

# NRES Committee London - Riverside

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Riverside
<b>Type of REC:</b>	REC recognised to review CTIMPS in healthy volunteers - type i REC recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase 1 Studies in Healthy Volunteers Research Involving Children
<b>Chair:</b>	Dr Sabita Uthaya
<b>Vice-Chair:</b>	Dr Mark Atkins
<b>Alternate Vice-Chair:</b>	Dr Margaret Jones
<b>REC Manager:</b>	Miss Tina Cavaliere
<b>PRSC Co-ordinator:</b>	Miss Tina Cavaliere
<b>Assistant Co-ordinator:</b>	Miss Maeve Groot Bluemink
<b>Committee Address:</b>	Bristol Research Ethics Committee Centre Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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### Chair's overview of the past year:

It is a pleasure to write this foreword for what will be my seventh Annual Report of the Riverside Research Ethics Committee. A lot has changed in seven years, from the composition of the Committee, to the co-ordinators, the structure of the organisation and the process of ethics review. Throughout this period the priorities of this Committee have been to facilitate ethical research, ensure consistency in review and support applicants with advice and suggestions. I am pleased to see that the Committee has in the main met the targets set for timely review of applications. Credit is due to Tina Cavaliere, our co-ordinator and REC Manager for this. I would also like to thank Mark Atkins who left the Committee this year after having served as Vice Chair. We welcomed Dinah Smith and Julia Williams both lay members to the Committee and said farewell to Ms Effie Katsarma and Dr Karen Phekhoo. And finally, thank you to all the members for the different views and experience they bring to the Committee that makes being part of this Committee such a pleasure.

## NRES Committee London - Riverside Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Mark Atkins	Microbiologist	Expert	18/05/2005	Vice Chair 1/5/2014
Ms Anna Bischler	Pharmacist	Expert	01/11/2007	
Mr John Clifford	Lawyer	Lay Plus	18/05/2005	
Dr Julian Collinson	Consultant Cardiologist	Expert	01/03/2011	
Dr Matthew Hyde	Research Scientist	Lay	01/09/2009	
Dr Margaret Jones	General Practitioner	Expert	26/09/2007	
Miss Effie Katsarma	Consultant Plastic and Hand Surgeon	Expert	01/03/2011	01/05/2013
Ms Alexandra Mancini	Modern Matron	Expert	06/04/2009	
Ms Fanny Mitchell	Retired	Lay Plus	01/10/2009	
Dr Karen Phekoo	Researcher	Expert	01/10/2009	29/01/2014
Mr Kamen Shoylev	Lawyer	Lay Plus	01/12/2011	
Ms Fiona Slomovic	Advocacy and Mediation Consultant	Lay Plus	01/03/2011	
Mrs Dinah Smith	Head Teacher	Lay Plus	11/06/2013	
Dr Sabita Uthaya	Consultant Neonatologist	Expert	01/07/2005	
Ms Julia Williams	Senior Producer	Lay Plus	13/06/2013	
Dr Daniel Wood	Clinical Psychologist	Expert	01/09/2009	
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	01/09/2012	

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

Name	Declaration of Interest	Date
Dr Julian Collinson	No declarations of interest.	17/01/2014
Ms Stephanie Ellis	No declarations of interest.	17/01/2014
Mr John Clifford	No declarations of interest.	17/01/2014
Dr Daniel Wood	No declarations of interest.	17/01/2014
Dr Margaret Jones	No declaration of interest.	18/01/2014
Mrs Dinah Smith	No declarations of interest.	19/01/2014
Mr Kamen Shoylev	No declarations of interest.	19/01/2014
Ms Anna Bischler	No declarations of interest.	20/01/2014
Dr Mark Atkins	Consultant to Director's Laboratory, 65 Whitfield St, London	29/01/2014
Ms Julia Williams	No declaration of interest.	11/02/2014
Dr Sabita Uthaya	No declarations of interest.	03/02/2014
Ms Fiona Slomovic	Director of All About Autism.	03/02/2014
Ms Fanny Mitchell	No declarations of interest.	07/02/2014
Ms Alexandra Mancini	No declarations of interest.	30/01/2014
Dr Matthew Hyde	Employed by Imperial College London	27/02/2014

**Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	08/04/2013	10
June	03/06/2013	10
July	01/07/2013	10
August	05/08/2013	11
September	02/09/2013	14
October	07/10/2013	10
December	02/12/2013	10
January	06/01/2014	12
February	03/02/2014	9
March	03/03/2014	14

10 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	15/04/2013	3
May	01/05/2013	3
June	17/06/2013	3
July	15/07/2013	3
September	16/09/2013	3
October	21/10/2013	3
November	18/11/2013	3
December	12/12/2013	3
January	20/01/2014	3
February	17/02/2014	3
March	17/03/2014	3

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

**Attendance of Members: 01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Stephanie Ellis	10
Dr Daniel Wood	9
Dr Mark Atkins	9
Ms Anna Bischler	9
Mr Kamen Shoylev	8
Mrs Dinah Smith	8
Dr Julian Collinson	8
Dr Margaret Jones	8
Dr Sabita Uthaya	7
Mr John Clifford	6
Dr Matthew Hyde	6
Ms Fanny Mitchell	6
Ms Fiona Slomovic	5
Ms Alexandra Mancini	5
Ms Julia Williams	3
Dr Karen Phekoo	3

**Number of inquorate meetings held: 0**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Sabita Uthaya	11
Dr Mark Atkins	3
Dr Julian Collinson	2
Mr Kamen Shoylev	2
Ms Fiona Slomovic	2
Ms Alexandra Mancini	2
Ms Stephanie Ellis	2
Dr Daniel Wood	1
Ms Anna Bischler	1
Ms Fanny Mitchell	1
Ms Julia Williams	1
Mrs Dinah Smith	1
Mr John Clifford	1
Dr Margaret Jones	1
Dr Matthew Hyde	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Margaret Jones	10/09/2013 - 10/09/2013	Chairing Skills, NRES
Mrs Dinah Smith	18/09/2013 - 18/09/2013	Induction, NRES
Ms Julia Williams	18/09/2013 - 18/09/2013	Induction, NRES
Mrs Dinah Smith	03/10/2013 - 03/10/2013	Equality & Diversity, NRES
Dr Sabita Uthaya	23/10/2013 - 23/10/2013	Equality & Diversity, Chelsea & Westminster Hospital
Dr Matthew Hyde	22/10/2013 - 22/10/2013	Personal Data in Research, Riverside REC Manager
Ms Julia Williams	26/11/2013 - 26/11/2013	Equality & Diversity, NRES
Dr Sabita Uthaya	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Dr Sabita Uthaya	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Dr Mark Atkins	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Dr Mark Atkins	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Dr Margaret Jones	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Dr Margaret Jones	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies , Riverside REC Manager
Ms Anna Bischler	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Ms Anna Bischler	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Dr Matthew Hyde	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Dr Matthew Hyde	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Mr Kamen Shoylev	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Mr Kamen Shoylev	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Mr John Clifford	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Mr John Clifford	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Mrs Dinah Smith	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager

