

Performance in Initiating Qtr 2 2022-23

Id	Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	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	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	Reasons for Delay	Comments	Reasons for delay correspond to:
208915	19/SC/0021	249552	OPTimal TIMing of Anticoagulation after acute ischaemic Stroke (OPTIMAS Trial)	Yes	10/03/2022	61	59	120	08/07/2021	10/11/2021	04/04/2019	10/01/2022	10/01/2022	Please Select...	17/01/2022	D - Sponsor Delays	Delays with sponsor confirming acceptance of contract. Other delays were due to Christmas sponsor closedown	Sponsor
208916	21/NW/0313	290490	Breakfast Group Interventions in Stroke Rehabilitation (BISTRo)	Yes	22/04/2022	8	16	24	03/09/2021	29/03/2022	05/01/2022	05/04/2022	06/04/2022	Please Select...	06/04/2022	E - Staff availability issues	Delays due to PI not having sufficient time to complete GCP. Therefore set-up put on hold until ready.	NHS Provider
208917	21/LO/0559	296584	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study Evaluating the Efficacy and Safety of Subcutaneous Anifrolumab in Adult Patients with Systemic Lupus Erythematosus (TULIP)	No		14			29/02/2020	10/03/2022	18/02/2022	24/03/2022	24/03/2022	Please Select...	12/05/2022		Study put on hold until procedure sorted out. This was sorted on 15.08.2022 and re-opened	Please Select...
208918	21/WS/0071	287716	Physiotherapy exercise rehabilitation with tailored exercise adherence support for people with osteoporosis and vertebral fractures: A randomised controlled trial. Osteoporosis Tailored exercise adherence INtervention (OPTIN)	No		13			12/01/2022	02/03/2022	18/06/2021	15/03/2022	15/03/2022	Please Select...	18/05/2022	D - Sponsor Delays	Training required for RNs and Physios before green light could be given. Last training held on 18.May.22 when green light has been given.	Sponsor
208919	21/EM/0205	289580	Randomised controlled trial comparing online behavioural sleep intervention with standard care in children with rolandic epilepsy (CASTLE Sleep-E)	No		10			29/03/2021	14/03/2022	10/12/2021	22/03/2022	24/03/2022	Please Select...	07/06/2022	D - Sponsor Delays	Sponsor delays in training and setting up study. 2 patients consented but withdrawn prior to randomisation	Sponsor
208920	19/WA/0337	261352	Confirming the Mechanism of Motivational Interviewing Therapy after Stroke: a multi-centre randomised controlled trial (COMMITTS)	Yes	09/12/2021	32	9	41	22/09/2021	29/10/2021	03/01/2020	29/11/2021	30/11/2021	Please Select...	14/06/2021	D - Sponsor Delays	Due to nature of study, training has had to be undertaken by all study team which has taken some time to set up	Sponsor
208921	22/LO/0020	1004368	An Open-Label, Randomised, Phase 4 Study of Continuing Sodium Zirconium Cyclosilicate (SZC) after Discharge in Participants with Chronic Kidney Disease treated for Hyperkalaemia (CONTINUITY)	No		69			10/01/2022	03/02/2022	02/02/2022	12/04/2022	13/04/2022	Please Select...		D - Sponsor Delays J - Other	1st site to open in UK and some initial queries regarding Protocol	Both
208922	22/EM/0040	306485	A Phase 2, Randomized, Double-blind, Placebo-controlled, Dose-finding Study to Evaluate the Efficacy and Safety of ALXN2050 in Adult Participants with Proliferative Lupus Nephritis (LN) or Immunoglobulin A Nephropathy (IgAN)	No		116			22/12/2021	24/02/2022	17/06/2022	17/06/2022	20/06/2022	Please Select...	29/06/2022	D - Sponsor Delays	Lengthy delays in setting up	Sponsor
209196	21/FT/0104	303394	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of BLIB059 in Adult Participants With Active systemic Lupus Erythematosus Receiving Background Nonbiologic Lupus Standard of Care	Yes	09/02/2022	127	0	127	23/07/2021	05/10/2021	04/10/2021	09/02/2022	09/02/2022	Please Select...	09/02/2022	D - Sponsor Delays	Sponsor wanted to do SIV face to face but due to COVID, this was constantly being delayed as Trust had a no face to face policy	Sponsor
209197	19/WA/0325	266292	A Randomised Controlled Trial of Early valve replacement in severe ASymptomatic Aortic Stenosis (EASY-AS)	Yes	15/08/2022	56	200	256	23/09/2021	02/12/2021	02/12/2019	26/01/2022	27/01/2022	Please Select...	15/03/2022	D - Sponsor Delays	Delays in C&C due to archiving queries with sponsor. Study also not due to open until Feb 22, so no rush on sponsor side	Sponsor

