

# NRES Committee London - Fulham

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Fulham
<b>Type of REC:</b>	Recognised, Type III
<b>Type of Flag:</b>	CTIMP, IRB & Paediatrics
<b>Chair:</b>	Dr Charles Mackworth-Young
<b>Vice-Chair:</b>	Dr Frank Miskelly
<b>Alternate Vice-Chair:</b>	Mr. Vassilios Papalois
<b>Co-ordinator:</b>	Miss Shehnaz Ishaq (March 2012 onwards)
<b>PRSC Co-ordinator:</b>	Miss Shehnaz Ishaq (March 2012 onwards)
<b>Assistant Co-ordinator:</b>	Miss Claire Noon (March 2012 onwards)
<b>Committee Address:</b>	HRA NRES Centre North West Barlow House 3rd Floor, 4 Minshull Street Manchester M1 3DZ
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### Chair's overview of the past year:

The principal feature of the year was the disruption caused by moves within the coordinators' office, and – more importantly - the lack of continuity in coordinator support. The Committee's business was managed by a series of individuals on temporary contracts who varied in commitment and ability. This led to significant difficulty in meeting deadlines; and communications with researchers were of variable quality. This situation was addressed with the appointment of an experienced coordinator – Miss Shehnaz Ishaq – who has efficiently put the Committee's work back on a sound footing. One drawback of her appointment is that she works out of the Manchester office. This has meant a radical change in the way the Committee and Subcommittees operate, and in the communication between the Chairman and the Coordinator. However, these changes in working practices are now functioning well.

Earlier in the year the Committee started considering applications for proportionate review. This system is now working smoothly.

## NRES Committee London - Fulham Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Marian Cohen	Retired Lawyer	Lay Plus	15/07/2010	
Prof Alison Crombie	Anthropologist Nurse	Expert	18/05/2005	
Dr David Evans	General Practitioner	Expert	30/10/2006	13/03/2012
Dr Kanagasabai Ganeshaguru	Retired Scientist	Lay	30/06/2006	
The Rev'd Nigel Griffin	Hospital Chaplain	Lay Plus	30/06/2006	
Dr Shaun Griffin	Director of Communications and Public Affairs	Expert	04/11/2008	
Dr Akil Jackson	Physician	Expert	01/10/2007	
Mr David Leonard	Pharmacist	Expert	28/04/2005	
Dr Charles Mackworth-Young	Consultant Physician (Chairman)	Expert	28/04/2005	
Dr Colin Michie	Paediatrician	Expert	27/03/2006	
Dr Frank Miskelly	Physician (Vice-Chairman)	Expert	30/06/2009	
Dr Shirlony Morgan	Psychiatrist	Expert	16/11/2009	
Professor Sandra Oliver	Retired Academic	Lay Plus	16/05/2011	
Mr Vassilios Papalois	Surgeon	Expert	04/03/2010	
Lady Roche	Lay Member	Lay Plus	23/02/2005	
Mrs Gillian Sichau	Occupational Therapist	Expert	15/07/2010	
Mrs Katie Wilkinson	Clinical Trials Centre Manager	Lay	08/11/2007	
Dr Ruth Williamson	Radiologist	Expert	07/05/2009	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

**NRES Committee London - Fulham: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr David Leonard	None	22/12/2011
Dr Shaun Griffin	Member of Executive Team at HTA	21/12/2011
Dr Akil Jackson	Employed in Clinical Research Unit, St Stephens Aids Trust	19/12/2011
Mrs Marian Cohen	None	19/12/2011
Dr Charles Mackworth-Young	Medical Director at King Edward Hospital & Consultant Physician at Imperial College NHS Healthcare Trust Chairman of Imperial College Peer Review Committee	08/05/2011
Dr Shirlony Morgan	Research Associate at University College London, Mental Health Science Department Honorary contracts for research purpose at North Essex Mental Health Partnership Trust and North East London Mental Health Partnership Trust.	01/04/2011
Prof Alison Crombie	Joint post as Professor engaged in bidding for research funds and supervising PhD supervision	11/04/2011
Dr Colin Michie	Medical advisory position to AHPMA	11/04/2011
Lady Alexandra Roche	Health consultant on ethics Has shareholdings in GSK & Astra Zeneca	01/12/2011
Professor Sandra Oliver	Other activities -Research generally vis a vis CIPR R&D unit Committees and 2)undertakes academic peer reviews occasionally and 3) eye tracking in her research interest from time to time.... these would be declared at REC meetings as a conflict of interest	01/12/2011
Dr Kanagasabai Ganeshaguru	None	11/04/2011
The Rev'd Nigel Griffin	None	11/04/2011
Mrs Katie Wilkinson	Operations Manager for St George's Clinical Research Facility	11/04/2011
Mrs Gillian Sichau	None	11/04/2011
Dr Frank Miskelly	None	11/05/2011
Mr Vassilios Papalois	None	06/06/2011

