

**London - South East Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - South East Research Ethics Committee
<b>Type of REC:</b>	Recognised CTIMP Type III
<b>Type of Flag:</b>	Establishing Research Databases Research Involving Adults Lacking Capacity Research Involving Prisoners or Prisons
<b>Chair:</b>	Professor David Caplin
<b>Vice-Chair:</b>	Ms Stephanie Cooper
<b>Alternate Vice-Chair:</b>	Mr Ron Driver
<b>REC Manager:</b>	Mrs Margaret Hutchinson
<b>REC Assistant:</b>	Miss Katie Souheard
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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## Chair's overview of the past year:

The year began with the responsibility for the REC being moved from Bristol to Manchester, only a couple of years after the move from the London office. Any concerns about the impact of the move were quickly dispelled, thanks to the planning and care of both Bristol and Manchester REC managers; in fact, it was an almost seamless change. We have welcomed a couple of new members, and we do now have a better balance between expert and lay members. Our very mixed workload provides an interesting diet, particularly with those studies where capacity is lacking, or with prisoners. Sometimes the challenges for these researchers are particularly severe, but Committee members are very positive in their approach, and creative in suggesting routes that might be more ethically appropriate. If we do issue an "Unfavourable" opinion, as far as possible we signpost the manner in which it could proceed.

One problem that continues to cause concern is that of poorly-designed student projects, often aggravated by the failure of the supervisor to attend the meeting. In writing our opinion, we are now explicit in criticizing the supervisor's absence, but that is little comfort to the time-pressured student.

I am grateful to all the REC members for the positive and cheerful atmosphere of the meetings, which includes a friendly and polite approach to researchers, and for the significant sub-committee workload outside of meetings.

Finally, at the end of the year our excellent REC assistant departed; given her skills we were sad, but not surprised, to lose her.

## London - South East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Ashok Bhiman	Consultant Psychiatrist	Expert	01/07/2007	
Professor David Caplin	Physicist	Lay	01/02/2007	
Ms Stephanie Cooper	Retired Solicitor	Lay Plus	23/01/2013	
Mr Ron Driver	Retired University Lecturer/Statistician	Lay	01/06/2009	
Professor John Eastwood	Consultant Renal Physician	Expert	01/01/2008	
Professor Anthony Fox	Pharmaceutical Medicine	Expert	21/08/2014	
Mr Guy Gardener	Retired Assistant Chief Constable	Lay Plus	01/10/2007	
Ms Janelle Hill	Former Banking Administrator	Lay Plus	01/06/2014	
Professor Atholl Johnston	Professor of Clinical Pharmacology	Expert	01/06/2015	
Dr Morven Leese	Reader in Biostatistics	Expert	01/02/2016	
Prof Eleni Palazidou	Consultant Psychiatrist	Expert	01/08/2014	
Mr Graham Smith	Business Consultant	Lay Plus	14/01/2013	
Ms Vanda Taylor	Senior Cancer Information Nurse	Expert	14/01/2013	
Ms Brigid Tucker	Head of Policy & Communications, General Osteopathic Council	Lay Plus	01/06/2015	
Professor Zahur Zaman	Retired Clinical Pathologist	Expert	24/02/2014	

## London - South East Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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## London - South East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Roy Sinclair	Pharmacist	Expert	12/08/2016

**London - South East Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Ashok Bhiman	None	31/03/2016
Professor David Caplin	College of Optometrists, member of Lay Advisory Panel and of Research Committee Emeritus Professor of Physics, Imperial College London	31/03/2016
Professor John Eastwood	Shares in AstraZeneca, held in 1996 Shares in AstraZeneca, 317 Ordinary Shares	31/03/2016
Mr Guy Gardener	No interests declared	02/06/2015
Ms Janelle Hill	None	30/03/2016
Dr Morven Leese	Shares in Unilever Shares in a number of general investment funds Post funding completion of projects, originally funded by NIHR (Publication of results)	03/02/2016
Ms Vanda Taylor	Works as a cancer information nurse for Cancer Research UK. However the role does not involve undertaking any research.	31/03/2016
Ms Brigid Tucker	Senior Manager employed by the healthcare professional regulator, the General Osteopathic Council, which commissions research that informs our regulatory functions. Representative of the General Osteopathic Council on the national Council for Osteopathic Research (NCOR) - a registered charity that has as its main aim the promotion of research and research education in the field of osteopathy.	31/03/2016
Professor Zahur Zaman	None	31/03/2016

**Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:**

Month	Date	Number of Members Present at Meeting
May	13/05/2015	9
June	10/06/2015	11
July	08/07/2015	13
August	12/08/2015	8
October	14/10/2015	13
November	11/11/2015	11
December	09/12/2015	10
January	13/01/2016	11
February	10/02/2016	10
March	09/03/2016	13

10 full committee meetings were held during the reporting period.

**Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:**

Month	Date	Number of Members Present at Meeting
April	15/04/2015	3
May	13/05/2015	3
July	24/07/2015	3
August	28/08/2015	3
September	25/09/2015	3
December	18/12/2015	3
January	21/01/2016	3
February	17/02/2016	3
March	22/03/2016	3

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

**Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:**

Month	Date	Number of Members Present at Meeting
April	01/04/2015	2
April	15/04/2015	3
May	01/05/2015	2
May	15/05/2015	2
June	01/06/2015	2
June	01/06/2015	2
June	11/06/2015	3
June	15/06/2015	2
June	15/06/2015	2
July	01/07/2015	2
July	01/07/2015	2
July	15/07/2015	3

August	01/08/2015	6
August	15/08/2015	4
September	01/09/2015	4
September	15/09/2015	2
October	01/10/2015	5
October	15/10/2015	4
November	01/11/2015	3
November	15/11/2015	4
December	01/12/2015	4
December	15/12/2015	4
January	04/01/2016	3
January	15/01/2016	2
February	01/02/2016	3
February	15/02/2016	4
March	01/03/2016	4
March	15/03/2016	4

28 sub-committee meetings were held during the reporting period.

#### Details of inquorate meeting held:01 April 2015 - 31 March 2016

0

**Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ashok Bhiman	7
Professor David Caplin	8
Ms Stephanie Cooper	9
Mr Ron Driver	10
Professor John Eastwood	9
Professor Anthony Fox	8
Mr Guy Gardener	8
Ms Janelle Hill	9
Professor Atholl Johnston	7
Dr Morven Leese	1
Prof Eleni Palazidou	6
Mr Graham Smith	6
Ms Vanda Taylor	5
Ms Brigid Tucker	7
Professor Zahur Zaman	8

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ashok Bhiman	2
Professor David Caplin	7
Ms Stephanie Cooper	1
Mr Ron Driver	1
Professor John Eastwood	2
Mr Guy Gardener	2
Ms Janelle Hill	4
Prof Eleni Palazidou	2
Mr Graham Smith	2
Ms Brigid Tucker	1
Professor Zahur Zaman	3

**Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Professor Eleni Palazidou	1
Dr Ashok Bhiman	4
Professor David Caplin	24
Ms Stephanie Cooper	9



Mr Ron Driver	8
Professor John Eastwood	3
Professor Anthony Fox	3
Mr Guy Gardener	6
Ms Janelle Hill	6
Professor Atholl Johnston	1
Prof Eleni Palazidou	4
Mr Graham Smith	7
Ms Vanda Taylor	2
Ms Brigid Tucker	4
Professor Zahur Zaman	5

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Ashok Bhiman	24/04/2015	Equality and Diversity
Professor David Caplin	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Ms Stephanie Cooper	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Ms Stephanie Cooper	09/12/2015	National Training Day for Committee Chairs
Professor John Eastwood	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Professor Anthony Fox	10/06/2015	Equality & Diversity
Professor Anthony Fox	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Mr Guy Gardener	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Mr Guy Gardener	09/02/2016	Training - Equality and Diversity (e-learning module)
Ms Janelle Hill	08/02/2016	Training - Equality and Diversity (e-learning module)
Mr Graham Smith	18/02/2016	Training - National Members Training Day
Ms Vanda Taylor	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Ms Brigid Tucker	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Professor Zahur Zaman	21/04/2015	Equality & Diversity Training
Professor Zahur Zaman	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers

## 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	13	23.21
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	8	14.29
Others	35	62.50
<b>Total Applications Reviewed</b>	<b>56</b>	<b>100</b>

**Table 2: Breakdown of full applications and other activity during reporting period**

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	14
Number of paediatric applications reviewed	6
Number of device applications reviewed	3
Number of prisoner applications reviewed	9
Number of applications involving adults unable consent reviewed	11
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	5

**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	8.93
Favourable Opinion with Additional Conditions	6	10.71
Unfavourable Opinion	7	12.50
Provisional Opinion	37	66.07
Provisional Opinion Pending Consultation with Referee	1	1.79
<b>Total</b>	<b>56</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	30	53.57
Further Information Favourable Opinion with Additional Conditions	3	5.36
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	8.93
Favourable Opinion with Additional Conditions	6	10.71
Unfavourable Opinion	7	12.50
Provisional Opinion	2	3.57
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	3	5.36
<b>Total</b>	<b>56</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>24</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	5
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

**Table 7: 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	14	58.33
Favourable Opinion with Additional Conditions	3	12.50
No Opinion transfer to full committee for review	2	8.33
Provisional Opinion	5	20.83
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>24</b>	<b>100</b>

**Table 8: Other Management Information based on the number of completed applications for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.60
<b>Number of completed applications for full ethical review</b>	53
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	6
<b>Number of completed applications over 40 days as a % of total</b>	10.71%
<b>Number of days taken to final decision – average (mean)</b>	33
<b>Number of completed proportionate review applications for ethical review</b>	22
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	2
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	9.09%
<b>Number of SSAs (non-Phase 1) reviewed</b>	6
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	86
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.16%
<b>Number of completed substantial amendments over 28 days</b>	12
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	13.95%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of minor amendments received</b>	83
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	48
<b>Number of annual progress reports received</b>	140

<b>Number of safety reports received</b>	29
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	33

**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
03/1/096/AM03	A National Study of Breast Cancer After Hodgkin's Disease	Five	30/07/2015	33
04/MRE01/24/AM02	Kennedy disease study and registers	Two	11/11/2015	13
07/H1102/84/AM41	A6181109- Sunitinib treatment of renal adjuvant cancer (S-TRAC)	IB	28/08/2015	12
07/MRE01/10/AM47	SORCE-version 1.0	Twenty-eight	19/05/2015	20
08/H1102/37/AM34	Trial of Perioperative Endocrine Therapy-Individualising Care (POETIC)	9	20/07/2015	30
09/H1102/54/AM07	Safety of Maraviroc with background therapy in HIV-1 patients	Change of CI	02/06/2015	6
09/H1102/55/AM15	A Randomised Controlled Trial of Multi Systemic Therapy in the UK v1.0	SA14	06/11/2015	21
10/H1102/16/AM23	BIBW 2992 and Paclitaxel versus Chemotherapy in NSCLC	18	07/04/2015	34
10/H1102/77/AM07	UK Vasculitis Susceptibility and Outcomes	Four	29/05/2015	13
10/H1102/77/AM08	UK Vasculitis Susceptibility and Outcomes	Five	26/01/2016	10
10/H1102/85/AM14	Open Label Phase 3 study of Solanezumab in Alzheimer's Disease	Scales for visit 66 and 79/SP3	23/06/2015	6
10/H1102/87/AM19	OPTiMiSE	Thirteen	06/07/2015	7
11/H1102/8/AM12	A multi-centre focal HIFU trial in men with localised prostate cancer	Nine	01/02/2016	20
11/LO/0025/AM01	Saccadometry in Primary Headache Syndromes	One	03/03/2014	5
11/LO/0218/AM15	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	Six	15/01/2016	2
11/LO/0439/AM04	Genetic fMRI	Three	05/02/2016	6
11/LO/0566/AM01	TransMAGIC	One	20/04/2015	29
11/LO/1369/AM09	Phase 3 Study of ADI-PEG 20 in Patients with Hepatocellular Carcinoma	Six	02/04/2015	7
11/LO/1369/AM10	Phase 3 Study of ADI-PEG 20 in Patients with Hepatocellular Carcinoma	Seven	10/06/2015	9
12/LO/0567/AM04	Small Area Health Statistics Unit - extended application	Six	29/04/2015	25
12/LO/1076/AM07	Denosumab in Patients with Newly Diagnosed Multiple Myeloma	Six	22/05/2015	16
12/LO/1076/AM12	Denosumab in Patients with Newly Diagnosed Multiple	Substantial	28/09/2015	14



