

# PID Q1 18-19 (Performance Delivery)

Research Ethics Committee Reference Number	Integrated Research Application System 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
17/YH/0345	233852	A phase 3, randomised, multicentre study of subcutaneous vs intravenous administration of daratumumab in subjects with relapsed or refractory multiple myeloma	Number Agreed	5	5	Date Agreed	01/10/2020	3	20/06/2018	0	Recruitment Finished
17/SC/0242	222650	Phase 2A, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Intravenous FDY-5301 in Acute Myocardial Infarction (Protocol No. FDY-5301-201)	Number Agreed	4	4	Date Agreed	30/06/2018	12	30/06/2018	3	Recruitment Finished
14/NW/0001	138498	A Phase 3b Continuation study of the Safety and Efficacy of PEGylated Recombinant Factor VIII (PEG-rFVIII; BAX 855) in Prophylaxis of Bleeding in Previously Treated Patients with Severe Hemophilia A	Number Agreed	1	1	Date Agreed	30/09/2017	1	27/06/2018	12	Recruitment Finished
17/SC/0294	224828	Title: A Phase III Randomised Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Neoadjuvant Anthracycline/Nab-paclitaxel Based Chemotherapy Compared with Placebo and Chemotherapy in Patients with P	Number Agreed	3	3	Date Agreed	01/09/2018	1	12/06/2018	1	Recruitment Finished
17/LO/0065	219950	A randomized, double-blind, placebo-controlled, phase III study comparing the combination of PDR001, dabrafenib and trametinib versus placebo, dabrafenib and trametinib in previously untreated patients with unresectable or metastatic BRAF V600 mutant	Number Agreed	3	3	Date Agreed	21/12/2020	2	07/06/2018	1	Recruitment Finished
17/SC/0201	209172	IP Rollover Study (XRuST): An Open-Label, Rollover Study	Number Agreed	1	1	Date Agreed	01/09/2023	0	24/05/2018	2	Recruitment Finished
16/NW/0086	198831	A Phase 1, Single-Agent, Dose-Escalation, Pharmacokinetic (PK)-Pharmacodynamic (PD) Study of Avelumab in Patients with Advanced or Refractory Classical Hodgkin Lymphoma	Number Agreed	2	2	Date Agreed	30/03/2018	3	09/05/2018	0	Recruitment Finished

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17/EM/0055	222279	A Randomized, Double-Blind, Placebo controlled, Parallel Group Study of Patiromer for the Enablement of Spironolactone Use for Blood Pressure Control in Patients with Resistant Hypertension and Chronic Kidney Disease: Evaluation of Safety and Efficac	Number Agreed	3	3	Date Agreed	04/05/2018	1	04/05/2018	3	Recruitment Finished
17/NE/0115	218417	Phase II study of Pirfenidone vs placebo in patients with fibrotic ILD that cannot be classified with moderate or high confidence into any other category of fibrotic IP by Multidisciplinary Team (MDT) review (?unclassifiable? ILD).	Number Agreed	2	2	Date Agreed	14/04/2019	2	26/04/2018	1	Recruitment Finished
17/EM/0275	227425	A Multi-center, Double-blind, Randomized, Three-Arm, Parallel-Group, Placebo Controlled Study to Assess the Efficacy and Safety of NTRA-2112 on Intestinal Malabsorption in Preterm Infants	Number Agreed	5	5	Date Agreed	31/12/2020	5	25/04/2018	2	Recruitment Finished
14/LO/1486	159398	A Phase 1b/2, Multicenter, Open-label Trial of Talimogene Laherparepvec in Combination with MK-3475 for Treatment of Previously Untreated, Unresected, Stage IIIB to IVM1c Melanoma (MASTERKEY-265)	Number Agreed	5	5	Date Agreed	10/04/2019	2	30/03/2018	5	Recruitment Finished
13/NW/0003	117310	A randomized, double blind, placebo controlled phase 3 study to assess the safety and efficacy of art-123 in subjects with severe sepsis and coagulopathy (protocol number 3-001)	Number Agreed	6	6	Date Agreed	31/05/2016	0	08/03/2018	2	Recruitment Finished
17/EM/0190	219055	A Phase 3b, Randomized, Active Comparator, Open-label, Multicenter Study to Compare the Efficacy, Safety, and Tolerability of ITCA 650 to Empagliflozin and to Glimepiride as Add-on Therapy to Metformin in Patients with Type 2 Diabetes	Number Agreed	10	10	Date Agreed	11/10/2019	0	04/03/2018	0	Recruitment Finished
15/EM/0179	177000	Understanding Outcomes with the EMBLEMT S-ICD in Primary Prevention Patients with Low Ejection Fraction	Number Agreed	15	15	Date Agreed	30/05/2018	7	28/02/2018	0	Recruitment Finished

