

**London - Fulham Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Fulham Research Ethics Committee
<b>Type of REC:</b>	Recognised
<b>Type of Flag:</b>	IRB Registered, Research Tissue Banks
<b>Chair:</b>	The Rev'd Nigel Griffin (Chair)
<b>Vice-Chair:</b>	Dr Shaun Griffin
<b>Alternate Vice-Chair:</b>	Vacant from 01/04/2017 to 31/10/2017 Dr Frank Miskelly from 01/11/2017
<b>REC Manager:</b>	Miss Anna Bannister
<b>REC Assistant:</b>	Mr Ewan Waters
<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:

It has been another enjoyable year and I am grateful to everyone on the committee. I know we enjoy the work but it is hard work and takes a lot of commitment. I am particularly pleased with what a friendly helpful group of people the committee is. We are fortunate to have members who come from a variety of disciplines. They are all committed to the objective of supporting high quality research and at the same time protecting and promoting the interests of patients and the public.

During the year, the committee has continued to review varied and interesting studies. Our committee has enjoyed meeting researchers from drug trial units as well as NHS organisations. We have become particularly aware of the need to involve patients and lay people in both the overall design and also the participant information sheets in all studies and have stressed this to our researchers. We are fortunate to have on our committee members who have a special interest in this area.

We have had to co-opt outside colleagues to be quorate for only a small number of meetings and have been able to issue opinions in a timely fashion. Once again, I am most grateful for the support which we receive from the administrative staff and in particular from our Manager, Anna Bannister, who combines practical advice with good humour, a friendly manner and excellent efficiency.

## London - Fulham Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Keith Berelowitz	Director of Operations Richmond Pharmacology	Expert	01/08/2017	
Dr Susan Brown	Retired Associate Specialist in Occupational Health	Expert	03/07/2017	01/12/2017
Dr Anthony Farrant	Lecturer in Healthcare Law and Ethics	Lay Plus	01/09/2015	
Dr Shaun Griffin	Communications Manager	Lay	01/11/2008	
The Rev'd Nigel Griffin	Parish Priest	Lay Plus	01/06/2006	
Ms Lesley Honeyfield	Research Radiographer	Expert	05/02/2015	
Dr Akil Jackson	Research Fellow	Expert	01/12/2007	
Dr Mays Jawad	Research Governance Operations Manager	Lay	01/07/2016	
Mr Greg Kyle-Langley	Private Banker	Lay Plus	01/03/2016	
Dr Monsey McLeod	Pharmacist	Expert	01/11/2015	
Dr Frank Miskelly	Physician	Expert	01/04/2005	
Mrs Elizabeth Reeves	Clinical Trials Training Executive	Lay	01/11/2015	
Mrs Gillian Sichau	Retired Occupational Therapist	Lay	01/07/2010	
Miss Onyinyechi Uwasomba	Medical Technologist	Expert	01/08/2017	
Mrs Marney Williams	Teacher	Lay Plus	11/06/2013	

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

Name	Profession	Status	Meeting date attended
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	19/06/2017, 15/01/2018
Mr Maurice Hoffman	Retired Teacher	Lay Plus	19/06/2018

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

Name	Declaration of Interest	Date
Mr Keith Berelowitz	Executive director of Richmond Pharm a CRO involved in the conduct of early clinical trials. Shareholder of Richmond Pharm	12/07/2017
Dr Susan Brown	None	03/07/2017
Dr Anthony Farrant	None	11/12/2017
Dr Shaun Griffin	None	11/12/2017
The Rev'd Nigel Griffin	None	11/12/2017
Ms Lesley Honeyfield	None	15/01/2018
Dr Akil Jackson	Senior Medical Project Manager, employed by Gilead Sciences Ltd and stocks in Gilead Sciences.	11/12/2017
Dr Mays Jawad	Work as research governance operations manager at Barts Health NHS Trust and Queen Mary University of London	15/01/2018
Mr Greg Kyle-Langley	Ownership of UK & Global tracker funds in pension which may have exposure to pharma companies but no direct holdings	11/12/2017
Dr Monsey McLeod	Current position held: Lead Pharmacist, Medication Safety and Anti-infective Research at Imperial College Healthcare NHS Trust, NIHR Imperial Patient Safety Translational Research Centre. Responsibilities include designing and conducting health services research, submitting grant applications for research funding, research capacity building, and research dissemination. Honorary positions as above at the NIHR Health Protection Research Unit at Imperial College London, and as Research Associate at University College London.	31/03/2018
Dr Frank Miskelly	None	31/03/2018
Mrs Elizabeth Reeves	QA Manager Great Ormond Street Children's Hospital	19/03/2018
Mrs Gillian Sichau	None	15/01/2018
Miss Onyinyechi Uwasomba	None	20/07/2017
Mrs Marney Williams	Reviewer and lay member for NIHR CRN and stroke association	11/12/2017

