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/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/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 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	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 activate us. There was a 3 month screening period for this study and so due to the study design it was 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 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 D - Sponsor Delays	HRA Approval and pharmacy manual receipt delayed	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	I - Rare diseases 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 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 HRA Approval still pending	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	D - Sponsor Delays J - Other	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 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		Within 70 Days		Still within the 70 Day Recruitment Window.	Neither

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 J - Other	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...			Within 70 Days		Site confirmation pending and site not yet open to recruitment at reporting cut off point. Still within the 70 day recruitment window.	Neither