Performance in Initiating

REC Ref	IRAS ID	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start	Date of First Patient Recruited	Comments	Reasons for delay(s) corresponds to:
18/SC/0412	250170	Pembro/Placebo+Trastuzumab+Chemo in HER2+ Metastatic Gastric/GEJ	16/03/2018	08/08/2018	30/01/2019	16/10/2018	21/01/2019		06/02/2019		DSS-DSC delayed due to staff workload meaning that local review has not been completed in time.	NHS Provider
18/SW/0130	246372	Prospective Evaluation of Thin-strut Biodegradable Polymer-coated Supraflex Sirolimus-Eluting Stents in an All-comers Patient Population (S-FLEX UK-II)	15/06/2018	06/07/2018	29/06/2018	06/08/2018					DSC-FPR exceeded 30 days as sponsor has not confirmed green light to start recruiting. Sponsor is awaiting amendment approval for an updated stent to be used.	Sponsor
17/NW/0634	209375	Randomised Phase II Trial of Cediranib and Olaparib Maintenance in Advanced/Recurrent Cervical Cancer (COMICE)	22/11/2017	06/08/2018	16/01/2018	07/08/2018	15/08/2018		26/09/2018	09/10/2018	Delays with sponsor providing the green light for study recruitment due to staff resourcing issues, therefore DSC-FPR could not be met.	Sponsor
18/LO/0612	235872	CLEAR SYNERGY (OASIS 9): A 2x2 factorial randomized controlled trial of CoLchicine and spironolactonE in patients with ST elevation myocARdial infarction/SYNERGY Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9	09/08/2017	09/08/2018	16/07/2018	20/08/2018	28/08/2018		25/10/2018	17/01/2019	DSC-FPR metric not met as site is awaiting green light confirmation from Sponsor. Delay from sponsor is due to pending HRA approval for an amendment.	Neither
18/SW/0039	229163	Induction of labour for predicted macrosomia	15/06/2018	07/09/2018	20/03/2019	08/11/2018	15/11/2018			11/03/2019	Both 40 and 30 day targets were missed due to contracting delays and an error in the Statement of Activites, meaning that an amendment was required to be submitted.	Sponsor
18/SC/0024	219560	Should the nail place be replaced or discarded after nail bed repair in children?	09/08/2018	25/09/2018	20/02/2018	26/09/2018	01/10/2018			14/10/2018		
16/EE/0294	199550	ComparIsoN oF Optimal Hypertension RegiMens (Part of the Ancestry Informative Markers in Hypertension (AIM HY) Programme – AIM HY-INFORM)	10/08/2018	21/09/2018	04/11/2018	15/11/2018	23/11/2018			22/02/2019	DSS-DSC metric exceeded 40 days as study did not receive HRA approval until 04/11/2018. Contract was therefore not signed by the sponsor until 15/11/2018. DSC-FPR has exceeded 30 days due to a lack of eligible patients being seen.	Both

18/LO/1187	240011	ATHENA (A Multicenter, Randomized, Double-Blind, Placebo Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy)	09/04/2018	22/09/2018	11/09/2018	25/02/2019	12/03/2019		26/03/2019	26/03/2019	Due to the study screening timelines, DSC-FPR has exceeded 30 days.	Neither
18/NW/0430	233866	APPLE trial: Feasibility and activity of AZD9291 (osimertinib) treatment on Positive PLasma T790M in EGFR mutant NSCLC patients.	14/08/2018	14/08/2018							DSS-DSC 40 day metric has not been met as site local review has not been completed in time.	NHS Provider
17/SC/0253	226685	MonarchE: Protocol I3Y-MC-JPCF A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer	17/09/2018	17/09/2018	05/07/2018	24/09/2018	19/10/2018		27/11/2018	14/12/2018	DSC-FPR metric missed as green light was not given by the sponsor until 27/11/2018.	Sponsor
18/LO/0071	229507	Adjuvant treatment for high-risk triple negative breast cancer patients with the anti-pd-l1 antibody Avelumab: A phase III randomized trial	29/05/2018	10/08/2018	03/04/2018	24/10/2018	27/11/2018		08/01/2019		DSS-DSC has exceeded 40 days as site listed incorrectly as Hillingdon Hospital and local review has not been completed. Awaiting for an amendment to be submitted by the sponsor.	Both
18/LO/1172	245733	A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study Comparing CB-839 in Combination with Cabozantinib (CB-Cabo) vs. Placebo with Cabozantinib (Pbo-Cabo) in Patients with Advanced or Metastatic Renal Cell Carcinoma (RCC)	20/04/2018	28/08/2018	13/08/2018	05/09/2018	05/09/2018		26/09/2018	17/12/2018	DSC-FPR metric exceeded 30 days due to a lack of eligible patients seen on site.	NHS Provider

