UHSM CTP DOH Q2 2016 2017 Performance in Delivering Report

Id	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	Comments
13109	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	3	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 negotioated a reduction in our target from 4 to 2 so we did make target by study closure.
13114	14/EM/1141	159136	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of ISIS 304801 Administered Subcutaneously to Patients with Familial Chylomicronemia Syndrome (FCS) (Approach)	Number Agreed	1	1	Date Agreed	01/12/2015	2	01/12/2015	2	Recruitment Finished	
13115	15/EE/0003	167949	CS16 - A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of ISIS 304801 Administered Subcutaneously to Patients with Hypertriglyceridemia. (Compass)	Number Agreed	3	3	Date Agreed	15/03/2016	2	15/03/2016	2	Recruitment Finished	This study did not meet target due the fact eligble patients seen chose not to participate in the study
13116	13/NW/0283	125941	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 bivalirudin and Bio	Range Agreed	50	150	Date Agreed	27/10/2015	88	27/10/2015	88	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.
13117	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	17	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.
13120	13/SS/0044	124637	Efficacy and safety of lidocaine 5% medicated plaster in localisedchronic post-operative neuropathic pain	Number Agreed	6	6	Date Agreed	30/04/2016	4	30/04/2016	4	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.
13121	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/Emtricitab	Number Agreed	3	3	Date Agreed	31/12/2015	1	31/12/2015	1	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.
13123	13/EM/0294	180267	A Phase 3 Randomized, Placebo-Controlled, Blinded Study to Investigate the Safety and Efficacy of a Topical Gentamicin-Collagen Sponge in Combination with Systemic Antibiotic Therapy in Diabetic Patients with an Infected Foot Ulcer (Inn-Top 005)	Number Agreed	5	5	Date Agreed	06/06/2016	4	06/06/2016	4	Recruitment Finished	
13124	15/YH/0309	18836	A 52-week International, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3bTrial with a Blinded 104-week Long -term Extension Period to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin	Number Agreed	4	4	Date Agreed	01/08/2016	0	21/05/2016	0	Withdrawn By Sponsor	We were closed as a site by sponsor before we started to recruit.
13125	14/YH/1124	160884	A phase IIIb/IV randomised, controlled, open-label, parallel group study to compare the efficacy of vancomycin therapy to extended duration fidaxomicin therapy in the sustained clinical cure of Clostridium difficile infection in an older population.	Number Agreed	6	6	Date Agreed	28/02/2016	0	28/02/2016	0	Recruitment Finished	This study did not meet target due the fact Clinical processes conflicting with the inclusion criteria.
13878	15/YH/0178	174447	A Phase 3, Randomized, Double-Blinded, Ivacaftor-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of VX-661 in combination with Ivacaftor in subjects aged 12 years and older with Cyctic Fibrosis, Heterozygous for the F508del-CFTR	Number Agreed	4	4	Date Agreed	31/03/2016	4	31/03/2016	4	Recruitment Finished	
13879	13/NI/0148	102251	(Lebrikizumab) A Phase II, Randomized, Double-Blind,Placebo Controlled, Multicenter Trial To Assess The Oral Corticosteroid {Sparing Effect Of Lebrikizumab In Patients With Severe Corticosteroid Dependent Asthma (VOCALS)	Number Agreed	12	12	Date Agreed	31/03/2016	15	31/03/2016	15	Recruitment Finished	We recruited over target because recruitment was competetive
13880	16/NE/0014	192732	A 12-Week Study to Assess the Efficacy and Safety of AF-219 in Subjects with Treatment Refractory Chronic Cough	Number Agreed	6	6	Date Agreed	15/07/2016	13	15/07/2016	13	Recruitment Finished	We recruited over target because recruitment was competetive
14442	13/NW/0583	124224	A 24 Week International, Multi-center, Randomised, Parallel-group, Double-blind Trial to Evaluate Metformin Extended Release Monotherapy Compared to Metformin Immediate Release Monotherapy in Adult Subjects with Type 2 Diabetes who have Inadequate Gl	Number Agreed	5	5	Date Agreed	21/12/2015	2	21/12/2015	2	Recruitment Finished	We did not meet target due to higher than anticipated screen failure rate.
14443	15/EE/0405	189187	A Randomized, DoubleBlind, PlaceboControlled, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab in Insulin Treated Patients with Type 1 or Type 2 Diabetes and With Hypercholesterolemia at High Cardiovascular Risk Not Adequately C	Number Agreed	5	5	Date Agreed	01/07/2016	3	15/08/2016	3	Recruitment Finished	We did not meet target due to unexpected staff shortages and lower than anticipated screening.