Performance In Initiating Q3 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:
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_IP01S	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
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 C&C. Eligible participants 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
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 the effects 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. Discussions over protocol pathway.	Please Select...
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 early. Recruitment target for this study is 1 participant in total.	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
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. FPR 05October2018	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	11/08/2017	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

Performance In Initiating Q3 2018-2019

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17/LI/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
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, , therefore the site selected date was after the date of site and sponsor confirmed dates.	Please Select...
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 EMPAglifiozin 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.Training started on 11/12 December 2018. No patients recruited to date.	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 wasn't met. 6 patients were approached by that date but none consented by then. 31/12/2018 Overall 5 participants recruited to date, out of 43 screened.	Neither
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	Sponsor wanted the lead site to open up first, so initiation target not met.	Sponsor
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				Sponsor declined site confirmation			Sponsor declined site confirmation	Please Select...
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
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...	24/07/2018	F - No patients seen	None	Neither

Performance In Initiating Q3 2018-2019

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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...	13/06/2018	F - No patients seen	No eligible patients seen so far despite intensive screening and social media recruitment campaigns & screening over 150 patients. Issues with recruitment study wide.	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
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	D - Sponsor Delays	BSUH is the first amongst 30 sites to be ready to recruit for this study but sponsor decided to use a new stent which required CE marking, so initiation target not met.	Sponsor
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...	05/12/2018	D - Sponsor Delays F - No patients seen	No patients recruited at the reporting time point.	Both
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	18/04/2018	22/05/2017			Please Select...			Study was still in set up at the reporting cut off time point	Please Select..
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	G - No patients consented	Large numbers of approached participants declining to take part.	Neither
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	Yes	12/12/2018	20/06/2018	27/07/2018	12/09/2018	26/09/2018	01/10/2018	Please Select...	03/10/2018	D - Sponsor Delays	Initiation target not met. There was a sponsor delay in organizing the SIV. Also incorrect hospitals details were on IRAS, therefore, a NSA had to be processed.	Sponsor
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

Performance In Initiating Q3 2018-2019

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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
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.	Yes	31/10/2018	03/08/2018	03/08/2018	10/07/2018	03/08/2018	03/08/2018	Please Select...	03/08/2018	F - No patients seen	Out of 5 participants screened, one was recruited and only became eligible after the initiation target date.	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	04/10/2018	13/11/2018	13/11/2018	Please Select...	13/11/2018	G - No patients consented	Initiation target not met, no participants recruited as at 31/12/2018. Only 36 potential participants out of a cohort of 2300. Strict inclusion exclusion criteria. Pts unwilling to switch stable drug regime. Green light 13/11/2018	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...	26/09/2018	A - Permissions delayed/denied	First patient recruited, however 30 day first patient recruitment target was missed as HRA approval was awaited.	Neither
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	16/07/2018	08/08/2018	17/09/2018	Please Select...	05/12/2018	D - Sponsor Delays	Sponsor wanted to delay shipping drugs until after the New Year because their distributor had a backlog so it has not been possible to recruit a participant yet.	Sponsor
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	Yes	23/10/2018	13/06/2018	18/09/2018	19/01/2018	12/07/2018	24/07/2018	Please Select...	18/09/2018	E - Staff availability issues	Initiation target not met due to staffing issues at site.	NHS Provider
18/LO/0995	244737	A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with Advanced Endometrial Cancer	No		05/06/2018	21/09/2018	20/09/2018	28/08/2018	20/09/2018	Please Select...	14/11/2018	A - Permissions delayed/denied F - No patients seen	Initiation Target Not Met. Delays in confirming capacity and capability and no eligible patients seen at the reporting cut off point.	NHS Provider
18/LO/0864	245423	Safety & efficacy of Venetoclax + Fulvestrant in ER+ MBC patients	No		03/07/2018	03/07/2018	19/09/2018	30/08/2018	04/09/2018	Please Select...	07/12/2018	J - Other	Aim to recruit by 06th January 2019. Delays with ARSAC approvals due to national change in licence system. First patient consented 31/12/2018 but not yet fully on study	Neither
15/WM/0443	188505	PDCOMM A multicentre randomised controlled trial to compare the clinical and cost effectiveness of Lee Silverman Voice Treatment versus standard NHS speech and language therapy versus control in Parkinson's disease	No		22/06/2018	12/10/2018	20/06/2016	01/08/2018	28/08/2018	Please Select...	18/10/2018	G - No patients consented	Initiation Target Not Met. Participants did not wish to consent due to the travel involved.	Neither
18/EE/0234	248832	Surveillance of arteriovenous fistulae using ultrasound (SONAR) v1.0	No		04/10/2018	12/12/2018	07/08/2018	12/12/2018	12/12/2018	Please Select...	28/12/2018		Still within the initiation recruitment window at the reporting cut off point	Please Select...
17/LO/2041	234256	Chronic Hypertenion in pregnAncy iMPlementatION study (CHAMPION)	Yes	01/08/2018	05/06/2018	09/07/2018	11/01/2018	09/07/2018	09/07/2018	Please Select...	09/07/2018		Initiation target met	Please Select...
18/YH/0417	247000	Phase 1 Multiple-Ascending-Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of BIIB078 Administered Intrathecally to Adults with C9ORF72-Associated Amyotrophic Lateral Sclerosis	No		29/11/2018	29/11/2018				Please Select...			Study still in set up at reporting cut off timepoint	Please Select...