

Working with a UKCRC registered Trials Unit

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Workshop 10th July 2009

Summary



- What a trials unit can offer
- Planning your trial – design considerations
- Managing you trial – recruitment, quality and safety

What is a registered CTU?

- Track record
- Core staff – funding, experience, retention
- Core activities – programming, statistics, randomisation, data managers, co-ordination
- SOPs and Quality Assurance
- Pharmacovigilance- ‘MHRA inspection ready’

- 30 UKCRC registered CTUs

Agenda – Chief Investigators

- Leadership and Responsibilities
- Funding and Research Costs
- 
- Conducting the trial: GCP and SOPs
- Applications, Agreements, Approvals
- 
- Consent
- Recruitment
- Data Management
- 
- Risk Assessment and Monitoring
- Data Monitoring Ethics Committee
- Training and Trial Documentation

A TRIAL TEAM

Trial Management Group

- Chief Investigator (CI)
- Principal Investigator(s) (PI) (remote)
- Trial co-ordinator (or trial manager)
- Clinical research fellows
- Recruitment team
- Trial Statistician, economist, programmer
- Clerical/ administrative staff
- Quality assurance staff

SOP 12

Working with WMSCTU

- General support to all people undertaking trials in WMS – SOPs, web-site
- Specific services – randomisation, programming, governance & advice on running projects
- In-house management system – bring selected projects into CTU for management – larger projects, HTA/MRC funded.
- Occasional services – statistics
- Request to collaborate forms

- UKCRC Full Registration
- Conducting trials in:
 - Rehabilitation (OPERA, MINT, BeST, CAST)
 - Resuscitation (BALTI-2, BALTI-prevention, OSCAR)
 - Cancer (PERSEPHONE, PET-NECK, Artemis, Neo-Escape)
- >13,000 patients
- £8.3m income in last 5 years
- Further work through collaborations

Persephone

Duration of Trastuzumab Study with Chemotherapy in Early Breast Cancer: Six versus twelve months



THE UNIVERSITY OF
WARWICK



Persephone Recruitment

