Guidance 13

PaCCSC and CST Pilot/Feasibility Studies

PaCCSC and CST have experienced significant issues (major protocol changes and study cessation) which may have been avoided if pilot/feasibility work had been conducted prior to the full Phase III study.

The reasons for conducting a pilot/feasibility study may differ with individual studies. In general, the purposes of such studies will be a combination of[1]:

- *Process* – Assessment of 'the steps that need to take place as part of the main study', such as recruitment rates, retention rates, completion rates, etc.
- *Resources/Logistics* – Assessment of 'time and budget problems that can occur during the main study', including the feasibility and time components of each aspect of the research protocol.
- *Management* – Assessment of personnel issues and data collection/management at each participating centre.
- *Scientific* – Assessment of 'treatment safety, determination of doses and responses, and estimation of treatment effect and its variance'.

Stand-alone pilot/feasibility studies and those completed as part of a Phase III protocol ensure that the Phase III study protocol is feasible, practicable and that the outcomes are measurable.The IMPACCT (including PaCCSC) and CST Scientific Advisory Committees (SACs) require that each new Phase III study proposal exploring a new paradigm includes a pilot/feasibility study protocol.This document outlines the purpose and outcome measures for the associated pilot/feasibility part of the Phase III study.

The IMPACCT (including PaCCSC) and CST SACs recommend that the pilot/feasibility study protocols are adaptive to allow design modifications for the future Phase III study[1].

If an investigating team considers that there is a strong argument not to conduct a pilot/feasibility study for a particular planned Phase III study, the investigators are required to submit to the IMPACCT (including PaCCSC) SAC (for PaCCSC studies) or the CST SAC (for CST studies), a separate covering document explaining their argument. For example, the planned Phase III study is an extension of a previous study in the same centres, using the same patient groups with similar treatments and outcome measures.

Pilot/feasibility studies (whether stand-alone or as part of a Phase III study) are submitted using the PaCCSC or CST pilot/feasibility template (Template 31a or 31b, respectively).

Following endorsement by the IMPACCT (including PaCCSC) or CST SAC, the protocol is submitted (with all appropriate accompanying documentation) to the institutional human research ethics committees (HREC) and ratified by UTS HREC (*refer* SOP 6.12 Ethics Approval and Reporting).

Following completion of a pilot/feasibility study, a concise report is submitted to the IMPACCT (including PaCCSC) or CST SAC concerning the performance of the pilot/feasibility phase against its planned outcome measures.The IMPACCT (including PaCCSC) or CST SAC expedites the review of this report using electronic communication between members. A recommendation is made by the SAC following review of this report:

- Continue without modifications – feasible as is;
- Continue without modifications, but monitor closely – feasible with close monitoring;
- Continue, but modify protocol – feasible with modifications;
- Stop – main study not feasible.

If the IMPACCT (including PaCCSC) or CST SAC recommend progressing to full Phase III study, a decision will be made regarding the inclusion of the pilot/feasibility study data in the full Phase III study.

The report of the pilot/feasibility phase and the report from the IMPACCT (including PaCCSC) or CST SAC following consideration of the pilot/feasibility study's results are sent to all institutional HRECs who have given approval for the study to proceed.

Where possible, a paper is prepared for the publication of the results of the pilot/feasibility study, notwithstanding the IMPACCT (including PaCCSC) or CST SAC's decision about the study's continuation or otherwise. A paper for publication can be prepared and submitted while the main study is still in progress.

The final Phase III study protocol is developed, circulated to, and approved by, the IMPACCT (including PaCCSC) or CST SAC prior to the study commencing, and the study is registered with the Australian New Zealand Clinical Trials Registry.

References

1. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, Robson R, Thabane M, Giangregorio L, Goldsmith CH. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010; 10: 1-10.