NHS
Health Research Authority

Research Ethics Service

London - Bloomsbury Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	London - Bloomsbury Research Ethics Committee
Type of REC:	Recognised, Type I and Type III
Type of Flag:	Phase 1 studies in healthy volunteers Research involving children
Chair:	Reverend Jim Linthicum
Vice-Chair:	Dr Paul Gorczynski
Alternate Vice-Chair:	Mrs Sally Gordon Boyd
REC Manager:	Mr Matt Rogerson from 01/04/2017 to 30/11/2017 Miss Ewa Grzegorska from 01/12/2017 to date
REC Assistant:	Miss Ewa Grzegorska from 01/04/2017 to 30/11/2017 Miss Dami Odunlami from 01/12/2017 to date
Committee Address:	HRA RES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

After some challenging years with several changes to administrators and fluctuating numbers of members, the Committee has become much more stable. The administration throughout the changes has been excellent, however, the current team has been exceptional and has worked hard to maintain the viability, credibility and ethical integrity of the committee. Numbers continue to fluctuate to an extent in terms of membership. Here again stability is being realized and additional team members who have been appointed have abilities far in excess of just 'making up numbers.' As the numbers indicate, more work needs to be done in terms of gaining equity of attendance at Proportionate Review and Subcommittees. This is in hand.

In terms of submissions, the Committee has shown both diligence and support to the researchers in equal measure. The Committee continues to issue a high number of Favourable and positive Provisional Opinions. These have not been obtained, however, easily or without appropriate scrutiny. Increased training requests and uptake has broadened the scope of applications reviewed, particularly with the return of CTIMPs and Proportionate Reviews.

On the whole, the year has been positive and growth filled. Again a debt of gratitude to the administrative team. It now looks like the Committee has been placed to go from strength to strength.

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	11/01/2018
Ms Kalvinder Gahir	Practice Support Pharmacist	Expert	01/09/2017	
Dr Paul Gorczynski	Chartered Psychologist	Expert	25/07/2016	
Mrs Sally Gordon Boyd	Medical Ethicist	Lay Plus	01/10/2015	
Professor Richard Green	Professor of Psychiatry and Lecturer in Law (retired)	Expert	01/02/2017	
Dr Leah Li	Statistician	Lay Plus	07/01/2013	07/01/2018
Reverend Jim Linthicum	Hospital Chaplain	Lay Plus	30/05/2007	
Ms Cathy MacLean	Clinical Project Manager	Expert	01/03/2017	
Ms Clare Madin	Semi-Retired Clinical Data Management Manager	Lay	01/10/2014	
Ms Michelle McPhail	Senior Lecturer in Management Studies	Lay Plus	17/04/2013	
Dr Katie Elizabeth Myers Smith	Health Psychologist	Expert	11/06/2013	01/04/2017
Miss Chika Ozongwu	Clinical Scientist	Expert	01/02/2017	
Dr Sahar Parvizi	ST5 (Specialist Trainee) Ophthalmology	Expert	01/03/2017	29/08/2017
Mr Nabeel Uddin	Biosample Operations Analyst	Expert	01/04/2017	06/03/2018
Dr Ruth Williams	Consultant Paediatric Neurologist	Expert	01/04/2017	
Dr Nabila Youssouf	Research Fellow in Clinical Trials	Expert	01/12/2011	05/09/2017

London - Bloomsbury Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	02/08/2017
Dr Margaret Jones	Retired General Practitioner	Expert	07/02/2018
Ms Sharon Levy	Solicitor (Non-practicing)	Lay Plus	07/02/2018
Dr Imogen Savage	Pharmacist (retired)	Expert	07/02/2018
Miss Monica Jefford	Retired Midwife	Expert	14/06/2018 PRS meeting

