UHSM - PERFORMANCE IN INITIATING Quarter 4 2015/2016

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	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	Date Study Initiated	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start	A - Permissions delayed/denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
15/NW/0100	166703	NHS Permission	Detection of atrial fibrillation in community locations using novel technology`s as a method of stroke prevention in the over 65`s asymptomatic population should it become standard practice	02/04/2015	13/04/2015	Yes	14/04/2015	11	1	12	Yes																				Please Select...
15/LO/0018	167680	NHS Permission	A Randomized double blind placebo controlled multiple dose study of subcutaneous ACZ885 for the treatment of abdomial aortic aneurysm	07/04/2015	10/04/2015	Yes	10/06/2015	3	61	64	Yes																				Please Select...
15/EE/0003	167949	NHS Permission	A randomized, double-blind, placebo-controlled Phase 3 study of ISIS 304801 administered subcutaneously to patients with hypertriglyceridemia	09/04/2015	13/04/2015	Yes	09/10/2015	4	179	183	No														Y					Patients screened but no eligible patients identified.	Neither
14/EM/1141	167949	NHS Permission	A randomized double blind placebo controlled phase 3 study of ISIS 304801 administered subcutaneously to patients with familial chylomicronemia syndrome	14/04/2015	14/04/2015	Yes	12/08/2015	0	120	120	No														Y					Patients screened but no eligible patients identified.	Neither
15/NW/0255	163780	NHS Permission	A phase 3, multi-center, randomised, open-label study of Carbavance (Meropenem/RPX7009) versus best available therapy in subjects with selected serious infections due to Carbapenem-resistant Enterobacteriaceae	20/05/2015	29/05/2015	Yes	08/07/2015	9	40	49	Yes																				Please Select...
14/NW/1337	163452	NHS Permission	A Multicentre, Randomised, Parallel Group, Phase 3 Safety Extension Study to Evaluate the Safety and Tolerability of Benralizumab (MEDI-563) in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Long-Acting B2-Agonist (BORA)	16/06/2015	17/06/2015	Yes	01/07/2015	1	14	15	Yes																				Please Select...
14/LO/0324	146711	NHS Permission	A multi-centre, randomised, double-blind, placebo-controlled study to Evaluate the Safety and Efficacy of Pulmaquin? in the Management of Chronic Lung Infections with Pseudomonas Aeruginosa in Subjects with Non-Cystic Fibrosis Bronchiectasis, including 28 Day Open-Label Extension and Pharmacokinetic Substudy	25/06/2015	30/06/2015	Yes	14/07/2015	5	14	19	Yes																				Please Select...
12/WM/0335	97743	NHS Permission	A pilot study for developing and evaluating a care pathway for cognitive problems after stroke (OCS-care)	02/06/2015	18/06/2015	Yes	13/07/2015	16	25	41	Yes																				Please Select...
12/YH/0539	113983	NHS Permission	an open label multi centre preoperative window of oppurtunity study of afatinib in stage la to llb non small cell lung cancer	11/05/2015	01/06/2015	No		21			No														Y				Y	Main source of delay is F patients screened but no eligible patients identified. Low recruitment target 1-2 patients per year as this is the main source of the delay the source is neither. The delay also relates to J Other; there was a lengthy period of technical problems at the Christie with the PET scans so we couldnt start screening straight away.	Neither
15/NW/0163	156862	NHS Permission	PATHWAY: Improving the effectiveness if Psychological Interventions for Depresseion and Anxiety in the Cardiac Rehabilitation Pathway. A single-blind, pilot, randomised, controlled trial with four-month and twelve-month follow-up comparing Group MCT plus usual CR (intervention) with usual CR (control).	09/06/2015	11/06/2015	Yes	23/07/2015	2	42	44	Yes																				Please Select...
15/WA/0132	173287	NHS Permission	EPIC AAA Study: Exercise Capacity, Physical Inactivity and Cardiovascular Risk in AAA Patients	08/04/2015	29/04/2015	Yes	14/05/2015	21	15	36	Yes																				Please Select...
14/EM/1280	163096	NHS Permission	A randomised controlled trial to investigate the effectiveness of ThOracic epidural and Paravertebral blockade In-thoracotomy pain - TOPIC Feasibility Study	04/08/2015	17/08/2015	Yes	14/09/2015	13	28	41	Yes																				Please Select...
15/NW/0485	150625	NHS Permission	The Goal Directed Perfusion Trial	27/08/2015	01/09/2015	Yes	15/09/2015	5	14	19	Yes																				Please Select...
