

**South East Coast - Brighton & Sussex Research
Ethics Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	South East Coast - Brighton & Sussex Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Research Involving Adults Lacking Capacity, Research Involving Children
Chair:	Dr Simon Walton
Vice-Chair:	Dr John Bull
Alternate Vice-Chair:	Mr Maurice Marchant
REC Manager:	Miss Kirstie Shearman Ms Alison O’Kane (until August 2015)
REC Assistant:	Mr Ian Braddick Mr Ali Hussain (from April 2015 to August 2015) Mr Claude Beckles (until April 2015)
Committee Address:	Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

Brighton and Sussex REC has continued to provide quality ethical review for many different types of study over the last year. We have been fortunate in gaining this year Ruth Stirton, Tom Levett and Philippa Case as new members for the committee. We are also very fortunate in having Kirstie Shearman appointed as our new REC manager and thank her and Ian Braddick for the help they have provided. The vice chairs John Bull and Maurice Marchant have worked unstintingly to review the numerous substantial amendments and safety reports we have received over the year.

South East Coast - Brighton & Sussex Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Jill Adams	GP	Expert	01/03/2011	
Dr Duncan Angus	Consultant Psychiatrist	Expert	Full REC Member Appointment Dates: 25/09/2016 Deputy REC Member Appointment Dates: 01/03/2011 – 24/09/2016	
Dr John Bull	Consultant Physician (retired)	Expert	01/03/2011	
Miss Philippa Case	Lead Clinical Studies Officer	Expert	15/11/2015	
Mr Gerard Cronin	Business Development Manager	Lay Plus	01/03/2011	
Mrs Janine Hobbs	Retired Civil Servant	Lay Plus	01/07/2014	
Mr Bill Kent	Retired Civil Servant	Lay Plus	01/03/2011	
Dr Tom Levett	Clinical Research Fellow	Expert	15/11/2015	
Mr Maurice Marchant	Public Health Information Specialist (retired)	Lay Plus	01/03/2011	
Mrs Carrie Ridley	Clinical Research Nurse (Emergency Medicine)	Expert	01/07/2014	
Dr Paul Seddon	Consultant Paediatrician	Expert	01/05/2011	
Dr Ruth Stirton	Academic Lawyer	Lay Plus	15/08/2015	
Mrs Kathy Stott	Pharmacist	Expert	01/03/2011	
Dr Simon Walton	Consultant in Anaesthesia and Intensive Care	Expert	01/03/2011	
Mrs Susan Waton	School Librarian	Lay Plus	01/03/2011	
Dr Stuart White	Consultant Anaesthetist	Expert	01/03/2011	

South East Coast - Brighton & Sussex Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Dr Duncan Angus	Consultant Psychiatrist	Expert	05/11/2015
Miss Samantha Lippett	Lead Microbial Pharmacist	Expert	06/08/2015
Miss Samantha Lippett	Lead Microbial Pharmacist	Expert	04/06/2015
Ms Nicola Mason	Specialist Midwife - Practice Development	Expert	04/06/2015
Ms Nicola Mason	Specialist Midwife -	Expert	03/12/2015

	Practice Development		
Ms Nicola Mason	Specialist Midwife - Practice Development	Expert	09/04/2015

South East Coast - Brighton & Sussex Research Ethics Committee : Co-opted

Name	Profession	Status	Meeting date attended
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	09/04/2015
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	06/08/2015

South East Coast - Brighton & Sussex Research Ethics Committee : Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Jill Adams	GP for a practice affiliated to CRN and recruiting patients for research studies.	04/02/2016
Dr Duncan Angus	No interests declared	31/03/2016
Dr John Bull	Chair of the Individual Funding Review Panel Coastal Sussex CCG	04/02/2016
Miss Philippa Case	R&D Manager at Sussex Partnership NHS Foundation Trust.	29/11/2015
Miss Philippa Case	R&D Manager at Sussex Partnership NHS Foundation Trust.	04/02/2016
Mr Gerard Cronin	None	04/02/2016
Mrs Janine Hobbs	None	04/02/2016
Mr Bill Kent	Secretary of registered charity (reMEMber) which supports research into ME (Chronic Fatigue Syndrome)	31/03/2016
Dr Tom Levett	Sits on the BSUH NHS Trust sponsorship Committee. Involved in study review prior to sponsorship being granted.	30/11/2015
Dr Tom Levett	Sits on the BSUH NHS Trust sponsorship Committee. Involved in study review prior to sponsorship being granted. Clinical Research Fellow at BSUH.	04/02/2016
Mr Maurice Marchant	Committee Member of the Royal Statistical Society. Primary Health Care Special Interest Group.	04/02/2016
Ms Nicola Mason	Periodic reviewer for the NIHR Health Technology assessment programme. This is a voluntary position. If one of the studies previously reviewed came to the REC this would be declared as a conflict of interest. The chances of this happening are rare.	30/03/2016
Mrs Carrie Ridley	Senior Research Nurse at BSUH NHS Trust	04/03/2016
Dr Ruth Stirton	None	04/02/2016
Mrs Kathy Stott	None	04/02/2016
Dr Simon Walton	No interested declared.	24/03/2016
Dr Stuart White	Represents the AABI at the National Institute of Academic Anaesthesia Grants Committee. National Hip Fracture Database Research Priority Committee.	04/02/2016

