Performance in initiating research Q3, 2015/16, 12th January 2016

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 for delay	Comments	Reasons for delay correspond to:
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	Neither
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.	Neither

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 concerns relating to indemnity and data protection. Study wide checks were completed on 18.02.15 and NHS permission was granted the same day.	Neither
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	Neither
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	25/03/2015	27/03/2015	Yes	18/05/2015	2	52	54	Yes			

	of Folic Acid supplementation in pregnancy for the prevention of preeclampsia											
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				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	Neither
15/NW/0371	READYSPEECH For people with dysarthria after stroke: a feasibility study	16/06/2015	25/06/2015	Yes	21/10/2015	9	118	127	No	D - Sponsor Delays	Although a valid application was submitted and permission granted in June, the sponsor has indicated that recruitment	Sponsor

											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	Neither
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				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	Neither
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			

15/NW/0319	A phase 3 randomised double blind placebo controlled parallel group multicenter study to evaluate the efficacy, safety, and tolerability of LX4211 as adjunct therapy in adult patients with type 1 diabetes mellitus who have inadequate glycemic control with insulin therapy	16/10/2015	16/10/2015	Yes	29/10/2015	0	13	13	Yes			
13/LO/1207	StereoTactic radiotherapy for wet Age-Related macular degeneration (STAR): A randomised, double-masked sham-controlled, clinical trial comparing low-voltage X-ray irradiation with as needed bevacizumab, to as needed bevacizumab monotherapy	19/10/2015	20/10/2015	No		1				E - Staff availability issues	Support activity is required by Specialist Ophthalmology Photographer. Only written instructions are available. Photography staff will visit another site in London for training when a patient is available	Sponsor

14/WM/0057	Multi-centre randomised controlled trial to compare the clinical and cost effectiveness of a vein bypass first with a best endovascular first revascularisation strategy for severe limb ischaemia due to infra-popliteal arterial disease: Bypass vs. Angioplasty in Severe Ischaemia of the Leg. The BASIL-2 Trial	03/11/2015	03/11/2015	No		0				F - No patients seen	The expected number of research participants at this site is 10 in 18 months therefore it may not be likely that a patient will present within the first 30 days	Neither
15/NW/0592	A randomised, double-blind, double-dummy, placebo-controlled, parallel-group multi-centre clinical proof-of-principle trial in adult subjects with newly diagnosed type 1 diabetes mellitus investigating the effect of NNC0114-0006 and liraglutide on preservation of beta-cell function	04/11/2015	10/11/2015	Yes	16/11/2015	6	6	12	Yes			

15/YH/0392	Randomised controlled trial comparing the efficacy of foot orthoses produced by traditional and digital design processes, to reduce pressure and assess the impact on clinical practice	04/11/2015	16/11/2015	Yes	08/12/2015	12	22	34	Yes			
15/YH/0343	Accelerating Delivery of Psychological Therapies after Stroke (ADOPTS)	01/12/2015	02/12/2015	Yes	07/12/2015	1	5	6	Yes			
13/NW/0621	The early use of Antibiotics for at Risk Children with influEnza in primary care (ARCHIE): a double-blind randomised placebo-controlled trial	01/12/2015	02/12/2015	No		1						

13/NE/0339	A pragmatic group sequential placebo controlled randomised trial to determine the effectiveness of Glyceryl trinitrate for retained placenta (GOT-IT Trial)	11/12/2015	11/12/2015	No		0						
14/EE/1293	The Cerciage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH) Trial: A randomised controlled trial of monofilament versus braided sutures for insufficient cervix	09/12/2015	11/12/2015	No		2				F - No patients seen	The expected number of research participants at this site is 8 in 12 months therefore it may not be likely that a patient will present within the first 30 days	Neither