

DOH Submission Q1 2015 2016 Performance in delivering

ID	Trust Id	Submission Id	Meta Submission 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
####	965	2109	32	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.
####	965	2109	32	13/NW/0215	A double blind, randomized, placebo controlled phase II study to assess the efficacy of recPRAME +AS15 Antigen-Specific Cancer Immunotherapeutic as adjuvant therapy in patients with resected PRAME-positive, Non-Small Cell Lung Cancer (PEARL-PRAME)	Available	4	Available	01/08/2014	Closed - Follow Up Complete	Y	Recruitment closed early. (august 2014)
####	965	2109	32	13/WN/0234	A prospective, Multicentre, Controlled Study of implant-based breast reconstruction, measuring the safety, effectiveness and cost consequences, of Immediate Single Stage Breast Reconstruction with Stratitice Reconstructive Tissue Matrix versus Immediate Two	Available	10	Available	07/07/2014	Closed - In Follow Up	Y	
####	965	2109	32	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	
####	965	2109	32	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	Open	Y	
####	965	2109	32	13/YH/0232	A randomised double-blind (sponsor-unblind) placebo controlled, cross-over study to investigate the efficacy, effect on cough reflex sensitivity, safety, tolerability and pharmacokinetics of inhaled GSK2339345 in patients with chronic idiopathic cough using an aqueous droplet inhaler. Echo	Available	10	Available	21/08/2014	Closed - Follow Up Complete	Y	Original target was 20 patients, this target was reduced to 10 during the study.
####	965	2109	32	13/SC/0348	A randomised, open label Phase II study evaluating LY2875358 plus Erlotinib and LY2875358 monotherapy in MET diagnostic positive NSCLC patients with acquired resistance to Erlotinib	Available	1	Available	29/08/2014	Closed - Follow Up Complete	Y	Closed early in August 2014
####	965	2109	32	13/LO/0219	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)	Available	3	Available	21/04/2015	Closed - In Follow Up	N	This study had a high screen failure rate and it was competitive recruitment.
####	965	2109	32	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
####	965	2109	32	13/NE/0094	Phased RF Evaluation of Acute Pulmonary Vein Isolation in Paroxysmal AF with new GENIUS UI and PVAC GOLD.	Available	10	Available	01/06/2014	Closed - In Follow Up	N	Recruitment closed early, original end of recruitment date was July 2014.
####	965	2109	32	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	15/09/2015	Open	N/A	
####	965	2109	32	13/LO/1348	Lutonix	Available	13	Available	31/07/2014	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
####	965	2109	32	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	
####	965	2109	32	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
####	965	2109	32	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	
####	965	2109	32	13/SS/0044	Efficacy and safety of lidocaine 5% medicated plaster in localised chronic post-operative neuropathic pain	Available	6	Available	30/04/2016	Open	N/A	
####	965	2109	32	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	
####	965	2109	32	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	Open	N/A	
####	965	2109	32	13/EE/0326	REVACEPT, AN INHIBITOR OF PLATELET ADHESION IN SYMPTOMATIC CAROTID STENOSIS: A PHASE II, MULTICENTRE, RANDOMISED, DOSE-FINDING, DOUBLE-BLIND AND PLACEBO-CONTROLLED SUPERIORITY STUDY WITH PARALLEL GROUPS	Available	48	Available	01/08/2015	Open	N/A	
####	965	2109	32	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-agonist in patients with Uncontrolled asthma (SIROCCO)	Available	1	Available	13/02/2015	Closed - Follow Up Complete	Y	
####	965	2109	32	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
####	965	2109	32	12/EM/0284	A multi-centre, open-label, long-term safety study of mepolizumab in asthmatic subjects who participated in the MEA112997 trial.	Available	3	Available	18/02/2014	Closed - In Follow Up	N	this study was a follow on study and only patients that had taken part in the initial study were eligible. Not all patients wanted to take part in this study.
####	965	2109	32	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
####	965	2109	32	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 patients with unresectable malignant pleural 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.

