

**NRES Committee London - South  
East**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - South East
<b>Type of REC:</b>	Type 3
<b>Type of Flag:</b>	Adults lacking capacity, Prison, Research Databases,
<b>Chair:</b>	Professor David Caplin
<b>Vice-Chair:</b>	Mrs Vera Hughes
<b>Alternate Vice-Chair:</b>	Professor Liz Meerabeau
<b>Co-ordinator:</b>	Mr Jay McGregor (from April 2012) Mr Danyal Enver (up to April 2012) Mr Dean Beattie (up to December 2011)
<b>PRSC Co-ordinator:</b>	n/a
<b>Assistant Co-ordinator:</b>	n/a
<b>Committee Address:</b>	Health Research Authority Ground Floor Skipton House 80 London Road London SE1 6LH
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## Chair's overview of the past year:

This has been a tumultuous year for the Committee: four members, including the Chair, came to the end of their terms, and another resigned; all were very experienced, and to date no new members have been appointed.

Further, the changes arising from the formation of the HRA have had major impact: the Ashford office closed, and the administration moved temporarily to Charing Cross Hospital; the consequent resignation of our very experienced Coordinator, Mr Dean Beattie; an extended hiatus after Dr Ruben's departure with the previous Vice-Chairs as Acting Chairs until I was appointed Chair with effect from 1 February 2012.

Unsurprisingly, these difficulties impacted negatively on the Committee's work. We managed to cope reasonably well with appraisal of new studies and reaching final decisions on them. The "back-office" work of Substantial Amendments and so forth fared less well, with papers getting mislaid or not always acted on promptly. The situation would have been much worse had not two very experienced staff, Louise Braley and Uzma Chaudry, worked with us on an ad hoc basis to sort and clear the backlog; special thanks to them.

I believe that this Committee under Dr Ruben's chairmanship had an excellent reputation with the research community; I would like to thank my colleagues on the Committee who have striven to maintain that reputation, particularly the current Vice-Chairs.

Looking forward, it is indeed urgent to recruit new members (two more members are due to retire shortly) with the expertise to address our challenging workload, and also to ensure that the Committee has the appropriate support from the secretariat.

## NRES Committee London - South East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Ashok Bhiman	Consultant Psychiatrist	Expert	01/07/2007	
Professor Bob Brecher	Reader in Moral Philosophy	Lay Plus	23/01/2012	29/02/2012
Professor David Caplin	Physicist	Lay	01/10/2003	
Professor David Croisdale-Appleby	Professor in Medical Research and Medical Education	Lay	01/01/2002	01/01/2012
Mr Ron Driver	University Lecturer/Statistician	Expert	01/06/2009	
Professor John Eastwood	Consultant Renal Physician	Expert	01/01/2008	
Dr Alan Fishtal	GP	Expert	01/01/2008	
Dr Ann Gallagher	Reader in Nursing Ethics (Nurse Member)	Expert	01/06/2007	
Mr Guy Gardener	Retired Assistant Chief Constable	Lay Plus	01/10/2007	
Mrs Vera Hughes	Training Consultant	Lay Plus	01/10/2003	
Dr Anton Joseph	Consultant Radiologist	Expert	01/06/2001	31/12/2011
Professor Cornelius Katona	Academic Psychiatrist	Expert	01/10/2007	
Dr Robin MacKenzie	Director Medical Law & Ethics	Lay	01/01/2007	
Professor Liz Meerabeau	University Professor (Nurse Member)	Expert	01/01/2002	
Dr L. Alan Ruben	GP	Expert	01/01/2001	30/08/2011
Mr Roy Sinclair	Pharmacist	Expert	01/01/2002	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr L. Alan Ruben	GP	Lay	07/12/2011 20/12/2011
Stephanie Ellis	Former Civil Servant	Lay Plus	07/12/2011 20/12/2011

