National Institute for Health Research

NIHR Trial Managers' Network, NIHR Trainees Coordinating Centre and the NCRI Accredited CTU Training Sub-Group Joint Project

Task, Knowledge and Competency Framework for Trial Managers

Status	*Final version July 2012 v1*
Authors	*Jane Nixon, Lisa Cotterill, Monica Cooper, Helen Meadows*

1. Introduction

The *Task, Knowledge and Competency Framework* is designed to support CTUs/employers, funders and researchers in determining the appropriate level of knowledge and skills required for trial managers involved in the delivery of NIHR trials. The framework can be linked to personal development and should help identify training and experience to progress individuals through novice, experienced and senior roles.

2. Task, Knowledge and Competency Framework Project and Objectives

It was agreed that the NIHR TMN, NIHR TCC and the NCRI Accredited CTU Training Sub-Group would undertake a time-limited project to undertake a joint piece of work to identify core competencies for Trial Managers. Project objectives were to:

1. Develop and agree a task and knowledge list for Trial Managers;
2. Develop and agree competency levels;
3. Map task, knowledge and competency levels by trial complexity
4. Outline (broadly) the type of training currently provided for Trial Managers;

3. Project Implementation

We established a Project Team (Nixon, Cottrill, Cooper and Meadows) developed a draft Trial Managers task list, 'knowledge required' list and competency definitions utilising previous work undertaken at national and local CTU levels.

We held a Workshop on 15 November in York with invited members from NETSCC Support Funded CTUs and members from the NCRI Accredited CTU Training Sub-Group (Appendix 1) to review the draft documents. The documents were reviewed and refined through group work with the resulting task list which details the components of the Trial Manager role, through the various stages of trial development and implementation (Appendix 2). The knowledge list details the knowledge required by a Trial Manager to deliver components of the role (Appendix 3). The competency definitions utilised were those previously developed by ICR CTU and describe three levels of competency (Appendix 4).

These components were combined into the *Task, Knowledge and Competency Framework* which includes an assessment of the competency required to complete each task and the competency level expected for three levels of Trial Manager (Senior, Experienced and Novice) (Appendix 2). In the dissemination of the Framework it must be recognised that in CTUs it is common to have different levels of staff undertaking different component parts of the role and in some CTUs some of the higher level activity (for example, grant application and pre-award stage) is not undertaken by Trial Managers.

The Workshop members did not consider it appropriate to develop the *Task, Knowledge and Competency Framework* further by trial complexity. Instead they agreed that the basic framework could be adapted as required according to trial complexity and also adapted to take into account the preferences of the employing organisations. The workshop output included a list of potential trial design, interventions and settings which add complexity and require specialist knowledge (Appendix 5).

Workshop attendees also outlined current training provision in their respective CTUs (Appendix 6). Common themes emerged in provision of training. The majority of training is a combination of 'on the job', internal CTU training and generic skills development through employer staff development and training. External courses, masters training is limited by paucity of provision, lack of relevance and/or cost.

4. Summary

The work initially focused upon the various tasks, which together make up the complex role of a Trial Manager. The knowledge and experience required for the component parts is varied, but the *Task, Knowledge and Competency Framework* does illustrate the broad range of knowledge, expertise and experience required to undertake the role.

Appendix 1 Delegate List Trial Managers Event 15 November 2011

Organisation:	Name:
Bristol Randomised Trials Collaboration (University of Bristol)	Joanne Simon
Clinical Trials Research Centre (University of Liverpool)	Helen Hickey Rachel Breen
Clinical Trials Research Unit (University of Leeds)	Svet Mihaylov
Imperial Clinical Trials Unit (Imperial College London)	Alison Adderkin Jane Field
London School of Hygiene & Tropical Medicine (LSHTM) Clinical Trials Unit (University of London)	Taemi Kawahara
Newcastle Clinical Trials Unit (Newcastle University)	Chris Speed Jennifer Wilkinson
Nottingham Clinical Trials Unit (University of Nottingham)	Matthew Leighton Margaret Childs
York Trials Unit (University of York)	Stephen Brealey Jude Watson
Leeds CTRU (University of Leeds)	Gill Booth
ICR-CTSU (The Institute of Cancer Research, Sutton, Surrey)	Claire Snowdon Sara Quirk

Observers:

- Ann Deehan, Research Faculty Manager, Department of Health, London
- Liz Tremain, NIHR Evaluation Trials and Studies Coordinating Centre, Southampton

