

**London - South East Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - South East Research Ethics Committee
<b>Type of REC:</b>	Recognised Type III (CTIMP)
<b>Type of Flag:</b>	Establishing Research Databases Research Involving Adults Lacking Capacity Research Involving Prisoners or Prisons
<b>Chair:</b>	Professor David Caplin 01/04/2018-01/02/2018 Ms Stephanie Cooper 02/02/2018-Present
<b>Vice-Chair:</b>	Ms Stephanie Cooper 01/03/2018-01/02/2018 Professor Anthony Fox- 02/02/2018-Present
<b>Alternate Vice-Chair:</b>	Mr Ron Driver
<b>REC Manager:</b>	Mrs Margaret Hutchinson
<b>REC Assistant:</b>	Ms Julie Acourt
<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:

David Caplin – Chair up to 31<sup>st</sup> January 2018

Having come to the end of my term as Chair of London South-East REC, I am perhaps allowed a few words of reflection. Over the dozen or more years that I have been a member of this REC, there have been substantial changes – mostly for the better – in the whole review process. Starting at the top, the formation of the Health Research Authority has enhanced the status of research within the NHS, and has helped ensure confidence in the integrity of ethical review. In general, the quality of submitted studies has improved greatly, and researchers (mostly) take the ethical and communication aspects very seriously. That has encouraged the REC to work constructively with researchers in enabling or otherwise improving their studies.

I was fortunate to inherit the Chair of this REC from an excellent mentor, Dr Alan Ruben (who sadly died a few months ago), and to have worked with a very strong Committee, but one that tolerated my style of Chairmanship. A particular thanks to the hard-working Vice Chairs: Vera Hughes, Ron Driver and Stephanie Cooper.

None of this would have been possible without the exceptionally able and patient efforts of the REC's managers in Bristol ( Raj Khullar) and then in Manchester (Maggie Hutchinson and Julie Acourt).

I am delighted that Stephanie Cooper has taken over as Chair, and that Tony Fox has become Vice-Chair in her stead, while Ron Driver has continued as Alternate Vice-Chair. My very best wishes for the future to them and the other REC members, and of course to the Manchester team too.

Stephanie Cooper's Comments - became Chair on 1<sup>st</sup> Feb

Thank you all our members for their hard work and commitment, good nature and willingness to commit to this valuable work. In addition we would not be able to function as efficiently as I think we do, if we did not have the excellent support we receive from our co-ordinators.

## London - South East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Ashok Bhiman	Consultant Psychiatrist	Expert	01/07/2007	31/10/2017
Professor David Caplin	Physicist	Lay	01/02/2007	01/02/2018
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	31/01/2008	
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	
Professor Eleni Palazidou	Consultant Psychiatrist	Expert	01/08/2014	
Ms Lois Rogers	Journalist	Lay Plus	30/08/2017	
Mr Graham Smith	Business Consultant	Lay Plus	14/01/2013	
Ms Vanda Taylor	Senior Cancer Information Nurse	Expert	14/01/2013	
Ms Brigid Tucker	Comms Consultant	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:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Professor David Caplin	None	13/12/2017
Ms Stephanie Cooper	Member of Audit & Risk Committee of Jewish Care - Social care Charity	13/12/2017
Mr Ron Driver	None	13/12/2017
Professor John Eastwood	Astrazeneca 150-160 shares	13/12/2017
Professor Anthony Fox	Managing Director and majority shareholder of: EBD London Ltd, (London, UK) and EBD Consulting Inc and FGK legal representative Service GMBH. Professor, Pharmaceutical medicine Group Inst. Pharmaceutical Sciences. Faculty of Life Sciences & medicine College London. Occasional Data Safety Monitoring Boards	13/12/2017
Mr Guy Gardener	None	13/12/2017
Ms Janelle Hill	None	14/02/2018
Professor Atholl Johnston	Director at Analytical Services International Ltd, Esprit and Seahorse Scientific. Ownership in Analytical Services International Ltd Shares in various Pharma companies. Peer reviewer William Harvey Research Institute	13/12/2017
Dr Morven Leese	Shares in Unilever	13/12/2017
Professor Eleni Palazidou	None	13/12/2017
Ms Lois Rogers	None	18/09/2017
Mr Graham Smith	None	18/12/2017
Vanda Taylor	Employed by Cancer Research UK but not involved directly in any research activities	31/03/2018
Ms Brigid Tucker	None	13/12/2017
Professor Zahur Zaman	None	13/12/2017

### Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
May	10/05/2017	10
June	14/06/2017	12
July	12/07/2017	10
September	13/09/2017	13
October	11/10/2017	11
November	08/11/2017	11
December	13/12/2017	12
January	10/01/2018	13
February	14/02/2018	10
March	14/03/2018	10

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
May	25/05/2017	3
June	22/06/2017	4
July	21/07/2017	3
September	15/09/2017	3
November	17/11/2017	3
December	15/12/2017	3
January	19/01/2018	3
February	16/02/2018	3
March	16/03/2018	3

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

### Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	01/04/2017	5
April	07/04/2017	3
April	15/04/2017	4
April	21/04/2017	2
May	01/05/2017	5
May	15/05/2017	3
June	01/06/2017	5
June	15/06/2017	5
July	01/07/2017	3
July	15/07/2017	4
August	01/08/2017	5
August	11/08/2017	3

August	15/08/2017	4
September	01/09/2017	4
September	15/09/2017	3
October	01/10/2017	5
October	15/10/2017	3
October	23/10/2017	4
November	01/11/2017	3
November	15/11/2017	4
November	23/11/2017	6
December	01/12/2017	4
December	15/12/2017	3
January	01/01/2018	3
January	15/01/2018	4
January	24/01/2018	2
February	01/02/2018	4
February	15/02/2018	3
March	01/03/2018	3
March	15/03/2018	5

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

#### Details of inquorate meeting held: 01 April 2017 - 31 March 2018

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### Attendance of Members at full committee meetings:01 April 2017 - 31 March 2018

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

### Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Ashok Bhiman	2
Professor David Caplin	5
Ms Stephanie Cooper	2
Mr Ron Driver	3
Professor Anthony Fox	2
Mr Guy Gardener	3
Ms Janelle Hill	2
Professor Atholl Johnston	2
Dr Morven Leese	1
Professor Eleni Palazidou	1
Mr Graham Smith	1
Ms Brigid Tucker	3
Professor Zahur Zaman	1

### Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Ashok Bhiman	3
Professor David Caplin	23



Ms Stephanie Cooper	10
Mr Ron Driver	9
Professor John Eastwood	5
Professor Anthony Fox	9
Mr Guy Gardener	10
Ms Janelle Hill	7
Professor Atholl Johnston	6
Dr Morven Leese	5
Professor Eleni Palazidou	4
Mr Graham Smith	6
Ms Brigid Tucker	6
Professor Zahur Zaman	7

**Training 01 April 2017 - 31 March 2018**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Professor David Caplin	03/05/2017	Chairs' Meeting
Ms Stephanie Cooper	01/06/2017	Local Training Day
Ms Stephanie Cooper	01/08/2017	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Ms Stephanie Cooper	06/11/2017	Chairs' Meeting
Ms Stephanie Cooper	24/11/2017	HRA National Chairs' Day and Policy Event
Ms Stephanie Cooper	28/02/2018	Ethical Issues in Phase One Research: An Advanced Training Course
Mr Ron Driver	14/02/2018	Self-Directed Learning -Training has included the mentoring of a new REC Member on the West London REC and a member of the Panel interviewing for new REC Members during the year. Total of 12 hours
Professor John Eastwood	15/02/2018	SDL 2017-2018 Journal Reading and Writing Academic papers
Professor Anthony Fox	01/06/2017	Local Training Day
Professor Anthony Fox	17/10/2017	Training for New REC Chairs
Professor Anthony Fox	03/03/2018	Equality, Diversity and Human Rights - General Awareness
Professor Anthony Fox	03/03/2018	Equality and Diversity
Mr Guy Gardener	01/06/2017	Local Training Day
Mr Guy Gardener	01/08/2017	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Ms Janelle Hill	12/12/2017	National Members Training Day
Ms Janelle Hill	14/02/2018	SDL 2017-2018 RNIB Forum 2 hour discussion session - It covered aspects of living with blindness and in particular demonstrated a wide range of technology options to help blind people and a lengthy discussion of various types of eye disorders which lead to blindness, including research 09/10/17 Focus counselling session in Bath, discussion about Teenage Mental Health. 1 hour
Professor Atholl Johnston	12/12/2017	National Members Training Day
Dr Morven Leese	01/06/2017	Local Training Day
Dr Morven Leese	12/12/2017	National Members Training Day
Professor Eleni Palazidou	12/12/2017	National Members Training Day
Ms Lois Rogers	11/01/2018	Committee Members Induction
Mr Graham Smith	01/06/2017	Local Training Day
Mr Graham Smith	31/03/2018	SDL- Training included the review of the slides from the National Member Training Day which the member could not attend. Total 3 hours
Ms Brigid Tucker	12/12/2017	National Members Training Day
Professor Zahur Zaman	01/08/2017	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Professor Zahur Zaman	12/12/2017	National Members Training Day
Professor Zahur Zaman	08/03/2018	Local 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	14	26.42
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	10	18.87
Others	29	54.72
<b>Total Applications Reviewed</b>	<b>53</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	4
Number of student applications reviewed	10
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
Number of prisoner applications reviewed	5
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	2

