UHSM Q3 CTP DOH 16 17 Performance in Initiating

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 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:
93091	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							Please Select...					Y								sponsor delay in provision of study documentation and provision of IMP/device/equipment	Sponsor
93092	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? (margin probe)	21/03/2016	22/03/2016	Yes	29/04/2016	1	38	39	Yes							Please Select...													Please Select...
93093	15/NW/0478	172209	NHS Permission	A pilot prevention study of the effects of the antiprogestin Uliprista l 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...
93094	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...													Please Select...
93095	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...
93096	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			No							Please Select...				Y									Study closed by sponsor at all sites	Sponsor
93097	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
93098	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
93099	15/NW/0821	191169	NHS Permission	Calprotectin in IBD ORI-CAL-01 (OriCol) - 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...													Please Select...
93100	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...													Please Select...
93101	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...													Please Select...
93102	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...													Please Select...
93103	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	Yes	04/05/2016	1	106	107	No							Please Select...							Y						low recruitment target - this is a niche study and only one patient is expected per year.	Neither
93104	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	Yes	27/04/2016	1	96	97	No							Please Select...							Y						Strict patient eligibility criteria	Neither
93105	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...													Please Select...
93106	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...													Please Select...
93107	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...													Please Select...
93108	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	Yes	31/05/2016	9	61	70	Yes							Please Select...													Please Select...
93109	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 six month extension.	14/03/2016	31/03/2016	Yes	25/05/2016	17	55	72	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
93110	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	Yes	04/08/2016	7	128	135	No							Please Select...					Y								sponsor delay in provision of equipment	Sponsor
93111	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...													Please Select...
93112	14/ss/1096	164274	NHS Permission	Rapid Assessment of Potential Ischaemic Heart Disease with CTCA - The role of early CT Coronary Angiography in the evaluation, intervention and outcome of patients presenting to the Emergency Department or Medical Assessment Unit with suspected or confirmed Acute Coronary Syndrome (The RAPID-CTCA Trial).	31/03/2016	12/05/2016	Yes	27/06/2016	42	46	88	No							Please Select...		Y					Y						VRA to NHS over 30 days due to 'A 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 ' F Patients screened but no eligible patients identified'	NHS Provider
93113	15/LO/0732	172401	NHS Permission	Pragmatic randomised trial of low versus high volume initiated trans-anal irrigation therapy in adults with chronic constipation (CapaCITY 2)	23/03/2016	11/04/2016	No		19			No							Please Select...							Y						Patients screened but no patients identified.	Neither
93114	16/EM/0037	196490	NHS Permission	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 16 Week Study Followed by Long Term Evaluation of Efficacy and Safety of Ixekizumab (LY2439821) in TNFi-Experienced Patients with Radiographic Axial Spondyloarthritis	23/03/2016	25/04/2016	Yes	17/06/2016	33	53	86	No							Please Select...		Y					Y						VRA to NHS was over 30 days due to 'A - study wide review not completed in time by NHS provider' this delay corresponds to 'NHS provider'. NHS to FPR is over 40 days due to 'F - strict patient eligibility criteria/low recruitment target' this delay corresponds to 'neither'	NHS Provider
93115	15/LO/0609	171006	NHS Permission	Stepped Wedge Randomised Trial of Laparoscopic Ventral Mesh Rectopexy in Adults with Chronic Constipation (CapaCITY 3)	23/03/2016	04/05/2016	No		42			No							Please Select...		Y					Y						VRA to NHS was over 30 days due to 'A - study wide review not completed in time by NHS provider' SSI was submitted early and reason for this delay corresponds to 'NHS provider'. NHS to FPR is over 40 days due to ' F - patients screened but no eligible patients identified' reason for delay corresponds to 'neither'.	NHS Provider
93116	15/YH/0531	166392	NHS Permission	A Psychosocial Therapy to Benefit People with Parkinson?s-related Dementia: A Feasibility and Exploratory Pilot Study of Individual Cognitive Stimulation Therapy (INVEST).	29/03/2016	10/05/2016	Yes	02/06/2016	42	23	65	Yes							Please Select...													Please Select...
