The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

Majority of the research studies opened are for a period covering up to 3 years, but in some cases this can be longer.

*** adopted on to the National Institute for Health Research (NIHR) portfolio database**

ACTIVE RESEARCH STUDIES – 1 April 2012 – 30 September 2012

Title	Summary	Date of Trust approval	Estimated recruitment	Total recruitment as of September 2012
ACCIDENT AND EMERGENCY				
* The AHEAD study: Managing anticoagulated patients who suffer head injury.	Whilst it is recognised that these patients are at increased risk of suffering from associated bleeding, there is currently very little research that supports the most appropriate way to manage them, and better evidence and guidance is needed for medical staff both in the UK and internationally.	12/09/2011	300 participants total	65
CRITICAL CARE				
* PROMISE: Protocolised Management in Sepsis: A multicentre, randomised controlled trial of the clinical and cost effectiveness of early goal directed protocolised resuscitation for emerging septic shock.	The trial aims are to evaluate the clinical and cost effectiveness of an early goal directed resuscitation protocol for patients admitted to the Emergency Department with severe sepsis or septic shock.	20/12/2010	14 participants per year	39
* OPTIMISE:Optimisation of Perioperative Cardiovascular Management to Improve Surgical Outcome	The aim of this study is to assess the effect of a perioperative haemodynamic optimisation protocol on complication rates following after major gastrointestinal surgery when compared to conventional medical care.	31/03/2011	25-50 participants total	59
* CALORIES: Clinical and cost effectiveness of early parenteral compared with early enteral nutritional support in critically ill patients.	This is a clinical trial comparing two methods of feeding critically ill patients, following admission to the critical care unit.	10/01/2012	100 participants total	16
DERMATOLOGY				
* BADBIR: British Association of Dermatologists' Biological Interventions Register	The purpose of the research study is to assess whether the new biological treatments used in the treatment of psoriasis have any side effects when used long-term in real life not revealed during shorter- term clinical trials. These side effects, if any, will be compared to those seen with established treatments such as ciclosporin, methotrexate and PUVA. The study therefore involves following up patients taking a number of different drugs for psoriasis and assessing the frequency that long-term side effects occur.	07/03/2011	20 participants in total – biologic 100 participants in total – conventional therapy	14

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ENT				
* A Study of Medical, Psychological and Socio−economic Factors Influencing the Severity of Chronic Rhinosinusitis.	To date no large scale UK study has been undertaken, especially not across a wide region of the population. By obtaining information on social and economic factors and other illness in these patients that may influence this disease, specific groups in the community may be identified that will help doctors in treating these patients both in the community and in hospitals.	17/02/2012	120 participants total	0
GASTROENTEROLOGY				
* PBC: Investigation of the genetic and molecular pathogenesis of primary biliary cirrhosis	Aim of the study is to identify genetic factors which contribute to the development of primary biliary cirrhosis.	02/05/2008	25 participants total	31
* A UK collaborative study to determine the genetic basis of Primary Sclerosing Cholangitis (UK-PSC)	By studying DNA obtained from people with PSC, the study hopes to achieve a better understanding of how genetic factors contribute to this disease.	10/11/2008		**4**
HAEMATOLOGY				
* Primary Thrombocythaemia 1(amended) trial: a randomised trial to compare aspirin with hydroxyurea plus aspirin in intermediate risk Primary Thrombocythaemia. PT1	To collect long term data on patients with PT to assess best treatment and the risk of the disease associated events and transformation	30/07/1997	10 participants total	8
* United Kingdom Adult Idiopathic Thrombocytopenic Purpura (ITP) Registry: an investigation of disease progression, treatment effectiveness, and co-morbid conditions.	This study seeks to uncover information regarding the burden, natural progression, treatment effectiveness, and co−morbidities of adult ITP in the United Kingdom via establishment of a multi−centre disease registry.	02/03/2009	5-10 participants per year	13
* AML 17: A Programme of Development for the Treatment of Younger Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome	The rationale is that the expensive technology may have a high chance of predicting relapse a few weeks before it actually happens, but we do not know the clinical value of knowing that. In other words is it better to give more treatment at this point rather than dealing with the relapse if/when it happens? If the latter therapeutic is just as valuable monitoring is not needed. The trial aims to answer this by inviting patients to be randomised to be monitored or not to be monitored	19/05/2009	3 participants per year	11
* National Study of Hodgkin's Lymphoma Genetics – NSHLG	Hodgkin's lymphoma (HL) affects ~2−3 per 100,000 individuals in the United Kingdom each year and is more common in males than females, exhibiting a bimodal distribution with one peak at 25 years and a secondary peak in later life. This study aims to collect blood samples from a large series of patients with Hodgkin's lymphoma and in turn this resource will be used to help identify genetic susceptibility variants for Hodgkin lymphoma.	11/06/2010	15 participants per year	10

