Q2 Performance In Initiating 2018-2019

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	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	Reasons for Delay	Comments	Reasons for delay correspond to:		Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant Recruited
17/EE/0431	234555	Dose Ranging Trial of MK-8591 Given in Combination Therapy	Yes	09/02/2018	05/10/2017	26/10/2017	18/12/2017	22/12/2017	04/01/2018	Please Select...	09/01/2018	D - Sponsor Delays	Sponsor delays with study lab manual, PIS and HRA approval letter.. First patient recruited 09/02/2018 which was within 30 days of sponsor green light being given.	Sponsor		36	106
16/LO/1979	193891	A randomised trial of non-Selective versus selective adjuvant Therapy in high risk Apparent sTage 1 Endometrial Cancer	No		06/11/2018	06/11/2017	20/12/2016	15/01/2018		Site declined to participate		A - Permissions delayed/denied	Decision was taken by the site not to proceed with this study.	Neither			
17/EE/0429	234063	Evaluation of Lumicitabine in young children hospitalised with RSV	No		14/11/2017	14/11/2017				Site declined to participate		J - Other	Site Declined to Participate	Neither			
14/WS/1096	149204	Shortcourse radiotherapy plus olaparib for newly diagnosed glioblastoma in patients unsuitable for radical chemoradiation: a randomised phase II clinical trial preceded by a leadin phase I dose escalation study.	Yes	03/07/2018	21/11/2017	21/11/2017	03/11/2014	04/01/2018	18/01/2018	Please Select...	17/04/2018	E - Staff availability issues	Recruitment target missed due to delays with local IRMER approvals in relation to staffing capacity issues at site	NHS Provider		166	224
17/EM/0371	229496	Strategic MAnagement to Optimize Response To Cardiac Resynchronization Therapy. SMART CRT	Yes	09/03/2018	23/06/2017	30/11/2017	21/11/2017	29/09/2017	03/10/2017	Please Select...	18/12/2017	D - Sponsor Delays	Recruitment target missed. The sponsor changed essential documents after capacity and capability was issued.	Sponsor		157	99
17/LO/2058	231907	A PROSPECTIVE, MULTICENTER, NON-RANDOMIZED, POST-MARKET CLINICAL FOLLOW-UP STUDY TO CONFIRM SAFETY AND PERFORMANCE OF THE COHEREX WAVECREST® LEFT ATRIAL APPENDAGE OCCLUSION SYSTEM IN CURRENT MEDICAL PRACTICE IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION WAVECREST PMCF STUDY - CHX_IP015	Yes	07/03/2018	16/10/2017	02/01/2018	08/01/2018	07/12/2017	11/12/2017	Please Select...	01/03/2018	J - Other	Initiation recruitment target as it was at this timepoint met	Neither		86	64
17/EE/0382	220851	PRedicting Outcomes For Crohn's dIsease using a moLecular biomarkEr (PROFILE) trial	No		11/12/2017	02/01/2018	19/01/2018	30/01/2018	07/02/2018	Please Select...	24/05/2018	E - Staff availability issues	Initiation recruitment target not met. Delays with IRMER and pharmacy department confirmation of C&C. Eligible patients seen but did not consent.	Sponsor			
17/EE/0448	226368	Randomised Controlled Trial of Cryo Ablation versus Cardioversion in Persistent Atrial Fibrillation	Yes	08/03/2018	17/08/2017	04/01/2018	19/12/2017	16/11/2017	23/02/2018	Please Select...	26/02/2018	J - Other	Initiation recruitment target as it was met. 3 patients recruited and randomised by recruitment target date.	Neither		13	63
17/EM/0361	234065	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study in Subjects With Relapsing Multiple Sclerosis to Evaluate the Efficacy and Safety of BIIB033 as an Add-On Therapy to Anti-Inflammatory Disease-Modifying Therapies	No		28/06/2017	12/01/2018	11/01/2018	05/02/2018	19/02/2018	Please Select...	21/03/2018	D - Sponsor Delays	Initiation target not met. Sponsor changed pharmacy relevant information when site were close to opening and pharmacy SOPs had to be re-written. Unblinded pharmacy SIV was after main SIV.	Sponsor			
