

Connect1d Canada Community Advisory Committee Governance Plan

Overview

Connect1d Canada is a patient-driven digital platform that allows those with type 1 diabetes (T1D) to easily learn about advances in innovative care, while contributing to Canadian research in the areas that matter most to them. Connect1d Canada also allows researchers to easily engage people living with T1D of diverse backgrounds from across Canada, enabling rapid recruitment into research studies.

The idea of Connect1d Canada was sparked early in the initial funding term of Diabetes Action Canada, when it became clear that Canadian researchers struggle to recruit subjects into their clinical trials. In Canada, there has been no systematic process in place to identify and engage those living with T1D, leaving some studies unable to reach their recruitment targets for years. Conversely, those living with T1D have been unaware of recruitment opportunities as most clinical research initiatives are run from large academic centres where recruitment is conducted largely from the local patient population.

In its initial concept, Connect1d Canada was called the Diabetes Action Canada T1D Registry and focused more on gathering health information from those willing to donate their data for research. With this, we began our patient engagement, which included workshops, focus groups and one-on-one consultations, and quickly learned this concept was not enough to inspire those living with T1D to participate.

It became clear that for this platform to become successful, users must have ownership of their data, experiences and involvement in research. Therefore, Connect1d Canada developed as a digital platform that collects information about persons with T1D experiences through user-reported data in a transparent and customized manner. Account holders have complete control over the information they consent to share, all while volunteering for research studies that match their research interest and eligibility. This is by no means the last iteration of the platform. Rather it is the start of a journey that will accelerate innovation in improving the health and wellness of Canadians living with T1D by connecting and engaging them with researchers.

Why do we need governance?

For years, decisions on research in Canada has been at the discretion of researchers who have applied for funding to answer research questions with little to no consultation with those living with the conditions being investigated. With the adoption of patient-oriented research, the cornerstone for Diabetes Action Canada and a requirement for all its projects, citizens who live with diabetes must be engaged to ensure research planning is relevant to the community and produces meaningful results for improving the health outcomes of those living with diabetes. This layer of governance will focus on decision-making on how Connect1d Canada is managed, how participants and staff are protected, and how accountability is assured. This is particularly important once there is an increase in both citizen and research users to ensure that Connect1d Canada is growing to continuously meet the needs of the T1D community. In the following plan, we propose to establish a stakeholder Community Advisory Committee that will consult on developing a Connect1d Canada strategic roadmap, patient engagement activities including research study recruitment, and sustainability planning.

The key questions to consider for research governance are the following.

- Does our strategic roadmap align with the mandate of Connect1d Canada and the needs of the T1D Community?
- Do we have the right people engaged with the platform at the right time?
- Are researchers using the platform to its full potential?
- What strategies are we using to engage those living with T1D from across Canada?
- Do the benefits of using the platform for research recruitment outweigh any risks for the participants?

To answer these questions, we wish to establish a Connect1d Canada Community Advisory Committee (CCAC) to advise the operations and management team on future directions to ensure that Connect1d Canada remains a patient-driven platform and that all related activities satisfy legal, ethical, privacy and confidentiality obligations.

Governing Principles

The Connect1d Canada governance process is guided by eight principles as summarized below:

1. Transparency

- All decisions, policies, and practices regarding data use are freely accessible to those affected by the decisions and to the public. These shall be available in an easily understandable format.

2. Customizability

- Every user has the option to customize their profile in Connect1d Canada to match their personal experience and preferences. This includes customizable options for opt-in and opt-out for the sharing of data collected to ensure individual comfort levels.

3. Integrity

- The CCAC ensures that uses of the data have a clear patient/public interest consistent with the intended purpose of Connect1d Canada, are of high scientific and ethical integrity; and are maintained in a secure and private manner.

4. Participation and Inclusiveness

- Those living with T1D and their families, health care professionals, and researchers should participate in governance over data. Participation on the CCAC should be inclusive, equitable, informed and organized.

5. Impartiality and independence

- The CCAC reaches a broad consensus on what is in the best interest of those living with T1D and their families. All members in the process must look beyond their personal interests as patients, health care providers, or researchers. In addition, the CCAC operates in a zone of bounded independence from management, to ensure that its decisions are free from institutional conflicts of interest.

6. Effectiveness, Efficiency and Responsiveness

- Research governance ensures the objectives of Diabetes Action Canada and Connect1d Canada are met effectively and efficiently.

PROPOSED TERMS OF REFERENCE for CCAC

Name: Connect1d Canada Community Advisory Committee (CCAC)

Purpose: To provide guidance, from the public and T1D community perspectives, for Connect1d Canada about its priorities, development, and operations

