

University Hospitals of Leicester NHS Trust
Research & Development Directorate
Performance in Initiating Research

01/07/2015 to 31/06/2016

REC Number	IRAS Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met? (Yes or No)	Reasons for not achieving the 70 day benchmark									
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15/LO/1500	187068	RESP 4698	18/04/2016		No							Y			
13/WA/0205	127379	A Trial for Older Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome	12/08/2015	25/11/2015	No				Y						
15/ES/0115	183031	Open Label, Multinational, Multicenter, Real World Treatment Study of Single Agent AZD9291 for Patients with Advanced/Metastatic Epidermal Growth Factor Receptor (EGFR) T790M Mutation Positive Non Small Cell Lung Cancer (NSCLC) Who Have Received Prior Therapy with an EGFR Tyrosine Kinase Inhibitor (EGFR TKI) The ASTRIS Study	03/11/2015		No		Y								
14/EM/0172	142310	Baby-OSCAR Trial	26/10/2015		No						Y				
15/NW/0668	173723	FUTURE 5: A phase III, randomised, double-blind, placebo controlled multicentre study of subcutaneous secukinumab (150 mg and 300 mg) in prefilled syringe to demonstrate efficiency (including inhibition of structural damage), safety and tolerability up to 2	05/11/2015	14/04/2016	No							Y			
15/LO/0519	176955	A Multiarm-arm Phase 3 Randomized Placebo Controlled Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1	27/10/2015		No							Y			
14/LO/1043	137864	LEAVO	16/09/2015	02/02/2016	No						Y				
13/EE/0345	135062	Multi-arm, non-randomised, open-label phase 1B study to evaluate GSK3052230 in combination with paclitaxel and carboplatin, or docetaxel or as single agent in subjects with solid malignancies and deregulated FGF pathway signalling	17/08/2015		No				Y		Y				
13/LO/0706	119677	UK Multicentre Study of Children with Opsoclonus Myoclonus Syndrome (UMSCOM)	01/03/2016		No						Y				
13/EM/0462	136755	RomiCar: Phase I/II study to determine the MTD and overall response rate of the combination of romidepsin and carfilzomib in relapsed / refractory peripheral T-cell lymphoma	18/12/2015		No						Y				
15/NW/0492	181246	A randomized, multicenter, open label, non-inferiority, phase 3 study of ACP-196 versus Ibrutinib in previously treated subjects with high risk chronic lymphocytic leukaemia	21/03/2016	26/07/2016	No						Y				
16/EM/0007	190428	Global multicenter, open-label, randomized, event-driven, active-controlled study comparing a rivAroxaban-based	11/03/2016		No						Y				
13/EE/0397	132094	A randomised placebo-controlled trial of synchronous NIMorazole versus RADiotherapy alone in patients with locally advanced head and neck squamous cell carcinoma not suitable for synchronous chemotherapy or cetuximab - NIMRAD	29/03/2016		No						Y				
14/SC/0171	120104	A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours	15/12/2015		No						Y				

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14/LO/0203	137863	Clinical Efficacy and Mechanistic Evaluation of Aflibercept for Proliferative Diabetic Retinopathy (acronym CLARITY). A Multicentre Phase IIb Randomised Active-Controlled Clinical trial	12/08/2015	29/10/2015	No							Y			
15/LO/0718	174025	CHIL3887 mepolizumab in children from 6 to 11 years of age with severe eosinophilic asthma	18/08/2015		No						Y				
15/LO/0288	169194	PLAIT - A Pivotal Multicenter Trial of Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukemia	18/09/2015		No									Y	
