PERFORMANCE IN DELIVERING CLINICAL RESEARCH (Q2, 2015/16)

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
12/LO/1981	A Randomized, Multicenter, Open-Label Phase III Study To Evaluate The Efficacy And Safety Of Trastuzumab Emtansine Versus Trastuzumab As Adjuvant Therapy For Patients With Her2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologic	Number Agreed	2	3	Date Agreed	01/03/2016	3	01/03/2016	14	Recruitment Finished	Study recruited to time and target.
13/EE/0444	Maximizing CRT Delivery by using Multipolar Coronary Sinus Lead Acuity x4	Number Agreed	20	20	Date Agreed	31/12/2014	12	01/03/2016	12	Withdrawn By Sponsor	
13/EM/0348	Safety and Efficacy assessment of Monoprost® (unpreserved latanoprost) in comparison with Lumigan® 0.01 % and Lumigan® 0.03% UD, in patients with primary open angle glaucoma or ocular hypertension, stabilized by Lumigan® 0.01 % with ocular surface in	Number Agreed	6	6	Date Agreed	31/08/2015	4	06/01/2016	4	Recruitment Finished	Several patients were screened by the agreed date but were not eligible.
13/LO/0326	A RANDOMIZED, PHASE 3 STUDY OF GANETESPIB IN COMBINATION WITH DOCETAXEL VERSUS DOCETAXEL ALONE IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG ADENOCARCINOMA	Number Agreed	1	2	Date Agreed	30/09/2016	2	31/10/2015	2	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and Progression Free Survival in Patients receiving Deep Subcu	Number Agreed	5	5	Date Agreed	31/08/2016	7	30/07/2016	7	Withdrawn By Sponsor	Study recruited to time and target.
13/LO/1682	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rucaparib as Switch Maintenance Following Platinum-Based Chemotherapy in Patients with Platinum-Sensitive, High-Grade Serous or Endometrioid Epithelial Ovarian, Primary Peri	Number Agreed	5	5	Date Agreed	31/12/2016	2	31/03/2016	2	Recruitment Finished	A change in practice meant there were fewer potential patients than originally anticipated. Protocol required platinum sensitive patients but these were switched to maintenance Avastin treatment, so could not be recruited. A few patients were identified and screened but either declide to participate or were eventually inegible. This strict exclusion criteria was not clear in the protocol; sponsor was alerted and had to submit protocol amendment. Still we only recruited 2/5 patients.
13/NI/0188	A singlearm trial to evaluate the effectiveness of PCI of de novo 3vessel disease applying the SYNTAX score II with pressure wire functional assessment and IVUS guidance, using an everolimuseluting stent with biodegradable abluminal coating	Number Agreed	17	17	Date Agreed	31/12/2019	27	13/11/2015	27	Recruitment Finished	Study recruited to time and target.
14/EM/0186	A Randomized Controlled Phase 3 Study of Oral Pacritinib versus Best Available Therapy in Patients with Thrombocytopenia and Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis.	Number Agreed	2	2	Date Agreed	14/08/2018	0	25/02/2016	0	Withdrawn By Sponsor	Study closed early without recruitment. No patient satisfied the stringent entry criteria but meanwhile patients have had increased mortality in an arm of the study, so FDA has placed a hold on the drug/all trials and all patients on pacritinib have to come off. So we are grateful the trial did not recruit here.
14/EM/1059	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	Number Agreed	1	1	Date Agreed	30/09/2016	2	08/01/2016	2	Recruitment Finished	Study recruited to time and target.
14/EM/1060	A Phase 3 Open Label Extension Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	Number Agreed	1	1	Date Agreed	30/09/2016	2	15/04/2016	2	Recruitment Finished	Study recruited to time and target.

14/EM/1286	A Randomized, Double-Blind Study of Ruxolitinib or Placebo in Combination With Regorafenib in Subjects With Relapsed or Refractory Metastatic Colorectal Cancer	Number Agreed	3	3	Date Agreed	30/11/2016	3	29/10/2015	3	Recruitment Finished	Study recruited to time and target.
14/LO/0673	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Citrate (MLN9708) Maintenance Therapy in Patients With Multiple Myeloma Following Autologous Stem Cell Transplant	Number Agreed	7	7	Date Agreed	31/03/2018	5	03/02/2016	5	Recruitment Finished	Rare disease study so very challenging to reach target.