####	965	2109	32	14/EM/0024	A phase III, randomized, double-blind, placebo-controlled multicenter study of subcutaneous secukinumab in autoinjectors, to demonstrate efficacy at 24 weeks and to assess the long term safety, tolerability and efficacy up to 3 years in subjects with active Psoriatic Arthritis	Available	3	Available	22/09/2014	Closed - In Follow Up	N	site activation delayed due to delay from sponsor with GRAPPA training not being sent to the site on time
####	965	2109	32	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 lisduloxetine 10mg once daily in female patients with Irritable Bowel Syndrome with Diarrhoea (IBS-D)	Available	10	Available	16/01/2015	Closed - In Follow Up	N	Staff availability
####	965	2109	32	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 - In Follow Up	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
####	965	2109	32	14/WS/0004	Open-label Extension Study of EFC12492, R727-CL-1112, EFC12732 & LTS11717 Studies to Assess the Long-Term Safety and Efficacy of Alirocumab in Patients with Heterozygous Familial Hypercholesterolemia	Available	4	Available	01/09/2014	Closed - In Follow Up	Y	
####	965	2109	32	14/NW/0008	Golimimumab: 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
####	965	2109	32	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
####	965	2109	32	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	01/09/2015	Open	N/A	
####	965	2109	32	08/H0711/4	A multicentre, randomised, phase III trial of platinum-based chemotherapy versus non-platinum chemotherapy, after ERCC1 stratification in patients with advanced/metastatic non-small cell lung cancer	Available	4	Available	01/07/2014	Closed - Follow Up Complete	Y	original target of 5 over 3 years (5 a year) recruitment was closed a year early and target reduced to 2 a year
####	965	2109	32	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	
####	965	2109	32	12/NW/0431	A multi-centre, open-label, adaptive, randomised study of Palifosamide-tris, a novel DNA Crosslinker, in combination with Carboplatin and Etoposide (PaCE) chemotherapy versus Carboplatin and Etoposide (CE) alone in chemotherapy naive patients with extens	Available	12	Available	01/09/2014	Closed - Follow Up Complete	N	recruitment was on track but sponsor closed study due to financial reasons
####	965	2109	32	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	30/09/2015	Open	N/A	
####	965	2109	32	14/LO/1513	A randomized, Open-Label, Phase 4 Study Evaluating the Renal Effect of 'elivitegravir/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
####	965	2109	32	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 Cancer	Available	4	Available	31/10/2015	Open	N/A	
####	965	2109	32	12/YH/0539	an open label multi centre preoperative window of opportunity study of afatinib in stage Ia to Ib non small cell lung cancer	Available	3	Available	01/01/2017	Open	N/A	
####	965	2109	32	11/H1003/9	A Sideguard Coronary Sidebranch Registry: A post market registry to observe the clinical outcomes of the Bare Metal Sideguard* Coronary Sidebranch stent in de novo Bifurcation Lesions of Native Coronary Arteries	Available	10	Available	31/05/2013	Closed - Follow Up Complete	N	
####	965	2109	32	13/EM/0343	A randomized, comparative effectiveness 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	
####	965	2109	32	15/LO/0018	A Randomized double blind placebo controlled multiple dose study of subcutaneous AC2885 for the treatment of abdominal aortic aneurysm	Available	20	Available	31/10/2015	Open	N/A	
####	965	2109	32	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	
####	965	2109	32	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	
####	965	2109	32	13/NE/0006	A pilot Randomised controlled trial of the use of ReCell autologous cell harvesting device for venous Leg Ulcers	Available	10	Available	31/10/2015	Open	N/A	
####	965	2109	32	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	
####	965	2109	32	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	Open	Y	
####	965	2109	32	14/NW/1350	Evaluation of orvepitant in an exploratory open label clinical study in chronic treatment refractory cough	Available	12	Available	30/10/2015	Open	N/A	
####	965	2109	32	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	15/05/2015	Open	N/A	
####	965	2109	32	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	Open	N/A	