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

Name	Declaration of Interest	Date
Ms Sally Doganis	None.	31/03/2018
Mrs Gila Falkus	None	17/09/2017
Ms Kalvinder Gahir	Clinical Pharmacist for Sussex Community Foundation Trust. Visiting Research Fellow University of Surrey. Peer review of medical articles at University of Surrey.	01/11/2017
Dr Paul Gorczynski	Science Faculty Ethics Committee - University of Portsmouth. Bent Bars - Volunteer. Age UK, Open Doors - Volunteer	28/02/2018
Mrs Sally Gordon Boyd	Fellow of the Royal Society of Medicine.	18/09/2017
Professor Richard Green	None	01/03/2018
Reverend Jim Linthicum	Deputy Director of Great Ormond St Hospital Clinical Ethics Service	07/03/2018
Ms Cathy MacLean	None	28/02/2018
Ms Clare Madin	Ethics & Governance Committee Public Health England	31/03/2018
Ms Michelle McPhail	20 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	04/05/2017
Miss Chika Ozongwu	Contracted employment with GlaxoSmithKline since July 2017.	31/03/2018
Dr Ruth Williams	The Evelina London Children's Hospital Dietry Epilepsy Service has been supported financially in the past by The Daisy Garland, and we also enjoy good working relationships with Mathew's Friends, Nutricia Metabolics and Vitaflo.I was medical advisor to the Batten Disease Family Association from its inception until 2012, when I stepped down in order to work with BioMarin Pharmaceutical Inc. in the preparatory stages of a Phase I/II clinical trial. I was the UK Principle Investigator for this trial between November 2013 and November 2014.I have attended epilepsy congresses and educational meetings partially sponosored by Pharmaceutical companies (Cyberonics, Eisai, Janssen-Cilag, UCB Pharma Ltd and bioMarin Pharmaceuticals. Inc.)I very rarely see Commercial Representatives.	30/10/2017

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

Month	Date	Number of Members Present at Meeting
April	05/04/2017	12
May	03/05/2017	10
June	07/06/2017	9
August	02/08/2017	9
September	06/09/2017	11
November	01/11/2017	10
December	06/12/2017	10
February	07/02/2018	8
March	07/03/2018	6
March	14/03/2018	8

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
June	14/06/2017	3
September	13/09/2017	3
October	11/10/2017	3
November	08/11/2017	3
December	13/12/2017	3
January	10/01/2018	3
February	14/02/2018	3
March	15/03/2018	3

8 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	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	3
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	28/07/2017	2
August	11/08/2017	2
August	25/08/2017	2
September	08/09/2017	2
September	22/09/2017	2

October	06/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	15/12/2017	2
December	29/12/2017	2
January	09/01/2018	8
January	12/01/2018	2
January	16/01/2018	4
January	26/01/2018	2
February	09/02/2018	2
February	23/02/2018	2
February	28/02/2018	4
March	09/03/2018	2
March	23/03/2018	2

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

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

Date	Reason	Action taken
07/03/2018	Due to extreme weather conditions, a number of members gave last minute apologies.	REC Meeting was re-convened to be held via telephone conference on 14 March 2018

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

Name	Number of Meetings Attended
Ms Sally Doganis	6
Mrs Gila Falkus	6
Ms Kalvinder Gahir	4
Dr Paul Gorczynski	6
Mrs Sally Gordon Boyd	10
Professor Richard Green	9
Dr Leah Li	4
Reverend Jim Linthicum	9
Ms Cathy MacLean	5
Ms Clare Madin	6
Ms Michelle McPhail	7
Miss Chika Ozongwu	5
Mr Nabeel Uddin	2
Dr Ruth Williams	8
Dr Nabila Youssouf	2

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

Name	Number of Meetings Attended
Ms Sally Doganis	1
Dr Paul Gorczynski	2
Mrs Sally Gordon Boyd	5
Dr Leah Li	1
Reverend Jim Linthicum	5
Ms Cathy MacLean	2
Ms Michelle McPhail	2
Miss Chika Ozongwu	1
Mr Nabeel Uddin	1
Dr Ruth Williams	3

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

Name	Number of Meetings Attended
Ms Sally Doganis	3
Ms Kalvinder Gahir	2
Dr Paul Gorczynski	6
Mrs Sally Gordon Boyd	18
Professor Richard Green	1

Dr Leah Li	1
Reverend Jim Linthicum	15
Ms Cathy MacLean	7
Ms Clare Madin	3
Ms Michelle McPhail	1
Miss Chika Ozongwu	1
Dr Ruth Williams	5
Dr Nabila Youssouf	6