Mrs Dinah Smith	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Ms Julia Williams	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Ms Julia Williams	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Ms Stephanie Ellis	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Ms Stephanie Ellis	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Ms Fanny Mitchell	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Ms Fanny Mitchell	04/11/2013 - 04/11/2013	Conduct of large prospective studies , Riverside REC Manager
Ms Alexandra Mancini	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Ms Alexandra Mancini	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies, Riverside REC Manager
Dr Karen Phekoo	04/11/2013 - 04/11/2013	Children's research, Riverside REC Manager
Dr Karen Phekoo	04/11/2013 - 04/11/2013	Conduct of large scale prospective studies , Riverside REC Manager
Dr Sabita Uthaya	11/12/2013 - 11/12/2013	NRES National Chairs Training Day, NRES
Dr Matthew Hyde	30/01/2014 - 30/01/2014	Equality & Diversity, NRES
Ms Alexandra Mancini	30/01/2014 - 30/01/2014	Equality & Diversity, HRA
Ms Stephanie Ellis	05/12/2013 - 05/12/2013	Chair's National Day Training programme, HRA
Ms Stephanie Ellis	02/09/2013 - 02/09/2013	NREAP meeting, HRA
Dr Mark Atkins	02/09/2013 - 02/09/2013	NREAP meeting for Chairs
Dr Daniel Wood	28/02/2014 - 28/02/2014	Self-Directed Learning - Reading of NRES training material - Guidance on PIS & Consent forms, NRES - 2 hours of training (reading material)
Ms Anna Bischler	27/02/2014 - 27/02/2014	Self-Directed Learning Log - Written report from the HRA 'Approval for medical devices', NRES - 1 hour of training (reading material)
Ms Anna Bischler	27/02/2014 - 27/02/2014	Self-Directed Learning Log - Read & used the written report from the Shared Ethical Debate , NRES - 1 hour of training (reading material)



Mr John Clifford	01/05/2013 - 01/05/2013	Self-Directed Learning Log - Update on Bioethics, International Eye Surgery - 1 hour conference
Ms Fiona Slomovic	14/02/2014 - 14/02/2014	Self-Directed Learning Log - Approval for research involving ionising radiation and Language and exclusions NRES - 2.5 hours training (reading material)
Ms Fiona Slomovic	14/02/2014 - 14/02/2014	Self-Directed Learning Log - NRES language & exclusion, NRES - 1 hour training (reading material)
Dr Julian Collinson	20/09/2013 - 20/09/2013	Self-Directed Learning Log - Good Clinical Practice , NHS - 2 hours training
Dr Julian Collinson	04/03/2014 - 04/03/2014	Self-Directed Learning Log - Guidance on PIS and consent forms, NRES - 2 hour training (reading material)
Dr Julian Collinson	04/03/2014 - 04/03/2014	Self-Directed Learning Log - NRES Language & exclusion, NRES - 1 hour training (reading material)
Mr Kamen Shoylev	01/01/2014 - 01/03/2014	Self-Directed Learning Log - Morality in life/basis of morality, Yate University - 36 hour training course
Ms Alexandra Mancini	27/02/2014 - 27/02/2014	Self-Directed Learning Log - Greater understanding of ethical issues, NRES - 2 hours training (training materials)
Ms Alexandra Mancini	01/01/2014 - 01/03/2014	Self-Directed Learning Log - undertaking MSc modules in ethical decision making, University - 10 hours
Ms Fanny Mitchell	03/03/2014 - 03/03/2014	Self-Directed Learning Log - NRES Guidance on PIS and consent forms, NRES - 1 hour training (reading material)
Ms Fanny Mitchell	03/03/2014 - 03/03/2014	Self-Directed Learning Log - NRES language and exclusion, NRES - 1 hour training (reading material)
Ms Fiona Slomovic	01/01/2014 - 01/01/2014	Equality & Diversity, Training day on Diversity, Discrimination, Equality & Safeguarding - 6 hours training
Ms Fiona Slomovic	01/07/2013 - 01/07/2013	Equality & Diversity, Representation at Disability Discrimination Tribunals - 6

		hours
Mr John Clifford	01/09/2013 - 01/09/2013	Self-directed learning Log - Update on Law and Bioethics, Society of Legal Scholars
Mr John Clifford	01/09/2013 - 01/09/2013	Equality & Diversity, BPP University Law School