	Myeloma	Amendment 8		
12/LO/1334/AM05	EMPIRIKAL Version 1	Five	30/06/2015	25
12/LO/1334/AM09	EMPIRIKAL Version 1	Seven	15/02/2016	14
12/LO/1808/AM04	Bridging the Age Gap in Breast Cancer	Two	09/07/2015	13
12/LO/1808/AM05	Bridging the Age Gap in Breast Cancer	Three	07/10/2015	7
13/LO/0873/AM02	Evaluating the Integrate Model for socially excluded young people	Two	07/12/2015	14
13/LO/0873/AM03	Evaluating the Integrate Model for socially excluded young people	Three	07/12/2015	14
13/LO/1096/AM05	MID-FRAIL Study - version 01	Four	02/03/2016	11
13/LO/1339/AM03	A palliative care intervention for people with dementia in care homes	Three	08/04/2015	14
13/LO/1407/AM03	The Role of the Circadian Clock in Alzheimer's Disease	Two	12/05/2015	34
13/LO/1656/AM05	The LIXI study	Four	23/07/2015	3
14/LO/0203/AM04	CLARITY Version 1.0	Four	03/10/2015	12
14/LO/0383/AM01	ASSERT 2 Database (Version 1)	One	31/03/2015	29
14/LO/0397/AM08	M12-999: Chronic HCV infection in adult liver transplant recipients	Five	07/04/2015	14
14/LO/0397/AM10	M12-999: Chronic HCV infection in adult liver transplant recipients	Annual IB Update	10/06/2015	35
14/LO/0397/AM11	M12-999: Chronic HCV infection in adult liver transplant recipients	Protocol Amendment 6	15/09/2015	27
14/LO/0397/AM12	M12-999: Chronic HCV infection in adult liver transplant recipients	Eight	25/11/2015	23
14/LO/0543/AM02	Thyroid Eye Disease (TED)	Two	28/09/2015	1
14/LO/1152/AM01	Swallowing Intervention Package for Head & Neck Cancer Patients	One	05/02/2016	9
14/LO/1206/AM04	PLATFORM	Four	10/04/2015	27
14/LO/1206/AM07	PLATFORM	Eight	26/11/2015	37
14/LO/1208/AM01	The National IIH Database: The IIH LIFE, version 1.0	One	10/03/2015	8
14/LO/1373/AM01	UK register for hereditary spastic paraplegia	One	12/07/2015	12
14/LO/1696/AM02	MBT for Antisocial Personality Disorder	One	07/01/2016	11
14/LO/1753/AM01	COPD patients and exacerbation rescue medications	One	13/04/2015	12
14/LO/1765/AM01	OPTCARE Neuro	One	03/06/2015	29
14/LO/1765/AM04	OPTCARE Neuro	Two	07/12/2015	13
14/LO/1794/AM02	GWEP1415- Study of GWP42003-P in Dravet and Lennox-	Two	03/07/2015	23

