

Performance Against Dirst Patient Visit Benchmark

Ethics Committee Ref	Project Title	Project Site R&D Submission	Date of First Patient Consented	Benchmark Met or Reason for Delay
11/LO/1873	'Stent Oesophageal Varices'' (SOV) Study	09/07/2012	05/02/2013	Reasons for delay rest with both sponsor and Trust
11/SC/0410	VIT 09-10	02/07/2012		Reasons for delay rest with the Sponsor
12/SW/0177	Electrical muscle stimulation in mechanical ventilation – E-Vent.	02/08/2012	09/10/2012	Benchmark met
12/SC/0318	SWAP 2: A Pharmacodynamic Evaluation of Switching from Ticagrelor to Prasugrel (CS747S-B-U4003)	09/07/2012	25/09/2012	Reasons for delay rest with the Sponsor
10/H1308/65	EPI-STREP: NTHi and chronic cough epidemiology study in the UK	17/04/2012		Reasons for delay rest with the Sponsor
11/EM/0450	Pazopanib in patients with renal cancer (PaZ02)	18/07/2012		Reasons for delay rest with the Sponsor
11/LO/1810	DEFLECT I Trial	17/08/2012	28/08/2012	Benchmark met
12/LO/0482	PERUSE (MO28047): Global safety study with pertuzumab in Her2+ advanced BC	02/08/2012		Reasons for delay rest with the Sponsor
11/WS/0114	ARomatase Inhibition + SaracaTinib as Advanced breast CANcer Therapy (ARISTACAT)	20/08/2012	16/10/2012	Benchmark met
12/NE/0004	PBC OCA International Study of Efficacy (POISE 747-301)	28/08/2012	17/10/2012	Benchmark met
10/H0405/90	The seAFOod Polyp Prevention Trial	03/09/2012	09/01/2013	Delays due to external factors outside the control of the Sponsor and Trust
12/EM/0018	CANTOS: CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	16/08/2012		Reasons for delay rest with both sponsor and Trust
11/05/2012	B1931022 Inotuzumab in Acute Lymphoblastic Leukaemia	05/09/2012	08/07/2013	Delays due to external factors outside the control of the Sponsor and Trust
11/AL/0142	Bronchiolitis of Infancy Discharge Study (BIDS).	31/08/2012	04/10/2012	Benchmark met
11/NW/0782	POUT	23/08/2012	05/02/2013	Delays due to external factors outside the control of the Sponsor and Trust
11/LO/0886	(CCRN 311)ATOMIC-HF - Phase 2 Study with AMG 423 in Acute Heart Failure	14/09/2012		Reasons for delay rest with the Sponsor

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12/NE/0266	Study of GS7977 with Ribavirin in patients with HCV infection (GS-US-334-0133 - Valence)	05/10/2012	02/11/2012	Benchmark met
11/LO/2024	STRASS: A phase III randomized study of preoperative radiotherapy plus surgery versus surgery alone for patients with Retroperitoneal sarcoma (RPS)	08/08/2012		Reasons for delay rest with the Sponsor
12/SW/0237	116023 (FLU D-QIV-009 EXT 004)	05/10/2012	30/10/2012	Benchmark met
11/WM/0381	De-ESCALaTE HPV	10/09/2012	11/02/2013	Delays due to external factors outside the
10/S0501/31	SUSPEND	29/09/2012	04/12/2012	Benchmark met
11/AL/0213	Phase 1 trial of olaparib with temozolomide in relapsed glioblastoma (OPARATIC)	23/08/2012	22/02/2013	Reasons for delay rest with the Sponsor
08/H1008/32	HOPON	29/06/2012	28/01/2013	Reasons for delay rest with the Sponsor
12/WM/0079	Long term continuous infusion ch14.18/CHO plus s.c. aldesleukin (IL2)	29/10/2012		Reasons for delay rest with the Sponsor
12/LO/0372	ALLERGAN DME 206207-024	04/10/2012	21/01/2013	Reasons for delay rest with the Sponsor
12/EE/0355	Dynamics of free cortisol during surgical and medical stress	19/11/2012	16/04/2013	Reasons for delay rest with both sponsor and Trust
12/LO/0582	GO27819 Phase II Study of MetMab in Patients with Recurrent Glioblastoma	19/10/2012	03/12/2012	Benchmark met
12/NW/0585	Trastuzumab Emtansine (TDM1) (GATSBY)	09/10/2012	17/04/2013	Reasons for delay rest with the Sponsor
11.WM.0287	DESKTOP III	05/11/2012		Reasons for delay rest with the Sponsor
11/EM/0358	EuroNet PHL-LP1 Hodgkin's	22/11/2012		Reasons for delay rest with both sponsor and Trust
12/SW/0213	ErLaPara	30/10/2012	07/01/2013	Benchmark met
12/NE/0234	ROSA - RCT of CPAP in patients with diabetic retinopathy and OSA (ROSA Trial)	23/11/2012	09/05/2013	Reasons for delay rest with both sponsor and Trust
12/SC/0469	EFC12492: Odyssey FH I	05/12/2012	17/01/2013	Benchmark met