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HAEMATOLOGY				
* PACIFICO: Purine−Alkylator Combination In Follicular lymphoma Immuno−Chemotherapy for Older patients: a phase III comparison of first line R−CVP versus R−FC	The primary aim of the trial will be to compare two different induction regimens in order to determine which achieves the best balance between efficacy and toxicity.	04/01/2011	5 participants per year	1
* REMODL-B: A randomised evaluation of molecular guided therapy for diffuse large Bcell lymphoma with Bortezomib	To determine whether adding bortezomib to standard combination chemotherapy and rituximab (RCHOP) can improve progression free survival. Molecular studies have	16/06/2011	15 participants per year	0
* INCITE: Case-Control Study of Intra-Cranial Haemorrhage in Thrombocytopenic Haematology Patients.	In patients with haematological malignancies, such as acute leukaemia, a rare but important complication is bleeding inside the head (intracranial haemorrhage). To advance the quality of care for haematology patients (when they are receiving intensive chemotherapy or a stem cell transplant) it is important to gain greater understanding of the risk factors for life threatening haemorrhage	13/10/2011	one case and one control over a two year period	0
* TEAMM: Tackling Early Morbidity and Mortality in myeloma: assessing the benefit of antibiotic prophylaxis and its effect on healthcare associated infections	The aim of this research trial is to find out if taking an antibiotic once a day for the first 12 weeks after diagnosis can reduce the risk of infection and reduce the chances of being admitted to hospital with a severe infection. The antibiotic being used in the trial is called levofloxacin which is taken once daily and has been used worldwide for many years.	07/06/2012	13-20 participants per year	0
HEALTH SERVICES RESEARCH				
* Investigating the performance of newly qualified doctors	Investigating the performance of newly qualified doctors with reference to patient satisfaction and patient safety	03/06/2010	Interviews 3: Focus Groups 8: Patient satisfaction questionnaire 3: Patient satisfaction questionnaire 60 Patient experience assisted questionnaire 24 Online questionnaire with F1 doctors	103

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HISTOPATHOLOGY				
* Survey of the prevalence of abnormal PrP using archived appendix tissue in the English population	These samples will be unlinked and irreversibly anonymised and tested by immunohistochemistry (IHC) for the presence of abnormal prion protein. This should enable discepancies between the current estimates for the prevalence of subclinical v CJD infection to be resolved.	30/11/2011	500 archived appendix blocks	Data supplied – waiting to hear if any archived appendix blocks are required
MICROBIOLOGY				
* CODIFI: Concordance in Diabetic Foot Infection	CODIFI is a multicentre study involving people with diabetes who have a foot ulcer with suspected infection requiring antibiotic therapy. Consenting patients will have bacteria collected from their ulcer in two ways: a swab and curettage. Results will be compared to see if swabs and curettage reported the same number and types of bacteria, and clinicians will evaluate whether patient treatment would have differed based on the results. The study sets out to provide a recommendation for the most appropriate sampling technique to be used by clinicians when collecting bacteria from a clinically infected wound.	18/07/2012	40 participants per year	0
* MRSA: A Study of Methicillin resistant Staphylococcus aureus (MRSA) Carriage and Infection in the United Kingdom	To use bacterial whole genome sequencing to look at genetic variation within HA-MRSA strains in the UK. This would enable us to determine the population genetic structure of MRSA within the UK and has the potential to revolutionise our understanding of MRSA transmission events and pathways within and between hospitals. This in turn would enable us to identify potential control points for intervention and fulfil an unmet healthcare need.	07/06/2012	5 participants/samples	1
MIDWIFERY				
* BABY MILK TRIAL: Establishing a healthy growth trajectory from birth: a randomised controlled trial of a theory based, Multicomponent intervention to reduce formula milk intake and prevent excess weight gain during infancy.	The primary objective is to evaluate the cost-effectiveness and acceptability of a complex behavioural intervention to avoid excess formula-milk intake and prevent rapid infancy weight gain among babies who are introduced to formula-milk feeds within six weeks of birth.	05/07/2011	Referral site	