18/YH/0215	242715	A Randomized, Placebo-controlled Phase 2b Study to Evaluate the Safety and Efficacy of MEDI6012 in Acute ST Elevation Myocardial Infarction	17/05/2018	07/11/2018	08/08/2018	15/11/2018	19/11/2018		08/02/2019	12/03/2019	DSC-FPR missed due to delays with the sponsor providing the green light for recruitment. These delays are due to the site team not yet providing necessary radiology documents.	NHS Provider
17/YH/0120	208838	"A pragmatic multi-centre randomised controlled non-inferiority, cost effectiveness trial comparing injections of collagenase into the cord to surgical correction in the treatment of moderate Dupuytren's Contracture in adult patients."	23/03/2018	03/10/2018	25/05/2017	21/11/2018	27/11/2018		12/12/2018	19/12/2018	Due to delays in contract signature, the DSS-DSC metric has exceeded 40 days.	Both
17/LO/0887	226610	Weaning from mechanical ventilation: comparison of open-loop decision support system and routine care, in general medical ICU.	26/10/2018	05/11/2018	11/09/2017						DSS-DSC and DSC-FPR metrics missed due to staff availability causing a delay in internal feasibility assessments, therefore C&C cannot be issued.	NHS Provider
18/SC/0429	247545	A Randomized, Open-label, Phase II Clinical Trial of Relatlimab (anti-LAG-3) plus Nivolumab in Combination with Chemotherapy Versus Nivolumab in Combination with Chemotherapy as First-Line Treatment in Patients with Gastric or Gastroesophageal Junction Adenocarcinoma	11/10/2018	15/10/2018	22/11/2018	07/02/2019	27/02/2019		06/03/2019	26/03/2019	HRA approval has not yet been issued for this study, meaning that both DSS-DSC and DSC-FPR metrics are unable to be met.	Neither
18/NW/0514	249725	SELECT - Semaglutide effects on cardiovascular outcomes in people with overweight or obesity	14/06/2018	31/07/2018	03/01/2019	09/01/2019	23/01/2019		27/02/2019	16/04/2019	HRA approval was not issued until 07/01/2019, and the full HRA pack was not received on site until 11/01/2019. This therefore means that both 30 and 40 day metrics were unable to be met.	Neither
17/YH/0163	223768	IMPROVING GLUCOSE CONTROL IN PATIENTS WITH DIABETES FOLLOWING MYOCARDIAL INFARCTION: THE ROLE OF A NOVEL GLYCAEMIA MONITORING STRATEGY	01/11/2018	01/11/2018	04/07/2017	05/02/2019	22/02/2019		12/03/2019	11/04/2019	DSS-DSC delayed as the negotiation of site recruitment target between the NHS Site and Sponsor is currently delaying contract execution.	Both

