

Performance First Patient Visit Benchmark

Ethics		Project Site R&D	Date of First Patient	Benchmark Met or Reason for Delay
Committee Ref	Project Title	Submission	Consented	
12/NW/0790	The BASICS Trial	03/10/2014	09/10/2014	Benchmark met
14/NW/1256	RVENCH	29/09/2014	26/10/2014	Benchmark met
11/H1307/6	SWITCH	14/10/2014	10/11/2014	Benchmark met
13/SC/0619	Group B streptococcus Immunisation Attitudes	01/10/2014	23/10/2014	Benchmark met
13/EM/0154	SWIFFT Trial	04/09/2014	12/11/2014	Benchmark met
14/NS/0089	Hip 'Op	17/10/2014		Delays due to external factors outside the control of the Sponsor and Trust
14/SC/0221	CONCEPT: A Phase II pilot study of 3 weekly Cabazitaxel versus weekly Paclitaxel chemotherapy in the first line treatment of Her2 negative metastatic breast cancer (mBC)	21/10/2014	18/12/2014	Benchmark met
14/EE/1063	AZD9291 v chemotherapy in NSCLC, following EGFR TKI therapy (AURA3)	29/10/2014		Delays due to external factors outside the control of the Sponsor and Trust
13/SC/0007	An Open-Label, Phase 1, Dose Escalation Study of MLN2480 in Patients with Relapsed or Refractory Solid Tumors Followed by a Dose Expansion Phase in Patients With Unresectable Melanoma.	03/11/2014	28/11/2014	Benchmark met
12/WM/0187	ROCSS	13/11/2014	09/12/2014	Benchmark met
14/EE/1001	OTO-104 in Meniere's Disease	13/11/2014	17/12/2014	Benchmark met
14/SW/1101	The effect of Plasma Rich in Growth Factors (PRGF) on the treatment of dry sockets	03/11/2014	24/11/2014	Benchmark met
14/WM/0085	Robot Assisted Fracture Surgery (RAFS)	12/11/2014	19/12/2014	Benchmark met
14/SC/1014	CANC - 3482 JANUS 1: Ruxolitinib or placebo + Capecitabine in pancreatic adenocarcinoma	20/11/2014	21/01/2015	Benchmark met
14/LO/1428	Adjunctive Steroid Combination in Ocular Trauma (ASCOT) Study	01/12/2014	25/06/2015	Delays due to external factors outside the control of the Sponsor and Trust
14/SC/1269	CAIRO WPC: PROXY: Post ROSC OXYgenation Study	18/12/2014	17/01/2015	Benchmark met
07/H0718/57	UKAITPR	18/12/2014	08/01/2015	Benchmark met
13/SC/0268	CCRN2100 (Cystic fibrosis)	09/12/2014	17/04/2015	Reasons for delay rest with the Sponsor
14/SW/1078	DRIFT School age follow-up	14/01/2015	07/02/2015	Benchmark met
13/WM/0143	Study of Moxetumomab Pasudotox in pALL or LL of B-Cell	22/01/2015	24/02/2015	Benchmark met
14/LO/1043	LEAVO	23/01/2015	16/02/2015	Benchmark met
14/YH/0085	FLAIR: Front-Line therapy in CLL: Assessment of Ibrutinib + Rituximab	16/01/2015	06/03/2015	Benchmark met
14/EM/1319	The benefit of ultrasound imaging prior to heart bypass surgery to prevent leg wound complications.	30/01/2015	23/02/2015	Benchmark met
13/WA/0205	AML18	10/02/2015	06/03/2015	Benchmark met
14/SC/1425	CCRN 2738 (AMD)	12/02/2015	25/02/2015	Benchmark met
14/LO/1617	GLP110933 study Type I DM Study (DRN 3266)	06/02/2015	27/05/2015	Delays due to external factors outside the control of the Sponsor and Trust
14/NI/1075	CHIL3670 (ALX0171-C104)	16/02/2015		Delays due to external factors outside the control of the Sponsor and Trust
14/NE/1099	GA29103: PHASE III, RANDOMIZED, MULTICENTER DOUBLE-BLIND, DOUBLE-DUMMY STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ETROLIZUMAB COMPARED WITH INFlixIMAB IN PATIENTS WITH MODERATE TO SEVERE ACTIVE ULCERATIVE COLITIS WHO ARE NAIVE TO TNF INHIBITORS	27/02/2015		Delays due to external factors outside the control of the Sponsor and Trust
14/EM/0215	M12-914 Phase III Veliparib/Placebo + C/P Breast Cancer Study	02/03/2015		Delays due to external factors outside the control of the Sponsor and Trust
14/YH/1124	EXTEND (2819MA1002)	04/03/2015		Reasons for delay rest with the Trust
14/WM/1228	CHIL3846 Abbott Sensor Based Glucose Monitoring System Paediatric Study (BEAGLE)	05/03/2015	01/04/2015	Benchmark met
15/NW/0009	MCRN3127 (20130173)	17/03/2015		Delays due to external factors outside the control of the Sponsor and Trust
14/NW/1067	PROteKT	24/03/2015	21/09/2015	Reasons for delay rest with the Sponsor
13/LO/0451	The UK TAVI Trial	07/04/2015		Delays due to external factors outside the control of the Sponsor and Trust
12/SC/0090	Dual Erb B Inhibition in Oesophago-gastric Cancer	08/04/2015	27/05/2015	Benchmark met
14/SC/0181	Elagolix in Endometriosis Associated Pain - Extension	10/04/2015	28/04/2015	Benchmark met
11/SC/0173	VIABLE	28/04/2015	25/06/2015	Benchmark met
12/EE/0368	Adrenal study	12/05/2015	15/06/2015	Benchmark met
15/LO/0104	Albumin To prevenT Infection in chronic liver failurE (ATTIRE)	13/05/2015	03/06/2015	Benchmark met
GTAC 128	WT1 TCR-001	15/05/2015	01/07/2015	Benchmark met
14/SC/1311	MCRN3165 (SD744) Cubist PSI Osteomyelitis	20/05/2015		Reasons for delay rest with the Sponsor
14/SW/1016	Validity of the Children's Cognitive Screening Instrument (CCoSI)	23/04/2015	15/06/2015	Benchmark met
14/WS/1149	An Exploratory RCT of a Psychosocial Group Intervention for Epilepsy	12/06/2015	14/08/2015	Benchmark met
14/NI/1037	NCRN - 3245 - Betalutin radioimmunotherapy for treatment of relapsed CD37+ NHL	16/06/2015	10/09/2015	Delays due to external factors outside the control of the Sponsor and Trust

