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Sheffield Clinical Trials Research Unit

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How do we differ from RDS?

- Research Design Service
 - Assistance with design (portfolio studies):
- Clinical Trials Research Unit
 - Assistance with design, with either:
 - Advice & services ('Services'); or,
 - Advice, services, & study management ('Collaboration')

CREATE

REFINE

EVALUATE

APPRAISE

USE

Basic Research
- MRC and others

Research for Innovation,
Speculation & Creativity

Healthcare Technology Cooperatives

NEAT | HTD

Biomedical Research
Centres and Units
Patient Safety and Quality
Research Centres

RDS remit

Research for Patient Benefit

CTRU Remit

National Institute
for Health Research

Programme Grants for
Applied Research

Health Technology Assessment

Service Delivery & Organisation

Challenge Fund for Innovation

NHS CfH Research Capability Programme

Collaborations for Leadership
in Applied Health Research and Care

NHS Purchasing & Supplies Agency

Centre for Evidence-based Purchasing

National Institute for
Health & Clinical Excellence

Appraisals & Guidance
Clinical Guidelines

National Institute for
Innovation & Improvement

National Innovation
Centre
Support for Commissioners
and Providers

Primary Care Trusts

World-class Commissioning

NHS Providers

Patient Care



The University of Sheffield.

**NIHR
CCF**

RISC

Annual Budget
£5m

I4I

Annual Budget
£13m

RfPB

National Budget
£25m

PGfAR

Annual Budget
£75m

NETSCC

EME

Annual Budget
£15m

HSR

Annual Budget
£5m

HTA

National Budget
£88m

PHR

Annual Budget
£10m

SDO

Annual Budget
£11m



Input in study design

- Detailed methodological input and review
- Co-ordination of expertise
- Assistance with costing (collaboration)
- Insights from those who understand
 - The working of the award panels
 - NHS policy priorities
 - What makes a trial feasible...



CTRU services

- Randomisation
- Statistics
 - Sample size calculation
 - Advice during study
 - Analysis (with data management)
- Data management
 - Database design and maintenance
 - Data management



Example 1.

- 3 year pilot study, RfPB (ceiling £250k), n=30
 - Database design and maintenance
 - Statistical advice (no analysis)
 - Health economics analysis
- Total CTRU cost: £68k



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CTRU 'collaboration'

- Study management
- Monitoring and quality assurance
- Health economic modelling
- Qualitative research
- Statistics



Example 2

- 5 yr multicentre trial, HTA , n=280
 - Full time study manager
 - Statistics
 - Database design, setup and data management
 - Quality assurance and monitoring (MHRA)
 - Health economics
- Total CTRU cost £0.9m /Total trial - £1.8m



Study management

- Co-ordination of all components:
Health economics, statistics, qualitative research,
PPI, data management, pharmacy and support
services
- Supporting oversight committees
TMG, TSC, DMC
- CRF design and protocol development



- Obtaining regulatory approvals:
MHRA, Ethics, R&D approvals / research passports,
contracts, subcontracts
- GCP and Monitoring and site visits
- Annual reports to:
Sponsor, Ethics, R&D offices
- Preparation of papers and generation of
further research



- ~~“Expensive”~~
- “Loves the jobs you hate”
 - Quality assurance
 - Safety and oversight reporting
 - Data management



Activity since Nov 2007

- NETSCC
 - HTA open and commissioned calls, PHR and EME
 - 22 outline proposals
 - 9 successful; 10 unsuccessful; 3 pending
 - 12 full submissions
 - 6 successful; 3 unsuccessful; 2 resubmission with changes; 1 pending
- RfPB: applied for and won 3 grants



Current Activity

- 20 studies active / in setup
- Currently supporting 20 grant applications (various stages of development)



Portfolio - Complex Interventions

- Emergency Medicine e.g. 3Mg (HTA), DAVROS (MRC)
- Behaviour change e.g. BOOSTER (HTA), DAFNE (NIHR)
- Psychotherapy services e.g. REEACT (HTA)
- South Yorkshire Cohort (CLAHRC)



Summary

- NHS R&D grant proposals require CTU or RDS input
- CTRU can provide investigators with a wide range of support
- Contact us as early as possible.



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THANK YOU



Portfolio (4): methods

- Recruitment projection
- Pilot and feasibility studies
- Adaptive designs
- Sample size calculation