

**London - Fulham Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## 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>	Yet to be appointed
<b>REC Manager:</b>	Miss Anna Bannister
<b>REC Assistant:</b>	Miss Nafeesa Khanam (06.06.16 to 06.03.17) Mr Ewan Waters (from 07.03.17)
<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:

This has been a time of consolidation and stability, though during this year we have lost two members who had completed 10 years of service and whose expertise was invaluable, Dr Kanagasabai Ganeshaguru and Mrs Katie Wilkinson. Dr Shaun Griffin who has had useful experience with the Human Tissue Authority and the Health Research Authority was appointed Vice-Chairman, which has helped to deal with the significant number of substantial amendments received. All our meetings over the past year have been quorate. The Manager, Miss Anna Bannister, has continued to provide a highly competent service supporting the committee. We have continued to receive a great variety of submissions, though we are not currently flagged for any specialist areas and some thought should be given to where there may be current gaps in flagging that the committee could address.

## London - Fulham Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Anthony Farrant	Lecturer in Healthcare Law and Ethics	Lay Plus	01/09/2015	
Dr Kanagasabai Ganeshaguru	Retired Scientist	Lay	01/06/2006	01/06/2016
Dr Shaun Griffin	Communications Manager	Lay	01/11/2008	
The Rev'd Nigel Griffin	Parish Priest	Lay Plus	01/06/2006	
Miss Lesley Honeyfield	Principle Research Radiographer for the Imaging Department	Expert	05/02/2015	
Dr Akil Jackson	Research Fellow	Expert	01/10/2007	
Dr Mays Jawad	Research Portfolio Manager	Lay	01/07/2016	
Mr Greg Kyle-Langley	Private Banker	Lay Plus	01/03/2016	
Ms 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	Occupational Therapist	Lay	01/07/2010	
Mrs Katie Wilkinson	Clinical Trials Centre Manager	Lay	09/11/2007	12/12/2016
Mrs Marney Williams	Teacher	Lay Plus	11/06/2013	

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Anthony Farrant	Occasional expert reviews for horizon 2010 and IMI	12/12/2016
Dr Shaun Griffin	None	11/12/2016
The Rev'd Nigel Griffin (Chair)	None	12/12/2016
Miss Lesley Honeyfield	Imperial College Healthcare Imaging Research Department Lead	16/01/2017
Dr Akil Jackson	Senior Medical Project Manager, Liver Diseases, employed by Gilead Sciences Ltd. UK. PhD student at University of Liverpool, stockholder Gilead	12/12/2016
Dr Mays Jawad	Work as a research portfolio manager at Moorfields Eye Hospital.	18/07/2016
Mr Greg Kyle-Langley	Ownership of UK & Global tracker funds in pension which may have exposure to pharma companies but no direct holdings	12/12/2016
Dr Frank Miskelly	Member of NICE Oct 2016	16/01/2017
Mrs Elizabeth Reeves	QA Manager Great Ormond Street Childrens Hospital Bank Staff - Guy's & St Thomas' NHS Foundation Trust Member of a trial Steering Committee – Parrot Study	20/02/2017
Mrs Gillian Sichau	Discontinued Professional Registration in 2016	16/01/2017
Mrs Marney Williams	Reviewer for NIHR and stroke association, Lay member on PPI panel of NIHR London and Imperial	12/12/2016
Ms Monsey McLeod	Lead pharmacist for medication safety and anti-infective research at centre for medication safety and services quality affiliated with the NIHR imperial patient safety translation research centre. Work at imperial college healthcare NHS trust in research pharmacist capacity.	01/03/2017

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

Month	Date	Number of Members Present at Meeting
April	18/04/2016	9
May	16/05/2016	10
June	20/06/2016	8
July	18/07/2016	10
September	19/09/2016	9
October	17/10/2016	11
December	12/12/2016	9
January	16/01/2017	8
February	20/02/2017	11
March	20/03/2017	12

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	18/04/2016	3
May	16/05/2016	3
June	20/06/2016	3
July	18/07/2016	3
October	17/10/2016	3
November	21/11/2016	3
December	12/12/2016	3
January	16/01/2017	4
February	20/02/2017	3
March	20/03/2017	3