**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	2	3.51
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	40	70.18
<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	12
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	18
Number of paediatric applications reviewed	9
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	8	14.04
Favourable Opinion with Additional Conditions	16	28.07
Unfavourable Opinion	0	0.00
Provisional Opinion	33	57.89
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>
Further Information Favourable Opinion with Standard Conditions	31	54.39
Further Information Favourable Opinion with Additional Conditions	1	1.75
Further Information Unfavourable Opinion	1	1.75
Favourable Opinion with Standard Conditions	8	14.04
Favourable Opinion with Additional Conditions	16	28.07
Unfavourable Opinion	0	0.00
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	0	0.00
<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>18</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	10	55.56
Favourable Opinion with Additional Conditions	2	11.11
No Opinion transfer to full committee for review	2	11.11
Provisional Opinion	4	22.22
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>18</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.70
<b>Number of applications for full ethical review over 60 days</b>	1
<b>Number of applications over 60 days as a % of total</b>	1.75%
<b>Number of days taken to final decision - average</b>	35
<b>Number of days taken to final decision - mode</b>	23
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	140
<b>Number of substantial amendments over 35 days</b>	4
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	2.9%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	9
<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>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days</b>	2
<b>Number of proportionate review applications over 14 days as a % of total</b>	12.5%

**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>
13/LO/0396	Policy and Practice for Patient Transitions (Version 1)	31
13/LO/0410	Healthy Start, Happy Start: Helping with children's behaviour	30
13/LO/0416	Problem Solving Treatment in Visual Impairment (POSITIVE)	33
13/LO/0420	The safety and immunogenicity of a potential HIV vaccine; version 1	34
13/LO/0699	ELAD study	35
13/LO/0725	Do audio-visual materials improve voice therapy outcomes in adults?	3
13/LO/0753	The investigation and treatment of chondro-labral pathology of the hip	50
13/LO/0760	Interceptive awareness in Body Dysmorphic Disorder	48
13/LO/0930	Study of engagement in treatment by medium secure psychiatric patients	18
13/LO/0931	Comparing psoriasis treatments and care pathways using routine data	42
13/LO/0945	KOGNITO - Kuvan®'s effect in children with phenylketonuria	33
13/LO/1075	A Phase I study comparing GP2019 and Avastin in healthy ma??	43
13/LO/1097	Evaluating effects of LCZ696 in subjects with Essential Hypertension	47
13/LO/1099	Gastro-oesophageal reflux and apnoea	42
13/LO/1112	Investigating the impact of fatigue and anxiety provocation in CFS	40
13/LO/1117	TAVI in Women Registry	19
13/LO/1212	FOT-vent: autotitration of EPAP in chronic respiratory disease	37
13/LO/1214	Psychosexual functioning, fertility, and menopause in women with HIV.V1	54
13/LO/1216	Exam Nerves: A Multimodal Biopsychological Investigation.	41
13/LO/1253	Temsirolimus and Neratinib in patients with breast cancer - Amdt 10	29
13/LO/1257	MP4CO for the Acute Treatment of Vaso-occlusive Crises V1	25
13/LO/1443	Early identification of alcoholic liver disease	28
13/LO/1449	OXYCAP STUDY	62
13/LO/1723	PCSK9 levels in patients presenting with lipoprotein abnormalities	30
13/LO/1787	PROFILE Study Version 1.1	34
13/LO/1908	Nutritional adequacy of a low FODMAP diet in children	51
14/LO/0018	NOCOMPOUNDLUP0001	39
14/LO/0104	Evaluation of cortisol levels during physiological stress	46
14/LO/0115	Imaging Brain Structures in Children with Congenital Hypothyroidism	40

14/LO/0278	Study to compare Gammaplex 10% & 5% in Primary Immunodeficiency	54
14/LO/0324	Pulmaquin® with Non-Cystic Fibrosis Bronchiectasis (ORBIT 3)	47
14/LO/0339	The ACORN study: Coping and Relaxation in Pregnancy	51
14/LO/0348	Pre-op nutritional status in colorectal cancer surgical patients	48
14/LO/0524	Improving Assent in Research	36

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0001	Obstructive sleep apnoea and atopy	36
14/LO/0510	The Lived Experience Of Low Back Pain In Multi-ethnic Leicester, V1	14

