PID Q1 18-19 (Performance Initiation)

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant Recruited	Benchmark Met	Date Study Initiated	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 patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
18/ES/0013	240837	HRA Approval	PRospective Observation of aortic reGuRgitation aftEr TAVI and progreSS over time: PROGRESS PVL Registry	Yes	04/06/2018	316	17	333	No		12/12/2016	06/07/2017	29/01/2018	24/06/2018	18/05/2018	18/05/2018										Y	Staff who is involved in the setup of the study sadly passed away.	Neither
17/NW/0371	216207	HRA Approval	A Randomized, Double-Blind, Multicenter, 3 Stage, Efficacy and Safety Study of NI-071 and US-Licensed Remicade? (Infliximab) for the Treatment of Patients with Rheumatoid Arthritis	No		34			No		13/10/2016	15/08/2017	25/07/2017	15/08/2017	18/09/2017	18/09/2017				Y								Delay in sponsor green light	Sponsor
16/EE/0370	198596	HRA Approval	MesoTRAP: A feasibility study comparing video-assisted thoracoscopic partial pleurectomy/decortication with indwelling pleural catheter in patients with trapped lung due to malignant pleural mesothelioma designed to address recruitment and randomisation uncertainties and sample size requirements for a phase III trial.	No		33			No		24/02/2017	23/08/2017	11/01/2017	21/09/2017	25/09/2017	25/09/2017						Y						Eligible patients seen during the relevant period but did not consent to participate the trial	Neither
17/EM/0063	213979	HRA Approval	A Phase 3 Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial of the FLT3 Inhibitor Gilteritinab (ASP2215) Administered as Maintenance Therapy Following Induction/Consolidation Therapy for Subjects with FLT3/ITD AML in First Complete Remission	No		53			No		10/08/2016	10/08/2017	27/04/2017	22/09/2017	02/10/2017	02/10/2017						Y						No eligible patients seen during the recorded period	Neither
17/EE/0081	219405	HRA Approval	An open label, single arm safety study of OncoSil?, administered to study participants with unresectable locally advanced pancreatic adenocarcinoma, given in combination with FOLFIRINOX or gemcitabine+nab-paclitaxel chemotherapies.	Yes	30/04/2018	9	277	286	No		07/04/2017	18/07/2017	08/05/2017	20/07/2017	27/07/2017	27/07/2017						Y						Screening ongoing. Niche population and tight criteria.	Neither
17/WS/0072	221444	HRA Approval	EDOXABAN VERSUS STANDARD OF CARE AND THEIR EFFECTS ON CLINICAL OUTCOMES IN PATIENTS HAVING UNDERGONE TRANSCATHETER AORTIC VALVE IMPLANTATION ? IN ATRIAL FIBRILLATION	No		18			No		11/05/2017	21/09/2017	06/06/2017	04/10/2017	09/10/2017	09/10/2017				Y		Y						Very tight inclusion, screened just under 50 patients. Green light not given until 10th Dec 2017, surgeons were off and not there is a back up of elevative patients	Both
17/NW/0292	223951	HRA Approval	Phase 1b multi-indication study of anetumab ravtansine (BAY 94-9343) in patients with mesothelin expressing advanced or recurrent malignancies	No		15			Yes		13/06/2017	26/09/2017	27/07/2017	05/10/2017	11/10/2017	11/10/2017						Y						Screening ongoing. No Suitable patients	Neither
17/EM/0190	219055	HRA Approval	A Phase 3b, Randomized, Active Comparator, Open-label, Multicenter Study to Compare the Efficacy, Safety, and Tolerability of ITCA 650 to Empagliflozin and to Glimepiride as Add-on Therapy to Metformin in Patients with Type 2 Diabetes	No		8			No		01/03/2017	28/09/2017	01/08/2017	03/08/2017	06/10/2017	06/10/2017				Y								Study closed by sponsor	Sponsor
16/LO/1355	168344	HRA Approval	InPACT trial- International Penile Advanced Cancer Trial (International Rare Cancers Initiative study)	No		14			No		16/12/2016	01/12/2017	11/10/2016	14/12/2017	15/12/2017	15/12/2017						Y			Y		It's rare but we will be taking referrals regionnally. Leave for now.?	Neither
