PERFORMANCE IN DELIVERING CLINICAL RESEARCH (Q1, 2017/18)

Research Ethics Committee Reference 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
14/EM/0130	A Phase 3, Open-Label, Randomized Study of Quizartinib (AC220) Monotherapy vs. Salvage Chemotherapy in Subjects with FLT3-ITD Positive Acute Myeloid Leukemia (AML) Refractory to, or Relapsed after, First-Line Treatment with or without Hematopoietic S	Number Agreed	2	2	Date Agreed	31/01/2017	0	31/10/2016	0	Withdrawn By Sponsor	Study did not meet target as this is a rare disease.
15/EE/0464	A phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH)	Number Agreed	3	3	Date Agreed	30/09/2016	0	01/12/2016	0	Withdrawn By Sponsor	Study team looked actively and screened several patients but none suitable.
14/WS/1105	A Multicenter, Randomized, Open-Label Study to Assess the Impact of Natalizumab versus Fingolimod on Central Nervous System Tissue Damage and Recovery in Active Relapsing Remitting Multiple Sclerosis Subjects	Range Agreed	5	20	Date Agreed	25/01/2016	0	19/11/2016	0	Withdrawn By Sponsor	Sponsor delays with contract negotiations, site set up and delivering study supplies. Sponsor closed site.
14/LO/2196	A phase 2, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the safety and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour	Number Agreed	7	7	Date Agreed	04/01/2016	0	25/07/2016	0	Recruitment Finished	None of the study sites in the UK recruited due to difficulty in finding eligible patients.
14/SC/1059	A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy	Range Agreed	5	10	Not Available / Not Agreed			14/09/2016	0	Withdrawn By Sponsor	Sponsor withdrew study. Long delays setting up PIC sites - no patients referred to site.
15/SC/0521	A phase 2, randomized, open-label, Multicenter study to assess safety and efficacy of nab?-paclitaxel (abi-007) with epigenetic modifying therapy of cc-486, and nab?-paclitaxel monotherapy as Second-line treatment in subjects with advanced nonsquamou	Number Agreed	4	4	Date Agreed	01/12/2016	4	01/07/2016	13	Recruitment Finished	Rare disease study.
14/SW/0115	Safety and Efficacy of the Veniti Vici? Venous Stent System (Veniti Inc.) when Used to Treat Clinically Significant Chronic Non-malignant Obstruction of the Iliofemoral Venous Segment Subtitle: A Study Looking at the Veniti Vici? Venous Stent Syste	Number Agreed	12	12	Date Agreed	31/03/2017	1	28/10/2016	1	Withdrawn By Sponsor	Late amendments to study which then fully recruited globally.
15/EE/0350	A Phase III, randomised, double blind, placebo-controlled, parallel group, efficacy, safety and tolerability trial of once daily, oral doses of Empagliflozin as Adjunctive to insulin therapy over 26 weeks in patients with Type 1 Diabetes Mellitus	Range Agreed	2	5	Date Agreed	31/12/2016	1	31/12/2016	1	Recruitment Finished	Study team absences.
16/EE/0013	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Safety and Efficacy of GS-9620 in combination with Tenofovir Disoproxil Fumarate (TDF) for the Treatment of Subjects with Chronic Hepatitis B and who are curr	Number Agreed	5	5	Date Agreed	28/08/2016	1	01/07/2016	1	Recruitment Finished	Sponsor closed recruitment early - globally fast recruitment.
14/LO/0362	Prospective, randomized, placebo-controlled, double-blind, multicenter, parallel-group, 24-week study to assess the efficacy, safety and tolerability of macitentan in subjects with inoperable chronic thromboembolic pulmonary hypertension	Number Agreed	3	3	Date Agreed	28/07/2016	1	15/08/2016	1	Withdrawn By Sponsor	Strict inclusion criteria. Sponsor eventually closed study.
15/LO/0691	An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic Squamous Cell (Sq) Non-Small Cell Lung Cancer (NSCLC) who Have Received at Least Two Prior Systemic Regimens for the Treatment o	Number Agreed	4	4	Date Agreed	15/04/2016	4	06/07/2016	6	Recruitment Finished	Study recruited to time and target.
15/WS/0147	A Multicenter, Open Label, Prospective, Post Approval Study of the INCRAFT? AAA Stent Graft System in Subjects with Abdominal Aortic Aneurysms	Number Agreed	24	24	Date Agreed	30/06/2021	5	01/09/2016	5	Withdrawn By Sponsor	Sponsor closed study early.

13/NW/0002	Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL? Hemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery (VICTORY Study	Number Agreed	20	20	Date Agreed	31/08/2016	5	02/12/2016	5	Withdrawn By Sponsor	PI left Trust.
