A lifetime of specialist care

Royal Brompton & Harefield NHS
NHS Foundation Trust

Performance in Initiation

Commercial and non-commercial clinical trials for which Royal Brompton & Harefield NHS FT was selected as a site between 01.10.2016 and 30.09.2017

REC Reference	IRAS Number	Name of Trial	Date First Patient 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	Source of Delay
16/NW/0629	211995	Cystic fibrosis (CF) anti-staphylococcal antibiotic prophylaxis trial (CF START); a randomised registry trial to assess the safety and efficacy of flucloxacillin as a long-term prophylaxis agent for infants with CF	25/04/2017	20/10/2016	20/10/2016	22/09/2016	20/01/2017	31/01/2017		24/04/2017	Sponsor
16/LO/1822	212944	Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Centre Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral Sgc Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction - VerICiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA)		30/09/2016	10/10/2016	07/12/2016	21/12/2016	05/01/2017		10/01/2017	Both
16/LO/0933	179313	Identifying REsponders and exploring mechanisms of ACTION of the endobronchial coil treatment for emphysema (REACTION-TRIAL)	05/12/2016	14/10/2016	14/10/2016	14/10/2016	22/11/2016	22/11/2016		28/11/2016	
16/WM/0276	207822	Safety of Nasal Influenza Immunisation in Children with Asthma: The SNIFFLE 4 study	02/11/2016	07/07/2016	28/10/2016	22/08/2016	28/10/2016	31/10/2016		31/10/2016	
16/LO/1424	207336	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia. A Phase 2a, Randomized, Double-blind, Placebo-controlled, Incomplete Block Cross-over Study to Evaluate the Safety and Efficacy of VX-371 Solution for Inhalation in Subjects With Primary Ciliary Dyskinesia	01/03/2017	13/07/2016	04/11/2016	04/11/2016	05/12/2016	19/12/2016		19/12/2016	Both
16/LO/0324	190140	REDUCER-I: An Observational Study of the Neovasc Reducer System	14/08/2017	02/02/2015	06/11/2016	22/08/2016	07/11/2016	16/11/2016		16/11/2016	Both
16/LO/1954	206351	Multicentre, open-label study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of LCZ696 followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared with enalapril in paediatric patients from 1 month to <18 years of age with heart failure due to systemic left ventricle systolic dysfunction		14/09/2016	06/12/2016	17/01/2017	17/01/2017	22/06/2017		22/06/2017	Sponsor
16/WM/0522	220157	Feasibility study of a new peripheral oedema monitor for heart failure	31/01/2017	14/12/2016	14/12/2016	11/01/2017	09/01/2017	18/01/2017		18/01/2017	
17/EM/0005	215706	A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv Mecarbil on Mortality and Morbidity in Subjects With Chronic Heart Failure With Reduced Ejection Fraction		20/12/2016	20/12/2016	15/02/2017	27/03/2017	30/03/2017		31/03/2017	Sponsor
17/LO/0041	219676	CardioMEMS HF System Post Approval Study	07/08/2017	08/03/2017	08/03/2017	06/03/2017	14/04/2017	18/04/2017		18/04/2017	Both
16/LO/1875	207883	Phase 2, Randomized, Double-blind, Controlled Study to Evaluate the Safety and Efficacy of VX-440 Combination Therapy in Subjects Aged 12 Years and Older With Cystic Fibrosis		20/09/2016	02/11/2016	16/01/2017	11/01/2017	31/01/2017		08/02/2017	Neither
16/EE/0355	204579	Iron and Chronic Obstructive Pulmonary Disease (COPD) Exercise Trial - ICE-T	03/05/2017	30/08/2016	17/01/2017	17/01/2017	17/01/2017	21/02/2017		24/04/2017	Both