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MIDWIFERY				
* Surveillance of near-miss maternal morbidity using the UK Obstetric Surveillance System (UKOSS)	The National collaboration of clinicians in the UK Obstetric surveillance system (UKOSS) provides a unique opportunity to undertake a study of near-miss severe maternal morbidity. Using UKOSS, the study aims to provide a collection of anonymous information about women who have specific near-miss morbidity in pregnancy.	16/07/2010	No consent taken – data collection only	
NEUROLOGY				
* The genetic analysis of multiple sclerosis	Primary aim of this project is to identify heritable variation conferring susceptibility to multiple sclerosis. Secondary aims include a) Identifying heritable variation influencing other disease features (such as age at onset, course, rate of progression and response to treatment etc.) b) Understanding the functional effects of genetic variation on dependent biological processes such as expression and cell functioning. This knowledge will provide invaluable insights into the pathogenesis of the disease, which in turn will suggest new opportunities for further research and perhaps ultimately even treatment.	02/11/2009	500 participants total	47
Use of the **TYM** (test your memory) test to assess cognition in patients and controls. Validation of TYM test derivatives. The use of the TYM test and its derivatives in the diagnosis and monitoring of patients with alzheimer's disease. ***THIS STUDY IS SPONSORED BY OUR TRUST***	The Test Your Memory (TYM) is a new memory test. It is a single, double-sided A4 card, which the patient completes. The test is an improvement on earlier tests because it is much quicker to administer, tests 10 different skills, and is more sensitive in detecting mild Alzheimer's disease.	09/11/2009	Approx 3000 participants total	540
* Neurological conditions and oncology: immunology and interactions	This study is designed to investigate immune responses and inflammation in neurological diseases and cancer by enabling a unique multidisciplinary approach.	25/08/2011	No figure has been quoted as it is not expected our site will recruit as the study is looking at a very rare condition.	0
* PRoBaND: Parkinson's Repository of Biosamples and Network Datasets: Prospective observational study of Parkinson's disease with repeat clinical assessment and biobanking of blood samples.	The study aims to understand better the reasons for variation in the symptoms and response to medication that Parkinson's disease patients frequently report, for example, why some patients have significant tremor while others are spared having a tremor; why some patients have involvement of memory and thinking processes while others do not; and why some patients respond extremely well to medication while others have a much poorer response.	12/12/2011	20 – 30 participants per year	2