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

### Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	13/04/2016	2
April	27/04/2016	2
May	11/05/2016	2
May	25/05/2016	2
June	15/06/2016	2
July	05/07/2016	2
July	27/07/2016	2
August	10/08/2016	2
September	07/09/2016	2
September	21/09/2016	2
October	05/10/2016	2

October	19/10/2016	2
November	02/11/2016	2
November	16/11/2016	2
November	30/11/2016	2
December	16/12/2016	2
January	04/01/2017	2
January	18/01/2017	2
January	18/01/2017	2
February	01/02/2017	2
February	15/02/2017	2
March	01/03/2017	2
March	15/03/2017	2
March	29/03/2017	2

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

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

0

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Anthony Farrant	9
Dr Kanagasabai Ganeshaguru	2
Dr Shaun Griffin	9
The Rev'd Nigel Griffin (Chair)	9
Miss Lesley Honeyfield	9
Dr Akil Jackson	6
Dr Mays Jawad	5
Mr Greg Kyle-Langley	8
Ms Monsey McLeod	5
Dr Frank Miskelly	9
Mrs Elizabeth Reeves	6
Mrs Gillian Sichau	6
Mrs Katie Wilkinson	6
Mrs Marney Williams	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Anthony Farrant	2
Dr Shaun Griffin	3
The Rev'd Nigel Griffin (Chair)	8
Miss Lesley Honeyfield	5
Dr Akil Jackson	2
Mr Greg Kyle-Langley	1
Dr Frank Miskelly	2
Mrs Elizabeth Reeves	1
Mrs Gillian Sichau	2
Mrs Katie Wilkinson	1
Mrs Marney Williams	4

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Anthony Farrant	3
Dr Kanagasabai Ganeshaguru	1
Dr Shaun Griffin	5
The Rev'd Nigel Griffin (Chair)	19
Miss Lesley Honeyfield	2



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

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Anthony Farrant	06/07/2016	Local Training Day - York
Dr Anthony Farrant	16/08/2016	Equality Diversity and Human Rights
Dr Shaun Griffin	03/08/2016	Equality Diversity and Human Rights
Dr Shaun Griffin	03/08/2016	Clinical Trials
Dr Shaun Griffin	11/10/2016	Self-Directed Learning for 2016 HTA code of practice – revised draft post-consultation Review of revised HRA SOPs (partial)
Dr Shaun Griffin	07/11/2016	The Practicalities of Running a REC - a workshop for Chairs and REC Managers (formerly 'Nuts and Bolts')
The Rev'd Nigel Griffin (Chair)	15/06/2016	Equality Diversity and Human Rights
Miss Lesley Honeyfield	10/06/2016	Equality Diversity and Human Rights
Miss Lesley Honeyfield	06/12/2016	Committee Members Induction
Dr Akil Jackson	12/04/2016	Self-Directed Learning Review of Pharmaceuticals study of HIV - Approval of publication by peer review ABPI code of practice for the pharmaceutical Industry - Formal assessment for nomination to MHRA notification compliance signatory
Dr Akil Jackson	31/10/2016	Equality Diversity and Human Rights
Dr Akil Jackson	16/02/2017	National Members Training Day
Dr Mays Jawad	30/01/2017	Committee Members Induction
Dr Mays Jawad	01/02/2017	Medical Device Training
Mr Greg Kyle-Langley	04/08/2016	Equality Diversity and Human Rights
Mr Greg Kyle-Langley	30/11/2016	Committee Members Induction
Ms Monsey McLeod	06/05/2016	Equality & Diversity training
Mrs Elizabeth Reeves	16/08/2016	Equality Diversity and Human Rights
Mrs Gillian Sichau	25/08/2016	Equality & Diversity and Human Rights
Mrs Gillian Sichau	16/02/2017	National Members Training Day
Mrs Katie Wilkinson	17/10/2016	Self-Directed Learning Preparation of documents for ethical review - Research into ethical issues relating to paediatric research.
Mrs Marney Williams	01/02/2017	Medical Devices 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	16	30.19
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.89
Others	36	67.92
<b>Total Applications Reviewed</b>	<b>53</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	4
Number of device applications reviewed	3
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	4
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	2	3.77
Favourable Opinion with Additional Conditions	19	35.85
Unfavourable Opinion	1	1.89
Provisional Opinion	30	56.60
Provisional Opinion Pending Consultation with Referee	1	1.89
<b>Total</b>	<b>53</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	31	58.49
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.77
Favourable Opinion with Additional Conditions	19	35.85
Unfavourable Opinion	1	1.89
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
<b>Total</b>	<b>53</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>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	14
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	5
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of qualitative applications reviewed	3