15/NW/0022	160532	NHS Permission	A multicentre randomised clinical trial to investigate whether Bone Anchored Maxillary Protraction (BAMP) reduces the need for orthognathic (facial) surgery	23/07/2015	23/09/2015	No		62			No									Y					Y					Main source of delay(VRA to FPR) is F No Patients Seen - due to Strict patient eligibility criteria and low recruitment target as this is the main source of delay the source is neither. VRA to NHSP is over 30 days due to the SSI being submitted before the research admin team were aware of the study to collate documents and set up the study.	Neither
14/NE/1176	161888	NHS Permission	Multi-centre randomised controlled trial with economic evaluation and nested qualitative study comparing early structured physiotherapy versus manipulation under anaesthesia versus arthroscopic capsular release for patients referred to secondary care with a frozen shoulder (Adhesive Capsulitis)	17/08/2015	01/09/2015	Yes	22/09/2015	15	21	36	Yes																				Please Select...
15/NW/0371	172337	NHS Permission	ReaDySpeech for people with dysarthria after stroke: a feasibility study	16/06/2015	20/07/2015	Yes	15/09/2015	34	57	91	No									Y				Y						Main source of delay was E NHS Provider staff availability - recruitment could not begin within 70 days due to staff being on annual leave. VRA to NHSP was over 30 days due to A local review not completed in time (SSI was submitted too soon.)	NHS Provider
14/LO/1800	146057	NHS Permission	The Efficacy and Mechanism Evaluation of Treating Idiopathic Pulmonary Fibrosis wth the addition of Co-trimoxazole (EME-TIPAC)	07/09/2015	22/09/2015	Yes	03/11/2015	15	42	57	Yes																				Please Select...
14/NW/1497	166166	NHS Permission	The Role of GABA(B) Receptor Mechanisms in Cough: Double-Blind Randomised Controlled Trial of Lesgaberan in Chronic Cough Patients with Positive and Negative Symptom Association Probabilities	10/07/2015	10/07/2015	Yes	23/07/2015	0	13	13	Yes																				Please Select...
15/EM/0294	180267	NHS Permission	A Phase 3 Randomised, Placebo-Controlled, Blinded Study to Investigate the Safety and Efficacy of a Topical Gentamicin-Collagen Sponge in Combination with Systemic Antibiotic Therapy in Diabetic Patients with an Infected Foot Ulcer	22/09/2015	29/09/2015	Yes	26/10/2015	7	27	34	Yes																				Please Select...
14/YH/1199	153953	NHS Permission	GALACTIC: GA101 (obinutuzumab) monocLonal Antibody as Consolidation Therapy In CLL	16/09/2015	02/10/2015	Yes	19/10/2015	16	17	33	Yes																				Please Select...
14/YH/1162	154011	NHS Permission	A study to determine the feasibility and acceptability of conducting a phase III randomised controlled trial comparing sterotactic Ablative Radiotherapy (SABR) with surgery in paTients with peripheral stage I nOn-small cell lung cancer (NSCLC) cOnsidered Higher risk of complication from surgical resection	25/09/2015	09/10/2015	Yes	19/02/2016	14	133	147	No															Y					Patients screened but no eligible patients identified.	Neither
15/YH/0178	174447	NHS Permission	A Phase 3, Randomized, Double-Blinded, Ivacaftor-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of VX-661 in combination with Ivacaftor in subjects aged 12 years and older with Cyctic Fibrosis, Heterozygous for the F508del-CFTR Mutation and a second CFTR Allele with a gating defect that is clinically demonstrated to be Ivacaftor responsive	05/10/2015	12/10/2015	Yes	26/10/2015	7	14	21	Yes																				Please Select...
14/SC/0171	120104	NHS Permission	A phase III, double-blind, placebo- controlled, randomised trial assessing the effects of asprin on disease recurrence and survival after primary therapy in common non- metastatic solid tumours.	15/10/2015	22/10/2015	Yes	14/12/2015	7	53	60	Yes																				Please Select...
14/LO/2195	165351	NHS Permission	Phase II window of opportunity study of short term preoperative treatment with enzalutamide (alone or in combination with exemestane) in patients with primary breast cancer	20/10/2015	26/10/2015	Yes	30/11/2015	6	35	41	Yes																				Please Select...
15/LO/1289	181953	NHS Permission	An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of Rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures	29/10/2015	02/11/2015	No		4			No															Y					Patients screened but no eligible patients identified. Strict patient eligibility criteria; we are using the 30% of patients seen who are resistant to Clopidogrel This makes the trial very difficult to recruit to.	Neither
15/NW/0032	151852	NHS Permission	Imaging cerebral neuroinflammation in acute and chronic cerebrovascular disease: a predictor of outcome and biomarker for guidijng treatment (IN-CVD)	01/10/2015	05/11/2015	Yes	10/11/2015	35	5	40	Yes																				Please Select...
