

NRES Committee London - City & East

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - City & East
Type of REC:	Recognised to review CTIMPS in patients - type iii
Type of Flag:	IRB Registered Phase 1 Studies in Patients Research Involving Children
Chair:	Dr Arthur T. Tucker
Vice-Chair:	Dr Louise Abrams
Alternate Vice-Char:	None
Co-ordinator:	Mr Rajat Khullar
PRSC Co-ordinator:	Mr Rajat Khullar
Assistant Co-ordinator:	None
Committee Address:	South West REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

NRES Committee London - City & East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Louise Abrams	Pharmacology (Vice Chair)	Expert	01/05/2004	
Dr Chandan Alam	Experimental Pathology	Expert	01/02/2005	
Dr Marie E Bardsley	Director	Lay	17/02/2009	
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging	Lay Plus	02/02/2012	
Dr Ayse Baxter	Independent Consultant Pharmaceutical Physician	Expert	01/07/2007	
Mr Frank Cross	Consultant General and Vascular Surgeon	Expert	13/11/2008	
Ms Stephanie Ellis	Lay	Lay Plus	28/01/2011	02/02/2012
Dr Miran Epstein	Senior Lecturer Medical Ethics	Expert	01/05/2004	
Mrs Janelle Hill	Non-medical lay member	Lay Plus	01/05/2004	
Professor Atholl Johnston	Professor of Clinical Pharmacology	Expert	01/05/2004	
Professor Malcolm Law	Epidemiologist	Expert	01/04/2004	
Mr John Lynch	Non-Medical Lay Member	Lay Plus	01/10/2007	
Mr Roger Maran	Non-Medical Lay Member	Lay Plus	06/10/2011	
Dr Eleni Palazidou	Consultant Psychiatrist & Honorary Senior Lecturer	Expert	01/05/2004	
Professor Kim Piper	Consultant Histopathologist/Professor of Oral Pathology	Expert	01/03/2008	
Dr Melanie Powell	Consultant Clinical Oncologist	Expert	01/04/2004	
Ms Brigid Tucker	Non-Medical Lay Member	Lay Plus	01/05/2004	
Dr Arthur T. Tucker	Principal Clinical Scientist & Honorary Reader, (REC Chairman)	Expert	01/05/2004	
Professor David Wingate	Gastroenterologist	Expert	01/05/2004	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Ariel Zosmer	Honorary Clinical Senior Lecturer	Expert	07/04/2011, 05/05/2011, 03/06/2011, 01/09/2011, 06/10/2011, 03/11/2011, 01/12/2011, 01/03/2012

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
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Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
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NRES Committee London - City & East: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Roger Maran	I hold some shares in GlaxoSmithKline as part of a professionally managed share portfolio.	07/10/2011
Dr Ariel Zosmer	None	01/12/2011
Dr Arthur T. Tucker	Manager of Seahorse Scientific Services Ltd. A privately owned academically centre laboratory data services company. Other Positions - Barchester Group Ltd. Shareholdings - Epixmed Ltd. Skymed Technology Ltd. Tarix AG Parent Advisor, Great Ormond Street Hospital Clinical Contract Research Association Barts & The London NHS Trust Homerton Hospital Shifa Hospital, Pakistan	01/12/2011
Professor Atholl Johnston	Positions - Various Pharma Companies Consultant, Director – Esprit Other ownership/ involvement- ASI Ltd. , Seahorse Scientific Services Ltd. Queen Mary University of London	02/02/2012
Dr Ayse Baxter	Principal, AB MedEx Consulting Clinical and Medical Regulatory Consultancy to Pharmaceutical Industry.	01/12/2011
Ms Brigid Tucker	None that are NHS related currently. Currently employed by a UK statutory healthcare regulator (General Osteopathic Council) and represent the regulator on the UK National Council for Osteopathic Research (NCOR). As a healthcare regulator, we periodically commission research that informs policy development. This forms part of my remit.	01/12/2011
Dr Chandan Alam	Director - Transdermal Delivery Solutions Corp. , Florida, US Director, Medical - Cells United, Oslo, Norway	01/12/2011
Professor David Wingate	None	01/12/2011
Mr Frank Cross	None	02/02/2012
Mrs Janelle Hill	None	01/12/2011
Mr John Lynch	None	01/12/2011
Professor Kim Piper	None	01/12/2011
Dr Louise Abrams	None	01/12/2011
Dr Miran Epstein	None	02/02/2012
Professor Malcolm Law	None	01/12/2011
Dr Marie E Bardsley	Director, E-Med Ltd. - This is a publishing company and unlikely to be involved in research.	01/12/2011
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging, William Harvey Research Institute, QMUL	03/02/2012
Dr Eleni Palazidou	None	01/12/2011