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

Month	Date	Number of Members Present at Meeting
May	15/05/2017	7
June	19/06/2017	8
July	17/07/2017	8
September	18/09/2017	10
October	16/10/2017	11
November	20/11/2017	8
December	11/12/2017	7
January	15/01/2018	9
February	19/02/2018	13
March	19/03/2018	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
April	18/04/2017	3
May	15/05/2017	3
June	19/06/2017	3
July	17/07/2017	3
September	18/09/2017	3
October	16/10/2017	3
November	20/11/2017	3
December	11/12/2017	3
January	15/01/2018	3
February	19/02/2018	3
March	19/03/2018	3

11 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	12/04/2017	2
April	26/04/2017	2
May	10/05/2017	2
May	24/05/2017	2
June	07/06/2017	2
June	21/06/2017	2
July	05/07/2017	2
July	19/07/2017	2
August	02/08/2017	2
August	23/08/2017	2

September	06/09/2017	2
September	20/09/2017	2
October	04/10/2017	2
October	18/10/2017	2
November	01/11/2017	2
November	15/11/2017	2
November	29/11/2017	2
December	13/12/2017	2
January	03/01/2018	2
January	17/01/2018	2
January	31/01/2018	2
February	14/02/2018	2
February	28/02/2018	2
March	14/03/2018	2
March	28/03/2018	2

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

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

None

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

Name	Number of Meetings Attended
Mr Keith Berelowitz	4
Dr Susan Brown	1
Dr Anthony Farrant	6
Dr Shaun Griffin	7
The Rev'd Nigel Griffin	9
Ms Lesley Honeyfield	8
Dr Akil Jackson	5
Dr Mays Jawad	5
Mr Greg Kyle-Langley	5
Dr Monsey McLeod	3
Dr Frank Miskelly	10
Mrs Elizabeth Reeves	4
Mrs Gillian Sichau	7
Miss Onyinyechi Uwasomba	6
Mrs Marney Williams	8

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

Name	Number of Meetings Attended
Dr Anthony Farrant	5
Dr Shaun Griffin	2
The Rev'd Nigel Griffin	9
Ms Lesley Honeyfield	5
Dr Akil Jackson	1
Dr Mays Jawad	1
Mr Greg Kyle-Langley	1
Dr Monsey McLeod	2
Dr Frank Miskelly	4
Mrs Elizabeth Reeves	1
Mrs Gillian Sichau	1
Mrs Marney Williams	1

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

Name	Number of Meetings Attended
Dr Anthony Farrant	2
Dr Shaun Griffin	4
The Rev'd Nigel Griffin	21



Ms Lesley Honeyfield	2
Dr Akil Jackson	3
Dr Mays Jawad	3
Mr Greg Kyle-Langley	3
Dr Monsey McLeod	3
Dr Frank Miskelly	2
Mrs Elizabeth Reeves	1
Mrs Gillian Sichau	2
Mrs Marney Williams	3

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Anthony Farrant	23/03/2018	Medical Devices
Dr Shaun Griffin	06/11/2017	Chair's Meeting
Dr Shaun Griffin	31/03/2018	SDL - Wrote briefing for parliamentarians on ethical issues in bioscience and health policy.
The Rev'd Nigel Griffin	04/06/2017	8th Colloquium of the International Association of Catholic Bioethics Healing Relationships and Transformations in Health Care
The Rev'd Nigel Griffin	24/11/2017	HRA National Chairs' Day and Policy Event
Ms Lesley Honeyfield	18/01/2018	Quantitative Research Methods and Statistics: A Health Research
Dr Mays Jawad	14/11/2017	Training - Handling Health-Related Findings in Research
Dr Mays Jawad	23/11/2017	Ethical Issues in Phase One Research: An Advanced Training Course
Mr Greg Kyle-Langley	23/01/2018	Medical Devices
Dr Monsey McLeod	31/03/2018	Medical Devices
Mrs Elizabeth Reeves	11/12/2017	ICR Ethics & GCP Forum
Mrs Elizabeth Reeves	08/03/2018	Informed Consent in Paediatric Research
Mrs Elizabeth Reeves	08/03/2018	Introduction to Good Clinical Practice eLearning (Secondary Care)
Mrs Gillian Sichau	13/11/2017	Medical Devices
Mrs Gillian Sichau	28/02/2018	Regional Training Day - North West
Miss Onyinyechi Uwasomba	02/08/2017	Equality Diversity and Human Rights
Miss Onyinyechi Uwasomba	02/08/2017	Induction for new Research Ethics Service Committee Members
Miss Onyinyechi Uwasomba	03/08/2017	Reviewing the Research Design of Clinical Trials
Miss Onyinyechi Uwasomba	11/01/2018	Training - Committee Members Induction
Mrs Marney Williams	12/09/2017	Training - Genetic and Genomic Research (previously HTA Advanced)