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Ms Sally Doganis	12/06/2017	Equality Diversity and Human Rights
Ms Sally Doganis	07/02/2018	Introduction to Phase 1 Research - Trials & Regulation
Mrs Gila Falkus	05/04/2017	HRA PPI Workshop
Dr Paul Gorczynski	05/04/2017	HRA PPI Workshop
Mrs Sally Gordon Boyd	05/04/2017	HRA PPI Workshop
Mrs Sally Gordon Boyd	07/12/2017	2017 Recent advances in medicine and surgery
Professor Richard Green	02/05/2017	Committee Members Induction
Dr Leah Li	02/05/2017	UCL Staff Online Diversity Training
Reverend Jim Linthicum	05/04/2017	HRA Patient & Public Involvement Workshop
Ms Cathy MacLean	05/04/2017	HRA PPI Workshop
Ms Cathy MacLean	15/06/2017	Equality Diversity and Human Rights
Ms Cathy MacLean	25/07/2017	Committee Members Induction
Ms Cathy MacLean	23/11/2017	Ethical Issues in Phase One Research : An Advanced Training Course
Ms Clare Madin	05/04/2017	HRA PPI Workshop
Ms Michelle McPhail	05/04/2017	HRA PPI Workshop
Ms Michelle McPhail	11/10/2017	Equality & Diversity
Ms Michelle McPhail	07/02/2018	Introduction to Phase 1 Research - Trials & Regulation
Miss Chika Ozongwu	05/04/2017	HRA PPI Workshop
Miss Chika Ozongwu	14/06/2017	Equality Diversity and Human Rights
Dr Ruth Williams	05/04/2017	HRA PPI Workshop
Dr Ruth Williams	21/04/2017	Equality Diversity and Human Rights
Dr Ruth Williams	24/04/2017	Induction for new Research Ethics Service Committee Members
Dr Ruth Williams	05/10/2017	Introduction to Phase 1 Research - Trials & Regulation
Dr Ruth Williams	16/11/2017	Committee Members Induction
Dr Ruth Williams	12/12/2017	National Members Training Day
Dr Ruth Williams	18/01/2018	Quantitative Research Methods and Statistics:
Dr Ruth Williams	13/03/2018	Human Tissue Act & Consent Training

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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.55
Research Database (including renewals)	1	2.27
Others	41	93.18
Total Applications Reviewed	**44**	**100**

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	14
Number of device applications reviewed	7
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	0

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	1	2.27
Favourable Opinion with Additional Conditions	20	45.45
Unfavourable Opinion	0	0.00
Provisional Opinion	22	50.00
Provisional Opinion Pending Consultation with Referee	1	2.27
Total	**44**	**100**
Number of studies sent back to full committee meeting for final opinion	5	

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	20	45.45
Further Information Favourable Opinion with Additional Conditions	2	4.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.27
Favourable Opinion with Additional Conditions	20	45.45
Unfavourable Opinion	1	2.27
Provisional Opinion	0	0.00
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	0	0.00
Total	**44**	**100**

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

Total Applications Reviewed	**15**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	3
Number of paediatric applications reviewed	2
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**

Decisions taken at proportionate review sub-committee meetings	**Number**	**%**
Favourable Opinion with Standard Conditions	6	40.00
Favourable Opinion with Additional Conditions	4	26.67
No Opinion transfer to full committee for review	1	6.67
Provisional Opinion	4	26.67
Unfavourable Opinion	0	0.00
Total	**15**	**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	4.40
Number of completed applications for full ethical review	44
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 days taken to final decision – average (mean)	34

Number of completed proportionate review applications for ethical review	14
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%

Number of SSAs (non-Phase 1) reviewed	7
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	111
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.80%

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	66
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	21
Number of annual progress reports received	62
Number of safety reports received	53
Number of Serious Adverse Events received	3
Number of final reports received	20

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**
17/LO/0563	Prospective study in patients with pulmonary vascular disease	32
17/LO/0746	Pre-surgery dietetic services in resectable pancreatic cancer - V1	30
17/LO/0948	FABULAS	38
17/LO/0955	RCT: Makoplasty vs Navigated Oxford Unicondylar Knee Arthroplasty	51
17/LO/1266	PHAGO-PET	27
17/LO/1268	Retrospective Study of Burden of Disease stage 3 Adjuvant Melanoma	40
17/LO/1297	Tourette Syndrome GOSH	23
17/LO/1328	Exploring loss of interest and pleasure in depressed adolescents	40
17/LO/1402	Deep phenotyping of childhood paroxysmal events	44
17/LO/1415	Computer analysis of fetal and infant movements (CAFIM) Version 001	44
17/LO/1428	Imaging analysis following periodontal surgery	40
17/LO/1628	Biomarker and cohort study of localised scleroderma in childhood	50
17/LO/1783	(duplicate) GOSH Rare Dermatology Diseases Resource	54
17/LO/1842	Hydrogen sulphide production in children and neonates	55
17/LO/1990	PULSE trial	40
17/LO/2076	Comparing Patient Preferences for AT for Acute/Chronic MI Patients	36
18/LO/0159	Vascular Injury and repair in children with chronic infection	40
18/LO/0192	Personality trait tendencies in impaired hypoglycaemia awareness	34
18/LO/0399	METACIR: METAbolic Control of the Immune Response	53
18/LO/0429	Quality of life, weight, and symptom burden in atrial fibrillation	56