**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	11	20.75
Favourable Opinion with Additional Conditions	7	13.21
Unfavourable Opinion	3	5.66
Provisional Opinion	31	58.49
Provisional Opinion Pending Consultation with Referee	1	1.89
<b>Total</b>	<b>53</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	26	49.06
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	11	20.75
Favourable Opinion with Additional Conditions	7	13.21
Unfavourable Opinion	3	5.66
Provisional Opinion	3	5.66
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.89
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.89
<b>Total</b>	<b>53</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>21</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	4
Number of student applications reviewed	6
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	1

**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	66.67
Favourable Opinion with Additional Conditions	2	9.52
No Opinion transfer to full committee for review	1	4.76
Provisional Opinion	4	19.05
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>21</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>	5.30
<b>Number of completed applications for full ethical review</b>	52
<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 days taken to final decision – average (mean)</b>	36
<b>Number of completed proportionate review applications for ethical review</b>	20
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	2
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	10.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	14
<b>Number of completed applications for SSA review over 25 days</b>	3
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	21.43%
<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>	103
<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>	0.97%
<b>Number of modified amendments reviewed</b>	2
<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 non substantial amendments received</b>	87
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	32
<b>Number of annual progress reports received</b>	71
<b>Number of safety reports received</b>	37
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	13

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0776	Preoperative Radiotherapy And E7046 in Rectum Cancer (PRAER 1)	38
17/LO/0780	Sphingosine-1-phosphate in asthma	56
17/LO/0884	RADicAL2 V 1.0	38
17/LO/0952	Refractive CXL	40
17/LO/0971	Breaking Free from Smoking - Research Database	52
17/LO/0973	Pillars of Recovery assessment site - research database	52
17/LO/1136	KBP-042 in Type 2 Diabetes	42
17/LO/1137	Acute Transcutaneous CO2 monitoring	36
17/LO/1140	Phase II Study of Tipifarnib in non-haematological cancer and HRAS	42
17/LO/1478	SMART-C	37
17/LO/1500	AG120_C_009	30
17/LO/1516	FAM-Survey	44
17/LO/1589	Brainfit (Version 1.0)	36
17/LO/1666	WMUK Registry	30
17/LO/1716	EHVA T01(European HIV Vaccine Alliance Therapeutic Trial01)/ANRS VRI05	50
17/LO/1735	LIFT: Limb Loss In patients Following Traumatic injury	43
17/LO/1861	NEOlung	52
17/LO/1881	Experiencing Loss and Planning Ahead Study - Carer Interviews	38
17/LO/2022	Validation Of Bioarray In Stroke	52
17/LO/2081	PROFIT	34
18/LO/0046	Assertive Responding to Voices (AppRoVE)	36
18/LO/0047	ARTISAN-SNM 105-0050	31
18/LO/0058	The Role of Body Composition in Colorectal Cancer Outcomes	39
18/LO/0122	Chemo +/- MK-3475 as Perioperative Therapy for Resectable NSCLC	43
18/LO/0180	Fitness to Plead: Impact of Mental Illness in Remand Prison Population	47
18/LO/0397	MORPHEUS-TNBC	33