**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	9	40.91
Favourable Opinion with Additional Conditions	7	31.82
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	22.73
Unfavourable Opinion	1	4.55
<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>	5.30
<b>Number of completed applications for full ethical review</b>	53
<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>	5.66%
<b>Number of days taken to final decision – average (mean)</b>	28
<b>Number of completed proportionate review applications for ethical review</b>	22
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timelines for review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	5
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	22.73%
<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	14.29%
<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>	115
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	24
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	20.87%
<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>	67
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new</b>	23

<b>sites/PIs</b>	
<b>Number of annual progress reports received</b>	92
<b>Number of safety reports received</b>	46
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	67

**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>
16/LO/0611	Prediction of Complications in Multiple Pregnancies (version 1.0)	30
16/LO/0639	Exhaled Breath Biomarkers in Acute Asthma: A Feasibility Study	39
16/LO/0640	GLIDE study	24
16/LO/0642	The lymphoid stress surveillance response in human intestine	26
16/LO/0716	Comparison of Lotrafilcon B Lenses with Different Packaging Solutions	27
16/LO/0838	TOP1288-TV-02 Rectal Solution Ulcerative Colitis	24
16/LO/0839	Fetal ECG in Diabetes Study	30
16/LO/0875	Calcitonin receptor over-expression in multiple myeloma (version 1)	29
16/LO/0876	Long-term safety and efficacy of revusiran in patients with TTR-FAC	34
16/LO/1099	TIGER	30
16/LO/1107	UK Lung Volume Reduction - multicentre observational study	36
16/LO/1112	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	30
16/LO/1113	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	30
16/LO/1130	Cereal bar or oral supplementation with tablets (BOOST)	28
16/LO/1263	PREdiCt Ablation Strategy for Atrial Fibrillation (PRECAST-AF)	30
16/LO/1297	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	43
16/LO/1298	Feasibility Study Comparing the Accuracy of G5 Mobile vs. Abbott Libre	21
16/LO/1587	GETUG-AFU 23 UC-0160/1202	26
16/LO/1651	JVDK: Ramucirumab Combined with Other Medications in Advanced Cancers	53
16/LO/1657	Comparing two stop smoking intervention efficacies' 1.0	28
16/LO/1662	Retrospective meta-analytics of the lexicon via email processing	23
16/LO/1784	IMM-101 in patients with metastatic cancer or unresectable cancer	39
16/LO/1799	E7080-M000-213 Anaplastic Thyroid Cancer	37
16/LO/1850	Psychiatry Research and Motherhood at 6 to 8 (PRAM-D@6to8)	39
16/LO/2141	Biomede	56
16/LO/2165	Examination of Mentalization Ability in Eating Disorders	30
17/LO/0065	PDR001 with dabrafenib + trametinib in BRAF+ve advanced Melanoma	24
17/LO/0295	Maudsley Tobacco Dependence Clinic Database (Maudsley Clinic Database)	32
17/LO/0300	Oxidative metabolism and atrophy in primary human skeletal muscle cell	35
17/LO/0451	177Lu-edotreotide vs. everolimus in GEP-NET – COMPETE	22
17/LO/0493	Cocoa and Cognition version 1.0	30



<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/0059	A psychoeducational intervention for inherited heart conditions	18
17/LO/0071	Direct REporting of Awareness in MaternitY patients (DREAMY)	18

