Q3 2019/20 Performance in Delivering Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial
14/NE/1050	155345	Multicentre, open-label, active-controlled, randomized study to evaluate the efficacy and safety of an age and body weight-adjusted rivaroxaban regimen in children with acute venous thromboembolism	Number Agreed	1	1	Date Agreed	01/03/2019	1	30/01/2019	1	Recruitment Finished
14/LO/2129	163516	VIdeo assisted thoracoscopic lobectomy versus conventional Open LobEcTomy for lung cancer, a multi-centre randomised controlled trial with an internal pilot	Number Agreed	60	60	Date Agreed	23/04/2019	201	12/02/2019	201	Recruitment Finished
18/WS/0165	247486	Clinical evaluation of higher density mapping in complex arrhythmias with the CARTO® OCTARAY™ HD Mapping Catheter	Number Agreed	2	2	Date Agreed	31/01/2019	4	31/01/2019	4	Recruitment Finished
18/LO/0503	239042	Safety, tolerability, and pharmacokinetics of multiple rising oral doses of BI 1015550 in patients with idiopathic pulmonary fibrosis (IPF) on no background anti-fibrotic (Part 1) and safety and tolerability of BI 1015550 on top of Nintedanib and Pir	Number Agreed	1	1	Date Agreed	18/09/2019	1	23/07/2019	1	Recruitment Finished
18/WA/0210	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	Number Agreed	1	1	Date Agreed	31/01/2019	6	31/01/2019	6	Recruitment Finished
12/SS/0037	87162	The Effects of Inorganic Nitrite on cardiac and skeletal muscle: Physiology, Pharmacology, and Therapeutic Potential in patients with Chronic Heart Failure	Number Agreed	16	16	Date Agreed	28/06/2019	18	28/06/2019	18	Recruitment Finished
17/LO/1088	228921	A 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	Number Agreed	3	3	Date Agreed	24/11/2018	5	24/08/2019	5	Recruitment Finished

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial
16/LO/0286	188120	The CELEB trial: Comparative Effectiveness of Lung volume reduction surgery for Emphysema and Bronchoscopic lung volume reduction with valve placement	Range Agreed	30	40	Date Agreed	28/08/2019	30	28/08/2019	30	Recruitment Finished
19/NW/0026	249432	A Phase 2, Randomized, Double-blind, Controlled Study to Evaluate the Safety and Efficacy of VX-121 Combination Therapy in Subjects Aged 18 Years and Older With Cystic Fibrosis	Number Agreed	1	1	Date Agreed	31/08/2019	3	05/09/2019	3	Recruitment Finished
18/LO/0295	238305	An Open-label, non-controlled, multicentre, Pilot clinical Trial of Inhaled Molgramostim in subjects with Antibiotic-resistant non-tuberculosis mycobacterial (NTM) infection - OPTIMA	Number Agreed	1	1	Date Agreed	25/10/2019	2	25/10/2019	2	Recruitment Finished
16/WS/0223	213242	A prospective, randomized, international, multicenter, double-arm, controlled, open-label study of Riociguat in patients with pulmonary arterial hypertension (PAH) who are on a stable dose of phosphodiesterase-5 inhibitors (PDE-5i) with or without en	Number Agreed	2	2	Date Agreed	31/10/2019	1	31/10/2019	1	Recruitment Finished
18/EE/0092	235968	A randomised, double-blind (sponsor unblind), placebo-controlled, multi-centred phase IIa study to evaluate the safety and efficacy of 13 weeks of once daily oral dosing of the selective androgen receptor modulator (SARM) GSK2881078 in older men and	Number Agreed	6	6	Date Agreed	31/07/2019	8	06/12/2019	8	Recruitment Finished
18/NI/0178	253727	A Phase 1/2, Drug-Drug Interaction Study of FDL169 and FDL176 in Healthy Subjects and in Cystic Fibrosis Subjects Homozygous for the F508del-CFTR Mutation	Number Agreed	2	2	Date Agreed	30/12/2019	0	10/12/2019	0	Withdrawn By Sponsor

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial
18/LO/0967	230460	Clinical Investigation of the VytronUS Ablation System for Treatment	Number Agreed	15	15	Date Agreed	31/12/2019	6	06/09/2019	6	Withdrawn By Sponsor

