UHSM CTP DOH Performance in Initiating Q1 16 17

Id	REC	IRAS	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Date Study Initiated	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	A - Permissions delayed/denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
81249	14/EM/1280	163096	NHS Permission	A randomised controlled trial to investigate the effectiveness of ThOracic epidural and Paravertebral blockade In-thoracotomy pain - TOPIC Feasibility Study	04/08/2015	17/08/2015	Yes	14/09/2015	13	28	41	Yes																				Please Select...
81250	15/NW/0485	150625	NHS Permission	The Goal Directed Perfusion Trial (GtFT Trial)	27/08/2015	01/09/2015	Yes	15/09/2015	5	14	19	Yes																				Please Select...
81251	15/NW/0022	160532	NHS Permission	A multicentre randomised clinical trial to investigate whether Bone Anchored Maxillary Protraction (BAMP) reduces the need for orthognathic (facial) surgery	23/07/2015	23/09/2015	No		62			No									Y					Y						Main source of delay(VRA to FPR) is 'F No Patients Seen - due to Strict patient eligibility criteria and low recruitment target' the reason for this delay corresponds to 'neither'. VRA to NHSP is over 30 days due to 'A permissions delyaed' the SSI was submitted before the research admin team were aware of the study to collate documents and set up the study the reason for this delay corresponds to 'NHS provider'.	NHS Provider
81252	14/NE/1176	161888	NHS Permission	Multi-centre randomised controlled trial with economic evaluation and nested qualitative study comparing early structured physiotherapy versus manipulation under anaesthesia versus arthroscopic capsular release for patients referred to secondary care with a frozen shoulder (Adhesive Capsulitis)	17/08/2015	01/09/2015	Yes	22/09/2015	15	21	36	Yes																				Please Select...
81253	15/NW/0371	172337	NHS Permission	ReaDySpeech for people with dysarthria after stroke: a feasibility study	16/06/2015	20/07/2015	Yes	15/09/2015	34	57	91	No									Y				Y						Main source of delay was 'E NHS Provider staff availability' recruitment could not begin within 70 days due to staff being on annual leave. VRA to NHSP was over 30 days due to 'A local review not completed in time' the SSI was submitted too soon the reason for these delays corresponds to 'NHS provider.	NHS Provider
81254	14/LO/1800	146057	NHS Permission	The Efficacy and Mechanism Evaluation of Treating Idiopathic Pulmonary Fibrosis wth the addition of Co-trimoxazole (EME-TIPAC)	07/09/2015	22/09/2015	Yes	03/11/2015	15	42	57	Yes																				Please Select...
81255	14/NW/1497	166166	NHS Permission	The Role of GABA(B) Receptor Mechanisms in Cough: Double-Blind Randomised Controlled Trial of Lesgaberan in Chronic Cough Patients with Positive and Negative Symptom Association Probabilities	10/07/2015	10/07/2015	Yes	23/07/2015	0	13	13	Yes																				Please Select...
81256	15/EM/0294	180267	NHS Permission	A Phase 3 Randomised, Placebo-Controlled, Blinded Study to Investigate the Safety and Efficacy of a Topical Gentamicin-Collagen Sponge in Combination with Systemic Antibiotic Therapy in Diabetic Patients with an Infected Foot Ulcer (INN TOP)	22/09/2015	29/09/2015	Yes	26/10/2015	7	27	34	Yes																				Please Select...
81257	14/YH/1199	153953	NHS Permission	GALACTIC: GA101 (obinutuzumab) monocLonal Antibody as Consolidation Therapy In CLL	16/09/2015	02/10/2015	Yes	19/10/2015	16	17	33	Yes																				Please Select...
