

BARRIERS TO RESEARCH: RESULTS OF THE CLRN SURVEY

Summary

- The CLRN has an annual budget of just over £750,000 over two years for Key Service Support. The remit is to identify and overcome local ‘blocks’ that exist in the provision of clinical service support for UKCRN Portfolio research. The aim is to make the conduct of research in the NHS easier by providing targeted NHS support and facilitating the management of the changes that this requires.
- To identify these “blocks”, the CLRN sent out a survey (see appendix 1) in June 2008, on perceived barriers to clinical research, to all PIs/CIs on its local database, members of its Network Board and R&D Forum, its Specialty Leads and TCRN Directors. One month was allowed for completion and return of responses.
- 87 responses were received, some consolidated for several individuals from a particular Trust or Consortium and almost all Trusts in the CLRN were represented. 63% of responses came from CIs/PIs.
- 35 (40%) respondents indicated that research had **not** been delayed or prevented by any particular barrier, which suggests that in a significant minority of cases, clinical research is being well run (1 additional respondent did not respond to any of the questions).
- Of the 51 (59%) respondents who indicated that clinical research had been delayed or prevented, 31% highlighted problems with pharmacy, 27% with imaging, 23% with laboratory services and 33% with other barriers.
- The issues most commonly mentioned are listed in Appendix 2 but the main ones were:
 1. Fund more Core R&D support to reduce bureaucracy for CIs/PIs and streamline the approvals and ethics processes; and to provide support for UKCRN returns.
 2. Use agreed standard costs for pharmacy, imaging and laboratory services for non-commercial studies, to reduce delays in approving studies.
 3. Fund more dedicated research Pharmacists to improve access to pharmacy.
 4. Fund more dedicated research time for clinicians/GPs, coordination in imaging and generally.
 5. Fund more high quality Research Nurses, providing training and possibly a pool of roving Nurses for Consortia within the CLRN.
 6. Establish a streamlined, fast decision making process to fund service support costs for research.
- The CLRN has provided solutions to most of these issues, which include:
 1. Investment in research management and governance of over £600,000 per annum (see Appendix 3). A streamlined mechanism for the generation of NHS permissions was initiated nationally in November 2008.
 2. Adoption of agreed tariffs for all services throughout the Network for non-commercial studies (see Appendix 4).
 3. Investment in pharmacy and imaging of around £500,000 per annum (see appendix 2). Other local issues also addressed where possible.
 4. Set up a £1.5M investment fund for applications for Research Nurses, trial staff and service support costs.

A. Summary of the Response to the Survey

Total No. of Respondents: 87

Trusts

UCLH	21 (24%)
Other Trusts/HEIs	16 (18%)
BLT	14 (16%)
GOSH	9 (10%)
Moorfields	7 (8%)
RFH	4 (<5%)
Whittington	4 (<5%)
Homerton	3(<5%)
NUHT	3(<5%)
RNOH	3(<5%)
Whipps Cross	3(<5%)

Groups

CIs/PIs	55 (63%)
CLRN Board/R&D	14 (16%)
Specialty Leads	7 (8%)
TCRNs	6 (7%)
Pharmacy/Radiology	5 (6%)

B. The Most Commonly Identified Barriers to Research and Specific Solutions and Investments from the CLRN:

Common Barrier Identified	Solution																						
R&D Processes, Trial Set Up, Approval and Documentation	<p>(i) Research management and governance funded by the CLRN, with provision relating to activity, and service level agreements in place to ensure R&D departments meet the objectives of the CLRN (see Appendix 3 for details of the RM&G provision).</p> <p>(ii) November 2008 implementation of CSP; the streamlined process for preparing documentation for trial approval.</p>																						
Pharmacy Access and Support	<p>(i) Funding of dedicated trial Pharmacists (grade 7), allocation relating to activity/accrual, in:</p> <table> <tr> <td>BHR (via NELCRN)</td> <td>0.5FTE</td> </tr> <tr> <td>BLT</td> <td>1.0FTE</td> </tr> <tr> <td>GOSH</td> <td>1.0FTE</td> </tr> <tr> <td colspan="2"><i>(inc. "specials" formulation)</i></td> </tr> <tr> <td>Moorfields</td> <td>1.0FTE</td> </tr> <tr> <td>NUHT</td> <td>0.5FTE</td> </tr> <tr> <td>RFH</td> <td>1.0FTE</td> </tr> <tr> <td>RNOH</td> <td>0.5FTE</td> </tr> <tr> <td colspan="2"><i>(inc. facilitation for research drug storage)</i></td> </tr> <tr> <td>Whipps Cross</td> <td>0.5FTE</td> </tr> <tr> <td>UCLH</td> <td>1.0FTE</td> </tr> </table> <p>(ii) Adoption of transparent costing tariffs (see Appendix 4)</p>	BHR (via NELCRN)	0.5FTE	BLT	1.0FTE	GOSH	1.0FTE	<i>(inc. "specials" formulation)</i>		Moorfields	1.0FTE	NUHT	0.5FTE	RFH	1.0FTE	RNOH	0.5FTE	<i>(inc. facilitation for research drug storage)</i>		Whipps Cross	0.5FTE	UCLH	1.0FTE
BHR (via NELCRN)	0.5FTE																						
BLT	1.0FTE																						
GOSH	1.0FTE																						
<i>(inc. "specials" formulation)</i>																							
Moorfields	1.0FTE																						
NUHT	0.5FTE																						
RFH	1.0FTE																						
RNOH	0.5FTE																						
<i>(inc. facilitation for research drug storage)</i>																							
Whipps Cross	0.5FTE																						
UCLH	1.0FTE																						

Common Barrier Identified	Solution												
Imaging Access and Support	(i) Funding of 21 dedicated clinician research sessions for imaging per annum, number relating to activity/accrual, in: <table data-bbox="703 309 1337 566"> <tr> <td>BLT (inc. an Imaging Coordinator)</td> <td>5PAs</td> </tr> <tr> <td>GOSH inc sedation nurse sessions)</td> <td>2.5PAs</td> </tr> <tr> <td>Moorfields (inc tech and photographer)</td> <td>2.5PAs</td> </tr> <tr> <td>North Middlesex</td> <td>1PA</td> </tr> <tr> <td>RFH</td> <td>4PAs</td> </tr> <tr> <td>UCLH</td> <td>6PAs</td> </tr> </table> (ii) Adoption of transparent costing tariffs (see Appendix 4)	BLT (inc. an Imaging Coordinator)	5PAs	GOSH inc sedation nurse sessions)	2.5PAs	Moorfields (inc tech and photographer)	2.5PAs	North Middlesex	1PA	RFH	4PAs	UCLH	6PAs
BLT (inc. an Imaging Coordinator)	5PAs												
GOSH inc sedation nurse sessions)	2.5PAs												
Moorfields (inc tech and photographer)	2.5PAs												
North Middlesex	1PA												
RFH	4PAs												
UCLH	6PAs												
Standard Fees for Costing Trials	Adoption of transparent cost tariffs agreed (see Appendix 4)												
Transparent and Quick Access to Funding for Support Costs	Mechanisms for approaching the CLRN for funding have been set up and widely disseminated. A £1.5M fund has been set aside for such requests. Monthly decision-making.												
Health Economist and Statistical Support services needed	Possible provision through the new London Research Design Service (sites at UCL and Queen Mary, University of London) – under negotiation												
Research Nurse Support	A CLRN Fund has been set up to support clinical trials staff including Nurses. This has been publicised to CIs/PIs to encourage applications.												
IT Systems and Access across Trusts	Information Manager to assess current situation and develop plans for better networking and access, if possible, within the NHS												
Local Trust Issues Mentioned 1. Radiotherapy and QA requirements at BLT 2. Advocacy Support at NUHT 3. Histopathology Technical Support at UCLH	Fund Radiotherapy Physicist at BLT (grade 7, 1FTE) Fund Advocacy Service at the Homerton, Newham, Whipps Cross Consortium (equivalent to grade 6, 1FTE) Fund histopathology technician (grade 6,1FTE) at UCLH												
Lack of engagement by PCTs and GPs	Liaise with the PCRN and discuss possible means of improving GP/PCT involvement												

C: A Breakdown of the Expenditure

The CLRN's £750,000 budget for key service support to overcome local barriers has been allocated for:

5FTE Research Facilitators (grade 4)	£141,072
7FTE Trial pharmacists (grade 7)	£341,833
21 dedicated clinician research sessions in imaging	£157,500
1FTE Radiotherapy Physicist	£48,833
1FTE Histopathology Technician	£41,705
1FTE Patient Advocate	£41,705
TOTAL	£772,648

This investment, in the first instance for two years, will be monitored to ensure objectives are met by the Trusts allocated the funds. If, as anticipated, barriers are minimised, then the expectation is that continued funding, possibly even greater investment, if needed, will be possible, assuming the trial activity and patient recruitment into trials increases in the Network.

