

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 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 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 (d-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 Edobaxan Versus Standard of Care and Their Effects on Clinical Outcomes in Patients Having Undergone Transcatheter Aortic Valve Implantation - In Atrial Fibrillation | 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 | MANagement of high bleeding risk patients post bioresorbable polymer coated STEnt implantation with an abbreviated versus prolonged DAPT regimen – MASTER DAPT | 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 |