Health Research Authority

Research Ethics Service

London - Dulwich Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	London - Dulwich Research Ethics Committee
Type of REC:	Recognised to review CTIMPs in Patients Type III
Type of Flag:	Medical Devices
Chair:	Dr Michael Philpot
Vice-Chair:	Mr Colin Standfield
Alternate Vice-Chair:	Dr Thomas Kabir
REC Manager:	Mr Michael Higgs (April 2016 – October 2016) Mr Patrick Walsh (November 2016 – March 2017)
REC Assistant:	Mrs Asha Jama (November 2016 – March 2017)
Committee Address:	Health Research Authority Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

After the departure of several long-serving members of the Committee in recent years, 2016-17 has seen a period of re-building. We welcomed Mrs. Sophie Bulmer and Mrs. Humra Chadwick - both with experience in managing research, and Mr. Stuart Chandler, our new Pharmacist member with extensive experience in clinical trials. Meeting attendance has been good and there were no inquorate meetings.

REC activity has remained relatively stable – a slight reduction in new studies (47) was offset by an increase in substantial amendments (102) and the re-starting of proportionate review during the summer (14). 25% of the new studies reviewed by the full REC were CTIMPs and a third of the remainder were medical devices studies.

Provisional opinion remains the most popular of decisions (89%) but there were no Unfavourable opinions: REC members continue to see the value in working with researchers to achieve a Favourable outcome. Targets continue to be met and final decisions are achieved in an average of 29 days. No new applications exceeded the 60 day limit.

I would like to thank our REC Manager Patrick Walsh and REC Assistant Asha Jama for their hard work since they joined the REC in November 2016. They have both settled in well and are providing excellent support to the members.

Lastly, I thank Michael Higgs who joined us as REC Manager in January 2016 and left in October 2016 to work in the HRA Approvals team.

London - Dulwich Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Urmi Bapat	Pharmaceutical Physician	Expert	17/07/2014	
Mrs Sophie Bulmer	Programme Manager	Lay Plus	01/09/2016	

Mrs Humra Chadwick	Trial Manager	Expert	01/05/2016	
Mr Stuart Chandler	Pharmacy Clinical Trials Team Leader	Expert	01/06/2016	
Dr Jiafeng Feng	Research Assistant	Lay Plus	01/09/2015	
Mr Kenny Ip	Clinical Trials Specialist	Lay	01/09/2014	
Dr Thomas Kabir	Public Involvement in Research Manager	Lay	10/02/2010	
Dr Martin Keech	Clinical Project Manager	Lay	22/09/2014	
Dr Edward Lavender	GP	Expert	03/12/2014	
Dr Joanne Lawson	Civil Servant	Lay Plus	11/02/2014	
Dr Michael Philpot	Consultant Psychiatrist	Expert	30/12/2007	
Ms Anna Ramberg	Research Governance & Compliance Manager	Lay Plus	01/10/2010	
Mr Colin Standfield	Charity Worker	Lay	01/02/2012	
Dr Traiani Stari	Associate Director - Biostatistics	Expert	01/09/2015	
Ms Catherine Walton	Consultant Midwife	Expert	30/06/2006	