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12/LO/0515	OPTIMA Version 1.0, 08 March 2012	04/12/2012	18/04/2013		Reasons for delay rest with the Sponsor
09/HO504/112	PCV13 in ALL	04/12/2012	24/01/2013		Benchmark met
12/SC/0384	V72P12E2 - A new vaccine against meningitis groupB: A second follow-on	20/12/2012	15/02/2013		Benchmark met
12/LO/1090	YO28322	05/12/2012	06/03/2013		Reasons for delay rest with the Trust
12/SW/0277	CAROTID BODY REMOVAL for the treatment of chronic diseases characterised by excessive central sympathetic activity including RESISTANT HYPERTENSION: a pilot study	26/11/2012	25/02/2013		Reasons for delay rest with the Sponsor
12/LO/1534	OZDRY	08/01/2013	04/03/2013		Benchmark met
12/NW/0766	PREDNOS 2	14/01/2013	29/04/2013		Reasons for delay rest with the Sponsor
12/SW/0264	Pulmonary ArTerial Hypertension: Working on AnxietY and Stress (PATHWAYS)	11/01/2013	08/02/2013		Benchmark met
12/LO/1156	COMET-1 XL184-307	21/12/2012	07/05/2013		Reasons for delay rest with the Sponsor
12/SW/0228	A randomized control trial of non-invasive ventilation during an exercise programme following acute acidotic exacerbation of COPD in hospital and follow-up use at home: feasibility of using the Trilogy Ventilator.	18/10/2012	19/03/2013		Reasons for delay rest with the Sponsor
12/SW/0280	The Bristol Fetal Brain Imaging Study (BFBI study)	28/01/2013			Reasons for delay rest with the Sponsor
12/SC/0540	BI 207127 in Treatment-Naïve Patients with HCV	30/01/2013	13/02/2013		Benchmark met
12/SW/0281	REVERT Study	30/01/2013	22/02/2013		Benchmark met
11/LO/0743	PARACHUTE III	01/02/2013	12/03/2013		Benchmark met
12/SW/0112	STARRCAT Trial: Surgical Timing After Radiotherapy for Rectal Cancer	25/01/2013			Delays due to external factors outside the control of the Sponsor and Trust
12/EE/0499	MK-5172 with peg-IFN and RBV in HCV Infected Subjects	11/01/2013	26/02/2013		Benchmark met
12/WA/0303	ANEMONES	08/02/2013	28/02/2013		Benchmark met

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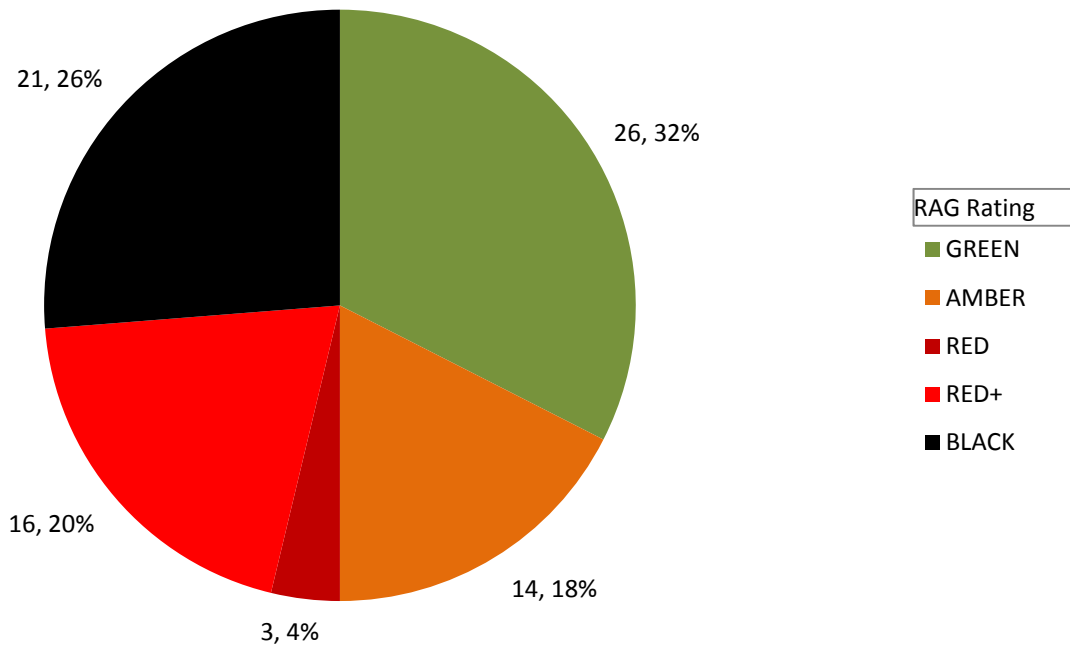
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12/LO/1358	TPU-TAS-102-301	24/01/2013	14/05/2013	Reasons for delay rest with the Sponsor
12/SW/0286	GRAPhICS	20/02/2013	11/03/2013	Benchmark met
12/LO/0082	A3291139: 009: Open- label oral CP690,550 for Treatment of Ulcerative Colitis	15/10/2012		Reasons for delay rest with the Sponsor
12/LO/0080	A3921095: 007: Oral CP690,550 as an Induction Therapy for Ulcerative Colitis	15/10/2012		Reasons for delay rest with the Sponsor
12/LO/0081	A3921096: 008: Oral CP-690, 550 as Maintenance Therapy for Ulcerative Colitis	15/10/2012		Reasons for delay rest with the Sponsor
12/SW/0161	ROMIO feasibility: RCT of minimally invasive or open oesophagectomy v1	04/03/2013	22/04/2013	Benchmark met
08/H0713/82	Molecular genetics of Human Birth Defects	20/03/2013		Delays due to external factors outside the control of the Sponsor and Trust
12/SW/0377	CADME :A Study to Compare Anti- VEGF in the Treatment of DME	15/03/2013	15/04/2013	Benchmark met
12/LO/0050	H6D-MC-LVIG: Study of Tadalafil in Children with Pulmonary Arterial Hypertension (MCRN159)	05/07/2012		Reasons for delay rest with the Sponsor
12/SC/0502	B1181003 Clinical Study of RN6G (PF-04382923)	28/03/2013		Reasons for delay rest with the Sponsor
13/YH/0021	MCI-196-E15 Extension Study Evaluating Colestilan	10/04/2013		Reasons for delay rest with the Sponsor
13/YH/022	MCI-196-E16	10/04/2013		Reasons for delay rest with the Sponsor
06/Q1603/07	ChOPIN	19/04/2013	29/05/2013	Benchmark met
13/LO/0504	Detection of Coagulopathy in Paediatric Heart Surgery (DECISION)	10/04/2013	01/05/2013	Benchmark met
12/SC/0515	'Breathe'	24/04/2013		70 days not yet reached
12/EE/0271	SIOP CNS GCT II	24/04/2013		70 days not yet reached
12/WA/0058	NCRN398 IMAGE: Observational Study in Patients with Unresectable or Metastatic Melanoma	13/05/2013		70 days not yet reached

