The CTU
A UK model for managing investigator lead trials

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Motivation for establishing CTUs

- Pockets of excellence
- Poor quality trials
- Limited capacity/research training
- Increasing demand on clinicians/poor resources
Motivation for establishing CTUs

Increasing regulatory requirements
- EU Clin Trials Directive
- GCP
- Sponsorship burden

NATIONAL PRIORITY
UKCRC

CTU

46 Registered CTUs

UKCRN

Topic Specific networks

CLRN
'To provide the dedicated expertise and support necessary for the design, development, management, analysis and publication of high quality clinical trials and other good studies’

UKCRN, 2009

Based in academic institutions
46 registered CTU in 2012
Comprehensive geographical representation
Good disease representation
Support phase II-IV (few qualified to support phase I)
**Models of registered CTUs**

**General**
Trials in any disease area

**Multiple but defined topics**
Eg; Cancer, Musculoskeletal, Diabetes

**Single topic**
Eg. Cancer only
Core capacity - funded staff in CTUs

Clinical Director - P/T
Non Clinical Director – F/T
Senior statistician
Trial Manager/s
Data Manager
Health economist - P/T
QA staff
Business manager
Core Capacity for a CTU: Staff

1. Core staff funded by:
   University
   MRC
   Wellcome Trust
   CRUK

2. Non-core staff:
   Grant funded.
Non-Core Staff

- Trial specific
- Jnr Statistician
- Trial co-ordinator
- Research Nurse
CTU Organogram

LCTU SENIOR MANAGEMENT TEAM

- Director
- Associate Directors
- CR-UK Senior Research Nurse
- Senior IS Developer

Head of Statistics & Bioinformatics
- Operational Director
- Deputy Operational Director
- Monitoring Team
- Pharmacovigilance Team
- Information Systems Team

LCTU Statistics and Bioinformatics Team
- Senior Statisticians
- Statisticians
- Bioinformaticians

Administrator/Document Controller
- LCTU PA/Administrator

OPERATIONAL TUMOUR GROUPS

HAEMATO-ONCOLOGY
- HEAD & NECK/LUNG
- HEPATO-BILIARY
- PANCREAS
- MELANOMA/UROLOGY
- PALLIATIVE MEDICINE
- DEVELOPMENT AREAS

LCTU Advisory and Management Board

LECMC
- LECMC GCLP Labs
- RLBUHT R&D Department
- PBRU
Core Capacity for a CTU: ITS requirements

Post EU regulation CTU.

- 2 independent servers
- 1 database management system
- 1 clinical trial management system
- IT Manager
Trial functions of a CTU: One-Stop-Shop

**Trial Specific**

1. **Support**
   - Design/statistics/Ethics/regulatory requirements/legal (IP)/funders /Training /costing

2. **Management**

3. **Quality control: Monitoring/Audit**
Non-Trial Functions of a CTU

- Maintenance of non-project specific CTU systems and processes (e.g. quality assurance; data management; business and financial)

- Management and strategic development of the CTU

- Methodological development

- Training and professional development
Quality Assurance & Control

1. SOPs
2. CPD for staff/Clinician Training
3. Monitoring/Audit
4. ISO9001 & ISO14155 certification
Creating and Building on Partnerships

- Clin Research Teams
- R&D Offices
- CTU
- UCT Research Support
  FHS Research Centres
  UCT Faculties
- Statistical Unit
- Research Networks
Features of a successful CTU

- Institutional commitment/investment
- Sound management and team cohesion
- ‘Marketing’ plan (Clinicians, Academics, Commercial)
- Input at point of trial design/mentoring
- Collaboration with partners

Successful grant applications