	Gastaut Syndrome			
14/LO/1794/AM05	GWEP1415- Study of GWP42003-P in Dravet and Lennox-Gastaut Syndrome	Three	17/11/2015	21
14/LO/1965/AM01	Monitoring bloodstream infection in neonatal intensive care units	One	15/07/2015	16
14/LO/1975/AM01	Human Motion Analysis Database	One	29/06/2015	26
14/LO/1988/AM01	PETRA: Threatened preterm labour - risk and care management v.1	One	28/04/2015	5
14/LO/1988/AM02	PETRA: Threatened preterm labour - risk and care management v.1	Two	09/10/2015	22
14/LO/2000/AM01	Problem solving intervention in prisons	One	25/07/2015	1
14/LO/2000/AM02	Problem solving intervention in prisons	Two	05/01/2016	6
14/LO/2172/AM01	Liver Immunosuppression Free Trial ("LIFT"), version 1	One	26/03/2015	9
14/LO/2172/AM02	Liver Immunosuppression Free Trial ("LIFT"), version 1	Two	17/07/2015	3
15/LO/0037/AM02	SSAT054: Non-genetic factors in the pathogenesis of IBD in Twins	One	20/08/2015	26
15/LO/0052/AM01	An extension study of LON002 in patients with cancer.	Substantial Amendment 1 - temp	22/09/2015	26
15/LO/0053/AM01	Phase 2: Schwartz Rounds evaluation - Survey & Ethnographic fieldwork	One	13/04/2015	9
15/LO/0053/AM03	Phase 2: Schwartz Rounds evaluation - Survey & Ethnographic fieldwork	Two	05/05/2015	27
15/LO/0053/AM05	Phase 2: Schwartz Rounds evaluation - Survey & Ethnographic fieldwork	Three	03/07/2015	24
15/LO/0053/AM06	Phase 2: Schwartz Rounds evaluation - Survey & Ethnographic fieldwork	Substantial Amendment 4	08/09/2015	33
15/LO/0190/AM01	Sleep disturbance in people with dementia in care homes: pilot	One	03/12/2015	27
15/LO/0238/AM01	Noninvasive and invasive characterisation of HFpEF	One	27/01/2016	8
15/LO/0716/AM01	TOPCAT-G	One	10/07/2015	13
15/LO/0716/AM03	TOPCAT-G	Substantial Amendment 2	23/09/2015	32
15/LO/0723/AM01	Southwark: prompts to staff to increase NHS Health Check uptake	One	01/05/2015	29
15/LO/0771/AM02	APTITUDE	Substantial Amendment 01	18/09/2015	27

15/LO/0771/AM03	APTITUDE	Two	12/11/2015	20
15/LO/0771/AM05	APTITUDE	Three	17/02/2016	6
15/LO/0937/AM01	Prevalence mental disorders Foreign and Local Prisoners at Wandsworth	One	22/01/2016	12
15/LO/0996/AM01	Inpatient mental health care for patients with Autism	Substantial Amendment 1	15/09/2015	26
15/LO/1102/AM02	MLN1117-1501, Phase 1b/2, NSCLC treatment with Docetaxel and MLN1117	Two	20/10/2015	18
15/LO/1102/AM03	MLN1117-1501, Phase 1b/2, NSCLC treatment with Docetaxel and MLN1117	Three	28/01/2016	4
15/LO/1105/AM04	JNJ-63935937 (imetelstat)	One	09/12/2015	4
15/LO/1261/AM02	UNIFI	One	14/07/2015	8
15/LO/1261/AM04	UNIFI	Two	19/11/2015	15
15/LO/1267/AM01	Myelin changes in RRMS patients	One	13/02/2016	8
15/LO/1268/AM01	Myelin changes in RRMS patients	One	13/02/2016	8
15/LO/1282/AM01	Phase 1 Ramucirumab plus Pembrolizumab in different types of Cancer	Substantial Amendment 1	18/09/2015	19
15/LO/1758/AM01	Guillain-Barre Syndrome: electro-clinical patterns	One	18/02/2016	6
15/LO/1971/AM01	MOL-PAP-002 Version 1.0	One	25/01/2016	12
15/LO/2218/AM01	Effectiveness of Primary Prevention Education	One	05/02/2016	1

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0720/AM02	NREM parasomnia: natural course, triggers and influence on QoL	One	02/06/2015	8

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

#### Favourable opinion timeline

Amendment REC	Title	Version	Date	Number of Days on
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<b>Reference</b>				<b>Clock</b>
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<b>Unfavourable opinion timeline</b>				
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<b>Amendment REC</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on</b>
<b>Reference</b>				<b>Clock</b>

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
15/LO/1564	A registry for patients with Short Bowel Syndrome	15
15/LO/1754	The psychological impact of the diagnosis of Gestational Diabetes.V01	38

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1206/AM07	PLATFORM	Eight	26/11/2015	37

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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