16/LO/0680	186642	HRA Approval	SMILE: Strategy for Maintenance of HIV suppression with elvitegravir+darunavir/ritonavir in children (PENTA 17). A two-arm, Phase 2/3 multicentre, open-label, randomised study evaluating safety and antiviral effect of current standard antiretroviral therapy compared to elvitegravir (EVG) administered with darunavir/ritonavir (DRV/r) in HIV-1 infected, virologically suppressed paediatric participants.	No		2			No		27/11/2017	07/03/2018	28/07/2016	02/03/2018	09/03/2018	09/03/2018						Y						Screening going but no eligible patients very tight inculsion criteria	Neither

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17/LO/1672	209107	HRA Approval	Investigating the clinical utility of the MDS Test for the oncogenic activity in nevi suspected of being melanoma	No		23			No		23/11/2017	11/04/2018	17/04/2018	04/04/2018	04/05/2018	04/05/2018				Y								The reason for the delay in recruiting the first patient for the above study was due to (1) Sponsor delay.	Sponsor
17/EE/0481	226412	HRA Approval	Pre-Implantation Trial of Histopathology In renal Allografts (PITHIA)	No		15			Within 70 Days		29/08/2017	23/01/2018	18/01/2018	07/02/2018	07/02/2018	07/02/2018						Y						This is not a typical trial that involves sites being randomised to one of five groups and randomisation will determine the start of recruitment. The earliest for any recruitment to happen is 4 months from the ransomisation (considering the site is randomised to a group 1). In principle it makes impossible to meet the target of 30 days.Refer to attached information from the Sponsor explaining the reason behind non-compliance with the target of recruiting within 30 days.	Neither
16/EM/0172	194491	HRA Approval	Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High rate episodes	Yes	09/01/2018	8	159	167	Yes		22/09/2016	26/07/2017	24/05/2016	30/05/2017	03/08/2017	03/08/2017						Y						strict inclusion criteria	Neither
17/LO/1451	229939	HRA Approval	A Randomized, Double-blind, Placebo-controlled, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Basal Insulin Alone or in Addition to Oral Antidiabetes Drugs (OADs)	No		0			No		03/07/2017	20/02/2018	24/01/2018	29/01/2018	20/02/2018	20/02/2018							Y						Very tight inclusion Criteria	Neither
17/YH/0228	222492	HRA Approval	CALM- 2 ? CONTROLLING AND LOWERING BLOOD PRESSURE WITH THE MOBIUSHD?	No					No		29/03/2018	10/04/2018	05/10/2017				Y							Y				UHL approval delay due to study costing issue	NHS Provider
16/EM/0380	198726	HRA Approval	Study 15	No		50			Yes		25/07/2017	30/04/2018	09/11/2016	25/06/2018	19/06/2018	19/06/2018													Please
17/EE/0463	227579	HRA Approval	A Randomized, Double-blind, Placebo-controlled, Adaptive Study to Evaluate Symptom Improvement and Metabolic Control Among Adult Subjects With Symptomatic Hypoparathyroidism Treated With Recombinant Human Parathyroid Hormone [rhPTH(1-84)]	No		28			No		01/12/2017	03/04/2018	15/02/2018		01/05/2018	01/05/2018						Y						1 patient consented on 31/05/2018 waiting to be randomised	Neither
17/LO/2072	209317	HRA Approval	Ways Back to Work. The occupational health management of NHS staff with mental health disorders: a feasibility study.	Yes	23/04/2018	79	61	140	Within 70 Days		15/11/2017	04/12/2017	13/12/2017	21/02/2018	21/02/2018	21/02/2018				Y		Y		Y				Difficult inclusion & Exclution Criteria, Now the study is recruited, Delay in Contract Negotiations. Screening going on now study is recruited	Sponsor