81258	14/YH/1162	154011	NHS Permission	A study to determine the feasibility and acceptability of conducting a phase III randomised controlled trial comparing sterotactic Ablative Radiotherapy (SABR) with surgery in paTients with peripheral stage I nOn-small cell lung cancer (NSCLC) cOnsidered Higher risk of complication from surgical resection	25/09/2015	09/10/2015	Yes	19/02/2016	14	133	147	No															Y					Patients screened but no eligible patients identified.	Neither
81259	15/YH/0178	174447	NHS Permission	A Phase 3, Randomized, Double-Blinded, Ivacaftor-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of VX-661 in combination with Ivacaftor in subjects aged 12 years and older with Cyctic Fibrosis, Heterozygous for the F508del-CFTR Mutation and a second CFTR Allele with a gating defect that is clinically demonstrated to be Ivacaftor responsive (Vertex 109)	05/10/2015	12/10/2015	Yes	26/10/2015	7	14	21	Yes																				Please Select...
81260	14/SC/0171	120104	NHS Permission	A phase III, double-blind, placebo- controlled, randomised trial assessing the effects of asprin on disease recurrence and survival after primary therapy in common non- metastatic solid tumours.	15/10/2015	22/10/2015	Yes	14/12/2015	7	53	60	Yes																				Please Select...
81261	14/LO/2195	165351	NHS Permission	Phase II window of opportunity study of short term preoperative treatment with enzalutamide (alone or in combination with exemestane) in patients with primary breast cancer	20/10/2015	26/10/2015	Yes	30/11/2015	6	35	41	Yes																				Please Select...
81262	15/LO/1289	181953	NHS Permission	An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of Rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures	29/10/2015	02/11/2015	Yes	12/05/2016	4	192	196	No															Y					Patients screened but no eligible patients identified. Strict patient eligibility criteria; we are using the 30% of patients seen who are resistant to Clopidogrel This makes the trial very difficult to recruit to.	Neither
81263	15/NW/0032	151852	NHS Permission	Imaging cerebral neuroinflammation in acute and chronic cerebrovascular disease: a predictor of outcome and biomarker for guiding treatment (IN-CVD)	01/10/2015	05/11/2015	Yes	10/11/2015	35	5	40	Yes																				Please Select...
81264	15/EE/0130	170557	NHS Permission	A Randomized, Open Label, Multicenter Study of Liposomal Amikacin for Inhalation (LAI) in Adult Patients with Nontuberculous Mycobacterial (NTM) Lung Infections caused by Mycobacterium avium complex (MAC) that are refractory to treatment.	27/10/2015	09/11/2015	No		13			No															Y					Patients screened but no eligible patients identified	Neither
81265	14/YH/0128	150031	NHS Permission	Sacral nerve stimulation versus the FENIX magnetic sphincter augmentation for adult faecal incontinence: a Randomised Investigation (SaFaRI)	09/11/2015	10/11/2015	Yes	10/02/2016	1	92	93	No															Y				Eligible patients seen chose not to participate in the study, other options have been available to the patients and they do not want such an evasive procedure	Neither
81266	15/NW/0724	173790	NHS Permission	Evaluation of the fast fill technique for Anal Acoustic Reflectometry (AAR) in the Incontinent Anal Sphincter [PI - Mr Nicholas Heywood]	28/10/2015	11/11/2015	Yes	11/11/2015	14	0	14	Yes																				Please Select...
81267	15/LO/0699	173824	NHS Permission	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy and Safety of Ivacaftor and VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508del-CFTR Mutation, and a Second Allele With a CFTR Mutation Predicted to Have Residual Function	12/11/2015	19/11/2015	Yes	18/12/2015	7	29	36	Yes																				Please Select...