APPENDIX 1

A Survey On Barriers To Clinical Research In Key Service Support Within The Central And East London CLRN

INTRODUCTION

The CLRN has ring-fenced funding for key service support. The purpose is to overcome local 'blocks' that exist in the provision of clinical service support for UKCRN Portfolio research and make the conduct of research in the NHS easier.

The areas most widely cited as problematic are access to pharmacy and to imaging and improving these has been identified as a national priority. However, other local blocks that are identified by the CLRN can also be funded, such as access to laboratory services and defining who pays for tests associated with trials and cohort studies.

Therefore, to identify the most important local barriers to clinical research, we are directly approaching our member Trusts and stakeholders (see Appendix 1 for constituents) to find out what are the most critical improvements needed for the better running of clinical research in this CLRN.

As one of our stakeholders, we would welcome your views on this issue and would be grateful if you would complete this short questionnaire and return it to us by **31st July 2008**. An electronic version can be found at http://www.ukcrn.org.uk/index/networks/comprehensive/clrns/london_ne.html. If you prefer simply to send a free-text response (rather than use this questionnaire), do feel free to do this.

In answering the questions, you need not focus exclusively on your own Trust, but rather should try and capture the difficulties that exist in the region.

The results of this survey will be made available to all those involved and will be used to help the CLRN develop a strategy to make the best use of the ring-fenced funding to overcome the local barriers to clinical research.

[Note that the CLRN funds general service support costs for clinical trials through a different funding mechanism and these are not the focus of this questionnaire].

Please return your response (or for further information) to:

Dr Delphine Purves

Senior Manager

Email: delphine.purves@cancer.org.uk

Tel: (0)20 7014 0464

Fax: (0)20 7014 0461

Address:

Central and East London CLRN

Barts and The London

London

EC1M 6BQ

SECTION 1: BACKGROUND INFORMATION

- 1. Your Name:**
- 2. Your Organisation:**
- 3. Your Role:**
- 4. Your Involvement in Clinical Research:**

SECTION 2: POTENTIAL BARRIERS

- 5. Are you aware of clinical research within this CLRN region that has been prevented or delayed due to problems with access to PHARMACY?**

If yes, please provide details, specifying the nature of the problem and the Trust(s) affected:

5a.: What would you suggest is the best solution to this problem?

- 6. Are you aware of clinical research within this CLRN region that has been prevented or delayed due to problems with access to IMAGING?**

If yes, please provide details, specifying the nature of the problem and the Trust(s) affected:

6a.: What would you suggest is the best solution to this problem?

- 7. Are you aware of clinical research within this CLRN region that has been prevented or delayed due to problems with access to LABORATORY SERVICES?**

If yes, please provide details, specifying the nature of the problem and the Trust(s) affected:

7a.: What would you suggest is the best solution to this problem?

- 8. Are you aware of clinical research within this CLRN region that has been prevented or delayed due to problems with access to ANY OTHER SERVICES?**

If yes, please provide details, specifying the service, the nature of the problem and the Trust(s) affected:

8a.: What would you suggest is the best solution to this/these problem(s)?

- 9. If you could change one thing relating to key service support of clinical research in this region, what would it be?**

10. Any other comments on this issue?

11. Any other general comments for the CLRN?

APPENDIX 2
Specific Evidence from the Key Barriers Survey

General Barrier Identified	Trust	Group	Specific Comments
A. Trial Set up, Approval and Documentation	Barnet and Chase Farm Hospitals NHS Trust	Network Board	Develop the CLRN structure and increase support and awareness at the sites of low activity.
A. Trial Set up, Approval and Documentation	Barts and The London	CIs/PIs	The bureaucracy necessary to get anything done in this or other clinical research contexts is now extremely tedious and time-consuming. We need more administrative support to deal with the interminable bureaucracy now associated with clinical research, from grant-writing through ethics and R & D to completing CRFs on-line or on paper, and including how to access CLRN support.
A. Trial Set up, Approval and Documentation	Barts and The London	TCRN	The R&D departments themselves are often an impediment to clinical trials opening and accruing. This is especially the case at Queen's Hospital where there is an unwillingness to appoint staff to posts with short term funding.
A. Trial Set up, Approval and Documentation	Barts and The London	TCRN	The R&D departments themselves are often an impediment to clinical trials opening and accruing.
A. Trial Set up, Approval and Documentation	Barts and The London	CIs/PIs	Would like to have more support within the R+D office for statistics and public health costings
A. Trial Set up, Approval and Documentation	BLT	Specialty Lead	R&D delays have occurred especially at PCTs where ignorance abounds about process and governance. Remove PCTs from approval- they are unnecessary impediments to clinical trials
A. Trial Set up, Approval and Documentation	East London Mental Health	CIs/PIs	Participants have given us very strong feedback about the huge amount of paper work they receive (in order to achieve informed consent) which has in some instances been counter-productive.
A. Trial Set up, Approval and Documentation	GOSH	CIs/PIs	More support (administrative + expert) for completing R&D and ethical applications
A. Trial Set up, Approval and Documentation	GOSH	CIs/PIs	The main problem I have at present is with completing the returns for the UKCRN. Where large, multicentre studies are involved this is potentially a very time onerous and time consuming task. I am unable to do this for the studies I currently have registered, and have other studies that should be registered which will be recruiting several hundred cases per annum. The requirement to return recruitment figures to the UKCRN is onerous and not properly supported. There needs to be funding at point of recruitment for this, particularly where large studies are involved.

General Barrier Identified	Trust	Group	Specific Comments
A. Trial Set up, Approval and Documentation	GOSH	CI/PIs	Local research coordinators within units would make a huge difference for us. More streamlined paperwork is needed; I seem to spend so much of my time filling in forms or dealing with paperwork rather than thinking about or doing research. I think I'm more diligent than most, but it could be a full time job (from risk assessments, governance, ethics, DPA, employment/annual leave forms/sickness forms/appraisals, personal appraisals, human tissue act, research quality control, indemnity, transparency reviews, proper consent (very important and very time consuming), recruitment feedback – all even before starting to collect samples and undertake the above; and often annual reviews of all the above too)
A. Trial Set up, Approval and Documentation	Homerton	CI/PIs	The problem is one of increasing bureaucracy, limited time to do research and the change in funding from a system that guaranteed high quality research as evidenced by publications.
A. Trial Set up, Approval and Documentation	Moorfields	CI/PIs	The main delay I always encounter is with the Ethics Committee process.
A. Trial Set up, Approval and Documentation	Moorfields	CI/PIs	A recognition amongst NHS managers of the importance of clinical research and the need for them to help in allocating resources such for data managers and clerks for administration.
A. Trial Set up, Approval and Documentation	Moorfields	CI/PIs	Most helpful would be named contact to access support to implement research studies
A. Trial Set up, Approval and Documentation	Moorfields	R&D Forum	The administrative burden of conducting research is high and support services essential for PI/CI who do not have the time / knowledge or resources to meet the required standards without help. Sponsorship responsibilities also add to this burden. These issues have to be addressed as close as possible to the organisation that is co-ordinating / conducting / sponsoring the trial. Centralisation of the process may have benefits in terms of the regulatory affairs but successful trials depend on access to this support in the 'conduct' of the trial over several years.
A. Trial Set up, Approval and Documentation	Moorfields	CI/PIs	Patient's local PCT or central fund share the cost. Much more help with admin relating to regulation. The problem may not be greatest in my Trust but it is the biggest disincentive to any enquiring mind in clinical research in this country today.
A. Trial Set up, Approval and Documentation	North Middlesex University Hospital	CI/PIs	R&D itself needs investment and external support
A. Trial Set up, Approval and Documentation	Royal Free Hampstead NHS Trust	CI/PIs	Far more support required with administrative issues prior to study initiation with a more "joined up" process for ethics, R&D approval etc.

