

UHSM - PERFORMANCE IN DELIVERING Quarter 4 2015/2016

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	Reason For Closure Of Trial	Comments
13/EM/0230	131237	A Phase II Randomised, Double-Blind, Placebo-Controlled, Multicenter study of VS6063 in subjects with Malignant Pleural Mesothelioma.	Number Agreed	10	10	Not Available / Not Agreed		32	28/09/2015	Withdrawn By Sponsor	The Study was closed early by the sponsor following interim analysis on the basis of futility. We recruited over our target as it was competitive recruitment.
14/SW/0091	150889	Randomized, DoubleBlind, Multicenter, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous Non Small Cell Lung Cancer.(NSCLC)	Number Agreed	2	2	Date Agreed	01/03/2015	3	12/02/2016	Recruitment Finished	The Date agreed to recruit target number of patients extended. Due to our high screening rate and the study being difficult to recruit to the CLRN negotiated a reduction in our target from 4 to 2 so we did make target by study closure.
14/LO/0818	152364	A Randomised Open-label Phase III Trial of MK-3475 versus Platinum based Chemotherapy in 1L Subjects with PD-L1 Strong Metastatic Non-Small Cell Lung Cancer.	Number Agreed	1	1	Date Agreed	01/11/2015	1	21/09/2015	Recruitment Finished	This was a Niche study, we had much higher screen fail in PDL1 strong status than national average, no fault or reason. Study nationally showed geographical recruitment trends. CLRN renegotiated our target from 4 to 1 as we could demonstrate how may pts we screened but unfortunately came back with a higher than average PDL1 negative rate which was out of our control.
14/LO/0324	146711	A multi-centre, randomised, double-blind, placebo-controlled study to Evaluate the Safety and Efficacy of Pulmaquin? in the Management of Chronic Lung Infections with Pseudomonas Aeruginosa in Subjects with Non-Cystic Fibrosis Bronchiectasis, including 28	Number Agreed	3	3	Date Agreed	19/08/2015	1	19/08/2015	Recruitment Finished	This study did not meet target due to the High failure rate and short recruitment period which resulted in participants who were eligible not having time for re-screening.
14/NW/1337	163452	A Multicentre, Randomized, Parallel Group, Phase 3 Safety Extension Study to Evaluate the Safety and Tolerability of Benralizumab (MEDI-563) in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Longacting ?2 agonist. (BORA)	Number Agreed	1	1	Date Agreed	02/07/2015	1	02/07/2015	Recruitment Finished	
13/LO/0219	120842	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of GS-6624 in Subjects with Idiopathic Pulmonary Fibrosis. (RAINIER)	Number Agreed	3	3	Date Agreed	21/04/2015	1	21/04/2015	Recruitment Finished	This study did not meet target due the fact it had a high screen failure rate and it was competitive recruitment.
14/NW/0211	147648	A double-blind, Randomised, placebo-controlled, crossover study to assess the efficacy of XEN-D0501, a TRPV1 antagonist, in reducing the frequency of cough in patients with chronic idiopathic cough.	Number Agreed	10	10	Not Available / Not Agreed		8	12/05/2015	Withdrawn By Sponsor	This study did not meet target due the fact the overall target for the study was revised by the sponsor to 18 as this target was reached between the study sites and recruitment was stopped early.
14/NW/1350	163952	Evaluation of orpepitan open-label clinical study in chronic treatment-refractory cough. VOLCANO-1	Number Agreed	12	12	Date Agreed	30/08/2015	13	30/08/2015	Recruitment Finished	We recruited one more than the target for this study because one patients device failed and did not collect data so another was enrolled to ensure there was data from 12 patients.
