Data management: In addition to systems for storing and processing trial data, our dedicated team of IT developers build administrative systems to facilitate overall project data management. Our data managers use these systems to generate and resolve data queries, track data quality and data completeness, track the flow and disposition of trial participants, monitor recruitment activity and generate periodic progress reports.

Safety monitoring: We design systems for recording Adverse Events (AEs) and Serious Adverse Events (SAEs) in all studies and have robust mechanisms for safety reporting within CTIMPs (Clinical Trials of Investigational Medicinal Products).

Investigational Medicinal Product (IMP) management: We supervise all aspects of IMP management including designing regulatory-compliant product labels, reliable supply chains, robust drug accountability systems and procedures for emergency unblinding.

Oversight committees: Most studies require a Trial Steering Committee (TSC) to oversee the local management group. Some trials also need a Data Monitoring Committee (DMC). We can help with the proper constitution of these committees, identify appropriate members, arrange regular meetings and prepare the required reports.

Quality assurance & regulatory compliance: We use a suite of established Standard Operating Procedures, work instructions and templates as part of a Quality Management System to ensure trials are conducted according to the principles of GCP (Good Clinical Practice) and regulatory requirements. We devise project-specific risk assessments to inform proportionate monitoring and management plans, and perform central and remote monitoring accordingly.

Analysis and reporting: Trial statisticians in the PenCTU-affiliated University of Plymouth Medical Statistics group develop statistical analysis plans in collaboration with the Chief Investigator, prepare code for primary analysis using recognised statistical software applications, provide expertise in handling missing data, liaise with data managers to prepare exports of data for analysis, conduct the final analyses and take a significant role in writing up the final results.

Working with us
We welcome requests for collaboration from applicants in any location, working in any therapeutic area. We prefer initial requests to be made via our website and in a timely manner; a minimum of three months before a funding application deadline where possible.

The extent to which PenCTU engages in your project will depend on a number of factors, for example, the level of engagement sought, the experience of your research team, the size and complexity of the project, the source of funding and our own capacity.

In most circumstances we manage the project at all stages from design, through conduct and management, to analysis and reporting. In some cases, it may be appropriate to provide support in specific areas, such as statistical analysis, data management and/or randomisation.

We estimate the costs of our involvement on an individual basis, based on the nature and complexity of the project. The costs for PenCTU input will need to be covered by the grant. Major funders expect to see costs for CTU activity included in funding applications.

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The Peninsula Clinical Trials Unit (PenCTU) at the University of Plymouth, is a fully registered Clinical Trials Unit with a specific remit to design, conduct, analyse and report clinical trials and other well-designed studies.

This unit receives National Institute for Health Research CTU Support Funding. This funding has been awarded to support the unit in developing and supporting NIHR trials.
About us

Established in 2007 and hosted by the University of Plymouth within the Faculty of Medicine and Dentistry, PenCTU is part of the nationwide UKCRC network of registered Clinical Trial Units.

PenCTU has maintained full registration status since 2007 having consistently demonstrated a track record of designing and co-ordinating multi-centre randomised controlled trials and other well-designed studies.

The operational PenCTU team comprises more than 20 specialist staff working alongside the formally affiliated University of Plymouth Medical Statistics group, co-located in offices at the Plymouth Science Park.

PenCTU collaborates with clinical and academic investigators to support the design, delivery, analysis and reporting of high-quality clinical trials, by providing access to the core competencies of statistics, trial management, data management and quality systems.

Benefits of CTU involvement

Clinical trials are complex, often expensive projects, expected to be run to exacting ethical and regulatory standards. Even well designed trials, funded through national, peer-reviewed funding competitions, can go wrong: a large proportion of trials experience significant delays, early termination, or inability to draw conclusions at completion.

These challenges are recognised by NIHR, research councils, other major funders of research, sponsor organisations and regulators, such that investigators applying for funds to conduct clinical trials are encouraged to engage with a UKCRC-registered Clinical Trials Unit. The substantive involvement of a UKCRC-registered CTU may sometimes be a condition of funding and sponsorship.

Navigating these challenges begins with good research design. Through affiliation with the University of Plymouth Medical Statistics group and close working relationship with the South West NIHR Research Design Service, PenCTU provides bespoke research methodological input right at the start of a clinical trial’s lifecycle. At the core of PenCTU is a highly experienced trials operational team, comprising trial managers, quality assurance, trial administrators, information systems developers and data managers. The team has considerable experience in project-managing a portfolio of trials, with a focus on timely delivery and data quality.

What we can do

Research design: Specialist statistical input, including power and sample size calculations for a range of trial designs, is provided through the CTU-affiliated University of Plymouth Medical Statistics group. We are also co-located with the South West Research Design Service with whom we work very closely. We help investigators refine their research questions, identify suitable funding sources, consider regulatory/ethical issues, identify required resources for trial delivery and develop high-quality funding applications. Further methodological collaboration is facilitated through our links both locally and nationally to health economists, epidemiologists and qualitative researchers who work with us to design and deliver clinical trials and other well-designed studies.

Patient & public involvement and engagement (PPI):
The benefits of PPI in research are well documented. We can help you decide how to ensure effective PPI input throughout the lifecycle of your project.

Protocol development: Writing a trial protocol can be a complex business but we can help you to write your protocol in line with recommended guidelines using tried and tested templates.

Obtaining and maintaining permissions: We can guide you through the IRAS system in order to obtain a favourable ethical opinion, HRA approval and other permissions as required (including authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) in the case of drug trials). We ensure that essential documents are prepared on time and in the correct format, and that amendments are prepared and submitted to the relevant bodies in a timely and organised manner.

Investigator site set up: No matter whether your study is single or multi-centre, it is essential that all are adequately resourced to conduct the study and staff are fully acquainted with the protocol. We can help with site selection, design/delivery of staff training and coordination of site study supplies.

Dedicated trial management: Even well designed trials can stray off track. A dedicated trial manager can liaise daily with investigator sites, apply remedial actions to address performance issues, co-ordinate meetings and communications between management groups, oversight committees, approval bodies and funders, and be your go-to person from the outset until completion.

Randomisation: We can provide randomisation systems tailored to the needs of your trial. Our web-based randomisation systems facilitate 24-hour, seven-day availability, support static or dynamic randomisation algorithms, ensure robust allocation concealment measures in blinded trials and can auto-generate reports of random allocation to multiple staff, tailored according to role. Paper-based randomisation systems, which may be more suitable in certain trial settings, can also be developed if required.

Data collection: We design and develop efficient data collection tools which may be paper-based or electronic according to project scale and complexity. We have extensive experience in managing large postal and on-line questionnaire surveys as part of clinical studies, with excellent completion rates.

PenCTU Overview

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<th>Trial Design and Methodology</th>
<th>Trial Delivery</th>
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<tr>
<td>Statistical expertise</td>
<td>Centralised operational team</td>
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<td>Co-located with SW Research Design Service</td>
<td>Highly experienced trial managers</td>
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<td>Links with health economists</td>
<td>Project management from study set-up to close-out</td>
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<td>Links with qualitative researchers</td>
<td>Expertise in meeting regulatory and best practice standards</td>
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<th>Trial Data Management</th>
<th>Quality Management</th>
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<tr>
<td>Centralised team of systems developers and data managers</td>
<td>Suite of Standard Operating Procedures</td>
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<td>Electronic and paper-based data capture</td>
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<td>Bespoke web-based randomisation and trial management systems</td>
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<td>Robust data processing and storage procedures</td>
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