

NIHR 70 day Performance in Delivery Report Q3 2018-19

	REC Number	IRAS Number	Name of Trial	Target Number of Patients Agreed	Min Number of Patients Agreed	Max Number of Patients Agreed	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 the Trial Closed to Recruitment	Total Number of Study Participants Recruited	Reason for Closure of Trial
1	16/LO/1589	200691	A Phase 3, prospective, randomized, double-blind, multi-center study of the efficacy and safety of lanreotide Autogel/Depot 120 mg plus BSC vs. placebo plus BSC for tumor control in subjects with well differentiated, metastatic and/or unresectable, t	Range Agreed	2	10	Date Agreed	30/06/2018	2	11/07/2018	2	Withdrawn By Sponsor

2	16/LO/0 803	204170	Study of MiniMed? 640G Insulin Pump with SmartGuard? in prevention of Low Glucose Events in adults with Type 1 diabetes	Range Agreed	5	20	Date Agreed	30/03/2018	16	30/03/2018	16	Recruitment Finished
3	16/LO/0 675	147355	A PHASE 2, INTERNATIONAL, MULTICENTER, RANDOMIZED, OPENLABEL, PARALLEL GROUP STUDY TO EVALUATE THE EFFICACY AND SAFETY OF CC-486 (ORAL AZACITIDINE) ALONE AND IN COMBINATION WITH DURVALUMAB (MEDI4736) IN SUBJECTS WITH MYELODYSPLASTIC SYNDROMES WHO FAI	Range Agreed	1	3	Date Agreed	31/08/2018	0	29/09/2018	0	Recruitment Finished

4	17/EM/0055	222279	A Randomized, Double-Blind, Placebo-controlled, Parallel Group Study of Patiromer for the Enablement of Spironolactone Use for Blood Pressure Control in Patients with Resistant Hypertension and Chronic Kidney Disease: Evaluation of Safety and Efficac	Range Agreed	5	10	Date Agreed	31/03/2018	1	20/08/2018	1	Recruitment Finished
5	17/NE/0078	221507	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Evaluate the Efficacy and Safety of Elafibranor at doses of 80 mg and 120mg After 12 Weeks of Treatment in Patients With Primary Biliary Cholangitis and Inadequate Response	Range Agreed	2	5	Date Agreed	30/04/2019	4	06/07/2018	4	Recruitment Finished

6	13/WS/0034	120451	A non-interventional long-term safety study of ruxolitinib in myelofibrosis	Range Agreed	5	10	Date Agreed	29/12/2017	11	31/03/2018	11	Recruitment Finished
7	16/LO/1679	212545	A Microneurography Study to Assess Test-Retest Variability in Healthy Volunteers and in Patients with Diabetic Peripheral Neuropathy	Range Agreed	5	16	Date Agreed	28/02/2017	16	14/05/2018	18	Recruitment Finished
8	17/LO/0102	215259	A Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 Dose Regimens (Intravenous/Subcutaneous and Subcutaneous) of TEV-48125 versus	Range Agreed	2	6	Date Agreed	31/03/2018	1	06/04/2018	1	Withdrawn By Sponsor

			Placebo for the Prevention of Chronic									
9	17/WS/0071	224151	An International, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effect of Dapagliflozin on the Incidence of the composite of =40% sustained reduction in eGFR, entering ESRD, CV or Renal Death in patients with Albuminu	Range Agreed	8	10	Date Agreed	27/11/2020	11	06/07/2018	11	Recruitment Finished

10	17/ES/0 149	234601	Acceptability study of a new paediatric formulation of Orphacol? (cholic acid) in paediatric patients treated for inborn errors in primary bile acid synthesis due to 3?-Hydroxy-?5-C27-steroid oxidoreductase deficiency or ?4-3-Oxosteroid-5?-reductase	Number Agreed	1	1	Date Agreed	31/01/2018	1	10/01/2018	1	Recruitment Finished
11	17/SC/0 413	233152	Phase 1, First-in-human, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single and Multiple Ascending Oral Doses of XEN1101 and Single Dose Preliminary Open-label Pharmacodynamic Assessment in Hea	Number Agreed	12	12	Date Agreed	31/05/2018	20	21/05/2018	20	Recruitment Finished