18/EM/0045	232426	HRA Approval	Outcome of Balloon Arthroplasty in Irreparable Massive Rotator Cuff Tear	No		146			Within 70 Days		03/10/2017	23/01/2018	26/04/2018	18/06/2018	18/06/2018	18/06/2018	Y											Delay in CMG approval	NHS Provider
17/EM/0315	220334	HRA Approval	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients with Rheumatoid Arthritis Interstitial Lung Disease	Yes	19/04/2018	115	139	254	Yes		11/10/2016	08/08/2017	03/11/2017	22/05/2017	01/12/2017	01/12/2017				Y		Y						The delay and failure to meet the 30 day deadline was due to the subject not wishing to start the study before Christmas and us having to wait for Sponsor Green Light before we could screen the subject.	Sponsor
16/LO/1024	195085	HRA Approval	Safety and efficacy of Belimumab After B cell depletion therapy in systemic LUPUS erythematosus	No		29			Yes		11/07/2017	09/01/2018	20/09/2016	21/12/2017	07/02/2018	07/02/2018						Y						strict inclusion criteria	Neither
17/SC/0294	224828	HRA Approval	Title: A Phase III Randomised Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Neoadjuvant Anthracycline/Nab-paclitaxel Based Chemotherapy Compared with Placebo and Chemotherapy in Patients with Primary Invasive Triple-Negative Breast Cancer	Yes	13/03/2018	32	141	173	No		10/02/2017	21/09/2017	02/08/2017	11/10/2017	23/10/2017	23/10/2017						Y						Screening Going on no patient seen	Neither

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17/LO/0065	219950	HRA Approval	A randomized, double-blind, placebo-controlled, phase III study comparing the combination of PDR001, dabrafenib and trametinib versus placebo, dabrafenib and trametinib in previously untreated patients with unresectable or metastatic BRAF V600 mutant melanoma	Yes	21/05/2018	8	229	237	Yes		21/02/2017	26/09/2017	14/02/2017	26/09/2017	04/10/2017	04/10/2017						Y			Y		Rare Disease.	Neither
17/WM/0308	226910	HRA Approval	Randomized, Double-Blind, Phase 3B Trial to Evaluate the Safety and Efficacy of 2 Treatment Regimens of Aztreonam 75 mg Powder and Solvent for Nebulizer Solution / Aztreonam for Inhalation Solution (AZLI) in Pediatric Subjects with Cystic Fibrosis (CF) and New Onset Respiratory Tract Pseudomonas aeruginosa (PA) Infection/Colonization	No		159			No		02/08/2017	02/08/2017	09/10/2017	19/10/2017	08/01/2018	08/01/2018						Y					None of the children so far met the inculsion criteria .0	Neither
17/SC/0201	209172	HRA Approval	IP Rollover Study (XRuST): An Open-Label, Rollover Study	No		7			Yes		16/06/2017	26/04/2018	10/07/2017	05/05/2018	03/05/2018	03/05/2018												Please Select...
17/SC/0533	205320	HRA Approval	A PHASE II STUDY OF ATEZOLIZUMAB WITH RITUXIMAB, GEMCITABINE AND OXALIPLATIN IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA WHO ARE NOT CANDIDATES FOR HIGH-DOSE THERAPY.	No		32			No		06/03/2018	04/05/2018	31/01/2018	30/05/2018	05/06/2018	05/06/2018												Please Select...
17/NS/0018	223787	HRA Approval	Female Urgency, Trial of Urodynamics as Routine Evaluation (FUTURE study); a superiority randomised clinical trial to evaluate the effectiveness and cost effectiveness of invasive urodynamic investigations in management of women with refractory overactive bladder symptoms	No		34			Yes		18/01/2018	08/05/2018	01/10/2017	14/06/2018	11/06/2018	11/06/2018												Please Select...
16/LO/1677	191232	HRA Approval	Deciphering Antitumour Response and Resistance With INtratumour Heterogeneity A phase II, multi-centre, non-randomised, molecularly stratified trial for NSCLC patients to study tumour heterogeneity using genomic analysis	No		18			No		20/09/2016	18/05/2018	13/12/2016	13/06/2018	05/06/2018	05/06/2018												Please Select...