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17/SC/0016	218645	A Phase III, Randomized, Open Label Trial of Nivolumab in combination with Ipilimumab versus Pemetrexed with Cisplatin or Carboplatin as First Line Therapy in unresectable Pleural Mesothelioma	Number Agreed	6	6	Date Agreed	28/02/2019	8	22/02/2018	7	Recruitment Finished
17/LO/0504	224298	An open-label, single arm, repeat dose, multi-centre study to evaluate the use of an autoinjector for the subcutaneous administration of mepolizumab in subjects with severe eosinophilic asthma	Number Agreed	2	2	Date Agreed	07/02/2018	2	07/02/2018	8	Recruitment Finished
16/LO/0595	198560	monarcHER: A Phase 2, Randomized, Multicenter, 3-Arm, Open-Label Study to Compare the Efficacy of Abemaciclib plus Trastuzumab with or without Fulvestrant to Standard-of-Care Chemotherapy of Physician's Choice plus Trastuzumab in Women with HR+, HER2	Number Agreed	2	2	Date Agreed	30/06/2018	2	01/02/2018	2	Recruitment Finished
13/LO/0867	126972	1199.93 - 1199.93 LUME-Meso Double blind, randomised, multicentre, phase II/III study of nintedanib in combination with pemetrexed / cisplatin followed by continuing nintedanib monotherapy versus placebo in combination with pemetrexed / cisplatin fol	Number Agreed	5	5	Date Agreed	31/07/2018	10	08/01/2018	2	Recruitment Finished
16/WM/0512	218042	A Phase 1, open-label, randomised, repeat dose parallel group study to evaluate the pharmacokinetics, safety and tolerability of ferric maltol at three dosage levels in paediatric subjects (aged 10-17) with iron deficiency (with or without Anaemia)	Number Agreed	3	3	Date Agreed	31/12/2017	6	31/12/2017	10	Recruitment Finished

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15/YH/0535	190077	A multicenter, randomized, open label, parallel group study comparing pre-discharge and post-discharge treatment initiation with LCZ696 in heart failure patients with reduced ejection-fraction hospitalized for an acute decompensation event (ADHF) (th	Number Agreed	5	5	Date Agreed	27/05/2018	3	08/12/2017	6	Recruitment Finished
15/LO/2100	192155	RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY EVALUATING TAS-102 PLUS	Number Agreed	4	4	Date Agreed	30/11/2017	3	30/11/2017	3	Recruitment Finished
16/YH/0074	199143	Evaluation of a Multi-Electrode Linear Type Catheter (D-1368-01-SI) for Endocardial Ablation of Patients with Persistent Atrial Fibrillation.	Number Agreed	8	8	Date Agreed	31/12/2017	7	29/11/2017	3	Recruitment Finished
16/LO/1386	199366	A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Cardiac and Renal Effects of Short Term Treatment with Elamipretide in Patients Hospitalized with Congestion due to Heart Failure	Number Agreed	6	6	Date Agreed	27/12/2017	1	17/11/2017	7	Recruitment Finished
16/EE/0372	212494	DETECTION OF METHACHOLINE CHALLENGE INDUCED ASTHMA SYMPTOMS USING A NOVEL DEVICE.	Number Agreed	20	20	Date Agreed	13/11/2017	20	13/11/2017	1	Recruitment Finished
15/LO/1681	185104	A double blind, randomized, placebo-controlled trial evaluating efficacy and safety of oral nintedanib, 150 mg twice daily for 52 weeks (with follow up until last patient out up to a maximum of 2 years) in patients with Systemic Sclerosis associated	Number Agreed	1	1	Date Agreed	19/01/2018	0	31/10/2017	20	Recruitment Finished
15/LO/0545	172357	Clinical and device functional assessment of real world ICD patients - RTSY03	Number Agreed	10	10	Date Agreed	31/10/2017	11	31/10/2017	0	Recruitment Finished
16/LO/1717	212505	A Randomized, Multicenter, Open-Label, Phase 3 Study of Acabrutinib (ACP-196) Versus Investigator's Choice of Either Idelalisib Plus Rituximab or Bendamustine Plus Rituximab in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia	Number Agreed	3	3	Date Agreed	31/12/2020	0	25/10/2017	11	Recruitment Finished

