



**Australian Type 1 Diabetes  
Clinical Research Network**

## **Workshop Summary**

Melbourne, March 2014

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## BACKGROUND

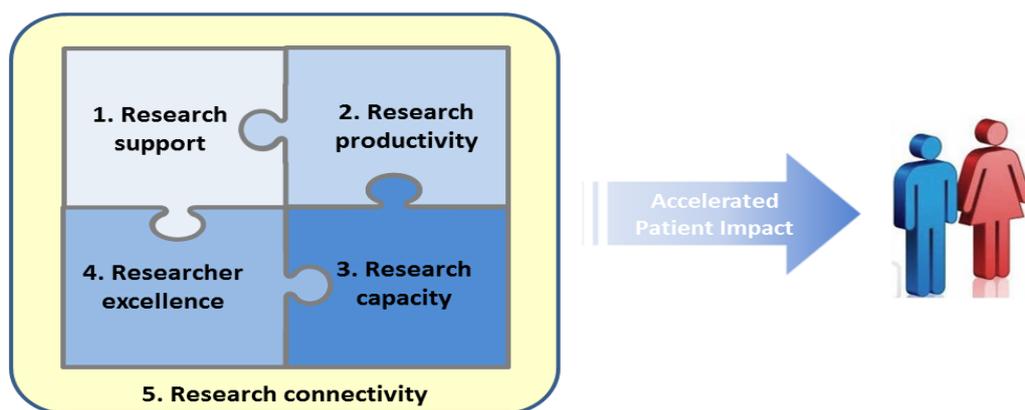
The JDRF Type 1 Diabetes Clinical Research Network (T1DCRN) was launched by JDRF in June 2011 through a \$5m grant from the Australian Government. The T1DCRN has been operating successfully since that time, and now funds three multi-centre clinical projects across Australia, nine pilot and feasibility projects, and the Mentored Clinical Researcher Fellowship which is in its third year with five recipients.

The first five years of the T1DCRN have shown that the network is delivering research excellence. The T1DCRN has gained government confidence and support in the form of a further \$35m to be invested in the Network by the Coalition Government over five years from 2014 - 2018, following an election commitment in 2013.

The principal goal of the T1DCRN is to **positively impact the life of people with type 1 diabetes in Australia through the support and promotion of clinical research.**

To achieve this goal, five mutually dependent objectives are being pursued in parallel to maximize the ultimate impact on patients from the investment made in the T1DCRN.

These five objectives are outlined in the diagram below and will be referred to in the workshop summary, where they are referred to as CRN Area 1- 5 (the objectives are covered in more detail in Appendix 5):



## WORKSHOP OVERVIEW

On Thursday 20<sup>th</sup> March 2014, the Type 1 Diabetes Clinical Research Network (T1DCRN) held a one-day workshop in Melbourne. This workshop was independently facilitated by Dr Matt Harris and Ayla Whittall from TM Ventures and was attended by 37 key opinion leaders in the clinical research in Australia and leadership from the Australian Research Council. The purpose of this workshop was to explore type 1 diabetes research and:

- discuss solutions to the current barriers in clinical research
- discuss novel approaches to collaborative research
- introduce draft of the future strategic plan for the next phase of the T1DCRN

The scope of this workshop was provided by a pre-workshop survey and the distribution of the 'T1DCRN Overview of Future Growth Plans' document.

The barriers, solutions and proposed models of research discussed during the workshop are summarised in this document and will help to inform the future directions of the T1DCRN.

The coming five years provide a transformative opportunity for T1D research as, together with the support and contribution from the research community, the T1DCRN continues to build upon the initial investment.

## BARRIERS AND SOLUTIONS IN CLINICAL RESEARCH

The tables below capture key themes discussed throughout the Workshop; with the left-hand column highlighting the discussed barriers and solutions to research raised at the Workshop and the right-hand column detailing T1DCRN initiatives that could address these barriers.

