

**NRES Committee London - Surrey  
Borders**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Surrey Borders
<b>Type of REC:</b>	Recognised
<b>Type of Flag:</b>	Type 1 and 3
<b>Chair:</b>	Dr Hervey Wilcox
<b>Vice-Chair:</b>	Mr Canon Christopher Vallins
<b>Alternate Vice-Chair:</b>	Mrs Wendy Brooks
<b>Co-ordinator:</b>	Ms Joan Bailey (Annual reporting period) Mrs Alka Bhayani
<b>PRSC Co-ordinator:</b>	Mr Atul Patel
<b>Assistant Co-ordinator:</b>	Kate Donaldson
<b>Committee Address:</b>	HRA Research Ethics Committee (REC) London Centre Ground Floor Skipton House 80 London Road London SE1 6LH
<b>Telephone:</b>	020 7972 2554
<b>Fax:</b>	020 7972 2592
<b>Email:</b>	NRESCommittee.London-SurreyBorders@nhs.net

### Chair's overview of the past year:

Chair during this reporting period no longer in post

## NRES Committee London - Surrey Borders Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Sylvia Aslangul	Retired Lecturer	Lay	01/01/2004	10/05/2011
Mrs Wendy Brooks	Stroke Nurse Consultant	Expert	01/01/2004	
Mr Derek Cock	Chief Pharmacist	Expert	03/02/2005	
Dr Jeff Corne	Retired Pharmacologist	Lay	12/02/2008	
Mrs Anne Davies	Chief Pharmacist	Expert	01/04/2004	
Mr Eddy Digman	Retired Local Government & Personnel Consultant	Lay Plus	01/01/2004	
Mr Dominic Fairclough	Solicitor	Lay Plus	16/03/2009	
Mrs Sheila Jackson	Senior Sister	Expert	01/04/2007	14/03/2012
Dr Arun Kundu	Consultant Paediatrician	Expert	30/10/2008	
Mrs Anne Laurie	Lecturer in Clinical Communications	Lay	30/05/2007	
Dr Rosemary O'Neil	Statistician	Lay Plus	12/04/2010	
Mrs Rebecca Quayle	Solicitor	Lay Plus		
Dr Nazira Sumar	Clinical Scientist/ Head of Research and Development	Expert	26/01/2010	
Canon Christopher Vallins	Regional Chaplaincy Adviser	Lay Plus	01/01/2004	
Dr Lawrence Webber	GP	Expert	01/01/2004	31/12/2011
Dr Hervey Wilcox	Consultant Chemical Pathologist	Expert	01/01/2004	

### 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 - Surrey Borders: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Derek Cock	Mr Derek Cock has declared that he does occasional consultations for Pharmaceutical companies and is a member of the local R&D committee.	14/12/2011
Dr Lawrence Webber	Dr Webber declared an interest (shares in AstraZeneca).	16/01/2012
Canon Christopher Vallins	No declared interests.	14/12/2011
Dr Jeff Corne	A member of the Vitiligo Society.	14/12/2011
Mrs Wendy Brooks	Member of R & D executive committee.	14/12/2011
Mr Eddy Digman	No declared interest.	14/12/2011
Mrs Anne Davies	As chief pharmacist responsible for the management of clinical trials involving CTIMPs in the Trust. Attends R & D committee as required.	14/12/2011
Mrs Rebecca Quayle	No declared interest.	31/12/2011
Dr Arun Kundu	No declared interest.	14/12/2011
Dr Nazira Sumar	Head of R & D of Immunology, St Helier Hospital.	03/01/2012
Dr Rosemary O'Neil	Occasional private work - usually data analysis on an ad-hoc basis-always after ethical approval and consent given.	14/12/2011
Mrs Anne Laurie	Small number of Shares in SmithKlien. Member and Chair of local women's groups that often fundraise for health and social care, these are the Ladies Circle, tangent club and inner wheel clubs of Wallington & Carshalton in Surrey.	03/01/2012
Mr Dominic Fairclough	No declared interest.	15/01/2012

## 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	13/04/2011	10
May	11/05/2011	10
June	08/06/2011	11
July	13/07/2011	13
August	24/08/2011	11
September	14/09/2011	10
October	12/10/2011	13
November	09/11/2011	10
December	14/12/2011	11
January	11/01/2012	8
March	14/03/2012	10

11 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	13/04/2011	4
June	08/06/2011	4
July	13/07/2011	4
August	24/08/2011	3
September	14/09/2011	3
October	12/10/2011	3
November	09/11/2011	4
December	14/12/2011	3
January	11/01/2012	3
March	14/03/2012	3

