

Submission Details	
Status	Accepted
Open Date	04/01/2022
Deadline Date	31/01/2022
Date Submitted	14/01/2022
Type	Performance in Initiating
NHS provider	North West Anglia NHS Foundation Trust

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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:
191018	21/LO/0179	292475	A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III STUDY OF THE EFFICACY AND SAFETY OF TRASTUZUMAB EMTANSINE IN COMBINATION WITH ATEZOLIZUMAB OR PLACEBO IN PATIENTS WITH HER2-POSITIVE AND PD-L1-POSITIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER WHO HAVE RECEIVED PRIOR TRASTUZUMAB-(+/- PERTUZUMAB) AND TAXANE-BASED THERAPY (KATE3)	No		170			02/03/2021	18/03/2021	31/03/2021	14/09/2021	04/09/2021	Please Select...	01/10/2021	J - Other	delay in receiving greenlight due to outstanding documents	NHS Provider
191019	21/FT/0012	290481	A Phase 2 Study to Evaluate the Efficacy and Safety of	No					23/10/2020	14/06/2021				Sponsor declined site confirmation	03/09/2021		Sponsor withdrew site before green light.	Please Select...

			LY3462817 in Participants with Moderately to Severely Active Rheumatoid Arthritis															
191020	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
191021	18/LO/2111	254025	Quality-Assured Follow-up of quiEscent Neovascular agE-relaTed maculaR dEgeneration by non-medical practitioners: a randomised controlled trial The FENETRE study	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
191022	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
191023	19/EM/0141	271764	A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO ASSESS THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF	Yes	01/11/2021	28	19	47	12/11/2019	15/09/2021	13/01/2020	05/10/2021	13/10/2021	Please Select...	13/10/2021			Please Select...

			BIMEKIZUMAB IN THE TREATMENT OF SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS.															
191024	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...
191025	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
191026	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					22/12/2020	04/08/2021	17/09/2021			Please Select...		H - Contracting delays	Slow responses from sponsor in confirming costing queries	Sponsor
191027	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

191028	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
191029	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
191030	19/EM/0253	263682	The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)	No		94			18/12/2019	14/06/2021	23/10/2019	10/09/2021	16/09/2021	Please Select...				Please Select...
191031	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
191088	20/SS/0039	277102	ENRICH-AF: Edoxaban for IntraCranial Haemorrhage survivors with AF	No		62			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
191089	21/WM/0196	297458	CP340 SUN- Study Investigation of patient benefits with a new supporting ostomy product and support service in patients with a	No					27/08/2021	10/11/2021	03/11/2021			Please Select...				Please Select...

			newly stoma formation.															
191117	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	No					09/11/2021	01/12/2021	27/03/2019			Please Select...				Please Select...
191130	20/LO/1110	284958	Giant PANDA - Pregnancy ANtihypertensive Drugs: which Agent is best?	No					12/08/2021	08/12/2021	17/12/2020			Please Select...				Please Select...