

Performance in Initiating HRA Approved Studies - Q4 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:
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
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	17/12/2018	Neither
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	Neither
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	13/12/2018	Neither
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	13/11/2018	14/11/2018			Neither
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						
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	02/10/2018	
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	09/05/2018	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		12/12/2018	18/12/2018			Neither
18/WM/0077	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					

17/LO/1170	219279	A multi-center, double-blind, placebo-controlled Phase 2b study to evaluate the efficacy and safety of macitentan in subjects with heart failure with preserved ejection fraction and pulmonary vascular disease	29/08/2018	06/09/2018	02/08/2017					
17/NW/0012	168647	Low dose interleukin-2 in patients with stable ischaemic heart disease and acute coronary syndromes (LILACS)	29/09/2017	20/07/2018		18/09/2018	28/09/2018	28/09/2018		
17/SC/0631	218932	Optimising wearable technology for the remote diagnosis and monitoring of REM sleep behaviour disorder	21/06/2018	24/06/2018	30/01/2018					
18/EE/0201	246757	A Multi-center, Prospective, Randomized Crossover Study with the NightBalance Lunoa SPT Compared to Positive Airway Pressure (PAP) for the Treatment of Positional Obstructive Sleep Apnea (POSA)	18/04/2018	03/05/2018		25/11/2018	30/11/2018			Sponsor
18/NW/0074	236316	Cryoballoon Pulmonary Vein Isolation as First line treatment for Typical Atrial Flutter (CRAFT)	11/10/2018	01/11/2018	28/02/2018					
18/LO/1193	242628	Optical Coherence Tomography (OCT) Guided Coronary Stent IMplantation Compared to Angiography: a Multicenter Randomized Trial in PCI	20/03/2018	26/10/2018						
18/YH/0330	236317	A Phase 2, Randomised, Double-Blind, Placebo-Controlled, Multicentre, Prospective Study to Assess Efficacy of Riociguat in Patients With Operable CTEPH Prior to Pulmonary Endarterectomy With High Preoperative Pulmonary Vascular Resistance						07/01/2019		Neither
18/LO/1848	247009	Developing a non-contact sleep apnoea detector, suitable for home studies - The Safescan study	17/10/2017 20/04/2018	01/08/2018 21/12/2018	04/12/2018 30/11/2018	19/12/2018 09/01/2019	21/12/2018 09/01/2019	09/01/2019	09/01/2019	