

UHSM CTP DOH Q3 16 17 Performance in Delivering

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
16700	14/SW/0091	150889	Randomized, DoubleBlind, Multicenter, Phase 3 Study Comparing Velliparib 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 negotiated a reduction in our target from 4 to 2 so we did make target by study closure.
16701	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 eligible patients seen chose not to participate in the study
16702	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plaster in localisedchronic post-operative neuropathic pain	Number Agreed	6	6	Date Agreed	30/04/2016	4	30/04/2016	4	Withdrawn By Sponsor	This study did not meet target due the fact we had no PI for over 12 months.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.
16703	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	
16704	15/YH/0309	18836	A 52-week International, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3b Trial 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.
16705	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 as no eligible patients were seen and a low C Diff occurrence.
16706	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 Cystic Fibrosis, Heterozygous for the F508del-CFTR	Number Agreed	4	4	Date Agreed	31/03/2016	4	31/03/2016	4	Recruitment Finished	
16707	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 competitive
16708	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 competitive
16709	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.
17936	15/EM/0473	187884	A randomized, open-label, active-controlled, Phase II study of intravenous anetumabravtansine (BAY 94-9343) or vinorelbine in patients with advanced or metastaticmalignant pleural mesothelioma overexpressing mesothelin and progressed on first linepla	Number Agreed	3	3	Date Agreed	31/03/2017	11	09/12/2016	11	Recruitment Finished	Recruitment was closed early but we still exceeded the target.
17937	5/SC/0521	185323	A Phase 2, randomized, open-label, multicenter study to assess safety and efficacy of nabpaclitaxel (ABI-007) with epigenetic modifying therapy of CC-486, and nab-paclitaxel monotherapy as second-line treatment in subjects with advanced nonsquamous n	Number Agreed	4	4	Date Agreed	31/12/2016	2	05/12/2016	2	Recruitment Finished	Recruitment was closed early. We were brought into the study to make up numbers and there was unexpected long term sick leave therefore we did not make the target.
17938	16/LO/0361	193839	PEANUT ALLERGY ORAL IMMUNOTHERAPY STUDY OF AR101 FOR DESENSITIZATION IN CHILDREN AND ADULTS (PALISADE)	Number Agreed	5	5	Date Agreed	16/11/2016	3	16/11/2016	3	Recruitment Finished	Target was not met due to no eligible patients seen and multiple screen failures.
17939	15/NW/0698	183781	Regain - TITLE: A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of transition to Toujeo? compared to standard of care insulin, in basal insulin treated pati	Number Agreed	4	4	Date Agreed	07/10/2016	0	07/10/2016	0	Recruitment Finished	This study did not meet target due the fact eligible patients seen chose not to participate in the study and short recruitment period.
17940	15/NW/0697	183760	Reach - A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of Toujeo? compared to standard of care insulin for initiating basal insulin in insulin na7ve patien	Number Agreed	4	5	Date Agreed	07/10/2016	5	07/10/2016	5	Recruitment Finished	
17941	15/WA/0241	183747	Depict 2 - A multi-centre, randomised, double blind, placebo controlled, parallel group, phase 3 study to evaluate the efficacy and safety of Dapagliflozin as an add-on to insulin therapy in subjects with Type 1 diabetes mellitus - study two	Number Agreed	4	4	Date Agreed	19/12/2016	2	19/12/2016	2	Recruitment Finished	Target was not met due to no eligible patients seen and multiple screen failures.
17942	15/EM/0294	180267	Inn Top 005 - 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	Number Agreed	5	5	Date Agreed	20/12/2016	4	17/11/2016	4	Withdrawn By Sponsor	Sponsor closed recruitment early.
17943	15/SC/0115	167694	Harmony - A long term, randomised, double blind, placebo-controlled study to determine the effect of albiglutide, when added to standard blood glucose lowering therapies, on major cardiovascular events in patients with Type 2 diabetes mellitus.	Number Agreed	8	10	Date Agreed	31/12/2016	6	23/11/2016	6	Recruitment Finished	We did not meet target as recruitment was closed early
17944	15/EE/0405	189187	Odyssey DM - A Randomized, double blind, placebo controlled, parallel group, phase 3 study to evaluate the efficacy and safety of Alirocumab in insulin treated patients with Type 1 or Type 2 diabetes with Hypercholesterolemia not adequately controll	Number Agreed	5	5	Date Agreed	15/08/2016	3	15/08/2016	3	Recruitment Finished	Target was not met due to no eligible patients seen and multiple screen failures.
17945	14/EM/1141	159136	CS6 - 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	08/01/2016	2	08/01/2016	2	Recruitment Finished	
18376	15/EE/0130	170557	A randomised, open-label, multicentre study of liposomal amikacin for inhalation (LAI) in adult patients with nontuberculous mycobacterial (NTM) lung infections caused by mycobacterium avium complex (MAC) that are refractory to treatment	Number Agreed	1	1	Date Agreed	04/11/2016	0	04/11/2016	0	Recruitment Finished	no eligible patients seen, patients are rare which was the reason for the target of 1 patient.