**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	11/04/2011	11
May	16/05/2011	14
June	20/06/2011	15
July	18/07/2011	14
September	19/09/2011	13
October	17/10/2011	14
November	21/11/2011	14
December	19/12/2011	10
January	16/01/2012	10
February	20/02/2012	15

10 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	11/04/2011	3
May	16/05/2011	3
June	20/06/2011	3
July	18/07/2011	3
September	19/09/2011	3
October	17/10/2011	3
November	21/11/2011	4
January	16/01/2012	3
February	20/02/2012	3

9 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>
Dr Kanagasabai Ganeshaguru	10
Mrs Marian Cohen	10
The Rev'd Nigel Griffin	10
Dr Charles Mackworth-Young	9
Lady Alexandra Roche	9
Dr Ruth Williamson	8
Dr Shaun Griffin	8
Dr Akil Jackson	8
Dr Frank Miskelly	8
Mr David Leonard	7
Mrs Gillian Sichau	6
Mrs Katie Wilkinson	6
Prof Alison Crombie	6
Dr Colin Michie	6
Dr Shirlony Morgan	5
Mr Vassilios Papalois	5
Professor Sandra Oliver	4
Dr David Evans	4

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Frank Miskelly	5
Dr Akil Jackson	3
Dr Charles Mackworth-Young	4
Dr Shirlony Morgan	2
The Rev'd Nigel Griffin	2
Dr Ruth Williamson	2
Dr Kanagasabai Ganeshaguru	2
Mr Vassilios Papalois	2
Mrs Katie Wilkinson	2
Mrs Marian Cohen	1
Reverend Nigel Griffin	1
Dr Shaun Griffin	1
Dr David Evans	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Lady Roche	01/03/2012 - 01/03/2012	Adults Lacking Capacity, NRES
Lady Roche	14/03/2012 - 14/03/2012	National Training Day, NRES
The Rev'd Nigel Griffin	08/09/2011 - 08/09/2011	Human Embryo Research: Law Ethics & Public Policy, Corpus Christi college
The Rev'd Nigel Griffin	16/03/2012 - 16/03/2012	Law & Ethics in Intensive Care, Exeter College
Dr David Evans	14/03/2012 - 14/03/2012	NRES Members National Training Day , NRES
Dr Shaun Griffin	20/02/2012 - 20/02/2012	The environment for health research in the UK, Wellcome Trust
Dr Shaun Griffin	05/03/2012 - 05/03/2012	Health Research Authority – 'Improving research regulation', Health Research Authority
Dr Kanagasabai Ganeshaguru	07/11/2011 - 07/11/2011	Ethics & GCP Forum, The Insitute of Clinical Research

**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	22.22
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	49	77.78
<b>Total Applications Reviewed</b>	<b>63</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	14
Number of student applications reviewed	19
Number of paediatric applications reviewed	22
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	2

**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	12	19.05
Favourable Opinion with Additional Conditions	12	19.05
Unfavourable Opinion	6	9.52
Provisional Opinion	33	52.38
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>63</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	29	46.03
Further Information Favourable Opinion with Additional Conditions	3	4.76
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	12	19.05
Favourable Opinion with Additional Conditions	12	19.05
Unfavourable Opinion	6	9.52
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	1	1.59
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>63</b>	<b>100</b>

