

Submission Details	
Status	Accepted
Open Date	01/04/2022
Deadline Date	29/04/2022
Date Submitted	19/04/2022
Type	Performance in Initiating
NHS provider	North West Anglia NHS Foundation Trust

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:
197653	21/FT/0012	290481	A Phase 2 Study to Evaluate the Efficacy and Safety of LY3462817 in Participants with Moderately to Severely Active Rheumatoid Arthritis	No					23/10/2020	14/06/2021				Sponsor declined site confirmation	03/09/2021		Sponsor withdrew site before green light.	Please Select...
197654	21/EE/0039	290104	A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in Subjects with High-Risk HER2-Positive Primary Breast Cancer Who Have Residual Invasive Disease in Breast or Axillary Lymph Nodes Following Neoadjuvant Therapy	No		181			16/02/2021	30/04/2021	04/05/2021	12/10/2021	28/10/2021	Please Select...	29/10/2021	H - Contracting delays	Delays in costing review and feasibility completion	NHS Provider
197655	18/LO/2111	254025	Quality-Assured Follow-up of quiEscent Neovascular age-Related macular Degeneration by	Yes	14/09/2021	64	25	89	21/10/2020	17/06/2021	25/03/2019	20/08/2021	20/08/2021	Please Select...	20/08/2021	H - Contracting delays	Delays in study set up due to COVID-19 pressures	Neither

			non-medical practitioners: a randomised controlled trial The FENETRE study															
197656	20/EE/0127	277059	HUSH - The Humeral Shaft Fracture Trial	Yes	02/08/2021	63	35	98	04/01/2021	26/04/2021	02/06/2020	28/06/2021	28/06/2021	Please Select...	28/06/2021	E - Staff availability issues	Delays within the R&D team and Delivery team to incorporate, UPH, Restart and New studies	NHS Provider
197657	19/EM/0141	271764	A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO ASSESS THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF BIMEKIZUMAB IN THE TREATMENT OF SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS.	Yes	11/11/2021	28	29	57	12/11/2019	15/09/2021	13/01/2020	05/10/2021	13/10/2021	Please Select...	13/10/2021			Please Select...
197658	20/NE/0253	288479	COVID-NURSE: evaluation of the effects of a COVID-specific fundamental nursing care protocol compared to care as usual on experience of care for non-invasively ventilated patients in hospital with the SARS-CoV-2 virus: a randomised controlled trial.	Yes	02/09/2021	19	15	34	30/07/2021	30/07/2021	11/11/2020	18/08/2021	18/08/2021	Please Select...	25/08/2021			Please Select...
197659	21/SC/0121	294861	HElping Alleviate the Longer-term consequences of COVID-19(HEAL-COVID): a national platform trial	Yes	30/07/2021	90	17	107	09/04/2021	14/04/2021	08/04/2021	14/05/2021	13/07/2021	Please Select...	28/07/2021	E - Staff availability issues	Delays in study teams availability to review C&C	NHS Provider

197660	21/SC/0247	1003793	A Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA)	No		244				22/12/2020	04/08/2021	17/09/2021	27/03/2022	05/04/2022	Please Select...	05/04/2022	H - Contracting delays	Slow responses from sponsor in confirming costing queries	Sponsor
197661	19/WM/0364	257918	Letrozole or Clomifene, with or without metformin, for ovulation induction in women with polycystic ovary syndrome: a 2x2 factorial design randomised trial (The LOCI trial)	Yes	09/11/2021	82	33	115	26/11/2021	17/07/2021	09/06/2020	01/10/2021	07/10/2021	Please Select...	07/10/2021	H - Contracting delays	greenlight delayed by slow communication between site and sponsor	Both	
197662	21/EE/0055	1003560	A PHASE IIB, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF INTRAVENOUS PRASINEZUMAB IN PARTICIPANTS WITH EARLY PARKINSON'S DISEASE	Yes	23/11/2021	79	130	209	17/11/2020	28/04/2021	05/05/2021	14/07/2021	16/07/2021	Please Select...	16/07/2021	A - Permissions delayed/denied	Disease specific training requirements delayed	Neither	
197663	21/NW/0199	293515	PROTEUS: A Prospective randomised controlled Trial Evaluating the Use of AI in Stress Echocardiography	No					09/07/2021	15/07/2021	22/07/2021				Site declined to participate		E - Staff availability issues	PI availability	NHS Provider
197664	19/EM/0253	263682	The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial	No		94			18/12/2019	14/06/2021	23/10/2019	10/09/2021	16/09/2021	Please Select...	16/09/2021	J - Other	Recruitment not expected until May 2022 as per sponsor discussions prior to C&C confirmation.	Neither	

			with economic and acceptability evaluations (GBS3)															
197665	19/EE/0377	266504	Trial of Ondansetron as a Parkinson's HALLucinations Treatment	Yes	15/11/2021	42	60	102	07/11/2019	05/08/2021	17/06/2020	13/09/2021	16/09/2021	Please Select...	16/09/2021	D - Sponsor Delays	Greenlight delayed as training required following updated protocol amendment	Sponsor
197666	20/SS/0039	277102	ENRICH-AF: Edoxaban for IntraCranial Haemorrhage survivors with AF	Yes	01/03/2022	62	82	144	29/06/2021	08/10/2021	03/02/2021	06/12/2021	09/12/2021	Please Select...	09/12/2021	E - Staff availability issues	Delivery staff unavailable	NHS Provider
197667	21/WM/0196	297458	CP340 SUN- Study Investigation of patient benefits with a new supporting ostomy product and support service in patients with a newly stoma formation.	No		85			27/08/2021	10/11/2021	03/11/2021	19/01/2022	03/02/2022	Please Select...	03/02/2022			Please Select...
197668	19/SW/0043	235625	CHIEF-PD (CHolinesterase Inhibitor to prEvent Falls in Parkinson's Disease): A phase 3 randomised double-blind placebo-controlled trial of rivastigmine to prevent falls in Parkinson's disease	Yes	24/03/2022	76	37	113	09/11/2021	01/12/2021	27/03/2019	14/02/2022	15/02/2022	Please Select...	15/02/2022	E - Staff availability issues	Delays in study set up due to COVID-19 re-deployment pressures	NHS Provider
197669	20/LO/1110	284958	Giant PANDA - Pregnancy ANtihypertensive Drugs: which Agent is best?	No		105			12/08/2021	08/12/2021	17/12/2020	17/03/2022	23/03/2022	Please Select...	23/03/2022	E - Staff availability issues	Delays in study set up due to COVID-19 re-deployment pressures	NHS Provider
197696	21/FT/0097	286505	A randomised trial of early detection of molecular relapse with circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard	No					03/11/2021	28/03/2022	14/09/2021			Please Select...				Please Select...

			endocrine therapy in patients with ER positive HER2 negative breast cancer															
197811	21/EM/0205	289580	Randomised controlled trial comparing online behavioural sleep intervention with standard care in children with rolandic epilepsy	No					15/03/2022	15/03/2022	10/12/2021			Please Select...			Please Select...	
197812	21/LO/0316	291855	Innovation in the Allied Health Professions: Evaluation of supplementary prescribing by dietitians and independent prescribing by therapeutic radiographers	No					10/02/2022	10/02/2022	30/04/2021			Site declined to participate	01/04/2022	E - Staff availability issues	Delivery staff have no capacity due to increased pressures following the pandemic.	NHS Provider