93117	16/ES/0001	193859	NHS Permission	REVOLVE - A Phase 3, randomized, double-blind, placebo-controlled, multicentre study to investigate the efficacy and safety of Mongersen (GED-0301) for the treatment of subjects with active Crohn?s Disease	23/03/2016	24/06/2016	No		93			No							Please Select...					Y								Sponsor delayed site initiation visit.	Sponsor

93118	15/NW/0406	167520	NHS Permission	Thrombin Inhibition Preoperatively in Early Breast Cancer (TIP)	21/01/2016	25/04/2016	Yes	25/05/2016	95	30	125	No							Please Select...					Y						Sponsor delay through research application amendments , old version of SmPC submitted to REC & MHRA at time of initial submission.	Sponsor
93119	15/LO/1500	187068	NHS Permission	BI 1199.229 - Investigation of drug-drug interaction between nintedanib and pirfenidone in patients with IPF (an open label, multiple-dose, two group study followed by nintedanib open label treatment)	29/03/2016	19/04/2016	Yes	03/05/2016	21	14	35	Yes							Please Select...												Please Select...
93120	16/SC/0018	191267	NHS Permission	A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of CTX-4430 Administered Orally Once-Daily for 48 Weeks in Adult Patients with Cystic Fibrosis [Empire (CTX-4430)]	23/03/2016	26/04/2016	Yes	06/06/2016	34	41	75	No							Please Select...						Y		Y			VRA to FPR is over 70 days delay reason is 'F - patients screened but no eligible patients identified'. VRA to NHS is over 30 days delay reason is 'H - Contracting / costing delays' the contact person for liaising about the contract and costings changed right at the end and the new person asked for clarifications for some things that were agreed already	Sponsor
93121	16/SC/0089	196789	NHS Permission	The REST Study - pRotective vEntilation with ven-venouS lung assisT in respiratory failure	31/03/2016	30/06/2016	No		91			No							Please Select...					Y						Sponsor delayed confirmation of study open to recruitment at site	Sponsor
93122	15/EM/0473	187884	NHS Permission	A randomized, open-label, active-controlled, Phase II study of intravenous anetumabravtansine (BAY 94-9343) or vinorelbine in patients with advanced or metastaticmalignant pleural mesothelioma overexpressing mesothelin and progressed on first lineplatinum/pemetrexed-based chemotherapy (Bayer 15743)	11/03/2016	07/04/2016	Yes	11/04/2016	27	4	31	Yes							Please Select...												Please Select...
93123	15/NW/0747	186601	NHS Permission	BIOSIMILAR A multicenter, randomized, double-blind Phase III trial to evaluate efficacy and safety of BI 695502 plus chemotherapy versus Avastin? plus chemotherapy in patients with advanced nonsquamous Non-Small Cell Lung Cancer	08/03/2016	20/04/2016	No		43			No							Please Select...					Y						sponsor delay in provision of study documentation and provision of equipment etc	Sponsor
93124	15/SC/0600	187954	NHS Permission	The Efficacy of Sonographic and Biological Pleurodesis Indicators of Malignant Pleural Effusion (SIMPLE) - a randomised trial	29/03/2016	16/06/2016	Yes	22/08/2016	79	67	146	No							Please Select...		Y				Y					VRA to NHS over 30 days due to 'A - Study wide review not completed in time by NHS provider' SSI was submitted early due to new HRA process. this delay corresponds to 'nhs provider'. NHS to FPR delay due to 'F - patients screened but no eligible patients identified' delay corresponds to 'neither'	NHS Provider
93125	15/EE/0298	186974	NHS Permission	LuCID: Lung Cancer Indicator Detection	24/03/2016	23/06/2016	Yes	07/07/2016	91	14	105	No							Please Select...		Y			Y						VRA to NHS over 30 days due to 'A - Study wide review not completed in time by NHS provider' SSI was submitted early due to new HRA process. this delay corresponds to 'nhs provider'. Also 'D - Sponsor delayed confirmation of study open to recruitment at site' this delay corresponds to 'sponsor'.	Sponsor
