NIHR | Manchester Biomedical Research Centre

Rapid Translational Incubator Theme

This document contains information for researchers to refer for help when setting up studies and trials. The information includes support available in Manchester, challenges that may occur and potential solutions. The first is a summary slide. Slides 2-7 look at the support, challenges and solutions for five different study types.

Attendees at the BRC and Translation Manchester workshop: helping resolve challenges with setting up trials and studies (December 2018) added information to these pathways. They have been created in the spirit of peer support and to provide a forum to learn from other people's experiences when setting up studies.

This information complements the training and specific information provided by other organisations and does not replace their advice and guidelines. This is a resource for all. It will be reviewed and added to on a regular basis.

Please send any comments or updates to the BRC Rapid Translational Incubator Theme:
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TranslationManchester

Trials and Studies Summary

	Support	Challenge	Solutions
Concept	• Public Programmes Team • Peer Review for early ideas • Research Design Service Manchester Clinical Trials Unit	• PPI: How to engage within the community. • Project management • Statistics support • Use of CRF or CTU	• Project Management time • Speak to sponsor early to identify level of risk • UoM Biostatistics Unit MFT Statistics
Governance and Sponsorship	• Trust R&D MFT, Christie, SRFT, UoM Clinical Trials Support • Manchester CRF • UoM Business Engagement • Pharmacy	• Identifying a sponsor • Regulatory approvals - IRAS / REC applications and MHRA Risk assessments • Information Governance	• Talk to R&D early for guidance with IRAS/REC/MHRA • Notify CRF asap • GDPR: UoM information governance
Funding	• UoM Strategic Funding Group • Costing via R&D Departments (MFT, Christie, SRFT, UoM) or UoM Research Support Team • NIHR costing template	• Identifying suitable funding streams is difficult. • Costings can take a lot of time • Ensure supporting dept. fees are fully costed.	• UoM Strategic Funding Group • Research Project Managers Network • Notify supporting departments early
Preparation	• Templates from studies • Manchester CRF • R&D departments and Research Design Service • NIHR Study support Service	• Factoring in clinician workload • Commercialisation Pathway • Complexity of MHRA and CE marking Issues with GDPR	• Early engagement - UMIP and TRUSTECH • MHRA help desk • Research Design Service North West
Contracting	• UoM Contracts Team • UoM Business Team contracts • R&D (MFT, Christie, SRFT, UoM) • IP ownership • Ethics	• Ethics potentially complex • IP consideration sometimes missed • Knowing who to contact	• Link in with Contract Managers • Identify clear contact for UoM/Trust • Link with UMIP and TRUSTECH early
Site Initiation	• R&D Departments (MFT, Christie, SRFT, UoM) • Manchester Clinical Trials Unit • Manchester CRF	• Time to target • Staff capacity • Engaging with additional sites • Rare patient populations	• Trial Management Group at MFT • Develop a communications plan. If opening multiple sites, open one first & iron out issues Manchester Clinical Trials Unit

Setting up an Experimental Medicine Study

	Support	Challenge	Solutions
Concept	• MRC Methodology Hub & Networks • Manchester CRF • PPIE - MFT UoM Citizen Science • Trusts R&D MFT Christie SRFT • Clinical Research Network (CRN) • Peer Support • Manchester Clinical Trials Unit	• Planning - correct timings • Project management	• Utilise peer review • Utilise PPIE teams PPIE (MFT Public Programmes UoM Citizen Science BRC • Include Project Management time in your funding application
Governance and Sponsorship	• Manchester Clinical Trials Unit • NIHR • UoM Clinical Trials Support	• Where is the drug coming from? • Is the CI placed in a NHS Trust or the UoM?	• Call the MHRA • Independent Data Monitoring Committee (IDMC)
Funding	• UoM Research Support Services • Macmillan / Marie Curie / CRUK / Roy Castle • NIHR costing template • Manchester CTU • UoM Strategic Funding Team		• Project managers have experience navigating funding streams/processes • UoM PANMAN • Link with sponsors • UK Clinical Research Collaboration(UKCRC)
Preparation	• HRA Templates • Contract Manager/s • NIHR Study support Service • Manchester Clinical Research Facility		• Vendor assessment • PPIE support (Public Programmes / UoM Citizen Science / BRC) • Early CI
Contracting	• UoM Contracts Team • UMIP • TRUSTECH	• Intellectual Property	• Contact relevant organisation early
Site Initiation	• R&D Departments (MFT, Christie, SRFT, UoM) • Manchester Clinical Trials Unit • Manchester CRF	• Rare patient populations • Staff capacity • Treatment vs research costs • Different templates	• MFT Trial Management Group • Back up sites • Trust Comms teams (aid recruitment) MFT R&I Comms Christie SRFT