12	16/LO/1 482	207680	An Open-label, Long-term, Safety Study of LAAsmiDitan (100 mg and 200 mg) in the Acute Treatment Of MigRaine (GLADIATOR)	Number Agreed	1	1	Date Agreed	30/06/2018	1	27/07/2018	1	Recruitment Finished
13	13/EE/0 326	137999	Revacept, an inhibitor of platelet adhesion in symptomatic carotid stenosis: a phase II, multicentre; randomised, dose-finding, double-blind and placebo-controlled superiority study with parallel groups	Number Agreed	12	12	Date Agreed	31/12/2018	10	31/05/2018	10	Recruitment Finished
14	16/LO/0 416	194523	A Phase 2a, Single-Blind, Randomized, Placebo-Controlled Study Evaluating the Safety, Anti-Viral Activity, and Pharmacokinetics of ARB-001467 in Non-Cirrhotic, HBeAg-Negative and Positive	Number Agreed	4	4	Date Agreed	20/01/2018	3	20/01/2018	3	Withdrawn By Sponsor

			Subjects with Chronic HBV Infection Receiving Nucleos(t)ide An									
15	16/LO/0805	200094	A Phase II Study of Pembrolizumab (MK-3475) as Monotherapy in Subjects with Previously Systemically Treated Advanced Hepatocellular Carcinoma	Range Agreed	2	4	Date Agreed	06/03/2016	3	09/02/2018	3	Recruitment Finished
16	17/LO/0012	213544	Clinical safety & efficacy of a new infant formula with specific medical purpose (FSMP) containing 2 human milk oligosaccharides (HMOs).	Range Agreed	2	5	Date Agreed	28/02/2018	0	28/02/2018	0	Withdrawn By Sponsor

17	17/LO/0 096	220205	A Phase 3b, 12-month, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of BIIB019, Daclizumab, in Subjects with Relapsing-Remitting Multiple Sclerosis (RRMS) Switching from Natalizumab (SUSTAIN)	Number Agreed	6	6	Date Agreed	31/03/2018	0	02/03/2018	0	Withdrawn By Sponsor
18	16/WM/ 0395	210507	Phase 3, randomised, open-label, active-controlled, parallel-group, multi-centre study to evaluate the safety and efficacy of GSK1278863 compared to recombinant human erythropoietin (rhEPO) in dialysis subjects with anemia associated with chronic kid	Range Agreed	4	6	Date Agreed	30/04/2018	4	07/06/2018	4	Recruitment Finished

19	17/LO/0 089	219229	A Phase 2, Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of Sofosbuvir/Velpatasvir for 12 Weeks in Subjects with Chronic HCV Infection Who are on Dialysis for End Stage Renal Disease	Range Agreed	1	3	Date Agreed	31/01/2018	1	31/01/2018	1	Recruitment Finished
20	16/SC/0 677	217105	A Phase 2 Randomised Double Blind Placebo controlled study evaluating the Safety, Tolerability and Efficacy of GS-9674 in Subjects with Primary Biliary Cholangitis without Cirrhosis	Number Agreed	3	3	Date Agreed	30/11/2017	3	16/03/2018	4	Recruitment Finished

21	17/LO/0 304	222475	A Double-Blind, Randomised, Placebo-Controlled, Parallel-Group, Phase 2, Dose Ranging Trial to Evaluate the Efficacy, Safety, and Tolerability of Oral Litoxetine 10mg,20mg and 40mg Twice Daily (BID) versus Placebo in Women with Mixed Urinary Incontin	Number Agreed	2	2	Date Agreed	04/06/2018	0	30/05/2018	0	Recruitment Finished
22	17/LO/0 783	225826	A Multicenter, Parallel-Group, Randomized, Cross-Over Trial to Compare the Efficacy of LUMINITY? and SonoVue? in the Evaluation of Left Ventricular Endocardial Border Definition	Number Agreed	15	15	Date Agreed	31/05/2018	29	22/03/2018	29	Recruitment Finished

23	17/LO/0 849	222165	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH)	Range Agreed	2	3	Date Agreed	19/08/2018	1	31/01/2018	1	Recruitment Finished
24	17/LO/0 848	222163	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis	Range Agreed	2	3	Date Agreed	19/08/2018	2	13/04/2018	2	Recruitment Finished