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

Month	Date	Number of Members Present at Meeting
April	07/04/2011	15
May	05/05/2011	14
June	02/06/2011	14
July	07/07/2011	15
September	01/09/2011	14
October	06/10/2011	13
November	03/11/2011	16
December	01/12/2011	16
February	02/02/2012	17
March	01/03/2012	13

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
November	14/11/2011	3
January	13/01/2012	3
February	16/02/2012	3

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

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

Name	Number of Meetings Attended
Professor David Wingate	10
Dr Marie E Bardsley	9
Mrs Janelle Hill	9
Ms Brigid Tucker	9
Dr Arthur T. Tucker	9
Dr Eleni Palazidou	9
Dr Ayse Baxter	8
Dr Miran Epstein	8
Mr Frank Cross	8
Mr John Lynch	8
Dr Ariel Zosmer	8
Professor Malcolm Law	8
Dr Louise Abrams	7
Dr Melanie Powell	7
Ms Stephanie Ellis	7
Professor Atholl Johnston	6
Professor Kim Piper	6
Dr Chandan Alam	6
Mr Roger Maran	4
Ms Jane Batchelor	1

Number of inquorate meetings held:

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

Name	Number of Meetings Attended
Dr Arthur Tucker	2
Ms Stephanie Ellis	2
Professor David Wingate	1
Dr Arthur T. Tucker	1
Dr Ayse Baxter	1
Dr Chandan Alam	1
Mrs Janelle Hill	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr John Lynch	19/05/2011 - 19/05/2011	NRES - Research with Adolescents (Code CO5001), NRES
Dr Eleni Palazidou	06/07/2011 - 06/07/2011	NRES Researcher Training Day (Code CO4001)
Dr Ayse Baxter	07/12/2011 - 07/12/2011	Statistics Training for NRES REC Members (code OP6002), NRES
Mr Frank Cross	07/12/2011 - 07/12/2011	Statistics Training for NRES REC Members (code OP6002), NRES
Professor Atholl Johnston	06/07/2011 - 06/07/2011	Researcher Training, NRES
Dr Arthur T. Tucker	26/07/2011 - 26/07/2011	NRES Medical Devices Training, NRES
Mr Frank Cross	16/06/2011 - 16/06/2011	Equality, Diversity and Interview techniques, RCS
Dr Arthur T. Tucker	12/04/2011 - 12/04/2011	Equality & Diversity, NHS Skills Academy for Health
Dr Ariel Zosmer	19/01/2012 - 19/01/2012	Shared Ethical Debate Training, NRES
Dr Ayse Baxter	19/01/2012 - 19/01/2012	Shared Ethical Debate Training, NRES
Mrs Janelle Hill	19/01/2012 - 19/01/2012	Shared Ethical Debate Training, NRES
Dr Arthur T. Tucker	08/03/2012 - 08/03/2012	Safeguarding Adults Level 1 e-learning course, Barts & The London NHS Trust
Dr Arthur T. Tucker	12/03/2012 - 12/03/2012	Safeguarding Adults Level 2 e-learning course, Barts & The London NHS Trust
Dr Ariel Zosmer	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review, NRES
Dr Melanie Powell	30/11/2011 - 30/11/2011	Equality & Diversity, Barts & The London NHS Trust
Dr Melanie Powell	01/10/2011 - 01/10/2011	Good Clinical Practice, Barts & The London NHS Trust
Dr Arthur T. Tucker	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Louise Abrams	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Arthur T. Tucker	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Chandan Alam	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Miran Epstein	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Miran Epstein	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Professor Malcolm Law	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Professor Malcolm Law	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES

Dr Eleni Palazidou	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Eleni Palazidou	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Ms Brigid Tucker	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Ms Brigid Tucker	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Professor David Wingate	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Professor David Wingate	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Ayse Baxter	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Professor Atholl Johnston	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Professor Atholl Johnston	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Mr Frank Cross	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Mr Frank Cross	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Professor Kim Piper	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Mrs Janelle Hill	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Mrs Janelle Hill	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Melanie Powell	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Melanie Powell	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Marie E Bardsley	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Marie E Bardsley	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Mr John Lynch	19/05/2011 - 19/05/2011	NRES - Research with Adolescents (Code CO5001), NRES
Mr John Lynch	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Mr John Lynch	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Mr Roger Maran	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Ariel Zosmer	07/07/2011 - 07/07/2011	Shared Ethical Debate (Application Review), NRES
Dr Ariel Zosmer	01/12/2011 - 01/12/2011	NRES Induction DVD, NRES
Dr Arthur T. Tucker	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Louise Abrams	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Miran Epstein	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Professor Malcolm Law	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Eleni Palazidou	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Ms Brigid Tucker	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Professor David Wingate	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Ayse Baxter	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Professor Atholl Johnston	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Melanie Powell	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Marie E Bardsley	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Mr John Lynch	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Dr Ariel Zosmer	02/06/2011 - 02/06/2011	GAfREC Training, REC Training
Ms Brigid Tucker	11/10/2011 - 11/10/2011	Patient records and data

		protection: internal update briefing, Field Fisher Waterhouse
Ms Brigid Tucker	03/03/2012 - 03/03/2012	Communicating risk and benefits effectively to patients, UCL
Dr Eleni Palazidou	23/02/2012 - 23/02/2012	Good Clinical practice in Clinical Trials, NHS