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ONCOLOGY				
* GLACIER: A study to investigate the genetics of lobular carcinoma in situ in Europe	The project aims to identify genes which predispose to lobular carcinoma *in situ* (LCIS) and invasive lobular carcinoma (ILC). A secondary aim is to identify cases of LCIS which may progress to invasive cancer.	01/09/2008	30 – 40 participants per year	25
* National Study of Colorectal Cancer Genetics (NSCCG)	This study's aims are to determine the contribution of mutations in known genes to the incidence of colorectal cancer, and to derive a genetic model of residual familial risks and also to identify low penetrance colorectal cancer predisposition genes through association studies.	11/12/2008	Recruitment target was not requested on initial paperwork	86
* SCOT: A study of adjuvant chemotherapy in colorectal cancer by the CaCTUS and OCTO groups	This study also aims to answer an important question in clinical trial methodology, in terms of the randomisation time-point in studies where the aim is to reduce standard treatment duration. All patients entering this study will be randomised to receive either 12 weeks or 24 weeks of treatment. This randomisation can take place before any treatment starts, or after patients have completed 12 weeks of treatment (patients who are fit to continue are randomised either to stop or continue treatment for a further 12 weeks).	17/12/2008	10 participants per year	25
* ICICLE: A study to investigate the genetics of in situ carcinoma of the ductal subtype	The aim of this study is to collect a large resource with which to identify inherited variation which predisposes women to develop ductal carcinoma in situ (DCIS). The study will identify how frequent these variants are, how big an effect they have on tumour risk, and how worthwhile it would be to test for them in the clinical setting, so that those at higher risk could be identified, counselled and screened. A secondary goal of this study will be the analysis of genetic changes within DCIS with the aim of identifying those cases which are more likely to develop invasive disease.	30/12/2008	15 – 20 participants per year	37
* QUARTZ: Quality of Life After Radiotherapy & Steroids A phase III multi-centre randomised controlled trial to assess whether optimal supportive care alone (including dexamethasone) is as effective as optimal supportive care (including dexamethasone) plus whole brain radiotherapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer	The objective of this study is to establish whether the overall disadvantages of whole brain radiotherapy outweigh the advantages. Therefore we wish to compare the overall combination of quality and duration of survival in patients receiving a) steroids and optimal supportive care alone with b) steroids, optimal supportive care and radiotherapy to the whole brain.	23/02/2009	8 participants per year	15
* PERSEPHONE : Duration of Trastuzumab with Chemotherapy in women with early breast cancer: Six months versus twelve	The objective of this phase III ramdomised trial is to compare 6 months trastuzumab (Herceptin) treatment with12 months, in women with HER2 positive early breast cancer.	30/03/2009	10 participants per year	10
* UKGPCS: UK Genetic Prostate Cancer Study: Epidemiology and Molecular Genetics Studies	Aim of study is to find genes which predispose to (increase the risk of) developing prostate cancer and investigate whether such genetic changes affect the behaviour of the disease.	12/05/2009	15 participants per year	30

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ONCOLOGY				
* RAPPER: Radiogenomics: Assessment of Polymorphisms for Predicting the Effects of Radiotherapy	The RAPPER study aims to identify the genetic variations that are linked with radiotherapy side effects. It is hoped that the findings will enable us, in the future, to predict how a patient will respond to radiotherapy. This would allow dose to be increased or decreased as appropriate, to provide the best chance of controlling the tumour with the smallest risk of side effects.	26/08/2010	40 participants in first year Recruitment in following years will depend on eligibility criteria, and which other clinical trials RAPPER will be linked with.	54
* IMPORT HIGH: Randomised Trial testing Dose Escalated Intensity Modulated Radiotherapy for women treated by Breast Conservation Surgery and Appropriate Systemic Therapy for Early Breast Cancer	To test dose escalated intensity modulated radiotherapy (IMRT) after conservation surgery for women with higher than average local recurrence risk early breast cancer.	04/11/2010	8 – 10 participants per year	2
* PIVOTAL: A randomised phase II trial of Prostate and pelvIs Versus prOsTate Alone treatment for Locally advanced prostate cancer	PIVOTAL aims to find out whether toxicity levels at 18 weeks from the start of radiotherapy remain acceptable when treatment is given in multiple cancer centres across the UK.	10/01/2012	24 participants per year	2
* OPTIMA: Optimal Personalised Treatment of early breast cancer using Multiparameter Analysis.	The OPTIMA trial will evaluate technologies for use in the NHS that could offer a better selection of patients who benefit from chemotherapy. Specifically, it will examine whether theses tests provide equivalent outcomes for patients, but with lower utilisation of chemotherapy and lower total costs of care including the costs of the tests.	13/09/2012	20-25 participants per year	0
* FASTFORWARD: a randomised clinical trial testing a 1week course of curative whole breast radiotherapy against a standard 3 week schedule in terms of local cancer control and late adverse effects in women with early breast cancer	This is a trial comparing the UK standard 15 fractions of radiotherapy over three weeks with two schedules of 5 fractions delivered over a week. The aim is to find a 5 fraction schedule that is as effective and safe as the 15 fraction standard radiotherapy. The primary goal is to compare the rate of cancer recurrence within the treated areas between the three treatments. Important secondary aims are to compare the late side effects and quality of life.	13/09/2012	25 participants per year	0
PAEDIATRICS				
* International collaborative infantile spasms study (ICISS)	The aim of this study is to examine if combining hormonal treatment and vigabatrin is better at controlling infantile spasms and at helping development at 18 months of age than taking a hormonal treatment alone.	21/12/2007 Study received an extension	10 participants total	1