**Table 5: Applications assigned to a proportionate review sub-committee within the reporting period:**

<b>Total Applications Reviewed</b>	<b>26</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	17	65.38
Favourable Opinion with Additional Conditions	3	11.54
No Opinion transfer to full committee for review	3	11.54
Provisional Opinion	2	7.69
Unfavourable Opinion	1	3.85
<b>Total</b>	<b>26</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.30
<b>Number of applications for full ethical review over 60 days</b>	3
<b>Number of applications over 60 days as a % of total</b>	4.76%
<b>Number of days taken to final decision - average</b>	31
<b>Number of days taken to final decision - mode</b>	25
<b>Number of SSAs (non-Phase 1) reviewed</b>	6
<b>Number of applications for SSA review over 25 days</b>	2
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	33.3%
<b>Number of SSAs (Phase 1) reviewed</b>	1
<b>Number of applications for SSA review over 14 days</b>	1
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	100.0%
<b>Number of substantial amendments reviewed</b>	142
<b>Number of substantial amendments over 35 days</b>	16
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	11.3%
<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>	15
<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>	26.7%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	9
<b>Number of proportionate review applications over 14 days as a % of total</b>	39.13%

**\*NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

**Table 8: 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/0249	Bleeding in Previously Treated Subjects With Severe Haemophilia A	42
11/LO/0275	GS 0110 Open Label Single Tablet Comparison in HIV Patients	56
11/LO/0410	Attachment style, self-capacities and violence (1)	71
11/LO/0540	ARQ197 plus Erlotinib for treating non-small-cell lung cancer	25
11/LO/0560	The Emotional Impact on Sibling Bone Marrow Donors. 1	39
11/LO/0716	GPs' awareness of allergic rhinitis guidelines.	6
11/LO/0777	A study of the genetics and physical properties of dental anomalies	27
11/LO/0799	Neuroimaging of child physical abuse	34
11/LO/0831	The use of PILLGLIDE® in children	54
11/LO/0875	Changes in lung inflammatory markers in Paediatric Acute Lung Injury	29
11/LO/0887	BIAsp-3878: Investigator driven vs subject driven titration of BIAsp30	23
11/LO/1022	Doctors' Attitudes towards Female Genital Alteration (DAFGA)	20
11/LO/1024	Biliopancreatic limb study	17
11/LO/1031	Weight restoration and OCD symptoms in Anorexia Nervosa	16
11/LO/1050	Epigenetic control of glycolytic enzyme genes	30
11/LO/1059	Magnetic resonance of carotid artery ageing in HIV individuals	17
11/LO/1465	MAPPING	48
11/LO/1498	PROTEase inhibitor in HIV-1 patients	37
11/LO/1683	Variability of IOP measurements	22
11/LO/1689	Barts and the London Immunology Registry Version 1.0	18
11/LO/1826	Immunity against RSV & influenza in a human challenge model	24
11/LO/1833	Self awareness following paediatric brain injury	64
11/LO/1934	Bladder diary variables in asymptomatic pregnant women	13
11/LO/1996	Response and resistance to targeted therapy in renal cell carcinoma	40
12/LO/0049	The association between CTEV and DDH	50
12/LO/0067	Glucose control in Type 1 diabetic patients during athletic training	14
12/LO/0070	Asking terminally ill cancer patients about corneal donation	17
12/LO/0085	Panobinostat with Azacitidine in patients with leukemia	19
12/LO/0222	Understanding and managing the coagulopathy of APL (Pilot Study)	45
12/LO/0262	Study in patients with high cholesterol and at risk of heart disease	33

12/LO/0268	VX-950HPC3008 (INSIGHT)	72
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Further Information Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/LO/1064	A Phase 2 Study with AMG 145 in Subjects With Hypercholesterolemia	16
11/LO/1282	SABRE 3G - feasibility study	26
11/LO/1597	Family Therapy Outcome and Service Evaluation Questionnaire (SCORE-15)	25