## 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	17	28.81
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	3	5.08
Research Database (including renewals)	1	1.69
Others	38	64.41
<b>Total Applications Reviewed</b>	<b>59</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	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	8
Number of device applications reviewed	5
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	2
Number of qualitative applications reviewed	1

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	8.47
Favourable Opinion with Additional Conditions	15	25.42
Unfavourable Opinion	6	10.17
Provisional Opinion	32	54.24
Provisional Opinion Pending Consultation with Referee	1	1.69
<b>Total</b>	<b>59</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	32	54.24
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	8.47
Favourable Opinion with Additional Conditions	15	25.42
Unfavourable Opinion	6	10.17
Provisional Opinion	1	1.69
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
<b>Total</b>	<b>59</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>22</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	4
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

**Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	8	36.36
Favourable Opinion with Additional Conditions	5	22.73
No Opinion transfer to full committee for review	1	4.55
Provisional Opinion	8	36.36
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>22</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>	5.90
<b>Number of completed applications for full ethical review</b>	59
<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>	30
<b>Number of completed proportionate review applications for ethical review</b>	21
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	3
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	14.29%
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	140
<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>	0.71%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	95
<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	30
<b>Number of annual progress reports received</b>	77
<b>Number of safety reports received</b>	58
<b>Number of Serious Adverse Events received</b>	13
<b>Number of final reports received</b>	44

**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/0792	LCZ696 vs individualized medical therapy for patients with HFpEF	36
17/LO/0794	SPIRIT H2H: Ixekizumab versus Adalimumab in Psoriatic Arthritis	50
17/LO/0806	PROGRESS	32
17/LO/0815	New Dad Study (Version - 1)	30
17/LO/0928	Effect of Abatacept on T cell autoreactivity in Type 1 Diabetes	25
17/LO/0965	Prometheus	26
17/LO/0985	EORTC 1508	24
17/LO/1147	Tralokinumab in moderate-severe AD -1326	29
17/LO/1167	CALLS - CML and ALL Low Level Mutation Study	29
17/LO/1464	The effect of multinodular goitres on the airway	32
17/LO/1468	BYLieve:alpelisib + fulvestrant or letrozole in advanced breast cancer	33
17/LO/1488	CA209-9LA Nivolumab combination in patients with NSCLC	31
17/LO/1609	LEAP Trio	31
17/LO/1660	FEASIBILITY OF IMPROVING RISK STRATIFICATION IN BRUGADA SYNDROME	33
17/LO/1682	IPATASERTIB & ATEZOLIZUMAB AS ADJUNCT THERAPY FOR BREAST CANCER STUDY	33
17/LO/1714	BI 409306 in attenuated psychosis syndrome	30
17/LO/1715	PHERGain	30
17/LO/1900	Phase 1/2 study of INCB001158 in advanced or metastatic solid tumors	27
17/LO/1975	Roberts Study	29
17/LO/2025	ROLo	30
17/LO/2059	Phase 3 Study of Pembrolizumab with/without Epcadostat in UC	29
17/LO/2086	Clean Intermittent Catheterisation: factors for successful management	36
18/LO/0012	Effect of Visipaque on kidney function in adults with CKD after EVAR	39
18/LO/0049	PREDICT VF II	39
18/LO/0065	The use of Indocyanine Green (ICG) in laparoscopic cholecystectomy	42
18/LO/0214	Immune responses to sodium minimisation in inflammatory kidney disease	30
18/LO/0270	NIRS in Vascular Surgery	43
18/LO/0283	The impact of dance for cardiac and respiratory patients	32
18/LO/0410	A study to evaluate THR-317 and Lucentis combination treatment for DMO	34
18/LO/0439	CA224-047 Nivolumab and Relatlimab in melanoma	55
18/LO/0474	Brain reorganisation in amputees 1.0	26

