

Id	TrustId	SubmissionId	MetaSubmissionId	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 Participant Recruited?	Date of First Participant Recruited	Duration between VRA and NHS Permission
123369	1078	7642	55	16/EM/0194	194984	HRA Approval	MIAA DERM 5311 Effectiveness of an image analysing algorithm to diagnose melanoma compared to gold standard histological determination			Yes	17/10/2017	0
123370	1078	7642	55	17/YH/0055	215194	HRA Approval	MIDFUT: Multiple Interventions for Diabetic Foot Ulcer Treatment Trial			Yes	23/11/2017	0
123371	1078	7642	55	17/LO/0794	223700	HRA Approval	RHCF A 52-week Multicenter, Randomized, Open-Label, Parallel-Group Study Evaluating the Efficacy and Safety of Ixekizumab versus Adalimumab in Patients with Psoriatic Arthritis who are Biologic Disease-Modifying Anti-Rheumatic Drug Naive			Yes	20/11/2017	0

123372	1078	7642	55	15/NW/0926	178681	HRA Approval	PARTNER Randomised, phase II/III, 3-stage trial to evaluate the safety and efficacy of the addition of olaparib to platinum-based neoadjuvant chemotherapy in breast cancer patients with TNBC and/or gBRCA			Yes	06/03/2018	0
123373	1078	7642	55	12/NW/0766	111990	HRA Approval	PREDNOS 2 Short course daily prednisolone therapy at the time of upper respiratory tract infection in children with relapsing steroid sensitive nephrotic syndrome; the PREDNOS 2 study.			No		0
123374	1078	7642	55	17/LO/0334	214459	HRA Approval	FLO-ELA: FLuid Optimisation in Emergency LAparotomy. Open, multi-centre, randomised controlled trial of cardiac output -guided haemodynamic therapy compared to usual care in patients undergoing emergency bowel surgery.			Yes	19/09/2017	0

123375	1078	7642	55	17/LO/13 13	224703	HRA Approval	PEPTIC v1.0 Proton Pump Inhibitors vs. Histamine-2 Receptor Blockers for Ulcer Prophylaxis Therapy in the Intensive Care Unit (PEPTIC) study: A cluster randomised, crossover, registry-embedded clinical trial of proton pump inhibitors vs. histamine-2 receptor blockers for ulcer prophylaxis therapy in the Intensive Care Unit			Yes	09/01/2018	0
123376	1078	7642	55	14/SS/103 1	159610	HRA Approval	STOPPIT-2 An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability			No		0
123377	1078	7642	55	17/LO/11 47	222154	HRA Approval	ECZTRA 2 (ECZema TRAlokinumab trial no. 2) Tralokinumab monotherapy for moderate-to-severe atopic dermatitis			Yes	14/12/2017	0

123378	1078	7642	55	15/EM/05 51	191168	HRA Approval	IRONMAN: Effectiveness of intravenous iron treatment vs standard care in patients with heart failure and iron deficiency: a randomised, open-label multicentre trial			No		0
123379	1078	7642	55	16/SS/013 7	199347	HRA Approval	ATTEST 2 -Alteplase-Tenecteplase Trial Evaluation for Stroke Thrombolysis			No		0
123380	1078	7642	55	17/WM/0 371	228033	HRA Approval	INTEREST: Intervention to reduce sitting time in older adults undergoing orthopaedic surgery: a feasibility study			Yes	09/03/2018	0

123381	1078	7642	55	18/SC/009 5	235876	HRA Approval	BREEZE-AD4 - Baricitinib in moderate to severe atopic dermatitis A Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Safety and Efficacy of Baricitinib in Combination with Topical Corticosteroids in Patients with Moderate to Severe Atopic Dermatitis who have Experienced Failure to Cyclosporine or are Intolerant to, or have Contraindication to Cyclosporine			No		0
123387	1078	7642	55	18/LO/08 13	247105	HRA Approval	IDDSI Level 2 ONS study - IDDSIL2 An evaluation of the tolerance, compliance, acceptability and safety of a new oral nutritional supplement in dysphagic patients			No		0
123388	1078	7642	55	14/EE/129 3	164389	HRA Approval	C-STICH The Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes			No		0

123389	1078	7642	55	16/WM/0036	180476	HRA Approval	GBS2 Accuracy of a rapid intrapartum test for maternal group B streptococcal colonisation and its potential to reduce antibiotic usage in mothers with risk factors.			No		0
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Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant Recruited	Benchmark Met	Date Study Initiated	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start
0	0	44	26	70	Yes		10/07/2017	08/08/2017	24/06/2016	30/08/2017	21/09/2017	Please Select...	21/09/2017
0	0	49	22	71	No		23/05/2017	13/09/2017	24/05/2017	11/10/2017	01/11/2017	Please Select...	01/11/2017
0	0	48	69	117	No		27/02/2017	26/07/2017	28/07/2017	11/08/2017	12/09/2017	Please Select...	02/10/2017