19/WA/0005	246081	ATLANTA - Adjuvant Treatments to the Local tumour for metastatic prostate cancer: Assessment of Novel Treatment Algorithms	16/12/2018	18/12/2018								
18/SC/0243	240684	HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease	09/10/2018	09/10/2018	01/10/2018	12/03/2019	25/03/2019		23/04/2019	10/05/2019	Both DSS-DSC and DSC-FPR metrics missed as contract negotiations are still underway between the NHS site and the Sponsor.	Both
18/NI/0224	256190	A Phase II Randomized, Multi-Center, Double-Blind, Global Study to Determine the Efficacy and Safety of Durvalumab plus Olaparib Combination Therapy Compared with Durvalumab Monotherapy as Maintenance Therapy in Patients whose Disease has not Progressed Following Standard of Care Platinum-Based Chemotherapy with Durvalumab in First Line Stage IV Non Small Cell Lung Cancer (ORION)	29/11/2018	29/11/2018							Due to a lack of staff availability, both DSS-DSC and DSC-FPR have exceeded their 40 and 30 day targets.	NHS Provider
18/LO/0997	216343	Brain Imaging to predict Toxicity in Elderly patients after Radiotherapy	21/09/2018	18/12/2018	28/06/2018	18/12/2018	09/05/2019		17/05/2019	04/06/2019		
18/SC/0525	238638	A Phase II, Open Label, Randomised Study of Ipilimumab With Temozolomide Versus Temozolomide Alone after Surgery and Chemoradiotherapy in Patients with Recently Diagnosed Glioblastoma (IPI-GLIO)	15/06/2018	19/11/2018	05/11/2018	21/11/2018	30/11/2018		21/12/2018	22/01/2019	DSC-FPR exceeded 40 days due to no eligible patients being seen.	NHS Provider

18/LO/1843	232910	A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL STUDY COMPARING ATEZOLIZUMAB (ANTIPD-L1 ANTIBODY) IN COMBINATION WITH ADJUVANT ANTHRACYCLINE/TAXANE-BASED CHEMOTHERAPY VERSUS CHEMOTHERAPY ALONE IN PATIENTS WITH OPERABLE TRIPLE NEGATIVE BREAST CANCER	28/11/2017	13/12/2018	23/01/2019						Both DSS-DSC and DSC-FPR have been delayed due to staff availability issues.	NHS Provider
18/LO/0165	224726	A velumab plus fluoropyrimidine-based chemotherapy as adjuvant treatment for stage III dMMR or POLE exonuclease domain mutant colon cancer: A phase III randomised study.	01/05/2018	05/10/2018	09/05/2019						Both DSS-DSC and DSC-FPR metrics were unable to be met due to staff availability and workload, meaning there was reduced capacity to get the trial open within the target timeframe.	NHS Provider
18/SC/0305	246109	A randomized, open-label, phase II open platform study evaluting the efficacy and safety of novel Spartalizumab (PDR001) combinations in previously treated unresected or metastatic melanoma	22/06/2018	01/11/2018	19/10/2018	29/11/2018	05/12/2018		20/12/2018	12/03/2019	DSC -FPR has exceeded 30 days as no eligible patients have been seen.	NHS Provider
18/NI/0204	247205	A RANDOMIZED, OPEN-LABEL, MULTICENTER, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AVELUMAB IN COMBINATION WITH CHEMOTHERAPY FOLLOWED BY MAINTENANCE THERAPY OF AVELUMAB IN COMBINATION WITH THE POLY (ADENOSINE DIPHOSPHATE [ADP]-RIBOSE) POLYMERASE (PARP) INHIBITOR TALAZOPARIB IN PATIENTS WITH PREVIOUSLY UNTREATED ADVANCED OVARIAN CANCER	21/03/2018	04/01/2019							DSS-DSC and DSC-FPR were unable to be met as the study has been abandoned by the sponsor.	Sponsor

