

Please note that the NIHR is unable to analyse the data concerning the set-up of several studies due to the changeover to HRA Approval. There are therefore several clinical trials that we have opened that cannot be included in this report.

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			Please Select...			No	J - Other	HRA pack was received prematurely from sponsor. Delays with site capacity and capability review.	Both
16/SC/0147	183044	TRIMASTER V1: Randomised Double-Blind Crossover 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	20/05/2016	08/02/2017	07/07/2016	02/02/2017	09/02/2017	Please Select...	09/03/2017	28/04/2017	No	E - Staff availability issues J - Other	Commencement of study set-up delayed by IMP supply and staffing issues. Sponsor confirmed site selection on 08/02/2017. Green light 21.03.2017.	Both
16/LO/1113	209455	GEMINI 2 (205543) A Phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment-naive adults	03/05/2016	13/09/2016	05/09/2016	13/07/2016	14/07/2016	Please Select...	21/09/2016	08/11/2016	Yes		70 day target met	Neither
16/LO/1811	214264	A Phase II, Randomized, Double-Blind, Placebo Controlled Study of the Safety and Efficacy of GDC-0853 in Patients with Moderate to Severe Active Systemic Lupus Erythematosus	31/08/2016	07/12/2016	05/12/2016	07/12/2016	13/12/2016	Please Select...	07/02/2017		No	D - Sponsor Delays E - Staff availability issues F - No patients seen	There was difficulty finding a mutually convenient date for the SIV; Incubator delivery was delayed; CLASI training booked for PI on the 16/02 could not take place due to connectivity issue in US. Rescheduled for 23/02, but unable to open for recruitment until training completed. No patients recruited as at 30.06.2017, 5 patients screened. National	Both
15/WM/0276	207822	SNIFFL: Safety of Nasal Influenza Immunisation in Children with Asthma; The Sniffle 4 Study	14/07/2016	13/10/2016	22/08/2016	20/09/2016	04/10/2016	Please Select...	13/10/2016	27/10/2016	Yes		70 day target met	Neither
16/LO/1940	213099	An open label, single arm, multicenter, safety study of atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract	14/10/2016	19/10/2016	07/12/2016			Site declined to participate			Site Not Confirmed	J - Other	Site withdrew because the drug has become available through the open access mechanism, which could mean that recruitment would be challenging. There were also nursing capacity issues at site.	Neither
16/LO/1891	213918	A Phase 2, Double-Blind, Randomized Study Evaluating the Safety, Tolerability, and Efficacy of GS-4997 in Combination with Prednisolone versus	19/08/2016	09/11/2016	09/01/2017	10/04/2017	10/04/2017	Please Select...	11/05/2017		No	A - Permissions delayed/denied	First patient not recruited as at 30.06.2017 - Sponsor submitted an amendment for patients who would require transjugular biopsies which would	Sponsor

		Prednisolone Alone in Subjects with Severe Alcoholic Hepatitis (AH)											D - Sponsor Delays	affect all potential recruits at the trust, which required IRMER review at trust	
16/EE/0463	214371	An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and postmenopausal women with hormone receptor-positive (HR+) HER2-negative (HER2-) advanced breast cancer (ABC) with no prior hormonal therapy for advanced disease. CANC 31440	31/10/2016	18/11/2016	30/01/2017	24/11/2016	28/11/2016	Please Select...	09/03/2017	27/03/2017	No	D - Sponsor Delays	Sponsor delays in providing study EPRO device to site in time to check its functionality. Site study staff delays in completing study training due to availability. Study recruitment started 16.03.2017. Green light to give IMP still awaited 31/03/2017. Green light to give IMP to patients on 06.04.2017 at which point 3 patients consented and 3 in screening. FPR 27/03/2017.	Both	
												E - Staff availability issues			
16/EM/0386	211113	CAMG334A2301: A 12-week double-blind, randomized, multicenter study comparing the efficacy and safety of once monthly subcutaneous AMG 334 (x mg) against placebo in adult patients with episodic migraine who have failed 2-4 prophylactic migraine treatments	23/09/2016	08/12/2016	14/02/2017	10/02/2017	13/02/2017	Please Select...	06/03/2017		No	A - Permissions delayed/denied	Target date had passed before the SIV was held. Set-up delayed by protocol amendment requiring pharmacy and lab approval. There were also delays with the QP release and CRA training. On the day enrolment was opened we achieved joint Global First Patient First Visit for the study.	Sponsor	
												D - Sponsor Delays			
16/LO/1854	184654	A Phase 3, Randomized, Double-blind Study to Evaluate the Safety and Efficacy of Emtricitabine and Tenofovir Alafenamide (F/TAF) Fixed-Dose Combination Once Daily for Pre-Exposure Prophylaxis in Men and Transgender Women Who Have Sex with Men and Are at Risk of HIV-1 Infection	10/10/2016	14/12/2016	14/12/2016	01/11/2016	02/11/2016	Please Select...	21/12/2016	05/01/2017	Yes		70 Day Target Date Met. First eligible patient consented on 05/01/2017.	Neither	
16/LO/1987	207718	Clinical Monitoring and Biomarkers to stratify severity and predict outcomes in children with cystic fibrosis (CLIMB-CF). Complex Intervention Study. Stage 1: Pilot and Feasibility assessment	03/01/2017	03/01/2017	19/12/2016	03/03/2017	03/03/2017	Please Select...	03/03/2017	06/06/2017	No	D - Sponsor Delays	Sponsor delays in confirming supplies of laboratory equipment	Sponsor	
16/LO/1812	211705	Safety of DESCOVY (tenofovir alafenamide 10 or 25 mg plus emtricitabine (FTC, 200mg) in patients with a history of tubulopathy on tenofovir disoproxil fumarate (TDF)	13/01/2017	13/01/2017	28/11/2016	15/02/2017	21/02/2017	Please Select...	22/02/2017	13/06/2017	No	D - Sponsor Delays	Sponsor delayed the SIV on two occasions. National issue with recruiting due to the rare indication. 3 patients recruited as at 30.06.2017	Sponsor	
												I - Rare diseases			
16/LO/2122	211169	Validation study of mHealth technology in HIV to improve Empowerment and healthcare utilisation: Research and innovation to Generate Evidence for personalised care	23/01/2017	21/02/2017	31/01/2017	21/02/2017	21/02/2017	Please Select...	22/02/2017	27/03/2017	Yes		70 Day Target Met	Neither	