14/WM/1170	161147	Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and highrisk oropharyngeal cancer	10/11/2015		No									Y	
15/NW/0152	169540	CANC - 4235 - Herceptin + Perjeta +Docetaxel in HER2-Positive advanced breast cancer - MetaPHER	28/09/2015	14/01/2016	No					Y					
15/NE/0167	171524	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Maintenance Therapy After Initial Therapy in Patients With Newly Diagnosed Multiple Myeloma Not Treated With Stem Cell Transplantation	08/12/2015	01/03/2016	No						Y				
11/SC/0059	74662	INCA 2201, INC 424 - A Phase IB, Open-Label, Dose-Finding Study Of The JAK-inhibitor INC424 Tablets Administered Orally to Patients With Primary Myelofibrosis (PMF), Post-Polycythemia Vera-Myelofibrosis (PPV-MF) Or Post-Essential Thrombocythemia-Myelofibrosis (PET-MF) And Baseline Platelet Counts => 50x 10 9/L nad < 100 x 10 9/L	20/10/2015		No						Y				
14/WA/1056	154468	Adults with Acute Myeloid Leukaemia or High-Risk Myelodysplastic Syndrome (AML19)	28/10/2015		No						Y				
15/EM/0344	183906	A Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Amatuximab in Combination with	16/11/2015		No						Y				
15/NW/0468	182025	A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination with Chlorambucil, ACP-196 inCombination with Obinutuzumab, and ACP-196 Monotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia	14/01/2016		No						Y				
15/YH/0286	178790	The MATE study	16/03/2016		No						Y				
15/NI/0158	182421	A RANDOMISED PRAGMATIC TRIAL OF CORTICOSTEROID OPTIMISATION IN SEVERE ASTHMA USING A COMPOSITE BIOMARKER ALGORITHM TO ADJUST CORTICOSTEROID DOSE VERSUS STANDARD CARE	29/03/2016		No						Y				
14/LO/1426	158013	NCRN - 2960 - Unresected Stage IIIB - IVM1a Melanoma Treated with Talimogene Laherparepvec	18/12/2015		No							Y			
15/LO/1236	183416	A Phase 3, Randomized, Multicenter, DoubleBlind, PlaceboControlled, 2Arm, Efficacy and Safety Study of NEOD001 Plus Standard of Care vs. Placebo Plus Standard of Care in Subjects with Light Chain (AL) Amyloidosis	15/04/2016		No						Y				
15/LO/0485	138945	The prevention of pre-term birth in women who develop a short cervix. A multicentre randomised controlled trial to compare three treatments; cervical cerclage, cervical pessary and vaginal progesterone.	07/03/2016	06/06/2016	No					Y					

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13/SC/0436	108256	ASAP - Adjuvant Steroids in Adults with Pandemic Influenza	18/02/2016		No						Y				
12/LO/0803	99497	BEECH	15/07/2015		No				Y		Y				
14/LO/2011	159926	CCRN 2833 RE-DUAL PCI	23/11/2015		No				Y			Y			
15/EM/0473	187884	Phase II trial of anetumab ravtansine (BAY 94-9343) in patients with advanced or metastatic malignant pleural mesothelioma (MPM) overexpressing mesothelin after first line treatment with platinum in combination with pemetrexed	24/03/2016	01/06/2016	Yes										
15/YH/0212	174222	RCT Rehab for plantar fasciitis (hamstring stretches)	11/02/2016	07/04/2016	Yes										
16/EE/0011	194393	A PROSPECTIVE, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, MULTICENTER, PHASE 3 EFFICACY AND SAFETY STUDY OF OTO-104 GIVEN ASA SINGLE INTRATYMPANIC INJECTION IN SUBJECTS WITH UNILATERAL MENIERE'S DISEASE	29/03/2016	20/05/2016	Yes										
15/NI/0161	184748	Early switch to oral antibiotic therapy in patients with low risk neutropenic sepsis	10/03/2016	11/04/2016	Yes										
