Standard Operating Procedure

6.0.2 Pilot Studies

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Introduction / Background

The pilot study process underpins the future of studies conducted with the IMPACCT Trials Coordination Centre, including Cancer Symptom Trials (CST) and Palliative Care Clinical Studies Collaborative (PaCCSC). Evaluation and data from pilot studies informs the developments of CST and PaCCSC Phase III studies and contributes significantly to the success of CST and PaCCSC.

A pilot study is a small-scale investigation that aims to inform the development of a large scale, multi-centre Phase III study. Pilot studies are designed to test the methodology to be used in a subsequent Phase III study, particularly processes around recruitment and retention of participants.

The reasons for conducting a pilot study may differ with individual studies. In general, the purposes of pilot studies are a combination of (Thabane et al. 2010):

- *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'.

PACCSC/CST/ITCC pilot study ideas can be developed as part of a Phase III study protocol or as a 'stand-alone' pilot study. If successful, all pilot studies will progress to multi-centre Phase III studies (subject to funding and regulatory approval).

It is highly desirable that data from the pilot study is subsequently pooled with the Phase III study data in order to increase the efficiency of the Phase III study (Thabane et al. 2010). Therefore, the sampling frame and methodologies of both pilot and subsequent Phase III studies should be the same.

Objective

This Standard Operating Procedure (SOP) describes the process of developing, conducting, and evaluating a pilot study. PaCCSC/CST/ITCC recognise the iterative nature of pilot studies; therefore, this SOP provides an operating framework only. Specific issues that arise in pilot studies will be approached on a case by case basis.

Scope

This SOP applies to all individuals and/or organisations who have expressed interest in developing or undertaking new clinical studies with PaCCSC/CST/ITCC.

Ownership and Responsibility

Responsibilities of the Coordinating Principal Investigator (CPI)

- To develop the New Study Proposal using the CST *New Study Proposal Template* or PaCCSC *New Study Proposal Template* (refer to SOPs 6.0.1a *New Study Proposals* [PaCCSC] and 6.0.1b *New Study Proposals* [CST])
- To present new study ideas at the PaCCSC/CST Annual Research Forum, or the relevant Scientific Advisory Committee
- To develop the pilot study protocol (possibly as part of the multi-centre Phase III study protocol)
- To develop a Pilot Study Progress Plan (Template 27), with specific consideration given to potential future funding sources and publication plan
- To create a list of potential sites for the pilot studies and send to the ITCC
- To review and select sites for the pilot study, in collaboration with the ITCC, and in accordance with SOP 5.6.1 *Site Selection*
- To regularly liaise with the pilot site Principal Investigators (PI)
- To chair the pilot study management meetings (held monthly at a minimum)

Responsibilities of the CPI, Site Principal Investigators and/or other designee(s) (for e.g. sub-investigator, site coordinator, study nurse, etc.) as documented in the Staff Signatures and Delegation Log (refer to SOP 4.2.4 Delegation of Duties)

- To complete the Site Feasibility Checklist (Template 5) and return to the ITCC within the timeframe requested
- To conduct the pilot study at the site in line with the protocol and related SOPs
- To actively participate in the pilot study management meetings
- To provide feedback and data regarding the pilot study to the CPI and the ITCC within the timeframe requested

Responsibilities of the ITCC

- To facilitate the approval process for the pilot study, through the PaCCSC/CST Annual Research Forum and the relevant Scientific Advisory Committee
- To manage the site selection process for the pilot study
- To support the conduct of the pilot study in accordance with SOP 6.0.1a *New Study Proposals* (PaCCSC) and 6.0.1b *New Study Proposals* (CST)

Responsibilities of the relevant Scientific Advisory Committee

- To rigorously review the pilot study protocol
- To monitor the scientific conduct of the pilot study
- To nominate a member of the Committee as the specific liaison for the pilot study, to regularly liaise with the CPI of the pilot study and report back to the relevant Scientific Advisory Committee

