



*Health Research Authority*

Research Ethics Service

**London - Bloomsbury Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Bloomsbury Research Ethics Committee
<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>	Reverend Jim Linthicum
<b>Vice-Chair:</b>	Dr Nabila Youssouf
<b>Alternate Vice-Chair:</b>	Vacant
<b>REC Manager:</b>	Mrs Kieran Hall from 01 April 2016 to 30 September 2016 Mr Matt Rogerson 28 February 2017 to date
<b>REC Assistant:</b>	Miss Ewa Grzegorska
<b>Committee Address:</b>	HRA RES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	0207 104 8127 or 0207 104 8002
<b>Email:</b>	nrescommittee.london-bloomsbury@nhs.net

## Chair's overview of the past year:

The Bloomsbury Research Ethics Committee has had a challenging year and, as a result, has become stronger. Challenges included having another REC manager leave, spending a large portion of the year with only one officer and decreasing membership numbers. However, throughout all this the Committee has worked hard maintaining robust ethical review with integrity and seeking to meet all of the SOPs to the best of their ability.

The good news is that, following an audit, a new manager has been put into place and new members are beginning to come into the committee. PRs, which had been withheld for a time to allow the structure to embed, will shortly be reviewed by the committee again. The committee also is beginning to work with both new and existing members to create a real sense of identity. This is best exemplified in both its working practice and a bespoke training day in which topics decided by the committee and useful to its role will be explored in both a didactic and participatory fashion.

As the REC manager is often the pivotal person within the committee, special recognition must be given to Miss Ewa Grzegorska, REC assistant, who went well beyond the line of duty to use her expertise and patience to keep the committee going during all of the difficulties and transitions. Matt Rogerson, the new REC manager has also brought a level of skill and new thinking into the committee that is already having an effect and offers great hope for the future.

While the challenges have been many, the learnings that we are taking from them point to a great deal of realized growth and more to come. The committee neither is hardly the finished item nor should become complacent, but with the members and management in place the future looks bright indeed.

## London - Bloomsbury Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Sally Doganis	Executive Producer and Media Consultant	Lay Plus	23/03/2011	
Mrs Gila Falkus	Retired Team Leader for Early Years Speech & Language Therapy	Lay	01/09/2015	
Dr Rashmi Gandhi	Neonatal registrar	Expert	24/09/2012	03/08/2016
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	Expert	12/05/2005	31/08/2016
Dr Paul Gorczynski	Chartered Psychologist	Expert	25/07/2016	
Mrs Sally Gordon Boyd	Medical Ethicist	Lay Plus	01/10/2015	
Ms Zara Grant	Clinical Trial Manager	Expert	01/03/2016	30/06/2016
Professor Richard Green	Professor of Psychiatry and Lecturer in Law (retired)	Expert	01/02/2017	
Dr Leah Li	Statistician	Lay	07/01/2013	
Dr Vincenzo Libri	Co-Investigator	Expert	24/09/2012	16/06/2016
Reverend Jim Linthicum	Hospital Chaplain	Lay Plus	30/05/2007	
Ms Cathy MacLean	Clinical Trial Manager	Expert	01/03/2017	
Ms Clare Madin	Semi-Retired Clinical Data Management Manager	Lay	01/10/2014	
Ms Michelle McPhail	Lecturer in Management Studies	Lay Plus	17/04/2013	
Miss Chika Ozongwu	Clinical Scientist	Expert	01/02/2017	
Dr Sahar Parvizi	ST5 (Specialist Trainee) Ophthalmology	Expert	01/03/2017	
Dr Reecha Sofat	Senior Clinical Lecturer - Clinical Pharmacology	Expert	01/10/2015	20/07/2016
Dr Nabila Youssouf	Research Fellow in Clinical Trials	Expert	01/12/2011	

## London - Bloomsbury Research Ethics Committee: Co-opted Members

<b>Name</b>	<b>Profession</b>	<b>Status</b>	<b>Meeting date attended</b>
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	01/06/2016 & 03/08/2016
Professor Anthony Fox	Pharmaceutical Medicine	Expert	01/06/2016 & 05/10/2016
Dr Shaun Griffin	Executive Director of External Affairs	Lay	02/11/2016
Dr Martin Keech	Clinical Project Manager	Lay	04/05/2016 & 07/12/2016
Dr Dereck Prater	Pharmacist	Expert	05/10/2016
Ms Ann Rosenthal	Literary Consultant (Retired)	Lay Plus	07/12/2016
Dr Mike Schachter	Clinical Pharmacologist	Expert	03/08/2016
Mrs Cathy Walton	Consultant Midwife	Expert	04/05/2016 & 07/12/2016