15/EM/0095	166503	HRA Approval	A phase III, open label, multicentre randomised clinical study comparing Acelarin (NUC-1031) with Gemcitabine in patients with metastatic pancreatic carcinoma (ACELARATE: Acelarin first line randomised pancreatic study)	No		14			Within 70 Days		01/12/2017	26/03/2018	15/06/2016	04/05/2018	09/04/2018	09/04/2018				Y							Delay in sponsor green light	Sponsor
16/SW/0160	205879	HRA Approval	CHALLENGE-UK: A UK cohort of a Phase III study (CHALLENGE: the Colon Health and Lifelong Exercise Change	No		41			No		02/02/2018	14/03/2018	06/06/2017	12/04/2018	24/04/2018	24/04/2018						Y					Tight Inclusion Criteria	Neither
13/SC/0645	143871	HRA Approval	Mechanisms of action of intervention in the PHOENIX trial: in women with preterm pre-eclampsia; does planned delivery improve postpartum maternal cardiac function through attenuation of myocardial ischaemia at time of disease?	Yes	20/04/2018	128	81	209	Yes		23/09/2017	23/09/2017	15/06/2016	29/01/2018	29/01/2018	29/01/2018				Y		Y					Delay in target Negotiation and Delay in sponsor green light. Also very tight inclusion criteria	Sponsor
17/NW/0512	221775	HRA Approval	PETReA: Phase 3 evaluation of PET-guided, Response-Adapted therapy in patients with previously untreated, high tumour burden follicular lymphoma	Yes	30/05/2018	52	37	89	Yes		09/10/2017	02/03/2018	08/11/2017	30/04/2018	23/04/2018	23/04/2018				Y							Delay in sponsor green light	Sponsor

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17/LO/1068	224973	HRA Approval	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER TRIAL TESTING IPATASERTIB PLUS ABIRATERONE PLUS PREDNISONE/PREDNISOLONE, RELATIVE TO PLACEBO PLUS ABIRATERONE PLUS PREDNISONE/PREDNISOLONE IN ADULT MALE PATIENTS WITH ASYMPTOMATIC OR MILDLY SYMPTOMATIC, PREVIOUSLY UNTREATED, METASTATIC CASTRATE-RESISTANT PROSTATE CANCER	Yes	16/04/2018	11	167	178	No		20/04/2017	20/10/2017	27/07/2017	20/10/2017	31/10/2017	31/10/2017						Y					screening going on strict inclusion criteria	Neither
17/SC/0615	233555	HRA Approval	A Phase II, Open Label, Randomised, Multi-centre Study to Assess the Safety and Efficacy of Agents Targeting DNA Damage Repair in Combination with Olaparib versus Olaparib Monotherapy in the Treatment of Metastatic Triple Negative Breast Cancer Patients Stratified by Alterations in Homologous Recombinant Repair (HRR)-related Genes (including BRCA1/2)	No		29			No		02/02/2018	22/05/2018	16/03/2018	06/06/2018	20/06/2018	20/06/2018												Please Select...
17/SC/0070	215616	HRA Approval	RCT The Prepare Multi-Morbid Older People for End-stage Kidney Disease Trial	No		15			Yes		17/04/2018	04/06/2018	30/05/2017	06/06/2018	19/06/2018	19/06/2018												Please Select...
17/SW/0221	232448	HRA Approval	A randomized, partially-blinded, active-controlled,multicenter study of secukinumab to demonstrate reduction of radiographic progression versus GP2017 (adalimumab biosimilar) at 104 weeks and to assess the long term safety, tolerability and efficacy up to 2 years in patients with active ankylosing spondylitis	No		11			No		05/04/2018	07/06/2018	28/11/2017	14/05/2018	18/06/2018	18/06/2018												Please Select...
17/EE/0311	219032	HRA Approval	Does incremental initiation of haemodialysis preserve native kidney function? A multicentre feasibility randomised control trial	No		14			No		21/09/2017	11/06/2018	06/09/2017	19/06/2018	25/06/2018	25/06/2018												Please Select...
17/EE/0177	220722	HRA Approval	A phase 3 randomized, controlled, open-label study of selinexor, bortezomib, and dexamethasone (SVD) versus bortezomib and dexamethasone (VD) in patients with Relapsed or Refractory Multiple Myeloma (RRMM)	Yes	26/02/2018	2	46	48	No		31/08/2017	09/01/2018	24/07/2017	21/12/2017	11/01/2018	11/01/2018												Please Select...
17/LO/1015	223251	HRA Approval	Ankle Injury Rehabilitation - A multi-centre randomised controlled trial to assess the difference between plaster cast and functional bracing in the management of ankle fractures.	No		1			No		11/09/2017	12/06/2018	04/07/2017	19/06/2018	13/06/2018	13/06/2018												Please Select...
