

# NRES Committee London - London Bridge

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - London Bridge
<b>Type of REC:</b>	Type 1 and Type 3
<b>Type of Flag:</b>	Phase 1
<b>Chair:</b>	Professor David Bartlett
<b>Vice-Chair:</b>	Mr Brady Pohle
<b>Alternate Vice-Char:</b>	Dr Michael Goggin
<b>Co-ordinator:</b>	Stephanie Hill
<b>PRSC Co-ordinator:</b>	None
<b>Assistant Co-ordinator:</b>	Claude Beckles
<b>Committee Address:</b>	Health Research Authority Skipton House 80 London Road London SE1 6LH
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## Chair's overview of the past year:

NRES Committee London - London Bridge continues to be a busy and effective REC. The Committee has maintained a good attendance record (an average of just under 10 members attended each meeting, no meetings were cancelled due to inquoracy) and has reviewed just under 6 studies per meeting. Like last year the committee has received a number of informal comments about the style and friendliness of the main meeting from applicants. We continue to see most applications on time with few waiting more than 15 minutes for their interview. The scope of the applications has altered slightly with more of a focus on phase 1 studies and clinical trial of an investigational medicinal product which combined produced 43% of the total, an increase from 28% last year. Questionnaire based studies often take up more time as the preparation by the applicants is not often as good as other studies.

The number of CTIMPs reviewed were 16 an increase from 7 last year. The number of Phase 1 studies reviewed was 9, slightly down from 12 last year. Our REC has maintained good review times the average number of days taken to final decision is now 39 and mode 27 compared with last years' 44 and 24 respectively. The Committees work outside the main meeting continues to be high with the number of substantial amendments processed remaining roughly the same from 75 to the current 67. We continue to have a good relationship with the Guy's and St Thomas' R & D Department and the Joint Clinical Trials Office and the committee continues to be part of the SSA Network for Phase 1 Trials reviewing all SSIs for Quintiles Drug Research Unit at Guy's Hospital. The number of non-NHS SSIs has increased from 10 to 19.

The NRES Committee London - London Bridge has kept up with current legislation and guidance from NRES. Professor David Bartlett, Mr Brady Phole and Dr Michael Goggin all attended the chairs meeting held by NRES. There has been an increase in the amount of members taking part in training provided by or recommended by NRES, with 9 members (60% of the Committee) taking part in at least one training event. Efforts will continue to be made to ensure members are receiving the information and support they need to book themselves on to training in the future.

There have been a number of changes in the membership over the past year: There have been 5 new members and 1 leaving. The Vice-chair Dr Shane Tibby left in June 2011 after 10 years service. Mr Brady Pohle and Dr Mike Goggin were appointed as Vice-chair and Alternate Vice-chair respectively. The change over reflects normal patterns and the increase in numbers has allowed us to maintain numbers above quorate each meeting and also we have not needed to co-opt members from other committees at short notice. The co-ordinator was moved in early December to a large shared office at Charing Cross Hospital, Hammersmith. A further consultation was held in February 2012 to move all co-ordinators in London to Skipton House, Elephant and Castle. It is expected this move will take place later in the year as well as a further consultation on changing employers to the HRA as a single employer for all NRES REC co-ordinators.

