

**London - Fulham Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## 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 (from 01/01/2016) Dr Charles Mackworth-Young (from 01/04/15 to 31/12/2015)
<b>Vice-Chair:</b>	The Rev'd Nigel Griffin (until 31/12/2015)
<b>Alternate Vice-Chair:</b>	Dr Shaun Griffin ( from 15/12/2015)
<b>REC Manager:</b>	Miss Anna Bannister
<b>REC Assistant:</b>	Miss Katie Southeard
<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:

The principal feature of this year's activity has been the departure of a number of longstanding members from the Committee. In particular, mention should be made of the outstanding service of Dr Charles Mackworth-Young who had been a founding member and chairman of the Committee for over 10 years, having previously been a member of the Riverside Committee for 10 years. He has made a major contribution to research ethics generally, as well as initiating and chairing a highly valued peer review service for Imperial College. Dr Colin Michie our paediatric consultant stepped down after a full 10 years of service. Also with 10 years' service we lost our pharmacist, Mr David Leonard and our psychiatrist Dr Shirlony Morgan left to pursue her career in Singapore. It was a pleasure to welcome back Dr Frank Miskelly, who had left us for a while because of clinical commitments. The reduced number of members and lack of specific expertise meant there were three meetings for which we co-opted an additional member. Happily there have been some new appointments which have renewed the strength of the committee. Dr Anthony Farrant a Lecturer in Healthcare Law and Ethics, Ms Monsey McLeod a Pharmacist, Mr Greg Kyle-Langley a Private Banker and Mrs Elizabeth Reeves a Clinical Trials Training Executive have brought us new skills. The Rev'd Nigel Griffin was appointed Chairman in succession to Dr Mackworth-Young, and we are now seeking a Vice-Chairman to share the load.

Miss Anna Bannister and Miss Katie Southead, were Manager and Assistant Manager providing a highly competent service, though we were sad that Miss Southead left us at the end of the year.

We have continued to receive a great variety of submissions, though we are no longer flagged for research on children as we have no paediatrician in membership.

## London - Fulham Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Anthony Farrant	Lecturer in Healthcare Law and Ethics	Lay	01/09/2015	
Dr Kanagasabai Ganeshaguru	Retired Scientist	Lay	01/06/2006	
Dr Shaun Griffin	Executive Director of External Affairs	Expert	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	01/10/2007	
Mr Greg Kyle-Langley	Private Banker	Lay Plus	01/03/2016	
Mr David Leonard	Pharmacist	Expert	28/04/2005	28/10/2015
Dr Charles Mackworth-Young	Physician	Expert	01/01/2005	31/12/2015
Ms Monsey McLeod	Pharmacist	Expert	01/11/2015	
Dr Colin Michie	Paediatrician	Expert	27/03/2006	30/11/2015
Dr Shirlony Morgan	Psychiatrist	Expert	16/11/2009	01/02/2015
Mrs Elizabeth Reeves	Clinical Trials Training Executive	Lay	01/11/2015	
Mrs Gillian Sichau	Occupational Therapist	Expert	01/07/2010	
Mrs Katie Wilkinson	Clinical Trials Centre Manager	Lay	09/11/2007	
Mrs Marney Williams	Teacher	Lay Plus	11/06/2013	
Dr Frank Miskelly	Physician	Expert	01/04/2005	On break of service from 01/10/2014 21/03/2016

## London - Fulham Research Ethics Committee: Deputy Members

None

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

Name	Profession	Status	Full Main Meeting date attended
Dr Jan Downer	Consultant Anaesthetist	Expert	20/04/2015
Ms. Nabila Youssouf	Clinical Trials Manager	Expert	20/07/2015
Dr Yash Patel	Research Project Manager	Expert	15/02/2016

