East Lancashire Hospitals NHS Trust – NIHR performance in initiating clinical research – 01.07.2015 to 30.09.2015

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Reason	Comment
12/NE/0343	OPEN Study: Clarifying the management of men with recurrent urethral stricture: A pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy	16/10/2014	17/10/2014	Yes	26/02/2015	1	132	133	No	F – No patients seen	The expected number of research participants at this site is 4 in 48 months (1 a year) therefore it is not likely to present with a patient within the first 30 days
14/NS/0089	Hip Op: Timing of Surgical Intervention for Developmental Dysplasia of the Hip	12/01/2015	16/01/2015	No		4			No	F – No patients seen	The expected number of research participants at this site is 1 in 4 years therefore it is not likely to present with a patient within the first 30 days
14/NW/1462	TM Reverse: Prospective Post Market Clinical Follow-Up Study of the Zimmer Trabecular Metal Reverse Shoulder System	11/11/2014	16/01/2015	Yes	13/02/2015	66	28	94	No	A – Permissions delayed/denied	The study did not receive REC favourable opinion until 15.01.15 i.e. 65 days after receipt of a valid submission. NHS permission was granted immediately that REC approval was granted.
14/SC/1320	ReaDySpeech for people with dysarthria after stroke: initial clinical testing prior to feasibility study	22/01/2015	18/02/2015	Yes	22/06/2015	27	124	151	No	A – Permissions delayed/denied	Although the SSI was signed on 23.1.15 the lead network could not complete the global checks due to indemnity and data protection issues. Study wide checks were completed on 18.02.15 and NHS permission was granted the same day.
13/LO/1277	SPARTAN: A multi-centre, randomised, double blind, placebo-controlled, phase III of ARN-509 in men with non-metastatic (MO) castration-resistant prostate cancer	29/01/2015	06/02/2015	Yes	24/02/2015	8	18	26	Yes		
14/NW/1396	B-AHEAD 3 Breast Activity and Healthy Eating After Diagnosis. A randomised phase II trial of intermittent energy restriction and resistance exercise in women receiving chemotherapy for advanced breast cancer	06/01/2015	04/02/2015	No		29			No	F – No patients seen	The expected number of research participants at this site is 4 in 26 months therefore it is not likely to present with a patient within the first 30 days

14/SC/1161	Prospective single-arm, multi-centre, observational registry to further validate safety and efficacy of the ultimaster DES in real-world patients	11/03/2015	19/03/2015	Yes	25/03/2015	8	6	14	Yes		
12/NE/0401	FACT: Effect of folic acid supplementation in pregnancy on preeclampsia - Folic Acid Clinical Trial (FACT) A randomised, double-blind, placebo-controlled, Phase III, international multi-centre study of 4.0 mg of Folic Acid supplementation in pregnancy for the prevention of preeclampsia	25/03/2015	27/03/2015	Yes	18/05/2015	2	52	54	Yes		
14/NE/1214	A randomised, open-label, multicentre, phase 2 trial comparing veliparib plus carboplatin and paclitaxel versus investigator's choice of standard chemotherapy in subjects receiving first cytotoxic chemotherapy for metastatic or advanced non-squamous non-small cell lung cancer (NSCLC) and who are current or former smokers	27/03/2015	31/03/2015	Yes	20/04/2015	4	20	24	Yes		
13/NI/0123	MILES – UK: Post marketing, multicentre, single arm, observational clinical registry to evaluate safety and efficacy of biomime sirolimus eluting stent system in all comers real world population with coronary artery stenosis in United Kingdom	29/04/2015	06/05/2015	Yes	26/05/2015	7	20	27	Yes		
10/H0405/29	FIAT: The Fistula-In-Ano trial comparing Surgisis anal fistula plug versus surgeon's preference for transsphincteric fistula-In-ano	08/05/2015	11/05/2015	No		3			No	F – No patients seen	The expected number of research participants at this site is 2 in 20 months therefore it is not likely to present with a patient within the first 30 days
15/NW/0371	READYSPEECH For people with dysarthria after stroke: a feasibility study	16/06/2015	25/06/2015	No		9			No	D – Sponsor Delays	Although a valid application was submitted and permission granted in June, the sponsor has indicated that recruitment will not commence until 01 September 2015
14/SC/1345	Effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding: A randomised placebo-controlled trial (PRISM Trial: Progesterone in Spontaneous Miscarriage Trial)	14/07/2015	16/07/2015	Yes	31/07/2015	2	15	17	Yes		

15/LO/0802	The effect of standard versus high energy, low volume oral nutritional supplements in children requiring nutritional support: a pilot study	13/07/2015	17/07/2015	Yes	24/08/2015	4	38	42	Yes		
14/LO/1043	LEAVO: A Multicentre Phase III Double-masked Randomised Controlled Non-Inferiority Trial comparing the clinical and cost effectiveness of intravitreal therapy with ranibizumab (Lucentis) vs aflibercept (Eylea) vs bevacizumab (Avastin) for Macular Oedema due to Central Retinal Vein Occlusion (CRVO).	20/07/2015	23/07/2015	Yes	05/10/2015	3	74	77	No	F – No patients seen	The expected number of research participants at this site is 2 per year therefore it is not likely to present with a patient within the first 30 days
15/LO/0897	A phase III open-label randomised study of MPDL3280A (Anti PD-L1 antibody) in combination with bevacizumab vs sunitinib in patients with untreated advanced renal cell carcinoma	15/07/2015	23/07/2015	Yes	25/08/2015	8	33	41	Yes		
14/NW/0218	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 (Calibra)	14/08/2015	17/08/2015	Yes	10/09/2015	3	24	27	Yes		
14/SC/1059	CREDENCE: A randomized, Double-blind, Event-driven Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy	04/08/2015	05/08/2015	Yes	28/08/2015	1	23	24	Yes		
13/NW/0153	CiPHER: Phase II multicentre study assessing the efficacy of Cabazitaxel in Patients with HER2-negative metastatic breast cancer and having unresectable brain metastases	03/09/2015	03/09/2015	No		0			Still within 70 days	F – No patients seen	The expected number of research participants at this site is 3 per year therefore it is not likely to present with a patient within the first 30 days
15/NW/0431	A phase 2, two-arm multi-centre, open-label study to determine the efficacy and the safety of two different dose regimens of a pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in subjects with metastatic or surgically unresectable urothelial cancer with FGFR genomic alterations	03/09/2015	04/09/2015	Yes	05/10/2015	1	31	32	Yes		