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: Zoe Talks, Project Manager on zoe.talks@mft.nhs.uk or 0161 701 0720

This version: Version 1, April 2019
<table>
<thead>
<tr>
<th>Support</th>
<th>Challenge</th>
<th>Solutions</th>
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</table>
| **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 |
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</table>
| **Concept** | Planning - correct timings | • Utilise peer review  
• Utilise PPIE teams PPIE (MFT Public Programmes UoM Citizen Science BRC)  
• Include Project Management time in your funding application |
| • 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 | • 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) |
| **Governance and Sponsorship** | • Project managers have experience navigating funding streams/processes  
• UoM PANMAN  
• Link with sponsors  
• UK Clinical Research Collaboration(UKCRC) | • Preparing Contract Manager/s  
• NIHR Study support Service  
• Manchester Clinical Research Facility | • Vendor assessment  
• PPIE support (Public Programmes / UoM Citizen Science / BRC)  
• Early CI |
| • Manchester Clinical Trials Unit  
• NIHR  
• UoM Clinical Trials Support | • Intellectual Property | • Contact relevant organisation early |
| **Funding** | • Intellectual Property | • Contact relevant organisation early |
| • UoM Research Support Services  
• Macmillian / Marie Curie / CRUK / Roy Castle  
• NIHR costing template  
• Manchester CTU  
• UoM Strategic Funding Team | • Intellectual Property | • Contact relevant organisation early |
| • HRA Templates  
• Contract Manager/s  
• NIHR Study support Service  
• Manchester Clinical Research Facility | • Intellectual Property | • Contact relevant organisation early |
| • UoM Contracts Team  
• UMIP  
• TRUSTECH | • Intellectual Property | • Contact relevant organisation early |
| **Contracting** | • Intellectual Property | • Contact relevant organisation early |
| • R&D Departments (MFT, Christie, SRFT, UoM)  
• Manchester Clinical Trials Unit  
• Manchester CRF | • Intellectual Property | • Contact relevant organisation early |
| • R&D Departments (MFT, Christie, SRFT, UoM)  
• Manchester Clinical Trials Unit  
• Manchester CRF | • Intellectual Property | • Contact relevant organisation early |
| • R&D Departments (MFT, Christie, SRFT, UoM)  
• Manchester Clinical Trials Unit  
• Manchester CRF | • Intellectual Property | • Contact relevant organisation early |
| **Site Initiation** | • Intellectual Property | • Contact relevant organisation early |
| • MFT Trial Management Group  
• Back up sites  
• Trust Comms teams (aid recruitment) MFT R&I Comms Christie SRFT | • Intellectual Property | • Contact relevant organisation early |
## Setting up an Early Phase Study (1/2)

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<tr>
<th>Support</th>
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<th>Solutions</th>
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</table>
| **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. |
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<thead>
<tr>
<th>Preparation</th>
<th>Challenge</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support</td>
<td>GDPR regulations: guidance needed on what can be included in research, on developing patient information sheets etc.</td>
<td>Patient information sheet templates: MFT R&amp;I have guidelines on protocols for CTIMP and non-CTIMP trials</td>
</tr>
<tr>
<td>• Trust R&amp;D Departments MFT, Christie, SRFT, UoM</td>
<td>• Staff turnover/working in silos: Not knowing who is doing what.</td>
<td>• Potentially standardising training for staff groups/similar roles within different organisations.</td>
</tr>
<tr>
<td>• Research Design Service</td>
<td>• Factoring in clinician workload, pipeline of activity, and resources such as research nurses. Ensuring they are ready when the trial is starting.</td>
<td>• Early notice and engagement with clinicians and teams.</td>
</tr>
<tr>
<td>• Training and development programmes</td>
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<td>• Early communication that trials are due to start.</td>
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<tr>
<td>• Research Teams, PI</td>
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<tr>
<td>• Supporting departments</td>
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<tr>
<td>• NIHR Study support Service</td>
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<tr>
<td>Contracting</td>
<td>IP consideration sometimes missed</td>
<td>Discuss contracts and sub-contracts. Also bi-partite and tri-partite multi organisation contracts</td>
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<tr>
<td>• Contracts Managers UoM MFT SRFT CHRISTIE</td>
<td></td>
<td>Link with TRUSTECH / UMIP early on in the process. MFT Trust sponsored RPEAK workflow can prompt this via the R&amp;D office. UoM Research Support Team and MFT: Hospital Research and Innovation Managers will also prompt this.</td>
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<tr>
<td>• UoM Business Team contracts</td>
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<tr>
<td>Site Initiation</td>
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<tr>
<td>Support</td>
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<td>Solutions</td>
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<tr>
<td><strong>Concept</strong></td>
<td>• Peer Review for early ideas (e.g. informal lab meetings)</td>
<td>• When a team has lots of people; getting consensus, and when you are working alone • Statistics</td>
</tr>
<tr>
<td><strong>Governance and Sponsorship</strong></td>
<td>• Trust R&amp;D MFT, Christie, SRFT, UoM Clinical Trials Support</td>
<td>• Can be slow to get response from R&amp;D Depts. • Sponsorship (can be difficult). System is much more rigorous now.</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td>• Useful to have funding calls distributed • Costing is done via Trust R&amp;D Departments (MFT, Christie, SRFT, UoM) or UoM Research Support Team</td>
<td>• 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.</td>
</tr>
<tr>
<td><strong>Preparation</strong></td>
<td>• Examples/templates from previous studies • Previous examples from colleagues • NIHR Study support Service</td>
<td>• Available templates are not always appropriate</td>
</tr>
<tr>
<td><strong>Contracting</strong></td>
<td>• Ethics</td>
<td>• Ethics potentially complex • Knowing the right people • Electronic tools</td>
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<tr>
<td><strong>Site Initiation</strong></td>
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## Setting up a Medical Device Study

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

<table>
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<tr>
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<th>Solutions</th>
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</table>
| **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* | • 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. |
| **Site Initiation** | |

*NHIR Manchester Biomedical Research Centre*