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Anthony Farrant	Occasionally serve as an independent ethics expert for the European Commission horizon 2010	14/12/2015
Dr Kanagasabai Ganeshaguru	None	18/01/2016
The Rev'd Nigel Griffin	None	31/03/2016
Dr Shaun Griffin	Executive director of external affairs at Terrance Higgins trust	14/12/2015
Ms Lesley Honeyfield	None	14/12/2015
Dr Akil Jackson	Senior Medical Project Manager, Liver Diseases, employed by Gilead Sciences Ltd. UK. PhD student at University of Liverpool and honorary contract at Chelsea & Westminster NHS Foundation Trust.	19/01/2016
Mr Greg Kyle-Langley	Ownership of UK & Global tracker funds in pension which may have exposure to pharma companies but no direct holdings	01/03/2016
Ms Monsey McLeod	Lead pharmacist for medication safety and anti-infective research at imperial college healthcare NHS trust. centre for medication safety and services quality and NIHR health protection research unit for healthcare associated infection and antimicrobial resistance. The CMSSQ is affiliated with the NIHR Imperial Patient Safety Translation Research Centre. Clinical academic researcher and involved in all aspects of research activity from idea conception, planning, data collection, analysis, writing and publication.	18/01/2016
Dr Frank Miskelly	None	14/03/2016
Mrs Elizabeth Reeves	Previous (2009-2012): Regulatory Scientist for Eli Lilly & Company Ltd. Currently (2013-present): Clinical Trials Training Executive for King's Health Partners ( a collaboration between KCL and GKT, and South London and Maudsley NHS Foundation Trust)	28/10/2015
Mrs Gillian Sichau	None	14/12/2015
Mrs Marney Williams	Volunteer Reviewing research projects for funding with the stroke association. PPI Panel NIHR Imperial BRC	31/03/2016
Mrs Katie Wilkinson	Research Manager for British Paediatric Neurology Association - Charity	31/03/2016

**Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:**

Month	Date	Number of Members Present at Meeting
April	20/04/2015	7
May	18/05/2015	10
June	15/06/2015	9
July	20/07/2015	9
September	21/09/2015	9
November	16/11/2015	10
December	14/12/2015	9
January	18/01/2016	11
February	15/02/2016	8
March	21/03/2016	9

10 full committee meetings were held during the reporting period.

**Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:**

Month	Date	Number of Members Present at Meeting
April	20/04/2015	3
May	18/05/2015	3
June	15/06/2015	3
July	20/07/2015	3
September	21/09/2015	3
November	16/11/2015	3
December	14/12/2015	3
January	18/01/2016	3
March	21/03/2016	3

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

**Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:**

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	15/04/2015	2
April	29/04/2015	2
May	15/05/2015	2
May	28/05/2015	2
June	11/06/2015	2
June	24/06/2015	2
July	08/07/2015	2
July	22/07/2015	2
July	23/07/2015	2
August	05/08/2015	2
August	19/08/2015	2

September	02/09/2015	2
September	16/09/2015	2
September	30/09/2015	2
October	14/10/2015	2
October	15/10/2015	2
October	28/10/2015	2
November	18/11/2015	2
November	27/11/2015	2
December	11/12/2015	2
December	21/12/2015	2
January	11/01/2016	2
January	27/01/2016	2
February	10/02/2016	2
February	24/02/2016	2
March	09/03/2016	2

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

#### Details of inquorate meeting held: 01 April 2015 - 31 March 2016

0

**Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Anthony Farrant	6
Dr Kanagasabai Ganeshaguru	10
The Rev'd Nigel Griffin	9
Dr Shaun Griffin	8
Ms Lesley Honeyfield	9
Dr Akil Jackson	5
Mr Greg Kyle-Langley	1
Mr David Leonard	4
Dr Charles Mackworth-Young	7
Ms Monsey McLeod	3
Dr Colin Michie	3
Mrs Elizabeth Reeves	4
Mrs Gillian Sichau	8
Mrs Katie Wilkinson	3
Mrs Marney Williams	8

