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 (if applicable)	Date Site Ready To Start	Date of First Patient Recruited	A - Permissions delayed/denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	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	21/07/2016	20/07/2016			Please Select...			FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	Capacity and capability not completed within target timeframe. Decision is yet to made about whether this study will enter set-up, so HRA pack was received prematurely.	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		FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	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. Patients in screening but none recruited as at 31.03.2017. FPR Target Date 19.04.2017.	Neither
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-naïve adults	03/05/2016	13/09/2016	05/09/2016	13/07/2016	14/07/2016	Please Select...	21/09/2016	08/11/2016	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	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	11/10/2016	05/12/2016	07/12/2016	13/12/2016	Please Select...	07/02/2017		FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	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. 5 patients screened but none eligible as at 31.03.2017	Both

15/WM/0276	207822	SNIFFLE: Safety of Nasal Influenza Immunisation in Children with Asthma	14/07/2016	13/10/2016	22/08/2016	20/09/2016	04/10/2016	Please Select...	13/10/2016	27/10/2016	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	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	12/01/2017			Please Select...			TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	HRA pack received quickly from Sponsor, but local capacity & capabilty not yet confirmed.	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	19/12/2016	21/12/2016	Please Select...			TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Approval of an amendment to include transjugular biopsies is required before the SIV can be held.	Sponsor
16/LO/0831	196728	CAP IT: 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		FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	Sponsor requested to re-negotiate the recruitment target just prior to the SIV on 10/01/2017, which delayed contract negotiation and activation.	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	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	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

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		TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	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 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	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	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		FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Sponsor delays in confirming supplies of laboratory equipment, outstanding as of 31.03.2017	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		FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	Sponsor delayed the SIV on two occasions. National issue with recruiting due to the rare indication. No patients recruited as at 31.03.2017.	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	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	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		FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Still within target timeframe	Neither