Q3 2019/20 Performance in Initiating Clinical Research

MREC Number	IRAS Number	Project Full title	First site patient recruited (org)	Project site date site invited	Project site date site selected	HRA Approval Date	Project site date site confirmed by sponsor	Project site date site confirmed	Project site date open to recruitment	Reasons for delay correspond to:
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.	18/07/2019	13/12/2018	02/01/2019	29/04/2019	27/05/2019	27/05/2019	31/05/2019	Sponsor
18/SC/0392	244109	Phase 2 Multicenter, Double-Blind, Placebo-Controlled, Efficacy, Safety, and Pharmacokinetic Study of 2 Doses of CXA-10 on Stable Background Therapy in Subjects with Pulmonary Arterial Hypertension (PAH)		11/01/2019	11/01/2019	19/10/2018	16/04/2019	17/04/2019	24/04/2019	Sponsor
18/LO/1706	252196	A Phase 2, proof-of-concept, multicentre, double-blind, randomised, dose-ascending, sequential group, placebo-controlled study to evaluate the mechanistic effect, safety, and tolerability of 12 weeks twice daily oral administration of alvelestat (MPH966) in participants with alpha-1 (PiZZ or null genotype/phenotype) antitrypsin deficiency.	25/09/2019	11/06/2018	20/01/2019	30/11/2018	26/02/2019	28/02/2019	28/02/2019	NHS Provider
18/EM/0166	246673	A double-blind, placebo-controlled study to assess the effects of inhaled PC945 in the treatment of culture-positive Aspergillus fumigatus infection in subjects with moderate to severe asthma	06/11/2019	01/01/2019	12/02/2019	21/08/2018	12/06/2019	13/06/2019	02/08/2019	Sponsor
18/EE/0222	233921	A randomised controlled trial of very early versus delayed angiography +/-intervention on outcomes in patients with non ST-elevation myocardial infarction		25/07/2018	26/02/2019	12/09/2018	26/02/2019	04/04/2019	04/04/2019	NHS Provider
18/LO/0967	230460	Clinical Investigation of the VytronUS Ablation System for Treatment of Symptomatic Drug-refractory Paroxysmal Atrial Fibrillation (VITAL)	08/05/2019	08/08/2017	26/02/2019	01/11/2018	18/04/2019	01/05/2019	01/05/2019	NHS Provider
18/ES/0147	252929	A Trial of the Safety, Tolerability and Efficacy of 2 doses of Cayston (Aztreonam Lysine) compared to placebo in participants with bronchiectasis	30/10/2019	07/03/2019	22/03/2019	21/03/2019	05/06/2019	04/06/2019	24/09/2019	Sponsor
19/LO/0308	257755	VIVOTM non-invasive mapping of ventricular arrhythmia	03/07/2019	01/03/2019	05/05/2019	21/04/2019	15/05/2019	31/05/2019	31/05/2019	
19/LO/0784	264744	A Pilot Study to exPlOre the exisTence and impact of FRAILTY in patients over the age of 70 undergoing cardiac interventions	20/08/2019	01/04/2019	12/07/2019	09/07/2019	24/07/2019	09/08/2019	09/08/2019	
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		13/03/2019	24/07/2019	17/06/2019	27/08/2019	28/08/2019	28/08/2019	NHS Provider
19/SC/0050	259683	Pressure-controlled Intermittent Coronary Sinus Occlusion (PiCSO) in Acute Myocardial Infarction (PiCSO-AMI-I)	23/09/2019	01/04/2019	02/08/2019	16/07/2019	14/08/2019	11/09/2019	16/09/2019	
19/NW/0181	260431	A Randomized, Double-blind, Placebo-Controlled, Crossover, Dose Escalation Study of BLU-5937 in Subjects with Unexplained or Refractory Chronic Cough	18/09/2019	15/04/2019	05/08/2019	14/06/2019	01/08/2019	13/08/2019	13/08/2019	

MREC Number	IRAS Number	Project Full title	First site patient recruited (org)	Project site date site invited	Project site date site selected	HRA Approval Date	Project site date site confirmed by sponsor	Project site date site confirmed	Project site date open to recruitment	Reasons for delay correspond to:
19/EE/0185	260536	FIRST-line support for Assistance in Breathing in Children (FIRST-ABC): A master protocol of two randomised trials to evaluate the non-inferiority of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) for non-invasive respiratory support in paediatric critical care	03/09/2019	04/06/2019	23/08/2019	26/07/2019		23/08/2019	30/08/2019	
18/LO/2006	250980	A Phase 2, Multicenter, Blinded, Sham Procedure-Controlled Trial of Renal Denervation by the Peregrine System Kit, in Subjects with Hypertension, in the Absence of Antihypertensive Medications		28/11/2018	05/09/2019	14/02/2019	24/09/2019	04/10/2019	04/10/2019	NHS Provider
19/YH/0222	252494	Positional Therapy for Obstructive Sleep Apnoea: a Randomised Controlled Trial to assess the effect on Health and Wellbeing in Older and Younger People.	30/10/2019	17/06/2019	08/10/2019	24/07/2019	08/10/2019	08/10/2019	08/10/2019	
19/EM/0267	262581	SPACE FOR COPD© delivered as a maintenance programme on Pulmonary Rehabilitation discharge: a randomised controlled trial evaluating the long-term effects on exercise tolerance and mental wellbeing	15/11/2019	19/08/2019	16/10/2019	10/10/2019	10/10/2019	29/10/2019	29/10/2019	
19/LO/1318	268820	A study to evaluate the effectiveness and safety of VX 445/Tezacaftor/Ivacaftor in people with Cystic Fibrosis who are heterozygous for the F508del mutation and a gating or residual function mutation		19/06/2019	30/10/2019	29/10/2019	13/11/2019	09/12/2019	09/12/2019	
19/NW/0506	269510	A Phase 3 study of the efficacy, safety and the body's effects on a triple combination therapy of VX-445, tezacaftor and ivacaftor in children with cystic fibrosis aged 6 to 11		12/02/2019	04/11/2019	04/11/2019	04/12/2019	05/12/2019	05/12/2019	
19/NW/0540	269907	A Phase 3 study of the long-term safety of a triple combination therapy of VX-445, tezacaftor and ivacaftor in people with cystic fibrosis aged 12 and older		28/08/2019	12/11/2019	06/11/2019	04/12/2019	19/12/2019	19/12/2019	
18/LO/0020	226737	A Phase IIb, Randomised, Double-Blinded, Placebo-Controlled Study of the Efficacy and Safety of Intramyocardial Injection of Allogeneic Human Immunomodulatory Progenitor (iMP) cells in Patients Undergoing Coronary Artery Bypass Graft (CABG) Surgery. Protocol: CLX003-IMP-2-170121		20/11/2017	28/11/2019	18/03/2018	03/12/2019	10/12/2019	10/12/2019	