



Australian Type 1 Diabetes
Clinical Research Network

Australian Type 1 Diabetes Clinical Research Network Workshop 17th & 18th November 2011

Summary and Recommendations



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1 Executive Summary

The inaugural Clinical Research Network (CRN) workshop was held on 17th and 18th of November 2011. The meeting was the first opportunity for key members of the type 1 diabetes research community and JDRF to come together to explore and establish the best platform on which to build this network, since the official launch in June 2011. It was an interactive workshop where discussions took place regarding the drafted network charter, the network's governing bodies and operational structures, defining member rights and responsibilities, and network policies. The network's future direction and sustainability were discussed and ideas were exchanged.

The major recommendations that were generated by the participants of this meeting for consideration by JDRF Australia were:

- The establishment of a two-tier organisation structure to accommodate the immediate foundations of the CRN and an alternative structure for the fully-funded model;
- The CRN Executive Board should be responsible for final approval of CRN funded trials;
- The Network Steering Committee should be accountable for the operational activities of the CRN;
- Network participants should be referred to as affiliates and associates rather than members;
- JDRF International review of clinical trials for CRN funding should include Australian representation;
- Remaining CRN funds should be used to engage co-ordinating services to support the network's current clinical trials and to develop future research capacity including but not limited to:
 - the establishment of a clinician-patient database;
 - Mentoring of clinical researchers
 - Development of a diabetes biobank;
- The CRN should be considered an information hub, maintaining a current list of clinical trials being conducted in Australia;
- An annual 'united nations' meeting should be held as a forum for the exchange of ideas and networking among network affiliates and;
- A short term priority of the CRN will be the development of the CRN strategy and plan focussed on the development of initiatives to support the networks' future growth.

It is advised that this summary be read in parallel with the drafted Network Charters and policies to offer an overview of the outcomes of the CRN workshop. The revised network charters and policies which will be re-distributed for review prior to finalisation