**Member Bank**

<b>Name</b>	<b>Occupation</b>	<b>Expert or Lay</b>	<b>Meeting date attended</b>

## NRES Committee London - South East: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor John Eastwood	Professor Eastwood has shares in Astrazeneca.	09/05/2011
Mr Guy Gardener	Mr Gardener has declared no interests.	09/05/2011
Professor Liz Meerabeau	Prof Meerabeau has declared that she is the Dean of the School of Health & Social Care at the University of Greenwich.	09/05/2011
Dr Robin MacKenzie	Dr Mackenzie sits on the R&D Committee of the East Kent Hospital University NHS Trust.	09/05/2011
Professor David Croisdale-Appleby	Chairman: HFT	09/05/2011
Professor David Croisdale-Appleby	Chairman: Yarrow Housing	09/05/2011
Professor David Croisdale-Appleby	Chairman: Skills for Care	09/05/2011
Professor David Croisdale-Appleby	Chairman: Skills for Care and Development	09/05/2011
Professor David Croisdale-Appleby	Professor at the Wolfson Research Institute	09/05/2011
Professor David Croisdale-Appleby	Professor at the School of Medicine & Health at the University of Durham	09/05/2011
Professor David Croisdale-Appleby	Member of the Social Care Research Ethics Committee	09/05/2011
Dr Anton Joseph	Dr Joseph has declared no interests.	09/05/2011
Mr Roy Sinclair	Pharmacist: Professional Services Advisor, Day-Lewis Pharmacy, Croydon	09/05/2011
Mr Roy Sinclair	Lecturer: Pharmacy Law and Ethics, Kingston University, Kingston upon Thames	09/05/2011
Mrs Vera Hughes	Mrs Hughes has declared no interests.	09/05/2011
Professor David Caplin	Shareholding: Smith & Nephew (medical device manufacturer)	09/05/2011
Professor David Caplin	Lay partner with the Health Professions Council	09/05/2011
Professor Bob Brecher	Prof Brecher has declared no interests.	09/05/2011

**Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	13/04/2011	14
May	11/05/2011	14
June	08/06/2011	13
July	13/07/2011	14
August	10/08/2011	12
September	14/09/2011	11
October	12/10/2011	12
December	07/12/2011	6
December	20/12/2011	7
January	11/01/2012	13
February	08/02/2012	11
March	14/03/2012	9

12 full committee meetings were held during the reporting period.

The 07 December 2011 meeting was inquorate, the applications were reviewed at a subsequent meeting on 20 December 2011.

**Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:**

0 proportionate review sub-committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2011 – 31 March 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Roy Sinclair	12
Professor Liz Meerabeau	12
Mr Ron Driver	11
Professor David Caplin	11
Mr Guy Gardener	11
Mrs Vera Hughes	9
Dr Ashok Bhiman	8
Professor Cornelius Katona	8
Dr Robin MacKenzie	8
Professor John Eastwood	7
Dr Alan Fishtal	7
Dr Ann Gallagher	7
Dr Anton Joseph	6
Professor Bob Brecher	6
Dr L. Alan Ruben	7
Professor David Croisdale-Appleby	4
Miss Stephanie Ellis	2

**Number of inquorate meetings held: 1**

The 07 December 2011 meeting was inquorate, the applications were reviewed at a subsequent meeting on 20 December 2011.

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2011 – 31 March 2012:**



**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Roy Sinclair	19/05/2011 - 19/05/2011	Research with Adolescents
Mr Roy Sinclair	19/05/2011 - 19/05/2011	NRES – Research with Adolescents (Code CO5001)
Mr Roy Sinclair	24/05/2011 - 24/05/2011	Care of the Diabetic Patient
Mr Roy Sinclair	04/01/2012 - 04/01/2012	The Mental Capacity Act Toolkit (NRES)
Professor David Caplin	20/06/2011 - 25/06/2011	NRES Equality and Diversity online training module
Professor Bob Brecher	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web', NRES

**Part 2: REC workload and activity during the reporting period.**

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	14	19.18
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	11	15.07
Others	48	65.75
<b>Total Applications Reviewed</b>	<b>73</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	22
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
Number of prisoner applications reviewed	10
Number of applications involving adults unable consent reviewed	12
Number of applications reviewed funded by the US DHHS	0