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Kanagasabai Ganeshaguru	3
The Rev'd Nigel Griffin	5
Dr Shaun Griffin	1
Ms Lesley Honeyfield	4
Dr Akil Jackson	1
Dr Charles Mackworth-Young	4
Mrs Gillian Sichau	5
Mrs Marney Williams	4

**Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Kanagasabai Ganeshaguru	3
The Rev'd Nigel Griffin	12
Dr Shaun Griffin	3
Ms Lesley Honeyfield	3
Dr Akil Jackson	3
Dr Charles Mackworth-Young	19
Dr Colin Michie	3



Mrs Gillian Sichau	2
Mrs Katie Wilkinson	1
Mrs Marney Williams	5

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Anthony Farrant	04/11/2015	Members Induction
Dr Kanagasabai Ganeshaguru	26/11/2015	Local Training Day
Dr Kanagasabai Ganeshaguru	27/11/2015	CTIMP Training Day
The Rev'd Nigel Griffin	09/12/2015	National Training Day for Committee Chairs
Ms Lesley Honeyfield	26/11/2015	Local Training Day - London REC Member's Training Day
Dr Charles Mackworth-Young	01/04/2015	Self-Direct Learning for 2014 - 2015
Ms Monsey McLeod	04/11/2015	Members Induction
Mrs Elizabeth Reeves	04/11/2015	Members Induction
Mrs Gillian Sichau	12/10/2015	Complex Cases
Mrs Gillian Sichau	19/11/2015	Personal Data
Mrs Gillian Sichau	26/11/2015	Local Training Day
Mrs Marney Williams	16/04/2015	Quantitative Research Methods and Statistics
Mrs Marney Williams	12/10/2015	Complex Cases
Mrs Marney Williams	27/11/2015	CTIMP Training Day

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	9	18.75
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.17
Research Database (including renewals)	0	0.00
Others	37	77.08
<b>Total Applications Reviewed</b>	<b>48</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	3
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	1
Number of qualitative applications reviewed	2

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	6.25
Favourable Opinion with Additional Conditions	6	12.50
Unfavourable Opinion	3	6.25
Provisional Opinion	36	75.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>48</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	31	64.58
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	1	2.08
Favourable Opinion with Standard Conditions	3	6.25
Favourable Opinion with Additional Conditions	6	12.50
Unfavourable Opinion	3	6.25
Provisional Opinion	4	8.33
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>48</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>15</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	12
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	1

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	6	40.00
Favourable Opinion with Additional Conditions	4	26.67
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	33.33
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>15</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>	4.80
<b>Number of completed applications for full ethical review</b>	48
<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>	3
<b>Number of completed applications over 40 days as a % of total</b>	6.25%
<b>Number of days taken to final decision – average (mean)</b>	26
<b>Number of completed proportionate review applications for ethical review</b>	15
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	6.67%
<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>	131
<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>	1.53%
<b>Number of completed substantial amendments over 28 days</b>	20
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	15.27%
<b>Number of modified amendments reviewed</b>	2
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of minor amendments received</b>	66
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	39
<b>Number of annual progress reports received</b>	126
<b>Number of safety reports received</b>	32
<b>Number of Serious Adverse Events received</b>	3