18/LO/2067	253346	A Phase 2 Study of INCMGA00012 in Participants With Squamous Carcinoma of the Anal Canal Who Have Progressed Following Platinum-Based Chemotherapy	08/10/2018	16/01/2019	07/01/2019	11/04/2019	08/05/2019		05/06/2019		Both DSS-DSC and DSC-PFR metrics were unable to be met as there have been delays in contracting due to staff availability.	NHS Provider
18/NE/0223	249460	A prospective, single arm, multi-center, open-label, non-randomized trial to further evaluate the safety of 1 month (as short as 28 days) DAPT in HBR subjects undergoing PCI with XIENCE	20/11/2018	01/01/2019	26/09/2018	21/12/2018	05/02/2019		11/03/2019		The DSC-FPR 30 day target could not be met as the sponsor did not provide the green light to recruitment until 11/03/2019.	Sponsor
18/LO/0368	235386	NICO - CA209-891: Neoadjuvant and adjuvant nivolumab as Immune Checkpoint inhibition in Oral cavity cancer	08/03/2019	08/03/2019	18/05/2018							
19/NW/0046	227794	A parallel arm, biomaker driven, phase II feasiblity trial to determine the role of circulating tumour DNA in guiding a switch beetween targeted therapy and immune therapy in patients with advanced cutaneous melanoma	16/01/2019	25/02/2019	26/03/2019						Due to a lack of staff availability, both DSS-DSC and DSC-FPR have exceeded 40 and 30 days.	NHS Provider
19/LO/0123	258406	A single arm, open-label, multicentre Phase 2 study of regorafenib in participants who have been treated in a previous Bayer-sponsored regorafenib study (monotherapy or combined treatment) that has reached the primary completion endpoint or the main data anaylsis, or has been stopped prematurely.	16/01/2019	16/01/2019	22/02/2019	05/03/2019	07/03/2019		25/03/2019		Staff shortages and sickness has led to a delay in meeting the 40 day DSS-DSC target.	NHS Provider
19/SC/0172	256280	Elacestrant Monotherapy vs Standard of Care for the Treatment of Patients with ER+/HER2- Advanced Breast Cancer Following CDK4/6 inhibitor Therapy: A Phase 3 Randomised, Open-Label, Active Controlled, Multicentre Trial (EMERALD)	29/01/2019	18/03/2019	07/06/2019						DSS-DSC and DSC-FPR targets could not be met as the study did not receive HRA approval until 07/06/2019.	Neither

19/WM/0039	257987	FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease.	15/03/2019	15/03/2019	01/04/2019							
18/LO/1022	233151	An open-label, randomised, phase II trial of rucaparib combined with nivolumab +/- Ipilimumab to augment response in homologous repair deficient patients with relapsed Ovarian, primary peritoneal and fallopian tube cancer.	13/12/2018	30/01/2019	14/05/2019	14/05/2019	22/05/2019		24/05/2019	31/05/2019	DSS-DSC has exceeded 40 days as HRA approval is outstanding pending a study amendment.	Neither
17/EM/0372	233151	A Phase 2, Randomized, Open-Label Study of Nivolumab Combined with Ipilimumab Versus Sunitinib Monotherapy in Subjects with Previously Untreated and Advanced (unresectable or metastatic) non-clear Cell Renal Cell Carcinoma	03/11/2016	09/01/2019	04/05/2019						Both DSS-DSC and DSC-FPR metrics have exceeded their targets due to sponsor delays with the wording of the contract and providing the required documentation as requested by R&D, therefore delaying the issuing of C&C.	Sponsor
19/SW/0041	260477	A Phase 3, multicenter, randomized, open-label trial to compare the efficacy and safety of pemrbolizumab (MK-3475) in combination with lenvatinib (E7080/MK-7902) versus docetaxel in previously treated participants with metastatic non-small cell lung cancer (NSCLC) and progressive disease (PD) after platinum doublet chemotherapy and immunotherapy (anti-PD-1/PD-L1 inhibitor) (LEAP-008)	01/01/2019	05/03/2019	02/04/2019						DSS-DSC and DSC-FPR have exceeded 40 and 30 days due to a lack of staff availability causing a delay in finalising the contract.	NHS Provider
19/EE/0130	252786	A Randomised, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Efficacy and Safety of Tislelizumab (BGB-A317) in Combination with Chemotherapy as First-Line Treatment in Patients with Unresectable, Locally Advanced Recurrent or Metastatic Oesophageal Squamous Cell Carcinoma	16/08/2018	27/03/2019	03/06/2019						The DSS-DSC metric has exceeded 40 days as HRA approval for the study was not received unitl 03/06/2019.	Neither