16/EE/0183	199109	HRA Approval	Efficacy and safety of BI 655064 in patients with active lupus nephritis	No		0			Yes		16/02/2017	20/02/2018	01/07/2016	15/02/2018	20/02/2018	20/02/2018						Y					Due to the strict inclusion/exclusion criteria it has been difficult to recruit the right patient into the study, we have screened a number of patients but they have unfortunately failed for a number of reasons including language barrier and inconsistency in attending appointments	Neither

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18/LO/0396	238968	HRA Approval	A PHASE 1B STUDY EVALUATING RO7082859 IN COMBINATION WITH RITUXIMAB (R) OR OBINUTUZUMAB (G) PLUS CYCLOPHOSPHAMIDE, DOXORUBICIN, VINCRISTINE, AND PREDNISONE (CHOP) IN PARTICIPANTS WITH RELAPSED REFRACTORY FOLLICULAR LYMPHOMA (R/R FL) OR IN PARTICIPANTS WITH UNTREATED DIFFUSE LARGE B-CELL LYMPHOMA	No					Yes		09/02/2018	29/06/2018	16/05/2018	28/06/2018													Please Select...
17/EE/0221	223856	HRA Approval	A Phase 2, 24-week, Randomized, Double-Blind, Placebo-Controlled, Mulitcenter Study, Followed by a 24-Week Extension, to Evaluate the Efficacy and Safety of CC-90001 in Subjects with Idiopathic Pulmonary Fibrosis	Yes	16/05/2018	14	208	222	No		07/02/2017	06/10/2017	14/09/2017	12/07/2017	20/10/2017	20/10/2017				Y							Awaiting amendment to PIS before we can write to new patients.	Sponsor
17/LO/1427	216241	HRA Approval	The effects of Calcium Channel Blockers or Angiotensin converting enzyme inhibitor/Angiotensin Receptor Blocker Therapy on Blood Pressure Variability following acute ischaemic Stroke (CAARBS): A Feasibility Trial	Yes	05/03/2018	14	82	96	Yes		01/09/2017	29/11/2017	25/09/2017	22/11/2017	13/12/2017	13/12/2017						Y					First patient consented with in 30 days but later screening was failed. Actively screening . One patient is recruited	Neither
16/SC/0152	180853	HRA Approval	Prevention Of Post-operative Complications By Using HMG-CoA Reductase Inhibitor In Patients Undergoing Oesophagectomy ? A multicentre, randomised, double blind, placebo controlled trial. (Prevention HARP 2)	No		21			No		23/09/2016	12/06/2018	13/10/2016		03/07/2018													Please Select...
17/LO/1656	229212	HRA Approval	A PHASE III, OPEN-LABEL, MULTICENTER, TWO ARM, RANDOMIZED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF COBIMETINIB PLUS ATEZOLIZUMAB VERSUS PEMBROLIZUMAB IN PATIENTS WITH PREVIOUSLY UNTREATED ADVANCED BRAF WILD-TYPE MELANOMA	Yes	09/04/2018	52	88	140	Within 70 Days		28/09/2017	20/11/2017	14/11/2017	03/01/2018	11/01/2018	11/01/2018						Y					Active screening was going on but no patient interested in consenting	Neither
17/EM/0412	234907	HRA Approval	An adaptive seamless randomized, double-blind, placebo-controlled, dose ranging study to investigate the efficacy and safety of LNP023 in primary IgA nephropathy patients	Yes	07/02/2018	35	26	61	Within 70 Days		12/10/2017	08/12/2017	04/12/2017	10/01/2018	12/01/2018	12/01/2018												Please Select...