## London - Bloomsbury Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Sally Doganis	None Declared	26/07/2016
Mrs Gila Falkus	None declared	01/06/2016
Dr Rashmi Gandhi	None	01/04/2016
Dr Paul Gorczynski	I review for the Science Faculty Ethics Committee at the University of Portsmouth	05/12/2016
Mrs Sally Gordon Boyd	Small shareholdings in GSK, AstraZeneca, Reckitt Benckiser. On a Committee at the Royal Society of Medicine	04/05/2016
Professor Richard Green	None declared.	16/01/2017
Dr Leah Li	Senior Lecturer in Medical Statistics and Epidemiology. Life Course and Statistics Section . Population, Policy, and Practice Programme. UCL Institute of Child Health. Trial Oversight Committee for an NIHR PHR-funded study and a HTA study. Statistician on the MCRN/BSPED Diabetes and Endocrine Clinical Studies Group. Regular peer reviewer for NIHR Health Technology Assessment reports	01/04/2016
Reverend Jim Linthicum	None	31/03/2017
Ms Cathy MacLean	None declared.	16/02/2017
Ms Clare Madin	None declared	01/06/2016
Ms Michelle McPhail	UniLever shares, Member of Parkinsons UK, Lay reviewer for NIHR Member of 2 ethics Committees with delegated authority (ECDA) for University of Hertfordshire Member of Public Health England Research Governance Committee Ad hoc panel member for NIHR as public contributor/lay member	01/04/2016
Miss Chika Ozongwu	None declared.	01/02/2017
Dr Sahar Parvizi	None declared.	21/02/2017
Dr Nabila Youssouf	None	01/04/2016

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

Month	Date	Number of Members Present at Meeting
April	06/04/2016	8
May	04/05/2016	10
June	01/06/2016	9
August	03/08/2016	9
October	05/10/2016	9
November	02/11/2016	9
December	07/12/2016	8
February	01/02/2017	10
March	01/03/2017	11

9 full 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	08/04/2016	2
April	22/04/2016	2
May	06/05/2016	2
May	20/05/2016	4
June	03/06/2016	2
June	24/06/2016	3
July	08/07/2016	4
July	22/07/2016	2
August	05/08/2016	2
August	19/08/2016	2
September	02/09/2016	2
September	16/09/2016	2
September	30/09/2016	2
October	14/10/2016	2
October	28/10/2016	2
November	11/11/2016	2
November	21/11/2016	2
November	25/11/2016	2
December	08/12/2016	6
December	09/12/2016	2
December	23/12/2016	3
January	13/01/2017	2
January	27/01/2017	2
February	10/02/2017	2
February	24/02/2017	2
March	10/03/2017	2
March	24/03/2017	2

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

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

None

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Sally Doganis	4
Mrs Gila Falkus	7
Dr Rashmi Gandhi	1
Professor Faith Gibson	2
Dr Paul Gorczynski	5
Mrs Sally Gordon Boyd	9
Ms Zara Grant	2
Professor Richard Green	2
Dr Leah Li	3
Reverend Jim Linthicum	8
Ms Cathy MacLean	1
Ms Clare Madin	7
Ms Michelle McPhail	8
Miss Chika Ozongwu	2
Dr Sahar Parvizi	1
Dr Reecha Sofat	1
Dr Nabila Youssouf	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Sally Doganis	1
Mrs Gila Falkus	1
Dr Rashmi Gandhi	3
Professor Faith Gibson	4
Dr Paul Gorczynski	1
Mrs Sally Gordon Boyd	21
Dr Leah Li	1
Dr Vincenzo Libri	1
Reverend Jim Linthicum	17
Ms Clare Madin	1
Dr Nabila Youssouf	13



