

No	REC Reference Number	IRAS No	Title	Date of First Patient Recruitment	Benchmark Met	Date site invited	Date site selected	HRA Approval date	Date site confirmed by sponsor	Date site confirmed	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 Eligible Patients (No patient seen)	G - No Patients Consented	H - Contracting Delays	I - Rare disease	J - Other	Comments	Sources of delay		
1	15/EM/0551	191168	Effectiveness of Intravenous iron treatment vs standard care in patients with heart failure and iron deficiency: a randomised, open-label multicentre trial (IRONMAN)		N/A	26/08/2016	01/06/2017	07/07/2016	16/05/2017	01/06/2017	02/06/2017												N/A as 70 day benchmark not exceeded at time of report period		
2	16/EE/0234	194284	Three versus five years of adjuvant imatinib as treatment of patients with operable GIST with a high risk for recurrence: A randomised phase III study.		N/A	15/06/2016	25/05/2017	12/09/2016	25/05/2017	25/05/2017														N/A as 70 day benchmark not exceeded at time of report period	
3	16/EE/0370	198596	MesoTRAP: A feasibility study comparing video-assisted thoracoscopic partial pleurectomy/decortication with indwelling pleural catheter in patients with trapped lung and pleural effusion due to malignant pleural mesothelioma designed to address recruitment and randomisation uncertainties and sample size requirements for a phase III trial.		N/A	16/12/2016	05/05/2017	11/01/2017	05/05/2017	09/05/2017														N/A as 70 day benchmark not exceeded at time of report period	
4	16/LO/1992	216381	Beyond education: A Hypoglycaemia Awareness Restoration Programme for people with type 1 diabetes and problematic hypoglycaemia persisting despite optimised self-care (HARPdoc)		N/A	18/01/2017	09/05/2017	10/01/2017	16/05/2017	22/05/2017	25/05/2017													N/A as 70 day benchmark not exceeded at time of report period	
5	16/NW/0517	188554	Accord Myeloma XII: A phase 3 study to determine the role of ixazomib as an augmented conditioning therapy in salvage autologous stem cell transplant (ASCT) and as a post-ASCT consolidation and maintenance strategy in patients with relapsed multiple myeloma.		N/A	10/05/2016	22/06/2017	27/10/2016	22/06/2017	22/06/2017	22/06/2017													N/A as 70 day benchmark not exceeded at time of report period	
6	16/SC/0484	208568	An Open Label, Randomized, Two Arm Phase III Study of Nivolumab in Combination with Ipilimumab versus Extreme Study Regimen (cetuximab + cisplatin/carboplatin + fluorouracil) as First Line Therapy in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) CheckMate 651		N/A	04/01/2017	31/05/2017	10/02/2017	01/06/2017	12/06/2017	14/06/2017													N/A as 70 day benchmark not exceeded at time of report period	
7	16/WM/0514	213012	Accuracy of Detection using ENdocuff Optimisation of Mucosal Abnormalities: The B-ADENOMA Study		N/A	17/01/2017	28/06/2017	20/01/2017	28/06/2017	28/06/2017	28/06/2017													N/A as 70 day benchmark not exceeded at time of report period	
8	17/EM/0014	219556	Prospective Clinical Investigation for a Randomized, Controlled, Multicenter Non-inferiority Study Comparing Standard Wound Closure Technique with Drains (control) to Standard Wound Closure Techniques with TissuGlu® and No Drains (test) in Mastectomy.		N/A	13/04/2017	20/06/2017	10/03/2017	20/06/2017	23/06/2017	23/06/2017													N/A as 70 day benchmark not exceeded at time of report period	
9	17/LO/0243	219613	A randomized, double-blind, multi-dose, placebo-controlled study to evaluate the efficacy, safety and tolerability of GSK2330672 administration for the treatment of pruritus in patients with primary biliary cholangitis. (GLIMMER: GSK2330672 trial of Ibat inhibition with Multidose Measurement for Evaluation of Response)		N/A	09/03/2017	12/05/2017	27/03/2017	11/05/2017	23/05/2017														N/A as 70 day benchmark not exceeded at time of report period	