14/EM/1141	159136	Approach - A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of ISIS 304801 Administered Subcutaneously to Patients with Familial Chylomicronemia Syndrome (FCS)	Number Agreed	1	1	Date Agreed	01/12/2015	1	01/12/2015	Recruitment Finished	
15/EE/0003	167949	Compass CS16 - A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of ISIS 304801 Administered Subcutaneously to Patients with Hypertriglyceridemia.	Number Agreed	3	3	Date Agreed	15/03/2016	2	15/03/2016	Recruitment Finished	This study did not meet target due the fact eligible patients seen chose not to participate in the study
13/NW/0283	125941	GLOBAL LEADERS: Comparative effectiveness of 1 month of ticagrelor plus aspirin followed by ticagrelor monotherapy versus a current-day intensive dual anti-platelet therapy in all-comers patients undergoing percutaneous coronary intervention with bivalirud	Range Agreed	50	150	Date Agreed	27/10/2015	88	27/10/2015	Recruitment Finished	The target for this study was reduced by the CLRN to 50 as the study was very difficult to recruit to, we had a lab out of order and in repair, and we are a tertiary centre taking ACS referrals for primary PCI, therefore despite many patients consenting many failed at the angiogram stage. Some of the patients seen who were eligible chose not to participate in the study.
12/EE/0371	104294	A multi-centre, randomised, active-controlled efficacy and safety study comparing extended duration Betrixaban with standard of care Enoxaparin? for the prevention of venous thromboembolism in acute medically ill patients.	Number Agreed	33	33	Date Agreed	17/10/2015	17	17/10/2015	Recruitment Finished	This study did not meet target due the fact it was a difficult patient group to recruit to. All sites struggled to recruit. UHSM were the highest recruiter. CLRN reduced the target after it was adopted part way through the trial.
15/LO/0018	167680	A Randomized double blind placebo controlled multiple dose study of subcutaneous ACZ885 for the treatment of abdominal aortic aneurysm.	Range Agreed	15	20	Not Available / Not Agreed		3	23/06/2015	Withdrawn By Sponsor	This study did not meet target due the fact the sponsor closed the study early.
13/NE/0006	120694	A pilot Randomised controlled trial of the use of ReCell autologous cell harvesting device for venous Leg Ulcers	Number Agreed	10	10	Date Agreed	17/08/2015	3	17/08/2015	Recruitment Finished	This study did not meet target due the fact it had a very short recruitment period so limited number of eligible patients. There were points during the recruitment period when staffing was limited.
14/LO/0521	146148	A prospective, randomized, open label, two arm Phase III study to evaluate treatment free remission (TFR) rate in patients with Philadelphia positive CML after two different durations of consolidation treatment with Nilotinib 300mg BID (ENEST-PATH)	Range Agreed	0	2	Date Agreed	31/03/2015	0	31/03/2015	Recruitment Finished	This study did not recruit any patients as the eligibility criteria was very strict, there was 2 potentially eligible patients but they declined to take part because it would changing treatment, extra tests etc
13/SS/0044	124637	Efficacy and safety of lidocaine 5% medicated plaster in localisedchronic post-operative neuropathic pain	Number Agreed	6	6	Not Available / Not Agreed		4	30/04/2016	Withdrawn By Sponsor	This study did not meet target due the fact we had no PI for over 12 months. The sponsor wanted to hold off on the study until the PI returned.
14/LO/1513	158109	A randomized, Open-Label, Phase 4 Study Evaluating the Renal Effect of 'elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir DF or Efavirenz/Emtricitabine/Te	Number Agreed	3	3	Not Available / Not Agreed		1	31/12/2015	Withdrawn By Sponsor	This study did not meet target due the fact recruitment was closed early by the sponsor as overall recruitment to the study had been reached.
13/YH/0282	133239	Open-label, Phase IIb study to evaluate the efficacy and safety of subcutaneous (SC) Tocilizumab monotherapy or combination therapy with methotrexate (MTX) or other non-biologic disease modifying anti-rheumatic drugs (DMARDs) in patients with severe Rheum	Number Agreed	5	5	Not Available / Not Agreed		2	31/07/2015	Withdrawn By Sponsor	This study did not meet target due the fact recruitment was closed early by the sponsor, and we had 2 screen fails.