14/NW/1354	A Single Arm, Open-label, Long-term Efficacy and Safety Study of Romiplostim in Thrombocytopenic Pediatric Subjects With Immune Thrombocytopenia (ITP)	Number Agreed	5	5	Date Agreed	28/02/2017	6	02/08/2016	6	Recruitment Finished	Study recruited to time and target.
13/LO/1557	A Phase IV, Multicentre, Open label, Single Group Exploratory Study to Assess the Clinical Value of Enumeration of Circulating Tumour Cells (CTCs) to Predict Clinical Symptomatic Response and Progression Free Survival in Patients receiving Deep Subcu	Number Agreed	5	5	Date Agreed	31/08/2016	7	30/07/2016	7	Recruitment Finished	Study recruited to time and target.
11/LO/2036	A Phase I/II, Open-Label, Safety, Pharmacokinetic, and Preliminary Efficacy Study of Oral Rucaparib in Patients with gBRCA Mutation Ovarian Cancer or Other Solid Tumor	Number Agreed	3	3	Date Agreed	31/03/2016	8	30/09/2016	8	Recruitment Finished	Study recruited to time and target.
15/LO/0863	AG348-C-003: A Phase 2, Open Label, Randomized, Dose Ranging, Safety, Efficacy, Pharmacokinetic and Pharmacodynamic Study of AG-348 in Adult Patients with Pyruvate Kinase Deficiency.	Number Agreed	5	5	Date Agreed	18/08/2017	8	30/09/2016	8	Recruitment Finished	Study recruited to time and target.
13/LO/1758	A Phase III, Randomized, PlaceboControlled, ParallelGroup, DoubleBlind Clinical Trial to Study the Efficacy and Safety of MK8931 (SCH 900931) in Subjects with Amnestic Mild Cognitive Impairment Due to Alzheimer?s Disease (Prodromal AD).	Number Agreed	10	10	Date Agreed	31/10/2016	10	24/10/2016	10	Recruitment Finished	Study recruited to target.
14/SC/0032	PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS	Range Agreed	12	50	Date Agreed	27/07/2017	13	22/07/2016	13	Recruitment Finished	Study recruited to time and target.
15/NW/0385	A Four-Part Phase-1 Study Investigating the Tolerability, Safety and Pharmacokinetics (PK) of MBS2320 following Ascending Single and Multiple Oral Doses in Healthy Subjects and Multiple Oral Doses in Subjects with Rheumatoid Arthritis (RA) Also Treat	Range Agreed	2	7	Date Agreed	23/03/2017	4	23/03/2017	4	Recruitment Finished	Study recruited to time and target.
15/EE/0385	A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lun	Number Agreed	3	3	Date Agreed	24/08/2018	5	21/11/2016	5	Recruitment Finished	Study recruited to time and target.
15/SC/0306	A phase 3,Randomized,Double-Blind,Placebo-Controlled Study of Ramacirumab plus Doxetacel vs Placebo plus Doxetacel in Patients with Locally Advanced or Unresectable or Metasthatic Urothelial Carcinoma Who Progressed or After Platinum-Based Therapy	Number Agreed	3	3	Date Agreed	01/02/2017	3	20/03/2017	3	Recruitment Finished	Study recruited to time and target.
12/YH/0504	Assessment of the efficacy and safety of a new wound dressing in the local treatment of diabetic foot ulcers: A Prospective, randomised, controlled, doubleblind, European multicentre clinical trial.	Number Agreed	4	4	Date Agreed	29/11/2016	4	14/07/2016	4	Recruitment Finished	Study recruited to time and target.
16/LO/1984	A Phase 2, Open-Label Clinical Trial to Study the Efficacy and Safety of 12 weeks of the Combination Regimen of MK- 3682 + MK-8408 in Subjects with Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5 or 6 Infection	Number Agreed	4	4	Date Agreed	10/03/2017	5	29/03/2017	5	Recruitment Finished	Study recruited to time and target.
16/LO/0586	An Open Label Study to Evaluate the Efficacy and Safety of Ocrelizumab in Patients with Relasping Remitting Multiple Sclerosis who have had a Suboptimal Response to an Adequate Course of Disease- Modifying Treatment	Number Agreed	3	3	Date Agreed	31/07/2017	3	03/03/2017	3	Recruitment Finished	Study recruited to time and target.
15/EM/0344	A Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Amatuximab in Combination with Pemetrexed and Cisplatin in Subjects with Unresectable Malignant Pleural Mesothelioma	Number Agreed	2	2	Date Agreed	31/10/2017	1	11/01/2017	1	Withdrawn By Sponsor	Withdrawn By Sponsor

16/SC/0441	A Phase 1, First-in-Humans, randomized, double-blind (within dose level),placebo-controlled trial to evaluate the safety and immunogenicity of two intranasal doses of SynGEM?, an intranasal Respiratory Syncytial Virus (RSV) subunit candidate vaccine	Range Agreed	1	48	Date Agreed	31/12/2017	48	27/01/2017	48	Recruitment Finished	study recruited to time and target.