**Table 1: Funding Timelines**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>1. BARRIER IDENTIFIED:</b>  <b>Delivery of clinical trials and research outcomes is difficult within funding timelines</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Time pressure to complete a clinical trial within funding timelines, usually 3 years. However, clinical studies take 5-6 years to close; observational studies take a longer time to see trends.</li> <li>• Shortage of dedicated staff (project manager/coordinator, research nurse) to support clinicians. It takes a team to complete clinical research; these roles are usually poorly funded in tight study budgets.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>• Study design to be clear, sharp and not necessarily aim for definitive outcomes; allowing to build knowledge over the course of subsequent funding periods.</li> <li>• Commitment to fund shared infrastructure that can support trial implementation.</li> <li>• Dedicated funding to allow hire of qualified staff to support clinicians.</li> </ul>	<p><b>CRN AREA 1. Research support:</b>  <i>Increase the volume and impact of clinical research</i></p> <ol style="list-style-type: none"> <li>Develop a diverse portfolio of research projects with variable duration of timeframe and scope, <i>for example:</i> <ul style="list-style-type: none"> <li>○ Fund large, collaborative, clinical trials with national outreach of 4 years in duration.</li> <li>○ Support clinical innovation and adoption with grants of 1-2 years in duration.</li> <li>○ Support proof of concept and mechanistic projects as catalysts for clinical trials.</li> <li>○ Leverage funding opportunities with other networks and commercial partners</li> </ul> </li> <li>Introduce innovative measures of research progress that can punctuate important research milestones in long-term scientific studies.</li> </ol> <p><b>CRN AREA 2. Research productivity:</b>  <i>Efficient and productive delivery and adoption of clinical research</i></p> <ul style="list-style-type: none"> <li>• CRN recognises the importance of supporting research staff to deliver research outcomes. Funding of these positions will reflect on time/budget.</li> <li>• CRN will introduce shared and connected research infrastructure and systems that build on current initiatives and introduce new support as needed.</li> </ul>

**Table 2: Trial Recruitment**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>2. BARRIER IDENTIFIED:</b>  <b>Difficulty with trial patient recruitment within protocol timeframe.</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Study staff, in particular clinician researchers, are time-poor. However, patients respond best to clinicians approaching them about a trial they are conducting. The personal connection is crucial.</li> <li>• Awareness about clinical trials in the community is generally poor and hard to achieve.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>• The clinician’s ability to recruit patients could be facilitated by providing resources that ensure the required personnel dedicated to identifying and screening potential patients are available.</li> <li>• JDRF can aid in the area of research and clinical trial promotion to potential patients and the wider community.</li> </ul>	<p><b>CRN AREA 2. Research productivity:</b>  <i>Efficient and productive delivery and adoption of clinical research</i></p> <ul style="list-style-type: none"> <li>• A ‘Patient Recruitment Analysis’ across all clinical research areas in type 1 diabetes will be conducted to gain better understanding of recruitment challenges specific to type 1 diabetes, and to evaluate solutions applied. This analysis will inform development of new strategies to drive patient participation in clinical trials.</li> <li>• Project applications will allow budget for recruitment strategies and trial specific supporting research staff (Project Manager, Research Nurse) that engage in recruitment for clinical trial.</li> <li>• A sub-committee of researchers with assistance from JDRF staff will develop a plan for consumer engagement to promote research progress and trial awareness within the T1D community.</li> </ul>

**Table 3: Research Communication and Coordination**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>3. BARRIER IDENTIFIED:</b>  <b>Nationwide research communication and resource coordination needs improvement.</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Different states have varying systems for keeping patient records which makes linkages problematic.</li> <li>• Patient data is often lost in the transition of care from adolescent to adult.</li> <li>• Establishment of a bio-bank is expensive and samples are approached as preciously guarded resources.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>• Building research resources such as tissue collections and data should be included as a standard component of clinical trials protocols.</li> <li>• The current infrastructure such as datasets should be connected to increase their impact and scope and to create a truly national system. A good approach may be to start with mapping of the current clinical resources, and to consolidate the like resources.</li> </ul>	<p><b>CRN AREA 3. Research capacity:</b>  <i>Long-lasting impact on Australia's clinical research capacity</i></p> <ul style="list-style-type: none"> <li>• Extend and grow the Australasian Diabetes Data Network (ADDN) into regional areas, connect with adult databases and promote international connections.</li> <li>• Promote and fund ancillary studies that use the same dataset and samples to test specific research hypotheses.</li> <li>• Fund a 4-year project to create a virtual bio-bank via a national consortium for sample collections linked to the clinical database.</li> <li>• Improve the collation and sharing of trial results by creating a secure interactive platform to capture trial-data. The data sharing will support secondary analysis to test further research hypotheses. A sub-committee of researchers will be formed to guide this project.</li> <li>• The T1DCRN will undertake the mapping of existing clinical resources in Australia and take steps to address gaps identified.</li> <li>• Consolidate current resources by funding 'Value-Add' modules for existing clinical projects.</li> </ul>