General Barrier Identified	Trust	Group	Specific Comments
A. Trial Set up, Approval and Documentation	Royal Free Hampstead NHS Trust	Specialty Lead	Delays/complexities of ethical permission, and clinical trial approval processes. Genuine streamlined admin support
A. Trial Set up, Approval and Documentation	Royal National Orthopaedic	R&D Forum	The increase administration required to comply with new standards in clinical research and the reduction in junior doctor's hours as a result of the EWTD have had a significant impact on our research service delivery.
A. Trial Set up, Approval and Documentation	The Whittington	Network Board	Core R and D support for study support (not centrally generated reporting activity). Reduction of bureaucratic workload for investigators
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	Ethical approval and Research governance procedures still slow
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	Research administration and bureaucracy is a significant barrier to getting research done. The system at the point of setting up the processes around a grant once it has been obtained can be pretty unwieldy and potentially cause significant delays.
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	By far the biggest block to carrying out clinical research is the bureaucracy and paperwork necessary to obtain ethics and R&D approval for even the simplest studies. Clinicians do not want to take part in clinical research if that involves spending hours of their time filling in tedious paperwork even before the first patient is recruited.
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	Centralising or having common R&D processes to prevent the incredible duplication of effort required to achieve R&D approval in multiple Trusts for multicentre studies. This needs to include Trusts recognising each other's CRB checks for researchers applying for honorary clinical contracts.
A. Trial Set up, Approval and Documentation	UCLH	Network Board R&D Forum	R&D approval: The time taken for research applications to be approved by the R&D Office is not always as quick as investigators would like. Different approaches to R&D approval across different Trusts can also complicate matters for multicentre studies. Implement time limits on R&D approval decisions (as with REC applications) and work with R&D Offices to implement. Adopt a cautionary approach to presenting research governance as a set of tick box checks.
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	Slow and bureaucratic procedures around R&D governance have been taking up considerable time, e.g. lengthy form-filling in order to interview a single healthcare professional in a Trust. NHS Research Ethics Committees also remain overly complex for many areas of research with minimal ethical issues (e.g. no patient involvement).

General Barrier Identified	Trust	Group	Specific Comments
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	There should be a central R&D approval process that holds for all trusts within the CLRN to remove time-consuming and frustrating delays in getting separate approvals
A. Trial Set up, Approval and Documentation	UCLH	CIs/PIs	Biggest delay for us is the R&D office and contract issues. Simplification of the process for gaining approval for new studies. Most of my trainees have ideas for research that never happens because of the huge leadtime that is needed before any project can start.
A. Trial Set up, Approval and Documentation	Whipps Cross	Specialty Lead	Get R&D depts to be more proactive and operational; Support staff; Operational help with grant applications
B. CTIMP Monitoring	Barts and The London	R&D Forum	We believe that we have a current and future problem with regards to monitoring CTIMPs. We are required to meet the MHRA's exacting requirements in this area and are beginning to realise that we are woefully underfunded with respect to developing monitoring systems and implementing these to industry standards. The network needs to identify a core monitoring resource within its budget and employ centrally or at sites, a number of monitors that will work on studies within the portfolio that do not have monitoring funds attached to trial budgets.
B. CTIMP Monitoring	Moorfields	R&D Forum	A dedicated Data Monitoring Committee that could be accessed by all. We have a DMC that facilitates the conduct of clinical trials to a high standard of research governance but it is not well resourced and absences are difficult to cover. 'Independence' can also be a problem. If AHSCs develop with UCL this could be developed by 'programme'.
B. CTIMP Monitoring	UCLH	Network Board R&D Forum	The steps required to set up CTIMPs under the current regulatory framework are demanding and time consuming, particularly for CTIMP sponsors who are by necessity putting in place robust systems to ensure GCP compliance throughout the trial. UKCRN must acknowledge the roles and responsibilities that CTIMP Sponsors have and should ensure that the research networks work closely with the major CTIMP sponsors to facilitate the set up and running of CTIMPs through assistance with site selection and initiation and perhaps monitoring, in line with the Sponsors SOPs.

General Barrier Identified	Trust	Group	Specific Comments
C. Standard Fees for Costing Trials	Barts and The London	Specialty Lead	Approximately 18 months ago we were considering participating in an international, multi-centre trial funded by the Canadian Clinical Trials Group. There followed lengthy discussions about the pharmacy costs that were prohibitively high and in the end effectively prevented our participation in this study. The momentum required to organise participation in clinical trials can be lost when such difficulties seem to be insuperable. Our impression has been that pharmacy wish to control every aspect of such trials, that as a result the costs are inflated and that they may in the end not be able to deliver. Streamline the service and reduce costs.
C. Standard Fees for Costing Trials	Newham University Hospital NHS Trust	Network Board	There has been no wide agreement reached on the pharmacy fees for set up of non-commercial trials – agreement of standard rates for the set up of non-commercial trials would really help assist set up. We have had delays due to difficulties agreeing costs. . If UKCRN agreed to pay these standard fees, set up would be made far easier.
C. Standard Fees for Costing Trials	North Middlesex University Hospital	Pharmacy	Recently however there were some problems: - Trials sometimes delayed because pharmacist not involved in trial set up and only made aware of trial when first patient turns up - Trials sometimes delayed because lack of pharmacy resource to support trial - Impact on Pharmacy not fully taken into account by researchers. Often only consider resource for research - Pharmacy must be involved in the early stages of any trial being agreed before ethics approval -Education and training researchers - liaise / get agreement with pharmacy about impact etc.
C. Standard Fees for Costing Trials	Whittington	CIs/PIs	Adequate funding based on study activity. Clearly identified, adequate funding and appropriate internal cross-charge mechanism.
D. Transparent and Quick Access to Funding for Support Costs	East London NHS Foundation Trust	Network Board	Easier access to funding for additional treatment costs which are currently meant to be funded through normal commissioning procedures. This can be both extremely time consuming and unrealistic. Thus, a central mechanism to reach a quick decision as to whether funding for additional treatment costs will be available would simplify matters enormously.
D. Transparent and Quick Access to Funding for Support Costs	UCLH	CIs/PIs	Treatment costs for intervention studies are difficult to find and it is difficult to identify clearly who is responsible for meeting them.