**Table 3: Decisions given at meetings held within the reporting period:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	7	9.59
Favourable Opinion with Additional Conditions	3	4.11
Unfavourable Opinion	11	15.07
Provisional Opinion	52	71.23
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>73</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	49	67.12
Further Information Favourable Opinion with Additional Conditions	2	2.74
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	9.59
Favourable Opinion with Additional Conditions	3	4.11
Unfavourable Opinion	11	15.07
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	1	1.37
<b>Total</b>	<b>73</b>	<b>100</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.64
<b>Number of applications for full ethical review over 60 days</b>	12
<b>Number of applications over 60 days as a % of total</b>	16.44%
<b>Number of days taken to final decision - average</b>	46
<b>Number of days taken to final decision - mode</b>	27
<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	163
<b>Number of substantial amendments over 35 days</b>	39
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	23.9%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	7
<b>Number of modified amendments over 14 days</b>	4
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	57.1%

**Table 6: Breakdown of current status of all applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0277	Asthma Patient & Volunteer Database, Version 1	30
11/LO/0383	Continuity of Care and Prison based Integrated Drug Treatment	53
11/LO/0387	RCT of ketamine versus placebo after thoracotomy or VATS surgery (1)	51
11/LO/0417	Use of the Bluespier Database for Musculoskeletal Research	44
11/LO/0440	Optimisation of the bed acquisition time for PET/CT v1.0	42
11/LO/0533	Parental Questionnaire about Gastroenteritis	85
11/LO/0562	COPD AND CARDIOVASCULAR DISEASE COHORT DATABASE	39
11/LO/0567	Education and Research Database for healthcare communication	36
11/LO/0579	The formation of professional identity by newly qualified doctors	49
11/LO/0686	Surgical Metabolic Phenotyping	39
11/LO/0705	Assessing the impact of Sonas for people with dementia: a pilot study	36
11/LO/0755	Improving the care of homeless people	54
11/LO/0756	Acute effects of exercise on tobacco withdrawal during pregnancy	49
11/LO/0758	Experience of patients and equality of care in the trust: maternity v2	58
11/LO/0781	The Reflect Interview (pilot) v1	35
11/LO/0979	An exploration of midwives' perception in supporting smoking cessation	56
11/LO/1002	The use of section 136 of the Mental Health Act	50
11/LO/1009	Service users' experiences of recovery under the 2008 CPA - V1.0	57
11/LO/1029	URINARY NERVE GROWTH FACTOR LEVELS IN WOMEN WITH URINARY SYMPTOMS.V 1	54
11/LO/1032	Comparison of ability of agents to correct abnormal clotting in blood	30
11/LO/1039	Aplastic Anaemia Registry	37
11/LO/1144	UK Endocarditis Research Database	118
11/LO/1220	TMC435-TiDP16-C213	82
11/LO/1369	Phase 3 Study of ADI-PEG 20 in Patients with Hepatocellular Carcinoma	57
11/LO/1374	Neuroprotection with phenytoin in optic neuritis	48
11/LO/1405	GDC-0980 vs Everolimus in MRCC patients who failed anti - VEGF therapy	46
11/LO/1409	Mood and help-seeking in PD	30
11/LO/1467	Experience of patients and equality of care in the trust: GUM v2	76

11/LO/1482	Amphinex-based PCI of bleomycin (PCI/101/06 extension)	49
11/LO/1483	Connexin-43 protein expression in chronic wound-healing	54
11/LO/1569	Overexpression of chromosome 1q proteins in breast cancer	69
11/LO/1590	Developing a tool to stratify risk of medication harm in the elderly	47
11/LO/1927	Oritavancin vs Vancomycin in Patients with ABSSSI (SOLO I)	62
11/LO/1928	Oritavancin vs Vancomycin in Patients with ABSSSI (SOLO II)	65
11/LO/1931	Nature Of Therapeutic Encounter In Adolescent Psychotherapy Group	75
11/LO/1932	Continuous glucose monitoring in enteral feeding	54
11/LO/1939	Contingency management for cannabis use in early psychosis (CIRCLE)	72
12/LO/0040	Comparison of Memokath and TUR-P as Treatment for BOO due to BPH	114
12/LO/0054	CT327 Phase IIb Psoriasis Study	37
12/LO/0068	Sipuleucel-T Manufacturing Demonstration Study, ver .01	100
12/LO/0076	Breaking Free Online Research Database	53
12/LO/0117	Introductory Styles to Risk Discussions	86
12/LO/0188	Partner Coping: Communication Disorders following Brain Injury	51
12/LO/0201	Acute coronary syndrome Biomarker Cohort study	27
12/LO/0212	comparing ProAQT versus PiCCO	46
12/LO/0325	Examination of Patients with Defective DNA Repair	39
12/LO/0352	Management of Offenders with Mental Illness - Version 2	32
12/LO/0395	AN OBSERVATIONAL STUDY OF PATIENT ASSESSMENT IN THE TRAUMA SETTING	53
12/LO/0398	Towards a model of psychotherapeutic group work with young offenders	47