2 Organisation Chart

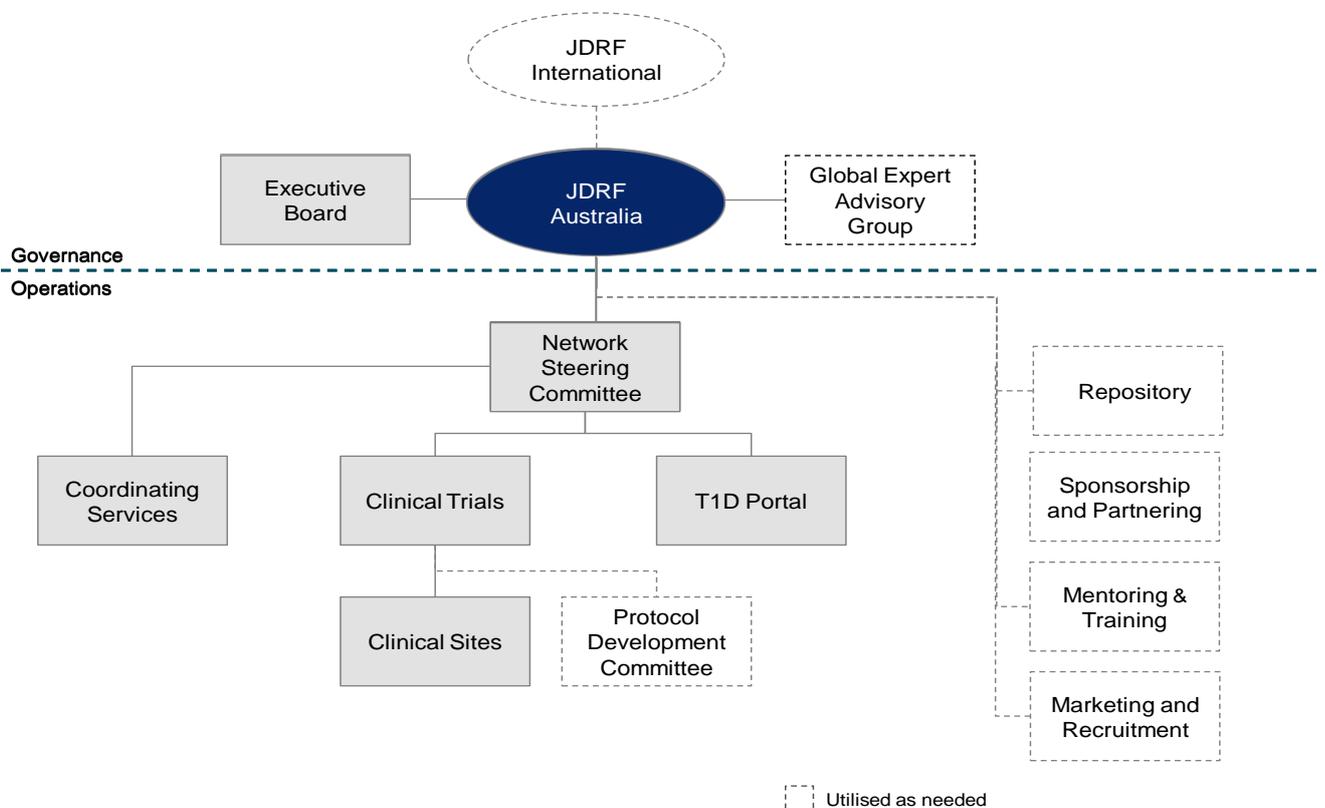
2.1 Overall model

Discussion:

The participants agreed that the overall model of the organisational structure will need to stimulate and support collaboration within the CRN. The proposed organisation chart was considered by some participants to be over-governed for \$5.5 million funding but adequate for the fully-funded (additional \$35m) CRN model. A structure was suggested to accommodate the immediate needs of the CRN and an alternative structure for when the CRN is fully funded. It was also suggested that a clear leader or leading centre, such as CRN Manager, be identified.

Recommendation:

The organisation chart (see below) has been updated to reflect these comments. The shaded boxes represent the immediate foundations of the CRN; the rest indicates the ultimate structure, when all elements are fully operational. The driver of the CRN is JDRF Australia, who will take on a leadership role. Additional clarification regarding the structure is described in the body of this report





2.2 Executive Board

Comments:

There was an agreement among attendees that Principal Investigators of funded trials should not become members of the Executive Board. A further requirement suggested was that individuals elected to the Board should have an understanding of the network's operations such as in depth clinical trials experience (preferably from a field outside of type 1 diabetes to avoid bias) or business acumen. It was recommended that the Executive Board remain responsible for the final approval of funding for CRN trials.

2.3 Global Expert Advisory Group

Discussion:

In the current, partially funded scenario, participants considered the CRN to be too small to have this group established without the risk of over-governance. Instead, experts are best represented on the Executive Board and Network Steering Committee until the CRN is sufficiently developed to accommodate an advisory group.

Recommendation:

In the long-term the Global Expert Advisory Group should become part of the organisational structure as a separate body to highlight its importance for the long term growth of the network and connection to global efforts. However, in the short term it represents an element to be utilised as required, with the final composition and profile of the members to be discussed at a later stage.

2.4 Network Steering Committee

Discussion:

There was consensus that the Principal Investigator of each CRN clinical trial be part of the committee. It was suggested that the committee include representatives of professional and health organisations such as the president of ADS or APEG. Others noted that a number of experts be included such as biostatisticians, trial monitoring experts, publication experts etc. The scope and purpose of the committee was also debated, but the majority of participants believed that the committee should be purely operational, leaving JDRF Australia responsible for grant administration and review.

Attendees expressed their interest in having an annual member's meeting and suggested that the Network Steering Committee be responsible for arranging such an event.

Recommendation:

The members of the Network Steering Committee should consist of Principal Investigators of current CRN clinical trials, a JDRF staff member and an additional 2-3 invited members. The expectation of the committee is to facilitate and support clinical research activity in Australia by guiding the operational activities of the CRN.



2.5 Ancillary Committees

Discussion:

Four major committees were discussed with regard to their relevance and priority for establishment: Mentoring and Training, Marketing and Recruitment, Sample Repository, and Sponsorship and Partnering.