Table 4: Research time in Clinics

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>4. BARRIER IDENTIFIED:</b>  <b>Clinician researchers are time-poor and research time is hard to prioritise</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Time dedicated to research is hard to come by for clinician researchers at all levels.</li> <li>• In particular, it is very difficult to find support for the mid-career progression.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>• Career support is needed to allow researchers to do research within their clinical positions.</li> <li>• Shift the administrative burden away from clinicians. Fund dedicated support staff to streamline processes such as HREC applications and recruitment. This could possibly also attract more clinicians to research.</li> <li>• Promote culture of research among the new doctors and health professionals. Train ‘leaders’ in type 1 diabetes clinical research.</li> </ul>	<p><b>CRN AREA 4. Researcher excellence:</b>  <i>Nurture the next generation of leaders</i></p> <ul style="list-style-type: none"> <li>• Fund career support scheme that attracts researchers to T1D research, mentor and train emerging talents, as well as to protect and retain those in the field.</li> <li>• The T1DCRN has been funding the Mentored Clinician Researcher Fellowship since 2012 and will also be introducing new mid-career support schemes in the second half of 2014.</li> </ul> <p><b>CRN AREA 2. Research productivity:</b>  <i>Efficient and productive delivery and adoption of clinical research</i></p> <ul style="list-style-type: none"> <li>• Project applications will include dedicated budget allowance to support research staff such as FTE support for Project Managers, Research Nurse to assist in the delivery of clinical trials.</li> <li>• Offer new training opportunities to encourage excellence in clinical trials, conduct and convey the importance of bench-to-bedside-to-bench cycle of research within the health system.</li> </ul>

**Table 5: Collaboration**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>5. BARRIER IDENTIFIED:</b>  <b>Collaboration under the current environment is difficult to cultivate</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Confusion over what infrastructure is available for common use.</li> <li>• Lack of established relationships between researchers – issue more pronounced interstate than within each state.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>• Best collaborations are established and matured when working together on large programs; Examples of such collaboration are already in place via large cohort studies.</li> <li>• Shared clinical infrastructure such as centralised patient recruitment solutions, shared protocols etc. would be mutually beneficial and build a long term capacity.</li> <li>• Face-to-face meetings are critical to foster genuine intellectual exchange and innovative interdisciplinary solutions.</li> <li>• Need clear and agreed guidelines between researchers before project commences: such as roles and responsibilities, communication, IP/publication etc.</li> </ul>	<p><b>CRN AREA 1. Research support:</b>  <i>Increase the volume and impact of clinical research</i></p> <ul style="list-style-type: none"> <li>• T1DCRN will develop procedures and policies that will support and clarify collaborative agreements and projects.</li> <li>• Funded projects will include clear collaboration agreements and all participating centres to be initiated with procedures and policies on roles and responsibilities, communication, data sharing/access, sample collection and IP/publication.</li> <li>• Clinical centres with trial experience and resources will extend guidance and support to smaller participating centres.</li> </ul> <p><b>CRN AREA 5. Research connectivity:</b>  <i>Create a connective and cohesive system</i></p> <ul style="list-style-type: none"> <li>• New opportunities will be created for interdisciplinary meetings for innovative solutions in type 1 diabetes; meetings may also engage different stakeholders within the type 1 diabetes field (such as regulators, commercial partners etc.) to participate at CRN-organised events (such as the annual T1DCRN meeting).</li> </ul>