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

Name	Declaration of Interest	Date
Dr Urmi Bapat	Employed as Medical Director, Women's Health Division, Gedeon Richter (UK) Ltd, 127 Shirland Road, London W9 2EPHold shares in Bristol-Myers Squibb Pharmaceuticals	15/03/2017
Mrs Sophie Bulmer	Current employee of the Health Foundation, an independent charity which funds improvement and research projects in health and health care. Current role is Programme Manager including responsibility for the assessment, selection and management of projects that the Health Foundation funds.	11/08/2016
Mrs Humra Chadwick	Employed as Trial Manager in cardiovascular research at St Thomas Hospital	15/03/2017
Mr Stuart Chandler	None	15/03/2017
Mr Kenny Ip	Employed as Manager, Marketing Business Development by PAREXEL Ltd that conducts drug trials for Pharma companies.	15/03/2017
Dr Thomas Kabir	Public Involvement in Research Manager at a mental health research charity called the McPin Foundation. Co-applicant on some NIHR funded research studies.	15/03/2017
Dr Martin Keech	Holds shares in GlaxoSmithKline and AstraZeneca.	15/03/2017
Dr Edward Lavender	None	15/03/2017
Dr Joanne Lawson	None	15/03/2017
Dr Michael Philpot	Member of Alzheimer's Society and Alzheimer's Disease International	15/03/2017
Ms Anna Ramberg	Employed as the Research Governance & Compliance Manager at City, University of London	15/03/2017
Mr Colin Standfield	Lay member of NICE Appeals Panel	15/03/2017
Dr Traiani Stari	Employed as Associate Director – Biostatistics at Astellas Pharma EMEA	15/03/2017
Ms Catherine Walton	None	15/03/2017

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

Month	Date	Number of Members Present at Meeting
April	13/04/2016	9
June	08/06/2016	8
July	13/07/2016	12
September	14/09/2016	12

October	12/10/2016	12
November	09/11/2016	8
December	14/12/2016	10
January	11/01/2017	13
February	08/02/2017	10
March	08/03/2017	11

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
May	19/05/2016	3
June	23/06/2016	3
July	21/07/2016	3
August	18/08/2016	3
November	17/11/2016	3
January	19/01/2017	3
February	16/02/2017	3

7 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	01/04/2016	2
April	15/04/2016	2
April	22/04/2016	2
May	13/05/2016	2
May	27/05/2016	2
May	31/05/2016	2
June	01/06/2016	2
June	06/06/2016	2
June	07/06/2016	2
June	10/06/2016	2
June	29/06/2016	2
July	31/07/2016	2
August	01/08/2016	2
August	26/08/2016	2
September	14/09/2016	3
September	21/09/2016	3
September	30/09/2016	2
October	31/10/2016	2
November	21/11/2016	2
November	30/11/2016	2
December	15/12/2016	2
December	16/12/2016	2
January	05/01/2017	2

January	19/01/2017	2
January	26/01/2017	3
February	02/02/2017	2
February	09/02/2017	2
February	23/02/2017	3
March	09/03/2017	2
March	24/03/2017	3

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

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

NONE

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

Name	Number of Meetings Attended
Dr Urmi Bapat	9
Mrs Sophie Bulmer	6
Mrs Humra Chadwick	5
Mr Stuart Chandler	7
Dr Jiafeng Feng	3
Mr Kenny Ip	9

Dr Thomas Kabir	8
Dr Martin Keech	9
Dr Edward Lavender	9
Dr Joanne Lawson	6
Dr Michael Philpot	9
Ms Anna Ramberg	6
Mr Colin Standfield	8
Dr Traiani Stari	6
Ms Catherine Walton	5

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

Name	Number of Meetings Attended
Dr Joanne Lawson	8
Dr Michael Philpot	8
Ms Anna Ramberg	8

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

Name	Number of Meetings Attended
Dr Urmi Bapat	2
Mr Stuart Chandler	2
Dr Jiafeng Feng	5
Mr Kenny Ip	3
Dr Thomas Kabir	3
Dr Martin Keech	9
Dr Edward Lavender	1
Dr Joanne Lawson	1
Dr Michael Philpot	29
Mr Colin Standfield	2
Dr Traiani Stari	1
Ms Catherine Walton	4

