

**TITLE:** Processes for ITCC Trial set up for ITCC academic – sponsored trial

**VERSION:** 1.0

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**SUPERSEDES:**  
First version

**AUTHORS:**  
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**REVIEWERS:**  
Members of the ITCC Sponsor Institutions Committee

**REASON FOR CHANGE**  
n/a

**IMPLEMENTATION PLAN :**  
Following approval by the ITCC Sponsor Institutions Committee, the SOP will be disseminated to the ITCC Sponsor Network.

## PURPOSE :

The purpose of this SOP is to have a clear process to confirm the Trial set up for an academic-sponsored ITCC clinical trial and to select the NCCs and sites to run the trial.

The aim is to have a clear procedure that is adhered to by all ITCC members (Sponsor Institutions Committee, NCC, sites)

## SCOPE:

This SOP is applicable for the ITCC Sponsors, NCCs and the selected sites.

## PROCEDURE

- 1) A Lead investigator proposes a trial.
- 2) This trial is presented to the CTC, which can add comments and suggest revisions before ITCC approval of the trial is given.
- 3) If the trial is approved, the CTC allocates a number to the trial on behalf of the ITCC (ITCC-XXX) and notifies the Sponsor Institutions Committee
- 4) If Sponsor known, the Sponsor Institutions Committee Chair sends a letter of approval to the approved ITCC academic sponsor (if sponsor not established, Sponsor Institutions Committee to discuss and propose ITCC sponsor)
- 5) The sponsor initiates ITCC NCC selection from approved list. (If a non-ITCC NCC is proposed; refer to the SOP describing the processes for ITCC Sponsor, NCC and participating site selection for ITCC academic – sponsored trials)
- 6) The Sponsor arranges an early planning meeting to discuss trial with NCCs via Skype or TC
- 7) During the meeting, the sponsor provides:
  - Trial synopsis
  - Funding model
  - Timelines for trial
  - Planned number of sites
  - Other information as required

NCCs provide information on:

- National feasibility issues
  - National funding plans
  - National timelines
  - National site selection
  - Other information as required
- 8) With all the information, the clinical trial can be developed, including preparation of the regulatory submissions and signing of NCC agreements and subsequent NCC/site initiation to commence recruitment

If it becomes apparent that there are insurmountable hurdles for the trial to be opened in one of more planned participating countries further TCs between NCC(s) and Sponsor should

be organized to try to resolve issues. If the problems/issues cannot be resolved, the Sponsor should notify the Sponsors Committee and Clinical Trial Committee.

DEFINITIONS:

NCC: National Coordination Centre

RELATED RESOURCES:

Flow diagram / Logigramme

## AUTHORISATION

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Signature:		Date:	

AUTHORISED BY:			
Name:	Pamela Kearns	Function:	Chair of the ITCC Sponsor Institutions Committee
Signature:		Date:	

EDITORIAL AMENDMENTS:			
Editorial amendments #	Reason for update	Person making update	Date of amendment

FULL REVIEWS			CHECK BOX IF NOT APPLICABLE <input type="checkbox"/>
Date of review	Reason for review	Reviewer	Outcome of review