ENHANCING THE CANADIAN CLINICAL RESEARCH ENVIRONMENT – THE mCTA AND FAIR MARKET VALUE INITIATIVES

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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.
**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**

**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**
- Due Summer 2016
- Clinical Trials Metrics Platform
- Results due MAR 2017
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)
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
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

Map of assets (1108)

CCTAM webinars available upon request.

www.cctam.ca
WHAT IS 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)
• Ongoing efforts to populate HealthCareCAN’s member institutions & investigators
• Access the CCTAM [here](http://www.cctam.ca)
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

• Introductions to Patient Registries are welcome
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
- Ultimate goal – ensuring Canada’s global competitiveness in attracting CTs
mCTA – CURRENT STATUS

• **Adoption 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

• Visit our website [here](#) to access all materials & for more information
mCTA – CURRENT STATUS

• Pan-Canadian consultation in 2016:
  ✓ 41 sites (through individual and provincial responses) provided feedback
  ✓ Open houses to educate sponsors, get further feedback & gain engagement from June to September 2016

• Reviewed by an independent legal counsel for consistency of terminology use and definitions, and clarifying ambiguous wording

• mCTA Version 8, consultation report & communication deck are available to early adopters

• Visit our website here to access all materials & for more information
Everyone is being encouraged to adopt the mCTA

Stakeholder meetings have been held in Toronto, Montréal and Calgary to discuss adoption and implementation logistics and align on the next steps in order to realize full usage of the model.

75 representatives from 55 different organizations in attendance.

Positive response and willingness to engage
mCTA – ADOPTION NEXT STEPS

- The contract is readily available on the CCTCC website for use
- Materials are being developed to increase awareness and understanding of the mCTA
- Two meetings will be held via teleconference in December to allow for both sites and sponsors to ask questions specifically regarding the language of the mCTA
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

WEEKS

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

INSTITUTIONS

ALL SITES
WHAT DOES FMV MEAN TO SPONSORS?

- Bona fide service fees
- Equitable fees
- Defendable payments
- Compliance
- Competitive Costs

FMV DEFINITION
WHAT DOES FMV MEAN TO SITES?

- Framework or resource to assist in budget development
- Where budget development is consistent (e.g. central budget management) then the negotiation process is faster
Approach:

- Scope out sponsors’ & sites’ FMV needs
- Clarify key budget-related questions of both sites and sponsors
- Develop understanding of both sites and sponsors’ requirements, pressures and barriers in CT budgeting
- Identify solutions such as best practices and benchmarks
DRIVERS FOR THE FMV INITIATIVE

- Variation in how budgets are created & negotiated
- Understanding of full costs & application of full cost recovery
- Sponsor and CRO inconsistency can drive site inconsistency
DRIVERS FOR THE FMV INITIATIVE

✓ Variation in how budgets are created & negotiated

- Decentralization of budgeting process creates inconsistency, and is a barrier to streamlining
- Everyone budgets differently, even within institutions
- Too many groups involved in budget development and negotiation
DRIVERS FOR THE FMV INITIATIVE

✓ Understanding of full costs & application of full cost recovery
  • Internal Hospital Services (Imaging, Pharmacy, Lab) set their own cost/fee structure; Research often has no input or ability to negotiate
  • Investigators often underestimate costs, & incur account deficits
  • Differences across institutions & provinces
  • Different understanding & costing for the same budget item
  • Complexity of studies & tests (e.g. molecular profiling)
DRIVERS FOR THE FMV INITIATIVE

✓ Sponsor and CRO inconsistency can drive site inconsistency

- Variation between sponsors leads to perception of variation at sites
- CROs present their own challenges
- Even if all fees have been justified with a sponsor in the past, CRO involvement means starting again with the process
FMV POTENTIAL BENEFITS

- Faster negotiation process
- Framework or resource (e.g. best practices) to assist in budget development
- Compliance
- Defendable payments
CONTACT US

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THANK YOU