16/NW/0787	216022	A phase IIa, randomized, double- blind, placebo-controlled study to evaluate GLPG2222 in ivacaftor-treated subjects with Cystic Fibrosis harbouring one F508del CFTR mutation and a second gating (class III) mutation GLPG2222-CL-202	03/04/2017	01/11/2016	15/11/2016	22/12/2016	03/03/2017	08/03/2017		08/03/2017	NHS Provider
16/SC/0515	215537	Phase 1, Randomized, Double-blind, Placebo-controlled, Dose Escalation, and Bioavailability Study Evaluating the Safety and Pharmacokinetics of VX-659 in Healthy Subjects and in Subjects With Cystic Fibrosis		02/11/2016	09/12/2016	22/12/2016	07/03/2017	10/03/2017		10/03/2017	NHS Provider
17/EM/0044	217658	1199.247 Nintedanib and placebo in patients with PF-ILD		10/08/2016	10/12/2016	24/04/2017	15/05/2017	22/05/2017		22/05/2017	Both
17/LO/0284	221453	A study of single doses to evaluate the safety, tolerability, pharmacokinetics and target engagement of nebulised GSK3008348 in idiopathic pulmonary fibrosis patients, using positron emission tomography (PET) imaging	21/08/2017	22/12/2016	10/02/2017	20/03/2017	10/02/2017	21/04/2017		21/04/2017	Both
17/EM/0183	220783	Effect of mepolizumab in severe bilateral nasal polyps		14/03/2017	27/09/2017	28/06/2017					
16/WA/0156	204506	UK Mini Mitral		15/06/2017	15/06/2017	19/07/2016					Sponsor
17/LO/0661	210591	Phase I/II, Multi-center, Randomized, Placebo-Controlled, Study Designed to Assess the Safety, Tolerability, and Pharmacokinetics of PTI-428 in Subjects with Cystic Fibrosis		15/06/2017	15/06/2017	31/08/2017			Sponsor declined site confirmation		
17/NI/0096	225743	HOPE-1 Study: Hydration for Optimal Pulmonary Effectiveness	13/10/2017	07/06/2017	19/06/2017	14/07/2017	06/08/2017	09/08/2017		07/10/2017	NHS Provider
17/SW/0128	222284	Assessment of the WATCHMAN Device in Patients Unsuitable for Oral Anticoagulation		05/05/2017	23/06/2017						Sponsor
17/LO/0035	218519	Development and evaluation of an intervention to support Adherence to treatment in adults with Cystic Fibrosis		12/06/2017	13/06/2017	03/04/2017	27/09/2017	10/10/2017		10/10/2017	Sponsor
16/YH/0500	217621	Double-Blind, Placebo-Controlled, Randomized, Repeat Dose Crossover Study (Part 1) Followed by a 12-Week Open-Label Extension Period (Part 2) to Assess the Safety, Tolerability, and Pharmacokinetics of LAM-001 in Female Patients With Lymphangioleiomyomatosis (LAM-001-LAM-CLN02)		08/12/2016	12/12/2016	31/01/2017	09/06/2017	14/06/2017		14/06/2017	Both
17/SC/0195	135459	Blood-Valves - Single arm pilot study of lung volume reduction in severe emphysema using bronchoscopic autologous blood instillation in combination with intra-bronchial valves		14/08/2017	14/08/2017	09/08/2017	18/08/2017	24/08/2017		24/08/2017	
16/EE/0358	212839	Randomized, blinded, parallel group, multi-center dose-finding study, to assess the efficacy, safety and tolerability of different doses of tobramycin inhalation powder in patients with Non-Cystic Fibrosis Bronchiectasis and pulmonary P. aeruginosa infection	27/03/2017	16/06/2016	20/01/2017	13/12/2016	02/02/2017	06/02/2017		10/02/2017	
17/EE/0115	218578	Study to Evaluate Safety, Pharmacokinetics and Pharmacodynamics of FDL169 in Cystic Fibrosis	28/09/2017	02/08/2017	02/08/2017	11/07/2017	31/08/2017	31/08/2017		31/08/2017	
17/LO/0683	226533	VXECD101 - Phase 2, Randomized, Double-blind, Controlled Study to Evaluate the Safety and Efficacy of VX-659 Combination Therapy in Subjects Aged 18 Years and Older With Cystic Fibrosis	11/09/2017	30/06/2017	02/08/2017	14/08/2017	14/08/2017	16/08/2017		16/08/2017	
16/LO/1987	207718	CLIMB-CF - Clinical Monitoring and Biomarkers to stratify severity and predict outcomes in children with cystic fibrosis	16/01/2017	25/07/2016	15/12/2016	19/12/2016	11/01/2017	11/01/2017		11/01/2017	
17/EM/0246	228635	ZEPHYR - Phase II open label study to evaluate the effect of GBT440 on hypoxemia in subjects with Idiopathic Pulmonary Fibrosis (IPF) who are using supplemental oxygen at rest		05/07/2017	22/08/2017	22/08/2017	25/09/2017	25/09/2017		29/09/2017	
17/LO/1088	228921	VX15-770-126 Cystic Fibrosis - Phase 3, 2-Arm, Open-label Study to Evaluate the Safety and Pharmacodynamics of Long-term Ivacaftor Treatment in Subjects With Cystic Fibrosis Who Are Less Than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation		07/08/2016	16/08/2017	03/08/2017	18/08/2017	25/09/2017		29/09/2017	