14/LO/1834	A Phase I randomised, placebo-controlled, double-blind, single and multiple ascending dose study of the tolerability and pharmacokinetics of GBT440 in healthy subjects and patients with Sickle Cell Disease	Range Agreed	4	6	Date Agreed	24/07/2015	2	01/02/2017	6	Recruitment Finished	Slow recruiting study; recruitment timeline extended by Sponsor.
16/EM/0078	Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter, Exploratory Phase IIa Study to Assess Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Properties of GLPG1690 Administered for 12 Weeks in Subjects with Idiopathic Pu	Number Agreed	1	1	Date Agreed	17/11/2016	0	31/01/2017	0	Recruitment Finished	Very rare disease.
15/NI/0258	A PERFORMANCE EVALUATION STUDY OF ARQUER?S MCM5 ELISA TEST TO AID IN THE DIAGNOSIS OF BLADDER CANCER	Number Agreed	130	130	Date Agreed	31/12/2016	130	28/02/2017	130	Recruitment Finished	Study recruited to time and target.
16/NW/0305	A phrase III multicentre, randomised, double blinded, parallel group placebo controllled study to assess the safety and efficacy of one or more intradetrusor treatments of 600 or 800 units of Dysport for urinary incontinence in subjects with neurogen	Number Agreed	20	20	Not Available / Not Agreed			07/03/2017	0	Withdrawn By Sponsor	Sponsor decided not to proceed with study at site (legal issue re: indeminity of loaned equipment).
15/SC/0409	Safety and Efficacy of Abicipar Pegol in patients with Neovascular Age-Related Macular Degeneration	Number Agreed	10	10	Date Agreed	03/06/2019	0	07/04/2017	0	Recruitment Finished	Delays in contract negotiation between Sponsor and site; then national target met.
16/LO/1767	The Efficacy and Safety of Solanezumab versuses Placebo in Prodromal Alzheimer's Disease	Number Agreed	12	12	Date Agreed	30/04/2019	0	10/11/2016	0	Withdrawn By Sponsor	Sponsor withdrew study in all UK sites.
16/LO/2038	A Double-blind, Randomized, Parallel-group, Placebo-controlled Study of MLE4901 for the Treatment of Polycystic Ovary Syndrome (PCOS)	Number Agreed	5	5	Date Agreed	31/05/2017	0	22/03/2017	0	Withdrawn By Sponsor	Sponsor terminated study early across all UK sites and suspended global recruitment due to an urgent safety measure.
17/LO/0401	An Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Combination with Sofosbuvir and Ribavirin in Chronic Hepatitis C (HCV) Infected Subjects Who Have Experienced Virologic Failure in AbbVie HCV Clinical Studies	Number Agreed	1	1	Date Agreed	09/02/2018	1	23/06/2017	1	Recruitment Finished	Sponsor closed recruitment early due to globally recruitment target being reached. Study recruited to time and target.
13/NE/0005	A Prospective registry providing continuing evaluation and periodic reporting of product safety, effectiveness and patient outcomes across Medtronic market-released products across diabetes, cardiac rhythm disorders, urological, gastrointestinal, spi	Number Agreed	7	7	Date Agreed	28/04/2017	8	28/04/2017	8	Recruitment Finished	Study recruited to time and target.
16/LO/0014	A Prospective multicentre phase III clinical evaluation of the safety and efficacy of Lumason/ Sonovue in subjects undergoing pharmacological stress Echocardiography with Dobutamine for diagnosis of Cornorary Artery Disease	Number Agreed	10	10	Date Agreed	10/04/2017	12	10/04/2017	12	Recruitment Finished	Study recruited to time and target.
16/SC/0293	A multicentre, randomised, open-label study in patients with oesophageal cancer refractory or intolerant to combination therapy with Fluoropyrimidine and Platinum-based drugs	Not Available / Not Agreed			Not Available / Not Agreed			15/12/2016	0	Withdrawn By Sponsor	Sponsor withdrew study from site; contractual issue.
16/SC/0161	A Phase III, open-label, randomised study of Atezolizumab (Mpdl3280a, Anti-Pd-L1 Antibody) in combination with Carboplatin or Cisplatin and Pemetrexed compared with Carboplatin or Cisplatin and Pemetrexed in patients who are chemotherapy-na?ve and h	Number Agreed	6	6	Date Agreed	01/07/2017	4	07/04/2017	4	Recruitment Finished	Sponsor closed recruitment early.
15/NW/0671	A phase II, randomised, double-blind, placebo-controlled study to assess the efficacy and safety of Enzalutamide in subjects with advanced Hepatocellular Carcinoma	Number Agreed	2	2	Date Agreed	25/04/2017	3	25/04/2017	3	Recruitment Finished	Study recruited to time and target.