<b>Number of final reports received</b>	37
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**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>
15/LO/0556	Epidermal grafting in wound healing	24
15/LO/0566	Qutenza® for amputation stump hypersensitivity and phantom limb pain.	27
15/LO/0633	Neurofibromatosis biobank and registry	25
15/LO/0656	Cognitive Control in Cocaine Dependence: A Stage 1 Pilot Study	22
15/LO/0668	The use of the FreeBody lower limb model as a clinical tool	27
15/LO/0675	Firesetting Dangerousness: A Comparison	28
15/LO/0788	Pasireotide (SOM230) in patients with acromegaly	31
15/LO/0798	Study of MORAb-003 with chemotherapy in subjects with ovarian cancer	23
15/LO/0830	Ticagrelor Flow	24
15/LO/0998	Collection of Clinical Material in Muscle Invasive Bladder Cancer v2.0	22
15/LO/1024	Stomas in IBD	31
15/LO/1040	Enhancing self-care in the housebound V3	22
15/LO/1208	Markers of peri-ictal cardiac injury in epileptic seizures	21
15/LO/1216	DYNAMIC CHANGES ON AIRWAYS AFTER FORCED EXPIRATORY MANOUVRE	20
15/LO/1227	Strengthening local Babies' Futures (SBF) by community-led action	31
15/LO/1487	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)	44
15/LO/1535	Neural responses to speech in people with auditory processing disorder	23
15/LO/1571	Limiting chemotherapy side effects by using moxa	28
15/LO/1616	M116 - Feasibility and performances of spleen stiffness measurement	33
15/LO/1731	Walking boot versus below knee cast in stable ankle fractures	22
15/LO/2072	Lung ultrasound for the assessment of heart failure	25
15/LO/2074	Idiopathic left ventricular hypertrophy and sudden death	40
15/LO/2120	261303 BAX 855 PK-guided Dosing Adults and Adolescents	29
15/LO/2121	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	19
16/LO/0005	Genes and Gene Function in Lipoedema	34
16/LO/0047	The role of phosphodiesterase 2A in PD with cognitive impairment	25
16/LO/0052	CARBON	26
16/LO/0250	Uncovering mechanisms of skeletal muscle specific force loss with age.	27
16/LO/0272	Feasibility study of MyPain Compass and MyPain Impact	24
16/LO/0304	VELOCITY	22
16/LO/0317	A feasibility study to explore predictors of dysphagia in COPD	41



<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>
15/LO/0676	M116 - Feasibility and performances of spleen stiffness measurement	42

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0848	Cerebral Visual Disorders Classification System	23
15/LO/1054	Evaluating a group for adjustment in Neurological conditions	21
15/LO/1133	EVD Immunology	13

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1858	GutBack	21
15/LO/2119	The AWARD study	18
16/LO/0045	Developing a grounded theory of engagement in group PBCT.	18
16/LO/0049	Assessment of thrombotic status in atrial fibrillation v1.0	37
16/LO/0286	CELEB: lung volume reduction in COPD - surgery vs endobronchial valves	18
16/LO/0459	PENELOPE-B - Protocol D Version 9 (09-FEB-2015)	23

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1045	A&E BBV Screening Study	21
15/LO/1543	Development and Evaluation of the PES-PD	23
15/LO/1806	Leukaemia Model in Humanized Mice Version 1	21

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0439	Study of GSK2140944 in Uncomplicated Urogenital Gonorrhoea	n/a

16/LO/0448	LY2606368 in Extensive Stage Disease Small Cell Lung Cancer	n/a
16/LO/0467	Effect of Dietary salt reduction on BP in kidney transplant recipients	n/a
16/LO/0598	Self soft tissue therapy for fibromyalgia syndrome; feasibility study	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**

#### Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0772	STAMINA - MRI pathology and pelvic pain in athletes(version 1.0)	14
15/LO/1314	GItractRS_SMART_RetroArchive	9
15/LO/1683	User feedback of MuJoã,ç Shoulder Solution	10
15/LO/1690	Investigating perceptions and experiences of an exo-skeleton service	14
16/LO/0548	Young carers of stroke survivors	15

#### 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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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0947	PTSS in fathers of very low birth weight infants. Version 1	7
15/LO/0951	The effect of branch stent choice on outcomes in complex aortic stents	8
15/LO/1130	Why do parents/carers choose to take their child to A&E? Version 1.0	7
15/LO/1310	Swallowing difficulties in advanced lung cancer: prevalence and impact	8
15/LO/2038	Music and Anxiety in Radiotherapy Head and Neck patients	9
15/LO/2171	Non-invasive Imaging of Ocular Blood Flow	11

