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		N/A		No				Y							SIV 12/09/16. Greenlight from sponsor 13/09/16. Sponsor's stringent training requirement significantly delayed the opening of this study.	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							Within timeframe												
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	N/A	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		N/A		No					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 but no eligible patients have been seen.	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							No				Y							Study on hold at sponsor request - unknown reason.	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			N/A		No				Y	Y						SIV 06/09/16. Currently awaiting randomisation details from sponsor. Staff availability issues regarding the training of all staff in two department across two sites. Unusual condition (Status Epilepticus).	Both
13/WA/0205	127379	HRA Light	A Trial for Older Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome		05/09/2016		15/06/2016																			
14/WA/1056	154468	HRA Light	Adults with acute myeloid leukaemia or high-risk myelodysplastic syndrome (AML19)		02/09/2016		15/06/2016																			

Please note this data has not been submitted to the Department of Health: as per the performance in Initiating and Delivering Clinical Research Guidelines Q2 2016/17.