**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Ms Sally Doganis	16/11/2016	London REC Members' Training Day
Mrs Gila Falkus	16/11/2016	London REC Members Training Day
Dr Paul Gorczynski	30/11/2016	Committee Members Induction
Mrs Sally Gordon Boyd	21/04/2016	Incentives, nudges and encouragement in health promotion and public health
Mrs Sally Gordon Boyd	26/05/2016	London REC Members Training Day
Mrs Sally Gordon Boyd	10/10/2016	The empowered patient: your right to choose
Professor Richard Green	26/01/2017	Equality Diversity and Human Rights
Dr Leah Li	31/05/2016	UCL Unconscious Bias online training
Dr Leah Li	01/12/2016	UCL SLIM Introduction to Information Governance course
Reverend Jim Linthicum	23/09/2016	Ethics of Faith And Religion In End Of Life Care
Reverend Jim Linthicum	01/11/2016	Moral Argument
Ms Cathy MacLean	14/02/2017	Induction for new Research Ethics Service Committee Members
Ms Clare Madin	16/02/2017	National Members Training Day
Ms Michelle McPhail	16/11/2016	London REC Members Training Day
Ms Michelle McPhail	17/01/2017	Obesity - science, food and waistlines and Otto Wolff lecture
Dr Nabila Youssouf	01/12/2016	National Training Day for Committee Chairs

## 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	11	28.21
Phase 1	1	2.56
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	5.13
Others	25	64.10
<b>Total Applications Reviewed</b>	<b>39</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	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	11
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	6

**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	7	17.95
Favourable Opinion with Additional Conditions	9	23.08
Unfavourable Opinion	1	2.56
Provisional Opinion	21	53.85
Provisional Opinion Pending Consultation with Referee	1	2.56
<b>Total</b>	<b>39</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	15	38.46
Further Information Favourable Opinion with Additional Conditions	5	12.82
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	17.95
Favourable Opinion with Additional Conditions	9	23.08
Unfavourable Opinion	1	2.56
Provisional Opinion	1	2.56
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	2	5.13
<b>Total</b>	<b>39</b>	<b>100</b>

**Table 5: Other Management Information based on the number of completed applications for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.33
<b>Number of completed applications for full ethical review</b>	37
<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>	9
<b>Number of completed applications over 40 days as a % of total</b>	23.08%
<b>Number of days taken to final decision – average (mean)</b>	33
<b>Number of SSAs (non-Phase 1) reviewed</b>	37
<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>	1
<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>	123
<b>Number of completed substantial amendments over 35 days</b>	2
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.63%
<b>Number of completed substantial amendments over 28 days</b>	25
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	20.33%
<b>Number of modified amendments reviewed</b>	3
<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>	112
<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	29
<b>Number of annual progress reports received</b>	81
<b>Number of safety reports received</b>	54
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	30

**Table 6.1: 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>
16/LO/0507	Breast PET feasibility study	51
16/LO/0553	Esperion 1002-040 - Phase 3 Study of ETC-1002 for Hyperlipidaemia	48
16/LO/0774	Views on the relationship between voice hearing and self-harm1	39
16/LO/0852	The Experience of Unemployment in Spinal Cord Injury (Version no. 1.1)	41
16/LO/0946	A study in HV to investigate a new drug for the treatment of fibrosis	33
16/LO/1268	B-Natural	43
16/LO/1323	HD-YAS v1.0	37
16/LO/1379	STAR mapping in AF, version 2	31
16/LO/1482	GLADIATOR	35
16/LO/1891	Phase 2 Study of GS-4997 with Prednisolone vs Prednisolone alone in AH	50
16/LO/1967	The transition to secondary school for young people with burn injuries	37
16/LO/2160	Acute Day Units as Crisis Alternatives to Residential Care (AD-CARE)	28
16/LO/2187	(duplicate) SUPERB trial	35
17/LO/0331	Hazardous and Harmful alcohol consumption among HIV-positive patients	31
17/LO/0362	Exploring perceptions of barriers to mobilisation in an ICU v1	41

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0718	BAX 802 in Congenital Haemophilia A with Inhibitors	29
16/LO/1937	Observational Study: Safety factors on a surgical ward	49
16/LO/2065	NIRS in moyamoya syndrome	48
16/LO/2108	Epistemic trust in adolescents	40
17/LO/0173	Application of innovations in women with suspected endometrial cancer	44

