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Submission

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Submission Details	
Status	Accepted
Open Date	01/10/2016
Deadline Date	31/10/2016
Date Submitted	20/10/2016
Type	Performance in Initiating
NHS provider	Northampton General Hospital NHS Trust

Id	Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?
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86998	15/SC/0310	167868	NHS Permissi on	BOX 3 ? The Bart?s-Oxford family study of childhood diabetes: Longitudinal and multi-generational analysis of a changing disease	17/12/2015	18/12/2015	Yes
86999	14/NW/1128	152982	NHS Permissi on	MaPLe ? Molecular profiling for lymphoma	18/11/2015	18/11/2015	Yes
87000	15/NW/0626	184626	NHS Permissi on	A phase 3, randomised, double-blind, placebo-controlled, parallel group, multi-centre study to evaluate the net clinical benefit of Sotagliflozin as adjunct to insulin therapy in type 1 diabetes	16/12/2015	16/12/2015	Yes
87001	15/LO/1895	181595	NHS Permissi on	Effective pre-oxygenation using high flow humidified nasal oxygen delivery system (EPOD)	23/11/2015	02/12/2015	Yes

87002	15/SC/044 3	173722	NHS Permissi on	OPTIMISE ? Long term clear skin maintenance treatment optimisation in patients with moderate to severe chronic plaque psoriasis: A randomised, multi-centre, open-label with blinded- assessment, comparative, 52 week study to evaluate the efficacy, safety and tolerability of secukinumab 300 mg s.c.	16/12/2015	16/12/2015	Yes
87003	14/SC/017 1	120104	NHS Permissi on	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	21/10/2015	22/10/2015	Yes

87004	11/SC/0528	73866	NHS Permissi on	A phase III multicentre trial of weekly induction chemotherapy followed by standard chemoradiation versus standard chemoradiation alone in patients with locally advanced cervical cancer	10/12/2015	11/12/2015	Yes
87005	15/NI/0169	184948	NHS Permissi on	The impact of severe hypoglycaemic events requiring interventions in patients with type I diabetes patients treated insulin therapy	22/10/2015	23/10/2015	Yes

87006	12/NW/03 61	103977	NHS Permissi on	A pragmatic randomised controlled trial comparing the effectiveness and cost effectiveness of levetiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard and New Antiepileptic Drugs (SANAD-II)	08/10/2015	08/10/2015	Yes
87007	13/NW/00 68	115309	NHS Permissi on	Investigation of Factors Influencing Psoriatic Arthritis and Psoriasis Response to Therapy with Biologic Drugs	13/10/2015	16/10/2015	Yes
87008	11/SW/01 60	50632	NHS Permissi on	UK Multiple Sclerosis Register	08/12/2015	08/12/2015	Yes
87009	09/H1008/ 137	24269	NHS Permissi on	The long-term Safety and Efficacy of Biologic Therapies in Children with Rheumatic Diseases (BSRBR-JIA)	12/01/2016	13/01/2016	Yes

87010	13/EM/0459	137785	NHS Permissi on	<p>POSNOC - POsitive Sentinel NOde: adjvant therapy alone versus adjvant 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.</p>	13/01/2016	13/01/2016	Yes
87011	15/NI/0207	187243	NHS Permissi on	<p>Toolkit to benchmark young person friendly services in rheumatology</p>	26/02/2016	08/03/2016	Yes
87012	14/YH/1259	163195	NHS Permissi on	<p>Comparison of Alitretinoin with PUVA as the first line treatment in patients with severe chronic hand eczema (ALPHA)</p>	21/03/2016	22/03/2016	Yes

87013	15/EM/049 2	189756	NHS Permissi on	A retrospective real world research study to describe the use of buccal midazolam maleate (Epistatus®) in adults in routine practice in the UK	18/01/2016	18/01/2016	Yes
87014	14/NW/10 14	141897	NHS Permissi on	UK CLL Biobank study	07/10/2015	16/11/2015	Yes