**Table 6: Idea Generation**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>6. BARRIER IDENTIFIED:</b>  <b>Lack of networking opportunities for idea generation</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Difficulty in connecting clinician and basic researchers. This connection is particularly important at protocol conception and development stages.</li> <li>• Sparse opportunities to interact with colleagues: interstate clinicians, clinician researchers with scientific researchers, researchers of related diseases (autoimmune), and in particular across different disciplines.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>• Learn from other areas and bring expertise that would help with a connectivity between the basic and clinical researchers e.g. genomics, imaging, microbiology expertise.</li> <li>• Support large scale projects with diverse clinical, quality of life and economic outcomes that allow cross-disciplinary interactions <ul style="list-style-type: none"> <li>○ A wide range of expertise is needed and encourages different groups to get involved</li> <li>○ Clinicians coming together to develop and standardise assessments /sample collection across all stages of T1D</li> </ul> </li> </ul>	<p><b>CRN AREA 2. Research productivity:</b>  <i>Efficient and productive delivery and adoption of clinical research</i></p> <ul style="list-style-type: none"> <li>• A biennial symposium dedicated to type 1 diabetes to be attended by multi-disciplinary research groups.</li> <li>• Build on the current achievements to explore and promote opportunities for leveraging with national and international stakeholders.</li> </ul> <p><b>CRN AREA 5. Research Connectivity:</b>  <i>Create a connected and cohesive system</i></p> <ul style="list-style-type: none"> <li>• Networking opportunities via workshops, and topic-specific symposia (database, biobanks).</li> <li>• Regular touch points with the research committee via the T1DCRN Steering Committee and regular meetings.</li> </ul> <p><b>CRN AREA 3. Research capacity:</b>  <i>Long-lasting impact on Australia's clinical research capacity</i></p> <ul style="list-style-type: none"> <li>• The T1DCRN will work closely with the research community with sub-committees made up of T1D KOLs and JDRF to guide capacity building initiatives such as: <ul style="list-style-type: none"> <li>○ Improvement of the sharing and collation of clinical trial results</li> <li>○ Consumer engagement for clinical trial promotion and patient recruitment.</li> </ul> </li> </ul>

**Table 7: Coordination across Therapeutic Areas.**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>7. BARRIER IDENTIFIED:</b>  <b>Other therapeutic areas are better established and coordinated.</b></p> <p>Example:</p> <ul style="list-style-type: none"> <li>The health impact of other diseases such as cancer means that they receive more funding, are more organised and translational pathways are more advanced.</li> <li>T1D is often perceived as a less profitable disease by commercial companies; it has a negative impact on paths to commercialisation and drug development.</li> </ul> <p><b>POTENTIAL SOLUTIONS DISCUSSED:</b></p> <ul style="list-style-type: none"> <li>Take advantage of the common mechanisms and pathways across autoimmune disorders such as rheumatoid arthritis and multiple sclerosis and cross-invest in solutions.</li> <li>Identify ‘low hanging fruit’, use existing knowledge to address clinical gaps, or investigate repurposed drug therapies such as metformin.</li> <li>Expand international collaboration for participation in large, worldwide studies e.g. stem cells therapy.</li> <li>Invest in Australian strengths in innovative fields such as device technology and drug development (biotech).</li> </ul>	<p><b>CRN AREA 5. Research Connectivity:</b>  <i>Create a connected and cohesive system</i></p> <ul style="list-style-type: none"> <li>Build on international investments such as trial protocols and global datasets.</li> <li>Investigate locally and internationally into opportunities in other related diseases.</li> </ul> <p><b>CRN AREA 1. Research support:</b>  <i>Increase the volume and impact of clinical research</i></p> <ul style="list-style-type: none"> <li>Explore leveraging opportunities by actively connecting with related international networks and trials.</li> </ul> <p><b>CRN AREA 2. Research productivity:</b>  <i>Efficient and productive delivery and adoption of clinical research</i></p> <ul style="list-style-type: none"> <li>Leverage existing projects with ‘Value-Add’ modules to optimise current investment.</li> <li>Utilise the Australian T1D research profile and outcomes to increase our attractiveness to pharmaceutical sector commercial involvement. An expert advisory group will be established to drive the translation to patient access.</li> </ul>

