

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 the Phase I data collection
- Phase 2 data collection of operational and quality metrics from IMC members using an independent third party
- Sources such as QuintilesIMS and Trial Trove
- Collaborating with the Network of Networks (N2), Canadian Association for Independent Clinical Research (CAICR) to collect operational and quality metrics data from clinical trial sites.