93126	15/LO/1079	177212	NHS Permission	A Phase 1/2 Study to Assess the Safety and Efficacy of MultiStem? Therapy in Subjects with Acute Respiratory Distress Syndrome (B04-01 CATAPULT)	29/03/2016	05/07/2016	Yes	29/09/2016	98	86	184	No							Please Select...					Y		Y				VRA to FPR is over 70 days delay reason is 'F - Patients screened but no eligible patients identified / Strict patient eligibility criteria' VRA to NHS is over 30 days delay reason is 'D - Sponsor delay in provision of study documentation (insurance renewal)'	Sponsor
93127	16/NW/0089	165834	NHS Permission	A Phase 4, Single-centre, Randomised, Double-blind, Placebo-controlled, Parallel-group, Fixed-dose Study of the Effect of Linaclotide on Abdominal Girth in Participants with Irritable Bowel Syndrome with Constipation.	23/03/2016	21/09/2016	Yes	20/12/2016	182	90	272	No							Please Select...		Y			Y						VRA to NHS was over 30 days due to 'A - study wide review not completed in time by NHS provider' SSI was submitted early due to new HRA process. and reason for this delay corresponds to 'NHS provider' NHS to FPR was over 40 days due to 'D - sponsor delayed confirmation of study open to recruitment at site.	Both
93129	16/LO/0793	203066	HRA Approval	Effect of nintedanib on biomarkers of ECM turnover in patients with IPF and limited FVC impairment (BI1199.227)			Yes	02/08/2016				No		09/03/2016	09/05/2016	28/06/2016	07/07/2016	11/07/2016	Please Select...	22/06/2016				Y						Sponsor delayed site initiation visit	Sponsor
94199	16EM/0193	190690	HRA Approval	A phase 111 double blind randomized placebo controlled study to evaluate the effects of dalcetrapib on cardiovascular risk in a genetically defined population with a recent acute coronary syndrome (ACS) THE dal-GenE trial			Yes	04/11/2016				Yes		22/04/2016	14/10/2016	14/06/2016	29/09/2016	06/10/2016	Please Select...	03/11/2016											Please Select...
94447	16/WM/0170	195010	HRA Approval	The APPROACH open label extension study. An open label extension study of Volanesorsen administered subcutaneously to patients with familial chylomicronemia syndrome (FCS)			Yes	14/12/2016				No		23/08/2016	25/04/2016	21/06/2016	11/03/2016	07/11/2016	Please Select...	13/12/2016				Y						Planned and agreed later start - follow on study	Sponsor
94449	16/sw/0231	207023	HRA Approval	A single centre open label pilot study measuring lower limb physiology in patients with venous leg unlcers using the geko t-2 or Geko tm plus [r-2] neuromuscular electro stimulation device			Yes	15/12/2016				No		12/08/2016	30/09/2016	28/09/2016	19/10/2016	20/10/2016	Please Select...	25/10/2016					Y					NHS provider training / equipement	NHS Provider
94452	16/nw/0787	216022	HRA Approval	phase Iia randomized double blind placebo controlled study of two doses of GLPG2222 in subjects with cystic fibrosis harbouring one F508del CFTR muttion and a second gating (Class 111) mutation and on stable treatment with ivacaftor			No					Within 70 Days		30/09/2016	07/11/2016	22/12/2016			Please Select...												Please Select...
94597	16/SC/0341	204761	HRA Approval	A Phase 2, Multicenter Study of the EZH2 Inhibitor Tazemetostat in Adult Subjects with Relapsed or Regractory Malignant Mesothelioma with BAP1 loss of Function			No					No		31/05/2016	30/08/2016	11/08/2016	04/11/2016	11/11/2016	Please Select...	11/01/2017				Y						Sponsor delayed confirmation of study open to recruitment at site	Sponsor