17/SS/0052	196827	HRA Approval	Early Valve Replacement guided by Biomarkers of Left Ventricular Decompensation in Asymptomatic Patients with Severe Aortic Stenosis	Yes	03/05/2018	41	93	134	Yes		04/07/2017	20/12/2017	17/06/2017	03/01/2018	30/01/2018	30/01/2018						Y					Screening going 2 patient consented but Ineligible - criteria failure / pre-screening failure	Neither
17/EE/0377	222607	HRA Approval	A double blind, placebo controlled, randomised dose escalation trial to investigate the safety and efficacy of topical salbutamol in the improvement of scar appearance when applied to approximated wound margins in healthy volunteers	Yes	15/01/2018	134	10	144	Yes		28/07/2017	24/08/2017	02/01/2018	05/01/2018	05/01/2018	05/01/2018				Y							Drug supply issues from sponsor contractor	Sponsor
17/EM/0275	227425	HRA Approval	A Multi-center, Double-blind, Randomized, Three-Arm, Parallel-Group, Placebo Controlled Study to Assess the Efficacy and Safety of NTRA-2112 on Intestinal Malabsorption in Preterm Infants	Yes	25/01/2018	40	93	133	Yes		20/07/2017	14/09/2017	13/09/2017	15/10/2017	24/10/2017	04/12/2017				Y							Sponsor Green Signal delay	Sponsor
17/LO/0782	227047	HRA Approval	Placebo-Controlled Proof of Concept Study to Investigate AN8020 Activity in Adult Patients with Severe Eosinophilic Asthma	Yes	14/12/2017	29	93	122	Within 70 Days		15/02/2017	14/08/2017	23/06/2017	14/08/2017	12/09/2017	12/09/2017						Y					Eligible patients seen during the relevant period but did not consent to participate the trial	Neither

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17/NE/0092	220929	HRA Approval	A phase 3 C Difficile vaccine efficacy study - PF-06425090 for prevention of Clostridium difficile infection (CDI)	Yes	01/12/2017	0	120	120	Yes		12/12/2016	03/08/2017	28/03/2017	05/07/2017	03/08/2017	03/08/2017						Y						Eligible patients seen during the relevant period but did not consent to participate the trial	Neither
17/SW/0207	231037	HRA Approval	Fractional Flow Reserve Derived from Computed Tomography Coronary Angiography in the Assessment and Management of Stable Chest Pain.	Yes	17/05/2018	54	17	71	Within 70 Days		03/10/2017	07/03/2018	03/10/2017	10/04/2018	30/04/2018	01/05/2018	Y											Delay in getting Clinical team approval in UHL	NHS Provider
17/SC/0242	222650	HRA Approval	Phase 2A, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Intravenous FDY-5301 in Acute Myocardial Infarction (Protocol No. FDY-5301-201)	Yes	12/12/2017	11	85	96	Yes		13/03/2017	07/09/2017	06/09/2017	07/09/2017	18/09/2017	18/09/2017						Y						Acute STEMI study patients have to fit eligiblity, there were also issues with the randomised system and we lost 2 patients that had assented. We have randomised a further 2 patients this week	Neither
17/LO/0085	216434	HRA Approval	Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease (DD-CKD) (INNO2VATE ? CONVERSION)	Yes	01/05/2018	40	15	55	Within 70 Days		30/01/2017	07/03/2018	21/02/2017	05/03/2018	16/04/2018	16/04/2018												Please Select...
17/LO/0023	215490	HRA Approval	MUK nine b: OPTIMUM. A phase II study evaluating optimised combination of biological therapy in newly diagnosed high risk multiple myeloma and plasma cell leukaemia.	Yes	20/11/2017	13	76	89	No		13/03/2017	23/08/2017	30/03/2017	23/08/2017	05/09/2017	06/09/2017						Y						Eligible patients seen during the relevant period but did not consent to participate the trial	Neither
17/YH/0345	233852	HRA Approval	A phase 3, randomised, multicentre study of subcutaneous vs intravenous administration of daratumumab in subjects with relapsed or refractory multiple myeloma	Yes	02/05/2018	60	44	104	No		03/11/2017	18/01/2018	17/01/2018	15/03/2018	19/03/2018	19/03/2018	Y			Y								Amendment request before approval	Sponsor
17/SC/0607	217496	HRA Approval	A randomised, controlled trial of the use of a dedicated ballooned intercostal drain	Yes	20/03/2018	16	19	35	Within 70 Days		31/10/2017	13/02/2018	18/12/2017	01/03/2018	01/03/2018	01/03/2018													Please Select...
