Australian Type 1 Diabetes
Clinical Research Network

Annual Meeting Summary
23rd April 2015
Charles Perkins Centre, University of Sydney

A Special Research Initiative funded by the ARC
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2 EXECUTIVE SUMMARY

In April 2015, JDRF Australia convened the Type 1 Diabetes Clinical Research Network (T1DCRN) Annual Meeting. The overarching purpose of the Meeting was “to build a collaborative Clinical Research Network”, in line with operating principles of the T1DCRN. A collaborative, cohesive network accelerates research progress by facilitating the sharing of existing data, resources and expertise to solve the complex issue of type 1 diabetes. The Meeting brought together key leaders in both clinical and basic type 1 diabetes research, as well as other members of the research community, to determine a collaborative model that will integrate current Clinical Centres into a cohesive, effective and progressive national network.

The meeting Agenda comprised 8 sessions each with the aim of identifying actions required to achieve this purpose. Sessions focussed on how best to build and support a collaborative network to ensure long-lasting legacy, including experience gained from previous T1DCRN-funded clinical studies, and ways to facilitate access to T1DCRN resources to accelerate and enable the progress of type 1 diabetes therapy development.

This document summarises the Meeting’s presentations and discussions, including an overview, key recommendations, and detailed action items for each session. The key recommendations from the Meeting are:

Recommendation 1: To form four Consortia within the T1DCRN based on JDRF Research Priority areas: Prevent; Cure; Treat: Glucose Control; and Treat: Complications.

Recommendation 2: JDRF Australia to facilitate the establishment of the Consortia. Face-to-face meetings will be held to establish scope, governance, operating principles and budget.

Recommendation 3: The Project Grant schemes to be prioritised for funding by the T1DCRN should be targeted towards Innovative and Hot Topics research.

Recommendation 4: More investment is required into Career Development funding, particularly from early- to mid-career. The T1DCRN should prioritise funding for this stage when releasing new CDAs.

Recommendation 5: Establish a national shared T1D biobank and/or a living biobank connected with the ADDN database.

Recommendation 6: Establish an organising committee to plan for a national T1D symposium to facilitate collaboration.

Recommendation 7: The T1DCRN Steering Committee is to be renewed, including the appointment of a new chair and nomination of new members to the T1DCRN Steering Committee.

More detailed information including attendees, presentations, photographs and transcripts, can be accessed by selecting the links provided throughout the document or by visiting the T1DCRN website: [www.t1dcrn.org.au](http://www.t1dcrn.org.au)
# MEETING AGENDA

The Agenda for the Meeting is shown below. For further information on each of the sessions, including presentations, images and discussion points, please click on the links provided.

<table>
<thead>
<tr>
<th>Time</th>
<th>Details</th>
</tr>
</thead>
</table>
| 10:00-10:30 | 1. Welcome *Dr Dorota Pawlak*  
  - Overview/Introduction to the Agenda |
| 10:30-12:05 | 2. Clinical Centres: Building a Collaborative CRN |
| 10:30-11:55 |  
  - How can Clinical Centres connect into a cohesive and progressive network?  
  - How best to increase excellence in Clinical Trials management?  
  - What are the opportunities for mentoring and staff training?  
  - How can the CRN connect to international Networks?  
  - How can the CRN connect non-clinician researchers?  
  - Group discussion |
| 11:55-12:05 |  
  - Steering Committee *This session was moved to Session 8 due to time constraints*  
  - Renewal and future direction |
| 12:05-12:15 | 3. Research Funding  
  - What future RFA schemes would best support CRN development and excellence?  
  - Research Funding Questionnaire  
  - Summary of Questionnaire comments |
| 12:15-12:35 | 4. Researcher Excellence – Emerging Leaders *Chair: Professor Kim Donaghe*  
  - Perspective from a Mentor and an Award Recipient *Dr Paul Benitez-Aguirre*  
  - Future options for Career Development Awards  
  - Panel discussion |
| 12:35-13:35 | Lunch |
| 13:40-14:10 | 5. Experience of trials in the T1DCRN  
  *Chairs: Professor Len Harrison & Professor Tony Keech*  
  13:40-13:55 *Predictive Low Glucose Management Study*  
  Professor Tim Jones (10min + 5min QA)  
  - Experience of working within the T1DCRN  
  - Lessons learnt – what can we improve on?  
  13:55-14:10 *REMOVAL Australian Substudy*  
  Professor Alicia Jenkins (10min + 5min QA)  
  14:10-14:15 *Australasian Diabetes Data Network*  
  Professor Maria Craig (10min + 5min QA)  
  - Value for the T1DCRN and community  
  - How can this resource be accessed?  
  14:25-15:05 *Conducting economic analyses alongside clinical studies in Type 1 Diabetes*  
  Professor Philip Clarke, Health Economist (30min +10min QA)  
  - How to include measures of health economics in a clinical trial to accelerate access and reimbursement?  
  15:10-15:30 Afternoon Tea  
  15:30-16:15 7. Research Enablers and Accelerators *Chair: Professor Tom Kay*  
  15:35-15:40 *Preview: Australian Type 1 Diabetes Clinical Resource Map*  
  Dr Alisa Knapman  
  15:40-16:15 *Research Translation from Basic to Clinical*  
  - Type 1 Diabetes Symposium – discuss scope, timing  
  - Resource sharing, “living biobank”  
  - Group discussion |
| 16:15-16:30 | 8. Feedback for future meetings and closing remarks *Professor Alicia Jenkins* |
4 SESSION 1: WELCOME