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PAEDIATRICS				
* A randomised controlled trial of iodide supplementation in preterm infants with follow-up at 2 years (I2S2)	This study will compare thyroid hormone levels in babies having our usual solutions and milks, with babies who are having a small amount of extra iodine added.	14/05/2010	Our Trust was classified for this study as a "continuing care site" Recruitment will have taken place at a recruiting site. It is unknown how many babies this could be.	0
* PLANET2:A randomised controlled trial to compare two different platelet count thresholds for prophylactic platelet transfusion to preterm neonates	The underlying rationale for this trial is the need to establish whether the benefits of platelet support outweigh the risks, and to define the most effective and safe strategy for platelet transfusion in preterm neonates. It has previously shown that neonatal thrombocytopenia and bleeding are common and important clinical problems for preterm neonates.	14/09/2011	6 participants per year	0
* PIPs: The probiotic Bifidobacterium breve strain BBG01 administered early to preterm infants to prevent infection, necrotising enterocolitis and death	This is a multi-centre double blind randomised controlled trial to study possible benefits of the early administration of the probiotic *Bifidobacterium breve* strain BBG (*B breve* BBG) to babies less than 31 weeks of gestation, recruited within 48 hours of birth. The primary endpoints are late onset blood stream infection diagnosed on a sample drawn after 72 hours, necrotising enterocolitis and death.	20/10/2011	As transfers are unpredictable we are unable to estimate how many participants (if any) will be admitted to our site.	0
* UKALL 2011 - United Kingdom National Randomised Trial for Children and Young Adults with Acute Lymphoblastic Leukaemia and Lymphoma 2011	The aim s to improve survival whilst reducing the burden of therapy for patients, carers and the NHS. Although over 80% of patients with these diagnoses can be cured, there are considerable short term and long term side effects associated with the treatment. The UKALL 2011 trial will build on the current best available treatment and will assess whether changes in the way some of the standard antileukaemia drugs are given can reduce the side effects associated with treatment.	15/05/2012	Our Trust will not be recruiting to this study, recruitment and consent will be obtained by the Principal treatment centre	
* An incident and high risk type 1 diabetes research cohort After Diagnosis Diabetes REsearch Support System 2 (ADDRESS2)	The study aims to establish a support system to facilitate future research into type 1 diabetes. The system will consist of a database of individuals with new−onset type 1 diabetes who will have consented to be contacted by the study team about future diabetes research.	25/06/2012	10 newly diagnosed + 10 siblings in total	0

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PAEDIATRICS				
* Diabetes Genes, Autoimmunity and Prevention (DGAP)	The study will involve asking brothers and sisters, aged 5-40, of young people with diabetes if they would take part in this study. To join the study volunteers must have a brother or sister who has type 1 diabetes who was diagnosed below the age of 16 years. Brothers and sisters share the genes inherited from the parents and it is likely that some of the brothers and sisters, although they do not have diabetes, will have the genes which could predispose to the disease. By studying siblings they will find out if there is any relationship between these genes and subtle abnormalities of the body's immune system (phenotypes).	25/06/2012	5 newly diagnosed per year and 20-50 unaffected siblings in total	Newly diagnosed – 0 Unaffected siblings - 14
East of England Paediatric Diabetes Registry	The Chancellor, Masters & Scholars of the University of Cambridge, through its paediatric department, would like to establish, on behalf of the East of England Regional Paediatric Diabetes network, a regional registry documenting the number of children & young people with all types of diabetes in the East of England and to gather data on movement of children in and out of the region, between District general Hospital and from paediatric to adult diabetes services. The information will be used to gauge the success of the network in trying to improve the care of young people with diabetes in the region, provide data for the National Diabetes Audit and researchers for academic purposes.	03/07/2012	N/A	
PHYSIOTHERAPY				
* Longitudinal cohort study of subjects referred to Physiotherapy with musculoskeletal shoulder pain to determine factors and characteristics which may predict recovery of pain and function over a 6 month period commencing at the start of physiotherapy	This study aims to identify what factors, identified during the first physiotherapy appointment are related to the resolution of shoulder pain following a course of physiotherapy treatment. That is, what factors might predict the extent to which a patient will have a good response to physiotherapy.	26/10/2011	2 participants per month	54

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