18/LO/0482	Theory of mind, empathy and prosocial behaviour in eating disorders	26
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#### Further Information Favourable Opinion with Additional Conditions

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

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

REC Reference	Title	Number of Days on Clock
17/LO/0655	Boston HF SCS PET Scan	25
17/LO/1569	Predicting flow to high-acuity services from 111: Data analysis plan	25
17/LO/1954	Healthy Eating & Active Lifestyles for Diabetes feasibility trial	22
17/LO/1972	RCT: Direct Superior Approach vs Posterior Approach THA	22
18/LO/0490	Retinoblastoma gene mutations and risk of secondary primary tumours	23

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0811	COPET	25
17/LO/0980	HALT - Stereotactic Body Radiotherapy for the treatment of OPD	23
17/LO/1094	(duplicate) TB Research Unit Tissue Bank	31
17/LO/1135	Studying Acute Exacerbations and Response: The COPD STARR 2 study	28
17/LO/1169	Efficacy of Ostom-i device in patients with ileostomy. A pilot study	28
17/LO/1530	UCL Infection DNA Bank	31
17/LO/1579	Secondary Cardiac Findings Evaluation – SCARFE	25
17/LO/1781	Chemsex	22
17/LO/1939	Pembrolizumab (MK-3475) plus Epacadostat vs SOC in mRCC	22
17/LO/2006	(duplicate) St John's Institute of Dermatology Research Tissue Bank	46
17/LO/2043	Development Of a haemophiLia physiotherapy intervention - Version 1	23
17/LO/2067	Calcific Potential	23
18/LO/0017	MBCT, Worry and Emotional Flexibility in Cancer - Version 1	29
18/LO/0181	Extended follow up of the TARGIT-A trial	29



18/LO/0492	Group intervention to reduce IPA by men in substance use treatment	24
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#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/1009	Feasibility of antenatal group to improve reflective functioning	23
17/LO/1052	GP training practices and quality of patient care: Ethnographic study	27
17/LO/1422	The impact of VIG Work - On The Mother's capacity for change	25
18/LO/0063	The effectiveness of Routine Antenatal Anti-D Prophylaxis. v.1.1	29
18/LO/0199	Prognostic dissonance of seriously ill HD patients	29
18/LO/0276	Immunothrombosis in neonates with Necrotizing Enterocolitis (NEC)	29

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
18/LO/0057	Body Composition manipulation in CoLorectal cancer (BiCyCLE) Database	n/a

#### Provisional Opinion Pending Consultation with Referee

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
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#### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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**Table 9.2: Breakdown of current status of all PRS 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/0636	Psoriasis and Emotions Questionnaire v1	25
17/LO/0645	D-serine as a potential biomarker for schizophrenia	18
17/LO/1033	Barriers to pre-emptive live donor kidney transplantation	19
17/LO/1798	Understanding Inspirational Experiences in Bipolar Disorder	21
17/LO/2023	Using MALDI-ToF/PCR in urine for diagnosis of tuberculosis	14
18/LO/0132	outcome of 2 TKR techniques using computer navigation.	8
18/LO/0321	The association of Candida with oral cancer.	9
18/LO/0328	Biomarkers of Functional Non-Epileptic Events: A Pilot Study	21

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

<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>
17/LO/0826	Prevention of Diabetes and Obesity in South Asians - linkage study	19
17/LO/0836	Investigating Interoception in Non-Epileptic Seizures	13
17/LO/1236	Monitoring of babies' heart rates during labour using mobile monitors	19
17/LO/1238	Activator poles use in rehabilitation following Spinal surgery	16
17/LO/1241	Gelatine in Paediatric patientS (GPS)	19
17/LO/1799	ST2 as a novel cardiovascular biomarker in renal transplant recipients	17
17/LO/2097	Arterial Stiffness and Abdominal Aortic Aneurysm Growth Rate (v.1.1)	16
17/LO/2099	Accelerating the development of infection diagnostics. Protocol v 3.4	15

<b>Favourable Opinion with Additional Conditions</b>		
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REC Reference	Title	Number of Days on Clock
17/LO/0692	Can optical flow distinguish Parkinson's patients from controls ?	19
17/LO/1594	Adult dental health 2017	19
17/LO/1794	Novel Cardiac PET-MR Acquisition and Reconstruction Techniques	15
17/LO/2095	Vision testing in amblyopia—should occlusion be worn before testing v1	22
18/LO/0127	Adapting ASyMS for colorectal cancer surgery - Part 1	28