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0767	Effect of medication versus CBT-informed psychoeducation on adult ADHD	9
15/LO/0768	Development of a web based resource for orthognathic surgery patients	8
15/LO/1313	Feasibility of volatile detection for naso-gastric tube placement	8
16/LO/0172	Real life experience of Vedolizumab in UK	8

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

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**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/AM04	NIAS – Neurological Injury associated with Aortic Stenting	Two	15/01/2015	13
09/H0711/39/AM19	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	IB Version 18	13/02/2015	13
09/H0711/56/AM31	COU-AA-302 Abiraterone Acetate in Metastatic Prostate Cancer April-09	IB Ed. 11	08/04/2015	28
09/H0711/56/AM32	COU-AA-302 Abiraterone Acetate in Metastatic Prostate Cancer April-09	IB Ed 12	26/08/2015	18
09/H0711/56/AM33	COU-AA-302 Abiraterone Acetate in Metastatic Prostate Cancer April-09	IB Addendum 1 to IB Edition 12	16/12/2015	21
09/H0711/90/AM36	UKALL14		29/04/2015	22
09/H0711/90/AM38	UKALL14		11/09/2015	19
10/H0711/66/AM21	Blinatumomab(MT103)in patients with MRD+ B-precursor ALL	Twelve	25/03/2015	35
11/LO/1826/AM10	Immunity against RSV & influenza in a human challenge model	Seven	01/05/2015	19
11/LO/1826/AM11	Immunity against RSV & influenza in a human challenge model	Eight	19/10/2015	24
11/LO/1826/AM12	Immunity against RSV & influenza in a human challenge model	Nine	12/02/2016	33
11/LO/1908/AM16	8HA01EXT Long-Term Safety and Efficacy of rFVIII Fc Haemophilia A	IB Version 6.0	10/04/2015	22
11/LO/1982/AM04	European Union Childhood Life-threatening Infectious Diseases Study	Three	06/01/2016	14
11/LO/1996/AM08	Response and resistance to targeted therapy in renal cell carcinoma	Six	30/06/2015	20
12/LO/0147/AM02	A New Method for Identifying Site of Origin of Ventricular Arrhythmias	Two	31/03/2015	15
12/LO/1078/AM15	MUK five	24/06/2015	24/06/2015	20
12/LO/1078/AM16	MUK five	5.0	16/09/2015	21
12/LO/1078/AM18	MUK five	5.0	06/01/2016	15
12/LO/1351/AM17	MO28231 T-DM1 Safety Study	Twelve	01/06/2015	18
12/LO/1391/AM03	PREMFOOD Version 1/010812	Three	04/03/2015	28
12/LO/1584/AM03	Improving access to dementia services for minority ethnic elders	Three	24/06/2015	22
12/LO/1584/AM04	Improving access to dementia services for minority ethnic	Four	21/10/2015	13

