Performance in Initiating Clinical Research

1 April 2016 - 31 March 2017

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type
15/EE/0464	183877	NHS Permission
13/SC/0645	143871	NHS Permission
16/SW/0130	203567	NHS Permission
14/SW/1166	164941	NHS Permission
16/EM/0133	184873	NHS Permission
16/EE/0053	172067	NHS Permission
14/EM/1295	163111	NHS Permission
15/LO/2202	190754	NHS Permission
16/NE/0027	187317	NHS Permission
15/LO/0545	172357	NHS Permission
15/WA/0191	160678	NHS Permission
16/WA/0034	187658	NHS Permission

14/SC/1150	158370	NHS Permission
15/LO/1595	183040	NHS Permission
16/LO/1625	173719	NHS Permission
16/NI/0163	211454	NHS Permission
16/SC/0349	154486	NHS Permission
16/SC/0462	208830	NHS Permission
16/EM/0384	182787	NHS Permission
13/EE/0411	139089	NHS Permission
15/EM/0055	167115	NHS Permission
16/EM/0193	190690	NHS Permission
16/NE/0071	180418	NHS Permission

Name of Trial	Date of Receipt of Valid Research Application
CRIT 4440 - A Phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH)	25/04/2016
Pre-eclampsia in Hospital: Early Induction or Expectant Management	02/04/2016
StartRight: Getting the right classification and treatment from diagnosis in young adults with diabetes	14/09/2016
INFORM - A multicentred randomised trial to compare 1stage with 2stage revision surgery for prosthetic hip joint infection	13/06/2016
A randomised, double-blind, placebo-controlled multicentre study of secukinumab to evaluate the safety, tolerability and efficacy up to 2 years in patients with active nonradiographic axial spondyloarthritis	12/07/2016
AdDIT Follow Up - Tracking of risk for diabetic nephropathy and cardiovascular disease in young people with Type 1 diabetes recruited to the AdDIT study	06/09/2016
Affinitie: Two cluster RCTs to evaluate feedback in blood transfusion audits	09/05/2016
BOSS - The British Orthopaedic Surgery Surveillance Study: A nationwide service evaluation, and nested-cohort study.	27/04/2016
Javelin - A phase 3, multicenter, randomized, open-label study of avelumab (msb0010718c) alone or in combination with pegylated liposomal doxorubicin versus pegylated liposomal doxorubicin alone in patients with platinum-resistant/refractory ovarian cancer	19/10/2016
CARAT - Clinical and device functional assessment of real world ICD patients	28/10/2016
MEMORYCARE - Investigating the management of refusal of care: people with Dementia	20/12/2016
PAIPMS - Psychological adjustment in people with progressive multiple sclerosis. A longitudinal study	30/10/2016

REDDS - Red blood cell transfusion thresholds and Quality of Life in myelodysplastic syndromes: a pilot, feasibility study	10/11/2016
Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: A pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery	04/10/2016
ARIADNE - Assessment of real life care- describing European heart failure management	28/11/2016
and neck cancer from across the United Kingdom. 5511 people from 76 separate centres were recruited making it one of the largest studies of its kind. The Head & Neck 5000 Follow Up Study aims to collect further outcome data on participants who have been in Head & Neck 5000 for	08/11/2016
Epidemiology of Critical Care provision after Surgery (EpiCCS) SNAP2	20/01/2017
DRAFFT 2: Distal Radius Acute Fracture Fixation Trial - A Randomised Controlled Trial of Manipulation and surgical fixation with K-wires versus Manipulation and Casting in the Treatment of Adult Patients with a Dorsally Displaced Fracture of the Distal Radius	10/02/2017
Clinical Trial to Evaluate the Safety of Apixaban vs. Vitamin K Antagonist and Aspirin vs. Aspirin Placebo in Patients with Atrial Fibrillation and Acute Coronary Syndrome or Percutaneous Coronary Intervention	08/12/2016
Evaluation of the Impact of HighIntensity SpecialistLed Acute Care (HiSLAC) on Emergency Medical Admissions to NHS Hospitals at Weekends.	13/04/2016
Rapid Intervention with Glyceryl trinitrate in Hypertensive stroke Trial-2 (RIGHT2): Assessment of safety and efficacy of transdermal glyceryl trinitrate, a nitric oxide donor, and of the feasibility of a multicentre ambulance-based stroke trial	13/04/2016
Dal-GenE Trial: A phase III, double-blind, randomised placebo-controlled study to evaluate the effects of dalcetrapid on cardiovascular (CV) risk in genetically defined population with a recent Acute Coronary Syndrome (ACS)	24/07/2016
US-PEx: Understanding how frontline staff use patient experience data	05/07/2016

Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient
27/04/2016	Yes	23/06/2016	2	57
02/04/2016	Yes	10/06/2016	0	69
15/09/2016	Yes	07/11/2016	1	53
02/08/2016	No		50	
11/08/2016	Yes	20/12/2016	30	131
07/09/2016	Yes	24/10/2016	1	47
21/06/2016	Yes	14/07/2016	43	23
18/08/2016	Yes	21/10/2016	113	64
07/11/2016	Yes	10/11/2016	19	3
02/12/2016	Yes	08/02/2017	35	68
21/12/2016	Yes	09/01/2017	1	19
06/12/2016	Yes	06/01/2017	37	31

08/12/2016	No		28	
24/01/2017	Yes	10/04/2017	112	76
13/01/2017	Yes	02/03/2017	46	48
21/02/2017	No		105	
01/03/2017	Yes	21/03/2017	40	20
03/03/2017	Yes	11/04/2017	21	39
01/03/2017	No		83	
20/05/2016	Yes	16/06/2016	37	27
16/12/2016	Yes	02/03/2017	247	76
18/08/2016	Yes	30/09/2016	25	43
05/07/2016	Yes	17/08/2016	0	43

Duration between VRA and First Patient	Benchmark Met	Reasons for Delay	Comments
59	Yes		
69	Yes		
54	Yes		
	No	D - Sponsor Delays	Delay as awaiting evidence of rec approval for trial documentation
161	No	D - Sponsor Delays	Site initiated 14/10/2016
48	Yes		
66	Yes		
177	No	A - Permissions delayed/denied	Permissions denied pending further clarification regarding use of ionising radiation
22	Yes		
103	No	D - Sponsor Delays	Sponsor requirements for device training
20	Yes		
68	Yes		

	No	I - Rare diseases	Patients screened, only 1 eligible but declined.
188	No	D - Sponsor Delays	Delay in study consumables
94	No	E - Staff availability issues	Issues with PI availability at site
	No	D - Sponsor Delays	Delays providing questionnaires over Christmas period
60	Yes		
60	Yes		
	No	I - Rare diseases	
64	Yes		
323	No	A - Permissions delayed/denied	Questions regarding scientific integrity of the the trial
68	Yes		
43	Yes		

Reasons for delay correspond to:
Unknown
Unknown
Unknown
Sponsor
Sponsor
Unknown
Unknown
Sponsor
Unknown
Sponsor
Unknown
Unknown

Neither
Sponsor
NHS Provider
Sponsor
Please Select...
Please Select...
Neither
Please Select...
Both
Unknown
Please Select...