

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/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
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	08/08/2013	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 control of the Sponsor and Trust
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	GD2: Long term continuous infusion ch14.18/CHO plus s.c. aldesleukin (IL-2)	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

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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/SW/0213	ErLaPara	30/10/2012	07/01/2013		Benchmark met
12/SC/0469	EFC12492: Odyssey FH I	05/12/2012	17/01/2013		Benchmark met
12/LO/0515	OPTIMA	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	NCRN469 COMET 1: Cabozantinib vs Prednisone in mCRPC after prior therapy	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 Trust
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

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12/SW/0112	STARRCAT Trial: Surgical Timing After Radiotherapy for Rectal Cancer	25/01/2013	15/04/2013		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
12/LO/1358	NCRN532 (TAS 102)	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/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/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/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/SC/0502	Pfizer 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	15/07/2013		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	30/04/2013		Benchmark met
12/SC/0515	'Breathe'	24/04/2013			Reasons for delay rest with the Sponsor

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12/EE/0271	SIOP CNS GCT II	24/04/2013		Delays due to external factors outside the control of the Sponsor and Trust
12/WA/0058	NCRN398 IMAGE: Observational Study in Patients with Unresectable or Metastatic Melanoma	13/05/2013	12/08/2013	Reasons for delay rest with both sponsor and Trust
12/LO/1361	Cardioprotection in CABG and AVR patients with RIPC	09/11/2012		Reasons for delay rest with the Sponsor
10/H0701/117	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	30/07/2013	Delays due to external factors outside the control of the Sponsor and Trust
10/H0701/111	ERICCA study Version 1.0	20/05/2013		Reasons for delay rest with the Sponsor
12/SC/0434	(MCRN194) DPM-CF-204 mannitol in CF aged 6-17	21/05/2013	30/09/2013	Reasons for delay rest with both sponsor and Trust
11/WS/0012	The REMOVAL study	03/06/2013	22/07/2013	Benchmark met
13/SW/0082	Myocardial Oedema in ST segment elevation myocardial infarction	28/05/2013	23/07/2013	Benchmark met
13/EM/0012	NCRN490: CA184-178 Ipilimumab in children(aged 12<18)with malignant melanoma	15/05/2013		Delays due to external factors outside the control of the Sponsor and Trust
13/SW/0072	CCRN 2149 - FTY720D2205	12/06/2013		Reasons for delay rest with the Sponsor
13/LO/0150	RESORCE: The regorafenib in patients with hepatocellular carcinoma	11/06/2013		Delays due to external factors outside the control of the Sponsor and Trust
12/LO/1201	UK Haplo	25/06/2013	14/07/2013	Benchmark met
12/NW/0367	MCRN177 (BEL114055)	14/06/2013		Delays due to external factors outside the control of the Sponsor and Trust
11/LO/1857	NEOMERO-2 PK and Safety of Meropenem in Infants with Meningitis	26/06/2013	02/08/2013	Benchmark met
13/LO/0520	OCTAVE, Ranibizumab in neovascular age-related macular degeneration(CRFB002A2405)	14/06/2013	06/08/2013	Benchmark met