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

Month	Date	Number of Members Present at Meeting
April	09/04/2015	8
June	04/06/2015	11
July	02/07/2015	8
August	06/08/2015	8
September	03/09/2015	8
October	01/10/2015	10
November	05/11/2015	9
December	03/12/2015	9
February	04/02/2016	14
March	03/03/2016	8

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	28/04/2015	3
May	26/05/2015	3
June	23/06/2015	3
July	28/07/2015	3
August	25/08/2015	3
September	22/09/2015	3
October	27/10/2015	3
November	24/11/2015	3
December	15/12/2015	3
January	19/01/2016	3
February	16/02/2016	3
March	22/03/2016	3

12 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	03/04/2015	2
April	17/04/2015	2
April	20/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	26/06/2015	2

July	10/07/2015	2
July	24/07/2015	2
July	28/07/2015	3
August	07/08/2015	2
August	07/08/2015	2
September	04/09/2015	2
September	20/09/2015	2
October	02/10/2015	2
October	05/10/2015	2
October	16/10/2015	2
November	13/11/2015	2
December	11/12/2015	2
December	21/12/2015	2
January	20/01/2016	3
January	30/01/2016	2
February	20/02/2016	3
March	11/03/2016	2

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

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

Name	Number of Meetings Attended
Dr Jill Adams	6
Dr Duncan Angus	3
Dr John Bull	10
Miss Philippa Case	2
Mr Gerard Cronin	9
Mrs Janine Hobbs	8
Mr Bill Kent	9
Dr Tom Levett	3
Miss Samantha Lippett	2
Mr Maurice Marchant	8
Ms Nicola Mason	3
Mrs Carrie Ridley	8
Dr Ruth Stirton	2
Mrs Kathy Stott	6
Dr Simon Walton	5
Mrs Susan Waton	1
Dr Stuart White	6

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

Name	Number of Meetings Attended
Dr Jill Adams	2
Dr Duncan Angus	1
Dr John Bull	7
Mr Gerard Cronin	3
Mrs Janine Hobbs	2
Mr Bill Kent	4
Miss Samantha Lippett	2
Mr Maurice Marchant	5
Ms Nicola Mason	1
Mrs Carrie Ridley	2
Mrs Kathy Stott	1
Dr Simon Walton	4
Dr Stuart White	2

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

Name	Number of Meetings Attended
Dr John Bull	15
Miss Philippa Case	1
Mr Gerard Cronin	1
Mrs Janine Hobbs	1
Mr Bill Kent	2
Miss Samantha Lippett	1
Mr Maurice Marchant	10
Ms Nicola Mason	1
Dr Ruth Stirton	1
Mrs Kathy Stott	1
Dr Simon Walton	19

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Jill Adams	01/01/2016	GDP e-Learning Update
Dr Duncan Angus	13/04/2015	interactions between, and applications of Mental Capacity Act, Mental Health Act and Deprivation of Liberty Safeguards in light of amendments to Mental Health Act and New Code of Practice.
Dr Duncan Angus	09/03/2016	Complex Trait Genetics conference
Dr John Bull	31/03/2016	Mentoring Lay Committee Member
Miss Philippa Case	10/03/2016	Members' Induction
Mr Gerard Cronin	04/12/2015	Local Training Day - Paediatric Studies and Statistics
Mr Bill Kent	26/11/2015	London REC Members' Training Day
Dr Tom Levett	10/03/2016	Members' Induction
Mr Maurice Marchant	26/11/2015	London REC Members' Training Day
Mrs Carrie Ridley	01/09/2015	Teaching Research Ethics on Advanced Research Nursing course
Mrs Carrie Ridley	02/03/2016	Teaching Research Ethics on NIHR Fundamentals to new research nurses
Mrs Kathy Stott	31/03/2016	Good Research Practice
Mrs Kathy Stott	31/03/2016	Research and Human Tissue Legislation
Mrs Kathy Stott	31/03/2016	Adults unable to consent for themselves
Dr Simon Walton	19/05/2015	Chairs' NREAP Meeting
Dr Simon Walton	02/11/2015	Chairs' NREAP Meeting
Dr Stuart White	30/08/2015	Read 'Bad Pharma'
Dr Stuart White	31/12/2015	Read 'Big Data ethics' via Big Data and Society website
Ms Nicola Mason	02/10/2015	Expert Review of the Health Technology Assessment (HTA)

