Study Initiation Q4 2017 - 18

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	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	Date of First Patient Recruited	Benchmark Met	Reasons for Delay	Comments	Reasons for delay correspond to:
16/YH/0157	204585	PLATO - PersonaLising Anal cancer radioTherapy dOse - Incorporating Anal Cancer Trials (ACT) ACT3, ACT4 and ACT5	21/07/2016	12/04/2017	20/07/2016	30/06/2017	13/06/2017	Please Select...	14/08/2017	21/06/2017	Yes	A - Permissions delayed/denied	HRA pack was received prematurely from sponsor. Delays with site capacity and capability review.	Both
17/LO/0108	221119	MAnagement of high bleeding risk patients post bioresorbable polymer coated STEnt implantation with an abbReviated versus prolonged DAPT regimen – MASTER DAPT	23/12/2016	10/04/2017	10/04/2017	29/03/2017	04/04/2017	Please Select...	30/05/2017	01/08/2017	No	A - Permissions delayed/denied	A - Site documentation delays. Rare patient group	NHS Provider
16/LO/1130	187152	Cereal Bar or oral supplementation with tablets to increase serum folate in young pregnant women	01/02/2017	05/05/2017	01/11/2016			Site declined to participate			Site Not Confirmed	D - Sponsor Delays	Delays by sponsor - portfolio adoption awaited and then site pharmacy concerns remained unresolved by sponsor and it was decided to close BSUH as a site on the 17/08/17, therefore we did not open as a site for this study	Sponsor
17/WM/0207	222284	Assessment of the WATCHMAN Device in Patients Unsuitable for Oral Anticoagulation	23/05/2017	23/05/2017		08/06/2017	12/06/2017	Please Select...			No	D - Sponsor Delays	70 Day target date missed due to sponsor delays with devices and delays with MHRA & HRA Approvals. Sponsor delayed set up as devices were unavailable until November 2017. Sponsor submitted an amendment to the clinical trial agreement in December 2017, therefore the site waited longer for relevant regulatory approvals.	Sponsor
16/SC/0416	210405	A Phase 2b Randomised, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants	31/05/2017	31/05/2017	30/09/2016	21/08/2017	28/08/2017	Please Select...	22/09/2017	10/10/2017	No	A - Permissions delayed/denied D - Sponsor Delays	70 Day Target Date not met because sponsor requested that the study initiation took place after the investigator meeting and during the right season for the disease indication. Delays due to review and clarification of the protocol by clinical teams and pharmacy. SIV 29/09/2017.	Both
17/SC/0039	220282	MEOF-002 - Methoxyflurane AnalGesia for Paediatric InjuriEs (MAGPIE)	28/07/2017	28/07/2017	18/04/2017	05/09/2017	12/09/2017	Please Select...	25/10/2017		No	E - Staff availability issues H - Contracting delays	70 Day Target Date Not Met. Contracting and Site Staffing Delays	Both
17/LO/1245	208149	Metronidazole Versus lactic acId for Treating bacterial vAginosis–VITA	20/09/2017	20/09/2017	12/09/2017	30/10/2017	09/11/2017	Please Select...	13/11/2017	29/11/2017	Yes	D - Sponsor Delays F - No patients seen	70 Day Target Date Not Met. Draft CTA received 23.10.2017; Sponsor took CTA with them from the SIV on 31.10.2017. Fully executed CTA was still awaited on 13.11.2017, when C&C was issued. Green light received from Sponsor on 17.11.2017. Study difficult to recruit to because only c.8.5% of potential participants are eligible.	Sponsor
17/LO/1363	226980	Safety and Efficacy of Two TAVI Systems	24/10/2017	24/10/2017	31/10/2017	18/09/2017	27/10/2017	Please Select...	23/11/2017	29/11/2017	Yes		70 Day Target Date Met	Neither
14/SW/1061	131169	CTLA4 Ig (Abatacept) for prevention of abnormal glucose tolerance and diabetes in relatives at risk for Type 1 diabetes mellitus	22/09/2017	22/09/2017	13/11/2017		05/12/2017	Please Select...			No	J - Other	Sponsor and site agreed that the study would start in Jan 2018 due to the potential participant.'s care pathway. Sponsor not confirmed at the reporting cut off point and so site not open to recruitment.	Neither