15/SC/0475	174852	An Open-Label, Randomized Phase 3 Trial of Nivolumab and Nivolumab plus Ipilimumab versus Platinum Doublet Chemotherapy in Patients with Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)	21/01/2016	19/02/2016	Yes										
14/SC/1161	155743	Prospective, single-arm, multicentre, observational registry to further validate safety and efficacy of the ultimaster DES in real-world patients	29/03/2016	12/04/2016	Yes										
14/NW/0218	149200	GLYCEMIC CONTROL AND TREATMENT SATISFACTION USING FINESSE VERSUS PEN FOR INITIATING BOLUS INSULIN DOSING IN TYPE 2 DIABETES MELLITUS PATIENTS NOT ACHIEVING GLYCEMIC TARGETS ON BASAL INSULIN WITH/WITHOUT ANTI-HYPERGLYCEMIC AGENTS	12/08/2015	20/10/2015	Yes										
16/NW/0041	197706	CANC - 4492 - SOLAR-1	12/04/2016	20/06/2016	Yes										
15/NW/0090	162325	Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus	26/10/2015	31/12/2015	Yes										
14/NE/0103	141927	A randomised double blind dose non-inferiority trial of a daily dose of 600mg versus 300mg versus 100mg of enteric coated aspirin as a cancer preventive in carriers of a germline pathological mismatch repair gene defect, Lynch Syndrome. Project 3 in the Cancer Prevention Programme (CaPP3).	26/08/2015	30/10/2015	Yes										
14/WS/1146	166537	Multicenter, randomised, double-blind, double-dummy, active-comparator event-driven, superiority phase III study of secondary prevention of stroke and prevention of systemic embolism in patients with a recent Embolic Stroke of Undetermined Source (ESUS). Patients will be randomly allocated to receive either rivaroxaban 15 mg once daily or aspirin 100 mg once daily in a 1:1 ratio.	24/09/2015	28/11/2015	Yes										
15/EM/0055	167115	Rapid Intervention with Glyceryl trinitrate in Hypertensive stroke Trial-2	13/10/2015	15/12/2015	Yes										
16/NE/0014	192732	A 12-Week Study to Assess the Efficacy and Tolerability of AF-219 in Subjects with Treatment Refractory Chronic Cough	11/04/2016	13/06/2016	Yes										

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13/EM/0118	101849	A multicentre randomised placebo controlled trial of prophylactic enteral lactoferrin supplementation to prevent late onset invasive infection in very preterm infants. ELFIN.	13/11/2015	14/01/2016	Yes											
15/NW/0507	178583	A phase IIa, randomized, double-blind, placebo controlled, parallel group study to assess the safety and efficacy of subcutaneously administered BI 655066 as add-on therapy over 24 weeks in patients with severe persistent asthma.	11/11/2015	12/01/2016	Yes											
14/SC/1206	142485	ElaTION	11/12/2015	10/02/2016	Yes											
15/EM/0313	168769	Gene expression profiling in asthma	07/01/2016	07/03/2016	Yes											
15/EM/0087	160899	An Open Label Oxygen Enhanced Imaging Biomarker Study to Assess the Role of Fluticasone/Formoterol upon Airway Function in Moderate to Severe Persistent Asthma.	13/07/2015	09/09/2015	Yes											
14/EM/0121	143800	RITUXILUP - An open label randomised multicentre controlled trial of RITUXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis	16/12/2015	12/02/2016	Yes											
12/SW/0206	87759	SPUtNIK	28/07/2015	23/09/2015	Yes											
14/NE/1214	162696	ABBVIE - M14-359	20/04/2015	16/06/2015	Yes											
14/NW/1067	137736	PROteKT	01/10/2015	23/11/2015	Yes											
15/EM/0077	173584	MIRRA LAP	20/07/2015	09/09/2015	Yes											
15/LO/0183	170760	STRIVE HF	07/10/2015	25/11/2015	Yes											
09/H0709/56	27957	PEXIVAS (Version 1)	26/08/2015	13/10/2015	Yes											