## NRES Committee London - London Bridge Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Professor David Bartlett	Honorary Consultant	Expert	22/03/2007	
Dr Frances Dockery	Consultant Physician	Expert	13/02/2012	
Mr David Gallacher	Consultant Physicist	Expert	22/08/2010	
Dr Michael Goggin	Consultant Physician	Expert	03/08/2009	
Dr Nedim Hadzic	Consultant and Honorary Reader in Paediatric Hepatology	Expert	07/08/2010	
Ms Christine Higgins	Lay Member	Lay Plus	18/05/2009	
Miss Tamsin Jones	Lay Member	Lay	22/07/2011	
Dr Margreet Luchtenborg	Cancer Epidemiologist	Expert	17/08/2010	
Mrs Marion Maidment	Lay Member	Lay	13/06/2011	
Mr Barry Moody	Lay Member	Lay Plus	10/10/2011	
Mr Brady Pohle	Legal Services Advisor	Lay Plus	12/12/2006	
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Expert	06/06/2006	
Miss Josephine Studham	Clinical Research Facilities Manager	Expert	25/02/2010	
Ms Lorna Sutcliffe	Project Manager/Researcher	Expert	14/10/2004	
Dr Shane Tibby	Paediatric ITU Consultant/Expert	Expert	11/12/2001	30/06/2011
Mr Paul Tunstell	Pharmacist	Expert	28/03/2006	
Dr Ralph White	Lay Member	Lay	25/03/2011	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr William Thornhill	Senior Pharmacist, Paediatric Renal Services	Expert	20/04/2011 31/08/2011 28/09/2011 25/01/2012 28/03/2012

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

**Member Bank**

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

## NRES Committee London - London Bridge: Members' Declarations of Interest:

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Professor David Bartlett	Consultancies for GSK Dental, P & G Dental and Colgate Dental, not medical. Treasurer for the British Society for Oral and Dental Research, does not award grants.	30/03/2012
Mr Brady Pohle	Member of Guy's and St Thomas' NHS Foundation Trust. Acting Head of Legal Services (Solicitor) King's College Hospital NHS Foundation Trust. Staff Governor, King's College Hospital NHS Foundation Trust.	30/03/2012
Dr Michael Goggin	Trustee of the Alan Squirrell Artificial Kidney Fund. Member of Christ Church University Governance and Research Ethics Committee.	30/03/2012
Mr Paul Tunstell	Member of the Pharmacy R & D Committee, GSTFT.	30/03/2012
Ms Karen Sanders	Member of London South Bank Ethics Committee.	30/03/2012
Miss Josephine Studham	Member of the Quintiles/King's Health Partners collaboration in role as Clinical Research Facility Manager at GSTFT. This group manages the relationship between Quintiles and KHP. It does not discuss ethical issues relating to studies undertaken at Quintiles or KHP.	30/03/2012
Dr Nedim Hadzic	Ad hoc consultant for Isis Inc., California, USA.	30/03/2012
Dr Margreet Luchtenborg	None.	30/03/2012
Mr David Gallacher	Involved with the Medical Physics Research Facility (MPRF), GSTFT.	30/03/2012
Dr Ralph White	Director and Owner of PPMLD Ltd. Shareholder GlaxoSmithKline.	30/03/2012
Miss Tamsin Jones	None.	30/03/2012
Ms Lorna Sutcliffe	None.	30/03/2012
Mr Barry Moody	Shareholder AstraZeneca Plc and GlaxoSmithKline Plc. A "voice" of the Prostate Cancer Charity - a supporter and helper with various projects and initiatives.	30/03/2012
Dr Frances Dockery	Have applied for research grants (NIHR, GSTT Charity) 2011, 2012. NICE Clinical Guideline Group Member 2011/2012 on Osteoporosis, Fracture Risk Assessment.	30/03/2012
Mr Will Thornhill	None.	30/03/2012

**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	20/04/2011	10
May	25/05/2011	10
June	29/06/2011	11
August	31/08/2011	10
September	28/09/2011	11
October	26/10/2011	10
December	14/12/2011	10
January	25/01/2012	13
February	29/02/2012	10
March	28/03/2012	9

10 full 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 Michael Goggin	10
Dr Ralph White	10
Professor David Bartlett	9
Mr David Gallacher	8
Dr Margreet Luchtenborg	8
Miss Josephine Studham	7
Mr Brady Pohle	7
Ms Christine Higgins	7
Dr Nedim Hadzic	6
Mrs Marion Maidment	5
Mr William Thornhill	5
Ms Karen Sanders	4
Ms Lorna Sutcliffe	4
Miss Tamsin Jones	4
Mr Barry Moody	3
Mr Paul Tunstell	3
Dr Shane Tibby	2
Dr Frances Dockery	2