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209198	21/WM/0013	283141	Hysteroscopic Excision of Leiomyoma and Polyp in Infertility - two randomised controlled trials	No		37			06/12/2021	14/02/2022	10/02/2021	08/03/2022	23/03/2022	Please Select...	11/05/2022	F - No patients seen G - No patients consented	Screened over 400 potential patients and only 1 eligible.	Neither
209199	21/LO/0911	1004301	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, Pharmacodynamics, and Pharmacokinetics of Lumasiran in Patients with Recurrent Calcium Oxalate Kidney Stone Disease and Elevated Urinary Oxalate Levels	No		81			25/11/2021	11/02/2022	10/02/2022	03/05/2022	03/05/2022	Please Select...	13/06/2022	D - Sponsor Delays	Study set-up for delivery team has been chaotic in terms of Sponsor sample courier process and possible 'home visit' arrangements (not available now). Awaiting substantial amendment to be approved. The changes will ease the burden of the study for participants and simplify the delivery for the research team.	Sponsor
209200	22/YH/0016	296694	POSE-D: Providing Online guided Self-help for Eating disorders in adults with type	Yes	12/09/2022	70	41	111	03/06/2021	24/05/2022	14/03/2022	02/08/2022	02/08/2022	Please Select...	02/08/2022	D - Sponsor Delays	Original set-up delays due to COVID. Delays also in receiving contract.	Sponsor
209201	20/LO/1110	284958	Pregnancy ANtihypertensive Drugs: which Agent is best? (Giant PANDA)	Yes	06/10/2022	78	42	120	17/12/2021	08/06/2022	17/12/2020	22/08/2022	25/08/2022	Please Select...	31/08/2022	F - No patients seen	No patients seen who meet eligibility	Neither
209202	22/FT/0062	308989	A randomized, double-blind, placebo controlled, multicenter phase III study to assess the efficacy and safety of ianalumab in patients with active Sjögren's syndrome (NEPTUNUS)	No		84			04/04/2022	09/05/2022	06/06/2022	29/06/2022	01/08/2022	Please Select...	04/09/2022	F - No patients seen	The inclusion criteria is also looking at patients in active disease which narrows the recruitment down further for our Trust.	Neither
209203	22/NW/0131	308989	Effectiveness of supervised versus self-directed rehabilitation for people aged 50 years and over with ankle fractures: the AFTER trial	No		36			09/02/2022	13/04/2022	12/05/2022	18/05/2022	19/05/2022	Please Select...	15/09/2022	J - Other	Physio training required which took place after Trust C&C issued, also Sponsor setting up database and not given Green light until Sept once everything had been set up.	Sponsor
209204	22/FT/0018	1004748	A TWINSS extension trial to evaluate the safety and tolerability of CFZ533 (iscalimab) at two dose levels administered subcutaneously in patients with Sjögren's Syndrome	No		73			22/02/2022	22/02/2022	15/02/2022	04/05/2022	06/05/2022	Please Select...	06/05/2022	D - Sponsor Delays	Set-up delays due to Sponsor not providing study documents prior to patient rolling over to extension study.	Sponsor