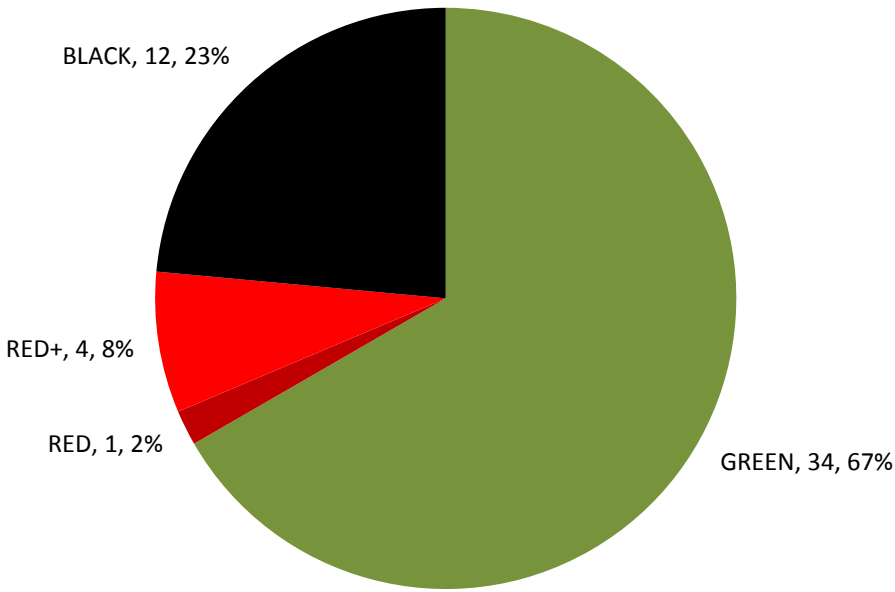
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Ethics Committee Ref	Project Title	Project Site R&D Submission	Date of First Patient Consented	Benchmark Met or Reason for Delay
14/YH/1263	GLYSURE Study	19/05/2015		Reasons for delay rest with both sponsor and Trust
15/SC/0054	CheckMate 238 (Nivolumab vs Ipilimumab in Melanoma)	22/06/2015	22/07/2015	Benchmark met
15/SC/0287	Provision Of Psychological support to People in Intensive care (POPPi)	11/07/2015	05/09/2015	Benchmark met
14/LO/1490	CANC-3574 - Nivolumab (BMS-936558) in Stage III (unresectable) or stage IV Melanoma (CA209-172)	17/07/2015	02/09/2015	Benchmark met
14/LO/1578	DMID 11-0069 Valgan Toddler	21/07/2015		Delays due to external factors outside the control of the Sponsor and Trust
12/YH/0452	INCA	14/07/2015		Delays due to external factors outside the control of the Sponsor and Trust
15/EM/0185	Dietary manipulation in cystic fibrosis related diabetes	12/08/2015		70 days not yet reached
14/YH/1269	CHIL3644 I.V. Tapentadol in post op pain	14/08/2015		70 days not yet reached
15/LO/0517	CANC - 4281 - YOSEMITE	11/08/2015		70 days not yet reached
15/SC/0242	HAEM 4448	27/08/2015		70 days not yet reached
14/YH/1090	QUIET-1	25/08/2015		70 days not yet reached
14/SC/1345	PRISM - Progesterone In Spontaneous Miscarriage	08/09/2015	17/09/2015	Benchmark met
15/NW/0090	EclIPSE:Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus	11/09/2015		70 days not yet reached
15/NW/0573	CHIL4421 (NP25737)	10/09/2015		70 days not yet reached
14/YH/1037	MCRN3102 (SD653) Grunenthal Tapentadol Acute/Postoperative Pain (KF65)	23/09/2015		70 days not yet reached
15/WA/0156	SILKIE	18/09/2015		70 days not yet reached
14/SC/0171	Add-Aspirin Trial	14/09/2015		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, 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.