4.1 OVERVIEW

Speaker: Dr Dorota Pawlak, Director of the T1DCRN

Purpose: To welcome attendees and outline the Agenda in line with the goal of the Meeting: To build a collaborative Clinical Research Network.

Format: Presentation

Highlights: The T1DCRN is funded through the ARC’s Special Research Initiative (SRI) in Type 1 Diabetes. JDRF has developed specific T1DCRN Program Guidelines in consultation with the ARC which are available on the T1DCRN website.

5 SESSION 2: CLINICAL CENTRES: BUILDING A COLLABORATIVE CRN

5.1 OVERVIEW

Facilitators: Dr Dorota Pawlak and Dr Julia Warning, JDRF

Purpose: To establish the collaborative model to be adopted by the T1DCRN, and to outline the preliminary scope and operating principles of the collaborative model.

Summary: The integration of T1DCRN Clinical Centres into a cohesive, effective and progressive national network was discussed. The focus was on establishing a collaborative model that would facilitate participation of all Clinical Centres in the Network, regardless of individual funding outcomes of Centre Concept Proposals.

5.2 RECOMMENDATIONS

Recommendation 1: To form four Consortia within the T1DCRN based on JDRF Research Priority areas:

- Prevent;
- Cure;
- Treat: Glucose Control; and
- Treat: Complications.

A preliminary scope was developed in discussion groups and is outlined for each Consortium in the following section.

Recommendation 2: JDRF Australia to facilitate the establishment of the Consortia. Face-to-face meetings will be held to establish scope, governance, operating principles and budget. Items requiring actioning are outlined in section 5.3.
5.3 **PRELIMINARY SCOPE OF T1DCRN CONSORTIA**

Meeting attendees representing the Clinical Centres self-nominated into groups representing each Consortium. These groups do not necessarily represent final Consortia membership, which will be extended to those who were not present at the meeting.

A summary of the preliminary scope for each of the Consortia is presented below. To view images of the posters developed by each Consortia discussion group, as well as members of each group, click here.