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0439	Genetic fMRI	42
11/LO/0582	Opportunities for innovation in MND Occupational Therapy Services	55

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0331	CONCORD-2	22
11/LO/0547	MRI and Dementia: A multi-centre study of autopsy proven cases	27
11/LO/0566	TransMAGIC	41
11/LO/1616	A study of violent and/or self harming women in prison	29
11/LO/1746	Impact of primary health care outreach on a probationer population	28
12/LO/0039	Assessing the protective effect of autophagy in a breast cancer.	27
12/LO/0211	MCL5 MARiT Study	25

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0778	Haemofiltration and cerebral microembolisation	23
11/LO/1192	Recording and analysing speech patterns: a pilot study	26
12/LO/0192	UCL CPET Database	25

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0356	The impact of an antenatal group intervention on attachment	21
11/LO/0423	UCLH/UCL CBRC Surgical Outcomes Research Centre CPET database	27
11/LO/0977	Psychosocial functioning in patients using different stoma appliances	31
11/LO/1052	Quality of Life in Eosinophilic Oesophagitis	54
11/LO/1132	Efficacy and Safety of TAK-491 in Grade 2 or 3 Essential Hypertension.	26
11/LO/1195	Impact of primary care outreach on hard to reach service users	34
11/LO/1407	Mindapples: 5-a-day for your mind (v2)	28
11/LO/1620	Efficacy and Safety of TAK-491 in Grade 2 or 3 Essential Hypertension.	21
11/LO/1623	Breaking Free Online Research Database	27
12/LO/0186	How we interpret unusual experiences and their link to life events V.1	25
12/LO/0342	Phenomenology of sexual and violent thoughts and images in OCD	42

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/1259	GE-135-009 Phase 2 Study	28

<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>



**Table 7: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0533	Parental Questionnaire about Gastroenteritis	85
11/LO/1144	UK Endocarditis Research Database	118
11/LO/1220	TMC435-TiDP16-C213	82
11/LO/1467	Experience of patients and equality of care in the trust: GUM v2	76
11/LO/1569	Overexpression of chromosome 1q proteins in breast cancer	69
11/LO/1927	Oritavancin vs Vancomycin in Patients with ABSSSI (SOLO I)	62
11/LO/1928	Oritavancin vs Vancomycin in Patients with ABSSSI (SOLO II)	65
11/LO/1931	Nature Of Therapeutic Encounter In Adolescent Psychotherapy Group	75
11/LO/1939	Contingency management for cannabis use in early psychosis (CIRCLE)	72
12/LO/0117	Introductory Styles to Risk Discussions	86
12/LO/0040	Comparison of Memokath and TUR-P as Treatment for BOO due to BPH	114
12/LO/0068	Sipuleucel-T Manufacturing Demonstration Study, ver .01	100

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
03/1/014/AM01	Epidemiology study on breast cancer	No 15 11th January 2011	90
03/1/014/AM02	Epidemiology study on breast cancer	No 16 11th February 2011	56
03/1/014/AM03	Epidemiology study on breast cancer	No 17 1st March 2011	38
07/H1102/101/AM12	A Phase I trial of intravenous GSAO (Protocol PH1/109)	CTA Amendment 12, dated 08 August 2011 (including	63
03/1/082/AM03	National Collaborative Usher Study	version 2, July 2011	58

