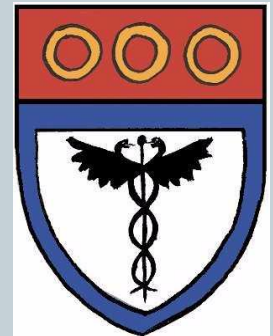


# The CTU

## 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



UKCRC

CTU



46 Registered CTUs

UKCRN



Topic Specific  
networks

CLRN

# Aim of Clinical Trials Units (CTUs)



‘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

# National Registration - Current CTU provision in UK



- 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



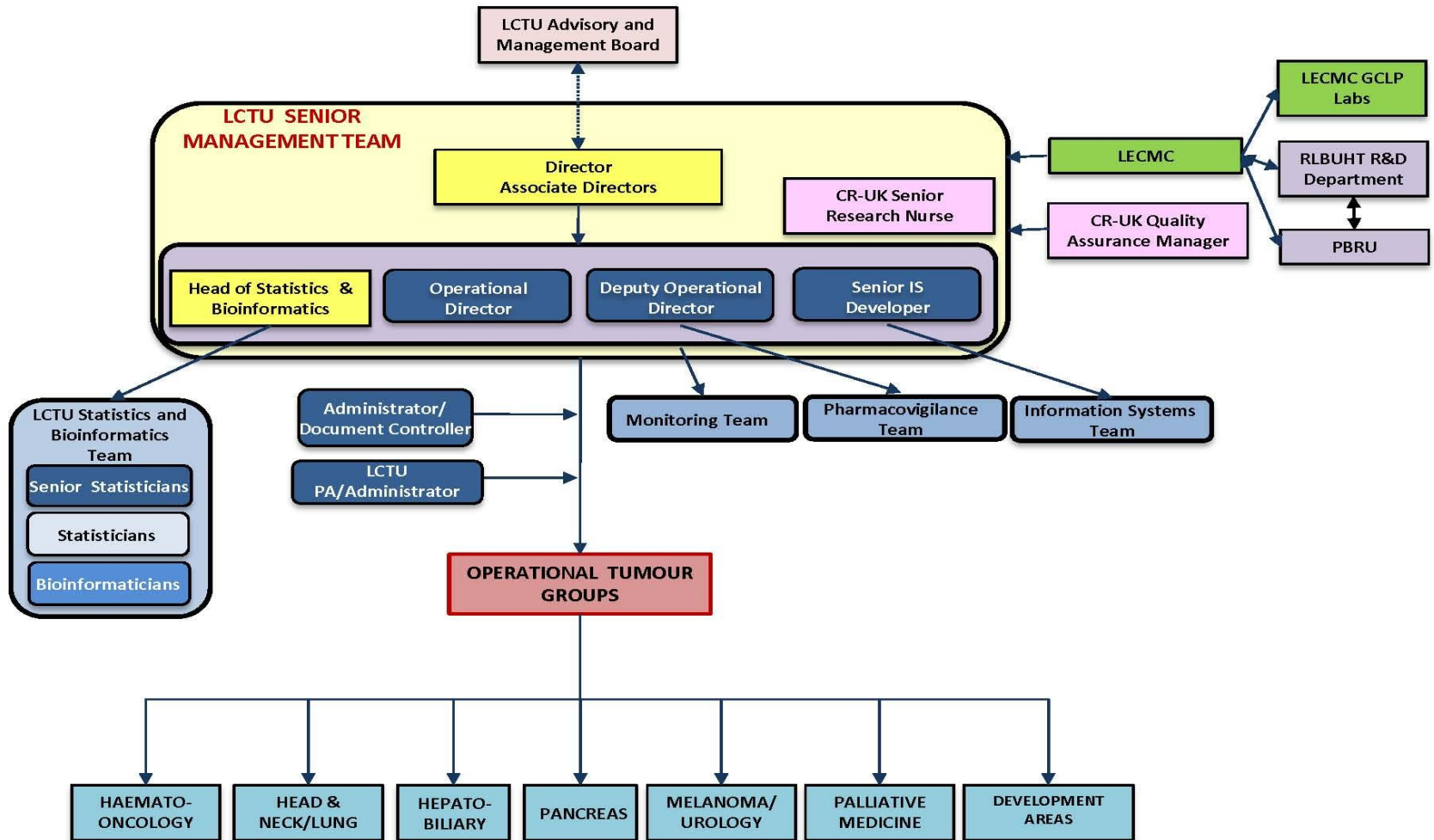
1. Core staff funded by:
  - University
  - MRC
  - Wellcome Trust
  - CRUK
2. Non-core staff:
  - Grant funded.

# Non-Core Staff



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

# CTU Organogram



# 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

UCT Research Support  
FHS Research Centres  
UCT Faculties

**CTU**

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**