25	17/LO/1 750	232325	An open label, single-arm, Phase I/II study of vandetanib-eluting radiopaque embolic beads (BTG-002814) in patients with hepatocellular carcinoma (HCC) without curative options.	Range Agreed	3	6	Date Agreed	31/01/2019	0	24/05/2018	0	Withdrawn By Sponsor
26	17/SC/0 542	233315	A Double-blind, Placebo-controlled Crossover Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Effects on Transcranial Magnetic Stimulation of Oral Administration of XEN1101 in Healthy Male Subjects	Number Agreed	15	15	Date Agreed	31/05/2018	20	31/05/2018	20	Recruitment Finished

27	16/LO/2 091	213987	Non-interventional Study to Investigate the Short and Longterm Real-life Safety, Effectiveness, and Adherence of Velphoro? in Patients with hyperphosphataemia Undergoing Haemodialysis or Peritoneal Dialysis	Range Agreed	1	10	Date Agreed	30/04/2018	7	23/03/2018	7	Recruitment Finished
28	15/SS/0 171	177936	A Multi-national, Multi-center, Prospective, Randomized, Double Blinded, Placebo-controlled Trial to Evaluate the Efficacy of HyperBox Cyclical Topical Wound Oxygen Therapy (TWO2) in the Treatment of Chronic Diabetic Foot Ulcers	Number Agreed	10	10	Date Agreed	31/12/2017	15	13/02/2018	15	Recruitment Finished

29	17/LO/0 960	223431	A Phase 1b/2a, Dose-Ranging Study of the Safety, Tolerability, Pharmacokinetics, and Initial Efficacy of ABI-H0731 in Patients with Chronic Hepatitis B	Number Agreed	5	5	Date Agreed	30/06/2018	8	23/04/2018	8	Recruitment Finished
30	17/SC/0 216	223931	A Phase 1/2 Proof-of-Concept Study of the Combination of Acalabrutinib and Vistusertib in Subjects with Relapsed/Refractory B-cell Malignancies	Range Agreed	2	4	Date Agreed	30/04/2019	0	24/05/2018	0	Withdrawn By Sponsor
31	18/NE/0 201	244419	A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-445 Combination Therapy in Subjects With Cystic Fibrosis Who Are Homozygous for the F508del Mutation (F/F)	Range Agreed	1	3	Date Agreed	01/10/2018	2	07/10/2018	3	Withdrawn By Sponsor

32	15/SC/0448	183584	A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes	Number Agreed	6	6	Date Agreed	12/10/2018	7	28/09/2018	7	Recruitment Finished
33	15/SW/0194	185459	A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with typ	Number Agreed	6	6	Date Agreed	22/10/2018	7	08/05/2018	15	Recruitment Finished

34	18/NE/0 200	244356	A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-445 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)	Range Agreed	1	3	Date Agreed	31/10/2018	1	07/10/2018	2	Withdrawn By Sponsor
35	17/LO/1 673	233083	A Phase 2, Open-label Study to Evaluate the Safety and Efficacy of Switching to Tenofovir Alafenamide (TAF) from Tenofovir Disoproxil Fumarate (TDF) and/or Other Oral Antiviral Treatment (OAV) in Virologically Suppressed Chronic Hepatitis B Subjects	Number Agreed	3	3	Date Agreed	28/11/2018	1	17/10/2018	1	Recruitment Finished

36	18/EM/0027	235145	A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with neovascular age-related macular degeneration (wet AMD)	Range Agreed	1	5	Date Agreed	30/11/2018	1	30/10/2018	1	Recruitment Finished
37	14/LO/1459	161800	A Phase 3, Multicenter, Randomized, Double-blind Study to Determine the Safety and Efficacy of MMX Mesalamine/Mesalazine in Pediatric Subjects with Mild to Moderate Ulcerative Colitis, in both Acute and Maintenance Phases	Range Agreed	1	6	Date Agreed	30/11/2018	5	20/09/2018	5	Recruitment Finished

38	16/LO/1 709	212830	Investigation of efficacy and safety of three dose levels of subcutaneous semaglutide once daily versus placebo in subjects with non-alcoholic steatohepatitis	Number Agreed	2	2	Date Agreed	31/12/2018	2	19/07/2018	2	Recruitment Finished
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