08/H1102/52/AM14	A6181170 Sunitinib vs sorafenib in patients with Primary liver cancer	Updated Investigator Brochure July 2011	42
10/H1102/75/AM01	Alzheimer's disease-related proteins in Down's syndrome cells	1, 05/09/11	76
07/H1102/84/AM21	A6181109- Sunitinib treatment of renal adjuvant cancer (S-TRAC)	Updated Investigator Brochure July 2011	38
09/H1102/116/AM11	Extension Trial of Bapineuzumab Alzheimer Disease ApoE4 Non Carriers	(3133K1-3002-WW) Protocol Amendment 2 dated 26 Jul	42
09/H1102/55/AM05	A Randomised Controlled Trial of Multi Systemic Therapy in the UK v1.0	substantial amendment 5	50
11/LO/1002/AM02	The use of section 136 of the Mental Health Act	Substantial Amendment 1	42
11/LO/1405/AM02	GDC-0980 vs Everolimus in MRCC patients who failed anti - VEGF therapy	Substantial Amendment 2	42
11/LO/1220/AM01	TMC435-TiDP16-C213	Substantial Amendment 1	36
10/H1102/43/AM07	Subcutaneous Tocilizumab in Rheumatoid Arthritis	Substantial Amendment 7	36
09/H1102/55/AM06	A Randomised Controlled Trial of Multi Systemic Therapy in the UK v1.0	Substantial Amendment 6	42
08/H1102/74/AM06	Abigail - Avastin & Chemotherapy Biomarker Lung Cancer Study	Substantial Amendment 4	36
05/MRE01/65/AM05	Tenofovir DF vs. Adefovir Dipivoxil for treating HBeAg positive Hep B	Substantial Amendment 5	124
05/MRE01/64/AM07	Tenofovir DF vs. Adefovir Dipivoxil for treating HBeAg negative Hep B	Substantial Amendment 5	124
07/MRE01/26/AM03	CVD Prevention	Study Extension	48
07/MRE01/10/AM27	SORCE-version 1.0	Substantial Amendment 27	55
10/H1102/32/AM11	OMS210 vs placebo in diarrhoea predominant irritable bowel syndrome	Substantial Amendment 11	64
09/H1102/117/AM15	Extension Trial of Bapineuzumab Alzheimer Disease ApoE4 Carriers	aub am 14	49
09/H1102/116/AM14	Extension Trial of Bapineuzumab	sub am 13	49

	Alzheimer Disease ApoE4 Non Carriers		
08/H1102/24/AM34	Bapineuzumab (AAB-001) in Alzheimer's Disease, ApoE carriers.	sub am 33	61
10/H1102/51/AM04	Platelet response & remission in adults with ITP receiving romiplostim	sub am 4	64
07/MRE01/1/AM09	National case-control study of breast cancer in men, Version 1	sub am 4	61
10/H1102/16/AM10	BIBW 2992 and Paclitaxel versus Chemotherapy in NSCLC	sub am 9	64
02/1/078/AM05	Monitoring Outcomes in Multiple Sclerosis	sub am 6	64
09/H1102/82/AM02	Prevention of metabolic complications of glucocorticoid excess	sub am 2	83
09/H1102/115/AM08	PANTHER (version 1, 16 November 2009)	Substantial Amendment 3	47
12/LO/0054/AM01	CT327 Phase IIb Psoriasis Study	Substantial Amendment 1	38
11/LO/0755/AM02	Improving the care of homeless people	Substantial Amendment 1	58
11/LO/1590/AM01	Developing a tool to stratify risk of medication harm in the elderly	Substantial Amendment 1	38
10/H1102/30/AM05	RCTs within the database: a feasibility study of statin effectiveness	Substantial Amendment 3	47
11/LO/0772/AM02	A Randomised Controlled Trial to evaluate MST-PSB in the UK V1.0	Substantial Amendment 2	44
10/H1102/64/AM02	Rubidium-82 PET and Tc-99m-MIBI SPET: A head to head comparison	Substantial Amendment 2 - Restart clinical study	69
07/MRE01/30/AM10	Bone Health Study GLOW	Amendment 6, 8 February 2012	55
09/H1102/86/AM07	111 trial	sub am 7	53
08/H1102/23/AM35	Bapineuzumab (AAB-001) in Alzheimer's Disease, ApoE non-carriers.	sub am 34	75

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
09/H1102/88/AM04/1	Human Motion Analysis Database	sub am 5 (mod.)	128
07/H1102/96/AM07/1	Diabetes Prevention in People from Bangladesh: Phase 2+3	sub am 8 (mod)	17
09/H1102/110/AM09/1	Wheeze And Intermittent Treatment; WAIT	Modified amendment	53
09/H1102/55/AM06/1	A Randomised Controlled Trial of Multi Systemic Therapy in the UK v1.0	Modification to Amendment 6.0 dated 14/12/2011. A	35

<b>Section 30 application over 60 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>