17/YH/0432	236091	HRA Approval	A double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate the efficacy and safety of repeat doses of GSK3772847 in participants with moderate to severe asthma with allergic fungal airway disease (AFAD).	No		26			Within 70 Days		06/10/2017	23/02/2018	19/02/2018	15/03/2018	21/03/2018	21/03/2018						Y						Screening going on, Difficult Inclusion and Exclusion critetia	Neither
17/LO/1865	232414	HRA Approval	Randomized, open label, multicentre study assessing the clinical benefit of isatuximab combined with carfilzomib (Kyprolis?) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with 1 to 3 prior lines.	Yes	26/03/2018	4	73	77	Please Select...		09/10/2017	08/01/2018	13/12/2017	10/01/2018	12/01/2018	09/02/2018				Y								Delay in site initiation visit	Sponsor
16/SW/0256	188499	HRA Approval	A Randomised, Controlled feasibility trial of Intraoperative Cell Salvage vs Donor Blood Transfusion in Ovarian Cancer Surgery (TICTOC)	Yes	20/11/2017	1	67	68	Please Select...		26/05/2017	13/09/2017	11/11/2016	13/09/2017	14/09/2017	14/09/2017													Please Select...
17/EE/0040	222216	HRA Approval	Emergency Cerclage in Twin pregnancies at Imminent Risk of Preterm Birth: an Open-Label Randomised Controlled Trial	No		1			Please Select...		05/12/2017	26/02/2018	02/03/2017	27/02/2018	27/02/2018	27/02/2018						Y						Screening going on, Difficult Inclusion and Exclusion critetia	Neither
17/EE/0255	227279	HRA Approval	A DOUBLE-BLIND, RANDOMISED, PLACEBO CONTROLLED STUDY OF THE EFFICACY AND SAFETY OF THREE DOSES OF ORVEPITANT IN PATIENTS WITH CHRONIC REFRACTORY COUGH	Yes	01/11/2017	5	58	63	Please Select...		10/04/2017	30/08/2017	26/07/2017	22/08/2017	04/09/2017	04/09/2017													Please Select...

PID Q1 18-19 (Performance Initiation)

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant Recruited	Benchmark Met	Date Study Initiated	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 patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
17/NE/0377	233847	HRA Approval	A phase 3b, multicenter, prospective, randomized, double blind, placebo-controlled study to reduce the incidence of pre-dialysis hyperkalemia with Sodium Zirconium Cyclosilicate (DIALIZE)	Yes	23/04/2018	34	27	61	Please Select...		10/10/2017	21/02/2018	19/02/2018	26/02/2018	27/03/2018	27/03/2018												Please Select...
17/WS/0071	224151	HRA Approval	An International, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effect of Dapagliflozin on the Incidence of the composite of =40% sustained reduction in eGFR, entering ESRD, CV or Renal Death in patients with Albuminuria and Moderate to Severe Renal Impairment (CKD 3-4)	Yes	11/12/2017	24	35	59	Please Select...		09/02/2017	13/10/2017	22/05/2017	25/10/2017	06/11/2017	06/11/2017												Please Select...
17/EE/0264	228153	HRA Approval	POSEIDON - A Phase III, Randomized, Multi-Center, Open-Label, Comparative Global Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination With Platinum-Based Chemotherapy for First-Line Treatment in Patients With Metastatic Non-Small-Cell Lung Cancer (NSCLC)	Yes	09/01/2018	1	56	57	Please Select...		16/06/2017	13/11/2017	12/09/2017	09/11/2017	14/11/2017	15/11/2017												Please Select...
17/LO/0035	218519	HRA Approval	Development and evaluation of an intervention to support Adherence to treatment in adults with Cystic Fibrosis. A randomised controlled trial and parallel process evaluation.	Yes	08/02/2018	16	36	52	Please Select...		20/01/2017	18/12/2017	03/04/2017	16/10/2017	03/01/2018	03/01/2018												Please Select...
18/NW/0173	242176	HRA Approval	Effect and safety of semaglutide 2.4 mg once-weekly in subjects with overweight or obesity and type 2 diabetes	Yes	04/07/2018	8	40	48	Please Select...		08/03/2018	17/05/2018	10/05/2018	11/05/2018	25/05/2018	30/05/2018												Please Select...
17/NE/0061	215780	HRA Approval	CONVINCE - COLchicine for preventIoN of Vascular Inflammation in Non-CardioEmbolic stroke) - a randomised clinical trial of low-dose colchicine for secondary prevention after stroke.	Yes	21/03/2018	12	29	41	Please Select...		01/12/2017	08/02/2018	25/07/2017	15/01/2018	20/02/2018	20/02/2018												Please Select...