17/SC/0164	210735	A multi-centre, randomised, controlled trial evaluating theeffects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage requiring majorhaemorrhage protocol (MHP) activation	Yes	10/05/2018	22/11/2017	01/02/2018	26/05/2017	18/12/2017	19/02/2018	Please Select...	16/03/2018		Recruitment Target Not Met.	Please Select...		80	98
16/NW/0629	211995	The cystic fibrosis (CF) anti-staphylococcal antibiotic prophylaxis trial (CF START); a randomised registry trial to assess the safety and efficacy of flucloxacillin as a longterm prophylaxis agent for infants with CF.	No		09/02/2018	09/02/2018	22/09/2016	26/03/2018	13/03/2018	Please Select...	16/04/2018	I - Rare diseases J - Other	FPR 30 Day Target was 26/05/2018, not met. Rare patient group, sponsor sent us the HRA pack too early. Recruitment target for this study is 1 participant in total. C&C issued 16/04/2018. SIV took place 24/04/2018.	Neither			
18/WM/0017	236521	Post-Market Clinical Investigation of the Clareon® IOL	Yes	04/06/2018	09/01/2018	18/05/2018	16/02/2018	16/04/2018	18/04/2018	Please Select...	16/12/2018	D - Sponsor Delays	BSUH were the first site in the UK to be open to recruitment. The sponsor wanted the site to open at a specific time point. First patient recruited within 17 days of site activation.	Sponsor		47	17
17/SW/0255	234748	Clinical Trial Evaluation of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System	No		22/02/2018	22/02/2018	21/02/2018	15/08/2017	06/09/2017	Please Select...	18/09/2018	D - Sponsor Delays	Sponsor submitted a substantial amendment during set up. Aim to recruit first patient by 17th October 2018	Sponsor			
17/NS/0018	223787	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		05/03/2018	05/03/2018		27/02/2018	23/04/2018	Please Select...		F - No patients seen	Initiation target not met despite screening for study. Media stories have had an impact on participants' willingnesst to participate.	Neither			
18/SC/0055	239091	Evaluating the effect of immunisation with group B meningococcal vaccines on meningococcal carriage	Yes	24/04/2018	05/02/2018	12/03/2018	05/03/2018	18/04/2018	18/04/2018	Please Select...	19/04/2018	F - No patients seen	Initiation target just missed. First patient recruited within 37 days, no eligible patients seen before this time point.	Neither		6	43
17/LL/2093	228763	A phase IV, open-label pilot study investigating non-invasive markers of hepatic fibrosis in people living with HIV-1 and non-alcoholic fatty liver disease randomised to receiving OBT plus maraviroc or OBT	Yes	06/04/2018	24/11/2017	19/03/2018	28/02/2018	19/03/2018	27/03/2018	Please Select...	28/03/2018	J - Other	Initiation target met	Neither		10	18
16/LO/1905	195890	A randomised study of interferon-free treatment for recently acquired hepatitis C in people who inject drugs and people with HIV coinfection (REACT)	Yes	23/04/2018	07/01/2018	12/04/2018	31/03/2017	28/03/2018	28/03/2018	Please Select...	13/04/2018		Initiation target met Opened to recruitment 13 April 2018. No HRA approval/ assessment documentation was received until 12 April because the sponsor forgot, therefore the site selected date was after the date of site and sponsor confirmed dates. 3 patients recruited to date.	Please Select...		26	11
17/NI/0204	230772	Nordic-Baltic-British Study on Optical Coherence	No		04/12/2017	10/07/2018	05/04/2018	28/06/2018	28/06/2018	Please Select...	10/07/2018	D - Sponsor Delays	Initiation target not met. Delays in receiving documents from the sponsor.	Sponsor			
18/SC/0155	236211	A multicentre international randomized parallel group double-blind placebo-controlled clinical trial of EMPAgliflozin once daily to assess cardio-renal outcomes in patients with chronic KIDNEY disease	No		23/04/2018	23/04/2018	26/04/2018	06/07/2018	17/07/2018	Please Select...	31/07/2018	J - Other	Initiation target not met. Sponsor and Site had agreed a later start date because training in Oxford was required before screening takes place.(30 day target) 26th August 2018 and the training starts on 11/12 December 2018.	Neither			
