



CCTCC

Canadian
Clinical Trials
Coordinating Centre

CCCEC

Centre canadien
de coordination
des essais cliniques

STRENGTHENING CLINICAL TRIALS FOR CANADIANS
RENFORCEMENT DES ESSAIS CLINIQUES POUR LES CANADIENS

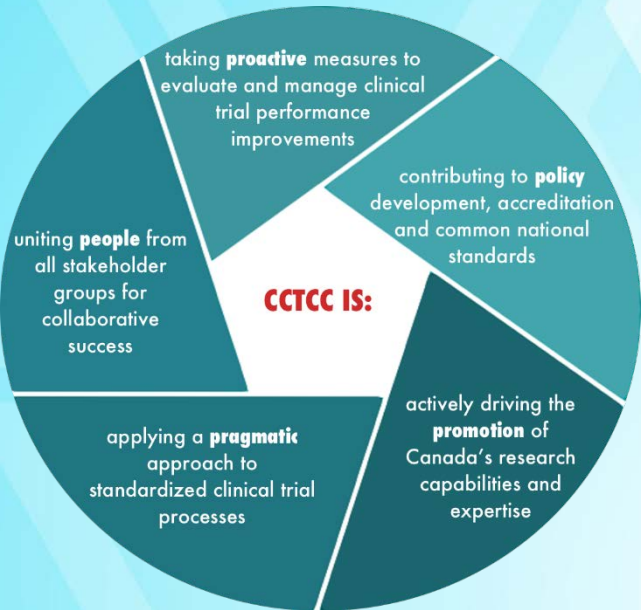
FAIR MARKET VALUE (FMV) PROJECT

Elena Aminkova, Interim Director of Project
Facilitation

www.cctcc.ca

eaminkova@cctcc.ca

FMV PROJECT



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

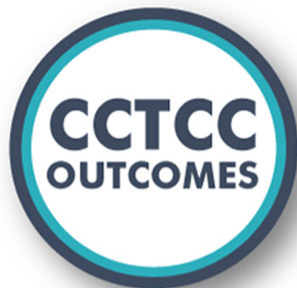


CCTCC's key objectives are to improve the operational environment for clinical trials in Canada and promote the country as a destination of choice for clinical trials.



www.cctcc.ca

CCTCC



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

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)

Due 2017



CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

Canadian Clinical Research Participation Survey

Results due 2016

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



CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

FMV PROJECT

FMV APPROACH

✓ 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



CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

FMV APPROACH

FMV STATUS

✓ Initial Observations:

- Key Drivers for Cost Variation:
 - Variation in budgets creation & negotiation
 - Understanding of site full costs and application of full cost recovery
 - Reasons for inconsistencies



FMV POTENTIAL BENEFITS

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



CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

FMV BENEFITS

CONTACT US

WEB: www.cctcc.ca

EMAIL: eaminkova@cctcc.ca

Phone: 1-844-452-5818



CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

CONTACT US



CCTCC

Canadian
Clinical Trials
Coordinating Centre

CCCEC

Centre canadien
de coordination
des essais cliniques

THANK YOU