Initiatives for enhancing the Canadian Clinical Research Environment
We are in a global leadership position in areas that include basic and translational research:

- Cutting-edge genomics research in British Columbia
- World-class resources for R&D in virology in Saskatchewan
- Exciting industry activity in virology in Alberta
- Groundbreaking infectious disease public health lab in Manitoba
- Top-ranked research in cancer, stem cell and regenerative medicine in Ontario
- Globally renowned centres for neuroscience and cardiovascular research in Quebec
- Exceptional facilities for vaccinology in Atlantic Canada
CANADIAN CLINICAL TRIALS COORDINATING CENTRE (CCTCC)

Kathryn Nijsse
Initiatives Manager

www.cctcc.ca  knijsse@cctcc.ca
CCTCC is a demonstration of the unique commitment between industry, government and healthcare institutions to improve the operational environment for clinical trials in Canada.

The CCTCC’s key objectives are to improve the operational environment for clinical trials in Canada and promote the country as a destination of choice for clinical trials.

www.cctcc.ca | info@cctcc.ca
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015
Patient Registries
Ongoing
Fair Market Value Project
Work started in 2016
model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

CCTCC OUTCOMES
Facilitating collaboration across Canada
Speeding-up clinical trials start-up times
Promoting Canada as a leading destination for clinical trials
Funding provided
Environmental pulse check

Canadian Clinical Research Participation Survey
Results due 2018

National Advisory Group
Est. SEPT 2014
Provincial Clinical Trials Organizations’ Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016
Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017
Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018
NATIONAL ADVISORY GROUP

• pan-Canadian expert group providing input & advice on CCTCC's activities

PROVINCIAL CT ORGANIZATIONS’ MEETINGS

• Foster collaboration
• Engage for projects
• Identify emerging issues
• Prevent duplication of effort
Provincial CT Organizations Meetings
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WHAT IS THE CCTAM?

• Web-based, ‘living, easily searchable, interactive database of Canadian clinical research capabilities:
  – investigators, clinical research sites, hospitals, institutions, research ethics boards, CROs, SMOs, etc.
• First pan-Canadian, pan-therapeutic, up-to-date, research inventory with an integrated map-based search function
• Currently over 1100 assets (40% asset growth since launch in June 2015)
• Access the CCTAM by visiting www.cctam.ca
Canadian Clinical Trials Asset Map (CCTAM)

Showcase Canadian clinical research assets

An essential tool for anyone on conducting clinical research in Canada

Place clinical trials effectively and efficiently

Expedite study feasibility process

Reduce clinical trial start-up times

Unique in the world

www.cctam.ca | cctam@cctcc.ca

CCTAM webinars available upon request.
PATIENT REGISTRIES

• Populating in the CCTAM to facilitate CT feasibility studies & patient recruitment

• Key criteria used in selecting registries:
  ✓ Active registry
  ✓ 10 registrants min.
  ✓ Point of contact
  ✓ Diagnosis identified by an approved care team
  ✓ Data accessible to external parties for purposes of CT recruitment

• Actively working to contact and populate in the CCTAM
MODEL CLINICAL TRIAL AGREEMENT (mCTA)

• Canada-wide initiative to:
  ✓ standardize CT agreements by developing language for all clauses
  ✓ bring efficiencies to clinical research process
• Collaboration with CLEAR (TransCelerate-supported) project to incorporate CLEAR language within the mCTA
• mCTA’s Team Canada consists of site/institution & sponsor representatives
mCTA – CURRENT STATUS

- **Adoption and Implementation stage** after comprehensive stakeholder consultations in 2015 & 2016
- Reviewed by an independent legal counsel\(^1\) for consistency of terminology use & definitions, & clarifying ambiguous wording
- **mCTA Version 8, consultation report & communication deck are available for use**
- Working with sponsors and sites to establish a review committee that will ensure the continued relevance of the contract
FAIR MARKET VALUE (FMV) PROJECT

• Direct result of the model CT Agreement (mCTA) project

✓ Goals:
  • Reduction of clinical trial (CT) budget negotiation times
  • Reduction of CT study start-up timelines
  • Introduction of CT efficiencies and streamlining of budget negotiations

✓ Reasons to tackle FMV:
  • Address increasing CT start-up times
  • Ensure Canada’s CT competitiveness globally
FMV BACKGROUND – STUDY START-UP

- Canada start-up is competitive compared to Europe for CV but not for Oncology trials
- Challenges with start-up in Canadian institutions (IRB, contracts, budgets)
CONTRACT TIMELINES

Average Time for Contract Execution
2015-2016

- Legal
- Budget
- Internal Sign-Off
- Draft to Fully Executed

INSTITUTIONS
ALL SITES
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“Clinical Trials – the Canadian Advantage”

Investment Case

- Consistent narrative communicating Canada's clinical trials advantages globally focused on:
  - Speed
  - Quality
  - Incentives

- Intended for presentations to global offices of CT sponsors
- Customizable based on audience’s needs
- Next steps:
  - Possible additional modules
  - Keep content updated

- Access [here](#)
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Clinical Research Participation Survey


Hosted at www.bccrin.ca/survey

- First pan-Canadian survey enabling patients & healthy volunteers to provide input & advice on their CT experience
- Anonymous, online experience survey by Clinical Trials BC (formerly BCCRIN). Part of the BC Academic Health Science Network
- Pan-Canadian Expansion supported by the CCTCC
- Adults, or parents of a child, who have been invited to participate in a clinical trial and either enrolled, declined or did not meet the screening requirements are eligible
- Part of a broader strategy to engage Canadians in the clinical research process
- Data will be used to improve recruitment and retention outcomes for clinical research sites, investigators and sponsors by developing strategies designed to address provincial and national research participant perspectives and concerns
Clinical Research Participation Survey
Update October 2017

- Enrollment target of > 1000 reached April 2017
- Analysis by CHEOS commenced September 2017
- Results expected November 2017
- Planned publication
- Knowledge translation planning has commenced

Questions: Alison Orth at Clinical Trials BC - aorth@bcahsn.ca
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RESEARCH ETHICS BOARD REPORT

• The impact of the Canadian experience of REB centralization & harmonization
• Recommendations for the future to ensure Canada’s competitiveness on a global scale
• CCTCC & Health Canada prepared a joint response to the WG’s report
• More information is available here
CLINICAL TRIALS METRICS

• Quantitative metrics, e.g.:
  ✓ # of newly randomized subjects, opened sites, trials, trials by phase in Canada & globally (phases I, II, II, IV, other)

• Operational metrics, e.g.:
  ✓ average time/days to REB approval, contract & budget

• Quality metrics, e.g.:
  ✓ patient recruitment, validity, retention, & protocol & dosing deviations (international comparison)

• Investment metrics, e.g.:
  ✓ total CT Investment in Canada (by province) vs. other countries (including CROs)
CONTACT US

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THANK YOU