A lifetime of specialist care

Royal Brompton & Harefield NHS
NHS Foundation Trust

Performance in Delivery

Commercial clinical trials which closed to recruitment between 1.10.2016 and 30.9.2017

REC reference	IRAS reference	Name of Trial	Target Number of Patients Agreed?	Minimum Number Agreed	Maximum Number Agreed	Target Date to Recruit Patients Agreed?	Date Agreed to Recruit Target	Total Recruitment at Agreed Target Date	Date Closed to Recruitment	Total Participants Recruited	Reason For Closure
15/LO/1500	187068	Investigation of drug-drug interaction between nintedanib and pirfenidone in patients with IPF (an open label, multiple-dose, two group study followed by nintedanib open label treatment)	Number Agreed	5	5	Date Agreed	29/07/2016	5	01/12/2016	5	Recruitment Finished
14/LO/1357	159642	A randomised, double-blind, multi centre, placebo-controlled dose escalation study in healthy subjects investigating the safety, tolerability and pharmacokinetic properties of TD139, a galectin-3 inhibitor, followed by an expansion cohort treating subjects with idiopathic pulmonary fibrosis (IPF)	Number Agreed	12	12	Date Agreed	28/02/2016	10	03/10/2016	10	Recruitment Finished
16/EM/0078	199717	Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter, Exploratory Phase IIa Study to Assess Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Properties of GLPG1690 Administered for 12 Weeks in Subjects with Idiopathic Pulmonary Fibrosis (IPF)	Number Agreed	2	2	Date Agreed	31/01/2017	2	01/02/2017	2	Recruitment Finished
16/ES/0063	202796	Prospective Registry on User Experience With The RHYTHMIATM Mapping System For Ablation Procedures	Number Agreed	20	20	Date Agreed	01/07/2017	51	17/03/2017	51	Recruitment Finished
15/SC/0599	187727	A Phase 2b, Randomized, Controlled Trial Evaluating GS-5806 in Lung Transplant (LT) Recipients with Respiratory Syncytial Virus (RSV) Infection	Number Agreed	2	2	Date Agreed	19/09/2016	0	15/02/2017	0	Recruitment Finished
13/LO/1328	137191	A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to valsartan, on morbidity and mortality in heart failure patients (NYHA Class II-IV) with preserved ejection fraction	Number Agreed	6	6	Date Agreed	15/08/2018	7	11/11/2016	7	Recruitment Finished
15/LO/1636	187947	A multicenter, randomized, double-blind, crossover placebo-controlled Phase II study to assess the effect of serelaxin versus placebo on high sensitivity cardiac troponin I (hs-cTnI) release in patients with chronic heart failure after exercise when used in addition to standard of care	Number Agreed	4	4	Date Agreed	31/03/2017	4	21/11/2016	4	Recruitment Finished
15/LO/1729	189383	A Phase 3b, 2-part, Randomized, Double-blind, Placebo-controlled Crossover Study With a Long-term Open-label Period to Investigate Ivacaftor in Subjects With Cystic Fibrosis Aged 3 Through 5 Years Who Have a Specified CFTR Gating Mutation	Number Agreed	2	2	Date Agreed	31/12/2016	3	31/12/2016	3	Recruitment Finished
16/LO/0793	203066	A 12-week, double-blind, randomised, placebo-controlled, parallel group trial followed by a single active arm phase of 40 weeks evaluating the effect of oral nintedanib 150 mg twice daily on change in biomarkers of extracellular matrix (ECM) turnover	Number Agreed	5	5	Date Agreed	31/03/2017	6	10/03/2017	6	Recruitment Finished
14/EE/1193	155911	AIRFLOW-1: A randomised study to compare the safety and efficacy of different energy levels after treatment with the Holaira lung denervation system in patients with moderate to severe COPD	Number Agreed	10	10	Date Agreed	31/03/2017	27	31/03/2017	27	Recruitment Finished

