

London - South East Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - South East Research Ethics Committee
Type of REC:	Recognised CTIMP Type III
Type of Flag:	Establishing Research Databases Research Involving Adults Lacking Capacity Research Involving Prisoners or Prisons
Chair:	Professor David Caplin
Vice-Chair:	Ms Stephanie Cooper
Alternate Vice-Chair:	Mr Ron Driver
REC Manager:	Mrs Margaret Hutchinson
REC Assistant:	Ms Julie Acourt March 2017- Present Miss Nafeesa Khanam May 2016-March 2017
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

It is a measure of the dedication and professional skills of our Manager and her Assistants (during the year we said farewell to Nafeesa Khanam, and welcomed Julie Acourt), and the contribution of Committee members, that the recent triennial audit resulted in Full Accreditation, and in all aspects the REC was graded "Favourable".

We were pleased to see the roll-out of the HRA Approval process, although the backlog of applications meant that their assessment did not always reach us prior to our ethical review. That process, complemented by the careful scrutiny that applications receive in the office, helps the REC enormously, allowing us to focus efficiently on the ethical issues.

We continue to battle with the communication skills – or lack thereof - of some researchers that is demonstrated within the IRAS form, and more importantly, in the Participant information. It is not just a matter of being picky about the use of language, but we suspect that researchers, who cannot be bothered to think about how they communicate with us, may not be communicating clearly and sympathetically with participants.

This year we have seen only a couple of studies within prisons (we are one of the handful of RECs flagged to review prison research). It would seem unlikely that the needs for research within the prison population have diminished; we suspect that the resources and time available for prison research are under pressure.

A new challenge comes from web-based research, raising issues of privacy, confidentiality, generalizability, potential for distress. We need discussion within HRA about how to go forward.

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: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Ashok Bhiman	None	08/02/2017
Professor David Caplin	College of Optometrists Lay member	08/02/2017
Ms Stephanie Cooper	Member of Audit & Risk Committee of Jewish Care (University)	08/02/2017
Mr Ron Driver	None	08/02/2017
Professor John Eastwood	Shareholdings in Astra Zeneca 307 shares. Chairman for Katherine Valles Charitable Trust, charity number 1077064 Student projects overseas, r/c small sums	08/02/2017
Professor Anthony Fox	Possible pension fund in organisation involved in research, Professor at Kings College London, previously involved with Clinical Trial design	08/02/2017
Mr Guy Gardener	None	08/02/2017
Ms Janelle Hill	None	14/02/2017
Professor Atholl Johnston	Director and part owner of Analytical Services International LTD (ASI) .Shares in Various Pharma companies, these are declared at the REC Meeting. Connected to Barts & The London, St George's University of London Queen Mary	08/02/2017
Dr Morven Leese	Shares in Unilever	09/02/2017
Prof Eleni Palazidou	Reviews research applications for NIHR, refers papers for Publications in coveted medical journals	08/02/2017
Mr Graham Smith	None	08/02/2017
Ms Vanda Taylor	Works as a cancer information nurse for Cancer Research UK. However the role does not involve undertaking any research.	10/02/2017
Ms Brigid Tucker	None	31/03/2017
Professor Zahur Zaman	None	08/02/2017

Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
May	11/05/2016	12
June	08/06/2016	11
July	13/07/2016	14
September	14/09/2016	9
October	12/10/2016	9
November	09/11/2016	14
December	14/12/2016	10
January	11/01/2017	9
February	08/02/2017	11
March	08/03/2017	11

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	28/04/2016	3
May	25/05/2016	3
June	21/06/2016	3
July	27/07/2016	3
August	24/08/2016	3
November	23/11/2016	3
December	21/12/2016	3
January	19/01/2017	3
February	23/02/2017	3
March	23/03/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	01/04/2016	3
April	15/04/2016	2
April	15/04/2016	2
May	01/05/2016	2
May	15/05/2016	2
May	31/05/2016	4
June	26/06/2016	2
July	01/07/2016	4
July	15/07/2016	4
August	01/08/2016	3
August	15/08/2016	3