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12/LO/1361	Cardioprotection in CABG and AVR patients with RIPC	09/11/2012		Reasons for delay rest with the Sponsor
10/HO701/117	Clinical Utility of PlGF in pregnancy	24/05/2013	29/05/2013	Benchmark met
13/EM/0084	CCRN 2010 - Baxter 261201: PEGylated Recombinant Factor VIII in Severe Hemophilia A	16/05/2013		70 days not yet reached
10/HO701/111	ERICCA study Version 1.0	20/05/2013		70 days not yet reached
12/SC/0434	(MCRN194) DPM-CF-204 mannitol in CF aged 6-17	21/05/2013		70 days not yet reached
11/WS/0012	The REMOVAL study	03/06/2013		70 days not yet reached
13/SW/0082	Myocardial Oedema in ST segment elevation myocardial infarction	28/05/2013		70 days not yet reached
13/EM/0012	NCRN490: CA184-178 Ipilimumab in children(aged 12<18)with malignant melanoma	15/05/2013		70 days not yet reached
13/LO/0150	RESORCE: The regorafenib in patients with hepatocellular carcinoma	11/06/2013		70 days not yet reached
12/LO/1201	UK Haplo	25/06/2013		70 days not yet reached
12/NW/0367	MCRN177 (BEL114055)	14/06/2013		70 days not yet reached
11/LO/1857	NEOMERO-2 PK and Safety of Meropenem in Infants with Meningitis	26/06/2013		70 days not yet reached
13/LO/0520	OCTAVE, Ranibizumab in neovascular age-related macular degeneration(CRFB002A2405)	14/06/2013		Reasons for delay rest with the Sponsor

No of days to First Patient Consented

Projects have been colour coded to identify length of time from submission of an application to first patient consented
 Key: BLACK - No recruitment > 70 days, RED+ - Recruited > 100 days, RED - Recruited 71 - 100 days, AMBER - No recruitment <70 days, GREEN - Recruited <70 days



Reasons for Delays in First Patient Consented

Internal delay: delay due to UH Bristol Trust issue
Both internal and external delay: contributing factors for delay from both UH Bristol and external party, e.g. contract review
External delay sponsor: examples include delayed site initiation visits, green light visit.
External delay protocol design: protocol stipulates that very rare patient group/low recruitment or other protocol design which means site is unable to reasonably expect to recruit within 70 days.
External delay University: any University involvement contributing to the delay- e.g. contract review
External delay other Trust: a delay caused by an external Trust e.g. reviewing contracts, delaying initiation.
External delay other: any other delays which fall outside the above categories and are due to factors external to the Trust.

