

CCTCC Informal CT Metrics Working Group Call
Wednesday, September 7th, 2016, 11:00 am to 12:00 pm EST
Toll Free: +1 (877) 394-5901 | Participant PIN Code: 3950626

Informal CT Metrics Working Group	Ms. Alison Sargent, IMC – Chair, Metrics WG Dr. Shurjeel Choudhri, Bayer Inc. Ms. Doreen D’Souza, Bayer Inc. Dr. Robert McMaster, VCH Ms. Laura Accettola, Amgen Ms. Heather Mustoe, CIHR
Staff	Ms. Elena Aminkova, CCTCC Ms. Marianna Medvid (Secretariat), CCTCC
Guests	Ms. Stephania Manusha, VCH

1. Welcome and Introductions.

2. Discussion:

There are multiple purposes for collecting clinical trials (CT) metrics:

- To evaluate if the current activities being implemented through CCTCC, provincial and other organization have an impact.
- Use selective metrics to promote Canada as a leading destination for clinical trials (CTs).
- Identify gaps that need to be addressed.

The main focus of this call is on the operational and quality CT metrics.

The following overall suggestions were made:

- Specify the timeframe for metrics to be collected when asked industry to provide data.
- Consider the value of the metrics:
 - Examine trends and how metrics change over time;
 - Ensure that the metrics identified can be consistently measured year after year.

2.1. Operational Metrics:

a.) REB approval metrics (time):

- It was suggested to include the following metrics:
 - Time from submission to REB review

- The number of cycles of REB review
- Average time for REB approval
- Time to first ethics approval and quantify in percentages (i.e. first 25%) the remaining approvals thereafter. This can be useful for global teams of companies.
- Filter the REB metrics by province, since each province has different REB process(s).
- For CTs in multiple provinces, provide context information since CTs can be very different in scope and size.

b.) Contracting metrics (time):

- Include metrics re: 'from the time of the first point of contact with sites (i.e. information/docs sent) to the time when a first draft is submitted and to the time by which signatures are obtained'.
 - Validate contract metrics with pharmaceutical companies and their clinical operations resources by finding out about the typical metrics tracked by companies
 - Filter the time for contract by province and by therapeutic areas (e.g. oncology, cardiology, etc.)
- E.g. BCCRIN collects metrics re:
- the time for contracting from the date that a research officer receives a contract to the time by which all signatures are obtained,
 - which mCTA version of mCTA is used.

c.) Budgeting metrics (time):

- Filter the time for budgeting metrics by province and therapeutic areas (e.g. oncology, cardiology, etc.)
- Identify the common budgeting metrics or points used by companies in order to identify trends.
- To evaluate the impact of contracting and budgeting delays, it was suggested to compare the typical/average time that it took to negotiate a contract between 2010 and 2015 and compare it to the same between 2015 and 2020.

d.) Other suggested operational metrics:

- Speed of sites initiation to recruit patients (in addition to REB, contact and budget approvals). Collect data re the time to first site initiation, and sites initiated thereafter (in set percentage categories similarly to the REBs metrics).
Examples of such metrics are:
 - From the time that the country is confirmed to the time that the first site is initiated.

- Use of an operational protocol available; the first site initiated is used as an overall start-up metric (i.e. site initiation to first site enrolled).

2.2. Qualitative Metrics:

- Include the following qualitative metrics as a starting point:
 - Inspections or internal audits findings
 - Number of queries for sites
 - Patient retention (i.e. out of all randomized patients, how many actually complete the CT).
- Stephania may have some qualitative metrics in few months (number of audits).

3. Closing Remarks and Next Steps:

- Stephania to share how contracting and budgeting metrics are collected in Vancouver Coastal Health.
- Doreen will provide info re budgeting metrics
- Connect with N2's Metrics Committee regarding their best metrics practices for sites.
- Schedule a meeting with Health Canada to inquire if they collected qualitative CT metrics and are able to share it (i.e. number of inspection done in Canada versus other countries).
- Heather will get further input from CIHR in regards to qualitative metrics.
- Validate the discussed CT metrics by surveying aa larger group from industry.



CCTCC
Canadian
Clinical Trials
Coordinating Centre

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

ACTION ITEMS - CCTCC Informal CT Metrics WG Call
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#	Details	Responsible
1.	Validate some of the metrics discussed with a larger industry group	Alison Sargent/IMC (lead) & CCTCC (support)
2.	Info re how contracting and budgeting metrics are collected in Vancouver Coastal Health	Stephania Manusha
3.	Info re budgeting metrics	Doreen D'Souza
4.	Schedule a meeting with Health Canada re qualitative CT metrics	CCTCC (lead) & IMC
5.	Connect with N2's Metrics Committee regarding their best metrics practices for sites	CCTCC & IMC
6.	Get further input from CIHR stakeholders in regards to qualitative metrics	Heather Mustoe