**Table 8: Clinical Adoption**

Workshop Identified Barriers and Solutions	Solutions Proposed by T1DCRN
<p><b>8. BARRIER IDENTIFIED</b>  <b>There is a translational “Valley of Death” between research outcomes, clinical adoption and health service delivery</b></p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Culture of research is not widely recognised in healthcare. There needs to be better integration of clinical trials with the healthcare system</li> <li>• Like other chronic diseases the ‘cost’ extends beyond management of the disease and onto treatment of related complications and psychological morbidity.</li> <li>• Data on patients’ psycho-social wellbeing and social economics are not conventionally collected in clinical trials or these questions are often asked too late and need to be included at the start of the trial.</li> </ul>	<p><b>CRN AREA 2. Research productivity:</b>  <i>efficient and productive delivery and adoption of clinical research</i></p> <ul style="list-style-type: none"> <li>• Funding will be provided for evidence based practices (health economics, psycho-socio measures) and included in protocols of T1DCRN-funded clinical trials.</li> <li>• Promote clinical acceptance of new practices via small targeted grants testing new approaches to remove barriers to adoption.</li> <li>• Support proof of concept and mechanistic projects to provide information that would contribute towards larger scale studies.</li> <li>• Set up an Advisory Committee tasked with strategic oversight of using research outcomes from T1DCRN projects to influence policy makers and modify guidelines.</li> </ul>

## PANEL DISCUSSION: CLINICAL GAPS AND RESEARCH AREAS

During the Workshop a panel of clinicians with a diverse expertise across the type 1 diabetes specialities discussed the key gaps in clinical care. A short list of issues in clinical care is provided below. These issues were selected based on the level of discussion they generated as well as feasibility of support by the T1DCRN.

### THE KEY CLINICAL CARE GAPS DISCUSSED:

1. **Clinical Care guidelines development**
  - a) Mapping gaps in evidence
  - b) Evaluating pre-conception and pregnancy care
  - c) Development and validation of critical clinical tools for screening psychosocial morbidity
  - d) Guidelines for developing personalized care
  - e) Childhood to adulthood transition care
  - f) Supporting novel approaches to increase adherence
2. **Establishing pathways to equitable access to clinical care**
  - a) Regional care
  - b) Clinical adoption support
  - c) Enhancing paths to access and subsidy support

### PRIORITARY RESEARCH FOCUS AREAS TO BE CONSIDERED FOR FUNDING:

Many of the Workshop participants emphasised the importance of supporting type 1 diabetes research areas that represent a clear Australian strength. The proposed list below outlines areas that could be supported by the T1DCRN funding based on the identified strengths of Australian research, take advantage of the Australian medical and regulatory systems, and build on prior initiatives and investments.

#### 1: At-Risk populations

- a) Studies that help with better characterization of heterogeneity of risk of T1D
- b) Studies that help with understanding the factors that affect the rate of progression including identification and validation of biomarkers
- c) Exploratory clinical research studies (including mechanistic) focused on arresting progression, including combination of therapeutic agents and repositioning of agents from other diseases

#### 2: New onset patients

- a) Better prediction of rate of progression, identification and validation of biomarkers
- b) Exploratory mechanistic clinical research studies focused on measures that indicate markers of disease progression
- c) New onset clinical trials to arrest progression and preserve residual beta cell function including single or combination therapies

### 3: Individuals with established T1D

- a) Improving metabolic control with devices
- b) Improving metabolic control with drugs (repurposed and new)
- c) Characterization of clinical heterogeneity to enable patient stratification and characterize basis of preservation of residual beta cell function
- d) Clinical studies to compare effectiveness of 2 or more therapeutic agents
- e) Approaches to prevention of hypoglycaemia
- f) Studies measuring impact of type 1 diabetes on neurologic and cognitive function
- g) Improving residual beta cell function and/or de novo regeneration of beta cells
- h) Targeted strategic clinical trials for diabetic eye or kidney disease for early intervention to prevent progression of disease stage
- i) Prevention of complications and interventions to reduce complications
- j) Discovery and validation of clinical biomarkers of nephropathy or retinopathy for disease staging and therapeutic response to facilitate shorter clinical trials
- k) Clinical mechanistic studies testing agents for tolerance induction
- l) Clinical studies testing encapsulation modalities and cell therapy to replace beta cell function

## CONCLUDING STATEMENT

The 20<sup>th</sup> March 2014 T1DCRN Workshop was a significant milestone for the Network in that it recognised T1DCRN achievements to date, and to provided opportunity for a collaborative approach in shaping the strategic direction to the Network expansion. The research community's insightful discussion during this Workshop has been summarised and is contained in this report. In addition to the proposed initiatives that could be implemented by the CRN, this report includes all diverse views as captured on the day. This adds to the richness of perspectives present in the community and will, no doubt, be revisited in future discussions and new initiatives planning.

The next step will involve the release of Requests for Applications (RFAs) that reflect the T1DCRN strategic overview. It is anticipated that the announcement for these RFAs for applications will occur in the first quarter of FY15.