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**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
17/LO/0790	Sexual assault survivors and cervical smears	28
17/LO/0846	Small Area Health Statistics Unit (SAHSU)	37
17/LO/0962	Pregnancy Trial of E-cigarettes and Patches (PREP)	29
17/LO/1557	Mini-EDACS	28
17/LO/2085	Road Accident In-Depth Studies v1.0 (RAIDS) 2017 Extension	34
18/LO/0039	NEMO (EORTC 08112-LCG): Nintedanib maintenance in mesothelioma	29
18/LO/0045	Study to test safety/efficacy of CIT treatment in NSCLC patients	29
18/LO/0204	ANIMATE	29
18/LO/0285	Research database: My Quit Route triage and intervention pathway	29
18/LO/0286	Research database: Lower My Drinking triage and intervention pathway	29
18/LO/0354	Developmental Disorders Research Database Renewal	29

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/LO/0789	EVOTION v1.0	28
17/LO/0796	Family Needs in Critical Care	28
17/LO/0970	HDiP - MCAFO	29
17/LO/1156	REGARD feasibility study	28
17/LO/1539	BTS Multidrug-resistant Tuberculosis Clinical Advice Service Database	28
17/LO/1871	Integrated rehabilitation for thoracic cancer	29
17/LO/2041	CHAMPION	34

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
17/LO/1887	Psychopathology and Burden In Dementia Caregivers: CARING Study	29
17/LO/1898	PKU Lophlex Evaluation	29
18/LO/0041	The wEight management in Renal Transplant Online Study- ExeRTiOn	29



Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0053	The acute effects of serum sodium concentration on blood pressure	n/a
18/LO/0282	WAVE study - Weaning Algorithms for mechanical VEntilation	n/a
18/LO/0396	NP40126 - A Phase 1B Study Evaluating RO7082859 in Lymphoma	n/a

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
18/LO/0183	Haemostatic markers in ECMO (HAE) study	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
17/LO/1667	Hepatitis C InformOut	28

**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
17/LO/1061	Genetic variation and immune cell function	21
17/LO/2118	FCS CONNECT Study	20
18/LO/0166	IRTIVS	21
18/LO/0318	ENACTED: ENdometrial Cancer deTEction stuDy	21

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
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**Favourable Opinion with Standard Conditions**

REC Reference	Title	Number of Days on Clock
17/LO/0910	Splinting versus unrestricted early mobilisation of hand fractures	13
17/LO/1072	How can compassion be identified and enhanced in a healthcare setting?	22
17/LO/1081	Risk of neurovascular injury from fine wires in the foot and ankle	21
17/LO/1084	Does methylation of DNA mark intraepithelial neoplasia for Cancer	21
17/LO/1285	Understanding the uptake of the flu vaccine in a high-secure hospital	5
17/LO/1566	The role of the marrow microenvironment in the pathogenesis of AML	15
17/LO/1571	Observational study of patients treated with a matched unrelated donor	19
17/LO/1584	GATOR: Gait Analysis of Total Hip Replacement	15
17/LO/2005	NEAT Long Term	15
17/LO/2007	Music and hearing aids online survey v1	21
17/LO/2120	Smartphone Weber Test	10
17/LO/2123	REEACaRS version 4	22
18/LO/0161	Oesophageal cancer immunophenotyping - CRUK Accelerator	21
18/LO/0299	Support and information needs for young people at end of treatment	20

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/LO/0915	PEMAGS: Minimal access gynaecological surgery	14
17/LO/1580	Fluorescent Assay for Chronic Liver Disease Detection (FACLD-D)	16

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
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**Provisional Opinion**

REC Reference	Title	Number of Days on Clock
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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**