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1298	Couples' illness representations in Fibromyalgia Syndrome	32
17/LO/1883	REALITY LHON Registry, v1.0	60

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**
17/LO/0742	Pre-oxygenation methods in bariatric patients	21

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0565	Pulmonary Hypertension Biobank at Imperial College	18
17/LO/0568	Motivating Structured walking Activity in Intermittent Claudication	19
17/LO/0745	An Oncology Pedometer Based Home Exercise Program. V1.0	21
17/LO/0769	Structured education group versus audio-visual information in IBS	21
17/LO/0775	Using EFT to work with the anorexic voice	21
17/LO/0939	Patient Empowerment Through Predictive Personalised Decision Support	21
17/LO/1246	SCOPE 1 Trial	21
17/LO/1423	ctDNA and Cartilaginous tumours	19
17/LO/1778	Non-intervention evaluation of digital technologies	23
17/LO/2049	Metabolic and Microbiome Profiling in Paediatric IBD	32
17/LO/2055	Social Skills in Autistic Teenagers version 1	27
17/LO/2083	LINDA-CKD	27
18/LO/0150	Interstim Amplitude study	27
18/LO/0177	Monitored Home Exercise Intervention before Urological Surgery	27
18/LO/0178	Severe Paediatric Asthma Collaborative in Europe	27
18/LO/0184	RCT comparing two approaches for managing protruding upper front teeth	27
18/LO/0388	DIALOG+ for Diabetes	26
18/LO/0389	LITE Study – Light Emitting Diode in Endoscopic Tissue Evaluation	26
18/LO/0403	Feasibility of TRAK to support Physio in ACL rehabilitation	26
18/LO/0433	Propionate and Energy Homeostasis	26

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/2087	Adjunctive sub-Tenon’s block to general anaesthesia in VR surgery V1	48

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**

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/1074	The Visual Effect of Glistenings on Vision (VEGoV) Study	20
18/LO/0271	You and Your Baby: A National Survey of Health and Care	17
18/LO/0277	The effects of collagen cross linking on aging fracture risks	19
18/LO/0459	Patient journey following lumbar discectomy surgery.	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**

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1745	Organisational integration and implementing new care models - V1.0	19

17/LO/1752	PAFR in Health and Disease	18
17/LO/1937	Immunoprofile of adenomatoid tumours	21
17/LO/1941	Describing treatment patterns in Malignant Pleural Mesothelioma	14
17/LO/2111	How to measure function in PsA? A pilot study	14
18/LO/0080	Reo13 Brain – Post-Trial Sample Analysis	20

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1525	InPath	15
18/LO/0078	An augmented breath test for earlier cancer diagnosis	20
18/LO/0457	Smartphone data for PROMS following Joint Replacement?	17
18/LO/0458	Validating duplex scanning of the pedal vessels	14

