



Research Management within CRN

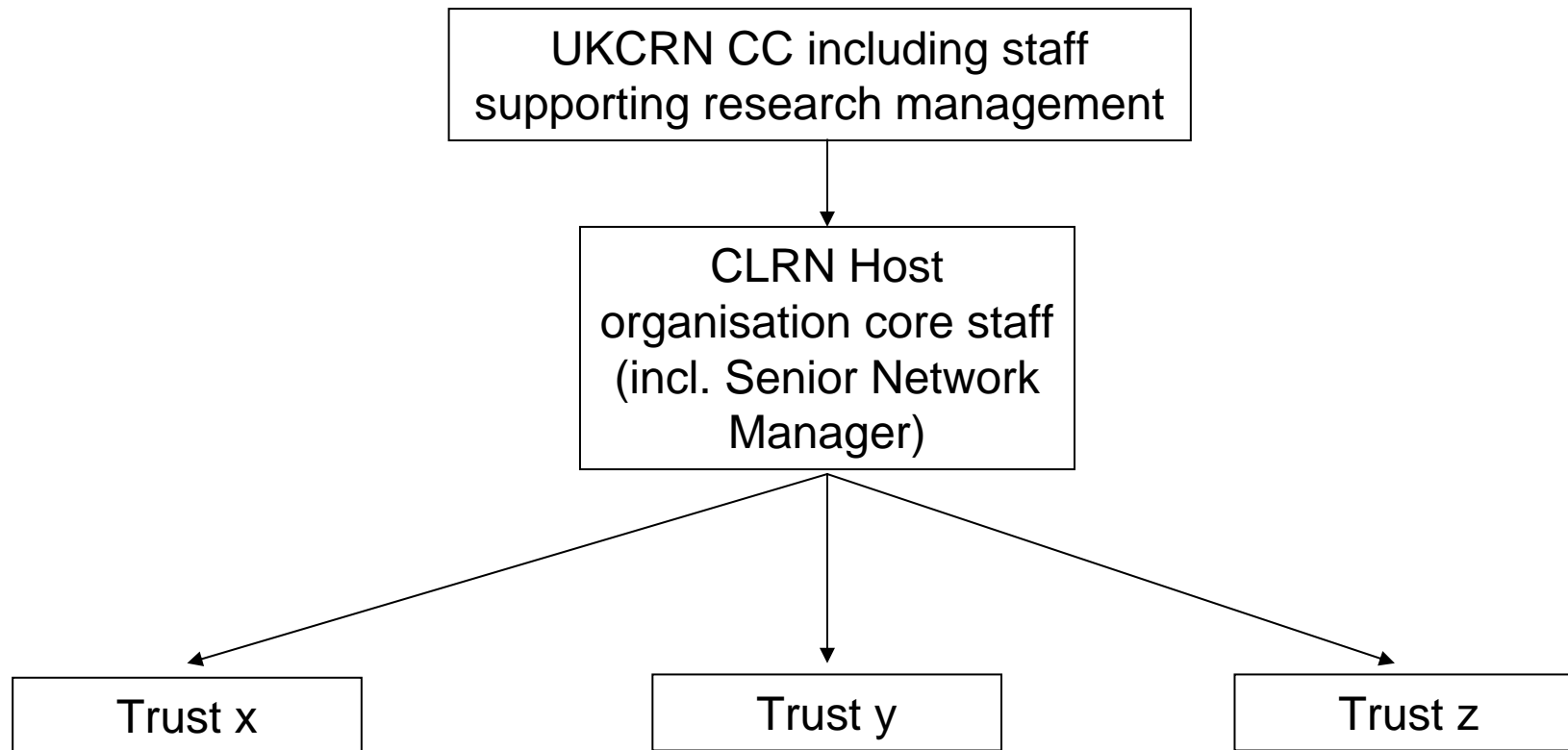
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What do we mean by Research Management?



- Study approvals
- Research Governance
- Overseeing ongoing studies
- Support to researchers
- Ensuring infrastructure support

How will Research Management be structured?



Distributed CLRN research management within Trusts

What are the issues?



- Study approval
 - *Inconsistencies across Trusts*
 - *Duplication of effort in multi-centre studies*
 - *Can be disincentive to starting a study*
- Honorary Research Contracts (HRCs)
 - *Cause of delay*
 - *Inconsistent approach taken by Trusts*

What are the issues?



- Governance/Trials Regulations
 - *Different approach to complying with RGF*
 - *Variable expertise and policies relating to compliance with EUCTD*
 - *MHRA Inspections*
- Contracting
 - *Lack of standardisation*
 - *Prolonged negotiations*
 - *Variable costing and pricing systems*

What are the issues?



- Regulatory advice to researchers
 - *Not coordinated*
 - *Inconsistent*
- Trusts retain same legal responsibilities as at present
- CLRNs will not undertake sponsor responsibilities

The Vision



- Consistent quality of Research Management
- Full range of Research Management available to all
- Streamlined approvals
- Support directed to activity

The Vision



- Better governance through adoption of standard approaches
- Performance management to ensure administrative efficiency
- Improved information systems for project management and reporting
- Distributed R & D Management across CLRNs
- **BUST BUREAUCRACY!!**

How to achieve the vision?

Specific initiatives



- CLRN R & D Management supported by a national Network
- Central Sign-off
- Research Passports
- Standard Agreement Templates
- Advice Service

Central Sign-off



- Mechanism for entering clinical research studies into the UKCRN Portfolio which ensures regulatory compliance
- A process for streamlining NHS permission for Portfolio studies
- A supportive process for Investigators and Sponsors from study conception to starting

Advantages of CSO



- Streamlined process
- Reduced variability
- Benefits for Industry and other funders

Research Passport Scheme



- Clarifies the type of NHS screening and required contractual arrangements that need to be in place
- Guidance for implementing HRCs for non-NHS staff
- Successful pilot and operates widely in North West
- Passport scheme removes need for replicated pre-employment checks facilitating quicker study start-up
- CLRN Framework Agreements expected to clarify and streamline arrangements for NHS staff working across NHS bodies

Standard Agreement Templates



- Increase uptake of mCTA for commercial studies by ensuring CRNs only use this contract
- Roll-out of standard agreement for non-commercial studies
- Implementing use of generic Confidentiality Agreements rather than being trial specific

Regulatory Advice Service



- Coordinating Team:
 - UKCRN Coordinating Centre
 - MRC Regulatory Support Centre

- Advice Network:
 - NRES
 - UK Health Departments
 - Gene Therapy Advisory Committee (GTAC)
 - Human Fertilisation and Embryology Authority (HFEA)
 - Human Tissue Authority (HTA)
 - MHRA
 - NHS R&D Forum
 - Patient Information Advisory Group (PIAG)
 - UKCRC

Regulatory Advice Service



- Provision of consistent, accurate advice to researchers and research managers
- Provision of local or national advice dependent on query
- Development of online resources (FAQs) and Toolkits

Challenges



- Stakeholder buy-in
- Clarify roles of CLRN and Trust R & D
- Developing activity-based allocation model
- Timescale

Comments



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