15/EE/0130	170557	NHS Permission	A Randomized, Open Label, Multicenter Study of Liposomal Amikacin for Inhalation (LAI) in Adult Patients with Nontuberculous Mycobacterial (NTM) Lung Infections caused by Mycobacterium avium complex (MAC) that are refractory to treatment.	27/10/2015	09/11/2015	No		13			No															Y					Patients screened but no eligible patients identified	Neither
14/YH/0128	150031	NHS Permission	Sacral nerve stimulation versus the FENIX magnetic sphincter augmentation for adult faecal incontinence: a Randomised Investigation (SaFaRI)	09/11/2015	10/11/2015	Yes	10/02/2016	1	92	93	No															Y					Eligible patients seen chose not to participate in the study, other options have been available to the patients and they do not want such an evasive procedure	Neither
15/NW/0724	173790	NHS Permission	Evaluation of the fast fill technique for Anal Acoustic Reflectometry (AAR) in the Incontinent Anal Sphincter [PI - Mr Nicholas Heywood]	28/10/2015	11/11/2015	Yes	11/11/2015	14	0	14	Yes																				Please Select...
15/LO/0699	173824	NHS Permission	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy and Safety of Ivacaftor and VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508del-CFTR Mutation, and a Second Allele With a CFTR Mutation Predicted to Have Residual Function	13/11/2015	19/11/2015	Yes	18/12/2015	6	29	35	Yes																				Please Select...
11/SS/0100	84669	NHS Permission	Fluoxetine Or Control Under Supervision	22/10/2015	25/11/2015	Yes	19/01/2016	34	55	89	No									Y					Y					The main reason for NHS to FPR being over 70 days is No eligble patients seen - strict patient eligibility criteria this is why the reason is neither. The VRA to NHS was over 30 days due to the fact the local review not completed in time.	Neither

14/WS/1106	157143	NHS Permission	A Comparison of Fractional Flow ReserveGuided Percutaneous Coronary Intervention and Coronary Artery Bypass Graft Surgery in Patients with Multivessel Coronary Artery Disease: The FAME 3 Trial	30/11/2015	02/12/2015	Yes	01/02/2016	2	61	63	Yes																			Please Select...
13/LO/1481	132746	NHS Permission	A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleurectomy decortication versus no pleurectomy decortication in the multimodality management of patients with malignant pleural mesothelioma.	02/12/2015	07/12/2015	Yes	05/01/2016	5	29	34	Yes																			Please Select...
11/EE/0347	75112	NHS Permission	The 2nd European Carotid Surgery Trial	20/10/2015	10/12/2015	No		51			No								Y					Y					The main reason for VRA to FPR being over 70 days is No eligble patients seen and strict patient eligibility criteria this is why the reason is neither. The VRA to NHS was over 30 days due to the fact the local review not completed in time.	Neither
15/LO/0833	165266	NHS Permission	FEASIBILITY of IBIS 3. An International Breast Intervention Study investigating Prevention Of Late Recurrence in ER+ breast cancer survivors following 5 years of adjuvant treatment	11/01/2016	12/01/2016	No		1			No											Y							sponsor delay in provision of study documentation and provision of IMP/device/equipment	Sponsor
15/NW/0306	161393	NHS Permission	Does intraoperative use of the MarginProbe device reduce the need for further reexcision procedures after conservation surgery for breast cancer?	21/03/2016	22/03/2016	No		1			Within 70 Days																			Please Select...
15/NW/0478	172209	NHS Permission	A pilot prevention study of the effects of the antiprogestin Ulipristal Acetate (UA) on surrogate markers of breast cancer risk	22/01/2016	22/01/2016	Yes	29/03/2016	0	67	67	Yes																			Please Select...
15/WM/0331	184594	NHS Permission	The HeartMate III PostMarket Registry	08/12/2015	14/01/2016	Yes	14/01/2016	37	0	37	Yes																			Please Select...
15/NW/0360	162622	NHS Permission	Trans-venous oncclusion of incompetent pelvic veins as a treatment for chronic pelvic pain in women: A randomised control trial	21/08/2015	24/08/2015	Yes	15/09/2015	3	22	25	Yes																			Please Select...
15/SC/0115	167694	NHS Permission	A long term, randomised, double blind, placebo-controlled study to determine the effect of albiglutide, when added to standard blood glucose lowering therapies, on major cardiovascular events in patients with Type 2 diabetes mellitus.	12/01/2016	18/01/2016	Yes	10/02/2016	6	23	29	Yes																			Please Select...
15/YH/0309	182015	NHS Permission	A 52-week International, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3bTrial with a Blinded 104-week Long -term Extension Period to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin in Combination with Metformin Compared to Glimepiride in Combination with Metformin in Adult Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Therapy Alone.	25/01/2016	29/01/2016	No		4			Within 70 Days																			Please Select...