**Number of inquorate meetings held: 0**



## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr Brady Pohle	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members (code OP6002), NRES
Ms Karen Sanders	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members , NRES
Dr Margreet Luchtenborg	26/07/2011 - 26/07/2011	NRES Medical Devices training (code PO3003), NRES
Dr Margreet Luchtenborg	19/05/2011 - 19/05/2011	NRES Research in Adolescents, NRES
Mr David Gallacher	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members (code OP6002), NRES
Mr David Gallacher	11/10/2011 - 11/10/2011	Induction, NRES
Dr Nedim Hadzic	10/01/2012 - 10/01/2012	Induction, NRES
Dr Ralph White	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code - PO1101), NRES
Dr Ralph White	28/09/2011 - 28/09/2011	NRES Phase 1 training (code PO4001), NRES
Professor David Bartlett	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Miss Tamsin Jones	08/02/2012 - 08/02/2012	Induction, NRES
Mr Barry Moody	10/01/2012 - 10/01/2012	Induction, NRES
Mr Brady Pohle	21/03/2012 - 21/03/2012	Chairing Skills, NRES
Dr Michael Goggin	21/03/2012 - 21/03/2012	Chairing Skills, NRES
Mr Paul Tunstell	01/05/2011 - 01/05/2011	Learning the requirements for handling blood products in a GMP manufacturing facility, SDL
Ms Lorna Sutcliffe	26/09/2011 - 26/09/2011	Attended course on technology and medicine at RSM, SDL
Ms Lorna Sutcliffe	01/01/2012 - 01/01/2012	Self- learning CD on Mental Capacity Act , SDL
Miss Josephine Studham	14/04/2011 - 14/04/2011	Research Nurse In service Development, including informed consent, SDL
Miss Josephine Studham	07/06/2011 - 07/06/2011	Research Nurse In service Development, MHRA inspections and Trial master files, SDL

## 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	16	27.59
Phase 1	9	15.52
Gene Therapy	0	0.00
Research Tissue Bank	1	1.72
Research Database	0	0.00
Others	32	55.17
<b>Total Applications Reviewed</b>	<b>58</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	8
Number of paediatric applications reviewed	7
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
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	9	15.52
Favourable Opinion with Additional Conditions	3	5.17
Unfavourable Opinion	4	6.90
Provisional Opinion	42	72.41
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>58</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	1	

**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	36	62.07
Further Information Favourable Opinion with Additional Conditions	1	1.72
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	9	15.52
Favourable Opinion with Additional Conditions	3	5.17
Unfavourable Opinion	4	6.90
Provisional Opinion	2	3.45
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	1	1.72
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.72
Number of studies withdrawn after the meeting	1	1.72
<b>Total</b>	<b>58</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.80
<b>Number of applications for full ethical review over 60 days</b>	9
<b>Number of applications over 60 days as a % of total</b>	15.52%
<b>Number of days taken to final decision - average</b>	40
<b>Number of days taken to final decision - mode</b>	27

<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<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>	66.7%

<b>Number of SSAs (Phase 1) reviewed</b>	19
<b>Number of applications for SSA review over 14 days</b>	13
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	68.4%

<b>Number of substantial amendments reviewed</b>	67
<b>Number of substantial amendments over 35 days</b>	36
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	53.7%

<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>	2
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	50.0%