13/NE/0005	100377	Micra™ Transcatheter Pacing System Post-Approval Registry	Number Agreed	10	10	Date Agreed	01/09/2018	11	28/04/2017	11	Recruitment Finished
16/SC/0336	208403	Utilizing Novel dipole density Capabilities to Objectively Visualize the Etiology of Rhythms in Atrial Fibrillation (UNCOVER-AF)	Number Agreed	25	25	Date Agreed	30/04/2017	4	30/04/2017	4	Withdrawn By Sponsor
15/NI/0064	170872	Phase 1B, Randomized, Double-blind, Placebo-controlled, Dose Escalation Study to evaluate the Safety, Tolerability and Pharmacokinetics of QR-010 in Subjects with Homozygous ΔF508 Cystic Fibrosis	Number Agreed	2	2	Not Available / Not Agreed			01/12/2016	1	Withdrawn By Sponsor
13/EE/0433	141819	Nanostim study for a leadless cardiac pacemaker system - The LEADLESS Observational Study	Number Agreed	9	9	Date Agreed	31/01/2015	2	31/10/2016	10	Recruitment Finished
15/EE/0130	170557	A Randomized, Open-Label, Multicenter Study of Liposomal Amikacin for Inhalation (LAI) in Adult Patients with Nontuberculous Mycobacterial (NTM) Lung Infections caused by Mycobacterium avium complex (MAC) that are refractory to treatment	Number Agreed	1	1	Date Agreed	31/12/2015	2	01/11/2016	5	Recruitment Finished
16/EE/0048	192528	A two-arm, randomised, assessor-blind, parallel group study to evaluate the effect of fluticasone/formoterol breath actuated inhaler (BAI) and Relvar Ellipta DPI on ventilation heterogeneity in subjects with partially controlled or uncontrolled asthma	Number Agreed	4	4	Date Agreed	30/04/2017	0	30/04/2017	0	Withdrawn By Host
15/LO/0040	155632	A Phase II/III Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effect of GS6615 on Exercise Capacity in Subjects with Symptomatic HCM	Number Agreed	4	4	Date Agreed	31/01/2017	0	08/12/2016	0	Withdrawn By Sponsor
14/LO/1744	159534	Lipid-riche Plaque (LRP) study - 3855 CARD LRP	Number Agreed	25	25	Date Agreed	31/12/2015	15	06/10/2016	25	Recruitment Finished
15/NI/0064	172879	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation	Number Agreed	3	3	Date Agreed	01/07/2016	5	06/10/2016	5	Recruitment Finished
15/LO/1891	180600	Early Feasibility Study of Tendyne Mitral Valve System	Number Agreed	5	5	Not Available / Not Agreed			01/12/2016	0	Withdrawn By Sponsor
16/SC/0515	215537	Phase 1, Randomized, Double-blind, Placebo-controlled, Dose Escalation and Bioavailability Study Evaluating Safety & PK of VX-659 in Healthy Subjects and Subjects With Cystic Fibrosis	Number Agreed	1	1	Not Available / Not Agreed			24/07/2017	0	Withdrawn By Sponsor
15/WS/0160	174507	Safety and Efficacy of the CARILLON Mitral Contour System® in Reducing Functional Mitral Regurgitation (FMR) Associated with Heart Failure	Number Agreed	5	5	Date Agreed	01/08/2016	2	01/08/2017	3	Recruitment Finished
15/NW/0229	170151	Worldwide Randomised Antibiotic Envelope Infection Trial (WRAP-IT)	Number Agreed	30	30	Date Agreed	01/10/2016	20	03/08/2017	30	Recruitment Finished