	elders			
12/LO/1687/AM01	Cancer Research UK Citizen Science Project v2	1	20/08/2015	16
12/LO/1735/AM02	Assessment of extramural venous invasion in rectal cancer	Two	06/11/2014	24
12/LO/1768/AM08	HepFree	Six	12/03/2015	18
12/LO/1962/AM07	Self-management education for adults with epilepsy (SMILE)	Four	06/01/2016	13
13/LO/0041/AM03	Functional Assessment of Bone Metastases-Integrin Expression (FAB-IE)	Four	13/10/2015	18
13/LO/0112/AM02	Defining Immune Tolerance in ANCA-associated Vasculitis	Two	15/04/2015	26
13/LO/0126/AM04	Risk of preterm labour after treatment for cervical precancer	Four	16/03/2015	35
13/LO/0126/AM05	Risk of preterm labour after treatment for cervical precancer	5	11/06/2015	16
13/LO/0161/AM09	MAESTRO: Macitentan in Eisenmenger Syndrome AC-055-305	Change of CI	16/06/2015	20
13/LO/0383/AM18	Odyssey - Alternative	Seven	15/01/2016	19
13/LO/0406/AM03	HepFree 2	One	07/05/2015	23
13/LO/0535/AM07	A Phase 3 Study of Pacritinib in Patients with Myelofibrosis	SA008	18/02/2016	13
13/LO/0706/AM04	UK Multicentre Study of Children with Opsoclonus Myoclonus Syndrome v1	2	08/07/2015	33
13/LO/1277/AM21	Study of ARN-509 in Prostate Cancer	12	10/06/2015	19
13/LO/1277/AM24	Study of ARN-509 in Prostate Cancer	14	24/09/2015	29
13/LO/1283/AM07	TAMIGA - Bevacizumab GBM Study	Six	16/01/2015	23
13/LO/1283/AM08	TAMIGA - Bevacizumab GBM Study	IB Version 23	23/11/2015	29
13/LO/1305/AM02	Wave intensity analysis in the pulmonary artery	Two	24/02/2015	19
13/LO/1479/AM10	ASPRE (Version 1)	Six	12/05/2015	20
13/LO/1479/AM11	ASPRE (Version 1)	AM07	07/10/2015	15
13/LO/1479/AM12	ASPRE (Version 1)	AM08	25/01/2016	19
13/LO/1517/AM12	Dolomites		18/05/2015	24
13/LO/1793/AM01	Impact of mode of delivery on infant health	One	28/02/2015	21
14/LO/0036/AM03	Phase 3 Blinatumomab in Philadelphia negative B-precursor ALL	Three	24/04/2015	27
14/LO/0036/AM04	Phase 3 Blinatumomab in Philadelphia negative B-precursor ALL	4	10/08/2015	14
14/LO/0036/AM06	Phase 3 Blinatumomab in Philadelphia negative B-precursor ALL	5	21/09/2015	16
14/LO/0037/AM03	Blinatumomab in adult patients with Acute Lymphoblastic Leukaemia	Three	21/04/2015	14
14/LO/0059/AM02	Developmental Coordination Disorder: A brain imaging study	Two	29/06/2015	15

	v1			
14/LO/0072/AM03	GENPROS	Three	15/09/2015	19
14/LO/0108/AM04	Southall And Brent REvisited (SABRE) - SABRE V3	Four	25/03/2015	20
14/LO/0108/AM05	Southall And Brent REvisited (SABRE) - SABRE V3	Five	10/06/2015	10
14/LO/0135/AM08	Radium-223 in subjects with bone predominant metastatic CRPC.	Eight	24/03/2015	15
14/LO/0135/AM09	Radium-223 in subjects with bone predominant metastatic CRPC.	Nine	11/05/2015	23
14/LO/0135/AM10	Radium-223 in subjects with bone predominant metastatic CRPC.		12/06/2015	14
14/LO/0169/AM03	Investigating early help-seeking for non-emergency cardiac symptoms	One	07/10/2015	15
14/LO/0345/AM02	Generation of human induced pluripotent stem cell-lines by CGaP (WTSI)	Two	01/02/2016	15
14/LO/0359/AM05	Extension study of EVP6124 in patients with Schizophrenia		21/09/2015	16
14/LO/0362/AM05	MERIT-1	Three	25/03/2015	14
14/LO/0507/AM04	Patient perceptions of multiple rib fracture rehabilitation	One	10/02/2015	29
14/LO/0721/AM01	SIPS jr RCT	One	20/02/2015	20
14/LO/0721/AM02	SIPS jr RCT	Two	27/07/2015	11
14/LO/0851/AM06	Open Label, Phase IIa of ALXN1007 for Antiphospholipid Syndrome	Three	27/01/2015	30
14/LO/0861/AM02	STAND UP - Cut-point validation study	Two	12/05/2015	35
14/LO/0865/AM02	Phase 2 Study of Fostamatinib for Subjects with IgA Nephropathy	Two	27/03/2015	16
14/LO/0865/AM05	Phase 2 Study of Fostamatinib for Subjects with IgA Nephropathy	Four	05/10/2015	15
14/LO/0871/AM02	EndoBarrier TM Gastrointestinal Liner Diabetes Trial	Two	16/03/2015	22
14/LO/0871/AM04	EndoBarrier TM Gastrointestinal Liner Diabetes Trial	Three	18/08/2015	22
14/LO/1179/AM05	A PK Study of Serelaxin in Paediatric Heart Failure Patients	Three	09/10/2015	25
14/LO/1179/AM06	A PK Study of Serelaxin in Paediatric Heart Failure Patients	4	21/10/2015	14
14/LO/1196/AM03	A study of LEE011 in ER+ HER2- breast cancer patients	Three	09/04/2015	22
14/LO/1196/AM04	A study of LEE011 in ER+ HER2- breast cancer patients	Four	26/10/2015	15
14/LO/1230/AM03	Ketogenic diet treatment of epilepsy in infants	Two	08/05/2015	20
14/LO/1230/AM06	Ketogenic diet treatment of epilepsy in infants	6 (Substantial Amendment 3)	02/09/2015	19
14/LO/1230/AM07	Ketogenic diet treatment of epilepsy in infants	Seven	27/10/2015	25