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

16/LO/0512	Intraocular Pressure And Tolerability Study SPORT II	23
16/LO/0799	Childhood Disintegrative Disorder Surveillance Study (CDD-SS)	26
16/LO/0910	Routine autopsy data	27
16/LO/0939	Qualitative investigation into the nature of low mood in young people	26
16/LO/0941	A novel prebiotic approach for the treatment of bacterial vaginosis	26
16/LO/1341	AiM-PD	22
16/LO/1416	BabyGro Infant Feeding Trial	22

### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0724	Oral Tolvaptan extension study in children with Hyponatremia	23
16/LO/0776	Tuning the immune response in TB version 1	23
16/LO/0859	UKALL60+	22
16/LO/1447	COL MIG-302 Lasmiditan Compared to Placebo to Treat Migraine	27
16/LO/1947	Lixisenatide Arterial Stiffness Trial (LAST) Version 3.0	26
17/LO/0164	National Large Airway Registry	23
17/LO/0281	East London Sickle Cell Disease Neonatal Cohort	21
17/LO/0344	Educational Outcomes in Children Born after ART	21
17/LO/0354	Fermentable carbohydrate and gut hormone release	21

### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/1977	SUPERB trial	26

### 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/1370	ANALOGY Adalimumab Equivalency Trial in Immunology	22
16/LO/1462	Clitoral reconstruction following FGM: a pilot study	55

**Table 7.1: 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>
06/Q0508/103/AM09	Non-verbal auditory long-term recognition memory in humans	Amendment 5	01/04/2016	11
06/Q0508/53/AM08	Auditory function in an inherited speech and language disorder	Amendment 6	01/04/2016	11
10/H0713/16/AM08	The sensorimotor system in children with CP assessed by DTI	Amendment 6.0	31/03/2016	24
10/H0713/54/AM16	GeDDiS	Amendment 15	23/03/2016	23
10/H0713/88/AM14	Phase II Ponatinib in Refractory CML and Ph+ALL Version 2.0 27Oct2010	Substantial Amendment Addendum	28/06/2016	23
11/LO/0420/AM16	IELSG 32	Amendment 11	24/03/2016	22
11/LO/1313/AM09	Cetuximab with chemoradiotherapy in bladder cancer (TUXEDO)	Substantial Amendment 7	23/09/2016	27
11/LO/1718/AM31	The 2012 TYA Cancer Cohort Study	15	09/05/2016	29
11/LO/1760/AM06	IMMUNOLOGICAL AND VIROLOGICAL EVALUATION OF ME/CFS - version 1	Substantial Amendment 4	08/06/2016	16
12/LO/0494/AM03	Vandetanib Phase IV study in Metastatic Medullary Thyroid Carcinoma	SA4	14/11/2016	23
12/LO/1201/AM16	UK Haplo v1.0	UCL/10/0411-(12) - Protocol V4	20/07/2016	28
12/LO/1201/AM17	UK Haplo v1.0	UCI/10/0411 - (13)	22/11/2016	27
12/LO/1217/AM01	Early lesions of bowel cancer	Substantial Amendment 1	05/12/2016	22
12/LO/1522/AM02	Great Ormond Street Hospital Rare Dermatology Diseases Resource	1	01/06/2016	20
12/LO/1835/AM03	JointTestV1	Amendment 1.1	06/05/2016	16
13/LO/0010/AM04	Rituximab in GPA / MPA paediatric patients	SA2 - Protocol WA25615 Version 5.0	17/05/2016	27
13/LO/0010/AM05	Rituximab in GPA / MPA paediatric patients	Amendment 04	13/01/2017	28
13/LO/0168/AM01	Study of inherited metabolic diseases	Substantial	07/04/2016	16