16/NS/0106	212541	Reducing Asthma Attacks in Children using Exhaled Nitric Oxide as a biomarker to inform treatment strategy – A randomised trial (RAACENO)	Yes	02/08/2018	09/03/2018	08/05/2018	04/04/2017	17/04/2018	07/05/2018	Please Select...	08/05/2018	G - No patients consented	Initiation target not met. This study is screening a large number of patients. 6 patients approached but none consented yet.	Neither		87	86

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18/LO/0727	245123	Post-Market Clinical Follow-Up Study to Monitor Device Performance and Outcomes of the CENTERA Heart Valve System	No		04/07/2018	04/07/2018	28/02/2018	04/07/2018	10/09/2018	Please Select...	05/10/2018	F - No patients seen	Initiation target missed, despite screening no patients seen/ recruited.	Neither			
18/NW/0228	240364	A Phase 2b, Randomised, Multi-Center, Double Blind, Dose-Ranging Study to Assess the Efficacy, Safety and Pharmacokinetics of Intravenous TAK-954 in Critically Ill Patients with Enteral Feeding Intolerance	No		18/05/2018	18/05/2018				Please Select...		D - Sponsor Delays	Initiation target not met. Further study documents awaited from the sponsor.	Sponsor			
17/LO/0731	219463	A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost	Yes	29/06/2018	23/11/2017	19/06/2018	27/07/2017	17/01/2018	18/01/2018	Please Select...	19/06/2018	A - Permissions delayed/denied	First patient recruited 29/06/2018, some delays with internal RTQA approvals	NHS Provider		162	10
18/NE/0132	242937	A PHASE III, RANDOMIZED, MULTICENTER, OPEN-LABEL, TWO-ARM STUDY TO EVALUATE THE PHARMACOKINETICS, EFFICACY, AND SAFETY OF SUBCUTANEOUS ADMINISTRATION OF THE FIXED-DOSE COMBINATION OF PERTUZUMAB AND TRASTUZUMAB & CHEMOTHERAPY IN PATIENTS WITH HER2 POSITIVE EARLY BREAST CANCER	Yes	09/08/2018	27/02/2018	24/05/2018	07/06/2018	25/05/2018	07/06/2018	Please Select...		F - No patients seen	First patient recruited within 70 days but 30 day target not met	Neither		63	77
17/YH/0228	222492	CALM- 2 – CONTROLLING AND LOWERING BLOOD PRESSURE WITH THE MOBIUSHD®	No		15/02/2018	12/06/2018	05/10/2017	03/05/2018	04/05/2018	Please Select...		F - No patients seen	No eligible patients seen so far despite intensive screening and social media recruitment campaigns. n clinic and identified 32 patients for further screening. This number reduced to 3, from which 2 eligible and 1 screen failed. have also done a Facebook campaign; 23 pts. referred and 2 eligible - will need further screening to check eligibility. 2 pt screening on 1st November	Neither			
18/SC/0211	241498	Comparing 2D and 3D photography with computerised analysis for earlier detection of craniofacial changes of fetal alcohol spectrum disorder in newborn infants with and without prenatal alcohol exposure	Yes	19/06/2018	19/06/2018	19/06/2018	23/05/2018	19/06/2018	19/06/2018	Please Select...	19/06/2018	J - Other	Delays with internal training after C&C was given.	NHS Provider		0	0
18/EM/0119	244650	A Randomized, Double-Blind, Phase 3 Study of Pemetrexed + Platinum Chemotherapy with or without Pembrolizumab (MK-3475) in TKI-resistant EGFR-mutated Tumors in Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) Participants (KEYNOTE-789)	No		19/04/2018	28/06/2018	06/07/2018	03/07/2018	05/07/2018	Please Select...	16/08/2018	F - No patients seen	No eligible patients seen, our target is 3 per annum	Neither			
18/SW/0130	246372	Prospective Evaluation of Thin-strut Biodegradable Polymer-coated Supraflex Sirolimus-Eluting Stents in an Allcomers Patient Population (S-FLEX UK-II)	No		02/07/2018	02/07/2018	29/06/2018	25/07/2018	30/07/2018	Please Select...	08/08/2018	E - Staff availability issues	Despite recruitment no eligible patients seen.	NHS Provider			