Facilitators:

- Jane Nixon, Deputy Director, Professor of Tissue Viability and Clinical Trials Research, Clinical Trials Research Unit, University of Leeds
- Lisa Cotterill, Director, NIHR Trainees Coordinating Centre, Leeds
- Helen Meadows, Training Education and Staff Development Lead, Cancer Research UK & UCL Cancer Trials Centre, London
- Monica Cooper, Senior Manager, NIHR Trainees Coordinating Centre, Leeds

Appendix 2 Trial Manager Role Technical Competencies Checklist

1. PROJECT INITIATION – Grant Application

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
Risk Assessment	Regulatory Environment, Trial Design, Scientific Field, Intervention	3	3	2	N/A
Grant Application (Process (P) and Content (C))	Scientific field, Scientific writing, Trial design, Trial implementation, Research funders, Clinical Pathway, Service Support Costs, Treatment Costs, Administration, Regulatory Environment	P: 2 C:3	P:2 C:3	P:2 C:1	P:1 C: N/A
Grant costings	Trial Implementation, Scientific field, Trial design, Intervention, Outcome measures, Regulatory environment, Legal Environment, Scientific field, Clinical field, Research funding, UKCRN Environment, Clinical Pathway, Supply chain,	3	3 or N/A	N/A	N/A
Obtain sponsorship in principle confirmation	Regulatory Environment	3	3	3	1

2. PROJECT INITIATION – Post Grant Award

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
Negotiate and agree start date (review and negotiate trial timelines, funders, Chief Investigator, internal team – stats, IS)	Trial implementation, Research Funders, Regulatory Environment, UKCRN Environment, Project Management	3	3	2 or N/A	N/A
Initiate review of contracts	Contracts, Regulatory environment, Trial implementation	3	3 or N/A	2 or N/A	N/A
Initiate set-up of research accounts	Trial implementation, Research Funders	3	3 or N/A	2 or N/A	N/A
Set up Project Team	Trial implementation, Project Management,	3	3	2 or N/A	N/A
Trial Oversight Committees Set up Trial Management Group (TMG) Set up Trial Steering Committee (TSC) Set up Data Monitoring and Ethics Committee (DMEC)	Trial implementation, Regulatory Environment, Clinical field	3	3	2 or N/A	N/A
Prepare and agree general progress and data monitoring plan with TMG, TSC and DMEC	Trial implementation, Regulatory Environment, Data Management, Intervention	3	3	2 or N/A	N/A
Agree Publication Policy with all	Scientific writing	3	3	2 or N/A	N/A

3. TRIAL LIFETIME

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
Meetings					
Organise meetings	Trial implementation, Administration, Project Management	3	3	2	1
Minutes	Administration, Project Management	2	3	2	1
Co-ordinate agendas and escalate issues	Trial implementation, Regulatory Environment, Trial design, Scientific field, Project Management				
• Local project team		2	3	2	1
• TMG		2	3	2	1
• TSC		3	3	2	1
• DMEC		2	3	2	1
Reports					
• TSC reports • DMEC reports • NRES progress/safety reports • Regulatory progress/safety reports	Research Funders, Trial design, Trial Implementation, Regulatory Environment, Project Management	2	3	2	1
		1	3	2	1
Trial registration and NIHR portfolio registration	UKCRN Environment and Trial implementation	1	3	2	1
Publicity / Promotion / Publication					
Newsletters	Trial Implementation, Trial Design, Scientific writing, Intervention	1	3	3	2
Conference abstract submissions	Scientific writing, Research Funders	3	3	2	1
Publication and publicity plan	Scientific writing, Research Funders	3	3	2	1
Marketing plan • Logos • incentives	Scientific/clinical management	1	3	2	1
Funder notifications?		1	3	3	1
Trial master file	Trial implementation, Regulatory Environment, Project management	3	3	2	1