10	17/LO/0326	221071	Using Virtual Reality as a distraction technique to reduce pain during burn treatments.		N/A	07/02/2017	03/05/2017	24/03/2017	03/05/2017	04/05/2017										N/A as 70 day benchmark not exceeded at time of report period		
11	17/LO/0380	218003	A phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety study of Crenezumab in patients with prodromal to mild Alzheimer's disease - Cread 2		N/A	05/01/2017	29/06/2017	18/05/2017	26/06/2017	29/06/2017	30/06/2017									N/A as 70 day benchmark not exceeded at time of report period		
12	17/NE/0115	218417	Multi-center, international, double-blind, two-arm, randomized, placebo-controlled phase II trial of pifredione in patients with unclassifiable progressive fibrosing ILD		N/A	07/12/2016	01/06/2017	26/05/2017	14/06/2017	23/06/2017	23/06/2017									N/A as 70 day benchmark not exceeded at time of report period		
13	17/YH/0083	220358	A randomised controlled trial of routine massage with a new lotion for the enhancement of skin health and cognitive development in infants		N/A	01/02/2017	08/06/2017	08/06/2017	15/06/2017	19/06/2017										N/A as 70 day benchmark not exceeded at time of report period		
14	15/SS/0225	169859	SYSTEMS-2: A Randomised Phase II trial of standard versus dose escalated radiotherapy in the treatment of pain in malignant pleural mesothelioma.	22/02/2017	No	18/01/2016	01/12/2016	05/10/2016	08/12/2016	09/02/2017	15/02/2017								Y	Contracting / costing delays with NHS Provider support service (Radiotherapy Physics)	NHS Provider	
15	16/EE/0243	207331	A 6-month, multicenter, Phase 3, open-label extension safety study of OTO-104 given at 3-month intervals by intratympanic injection in subjects with unilateral Meniere's disease	06/02/2017	No	21/07/2016	25/11/2016	01/08/2016	25/11/2016	01/12/2016	06/02/2017									Y	Sponsor delayed confirmation of study open to recruitment at site	Sponsor
16	16/EE/0356	207367	A Phase 2b, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of JNJ-64304500 in Subjects with Moderately to Severely Active Crohn's Disease.		No	27/10/2016	27/02/2017	21/11/2016	28/02/2017	09/03/2017	18/05/2017									Y	Sponsor delayed confirmation of study open to recruitment at site.	Sponsor
17	16/EM/0193	190690	A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The dal-GenE trial.	17/02/2017	No	11/03/2016	13/09/2016	14/06/2016	19/09/2016	28/09/2016	30/09/2016									Y	Patients screened but no eligible patients identified	Neither
18	16/EM/0376	211430	A 12-week, randomized, multi-center, double-blind, placebo-controlled, 3-arm, parallel-group, phase 3 trial to evaluate the efficacy and safety of 2 doses of AQX-1125 targeting the SHIP1 pathway in subjects with interstitial cystitis/bladder pain syndrome followed by a 2-arm, 14 or 40 week open label extension	09/05/2017	No	12/10/2016	12/01/2017	07/12/2016	07/02/2017	10/02/2017	10/02/2017									Y	Patients screened but no eligible patients identified until after 70 days had passed	Neither
19	16/EM/0384	182787	CV 185316: An Open-label, 2x2 Factorial, Randomized Controlled, Clinical Trial to Evaluate the Safety of Apixaban vs. Vitamin K Antagonist and Aspirin vs. Aspirin Placebo in Patients with Atrial Fibrillation and Acute Coronary Syndrome or Percutaneous Coronary Intervention	27/06/2017	No	25/08/2016	31/01/2017	21/11/2016	30/01/2017	01/02/2017	03/02/2017									Y	Strict patient eligibility criteria	Neither
20	16/LO/0913	186776	Corneal cross-linking versus standard care in children with keratoconus; a randomised, multicentre, observer-masked trial of efficacy and safety.	01/03/2017	No	25/08/2016	23/09/2016	04/08/2016	23/11/2016	28/11/2016	06/12/2016									Y	Costing delays by NHS Provider. Patients screened but no eligible patients identified.	NHS Provider
21	16/LO/1004	207544	Modulation of immune response and outcomes in ALS using IL-2 (MIROCAL-S-IL2)		No	09/09/2016	16/03/2017	06/10/2016	21/03/2017	04/04/2017										Y	Sponsor delayed confirmation of study open to recruitment at site	Sponsor