81268	11/SS/0100	84669	NHS Permission	Fluoxetine Or Control Under Supervision	22/10/2015	25/11/2015	Yes	19/01/2016	34	55	89	No									Y					Y					The main reason for NHS to FPR being over 70 days is ' F - No eligble patients seen - strict patient eligibility criteria' the reason for this delay corresponds to 'neither'. The VRA to NHS was over 30 days due to 'A - local review not completed in time' the reason for this delay corresponds to NHS provider.	NHS Provider
81269	14/WS/1106	157143	NHS Permission	A Comparison of Fractional Flow ReserveGuided Percutaneous Coronary Intervention and Coronary Artery Bypass Graft Surgery in Patients with Multivessel Coronary Artery Disease: The FAME 3 Trial	30/11/2015	02/12/2015	Yes	01/02/2016	2	61	63	Yes																				Please Select...
81270	13/LO/1481	132746	NHS Permission	A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleurectomy decortication versus no pleurectomy decortication in the multimodality management of patients with malignant pleural mesothelioma. (MARS 2)	02/12/2015	07/12/2015	Yes	05/01/2016	5	29	34	Yes																				Please Select...
81271	11/EE/0347	75112	NHS Permission	The 2nd European Carotid Surgery Trial (ECST2)	20/10/2015	10/12/2015	No		51			No									Y					Y					The main reason for VRA to FPR being over 70 days is 'F - No eligble patients seen and strict patient eligibility criteria' the reason for this delay corresponds to 'neither'. The VRA to NHS was over 30 days due to 'A - local review not completed in time' the reason for this delay corresponds to 'NHS provider'.	NHS Provider
81272	15/LO/0833	165266	NHS Permission	FEASIBILITY of IBIS 3. An International Breast Intervention Study investigating Prevention Of Late Recurrence in ER+ breast cancer survivors following 5 years of adjuvant treatment	11/01/2016	12/01/2016	No		1			No												Y							sponsor delay in provision of study documentation and provision of IMP/device/equipment	Sponsor
81273	15/NW/0306	161393	NHS Permission	Does intraoperative use of the MarginProbe device reduce the need for further reexcision procedures after conservation surgery for breast cancer? (margin probe)	21/03/2016	22/03/2016	Yes	29/04/2016	1	38	39	Yes																				Please Select...
81274	15/NW/0478	172209	NHS Permission	A pilot prevention study of the effects of the antiprogestin Ulipristal Acetate (UA) on surrogate markers of breast cancer risk	22/01/2016	22/01/2016	Yes	29/03/2016	0	67	67	Yes																				Please Select...
81275	15/WM/0331	184594	NHS Permission	The HeartMate III PostMarket Registry	08/12/2015	14/01/2016	Yes	14/01/2016	37	0	37	Yes																				Please Select...
81276	15/NW/0360	162622	NHS Permission	Trans-venous occlusion of incompetent pelvic veins as a treatment for chronic pelvic pain in women: A randomised control trial	21/08/2015	24/08/2015	Yes	15/09/2015	3	22	25	Yes																				Please Select...
81277	15/SC/0115	167694	NHS Permission	A long term, randomised, double blind, placebo-controlled study to determine the effect of albiglutide, when added to standard blood glucose lowering therapies, on major cardiovascular events in patients with Type 2 diabetes mellitus. (HARMONY)	12/01/2016	18/01/2016	Yes	10/02/2016	6	23	29	Yes																				Please Select...
81278	15/YH/0309	182015	NHS Permission	A 52-week International, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3bTrial with a Blinded 104-week Long -term Extension Period to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin in Combination with Metformin Compared to Glimepiride in Combination with Metformin in Adult Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Therapy Alone.	25/01/2016	29/01/2016	No		4			No													Y							Study closed by sponsor at all sites	Sponsor
81279	15/EE/0405	189187	NHS Permission	A Randomized, DoubleBlind, PlaceboControlled, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab in Insulin Treated Patients with Type 1 or Type 2 Diabetes and With Hypercholesterolemia at High Cardiovascular Risk Not Adequately Controlled on Maximally Tolerated LDLC Lowering Therapy.	25/02/2016	26/02/2016	Yes	12/05/2016	1	76	77	No											Y										Study wide review not completed in time by NHS provider - SSI form was submitted early due to new HRA process.	NHS Provider
81280	15/LO/2102	189922	NHS Permission	A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix ? Drug Coated Balloon PTA Catheter for Treatment of Below-the-Knee (BTK) Arteries	05/02/2016	11/02/2016	Yes	04/07/2016	6	144	150	No															Y					Patients screened but no eligible patients identified	Neither
81281	15/NW/0821	191169	NHS Permission	Calprotectin in IBD ORI-CAL-01 (OriCol) - Comparison of Calprotectin Levels in Stool and Rectal Mucus in Subjects with Suspected or Confirmed Inflammatory Bowel Disease	25/01/2016	26/01/2016	Yes	17/02/2016	1	22	23	Yes																				Please Select...
