

Submission Details	
Status	Accepted
Open Date	01/10/2021
Deadline Date	29/10/2021
Date Submitted	25/10/2021
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:
186644	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		14/09/2021	04/09/2021	Please Select...				Please Select...
186645	21/FT/0012	290481	A Phase 2 Study to Evaluate the Efficacy and Safety of LY3462817 in Participants with Moderately to	No					23/10/2020	14/06/2021				Sponsor declined site confirmation			Sponsor withdrew site before green light.	Please Select...

			Severely Active Rheumatoid Arthritis																
186646	20/LO/1114	1003435	A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF GDC-9545 COMBINED WITH PALBOCICLIB COMPARED WITH LETROZOLE COMBINED WITH PALBOCICLIB IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER	No		267				18/08/2020	20/10/2020	08/12/2020	13/07/2021	14/07/2021	Please Select...	15/07/2021	E - Staff availability issues	Covid-19 staff redeployment prevented trial opening at site.	Neither
186647	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						16/02/2021	30/04/2021	04/05/2021			Please Select...				Please Select...
186648	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				Please Select...

			non-medical practitioners: a randomised controlled trial The FENETRE study															
186649	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
186651	19/LO/1244	250308	The impact of a toolkit for healthcare professionals to support physically active pregnancies upon physical activity levels in pregnant women and new mothers: This Mum Moves	Yes	24/11/2020	20	27	47	11/12/2019	08/10/2020	14/10/2019	28/10/2020	28/10/2020	Please Select...	24/11/2020			Please Select...
186653	20/LO/1021	283786	Randomised, double-blind, placebo-controlled, clinical study to evaluate the effect of opicapone 50 mg on Parkinson's disease patients with motor fluctuations and associated pain	No					02/11/2020	02/11/2020				Site declined to participate				Please Select...
187489	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.	No					12/11/2019	15/09/2021	13/01/2020			Please Select...				Please Select...
187490	20/NE/0253	288479	COVID-NURSE: evaluation of the effects of a COVID-specific fundamental	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...

			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.															
187491	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
187492	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...				Please Select...
187493	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)	No		82			26/11/2021	17/07/2021	09/06/2020	01/10/2021	07/10/2021	Please Select...		H - Contracting delays		Both
187515	20/HRA/2618	282552	MATIS: Phase 2/3, Randomised, Open-Label, Single-Site, Multi-Arm Trial of Ruxolitinib Plus Best Supportive Treatment (BST) versus Fostamatinib Plus BST versus BST for COVID-19 pneumonia	No					01/12/2020	01/12/2020				Site declined to participate				Please Select...

187516	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	No		79				17/11/2020	28/04/2021	05/05/2021	14/07/2021	16/07/2021	Please Select...				Please Select...
187517	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			Please Select...	E - Staff availability issues	PI availability	Both	
187535	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...
187536	19/EE/0377	266504	Trial of Ondansetron as a Parkinson's HAllucinations Treatment	No		42				07/11/2019	05/08/2021	17/06/2020	13/09/2021	16/09/2021	Please Select...				Please Select...