Setting up an Early Phase Study (1/2)

	Support	Challenge	Solutions
Concept	• PPIE (MFT Public Programmes UoM Citizen Science • Trusts R&D MFT Christie SRFT • Research Design Service • Funding bodies/ finance	• CTU: Different CTUs have varying levels of expertise (ie, Birmingham CTU has specialist paediatric knowledge). For complex areas, the researchers can be signposted to the specialist CTUs. • Pharmacy: capacity to deliver trials • Research Design Service : not known what they offer • PPI: Not wanting to overwhelm patients – in regards to including them on PPI panels and inclusion in research. • Identifying suitable funding streams and criteria.	• Sponsor: Speak to sponsor early to identify level of risk. This may mandate the risk level and use of a CTU/CRF. • Pharmacy: give advance notice • Statistics: consult early. Can use statisticians in CTU. MFT Statistics Biostatistics Unit at UoM. • Research Design Service : RDS grant available for PPI. • PPI: BRC have a patient panel – could be used as PPI network. • Funding: Strategic Funding Group , UoM can help with this, and send suitable funding calls
Governance and Sponsorship	• Trust R&D Departments MFT, Christie, SRFT, UoM • UoM Clinical Trials Support • R&D and Pharmacy • R&D and MFT: Hospital Research and Innovation Managers UoM Research Support Team • R&D and Information Governance • Manchester CRF	• Identifying a sponsor for a project - not always clear which organisation should be the sponsor. • MHRA Applications • Regulatory approvals - IRAS / REC applications and MHRA applications • Issues with GDPR, and what data can be held and for what means • Early phase studies and risk assessments	• Trusts have sponsorship guidance document • Early notification to R&D and pharmacy of MHRA applications, and any governance considerations. • Inform UoM Research Support Team and Trust R&D early re: guidance with IRAS / REC / MHRA • GDPR: Liaise with information governance and R&D as early as possible. IRAS form has section on data collection and governance. • Notify CRF as soon as possible
Funding	• UoM Strategic Funding Group • Finance and MFT: Hospital Research and Innovation Managers • Supporting departments and infrastructure	• Identifying suitable funding streams is difficult. Requirements of funding calls and funding bodies can vary • Service Support Costs and ACCORD guidelines not always clear, difficult to interpret what is research and what isn't when applying for funding. • Make sure that supporting department fees are included in funding/ grant applications and are fully costed.	• Funding : Talk to the UoM Strategic Funding Group who can signpost suitable funding streams/ strategic grants. Also MFT: Hospital Research and Innovation Managers • Service support costs: Inform MFT: Hospital Research and Innovation Managers of grant applications as early as possible • Notify supporting departments as soon as possible. It takes time to get costs back from these areas .

Setting up an Early Phase Study (2/2)

	Support	Challenge	Solutions
Preparation	• Trust R&D Departments MFT, Christie, SRFT, UoM • Research Design Service • Training and development programmes • Research Teams, PI • Supporting departments • NIHR Study support Service	• GDPR regulations : guidance needed on what can be included in research, on developing patient information sheets etc. • Staff turnover/ working in silos: Not knowing who is doing what. • Factoring in clinician workload, pipeline of activity, and resources such as research nurses. Ensuring they are ready when the trial is starting.	• Patient information sheet templates: MFT R&I have guidelines on protocols for CTIMP and non-CTIMP trials • Potentially standardising training for staff groups/ similar roles within different organisations. • Early notice and engagement with clinicians and teams. • Early communication that trials are due to start.
Contracting	• Contracts Managers UoM MFT SRFT CHRISTIE • UoM Business Team contracts	• IP consideration sometimes missed	• Discuss contracts and sub-contracts. Also bi-partite and tri-partite multi organisation contracts • Link with **TRUSTECH / UMIP** early on in the process. MFT Trust sponsored RPEAK workflow can prompt this via the R&D office. UoM Research Support Team and MFT: Hospital Research and Innovation Managers will also prompt this.
Site Initiation			