4. PROJECT SET UP

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
General Set-up procedures and documentation					
Add trial details to CTRU website	Trial design, Administration	2	3	2	
Risk Assessment Review section 3?	Regulatory Environment, Intervention, Scientific field, Trial design, Trial implementation	3	3	2	1
Data Management plan	Data management, Trial implementation, Regulatory Environment, Intervention	2	3	3	1
Monitoring Schedule	Regulatory Environment, Intervention, Scientific field, Trial design, Trial implementation, Research funders,	3	3	22	1
Patient Group liaison (if applicable)	Trial implementation	2	3	2	1
Payments (CTU/sites/patients)	UKCRN Environment, Intervention, Research funders, Contracts, NHS Environment	3	3	2	1
Liaising with collaborators and 3rd party organisations	Trial implementation, Contracts	2	3	2	1
Initiate Trial Master File (paper and electronic)	Regulatory Environment, Trial implementation	2	3	3	2
Protocol Development and review• ISRCTN or other • Safety Reporting • Intervention delivery • Data collection • Endpoint review • Sponsor review of protocol • TSC and DMEC review of protocol	Scientific field, Regulatory Environment, Trial design, Trial implementation, Intervention	3	3	2	1
Initial Ethical and Regulatory Approvals • Identify lead centre and CLRN lead • IRAS • CSP Submission • Other regulatory approval	Regulatory Environment, UKCRN Environment, Scientific field, Trial design, Trial implementation, Intervention	2	3	2	1
CRF design	Data management, CRF design	2	3	2	1
Database • CRF Specifications • Validation Specifications • Reports Specifications • Testing • Database, validations and reports live	Database development, Data management, Trial implementation, Regulatory Environment	2	2	2	1
Randomisation and Blinding • Specification • Testing • Randomisation system live	Trial design, Data management	2	2	2	1
Intervention • Intervention requirements – staff, supplies, training • Intervention funding • Clinical Pathway • Payments	Regulatory environment, Intervention, UKCRN environment, Research funders, Contracts, Supply Chain, Trial Implementation, Clinical Pathway	3	3	2	1
Review Statistical Analysis Plan	Scientific writing, Scientific field, Trial design	3	3	2	1
Design trial specific procedures	Trial implement, Trial design, Intervention	2 or 3	3	2	1
Launch meeting	Administration, Intervention, Regulatory, Scientific Writing, Trial Implementation, Trial Design	2 or 3	3	2	1

5. CENTRE SET-UP

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
Agree Sponsor – Site Agreement	Regulatory environment	2	3	2	1
Identify sites/PIs • Registration of Interest/Feasibility • Define departments/organisations involved • Identify PIs • Identify key staff	Trial implementation, UKCRN environment, NHS environment, Intervention	2	3	2	1
SSI document • Draft SSI • Transfer SSIs to centres	Trial implementation	2	3	2	1
Liaise with PIs, R & D departments and networks to secure: • SSI submission • Service support/ treatment costs • Treatment delivery • Local NHS permissions	Trial implementation, UKCRN Environment, NHS Environment, Intervention	2	3	2	1
Collation of centre start up documentation • PI declaration • Authorisation logs •	Trial implementation, Regulatory environment	1	3	3	2
Site initiations • Presentation/Training materials • Date planning • Clinical/research/pharmacy/labs as required	Scientific field, Regulatory environment, Trial implementation	2	3	2	1
Prepare and send Investigator Site Files	Trial implementation, Regulatory environment, Intervention	2	3	2	1

6. RECRUITMENT

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
<u>Protocol Amendments</u> • Ethics • CSP • Centres • Sub studies/ Bolt on studies	Trial Implementation, Regulatory environment	2	3	2	1
<u>Recruitment</u> • Monitor screening and recruitment • Monitor withdrawals and lost to follow up • Raise issues to TMG/TSC/DMEC • Activities to promote recruitment (may include extending number of centres, site visits etc) • Recovery planning • Recruitment closure planning • NIMR upload	Trial implementation, Regulatory Environment, Trial design, UKCRN Environment, Service Support Costs, Treatment Costs	2 or 3	3	2	1
<u>Intervention delivery</u> • Monitor compliance • Co-ordinate supplies/payments • Intervention specific requirements • Patient Pathways • Ongoing Funding arrangements • Payments	Trial implementation, Regulatory Environment, Trial design	2 or 3	3	2	1
<u>Safety</u> • Safety monitoring • Oversee safety procedures • Undertake safety reporting	Trial implementation, Regulatory Environment, Trial design	2 or 3	3	2	1
<u>Data Management</u> • Co-ordinate data entry • Undertake data management • Oversee data management and quality • Monitor CRF compliance • Central monitoring (e.g. consent quality, intervention compliance) • Oversee central review processes • Data cleaning planning(final analysis) • Data cleaning DMEC downloads and/or interim analyses	Data management, Trial implementation, Regulatory environment	2 or 3	3	2	1 or 2
<u>On Site Monitoring (where required)</u> • Ongoing site training • Trouble shooting		2	3	2	1

