

**UHSM CTP DOH Q2 2016 2017 Performance in initiating Report**

Id	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 nVRA and NHS Permission	Duration between nVRA and First Patient	Duration between nVRA 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 - Permission delay/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:			
86492	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...															Please Select...	
86493	14/YH/1162	154011	NHS Permission	A study to determine the feasibility and acceptability of conducting a phase III randomised controlled trial comparing stereotactic 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							Please Select...							Y						Patients screened but no eligible patients identified.	Neither		
86494	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 Cystic Fibrosis, Heterozygous for the F508del-CFTR Mutation and a second CFTR Allele with a gating defect that is clinically demonstrated to be Ivacaftor responsive (Vertex 109)	05/10/2015	12/10/2015	Yes	26/10/2015	7	14	21	Yes							Please Select...															Please Select...	
86495	14/SC/0171	120104	NHS Permission	A phase III, double-blind, placebo-controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours. (add aspirin)	15/10/2015	22/10/2015	Yes	14/12/2015	7	53	60	Yes							Please Select...															Please Select...	
86496	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 (AR8)	20/10/2015	26/10/2015	Yes	30/11/2015	6	35	41	Yes							Please Select...															Please Select...	
86497	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	Yes	12/05/2016	4	192	196	No							Please Select...							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		
86498	15/NW/0032	151852	NHS Permission	Imaging cerebral neuroinflammation in acute and chronic cerebrovascular disease: a predictor of outcome and biomarker for guiding treatment (N-CVD)	01/10/2015	05/11/2015	Yes	10/11/2015	35	5	40	Yes							Please Select...															Please Select...	
86499	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	Yes	05/07/2016	13	239	252	No							Please Select...															Patients screened but no eligible patients identified	Neither
86500	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							Please Select...								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		
86501	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...															Please Select...	
86502	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	12/11/2015	19/11/2015	Yes	18/12/2015	7	29	36	Yes								Please Select...															Please Select...
86503	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							Please Select...		Y					Y							The main reason for NHS to FPR being over 70 days is 'F - No eligible patients seen - strict patient eligibility criteria' the reason for this delay corresponds to 'neither'. The VRA to NHS was over 30 days due to 'A - local review not completed in time' the reason for this delay corresponds to NHS provider.	NHS Provider	
86504	14/WS/1106	157143	NHS Permission	A Comparison of Fractional Flow Reserve Guided 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...															Please Select...	
86505	13/LO/1481	132746	NHS Permission	A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleuroctomy decortication versus no pleuroctomy decortication in the multimodality management of patients with malignant pleural mesothelioma. (MARS 2)	02/12/2015	07/12/2015	Yes	05/01/2016	5	29	34	Yes							Please Select...															Please Select...	
86506	11/EE/0347	75112	NHS Permission	The 2nd European Carotid Surgery Trial (ECST2)	20/10/2015	10/12/2015	No		51			No							Please Select...		Y					Y							The main reason for VRA to FPR being over 70 days is 'F - No eligible patients seen and strict patient eligibility criteria' the reason for this delay corresponds to 'neither'. The VRA to NHS was over 30 days due to 'A - local review not completed in time' the reason for this delay corresponds to 'NHS provider'.	NHS Provider	
86507	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. Does intraoperative use of the MarginProbe device reduce the need for further reexcision procedures after conservation surgery for breast cancer? (margin probe)	11/01/2016	12/01/2016	No		1			No							Please Select...				Y										sponsor delay in provision of study documentation and provision of IMP/device/equipment	Sponsor	
86508	15/NW/0306	161393	NHS Permission		21/03/2016	22/03/2016	Yes	29/04/2016	1	38	39	Yes							Please Select...															Please Select...	
86509	15/NW/0478	172209	NHS Permission	A pilot prevention study of the effects of the antiprogesterin 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...															Please Select...	
86510	15/MM/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...															Please Select...	
86511	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. (HARMONY)	12/01/2016	18/01/2016	Yes	10/02/2016	6	23	29	Yes							Please Select...															Please Select...	
86512	15/YH/0309	182015	NHS Permission	A 52-week international, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3b Trial with a Blinded 104-week Long-term Extension Period to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Daagliptin 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			No							Please Select...				Y											Study closed by sponsor at all sites	Sponsor
86513	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	Yes	12/05/2016	1	76	77	No							Please Select...			Y			Y								Study wide review not completed in time by NHS provider - SSI form was submitted early due to new HRA process. NHS to FPR is over 40 days delay is due to 'E unexpected long term staff absence'	NHS Provider	
86514	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	Yes	04/07/2016	6	144	150	No							Please Select...								Y							Patients screened but no eligible patients identified	Neither