#### 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
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#### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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**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>
08/H0711/59/AM05	NIAS – Neurological Injury associated with Aortic Stenting	3	04/12/2017	14
09/H0711/39/AM22	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	v21	14/06/2017	21
09/H0711/39/AM23	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	Revlimid IB V22	05/02/2018	17
09/H0711/90/AM45	UKALL14	Protocol 10	06/06/2017	29
09/H0711/90/AM46	UKALL14	45	10/08/2017	26
09/H0711/90/AM47	UKALL14	Protocol Amendment 11	18/10/2017	12
10/H0711/66/AM25	Blinatumomab(MT103)in patients with MRD+ B-precursor ALL	SA#16	15/08/2017	16
11/H0711/7/AM03	The acquisition of normal control human tissue for medical research	3	25/10/2017	26
11/LO/1465/AM17	MAPPING	14	31/10/2017	19
11/LO/1908/AM20	8HA01EXT Long-Term Safety and Efficacy of rFVIII Fc Haemophilia A	21	15/11/2017	30
12/LO/0560/AM04	Longitudinal study of corneal endothelium cell density in glaucoma	Amendment 4	13/03/2017	15
12/LO/1409/AM22	POPPY Pharmacokinetic and clinical observations in people over fifty	13	15/06/2017	22
13/LO/0176/AM05	ISKS study	Amendment 5, 24th March 2017	24/03/2017	20
13/LO/0671/AM07	Long-term extension study to evaluate safety and efficacy of DAC HYP	6	29/03/2017	35
13/LO/0671/AM09	Long-term extension study to evaluate safety and efficacy of DAC HYP	Investigator Brochure (IB), Version 15, 02 January 2018, Informed Consent Form, Version 6.1.0, 19 February 2018, Protocol 205MS303	21/12/2017	23

13/LO/0706/AM09	UK Multicentre Study of Children with Opsoclonus Myoclonus Syndrome v1	6	16/01/2018	28
13/LO/1277/AM31	Study of ARN-509 in Prostate Cancer	19	04/08/2017	32
13/LO/1277/AM32	Study of ARN-509 in Prostate Cancer	SA20	25/10/2017	15
13/LO/1277/AM34	Study of ARN-509 in Prostate Cancer	SA22	08/03/2018	21
13/LO/1517/AM21	Dolomites	6.0GBRv1	09/03/2017	30
13/LO/1517/AM22	Dolomites	v6.0GBRv3.0 dated 04May2017	25/05/2017	35
13/LO/1517/AM23	Dolomites	v1.0GBRv1.0	15/06/2017	17
13/LO/1517/AM24	Dolomites	SA16	16/01/2018	24
13/LO/1687/AM06	ARCADIA. Association of ncRNAs with CAD and type 2 diabetes	4	19/07/2017	23
14/LO/0108/AM09	Southall And Brent REvisited (SABRE) - SABRE V3	8	27/04/2017	21
14/LO/0108/AM10	Southall And Brent REvisited (SABRE) - SABRE V3	Amendment 9_5/6/2017	05/06/2017	22
14/LO/0108/AM11	Southall And Brent REvisited (SABRE) - SABRE V3	10	06/11/2017	23
14/LO/0108/AM12	Southall And Brent REvisited (SABRE) - SABRE V3	Amendment 11	18/12/2017	23
14/LO/0135/AM16	Radium-223 in subjects with bone predominant metastatic CRPC.	SA15 - Phone consent	06/03/2017	25
14/LO/0135/AM17	Radium-223 in subjects with bone predominant metastatic CRPC.	SA16 - IB V6.0	12/04/2017	21
14/LO/0135/AM19	Radium-223 in subjects with bone predominant metastatic CRPC.	SA17 - Increase in bone scans	24/07/2017	22
14/LO/0865/AM11	Phase 2 Study of Fostamatinib for Subjects with IgA Nephropathy	Protocol Version 5.0 / 17 Mar 2017, IB V14 Addendum, ICF V5.0, Patient Recruitment Material	17/03/2017	17
14/LO/0865/AM12	Phase 2 Study of Fostamatinib for Subjects with IgA Nephropathy	Investigator Brochure Ed. 15 and PIS-ICF	21/08/2017	24
14/LO/0871/AM07	EndoBarrier TM Gastrointestinal Liner Diabetes Trial	4	05/03/2018	30
14/LO/1023/AM02	The Impact of Age on Adaptive Immunity in Adults Infected with RSV	SA2	06/03/2018	16
14/LO/1179/AM09	A PK Study of Serelaxin in Paediatric Heart Failure Patients	SA6 Halt to	29/03/2017	26