7. FOLLOW UP & ANALYSIS

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
Protocol Amendments (as above)	Trial implementation, Regulatory Environment	2	3	2	1
End of Recruitment • In-house recruitment closure process • Centre recruitment closure process	Data management, Trial implementation, Regulatory environment	2	3	2	1 or 2
Data Management • Monitor data flow • Review database reports • Statistics monitoring • Site and central monitoring • Central review • Data cleaning planning • Investigator Key Data Sign Off • Data cleaning DMEC downloads and/or interim analyses	Scientific writing, Scientific field, Trial design	2 or 3	3	2	1 or 2
Analysis (Final and Follow-up) • Review final Statistical Analysis Plan • Review tables, reports circulated, agreed and signed off • Data collection, entry, chasing and cleaning • Data download, checking and queries • Analysis • Review final Statistical Report	Scientific writing, Scientific field, Trial design	2	3	2 or 3	1
Dissemination • Dissemination plan • Drafting of manuscripts • Abstract submission and conference presentation		2	2	2	1

8. TRIAL CLOSURE

Task	Knowledge Required	Competency Level			
		Competency Required	Senior Trial Manager	Experienced Trial Manager	Novice Trial Manager
Contract review	Trial implementation, Regulatory Environment	2 or 3	3	2	1
Notification of closure • Regulatory End of Trial Notification • Regulatory End of Trial Report • NRES End of Trial Notification • NRES End of Trial Report	Data management, Regulatory environment	2	3	2	1 or 2
Data management completion	Trial implementation, Regulatory environment, Administration	2	3	2	1 or 2
Investigator Site Files	Trial implementation, Regulatory environment, Administration	2	3	2	1 or 2
Trial Master File	Trial implementation, Regulatory environment	2	3	2	1 or 2
Centre closure visits/instructions	Regulatory environment, Contract	2	3	2	1 or 2
Central Archiving		2 or 3	3	2	1

Appendix 3 Knowledge list for Trial Managers

Administration

Clinical Pathway

Contracts

CRF Design

Data management procedures

Database development

NHS environment

Intervention specific knowledge

Legal environment

Outcome measures

Project management

Regulatory Environment

Research funders (includes NIHR/Charity/pharma/NHS Service Support Cost/ NHS Treatment costs)

Risk Assessment

Scientific field (includes disease knowledge/management)

Scientific writing

Supply chain

Trial design

Trial implementation

UKCRN environment

Appendix 4 Competency Framework

ICR-CTSU

Level 1: Has a basic level of understanding/experience of the technical competency and is able to apply it with guidance

Level 2: Has a good level of understanding/experience of the technical competency and is able to apply it with little or no guidance

Level 3: Has an expert level of understanding/experience of the technical competency. Is able to continually review and refine systems to ensure procedural efficiency and regulatory compliance. Able to guide others in this competency.

Appendix 5 Factors adding complexity to trial development and delivery

Population
Paediatrics
Special consent issues/vulnerable groups

Disease area
New Disease (to CTU)
Rare diseases
Complex patient pathways

Intervention
CTIMPS
Advanced therapies (gene therapy)
Complex interventions
Interventions with a associated specialist regulations (eg radiotherapy)
Multiple specialties

Comparator
Placebo control

Setting
Multi-centre
Devolved nations
International
Cross-boundary (acute/community)
NIGB (section 60)

Design
Phase I/II
Adaptive designs
Multi-arm
Cluster
Blinded

Outcome/Measures
Human tissues act/sample collection
Health economics
Complex patient pathways

Appendix 6 Summary of Current Training and Development Provision

Induction
Training needs assessment and training plan
Training planning using internal/external training provision matrix
University training courses for generic skills training

Work with experienced TM (start as monitors)
Mentoring by senior staff
On the job training

Internal CTU workshops/sessions
SOPs
GCP
Webinars
Invited external speakers

External Training
TM Forum
CLRN Training
NHS Training
NCRN Training

External courses (funding is an issue)
European eg EORTC (~£1000)
UK Short Courses eg Edinburgh (~£400)
Trial related Masters eg LSHTM, Liverpool
Various generic applied health research Masters and Masters modules