<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>
07/MRE01/10/AM62	SORCE-version 1.0	Substantial Amendment 41	12/07/2017	8
07/MRE01/38/AM02	Cohort study trigeminal neuralgia	1	06/02/2017	25
07/MRE01/38/AM03	Cohort study trigeminal neuralgia	Substantial Amendment 2	16/10/2017	30
08/H1102/37/AM41	Trial of Perioperative Endocrine Therapy-Individualising Care (POETIC)	10	09/02/2017	33
11/H1102/8/AM15	A multi-centre focal HIFU trial in men with localised prostate cancer	11	21/08/2017	8
11/LO/0218/AM19	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	Substantial Amendment 10	12/12/2017	9
11/LO/0218/AM20	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	11	08/02/2018	24
11/LO/1483/AM02	Connexin-43 protein expression in chronic wound-healing	Substantial Amendment 2	25/08/2017	21
11/LO/1939/AM09	Contingency management for cannabis use in early psychosis (CIRCLE)	Substantial Amendment 7	20/07/2017	13
12/LO/0510/AM02	Familial Evaluation in Sudden Infant Death Syndrome v2	Substantial Amendment 3	01/05/2017	10
12/LO/1067/AM04	Investigation of the effects of nitrite on human cardiac function	4	11/04/2017	35
12/LO/1076/AM15	Denosumab in Patients with Newly Diagnosed Multiple Myeloma	Substantial Amendment 10	09/08/2017	22
12/LO/1076/AM16	Denosumab in Patients with Newly Diagnosed Multiple Myeloma	Substantial Amendment 11	01/02/2018	31
12/LO/1808/AM11	Bridging the Age Gap in Breast Cancer	6	20/04/2017	8
12/LO/1808/AM15	Bridging the Age Gap in Breast Cancer	Substantial Amendment 7	15/12/2017	52
13/LO/1508/AM05	Immediate coronary angiography after out of hospital cardiac arrest	1	27/06/2017	32
13/LO/1508/AM06	Immediate coronary angiography after out of hospital cardiac arrest	Substantial Amendment 2	16/11/2017	28
13/LO/1857/AM03	Physiology of Schizophrenia Spectrum Disorders	Substantial	03/09/2017	12

		Amendment 3		
14/LO/0397/AM18	M12-999: Chronic HCV infection in adult liver transplant recipients	9	08/06/2017	10
14/LO/0858/AM01	Remote Postoperative Home Monitoring using tablet PC technology	Substantial Amendment 1	20/07/2017	31
14/LO/1206/AM12	PLATFORM	Substantial Amendment 14	14/06/2017	13
14/LO/1206/AM16	PLATFORM	Substantial Amendment 18	13/02/2018	30
14/LO/1240/AM04	Genes & Health (version 1)	5.5.1	28/07/2017	6
14/LO/1794/AM09	GWEP1415- Study of GWP42003-P in Dravet and Lennox-Gastaut Syndrome	6	19/04/2017	15
14/LO/1794/AM10	GWEP1415- Study of GWP42003-P in Dravet and Lennox-Gastaut Syndrome	Substantial Amendment 7	10/10/2017	6
14/LO/1988/AM06	PETRA:Threatened preterm labour - risk and care management v.1	Substantial Amendment 4	07/07/2017	22
15/LO/0238/AM02	Noninvasive and invasive characterisation of HFpEF	Substantial Amendment 2 (Documents V3)	04/10/2017	28
15/LO/0720/AM06	NREM parasomnia: natural course, triggers and influence on QoL	2	17/03/2017	11
15/LO/0771/AM13	APTITUDE	6.0	25/07/2017	16
15/LO/0824/AM01	Research to identify measures of quality and safety of healthcare	Substantial Amendment 1	06/02/2018	32
15/LO/1105/AM11	JNJ-63935937 (imetelstat)	Substantial Amendment 6	03/10/2017	20
15/LO/1261/AM11	UNIFI	Substantial Amendment 7	05/07/2017	8
15/LO/1267/AM03	Myelin changes in RRMS patients	Substantial Amendment 2	11/07/2017	10
15/LO/1268/AM03	Myelin changes in RRMS patients	Substantial Amendment 2	11/07/2017	10
15/LO/1282/AM06	Phase 1 Ramucirumab plus Pembrolizumab in different types of Cancer	5	24/04/2017	15
15/LO/1282/AM07	Phase 1 Ramucirumab plus Pembrolizumab in different types of Cancer	Substantial Amendment 6	11/07/2017	17
15/LO/1282/AM08	Phase 1 Ramucirumab plus Pembrolizumab in different types	Substantial	02/10/2017	20