Further Information Unfavourable Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/LO/0311	Colorectal cancer in the UK liver transplant population	30
11/LO/0312	Vascular Resection during Pancreatectomy	30
11/LO/0462	Delirium in intensive care:a questionnaire survey. Version 1.1	6
11/LO/0472	Effective support for patient with chronic liver disease	6
11/LO/0581	Autoimmune Addison's Disease of Childhood	30
11/LO/0695	Geriatric-oncology liaison pilot intervention	28
11/LO/0912	Evaluating the Incidence of VitaminD Deficiency in Newborn population	18
11/LO/0933	Early mobilization in ICU patients	17
11/LO/0949	Mentorship capacity in nursing (version 1)	20
11/LO/1012	Staphylococcus aureus Decolonisation Project	40
11/LO/1129	Polycystic ovarian syndrome (PCOS) and endometrial receptivity v.001	20
11/LO/1138	Dental workforce skill-mix study: modelling the workforce skill-mix	10
11/LO/1428	Frail and Elderly Patient Outcomes on Dialysis (FEPOD): Part 1	25
11/LO/1454	Assessment of coronary physiological reserve in aortic stenosis	25
11/LO/1468	Analysis of SHP-1, trkA and p53 in neuroblastoma	31
11/LO/1480	On Becoming a Service User Researcher	25
11/LO/1575	Retrospective Audit of Mortality in ALI/ARDS	12
11/LO/1722	Bioflow III Registry (CIP No: C1011 Version 2.0)	8
11/LO/1930	Knowledge of epilepsy at transition	8
11/LO/1938	Breast referrals - characteristics predicting no focal mass	15
11/LO/1944	Exploration of women's experiences of cigarette smoking in pregnancy	9

12/LO/0071	GenomALC Trial	10
12/LO/0142	Ethnicity and Blood Transfusion in Acute Upper GI Bleeding	1
12/LO/0143	Personalising screening with mammogram CAD and risk data: Pilot study	22
12/LO/0147	A New Method for Identifying Site of Origin of Ventricular Arrhythmias	19
12/LO/0203	Breast milk: a messenger between mother and baby? Version 1/090113	28
12/LO/0214	Vitamin B6 in Premature Newborns	32
12/LO/0364	Histological and molecular biomarkers of endometrial cancer	23
12/LO/0367	Correlation of SMA Expression with Survival in Head and Neck Cancer	23

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0586	Prevalence of Sexual Violence at London Sexual Health clinics	28
11/LO/0668	Paracetamol use in pregnant women	24
11/LO/0700	Sleep, Circadian Rhythms and Cluster Headache	57
11/LO/0744	FRA multiple discrimination in access to health care	9
11/LO/0806	Cryoanalgesia and Botulinum Toxin Injection. Version 1.0	23
11/LO/1081	HARNESS	14
11/LO/1714	Using Human Tissues for Comparison Testing of Biological Scaffolds-C	7
11/LO/1715	Using Human Tissues for Comparison Testing of Biological Scaffolds-M	7
11/LO/1886	Frail and Elderly Patient Outcomes on Dialysis (FEPOD): Part 2	28
11/LO/1895	Evaluation of anti-inflammatories for the reduction of Mosquito bites	22
11/LO/1908	8HA01EXT Long-Term Safety and Efficacy of rFVIII Fc Haemophilia A	35
11/LO/1966	In Vivo Changes In Oestrogen Receptor DNA Binding Events-Breast Cancer	35
11/LO/1982	European Union Childhood Life-threatening Infectious Diseases Study	35
12/LO/0060	Barriers and Facilitators of Oral Health, Version 1.0	14
12/LO/0193	Airway function in athletes with exercise induced bronchoconstriction	28

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0343	Mentoring within forensic mental health services	30
11/LO/0466	Parents' preference for preventive interventions in GA children	6
11/LO/0691	self-awareness in paediatric brain injury	48
11/LO/1427	Immunity against RSV & influenza in a human challenge model	36
11/LO/1819	NN7088-3859 Trial Evaluating Safety and Efficacy of N8-GP in Haem A	23

11/LO/1820	NN7088-3860 Efficacy and Safety of N8-GP during Surgery in Haem A	23
11/LO/1971	(duplicate) TIC genetics, version 1	35