18/SC/0243	240684	HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease	No		24/07/2018	24/07/2018				Please Select...		D - Sponsor Delays	This study is still in set up, HRA approval documentation awaited from the sponsor at the reporting cut off time point	Sponsor			
17/LO/0621	191390	STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury: A Multi-Centre, Randomized, Controlled Trial	No			18/04/2018	24/07/2018			Please Select...		D - Sponsor Delays	.The SoA was not available for site at the time of the reporting cut off.	Sponsor			
17/LO/1711	234276	Synbiotic Extensively Hydrolysed Feed Study	No		04/07/2018	25/07/2018	14/09/2018	25/07/2018	31/07/2018	Please Select...	14/09/2018	J - Other	Delays in organising the site training visit	NHS Provider			
18/EE/0222	233921	A randomised controlled trial of very early versus delayed angiography +/-intervention on outcomes in patients with non ST-elevation myocardial infarction	No		20/06/2018	27/07/2018	12/09/2018	26/09/2018	01/10/2018	Please Select...			Study not open to recruitment at the reporting cut off time point	Unknown			
18/HRA/1559	243467	The influence of social care on delayed transfers of care	No		27/07/2018	27/07/2018	28/02/2018	27/07/2018	27/07/2018	Please Select...	03/08/2018	J - Other	First patient recruitment date unknown	NHS Provider			
18/LO/0773	214890	Limiting Undetected Sexually Transmitted Infections to RedUce Morbidity: A qualitative exploratory approach to investigate the Accelerated Partner Therapy intervention in patients and health professionals (LUSTRUM Pre-trial Development Work)	No		20/07/2018	20/07/2018				Site declined to participate		A - Permissions delayed/denied	05/09/2018 Site declined to participate	Neither			
18/ES/0067	216343	Brain Imaging to predict Toxicity in Elderly patients after Radiotherapy	Yes	05/09/2018	03/07/2018	01/08/2018	28/06/2018	01/08/2018	01/08/2018	Please Select...	08/08/2018	J - Other	Initiation target met	Neither		35	35
0	247770	To evaluate the acceptability (including gastro intestinal tolerance and compliance) of a low calorie peptide based paediatric tube-feed formula; for children greater than 1 year of age.	No		03/08/2018	03/08/2018	10/07/2018	03/08/2018	03/08/2018	Please Select...	03/08/2018	F - No patients seen	No eligible participants seen	Neither			
18/WA/0161	238902	AN OPEN-LABEL, MULTI-CENTRE, RANDOMISED, SWITCH STUDY TO EVALUATE THE VIROLOGICAL EFFICACY OVER 96 WEEKS OF 2-DRUG THERAPY WITH DTG/RPV FDC IN ANTIRETROVIRAL TREATMENTEXPERIENCED HIV-1 INFECTED SUBJECTS VIROLOGICALLY SUPPRESSED WITH NNRTIS RESISTANCE MUTATION K103N	No		08/01/2018	06/08/2018				Please Select...		A - Permissions delayed/denied D - Sponsor Delays	Study in set up reporting cut off point. HRA approval for the study pending.	Neither			
18/NW/0476	246649	Involve-CAT: A Feasibility Randomised Controlled Trial of a Cataract Decision Aid	Yes	09/10/2018	06/08/2018	06/08/2018	06/09/2018	17/09/2018	21/09/2018	Please Select...		A - Permissions delayed/denied	First patient recruited, however 30 day first patient recruitment target was missed as HRA approval was awaited.	Neither		18	64
18/LO/0612	235872	CLEAR SYNERGY (OASIS 9): A 2x2 factorial randomized controlled trial of CoLchicine and spironolactonE in patients with ST elevation myocARdial infarction/SYNERGY Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9	No		28/05/2018	08/08/2018				Please Select...		A - Permissions delayed/denied	Study in set up at reporting cut off time point. 02/10/2018 Study HRA approvals awaited before site can open to recruitment	Neither			

17\NI\0162	232288	A phase 3 randomised, double blind, clinical trial investigating the effectiveness of repurposed simvastatin compared to placebo, in secondary progressive multiple sclerosis, in slowing the progression of disability	No		13/06/2018	18/09/2018	19/01/2018	12/07/2018	24/07/2018	Please Select...	18/09/2018	J - Other	Green light to recruit given on the 27th September 2018. First patient due in for screening soon.	Neither			