### 5.3.1 Prevent Consortium Preliminary Scope

<table>
<thead>
<tr>
<th>Knowledge Domains</th>
<th>Immunopathogenesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetics</td>
<td>Autoimmunity</td>
</tr>
<tr>
<td>At-risk genes</td>
<td></td>
</tr>
<tr>
<td>Epigenetics</td>
<td></td>
</tr>
<tr>
<td>Transcriptomics</td>
<td></td>
</tr>
<tr>
<td>Exposome</td>
<td></td>
</tr>
<tr>
<td>Nutrition</td>
<td></td>
</tr>
<tr>
<td>Microbiome</td>
<td></td>
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<tr>
<td>Metabolomics</td>
<td></td>
</tr>
<tr>
<td>Translomics</td>
<td></td>
</tr>
<tr>
<td>Metabolomics</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention Stages*</th>
<th>Scope of Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1° Prevention</td>
<td>1. Multidimensional studies incorporating all knowledge domains (e.g. ENDIA, EET1DPP)</td>
</tr>
<tr>
<td>Before disease onset, no</td>
<td>2. Mouse models of risk</td>
</tr>
<tr>
<td>antibodies detected</td>
<td>3. Study participant recruitment data collection</td>
</tr>
<tr>
<td></td>
<td>4. Sample collection (cells, DNA, RNA, sera)</td>
</tr>
<tr>
<td>2° Prevention</td>
<td></td>
</tr>
<tr>
<td>Before clinical onset,</td>
<td></td>
</tr>
<tr>
<td>antibodies detected</td>
<td></td>
</tr>
<tr>
<td>3° Prevention</td>
<td></td>
</tr>
<tr>
<td>At clinical onset of disease</td>
<td></td>
</tr>
</tbody>
</table>

5.3.2 Cure Consortium Preliminary Scope

<table>
<thead>
<tr>
<th>Knowledge Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>β-cell biology and replacement</strong></td>
</tr>
<tr>
<td>Human islet/xenotransplantation</td>
</tr>
<tr>
<td>ES and IP stem cells</td>
</tr>
<tr>
<td>Rescue of existing β-cells</td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
</tr>
<tr>
<td>microRNA/DNA methylation to validate cure</td>
</tr>
<tr>
<td><strong>Progenitor Cells</strong></td>
</tr>
<tr>
<td>Gallbladder and human islet-derived cell lines</td>
</tr>
</tbody>
</table>

**Goal and Function**

1. To use islet transplantation as platform for testing other replacement strategies (stem cells or xenotransplantation)
2. Develop biomarkers that can monitor loss of beta cell mass after transplantation or protection of remaining β-cell mass
3. Combine strategies for preservation of beta cell mass with immune therapies

**Scope of Activities**

1. **Progenitor cells**: Gallbladder and islet-derived progenitor cells show significant potential to differentiate to insulin-producing cells. Australian research strength.
2. **Biomarkers**: Need to follow these in clinical islet transplantation as a marker of graft survival
3. **β-cell biology and replacement**: Islet transplantation is the current time-tested cure therapy. Also explore strategies for rescuing remaining β-cells in T1D setting

5.3.3 Treat: Glucose Control Consortium Preliminary Scope

<table>
<thead>
<tr>
<th>Knowledge Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatments</strong></td>
</tr>
<tr>
<td>Technology</td>
</tr>
<tr>
<td>Drugs</td>
</tr>
<tr>
<td><strong>Lifestyle</strong></td>
</tr>
<tr>
<td>Exercise</td>
</tr>
<tr>
<td>Nutrition</td>
</tr>
<tr>
<td>Psychosocial</td>
</tr>
<tr>
<td><strong>Health care delivery</strong></td>
</tr>
<tr>
<td>Health economics</td>
</tr>
<tr>
<td>Translation</td>
</tr>
</tbody>
</table>

**Goal and Function**

**Goal**: Renewing methods and optimising control. Reducing burden of type 1 diabetes

**Composition**: Any clinical centres involved in trials, concept proposals and collaborations

**Meetings**: Specific aim and facilitation. Need administrative help from JDRF

**Scope of Activities**

1. **Facilitate trials**: New studies, specific concepts, recruitment
2. **Collaboration**: Develop links, industry and international
3. **Sharing resources and skills**: New ideas from interaction, ADDN database, adult and paediatric interactions
4. **Education**
5.3.4 Treat: Complications Consortium Preliminary Scope

### Knowledge Domains

<table>
<thead>
<tr>
<th>Prevention</th>
<th>Treatment</th>
<th>Evolving complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>For further discussion</td>
<td>For further discussion</td>
<td>Bone, brain, psychosocial</td>
</tr>
</tbody>
</table>

### Multicentre Potential

1. Databases  
2. Sharing  
3. Joint funding  
4. Long-term collaboration

### Scope of Activities

1. Meeting at ADS 26th-28th August  
2. Central coordination of trials

5.4 Action Items

To establish a defined and accepted scope for each Consortium, the following steps require actioning:

<table>
<thead>
<tr>
<th>Action</th>
<th>Owner</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Extend Consortia membership to those not present at the T1DCRN Meeting</td>
<td>JDRF Australia</td>
<td>June 2015</td>
</tr>
<tr>
<td>2. Set the date for Consortia face to face meetings</td>
<td>Consortia Members</td>
<td>July 2015</td>
</tr>
<tr>
<td>3. Consortia scope defined and accepted at face to face meeting including:</td>
<td>Consortia Members</td>
<td>October 2015</td>
</tr>
<tr>
<td>• Operating Procedures</td>
<td>(JDRF to provide Examples)</td>
<td></td>
</tr>
<tr>
<td>• Administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Communications/Publications Policy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Budget</td>
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</tr>
</tbody>
</table>
6 SESSIONS 3 AND 4: RESEARCH FUNDING

6.1 OVERVIEW

Speakers:  Professor Kim Donaghue and Dr Paul Benitez-Aguirre, The Children’s Hospital at Westmead

Purpose:  To determine future Project Grant and Career Development Schemes to be prioritised for funding by the T1DCRN.

Format:  1) Questionnaire on funding priorities distributed to attendees.
          2) Presentation by Prof Donaghue (mentor) and Dr Benitez-Aguirre (recipient) on their Mentored Clinician Researcher Fellowship experience; followed by open discussion on future Career Development schemes.

Summary:  1) Research Funding Questionnaire:

          Project Grants: There was strong support for funding of “Hot Topics” and “Innovative” schemes.

          Career Development Grants: Strong support for more funding at all stages of career progression, but particularly for early-mid career researchers.

          To view a summary of questionnaire comments, click here.

          2) CDA Discussion: Support is required for both clinician and non-clinician researchers. The MCRF was a successful scheme and should be considered for renewal.

6.2 RECOMMENDATIONS

Recommendation 3: Project Grant schemes to be prioritised for funding by the T1DCRN should be targeted towards Innovative and Hot Topics research.

Recommendation 4: More investment is required into Career Development funding, particularly from early- to mid-career. The T1DCRN should prioritise funding for this stage when releasing new CDAs.

6.3 ACTION ITEMS

To drive the release of RFAs in the recommended areas, the following steps require actioning:

<table>
<thead>
<tr>
<th>Action</th>
<th>Owner</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Circulate CDA/MCRF RFAs to Steering Committee</td>
<td>JDRF Australia</td>
<td>June 2015</td>
</tr>
<tr>
<td>2. Release of CDA/MCRF RFAs</td>
<td>JDRF Australia</td>
<td>June 2015</td>
</tr>
<tr>
<td>3. Release Project Grant RFA</td>
<td>JDRF Australia</td>
<td>Spring 2015</td>
</tr>
</tbody>
</table>
7 SESSION 5: EXPERIENCE OF TRIALS IN THE CRN

7.1 OVERVIEW

Chairs: Professor Len Harrison, Walter and Eliza Hall Institute, VIC
       Professor Anthony Keech, NHMRC Clinical Trials Centre, University of Sydney, NSW

Speakers: 1) Professor Tim Jones, Princess Margaret Hospital WA
           2) Professor Alicia Jenkins, NHMRC Clinical Trials Centre, University of Sydney, NSW

Purpose: An update on currently funded T1DCRN clinical research studies, including how to ensure efficient and effective delivery of future T1DCRN-funded studies.

Format: Presentations. To view slides, please click on the links below.

   Presentation: Professor Tim Jones, Predictive Low Glucose Suspend Study
   Presentation: Professor Alicia Jenkins, REMOVAL Study

Summary:

Outcomes relevant for T1DCRN

- Demonstrated feasibility of performing protocols in multiple sites
- Increased individual capacity of individual sites and of trial coordination
- Enhanced, fostered and established a track record of collaboration, including cross-disciplinary engagement
- Provided opportunity for junior training in clinical research
- Presentation and publication of results

Areas identified for improvement

- Contract management, greater closure of gap between actual costs and funding
- Data management
- Communications and face to face meetings
- Outreach to adult T1D community

Advantages of T1DCRN support

- T1DCRN may fund projects that would be unlikely to receive funding from NHMRC
- Strong collaborative sites and investigators
- Increased international profile and international support
- Increased profile and greater outreach to type 1 community
- Unrestricted support from industry
8 SESSION 6: TOOLS TO ACCELERATE PATIENT BENEFIT