August	22/08/2016	14
September	01/09/2016	3
September	15/09/2016	4
September	16/09/2016	7
October	01/10/2016	4
October	15/10/2016	4
November	01/11/2016	3
November	15/11/2016	3
November	24/11/2016	2
December	01/12/2016	4
December	15/12/2016	3
January	01/01/2017	2
January	15/01/2017	3
February	01/02/2017	3
February	15/02/2017	3
March	01/03/2017	4
March	02/03/2017	10
March	15/03/2017	4

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

0

Attendance of Members at full committee meetings:01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Dr Ashok Bhiman	8
Professor David Caplin	10
Ms Stephanie Cooper	9
Mr Ron Driver	10
Professor John Eastwood	6
Professor Anthony Fox	7
Mr Guy Gardener	9
Ms Janelle Hill	6
Professor Atholl Johnston	9
Dr Morven Leese	7
Prof Eleni Palazidou	6
Mr Graham Smith	6
Ms Vanda Taylor	4
Ms Brigid Tucker	8
Professor Zahur Zaman	5

Attendance of Members at proportionate review sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Professor David Caplin	7
Ms Stephanie Cooper	2
Mr Ron Driver	1
Professor John Eastwood	2
Professor Anthony Fox	1
Mr Guy Gardener	2
Ms Janelle Hill	3
Professor Atholl Johnston	1
Prof Eleni Palazidou	1
Mr Graham Smith	3
Ms Vanda Taylor	3
Ms Brigid Tucker	2
Professor Zahur Zaman	2

Attendance of Members at sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Dr Ashok Bhiman	3
Professor David Caplin	26

Ms Stephanie Cooper	10
Mr Ron Driver	8
Professor John Eastwood	6
Professor Anthony Fox	9
Mr Guy Gardener	7
Ms Janelle Hill	6
Professor Atholl Johnston	5
Dr Morven Leese	2
Prof Eleni Palazidou	5
Mr Graham Smith	6
Ms Vanda Taylor	3
Ms Brigid Tucker	8
Professor Zahur Zaman	7

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Ashok Bhiman	10/02/2017	Online course of Introduction of Research Ethics Global Training, MRC Training on HTA, reading various journal articles, SDL 2016-2017
Professor David Caplin	09/09/2016	Researcher Training Day
Professor David Caplin	07/11/2016	Practicalities of Running a REC
Professor David Caplin	01/12/2016	National Training Day for Committee Chairs
Professor David Caplin	27/03/2017	Chair's Review Programme Workshop
Ms Stephanie Cooper	07/11/2016	Practicalities of running a REC
Ms Stephanie Cooper	01/12/2016	National Training day for Chairs
Mr Ron Driver	08/02/2017	Self-Directed Learning 2016-2017 including Equality and Diversity, reading articles on rules of consent, care after research and research including ionising radiation
Professor John Eastwood	04/07/2016	HRA CTIMP Training day
Professor Anthony Fox	16/02/2017	National REC Member Training day
Mr Guy Gardener	08/02/2017	Self-Directed Learning 2016-2017- Equality and Diversity training
Ms Janelle Hill	10/02/2017	SDL Training 2016-2017 – Equality and diversity training, attended seminar- Hope in depression, read articles on therapy for Parkinson's disease.
Professor Atholl Johnston	15/02/2017	Equality Diversity and Human Rights
Professor Atholl Johnston	08/03/2017	2016-2017
Dr Morven Leese	30/11/2016	Committee Member Induction
Dr Morven Leese	12/02/2017	Equality and Diversity
Prof Eleni Palazidou	11/02/2017	Equality Diversity & Human Rights
Prof Eleni Palazidou	13/02/2017	SDL Training 2016-2017 – Lecture on Aristotle Ethics
Ms Vanda Taylor	06/02/2017	Self-Directed Learning 2016-2017 read the following articles, Cancer survival and Ethics, Research Ethics for counsellors and nurses, Medical stats made easy
Ms Brigid Tucker	03/03/2017	2016-2017
Ms Brigid Tucker	03/03/2017	Equality and Diversity Training
Professor Zahur Zaman	16/02/2017	National REC Member Training day

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	13	25.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	7	13.46
Others	32	61.54
Total Applications Reviewed	52	100

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

Number of applications made invalid by the REC Manager	4
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	6
Number of device applications reviewed	2
Number of prisoner applications reviewed	2
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