17/SC/0034	217773	Antibiotic Reduction and Conservation in Hospitals (ARK-Hospital)	28/02/2017	28/02/2017	21/03/2017	28/02/2017	03/04/2017	Please Select...	03/04/2017		No	G - No patients consented	70 Day Target Date Missed, 17 patients recruited to date	NHS Provider
13/LO/1691	135504	An Open label Phase I Randomised, Double Blind, Phase II Study in Metastatic Castration Resistant Prostate Cancer AZD5363 in combination with Docetaxel and Prednisolone Chemotherapy (PROCAID)	16/05/2016	10/11/2016	23/06/2016	10/11/2016	14/11/2016	Please Select...	30/04/2017	21/02/2017	No	A - Permissions delayed/denied	The sponsor required ARSAC certificate and IMP delivery confirmation before activating us as a site, first patient 22/02/2017	Both
												D - Sponsor Delays		
16/LO/1578	212919	A post-market registry of the BioMatrix Alpha TM (Cobalt Chromium Biolimus A9TM (BA9TM) drug-eluting stent)	16/11/2016	16/11/2016	31/10/2016	12/12/2016	29/12/2016	Please Select...	27/01/2017	01/03/2017	No	D - Sponsor Delays	Study sponsor were unable to sign contract for reasons for staffing availability and then requested changes	Sponsor
16/LO/0831	196728	Efficacy, safety and impact on antimicrobial resistance of duration and dose of amoxicillin treatment for young children with Community Acquired Pneumonia (CAP): A randomised controlled trial	07/11/2016	12/01/2017	11/11/2016	16/12/2016	09/02/2017	Please Select...	14/03/2017	12/05/2017	No	D - Sponsor Delays	Sponsor requested to re-negotiate the recruitment target just prior to the SIV which delayed contract negotiation and recruitment. First patient recruited within 30 days of capacity and capability statement being issued. BSUH are one of the highest recruiters for this Pneumonia study which opened in the spring and we are expecting recruitment to increase in the future.	Sponsor
												H - Contracting delays		
16/EM/0036	192044	Hip Fracture Intervention Study for Prevention of Hypotension (HIP-HOP) Trial: Pilot Study	22/02/2017	22/02/2017	22/06/2016	13/04/2017	20/04/2017	Please Select...	03/05/2017	05/06/2017	No	J - Other	Sponsor and site did not communicate through formal communication pathways	Both
16/LO/1611	208092	18F-Florbetaben PET-CT imaging of in vivo β -amyloid deposition in treated HIV-positive patients with cognitive impairment	13/03/2017	13/03/2017	26/01/2017	24/05/2017	24/05/2017	Please Select...	25/07/2017		No	A - Permissions delayed/denied	Regulatory approval letters received 25.07.2017. 30 day target date is 30/08/2017.	Sponsor
16/WM/0451	197521	Pilot Study for a trial comparing the influence of forced air versus resistive fabric warming technologies on postoperative infection rates following orthopaedic implant surgery in adults.	13/10/2016	17/03/2017	07/11/2016	21/03/2017	21/03/2017	Please Select...	21/03/2017	12/05/2017	Yes		70 Day Target Met	Please Select...
16/LO/1004	207544	Efficacy and safety of low-dose IL-2 (Id-IL-2) as a Treg enhancer for anti-inflammatory therapy in newlydiagnosed Amyotrophic Lateral Sclerosis (ALS) patients: A randomized, double-blind, placebo-controlled,phase-II Proof of Concept/ Proof of Mechanism Clinical Trial	18/11/2016	20/03/2017	06/10/2016	20/03/2017	06/07/2017	Please Select...	09/06/2017		No	D - Sponsor Delays	Sponsor contacted us 03.01.2017 to inform us that due to cytometry validation process, they would not be ready to activate us until late February, early March. There is a 3 month screening period for this study and so due to the study design it is not possible to recruit a patient within 70 days of HRA pack receipt	Sponsor

17/WS/0072	221444	Edobaxan Versus Standard of Care and Their Effects on Clinical Outcomes in Patients Having Undergone Transcatheter Aortic Valve Implantation - In Atrial Fibrillation	30/03/2017	30/03/2017				Please Select...			No	A - Permissions delayed/denied	HRA Approval and pharmacy manual awaited as at 30.06.2017	Sponsor
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		No	J - Other	Site documentation delays. No patient recruited as at 30.06.0217	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			Please Select...			Within 70 Days	D - Sponsor Delays	Delays by sponsor - portfolio adoption awaited, study IMP labelling queries	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...			Within 70 Days		Project site in set up, within the timeframe for the 70 Day Target	Neither