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

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	18	33.96
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	35	66.04
Total Applications Reviewed	53	100

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	15
Number of student applications reviewed	17
Number of paediatric applications reviewed	5
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	7	13.21
Favourable Opinion with Additional Conditions	7	13.21
Unfavourable Opinion	6	11.32
Provisional Opinion	32	60.38
Invalid	0	0.00
No Opinion Pending Consultation with Referee	1	1.89
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	53	100
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:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	28	52.83
Further Information Favourable Opinion with Additional Conditions	2	3.77
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	13.21
Favourable Opinion with Additional Conditions	7	13.21
Unfavourable Opinion	6	11.32
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	3	5.66
Total	53	100

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

Total Applications Reviewed	11
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Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	7	63.64
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	27.27
Unfavourable Opinion	1	9.09
Total	11	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.30
Number of applications for full ethical review over 60 days	5
Number of applications over 60 days as a % of total	9.43%
Number of days taken to final decision - average	42
Number of days taken to final decision - mode	44
Number of SSAs (non-Phase 1) reviewed	27
Number of applications for SSA review over 25 days	4
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	14.8%
Number of SSAs (Phase 1) reviewed	1
Number of applications for SSA review over 14 days	0
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	0.0%
Number of substantial amendments reviewed	133
Number of substantial amendments over 35 days	9
Number of substantial amendments over 35 days as a % of total substantial amendments	6.8%
Number of Section 30 applications reviewed	0
Number of Section 30 applications over 60 days	0
Number of Section 30 applications over 60 days as a % of total Section 30 applications	0%
Number of modified amendments reviewed	4
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	50.0%
Number of proportionate review applications for ethical review over 14 days*	2
Number of proportionate review applications over 14 days as a % of total	18.18%

***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:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0281	Outcomes of non-infected diabetic foot ulcers with/without antibiotics	89
11/LO/0325	Cardioprotective aspects of alcohol in a South Asian Population	79
11/LO/0328	TRICREST	64
11/LO/0456	Hep B Superiority Study, TDF & PEG in combination & monotherapy	32
11/LO/0524	PATENT PLUS	51
11/LO/0734	Transfusional hemosiderosis patients treated with Exjade.	30
11/LO/0948	Comparison of DES in Patients with Diabetes Mellitus	26
11/LO/0995	Speedy4	27
11/LO/1034	CogUK	34
11/LO/1226	Study of DE-109 Intravitreal Injections in patients with Uveitis V1	44
11/LO/1316	Deepening our Understanding of Quality Improvement in Europe (DUQuE)v1	58
11/LO/1391	Medicine Related Problems experienced by Ethnic Minority Populations	36
11/LO/1431	Optical Monitoring in Paediatric Intensive Care V4	34
11/LO/1439	Collection of blood for comparing different blood collection tubes	44
11/LO/1543	Signalling networks in IBD - version 1.0	40
11/LO/1595	FGFR	44
11/LO/1601	The effect of variations in bio-aerosol production on TB infectivity	54
11/LO/1618	ORCA	42
11/LO/1740	A4001095 Maraviroc comparator study in antiretroviral naive HIV pts	60
11/LO/1752	Use of ABT DAAs in Hep C	45
11/LO/1757	Pilot Pharmacological-fMRI Study	46
11/LO/1865	Efficacy and Safety of TAK-491 in Grade 2 or 3 Essential Hypertension.	21
11/LO/1913	Memory Overgenerality, Interpersonal Stress Generation And Depression	60
11/LO/1918	North West London Integrated Care Pilot: A qualitative evaluation.	57
11/LO/1919	Cochleotoxicity monitoring using extended high frequency audiometry	43
11/LO/1921	MO27775 PERTAIN Study	57
12/LO/0333	The information needs of parents of children with ASD	17
12/LO/0335	The use of video feedback to support teacher's communications	14
12/LO/0337	Patients' experience of MRSA screening	15

