

# Peninsula Clinical Trials Unit – Strategic Plan

## Background

Peninsula College of Medicine and Dentistry (PCMD) has built a strong reputation in running and contributing to local and national clinical trials and high quality observational studies, particularly in primary care, neurology, cancer, mental health, diabetes and child health.

On the strength of this activity, in November 2007, PCMD Peninsula Clinical Trials Unit (PenCTU), was of one 26 units to receive UK Clinical Research Collaboration (UKCRC) full registration following review by an international panel.

<http://www.ukcrc.org/infrastructure/ctu/ukcrcregisteredctus.aspx>

In addition to PCMD funding of CTU staff and support from PCMD methodologists, the CTU was successful in obtaining a National Institute for Health Research (NIHR) Clinical Trials Unit Infrastructure Support funding contract for 3 years commencing from 1 September 2008 for £150k per annum. It is anticipated that up to 80% of this funding will be reimbursed to NIHR as a result of successful funding bids to The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) programmes.<sup>1</sup> PenCTU's first full contract review will take place in September 2010 with interim 12-month reports to NIHR. This paper outlines the Strategic Plan for the PenCTU over the remaining 2 years of this 3-year funding period.

## Objective

The fundamental objective of PenCTU is provide the infrastructure in order to support and encourage researchers<sup>2</sup> across the Peninsula to design and deliver high quality clinical trials and other well designed studies (referred to collectively in this document as 'studies'). It is recognised that high quality studies require not only design and methodological expertise but also appropriate systems and processes to be in place to ensure governance, including Good Clinical Practice (GCP), and their efficient delivery.

PenCTU 'infrastructure' includes: (1) a multi-disciplinary team of health services researchers/methodologists, trial managers and IT staff skilled in study design and delivery; and (2) provision of support services to facilitate the running and delivery of studies (e.g. independent central randomisation, staff to provide data entry).

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<sup>1</sup> Health Technology Assessment; Public Health Research; Efficacy and Mechanism Evaluation; Health Services Research; and Service Delivery and Organisation funding programmes

<sup>2</sup> With particular focus on researchers in PCMD, Universities of Plymouth & Exeter and NHS focusing in the areas that relate to PCMD strategic research themes (diabetes, cardiovascular, aging/neuroscience/environmental & human health/health services research).

## **Staffing**

PenCTU is currently led by a Clinical Director and a Scientific Director, and staffed by a Quality Assurance Manager, Assistant Data Manager, Unit Coordinator and two Trial Coordinators (to be advertised) and is located on the Plymouth PCMD campus.

To fulfil its role, PenCTU draws upon the input of a number of PCMD methods groupings that include medical statistics, health economics, qualitative research and trial managers. Over the last 2-3 years, the provision of PCMD methodological support has been provided under the umbrella of the Clinical Research Methodology Unit (CRMU). CRMU is now 'rebadged' under the single heading of PenCTU.

## **Strategic direction**

PenCTU's strategic direction draws upon both the recently updated PCMD Research Strategy 2009-2015 and UKCRC strategy for CTUs.

The PenCTU will report to the SW Peninsula Clinical Research Collaboration (SWPRC) through its Management Board. The CTU Operational Management Group will include representation from medical statistics, health economics, SW RDS, SW CLRN and disease-based trial leads and will meet two monthly reporting to SWPRC. The PenCTU Directors attend and report to the national UKCRC CTU Directors Meetings that take place two to three times per year.

## **Principles**

- Design and delivery of high quality studies led by Peninsula researchers.
- Prioritisation of support for clinical trial design and delivery according to PCMD's strategic research themes (diabetes, cardiovascular, aging/neuroscience/environmental & human health).
- Efficient and timely support of the provision methodological support for studies.
- Full and appropriate costing of methodological research support and infrastructure of funding applications.
- Maintenance of a database of clinical trial activity (applications and funded) across the Peninsula.
- Provision of support across the three institutes of PCMD (IHSR, IBCS & ICE), health service researchers in the Universities of Exeter and Plymouth and Peninsula NHS researchers.
- Close linkage with key research groupings across the Peninsula including SW RDS, SW CLRN & FOCUS.
- Contribute to the national network of CTU activity through the UKCRC.
- Foster collaboration with CTUs in South West and nationally and the Bristol MRC methodological Hub and develop an agenda of clinical trial methods research.
- Support the PCMD staffing strategy for training and development of local researchers, trial/managers and IT staff to ensure sustained CTU capacity.
- Close liaison with NHS partners

## **Way of working**

Whilst it is acknowledged that established research groups have the internal capacity to continue take forward the design and delivery of clinical trials, as outlined in the PCMD Research Strategy, future clinical trial funding applications are encouraged to seek some level of PenCTU involvement. Many funders (notably NIHR) now seek explicit evidence of CTU involvement in funding applications. PenCTU support may include facilitating local peer review of funding applications to the provision of methodological and trial support to aid the delivery and management of funded trials. It is also recognised that a proportion of important research questions will be proposed by clinicians/researchers with little or no previous experience of previously running trials. In appropriate circumstances, the PenCTU will support these investigators develop their proposal with the understanding and agreement that the trial will be managed and 'run through' the CTU.