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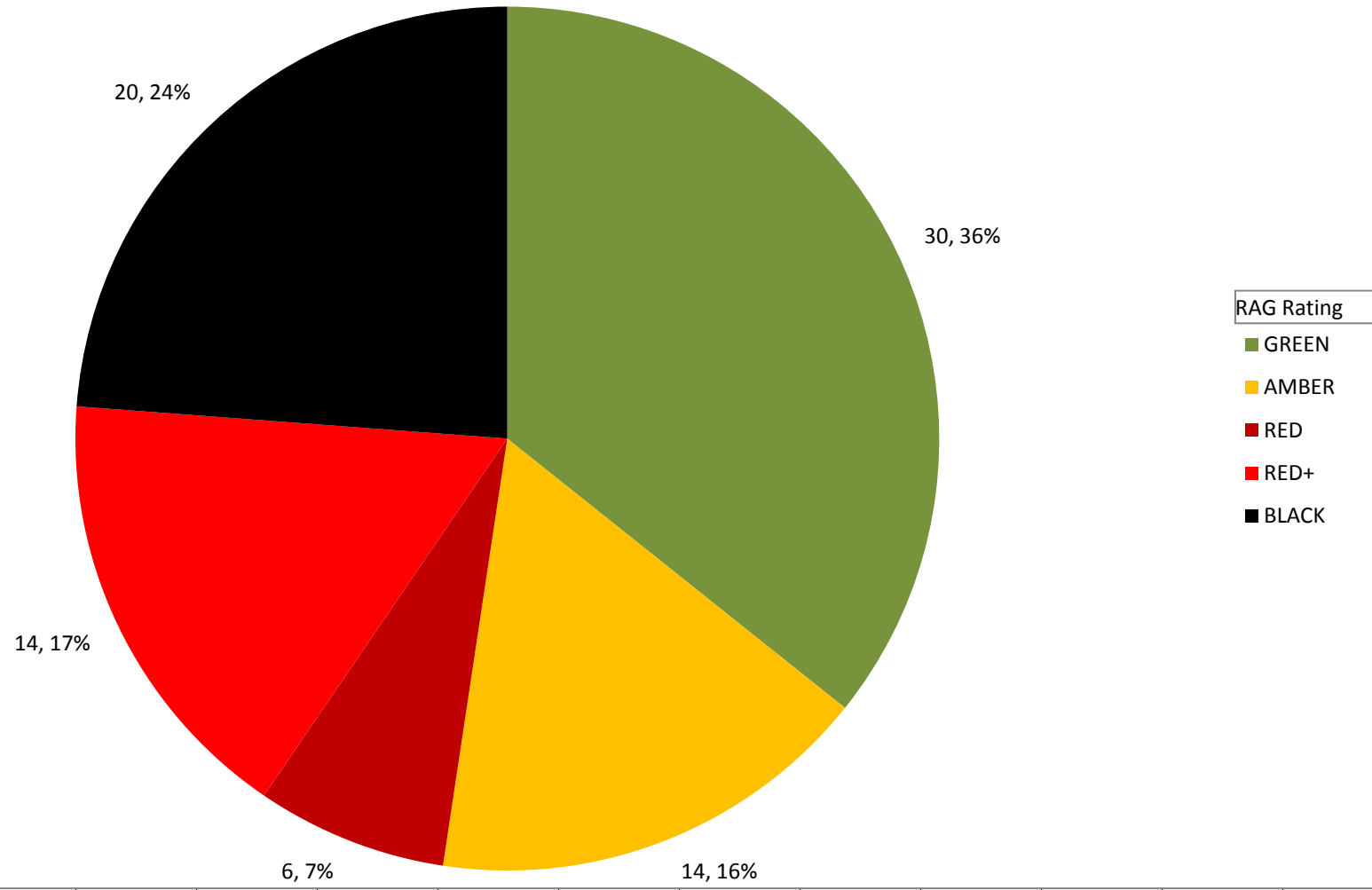
Ethics Committee		Project Site R&D	Date of First Patient	
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13/NW/0320	Jigsaw WA28117 [POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS]	24/06/2013	09/07/2013	Benchmark met
12/LO/1876	COBRIM - GO28141	28/06/2013		Reasons for delay rest with the Trust
12/NW/0641	NCRN442 BRIM 8: Vemurafenib in adjuvant melanoma	18/07/2013	07/08/2013	Benchmark met
13/SC/0213	ACT IV Study - Protocol CDX110-04	18/07/2013	05/08/2013	Benchmark met
13/SC/0171	VX12-809-104 Lumacaftor + Ivacaftor in Cystic Fibrosis	13/08/2013	03/09/2013	Benchmark met
12/WA/1064	ZEST	07/08/2013		70 days not yet reached
12/EE/0400	Extension study of GS-7977 in patients with HCV infection (GS-US-334-0109)	08/08/2013		70 days not yet reached
13/WM/0231	SNIFFLE study	03/09/2013		70 days not yet reached
13/NW/0464	Pharmacokinetic and Pharmacodynamic Trial of IDN6556	30/08/2013		70 days not yet reached
13/WA/0101	CCRN 2088 (Pneumonia)	22/08/2013		70 days not yet reached
01/12/2009	TREC	09/09/2013		70 days not yet reached
11/EM/0237	IVICA: Intravenous iron in colorectal cancer associated anaemia	10/09/2013		70 days not yet reached
12/WA/0345	NeoSCOPE: Neoadjuvant - Study of Chemoradiotherapy in OesoPhagEal Cancer	04/09/2013		70 days not yet reached
12/YH/0404	CE-MARC 2	23/09/2013		70 days not yet reached
13/EM/0331	PA for the management of fatigue in RA (FRAPA)	23/09/2013		70 days not yet reached
11/SS/01000	Fluoxetine or Control Under Supervision (FOCUS)	24/09/2013		70 days not yet reached
13/EM/0254	CCRN 2232 - PROMETHEUS: Visual impairment due to VEGF driver	23/09/2013		70 days not yet reached
13/EE/0263	MASTER II	20/09/2013		70 days not yet reached
13/LO/0418	SD560 Pfizer PPHN Sildenafil A1481316 (MCRN228)	23/08/2013		70 days not yet reached

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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



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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.

