Performance in Delivering Clinical Research Guy's and St Thomas' NHS Foundation Trust 01 October 2021 to 30 September 2022

Ethic Com Refe	earch cs nmittee erence nber	IRAS Number	Name of Trial	Target Number of Patients Agreed?	Minimum Patients	Maximum Patients	Date Agreed to recruit target number of patients available	Date agreed to recruit target number of patients	Total number patients recruited at target date	Date Trial closed to recruitment	Total number of study participants recruited	Reason for closure
1 19/L	LO/1628	269265	A Multicentre, Randomised, Open-Label, Parallel-Group, Active-Controlled, Phase IV Study to Assess the Reduction of Daily Maintenance ICS/LABA Treatment Towards Anti-Inflammatory Reliever Treatment in Patients with Severe Eosinophilic Asthma Treated with Benralizumab	Number Agreed	28	28	Date Agreed	31/12/2021	27	24/12/2021	27	Recruitment Finished
2 21/S	SC/0084	293797	A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study Evaluating the Efficacy and Safety of Remdesivir in Participants with Severely Reduced Kidney Function who are Hospitalized with COVID-19	Range Agreed	1	4	Date Agreed	22/11/2021	0	28/02/2022	0	Recruitment Finished
3 18/L	LO/0235	240315		Number Agreed	10	10	Date Agreed	20/12/2019	7	05/04/2022	7	Recruitment Finished
4 21/E	EE/0153	295343	A prospective, open, non-comparative, post-market clinical follow-up investigation to confirm the safety and performance of Avance Solo NPWT System in surgically closed incisions.	Range Agreed	10	20	Date Agreed	26/08/2022	6	27/05/2022	6	Recruitment Finished
5 19/E	EE/0057	253986	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Outpatient Study Evaluating the Pharmacokinetics, Efficacy, and Safety of Baricitinib in Pediatric Patients with Moderate to Severe Atopic Dermatitis		3	5	Date Agreed	30/11/2021	4	24/12/2021	4	Recruitment Finished
6 19/L	LO/1532	269933	A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy (STEADFAST)	Number Agreed	3	3	Date Agreed	25/10/2021	3	21/12/2021	3	Recruitment Finished
7 19/S	SW/0140	265506	A Randomized, Double-blind, Active-controlled 52-week Study with an Open-label Extension to Investigate the use of Benralizumab compared to Mepolizumab for Patients with Eosinophilic Granulomatosis with Polyangiitis (EGPA)	Number Agreed	5	5	Date Agreed	30/06/2022	7	02/12/2021	7	Recruitment Finished
8 20/L	LO/0977	284004		Range Agreed	10	20	Date Agreed	31/05/2023	11	25/07/2022	11	Recruitment Finished
9 19/E	ES/0100	261027	A Phase 3, Double-Blind, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Systemic Lupus Erythematosus (SLE)	Range Agreed	4	8	Date Agreed	30/10/2021	7	30/10/2021	7	Recruitment Finished
10 21/L	LO/0050	289029	A 2-stage, multicenter, randomized, placebo-controlled study to evaluate safety/tolerability, pharmacokinetics, and efficacy of UCB7858 in adult kidney transplant recipients with chronic allograft injury	Range Agreed	1	2	Date Agreed	31/08/2022	1	14/12/2021	1	Recruitment Finished
11 20/H	HRA/5234	290965	A randomised, double-blind, placebo-controlled, Phase III trial to determine the efficacy and safety of inhaled SNG001 for the treatment of patients hospitalised due to moderate COVID-19	Range Agreed	3	5	Date Agreed	11/11/2022	6	11/11/2021	6	Recruitment Finished
12 20/H	HRA/4623	287129	A Phase 2 Randomized, Double-blind, Placebo-controlled Safety and Efficacy Trial of Deupirfenidone (LYT-100) in Post-acute COVID-19 Respiratory Disease	Range Agreed	5	10	Date Agreed	31/12/2021	1	18/01/2022	1	Recruitment Finished