**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/0463	Evaluating Family Interventions in older adult mental health services	29
11/LO/0487	QBR110310 (060-102)	39
11/LO/0488	Communication and interpretation of risks of neutropenic sepsis	74
11/LO/0627	Effect of surgical sealant on range of motion in TKR	51
11/LO/0639	Lived experience of families of recently head injured patients	56
11/LO/0650	The Effects of Coadministration of Fostamatinib and Digoxin	40
11/LO/0703	Investigating the emergence of Peer Worker roles in Mental Health	34
11/LO/0844	Revised Affective Processing Project	31
11/LO/0851	A study of the safety, tolerability and handling of Dexpramipexole	25
11/LO/0871	Increasing walking in patients with PAD: version 1	33
11/LO/0892	Is there a constitutional 'global' lymphatic disturbance in BCRL?	104
11/LO/0906	Salivary markers for renal cancer	49
11/LO/1078	To investigate interaction of TC-5214 with antihypertensive medication	36
11/LO/1079	First in Human study of BAX 855 in Haemophilia A patients	30
11/LO/1236	Comorbidities in Severe Psoriasis	23
11/LO/1237	Prevalence of HIV associated neurocognitive disorder (HAND)	74
11/LO/1268	Radiofrequency ablation treatment for Neuromas	56
11/LO/1281	Near activities to enhance adherence with occlusion in amblyopia	74
11/LO/1397	Safety and tolerability of RV568 in patients with COPD	38
11/LO/1475	AZD3241 Extended release formulation study	35
11/LO/1528	Buprenorphine hemidepate with naloxone in opioid dependent patients	29
11/LO/1565	Immunology of the intestine informing the development of new vaccines	29
11/LO/1572	Graded Exercise Therapy guided Self-help Treatment for CFS/ME	59
11/LO/1640	Effects of oral doses of AZD5069 on neutrophil numbers	22
11/LO/1676	Sleep in CP- Validation of Sleep Diary and Actigraphy against PSG	88
11/LO/1692	Biomarker discovery in psoriasis and other inflammatory skin diseases	68
11/LO/1904	A study to investigate the efficacy of QBX258 in Asthma	27
11/LO/1972	SentiMAG Multicentre Trial	19
11/LO/2013	BIBW 2992 and Vinorelbine versus Trastuzumab and Vinorelbine.	30
11/LO/2042	A study of EMA401 for pain due to chemotherapy induced nerve damage	42

12/LO/0101	Improving Population Outcomes for Renal Tumours of Childhood (IMPORT)	67
12/LO/0154	FOSTER High Strength vs QVAR in Asthmatic Patients	51
12/LO/0174	To assess SAR228810 in patients with Alzheimer's disease - Guy's EC	36
12/LO/0275	To assess safety/tolerability and PK/PD of a SAD AZD8848	46
12/LO/0431	To investigate the effects of Multiple Ascending Doses of AZD8683	43
12/LO/0478	Inclusion in Education for Children and Young People with Epilepsy 1.0	121

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1232	CRT Perfusion Study	64

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0270	To evaluate safety, kinetics & dynamics of Solulin in hemophilia patients	33
11/LO/0392	Effect of information on anxiety in orthodontic patients - V1	50
11/LO/0655	Older Adults with Psychosis: Carer Experiences and Relationships	42
11/LO/0852	The effects of inhaled steroids on the LPS challenge model	20
11/LO/1558	Biopsy-defined kidney disease in HIV-positive patients	26
11/LO/1639	Fluticasone Propionate/Salmeterol Xinafoate combination Device	23
11/LO/1970	Cancer symptom appraisal in everyday life	21
12/LO/0098	AIN457 to assess safety, tolerability, efficacy & PK in asthma	22
12/LO/0274	Effects of XEN-D0103 on warfarin, midazolam, digoxin pharmacokinetics	27

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0636	The Brief Memory and Executive Test (BMET)	27
11/LO/1571	The influence of orthodontic treatment on bacterial pathogens.	26
12/LO/0401	PK study of Fluticasone Propionate/Salmeterol Xinafoate combinations	21

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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11/LO/0301	A multidisciplinary clinic for non-cardiac chest pain	27
11/LO/1553	Pelvic organ complaints in neurological diseases	20
11/LO/1671	Cancer symptom appraisal in everyday life	23
11/LO/2033	Detection of human Strongyloides stercoralis infections by LAMP	15