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16/EE/0463	214371	An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and postmenopausal women with hormone receptor-positive (HR+) HER2-negative (HER2-) advanced	Number Agreed	5	5	Date Agreed	16/10/2017	2	16/10/2017	0	Recruitment Finished
16/EM/0007	190428	Global multicenter, open-label, randomized, event-driven, active-controlled study comparing a rivAroxaban-based	Number Agreed	12	12	Date Agreed	30/09/2017	4	02/10/2017	2	Recruitment Finished
17/EM/0014	219556	Prospective Clinical Investigation for a Randomized, Controlled, Multicenter Non-inferiority Study Comparing Standard Wound Closure Technique with Drains (control) to Standard Wound Closure Techniques with TissuGlu? and No Drains (test) in Mastectomy	Number Agreed	15	15	Date Agreed	31/12/2017	10	30/09/2017	4	Recruitment Finished
14/WS/1146	166537	Multicenter, randomized, double-blind, double-dummy, active-comparator, event-driven, superiority phase III study of secondary prevention of stroke and prevention of systemic embolism in patients with a recent Embolic Stroke of Undetermined Source (E	Number Agreed	10	10	Date Agreed	30/09/2017	7	20/09/2017	10	Recruitment Finished
15/SC/0700	192904	Clinical Study Protocol M13-549A Phase 3, randomized, double-blind study comparing ABT-494 to placebo in subjects with moderately to severely active rheumatoid arthritis who are on a stable dose of conventional synthetic disease-modifying anti-rheum	Number Agreed	4	4	Date Agreed	21/12/2017	0	12/09/2017	7	Recruitment Finished
15/SC/0475	174852	An Open-Label, Randomized Phase 3 Trial of Nivolumab and Nivolumab plus Ipilimumab versus Platinum Doublet Chemotherapy in Patients with Chemotherapy-Na?ve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)	Number Agreed	5	5	Date Agreed	30/11/2016	15	06/09/2017	0	Recruitment Finished

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16/WM/0215	203334	An Assessment of Humacyte's Human Acellular Vessel in Patients Needing Renal Replacement Therapy: A comparison with ePTFE grafts as conduits for Hemodialysis	Number Agreed	10	10	Date Agreed	02/09/2022	5	31/08/2017	15	Recruitment Finished
16/LO/1940	213099	AN OPEN LABEL, SINGLE ARM, MULTICENTER, SAFETY STUDY OF ATEZOLIZUMAB IN LOCALLY ADVANCED OR METASTATIC UROTHELIAL OR NON-UROTHELIAL CARCINOMA OF THE URINARY TRACT	Number Agreed	5	5	Date Agreed	29/08/2017	9	29/08/2017	5	Recruitment Finished
16/YH/0113	198679	Phase 2 Study of the Efficacy and Safety of ACP-196 in Subjects with Relapsed/Refractory CLL and Intolerant of Ibrutinib Therapy: ACE-CL-208	Number Agreed	2	2	Date Agreed	21/08/2017	0	21/08/2017	9	Recruitment Finished
14/SC/1161	155743	Prospective, single-arm, multi-centre, observational registry to further validate safety and efficacy of the ultimaster DES in real-world patients.	Number Agreed	100	100	Date Agreed	31/05/2018	100	10/08/2017	0	Recruitment Finished
15/WA/0465	189501	Expanding MRI Access for Patients with New and Existing ICDS and CRT-Ds	Number Agreed	10	10	Date Agreed	10/08/2017	10	10/08/2017	100	Recruitment Finished
14/WM/1050	158411	A Placebo Controlled, Double-blind, Multi-centre, Repeat Dose, Parallel Group, Randomised Clinical Trial of GSK2862277 in Patients undergoing Oesophagectomy Surgery	Not Available / Not Agreed			Not Available / Not Agreed		0	09/08/2017	10	Recruitment Finished
16/EM/0165	203281	A Phase 3 Multicenter Open-label Study of Brigatinib (AP26113) versus Crizotinib in Patients with ALK-positive Advanced Lung Cancer	Number Agreed	9	9	Date Agreed	28/07/2017	4	28/07/2017	0	Recruitment Finished
13/NE/0005	100377	Product Surveillance Registry A prospective, noninterventional registry providing continuing evaluation and periodic reporting of product safety, effectiveness and patient outcomes across Medtronic market released products within diabetes, cardia	Number Agreed	5	5	Date Agreed	01/02/2018	3	03/07/2017	4	Recruitment Finished

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15/WA/0465	189501	Expanding MRI Access for Patients with New and Existing ICDs and CRT-Ds	Number Agreed	10	10	Date Agreed	10/08/2017	10	10/08/2017	10	Recruitment Finished