Id	Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type
92208	14/WA/1056	154468	NHS Permission
92209	12/EE/0445	106714	NHS Permission
92210	14/SC/0171	120104	NHS Permission
92211	15/NW/0698	183781	NHS Permission
92212	15/NW/0697	183760	NHS Permission

92822	16/EM/0193	190690	HRA Approval
94090	16/WM/0365	210358	HRA Approval
94091	16/LO/1384	211114	HRA Approval
94796	16/NW/0517	188554	HRA Approval
94874	16/LO/1810	209789	HRA Approval
94875	16/LO/1822	212944	HRA Approval

94876	16/LO/1386	199366	HRA Approval
97105	17/NW/0019	212375	HRA Approval
97106	17/EM/0005	215706	HRA Approval
97107	16/NE/0400	212212	HRA Approval

NIHR Performance in Initiation Q3; 2017/18				
Name of Trial	**Date of Receipt of Valid Research Application**	**Date of NHS Permission**	**First Patient Recruited?**	**Date of First Patient Recruited**
AML 19: Adults with Acute Myeloid Leukaemia or High-Risk Myelodysplastic Syndrome (AML19)	04/01/2016	05/01/2016	Yes	07/01/2016
PREVENTT: (Preoperative intravenous iron to treat anaemia in major surgery)	01/03/2016	02/03/2016	Yes	15/09/2016
ADD ASPIRIN: A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours	29/03/2016	08/04/2016	Yes	26/05/2016
REGAIN: (LPS14060) A randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of transition to Toujeor in basal insulin treated patients with uncontrolled type 2 diabetes mellitus	29/03/2016	21/04/2016	Yes	23/09/2016
REACH (LPS13931) A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of Toujeo® compared to standard of care insulin for initiating basal insulin in insulin naive patients with uncontrolled type 2 diabetes mellitus, with 6-month extension	29/03/2016	21/04/2016	Yes	25/08/2016

The dal-GenE trial: A phase III, double-blind, randomised placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS)			Yes	19/09/2016
GSK UC: A multicentre, randomised, double-blind (sponsor-unblinded), placebo-controlled study with open label extension to investigate the safety and tolerability, pharmacokinetics, pharmacodynamics, and efficacy of GSK2982772 in subjects with active ulcerative colitis			No	
ALLURE: Safety and tolerability of secukinumab in 2mL Prefilled syringes			No	
MYELOMA XII			No	
UNITY: A Phase 3, Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with TGR-1202 Compared to Obinutuzumab in Combination with Chlorambucil in Patients with Chronic Lymphocytic Leukemia (CLL)			No	
VICTORIA: A randomized parallel-group, placebo-controlled, double-blind, event-driven, multi-center pivotal phase III clinical outcome trial of efficacy and safety of the oral sGC stimulator Vericiguat in subjects with heart failure and reduced ejection fraction (HFrEF) - VerICiguaT glObal study in subjects with heart failure and Reduced ejectIon frAction			No	

STEALTH: A Phase 2 Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Cardiac and Renal Effects of Short Term Treatment with Elamipretide in Patients Hospitalized with Severe Congestion due to Heart Failure			No	
A39211912: A PHASE 3B/4 RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED STUDY OF METHOTREXATE (MTX) WITHDRAWAL IN SUBJECTS WITH RHEUMATOID ARTHRITIS (RA) TREATED WITH TOFACITINIB 11MG MODIFIED RELEASE (MR) FORMULATION			No	
GALACTIC-HF: A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv Mecarbil on Mortality and Morbidity in Subjects With Chronic Heart Failure With Reduced Ejection Fraction			No	
KREBS: A Randomised Controlled Trial of the effect of a Two-layer Compression Bandage System on Knee Function following total knee arthroplasty			No	

Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Date Site Invited	Date Site Selected
1	2	3	Yes		
1	197	198	No		
10	48	58	Yes		
23	155	178	No		
23	126	149	No		

			Site Not Conf	02/02/2016	17/06/2016
			No	08/07/2016	13/09/2016
			No	01/09/2016	21/09/2016
			Within 70 Da	29/06/2016	27/10/2016
			Within 70 Days		24/11/2016
			No	26/04/2016	11/10/2016

			No	01/09/2016	
			No		
			No		
			No		

HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start	A - Permissions delayed/ denied	B - Suspended by sponsor

14/06/2016	13/07/2016	12/07/2016	Sponsor decline	18/09/2016	Y	
09/11/2016	19/10/2016	08/11/2016		15/11/2016		
12/10/2016	25/10/2016	28/10/2016				
27/10/2016					Y	
07/12/2016	08/12/2016	12/12/2016		17/01/2017		

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
			Y	Y		
		Y		Y		
				Y	Y	
					Y	

	Y	Y				
			Y			
	Y					
	Y					
	Y					

J - Other	**Comments**	**Reasons for delay correspond to:**
	to establish; 2. developing a new clinical pathway; 3. some overestimation of levels of anaemia in Gynae patients requiring new lines of communication	NHS Provider
	Staffing levels in April and May prevented research nurses actively seeking out potential participants. Staffing levels subsequently improved in June 2016	NHS Provider
	Pharmacy required further time and clarification from Sponsor for safe dispensing	NHS Provider
	Pharmacy required further time and clarification from Sponsor for safe dispensing	NHS Provider

	Sponsor requirement that US forms must be completed for all staff prior to greenlight	Both
	Very tight inclusion criteria; seven pts pre-screened by 31/12/2016	
	The study was signed off in October, but there has been a long delay in delivery of IMP. As of 11/01/2017 we are still awaiting delivery of drug.	Sponsor
	Drug not yet available; contract ready, but still to be signed	Sponsor
	Supply of IMP not delivered until mid January 2017	Sponsor