15/NW/0319	174853	DIAB 4268	20/10/2015	07/12/2015	Yes											
15/LO/2066	193084	4222: Efficacy And Long-Term Safety Of Oral Semaglutide Versus Sitagliptin In Subjects With Type 2 Diabetes Mellitus. A 78-Week, Randomised, Double-Blind, Double-Dummy, Active-Controlled, Parallel-Group, Multi-Centre, Multi-National, Four-Armed Trial	23/03/2016	10/05/2016	Yes											
15/LO/0861	179571	RESP 4558	16/09/2015	02/11/2015	Yes											
15/LO/0691	174324	Checkmate - 171 - An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic Squamous Cell (Sq) Non-Small Cell Lung Cancer (NSCLC) who Have Received at Least One Prior Systemic Regimen for the Treatment of Stage IIIb/IV SqNSCLC	22/07/2015	04/09/2015	Yes											
14/NW/1189	152831	ACTION: Cancer patient involvement in medical decision making	30/07/2015	11/09/2015	Yes											
15/EM/0135	167922	An Open-label, Phase 2 Study of ACP-196 in Subjects with Mantle Cell Lymphoma	06/07/2015	18/08/2015	Yes											
14/NI/1120	149397	EDNA	14/09/2015	26/10/2015	Yes											
15/WM/0222	182089	The DIASTOLIC Study	02/10/2015	12/11/2015	Yes											
14/SC/1169	152408	SPACE FOR COPD in primary care: a pragmatic trial	30/03/2016	09/05/2016	Yes											
14/LO/2163	191851	Pomalidomide in relapsed and refractory multiple myeloma (RRMM)	12/04/2016	19/05/2016	Yes											
REC 1	193306	CHIL 5013 A real-world, point of care, randomized, 2-arm, open, 52-week study to evaluate the effect of a digital disease management support tool in patients with type 2 diabetes mellitus.	13/04/2016	19/05/2016	Yes											
14/EE/1293	164389	C-STICH	26/05/2016	27/06/2016	Yes											

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15/WM/0263	184150	An Open-label Study to Assess the Long-term Safety and Efficacy of ONO/GS-4059 in Subjects with Relapsed/Refractory B-cell malignancies	06/11/2015	08/12/2015	Yes											
12/EE/0230	102101	RITAZAREM	12/01/2016	12/02/2016	Yes											
15/WS/0135	183471	A Phase 1b Dose Escalation and Dose Expansion Study of ONO/GS-4059 Combined with Idelalisib in Subjects with B-cell Malignancies	09/11/2015	08/12/2015	Yes											
15/SC/0397	183591	NJ002	17/11/2015	15/12/2015	Yes											
15/EM/0122	159000	LEICSTES = LEICeSter Tendon Extracorporeal Shockwave Studies Assessing the benefits of the addition of Extra-Corporeal Shockwave Treatment to a structured home-rehabilitation programme for patients with tendinopathy.	01/07/2015	29/07/2015	Yes											
15/LO/2100	192155	RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY EVALUATING TAS-102 PLUS	19/04/2016	17/05/2016	Yes											
13/EM/0459	137785	POSNOc - POSitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early stage breast cancer who have metastases in one or two sentinel nodes.	25/08/2015	21/09/2015	Yes											
15/EM/0391	184466	Physical Activity, Immune Function and Inflammation in Kidney Patients ? A Pilot Study	29/09/2015	26/10/2015	Yes											
15/EE/0161	177265	DIAB 3771	11/08/2015	02/09/2015	Yes											
15/EM/0259	167328	GO for IT	20/10/2015	10/11/2015	Yes											
15/EM/0433	181453	COPDSEAT (Sitting and Exacerbations Trial)	13/01/2016	02/02/2016	Yes											
13/EM/0015	118772	CAN 3001 v1.0 - A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study	18/02/2016	08/03/2016	Yes											
14/EM/1267	166568	LCZ696 in patients from Paradigm HF study	30/07/2015	18/08/2015	Yes											