81282	15/NW/0916	188456	NHS Permission	Evaluation of the Recto-anal Inhibitory Reflex (RAIR) using Anal Acoustic Reflectometry (AAR)	10/02/2016	11/02/2016	Yes	25/02/2016	1	14	15	Yes																				Please Select...
81283	15/NW/0897	178630	NHS Permission	Investigating the role of portable VR intervention in phantom limb pain.	02/03/2016	03/03/2016	Yes	17/03/2016	1	14	15	Yes																				Please Select...
81284	15/LO/1419	183975	NHS Permission	A randomized, phase 3 trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy (PEARLS)	10/02/2016	23/03/2016	Yes	06/04/2016	42	14	56	Yes																				Please Select...
81285	14/SW/0075	151804	NHS Permission	A Randomised Controlled Trial Evaluating the Efficacy of Indwelling Pleural Catheters in Persistent Non Malignant Symptomatic Pleural Effusions	18/01/2016	19/01/2016	Yes	04/05/2016	1	106	107	No														Y					low recruitment target - this is a niche study and only one patient is expected per year.	Neither
81286	15/NI/0158	182421	NHS Permission	A RANDOMISED PRAGMATIC TRIAL OF CORTICOSTEROID OPTIMISATION IN SEVERE ASTHMA USING A COMPOSITE BIOMARKER ALGORITHM TO ADJUST CORTICOSTEROID DOSE VERSUS STANDARD CARE	21/01/2016	22/01/2016	Yes	27/04/2016	1	96	97	No															Y					Strict patient eligibility criteria	Neither
81287	15/EM/0309	184678	NHS Permission	A randomised, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of two doses of nebulised budesonide delivered by the VR475 Inhalation System, with an open-label comparison to conventionally nebulised budesonide, in patients with uncontrolled asthma despite treatment with high dose inhaled corticosteroid and at least a second controller (GINA Step 4) and those receiving oral corticosteroid (GINA Step 5)	02/02/2016	04/02/2016	Yes	05/04/2016	2	61	63	Yes																				Please Select...
81288	15/NW/0787	191007	NHS Permission	Investigating Neuronal responses by assessing capsaicin evoked Cough responses in an allergen challenge model of Asthma (INCA)	05/02/2016	08/02/2016	Yes	16/02/2016	3	8	11	Yes																				Please Select...
81289	15/SW/0248	186033	NHS Permission	A Phase 3, Openlabel, Rollover Study to Evaluate the Safety and Efficacy of Long term Treatment With VX 661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del CFTR Mutation	19/02/2016	22/02/2016	Yes	29/02/2016	3	7	10	Yes																				Please Select...

81290	15/NW/0697	183760	NHS Permission	A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of Toujeo? compared to standard of care insulin for initiating basal insulin in insulin na?ve patients with uncontrolled type 2 diabetes mellitus, with 6-month extension.	22/03/2016	31/03/2016	Yes	31/05/2016	9	61	70	Yes																							Please Select...
