

**Performance in Initiating HRA Approved Studies - Q2 2018/19**

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Date of First Patient Recruited	Source for delay correspond to:
17/WS/0120	225090	A multi-center, double-blind, placebo-controlled, Phase 4 study in patients with pulmonary arterial hypertension to assess the effect of selexipag on daily life physical activity and patient's self-reported symptoms and their impacts.	10/07/2017	25/10/2017	24/07/2017	30/10/2017	01/11/2017	15/11/2017	19/12/2017	
17/EE/0502	218716	Long-term, open label, multicenter, extension study to evaluate the safety and tolerability of QCC374 in patients with PAH	26/06/2017	05/12/2017	16/01/2018	19/12/2017	03/01/2018		02/02/2018	Neither
16/NW/0718	204299	A randomised controlled trial to determine the clinical and cost effectiveness of the Respiratory Distress Symptom Intervention for people with lung cancer	20/12/2017	16/01/2018	31/08/2017	20/03/2018	21/03/2018		10/05/2018	NHS Provider
18/NW/0006	237093	Assessment of safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of the combination of GLPG2451 and GLPG2222, with or without GLPG2737, in adult subjects with cystic fibrosis	15/01/2018	20/04/2018	01/05/2018	19/07/2018	26/07/2018	26/07/2018		NHS Provider
16/SC/0387	202827	Assessment of the effect of Positive Airway Pressure on energy and vitality in mild Obstructive Sleep Apnea patients. The Merge Study.	27/04/2017	30/01/2018	26/10/2016	04/05/2018	04/05/2018	09/05/2018	28/06/2018	NHS Provider
16/LO/1509	208393	Narcolepsy Trial Using Once Nightly Sodium Oxybate	04/12/2017	07/03/2018	23/02/2018					
17/SC/0025	213874	A Prospective, Randomized, Open-Label, Blinded Endpoint Evaluation (PROBE) Parallel Group Study Comparing Edoxaban vs. VKA in Subjects Undergoing Catheter Ablation of Non-valvular Atrial Fibrillation (ELIMINATE-AF).	01/06/2017	08/01/2018	28/02/2017	05/03/2018	08/03/2018	14/03/2018		NHS Provider
17/NW/0678	233267	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Study to Assess the Efficacy, Safety and Tolerability, and Pharmacokinetics of INS1007 Administered Once Daily for 24 Weeks in Subjects with Non-Cystic Fibrosis Bronchiectasis - The Willow Study	23/03/2018	16/06/2018	16/06/2018	25/09/2018	02/10/2018	02/10/2018		
18/NE/0103	241640	A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-659 Combination Therapy in Subjects With Cystic Fibrosis Who Are Homozygous for the F508del Mutation (F/F)	11/01/2018	15/05/2018	02/05/2018	30/04/2018	30/05/2018	30/05/2018	05/06/2018	
17/EM/0315	220334	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients with Rheumatoid Arthritis Interstitial Lung Disease	08/12/2017	25/04/2018	03/11/2017	14/06/2018	15/06/2018	19/06/2018	25/07/2018	Neither
18/LO/0621	184072	Safety of abatacept in Rheumatoid Arthritis associated Interstitial Lung Disease: A feasibility study	30/11/2016	08/06/2018		22/06/2018	25/06/2018	01/07/2018		
17/SS/0052	196827	Early Valve Replacement guided by Biomarkers of Left Ventricular Decomensation in Asymptomatic Patients with Severe Aortic Stenosis	17/10/2018	15/01/2018	17/06/2018	22/02/2018	02/03/2018	02/03/2018		
17/SW/0250	222991	Conventional versus Minimally Invasive extra-corporeal circulation in patients undergoing Cardiac Surgery: a randomised controlled trial (COMICS)	18/07/2018	18/07/2018	29/11/2017					

18/NE/0266	241641	A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-659 Combination Therapy in Subjects With Cystic Fibrosis Who Are Homozygous or Heterozygous for the F508del Mutation	20/07/2018	21/07/2018	21/08/2018	20/08/2018	23/08/2018	23/08/2018	24/08/2018	
18/EE/0162	229599	Use of right ventricular conductance catheter guidance to optimise balloon pulmonary angioplasty as a non surgical treatment of chronic thromboembolic pulmonary hypertension.	19/08/2018	19/08/2018						
17/EE/0472	235110	BAROSTIM NEO ? - Baroreflex Activation Therapy? for Heart Failure	02/10/2017	03/10/2017	09/01/2018	06/08/2018	10/09/2018			
18/NI/0060	242168	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to Evaluate Efficacy and Safety of Lenabasum in Cystic Fibrosis	09/08/2018	07/09/2018	29/06/2018	17/09/2018	19/09/2018	19/09/2018		
18/NE/0104	241180	A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-659 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)	11/01/2018	02/05/2018		30/04/2018	08/05/2018		08/06/2018	
18/LO/1258	248312	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BG00011 in Patients With Idiopathic Pulmonary Fibrosis	06/08/2018	13/08/2018						
17/EM/0315	239530	A subject-, investigator-, and sponsor-blinded, randomized, placebo-controlled, multicenter study to investigate efficacy, safety, and tolerability of VAY736 in patients with idiopathic pulmonary fibrosis	12/03/2018	25/06/2018	22/06/2018					