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0881	A snap shot of faecal incontinence patients	21
16/LO/1282	Does viral load testing shorten the window period for diagnosing HIV?	21
16/LO/1573	Placental Imaging Project (PiP)	18
16/LO/1659	Biomarkers of Mitochondrial Disease	18
16/LO/1829	EEG in the Early Phase of Psychosis	30
16/LO/1835	ImprovE Y2 - Involving involuntarily hospitalised patients in care.	29
16/LO/2110	SUSTAIN 8 NN9535-4270	35
16/LO/2175	The POPPY Sleep Sub-Study	25
16/LO/2178	On the Count	21
17/LO/0058	Development of Multisensory Integration	18
17/LO/0104	MR-simulation in Radiotherapy for Prostate Cancer	18
17/LO/0122	High-resolution mapping of human dual atrio-ventricular pathways	24
17/LO/0304	IXA-CSP-001 Litoxetine v Placebo in Urinary Incontinence 2016-12-09 V1	24
17/LO/0305	Effect of apixaban on endogenous fibrinolysis in atrial fibrillation	24
17/LO/0308	802NP301 Biogen - BIIB074 - SURGE-1- Trigeminal Neuralgia	24
17/LO/0465	ADJUNCTIVE GP ABLATION IN REDO-PVI STUDY (ADD-GP)	24
17/LO/0478	Angiogenesis and molecular imaging (AMI)	24
17/LO/0495	Decision-making and Mood	24
17/LO/0505	Feasibility of Intensive Group Music Therapy	23

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1291	A prospective evaluation of a multi-faceted digital intervention	21

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

<b>Provisional Opinion Pending Consultation with Referee</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 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>
16/LO/0940	Diabetes prevention indicators	13
16/LO/1187	Paediatric analgesia for inguinal-scrotal surgery: caudal vs. block	14
17/LO/0127	The AWArE Study: Version 1: 03/10/16	14
17/LO/0132	AO in PVR Study	19
17/LO/0511	Feraccru® Real World Effectiveness Study in Hospital Practice	24

<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>
16/LO/0768	Me-D-Links Version 1	16
16/LO/0770	Gingival Imaging in CCB patients	14
16/LO/0928	The role of telecare in health and social care use variations	9
16/LO/1902	Exploring older adult patient experiences of serious infection	14
16/LO/2117	SLEEP AND TKR - 1	13
16/LO/2210	Canine Olfactory Detection of Human Colorectal Cancer (version 1)	12
17/LO/0324	Quality of Life in Adults Living with Duchenne Muscular Dystrophy	9
17/LO/0326	VR Pain reduction for burn treatments	15
17/LO/0507	The effects of SAPS fluid pressure on kidney function post operatively	17

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1343	Microthin DSAEK vs DMEK - RCT	14
16/LO/1348	Multi-Centre Clinical Evaluation of Two Reusable Soft Contact Lenses	14
16/LO/1904	Feasibility of a serological assay for malaria elimination (v1.0)	14
16/LO/2209	Usage of bio-signals to detect epileptic seizures	12
17/LO/0123	Modelling polymicrobial infection of diabetic foot ulcers in vitro	9
17/LO/0135	Assessing Cervical Dystonia	8
17/LO/0327	SQUAD Pilot	9

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0515	HE4 in primary care .	14

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

**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>
07/H0711/98/AM08	The measurement of transmural myocardial perfusion in normal subjects and patients with left ventricular hypertrophy with Cardiovascular Magnetic Resonance (CMR)	5	30/11/2016	8
07/H0712/85+5/AM05	TB Research Unit Tissue Bank	4	16/06/2016	30
08/H0712/34+5/AM02	The Human Developmental Biology Resource	No version number	17/11/2016	26
09/H0711/39/AM20	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	Updated IB 19.0	15/06/2016	29
09/H0711/39/AM21	The "SPRINT" trial. A phase 2 study on the efficacy of Lenalidomide.	Updated IB 20.0	26/10/2016	26
09/H0711/90/AM41	UKALL14	Substantial Amendment 14.04.2016 REC (Additional PIS: Suspension of palifermin v1.0)	15/04/2016	25
09/H0711/90/AM42	UKALL14	Substantial Amendment 18.05.2016 REC (Protocol V8.0, PIS v6.0 and change of PI)	18/05/2016	19
09/H0711/90/AM43	UKALL14	Substantial Amendment (Protocol)	22/02/2017	15
10/H0711/66/AM23	Blinatumomab(MT103)in patients with MRD+ B-precursor ALL	14	23/06/2016	21
10/H0711/66/AM24	Blinatumomab(MT103)in patients with MRD+ B-precursor ALL	SA#15	09/03/2017	15
11/LO/1826/AM14	Immunity against RSV & influenza in a human challenge model	10	04/05/2016	27
11/LO/1826/AM16	Immunity against RSV & influenza in a human challenge model	11	06/02/2017	17