#### **Provisional Opinion**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0335	GUY'S AND ST THOMAS' Gastric and Oesophageal Tissue and Data Bank	N/A
12/LO/0295	Use of ABT DAAs in Chronic Hepatitis C	N/A

#### **Provisional Opinion Pending Consultation with Referee**

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

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
12/LO/0374	The effect of Maraviroc on gut and immune function in HIV+ patients	N/A

#### **Withdrawn after the meeting**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
12/LO/0441	Investigating the effect of AZD1981 on the combined oral contraceptive	21

#### **Invalid Application**

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

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

<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/0488	Communication and interpretation of risks of neutropenic sepsis	74
11/LO/0892	Is there a constitutional 'global' lymphatic disturbance in BCRL?	104
11/LO/1232	CRT Perfusion Study	64
11/LO/1237	Prevalence of HIV associated neurocognitive disorder (HAND)	74
11/LO/1281	Near activities to enhance adherence with occlusion in amblyopia	74
11/LO/1676	Sleep in CP- Validation of Sleep Diary and Actigraphy against PSG	88
11/LO/1692	Biomarker discovery in psoriasis and other inflammatory skin diseases	68
12/LO/0101	Improving Population Outcomes for Renal Tumours of Childhood (IMPORT)	67
12/LO/0478	Inclusion in Education for Children and Young People with Epilepsy 1.0	121

<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>

<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/1806	Mepolizumab(SB-240563) in Severe Bilateral Nasal Polyposis	34
11/LO/0993	Alzheimer's disease-related proteins in Down's syndrome cells	70

<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>
11/LO/0544	A Phase I Study to Determine Bioavailability of AZD8931	28
11/LO/0671	AZD2820 SAD study in healthy male volunteers	47
11/LO/0696	The absorption,excretion & pharmacokinetics of 14C-AZD5069	47
11/LO/0748	To assess safety/tolerability and effect on biomarkers of AZD3839	22
11/LO/0749	First in Human Study of GSK2269557 in healthy males.	22
11/LO/1301	A first-in-human study of XmAb@5871 in healthy adult men	55
11/LO/1495	Interaction study of Avibactam and Ceftazidime	39
11/LO/1679	To investigate the effects of MAD of AZD2115	15



11/LO/1677	An open-label, single-dose bioavailability study of MLDL1278A	35
11/LO/1807	Administration of multiple ascending doses of AZD2820 to obese men	19
11/LO/1808	A study comparing different Aspirin and Esomeprazole formulations	19
11/LO/1961	To assess ceftaroline in various infusion volumes	49
11/LO/1959	LY2979165 and LY2140023 on the Ketamine-Challenge PhMRI Assay	49

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0804/45/AM04	ALN-TTR01 in Patients with Amyloidosis of Transthyretin (TTR)	Amendment dated 17 March 2011	49
10/H0804/71/AM01	A phase 1 Pilot PK Study of salmeterol/fluticasone in healthy subjects	Amendment dated 10 February 2011	74
10/H0804/54/AM02	First in Human Study of ARC19499 in haemophilia patients	Amendment dated 08 March 2011	46
10/H0804/63/AM01	To investigate multiple ascending doses of AZD8329	Amendment dated 10 March 2011	87
09/H0804/110/AM03	Randomized trial of rituximab in renal transplantation	Amendment dated 17 February 2011	80
09/H0804/98/AM03	A Phase 1 Study of PKI-587 in Subjects with Solid Tumours	Amendment dated 18 March 2011	52
09/H0804/73/AM06	Reduced Intensity Allograft in Chemosensitive Hodgkin Lymphoma (ReACH)	Amendment dated 02 February 2011	42
09/H0804/74/AM07	Pilot of Allogeneic Immunotherapy in Refractory Disease (PAIReD)	SA1.4 dated 01/02/2011	42
10/H0804/78/AM01	Assessment of the supportive needs of breast cancer patients.	Amendment dated 07 April 2011	53
09/H0804/43/AM03	The effect of Omalizumab in non-atopic asthma -(version1- 11/03/09)	Amendment dated 06 April 2011	53
08/H0804/8/AM12	APRIL SLE: Atacicept in generalised SLE Phase II/III	Amendment dated 03 March 2011	91
08/H0804/162/AM03	he impact of early environmental	Amendment dated 25 April 2011	51