Procedure

1. Developing a pilot study

- PaCCSC/CST/ITCC pilot study ideas can be developed as 'stand-alone' pilot studies or as part of Phase III study protocols. The latter is the preferred approach to pilot study development
- New pilot study ideas are pitched and managed in line with SOP 6.0.1a *New Study Proposals* (PaCCSC) and 6.0.1b *New Study Proposals* (CST)
- New pilot study proposals that are approved to progress to stage 2 of the selection process require the development of a draft protocol:
    - Pilot study protocols (developed either as standalone documents or as part of a Phase III study protocol) use the Protocol Template (refer to SOP 6.0 *Protocol Development*). Section 2 of the template addresses the pilot phase of a Phase III study
- The pilot study protocol is developed in line with SOP 6.0 *Protocol Development* and includes clear feasibility objectives with regards to:
    - Process (for e.g. recruitment and retention rates)
    - Resources/logistics (for e.g. time and budget considerations)
    - Management (for e.g. personnel issues)
    - Scientific (for e.g. treatment safety, determination of dose, etc.)
- The focus of the pilot study protocol is on the assessment of feasibility (not statistical significance) (Guidance 13)
- A Pilot Study Progress Plan (Template 27) is developed and submitted to the relevant Scientific Advisory Committee with the pilot study protocol

2. Selecting appropriate sites for the pilot study

- The ITCC recommend that a minimum of two sites are included in the pilot study. This tests the methodology across different sites, thus providing a more rigorous evaluation of the study feasibility and logistics for a future multi-centre Phase III study
- The ITCC conduct site feasibility and study feasibility evaluations of all potential pilot sites, using the *Site Feasibility Checklist* (Template 5), *Study Feasibility Checklist* (Template 21) and *Site Risk Assessment Toolkit* (Template 6):
    - The *Site and Study Feasibility Checklists* are sent by the ITCC to the Principal Investigator at all potential pilot sites
    - The *Site and Study Feasibility Checklists* are completed by the Principal Investigators and returned to the ITCC prior to the relevant Scientific Advisory Committee for review of the template
    - In collaboration with the CPI, the ITCC reviews the completed *Site Feasibility Checklist*, completes the *Site Risk Assessment Toolkit* (refer to SOP 5.6.1 *Site Selection*) and selects appropriate sites
    - The CPI incorporates the selected pilot study sites into the study protocol prior to submission to the relevant Scientific Advisory Committee

3. Conducting a pilot study

- A management committee for the pilot study is established following approval to proceed from the relevant Scientific Advisory Committee. This committee includes the CPI, PaCCSC/CST National Manager (or delegate), and site PIs
- Meetings occur on a monthly basis at a minimum (via teleconference) and include review of the following:
    - Recruitment
    - Logistics
    - Safety
    - Study design
- The data collection (recruitment) phase of the pilot study is 12 months (see Figure 1). Recruitment beyond 12 months is negotiated with the relevant Scientific Advisory Committee
- The CPI reports the progress of the pilot study to the nominated member of the relevant Scientific Advisory Committee and the Pilot Studies Subcommittee
- At the end of the pilot study:
    - A final report is submitted to the relevant Scientific Advisory Committee
    - The CPI and Scientific Advisory Committee jointly determine if the study proceeds to multi-centre Phase III trial
    - If approved, the CPI progresses applications for funding to sources identified in the *Pilot Study Progress Plan*
    - The pilot study results are published in an appropriate peer-reviewed journal