18/EM/0051	227456	HRA Approval	Testing the feasibility of a combined exercise rehabilitation programme for COPD and/or heart failure patients	Yes	30/05/2018	20	21	41	Please Select...		02/02/2018	19/04/2018	16/04/2018	09/05/2018	09/05/2018	09/05/2018												Please Select...
17/LO/0041	219676	HRA Approval	CardioMEMS OUS	Yes	22/11/2017	4	36	40	Please Select...		23/01/2017	13/10/2017	06/03/2017	17/08/2017	17/10/2017	17/10/2017												Please Select...
17/WS/0184	222904	HRA Approval	The effects of an 8-week vegan diet on Trimethylamine-N-Oxide (TMAO) levels and post-challenge glucose levels in individuals with dysglycaemia..	Yes	17/10/2017	26	13	39	Please Select...		03/08/2017	08/09/2017	08/09/2017	04/10/2017	04/10/2017	04/10/2017												Please Select...
17/EM/0367	231327	HRA Approval	A multi-centre, open-label extension, safety study to describe the longterm clinical experience of mepolizumab in participants with hypereosinophilic syndrome (HES) from Study 200622	Yes	22/12/2017	18	18	36	Please Select...		06/09/2017	16/11/2017	10/11/2017	27/11/2017	04/12/2017	04/12/2017												Please Select...
17/EM/0166	222665	HRA Approval	AVAIL-T: A Phase 2a trial of Avelumab, an anti-PDL1 antibody, in relapsed and refractory peripheral T-cell lymphoma (PTCL)	Yes	08/12/2017	6	29	35	Please Select...		13/04/2017	03/11/2017	30/06/2017	02/11/2017	09/11/2017	09/11/2017												Please Select...
17/NW/0517	232120	HRA Approval	Effectiveness and cost of integrating a protocol with use of liraglutide 3.0mg into an obesity service (STRIVE Study)	Yes	28/11/2017	27	7	34	Please Select...		10/08/2017	25/10/2017	16/10/2017	14/11/2017	21/11/2017	21/11/2017												Please Select...
18/EM/0006	232310	HRA Approval	The effects of reducing prolonged sitting bouts with regular light upright movement breaks on glucose regulation in individuals at high risk of or with type 2 diabetes.	Yes	08/03/2018	19	15	34	Please Select...		18/07/2017	02/02/2018	31/01/2018	21/02/2018	21/02/2018	21/02/2018												Please Select...

PID Q1 18-19 (Performance Initiation)

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16/WM/0512	218042	HRA Approval	A Phase 1, open-label, randomised, repeat dose parallel group study to evaluate the pharmacokinetics, safety and tolerability of ferric maltol at three dosage levels in paediatric subjects (aged 10-17) with iron deficiency (with or without Anaemia)	Yes	11/12/2017	3	25	28	Please Select...		01/09/2017	13/11/2017	23/02/2017	07/11/2017	16/11/2017	16/11/2017												Please Select...
17/SC/0391	227067	HRA Approval	The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial	Yes	19/03/2018	12	7	19	Please Select...		22/11/2017	28/02/2018	07/09/2017	09/02/2018	12/03/2018	13/03/2018												Please Select...
17/SC/0083	218035	HRA Approval	A Prospective, Randomized, Open Label, Multi-center Study of the Safety and Pharmacokinetics of Apixaban versus Vitamin K Antagonist or LMWH in Pediatric Subjects with Congenital or Acquired Heart Disease Requiring Chronic Anticoagulation for Thromboembolism Prevention	Yes	11/09/2017	0	18	18	Please Select...		10/01/2017	24/08/2017	07/07/2017	18/08/2017	24/08/2017	24/08/2017												Please Select...
16/NS/0094	206213	HRA Approval	BioImpedance Spectroscopy to Maintain Renal Output: The BISTRO Trial	Yes	27/11/2017	6	12	18	Please Select...		15/11/2016	09/11/2017	04/10/2016	03/11/2017	15/11/2017	15/11/2017												Please Select...
17/EE/0361	231209	HRA Approval	A 2-treatment epoch, randomized, placebo-controlled, multicenter parallel-group study to assess the safety of QAW039 when added to existing asthma therapy in patients with uncontrolled severe asthma	Yes	08/11/2017	0	7	7	Please Select...		15/09/2017	01/11/2017	31/10/2017	09/10/2017	01/11/2017	01/11/2017												Please Select...