14/LO/1267/AM02	Adolescent hip disease. Version 1	One	30/01/2015	31
14/LO/1291/AM06	PALLET	REC4MHRA1	08/10/2015	19
14/LO/1291/AM09	PALLET	REC5MHRA2	08/02/2016	8
14/LO/1295/AM01	One Stop Vein Clinic	One	03/03/2015	19
14/LO/1318/AM01	PREDICT-VF	One	24/03/2015	22
14/LO/1318/AM02	PREDICT-VF	Two	15/06/2015	11
14/LO/1561/AM02	VITAL	Two	13/10/2015	25
14/LO/1601/AM01	18F-FMC and MRS in gliomas	1	17/07/2015	21
14/LO/1812/AM02	PROSPECT-R	Two	26/01/2015	30
14/LO/1812/AM03	PROSPECT-R	Three	27/07/2015	18
14/LO/1837/AM02	ARPEGGIO: Laquinimod for Primary Progressive Multiple Sclerosis (PPMS)	1	01/07/2015	15
14/LO/1837/AM04	ARPEGGIO: Laquinimod for Primary Progressive Multiple Sclerosis (PPMS)	Two	23/02/2016	30
14/LO/1851/AM01	INTRA-DIALYTIC EXERCISE IN RENAL FAILURE	One	02/04/2015	24
14/LO/1851/AM02	INTRA-DIALYTIC EXERCISE IN RENAL FAILURE	Two	23/07/2015	11
14/LO/1851/AM03	INTRA-DIALYTIC EXERCISE IN RENAL FAILURE	3	01/02/2016	20
14/LO/2058/AM01	Immunological analysis of an acute HIV-1 Infection cohort	One	01/05/2015	18
14/LO/2131/AM01	The Prevalence of Anorexia with Autism Spectrum Disorder	One	04/06/2015	19
14/LO/2219/AM02	ENZARAD Trial	Two	06/10/2015	17
14/LO/2219/AM03	ENZARAD Trial	Three	09/12/2015	12
14/LO/2219/AM05	ENZARAD Trial	Four	03/02/2016	14
15/LO/0032/AM02	BO28984 Alectinib versus Crizotinib in advanced NSCLC	One	31/03/2015	24
15/LO/0032/AM04	BO28984 Alectinib versus Crizotinib in advanced NSCLC	Three	15/05/2015	19
15/LO/0032/AM05	BO28984 Alectinib versus Crizotinib in advanced NSCLC	Four	16/12/2015	29
15/LO/0071/AM01	Drama based environments as a tool to aid diagnosis in ASD	One	14/07/2015	34
15/LO/0181/AM01	Compression therapy following endovenous thermal ablation	One	03/06/2015	19
15/LO/0289/AM01	MAGSTAR Trial	One	19/03/2015	24
15/LO/0290/AM01	METformin And Longevity (METAL)-Version One	One	30/03/2015	19
15/LO/0290/AM02	METformin And Longevity (METAL)-Version One	Two	06/08/2015	8
15/LO/0290/AM03	METformin And Longevity (METAL)-Version One	Three	08/09/2015	15
15/LO/0458/AM02	Pneumo carriage, PIN study	One	23/04/2015	27
15/LO/0470/AM04	AF-219 on Cough Reflex Sensitivity in Healthy + Chronic Cough Patients	1	02/09/2015	15
15/LO/0470/AM08	AF-219 on Cough Reflex Sensitivity in Healthy + Chronic Cough Patients	2	20/01/2016	14

