

Performance in Initiating - Q2: 2017/2018 (1st October 2016 - 30th September 2017) - HRA studies

Research Ethics Committee Reference Number	IRAS number	Name of Trial	Site Invited	Site Selected	HRA Approval	Site Confirmed by Sponsor	Site Confirmed	Non Confirmation Status	Site Ready to Start	First Patient Recruited	Reasons for delay
16/SS/0014	187949	GEM3: A double blind placebo controlled trial of a combination of methotrexate and gefitinib versus methotrexate alone as a treatment for ectopic pregnancy	08/11/2016	13/01/2017	14/10/2016	09/02/2017	27/02/2017	NA	28/04/2017	08/06/2017	Sponsor. Pharmacy had ongoing issues and queries with pharmacy manual
16/SC/0502	199315	ACL Snap: ACL Surgery Necessity in Non Acute Patients. Comparison of the clinical and cost effectiveness of two management strategies for non-acute Anterior Cruciate Ligament (ACL) injury: Rehabilitation versus surgical Reconstruction. (FP and WP)	31/10/2016	06/12/2016	16/11/2016	02/03/2017	14/03/2017	NA	12/04/2017	18/04/2017	NHS Provider. PI unexpectedly off sick at FP. WP delays in PI responses.
16/SW/0232	201854	R-RID: multi-centre, double-blind, randomised, controlled clinical trial of Rifaximin to reduce infection in patients admitted to hospital with decompensated cirrhosis	20/05/2016	06/12/2016	31/10/2016	17/02/2017	23/02/2017	NA	07/06/2017	19/07/2017	Sponsor Delays. Amendments required to the protocol before FPH could start recruiting therefore delay in 40 day and 30 day metrics.
16/SC/0651	213404	An evaluation of the tolerance, compliance and acceptability of a ready to use, liquid, high energy, high protein, peptide-based feed for adults in need of nutrition support – a pilot study	07/12/2016	18/01/2017	13/01/2017	22/05/2017	24/05/2017	NA	13/07/2017		Sponsor. Feed not yet been manufactured but document pack sent therefore delay in 40 day and 30 day metrics. Study then put on hold due to feed by Sponsor
17/SC/0022	215467	Panorama: A Phase 3, Double-Masked, Randomised Study of the Efficacy and Safety of Intravitreal Aflibercept Injection in Patients with Moderately Severe to Severe Nonproliferative Diabetic Retinopathy	07/02/2017	07/02/2017	28/03/2017	10/02/2017	23/02/2017	NA	06/04/2017	20/06/2017	Sponsor. Feed not yet been manufactured

17/LO/0035	218519	Actif - Development and evaluation of an intervention to support Adherence to treatment in adults with Cystic Fibrosis. A randomised controlled trial and parallel process evaluation	06/01/2016	26/06/2017	17/05/2017	31/08/2017	01/09/2017	NA	15/09/2017		Sponsor. Document pack sent early in order to sign the contract so the CQUIN payment could be released. Study schedule meant recruitment could not start until September 2017.
17/SC/0014	219973	OPEN WATER - OPEN WATER, Global Post-Market Registry using Waterjet Ablation Therapy for Endoscopic Resection of prostate	07/12/2016	27/07/2017	13/04/2017	17/08/2017	22/08/2017	NA	23/08/2017	31/08/2017	None
17/WM/0106	201079	MOTILITY: Small bowel motility quantified by cine MRI as a predictor of long term response in patients with Crohn's disease commencing biological therapy	05/09/2017	05/09/2017	28/04/2017						
17/SC/0034	217773	ARK - Antibiotic Reduction and Conservation in Hospitals	28/07/2017	12/09/2017	21/03/2017						
16/LO/2195	219516	TRITON 2: A Multicenter, Open-label Phase 2 Study of Rucaparib in Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	19/04/2017	18/07/2017	28/03/2017	30/08/2017	04/09/2017	NA	04/09/2017	20/09/2017	40 day metric not achieved due to Sponsor taking 3 weeks to respond to budget negotiations
17/EM/0120	222298	TRITON 3: A Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	19/04/2017	11/07/2017	30/06/2017	30/08/2017	04/09/2017	NA	04/09/2017		Neither - Protocol design means timings would not adhere to the 70 day metric. 40 day metric not achieved due to Sponsor taking 3 weeks to respond to budget negotiations