Setting up a Study to Re-Purpose a Drug

	Support	Challenge	Solutions
Concept	• Peer Review for early ideas (e.g. informal lab meetings)	• When a team has lots of people; getting consensus, and when you are working alone • Statistics	• Plan ahead for stats support. UoM Biostatistics Unit contact at early stage, cost them at grant application. MFT Statistics
Governance and Sponsorship	• Trust R&D MFT, Christie, SRFT, • UoM Clinical Trials Support	• Can be slow to get response from R&D Depts. • Sponsorship (can be difficult). System is much more rigorous now.	• More funding for Trust R&D departments, improve staff retention and increase infrastructure funding.
Funding	• Useful to have funding calls distributed • Costing is done via Trust R&D Departments (MFT, Christie, SRFT, UoM) or UoM Research Support Team	• Can waste a lot of time applying to funding calls. Good to phone up the funding body to check. • Costings can take a lot of time. Standard costs are easy but specific costs can be tricky and time consuming. Important to know right people.	• Is the solution to have an electronic system that gives you a ball park cost? Can Manchester develop such a tool? Imperial have a good tool which outlines costs
Preparation	• Examples/templates from previous studies • Previous examples from colleagues • NIHR Study support Service	• Available templates are not always appropriate	• Useful to have a Manchester wide or individual Trust wide workbook and reference guide and templates. • Contract templates to be set up – need to solve the bit between the UoM and the Trusts.
Contracting	• Ethics	• Ethics potentially complex • Knowing the right people • Electronic tools	• Generate template contracts between BRC and Trust and between the different Trusts
Site Initiation			

Setting up a Medical Device Study

	Support	Challenge	Solutions
Concept	• PPI support from BRC / PPIE team • Data management team • Research Design Service	• Machine learning – use of patient data to build device and systems that continue to learn • Software – when does it become medical device? • Does the study need to go to MHRA? Where do apps sit? • MHRA financial hurdles – when to register?	• Utilise the Research Design Service • Talk to people that have been through it • Develop groups of peer experts for technologies • Work with a single BRC contact who can help guide the process and ensure study protocol is feasible before starting
Governance and Sponsorship	• UMIP • TRUSTECH • Manchester CRF • UoM Clinical Trials Support • UoM Business Engagement	• Who will sponsor the study UoM or NHS? • Knowing whether MHRA needed • When working with researchers overseas to develop product who pays and who owns IP?	• Talk to site R&D department • Speak with someone who has done a similar study
Funding	• UMIP • TRUSTECH • UoM Research Support Services	• MHRA fees? Who pays? • Help with funding to translate lab software to be a device	• Talk to the UoM Strategic Funding Group • Charity research grants
Preparation	• UMIP • TRUSTECH • NIHR Study support Service	• Commercialisation Pathway • Complexity of MHRA and CE marking regulations • How do you proceed if new interventions improves care but is against current standards/guidelines? • Identification and recruitment of participants	• Establish network of regulatory experts • MHRA help desk can advise on MHRA involvement • Research Design Service • PPIE to recruit patients against current guidelines • PPIE discuss commercialisation
Contracting	• UoM contracts team • MFT contracts • UoM Business Team contracts	• Ethics potentially complex • Who is responsible for the safety & performance of the medical device (pre clinical support)?	• **GM CRN** portfolio adoption • Identify clear point of contact for UoM / Trust
Site Initiation	• Research office for Trust sponsored studies (MFT Christie SRFT)		• Single point of contact who can coordinate communication between UoM & Trust • Use Manchester Clinical Trials Unit

Setting up a Biomarkers Study

	Support	Challenge	Solutions
Concept	• Talk to PPIE forums to validate your idea. (UoM MFT SRFT BRC) Check whether the proposal sample collection method is acceptable. • Talk to staff groups who may be collecting the samples to understand whether what you are proposing is viable.	• How to engage with patients within community? • Project management • How to identify the target recruitment figure, especially if coding is lacking. Are patients available high enough to get a significant number?	• Ask for advice from statisticians MFT Statistics • Look at the Open Data Platform (CRN) for information on research performance, recruitment and study activity for NIHR CRN portfolio studies • Farsite: North West EHealth's tool to help identifying and recruiting patients for Portfolio studies
Governance and Sponsorship	• HRA has a good website. Trust R&D departments (MFT, SRFT, Christie) and CRN • Is there a local or national biobank? • UoM Clinical Trials Support	• An understanding of how long each approval takes to factor into overall set up time. • Handling of tissue - both storage and transportation	• Likely to need a discussion with the HTA license holder for the organisation / sponsor. • Test handling of samples in advance. • Ensure everything is in your contract.
Funding	• SMEs and Pharma may have funding	• Lack of discrete funding calls for biomarker specific studies.	• Link in with BRC Biomarker cross-cutting theme. They may have industry links you could link to. • MMPathIC also helpful - may also have funding
Preparation	• NIHR Study support Service	• What if you want to include patients in the study who may not have capacity to consent?	
Contracting	• Could there be new IP if developing a assay or biomarker test? Talk to TRUSTECH or UMIP		
Site Initiation		• How to engage with additional sites if a multi-centre study? • Time to target • Communicating with sites	• NIHR GM CRN • Exploit personal relationships of PI • Multiple sites: open one site first, resolve any issues before opening additional sites • Develop a communications plan to identify frequency of contact and who talks to who.