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	10	19.23
Favourable Opinion with Additional Conditions	11	21.15
Unfavourable Opinion	5	9.62
Provisional Opinion	22	42.31
Provisional Opinion Pending Consultation with Referee	4	7.69
Total	52	100
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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	24	46.15
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	10	19.23
Favourable Opinion with Additional Conditions	11	21.15
Unfavourable Opinion	5	9.62
Provisional Opinion	1	1.92
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	1	1.92
Total	52	100

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

Total Applications Reviewed	21
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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	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	6
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	1

Table 7: 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	15	71.43
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	28.57
Unfavourable Opinion	0	0.00
Total	21	100

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

Average number of applications reviewed per full meeting	5.20
Number of completed applications for full ethical review	51
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	16
Number of completed applications over 40 days as a % of total	30.77%
Number of days taken to final decision – average (mean)	37
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 14 days (please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016).	3
Number of completed proportionate review applications for ethical review over 21 days.	0
Number of completed proportionate review applications over 14 days as a % of total	14.29%
Number of SSAs (non-Phase 1) reviewed	2
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	92
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	2.17%
Number of completed substantial amendments over 28 days	19
Number of completed substantial amendments over 28 days as a % of total substantial amendments	20.65%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non substantial amendments received	86
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	27
Number of annual progress reports received	112
Number of safety reports received	36
Number of Serious Adverse Events received	0
Number of final reports received	41

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/HRA/3327	Acute Coronary Syndrome Health Informatics Collaborative	29
16/LO/0814	Dose finding study of Sarilumab in children with pcJIA	60
16/LO/0815	Can a prison peer-led intervention address NCD risk factors	49
16/LO/0991	Exploring the processes of change; Version 1	47
16/LO/1177	ECMO ULTRASOUND	57
16/LO/1205	Psychoeducational intervention for women prescribed tamoxifen	37
16/LO/1246	Can patient video testimonials augment consent? A RCT	59
16/LO/1499	The REMAP study	41
16/LO/1612	Follow-up Study for Patients who Completed Study ALX0681-C301	40
16/LO/1620	The pathophysiological role of cortical oscillations in restlessness	51
16/LO/1660	Optimisation of Neonatal Ventilation - NAVA vs PAV	41
16/LO/1747	EMBER Study	35
16/LO/1765	Acute Opioid Overdose (v1.1)	35
16/LO/1960	Dose finding study of Sarilumab in children with sJIA	53
16/LO/1971	Non-invasive multimodal brain monitoring in clinical neuroscience	35
16/LO/2136	A Multicentre Biomarker Study in Neurodegeneration	39
16/LO/2147	FRESH	58
17/LO/0029	POPPIE	35
17/LO/0042	MIND-MAPS-PD	32
17/LO/0100	CREDIBLE	59
17/LO/0169	MD1003 in progressive multiple sclerosis	50
17/LO/0250	Predictors of Treatment Outcome in Anorexia Nervosa	37
17/LO/0278	Breaking Free Online database - renewal of ethical approval	60
17/LO/0363	Insulin intervention development for people with type 2 diabetes.	41
17/LO/0380	BN29553 (CREAD-2) - Crenezumab in patients with Prodromal to Mild AD	60

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0895	Teenage and Young Adult Cancer Survivor Study (TYACSS) - Renewal	57
16/LO/1247	Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JGDM)	28
16/LO/1283	West Midlands Regional Children's Tumour Registry	28
16/LO/1717	ACP-196 with Relapsed or Refractory Chronic Lymphocytic Leukemia	28
16/LO/1909	HHT and wider medical issues	27
16/LO/2046	MRI and Dementia: A multi-centre study of autopsy proven cases	39
16/LO/2174	NICE FIT	33
17/LO/0008	Use of routine GOSH data for research	29
17/LO/0022	MUK Nine a: Screening Study	29
17/LO/0023	MUK Nine b: Optimum	29

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0800	Dementia and the memory service: The ethnic minority experience v1	28
16/LO/0803	SMILE study (CEP311)	28
16/LO/0829	Automated ultrasound image analysis to assess heart function	28
16/LO/1215	STATUS trial	28
16/LO/1720	MODET	28
16/LO/1989	Cancer Pain Research Database	27
16/LO/2167	PACE 10 year follow-up: feasibility study	33
16/LO/2173	The Response To Ajmaline Provocation in Healthy Subjects	33
17/LO/0236	PROMINENT (K-877-302 - DIABETES STUDY)	29
17/LO/0253	Optical research for biopsy triaging (ORBiT)	27
17/LO/0282	Fetal Imaging with Maternal Oxygen (FIMOX)	33