15/EM/0325	171407	Model-based versus traditional warfarin dosing in children	14/10/2015	02/11/2015	Yes											
07/80706/81	46584	Molecular basis of chronic inflammatory and degenerative diseases	13/11/2015	01/12/2015	Yes											
15/LO/0545	172357	CARD 4478 CARAT	08/07/2015	24/07/2015	Yes											
15/EM/0208	177707	PEARL	03/08/2015	19/08/2015	Yes											
14/WA/1075	150715	HeadPoST Version 2.1	20/04/2016	06/05/2016	Yes											
14/SC/1333	146684	PATH2: Platelet Rich Plasma in Achilles Tendon Healing	12/08/2015	27/08/2015	Yes											
14/YH/1202	160376	PREVAIL NICU Study	31/07/2015	12/08/2015	Yes											
14/NW/1405	164557	RESP 3913 (Idiopathic Pulmonary Fibrosis)	22/07/2015	03/08/2015	Yes											
REC 2	165982	A cluster randomised controlled trial to investigate the effectiveness and cost effectiveness of the 'Girls Active' intervention	16/10/2015	26/10/2015	Yes											
15/WS/0123	178400	MIDNIGHT	13/07/2015	20/07/2015	Yes											
15/EE/0077	169447	AXAFA - AFNET 5	03/09/2015	10/09/2015	Yes											
15/EM/0048	150024	Ticagrelor for prevention of tumour cell-induced platelet aggregation	27/10/2015	02/11/2015	Yes											
15/EM/0247	179169	CANC - 4517	22/10/2015	26/10/2015	Yes											
15/WM/0285	173283	Evaluation of a wireless monitoring system	11/12/2015	11/12/2015	Yes											
15/NW/0626	184626	DIAB 4826	21/04/2016													
16/EM/0006	191553	A 24 week, Multicentre, Randomized, Open Label, 2 ARm Parallel-group study evaluating the Efficacy and Safety of Patient - versus Physician-managed Titration of Insulin Glargine U300 in Type 2 Diabetes Mellitus	22/04/2016													

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05/MRE00/74	15072	Genetic disorders of human brain development	27/04/2016													
15/NS/0093	171568	Hartmann's procedure versus intersphincteric APE: a prospective study	03/05/2016													
14/WA/1054	136117	A randomised phase II trial of oral vinorelbine as second line therapy for patients with malignant pleural mesothelioma (MPM)	03/05/2016													
14/WM/1050	158411	CCRN 3134 (Oesophagectomy)	04/05/2016													
14/YH/1259	163195	ALPHA.	04/05/2016													
16/EE/0048	192528	A two-arm, randomised, assessor-blind, parallel group study to evaluate the effect of fluticasone/formoterol breath actuated inhaler (BAI) and Relvar Ellipta DPI on ventilation heterogeneity in subjects with partially controlled or uncontrolled asthma	13/05/2016													
16/NW/0169	196447	An open-label, randomised, phase II study comparing TAS-102 plus bevacizumab to capecitabine plus bevacizumab in patients with previously untreated metastatic colorectal cancer who are eligible for non-intensive therapy	19/05/2016													
15/LO/1595	183040	PRISM	31/05/2016													
14/YH/1199	153953	galactic	02/06/2016													
15/YH/0125	172742	An open label, phase Ib/2 study of ACP-196 in subjects with Waldenstrom Macroglobulinemia	08/06/2016													
16/NW/0086	198831	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	13/06/2016													
16/WM/0009	182266	A Randomised Controlled Trial for People with Established Type 2 Diabetes during Ramadan: Canagliflozin	13/06/2016													
15/LO/1419	183975	A randomized, phase 3 trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy (PEARLS)	15/06/2016													
14/SC/1346	151280	Multi-drug, genetic marker-directed, non-comparative, multi-centre, multi-arm phase II trial in non-small cell lung cancer	27/06/2016													