To ensure efficient, timely and equitable service support, the PenCTU will operate through a single point of contact. Project chief investigators seeking the input of unit should complete a short form detailing the nature of their project and request for support, either online (at the PenCTU website) or by phone (through the Unit's coordinator) at least 6 weeks before any funding applications are submitted. At its regular meeting, requests for support will be discussed and the appropriate level and nature of PenCTU support identified (e.g. forward request to statistics or health economics research group for advice on trial design). The requestor will then be contacted and support action/timescale agreed. Where necessary, PenCTU will assist coordinate necessary project meetings and assist with the preparation of the funding application.

Chief investigators of projects receiving PenCTU support will be responsible for ensuring that CTU endorsed SOPs are followed. Compliance will be monitored by PenCTU.

## **Services**

It is envisaged that PenCTU service support will broadly fall into two categories – 'project design' i.e. support for PCMD led research projects in seeking external research support and 'project delivery' i.e. support for PCMD led projects following the funding. Whilst researchers encouraging early PenCTU engagement and at the beginning of the design and conception of a project design, it is also recognised that the unit will need to capacity to provide support for the delivery of funded projects (particularly if led externally to the Peninsula).

### **1. Design**

PenCTU seeks to provide the necessary range of support to allow researchers prepare high quality funding applications that are likely to be successful. PenCTU design support and expertise include:

- Trial and study design
- Statistics and data analysis
- Epidemiology
- Health economics

## Revised 25<sup>th</sup> January 2010

- Outcome measurement
- Qualitative methods
- Database design and development
- GCP & research governance
- Trial management
- Study costings

And act as a sign-post and facilitate linkage with local research networks and PCMD groups with expertise in evidence synthesis/systematic review, modelling and simulation and patient involvement in research.

Whilst in principle PenCTU seeks to provide such a design service to support all applications, given its finite capacity and in accord with PCMD's research strategy and local NHS considerations, where necessary, priority will be given to NIHR and Research Council applications. In view of the specific remit of NIHR to provide support for the design of RfPB applications, PenCTU will closely liaise with SWRDS support for such funding applications, and under normal circumstances SWRDS will be the first point of contact for researchers considering such applications.

Named PenCTU support on funding applications will require input into the project design/conception by PenCTU staff, full and appropriate costing of PCMD HSR and methodological resources supporting the delivery of the project, and peer review/sign off by one of the two PenCTU Directors.

### 2. Delivery

PenCTU seeks to provide the necessary range of methodological and trial management skills and resources to allow researchers to undertake and deliver high quality studies following external funding. The economic basis and future development of the PenCTU, is dependent on the explicit allocation of funding of staff that would be expected to lead or undertake specific roles in successfully undertaking and completing a research study. Normally such budgetary planning would be put into place in the design and funding application phase. However, it is recognised that researchers may also seek PenCTU support for delivery of their study without such downstream design involvement. PenCTU will consider such requests on the basis of the nature of study, availability of funding and PenCTU staff resource and time.

It is intended PenCTU support include:

- Data analysis – quantitative, economic and qualitative, e.g.
  - o Statistical analysis planning
  - o Statistical advice and analysis
  - o Contribution to report writing
- Randomisation/concealment – stratification/minimisation, web & phone based methods
- Trial management and quality assurance, e.g.
  - o Advice on IMP trials
  - o Advice on adverse event monitoring
  - o Access to and advise on about PenCTU endorsed SOP templates

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- Data capture and storage
  - o Data entry
  - o Data management advice
  - o Database set-up
- Administrative support
  - o Statistical and health economics input on TSGs, DMECs

### Deliverables & Measurables

- An increase in the rate of success of external peer review funding applications from PCMD and the NHS across the Peninsula.
- The delivery of high quality studies across the Peninsula.
  - o Establishment of systems and processes for local monitoring and quality assurance checks of funded Peninsula studies.
- Development (in collaboration with SWCRLN, SW RDS) of a database for the prospective recording of key data (based on UKCRC requirements viz. time from approval to first patient recruited, time to completion of recruitment, proportions of studies completed on budget and on time) on all Peninsula study activity (funding applications and funded studies).
- Development of a system for the tracking the contribution and funding (core and FEC) of the PenCTU staff to the design and delivery of studies.
- Fulfilment of the objectives UKCRC strategy for CTUs and NIHR CTU infrastructure objectives.

**Risk analysis**

Risks	Solutions
Inability to meet the demands and expectations of Peninsula researchers for study design and delivery support.	<ul style="list-style-type: none"> <li>➤ Review of current PCMD staff job descriptions to reflect a level of PenCTU service support</li> <li>➤ Continued recruitment of high quality methodological and trial support staff</li> <li>➤ Carefully review of the number trials 'run through' the PenCTU</li> </ul>
Submission of poor quality application bids to external peer review funding to the detriment of the reputation of PenCTU.	System of formal 'sign off' of PenCTU supported funding bids following peer review of protocol study.
Reluctance of study CIs to comply with PenCTU QA requirements	System of formal 'sign off' of PenCTU support that depends on commitment of CIs to adopt PenCTU QA approaches
Unit Sustainability	<ul style="list-style-type: none"> <li>➤ Development of a business plan that accommodates 80% payback of 80% NIHR Infrastructure Support at end of 3-year funding cycle</li> <li>➤ Need for medium to long-term investment by PCMD, local Universities and NHS partners to support PenCTU infrastructure and recruitment of staff.</li> </ul>