		Amendment 1		
13/LO/0168/AM02	Study of inherited metabolic diseases	Substantial Amendment 2	20/07/2016	28
13/LO/0168/AM03	Study of inherited metabolic diseases	Amendment 3	19/08/2016	24
13/LO/0563/AM15	THE TREATCASP STUDY	Substantial Amendment 6	04/11/2016	21
13/LO/0631/AM01	Dental pulp derived stem cells to enhance cornea and nerve repair	Substantial Amendment 1	26/09/2016	26
13/LO/1272/AM16	Phase 1/2 study of nab-paclitaxel in children with solid tumours	Protocol Amendment 5	23/08/2016	17
13/LO/1272/AM17	Phase 1/2 study of nab-paclitaxel in children with solid tumours	PIS & ICF Amendment	02/02/2017	18
13/LO/1272/AM18	Phase 1/2 study of nab-paclitaxel in children with solid tumours	Substantial Amendment - IB Upd	27/02/2017	14
13/LO/1444/AM07	Safety, Effectiveness Study of RP103 in Patients with Cystinosis	Substantial Amendment 4	08/07/2016	28
13/LO/1608/AM06	Study of efficacy and safety of nilotinib in paediatric CML patients	Protocol Amendment 03	03/05/2016	35
13/LO/1798/AM09	Sotatercept (ACE-011) in Subjects with End-Stage Kidney Disease	Substantial Amendment ACE-011	03/08/2016	27
13/LO/1830/AM06	Diffusion Tensor Imaging of the myocardium	Substantial Amendment 4	06/01/2017	14
14/LO/0009/AM06	Study to investigate CSL689 in subjects with haemophilia (A or B)	Protocol Amendment 2	15/06/2016	20
14/LO/0226/AM03	Growing bladders in the laboratory	Substantial Amendment 2	31/05/2016	23
14/LO/0344/AM10	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	SA - IB	29/03/2016	28
14/LO/0344/AM11	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	GP Letter	29/06/2016	24
14/LO/0344/AM13	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	Substantial Amendment - IB v8	18/08/2016	22
14/LO/0344/AM14	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	Substantial Amendment PIS-	21/09/2016	27

		ICF		
14/LO/0378/AM06	Paediatric MS patients - Fingolomid versus interferon	Substantial Amendment 5	28/10/2016	31
14/LO/0378/AM08	Paediatric MS patients - Fingolomid versus interferon	Substantial Amendment 6	14/02/2017	28
14/LO/0664/AM03	RCT of a web-based alcohol treatment programme	Amendment 3	26/04/2016	31
14/LO/0807/AM10	TARVA: Total Ankle Replacement versus Arthrodesis Trial	Amendment 6	14/11/2016	27
14/LO/0816/AM11	Long term efficacy of Lubiprostone for paed. functional constipation	SA7	29/09/2016	31
14/LO/0863/AM01	Amniotic Fluid, Placental and Fetal Stem Cells	Amendment 1, 10th May 2016	13/05/2016	31
14/LO/1113/AM11	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 6	20/06/2016	25
14/LO/1113/AM12	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 7	05/01/2017	35
14/LO/1162/AM04	Brain Functioning in Typically-Developing and At-Risk Teens	Amendment 4	01/11/2016	23
14/LO/1509/AM04	FM systems on children with Auditory Processing Disorders	Amendment 5	23/03/2016	49
14/LO/1565/AM05	MYPAN	Substantial Amendment 5.0	23/09/2016	31
14/LO/1565/AM06	MYPAN	Substantial Amendment 6	19/12/2016	28
14/LO/1602/AM11	UCON	AM03	03/03/2016	23
14/LO/1743/AM04	90Y-antiCD66 monoclonal ab in childhood relapsed/refractory leukaemia	Substantial Amendment 1	14/12/2016	23
14/LO/1767/AM02	Using MRI tissue parameter maps to detect and delineate FCD	Amendment 1	09/01/2017	27
14/LO/1770/AM03	Exome Sequencing to Discover new causative genes for TAAD	Substantial Amendment 001	02/02/2017	25
14/LO/2150/AM03	Pfizer B1371013 - Phase 2 PF-04449913 for Myelofibrosis	Amendment 4	09/05/2016	30
15/LO/0082/AM01	Remodulin in PPHN, Version Am 2.0 30 Oct 2015	Amendment 3	29/05/2016	26
15/LO/0141/AM05	Bimatoprost SR in Open-angle Glaucoma or Ocular Hypertension	Substantial Amendment 4	05/08/2016	19
15/LO/0385/AM04	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	SA03	25/07/2016	27
15/LO/0385/AM05	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	Substantial Amendment 002	22/12/2016	24
15/LO/0495/AM05	FTC/RPV/TAF switch from FTC/RPV/TDF in HIV-1 positive	4	05/05/2016	34

