
How can an External (non-McMaster) CANNeCTIN Investigator Work Effectively with PHRI Teams ?

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Highlights of this Presentation

External CANNeCTIN Investigators

- A. The local PI in a trial coordinated by PHRI (Dagenais)**
- Implications for the external investigator
 - Opportunities for the external investigator
 - within a first trial
 - within subsequent trials
- B. The Principal or Co-principal investigator of a trial coordinated by PHRI (Cairns)**
- Proposing a CANNeCTIN study
 - Protocol and application development
 - Post-funding, Pre-implementation
 - Study conduct
- C. The PI of a trial not coordinated by PHRI but with PHRI collaborators**

A. Participating as the local PI in a trial coordinated by PHRI

The external CANNeCTIN investigator

It is expected that the external investigator

- demonstrates interest
- achieves a good performance at his/her center
- participates at the meetings

A. Participating as the local PI in a trial Coordinated by PHRI

Opportunities within a first trial

Main study: teamwork: authorship: *Name of the trial*
investigators

Substudies: open to all active and interested external investigators. The investigator has to write a short proposal that needs to be accepted by the Substudy Committee

Several colleagues from Europe, America, Asia wrote one of the major substudies of large clinical trials.

A. Participating as the local PI in a trial Coordinated by PHRI

Opportunities within subsequent trials

- Main study: teamwork
- Substudies: open to all active and interested external investigators
- Member of a Committee: Adjudication, Substudies
- National leader and participating to the Steering Committee.

Several colleagues from Europe, America, Asia wrote one of the major substudies and became member of one or more of the above committees.

A. Participating as the local PI in a trial Coordinated by PHRI

Other opportunities

- Participating in other studies (epidemiological and/or clinical trials)
- Writing review papers or meta-analyses with the expertise of PHRI.
- Presenting at international meetings
- Developing substudies, approved by the substudy committee, for a grant application; PHRI may facilitate the realization of such application.

B. Participating as the Principal or co-Principal Investigator of a trial coordinated by PHRI

Proposing a CANNeCTIN Study

- WG selects a priority question
- WG identifies a PI with content expertise, appropriate leadership skills and clinical trial experience
- An appropriate McMaster investigator is identified as a co-applicant on eventual grant
- There may be an advantage in a co-principal role with a McMaster investigator if this is your first experience as an external PI with PHRI
- WG seeks priority designation by CANNeCTIN Operations Committee

B. Participating as the Principal or co-Principal Investigator of a trial coordinated by PHRI

Protocol and Application Development

- **Early engagement** with PHRI teams
 - a) The team members are seen as colleagues who can help you at all stages of the study. **You bear the heavy responsibilities of PI (or co-PI)**
 - b) refine protocol and develop grant application (including sample size and analyses plans) **working with co-applicants and PHRI teams**
 - c) ensure realistic and accurate budgeting of PHRI resources, time and costs.
- **On site meetings** with PHRI teams (particularly early) in addition to regular conference calls

B. Participating as the Principal or co-Principal Investigator of a trial coordinated by PHRI

Post-Funding, Pre-implementation Activities

As PI or co-PI, your responsibilities include

- Executive management (sort out roles of co-PIs, steering committee chair, etc)
- Liaison with PHRI teams
- Selection of committees: Steering/executive, events adjudication, core labs, DSMB, publications/writing committee
- Interactions with sponsor(s)
- Recruitment of sites
- Ethics review documents
- Study timetable

B. Participating as the Principal or co-Principal Investigator of a trial coordinated by PHRI

Post-Funding, Pre-implementation Activities

PHRI will provide support, technical and operational expertise with such matters as:

- Formal protocol development
- Financial planning
- Communications and meeting organization/logistics
- CRFs, site monitoring protocols, progress reports
- Site contracts
- Drug packaging, distribution, logistics
- Sample collection, transportation, storage, analysis

B. Participating as the Principal or co-Principal Investigator of a trial coordinated by PHRI

Study Conduct

As PI or co-PI, your responsibilities include:

- Executive management (sort out roles of co-PIs, steering committee chair, etc), including meetings and interactions with leadership/management committees
- Liaison with PHRI teams (including on-site visits to PHRI)
- Leadership for site communications, recruitment targets, quality/discipline
- Investigator meetings
- Monitoring of relevant developments external to study
- “Cheer leading”, building and maintaining morale
- Final analysis, closeout, presentation and publication plans (in consultation with study leadership groups and PHRI teams)

B. Participating as the Principal or co-Principal Investigator of a trial coordinated by PHRI

Study Conduct

PHRI will provide support, technical and operational expertise with such matters as:

- Site initiation
- Communications and meeting organization/logistics
- Drug packaging, distribution, logistics
- Randomization/enrolment, data transmission/checking/storage
- Sample collection, transportation, storage, analysis
- Financial management, site payments
- Site monitoring
- Progress reports, quality control, DSMB reports

C. Participating as the Principal Investigator of a trial not coordinated by PHRI with PHRI members

PHRI members participate under the leadership of external Principal Investigators in

- Clinical trials
- Epidemiological studies
- Reviews/meta-analyses
- Committees: Advisory, DSMB, Adjudication,...