UHSM CTP DOH Performance in Delivering Q3 2015 2016

Id	Research Ethics Committee Reference Number	Name of Trial	Target number of patients available	Target number of patients	Date Agreed to recruit target number of patients available	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
68877	12/WM/0341	A double-blind, randomised, placebo-controlled, multicentre study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardio	Available	22	Available	26/01/2015	Closed - In Follow Up	N	Recruitment to the study was closed early.
68878	13/NW/0462	Randomised, double-blind, dose-finding Phase II study to assess the efficacy of APD403 in the prevention of nausea and vomiting caused by cisplatin - or anthracycline / Cyclophosphamide (AC)-based chemotherapy	Available	10	Available	30/01/2015	Closed - Follow Up Complete	Y	
68879	13/EM/0230	A Phase II Randomised, Double-Blind, Placebo-Controlled, Multicenter study of VS6063 in subjects with Malignant Pleural Mesothelioma	Available	10	Available	01/09/2015	Closed - Follow Up Complete	Y	
68880	13/LO/0219	A Phase 2, Randomized, Double-Blind, Placebo-Conrolled, Multi-Center Study to Assess the Efficacy and Safety of GS-6624 in Subjects with Idiopathic Pumlmonary Fibrosis (RAINIER)	Available	3	Available	21/04/2015	Closed - In Follow Up	N	This study had a high screen failure rate and it was competitive recruitment.
68882	13/NW/0283	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 bivalirudin and Biomatrix family drug-eluting stent use.	Available	150	Available	06/11/2015	Closed - In Follow Up	N	This study was very difficult to recruit to we recruited a total of 90 patients to this study, we also had a lab out of order and in repair, and we are a tertiary centre taking ACS referrals for primar PCI, therefore despite many patients consenting many failed at angiogram stage.
68883	13/LO/1348	Lutonix	Available	13	Available	31/07/2015	Closed - In Follow Up	Y	The target for the study and end of recruitment date was reduced
68884	13/NI/0148	A phase ll, randomised, double-blind, placebo-controlled, multicentre trial to assess the oral corticosteroid-sparing effect of lebrikizumab in patients with severe corticosteroid-dependent asthma - VOCALS	Available	12	Available	31/03/2016	Open	Y	
68885	13/WM/0235	Atrial FibrillaTion ProgrESsion Trial (ATTEST Trial)	Available	5	No Date Agreed With Sponsor		Open	N/A	recruitment to the study is ongoing as per sponsor, no end to recruitment planned as of yet
68886	13/NW/0583	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 Glycaemic Control with Diet and Exercise	Available	5	Available	21/11/2015	Closed - In Follow Up	N	Our site was reliant on a PIC site to refer patients unfortunately very few pateints were reffered and those who were reffered were not keen. 7 were consented but only 2 went on to randomise and one withdrew.
68887	13/SS/0044	Efficacy and safety of lidocaine 5% medicated plaster in localisedchronic post-operative neuropathic pain	Available	6	Available	30/04/2016	Open	N/A	
68889	13/YH/0282	Open-label, Phase lllb 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 Rheumatoid Arthritis (RA) who are being treated with an anti-tumour necrosis factor (anti-TNF) agent and that have not achieved an adequate response to treatment	Available	5	Available	31/07/2015	Closed - In Follow Up	N	Recruitment to the study was closed early.
68890	13/EE/0326	REVACEPT, AN INHIBITOR OF PLATELT ADHESION IN SYMPTOMATIC CAROTID STENOSIS: A PHASE II, MULTICENTRE; RANDOMISED, DOSE-FINDING, DOUBLE-BLIND AND PALCEBO-CONTROLLED SUPERIORITY STUDY WITH PARALLEL GROUPS	Available	48	Available	27/05/2017	Open	Y	
68891	13/NW/0612	A multicentre, randomised, double-blind, parallel group, placebo-controlled, phase lll efficacy and safety study of benralizumab (MEDI-563) added to high-dose inhaled corticosteroid plus long-acting B2-agnoist in patients with Uncontrolled asthma (SIROCCO)	Available	1	Available	13/02/2015	Closed - Follow Up Complete	Y	
68893	14/ES/0001	Randomised, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess Cardiovascular Outcomes Following Treatment with Ertugliflozin (MK-8835/PF-04971729) in Participants with Type 2 Diabetes Mellitus and Established Vascular Disease	Available	7	Available	01/06/2015	Closed - In Follow Up	N	The ponsor closed recruitment early.
68895	14/NE/0016	IRIS-3: A 12 week double-blind, randomised, placebo-controlled, parallel group phase III study, followed by a 4-week randomised withdrawal period to evaluate the efficacy and safety of oral Ibodutant 10mg once daily in female patients with Irritable Bowel Syndrome with Diarrhoea (IBS-D)	Available	10	Available	16/01/2015	Closed - Follow Up Complete	N	Staff availability
68896	14/NW/0211	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.	Available	10	Available	01/03/2015	Closed - Follow Up Complete	N	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.