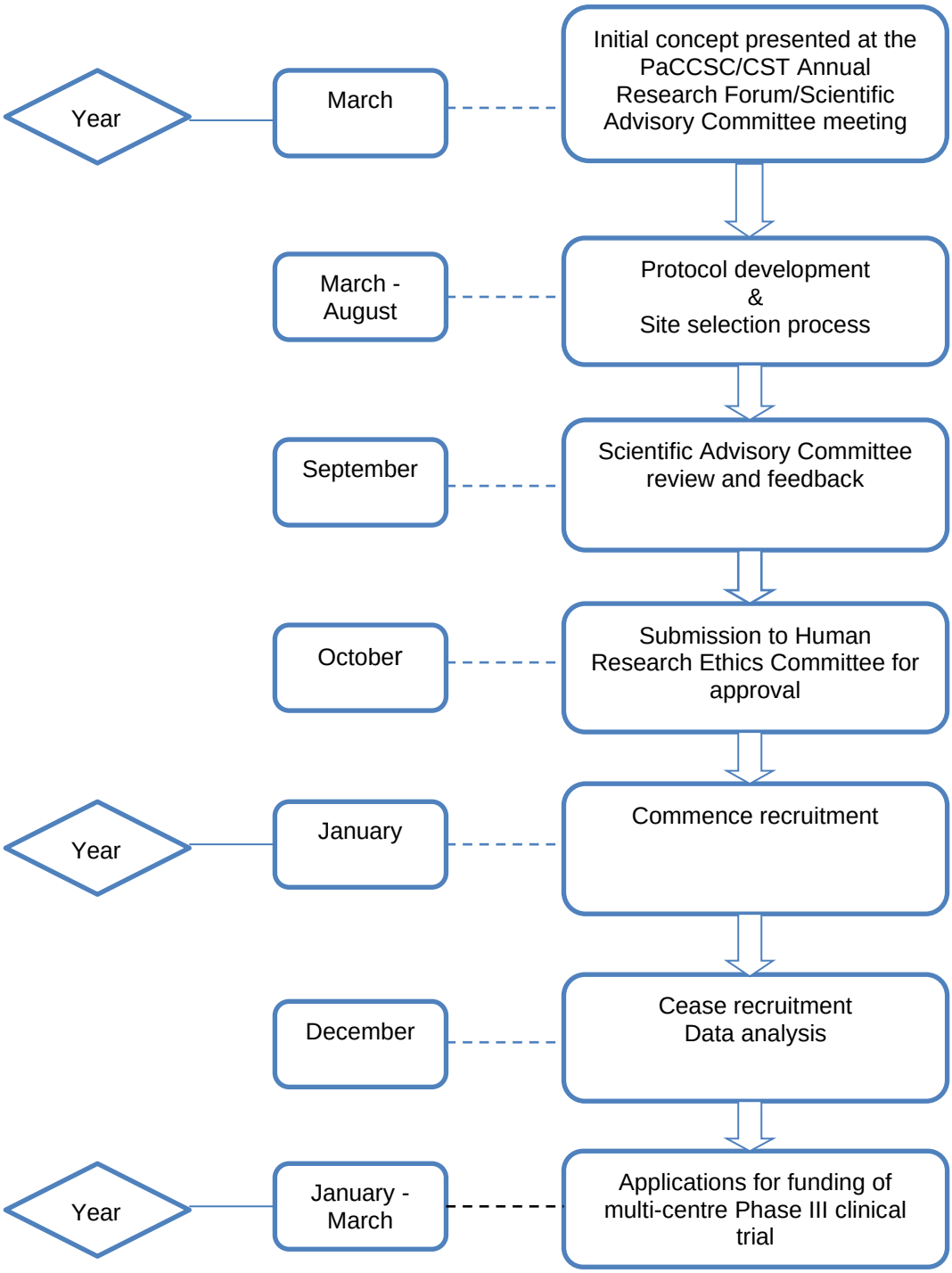

Figure 1. Typical Timelines for PaCCSC/CST/ITCC Pilot Studies

Related SOPs

4.2.4 Delegation of Duties

5.6.1 Site Selection

6.0 Protocol Development

6.0.1 New Study Ideas/Proposals

Related documents

Template 5: Site Feasibility Checklist

Template 6: Site Risk Assessment Toolkit

Template 21: Study Feasibility Checklist

Template 27: Pilot Study Progress Plan

Guidance 13: Pilot/Feasibility Studies

References

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 06/01/2022)

https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014 - (accessed 06/01/2022) https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 06/01/2022)

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Acknowledgements

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History			
Version	Date	Author	Reason
1.0	14/07/2015	C Hope	New procedure
1.1	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.2	28/02/2020	V. Yenson	Periodic review – CST
1.3	19/01/2022 2/02/2022	V. Yenson G. Prael	Periodic review – CST Periodic review - PaCCSC

Approval		
Version	Approval Name	Approval Signature
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