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/0827	A Model of Sibling Relationships in Perinatally Acquired HIV	28
16/LO/1016	Efficacy of IVS Midazolam when interacting with cannabis	25
16/LO/1030	Reviewing and modifying beliefs in people who hear voices	22
16/LO/1986	Prognostic dissonance of seriously ill HD patients	29
16/LO/2215	Optimal: reduction in readmissions by using discharge co-ordinators	29

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
16/LO/1761	International Hemospray Registry	26

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0836	Relvar Ellipta in Patients with COPD and Asthma	14
16/LO/1190	Performance Variation on Common Tests of Processing Speed	14
16/LO/1197	Examining Emotion Perception in Cochlear Implant Users	13
16/LO/1996	Navimed 2 - Real Time pain feedback study	12

16/LO/2042	Cognition and the deep brain	15
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
16/LO/0834	Parenting interventions and reflective functioning	11
16/LO/0849	ARCHIVES study v.1.0	13
16/LO/0909	MINIMUM study retrospective data analysis	12
16/LO/1038	PENTHROX-SURVEY	14
16/LO/1042	A pragmatic evaluation of the NHS Tayside weight management service	12
16/LO/1046	Pilot study of the hand therapy online data collection system	13
16/LO/1189	Attentional bias in adults with non epileptic seizures	14
16/LO/1464	FOB testing for GI malignancy in IDA	13
16/LO/1613	Plasma proteomics in coronary artery disease	13
16/LO/1630	Use of pancreatic disease specimens for biological analysis	13
16/LO/2273	Cancer biomarker detection in non-invasively sampled colorectal mucus	11
16/LO/2275	Validation of LIBSS and biomarker identification	10
17/LO/0165	Philips Health Watch Pilot usability Study in CAD patients	4
17/LO/0172	Changes in the Immune System in demyelinating autoimmune disorders	16
17/LO/0377	MAGIC- a self-management education programme for people with CFRD	13

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0544	MECANO study V2	n/a

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

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
03/1/022/AM01	UK Flexible sigmoidoscopy screening trial	1	10/06/2016	12
07/H1102/84/AM44	A6181109- Sunitinib treatment of renal adjuvant cancer (S-TRAC)	15	15/11/2016	10
07/H1102/88/AM22	NeoALTTO Neoadjuvant Lapatinib/Trastuzumab in early breast cancer	5	01/09/2016	28
07/H1102/88/AM24	NeoALTTO Neoadjuvant Lapatinib/Trastuzumab in early breast cancer	6	18/01/2017	34
07/MRE01/10/AM52	SORCE-version 1.0	5.3.1	11/07/2016	30
07/MRE01/68/AM56	ALTTO - Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation	11	13/06/2016	22
07/MRE01/68/AM58	ALTTO - Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation	12	12/09/2016	16
08/H1102/112/AM44	Triple Antiplatelets for Reducing Dependency after Ischaemic Stroke	SA03/16	23/03/2016	2
09/H1102/114/AM22	TACE-2	15	26/10/2016	4
09/H1102/54/AM08	Safety of Maraviroc with background therapy in HIV-1 patients	3	09/01/2017	21
10/H1102/2/AM09	An RCT of MBT for patients with complex eating disorders	Eight	03/03/2016	22
10/H1102/2/AM10	An RCT of MBT for patients with complex eating disorders	9	24/10/2016	24
10/H1102/2/AM11	An RCT of MBT for patients with complex eating disorders	10	03/12/2016	21
10/H1102/85/AM16	Open Label Phase 3 study of Solanezumab in Alzheimer's Disease	10	15/02/2017	15
11/H1102/8/AM14	A multi-centre focal HIFU trial in men with localised prostate cancer	10	22/02/2017	18
11/LO/0218/AM16	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	7	25/03/2016	15
11/LO/0218/AM17	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	8	06/10/2016	22
11/LO/0218/AM18	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	9	28/11/2016	9
11/LO/0331/AM01	CONCORD programme	1	27/01/2017	25
11/LO/0439/AM07	Genetic fMRI	4	15/12/2016	33