Clinicians, scientists, advocacy organisations and the T1D community are well placed to embark on the next exciting phase of the Network and to deliver the goal to **positively impact the life of people with type 1 diabetes in Australia through the support and promotion of clinical research.**

## APPENDIX 1

## WORKSHOP AGENDA

<b>Agenda</b>	
<b>Georgia Lindemans</b> 10 year-old JDRF youth advocate	Why I campaigned for the CRN
<b>Mr Mike Wilson</b> CEO, JDRF Australia	Address: The role of the Australian type 1 diabetes community in shaping the CRN
<b>Prof. James Best</b> Chair of CRN Steering Committee	Address: The future and impact of the CRN
<b>Dr Dorota Pawlak</b> Head of Research Development, JDRF Australia	Introduction to the Workshop: Sharing the draft of the strategic plan for the CRN
<b>Dr Matt Harris</b> Facilitator	<p>Workshop 1: How can we address barriers faced in delivering positive clinical outcomes in type 1 diabetes?</p> <p>Presentation of consolidated recommendations from past surveys and workshops</p> <p>Developing solutions to identified barriers that can be implemented by the CRN with a particular focus on:</p> <ul style="list-style-type: none"> <li>• Lack of adequate opportunities for collaboration</li> <li>• Fragmented resources and infrastructure</li> </ul>
<b>Dr Dorota Pawlak</b>	<p>Addressing clinical gaps in type 1 diabetes research – what can the CRN achieve?</p> <p>What alternative measures of success can we apply to the CRN?</p>
<b>Members of the CRN Steering Committee</b>	Clinical gaps in type 1 diabetes research: Clinician/researcher perspectives of key clinical gaps in type 1 diabetes patient care that can be addressed by the CRN
<b>Dr Matt Harris</b>	<p>Workshop 2: How can initiatives funded through the CRN facilitate improved patient outcomes in type 1 diabetes?</p> <ul style="list-style-type: none"> <li>• What is needed to address the key gaps in clinical care in type 1 diabetes?</li> <li>• How can the CRN implement research enablers identified during the course of the day?</li> </ul>

## APPENDIX 2

### WORKSHOP ATTENDEES

Attendees	Institution
Prof Alan Baxter	James Cook University, QLD
Dr Paul Benitez-Aguirre	The Childrens Hospital at Westmead, NSW
Prof James Best	University of Melbourne, VIC
Prof Fergus Cameron	Royal Children's Hospital Melbourne, VIC
A/Prof Toby Coates	Royal Hospital of Adelaide, SA
Prof Peter Colman	Royal Melbourne Hospital, VIC
Dr Melinda Coughlan	Baker IDI Heart and Diabetes Institute, VIC
Prof Jennifer Couper	Women and Children's Hospital, Adelaide, SA
A/Prof Maria Craig	The Childrens Hospital at Westmead, NSW
A/Prof Patricia Crock	John Hunter Childrens Hospital, NSW
Prof Elizabeth Davis	Princess Margaret Hospital, WA
Prof Kim Donaghue	The Childrens Hospital at Westmead, NSW
A/Prof Josephine Forbes	Mater Medical Research Institute, QLD
A/Prof Shane Grey	Garvan Institute, NSW
Dr Emma Hamilton-Williams	Diamantina Institute, University of Queensland, QLD
Prof Anand Hardikar	NHMRC Clinical Trial Centre, University of Sydney, NSW
Prof Len Harrison	Walter and Eliza Hall Institute, QLD
Dr Christel Hendrieckx	The Australian Centre for Behavioural Research in Diabetes, VIC
Dr Jane Holmes-Walker	Westmead Hospital, University of Sydney, NSW
Dr Andrzej Januszewski	NHMRC Clinical Trial Centre , University of Sydney, NSW
Prof Tim Jones	Princess Margaret Hospital, WA
Prof Tom Kay	St Vincent's Institute of Medical Research, VIC
Prof Anthony Keech	NHMRC Clinical Trial Centre, University of Sydney, NSW
Dr Bruce King	John Hunter Childrens Hospital, NSW