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Urmi Bapat	24/05/2016	Introduction to Phase 1 Research
Dr Urmi Bapat	04/07/2016	CTIMP Training Day
Dr Urmi Bapat	14/07/2016	Personal Data in Research
Dr Urmi Bapat	16/11/2016	REC Member Training
Mrs Sophie Bulmer	19/08/2016	Equality and Diversity
Mrs Sophie Bulmer	19/08/2016	Members Induction Online course
Mrs Sophie Bulmer	30/11/2016	Committee Member Induction
Mrs Humra Chadwick	30/11/2016	Committee Member Induction
Mr Stuart Chandler	02/05/2016	Induction for new Research Ethics Service Committee members (e-learning)
Mr Stuart Chandler	30/11/2016	Committee Members Induction
Mr Stuart Chandler	16/02/2017	National Members Training
Mr Kenny Ip	01/09/2016	A framework for Risk-benefit Evaluations in Biomedical Research.”
Mr Kenny Ip	03/10/2016	Selective clinical trial reporting: betraying trial participants, harming patients Reporting biases found in trials of cardiovascular devices
Mr Kenny Ip	03/10/2016	Selective reporting in trials of high risk cardiovascular devices: cross sectional comparison between premarket approval summaries and published reports
Mr Kenny Ip	01/11/2016	Sense and readability: participant information sheets for research studies
Dr Martin Keech	16/11/2016	REC Member Training
Dr Edward Lavender	07/02/2017	Medical Devices
Dr Edward Lavender	16/02/2017	National Members Training Day
Dr Joanne Lawson	16/11/2016	REC Members Training
Dr Michael Philpot	04/05/2016	Chair's training
Dr Michael Philpot	07/11/2016	Chair's Training
Dr Michael Philpot	27/03/2017	Chair's Review Programme Workshop
Ms Anna Ramberg	16/02/2017	National Member Training Day
Mr Colin Standfield	16/11/2016	REC Members Training
Dr Traiani Stari	30/11/2016	Committee Member induction
Ms Catherine Walton	16/11/2016	REC Members Training

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	12	25.53
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	35	74.47
Total Applications Reviewed	**47**	**100**

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

Number of applications made invalid by the REC Manager	4
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	4
Number of device applications reviewed	14
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	0

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	2.13
Favourable Opinion with Additional Conditions	4	8.51
Unfavourable Opinion	0	0.00
Provisional Opinion	42	89.36
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**47**	**100**
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**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	36	76.60
Further Information Favourable Opinion with Additional Conditions	2	4.26
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.13
Favourable Opinion with Additional Conditions	4	8.51
Unfavourable Opinion	0	0.00
Provisional Opinion	3	6.38
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	1	2.13
Total	**47**	**100**

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

Total Applications Reviewed	**14**

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

Number of applications made invalid by the REC Manager	9
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	6
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	0

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	3	21.43
Favourable Opinion with Additional Conditions	5	35.71
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	42.86
Unfavourable Opinion	0	0.00
Total	**14**	**100**

Table 8: **Other Management Information based on the number of completed applications for the reporting period:**

Average number of applications reviewed per full meeting	4.70
Number of completed applications for full ethical review	46
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	5
Number of completed applications over 40 days as a % of total	10.64%
Number of days taken to final decision – average (mean)	29

Number of completed proportionate review applications for ethical review	14
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	1
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 14 days as a % of total	7.14%

Number of SSAs (non-Phase 1) reviewed	4
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%

Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%

Number of substantial amendments reviewed	102
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.96%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	6.86%

Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non-substantial amendments received	77
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	19
Number of annual progress reports received	58
Number of safety reports received	23
Number of Serious Adverse Events received	1
Number of final reports received	20

Table 9.1: **Breakdown of current status of all full applications reviewed within the reporting *period***

