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Executive Director, C17 Council

Developing an Integrated Strategy to Support Pediatric and Perinatal Clinical Trials
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Children's Cancer & Blood Disorders

C^{17} Council

The goal of C^{17} is to provide coordinated national leadership in pediatric hematology/oncology to improve the outcomes and quality of life for children with cancer and blood disorders and their families

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- C^{17} Council and Executive
- C^{17} Program Administrators
- C^{17} Research Network
- COG SMO Canadian Regulatory Office
  - Expanding beyond COG
- C^{17} DVL Committee
- C^{17} Education Committee
- C^{17} Standards and Guidelines Committee
- C^{17} Human Resources Committee
- Cancer in Young People in Canada (CYP-C)
- C^{17} CPAC AYA Task Force
- C^{17} International Development Committee

C^{17} Senior Medical Office

- C^{17} Council, in a contractual collaboration with the Children's Oncology Group (COG), established the C^{17} Canadian Regulatory Office and appointed a Senior Medical Officer for Canada in 2002.

- Responsibility for COG site compliance with the Health Canada, Food and Drug Regulations, Division 5 "Drugs for Clinical Trials Involving Human Subjects"

- 16 – 17 sites participate in COG clinical trials

- To date we have opened over 185 clinical trials in Canada

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C^{17} Senior Medical Office

- COG acts as sponsor
  - Chair of COG signs the Clinical Trial Application (CTA) 3011 form
  - COG monitors, in person and centrally, under NCI Guidelines
- C^{17} office and Senior Medical Officer
  - Files the CTA and distributes the No Objection Letter
  - Organizes drug importation and labelling (if necessary)
  - Tracks CTSI, QIU and REBA (or REB approval letter) forms
- 2 Health Canada Inspections since 2009, major issues raised:
  - Lack of SOPs at sites
  - Insufficient monitoring

C17 Senior Medical Office

- So we developed a monitoring plan…
  - While we may have lots of funding (relative to other academic health related non-profits), we do not have a large enough budget for on-site monitoring every few months
  - Developed a centralized and peer-to-peer monitoring program
  - CIHR funding for a Monitoring workshop to train staff at all sites
  - Collaborated with NCIC Clinical Trials Group (adult oncology academic clinical trials group) and COG's current auditing and monitoring program
  - Includes monitoring of 20% of the patients enrolled in the previous year (in the off-cycle COG years)
  - Protocols are selected based on risk (high enrollment/investigational drugs)

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Research Network

COG SMO is not the largest part of our work. At the same time, research initiatives within C^{17} were growing and expanding:

- Research grants competition
  - 13 Competition rounds since 2004, $2.3 M and 20 grants funded
  - Up to $100,000.00 per year for 2 years
  - Clinical Trials occasionally submitted

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DVL Network

- DVL and Pre-Clinical Network
  - 8 centres participating (9th one interested in joining)
  - Collaboration with NCIC CTG and pharmaceutical companies
  - Starting to get PI –initiated clinical trials in development
  - Anticipate identifying drugs of interest through the pre-clinical collaborations that can be moved into Phase I/II clinical trials in the DVL network before being moved into larger studies in COG

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Cooperative Groups

- Multiple sites were joining other international academic cooperative groups
- TACL, NANT, PBMTC, POETIC
- Most are smaller than COG and not legal entities
- When multiple sites want to participate, how can institutions or investigators comply with the Health Canada regulations?
- We decided to start with 1 cooperative group - TACL

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Risk Management

Need to address risk management issues:

- We were asked to start filing CTAs for other multi-site studies
- When you sign a CTA you are agreeing to ensure compliance of all the sites in Canada
- We are not a formal part of a university or health authority
- Who will/can sponsor multicentre clinical trials in pediatrics?
- Approached HIROC for insurance
- Acquired insurance in April 2011

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Risk Management

Working with HIROC to establish what the risk management issues are:

- Monitoring of clinical trials at sites
- Agreements in place with cooperative groups we work with
- Training of site staff
- Conflict of interest, confidentiality agreements with committee members
- SOPs at each site (working on implementing N2 SOPs)
- Database that tracks compliance with regulatory documents (pre-populated CTSI forms, rule based date entry, etc.)

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Hiccups and Pitfalls

- Funding – what do we do if our funding drops?
- Staffing – finding, training and retention of staff
- Developing the infrastructure always takes longer than anticipated (website, on-line regulatory database)
- What if insurance costs go up too high?

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