General Barrier Identified	Trust	Group	Specific Comments
D. Transparent and Quick Access to Funding for Support Costs	UCLH	CIs/PIs	The central fund for treatment costs for studies evaluating interventions needs to be re-established and accessible for funded studies.
D. Transparent and Quick Access to Funding for Support Costs	Whittington	CIs/PIs	As a clinical studies unit we are unsure of the support available from the CLRN. More clarity of what support the CRN can offer is needed.
E. Health Economist services needed	Royal National Orthopaedic	CIs/PIs	The services of a Health Economist linked to our Hospital would be important to enable grant applications to the NIHR in the first place. Provide a training programme to produce more Health Economists perhaps as a central resource by the CLRN
F. Statistical Support Needed	UCLH Homerton BLT	CIs/PIs Network Board CIs/PIs	Suggested change in key service support in clinical research: Statistical Support The support with statistics is useful. Lack of trial statistician
G. Pharmacy Access and Funding	Barts and The London	TCRN	Pharmacists need to be trained more readily on research. What tends to happen is that they perceive research patients as wanting to “jump the queue”. However for a research patient who may already been waiting and participating in a clinical trial sometimes for 2 hours it is difficult to ask research patients to wait for their medication. We have tried to get around this in the past by phoning the department and faxing the prescription but without dedicated staff to handle the research prescriptions this did not improve the wait times. Many of the prescriptions are also not known to the general pharmacists and so delays are inevitable as they find out the correct procedure. Cultural change needs to take place where pharmacists can begin to appreciate the varied amount of research being undertaken at our BLT trust and the revenue that this in fact brings to their department. Therefore research needs to be on the agenda at all pharmacist meetings.

General Barrier Identified	Trust	Group	Specific Comments
G. Pharmacy Access and Funding	Barts and The London	CIs/PIs	<p>High cost of dispensing of drug. No storage facilities available. Unable to prepare drug or even mixing drugs. One member of staff responsible for a large number of studies. Clinical trials are not considered of high priority. Investigator led studies given less importance. Cytotoxics prepared off site at Barts Hospital, unable to transport drugs across to the Royal London in a timely fashion. Cost of courier restrictive. PHARMACY:Increase the number of staff in pharmacy. Employ staff solely for commercial/investigator studies and not have them covering NHS pharmacy. Have a separate pharmacy location for commercial/investigator studies therefore not sharing facilities with NHS pharmacy. Pharmacy located in the Outpatient's department.</p>
G. Pharmacy Access and Funding	Barts and The London	TCRN	<p>Newham University Hospital NHS Trust have informed the NELCRN that they are unable to open CTIMPs due to capacity issues within their pharmacy. In the last week, Dr Chris Gallagher has persuaded them of the cost effectiveness (due to free drug provided from the sponsor) of attempting to open two specific CTIMPs in Breast Cancer. Even in this limited case, these two studies have already been delayed by more than 12 months.</p> <p>The North East London Research Network is currently funding two 0.5 W.T.E pharmacy clinical trials coordinators, one based at BHR NHS Trust and one at BLT NHS Trust. The Network will not be able to extend this funding into the next FY and is currently accruing a potentially unsupportable overspend in this FY as a result of these posts. The inability of Newham to support CTIMPs without such support provides a worrying model for what may happen at BLT and BHR if these two posts cannot be replaced.</p> <p>The allocation of resources required by pharmacy to support CTIMPs must be recognised and supported on an activity based model. Specifically, financial allocation must be made to ensure that current provision is reprovided at the earliest opportunity.</p>

General Barrier Identified	Trust	Group	Specific Comments
G. Pharmacy Access and Funding	Barts and The London	TCRN	Difficulty opening a number of Cancer studies have been encountered at Newham, Whipps Cross and Queen's Hospital because of lack of access of pharmacy staff. There have been less frequent occurrences at BLT. The allocation of resources required by pharmacy to support CTIMPs must be recognised and supported on an activity based model. Specifically, financial allocation must be made to ensure that current provision is reprovided at the earliest opportunity.
G. Pharmacy Access and Funding	Barts and The London	R&D Forum	Our Pharmacy is resourced, as is the case with many other Trusts, according to specific parameters on service provision. R&D establishments at BLT were determined by allocations from our R&D levy, which was £33m and has now disappeared. There is currently no mechanism for determining how we provide clinical trials pharmacy services to NIHR or network studies. This means that we are unable to increase our staff numbers to cope with an increase in Clinical Trials Pharmacists to cover the exacting requirements of these trials. This may lead to restrictions or limitations to the type of trials we will be able, in future to accommodate. Network support is required in this area.
G. Pharmacy Access and Funding	Barts and The London	Network Board	CLRN should provide funding to offset loss of R&D levy funding for a full time clinical trials Pharmacist to work under the direction of the Trust's current Senior Clinical Trials Pharmacist. There is nothing in place to offset the loss of R&D levy, to establish how clinical trials pharmacy services are resourced re NIHR portfolio studies. Loss of resource (specifically staff) could lead to restrictions or limitations to the type of trials we will be able to accommodate.
G. Pharmacy Access and Funding	GOSH	TCRN	A number of trials in children involve "specials", that is medicines made by a company without an IMP license. This occurs 2-3 times per year; Many trials in children require specific formulations and often placebo versions of that formulation. Most PI/CIs underestimate the time and issues related to the provision of medicines in trials.
G. Pharmacy Access and Funding	GOSH	CI/PIs	Problems in obtaining pharmacy support for a pilot trial of inositol in pregnancy.
G. Pharmacy Access and Funding	GOSH	CI/PIs	Considerable problems with agreement to supply etc drugs for several studies in Paed Rheumatology; Dedicated funded research links in every pharmacy dept; support with MHRA applications

General Barrier Identified	Trust	Group	Specific Comments
G. Pharmacy Access and Funding	Moorfields	Specialty Lead	<p>There is a major problem recruiting and holding on to qualified pharmacists especially in a single specialty hospital, presumably for career progression reasons. Although we have a dedicated Clinical Trial Pharmacist, more often than not they are hijacked by the needs of the clinical services and unavailable when required.</p> <p>Since we cannot justify a wte trial pharmacist there are 2 possible solutions. Operate a ‘satellite’ pharmacy dispensing unit in the CTU and employ a p/t trial pharmacist. Alternatively the service could be contracted out to a larger unit (eg. UCLH) under a SLA.</p>
G. Pharmacy Access and Funding	Newham University Hospital NHS Trust	Pharmacy	Lack of funding for pharmacy set up, lack of capacity. Pharmacy needs adequate funding so as not to divert funds from the NHS
G. Pharmacy Access and Funding	Newham University Hospital NHS Trust	Network Board	2 recent Cancer research network trials were not opened here despite the Lead Clinician being very keen to do so – as our Pharmacy department was unable to support them. The Pharmacy office is very supportive of R & D but as they have just been through a Trust turnaround process, they are under resourced and unable to take these trials on. The R & D allocation that NUHT has received has been very small and is unable to pay for this. The Trust is trying to achieve financial balance and is no longer able to subsidise research (as it has done in the past). With the new MHRA guidelines, setting up a trial (commercial or non-commercial) is very labour intensive and set up costs are high, despite the numbers recruited The Pharmacy department at Newham still has capacity issues. For trials that involve ‘technical services’ the additional workload involved (manpower) is a problem, even if the set up fee is provided (one off set up fees still do not go far enough to address the issue of manpower).
G. Pharmacy Access and Funding	North Middlesex University Hospital	Pharmacy	<p>Cannot give specific details; recently however there were some problems:</p> <ul style="list-style-type: none"> - Trials sometimes delayed because pharmacist not involved in trial set up and only made aware of trial when first patient turns up - Trials sometimes delayed because lack of pharmacy resource to support trial - Impact on Pharmacy not fully taken into account by researchers. Often only consider resource for research - Pharmacy must be involved in the early stages of any trial being agreed before ethics approval - Education and training researchers - liaise / get agreement with pharmacy about impact etc.