22	16/LO/1138	207606	A Phase II, randomized, double-blind, placebo-controlled, parallel-group, multicenter trial to evaluate the efficacy and safety of abtuzumab in subjects with systemic sclerosis-associated interstitial lung disease (SSc-ILD).	No	25/05/2016	10/11/2016	30/08/2016	10/11/2016	14/11/2016	16/11/2016										Patients screened but no eligible patients identified. Strict patient eligibility criteria.	Neither
23	16/LO/1386	199366	Phase 2 Study: A Phase 2 Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Cardiac and Renal Effects of 7 Day Treatment with 'Elamipretide' in Patients Hospitalized with Severe Congestion due to Heart Failure.	No	07/06/2016	09/02/2017	14/11/2016	15/02/2017	20/02/2017	10/03/2017										Patients screened but no eligible patients identified. In addition, sponsor delayed confirmation of study open to recruitment at site.	Neither
24	16/LO/1697	212844	A Phase III randomised, controlled clinical trial of Pembrolizumab with or without platinum-based combination chemotherapy versus chemotherapy in subjects with advanced or metastatic urothelial carcinoma.	No	28/07/2016	08/11/2016	11/11/2016	11/11/2016	17/11/2016											Sponsor delayed confirmation of study open to recruitment at site	Sponsor
25	16/NE/0238	204031	The British Heart Foundation older patients with non-ST Segment elevation myocardial infarction randomized interventional treatment trial	No	07/03/2017	01/09/2016	05/09/2016	08/08/2016	18/10/2016	07/10/2016	18/10/2016									Sponsor delayed confirmation of study open to recruitment at site.	Sponsor
26	16/NE/0253	185463	Rituximab - a potential cure for the young patient with Graves' disease	No	07/04/2016	05/10/2016	22/09/2016	07/02/2017	17/02/2017	10/05/2017										Contracting delays by Sponsor, further exacerbated by incomplete funding information from Sponsor.	Sponsor
27	16/NE/0382	215735	A COMBined progRamme of exercise and dietary ADvice in mEn with castrate resistant prostate cancer - COMRADE trial	No	15/03/2017	31/10/2016	19/12/2016	18/01/2017	18/01/2017	23/01/2017	08/02/2017									NHS Provider staff availability	NHS Provider
28	16/NI/0145	207927	Diabetic Macular Oedema and Diode Subthreshold Micropulse Laser (DIAMONDS): A pragmatic, multicentre, allocation concealed, prospective, randomised, non-inferiority double masked trial	No	29/03/2017	23/09/2016	14/12/2016	29/11/2016	16/01/2017	01/02/2017	28/02/2017									Contracting delays by Sponsor and Lead Site, with participating sites. Sponsor delayed confirmation of study open to recruitment at site.	Sponsor
29	16/NW/0305	201856	A Phase III, Multicentre, Randomised, Double Blind, Parallel Group, Placebo Controlled Study to Assess the Efficacy and Safety of one or more Intradetrusor Treatments of 600 or 800 Units of DYSPORE® for the Treatment of Urinary Incontinence in Subjects with Neurogenic Detrusor Overactivity due to Spinal Cord Injury or Multiple Sclerosis.	No	03/05/2016	19/10/2016	28/07/2016	19/10/2016	24/10/2016	24/10/2016										NHS Provider staff availability	NHS Provider
30	16/NW/0396	191940	Very Low Dose Dexamethasone versus Placebo For the Treatment of Ventilator Dependent Preterm Babies.	No	22/09/2016	24/10/2016	30/06/2016	16/02/2017	22/02/2017	13/03/2017										Contracting delays by sponsor.	Sponsor
31	16/NW/0606	211110	A Phase II single-arm, open-label monotherapy clinical trial of Pembrolizumab (MK-3475) in locally advanced/metastatic renal cell carcinoma (mRCC) (KEYNOTE-427)	No	03/08/2016	11/11/2016	23/09/2016	14/02/2017	16/02/2017	08/06/2017										Sponsor delay in provision of study documentation. Trust provided budget feedback to sponsor in October 2016 and Sponsor did not respond to this until January 2017.	Sponsor
32	16/NW/0620	206738	Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating The Efficacy And Safety Of Oral Vadadustat For The Correction Of Anemia In Subjects With Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD) (PRO2TECT - CORRECTION)	No	13/10/2016	08/03/2017	17/11/2016	08/03/2017	20/03/2017	17/05/2017										Sponsor delayed confirmation of study open to recruitment at site until after 70 days had passed	Sponsor