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0547	Novel vascular manifestations of COPD, part 3	21
16/LO/0588	Compassion Focused Therapy for people with Dementia	21
16/LO/0603	Mild to Moderate Acne Study with IPL (CD3061_FINAL_V2.0)	23
16/LO/1025	The Contraception Continuation Study	24
16/LO/1060	M14-730 DAA treatment for HCV/HIV Co-infection	21
16/LO/1064	PHNA study to assess the peripheral immune system in NOT1D pts	23
16/LO/1086	CNTO136 sirukumab	20
16/LO/1213	Understanding the experiences of women after bariatric surgery V1.0	20
16/LO/1242	Predicting outcome from adrenalectomy	29
16/LO/1250	Continuous TAP blocks for major gynaecological surgery	29
16/LO/1252	Analysis of cell-free DNA (cfDNA) in men with elevated PSA levels.	21
16/LO/1585	A4250 in paediatric cholestasis	33
16/LO/1610	Pacing in Heart Failure Study	27
16/LO/1635	Pavlovian influence on behaviours in eating disorders	28
16/LO/1647	Customisation of musculoskeletal shoulder modelling	27
16/LO/1648	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	42
16/LO/1755	Fractyl Laboratories inc REVITA-2 Study C-30000	22
16/LO/1797	Assessment of radiation damaged bone	21
16/LO/1808	Trial of sitagliptin for depressive symptoms in type 2 diabetes	34
16/LO/1824	EnSite Precision 2.0 Registry	28
16/LO/1984	MK-3682 + Ruzasvir for 12 weeks in Subjects with HCV GT1-6 Infection	44
16/LO/1990	Characterising Cognitive Decline	29
16/LO/1992	Hypoglycaemia Awareness Restoration Programme - the RCT v1.0	33
16/LO/2002	Study 4045-301: Phase 3 of SRP-4045 and SRP-4053 in DMD Patients	34
16/LO/2153	Affirm-AHF	28
16/LO/2199	T-PrEP	28
16/LO/2208	Lifebox Project	26
17/LO/0041	CardioMEMS Outside US Study	39
17/LO/0045	Sleep Positional Trainer Research Projects	11
17/LO/0053	Footjacks Flat Orthotic Version 1	40
17/LO/0054	PROSPECTS	35
17/LO/0232	Sunovion CTH-302	26

17/LO/0339	Pembrolizumab/placebo in combination with CRT- locally advanced HNSCC	53
17/LO/0396	Fathers' and health professionals' views of paternal perinatal support	32
17/LO/0398	Self and memory in psychosis	49
17/LO/0423	Realist Evaluation of a CM Intervention for Alcohol Dependence - V.1.	43

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/1577	Portable manometry (Anopress THD): a pilot study	34
17/LO/0171	Understanding the experience of psychosis	35

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/1056	VITTAL Viability testing and transplantation of marginal livers	20

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/1776	TIPSÂ microspheresÂ forÂ perianalÂ fistula	16
16/LO/1812	FANCONI-TAF (FANTA) study	16
16/LO/2196	Post static cold storage normothermic machine liver perfusion	21
17/LO/0219	The young adult cancer patient journey	28

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

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0604	(duplicate) Do Parents Know What Children are Watching? Screen Time.	n/a

17/LO/0459	EG-RPC-04 Safety Evaluation in Peri-orbital Region	n/a
17/LO/0460	EG-RPC-03 Pilot Safety Evaluation in Lips	n/a

Provisional Opinion Pending Consultation with Referee		
REC Reference	**Title**	**Number of Days on Clock**

Further information response not complete		
REC Reference	**Title**	**Number of Days on Clock**

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0183	A study investigating IFNÎ±- Kinoid (IFN-K) in adults	28

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**
16/LO/1232	Markers of Nociception in Chronic Pelvic Pain	8
16/LO/1248	Hand Sensation: What is Normal?	8
16/LO/1391	Comparison of two cleaning methods for Wave One files.	10
16/LO/1603	Objective Assessment of Radiation Induced Skin Fibrosis	12
17/LO/0170	Accu Chek DiaPort PMCF study	10

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0184	Distribution of cell-cell junction proteins in arrhythmic disorders #1	9

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/1410	Maternal obesity and offspring mental health	7
16/LO/2092	Effort test performance in a NHS acquired brain injury sample	7
17/LO/0315	Posterior Fossa ICH – data pooling project	18

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0981	Outcomes following liver surgery for colorectal liver metastases	8
16/LO/0986	Characterising safe walking aid use	10
16/LO/1385	The PodPAD Project	11
16/LO/1579	GSK2862277 anti-drug antibody (ADA) Study	8
16/LO/2100	Does the depth of the cricothyroid membrane correlate with weight? V1	12