8.1 OVERVIEW

Chairs: Professor Fergus Cameron, Royal Children’s Hospital Melbourne, VIC
       Professor Timothy Jones, Princess Margaret Hospital, WA

Speakers: 1) Professor Maria Craig, Children’s Hospital at Westmead, NSW
          2) Professor Philip Clarke, The University of Melbourne, VIC

Purpose: To promote tools to accelerate patient benefit:
          1) Australasian Diabetes Data Network
          2) Embedding measures of health economics into type 1 diabetes research

Format: Presentations. To view slides, please click on the links below.
        Presentation: Professor Maria Craig, ADDN
        Presentation: Professor Philip Clarke, Conducting economic analyses alongside
          clinical studies in type 1 diabetes.

9 SESSION 7: RESEARCH ACCELERATORS AND ENABLERS

9.1 OVERVIEW

Chair: Professor Thomas Kay, St Vincent’s Institute of Medical Research, VIC

Speaker: Dr Alisa Knapman, JDRF Australia

Purpose: To provide a preview of the new Type 1 Diabetes Clinical Research Resource Map,
          and to discuss potential initiatives that the T1DCRN could support to facilitate
          resource sharing and access.

Format: Presentation, followed by an open discussion
        To view presentation, click here.
        To view a summary of the discussion, click here.

9.2 RECOMMENDATIONS

Meeting attendees voiced the need for access to more biosamples and more opportunities for
   collaboration, particularly between basic and clinical researchers.

Recommendation 5: Establish a national shared T1D biobank and/or a living biobank connected with
   the ADDN database

Recommendation 6: Establish an organising committee to plan for a national T1D symposium to
   facilitate collaboration.
9.3 Action Items

<table>
<thead>
<tr>
<th>Action</th>
<th>Owner</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Extend invitation to T1DCRN members to participate in working group for Resource Sharing and T1D Symposium initiatives</td>
<td>JDRF Australia</td>
<td>July 2015</td>
</tr>
<tr>
<td>2. Facilitate preliminary teleconference with working groups for Resource Sharing and T1D Symposium initiatives</td>
<td>JDRF Australia</td>
<td>August 2015</td>
</tr>
<tr>
<td>3. Set up face to face meeting to develop scope, plan and timelines for each initiative</td>
<td>Working Groups</td>
<td>September 2015</td>
</tr>
</tbody>
</table>

10. SESSION 8: STEERING COMMITTEE AND CLOSING REMARKS

10.1 Overview

Speaker: Professor Alicia Jenkins, NHMRC Clinical Trials Centre, University of Sydney NSW

Purpose: To discuss the role and renewal of the T1DCRN Steering Committee and close the 2015 Annual Meeting

Format: Address by Steering Committee member Professor Jenkins

10.2 Recommendations

Recommendation 7: The T1DCRN Steering Committee is to be renewed, including the appointment of a new chair and nomination of new members to the T1DCRN Steering Committee. This invitation of new members will be extended and opened up to early-mid career researchers.

10.3 Action Items

<table>
<thead>
<tr>
<th>Action</th>
<th>Owner</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nominations for Steering Committee Chair</td>
<td>Current Steering Committee</td>
<td>June/July 2015</td>
</tr>
<tr>
<td>2. Steering Committee Chair appointed</td>
<td>JDRF Australia Board</td>
<td>July 2015</td>
</tr>
<tr>
<td>3. Nomination/appointment of new members</td>
<td>Current Steering Committee and New Chair</td>
<td>August 2015</td>
</tr>
<tr>
<td>4. First meeting of new Steering Committee</td>
<td>New Steering Committee</td>
<td>TBC</td>
</tr>
<tr>
<td>5. Review of T1DCRN Steering Committee Charter</td>
<td>New Steering Committee*</td>
<td>TBC</td>
</tr>
</tbody>
</table>

* The T1DCRN Steering Committee charter is currently under review and input from members of the T1DCRN is welcomed and encouraged.
11 SUPPLEMENTARY MATERIAL

Letter from Professor James Best
Meeting Attendees List
Meeting Posters
Meeting Photos