10 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 Hervey Wilcox	10
Canon Christopher Vallins	10
Mr Derek Cock	10
Mrs Anne Davies	10
Mrs Rebecca Quayle	10
Mrs Wendy Brooks	8
Mr Eddy Digman	8
Dr Lawrence Webber	8
Dr Jeff Corne	8
Dr Nazira Sumar	7
Dr Arun Kundu	7
Mrs Anne Laurie	6
Mr Dominic Fairclough	6
Mrs Sheila Jackson	6
Dr Rosemary O'Neil	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Canon Christopher Vallins	10
Mr Derek Cock	9
Mrs Rebecca Quayle	7
Mrs Anne Laurie	5
Dr Jeff Corne	3

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Canon Christopher Vallins	05/09/2011 - 05/08/2011	Reflective Practice meeting with colleagues. CPD
Canon Christopher Vallins	08/09/2011 - 08/09/2011	One to one Mentoring session - CPD
Dr Jeff Corne	21/04/2011 - 21/04/2011	British Academy of Dermatology meeting to discuss PUVA guidelines for treatment of Vitiligo.
Mrs Sheila Jackson	12/09/2011 - 12/09/2011	R&D - ICH / GCP training
Mrs Sheila Jackson	06/10/2011 - 06/10/2011	NRES Researcher Training Day, NRES
Mrs Sheila Jackson	10/10/2011 - 10/10/2011	Information Governance, NHS Trust
Dr Nazira Sumar	08/09/2011 - 09/09/2011	Train the trainers programme
Dr Arun Kundu	28/11/2011 - 28/11/2011	Self-Directed Learning - Taught Advanced Life support in Children
Mrs Sheila Jackson	01/11/2011 - 01/11/2011	NRES CTiMP Training, NRES
Mrs Sheila Jackson	07/11/2011 - 07/11/2011	Ethics & GCP Forum, The Institute of Clinical Research
Mr Dominic Fairclough	07/04/2011 - 07/04/2011	Reviewer Training
Mr Dominic Fairclough	18/07/2011 - 18/07/2011	Trainee Interviewing Training
Mrs Wendy Brooks	27/01/2012 - 27/01/2012	Mental Capacity Act DVD, NRES
Dr Rosemary O'Neil	30/11/2011 - 30/11/2011	MCA DVD (NRES), NRES
Dr Rosemary O'Neil	01/06/2011 - 30/06/2011	Statistical Analysis of IVF Cycle Data
Dr Rosemary O'Neil	25/10/2011 - 26/10/2011	R Statistical Software, RSS PDC
Mrs Rebecca Quayle	19/01/2012 - 19/01/2012	Members Shared Ethical Debate: Children's Clinical Trials (CTiMP), NRES
Dr Nazira Sumar	19/12/2011 - 19/12/2011	The Human Tissue Act" A simple guide to compliance, St Georges University
Mrs Sheila Jackson	13/02/2012 - 13/02/2012	ICR GCP training day , Institute of Clinical Research
Dr Arun Kundu	14/03/2012 - 14/03/2012	NRES National Training Day, 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	15	26.32
Phase 1	4	7.02
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	38	66.67
<b>Total Applications Reviewed</b>	<b>57</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	21
Number of student applications reviewed	17
Number of paediatric applications reviewed	13
Number of device applications reviewed	2
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	5	8.77
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	1	1.75
Provisional Opinion	44	77.19
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>57</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>
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Further Information Favourable Opinion with Standard Conditions	41	71.93
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	8.77
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	1	1.75
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	5.26
<b>Total</b>	<b>57</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>32</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	11	34.38
Favourable Opinion with Additional Conditions	13	40.63
No Opinion transfer to full committee for review	2	6.25
Provisional Opinion	5	15.63
Unfavourable Opinion	1	3.13
<b>Total</b>	<b>32</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.18
<b>Number of applications for full ethical review over 60 days</b>	15
<b>Number of applications over 60 days as a % of total</b>	26.32%
<b>Number of days taken to final decision - average</b>	49
<b>Number of days taken to final decision - mode</b>	26

<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<b>Number of applications for SSA review over 25 days</b>	1
<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>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0.0%

<b>Number of substantial amendments reviewed</b>	80
<b>Number of substantial amendments over 35 days</b>	26
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	32.5%

<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>	0
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0%

<b>Number of proportionate review applications for ethical review over 14 days*</b>	17
<b>Number of proportionate review applications over 14 days as a % of total</b>	56.67%