11/LO/1908/AM17	8HA01EXT Long-Term Safety and Efficacy of rFVIII Fc Haemophilia A	Investigator Brochure v6.0	01/09/2016	14
11/LO/1982/AM05	European Union Childhood Life-threatening Infectious Diseases Study	4	26/05/2016	27
11/LO/1996/AM09	Response and resistance to targeted therapy in renal cell carcinoma	7	24/05/2016	22
12/LO/0070/AM01	Asking terminally ill cancer patients about corneal donation	1	16/02/2017	32
12/LO/0560/AM03	Longitudinal study of corneal endothelium cell density in glaucoma	3	02/06/2016	35
12/LO/1078/AM20	MUK five	HM12/10191/Docs/201610xx Version: 6.0	26/10/2016	30
12/LO/1351/AM22	MO28231 T-DM1 Safety Study	17	17/01/2017	20
12/LO/1391/AM04	PREMFOOD Version 1/010812	4	25/04/2016	19
12/LO/1409/AM20	POPPY Pharmacokinetic and clinical observations in people over fifty	11	17/08/2016	22
12/LO/1768/AM09	HepFree	8	18/08/2016	25
12/LO/1768/AM10	HepFree	9	23/01/2017	19
13/LO/0161/AM10	MAESTRO: Macitentan in Eisenmenger Syndrome AC-055-305	IB V13	01/11/2015	34
13/LO/0161/AM11	MAESTRO: Macitentan in Eisenmenger Syndrome AC-055-305	Investigator's Brochure Version 14 dated October 2016	11/10/2016	16
13/LO/0176/AM04	ISKS study	version 3.2 dated 04/01/2013	09/03/2016	35
13/LO/0383/AM19	Odyssey - Alternative	8	03/05/2016	17
13/LO/0406/AM04	HepFree 2	2	05/09/2016	21
13/LO/0671/AM06	Long-term extension study to evaluate safety and efficacy of DAC HYP	Protocol Amendment V3.1 29Jan2016 - Daclizumab IB V12 18Feb2016, PISCF V3.0 18Apr2016	26/04/2016	24
13/LO/0814/AM04	Buprenorphine Research into Injectable Opioids BRIO	6	06/12/2016	7
13/LO/0814/AM05	Buprenorphine Research into Injectable Opioids BRIO	7	14/03/2017	28
13/LO/1277/AM26	Study of ARN-509 in Prostate Cancer	15	02/09/2016	28

13/LO/1277/AM27	Study of ARN-509 in Prostate Cancer	16	07/10/2016	27
13/LO/1277/AM29	Study of ARN-509 in Prostate Cancer	17	07/02/2017	16
13/LO/1277/AM30	Study of ARN-509 in Prostate Cancer	Protocol Amendment 8	15/03/2017	32
13/LO/1283/AM09	TAMIGA - Bevacizumab GBM Study	8	13/07/2016	15
13/LO/1283/AM10	TAMIGA - Bevacizumab GBM Study	9	03/01/2017	24
13/LO/1479/AM13	ASPRE (Version 1)	9	07/07/2016	35
13/LO/1517/AM15	Dolomites	Amendment 8 Protocol V3	31/03/2016	19
13/LO/1566/AM07	A Pilot Study - Does Bowel Preparation Affect the microbiome? v1	One	23/03/2016	21
13/LO/1687/AM04	ARCADIA. Association of ncRNAs with CAD and type 2 diabetes	3	30/11/2016	25
14/LO/0059/AM03	Developmental Coordination Disorder: A brain imaging study v1	3	06/04/2016	24
14/LO/0108/AM06	Southall And Brent REvisited (SABRE) - SABRE V3	6	20/04/2016	19
14/LO/0108/AM07	Southall And Brent REvisited (SABRE) - SABRE V3	7	11/05/2016	25
14/LO/0135/AM11	Radium-223 in subjects with bone predominant metastatic CRPC.	Change of Sponsor	06/06/2016	35
14/LO/0135/AM13	Radium-223 in subjects with bone predominant metastatic CRPC.	Protocol Amendment #4 Version: v4.0	13/09/2016	16
14/LO/0345/AM03	Generation of human induced pluripotent stem cell-lines by CGaP (WTSI)	3	31/05/2016	35
14/LO/0345/AM04	Generation of human induced pluripotent stem cell-lines by CGaP (WTSI)	4	09/08/2016	21
14/LO/0362/AM06	MERIT-1	Version 13 dated November 2015	01/11/2015	34
14/LO/0865/AM08	Phase 2 Study of Fostamatinib for Subjects with IgA Nephropathy	PI change 03/08/2016	04/08/2016	27
14/LO/1023/AM01	The Impact of Age on Adaptive Immunity in Adults Infected with RSV	1	28/11/2016	13
14/LO/1179/AM08	A PK Study of Serelaxin in Paediatric Heart Failure Patients	5	18/01/2017	27
14/LO/1230/AM08	Ketogenic diet treatment of epilepsy in infants	8	07/11/2016	14
14/LO/1330/AM02	Modelling retinal disease mechanisms and ocular cell development	2	02/02/2017	21