<b>Provisional Opinion</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Provisional Opinion Pending Consultation with Referee</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Further information response not complete</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Withdrawn after the meeting</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Invalid Application</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>No Opinion Pending Consultation with Referee</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Not Requiring Review by NHS REC</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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**Table 9: 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/0410	Attachment style, self-capacities and violence (1)	71
11/LO/1833	Self awareness following paediatric brain injury	64
12/LO/0268	VX-950HPC3008 (INSIGHT)	72

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0933	Early mobilization in ICU patients	17
11/LO/0949	Mentorship capacity in nursing (version 1)	20
11/LO/0912	Evaluating the Incidence of VitaminD Deficiency in Newborn population	18
11/LO/1129	Polycystic ovarian syndrome (PCOS) and endometrial receptivity v.001	20
11/LO/1938	Breast referrals - characteristics predicting no focal mass	15
12/LO/0147	A New Method for Identifying Site of Origin of Ventricular Arrhythmias	19
12/LO/0143	Personalising screening with mammogram CAD and risk data: Pilot study	22
12/LO/0364	Histological and molecular biomarkers of endometrial cancer	23
12/LO/0367	Correlation of SMA Expression with Survival in Head and Neck Cancer	23

<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>
11/LO/0910	COPD Biomarker Identification Study V1.0	49
12/LO/0368	Barriers and Facilitators of Oral Health, Version 1.0	49

<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>
12/LO/0554	A study to evaluate the effects of Sabarep™ cream (zinc lactate1% w/w)	16

<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>



10/H0711/87/AM04	OPTIMIZE: BID vs q8h telaprevir in HCV G1 naive	Substantial Amendment 2.0, version 1.0, 11MAR2011	37
09/H0711/39/AM09	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	Lenalidomide IB version 14, dated 17 Decemeber 201	36
10/H0711/88/AM01	TRIO 014 - version 3.0	CTA-A#1: revised main PICF dated 7th March 2011	42
10/H0711/11/AM09	Phase 3 study of the efficacy and safety of DAC HYP in MS patients	Substantial Amendment 1 06/04/2011	46
07/H0712/137/AM01	Scavenging free haemoglobin during cardiac surgery	Amendment 1; date 25/01/2011	130
09/H0712/59/AM03	Mechanisms of Rhinovirus Induced Asthma Exacerbations	Amendment Number 3 (AM03), 9th June 2011	38
09/H0711/39/AM10	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	Amendment 6 (Protocol Amendment 3)	39
07/H0712/150/AM09	Investigation into heart disease and stroke – the LOLIPOP study	Amendment 5	44
10/H0711/6/AM31	Alecardio Study	Amendment 6	63
10/H0712/3/AM02	Injury Mechanics of Cadaveric Lower Limbs	Taking additional samples	51
11/LO/0097/AM03	VIP Version: 1	Implementation of urgent safety measure	45
09/H0711/56/AM18	COU-AA-302 Abiraterone Acetate in Metastatic Prostate Cancer April-09	Amendments to patient letter and informed consent	51
11/LO/0887/AM03	BIAsp-3878: Investigator driven vs subject driven titration of BIAsp30	Addition of a leaflet created by National Inst. fo	40
10/H0711/14/AM11	Cognitive training and modafinil for cognition in schizophrenia-V2	Addition of conventional or typical antipsychtics	39
10/H0711/91/AM02	Acute weight loss and body composition	Randomisation of current volunteers into study, ad	44
11/LO/0101/AM05	Efficacy and safety of AT1001 and ERT in patients with Fabry Disease	Addition of new site to study	44

<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>
10/H0711/88/AM01/1	TRIO 014 - version 3.0	Modified Amendment 1.1	18
10/H0711/36/AM01/2	Immune Monitoring Study	Modified Amendment 1.2	20
10/H0711/97/AM03/1	Phase 3 study of AA500 in men with Peyronie's disease (V2:08Sep10)	Modified Amendment 2.1	27
10/H0712/1/AM01/1	Mapping Educational Activity in the Operating Theatre	Substantial Amendment 1	19

<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>