	of Cancer	Amendment 7		
15/LO/1327/AM01	Registry for Patients with Niemann-Pick Type C Disease	Substantial Amendment 1	12/09/2017	21
15/LO/1564/AM04	A registry for patients with Short Bowel Syndrome	Substantial Amendment 1	12/12/2017	35
15/LO/1642/AM01	Cortical Excitability in Neurological Genetic Conditions	Substantial Amendment 1	13/12/2017	10
15/LO/1876/AM06	APD334003_ OASIS_Version 1	Substantial Amendment 5	02/06/2017	9
15/LO/1971/AM06	MOL-PAP-002 Version 1.0	Substantial Amendment 4	22/06/2017	25
15/LO/1971/AM09	MOL-PAP-002 Version 1.0	13	01/12/2017	35
16/LO/0125/AM05	Extension Study of APD334-003 in Patients with Ulcerative Colitis	Substantial Amendment 4	02/06/2017	17
16/LO/0365/AM01	Face recognition in patients at risk of deterioration: VIEWS study	1	22/06/2017	5
16/LO/0416/AM08	ARB-001467-002 Phase 2a HBeAg-Neg & Positive Subjects With Chronic HBV	Substantial Amendment 6	28/06/2017	9
16/LO/0814/AM04	Dose finding study of Sarilumab in children with pcJIA	3	27/03/2017	31
16/LO/0814/AM05	Dose finding study of Sarilumab in children with pcJIA	Substantial Amendment 4	27/04/2017	17
16/LO/0814/AM06	Dose finding study of Sarilumab in children with pcJIA	5	04/08/2017	31
16/LO/0815/AM02	Can a prison peer-led intervention address NCD risk factors	Substantial Amendment 2	09/05/2017	4
16/LO/1197/AM02	Examining Emotion Perception in Cochlear Implant Users	2	03/04/2017	35
16/LO/1215/AM02	STATUS trial	2	28/03/2017	31
16/LO/1247/AM03	Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JGDM)	Substantial Amendment 3	12/05/2017	11
16/LO/1247/AM04	Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JGDM)	Substantial Amendment 4	28/06/2017	9
16/LO/1464/AM03	FOB testing for GI malignancy in IDA	1	26/09/2017	6
16/LO/1612/AM03	Follow-up Study for Patients who Completed Study ALX0681-C301	1	04/04/2017	34
16/LO/1717/AM03	ACP-196 with Relapsed or Refractory Chronic Lymphocytic Leukemia	Substantial Amendment 2	10/08/2017	11
16/LO/1717/AM05	ACP-196 with Relapsed or Refractory Chronic Lymphocytic	Substantial	29/08/2017	35

	Leukemia	Amendment 3		
16/LO/1717/AM08	ACP-196 with Relapsed or Refractory Chronic Lymphocytic Leukemia	Substantial Amendment 5	14/12/2017	34
16/LO/1747/AM01	EMBER Study	Substantial Amendment 1	01/11/2017	14
16/LO/1765/AM02	Acute Opioid Overdose (v1.1)	Substantial Amendment 1	08/06/2017	8
16/LO/1909/AM01	HHT and wider medical issues	1	29/03/2017	34
16/LO/1960/AM03	Dose finding study of Sarilumab in children with sJIA	1	05/04/2017	30
16/LO/1960/AM04	Dose finding study of Sarilumab in children with sJIA	3	01/11/2017	12
16/LO/2042/AM01	Cognition and the deep brain	Substantial Amendment 1	26/07/2017	12
16/LO/2147/AM01	FRESH	Substantial Amendment 1	12/12/2017	6
16/LO/2173/AM02	The Response To Ajmaline Provocation in Healthy Subjects	Substantial Amendment 1	26/07/2017	34
16/LO/2173/AM03	The Response To Ajmaline Provocation in Healthy Subjects	Substantial Amendment 3	24/11/2017	35
16/LO/2174/AM03	NICE FIT	Substantial Amendment 1	18/05/2017	7
16/LO/2174/AM08	NICE FIT	Substantial Amendment 2	17/01/2018	15
16/LO/2275/AM02	Validation of LIBSS and biomarker identification	Substantial Amendment 2	17/11/2017	8
17/LO/0029/AM01	POPPIE	Substantial Amendment 1	04/07/2017	17
17/LO/0042/AM01	MIND-MAPS-PD	Substantial Amendment 1	30/06/2017	12
17/LO/0042/AM02	MIND-MAPS-PD	2.0	20/07/2017	10
17/LO/0100/AM01	CREDIBLE	Substantial Amendment 1	11/05/2017	6
17/LO/0100/AM03	CREDIBLE	Substantial Amendment 2	07/07/2017	25
17/LO/0100/AM04	CREDIBLE	Substantial Amendment 3	28/09/2017	11
17/LO/0100/AM05	CREDIBLE	Substantial	26/01/2018	6