0	0	94	113	207	No		17/12/2015	11/08/2017	11/05/2016	09/11/2017	13/11/2017	Please Select...	24/11/2017
0	0	37			No		13/02/2017	26/09/2017	20/09/2017	11/10/2017	02/11/2017	Please Select...	06/11/2017
0	0	14	18	32	Yes		09/01/2017	18/08/2017	29/03/2017	21/08/2017	01/09/2017	Please Select...	13/09/2017

0	0	15	21	36	Yes		10/08/2017	04/12/2017	11/10/2017	08/12/2017	19/12/2017	Please Select...	08/01/2018
0	0	50			No		04/08/2017	25/10/2017	07/07/2016	23/11/2017	14/12/2017	Please Select...	08/01/2018
0	0	28	45	73	No		15/11/2016	02/10/2017	10/08/2017	24/10/2017	30/10/2017	Please Select...	03/11/2017

0	0				No		03/05/2017	12/10/2017	07/07/2016			Please Select...	
0	0				No		23/06/2017	18/10/2017	11/01/2017			Please Select...	
0	0	13	43	56	Yes		31/07/2017	12/01/2018	02/11/2017	25/01/2018	25/01/2018	Please Select...	29/01/2018

0	0	31			Please Select...		06/09/2017	09/04/2018	05/04/2018	26/04/2018	10/05/2018	Please Select...	14/05/2018
0	0				Please Select...		01/02/2018	06/04/2018				Please Select...	
0	0	61			Please Select...		11/01/2018	10/05/2018	10/08/2016	11/06/2018	10/07/2018	Please Select...	10/07/2018

0	0				Please Select...		01/06/2018	08/06/2018	23/08/2016			Please Select...	
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AddedBy UserId	Amended ByUserId	DateAdded	DateAmended	A - Permissio ns delayed/d enied	B - Suspende d by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availabilit y issues	F - No patients seen	G - No patients consented	H - Contractin g delays	I - Rare diseases	J - Other	Reasons for Delay
Unknown	Unknown	09/04/2018	27/07/2018	Y										Both
Unknown	Unknown	09/04/2018	27/07/2018					Y						Sponsor
Unknown	Unknown	09/04/2018	27/07/2018						Y	Y				Sponsor

Unknown	Unknown	09/04/2018	27/07/2018				Y							
Unknown	Unknown	09/04/2018	27/07/2018					Y			Y		Y	
Unknown	Unknown	12/04/2018	27/07/2018							Y				

Unknown	Unknown	20/07/2018	27/07/2018				Y			Y				
Unknown	Unknown	20/07/2018	27/07/2018	Y										
Unknown	Unknown	20/07/2018	27/07/2018					Y			Y			

Comments	Reasons for delay correspond to:		Errors	Warnings	Check Rows to Delete on Upload Submission
HRA confirmation of site added received 19.09.17	Sponsor				
Due to site staff availability, study training took place on 30.10.17, therefore C&C issued 01.11.17	NHS Provider				
no suitable patients seen within 30 day timeframe	NHS Provider				

DELAYS WITH HISTOPATHOLOGIST CAPACITY AT SITE. nO SUITABLE PATIENTS SEEN	NHS Provider				
patients screened; none met eligibility criteria	NHS Provider				
	Please Select...				

Did not start to over Christmas/New Year period due to PI and research nurse availability.	NHS Provider				
To await sponsor green light - to commence recruitment 08/01/2018 due to Christmas break.	Both				
SIV booked for 31/08/2017 - postponed due to CRA a/l. Re-booked for 18/10/2017. Then re-arranged to 24/10/2017 - postponed due to study centre not received study documents not back from printers .	Sponsor				

awaiting costs to be sent from sponsor	Sponsor			If available please indicate Date Site Confirmed By	
Pharmacy capacity limited. Additional equipment required eg fridge thermometer; contracting issues	NHS Provider			If available please indicate Date Site Confirmed By	
A large pool of patients to approach, but many do not want to be involved	Neither				

<p>Site was invited at early stage, no delays occurred with study set up. Delays with First patient recruited due to reason G</p>	<p>Both</p>				
<p>Set up delayed due to Sponsor, as changes required by REC/HRA</p>	<p>Sponsor</p>			<p>If available please indicate HRA Approval If</p>	
<p>delays with sponsor and sending the contract, Site delays due to R&D director on leave to be able to sign contract</p>	<p>Both</p>				

currently in set up	Please Select...			If available please indicate Date Site Confirmed By Sponsor	
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