## UHSM CTP Performance in Delivering Quarter 2 2015/2016

| Id | Trustid | Submissionid | Meta Submissionid | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 60820 | 965 | 2535 | 34 | 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 closed early. |
| 60823 | 965 | 2535 | 34 | 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 | |
| 60824 | 965 | 2535 | 34 | 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 | |
| 60827 | 965 | 2535 | 34 | 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. |
| 60828 | 965 | 2535 | 34 | 13/LO/1121 | A randomized, controlled phase 2 study evaluating LY2875358 plus Erlotinib versus Erlotinib as first-line treatment in Metastatic non-small cell lung cancer patients with activating EGFR mutations who have disease control after 8-week lead-in treatment with Erlotinib | Available | 6 | Available | 12/11/2014 | Closed - Follow Up Complete | N | Extremely niche study and not enough patients on erlotinib |
| 60830 | 965 | 2535 | 34 | 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 | Open | N/A | |
| 60831 | 965 | 2535 | 34 | 13/LO/1348 | Lutonix | Available | 13 | Available | 31/07/2015 | Closed - In Follow Up | Y | original target was 20-24 with an end of recruitment date of 1/6/15 the target and end of recruitment date was reduced |
| 60832 | 965 | 2535 | 34 | 13/NI/0148 | A phase II, 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 | |
| 60833 | 965 | 2535 | 34 | 13/WM/0235 | Atrial FibrillaTion ProgrESsion Trial (ATTEST Trial) | Available | 5 | No Date Agreed With Sponsor | | Open | N/A | recruitment ongoing as per sponsor, no end to recruitment planned as of yet |
| 60834 | 965 | 2535 | 34 | 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 | Open | N/A | |
| 60835 | 965 | 2535 | 34 | 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 | |
| 60836 | 965 | 2535 | 34 | 13/SC/0384 | A Phase 2, Randomized, Double-blind Study Comparing Tremelimumab to Placebo in Second-or Third-line Treatment of Subjects with Unresectable Pleural or Peritoneal Malignant Mesothelioma | Available | 10 | Available | 01/11/2014 | Closed - In Follow Up | Y | |
| 60837 | 965 | 2535 | 34 | 13/YH/0282 | Open-label, Phase IIIb 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 | did not meet target as recruitment was closed early plus has 2 screen fails |
| 60838 | 965 | 2535 | 34 | 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 | |
| 60839 | 965 | 2535 | 34 | 13/NW/0612 | A multicentre, randomised, double-blind, parallel group, placebo-controlled, phase III 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 | |
| 60840 | 965 | 2535 | 34 | 13/WA/0084 | A randomised, Double-Blind, Placebo-Controlled, Multicentre Study to Assess Cardiovascular Outcomes Following Treatment with MK-3102 in Subjects with Type 2 Diabetes Mellitus | Available | 7 | Available | 01/10/2014 | Closed - Follow Up Complete | N | original date agreed to recruit target number of patients cut short |
| 60842 | 965 | 2535 | 34 | 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 | recruitment closed early by sponsor |
| 60843 | 965 | 2535 | 34 | 13/LO/0867 | Double-blind, randomised, multicentre, phase II study of nintedanib in combination with pemetrexed/cisplatin followed by continuing nintedanib monotherapy versus placebo in combination with pemetrexed/cisplatin followed by continuing placebo monotherapy for the treatment of patinets with unresectable malignant plaural mesothelioma | Available | 4 | Available | 01/12/2014 | Suspended | Y | DMC reviewed and asked for further patients to be enrolled following an amendment to make the study confirmatory. Should reopen quarter 4 of 2015. |
| 60845 | 965 | 2535 | 34 | 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 |
| 60846 | 965 | 2535 | 34 | 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 | overall target for the study was revised by the sponsor to 18 as this target was reached between the study sites recruitment was stopped |
| 60848 | 965 | 2535 | 34 | 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 | green light given to us 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 wasn't the case at the start. This reduced the incentive to go on this study |
| 60849 | 965 | 2535 | 34 | 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 |
| 60850 | 965 | 2535 | 34 | 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 | 4 | Available | 31/12/2015 | Open | N/A | |
| 60852 | 965 | 2535 | 34 | 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 | |
| 60854 | 965 | 2535 | 34 | 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 | Open | N/A | |
| 60855 | 965 | 2535 | 34 | 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 | Open | N | patients have already been pre treated with contraindicating antibiotics |
| 60856 | 965 | 2535 | 34 | 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 | 4 | Available | 31/10/2015 | Closed - Follow Up Complete | N | Niche study, had much higher screen fail in PDL1 strong status than national average, no fault or reason. Study nationally showed geographical recruitment trends. |
| 60857 | 965 | 2535 | 34 | 12/YH/0539 | an open label multi centre preoperative window of oppurtunity study of afatinib in stage Ia to IIb non small cell lung cancer | Available | 3 | Available | 01/01/2017 | Open | N/A | |
| 60859 | 965 | 2535 | 34 | 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 | |
| 60860 | 965 | 2535 | 34 | 15/LO/0018 | A Randomized double blind placebo controlled multiple dose study of subcutaneous AZ2885 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 |
| 60861 | 965 | 2535 | 34 | 15/EE/0003 | A randomized, double-blind, placebo-controlled Phase 3 study of ISIS 304801 administered subcutaneously to patients with hypertriglyceridemia | Available | 4 | Available | 01/12/2015 | Open | N/A | |
| 60862 | 965 | 2535 | 34 | 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 | 01/12/2015 | Open | N/A | |
| 60863 | 965 | 2535 | 34 | 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 | site closed prior to study closure as vascular venous research fellow and vascular specialist venous ulcer nurse no longer in post and not possible to continue recruitment |
| 60864 | 965 | 2535 | 34 | 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 | 01/12/2015 | Open | N/A | |
| 60865 | 965 | 2535 | 34 | 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 | |
| 60866 | 965 | 2535 | 34 | 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 - In Follow Up | Y | |
| 60867 | 965 | 2535 | 34 | 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 | |
| 60868 | 965 | 2535 | 34 | 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 that participants who were eligible did not have time for re-screening. |