87015	15/WA/0241	183747	NHS Permissi on	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus - Study Two	22/03/2016	22/03/2016	Yes
87016	15/EE/0464	183877	NHS Permissi on	A Phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH)	25/04/2016	27/04/2016	Yes
87018	13/SC/0645	143871	NHS Permissi on	Pre-eclampsia in Hospital: Early Induction or Expectant Management	02/04/2016	02/04/2016	Yes

88965	16/SW/0130	203567	NHS Permissi on	StartRight: Getting the right classification and treatment from diagnosis in young adults with diabetes	14/09/2016	15/09/2016	No
88967	14/SW/1166	164941	NHS Permissi on	INFORM - A multicentred randomised trial to compare 1stage with 2stage revision surgery for prosthetic hip joint infection	13/06/2016	02/08/2016	No
88970	16/EM/0133	184873	NHS Permissi on	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 nonradiograp hic axial spondyloarthr itis	12/07/2016	11/08/2016	No

88971	16/EE/0053	172067	NHS Permissi on	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	07/09/2016	No
89174	14/EM/1295	163111	NHS Permissi on	Affinitie: Two cluster RCTs to evaluate feedback in blood transfusion audits	09/05/2016	21/06/2016	No
89177	15/LO/2202	190754	NHS Permissi on	BOSS - The British Orthopaedic Surgery Surveillance Study: A nationwide service evaluation, and nested-cohort study.	27/04/2016	18/08/2016	No



Date of First Patient Recruited	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	HRA Approval Date	Date Site Confirmed By Sponsor
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15/02/2016	1	59	60	Yes				
04/01/2016	0	47	47	Yes				
26/01/2016	0	41	41	Yes				
03/12/2015	9	1	10	Yes				

27/01/2016	0	42	42	Yes				
07/01/2016	1	77	78	No				

26/07/2016	1	228	229	No				
17/11/2015	1	25	26	Yes				

16/11/2015	0	39	39	Yes				
05/11/2015	3	20	23	Yes				
05/01/2016	0	28	28	Yes				
21/03/2016	1	68	69	Yes				

21/03/2016	0	68	68	Yes				
14/03/2016	11	6	17	Yes				
15/08/2016	1	146	147	No				

02/02/2016	0	15	15	Yes				
04/03/2016	40	109	149	No				

09/05/2016	0	48	48	Yes				
23/06/2016	2	57	59	Yes				
10/06/2016	0	69	69	Yes				

	1			Within 70 Days				
	50			No				
	30			No				

	1			Within 70 Days				
	43			No				
	113			No				

Date Site Confirmed	Non- Confirmation Status	Date Site Ready To Start	A - Permissi ons delayed/ denied	B - Suspend ed by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availabili ty issues	F - No patients seen
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	Please Select...							
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	Please Select...						Y	
	Please Select...		Y					

G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
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					Unknown
					Please Select...
				Awaiting sponsor providing a prescription form	Sponsor
				20 patients recruited, recruitment complete	Please Select...

					Unknown
			Y	Sponsor initiated site on 26/11/2015. Delays in provision of the imp caused delays to first patient recruited .	Sponsor

			Y	Delays in radiothe rapy QA.	Both
					Please Select...

					Please Select...
					Please Select...
					Please Select...
					Unknown

					Unknown
					Unknown
				Sponsor has insisted on processing an amendment before recruitment could commence	Sponsor

					Unknown
				Sub study not available to existing patients. The delay between VRA and NHSP was due to discrepancies in version control on paperwork	Sponsor

					Unknown
					Unknown
					Unknown

					Unknown
				Delay as awaiting evidence of rec approval for trial documentation	Sponsor
				Site initiated 14/10/2016	Sponsor

					Unknown
				Awaiting confirmation of local collaborator involvement	NHS Provider
				Permissions denied pending further clarification regarding use of ionising radiation	Sponsor