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	30/06/2017	13/06/2017	Please Select...	14/08/2017	21/06/2017	Yes	A - Permissions delayed/denied 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/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 issues with recruitment.	Both
16/WM/0276	207822	SNIFFLE: 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		26/09/2017	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 Prednisolone Alone in Subjects with Severe Alcoholic Hepatitis (AH)	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 D - Sponsor Delays	First patient not recruited as at 30.06.2017 - Sponsor submitted an amendment for patients who would require transjugular biopsies which would affect all potential recruits at the trust, which required IRMER review at trust	Sponsor
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 E - Staff availability issues	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. 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
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	04/04/2017	No	A - Permissions delayed/denied D - Sponsor Delays	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
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	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 fumerate (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 I - Rare diseases	Sponsor delayed the SIV on two occasions. National issue with recruiting due to the rare indication. 6 patients recruited so far.	Sponsor
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

16/LO/1578	212991	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 F - No patients seen	Study sponsor was unable to sign contract due to staffing availability and then they requested changes. Once open, no suitable patients were found within the target timeframe.	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 H - Contracting 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	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	Neither
16/LO/1004	207544	Efficacy and safety of low-dose IL-2 (ld-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	18/11/2016	20/03/2017	06/10/2016	20/03/2017	06/07/2017	Please Select...	09/06/2017	11/07/2017	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 actThe sponsor had problems with the cytometry validation process.There	Sponsor
17/WS/0072	221444	Edobaxan Versus Standard of Care and Their Effects on Clinical Outcomes in Patients Having Underone Transcatheter Aortic Valve Implantation - In Atrial Fibrillation	30/03/2017	30/03/2017	08/09/2017	01/06/2017	06/06/2017	Please Select...	19/07/2017	04/10/2017	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	01/08/2017	No	J - Other	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 Pharmacy concerns remained unresolved by sponsor and it was decided to close BSUH as a site on the 17/08/17, therefore we were not fully	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	Sponsor delays with MHRA and HRA approvals	Neither
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		No	D - Sponsor Delays J - Other	FPR Target Date not met because sponsor requested that the study initiation took place after IM and during the right season. 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...			Within 70 Days		Still within target timeframe	Neither