		Amendment 4		
17/LO/0169/AM01	MD1003 in progressive multiple sclerosis	1	21/04/2017	6
17/LO/0169/AM03	MD1003 in progressive multiple sclerosis	3	08/03/2018	15
17/LO/0236/AM02	PROMINENT (K-877-302 - DIABETES STUDY)	Substantial Amendment - PICS	11/04/2017	21
17/LO/0236/AM03	PROMINENT (K-877-302 - DIABETES STUDY)	Substantial Amendment 3	10/05/2017	7
17/LO/0236/AM05	PROMINENT (K-877-302 - DIABETES STUDY)	substantial Amendment 6	08/06/2017	8
17/LO/0236/AM07	PROMINENT (K-877-302 - DIABETES STUDY)	Substantial Amendment 8	06/07/2017	19
17/LO/0236/AM08	PROMINENT (K-877-302 - DIABETES STUDY)	Substantial Amendment 9	18/07/2017	34
17/LO/0236/AM10	PROMINENT (K-877-302 - DIABETES STUDY)	Substantial Amendment 11	20/12/2017	28
17/LO/0236/AM12	PROMINENT (K-877-302 - DIABETES STUDY)	13	26/02/2018	25
17/LO/0250/AM01	Predictors of Treatment Outcome in Anorexia Nervosa	Substantial Amendment 1	22/05/2017	34
17/LO/0250/AM03	Predictors of Treatment Outcome in Anorexia Nervosa	Substantial Amendment 2	21/08/2017	34
17/LO/0253/AM01	Optical research for biopsy triaging (ORBiT)	Substantial Amendment 1	24/05/2017	12
17/LO/0380/AM03	BN29553 (CREAD-2) - Crenezumab in patients with Prodromal to Mild AD	2.0	21/07/2017	35
17/LO/0380/AM08	BN29553 (CREAD-2) - Crenezumab in patients with Prodromal to Mild AD	Substantial Amendment 4	15/01/2018	9
17/LO/0544/AM02	MECANO study V2	Substantial Amendment 2	24/01/2018	19
17/LO/0776/AM01	Preoperative Radiotherapy And E7046 in Rectum Cancer (PRAER 1)	1	01/03/2017	7
17/LO/0780/AM02	Sphingosine-1-phosphate in asthma	1	29/09/2017	9
17/LO/0789/AM02	EVOTION v1.0	Substantial Amendment 1	23/10/2017	21
17/LO/0796/AM01	Family Needs in Critical Care	Substantial Amendment 1	29/12/2017	21
17/LO/0962/AM02	Pregnancy Trial of E-cigarettes and Patches (PREP)	1	29/08/2017	8



17/LO/0962/AM04	Pregnancy Trial of E-cigarettes and Patches (PREP)	Substantial Amendment 3	08/01/2018	14
17/LO/1072/AM01	How can compassion be identified and enhanced in a healthcare setting?	Substantial Amendment 1	04/10/2017	9
17/LO/1140/AM01	Phase II Study of Tipifarnib in non-haematological cancer and HRAS	1	07/07/2017	9
17/LO/1156/AM01	REGARD feasibility study	Substantial Amendment 1	12/01/2018	5

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/LO/0029/AM02	POPPIE	2	26/10/2017	35

**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/0880/AM01/2	Assessment of a new protocol for indirect pulp capping procedures	1	28/03/2017	14
17/LO/0029/AM02/1	POPPIE	Substantial Amendment 3	17/01/2018	5

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

**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
17/LO/1072	How can compassion be identified and enhanced in a healthcare setting?	22
17/LO/2123	REEACaRS version 4	22

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

REC Reference	Title	Number of Days on Clock
17/LO/0680	PROMINENT PEMA FIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES	46
17/LO/1050	A Phase III, multicentre, randomised, double-blind, placebo-controlled, parallel-group, efficacy and safety study of Crenezumab in patients with Prodromal to mild Alzheimer's disease	40
17/LO/1239	A Double-blind, Placebo-controlled, Randomized Study to Evaluate the Efficacy and Safety of KBP-042 in Patients with Type 2 Diabetes	33

**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
12/LO/1808/AM15	Bridging the Age Gap in Breast Cancer	Substantial Amendment 7	15/12/2017	52

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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