**\*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/0350	Cortical Pain Responses in Human Infants	66
11/LO/0398	Study of XL184 in Subjects with Advanced Solid Tumours	51
11/LO/0419	BKM120 in patients with metastatic NSCLC with activated PI3K pathway	71
11/LO/0500	Processes of Change/Long-Term Outcomes in MST	64
11/LO/0574	Emotion Processing in BPD. Version 1	59
11/LO/0619	E7080 alone or with Everolimus in patients with renal cell carcinoma	59
11/LO/0676	A fMRI pilot study of the effects of meal-support in eating disorders.	40
11/LO/0760	Aerobic Training in Neuromuscular Diseases	66
11/LO/0763	Cross-over study with fentanyl patch in healthy Japanese volunteers	41
11/LO/0764	The effect of food content and insulin on QTc interval	35
11/LO/0808	Health visitors perception of changes to their role	16
11/LO/0815	Continued Parental Attendance at adult "Child Cancer Survivor Clinic"	29
11/LO/0886	Phase 2 Study with AMG 423 in Acute Heart Failure	59
11/LO/0982	Exploring Fathers' Experiences of Behavioural Family Therapy	72
11/LO/1033	Effects of laparoscopic sacrocolpopexy on defecatory dysfunction	78
11/LO/1036	Shape Coding Therapy for past tense morphology v.3a	94
11/LO/1066	MAPPING	44
11/LO/1116	Carbon monoxide poisoning algorithm awareness	25
11/LO/1128	Nurse perceptions of Infection Prevention High Impact Interventions	16
11/LO/1267	The ATLAS Trial	40
11/LO/1297	Key Components of a Complex Cases Service Treatment Model	14
11/LO/1306	TMC435-C212 : open label chronic Hep-C trial with HIV-1 co-infection	71
11/LO/1311	Service Users' Experience of Receiving a Diagnosis of Bipolar Disorder	57
11/LO/1329	The Impact of Nursing Work Environment on Patient's Evaluation of Care	49
11/LO/1360	Anti Mullerian Hormone(AMH)and oocyte quality	42
11/LO/1363	Evaluation of IMT effect on AHI in patients with OSA: Version 6	97
11/LO/1411	Proximal Periosteal Block in Distal Radial and Ulnar fractures	69
11/LO/1414	Prostate cancer in men from African/Afro-Caribbean background/1	37
11/LO/1415	Efficacy of OXN PR in severe Parkinson's disease associated pain	61

11/LO/1421	Improving epilepsy surgery in childhood using fMRI and EEG	84
11/LO/1438	Effect of Ranolazine on Myocardial Perfusion - Amend 3	57
11/LO/1450	A feasibility study of a stroke self-management programme (SMP) V1	45
11/LO/1567	PGRx - Autoimmune Diseases version 4.0 25 August 2011	48
11/LO/1652	Neurophysiology and cognition in autism and Williams syndrome	68
11/LO/1747	Phase IIa Study to Investigate the Biological Activity of Oral FX125L	29
11/LO/1762	The Use of DBS to Manage Dystonia in Children	83
11/LO/1803	Sensorimotor Replacement of Cigarettes (SeROC) Version 1	77
11/LO/1812	A3921080 Use of CP-690,550 & Etanercept in Plaque Psoriasis	50
11/LO/2022	A phase 1b study of patients with selected advanced solid tumours	54
11/LO/2024	STRASS (EORTC 62092-22092)	58
11/LO/2031	FETO vs. expectant management for congenital diaphragmatic hernia	45
12/LO/0032	A Pilot Study of Biofeedback training in trans-femoral amputees	48
12/LO/0105	Blood Donation	38
12/LO/0404	Relating with the self and others amidst living with Fibromyalgia	43
12/LO/0424	MR-HIFU for Bone Metastases - Multicenter	43
12/LO/0430	Bioequivalence 100mg & 2x50mg Diethylcarbamazine tablets (QBR112879)	38

#### 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/0365	Evaluation of "Germ Genie" UV lamp to decontaminate computer keyboards	38
11/LO/0374	Schemas and cognitive distortions in mentally disordered sex offenders	34
11/LO/0470	Making Technology Emerge: Mobile health care in Finland and the UK	12
11/LO/0801	Syringomyelia and Scoliosis: Management and Outcomes.	2
11/LO/0870	Cognitive Decline in Chronic Obstructive Pulmonary Disease	16
11/LO/0969	Paediatric psychosocial screening tool validation	31
11/LO/1020	Understanding young people's experiences of anti-obesity drugs v1.0	35