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

Provisional Opinion		
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**

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**
05/Q0508/95/AM07	Factors that determine response to standard management of JIA.	Amendment 6	24/04/2017	27
07/Q0508/43/AM02	Thymus transplantation for Complete DiGeorge Syndrome	Amendment 2	15/05/2017	25
11/LO/1718/AM32	The 2012 TYA Cancer Cohort Study	16	23/08/2017	17
11/LO/1760/AM07	IMMUNOLOGICAL AND VIROLOGICAL EVALUATION OF ME/CFS - version 1	Amendment 5	13/11/2017	32
12/LO/0905/AM01	Tissue expression using proteomics	Amendment 1.1	15/09/2017	20
12/LO/1201/AM18	UK Haplo v1.0	UCL/10/0411 - (15) - Protocol 5.0	07/09/2017	25
12/LO/1822/AM07	PANTHER	Substantial Amendment 8	05/04/2017	26
12/LO/1822/AM08	PANTHER	Substantial Amendment 9	23/02/2018	26
13/LO/0004/AM03	CREATE (EORTC 90101)	UK03	29/11/2017	21
13/LO/0168/AM04	Study of inherited metabolic diseases	Substantial Amendment 4	03/04/2017	26
13/LO/0418/AM16	SILDENAFIL IN NEONATES WITH PERSISTENT PULMONARY HYPERTENSION	SA - Change of CI & PI	01/09/2017	28
13/LO/1272/AM19	Phase 1/2 study of nab-paclitaxel in children with solid tumours	SA - IB edition 20	01/03/2018	14
13/LO/1329/AM05	Influence of HDF vs HD on growth and heart disease in children - V1	Version 6	21/03/2017	28
13/LO/1444/AM08	Safety,Effectiveness Study of RP103 in Patients with Cystinosis	5	26/02/2018	17
13/LO/1600/AM12	Extension study of LUM001 in Alagille Syndrome paediatric patients.	Substantial Amendment – Updates to IB	05/05/2017	22
13/LO/1600/AM13	Extension study of LUM001 in Alagille Syndrome paediatric patients.	PA5	05/06/2017	29
13/LO/1608/AM07	Study of efficacy and safety of nilotinib in paediatric CML patients	Protocol Amendment 5	25/05/2017	13
14/LO/0009/AM08	Study to investigate CSL689 in subjects with haemophilia (A or B)	Protocol Amendment 3	28/06/2017	30

14/LO/0009/AM09	Study to investigate CSL689 in subjects with haemophilia (A or B)	Updates to the Investigator's Brochure V4.0	15/01/2018	15
14/LO/0452/AM07	Generic EORTC QL Phases I-III	Amendment 7	18/07/2017	20
14/LO/0452/AM10	Generic EORTC QL Phases I-III	Amendment 10	11/10/2017	29
14/LO/0807/AM12	TARVA: Total Ankle Replacement versus Arthrodesis Trial	7	20/03/2017	27
14/LO/1035/AM04	Extension study to investigate CSL627 in Subjects with Haemophilia A	Substantial Amendment 3	28/04/2017	19
14/LO/1035/AM05	Extension study to investigate CSL627 in Subjects with Haemophilia A	Substantial Amendment 4	07/09/2017	18
14/LO/1113/AM13	Risky Beginnings: A 3-year longitudinal study of expectant parents	Substantial Amendment 8	07/04/2017	20
14/LO/1565/AM10	MYPAN	Substantial Amendment 10	06/02/2018	12
14/LO/1602/AM14	UCON	Substantial Amendment 5	03/11/2016	29
14/LO/1602/AM20	UCON	AM08	26/02/2018	17
14/LO/1743/AM06	90Y-antiCD66 monoclonal ab in childhood relapsed/refractory leukaemia	2	13/11/2017	13
14/LO/1743/AM07	90Y-antiCD66 monoclonal ab in childhood relapsed/refractory leukaemia	SA3	22/02/2018	21
15/LO/0141/AM10	Bimatoprost SR in Open-angle Glaucoma or Ocular Hypertension	Amendment 9	22/06/2017	28
15/LO/0141/AM11	Bimatoprost SR in Open-angle Glaucoma or Ocular Hypertension	11	01/12/2017	15
15/LO/0385/AM06	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	SA005	16/06/2017	29
15/LO/0385/AM07	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	SA006 - Updates to ICF	02/11/2017	36
15/LO/0495/AM07	FTC/RPV/TAF switch from FTC/RPV/TDF in HIV-1 positive	Substantial Amendment 6	09/06/2017	26
15/LO/0496/AM09	EFV/FTC/TDF switch to FTC/RPV/TAF in HIV-1 Patients	Substantial Amendment 7	09/06/2017	26
15/LO/0523/AM12	Efficacy & safety of PT003, PT005 and PT001 in moderate to severe COPD	Substantial Amendment 08	13/06/2017	34
15/LO/0691/AM10	Nivolumab monotherapy in patients with Non-Small Cell Lung Cancer	Substantial Amendment 9	16/11/2017	32