14/LO/1370/AM03	MERIT-2	13	01/11/2015	34
14/LO/1370/AM04	MERIT-2	Macitentan Investigator's Brochure v14 - October 2016	31/10/2016	29
14/LO/1600/AM01	Diffusion imaging in gliomas V1.0	2.0	15/03/2017	24
14/LO/1837/AM06	ARPEGGIO: Laquinimod for Primary Progressive Multiple Sclerosis (PPMS)	Laquinimod IB Update & Change of EU Legal Representative IB version 12	20/09/2016	28
14/LO/1846/AM01	An Investigation of Lumbar Spinal Nerves	1	05/09/2016	12
14/LO/1851/AM04	INTRA-DIALYTIC EXERCISE IN RENAL FAILURE	AM04 (19/09/2016)	19/09/2016	26
14/LO/1851/AM05	INTRA-DIALYTIC EXERCISE IN RENAL FAILURE	5	11/01/2017	20
14/LO/2181/AM03	RIO - Rucaparib Window of Opportunity Study	3	11/05/2016	26
14/LO/2181/AM04	RIO - Rucaparib Window of Opportunity Study	4	12/09/2016	21
14/LO/2181/AM05	RIO - Rucaparib Window of Opportunity Study	5.0	04/11/2016	15
14/LO/2219/AM06	ENZARAD Trial	5	30/06/2016	35
14/LO/2219/AM09	ENZARAD Trial	6	29/09/2016	18
15/LO/0032/AM06	BO28984 Alectinib versus Crizotinib in advanced NSCLC	5	05/07/2016	30
15/LO/0032/AM07	BO28984 Alectinib versus Crizotinib in advanced NSCLC	6	11/10/2016	23
15/LO/0042/AM04	Thrombotic status in patients with coronary disease	Amendment No.2 - 04/01/2017	04/01/2017	14
15/LO/0290/AM07	METformin And Longevity (METAL)-Version One	6	23/08/2016	14
15/LO/0556/AM02	Epidermal grafting in wound healing	1	26/04/2016	35
15/LO/0788/AM02	Pasireotide (SOM230) in patients with acromegaly	2	19/05/2016	18
15/LO/1024/AM03	Stomas in IBD	v3	12/02/2016	25
15/LO/1133/AM01	EVD Immunology	1	26/10/2016	26
15/LO/1487/AM05	RELAY - Ramucirumab in Metastatic NSCLC (JVCY study)	4	30/09/2016	27
15/LO/1571/AM02	Limiting chemotherapy side effects by using moxa	2	01/07/2016	28
15/LO/1616/AM01	M116 - Feasibility and performances of spleen stiffness measurement	1	15/06/2016	30
15/LO/1683/AM01	User feedback of MuJoã,ç Shoulder Solution	2	04/10/2016	32
15/LO/2120/AM01	261303 BAX 855 PK-guided Dosing Adults and Adolescents	1	11/07/2016	24
15/LO/2120/AM02	261303 BAX 855 PK-guided Dosing Adults and Adolescents	SA 2/Urgent Safety Measure - Protocol	29/11/2016	14