	peanut and egg protein exposure & all		
10/H0804/16/AM07	Efficacy and Safety of CNTO328 in Multicentric Castleman's Disease	Amendment dated 01 April 2011	77
09/H0804/87/AM04	Sensory stimulation and upper limb task specific training after stroke	Amendment dated 24/05/2011	48
06/Q0704/175/AM05	Smoking and Asthma	Amendment dated 18 May 2011	48
10/H0804/33/AM01	Genome Profiling in ER Negative Metastatic Breast Cancer	Amendment dated 22/06/2011	50
08/H0804/87/AM01	Smoking and Asthma Functional Work	Amendment dated 25 February 2011	42
08/H0804/135/AM02	A Pilot trial of open, laparoscopic and robotic radical cystectomy	Amendment dated 22 August 2008	60
11/LO/0636/AM01	The Brief Memory and Executive Test (BMET)	Amendment dated 18 July 2011	86
08/H0804/84/AM10	Does vitamin D3 enhance corticosteroid activity in severe asthma?	Amendment dated 15/08/2011	70
10/H0804/86/AM01	IgE and Non-Atopic Asthma Version 01 of 06/10/10	Amendment dated 29/07/2011	58
09/H0804/72/AM05	The Origins of Autoimmunity in ANCA-associated Vasculitis	Amendment dated 09 August 2011	49
10/H0804/61/AM05	Phase Ib/II study with RO5083945 and chemotherapy in NSCLC patients	Amendment dated 28th September 2011	66
07/H0804/131/AM02	Guy's & St Thomas' Breast Tissue & Data Bank	Amendment dated 27/10/2011	74
11/LO/0270/AM01	To evaluate safety, kinetics & dynamics of Solulin in hemophilia patients	Amendment dated 06/10/2011	39
10/H0804/17/AM02	The use of Surface Electromyography in Dysphagia Rehabilitation - V1	Amendment dated 01 September 2011	112
10/H0804/16/AM09	Efficacy and Safety of CNTO328 in Multicentric Castleman's Disease	Amendment dated 04 August 2011	95
11/LO/0851/AM03	A study of the safety, tolerability and handling of Dexamipexole	Amendment dated 10 November 2011	56
10/H0804/16/AM10	Efficacy and Safety of CNTO328 in	Amendment dated 18 October	49

	Multicentric Castleman's Disease	2011	
11/LO/1079/AM01	First in Human study of BAX 855 in Haemophilia A patients	Amendment dated 01/11/2011	67
09/H0804/98/AM04	A Phase 1 Study of PKI-587 in Subjects with Solid Tumours	Amendment dated 01 November 2011	60
09/H0804/108/AM02	Effect of air pollutants a on cells isolated from the human lung	Amendment dated 17 November 2011	70
09/H0804/110/AM06	Randomized trial of rituximab in renal transplantation	Amendment dated 26 January 2012	38
09/H0804/43/AM05	The effect of Omalizumab in non-atopic asthma -(version1- 11/03/09)	Amendment dated 02 December 2012	65
10/H0804/33/AM04	Genome Profiling in ER Negative Metastatic Breast Cancer	Amendment dated 02 February 2012	40
11/LO/0871/AM01	Increasing walking in patients with PAD: version 1	Amendment 1 25/01/2012	62

#### Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0804/33/AM01/1	Genome Profiling in ER Negative Metastatic Breast Cancer	Amendment dated 22 September 2011	28

#### Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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