		Recruitment		
14/LO/1230/AM10	Ketogenic diet treatment of epilepsy in infants	10	16/05/2017	22
14/LO/1230/AM12	Ketogenic diet treatment of epilepsy in infants	11	02/01/2018	15
14/LO/1318/AM04	PREDICT-VF	3	30/08/2017	27
14/LO/1318/AM05	PREDICT-VF	4	03/10/2017	25
14/LO/1318/AM07	PREDICT-VF	5.0	16/02/2018	17
14/LO/1370/AM06	MERIT-2	Updated IB V14	01/06/2017	33
14/LO/1370/AM07	MERIT-2	V15	01/10/2017	15
14/LO/1527/AM01	Predicting drug and radiation sensitivity in thoracic cancers	1	19/06/2017	15
14/LO/1837/AM08	ARPEGGIO: Laquinimod for Primary Progressive Multiple Sclerosis (PPMS)	IB Edition 13	01/06/2017	34
14/LO/1851/AM06	INTRA-DIALYTIC EXERCISE IN RENAL FAILURE	AM06 - 23.10.2017	23/10/2017	22
14/LO/2181/AM08	RIO - Rucaparib Window of Opportunity Study	AM07	22/01/2018	23
14/LO/2219/AM12	ENZARAD Trial	8	13/03/2018	29
15/LO/0032/AM08	BO28984 Alectinib versus Crizotinib in advanced NSCLC	Amendment 7 - Alectinib IB Addendum 1 to v7 and UK PIS Addendum No.1 to v5.0	03/05/2017	21
15/LO/0032/AM09	BO28984 Alectinib versus Crizotinib in advanced NSCLC	8	08/01/2018	15
15/LO/0042/AM05	Thrombotic status in patients with coronary disease	Amendment No. 3	09/06/2017	20
15/LO/0181/AM02	Compression therapy following endovenous thermal ablation	2	04/05/2017	22
15/LO/0830/AM01	Ticagrelor Flow	Amendment number 1	01/03/2017	28
15/LO/1314/AM02	GItractRS_SMART_RetroArchive	1	15/09/2017	16
15/LO/1487/AM06	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)	Protocol (d), ICD and Recruitment materials	27/03/2017	21
15/LO/1487/AM07	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)	Substantial amendment 5	29/03/2017	14
15/LO/1487/AM08	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)	PI change site 406, Patient Diary V3	16/08/2017	14
15/LO/1487/AM10	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)	ICD V6, Protocol e	08/09/2017	13
15/LO/2120/AM03	261303 BAX 855 PK-guided Dosing Adults and Adolescents	3	20/06/2017	15

15/LO/2120/AM05	261303 BAX 855 PK-guided Dosing Adults and Adolescents	4	01/11/2017	27
15/LO/2120/AM06	261303 BAX 855 PK-guided Dosing Adults and Adolescents	5	14/02/2018	22
15/LO/2121/AM12	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	SA10	07/06/2017	28
15/LO/2121/AM13	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	11	29/08/2017	29
15/LO/2171/AM01	Non-invasive Imaging of Ocular Blood Flow	1	27/11/2017	20
16/LO/0052/AM03	CARBON	Version 4.0	31/03/2017	8
16/LO/0052/AM05	CARBON	Version 5.0	20/07/2017	22
16/LO/0052/AM06	CARBON	Version 6.0	12/12/2017	30
16/LO/0448/AM04	LY2606368 in Extensive Stage Disease Small Cell Lung Cancer	3	16/05/2017	34
16/LO/0459/AM03	PENELOPE-B - Protocol D Version 9 (09-FEB-2015)	Protocol G Version 11	26/10/2017	28
16/LO/0467/AM01	Effect of Dietary salt reduction on BP in kidney transplant recipients	1	29/11/2017	37
16/LO/0639/AM02	Exhaled Breath Biomarkers in Acute Asthma: A Feasibility Study	2	29/03/2017	20
16/LO/1112/AM04	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	SA	14/03/2018	32
16/LO/1113/AM07	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	PA1/IB11/IB11 supp/ICFV2.0	14/03/2018	34
16/LO/1130/AM03	Cereal bar or oral supplementation with tablets (BOOST)	Substantial amendment 2	30/03/2017	21
16/LO/1130/AM05	Cereal bar or oral supplementation with tablets (BOOST)	3	08/09/2017	9
16/LO/1263/AM01	PREdiCt Ablation STRategy for Atrial Fibrillation (PRECAST-AF)	1	14/08/2017	12
16/LO/1297/AM03	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	3	24/05/2017	29
16/LO/1297/AM06	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	5	03/08/2017	33
16/LO/1297/AM07	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	Substantial Amendment 6 (SA6)	12/09/2017	30
16/LO/1297/AM11	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	8	15/11/2017	16