81291	15/NW/0698	183781	NHS Permission	A twenty six week, randomized, openlabel, 2 arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of transition to Toujeo? compared to standard of care insulin, in basal insulin treated patients with uncontrolled type 2 diabetes mellitus, with sixmonth extension.	14/03/2016	31/03/2016	Yes	25/05/2016	17	55	72	No									Y												Study wide review not completed in time by NHS provider - SSI form was submitted early due to new HRA process.	NHS Provider
81292	15/WA/0241	183747	NHS Permission	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus - Study Two	22/03/2016	29/03/2016	No		7			No												Y								sponsor delay in provision of equipment	Sponsor
81293	16/NW/0033	192134	NHS Permission	Correlation of Anal Acoustic Reflectometry parameters with degree of Rectal Intussusception and Prolapse	16/03/2016	31/03/2016	Yes	06/04/2016	15	6	21	Yes																					Please Select...
81679	14/ss/1096	164274	NHS Permission	Rapid Assessment of Potential Ischaemic Heart Disease with CTCA - The role of early CT Coronary Angiography in the evaluation, intervention and outcome of patients presenting to the Emergency Department or Medical Assessment Unit with suspected or confirmed Acute Coronary Syndrome (The RAPID-CTCA Trial).	31/03/2016	12/05/2016	Yes	27/06/2016	42	46	88	No									Y												Study wide review not completed in time by NHS provider - SSI form was submitted early due to new HRA process.	NHS Provider
81680	15/LO/0732	172401	NHS Permission	Pragmatic randomised trial of low versus high volume initiated trans-anal irrigation therapy in adults with chronic constipation (CapaCITY 2)	23/03/2016	11/04/2016	No		19			No																					Patients screened but no patients identified.	Neither
81681	16/EM/0037	196490	NHS Permission	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 16 Week Study Followed by Long Term Evaluation of Efficacy and Safety of Ixekizumab (LY2439821) in TNFi-Experienced Patients with Radiographic Axial Spondyloarthritis	23/03/2016	25/04/2016	Yes	17/06/2016	33	53	86	No									Y						Y						VRA to NHS was over 30 days due to 'A - study wide review not completed in time by NHS provider' this delay corresponds to 'NHS provider'. NHS to FPR is over 40 days due to 'F - strict patient eligibility criteria/low recruitment target' this delay corresponds to 'neither'	NHS Provider
81682	15/LO/0609	171006	NHS Permission	Stepped Wedge Randomised Trial of Laparoscopic Ventral Mesh Rectopexy in Adults with Chronic Constipation (CapaCITY 3)	23/03/2016	04/05/2016	No		42			No									Y						Y					VRA to NHS was over 30 days due to 'A - study wide review not completed in time by NHS provider' SSI was submitted early and reason for this delay corresponds to 'NHS provider'. NHS to FPR is over 40 days due to ' F - patients screened but no eligible patients identified' reason for delay corresponds to 'neither'.	NHS Provider
81683	15/YH/0531	166392	NHS Permission	A Psychosocial Therapy to Benefit People with Parkinson?s-related Dementia: A Feasibility and Exploratory Pilot Study of Individual Cognitive Stimulation Therapy (INVEST).	29/03/2016	10/05/2016	Yes	02/06/2016	42	23	65	Yes																							Please Select...