15/LO/1382/AM07	Delivering primary health care to homeless people	Substantial Amendment 2	30/03/2017	21
15/LO/1382/AM08	Delivering primary health care to homeless people	Substantial Amendment 3	15/06/2017	29
15/LO/1608/AM07	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	Temporary Halt to Study	15/05/2017	23
15/LO/1632/AM03	The DESiGN Trial - Detection of small for gestational age fetus (SGA)	Substantial Amendment 3	19/06/2017	28
15/LO/1632/AM05	The DESiGN Trial - Detection of small for gestational age fetus (SGA)	Amendment 4	04/08/2017	34
15/LO/1632/AM06	The DESiGN Trial - Detection of small for gestational age fetus (SGA)	Amendment 5	14/11/2017	8
15/LO/1632/AM07	The DESiGN Trial - Detection of small for gestational age fetus (SGA)	Amendment 6	18/01/2018	22
15/LO/1637/AM04	The WATER Study	Amendment 4	20/04/2017	26
15/LO/1824/AM03	Cardiac Output optimisation following Liver Transplantation (COLT) Trial	Substantial Amendment 3	04/04/2017	19
15/LO/1829/AM06	Study Reference CLS001-CO-PR-005	Substantial Amendment 4	12/04/2017	25
15/LO/1838/AM01	RAVICTI and NaPBA in Patients with Urea Cycle Disorders	Amendment 7 to Protocol	16/11/2017	21
15/LO/1990/AM10	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	SA05 - Protocol Amendment 02	26/04/2017	22
15/LO/1990/AM12	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	Substantial Amendment 9	30/08/2017	12
15/LO/1990/AM13	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	Substantial Amendment 11	05/10/2017	25
15/LO/1990/AM14	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	12	12/12/2017	28
15/LO/1990/AM15	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	13	06/03/2018	29
16/LO/0083/AM05	A Phase 3 Study of Luspatercept versus Placebo in Beta-Thalassemia	Substantial Amendment - Protocol	22/06/2017	32
16/LO/0110/AM07	MLN0002SC-3030 Vedolizumab SC Long-Term, Open-Label, Extension Study	Substantial Amendment 06	22/06/2017	32
16/LO/0136/AM07	STARTRK-2 Open Label Phase 2 of Entrectinib in Solid	Substantial	16/05/2017	21

	Tumours	Amendment 5		
16/LO/0136/AM08	STARTRK-2 Open Label Phase 2 of Entrectinib in Solid Tumours	Substantial Amendment 6	06/09/2017	19
16/LO/0138/AM06	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	Substantial Amendment 5	22/03/2017	26
16/LO/0138/AM07	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	Substantial Amendment 6	21/06/2017	33
16/LO/0138/AM08	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	Substantial Amendment 7	07/07/2017	26
16/LO/0138/AM10	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	Substantial Amendment 8	21/08/2017	21
16/LO/0138/AM11	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	SA09	17/11/2017	35
16/LO/0138/AM13	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	11	27/02/2018	16
16/LO/0361/AM07	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	Substantial Amendment 7	02/10/2017	28
16/LO/0361/AM08	PEANUT ALLERGY STUDY IN CHILDREN AND ADULTS	8	06/02/2018	14
16/LO/0364/AM01	Measurement of sodium pump inhibitor in plasma	1	05/01/2018	16
16/LO/0553/AM07	Esperion 1002-040 - Phase 3 Study of ETC-1002 for Hyperlipidaemia	Protocol Amendment 5	13/06/2017	34
16/LO/0553/AM09	Esperion 1002-040 - Phase 3 Study of ETC-1002 for Hyperlipidaemia	1002-040- IB and Addendum	02/02/2018	28
16/LO/0718/AM05	BAX 802 in Congenital Haemophilia A with Inhibitors	Substantial Amendment 2	07/03/2018	35
16/LO/0724/AM02	Oral Tolvaptan extension study in children with Hyponatremia	Substantial Amendment – IB Update	22/03/2017	27
16/LO/0724/AM03	Oral Tolvaptan extension study in children with Hyponatremia	Temporary Halt to Study	15/05/2017	23
16/LO/0776/AM03	Tuning the immune response in TB version 1	2	22/02/2018	28
16/LO/0946/AM07	A study in HV to investigate a new drug for the treatment of fibrosis	Temporary Halt	08/06/2017	27
16/LO/0946/AM09	A study in HV to investigate a new drug for the treatment of fibrosis	Restart of Trial - Protocol Amendment 4.0	04/08/2017	7
16/LO/0946/AM10	A study in HV to investigate a new drug for the treatment of	Substantial	02/03/2018	13

