

Canadian Critical Care Trials Group Principles of Collaboration for International Trials

Preamble: There is an increasing need for international collaboration for clinical trials in critical care. For the reasons of sample size, representativeness, and generalizability, trials often require international collaboration. With this increasing international collaboration, there is a need for guidance on how to best facilitate CCCTG-endorsed contributions to international trials, as well as to foster international support for Canadian-led initiatives.

International collaboration for critical care trials is predicated on the following: 1) the hypotheses are sound; 2) the intervention is relevant for Canadian patients; 3) there is interest within the Canadian critical care community to contribute to the study; and 4) there is an expectation of reciprocity, where Canadian-led initiatives should expect their international collaborations are recognized in a similar spirit as international collaborations seeking CCCTG endorsement/contribution.

Whether CCCTG investigators are approached by international investigators, or CCCTG leadership is approached by leadership of an international consortium, the process for CCCTG endorsement will follow the usual formalized process. The lead CCCTG investigator will present the program of research to the larger CCCTG community for consideration and approval of endorsement.

For CCCTG-approved international trials, disputes arising on any of the below will escalate to involve the international steering committee of the trial, and failing a satisfactory resolution, to the independent chairs of the relevant trials groups to come to a solution on a case-by-case basis.

CCCTG formal endorsement criteria

For each formal adoption of an international project by the CCCTG, the following checklist should be integrated:

- A CCCTG investigator (ideally an early-career investigator) must lead the Canadian component, be a member of the international trial steering committee, and be included in the writing committee as a listed co-author on the main manuscript.
- The trial does not directly compete with existing CCCTG initiatives.
- If including the CCCTG in the authorship title, it has been approved by the manuscripts committee and satisfies CCCTG authorship policies.
- Co-enrolment with existing CCCTG initiatives is required at every possible opportunity.
- The trial steering committee aims to satisfy CCCTG policies on equity, diversity, and inclusion.
- There will be an opportunity for secondary analyses, as pertinent, of the data for the CCCTG investigators.
- International collaborators will support a funding application in Canada for Canadian participation, if relevant.
- The trial is endorsed by the international PIs national trials group, if one exists