68897	14/NW/0008	Golimumab: A Phase 4, UK Open Label, Single arm Study on its Utilization and Impact in Ulcerative Colitis	Available	7	Available	30/01/2015	Closed - Follow Up Complete	N	We were given the green light late losing us 40 days in recruitment. There were issues with the setup of the home care company, which caused delays. The sponsor had a problem with the QP release from the MHRA so there were lots of issues around drug supply and labelling, again causing delays. The NICE guidelines changed during the study and this group of patients were able to access another biologic treatment easily, which wasnt the case at the start. This reduced the incentive to go on this study.
68898	14/LO/0521	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.	Available	2	Available	31/03/2015	Closed - In Follow Up	N	Difficult study to recruit to, general problem across the UK.
68899	14/SW/0091	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)	Available	2	Available	31/12/2015	Closed - In Follow Up	Y	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.
68900	12/NW/0002	A Randomized, Open-label, Multicenter, Phase 3 Study to Compare the Efficacy and Safety of Eribulin with Treatment of Physician?s Choice in Subjects with Advanced Non-Small Cell Lung Cancer (Elevate)	Available	6	Available	01/05/2015	Closed - Follow Up Complete	Y	
68901	12/EE/0371	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.	Available	320	Available	31/10/2015	Closed - In Follow Up	N	Recruitment to the study was difficult due to strict criteria and time constraints (96 hrs from admission to randomisation). 22 randomisations in total in the UK - 17 of which were at UHSM
68902	14/LO/1513	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/T	Available	3	Available	31/12/2015	Closed - In Follow Up	N	The study is difficult to recruit to as patients have already been pre treated with contraindicating antibiotics.

68903	14/LO/0818	A Randomised Open-label Phase II Trial of MK-3475 versus Platinum based Chemotherapy in 1L Subjects with PD-L1 Strong Metastatic Non-Small Cell Lung Cance	Available	1	Available	31/10/2015	Closed - Follow Up Complete	Y	Niche study, 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.
68905	13/EM/0343	A randomized, comparative effectivness study of complete versus culprit-only revascularization strategies to treat multi-vessel disease after primary percutaneous coronary intervention for ST-segment elevation myocardial infarction.	Available	20	Available	16/03/2017	Open	N/A	
68906	15/LO/0018	A Randomized double blind placebo controlled multiple dose study of subcutaneous ACZ885 for the treatment of abdomial aortic aneurysm	Available	20	Available	01/07/2015	Closed - In Follow Up	N	The Trial was closed to recruitment early due to the internim analysis. Recruitment was not reopened and the trial was stopped due to negative resuts from the interim analysis. The site were on target to meet the recruitment target prior to premature study closure
68907	15/EE/0003	A randomized, double-blind, placebo-controlled Phase 3 study of ISIS 304801 administered subcutaneously to patients with hypertriglyceridemia	Available	3	Available	29/02/2016	Open	N/A	
68908	14/EM/1141	A randomized double blind placebo controlled phase 3 study of ISIS 304801 administered subcutaneously to patients with familial chylomicronemia syndrome	Available	1	Available	08/01/2016	Closed - In Follow Up	Y	
68909	13/NE/0006	A pilot Randomised controlled trial of the use of ReCell autologous cell harvesting device for venous Leg Ulcers	Available	10	Available	30/06/2015	Closed - Follow Up Complete	N	Our site closed prior to study closure as vascular venous research fellow and vascular specialist venous ulcer nurse no longer in post and it was not possible to continue recruitment
68910	14/YH/1124	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	Available	6	Available	28/02/2016	Open	N/A	
68911	14/NW/1337	A Multicentre, Randomised, 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 Long-Acting B2-Agonist (BORA)	Available	1	Available	01/07/2015	Closed - In Follow Up	Y	
68912	14/NW/1350	Evaluation of orvepitant in an exploratory open lable clinical study in chronic treatment refractory cough	Available	12	Available	30/10/2015	Closed - Follow Up Complete	Y	
68913	15/NW/0255	A phase 3, multi-center, randomised, open-label study of Carbavance (Meropenem/RPX7009) versus best available therapy in subjects with selected serious infections due to Carbapenem-resistant Enterobacteriaceae	Available	4	Available	15/05/2016	Open	N/A	
68914	14/LO/0324	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 Day Open-Label Extension and Pharmacokinetic Substudy	Available	3	Available	31/07/2015	Closed - In Follow Up	N	High failure rate and short recruitment period which resulted in participants who were eligible not having time for re-screening.
72518	15/YH/0178	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 Mutation and a second CFTR Allele with a gating defect that is clinically demonstrated to be Ivacaftor responsive	Available	4	Available	31/03/2016	Open	N/A	
72519	15/LO/0699	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy and Safety of Ivacaftor and VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508del-CFTR Mutation, and a Second Allele With a CFTR Mutation Predicted to Have Residual Function	Available	4	Available	31/07/2016	Open	N/A	
72520	15/EM/0294	A Phase 3 Randomised, 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	Available	5	Available	01/02/2016	Open	N/A	
72521	15/EE/0130	A Randomized, Open Label, Multicenter 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.	Available	1	Available	04/01/2018	Open	N/A	
72522	15/LO/1289	An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of Rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures	Available	20	Available	01/03/2018	Open	N/A	