	fibrosis	Amendment 5		
16/LO/1323/AM03	HD-YAS v1.0	Substantial Amendment June 2017	14/07/2017	17
16/LO/1323/AM04	HD-YAS v1.0	Substantial Amendment V4.0	01/08/2017	24
16/LO/1323/AM05	HD-YAS v1.0	5.0	11/01/2018	10
16/LO/1416/AM01	BabyGro Infant Feeding Trial	Amendment 1	13/06/2017	33
16/LO/1447/AM06	COL MIG-302 Lasmiditan Compared to Placebo to Treat Migraine	Substantial Amendment 6	16/05/2017	27
16/LO/1482/AM05	GLADIATOR	Substantial Amendment 4	27/04/2017	33
16/LO/1482/AM06	GLADIATOR	SA5	12/06/2017	30
16/LO/1482/AM08	GLADIATOR	Substantial Amendment 7	08/08/2017	28
16/LO/1482/AM10	GLADIATOR	SA9	06/10/2017	20
16/LO/1891/AM04	Phase 2 Study of GS-4997 with Prednisolone vs Prednisolone alone in AH	SA#4	01/09/2017	13
16/LO/1937/AM01	Observational Study: Safety factors on a surgical ward	Substantial Amendment 1	09/01/2018	35
16/LO/1947/AM03	Lixisenatide Arterial Stiffness Trial (LAST) Version 3.0	1	21/11/2017	20
16/LO/2160/AM01	Acute Day Units as Crisis Alternatives to Residential Care (AD-CARE)	Substantial Amendment 1	21/03/2017	31
16/LO/2160/AM03	Acute Day Units as Crisis Alternatives to Residential Care (AD-CARE)	Substantial Amendment 2	21/08/2017	20
16/LO/2187/AM01	(duplicate) SUPERB trial	Amendment 1	09/05/2017	20
17/LO/0354/AM01	Fermentable carbohydrate and gut hormone release	Amendment 1	12/06/2017	29
17/LO/0354/AM02	Fermentable carbohydrate and gut hormone release	Amendment 2	14/08/2017	13
17/LO/0354/AM03	Fermentable carbohydrate and gut hormone release	Amendment 3	11/10/2017	28
17/LO/0362/AM01	Exploring perceptions of barriers to mobilisation in an ICU v1	1	10/01/2018	13
17/LO/0563/AM01	Prospective study in patients with pulmonary vascular disease	Amendment 1	05/10/2017	15
17/LO/0568/AM01	Motivating Structured walking Activity in Intermittent Claudication	Amendment 1	07/08/2017	13
17/LO/0568/AM02	Motivating Structured walking Activity in Intermittent Claudication	Amendment 2	11/12/2017	31
17/LO/0568/AM03	Motivating Structured walking Activity in Intermittent	Amendment 3	08/02/2018	14

	Claudication			
17/LO/0742/AM01	Pre-oxygenation methods in bariatric patients	SA01	30/05/2017	28
17/LO/0742/AM02	Pre-oxygenation methods in bariatric patients	Amendment 2	08/10/2017	32
17/LO/0775/AM02	Using EFT to work with the anorexic voice	Substantial Amendment 1	10/10/2017	24
17/LO/0775/AM03	Using EFT to work with the anorexic voice	2	08/02/2018	20
17/LO/0939/AM01	Patient Empowerment Through Predictive Personalised Decision Support	SA 1.1	22/08/2017	13
17/LO/1266/AM03	PHAGO-PET	1	28/02/2018	19
17/LO/1298/AM01	Couples' illness representations in Fibromyalgia Syndrome	1	13/12/2017	27
17/LO/1752/AM01	PAFR in Health and Disease	Amendment 1.1	22/02/2018	25
95RU04/AM03	Understanding Immune Cell Responses in Juvenile Idiopathic Arthritis	SA Version 4	31/01/2017	32

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
15/LO/1608/AM06	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	Substantial Amendment - IB	22/03/2017	27
15/LO/1990/AM09	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	Substantial Amendment 04	04/04/2017	28
16/LO/0138/AM12	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	10	30/11/2017	49

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**
15/LO/1990/AM09/1	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy	Modification of SA04	26/05/2017	10
16/LO/0138/AM12/1	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	SA10 - Modified - Protocol 06	16/02/2018	10

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**

Proportionate review applications for ethical review over 21 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**
15/LO/0385/AM07	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	SA006 - Updates to ICF	02/11/2017	36
16/LO/0138/AM12	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	10	30/11/2017	49

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**