11/LO/0772/AM08	A Randomised Controlled Trial to evaluate MST-PSB in the UK V1.0	7	14/04/2016	34
11/LO/1939/AM08	Contingency management for cannabis use in early psychosis (CIRCLE)	6	09/09/2016	25
12/LO/0567/AM05	Small Area Health Statistics Unit - extended application	7	20/12/2016	28
12/LO/0790/AM03	Developmental Disorders Research Database	3	11/08/2016	7
12/LO/1076/AM13	Denosumab in Patients with Newly Diagnosed Multiple Myeloma	9	26/08/2016	28
12/LO/1334/AM14	EMPIRIKAL	11	15/12/2016	4
12/LO/1808/AM08	Bridging the Age Gap in Breast Cancer	Four	09/03/2016	22
12/LO/1808/AM09	Bridging the Age Gap in Breast Cancer	5	30/01/2017	15
13/LO/0669/AM08	MINIMISE STEMI trial	Amendment 120533	01/04/2016	35
13/LO/0695/AM02	TRIPHIC project	2	21/12/2016	29
13/LO/1757/AM01	Reversible hypoxia in lung cancer (REPLICA) (version 1.0)	1	17/02/2017	6
13/LO/1857/AM02	Physiology of Schizophrenia Spectrum Disorders	2	04/08/2016	13
14/LO/0797/AM02	PACK: Progression of Arterial and Cardiac disease in Kidney patients	2	19/12/2016	25
14/LO/1156/AM01	Future Care Study	1	06/01/2017	10
14/LO/1206/AM09	PLATFORM	Substantial Amendment 10	24/08/2016	30
14/LO/1240/AM03	Genes & Health (version 1)	1	06/02/2017	23
14/LO/1696/AM03	Mentalization for Offending Adults Males (MOAM)	2	06/04/2016	22
14/LO/1794/AM08	GWEP1415- Study of GWP42003-P in Dravet and Lennox-Gastaut Syndrome	5	26/08/2016	34
14/LO/1988/AM03	PETRA:Threatened preterm labour - risk and care management v.1	3	11/07/2016	36
14/LO/2136/AM01	Cortical Visual Impairment in the absence of ON pathway signals	1	12/04/2016	28
14/LO/2172/AM06	Liver Immunosuppression Free Trial ("LIFT"), version 1	3	05/05/2016	35
14/LO/2172/AM08	Liver Immunosuppression Free Trial ("LIFT"), version 1	4	03/02/2017	18
15/LO/0037/AM04	SSAT054: Non-genetic factors in the pathogenesis of IBD in Twins	2	20/07/2016	8
15/LO/0533/AM01	Retinal scanning for biomarker discovery in MS	1	29/06/2016	6
15/LO/0716/AM04	TOPCAT-G	3	25/08/2016	27
15/LO/0771/AM10	APTITUDE	4		14