17/EM/0371	229496	SMART CRT_C2067_Boston Scientific_Heart Failure	23/06/2017	30/11/2017	21/11/2017	26/09/2017	03/10/2017	Please Select...	18/12/2017	09/03/2018	No	D - Sponsor Delays F - No patients seen	The sponsor changed essential documents after capacity and capability was issued. No eligible patients seen within the 70 day recruitment window, FPR recruited 08th March 2018	Sponsor
17/YH/0076	208944	CALM- DIEM – CONTROLLING AND LOWERING BLOOD PRESSURE WITH THE MOBIUSHD™ – DEFINING EFFICACY MARKERS	04/07/2017	05/07/2017	18/05/2017	17/10/2017	24/10/2017	Please Select...		13/12/2017	No	A - Permissions delayed/denied D - Sponsor Delays	70 Day Target Date Not Met. Delays from the sponsors end re costings, correct costings information received on 06.10.2017. Sponsor delay in sending regulatory approval letter for PIS. Site delays re IRMER queries.	Both
17/EM/0241	223736	FRED Registry Study	28/08/2017	28/08/2017	08/08/2017	12/12/2017	12/12/2017	Please Select...	05/11/2017	23/11/2018	No	A - Permissions delayed/denied F - No patients seen	70 Day Target Date Not Met. IRMER Section B Form Missing which Delayed IRMER Approvals. No eligible patients seen.	NHS Provider
17/EE/0431	234555	A Phase 2B, Randomized, Double-Blind, Active-Comparator-Controlled, Dose- Ranging Clinical Trial to Evaluate the Safety, Tolerability, Antiretroviral Activity, and Pharmacokinetics of MK-8591 Given in Combination with Doravirine (DOR) and Lamivudine (3TC) in HIV-1-Infected Treatment-Naïve Adults	05/10/2017	26/10/2017	18/12/2017	22/12/2017		Please Select...			No	A - Permissions delayed/denied D - Sponsor Delays H - Contracting delays	70 Day Target Not Met, Sponsor did not have a European lab manual available, needed to resubmit the PIS V2.0 on 24th Nov 2017 and did not provide HRA approval letter to site until 19th December 2017. Contracting delays - sponsor contacts for contracts and finances were different which resulted in some communication delays relating to the CTA.	Both
17/LO/0825	223457	Randomised, Phase 2, Double Blind, Placebo Controlled Study to Assess the Safety and Efficacy of Filgotinib, GS-9876 and GS-4059 in adult subjects with active sjogren's syndrome.	21/03/2017	05/07/2017	30/06/2017	07/08/2017	15/08/2017	Please Select...	13/09/2017	08/11/2017	No	F - No patients seen	5 patients screened but of those only one was booked for screening and potential consent. No eligible patients seen.	Neither
17/LO/1091	229631	A Phase 3 Clinical Study to Evaluate the Efficacy and Safety of the Combination Regimen of MK-3682-B (Grazoprevir/ Ruzavir/ Uprifosbuvir) in Participants with Chronic Hepatitis C Virus Genotype 3 Infection (MK-3682 Protocol 037)	13/07/2017	13/07/2017		20/07/2017	20/07/2017	Sponsor declined site confirmation			Site Not Confirmed	B - Suspended by sponsor	Sponsor cancelled the study at all sites globally as it was discontinuing investigation into the IMP as a result of Phase 2 efficacy data and growing treatment options for the prospective patient group. No information available re the date of HRA approval	Neither
15/NS/0113	188563	The clinical and cost effectiveness of surgical interventions for stones in the lower kidney: The PUrE RCTPercutaneous Nephrolithotomy (PNL), Flexible Ureterorenoscopy (FURS) and Extracorporeal Lithotripsy (ESWL) for lower pole Kidney stones.	27/07/2017	27/07/2017	13/06/2016	29/08/2017	12/09/2017	Please Select...	18/10/2017	24/04/2018	No	G - No patients consented	70 Day Target Not Met. FPR not yet recruited. 3 participants approached before the 70 Day Target, all of Whom Declined.	Neither
17/LO/0736	225746	A randomized, Double-Blind, Placebo-Controlled, Parellel Group Study to Evaluate the Efficacy and Safety of Intravenously Administered BMS-986168 in Participants with Progressive Supranuclear Palsy (CN002012	03/02/2017	25/09/2017	21/07/2017	28/09/2017	25/09/2017	Please Select...	08/12/2017	27/02/2018	No	D - Sponsor Delays	70 Day Target Not Met. Sponsor delays in providing essential information to pharmacy	Sponsor
16/LO/2079	215192	EDMONd – A feasibility study of Elemental Diet as an alternative to parenteral nutrition for patients with inoperable Malignant bowel Obstruction	09/10/2017	09/10/2017	20/02/2017	06/02/2018	06/02/2018	Please Select...	06/02/2018	12/02/2018	No	D - Sponsor Delays	70 Day Target Date Not Met. Study sponsor delays in confirming they still wanted additional sites, the sponsor wished to make some amendments, and then in confirming site initiation visit date.	Sponsor