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

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

Further information response not complete		
REC Reference	**Title**	**Number of Days on Clock**

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**

Table 10.1: **Breakdown of current status of all substantial amendments reviewed within the reporting period**

Favourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
02-03-033/AM08	Prediction of pre-eclampsia and fetal growth restriction (Version 3)	13 Dated February 2017	17/02/2017	20
06/Q0703/40/AM16	PEG-IFN Â± Lamivudine for chronic HBV infection in children	14	01/09/2016	19
06/Q0703/40/AM17	PEG-IFN Â± Lamivudine for chronic HBV infection in children	15	31/10/2016	13
07/Q0703/24/AM07	Improving outcomes in robotic prostate surgery using AR guidance	7	27/10/2016	25
09/H0808/15/AM04	Non-invasive biomarkers and paediatric NAFLD v1.0	4	08/02/2017	14
09/H0808/98/AM05	Cartiva MOTION Study	Revision E	04/10/2016	28
10/H0808/127/AM02	To determine conjunctival gene expression following glaucoma surgery	2	15/03/2016	6
10/H0808/127/AM03	To determine conjunctival gene expression following glaucoma surgery	3	18/08/2016	5
10/H0808/135/AM10	Psychological risk factors for fatigue in Rheumatoid Arthritis	11	18/10/2016	9
10/H0808/137/AM05	The Gore REDUCE Clinical Study	3	28/11/2016	8
11/LO/1408/AM10	ABSORB II RCT: 10-393	7	30/03/2016	5
11/LO/1453/AM03	AL Amyloidosis Bone Marrow Study	2	30/11/2016	58
12/LO/0588/AM30	MF/F Safety Study in Adolescent and Adult Persistent Asthmatics	23	23/05/2016	10
12/LO/0588/AM33	MF/F Safety Study in Adolescent and Adult Persistent Asthmatics	24	31/08/2016	8
12/LO/0917/AM10	MOVE-IT (Motivational Enhanced Interviewing)	9	01/03/2016	15
12/LO/0990/AM06	EMTICS	6	06/06/2016	26
12/LO/1473/AM07	Cardiovascular function in hypertension	4	05/04/2016	17
12/LO/2017/AM09	Brain Imaging in Babies (BIBS)	8	22/03/2016	5
13/LO/0145/AM07	CLEOPATRA	6	03/08/2016	22
13/LO/0972/AM03	The PEACE Study	3	27/05/2016	14
13/LO/0972/AM04	The PEACE Study	4	11/11/2016	31
13/LO/1424/AM01	Valiant Mona LSA Thoracic Stent Graft Early Feasibility Study	1	27/06/2016	19
13/LO/1468/AM02	Patients perception of anticoagulation therapy	1	09/05/2016	10
13/LO/1475/AM04	CRT in narrow QRS heart failure with MRI dyssynchrony assessment	5.0	02/08/2016	15
13/LO/1542/AM04	Haemodynamic Changes After Percutaneous Aortic Valve Intervention	4	05/04/2016	11
13/LO/1651/AM07	Evaluation of the NSPCC UK Minding the Baby Programme	7	11/01/2017	22
14/LO/0020/AM02	Neurofeedback for Stroke Rehabilitation	3.1	20/11/2015	18
14/LO/0609/AM06	E5501-G000-310 Thrombocytopenia associated with Liver Disease	5	29/04/2016	24
14/LO/0609/AM09	E5501-G000-310 Thrombocytopenia associated with Liver Disease	7	26/10/2016	43
14/LO/0609/AM10	E5501-G000-310 Thrombocytopenia associated with Liver Disease	12	20/04/2016	17