General Barrier Identified	Trust	Group	Specific Comments
G. Pharmacy Access and Funding	RFH	CIs/PIs	Pharmacy in the RFH is very understaffed for time consuming clinical trials and there have been significant delays in pharmacy reviewing and approving protocols.
G. Pharmacy Access and Funding	Royal National Orthopaedic	R&D Forum	Pharmacy does not have a dedicated research pharmacist this therefore creates difficulties in reviewing protocols, dealing with the delivery and storage of research drug/consumables. There are also problem in recruiting Pharmacists in general. Moreover, we do not have sufficient temperature controlled facilities therefore necessitating in the requirement for a dedicated secure room for storage of trial drugs. The CLRN should facilitate reconfiguration of Pharmacy area to include dedicated Research Drugs.
G. Pharmacy Access and Funding	UCLH	Network Board R&D Forum	Some commercial sponsors comment that the speed of response from Pharmacy can be slow because of the lack of dedicated resources for clinical trials. This can affect the speed of turnaround of pharmacy costings and can have knock-on effects on clinical trial set-up times. It can also lead to time delays in setting up research protocols on the electronic prescribing system. Time delays in pharmacy can also occur if the trial agents require reconstitution. Additional resources are required for pharmacy, particularly: -Pharmacy production staff -Additional trial pharmacy technician support -Oncology pharmacist time to establish trial protocols on electronic prescribing system
G. Pharmacy Access and Funding	Whipps Cross	Network Board	The main issue for us is support needed for pharmacy. Trial activity for non commercial IMP studies is not covered at all and appears as if its been done as a favour which does not help us or Investigators. The type of pharmacy activities required to support for research trials are identified in the commercial costing template these activities are the same for non commercial studies but are not currently not covered.
G. Pharmacy Access and Funding	Whipps Cross	Specialty Lead	Pharmacy costs and expertise can be a challenge. Find dedicated pharmacy individuals who are happy and competent in the ways of research
G. Pharmacy Access and Funding	Whipps Cross University Hospital NHS Trust	Pharmacy	Lack of resource within the Pharmacy and -Lack of support from the Trust to address this issue. -Money generated by Pharmacy from commercial trials is poor and not even enough to fund pharmacy establishment.

General Barrier Identified	Trust	Group	Specific Comments
H. Imaging Access and Support	Barts and The London	Specialty Lead	Problems with imaging in VTE studies, for example, has been a major issue – radiology departments not being prepared to take on additional imaging solely for clinical trials and/or charging prohibitively – a number of Trusts across NE Thames. Allocation of resource, staff and / time to provide ‘slack’ in service to allow research investigations to be accounted for.
H. Imaging Access and Support	Barts and The London	CIs/PIs	Inability to access advanced cardiac imaging to use as surrogate endpoint markers in clinical trials
H. Imaging Access and Support	Barts and The London	Network Board	A new "Imaging Co-ordinator" post would be of great help here. Best use is not being made of resources: there is no-one whose job it is specifically to maximise use of the equipment and ensure that correct scans are undertaken, both in terms of patient healthcare and research work. Such a post should keep a record of work undertaken, ensure equipment is made best use of and so ensure that appropriate service support costs are reclaimed, relating these back to particular studies or clinical care.
H. Imaging Access and Support	Barts and The London	TCRN	Difficulty obtaining satisfactory reading of X-rays for purposes of clinical trials and in particular when RECIST criteria are required. This is encountered in all sites within the NELCRN. Clinician time must be allocated and funded to enable RECIST measurement and reporting in line with research protocols.
H. Imaging Access and Support	Barts and The London	R&D Forum	At present the Trust is fortunate to receive support through Technology Platform funding. This, however, runs out in March 2009. After this we will rely entirely on Service Support funding via the CLRN. The current Level of Service support required for our studies that include imaging is in excess of £1m. The total service support we have received via the CLRN for 2008/9 is significantly less than this and covers more aspects of Service Support i.e. Labs. Cardiac services, Pharmacy etc. If the network and other NIHR funding sources cannot fully cover the future cost of imaging in trials, then a restriction on the number of trials we can service will almost certainly develop. This is one to flag for the future. We would ask that BLT’s Imaging requirement be assessed and costed for 2009/10 and agreement reached with the CLRN to provide adequate costs to cover this expense.
H. Imaging Access and Support	Barts and The London	Specialty Lead	Radiology at most Trusts is inevitably service driven and machine time can be a problem. More academic imaging infrastructure which we are building through NIHR
H. Imaging Access and Support	Barts and The London	Network Board	One major trial relied on MRI scans that due to capacity problems had to be undertaken off site (so increasing the costs involved). There is also an issue of having trained technicians available even where the equipment is in situ.

General Barrier Identified	Trust	Group	Specific Comments
H. Imaging Access and Support	Barts and The London	CI/PIs	We usually use a private facility (MedTel) to overcome these problems, but we are trying to use NHS facilities more often. The main problems tend to be the scheduling of appointments in a timely manner, and within the time schedule. NHS MRI facilities not always able to do scans according to the MRI protocol. Sometimes new software has to be bought in to overcome this.
H. Imaging Access and Support	GOSH	CI/PIs	- I am aware of a study that was delayed due to negotiations with the trust on DEXA scans needed for a study; Need dedicated staff to liaise between PI's and imaging dept
H. Imaging Access and Support	GOSH	CI/PIs	- The Imaging department in high demand for clinical use as well as many research projects in hospital. Naturally the clinical work is prioritized as it is part of the patient's standard care whilst its use in the research project is novel and 'non-essential'. Getting imaging time can be difficult as a result. We have two standard slots a week for imaging our participants for this research, which often means participants coming to the hospital specifically for this study. As they are children parents are reluctant to take more of their time from school etc for 'non-essential' hospital time Ideally we would have greater and more flexible access to imaging to so that participation could be coordinated with their standard clinical visits, which could make recruitment easier...
H. Imaging Access and Support	GOSH	CI/PIs	It is difficult to get access to sedation nurses which are required for imaging children under the age of 6; The CLRN should employ sedation nurses that have a defined role in sedating children for research
H. Imaging Access and Support	Moorfields	CI/PIs	More funding for staff in clinical research imaging at Moorfields. Though no projects have been prevented or delayed the Glaucoma Research Unit, where most of the imaging is done, is very hard pressed.
H. Imaging Access and Support	Moorfields	R&D Forum	Imaging is a very significant part of ophthalmic research and we already employ technicians and a photographer dedicated to trials. A problem arises with our Medical Illustration Department particularly in terms of absence cover, out-of-hours service and imaging equipment capacity. This could not be sub-contracted out and funding is required for an additional technician, photographer as well as purchase of equipment to develop capacity.

General Barrier Identified	Trust	Group	Specific Comments
H. Imaging Access and Support	Newham University Hospital NHS Trust	Network Board	We have had delays due to difficulties agreeing costs. We continue to have problems on a project buy project basis because although we can agree reasonable costs with the radiology department we cannot promise them that they will get all these costs back exactly from the CLRN. The radiology department have agreed to use the fees provided for commercial research studies as part of the new national commercial research agreement. It would be good if these fees were more widely recognised in central and north east London as applying to both commercial and non-commercial research and if the CLRN could use these fees to re-imburse trials (until the pot runs out – when a case would have to be made to the UKCRN for more funding). If UKCRN agreed to pay these standard fees, set up would be made far easier. The need for local MPE (medical physics expert) review for studies involving ionising radiation has also made the approval process a bit longer.
H. Imaging Access and Support	North Middlesex University Hospital	CI/PIs	The RECIST Criteria for Metastatic cancer Studies including for network are measurements made preferably by the Radiologists characterising treatment response by imaging. Its hard to get the Radiologists to give any time as they have to compare to previous scans for each target Lesion. Currently our hard pressed PIs do this. Also negotiating extra scans where the protocol dictates and sticking to timing within the Protocols. Here at NMH they are great in CT and will always accommodate our requests but it should be recognised that this is sometimes over and above normal care so potential capacity issues”
H. Imaging Access and Support	RFH	CI/PIs	At the RFH, we have significant delays in getting scans reported in a timely fashion and to an acceptable level. There is no funding provided to the imaging department
H. Imaging Access and Support	Royal Free Hampstead NHS Trust	Network Board	Ability to undertake DaTscans for patients in Parkinson’s disease research projects (RFH). This has been limited only by resources available.
H. Imaging Access and Support	UCLH	CI/PIs	Inability to obtain MRI scans/fMRI in children with auditory processing disorders because difficult to obtain grant funding for auditory research.
H. Imaging Access and Support	UCLH	CI/PIs	Access to the MRI scanners at UCLH.

