Western Sussex Hospitals NHS
NHS Foundation Trust

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application (old metric)	Date Site Invited (new metric)	Date Site Selected (new metric)	HRA Approval Date (new metric)	Date Site Confirmed By Sponsor (new metric)	Date Site Confirmed (new metric)	Date Site Ready to Start (new metric)	Date of First Patient Recruited	Non-Confirmation Status (new metric)	Duration between VRA / Date site selected and First Patient (days)	Benchmark Met	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:
13/EM/0459	137785	HRA Light	POSNOC - POsitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early stage breast cancer who have metastases in one or two sentinel nodes.		19/01/2016	14/06/2016	04/05/2016	01/08/2016	17/08/2016	13/09/2016				No				Y			Y				SIV 12/09/16. Greenlight from sponsor 13/09/16. Sponsor's stringent training requirement significantly delayed the opening of this study. Eligible patients have decided not to participate.	Sponsor
12/NW/0751	110644	HRA Light	Hyperbaric oxygen treatment of mandibular osteoradionecrosis. A randomized clinical study.		18/02/2016	24/08/2016	22/08/2016	19/10/2016	02/12/2016					No								Y			Sponsor delays with contract.	Sponsor
16/LO/0553	194625	HRA Light	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER LONG-TERM SAFETY AND TOLERABILITY STUDY OF ETC 1002 IN PATIENTS WITH HYPERLIPIDEMIA AT HIGH CARDIOVASCULAR RISK WHO ARE NOT ADEQUATELY CONTROLLED BY THEIR LIPID-MODIFYING THERAPY		10/05/2016	05/07/2016	08/06/2016	22/06/2016	24/06/2016	19/07/2016	22/07/2016		17	Yes												
15/YH/0535	190077	HRA Light	A multicenter, randomized, open label, parallel group study comparing pre-discharge and posT-discharge tReatment initiation with LCZ696 in heArt failure patieNtS with reduced ejectIon-fracTion hospItalized for an acute decOmpensation eveNt (ADHF) (the TRANSITION study)		09/03/2016	29/06/2016	09/06/2016	16/08/2016	18/08/2016	25/08/2016				No					Y	Y	Y				SIV 17/08/2016 Greenlight given by sponsor 25/08/16. Staff availability issues caused a delay in the set-up of this study. Patient screening is taking place on a daily basis and as of 19/12/16 50 eligible patients had been screened, four of whom were eligible but declined to take part due to the protocl requirement for additional frequent visits to hospital.	NHS Provider
14/YH/1199	153953	HRA Light	GALACTIC: GA-101 (obinutuzumab) monocLonal Antibody as Consolidation Therapy In CLL		18/05/2016	06/07/2016	15/06/2016					Sponsor declined site confirmation		N/A											Letter received from trial office 11/07/2016 advising that recruitment into GALACTIC is being stopped. This is due to recruitment nationally being significantly slower than anticipated and trial office no longer think it is achievable to meet the recruitment target.	Sponsor
15/NW/0090	162325	HRA Light	Emergency Treatment with Levetiracetam or Phenytoin in Status Epilepticus in Children (EcLiPSE) – an open label randomised controlled trial		23/09/2015	14/07/2016	21/07/2016	10/08/2016	19/09/2016	31/10/2016				No				Y	Y	Y			Y		SIV 06/09/16. Sponsor delays with site initiation. Staff availability issues regarding the training of all staff in two department across two sites. Rare condition and no eligible patients yet seen	Both
13/WA/0205	127379	HRA Light	A Trial for Older Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome		05/09/2016	21/11/2016	15/06/2016	11/11/2016	21/11/2016	13/12/2016				Within timeframe											Within timelines.	
14/WA/1056	154468	HRA Light	Adults with acute myeloid leukaemia or high-risk myelodysplastic syndrome (AML19)		02/09/2016	21/11/2016	15/06/2016	23/11/2016	29/11/2016	01/12/2016	05/12/2016		45	Yes												
15/LO/1302	169660	HRA Light	OCTOPUS: Ovarian Cancer Trials of Weekly Paclitaxel - Umbrella StudyA Randomised, Phase II Umbrella Trial of a Weekly Paclitxel +/- Novel Agents in Platinum-Resistant Ovarian Cancer		11/11/2016		07/06/2016							Site not yet selected												

Please note this data has not been submitted to the Department of Health: as per the performance in Initiating and Delivering Clinical Research Guidelines Q3 2016/17.