14/LO/0714/AM01	Predictors of off-period distress in Parkinson's Disease	1	03/07/2016	14
14/LO/0775/AM06	Safety study of dCELLÂ® Meniscus Version 01	02	29/03/2016	18
14/LO/0830/AM02	SMART TARGET (Biopsy Study)	001	27/05/2016	12
14/LO/1588/AM05	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	3	08/04/2016	11
14/LO/1588/AM07	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	4	07/07/2016	15
14/LO/1588/AM09	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	7	02/12/2016	5
14/LO/1608/AM07	The GHB Trial	7	06/02/2017	6
14/LO/1615/AM05	Naltrexone Enhanced Addiction Treatment (NEAT)	SA4	11/03/2016	10
14/LO/1966/AM01	SSAT065 Dean Street HIV Cohort Study	1	03/10/2016	28
14/LO/2143/AM03	Cardialen CESS V5	5.7	01/10/2016	11
15/LO/0020/AM06	REVITA-1 study	4	22/04/2016	7
15/LO/0041/AM03	Uptake and implementation of CBT for psychosis: Phase 1	1	06/10/2016	7
15/LO/0047/AM02	Intrinsic PEEP and laryngeal aperture in COPD	AM02	09/08/2016	14
15/LO/0425/AM01	Brain abnormalities in COPD	AM01	12/08/2016	28
15/LO/0436/AM02	The PREDICT Study	001/2016/1902 2016	19/02/2016	24
15/LO/0652/AM03	BMS AI468-038: Phase 2b HIV-1 Maturation Inhibitor study	3	12/07/2016	18
15/LO/0652/AM04	BMS AI468-038: Phase 2b HIV-1 Maturation Inhibitor study	4	10/08/2016	22
15/LO/0652/AM05	BMS AI468-038: Phase 2b HIV-1 Maturation Inhibitor study	1	16/11/2016	21
15/LO/0928/AM02	MitrAl ValvE RepaIr Clinical Trial (MAVERIC Trial)	1	21/09/2016	4
15/LO/0982/AM02	AIRWAY EFFECTS OF TIOTROPIUM IN PATIENTS WITH COPD	2	30/08/2016	12
15/LO/1002/AM01	Tendinopathy: Treatment effects and mechanisms 1 (Tendinopathy TEAM 1)	1	16/12/2016	15
15/LO/1085/AM01	Venus P-Valve study, version A, Jan 2015	1	16/06/2016	17
15/LO/1108/AM02	Stratified medical and technological approaches to managing chronic orofacial pain patients (V1)	1	15/08/2016	22
15/LO/1553/AM03	POST 4	3	28/09/2016	6
15/LO/1640/AM01	SPYRAL HTN-ON MED Study	1	08/03/2016	13
15/LO/1640/AM02	SPYRAL HTN-ON MED Study	2	20/04/2016	12
15/LO/1640/AM03	SPYRAL HTN-ON MED Study	3	23/05/2016	11
15/LO/1640/AM04	SPYRAL HTN-ON MED Study	4	15/09/2016	29
15/LO/1641/AM01	SPYRAL HTN-OFF MED Study	1	08/03/2016	13
15/LO/1641/AM02	SPYRAL HTN-OFF MED Study	2	20/04/2016	12
15/LO/1641/AM03	SPYRAL HTN-OFF MED Study	3	24/05/2016	11
15/LO/1641/AM04	SPYRAL HTN-OFF MED Study	4	15/09/2016	29
15/LO/1700/AM01	Care.Know.Do Pilot: Version 1	1	11/05/2016	25