General Barrier Identified	Trust	Group	Specific Comments
H. Imaging Access and Support	UCLH	TCRN	<p>North Middlesex Hospitals NHS Trust radiology department would not sign off the ethics approval for CLOTS trial without prior guarantees of funding for the leg doppler scans. The trial requires 2 scans per patient and the Trust were asking £80 per scan (above the national average of £40-£60). The R&D department were reluctant to take on any more service support costs using transitional funding. This trial does not come with funding for scans. Experience from other Trusts suggests that this trial could recruit at least 1-2 patients per week from North Middlesex.</p> <p>UCLH radiology department have capped the number of patients we can recruit into CLOTS at 1-2 per week citing lack of capacity for dopplers.</p> <p>The imaging problems in all out Trusts are not purely related to finance but is as a result of a lack of time for radiology staff to carry out research. The payments are often to reimburse staff for overtime related to research.</p>
H. Imaging Access and Support	UCLH	Network Board R&D Forum	<p>The additional reporting requirements for research scans can cause bottlenecks, particularly as there are considerable clinical service demands on the Radiology Department, notably the 18 week target. A specific example is RECIST reporting, which is now essential in a large number of cancer studies. RECIST reporting of scans does not happen at all across the NLCRN due to the additional time required by Consultant Radiologists to report at this level.</p> <p>The time required to complete and monitor ARSAC licences is an issue in several Trusts. Currently Nuclear Medicine will not support ARSAC applications for non-commercial trials as there are no funding sources to cover the application.</p> <p>Clearly identifiable funding flows for clinical service support are required to help Imaging Departments balance up the twin priorities of clinical service and research. Specifically, additional resources are required for Imaging Departments to support the additional authorisation and reporting requirements of many research procedures. This may take the form of additional dedicated research PAs for Imaging.</p>
H. Imaging Access and Support	UCLH	CIs/PIs	<p>Not enough cardiac MRI slots available at UCLH. Need to transport our patients to Great Ormond Street Hospital for MRI scans Increase MRI slots at UCLH</p>

General Barrier Identified	Trust	Group	Specific Comments
H. Imaging Access and Support	UCLH	CIs/PIs	Access to academic imaging is at the discretion of a small group of senior UCL academics, it cannot be purchased and organised independently of them, as they have to be interested and involved in the imaging to agree to give access.
H. Imaging Access and Support	Whipps Cross	Network Board	Some studies have imaging described in the protocol, which is not done as part of routine care at this site. That cost must be covered to comply with the protocol. Fully cover the cost of each procedure no matter where it is done. Transparency needed in payments.
H. Imaging Access and Support	Whipps Cross	Specialty Lead	Costs/Access MRI scans – generic problem
I. Research Nurses	Barts and The London	TCRN	Research Nurse support is a major problem. The Network currently maintains the lowest complement of NCRN recruiting Research Nurses of any London Network, largely as a result of the comparatively small amount of Trust R&D funding historically committed. The NCRN was seen by some Trusts, it would appear, as sufficient cover for Cancer, unlike in the other Networks where it was clearly seen as an additional source of Research Nurse support to that already provided by the R&D levy. Even in BHR, where R&D funds were available for Research Nurse support, the introduction of BRfBH has led to an ongoing struggle to attempt to maintain the complement of Nurses provided. Unless re-provision of this Nursing cover can be made, to support recruitment and associated performance related income, Cancer research in the Network will atrophy.
I. Research Nurses	GOSH	CIs/PIs	On the ground dedicated staff at every level- eg research nurses (along the lines of the model used by the MCRN)
I. Research Nurses	GOSH	CIs/PIs	- It is difficult to get access to sedation nurses which are required for imaging children under the age of 6. Need to employ sedation nurses that have a defined role in sedating children for research
I. Research Nurses	Homerton	Network Board	Nursing support to recruit patients to portfolio studies
I. Research Nurses	Newham University Hospital NHS Trust	Network Board	We are also lacking cancer research nurse support which has meant that there is near to no recruitment here in cancer trials at the moment – although this is a cancer research network issue.
I. Research Nurses	Royal Free Hampstead NHS Trust	Network Board	Additional nurse or research officer e.g. psychologist help in recruitment and organisation.

General Barrier Identified	Trust	Group	Specific Comments
I. Research Nurses	Royal National Orthopaedic	R&D Forum	Need to ensure that the services of Research Nurses are available to every Trust. This will stimulate more research activities outside the large centres (UCLH, Bart and Royal Free). The smaller sites need help to upgrade their research infrastructure.
I. Research Nurses	Tower Hamlets	CIs/PIs	Ring fenced funding and time for nursing research development over a period of at least 5 years.
I. Research Nurses	Whipps Cross	Network Board	What ought to be considered is the critical lack of quality research nurses. There should be some push nationally and locally to address this either through specific training/buddy schemes/ some form of accreditation etc. The CLRN should be considering this It could be great to have a pool of nurses experienced clinically in the patch who could do a couple of days a week on a study on a secondment type basis this was felt to be a definite way to unblock the blocks!
J. IT system and access across Trusts	Barts and The London	CIs/PIs	Due to my clinical service being in a different NHS trust (East London Foundation Trust), to BLT, my team cannot access laboratory results by computer, and hard copy supply is variable. This has caused considerable delay to recruiting participants to the PACE trial
J. IT system and access across Trusts	GOSH	CIs/PIs	Better IT communication better NHS and research institutes, but again may be local issue
J. IT system and access across Trusts	Royal National Orthopaedic	R&D Forum	The Trust is in the process of establishing a Trauma Research Network with Barnet & Chase Farm Hospital. Patients will be reviewed at RNOH, however we do not have access to their PACS system to review and report on x-ray images. CLRN to fund the development of software to link with the PACS systems at other hospitals.
K Lab Test Costs	Barts and The London	Specialty Lead	Clinical biochemistry and haematology are approachable and helpful but are expensive, in some situations prohibitively so. For example for one of our projects we are sending our samples to another Trust where the analysis is significantly cheaper. This has involved obtaining approval under the human tissue act. Laboratory tests should be cheaper.
K Lab Test Costs	GOSH	CIs/PIs	Laboratory services always a challenge as I am often dealing with ad hoc samples so have to send out to specialist labs on a small scale; I've not undertaken clinical trials reliant on lab based services

General Barrier Identified	Trust	Group	Specific Comments
L. Local Trust Issue: Radiotherapy and QA requirements	Barts and The London	TCRN	The inability of R/T departments to meet the QA requirements of studies has caused severe delays to study initiation. This has now led to two commercial studies being potentially withdrawn completely from Barts and what amounts to a complete block to new R/T studies opening. The two main reasons for this difficulty in meeting QA requirements seem to be a pressure on staff time and a shortage of machine time to run the QA procedures. Adequate funding needs to be identified to allow QA procedures to be conducted, if necessary on an out of hours basis.
L. Local Trust Issue: Research Facilities	Moorfields	R&D Forum	Treatment / clean room. Increasingly many trials require access to dedicated treatment rooms and capacity is a major issue for us. We need a dedicated 'research' facility that could be used by services when capacity allowed rather than the other way around. Electrophysiology / diagnostics – capacity also an issue that could be addressed by a dedicated research technician. Eye bank – availability of tissue and the need for a dedicated person to retrieve donated tissue.
L. Local Trust Issue: Advocacy Support	Newham University Hospital NHS Trust	Network Board	There is often a lack of appreciation of language barriers and the need for Advocacy support services and the costs associated with this.
L. Local Trust Issue: Histopathology	UCLH	Network Board R&D Forum	Providing histopathology specimens for the translational elements of protocols and securing agreement on these arrangements can delay some protocols. There are also delays where more complex sets of tests are required. Resources for research histopathology technician support with responsibility for processing, collecting and dispatching specimens for trial subjects. Daycare facilities: There are insufficient day care facilities for recruiting patients for studies and carrying out follow-up visits. Dedicated clinical research facilities required.