15/LO/0495/AM06	FTC/RPV/TAF switch from FTC/RPV/TDF in HIV-1 positive	Substantial Amendment 5	15/08/2016	25
15/LO/0496/AM07	EFV/FTC/TDF switch to FTC/RPV/TAF in HIV-1 Patients	5	06/05/2016	33
15/LO/0496/AM08	EFV/FTC/TDF switch to FTC/RPV/TAF in HIV-1 Patients	Substantial Amendment 6	15/08/2016	25
15/LO/0523/AM11	Efficacy & safety of PT003, PT005 and PT001 in moderate to severe COPD	Substantial Amendment 7	29/12/2016	22
15/LO/0691/AM09	Nivolumab monotherapy in patients with Non-Small Cell Lung Cancer	Substantial Amendment 8	17/02/2017	31
15/LO/0718/AM11	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA07 - Protocol V3.0	31/03/2016	28
15/LO/0718/AM13	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA08 - ICF V5	29/04/2016	40
15/LO/0718/AM16	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA09	12/08/2016	18
15/LO/1022/AM03	Predictors of outcome in vein of Galen malformation	Substantial Amendment 1	03/10/2016	26
15/LO/1087/AM03	Phase 4 study of Voncento in Subjects with Von Willebrand Disease	Substantial Amendment 3	02/08/2016	30
15/LO/1382/AM02	Delivering primary health care to homeless people	Substantial Amendment 1	29/07/2016	21
15/LO/1608/AM05	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	Protocol Amendment 5	25/04/2016	17
15/LO/1632/AM01	The DESiGN Trial - Detection of small for gestational age fetus (SGA)	1	16/05/2016	30
15/LO/1637/AM02	The WATER Study	2	29/04/2016	28
15/LO/1637/AM03	The WATER Study	Substantial Amendment 3	09/09/2016	22
15/LO/1644/AM01	Exploring collateral influences in multivessel coronary artery disease	Substantial Amendment 1	26/08/2016	27
15/LO/1817/AM01	The REACT Study	Amendment 1	28/06/2016	14
15/LO/1824/AM02	Cardiac Output optimisation following Liver Transplantation (COLT) Trial	Amendment 2	17/01/2017	25
15/LO/1829/AM04	Study Reference CLS001-CO-PR-005	Substantial Amendment 3	09/09/2016	26
15/LO/1959/AM02	NI-0501 in Primary HLH	SA#2	17/01/2017	10
15/LO/1990/AM01	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	SA01	16/05/2016	30

15/LO/1990/AM05	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	Substantial Amendment 02	27/09/2016	28
15/LO/1990/AM07	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	SA03	25/11/2016	21
16/LO/0083/AM01	A Phase 3 Study of Luspatercept versus Placebo in Beta-Thalassemia	Substantial Amendment 1	25/05/2016	29
16/LO/0083/AM03	A Phase 3 Study of Luspatercept versus Placebo in Beta-Thalassemia	Substantial Amendment 3	10/10/2016	28
16/LO/0083/AM04	A Phase 3 Study of Luspatercept versus Placebo in Beta-Thalassemia	Substantial Amendment 4	30/01/2017	28
16/LO/0110/AM01	MLN0002SC-3030 Vedolizumab SC Long-Term, Open-Label, Extension Study	SA01	22/03/2016	28
16/LO/0110/AM04	MLN0002SC-3030 Vedolizumab SC Long-Term, Open-Label, Extension Study	SA04	13/12/2016	22
16/LO/0136/AM03	STARTRK-2 Open Label Phase 2 of Entrectinib in Solid Tumours	Substantial Amendment 2	13/10/2016	25
16/LO/0136/AM04	STARTRK-2 Open Label Phase 2 of Entrectinib in Solid Tumours	Substantial Amendment 3	16/11/2016	20
16/LO/0138/AM01	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	Substantial Amendment 1	28/06/2016	15
16/LO/0138/AM02	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	SA2 (protocol amendment 4)	26/08/2016	16
16/LO/0138/AM04	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	SA04	02/02/2017	18
16/LO/0173/AM01	MRI catheterization for congenital heart disease (v 1.0)	Substantial Amendment 1	02/09/2016	28
16/LO/0198/AM01	Diagnosis of CLAD using EIT	Substantial Amendment 1	13/04/2016	8
16/LO/0198/AM02	Diagnosis of CLAD using EIT	Substantial Amendment 2	14/06/2016	25
16/LO/0198/AM03	Diagnosis of CLAD using EIT	Substantial Amendment 3	05/09/2016	26
16/LO/0248/AM05	Personalising examination after death for bereaved parents	Substantial Amendment 1	09/01/2017	29
16/LO/0330/AM01	LEO 32731 - DDI Study with LEO 32731 and Midazolam in healthy males	Substantial Amendment 1	08/04/2016	7