14/LO/1053	A Phase 3 Randomised double blind Active study Evaluating Momelotinib vs Ruxolitinib in subjects with primary Myelofibrosis (PMF) or Post-poly cythemia Vera or Post-essential Thrombocythemia Myelofibrosis (Post-PV/ET MF)	Number Agreed	2	2	Date Agreed	01/12/2017	3	24/02/2016	3	Recruitment Finished	Study recruited to time and target.
14/LO/1370	Long Term, Multicenter, Single-arm, Open-label Extension Study of the MERIT-1 Study, to Assess the Safety, Tolerability and Efficacy of Macitentan in Subjects With Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH)	Number Agreed	1	1	Date Agreed	30/11/2016	1	01/04/2016	1	Recruitment Finished	Study recruited to time and target.
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	Withdrawn By Sponsor	None of the study sites in the UK recruited patients due to difficulty in finding eligible patients.
14/NE/1109	Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee)	Number Agreed	5	5	Date Agreed	01/01/2017	1	25/01/2016	1	Withdrawn By Sponsor	Sponsor delays with contracting process. Therefore, the time to recruit patients was shortened and we were not able to meet the recruitment target.
14/NW/0130	A randomised, double blind, multi-center, placebo-controlled study to evaluate the efficacy, safety, and tolerability of NT100 in pregnant women with a history of unexplained recurrent pregnancy loss (RPL)	Number Agreed	20	20	Date Agreed	01/06/2015	21	02/10/2015	21	Recruitment Finished	Study recruited to time and target.
14/NW/0156	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	Number Agreed	1	1	Date Agreed	31/10/2015	1	31/10/2015	1	Recruitment Finished	Study recruited to time and target.
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.
14/SC/0033	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	Number Agreed	5	5	Date Agreed	07/07/2016	13	26/01/2016	13	Recruitment Finished	Study recruited to time and target.
14/SC/1014	A Randomized, DoubleBlind, Phase 3 Study of the JAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to FirstLine Chemothera	Number Agreed	2	2	Date Agreed	26/01/2016	2	08/01/2016	4	Recruitment Finished	Study recruited to time and target.
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		0	14/09/2016	0	Withdrawn By Sponsor	Sponsor withdrew study. There were long delays setting up PIC sites therefore no patients wererereferred to our site.
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 NonSmall Cell Lung Cancer (NSCLC)	Number Agreed	6	6	Date Agreed	31/03/2016	6	12/02/2016	6	Recruitment Finished	Study recruited to time and target.
14/WM/0170	A Phase 3, Randomized Study To Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, or Post-essential Thrombocythemia Myelofibrosis	Number Agreed	2	2	Date Agreed	01/10/2020	3	14/01/2016	3	Recruitment Finished	Study recruited to time and target.
14/WM/1202	A Phase 1b, Randomized, Double-Blind (Sponsor Open), Placebo-Controlled Study To Evaluate The Safety, Tolerability, Pharmacokinetics, And Pharmacodynamics Of Pf-04447943, Co-Administered With And Without Hydroxyurea, In Subjects With Stable Sickle Ce	Number Agreed	5	5	Not Available / Not Agreed		1	31/05/2016	1	Withdrawn By Sponsor	Rare disease study so very challenging to reach target.

14/YH/1234	A phase III, doubleblind, randomised study to assess the efficacy and safety of AZD9291 versus a standard of care Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor as firstline treatment in patients with Epidermal Growth Factor Receptor Muta	Number Agreed	1	2	Date Agreed	28/02/2016	0	28/02/2016	0	Withdrawn By Sponsor	Initial sponsor delays with activation of site, and subsequently more delays in sending imaging equipment and giving site access to IWRS system necessary for recruitment into the study.
15/EM/0487	A Randomized, Open-Label, Active-Controlled, Multicenter Study to Compare Efficacy and Safety of ABT-493/ABT-530 to Sofosbuvir Co-Administered with Daclatasvir in Adults with Chronic Hepatitis C Virus Genotype 3 Infection (ENDURANCE-3)	Number Agreed	4	4	Date Agreed	30/04/2016	8	27/04/2016	8	Recruitment Finished	Study recruited to time and target.