81684	16/ES/0001	193859	NHS Permission	REVOLVE - A Phase 3, randomized, double-blind, placebo-controlled, multicentre study to investigate the efficacy and safety of Mongersen (GED-0301) for the treatment of subjects with active Crohn?s Disease	23/03/2016	24/06/2016	No		93			No												Y								Sponsor delayed site initiation visit.	Sponsor
81685	15/NW/0406	167520	NHS Permission	TIP - Thrombin Inhibition Preoperatively in Early Breast Cancer	21/01/2016	25/04/2016	Yes	25/05/2016	95	30	125	No												Y								Sponsor delay through research application amendments , old version of SmPC submitted to REC & MHRA at time of initial submission.	Sponsor
81686	15/LO/1500	187068	NHS Permission	BI 1199.229 - Investigation of drug-drug interaction between nintedanib and pirfenidone in patients with IPF (an open label, multiple-dose, two group study followed by nintedanib open label treatment)	29/03/2016	19/04/2016	Yes	03/05/2016	21	14	35	Yes																							
81687	16/SC/0018	191267	NHS Permission	A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of CTX-4430 Administered Orally Once-Daily for 48 Weeks in Adult Patients with Cystic Fibrosis [Empire (CTX-4430)]	23/03/2016	26/04/2016	Yes	06/06/2016	34	41	75	No														Y								patients screened but no eligible patients identified	Neither
81688	16/SC/0089	196789	NHS Permission	The REST Study - pRotective vEntilation with ven-venouS lung assisT in respiratory failure	31/03/2016	30/06/2016	No		91			No												Y								Sponsor delayed confirmation of study open to recruitment at site	Sponsor
81689	15/EM/0473	187884	NHS Permission	A randomized, open-label, active-controlled, Phase II study of intravenous anetumabravtansine (BAY 94-9343) or vinorelbine in patients with advanced or metastaticmalignant pleural mesothelioma overexpressing mesothelin and progressed on first lineplatinum/pemetrexed-based chemotherapy (Bayer 15743)	11/03/2016	07/04/2016	Yes	11/04/2016	27	4	31	Yes																							Please Select...
81690	15/NW/0747	186601	NHS Permission	BIOSIMILAR A multicenter, randomized, double-blind Phase III trial to evaluate efficacy and safety of BI 695502 plus chemotherapy versus Avastin? plus chemotherapy in patients with advanced nonsquamous Non-Small Cell Lung Cancer	08/03/2016	20/04/2016	No		43			No												Y								sponsor delay in provision of study documentation and provision of equipment etc	Sponsor
81691	15/SC/0600	187954	NHS Permission	The Efficacy of Sonographic and Biological Pleurodesis Indicators of Malignant Pleural Effusion (SIMPLE) - a randomised trial	29/03/2016	16/06/2016	No		79			No									Y						Y					VRA to NHS over 30 days due to 'A - Study wide review not completed in time by NHS provider' SSI was submitted early this delay corresponds to 'nhs provider'. NHS to FPR delay due to 'F - patients screened but no eligible patients identified' delay corresponds to 'neither'	NHS Provider
81692	15/EE/0298	186974	NHS Permission	LuCID: Lung Cancer Indicator Detection	24/03/2016	23/06/2016	No		91			No									Y				Y							VRA to NHS over 30 days due to 'A - Study wide review not completed in time by NHS provider' SI was submitted early this delay corresponds to 'nhs provider'. Also 'D - Sponsor delayed confirmation of study open to recruitment at site' this delay corresponds to 'sponsor'.	Sponsor
84266	16/NE/0014	192732	HRA Approval	AF219-012 12-Week Study in Subjects with Refractory Chronic Cough	n/a	n/a	Yes	10/05/2016	n/a	n/a	n/a	No	11/12/2015	16/10/2015	22/12/2015	02/03/2016	07/04/2016	13/04/2016	n/a	21/04/2016	Y											Other regulatory review not completed in time, This study went through the test cohort and so HRA approval was not issued within the 70 days.	Neither
84267	16/LO/0793	203066	HRA Approval	A 12-week, double blind, randomised, placebo controlled, parallel group trial followed by a single active arm phase of 40 weeks evaluating the effect of oral nintedanib 150 mg twice daily on change in biomarkers of extracellular matrix turnover in patients with idiopathic pulmonary fibrosis (IPF) and limited forced vital capacity (FVC) impairment.	n/a	n/a	No		n/a	n/a	n/a	No	07/04/2016	08/03/2016	09/05/2016	28/06/2016	07/07/2016	11/07/2016	n/a					Y								Sponsor delayed confirmation of study open to recruitment at site	Sponsor