15/EE/0405	189187	NHS Permission	A Randomized, DoubleBlind, PlaceboControlled, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab in Insulin Treated Patients with Type 1 or Type 2 Diabetes and With Hypercholesterolemia at High Cardiovascular Risk Not Adequately Controlled on Maximally Tolerated LDLC Lowering Therapy.	25/02/2016	26/02/2016	No		1			Within 70 Days																			Please Select...
15/LO/2102	189922	NHS Permission	A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix ? Drug Coated Balloon PTA Catheter for Treatment of Below-the-Knee (BTK) Arteries	05/02/2016	11/02/2016	No		6			Within 70 Days																			Please Select...
15/NW/0821	191169	NHS Permission	Comparison of Calprotectin Levels in Stool and Rectal Mucus in Subjects with Suspected or Confirmed Inflammatory Bowel Disease	25/01/2016	26/01/2016	Yes	17/02/2016	1	22	23	Yes																			Please Select...
15/NW/0916	188456	NHS Permission	Evaluation of the Recto-anal Inhibitory Reflex (RAIR) using Anal Acoustic Reflectometry (AAR)	10/02/2016	11/02/2016	Yes	25/02/2016	1	14	15	Yes																			Please Select...
15/NW/0897	178630	NHS Permission	Investigating the role of portable VR intervention in phantom limb pain.	02/03/2016	03/03/2016	Yes	17/03/2016	1	14	15	Yes																			Please Select...
15/LO/1419	183975	NHS Permission	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)	10/02/2016	23/03/2016	Yes	06/04/2016	42	14	56	Yes																			Please Select...
14/SW/0075	151804	NHS Permission	A Randomised Controlled Trial Evaluating the Efficacy of Indwelling Pleural Catheters in Persistent Non Malignant Symptomatic Pleural Effusions	18/01/2016	19/01/2016	No		1			No													Y					low recruitment target - this isa niche study and only one patient is expected per year.	Neither
15/NI/0158	182421	NHS Permission	A RANDOMISED PRAGMATIC TRIAL OF CORTICOSTEROID OPTIMISATION IN SEVERE ASTHMA USING A COMPOSITE BIOMARKER ALGORITHM TO ADJUST CORTICOSTEROID DOSE VERSUS STANDARD CARE	21/01/2016	22/01/2016	No		1			Within 70 Days																			Please Select...
15/EM/0309	184678	NHS Permission	A randomised, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of two doses of nebulised budesonide delivered by the VR475 Inhalation System, with an open-label comparison to conventionally nebulised budesonide, in patients with uncontrolled asthma despite treatment with high dose inhaled corticosteroid and at least a second controller (GINA Step 4) and those receiving oral corticosteroid (GINA Step 5)	02/02/2016	04/02/2016	Yes	05/04/2016	2	61	63	Yes																			Please Select...
15/NW/0787	191007	NHS Permission	Investigating Neuronal responses by assessing capsaicin evoked Cough responses in an allergen challenge model of Asthma (INCA)	05/02/2016	08/02/2016	Yes	16/02/2016	3	8	11	Yes																			Please Select...
15/SW/0248	186033	NHS Permission	A Phase 3, Openlabel, Rollover Study to Evaluate the Safety and Efficacy of Long term Treatment With VX 661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del CFTR Mutation	19/02/2016	22/02/2016	Yes	29/02/2016	3	7	10	Yes																			Please Select...
14/NW/1486	159054	NHS Permission	The manchester short splint in rehablitation of zone II felxor tendon repairs.	18/05/2015	01/06/2015	Yes	01/06/2015	14	0	14	Yes																			Please Select...
15/NW/0697	183760	NHS Permission	A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of Toujeo? compared to standard of care insulin for initiating basal insulin in insulin na?ve patients with uncontrolled type 2 diabetes mellitus, with 6-month extension.	22/03/2016	31/03/2016	No		9			Within 70 Days																			Please Select...
15/NW/0698	183781	NHS Permission	A twenty six week, randomized, openlabel, 2 arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of transition to Toujeo? compared to standard of care insulin, in basal insulin treated patients with uncontrolled type 2 diabetes mellitus, with sixmonth extension.	14/03/2016	31/03/2016	No		17			Within 70 Days																			Please Select...
15/WA/0241	183747	NHS Permission	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus - Study Two	22/03/2016	29/03/2016	No		7			Within 70 Days																			Please Select...
16/NW/0033	192134	NHS Permission	Correlation of Anal Acoustic Reflectometry parameters with degree of Rectal Intussusception and Prolapse	16/03/2016	31/03/2016	Yes	06/04/2016	15	6	21	Yes																			Please Select...