15/LO/0472/AM01	LT2762-PIV-11/13	1	19/11/2015	14
15/LO/0656/AM01	Cognitive Control in Cocaine Dependence: A Stage 1 Pilot Study	One	12/02/2016	22
15/LO/0767/AM01	Effect of medication versus CBT-informed psychoeducation on adult ADHD	One	30/04/2015	26
15/LO/0768/AM01	Development of a web based resource for orthognathic surgery patients	One	28/02/2016	29
15/LO/0788/AM01	Pasireotide (SOM230) in patients with acromegaly	1	05/08/2015	21
15/LO/0798/AM01	Study of MORAb-003 with chemotherapy in subjects with ovarian cancer	One	16/07/2015	21
15/LO/0848/AM01	Cerebral Visual Disorders Classification System	1	23/07/2015	20
15/LO/0947/AM01	PTSS in fathers of very low birth weight infants. Version 1	1	28/08/2015	17
15/LO/0947/AM02	PTSS in fathers of very low birth weight infants. Version 1	Two	02/10/2015	18
15/LO/0947/AM03	PTSS in fathers of very low birth weight infants. Version 1	3	05/02/2016	21
15/LO/1024/AM01	Stomas in IBD	1	12/08/2015	11
15/LO/1040/AM01	Enhancing self-care in the housebound V3	One	23/10/2015	20
15/LO/1054/AM01	Evaluating a group for adjustment in Neurological conditions	One	22/10/2015	18
15/LO/1227/AM01	Strengthening local Babies' Futures (SBF) by community-led action	One	12/02/2016	22
15/LO/1313/AM01	Feasibility of volatile detection for naso-gastric tube placement	One	06/10/2015	19
15/LO/1487/AM02	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)		18/12/2015	13
15/LO/1571/AM01	Limiting chemotherapy side effects by using moxa	One	12/02/2016	13
15/LO/1858/AM01	GutBack	One	24/02/2016	33
15/LO/2121/AM03	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	Two	12/02/2016	19
16/LO/0052/AM01	CARBON	One	25/02/2016	34

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/LO/0671/AM04	Long-term extension study to evaluate safety and efficacy of DAC HYP	Two	20/05/2015	36
13/LO/1277/AM23	Study of ARN-509 in Prostate Cancer	13	18/08/2015	37
15/LO/0848/AM02	Cerebral Visual Disorders Classification System	Two	08/10/2015	35



**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>
13/LO/0671/AM04/1	Long-term extension study to evaluate safety and efficacy of DAC HYP	Modified Amendment	20/05/2015	10
13/LO/1277/AM23/1	Study of ARN-509 in Prostate Cancer	Modified Amendment	05/10/2015	10

<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 14 day timeline**

REC Reference	Title	Number of Days on Clock
16/LO/0548	Young carers of stroke survivors	15

**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
13/LO/0671/AM04	Long-term extension study to evaluate safety and efficacy of DAC HYP	Two	20/05/2015	36
13/LO/1277/AM23	Study of ARN-509 in Prostate Cancer	13	18/08/2015	37

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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