15/LO/0800/AM01	PGE2 and immune suppression in decompensated cirrhosis	1	28/04/2016	26
15/LO/0810/AM03	MND Register for England, Wales and Northern Ireland	1	19/12/2016	28
15/LO/1105/AM08	JNJ-63935937 (imetelstat)	3	12/09/2016	8
15/LO/1105/AM09	JNJ-63935937 (imetelstat)	4	21/10/2016	21
15/LO/1235/AM01	Evaluation of a Prison Suicide Prevention Screening Tool	1	28/06/2016	33
15/LO/1261/AM09	UNIFI	5	12/10/2016	22
15/LO/1261/AM10	UNIFI	6	06/02/2017	15
15/LO/1282/AM02	Phase 1 Ramucirumab plus Pembrolizumab in different types of Cancer	2	11/02/2016	9
15/LO/1282/AM04	Phase 1 Ramucirumab plus Pembrolizumab in different types of Cancer	3	03/11/2016	34
15/LO/1282/AM05	Phase 1 Ramucirumab plus Pembrolizumab in different types of Cancer	4	13/03/2017	31
15/LO/1626/AM01	ORDIT	5.3.1	12/07/2016	10
15/LO/1689/AM01	Behavioural Activation Self-Help for Wellbeing in People with Dementia	1	26/04/2016	15
15/LO/1752/AM01	Cognitive and Clinical Profile of Prodromal Dementia with Lewy bodies	1	12/08/2016	13
15/LO/1876/AM02	APD334003_ OASIS_ Version 1	1	11/04/2016	35
15/LO/1876/AM03	APD334003_ OASIS_ Version 1	2	02/11/2016	22
15/LO/1876/AM04	APD334003_ OASIS_ Version 1	3	15/12/2016	6
15/LO/1876/AM05	APD334003_ OASIS_ Version 1	4	16/02/2017	14
15/LO/1971/AM02	MOL-PAP-002 Version 1.0	2	22/08/2016	1
15/LO/1971/AM03	MOL-PAP-002 Version 1.0	2	08/11/2016	35
16/LO/0032/AM01	Treatment decision making in West African women with breast cancer	1	15/10/2016	17
16/LO/0055/AM01	Managing nAMD with a T&E aflibercept regimen	1	29/06/2016	17
16/LO/0055/AM02	Managing nAMD with a T&E aflibercept regimen	Substantial Amendment 2 - IB	09/12/2016	12
16/LO/0125/AM01	Extension Study of APD334-003 in Patients with Ulcerative Colitis	1	11/04/2016	8
16/LO/0125/AM02	Extension Study of APD334-003 in Patients with Ulcerative Colitis	2	19/12/2016	21
16/LO/0125/AM04	Extension Study of APD334-003 in Patients with Ulcerative Colitis	3	16/02/2017	14
16/LO/0416/AM01	ARB-001467-002 Phase 2a HBeAg-Neg & Positive Subjects	1	11/05/2016	27

	With Chronic HBV			
16/LO/0416/AM05	ARB-001467-002 Phase 2a HBeAg-Neg & Positive Subjects With Chronic HBV	4	18/11/2016	8
16/LO/0416/AM07	ARB-001467-002 Phase 2a HBeAg-Neg & Positive Subjects With Chronic HBV	5	22/02/2017	20
16/LO/0803/AM01	SMILE study (CEP311)	1	26/08/2016	11
16/LO/0803/AM02	SMILE study (CEP311)	2	05/09/2016	26
16/LO/0814/AM01	Dose finding study of Sarilumab in children with pcJIA	1	14/11/2016	7
16/LO/0814/AM03	Dose finding study of Sarilumab in children with pcJIA	2	10/02/2017	10
16/LO/0815/AM01	Can a prison peer-led intervention address NCD risk factors	1	04/08/2016	10
16/LO/0836/AM01	Relvar Ellipta in Patients with COPD and Asthma	1	01/02/2017	19
16/LO/0991/AM01	Exploring the processes of change; Version 1	1	05/08/2016	28
16/LO/1205/AM02	Psychoeducational intervention for women prescribed tamoxifen	1	08/11/2016	12
16/LO/1215/AM01	STATUS trial	1	21/10/2016	33
16/LO/1247/AM01	Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JGDM)	1	20/09/2016	37
16/LO/1247/AM02	Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JGDM)	Substantial Amendment 2	07/12/2016	8
16/LO/1717/AM01	ACP-196 with Relapsed or Refractory Chronic Lymphocytic Leukemia	1	17/11/2016	5
16/LO/2275/AM01	Validation of LIBSS and biomarker identification	1	06/02/2017	24
17/LO/0023/AM01	MUK Nine b: Optimum	1	08/03/2017	19
97/1/004/AM22	PT-1 Trial	21	04/10/2016	28

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0880/AM01	Assessment of a new protocol for indirect pulp capping procedures	1	15/11/2016	35
14/LO/1696/AM04	Mentalization for Offending Adults Males (MOAM)	3	18/08/2016	28
15/LO/1105/AM10	JNJ-63935937 (imeteostat)	5	21/12/2016	34

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

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1696/AM04/1	Mentalization for Offending Adults Males (MOAM)	3	10/11/2016	12

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0880/AM01/1	Assessment of a new protocol for indirect pulp capping procedures	3	18/01/2017	14

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 21 day timeline

REC Reference	Title	Number of Days on Clock
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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/1988/AM03	PETRA:Threatened preterm labour - risk and care management v.1	3	11/07/2016	36
16/LO/1247/AM01	Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JGDM)	1	20/09/2016	37

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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