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 9 studies that cannot be included in this report. 3 of these studies achieved the 70-day benchmark, and BSUH was only implicated in the reasons for the delay of 1 of the 6 studies that did not meet the benchmark.

Research Ethics Committee Reference Number	IRAS no	Full Name of Trial	Site Invitation date	Site selection date	HRA Approval date	Date site confirmed by Sponsor	Date site confirmed	Non-confirmation status (if applicable)	Date when site ready to start	Date of First Patient Recruited	Reasons for not achieving the 70 day target from receipt of valid research application to 1st patient recruited									Study team comments	Reasons for delay correspond to:
											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	
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						Y									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	01/08/2016	07/07/2016									Y						Sponsor has delayed start date until early 2017 as they are unable to get the pharmacy supplies until the end of November 2016 at the earliest	Sponsor
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		21/09/2016	08/11/2016										70 day target met	Neither
15/LO/1904	173980	The Impact of Multiparametric MRI on the Staging and Management of Patients with suspected or confirmed Ovasian Cancer	11/10/2016	11/10/2016	09/08/2016	16/11/2016	29/11/2016		09/12/2016						Y					As at 31.12.16, radiographers and radiologists hadn't completed the training required. One on on long term sickness, one on maternity leave.	NHS
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								Y					There was a delay in opening the study due to difficulty finding a mutually convenient date for the SIV.	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		13/10/2016	27/10/2016										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							Y									HRA pack received quickly from Sponsor, but local capacity & capability not yet confirmed. Still awaiting HRA Approval.	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		19/12/2016	21/12/2016													Still within target timeframe, but likely to breach target as the approval of an amendment to include transjugular biopsies is required before the SIV can be held.	Neither
13/LO/1691	135504	An open-label phase IIrandomised, double blind phase II study in metastatic castration resistant Prostate Cancer of AZD5363 in combination with Docetaxel and prednisolone chemotherapy	16/05/2016	10/11/2016	23/06/2016	10/11/2016	14/11/2016													Still within target timeframe	Neither
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	14/07/2016	18/11/2016	11/11/2016															Still within target timeframe	Neither
16/EE/0463	214371	An open-label, multicenter, Phase IIb 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		24/11/2016	28/11/2016													Still within target timeframe. HRA pack received 18.11.16 but no manuals included - sponsor states they will not be providing these even though our site requires them. SIV scheduled 1.2.17	Neither
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																Still within target timeframe. Lab manual received 8.12.16 - this completes minimum doc set. Amendment in progress, sponsor requested that SIV be delayed.	Neither
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		21/12/2016											Still within target timeframe	Neither