19/NE/0022	254999	A Phase 3, Intravenous Sodium Thiosulfate for Acute Calciphylaxis Treatment: A Multicenter, Randomized, Double-blind, Placebo-controlled Clinical Trial	15/03/2019	04/04/2019	20/04/2019						Trial specific equipment is required to be checked by the NHS site EBME department prior to use. As equipment approval is still outstanding, both 40 and 30 day metrics could not be met.	NHS Provider
19/WA/0103	246243	Combination of targeted therapy (encorafenib and binimetinib) followed by combination of immunotherapy (ipilimumab and nivolumab) vs immediate combination of immunotherapy in patients with unresectable or metastatic melanoma with BRAF V600 mutation: an EORTC randomized phase II study (EBIN)	13/12/2018	02/05/2019	24/05/2019						DSS-DSC has exceeded 40 days due to staff availability issues.	NHS Provider
19/LO/0452	250324	Randomised factorial design controlled trial comparing carbazmazepine, levetiracetam or active monitoring combined with or without sleep behaviour intervention in treatment naïve children with rolandic epilepsy	18/10/2018	18/04/2019	02/05/2019						Due to limited staff availability, the 40 day target for DSS-DSC was unable to be met.	NHS Provider
19/LO/1024	263894	A Phase 3, Randomized, Placebo-Controlled Clinical Study to Evaluate the Safety and Efficacy of Stereotactic Body Radiotherapy (SBRT) with or without Pembrolizumab (MK-3475) in Participants with Medically Inoperable Stages I or IIA Non Small Cell Lung Cancer (NSCLC) (KEYNOTE-867)	14/03/2019	07/06/2019								
18/YH/0329	236786	A phase II study of pembrolizumab in patients with advanced gynaecological clear cell cancer	19/09/2018	09/04/2019	16/10/2018						Both 40 and 30 days metrics are unable to be met due to ongoing costing negotiations between the site and sponsor.	Neither
17/EE/0368	213669	STRESS-L: Study into the Reversal of Septic Shock with Landiolol (Beta Blockade)	29/04/2019	01/05/2019	10/11/2017						We have been unable to set up this study within 40 days due to limited staff capacity.	NHS Provider
18/LO/1470	235545	PERSONALISED CARE FOR PEOPLE WITH PARKINSON'S DISEASE	29/04/2019	13/05/2019	31/10/2018	12/06/2019	12/06/2019		17/06/2019			

19/EE/0168	262098	A Phase 3, Randomized, Double-blind Study to Compare the Efficacy and Safety of Pembrolizumab and Placebo as First Line Treatment for Locally Advanced or Metastatic Urothelial Carcinoma in Cisplatin-ineligible Participants Whose Tumours Express PD-L1, and in Participants Ineligible for Any Platinum-containing Chemotherapy Regardless of PD-L1 Expression (LEAP-011)	31/01/2019	30/04/2019	16/07/2019						Contracting delays due to staff availability mean that DSS-DSC has exceeded 40 days.	NHS Provider
17/ES/0071	213164	A multicentre prospective randomised open-label blinded end-point controlled trial of high-sensitivity cardiac troponin I-guided combination angiotensin receptor blockade and beta blocker therapy to prevent cardiac toxicity in breast cancer patients receiving anthracycline adjuvant therapy.	18/01/2019	29/05/2019	30/01/2018							