16/LO/1297/AM13	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	Substantial Amendment 7 (SA7)	13/11/2017	35
16/LO/1657/AM04	Comparing two stop smoking intervention efficacies' 1.0	Amendment number 1.0	21/04/2017	15
16/LO/1784/AM02	IMM-101 in patients with metastatic cancer or unresectable cancer	SA002	07/06/2017	29
16/LO/1799/AM02	E7080-M000-213 Anaplastic Thyroid Cancer	SA02 Enrolment Halt	16/08/2017	9
16/LO/1850/AM01	Psychiatry Research and Motherhood at 6 to 8 (PRAM-D@6to8)	1	05/05/2017	34
16/LO/1850/AM03	Psychiatry Research and Motherhood at 6 to 8 (PRAM-D@6to8)	2 23-8-17	23/08/2017	14
16/LO/1904/AM01	Feasibility of a serological assay for malaria elimination (v3.0)	3	04/10/2017	26
16/LO/2110/AM05	SUSTAIN 8 NN9535-4270	1.0	19/06/2017	24
16/LO/2165/AM03	Examination of Mentalization Ability in Eating Disorders	1	02/09/2017	32
16/LO/2165/AM06	Examination of Mentalization Ability in Eating Disorders	Amendment 2	30/10/2017	22
16/LO/2209/AM01	Usage of bio-signals to detect epileptic seizures	1	04/09/2017	14
16/LO/2210/AM02	Canine Olfactory Detection of Human Colorectal Cancer (version 1)	Amendment 1	02/11/2017	24
17/LO/0065/AM02	PDR001 with dabrafenib + trametinib in BRAF+ve advanced Melanoma	2	03/04/2017	22
17/LO/0065/AM04	PDR001 with dabrafenib + trametinib in BRAF+ve advanced Melanoma	3	28/04/2017	26
17/LO/0065/AM05	PDR001 with dabrafenib + trametinib in BRAF+ve advanced Melanoma	3	14/07/2017	14
17/LO/0295/AM01	Maudsley Tobacco Dependence Clinic Database (Maudsley Clinic Database)	1	16/06/2017	17
17/LO/0304/AM02	IXA-CSP-001 Litoxetine v Placebo in Urinary Incontinence 2016-12-09 V1	2	28/08/2017	13
17/LO/0304/AM05	IXA-CSP-001 Litoxetine v Placebo in Urinary Incontinence 2016-12-09 V1	v3.0	12/03/2018	30
17/LO/0305/AM01	Effect of apixaban on endogenous fibrinolysis in atrial fibrillation	2	15/06/2017	18
17/LO/0451/AM01	177Lu-edotreotide vs. everolimus in GEP-NET – COMPETE	1	25/07/2017	34
17/LO/0451/AM02	177Lu-edotreotide vs. everolimus in GEP-NET – COMPETE	Amendment_01	25/07/2017	24
17/LO/0465/AM01	ADJUNCTIVE GP ABLATION IN REDO-PVI STUDY (ADD-GP)	1	18/05/2017	27



