University of Hertfordshire Clinical Trial Support Network Overview

1. Background:

The Clinical Trials Support Network (CTSN) at the University of Hertfordshire has developed over the last 3 years to provide advice and assistance to UH staff as well as NHS clinicians and researchers in all aspects of the conduct of clinical trials and other research projects. The CTSN works with research teams to design, conduct, analyse and report high quality clinical trials and other research projects. It works closely with the Research Design Service (RDS) to develop funding applications and has a close working relationship with the Norwich Clinical Trials Unit (CTU). In addition the CTSN works with Centre for Research in Primary and Community Care (CRIPACC) at UH to draw upon expertise in qualitative research methods and patient and public involvement. The CTSN provides support to researchers by advising on and co-ordinating research projects and signposting researchers to other relevant groups. The over-riding aim is to enable trials to be conducted according to current safety and quality regulations as stipulated by EU and UK directives. Some services cannot currently be offered by UH, however we can facilitate collaborations with other organisations/staff to ensure the required support. We have academic partnerships with Hertfordshire Partnership Foundation University Trust (HPFT) and East and North Hertfordshire University Trust (ENHTs) and work closely with Norwich CTU.

2. What we do:

We develop collaborative partnerships with clinical and academic investigators, supporting them through each step of the clinical trial lifecycle. This enables Chief Investigators (Cis) to concentrate their time and expertise on the clinical details of the trial protocol. We promote clinical trial governance and provide clinical trials leadership and expertise to deliver high quality clinical trials from concept to dissemination of results. We also work collaboratively with the Research Design Service and have a close working relationship with the Norwich Clinical Trials Unit. We also facilitate Public and Patient Involvement (PPI).

3. Who we are:

The UH CTSN is led by Solange Wyatt, a senior research fellow based in the Centre for Health Services at Clinical Research (CHSCR) at UH. The CTSN works alongside the East of England RDS. Both are part of the Health Research Methods Unit at UH.

Dr David Wellsted is the Head of the Health Research Methods Unit and the Associate Director of the East of England Research Design Service. Dr Janine Hawkins and Megan Smith support the RDS East of England.
Professor Ken Farrington is Head of the Centre for Health Services and Clinical Research in which the Health Research Methods unit sits. He is also head of the CTSN management group and provides clinical input.

Dr Keith Sullivan leads the statistics group within the Health Research Methods unit, supported by Liam Blackwell.

Dr Silvana Mengoni and Dr Sarah Jane Besser are Clinical Trial Managers and support the Clinical Trial Operations Group.

4. Responsibilities:

- **CTSN Management Group**
  - Supports the CTSN and oversees the integrated functioning of the CTSN and the conduct and delivery of CTSN trials.
  - Responsible for trial adoption decisions – group consists of staff from stats, clinical trial operations, clinicians
  - Reviews protocols and amendments
  - Quality assurance/Quality management

- **CTSN Manager**
  - Manages the CTSN ensuring appropriate resources are in place
  - Monitors adherence to Good Clinical Practice (GCP) and research governance
- Ensures quality management
- Oversees the clinical operations group

• Clinical Trials Operations Group
  - Development and updating of Standard Operating Procedures (SOPs)
  - Project Management
  - GCP and research governance
  - Conduct and Trial Delivery
  - Trial Documentation
  - Risk Assessment
  - Data Management
  - Quality Management
    o On site monitoring
    o Central monitoring

• Statistics Group:
  - Sample size calculation and documentation
  - Randomisation – selecting methods and testing implementation
  - Statistical aspects of trial monitoring and conduct
  - Analysis and reporting
  - Data imports from laboratory and routinely collected data
  - Dataset production for analysis
  - Database reporting

5. Our research:
We currently have 7 studies in our portfolio mainly funded by the NIHR. Our focus is on clinical trials of psychological interventions and of clinical trials of investigational products. The CTSN has supported research projects in a range of areas including OCD, depression, learning disabilities, autism spectrum disorder and paediatric mental health.

UH CTSN can potentially provide support with the following:
  a. Development of new studies, identification of the right questions and appropriate design
  b. Writing the Risk Assessment document and maintaining it during the study
  c. Costing the trial and planning staff required to develop and manage the trial
  d. Contracts and collaboration agreements
  e. Co-ordinating protocol development and design of case report form
  f. Ensuring registration on NIHR Portfolio (if eligible) and any other databases as appropriate
  g. Setting up the trial and obtaining relevant permissions
h. Identifying and initiating participating centres, maintaining good communication with each centre
i. Working with pharmacy and suppliers to manage drug supply
j. Central co-ordination and management of essential trial documents and patient data
k. Writing any trial specific documentation. Eg working practice documents
l. Development of any training materials and training of site staff on trial protocol, conduct, data capture and GCP
m. With investigators, engage and organise meetings for trial specific oversight committees such as Trial Management Group, Trial Steering Committee, Data Monitoring Committee
n. Data management – including database build, randomisation
o. Data monitoring – including Adverse Event monitoring
p. Conducting interim and final analyses
q. Study close
r. Preparation of reports. (eg. For NRES, MHRA, Trial Steering Committees)
s. Final report writing
t. Public and Patient Involvement
u. Epidemiology
v. Outcomes selection with specific support with Patient Reported Outcome Measures (PROMs).