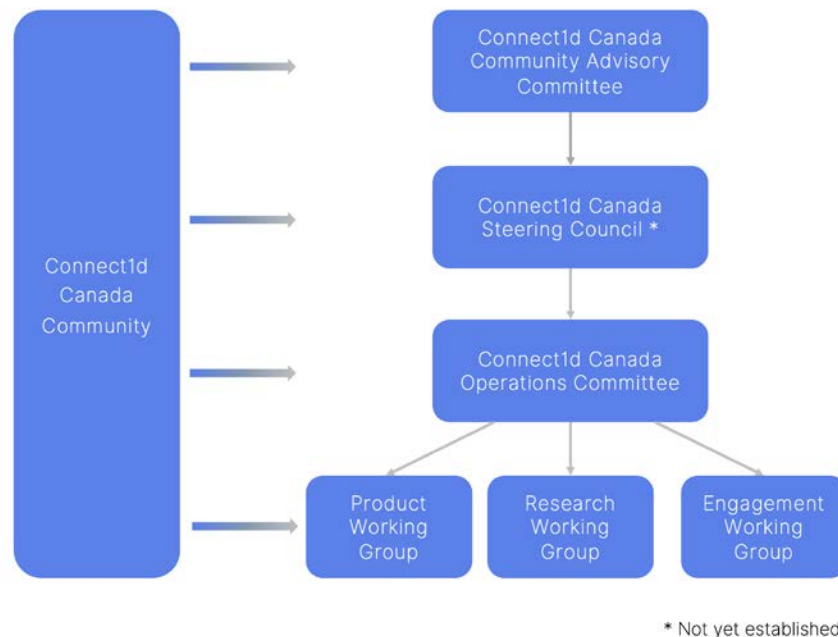
Responsibilities/Roles

- To advise Connect1d Canada about its short-term, medium-term, and long-term priorities
- To advise Connect1d Canada on the appropriateness of posting research projects including those clinical trials sponsored by industry and/or other revenue generating research organizations
- To advise Connect1d Canada when further or wider engagement with the public, or specific groups within the T1D community, is required or would be especially valuable for further co-design and development of the functionality of this platform
- To identify privacy concerns that may arise and to suggest ways to address those concerns and to communicate with the public about how they are being addressed
- To suggest strategies for Connect1d Canada to effectively inform the public at large or specific groups about the nature, processes, value, potential, and limitations of T1D research in Canada, and how individuals and communities can influence the priorities and function of Connect1d Canada
- To advise Connect1d Canada on its knowledge mobilization, in particular marketing and communication about its function, outcomes and future development

Reporting Relationship: The CCAC will initially report to the Connect1d Canada Operations Steering Committee, until the platform is mature enough for the Connect1d Canada Advisory Council to be established. The current Operations Steering Committee will be responsible for the day-to-day operations and working groups for the Connect1d Canada and the latter Advisory Council will be the decision making entity for Connect1d Canada. Please see figure 1 for governance structure.

The Chair of the CCAC will also interact directly with the Connect1d Canada Operations Steering Committee. Members the scientific leadership team will be invited to attend CCAC meetings and address the members, but will not have a voting role. Connect1d Canada will provide administrative support at meetings and facilitate communication within CCAC and with the larger operations team.

Figure 1: Proposed governance structure for Connect1d Canada. For the purposes of this document, we will focus on the CCAC in this structure. The Connect1d Canada Steering Council will be established once the platform has a working CCAC in place.



Terms of Reference: The CCAC may make recommendations to modify these Terms of Reference; any changes would need to be confirmed and agreed by the Connect1d Canada Operations Steering Committee and Diabetes Action Canada leadership team.

Membership:

- 6 to 8 individuals, plus a chair, broadly reflective of the Canadian T1D population in terms of geography, sex and gender, age, ethnicity, occupation, and socio-economic status. At least one member will have French as their first language.
- To make it easier for the CCAC to approach and perform its work primarily on behalf of the public at large, at least 50% of the members should be individuals whose experiences do not include being a patient partner (e.g., in an initiative funded by Canada’s Strategy for Patient Oriented Research [SPOR]) or being a member of a patient group.
- While some members may belong or have belonged to one or more organizations—whether a cultural organization, a patient group, a political or social advocacy organization, —they will not represent those organizations in their role or work as CCAC members. Individuals who work mainly in the area of health data or data privacy are not eligible to be CCAC member since other members might be inclined, consciously or not, to defer to them in some discussions.
- Administrative support will be provided by the Connect1d Canada team

Membership Terms: The initial members should have staggered one of two-year terms

Method of Selecting Members: An open call will be run through the Connect1d Canada platform asking those who have already enrolled to express interest. Members will be selected by the Connect1d Canada team. A Chair will be identified by the CCAC after an initial meeting and if necessary will rotate among individuals.

Preferred Method of Decision-Making: Consensus, though if consensus cannot be achieved members may vote on a question.

Quorum: At least 50% of the members.

Meetings: The PAC will meet at least five times a year occurring approximately bimonthly with a longer break during the summer months.

Expenses and Reimbursement: All expenses incurred by members in performance of their responsibilities will be reimbursed as promptly as possible, in accordance with the policies of Diabetes Action Canada. Diabetes Action Canada will endeavor to pay larger expenses, e.g. airfare and hotel charges, directly.

Compensation: Each member (excluding the Chair) will receive \$75/meeting in accordance with Diabetes Action Canada compensation policy. This includes participating in and preparing for Individuals for the five meetings per year, for responding to requests between meetings, for reviewing materials intended for the public, and for facilitating two-way communication between Connect1d Canada and various communities and organizations. Any additional time spent will be compensated in accordance with Diabetes Action Canada Compensation Policy and will be agreed upon before additional work commences.

The compensation for the Chair may be higher than that of other members and will be paid at an hourly rate of \$25/hour to compensate for meeting planning and preparation as well as any additional role required for the Chair position.

Requirements and Expectations of Members: All members will be made aware of conflict-of-interest principles and procedures and will be asked to declare any conflicts at each meeting. Members will also be made aware of confidentiality requirements and required to sign a confidentiality agreement. Members will also be expected to take part in at least 50% of meetings within each year of membership.

Leaves of Absence and Termination of Membership: Members may request a leave of absence for periods of up to six months. Members who are unable to be active for more than six months will be expected to resign. They may reapply when able to resume active membership.

Evaluation: The CCAC will be evaluated once a year in a process that includes an evaluation of itself in which all members will be invited to participate. The CCAC will also participate in the evaluation of the Connect1d Canada.