		v5 etc		
15/LO/2121/AM06	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	4 (IB v8)	15/06/2016	27
15/LO/2121/AM07	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	5	06/09/2016	28
15/LO/2121/AM09	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	7	07/10/2016	19
15/LO/2121/AM11	Switch HIV infected subjects with CNS toxicity from Atripla to MK1439A	9	13/02/2017	35
16/LO/0172/AM01	Real life experience of Vedolizumab in UK	1	06/07/2016	29
16/LO/0272/AM01	Feasibility study of MyPain Compass and MyPain Impact	1	22/07/2016	32
16/LO/0304/AM01	VELOCITY	One	31/03/2016	18
16/LO/0304/AM02	VELOCITY	2	14/12/2016	23
16/LO/0439/AM01	Study of GSK2140944 in Uncomplicated Urogenital Gonorrhoea	1	04/05/2016	21
16/LO/0448/AM01	LY2606368 in Extensive Stage Disease Small Cell Lung Cancer	a	15/03/2016	34
16/LO/0448/AM02	LY2606368 in Extensive Stage Disease Small Cell Lung Cancer	2	22/08/2016	25
16/LO/0459/AM01	PENELOPE-B - Protocol D Version 9 (09-FEB-2015)	Protocol E Version 10	13/10/2016	18
16/LO/0548/AM01	Young carers of stroke survivors	1	31/08/2016	27
16/LO/0639/AM01	Exhaled Breath Biomarkers in Acute Asthma: A Feasibility Study	1	21/07/2016	23
16/LO/0838/AM01	TOP1288-TV-02 Rectal Solution Ulcerative Colitis	1	09/05/2016	22
16/LO/0838/AM02	TOP1288-TV-02 Rectal Solution Ulcerative Colitis	2	28/11/2016	17
16/LO/1107/AM02	UK Lung Volume Reduction - multicentre observational study	2	07/10/2016	13
16/LO/1112/AM01	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	1	13/09/2016	21
16/LO/1112/AM02	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	Update to Dolutegravir Investigator's Brochure	21/12/2016	26
16/LO/1113/AM01	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	1	13/09/2016	21
16/LO/1113/AM03	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	Update to Dolutegravir	22/12/2016	25

		Investigator's Brochure		
16/LO/1113/AM05	Study to compare 2-drug with 3-drug regimen in patients with HIV-1	3	24/01/2017	20
16/LO/1130/AM01	Cereal bar or oral supplementation with tablets (BOOST)	1	20/12/2016	26
16/LO/1297/AM01	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	1	31/10/2016	23
16/LO/1297/AM02	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	2	21/12/2016	20
16/LO/1348/AM01	Multi-Centre Clinical Evaluation of Two Reusable Soft Contact Lenses	1	30/08/2016	14
16/LO/1573/AM01	Placental Imaging Project (PiP)	1	14/03/2017	10
16/LO/1784/AM01	IMM-101 in patients with metastatic cancer or unresectable cancer	1	13/02/2017	24
16/LO/1799/AM01	E7080-M000-213 Anaplastic Thyroid Cancer	SA01 IB update	11/07/2017	16
16/LO/2110/AM02	SUSTAIN 8 NN9535-4270	1	02/02/2017	21
16/LO/2141/AM01	Biomed	1	16/03/2017	18
16/LO/2178/AM01	On the Count	1	10/02/2017	13
17/LO/0304/AM01	IXA-CSP-001 Litoxetine v Placebo in Urinary Incontinence 2016-12-09 V1	1	21/03/2017	22

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/Q0411/41/AM04	Mechanisms of vascular permeability and tissue oedema in CIU	2	02/02/2016	22
16/LO/0876/AM01	Long-term safety and efficacy of revusiran in patients with TTR-FAC	1	07/09/2016	35

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

#### Favourable opinion timeline

Amendment REC	Title	Version	Date	Number of Days on
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<b>Reference</b>				<b>Clock</b>
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<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/0511	Feraccru <sup>®</sup> Real World Effectiveness Study in Hospital Practice	24

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

REC Reference	Title	Number of Days on Clock
16/LO/2016	Eli-Lilly 8D-MC-AZET Delayed Start study in Mild AD (DAYBREAK)	27

**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
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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