13 20/Y	YH/0263	1003409	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 2 Study of the Efficacy and the Safety and Tolerability of BMS-986278 in Participants with Pulmonary Fibrosis	Number Agreed	3	3	Date Agreed	30/06/2022	3	31/01/2022	3	Recruitment Finished
14 21/Y	YH/0071	295903	A PHASE 2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITYOF A SARS-COV-2 RNA VACCINE CANDIDATE (BNT162b2) AGAINST COVID-19 IN HEALTHY PREGNANT WOMEN 18 YEARS OF AGE AND OLDER	Number Agreed	10	10	Date Agreed	06/11/2021	0	25/10/2021	0	Recruitment Finished
15 21/Y		298529	Efficacy and safety of subcutaneous semaglutide 2.4 mg once-weekly in subjects with obesity and prediabetes	Number Agreed	5	5	Date Agreed	27/12/2021	5	20/12/2021	5	Recruitment Finished
16 22/H	HRA/0060	1004941	A Phase 2/3, Randomized, Stratified, Observer-blind Study to Evaluate the Immunogenicity and Safety of mRNA-1273.529 (B.1.1.529, Omicron variant) Booster Vaccine	Range Agreed	50	100	Date Agreed	17/06/2022	176	17/06/2022	176	Recruitment Finished
17 20/L		280729	A randomised, double-blind, placebo-controlled parallel group study in IPF patients over 12 weeks evaluating efficacy, safety and tolerability of BI 1015550 taken orally.	Number Agreed	2	2	Date Agreed	30/11/2021	2	16/11/2021	2	Recruitment Finished
18 21/F	F1/UU14	292548	A Phase 3 Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Elexacaftor/Tezacaftor/Ivacaftor Triple Combination Therapy in Cystic Fibrosis Subjects 2 Through 5 Years of Age	Number Agreed	3	3	Date Agreed	31/12/2021	2	01/12/2021	2	Recruitment Finished

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No	Research	IRAS	Name of Trial	Target Number	Minimum	Maximum	Date Agreed to	Date agreed to	Total	Date Trial closed	Total	Reason for
	Ethics Committee Reference Number	Number		of Patients Agreed?	Patients	Patients	recruit target number of patients available	recruit target number of patients	number patients recruited at target date	to recruitment	number of study participants recruited	closure
19	18/EE/0390	253601	A multicenter, randomized, double-blind, placebo-controlled, parallel-group, group-sequential, adaptive, Phase 3 study with open-label extension period to assess the efficacy and safety of selexipag as an add-on to standard of care therapy in subjects with inoperable or persistent/recurrent after surgical treatment Chronic Thromboembolic Pulmonary Hypertension.	Number Agreed	2	2	Date Agreed	02/09/2021	0	15/12/2021	0	Recruitment Finished
20	20/YH/0230	285206	A Study to Evaluate the Feasibility and Safety of the Millipede Transcatheter Annuloplasty Ring System in Patients with Functional Mitral RegurgitationMillipede Feasibility Study, S2436-92390788	Number Agreed	3	3	Date Agreed	30/06/2022	0	17/01/2022	0	Withdrawn By Sponsor
21	21/LO/0118	279496	A prospective, multicentre, open labelled, single arm, first in man interventional investigation to evaluate the safety and effectiveness of the ArterioSorb™ bioresorbable stent for the treatment of patients with coronary artery disease.	Number Agreed	10	10	Date Agreed	30/06/2022	0	27/07/2022	0	Withdrawn By Sponsor
22	21/NI/0196	308539	"AveirTM DR i2i Study" Aveir Dual-Chamber Leadless i2i IDE Study	Number Agreed	10	10	Date Agreed	31/08/2022	5	01/08/2022	5	Withdrawn By Sponsor
23	18/LO/1798	254544	A Phase 3, Multinational, Randomized, Placebo-Controlled Study of ARRY-371797 in Patients with Symptomatic Dilated Cardiomyopathy Due to a Lamin A/C Gene Mutation	Number Agreed	1	1	Date Agreed	01/03/2020	1	03/08/2022	1	Recruitment Finished