Transforming Clinical Trial Capacity in Canada: Implementation of National Infrastructure for NCC, IIT and Risk-Based Monitoring

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Children's Cancer & Blood Disorders

EXPANDING NATIONAL TRIAL CAPACITY

Goal: Expand C17's operational framework to support multi-center national and international investigator initiated and NCC model trials

C17 Council: Who We Are

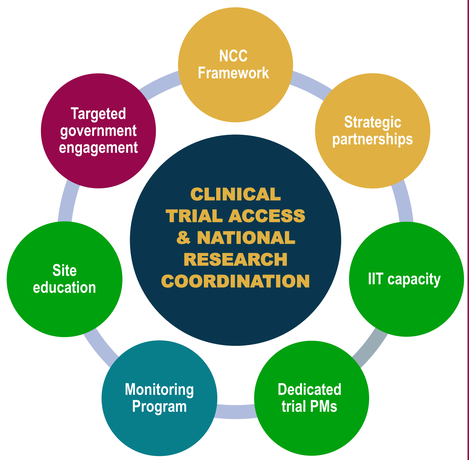
C17 Council is an organization composed of the 16 institutionally appointed heads from the sixteen pediatric hematology, oncology, and stem cell transplant programs across Canada. We represent the interests of children and adolescents with cancer and blood disorders and act as an authoritative Canadian voice. Since our establishment in 2003, C17 has filed over 300 academic Health Canada Clinical Trial Applications representing 20 academic networks based primarily in the US and Canada.

Q4 2024-Q1 2026 Objectives

- ✓ Match network research priority growth through increased capacity, particularly Project Managers
- ✓ Enhance national research activity coordination
- ✓ Expand innovative multi-centre clinical trials in Canada
- ✓ Expand education framework
- ✓ Targeted government engagement
- ✓ Expand partnerships with Canadian and international organizations that support advancing outcomes in pediatric oncology/hematology

How This Will Be Achieved

C17 Regulatory Office will continue to expand and enhance the operationalization of:



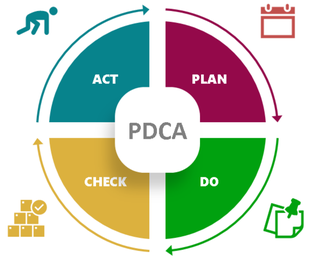
Clinical trial opportunities available for all Canadian children and teenagers regardless of where they live in Canada.

CENTRALIZED RISK-BASED MONITORING INFRASTRUCTURE

Goal: Renew C17's monitoring framework to provide central, risk-based support for academic/consortia-lead clinical trials in Canada

What We Set Out to Build

- ✓ Modernization of C17's current monitoring framework to focus on risk-based elements identified by ICH GCP E6(R3)
- ✓ New tools to assess protocol risk, identify critical data elements, and monitoring of site performance and CAPA plans across studies
- ✓ Create robust training structure for site CRAs and peer to peer monitors
- ✓ Utilize these tools to continuously improve the quality of pediatric clinical trials in Canada



What We Achieved

C17 Risk Based Monitoring

- Peer to Peer Onsite Monitoring
- Remote Monitoring
- Onsite Monitoring
- Central Monitoring
- Protocol Risk Assessment Tool and Implementation Guide
- Critical Data Elements
- Site Performance Tracker and Implementation Guide
- Corrective Action Plan (CAPA) Tracker
- Risk Library
- CRA Training Program
- Lessons Learned Register

ESTABLISHING THE C17 COUNCIL NCC MODEL

Goal: Establish C17 Council NCC Model for ANZCHOG OPTIMISE and ITCC studies FAR-RMS and Glo-BNHL

C17 Council NCC Model

C17 has a successful model for working with North American-based academic groups based in Canadian or US institutions. More recently, C17 has been working to develop the infrastructure required to work in a different model of collaboration – the model of a National Coordinating Centre (NCC). Europe, the UK and Australia work in this model.

What We Set Out to Build

A comprehensive C17 NCC & IIT model framework guidance document was developed for implementation in current and future studies.

The framework document covers all aspects of clinical trial management from study and site start-up, regulatory maintenance, and monitoring throughout the trial's lifecycle, to site/study close-out.

It is a living document that will serve as a documentation of C17 Regulatory Office working practices for management of NCC & IIT clinical trials, with references to all associated C17 Standard Operating Procedures and templates/tool.

What We Achieved

C17 Council Trials Governance and Oversight Framework: A National Coordinating Center Model

OPERATIONALIZING MODEL TO SUPPORT INVESTIGATOR-INITIATED TRIALS (IITs)

Goal: Transform C17 Council's IIT capacity with a national operational model piloted through DECRYPT-BABYBRAIN

What We Set Out to Build

- ✓ IIT framework adaptable to future trials
- ✓ Adaptable SOW and budget templates
- ✓ Financial accountability frameworks
- ✓ Master and site template agreements
- ✓ Health Canada Clinical Trial Application and NOL for C17-Sponsored IIT
- ✓ Activation of C17-Sponsored IIT participating sites

What We Achieved |nQ4 2024 – Q1 2026

- ✓ Adaptable EDC system
- ✓ SOPs
- ✓ Site training documents
- ✓ Safety plans

Scalable Infrastructure Developed

- ✓ Standardized templates and budgets
- ✓ ACT-based subsite agreement template

Financial & Contract Infrastructure

- ✓ Developed flexible plans for decentralization with NCC- and IIT-model trials

CRAFT Framework

- ✓ 5 site opened to accrual
- ⇨ 8 sites expected to open Q1/Q2 2026

Open to Accrual

- ⇨ Approaching 50% accrual for a rare infant cancer
- ⇨ 6 of 15 patients on treatment within 6 months

Rapid Patient Enrollment

What We Achieved | Timeline