33	16/SC/0147	183044	Randomised double-blind cross-over study of a DPP4 inhibitor, SGLT2 inhibitor and thiazolidinedione as third line therapy in patients with type 2 diabetes who have suboptimal glycaemic control on dual therapy with metformin and a sulphonylurea.	22/03/2017	No	08/03/2016	13/12/2016	07/07/2016	14/12/2016	13/01/2017	20/02/2017											Sponsor delayed confirmation of study open to recruitment at site	Sponsor	
34	16/SC/0382	196261	Effect of the Prevena Incision Management System on Sternal Wound Edge Perfusion in Patients undergoing CABG with Bilateral Mammary Artery grafts	15/02/2017	No	27/06/2016	30/08/2016	30/08/2016	30/08/2016	30/08/2016	13/09/2016										Y	Delay in delivery of equipment from supplier.	Neither	
35	16/SC/0439	199315	ACL Surgery Necessity in Non Acute Patients Comparison of the clinical and cost effectiveness of two management strategies for non-acute Anterior Ligament (ACL) injury: Rehabilitation versus surgical Reconstruction		No	23/02/2017	15/03/2017	16/11/2016	15/03/2017	10/04/2017	05/06/2017										Y	Patients screened but no eligible patients identified	Neither	
36	16/SC/0606	216489	Acceptability and tolerability of magnetic assisted capsule endoscopy compared to gastroscopy	09/03/2017	No	24/10/2016	24/11/2016	25/01/2017	25/01/2017	25/01/2017	07/03/2017										Y	Y	Costing delays by Sponsor. Also, delays with manufacturer in Korea visiting STH to train staff.	Sponsor
37	16/WM/0197	202991	A multi-center, randomized, double-blind, placebo controlled, parallel group phase 2a study to assess the efficacy of RO5459072 in patients with primary Sjogren's syndrome.		No	04/04/2016	28/07/2016	07/07/2016	14/06/2016	28/07/2016	22/08/2016										Y	Patients screened but no eligible patients identified	Neither	
38	16/WM/0359	211812	A Phase 2/3 Multi-center Study to Evaluate the Safety and Efficacy of Blinatumomab in Subjects with Relapsed/Refractory Aggressive B-Cell Non Hodgkin Lymphoma.	23/02/2017	No	29/07/2016	12/10/2016	12/10/2016	17/10/2016	02/11/2016	17/11/2016										Y	Y	Sponsor delay in provision of equipment (scanner). Patients screened but no eligible patients identified.	Sponsor
39	16/YH/0186	200765	A phase 4 double-blind, randomized, placebo-controlled, multi-center study to evaluate the efficacy, safety and tolerability of mirabegron in men with overactive bladder (OAB) symptoms while taking the alpha-blocker tamsulosin hydrochloride for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).		No	29/04/2016	10/10/2016	11/08/2016	11/10/2016	26/10/2016	29/11/2016											Y	Sponsor delayed confirmation to study open to recruitment at site.	Sponsor
40	16/YH/0212	200145	Unilateral and Bilateral Neurodynamic Sliding Techniques as a Means of Treating Non-compressive Sciatic Leg Pain: A Pilot Study for a Randomised Controlled Trial	05/01/2017	No	27/06/2016	25/10/2016	25/10/2016	25/10/2016	25/10/2016	25/10/2016											Y	Sponsor delay as a result of a protocol amendment - change of venue of intervention.	Sponsor
41	16/YH/0234	197040	Treatment of poor-grade Subarachnoid Haemorrhage Trial 2 - TOPSAT2		No	08/09/2016	13/10/2016	13/07/2016	22/11/2016	01/12/2016	19/12/2016										Y	Y	The main source of delay was due to rare disease group so not expected to recruit within 70 day benchmark. Other delays included contracting / costing delays with NHS Provider support services. Sponsor delayed confirmation of study open to recruitment at site.	Neither
42	16/YH/0450	213782	20150288: A Phase 2 Open-label Study Investigating the Safety and Efficacy of Blinatumomab After Frontline R-Chemotherapy in Adult Subjects With Newly Diagnosed High-risk Diffuse Large B-Cell Lymphoma (DLBCL)		No	25/01/2017	25/01/2017	25/01/2017	08/02/2017	13/02/2017	15/02/2017											Y	Patients screened but no eligible patients identified.	Neither