Participants believed there is a real need for training and mentoring in order to attract and retain clinical researchers. Several types of funding mechanisms were outlined such as a 'top up' of other grants, additional fellowship awards and partnering with training institutions. A group of 4-5 multi-disciplinary experts was suggested to act as mentors and facilitate training.

Marketing and Recruitment was seen as a critical component to the sustainability of the CRN. Attendees did not think that a committee was required, but that an individual be dedicated to this role.

A significant portion of discussion centred on the importance of systematic tissue collection and possibly formation of a biobank. Researchers noted that there was a real need for access to human tissue. It was suggested that a small user group with experience building biobanks be formed to provide direction in this area. Finally, the sponsorship and partnering committee was considered and participants found it more relevant to have an individual or consultant leading strategies in this space.

Recommendation:

The term 'committee' has been removed from these operations to acknowledge that a committee may not always be formed when conducting these functions. Under the direction of JDRF Australia and the Network Steering Committee, priorities and resources should be allocated accordingly to facilitate the development of each of these elements.

3 Members

Discussion:

The definition of 'members', their roles and responsibilities and levels of membership were discussed. There was general consensus that membership be categorised into organisations/institutions, clinical trial sites and individuals. Furthermore, the concept of being labelled as a member delivered a tone of segregation and the preference was to use different terms such as associates and affiliates rather than full and partial members.

Recommendation:

'Affiliates' and 'associates' should be used rather than 'members'. The CRN is to foster a collaborative approach and to be inclusive of a wide community in type 1 diabetes and therefore, any organisation; institution, site or individual not directly involved with a clinical trial, may become an affiliate of the CRN. Data generated from the CRN should be de-identified and available to affiliates once a clinical trial is complete and published. The Principal Investigators (PIs) of the trials conducted through the CRN and their Clinical Sites should automatically become part of the CRN and be defined as associates of the network. As associates, they will have a more active role in participating in the network.



4 Policies

Discussion:

There was an agreement between attendees that data sharing among CRN associates and affiliates is an essential component of collaboration and should become a policy within the CRN. The Intellectual Property (IP) and Conflict of Interest (COI) policies were also addressed during the meeting. There was some concern raised regarding IP ownership and whether the CRN should be seeking royalties for the commercialisation of IP.

Recommendation:

Ownership of IP should be held by the Institution/Researcher.

The data sharing, IP and COI policies should be drafted based on feedback received by attendees, with the intent of providing clear guidelines and expectations of conduct within the network. PIs/Institutions participating in CRN trials will need to agree to these policies as part of accepting CRN funding.

Since writing this summary, the IP and Data Sharing policy have been created. A copy is attached to the end of this document for your perusal.

5 Operations of the CRN

Discussion:

Discussions were centred on the core activities of the CRN. Further to the activities listed in the network charter, researchers highlighted the need for good data monitoring services including the availability of Clinical Research Associates and provision for a Data and Safety Monitoring Board (DSMB). Access to relevant experts and patient groups were highly regarded as a shared resource to be provided by the CRN.

With recruitment being a major problem hindering the timely completion of clinical trials, opportunities were explored such as partnerships, the establishment of a patient registry, referrals from diabetes educators and social networking via JDRF Australia.

National and International promotion of the CRN was also considered to play a pivotal role in the expansion of the network.

Recommendation:

In view of the overwhelming consensus for access to relevant experts and data monitoring resources, the role of the coordinating services has been emphasised as a core function to be provided by the CRN. DVDC was noted as a potential coordinating centre, to leverage on their services, facilities and expertise.

Additional activities that were highlighted as desirable and will be investigated by JDRF Australia and the Network Steering Committee include: developing a database that would assist with identifying suitable investigators to conduct clinical trials, establishing a registry of patients for study recruitment, conducting an annual face to face meeting with CRN participants to facilitate the exchange of ideas and networking, initiating a marketing campaign to maximise awareness of the network and developing industry relationships/partnerships.