General Barrier Identified	Trust	Group	Specific Comments
L. Local Trust Issue: Grade of Tests	Moorfields	R&D Forum	There is a particular problem associated with research in the field of Inherited Eye Disease and the collection / analysis of genetic material. This focuses on the accreditation of laboratories to give results that affect clinical management of patients. 'Clinical grade' laboratory services are much more expensive than 'research grade' services. The distinction between service and research in our Inherited Eye Disease clinics is extremely difficult, if not impossible to make as all families are recruited to the studies but receiving a clinical service at the same time. I would like to make 'research grade' analysis the default position and have 'clinical grade' analysis only available by specific request that might be justified clinically (usually for genetic counselling purposes). If extra funding were available for research grade analysis this would be a great incentive for them to use this first.

APPENDIX 3

Research Management and Governance Provision From the CLRN (Total Expenditure/annum £677,193)

Trust or Consortium Lead	RM&G Provision	Band	FTEs/ Trust	Total RM&G Funding	Total RM&G Funding per Consortium per annum
Barts and the London NHS Trust	R&D Facilitator	NHS 4	1.0	£28,199	
	RM&G Officer	NHS 6	1.0	£39,930	
	RM&G Senior Manager	NHS 8a	1.0	£55,362	£123,491
Great Ormond Street Hospital	R&D Facilitator	NHS 4	0.5	£14,100	
	RM&G Manager	NHS 7	1.0	£47,606	£61,706
Homerton University Hospital NHS Foundation Trust	R&D Facilitator	NHS 4	0.5	£14,100	
	RM&G Manager	NHS 7	1.0	£47,606	£61,706
East London NHS Foundation Trust	R&D Facilitator	NHS 4	0.5	£14,100	
	RM&G Officer	NHS 6	1.0	£39,930	£54,030
Moorfields Eye Hospital NHS Foundation Trust	R&D Facilitator	NHS 4	0.5	£14,100	
	RM&G Manager	NHS 7	1.0	£47,606	£61,706
NELCRAD	RM&G Officer	NHS 6	0.5	£19,965	£19,965
NoCLoR	R&D Facilitator	NHS 4	0.5	£14,100	
	RM&G Officer	NHS 6	1.0	£39,930	£54,030
University College London Hospital NHS Foundation Trust	R&D Facilitator	NHS 4	1.5	£42,299	
	RM&G Manager	NHS 7	1.0	£47,606	
	RM&G Officer	NHS 6	1.0	£39,930	
	RM&G Senior Manager	NHS 8a	1.0	£55,362	
	RM&G Senior Manager	NHS 8a	1.0	£55,362	£240,559

RM&G Consortia (lead organisation in bold where applicable) - the allocations above were based on the levels of UKCRN portfolio activity

1. UCL Consortium: **UCLH**, Royal Free, North Middlesex University Hospital, Whittington, Royal National Orthopaedic Hospital.
2. Barts and The London
3. NoCLoR: Camden PCT, Islington PCT, Barnet PCT, Enfield PCT, Haringey TPCT, Camden & Islington MHT, Barnet, Enfield & Haringey MHT
4. Moorfields
5. GOSH
6. Mental Health: **East London Foundation Trust**, North East London MHT, Tavistock & Portman
7. Homerton Consortium: **Homerton**, Whipps Cross, Newham University Hospital
8. NELCRAD: **Tower Hamlets**, Waltham Forrester PCT, City & Hackney PCT, Barking & Dagenham PCT, Newham PCT, Redbridge PCT
9. Central provision by the CLRN: Barking, Havering and Redbridge, Barnet & Chase Farm, Havering PCT
10. London Ambulance has selected to be served by the North West London CLRN to which this CLRN contributes an equal proportion for RM&G provision

APPENDIX 4
Adopted Costing Tarrifs for Non-Commercial Studies in
the Central and East London CLRN

A. Tariff of Charges for NHS Pharmacy Support of Clinical Trials 1.4.08 to 31.3.09

The recommendations are endorsed by trust Chief Pharmacists for trials conducted within NHS Trusts in London and are reviewed annually. Charges should be applied at the rate current at the time of invoicing.

Procedure	Details	Cost
1 Administration & Set Up (To include electronic software support, monitoring visits, close down and organising of trial).	Oral or injectable medicines issued by dispensary staff only	£ 975
	Oral and Injectable (issue involves dispensary and technical services staff)	£2250
	Issue by Technical Services staff only	£1420
	Extra storage space (per shelf)	£90
	Fridge storage	£150
	Receipt of goods (each delivery)	£15.50
	Controlled drugs	25% surcharge
2 Dispensing, including returns/compliance check	For each patient visit	£36
	Controlled drugs	25% surcharge
3 Re-labelling	Per episode	£20
4 From Technical Support/Services	Per item dispensed	£57
	Controlled drugs	25% surcharge
	Additional charges may be negotiated for trials involving novel or very complex manipulative procedures	
5 Other Charges	Extended working hours (per half hour)	£72
	Emergency Out of Hours call out to Emergency On-call Pharmacist for e.g. code break (per hour)	£139
	Participation in GMP/GCP Auditing of Trial (per hour)	Current hourly rate for staff

Procedure	Details	Cost
6 Disposal of any trial-related waste medicines	Per Burn Bin Controlled drugs	£40 (£60 minimum charge) 25% surcharge
7 Reviewing Archived Records		£36
8 Faxing Documentation	Per Fax	£1

B. Tariff of Charges for Other NHS Service Support

Investigation	Description	Price (£)
24 hour Cardio memo/ cardio diary	Electrocardiographic monitoring for 24 hours by continuous computerized monitoring and non-continuous recording, and real-time data analysis utilizing a device capable of producing intermittent full-sized waveform tracings, possibly patient activated; includes monitoring and real-time data analysis with report, physician review and interpretation	109.44
24 hour Holter monitoring with interpretation	Electrocardiographic monitoring for 24 hours by continuous original ECG waveform recording and storage, holter monitoring: Includes hook-up, recording, scanning analysis with report, physician review and interpretation, each 24 hours	91.2
24 hour Holter monitoring without interpretation	Electrocardiographic monitoring for 24 hours by continuous original ECG waveform recording and storage, holter monitoring; recording which includes hook-up, recording, and disconnection, each 24 hours	37.44
Biochemistry A	ALT, Amylase, Bone profile, Chloride, Creatinine Clearance, CRP, Creatinine Kinase, Glucose, Iron, Magnesium, Oestradiol, Osmolality, Paraprotein measurement, Progesterone, PSA, T3, T4, Testosterone, Total T3, Transferrin/TIBC, Tumour marker, U&E, Uric Acid, Urinalysis	6.752
Biochemistry B	Bicarbonate (Total CO2), CA125, Ca15-3, CA19-9, CEA, Cholesterol, Creatinine Clearance, CRP, Direct Bilirubin, Electrophoresis (EPS), Faecal occult blood,	9.36