Study Initiation Q4 2017 - 18

17/LO/1519	230794	A Prospective, Multicenter, Non-Randomized, Single-Arm, Open-Label Clinical Study to Evaluate the Safety and Feasibility of the Leaflex™ Performer (The Leaflex™ Performer Feasibility Study)	06/11/2017	06/11/2017	01/11/2017	31/01/2018	02/02/2018	Please Select...			No	D - Sponsor Delays	70 Day Target Date Not Met. Study Not Open to Recruitment at Data Cut Off Point due to Sponsor Delays in changing study device design during set up.	Sponsor
16/LO/1979	193891	A randomised trial of non-Selective versus selective adjuvant Therapy in high risk Apparent sTage 1 Endometrial Cancer	06/11/2017	06/11/2017	20/12/2016	15/01/2018		Site declined to participate			Site Not Confirmed	A - Permissions delayed/denied	The site declined to participate in this study as there were clinical reasons the site felt they would not be able to deliver recruits to this study.	Neither
17/EE/0429	234063	A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Antiviral Activity, Clinical Outcomes, Safety, Tolerability, and Pharmacokinetics of Orally Administered Lumicitabine (JNJ-64041575) Regimens in Hospitalized Infants and Children Aged 28 Days to 36 Months Infected with Respiratory Syncytial Virus	14/11/2017	14/11/2017				Site declined to participate			Site Not Confirmed	A - Permissions delayed/denied	The site declined to participate due to it being the wrong season for recruitment (Spring rather than Winter)	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.	21/11/2017	21/11/2017	03/11/2014	04/01/2018	18/01/2018	Please Select...			No	E - Staff availability issues	Delays with local IRMER approvals due to staffing capacity issues at site. Site not ready to start at data cut off point.	NHS Provider
17/EE/0382	220851	PROFILE - personalised medicine in Crohn's disease	11/12/2017	02/01/2018	02/11/2017		30/01/2018	Please Select...			No	D - Sponsor Delays	70 Day Target Not Met. Sponsor submitted an amendment during set up. Site not ready to recruit at data cut off timepoint, sponsor had not confirmed at data cut off point.	Sponsor
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	16/10/2017	02/01/2018	08/01/2018	07/12/2017	11/12/2017	Please Select...		13/03/2018	Yes		70 Day Target Met	Neither
17/EE/0448	226368	Randomised Controlled Trial of Cryo Ablation versus Cardioversion in Persistent Atrial Fibrillation	17/08/2017	14/01/2018	19/12/2017	16/11/2017	23/02/2018	Please Select...	26/02/2018	08/03/2018	Yes		70 Day Target Met	Neither
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	22/11/2017	01/02/2018	26/05/2017	18/12/2017	19/02/2018	Please Select...	16/03/2018		Within 70 Days		Still within the 70 Day Recruitment Window	Neither
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.	09/02/2018	09/02/2018	22/09/2016	13/03/2018	26/03/2018	Please Select...			Within 70 Days		Still within the 70 Day Recruitment Window. Site not ready to recruit at data cut off point.	Neither
17/SW/0255	234748	Clinical Trial Evaluation of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System	22/02/2018	22/02/2018				Please Select...			Within 70 Days	D - Sponsor Delays	Sponsor changed the protocol which affected ionising radiation risk assessments, meaning the study required re-review by regulatory authorities.	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.	05/03/2018	05/03/2018				Please Select...			Within 70 Days			Please Select...
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	24/11/2017	19/03/2018	28/02/2018	19/03/2018	27/03/2018	Please Select...	28/03/2018		Within 70 Days		Still within the 70 Day Recruitment Target Window.	Neither
17/EM/0281	220954	204862 Phase 3 switch study -TAF regimen to DTG + 3TC in HIV-1 adults	21/07/2017	18/08/2017		02/08/2017	16/08/2017	Please Select...	29/03/2018		No	D - Sponsor Delays	Sponsor Delays in Issuing Study Documentation due to a Drug Supply Issue and Lab Documentation Delays	Sponsor

Study Initiation Q4 2017 - 18

18/WM/0017	236521	Post-Market Clinical Investigation of the Clareon® IOL	09/01/2018	16/02/2018				Please Select...			Within 70 Days		Still within the 70 Day Recruitment Window	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	28/06/2017	12/01/2018	11/01/2018	05/02/2018	19/02/2018	Please Select...	21/03/2018		No	D - Sponsor Delays	70 Day Target Not Met. Sponsor changed pharmacy relevant information when site were close to opening and pharmacy SOPs had to be re-written, also requested that the site participate in additional training sessions.	Sponsor