15/LO/1781/AM01	Is alcohol dependence associated with increased 18F Amyvid binding?	1	15/06/2016	21
15/LO/1950/AM04	A Phase IIb/III study of ABT-414 for newly diagnosed glioblastoma	3	08/03/2016	28
15/LO/1950/AM08	A Phase IIb/III study of ABT-414 for newly diagnosed glioblastoma	4	29/09/2016	17
15/LO/1950/AM14	A Phase IIb/III study of ABT-414 for newly diagnosed glioblastoma	4	07/12/2016	10
15/LO/1974/AM02	Anti-atherogenic effects of anti-platelet agents (Version 1)	3	21/08/2016	15
15/LO/1999/AM01	FATTY LIVER DISEASE IN HIV	1.0	01/06/2016	11
16/LO/0002/AM01	Patient expectations and outcomes of orthodontic treatment	1	10/11/2016	8
16/LO/0026/AM02	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	Protocol Amendment 1	07/03/2016	14
16/LO/0026/AM07	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	1.1	07/04/2016	25
16/LO/0026/AM09	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	2.1	03/11/2016	16
16/LO/0028/AM01	EPOC	1	20/09/2016	4
16/LO/0061/AM02	Executive Dysfunction Partially Underlies Deficits in Theory of Mind	1.1	17/06/2016	7
16/LO/0240/AM03	Prose - CosentyxÂ®/Secukinumab/AIN457	2	28/04/2016	17
16/LO/0284/AM01	VOICE PD Views on inpatient care Version 1	1	08/11/2016	20
16/LO/0414/AM01	Randomised trial of LightPath Imaging in breast cancer surgery	1	26/05/2016	18
16/LO/0414/AM02	Randomised trial of LightPath Imaging in breast cancer surgery	2	12/07/2016	15
16/LO/0436/AM01	APRICOT_V1	2	28/04/2016	7
16/LO/0436/AM02	APRICOT_V1	2	01/09/2016	14
16/LO/0436/AM03	APRICOT_V1	3	05/12/2016	5
16/LO/0441/AM01	Safety & Performance of Shockwave Coronary Rx LithoplastyÂ® System	1	27/05/2016	10
16/LO/0603/AM01	Mild to Moderate Acne Study with IPL (CD3061_FINAL_V2.0)	2.0	08/08/2016	21
16/LO/1025/AM04	The Contraception Continuation Study	1	09/02/2017	20
16/LO/1056/AM01	VITTAL Viability testing and transplantation of marginal livers	1	25/01/2017	19
16/LO/1060/AM01	M14-730 DAA treatment for HCV/HIV Co-infection	3	12/07/2016	27
16/LO/1060/AM04	M14-730 DAA treatment for HCV/HIV Co-infection	3	23/12/2016	31
16/LO/1064/AM02	PHNA study to assess the peripheral immune system in NOT1D pts	1	09/11/2016	28
16/LO/1086/AM01	CNTO136 sirukumab	1.0	07/10/2016	33
16/LO/1086/AM04	CNTO136 sirukumab	3	09/02/2017	27
16/LO/1086/AM05	CNTO136 sirukumab	4	09/02/2017	27
16/LO/1242/AM01	Predicting outcome from adrenalectomy	1	22/11/2016	13
16/LO/1385/AM01	The PodPAD Project	2	22/11/2016	6
16/LO/1635/AM01	Pavlovian influence on behaviours in eating disorders	1	16/01/2017	15
16/LO/1648/AM02	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	2	13/01/2017	19
16/LO/1755/AM01	Fractyl Laboratories inc REVITA-2 Study C-30000	1	08/01/2017	14

16/LO/1776/AM01	TIPSÂ microspheresÂ forÂ perianalÂ fistula	1	19/12/2016	23
16/LO/1984/AM01	MK-3682 + Ruzasvir for 12 weeks in Subjects with HCV GT1-6 Infection	1	11/01/2017	15
16/LO/1984/AM02	MK-3682 + Ruzasvir for 12 weeks in Subjects with HCV GT1-6 Infection	2	15/02/2017	21
16/LO/1984/AM03	MK-3682 + Ruzasvir for 12 weeks in Subjects with HCV GT1-6 Infection	3	01/03/2017	15
16/LO/1990/AM01	Characterising Cognitive Decline	1	29/11/2016	13

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

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

Favourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Unfavourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

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

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
11/LO/1453/AM03	AL Amyloidosis Bone Marrow Study	2	30/11/2016	58
14/LO/0609/AM09	E5501-G000-310 Thrombocytopenia associated with Liver Disease	7	26/10/2016	43

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