17/LO/0465/AM02	ADJUNCTIVE GP ABLATION IN REDO-PVI STUDY (ADD-GP)	2	07/03/2018	28
17/LO/0511/AM01	Feraccru®Real World Effectiveness Study in Hospital Practice	1	09/05/2017	30
17/LO/0692/AM01	Can optical flow distinguish Parkinson's patients from controls ?	1	17/07/2017	16
17/LO/0692/AM02	Can optical flow distinguish Parkinson's patients from controls ?	Amendment 2	18/12/2017	28
17/LO/0792/AM04	LCZ696 vs individualized medical therapy for patients with HFpEF	SA03_Update to PICF	08/11/2017	20
17/LO/0792/AM07	LCZ696 vs individualized medical therapy for patients with HFpEF	4	15/11/2017	22
17/LO/0794/AM01	SPIRIT H2H: Ixekizumab versus Adalimumab in Psoriatic Arthritis	Protocol a & 1.1, IB 31May17,	06/07/2017	16
17/LO/0794/AM03	SPIRIT H2H: Ixekizumab versus Adalimumab in Psoriatic Arthritis	Patient Invitation Letter V1	11/09/2017	17
17/LO/0794/AM04	SPIRIT H2H: Ixekizumab versus Adalimumab in Psoriatic Arthritis	3	24/11/2017	13
17/LO/0794/AM05	SPIRIT H2H: Ixekizumab versus Adalimumab in Psoriatic Arthritis	4	12/01/2018	11
17/LO/0928/AM01	Effect of Abatacept on T cell autoreactivity in Type 1 Diabetes	1	11/10/2017	15
17/LO/0965/AM01	Prometheus	1	19/09/2017	22
17/LO/0965/AM02	Prometheus	2	04/12/2017	13
17/LO/0965/AM03	Prometheus	3	11/01/2018	22
17/LO/0980/AM03	HALT - Stereotactic Body Radiotherapy for the treatment of OPD	AM03-SA01	20/10/2017	17
17/LO/0985/AM01	EORTC 1508	1	09/08/2017	15
17/LO/1094/AM02	(duplicate) TB Research Unit Tissue Bank	AM01	06/11/2017	29
17/LO/1135/AM02	Studying Acute Exacerbations and Response: The COPD STARR 2 study	Substantial Amendment 1	23/01/2018	24
17/LO/1147/AM04	Tralokinumab in moderate-severe AD -1326	3	16/10/2017	12
17/LO/1147/AM05	Tralokinumab in moderate-severe AD -1326	4	06/12/2017	13
17/LO/1147/AM06	Tralokinumab in moderate-severe AD -1326	5	26/02/2018	29
17/LO/1236/AM01	Monitoring of babies' heart rates during labour using mobile monitors	1	01/02/2018	21
17/LO/1488/AM01	CA209-9LA Nivolumab combination in patients with NSCLC	1	27/11/2017	9
17/LO/1488/AM02	CA209-9LA Nivolumab combination in patients with NSCLC	2	14/02/2018	35
17/LO/1579/AM01	Secondary Cardiac Findings Evaluation – SCARFE	2.2	19/02/2018	23

17/LO/1609/AM01	LEAP Trio	Substantial Amendment 01	21/02/2018	15
17/LO/1660/AM02	FEASIBILITY OF IMPROVING RISK STRATIFICATION IN BRUGADA SYNDROME	1	16/02/2018	17
17/LO/1682/AM01	IPATASERTIB & ATEZOLIZUMAB AS ADJUNCT THERAPY FOR BREAST CANCER STUDY	Substantial Amendment 1	17/01/2018	28
17/LO/1714/AM01	BI 409306 in attenuated psychosis syndrome	1	20/11/2017	14
17/LO/1714/AM02	BI 409306 in attenuated psychosis syndrome	2	07/03/2018	29
17/LO/1900/AM01	Phase 1/2 study of INCB001158 in advanced or metastatic solid tumors	1.0	09/03/2018	20
17/LO/1939/AM01	Pembrolizumab (MK-3475) plus Epacadostat vs SOC in mRCC	SA01 - Protocol 01 + GP Letter	11/12/2017	33
17/LO/1939/AM02	Pembrolizumab (MK-3475) plus Epacadostat vs SOC in mRCC	2	09/03/2018	35
17/LO/1954/AM01	Healthy Eating & Active Lifestyles for Diabetes feasibility trial	HDA01	26/02/2018	27
17/LO/1975/AM01	Roberts Study	SA 1.0	22/01/2018	24
17/LO/2043/AM01	Development Of a haemophiLia physiotherapy intervention - Version 1	Amendment 1	15/02/2018	20
17/LO/2095/AM01	Vision testing in amblyopia—should occlusion be worn before testing v1	1	25/01/2018	10
18/LO/0012/AM01	Effect of Visipaque on kidney function in adults with CKD after EVAR	REV A03	25/01/2018	28

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

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

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

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

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/0636	Psoriasis and Emotions Questionnaire v1	25
17/LO/2095	Vision testing in amblyopia—should occlusion be worn before testing v1	22
18/LO/0127	Adapting ASyMS for colorectal cancer surgery - Part 1	28

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/LO/0467/AM01	Effect of Dietary salt reduction on BP in kidney transplant recipients	1	29/11/2017	37

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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