Prof Charles MacKay	Charles Perkins Centre, University of Sydney, NSW
Prof Grant Morahan	Harry Perkins Institute of Medical Research, WA
Dr Keats Nelms	Australian National University, ACT
Dr Jonathan Noonan	Centre for Eye Research, University of Melbourne, VIC
A/Prof David O'Neal	St Vincent's Institute of Medical Research, VIC
Prof Lin Perry	University of Technology Sydney, NSW
A/Prof Jonathan Shaw	Baker IDI Heart and Diabetes Institute, VIC
Dr Charmaine Simeonovic	Australian National University, ACT
Prof Ed Stanley	Murdoch Childrens' Research Institute, VIC
A/Prof Helen Thomas	St Vincent's Institute of Medical Research, VIC
Prof Ranjeny Thomas	Diamantina Institute, University of Queensland, QLD
Prof Merlin Thomas	Baker IDI Heart and Diabetes Institute, VIC
Dr John Wentworth	Walter and Eliza Hall Institute, VIC
Ms Leanne Harvey	Australian Research Council, ACT
Dr Matt Harris	<i>Facilitator</i>
Ms Aila Whittall	<i>Facilitator</i>
Dr Sarojini Balkrishna	JDRF
Ms Suzanne Culph	JDRF
Ms Maryanne Ng	JDRF
Dr Marie Nierras	JDRF
Dr Dorota Pawlak	JDRF
Mr Mike Wilson	JDRF
<i>Apologies:</i>	
<i>Prof Stephen Colagiuri</i>	University of Sydney, NSW
<i>Prof Mark Cooper</i>	Baker IDI Heart and Diabetes Institute, VIC
<i>Dr Andrew Cotterill</i>	Mater Children's Hospital, Brisbane, QLD
<i>Prof Chris Cowell</i>	The Childrens Hospital at Westmead, NSW
<i>Prof Nathan Efron</i>	Queensland University of Technology, QLD
<i>Prof Jenny Gunton</i>	Garvan Institute, NSW
<i>A/Prof Michelle Jack</i>	Royal North Shore Hospital, NSW

<i>Prof Alicia Jenkins</i>	NHMRC Clinical Trial Centre, University of Sydney, NSW
<i>Dr Balasubramanian Krishnamurthy</i>	St Vincent's Institute of Medical Research, VIC
<i>A/Prof Ecosse Lamoureux</i>	Centre for Eye Research, University of Melbourne
<i>Prof Phillip O'Connell</i>	Westmead Millennium Institute, NSW
<i>Dr Michele O'Connell</i>	The Royal Children's Hospital, Melbourne, NSW
<i>Prof Chris Parish</i>	Australian National University, ACT
<i>Prof Jane Speight</i>	The Australian Centre for Behavioural Research in Diabetes, VIC
<i>Ms Rhiannon Tate</i>	Australian Clinical Trials Alliance (ACTA)
<i>Prof Stephen Twigg</i>	Royal Prince Alfred Hospital, University of Sydney, NSW

## APPENDIX 3

### T1D CRN STRATEGIC PLAN

#### Background and context

The JDRF Type 1 Diabetes Clinical Research Network (CRN) was launched by JDRF in June 2011 through a \$5m grant from the Australian Government. The CRN has been operating successfully since that time, and now funds twelve projects and a number of other grants across Australia. A further \$35m will be invested in the JDRF CRN by the Coalition Government over five years from 2014 - 2018, following an election commitment in 2013. This document outlines the high level growth plans that will be enabled by this support.

#### Goal of the CRN

The principal goal of the CRN is to positively impact the life of people with type 1 diabetes in Australia through the support and promotion of clinical research.