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1499	Investigating healthcare in the construction of disability	38

#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0606	Efficiency of Mechanical vs Manual CPR during Ambulance Transportation	6
13/LO/0609	Is triaging effective in H1N1 influenza?	6
13/LO/0724	Advancing understanding of early diagnosis of invasive mould disease	8
13/LO/0822	VinCaP	25
13/LO/1013	Medical History Evaluation	7
13/LO/1052	Peri-op Respiratory Failure After Lung Transplantation	46
13/LO/1123	A Retrospective Study of Atrophy Secondary to Stargardt Disease	8
13/LO/1473	Telaprevir in genotype 3 HCV	23
13/LO/1496	Iodine intake and metabolism in Pregnant women.	3
13/LO/1680	Validating the Orthostatic Health Questionnaire for use in Clinic	4
13/LO/1795	Efficacy and safety of CSL830 in hereditary angioedema	22
13/LO/1929	Automatic analysis of natural language in online therapy transcripts.	6
13/LO/1967	PI3K/Akt/mTOR and RAF/MEK/ERK pathways in adrenocortical cancer	23
14/LO/0014	AI452-016 Observational f'up from BMS-914143 Hepatitis C trials	49
14/LO/0022	Randomised Phase II study in untreated advanced renal cell carcinoma	34
14/LO/0123	Novel post system for the restoration of endodontically treated teeth	4



14/LO/0172	Do women over 45 have adequate awareness of hypothyroidism? V1.1	3
14/LO/0199	Early Pregnancy Events and short and long-term pregnancy outcomes,EPOS	28

### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0423	Experiences of patients receiving psychological therapy (PEPT).	31
13/LO/0427	Effect of viscoseal on pain after subacromial decompression	26
13/LO/0710	Bayer 14727 randomised double blind hypertension study	21
13/LO/0719	Identifying barriers to returning to work after TKR and THR	7
13/LO/0752	Reconfiguring urban environments for families of preterm babies	21
13/LO/0924	Immuno-regulatory mechanisms in Autoimmune Diseases (version 1)	25
13/LO/0946	Trial Association of Two pathogens - In vitro (TAST-I) version 3	37
13/LO/1152	An exploratory breast lead interval study (EBLIS)	23
13/LO/1198	Exacerbations in severe asthma patients: mechanisms and biomarkers	23
13/LO/1362	Functional Cardiac MRI in Young Adults with Cancer	36
13/LO/1463	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial	23
13/LO/1752	CIM003JG - CIM331 v Placebo in Atopic Dermatitis Patients	22
13/LO/1776	An alternative group physiotherapy programme for chronic low back pain	22
14/LO/0113	AZ D1344C00001 (SUMIT) Uveal Melanoma	23
14/LO/0136	Improving palliative care in the Emergency Department	35
14/LO/0305	Investigating healthcare in the construction of disability. Version 2	40
14/LO/0338	In-house Donation of Saliva for Oral Health Research,V1.0	7
14/LO/0343	PET monitoring for MS therapy	31

### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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### 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
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**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:**

<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>
13/LO/1449	OXYCAP STUDY	62

<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>
13/LO/1117	TAVI in Women Registry	19
14/LO/0524	Improving Assent in Research	36

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

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

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
13/LO/0261/AM02	Lilly H7T-MC-TADO Paediatric Sickle Cell Disease	Substantial Amendment 1 - 18th June 2013	64
12/LO/1688/AM02	Gene variants influence on GSK1521498 effects on food & alcohol cues	Substantial Amendment 1 - 21st June 2013	45
12/LO/1156/AM10	XL184-307: Phase 3 study of XL184 vs Prednisone in mCRPC patients	Substantial Amendment 7 - 24th May 2013	43
13/LO/0752/AM01	Reconfiguring urban environments for families of preterm babies	Substantial Amendment 1 - 31st July 2013	36

<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</b>

			<b>Clock</b>
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<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>