East Lancashire Hospitals NHS Trust – NIHR performance in initiating clinical research – 01.01.2015 to 31.03.2015

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
14/SC/0065	CANVAS-R: A Randomised multicentre, double-blind, parallel, placebo-controlled study of the effects of Canagliflozin on Renal endpoints in adult subjects with type 2 diabetes mellitus CANVAS-R: CANaglifozin cardiovascular assessment study-renal	11/04/2014	15/04/2014	Yes	08/05/2014	4	23	27	Yes		
13/LO/1438	User assessment of the NovaLife one piece flat skin barrier	03/04/2014	07/05/2014	Yes	30/05/2014	34	23	57	Yes		
11/SW/0036	TABLET A randomised controlled trial of the efficacy and mechanism of levothyroxine treatment on pregnancy and neonatal outcomes in women with thyroid antibodies	03/06/2014	04/06/2014	Yes	04/07/2014	1	30	31	Yes		
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	No		1				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 Subjectsd With Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention	10/09/2014	11/09/2014	No		1				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
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				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 study	22/01/2015	18/02/2015	No		27					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				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	No	2						

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	No		4					