCRN and T1D community.

The eligible Collaborative application and associated Clinical Trial Proposals will be presented to an independent expert peer review panel compromising members from a range of national and international organisations, who will assess the application against

the selection criteria (section 11). The review panel provide written comments supporting their assessment and applicants will be provided with reviewers' reports.

Clinical Trial Proposals that the review panel deem as meritorious may be invited to provide additional detail. It will be at the discretion of JDRF whether a full peer review is required. We understand that the scientific merit may have been previously assessed and as such the focus of JDRF will be on extensively assessing the feasibility of implementation and capacity of the research team to successfully undertake the trial. The applicant must consider reviewers' reports and comments from JDRF Australia if asked to provide a rebuttal.

Successful applications will be recommended to the JDRF Board for final approval of the award.

11 Selection Criteria

11.1 Collaborative Application

The ability of the proposed Collaborative to achieve the goals and objectives (section 4) will be reviewed according to the selection criteria below. Applications must **address each of the following assessment criteria:**

1. Infrastructure (30%)
    - Are there appropriate testing facilities available?
    - Is there evidence of institutional commitment at each site to support the success of the Collaborative?
    - Does the proposed Collaborative include the appropriate infrastructure to form a national platform?
    - Is there evidence of substantial combined infrastructure?
2. Investigative team (30%)
    - Are the investigators at the sites appropriately trained and well-suited to carry out this work?
    - Is there appropriate leadership?
    - Are there adequate levels of staff?
    - Does the proposed Collaborative include appropriate experience and expertise and combined infrastructure to form a Collaborative and conduct clinical trials relating to T1D?
    - Is there adequate multidisciplinary and cross-institutional collaboration?
3. Feasibility and access to patients (30%)

- Do proposed Collaborative sites have access to patients diagnosed with T1D or to populations at-risk for T1D?
- Is the Collaborative nationally represented including regional and remote and disadvantaged populations?
- Does the scientific/clinical environment in which the work will be done contribute to the probability of success of the Collaborative?
- Are the conceptual framework, design, methods and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

4. Budget (10%)
    - Will any institutional or industry sites provide leveraged funding?
    - What level of in-kind support is provided?
    - The appropriateness of the proposed budget

11.2 Associated Clinical Trial Proposals

Applicants may submit up to five Associated Clinical Trial Proposals for Collaborative sites to participate in an existing or planned international immunotherapy trial. Clinical Trial Proposals must not exceed three pages each and must address the following criteria:

1. Relevance (20%)
    - How relevant is the work to the goals of JDRF, i.e. to target research at preventing or finding a cure for T1D and its complications?
2. Significance (20%)
    - Does this study involve the testing of immunotherapies in people at risk of or with T1D?
    - If the aims of the application are achieved, how will scientific knowledge be advanced?
    - What will be the effect of these results be on the T1D community?
3. Investigative team (20%)
    - Are the investigators appropriately trained and well suited to carry out this work?
    - Is the work proposed appropriate to the experience level of the investigator(s) and other researchers?

4. Feasibility (20%)
    - Does the scientific environment in which the work will be done contribute to the probability of success?
    - Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
5. Budget (20%)
    - The appropriateness of the proposed budget
    - Is there evidence of industry or institutional support in providing leveraged funding?

12 Contractual Requirements

Awards will be made to one single eligible organisation (or as otherwise proposed) to administer the funds awarded by JDRF Australia on behalf of the Collaborative. The award recipient will be required to sign a Funding Agreement with JDRF Australia (Agreement) for the Collaborative and each Clinical Trial undertaken. JDRF will endeavour to provide a template of the Agreement to applicants within ten business days of the RFA Release Date or as soon as practicable thereafter. A condition of application to this RFA is provision of certification of the PI, Co-PI(s) and their Organisation to have read and agree to abide by the terms of the Agreement.

JDRF has no obligation in respect of this RFA including any funding, unless and until JDRF and the successful applicant(s) have signed a formal Agreement.

The Agreement will include, but is not limited to, the following:

- A payment schedule dependent upon the achievement of project milestones. JDRF will determine such milestones to be included in the Agreement in consultation with the relevant Investigators
- An obligation to comply with all relevant JDRF Policies as further detailed in the template Agreement
- The proposed governance structure of the Collaborative will include JDRF executive representation

JDRF reserves the right to require changes to the template Agreement to address unique circumstances pertaining to an application.

12.1 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 JDRFs data and biosample sharing policy.

The sharing of data and biosamples must be supported by clear policies and guidelines, as well as mechanisms to satisfy this requirement. A Data Sharing Plan will be outlined in the Funding Agreement and must be completed by the Lead Principal Investigator(s) for the Collaborative and for each Clinical Trial Proposal.

12.2 Reporting

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 at any time as required.

13 Submission Instructions

Applications must be submitted online and certified by an authorised officer of the Administering Organisation, using JDRF Australia's online grants management system RMS360 (http://jdrf.smartsimple.us). Applications must be completed using templates provided in RMS360 where requested and all asterisked fields in RMS360 must be completed. No other documents other than those listed in section 8 and 9 will be accepted.

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. JDRF Australia's Network Conflict of Interest policy is available on the JDRF Website.

JDRF Australia will only consider complete applications that meet application formatting requirements. Information must be typed single-spaced and in black typeface no smaller than size 11 points Times New Roman font or an equivalent size, including text within images and figures, before converting to PDF format and must be legible to assessors. Avoid scanning.

An application is complete if all the:

- Documents listed in Sections 8 and 9 are included
- Mandatory fields in the online grant management system RMS360 are completed

Incomplete applications or incorrectly formatted applications will be deemed ineligible and declined without further assessment.

14 Submission Checklist

Primary information to be provided as outlined in Sections 8 and 9	
Clinical Trial Collaborative – Immunotherapy	1. Proposal Synopsis* 2. Collaborative Proposal^ 3. Operational Plan^ 4. Collaborative Proposal Budget^ 5. Budget Justification^ 6. Collaboration and Engagement Plan^ 7. Talent and Human Capacity Building Plan^ 8. Data and Biosample Sharing Plan^ 9. Biosketch of Principal Investigators^ 10. Letters of Support
Prospective Trials	11. Clinical Trial Proposal^ 12. Clinical Trial Proposal Budget^ 13. Clinical Trial Feasibility Assessment^

^Please use template provided in RMS360

Additional information required in RMS360 textboxes for RFA	
Please note that all information entered within the Project Description/Abstracts tab may be treated non-confidentially and uploaded to the JDRF website for a public audience, if proposal is successful. Please use appropriate and clear language. The word limit is 600 words per text box	1. General Audience Summary (lay summary) 2. Technical Abstract 3. General Audience Summary - Objective (lay summary) 4. General Audience Summary - Background/Rationale (lay summary) 5. General Audience Summary - Anticipated Outcome (lay summary) 6. General Audience Summary - Relevance to T1D (lay summary)

15 Program Contacts

Inquiries concerning this program are encouraged and should be directed to:

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