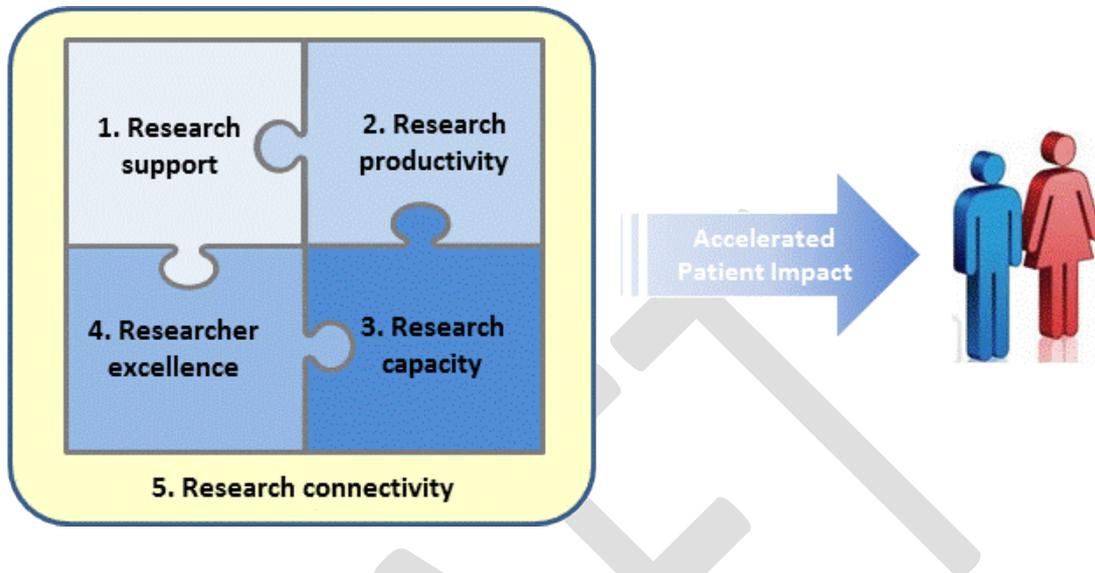
#### Operating Principles

The CRN is founded on the following operating principles, which will be embedded across the delivery of the objective of the program. They are:

- A. *Patient-focused*: Ultimate patient benefit is the foremost goal that underscores all the activities of the CRN. Hence, the engagement of type 1 diabetes community (research and public) is critical to the operation of the CRN.
- B. *Collaborative*: A collaborative approach will be applied to and required of clinical research in the CRN. Research teams will be assembled based on the expertise needed and ability of participants to solve complex issue of type 1 diabetes.
- C. *Inclusive and connected*: CRN will build partnerships to benefit from the existing international and domestic expertise and resources and leverage prior investments in Australia
- D. *Information sharing*: CRN is committed to sharing the value of the investment in research and will capture and make available outcomes and data generated by the CRN
- E. *Productivity-driven*: CRN is committed to maximizing the investment via a portfolio of critical schemes that ensure the implementation of research on time and budget as well as building along lasting research legacy.

## Objectives of the CRN

To achieve this goal, five mutually dependent objectives are being pursued in parallel to maximize the ultimate impact on patients of the investment made in the CRN. They are:



These are outlined in more detail below:

### 1. *Research support*: Increase the volume and impact of clinical research

1. Fund the most promising high impact clinical studies to cure and treat type 1 diabetes
  - a. Support hypothesis driven/researcher initiated clinical programs
  - b. Engage Australia in multi-site international trials
  - c. Create targeted and partnership trials
2. Drive clinical innovation, discovery and adoption
  - a. Fund emerging novel areas of clinical research
  - b. Support Proof of Concept and exploratory projects as catalysts for further clinical trials
  - c. Promote uniform adoption of the best proven clinical practice

### 2. *Research productivity*: Support the more efficient and effective delivery and adoption of clinical research

1. Support and drive the more effective implementation of clinical trials
2. Enhance researcher clinical trial knowledge in Australia
3. Engage the type 1 diabetes community in clinical trials
4. Support the adoption of new research outcomes into clinical practice and guidelines for individuals with type 1 diabetes

### 3. *Research capacity*: Build long-term clinical research capacity in Australia

1. Extend and grow the national type 1 diabetes clinical dataset
2. Create a virtual biobank to support clinical research
3. Improve the collation and sharing of clinical trial results
  - a. Create an interactive platform to share all of CRN-related trial data
  - b. Support secondary analysis studies

**4. Researcher excellence: Nurture the next generation of clinical research leaders**

1. Support the most promising emerging researchers
  - a. Mentored Clinical Researcher Awards
  - b. Career Development Awards
2. Protect and retain outstanding scientists
  - a. Clinical Career Transitions Support Program
  - b. “First Grant” funding schemes for outstanding mid-career researchers
3. Attract new outstanding researchers to the field of T1D
  - a. Innovative Grants scheme for researchers new to type 1 diabetes
  - b.

**5. Research connectivity: Create a more connected and cohesive clinical research system**

1. Connect actively with related international networks and trials
2. Connect funders and other key stakeholders in the diabetes field to develop shared goals and activities

DRAFT