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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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/0326	FIT for Follow-up Study	54
11/LO/0327	Factors that Influence substance misuse patients attitude to treatment	68
11/LO/0950	A qualitative study examining physical health monitoring in Psychosis	20
11/LO/0970	A study of people's views about HIV and its treatment	27
11/LO/1390	A prospective RCT comparing three high flexion knee systems	22
11/LO/1501	(PRS) Multiplex PCR for gastrointestinal infections	37
11/LO/1509	Nutritional status of the free living elderly and those living in care	22
11/LO/1881	Investigation into the diagnostic yield of ambulatory EEG	14
11/LO/1907	QUALICOPC: Quality and costs of primary care in Europe	14
12/LO/0120	The definition and measurement of stiffness in Polymyalgia Rheumatica	14
12/LO/0121	Food choices and implications for dietary change	14
12/LO/0126	Collection of blood and clinical data for biomarker studies in RA	11
12/LO/0128	fibrinolytic activation in thromboelastography	11
12/LO/0336	Immunohistochemical analysis of breast cancer blocks	14

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0493	Repeated Vestibular Stimulation in Hemi-spatial Neglect	29
12/LO/0008	GAMMA	48
12/LO/0102	Placebo-controlled study of oral VX-787 against influenza	48
12/LO/0156	Falls and balance impairments in neuromuscular diseases	49
12/LO/0315	Phase 2 Study of Anti-CCR4 MBA KW-0761 in subjects with PTCL	28
11/LO/1303	Panobinostat and ruxolitinib in patients with myelofibrosis.	60
11/LO/1559	SPIKE v4	31

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0315	Validation of a novel oral cancer screening tool. Version 1.0	75
11/LO/0525	Nutritional status of the elderly. Version One	43
11/LO/0709	Optical Measuring Techniques in Neonatal & Paediatric Intensive Care*	15
11/LO/1763	Live experience of Afro-caribbean men with prostate cancer in london	26
11/LO/1897	Exploring the attitudes to physiotherapy of Pakistani women with LBP	14
12/LO/0157	Dry ocular surface post cataract surgery	51
12/LO/0294	The HCV treatment journey	29

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/LO/0146	Comparison of the PRPP & other tools in HIV-related cog impairment	N/A
12/LO/0155	Can exercise reduce disability in peripheral neuropathy?	N/A
12/LO/0287	Predicting delusional ideation in patients with psychosis	N/A

Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0507	Unseen Heroes of the NHS	32
11/LO/0947	Scintigraphic assessment of colonic transit in health and constipation	20
11/LO/1925	Ovarian tissue cryopreservation and post-thaw functionality.	53

Invalid Application

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

REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC

REC Reference	Application Short Title	Number of Days on Clock
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Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0315	Validation of a novel oral cancer screening tool. Version 1.0	75
11/LO/0327	Factors that Influence substance misuse patients attitude to treatment	68
11/LO/0281	Outcomes of non-infected diabetic foot ulcers with/without antibiotics	89
11/LO/0325	Cardioprotective aspects of alcohol in a South Asian Population	79
11/LO/0328	TRICREST	64

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0337	Patients' experience of MRSA screening	15
12/LO/0333	The information needs of parents of children with ASD	17

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1093	Hindgut Sensorimotor Function post Rectal Resection	26
11/LO/1257	A3051139 - Smoking Cessation	33
11/LO/1958	Functional Outcomes after Rectal Cancer Surgery	32
11/LO/2065	Investigation of the influence of sex on cardiovascular inflammation	34

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

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0704/62/AM02	Multiple sclerosis endophenotype study	Amendment 1 dated 23.03.2011	38
10/H0703/79/AM01	CABANA Trial - Version 3.3 -03-March-2010	Substantial Amendment 01	39

07/H0703/160/AM32	Study of MK822 in osteoporotic fracture prevention	SA 31, Dated 3rd June 2011	36
10/H0703/69/AM07	OAM4861g:MetMab vs placebo in metastatic triple-negative breast cancer	Substantial Amendment 04 - Changes to Protocol	38
10/H0703/99/AM09	Phase 2 CDP6038 ACTIVE RHEUMATOID ARTHRITIS	Amendment 09 - Partner Pregnancy Consent Form	38
11/LO/0231/AM01	Gastroesophageal Intraoperative Functional Luminal Imaging	AM01 Substantial Amendment 01	53
10/H0703/6/AM05	Assessment of Cough Intensity	AM05 Substantial Amendment 4	38
10/H0703/107/AM09	A3921061 Long Term Safety&Tolerability of 2 oral doses of CP-690,550	AM07 Substantial Amendment 6	68
06/Q0605/80/AM02	Quality of assessment and management of parent-child interaction	AM02 Substantial Amendment 2 Dated 10th Feb 2012	47

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/LO/0057/AM02/1	CDP6038 rheumatoid arthritis, open label follow up study	Modification of Amendment dated 12th May 2011	35
05/Q0603/68/AM04/1	Diagnostic Evaluation of Invasive Aspergillosis	Modified Amendment for AM04 Dated 22/07/2011	15

Section 30 application over 60 day timeline

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