16/LO/0361/AM01	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 1	28/04/2016	13
16/LO/0361/AM02	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 2	22/06/2016	21
16/LO/0361/AM03	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 3	25/07/2016	22
16/LO/0361/AM04	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 4	04/10/2016	24
16/LO/0361/AM05	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 5	04/11/2016	24
16/LO/0361/AM06	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 6	23/02/2017	25
16/LO/0363/AM01	In vivo investigations of familial Parkinson's disease	Substantial Amendment 1	30/06/2016	22
16/LO/0363/AM03	In vivo investigations of familial Parkinson's disease	Substantial Amendment 2.0	05/10/2016	24
16/LO/0553/AM01	Esperion 1002-040 - Phase 3 Study of ETC-1002 for Hyperlipidaemia	Substantial Amendment 1002-040	31/08/2016	23
16/LO/0553/AM03	Esperion 1002-040 - Phase 3 Study of ETC-1002 for Hyperlipidaemia	Amendment 4	17/11/2016	21
16/LO/0553/AM05	Esperion 1002-040 - Phase 3 Study of ETC-1002 for Hyperlipidaemia	Substantial Amendment-Update	19/01/2017	25
16/LO/0724/AM01	Oral Tolvaptan extension study in children with Hyponatremia	Updated PIS-ICF Docs & Patient	29/09/2016	28
16/LO/0776/AM02	Tuning the immune response in TB version 1	1	29/11/2016	32
16/LO/0859/AM01	UKALL60+	5 Protocol V4.1	11/07/2016	23
16/LO/0946/AM03	A study in HV to investigate a new drug for the treatment of fibrosis	1	28/07/2016	20
16/LO/0946/AM04	A study in HV to investigate a new drug for the treatment of fibrosis	Substantial Amendment 2	30/08/2016	16
16/LO/0946/AM05	A study in HV to investigate a new drug for the treatment of fibrosis	Substantial Amendment 3	06/12/2016	27
16/LO/1323/AM01	HD-YAS v1.0	Substantial Amendment -	01/02/2017	31

		Version 2.0 (01/02/17)		
16/LO/1447/AM01	COL MIG-302 Lasmiditan Compared to Placebo to Treat Migraine	1	17/08/2016	28
16/LO/1447/AM03	COL MIG-302 Lasmiditan Compared to Placebo to Treat Migraine	Substantial Amendment 3	07/02/2017	24
16/LO/1447/AM05	COL MIG-302 Lasmiditan Compared to Placebo to Treat Migraine	Substantial Amendment 5	13/03/2017	29
16/LO/1482/AM03	GLADIATOR	Substantial Amendment 2	07/02/2017	24
16/LO/1891/AM01	Phase 2 Study of GS-4997 with Prednisolone vs Prednisolone alone in AH	SA#1	24/01/2017	27
16/LO/1891/AM03	Phase 2 Study of GS-4997 with Prednisolone vs Prednisolone alone in AH	Substantial Amendment #3	08/02/2017	23
95RU04/AM02	Understanding Immune Cell Responses in Juvenile Idiopathic Arthritis	3	04/05/2016	30

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/1822/AM03	PANTHER	5	16/05/2016	29
15/LO/1959/AM01	NI-0501 in Primary HLH	1	10/05/2016	29

**Table 7.2: 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
12/LO/1822/AM03/1	PANTHER	5.0 Modified	04/07/2016	9
14/LO/1113/AM08/2	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 5	04/03/2016	3
15/LO/1959/AM01/1	NI-0501 in Primary HLH	1	10/05/2016	12

**Unfavourable opinion timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------

**Table 8: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

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

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1509/AM04	FM systems on children with Auditory Processing Disorders	Amendment 5	23/03/2016	49
15/LO/0718/AM13	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA08 - ICF V5	29/04/2016	40

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------