11/LO/1112	Thinking mode and the use of diagnostic information	13
11/LO/1113	A study surveying GPs' guidance for vitamins D in certain patients.	17
11/LO/1769	Why people choose surgery or lifestyle intervention to lose weight v2	35
11/LO/1874	Myocardial alterations in failing human hearts	14
11/LO/1891	Prevalence and Predictors of Obesity Hypoventilation Syndrome	12
12/LO/0110	A Qualitative Review of the Patients' Own Drugs Scheme at UHSM (v 1)	67
12/LO/0111	Efficacy of a self-monitoring intervention for weight maintenance	58
12/LO/0113	How do family members come to understand Traumatic Brain Injury (TBI)	60
12/LO/0115	OMS and Sensory Processing	60

<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/0453	MIDWIVES' UNDERSTANDING OF ABNORMAL BLOOD RESULTS VERSION 2.0	13
11/LO/0475	Regenerating hair cells in the vestibular sensory epithelia (Vers 1)	14
11/LO/1335	Remote electronic Patient Reported Outcomes(ePROs)collection	9
11/LO/1343	Communicating with relatives of patients at end of life.	22
11/LO/1350	Prospective Study of Scoliosis in Children with Cerebral Palsy	8
11/LO/1413	Elucidation of Biochemical Mechanisms Responsible for Efficacy of KD	22
11/LO/1530	Antiplatelet therapy in non-cardiac surgery	15
11/LO/1531	Exploring Parental Experiences of Pierre Robin Sequence	9
11/LO/1669	Longitudinal study of anterior segment anatomy in 10-12 year old males	26
11/LO/1694	Investigation into parent's experience caring for their child with ABI	17
11/LO/1698	Exploring the Efficacy of Infant Feeding Policy	11
11/LO/1699	KT Study. Version 1.0	13
11/LO/2019	TOPARP	29
12/LO/0047	Pain management in osteoarthritis using centrally acting analgesics	27
12/LO/0057	GMK® Sphere Total Knee Replacement Surveillance Study	37
12/LO/0058	Zimmer Kinectiv Total Hip Replacement Surveillance Study	37
12/LO/0426	Molecular and cellular pathogenesis of bone marrow failure syndromes	28
12/LO/0501	Individual genome analysis in biliary atresia	19
12/LO/0506	Breast density, body composition and 3D breast kinematics	19
12/LO/0508	A preliminary survey of complementary and alternative medicine use	18

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0373	A fMRI pilot study of the effects of meal support in eating disorders.	28
11/LO/1532	Why people choose surgery or lifestyle intervention to lose weight v1	15

<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/1131	DOMINO Study	26
11/LO/1660	Phase Ib, CIF in combination with PA799	26
12/LO/0425	IMMUNOLOGICAL MECHANISMS IN HAY FEVER AND EFFECTS OF IMMUNOTHERAPY	21

<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 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/0419	BKM120 in patients with metastatic NSCLC with activated PI3K pathway	71
11/LO/0350	Cortical Pain Responses in Human Infants	66
11/LO/0500	Processes of Change/Long-Term Outcomes in MST	64
11/LO/0760	Aerobic Training in Neuromuscular Diseases	66
11/LO/1036	Shape Coding Therapy for past tense morphology v.3a	94
11/LO/0982	Exploring Fathers' Experiences of Behavioural Family Therapy	72
11/LO/1033	Effects of laparoscopic sacrocolpopexy on defecatory dysfunction	78
11/LO/1306	TMC435-C212 : open label chronic Hep-C trial with HIV-1 co-infection	71
11/LO/1363	Evaluation of IMT effect on AHI in patients with OSA: Version 6	97
11/LO/1411	Proximal Periosteal Block in Distal Radial and Ulnar fractures	69
11/LO/1415	Efficacy of OXN PR in severe Parkinson's disease associated pain	61
11/LO/1421	Improving epilepsy surgery in childhood using fMRI and EEG	84
11/LO/1652	Neurophysiology and cognition in autism and Williams syndrome	68
11/LO/1762	The Use of DBS to Manage Dystonia in Children	83
11/LO/1803	Sensorimotor Replacement of Cigarettes (SeROC) Version 1	77

<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/0808	Health visitors perception of changes to their role	16
11/LO/0815	Continued Parental Attendance at adult "Child Cancer Survivor Clinic"	29
11/LO/0870	Cognitive Decline in Chronic Obstructive Pulmonary Disease	16
11/LO/1113	A study surveying GPs' guidance for vitamins D in certain patients.	17
11/LO/1116	Carbon monoxide poisoning algorithm awareness	25
11/LO/1128	Nurse perceptions of Infection Prevention High Impact Interventions	16
11/LO/1343	Communicating with relatives of patients at end of life.	22
11/LO/1530	Antiplatelet therapy in non-cardiac surgery	15
11/LO/1532	Why people choose surgery or lifestyle intervention to lose weight v1	15
11/LO/1694	Investigation into parent's experience caring for their child with ABI	17



