

Performance in Initiating HRA Approved Studies - Q1 2019/20

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/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	01/01/2019	21/01/2019	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		13/02/2019	13/02/2019	13/02/2019		
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/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	18/09/2018	12/12/2018	18/12/2018	15/05/2019	29/05/2019	Neither
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	05/12/2018	10/12/2018	31/01/2019		
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	30/01/2019	01/02/2019	11/02/2019	13/03/2019	
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	25/10/2018	09/04/2019	11/04/2019			Sponsor
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	17/10/2017	01/08/2018	04/12/2018	19/12/2018	21/12/2018	07/01/2019	23/05/2019	Neither
18/LO/1848	247009	Developing a non-contact sleep apnoea detector, suitable for home studies - The Safescan study	20/04/2018	21/12/2018	30/11/2018	09/01/2019	09/01/2019	09/01/2019	09/01/2019	
14/NE/1180	145170	Effectiveness of the GRACE risk score on the management and outcome of patients hospitalised with non-ST elevation acute coronary syndrome.	11/01/2018	31/01/2019	21/03/2017	17/05/2019	08/05/2019	06/06/2019	10/06/2019	Sponsor
19/NW/0001	253853	IDL-2965 ? A Phase I, Randomized, Double-blind, Placebo-controlled, Single and Multiple Oral Dose, Safety, Tolerability, and Pharmacokinetic Study in Healthy Subjects and Subjects with Idiopathic Pulmonary Fibrosis	26/02/2019	26/02/2019						Neither
19/SC/0034	254823	A Phase 3, randomized, double-blind, parallel-group, placebo controlled multicenter study to evaluate the efficacy and safety of two doses of GLPG1690 in addition to local standard of care for minimum 52 weeks in subjects with idiopathic pulmonary fibrosis.	22/10/2018	22/10/2018						
19/EE/0104	255651	A randomised controlled trial of high-flow nasal oxygen (HFNO) vs. standard oxygen therapy in patients undergoing transfemoral transcatheter aortic valve implantation (TAVI) under conscious sedation.	22/11/2018	15/01/2019		18/04/2019	08/05/2019	08/05/2019	05/06/2019	
18/EE/0091	256412	An open-label, pilot study to assess safety, tolerability, pharmacokinetics and effects of inhaled PC945 in the pre-emptive treatment of Aspergillus fumigatus colonisation in lung transplant recipients	09/05/2018	18/10/2018						Neither

19/EM/0101	260487	Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Efficacy and Safety Study with Inhaled RVT-1601 for the Treatment of Persistent Cough in Patients with Idiopathic Pulmonary Fibrosis (IPF): SCENIC Trial	14/02/2019	13/03/2019	17/06/2019					
19/NI/0110	260538	EluNIR Ridaforolimus Eluting Coronary Stent System in patients at high bleeding risk (HBR)? EluNIR HBR study	22/05/2019	12/06/2019						