6 T1D Portal

Discussion:

In principal, attendees agreed that a platform was required to bring the elements of the CRN network together, to create a medium for communication, access to resources, education and data. Another element considered relevant to the portal was the establishment of a patient registry linked to a biobank database.

Recommendation:

There is an existing website for the CRN: <http://t1dcrn.org.au/>. JDRF Australia will build on the website to make it interactive, and will investigate opportunities for database linkage systems.

7 Clinical Research Funding

Discussion:

There was an agreement that the CRN should cater for type 1 diabetes clinical trials and offer services/support to network associates, independent of funding. Researchers also noted that there was not enough information available regarding the number and location of clinical trials being conducted in Australia.

The grant approval process was outlined and whilst most attendees were happy with JDRF International reviewing the grants, some raised concerns with the lack of local (Australian) input in the decision making process. The allocation of residual funds, currently held with the CRN was opened for discussion. While some participants commented that funding additional trials would bring collaborators together, the majority preferred that the money be invested into the network, to provide infrastructure and support for ongoing clinical trials. Investments that were suggested included the setting up of a database, workforce training, expert statisticians and a CRN annual meeting.

Recommendation:

JDRF Australia should investigate the possibility of providing visibility of clinical trials being conducted in Australia. The grant approval process should be updated to include Australian representation on the JDRF International review panel.

8 Sustainability

Comments:

Advocacy was seen as an important element for the CRN to gain support and commitment from the government. There was some concern raised with having network affiliates involved due to perceptions of self-interest however, it was suggested that patient groups (voters) be used to target both the federal and state governments. Attendees recommended that the CRN should seek industry sponsorship / co-sponsorship and partnering for the long term sustainability of the network. Such relationships could potentially bring more trials to Australia and provide an additional avenue for funding however; care would need to be exercised in approaching such organisations as a network.



9 Risks

Comments:

Participants were requested to identify potential risks and possible mitigations to ensure the success of the CRN. The risks raised were:

1. Lack of funding / sustainability
2. Lack of resources / access to resources / equal access to resources
3. Member conflict / lack of collaboration
4. Lack of action / inertia

In summary the key mitigations noted were to ensure that the organisation is well structured in order to adequately govern the network and facilitate effective collaboration and communication within the network. It would be the primary role of the Network Steering Committee to identify and leverage on the network's resources and initiate activities to benefit the participants of the CRN. The Executive Board would be responsible for funding approval and recommending the overall strategic direction of the CRN. With JDRF Australia as the key driver for the CRN, their role would be to ensure long term sustainability of the network by liaising with key stakeholders such as government and playing a support role to the Network Steering Committee and Executive Board.



Appendix 1

Attendees:

Prof. Peter Colman, The Royal Melbourne Hospital
Prof. Mark Cooper, Baker IDI Heart and Diabetes Institute
Dr. Andrew Cotterill, The Mater Children's Hospital
Prof. Jennifer Couper, Women's and Children's Hospital, Adelaide
A/Prof. Maria Craig, The Children's Hospital, Westmead
Dr. David O'Neal, St Vincent's Hospital Sydney
Dr. Elizabeth Davis, University of Western Australia
Prof. Kim Donaghue, The Children's Hospital, Westmead
Prof. Nathan Efron, IHBI, Queensland University of Technology
A/Prof. Alicia Jenkins, St. Vincent's Hospital Melbourne
Prof. Jim Best, University of Melbourne
Prof. Timothy Jones, Telethon Institute for Child Health
Dr. Bruce King, John Hunter Children's Hospital
Dr. Barbara Sheil, Telethon Institute for Child Health
Rowena Tucker, Diabetes Vaccine Development Centre
Dr. John Wentworth, The Royal Melbourne Hospital
Prof. Tom Kay, St. Vincent's Hospital
Dr. Michele O'Connell, Royal Children's Hospital, Melbourne
Dr. Matt Harris, TM Ventures (Facilitator)
Aila Whittall, TM Ventures (Facilitator)
Dr. Dorota Pawlak, JDRF Australia
Suzana Sovljanski, JDRF Australia