12/LO/0110	A Qualitative Review of the Patients' Own Drugs Scheme at UHSM (v 1)	67
12/LO/0111	Efficacy of a self-monitoring intervention for weight maintenance	58
12/LO/0113	How do family members come to understand Traumatic Brain Injury (TBI)	60
12/LO/0115	OMS and Sensory Processing	60
12/LO/0501	Individual genome analysis in biliary atresia	19
12/LO/0506	Breast density, body composition and 3D breast kinematics	19
12/LO/0508	A preliminary survey of complementary and alternative medicine use	18

#### SSAs (non Phase 1) over 25 days timeline

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0962	Molecular analyses of linear morphoea fibroblasts	52

#### SSAs (Phase 1) over 14 days timeline

REC Reference	Application Short Title	Number of Days on Clock
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#### Substantial Amendments over 35 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/H0806/10/AM01	Comparing Two Treatment Approaches for Benign Prostate Hyperplasia,V2	Substantial Amendment 1	38
10/H0806/48/AM06	FIN3001	Substantial Amendment 4	44
10/H0806/77/AM02	Posaconazole(IV)Study in Subjects at Risk of Invasive Fungal Infection	Substantial Amendment 2	36
11/LO/0180/AM01	KIACTA to prevent kidney function worsening in AA amyloidosis patients	Substantial Amendment 1	41
10/H0806/77/AM01	Posaconazole(IV)Study in Subjects at Risk of Invasive Fungal Infection	Substantial Amendment 1	41
11/H0806/10/AM04	Comparing Two Treatment Approaches for Benign Prostate Hyperplasia,V2	Substantial Amendment 5 (Change)	41
10/H0806/84/AM01	Evaluation of Methicillin Resistant Staphylococcus aureus (MRSA)	Substantial Amendment 1	68
10/H0806/99/AM02	192024-050: Bimatoprost/Timolol PF	Substantial Amendment 2	71

	compared with Ganfort		
10/H0806/106/AM02	Phase I Study of NY-ESO-1 +AS15 in Melanoma Version 1	Substantial Amendment 1	44
10/H0806/82/AM02	International Study of Incident Cancer(ISICA)-Breast Cancer & Diabetes	Substantial Amendment 1	77
10/H0806/84/AM02	Evaluation of Methicillin Resistant Staphylococcus aureus (MRSA)	Substantial Amendment 2	37
11/H0806/10/AM05	Comparing Two Treatment Approaches for Benign Prostate Hyperplasia,V2	Substantial Amendment 4 (Change)	44
11/H0806/10/AM06	Comparing Two Treatment Approaches for Benign Prostate Hyperplasia,V2	Substantial Amendment 6	38
11/H0806/10/AM08	Comparing Two Treatment Approaches for Benign Prostate Hyperplasia,V2	Substantial Amendment 7	44
10/H0806/31/AM01	Analysis of Virtual Wards: a multidisciplinary form of case management	Substantial Amendment 1	40
11/LO/0374/AM01	Schemas and cognitive distortions in mentally disordered sex offenders	Substantial Amendment 1	36
10/H0806/78/AM03	Immunological Impact of HCQ-1; SSAT 039	Substantial Amendment 3	36
10/H0806/20/AM06	Increasing Use of Smoking Cessation Services	Substantial Amendment 4	39
10/H0806/63/AM04	ARTEMIS AF Loading	Substantial Amendment 3	37
11/LO/0619/AM01	E7080 alone or with Everolimus in patients with renal cell carcinoma	Substantial Amendment 1	43
10/H0806/82/AM04	International Study of Incident Cancer(ISICA)-Breast Cancer & Diabetes	Substantial Amendment 3	43
10/H0806/88/AM01	Corin MiniHip and Trinity Cup Clinical Surveillance Study	Substantial Amendment 1	49
10/H0806/92/AM06	DEB025 in chronic hepatitis C G2/3	Substantial Amendment 5	54

	treatment naive patients		
10/H0806/100/AM03	AZD5363 Safety & Tolerability in Patients with Advanced Solid Tumours	Substantial Amendment 2	47
11/LO/0180/AM03	KIACTA to prevent kidney function worsening in AA amyloidosis patients	Substantial Amendment 3	42
08/H0806/72/AM08	Effects of an ARB on Microcirculation in Essential Hypertension	Substantial Amendment 6	46

#### Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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#### Section 30 application over 60 day timeline

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