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

CCTCC CT Metrics Project Call

Monday, Nov 20th, 2016, 8:30 am to 9:00 am EST
Toll Free: +1 (877) 394-5901| **Participant PIN Code:** 3950626

1. Welcome.
2. Goals/parameters of the Clinical Trials (CT) Working Group (WG). See page 2.
3. Parameters of the metrics to be collected. See page 2.
4. Next steps post-metrics collection, for e.g. ways to present the collected data.
5. Other items.
6. Close.

CCTCC Clinical Trials (CT) Metrics Working Group (WG)

Objectives:

To select metrics from available sources which can reflect in a sustainable manner the clinical trial performance of Canada

The metrics are to be used for collaborative efforts among academia, industry and F/P governments to maintain and improve attractive clinical research environment and contribute to the Federal Government's innovation agenda.

Pages 4-6 include more details about the project ‘s goals and objectives.

Parameters of the metrics:

- Objective and reliable source over time
- Used in other key countries to which Canada wants to be compared
- Common to academia and industry
- Limited number
- Clearly understandable and agreed by all stakeholders

Currently considered sources:

SOURCE	DETAILS	RECOMMENDATION
Rx&D 2011/IMC 2017 /CCTCC 2015 surveys	only ad hoc, limited reliability, sample restrictions, data from 2017 available to IMC	Use Rx&D2011 and CCTCC 2015 for comparison purposes if applicable TBD
Trial/Site Trove*	yes w intl. data, lower cost, comprehensive list; no consisted patient retention and cost metrics. Contract already in place.	Phase 1
QuintilesIMS/Iqvia	yes w intl. data, higher cost	TBD
Health Canada*	high reliability and value for public/government, not full alignment w other regulators; limited metrics list	Phase 1 Ask contract in HC if more data can be provided to us
Clinicaltrial.gov	not comprehensive of all CTs	TBD
N2	the data has to be collected; availability and sample size to be confirmed	Phase 2
Q-CROC	sample restrictions - only oncology sites in Quebec	TBD

CAICR – independent sites	the data has to be collected; availability and sample size to be confirmed. Some sites collect quality metrics.	Phase 2
Pharmaceutical companies	additional to IMC's 2017 survey operational and other metrics	TBD if needed

* Proposed as an optimal source for our objectives?

Timeline for agreement re metrics to collect: by December 31 (20th), 2017

BRIEFING NOTE

CANADIAN CLINICAL TRIALS COORDINATING CENTRE (CCTCC) CLINICAL TRIALS (CT) METRICS COLLECTION PROJECT

PURPOSE: To provide context to the CCTCC's CT Metrics collection project along with its goals, objectives and tentative plans

BACKGROUND:

In 2011, Innovative Medicines Canada (IMC) then Rx&D conducted a CT metrics survey of its member companies that conduct CTs (14 companies submitted data, representing 51.8% of the members that conducted CTs in Canada at the time). The survey inquired about CT activities from 2005 to 2010. The obtained results indicated that the number of CTs and CT sites in Canada was steadily declining. They also pinpointed problematic areas in Canadian CT environment which required attention in order for the country to regain its global CT competitiveness.

In 2015, CCTCC contracted IMS Brogan to provide a limited set of metrics, including number of CTs, overall cost per patient and cost per patient per specific therapeutic areas, time between country confirmation to first site initiation and others.

The most common and free of charge source of CT data for metrics such as number of CTs annually in Canada as compared to other countries is www.clinicaltrials.gov. However, data from clintrials.gov can be difficult to analyze and interpret and frequently does not provide comprehensive data set.

Over the last five years a number of pan-Canadian and provincial CT initiatives, including the CC#EtefoodTCC have worked on improving the Canadian CT environment. It is important to determine if these initiatives are having the desired effect in terms of facilitating clinical trials in Canada. Thus, there is a need to obtain data to compare how Canada is doing compared to the previous benchmark in 2011 and to establish a process of sustainable metric/KPI collection that will facilitate ongoing assessment of the Canadian clinical trials landscape. It is especially important to collect data on operational and quality metrics as there is currently an information gap in this area.

CONSIDERATIONS:

1. **Objectives:**

The CCTCC CT Metrics Project has the following objectives:

- Promote Canada as a destination of choice for clinical trials by comparing and benchmarking Canada's performance to selected global benchmarks such as other G7 countries
- Identify upcoming and/or ongoing challenges in the Canadian CT field
- Track the success of national and provincial initiatives for boosting clinical trial activity in Canada
- Track the success of national and provincial initiatives for improving the operational efficiency of clinical trials in Canada
- Track the success of national and provincial initiatives for improving the quality of clinical trials conducted in Canada
- Establish standardized definitions for the metrics to be collected
- Establish a sustainable process for metrics collection so that data can be collected and tracked over time by identifying the data sources to be used for ongoing metrics collection

2. CT Metrics to be collected:

- Investment metrics, including total investment in CTs in Canada, which will provide a snapshot of how Canada compares to its global competitors (from IMC Phase I data collection)
- quantitative metrics on the numbers of new trials, number of clinical trial sites and patient recruitment
- operational metrics, including timelines for contracts, budgets and research ethics boards (REB) approvals
- quantitative quality metrics: although the metrics to be collected still need to be finalized, the following are some of the suggestions provided to the CCTCC: patient validity; protocol and dosing deviations; number of queries and critical audit findings

The proposed list is attached. The newly established CCTCC CT Metrics WG consisting of varied CT stakeholders will finalize the list of CT metrics to be collected.

3. Sources of data collection:

- Several potential data sources are being considered and explored, including:
- CT metrics already collected by IMC in 2017 during their own data collection processes
- Another collection of operational and quality metrics from IMC members using an independent third party
- Sources such as QuintilesIMS/Iqvia, Health Canada and Trial Trove

- Collaborating with the Network of Networks (N2), Canadian Association for Independent Clinical Research (CAICR) and others to collect operational and quality metrics data from clinical trial sites.

4. Timelines:

The timeline for agreement on metrics to collect is by December 31 (20th), 2017.