15/ES/0184	A Phase 3, Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks in Direct-Acting Antiviral-Experienced Subjects with Chron	Range Agreed	3	5	Date Agreed	01/05/2016	2	25/03/2016	2	Recruitment Finished	
15/ES/0185	A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS9857 Fixed-Dose Combination for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Naïve S	Number Agreed	7	7	Date Agreed	30/04/2016	3	18/03/2016	3	Recruitment Finished	
15/ES/0192	A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Experienced S	Number Agreed	3	3	Date Agreed	30/04/2016	3	25/03/2016	3	Recruitment Finished	Study recruited to time and target.
15/LO/0016	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoreg	Number Agreed	3	3	Not Available / Not Agreed		0	20/10/2015	0	Withdrawn By Sponsor	Sponsor delays with providing lab kit to be used in patients so site activation was late (11 Aug 2015). A patient was eligible but declined to take part. Furthermore, the recruitment closed early nationally by sponsor as they achieved their global target sooner than anticipated.
15/LO/0140	CLEANER Assessment of efficacy and safety for a new wound dressing URGO 310 3166 in the local treatment of venous or mixed leg ulcers: a European, randomised clinical trial.	Number Agreed	4	4	Date Agreed	31/08/2016	4	31/05/2016	4	Withdrawn By Sponsor	Study recruited to time and target.
15/LO/0273	A Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study Evaluating Safety and Efficacy of the Addition of Veliparib Plus Carboplatin Versus the Addition of Carboplatin to Standard Neoadjuvant Chemotherapy Versus Standard Neoadjuvant Chemother	Number Agreed	2	3	Not Available / Not Agreed		0	15/12/2015	0	Withdrawn By Sponsor	Rare disease study so very challenging to reach target.
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/LO/0881	A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects	Number Agreed	5	5	Date Agreed	31/01/2016	0	08/01/2016	0	Withdrawn By Sponsor	Sponsor closed study early - just 2 weeks after site gained R&D approval. Recruitment was open during these two weeks but no eligible patients were seen.
15/LO/0940	A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Obinutuzumab Compared to Chlorambucil in Combination with Obinutuzumab for Previously Untreated Chronic Lymphocytic Leukemia	Number Agreed	4	4	Not Available / Not Agreed		0	14/03/2016	0	Withdrawn By Sponsor	Study terminated early by sponsor due to a change in the risk profile of the study drug idelalisib. The study was terminated for safety reasons.
15/LO/1228	An Open-Label Study to Evaluate the Safety and Efficacy of Ombitasvir/Paritaprevir/Ritonavir with or without Dasabuvir in Adults with Genotype 1a or Genotype 4 Chronic Hepatitis C Virus (HCV) Infection, with Severe Renal Impairment or End-Stage Renal	Number Agreed	4	4	Date Agreed	30/06/2016	2	29/02/2016	2	Recruitment Finished	Several patients were screened by the agreed date but were not eligible.
15/NW/0700	M13-583 A Single-Arm, Open-Label Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 4, 5, or 6 Infection (ENDURANCE-4)	Range Agreed	2	3	Date Agreed	31/03/2016	3	31/03/2016	3	Recruitment Finished	Study recruited to time and target.

15/NW/0871	A Single-Arm, Open-Label, Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Renally-Impaired Adults with Chronic Hepatitis C Virus Genotype 1 – 6 Infection (EXPEDITION-4)	Number Agreed	4	4	Date Agreed	31/03/2016	4	31/03/2016	4	Recruitment Finished	Study recruited to time and target.
15/SS/0186	A phase II randomized open-label clinical trial to study the efficacy and safety of the combination regimen of Grazoprevir/Elbasvir (GZR/EBR) and Sofosbuvir (SOF) with and without Ribavirin ® in cirrhotic subjects with chronic HCV GT3 infection	Number Agreed	6	6	Date Agreed	28/02/2016	7	12/02/2016	7	Recruitment Finished	Study recruited to time and target.
15/WM/0009	A Phase 3, Randomised, Controlled, Openlabel Study of VELCADE (Bortezomib MelphalanPrednisone ?	Number Agreed	5	5	Date Agreed	01/11/2021	1	13/05/2016	1	Withdrawn By Sponsor	Rare disease study so very challenging to reach target.
15/WS/0037	A single-arm, post-market study of the Endo GI Reinforced Reload with Tri-Staple Technology	Number Agreed	30	30	Date Agreed	01/05/2016	28	31/03/2016	32	Recruitment Finished	
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	
16/LO/0029	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults	Number Agreed	5	5	Date Agreed	30/06/2016	0	09/06/2016	0	Withdrawn By Sponsor	Sponsor closed study early.