East Lancashire Hospitals NHS Trust – NIHR performance in initiating clinical research – 01.04.2015 to 30.06.2015

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/NW/0361	SANAD II A pragmatic randomised controlled trial comparing the effectiveness and cost effectiveness of levetiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs	11/08/2014	12/08/2014	Yes	26/05/2015	1	287	288	No	F – No patients seen	The expected number of research participants at this site is 4 in 50 months (less than 1 a year) therefore it may be 12 months before we are presented with a patient
14/YH/0046	HELP: A Randomised Controlled Trial of Adjunctive Systemic Therapy for Vulval Erosive Lichen Planus	09/09/2014	11/09/2014	Yes	02/02/2015	2	144	146	No	I – Rare diseases	The incidence of ELPV is estimated at 0.01% as specified in the study protocol and is therefore classed as a rare condition
13/LO/0582	PIONEER: An Open-label, Randomised, Controlled, Multicenter Study Exploring Two Treatment Strategies of Rivaroxaban and a Dose-Adjusted Oral Vitamin K Antagoinst Treatment Strategy in Subjects with Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention	10/09/2014	11/09/2014	No		1			No	F – No patients seen	The expected number of research participants at this site is 1 patient in 7 months therefore it maybe 7 months before we are presented with a patient. A patient was identified but not entered into the study due to the fact that the study was closed at this site by the sponsor on 2 June 2015 ahead of the agreed recruitment end date of August 2015
12/NE/03	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	D - Sponsor Delays	The study did not receive REC favourable opinion until 15.01.15 i.e. 65 days after VAD.

14/SC/1320	ReaDySpeech for people with dysarthria after stroke: initial clinical testing prior to feasibility study22/01/2015	22/01/2015	18/02/2015	Yes	22/06/2015	27	124	151	No		Although the SSI was signed on 23.1.15 the lead network could not complete the global checks due to concerns relating to indemnity and data protection. Study wide checks were completed on 18.02.15
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 ? 3 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			Within 70 days	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			Within 70 days	D - Sponsor Delays	The sponsor has indicated that recruitment will not commence until 01 September 2015