Investigation	Description	Price (£)
	Free T4, GH, hCG, HDL-Cholesterol, Human Growth Hormone (HGH), LFT, LH, T3, T4, TSH, UFC	
Biochemistry basic metabolic panel, SMAC	Biochemistry basic metabolic panel, SMAC: Includes Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Urea, Nitrogen (BUN),	14.4
Biochemistry C	beta 2 microglobulin, BNP, EPS and paraprotein, FSH, IGF-1, Immunofixation - serum or urine, prolactin, TGB and free T4, Thyroglobulin/TG auto Ab, Transferrin/TIBC, Triglyceride, Troponin I, Troponin T, TSH	13.288
Biochemistry comprehensive metabolic panel, SMAC	Biochemistry comprehensive metabolic panel, SMAC: Includes Albumin, Bilirubin, total (Calcium, Carbon Dioxide (bicarbonate), Chloride, Creatinine, Glucose, Alkaline Phosphatase, Potassium, Protein, total (Sodium, Alanine Amino Transferase, (ALT) (SGPT), Aspartate Amino Transferase, (AST) (SGOT), Urea Nitrogen (BUN)	19.2
Biochemistry function panel	Hepatic Biochemistry Hepatic function panel: Includes Albumin, Bilirubin, Phosphatase, Alkaline, Protein, total, Transferase, Alanine amino Transferase (ALT) (SGPT), Aspartate amino transferase (AST) (SGOT),	9.6
Biochemistry Lipid Panel	Biochemistry Lipid Panel I: Includes Total Cholesterol, Lipoprotein, high density cholesterol (HDL cholesterol), Triglycerides,	9.6
Biopsy of Bone marrow	Biopsy of Bone marrow; by trocar or needle: Includes preoperative care (including a medical history and physical examination), anesthesia and typical postoperative care and reporting	48
Biopsy of muscle	Biopsy of muscle; deep: Includes preoperative care (including a medical history and physical examination), anesthesia and typical postoperative care.	177.76
Biopsy of skin	Biopsy of skin, subcutaneous tissue and/or mucous membrane, skin tumor: Includes preoperative care (including a medical history and physical examination), anesthesia and typical postoperative care.	46.08
Blood count	Blood count; haemogram and platelet count, automated and automated complete differential WBC count (CBC), haemogram, haematology	9.6

Investigation	Description	Price (£)
Blood count	Blood count; haemogram and platelet count, automated, and manual differential WBC count (CBC)	8.64
Bone and/or joint imaging	Bone and/or joint imaging, bone scan, bone scintigraphy, whole body: Includes the technical and professional components (reading)	177.6
Cardiac Troponin	Troponin, quantitative; Cardiac Troponin I (cTnI), Cardiac Troponin T (cTnT)	17.28
Cat, CT Scan) with contrast	Computerized axial tomography, (Cat Scan) (CT Scan); with contrast material. Includes the technical and professional components (reading) .	216.24
Cat, CT Scan) without contrast	Computerized axial tomography, (Cat Scan) (CT Scan); without contrast material. Includes the technical and professional components (reading) .	141.408
Central I.V. Line	Central I.V. Line	344.8
Copy of imaging investigation	Copy of imaging investigation on CD/DVD/Film	8
CT, CAT Scan complex with contrast	Computerized axial tomography, (Cat Scan) (CT Scan); Complex, multi area with contrast material : Includes the technical and professional components (reading) .	351.904
DEXA, BM, DXA	Dual energy x-ray absorptiometry (DEXA) (BMD) (DXA) bone density study: Includes the technical and professional components (reading)	72.96
ECG no report	Electrocardiogram, routine 12 lead ECG, Tracing only	14.4
ECG with report	Electrocardiogram, routine 12 lead ECG includes tracing, interpretation and report	24
Endoscopy - no biopsy	Upper gastrointestinal endoscopy diagnostic including oesophagus, stomach, and either the duodenum and/or jejunum as appropriate	228.48
Endoscopy - simple - no biopsy	Upper gastrointestinal endoscopy including oesophagus, stomach, and either the duodenum and/or jejunum as appropriate; simple primary examination	156.48
Endoscopy with biopsy	Upper gastrointestinal endoscopy including esophagus, oesophagus, stomach, and either the duodenum and/or jejunum as appropriate; with biopsy	336
Glucose test - finger prick	Glucose; blood, serum, reagent strip, finger stick test	3.84
GTT	Glucose Tolerance Test (GTT)	7.68

Investigation	Description	Price (£)
GTT, OGTT	Glucose tolerance test (GTT) (OGTT)	7.68
Haematology A	D Dimer, aPTT, Coombs test, Differential (manual), ESR, FBC, Fibrinogen, Iron stain, Prothrombin Time, reticulocyte, TCT	6.28
Haematology B	CD20, CD4, Clotting screen for line insertion, T Cell Count, TTC Code: Prothrombin time (PT) and Thromboplastin time, partial (PTT) (aPTT) combined	15.856
Hepatitis C antibody	Hepatitis C antibody (HCVab) (anti-HCV)	19.2
INR	International Normalised Ratio (INR)	8.64
IVUS	Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention (IVUS)	161.056
Microbiology A	Microbiology A, Chlamydia serology, Genital swab, Hep B vaccine Ab status, Legionella Ab, Rubella clinical, serology non-viral (syphilis), throat swab, Toxoplasma Ab, Urine culture (incl germ tube test), Viral Ab screen	8.744
Microbiology B	ASO, Cl. difficile, Hep A, Hep C screen, HIV, other bacteriology (incl mycology), Wound swab	10.072
Microbiology C	Antibiotic assay, Blood culture, Chlamydia detection, Faeces, Sputum, TB Culture	14.256
MRI more than one area with contrast	Magnetic resonance imaging, (MRI); with contrast material(s) more than one area (eg chest & abdo, abdo & pelvis). Includes the technical and professional components (reading)	534.424
MRI single area with contrast	Magnetic resonance imaging, (MRI); with contrast material(s) single area (eg extremities, joints, chest, brain, orbit, face). Includes the technical and professional components (reading)	412.48
MRI single area, no contrast	Magnetic resonance imaging (MRI); single area eg extremities, joints, chest, brain without contrast material(s): Includes the technical and professional components (reading)	340
MUGA RNV	Cardiac blood pool imaging, radionuclide ventriculography, left ventricular ejection fraction (LVEF) (RNV) (MUGA), single study at rest or stress: Includes the technical and professional components (reading)	140.68
Pregnancy test (blood)	Serum pregnancy, chorionic gonadotropin (HCG) (BetahCG); quantitative	9.6
Pregnancy test (urine)	Urine pregnancy, chorionic gonadotropin (hCG) (BetahCG); qualitative	7.376

Investigation	Description	Price (£)
Thyroid function test	Thyroid panel, thyroid function tests. Includes triiodothyronine, T3 thyroxine, T4, thyroid stimulating hormone, TSH	26.88
Thyroid function tests	Biochemistry Thyroid panel, thyroid function tests - Includes triiodothyronine(T3), thyroxine (T4), thyroid stimulating hormone (TSH)	26.88
Transthoracic ECHO	Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording	154.56
UDS	Urine Drug screen (UDS)	28.8
Ultrasound 1 with report	Ultrasound, (echography) (uls); B-scan: chest, extremities, non-vascular, soft tissues (head & neck). Includes the technical and professional components (reading)	52.8
Ultrasound 2 with report	Ultrasound, retroperitoneal (eg, renal, aorta, kidney, spleen, gallbladder) (echography) (uls); peripheral vascular system real time with image documentation. Includes the technical and professional components (reading).	76.8
Ultrasound 3 with report	Ultrasound, transrectal, prostate (echography) (uls). Includes the technical and professional components (reading)	115.2
Ultrasound 4 with report	Ultrasound, transvaginal, vaginal probe ultrasonography (TVUS) (echography) (uls): Includes the technical and professional components (reading)	52.8
Urinalysis	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose hemoglobin, ketones, leukocytes, nitrite gravity, urobilinogen (urine analysis) (UA); without microscopy	5.76
X-ray mutiple views with report	Radiologic examination, (X-Ray); multiple views. Includes the technical and professional components (reading)	28.8
X-ray single views with report	Radiologic examination, (X-Ray); single view. Includes the technical and professional components (reading)	21.12
X-ray -spine or bone with report	Radiologic examination(X-Ray); spine or bone survey. Includes the technical and professional components (reading)	48