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	15	31.25
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	33	68.75
Total Applications Reviewed	48	100

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

Number of applications made invalid by the REC Manager	5
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	6
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	0
Number of qualitative applications reviewed	5

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	0	0.00
Favourable Opinion with Additional Conditions	10	20.83
Unfavourable Opinion	10	20.83
Provisional Opinion	28	58.33
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	48	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	26	54.17
Further Information Favourable Opinion with Additional Conditions	2	4.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	10	20.83
Unfavourable Opinion	10	20.83
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	48	100

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

Total Applications Reviewed	25
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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	7
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	5	20.00
Favourable Opinion with Additional Conditions	5	20.00
No Opinion transfer to full committee for review	5	20.00
Provisional Opinion	9	36.00
Unfavourable Opinion	1	4.00
Total	25	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	4.80
Number of completed applications for full ethical review	48
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	6
Number of completed applications over 40 days as a % of total	12.50%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 14 days	4
Number of completed proportionate review applications over 14 days as a % of total	20.00%
Number of SSAs (non-Phase 1) reviewed	1
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	72
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	15
Number of completed substantial amendments over 28 days as a % of total substantial amendments	20.83%
Number of modified amendments reviewed	6
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 minor amendments received	59
Number of substantial amendments received for	1

information	
Number of substantial amendments received for new sites/PIs	16
Number of annual progress reports received	47
Number of safety reports received	29
Number of Serious Adverse Events received	1
Number of final reports received	21

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
15/LO/0560	Memory, language and complex thinking skills	52
15/LO/0981	DIPSS Asthma: Development of an asthma home management website	36
15/LO/0990	Clementia 201	26
15/LO/1035	The MASCOT Post Marketing Registry	28
15/LO/1114	The lived experiences of fear of falling in the elderly patient:	32
15/LO/1151	IXORAS S: Ixekizumab in Plaque Psoriasis	25
15/LO/1153	IPI-145 with rituxumab or obinutuzumab in subjects with untreated FL	33
15/LO/1163	1717 - Phase 3b switch study with F/TAF in HIV-1 infected subjects	55
15/LO/1219	Repeat Detentions Under Section 136: Views on "Breaking the Cycle"	47
15/LO/1249	Observational study looking at management of skin infection	20
15/LO/1289	VOYAGER PAD	43
15/LO/1380	ADAPTeM	29
15/LO/1573	An evaluation of an adapted STEPPS group within Forensic Services	26
15/LO/1599	REMAP-AF 1.0	57
15/LO/1654	Targeted energy-repletion as a novel treatment for non-ischaemic CM	31
15/LO/1666	Effect of OC459 on the response to rhinovirus challenge in asthma	35
15/LO/1669	Clementia 202	31
15/LO/1887	The AVICCI study	23
15/LO/1892	EBC MAIN Version 2.0 dated of September 22, 2015	29
15/LO/2084	Crossover Evaluation of Eye Drops in Symptomatic Contact Lens Wearers	36
15/LO/2087	Sulcus Anatomy using ultrasound biomicroscopy	29
15/LO/2092	Developing a symptom list for children with cancer	31
15/LO/2106	ABC-ONE (Version 1): Trial of BRS use in coronary bifurcation	36
16/LO/0176	Self-perceptions of emotion regulation in people with anorexia nervosa	27
16/LO/0199	Helping Families Pilot RCT V3	26
16/LO/0338	IMerge Imetelstat in Myelodysplastic syndrome (MDS)	31

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/1324	AMPLATZERâ„¢ Amuletâ„¢ Observational Post-Market Study	46

15/LO/2066	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	29
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Further Information Unfavourable Opinion

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

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

REC Reference	Title	Number of Days on Clock
15/LO/0632	Approaching childbirth aged 35 years and above	20
15/LO/1018	OPTIMUM Trial	20
15/LO/1302	OCTOPUS	22
15/LO/1446	1970 British Cohort Study: 2016-17 Survey	19
15/LO/1907	Minocycline and Depression (MINDEP) study	23
15/LO/1910	AMOUR	25
15/LO/2117	Body composition in pre-pubertal children with cystic fibrosis v1	25
16/LO/0206	Psychosocial & Demographic Sexual Health Survey v1	21
16/LO/0212	Collaborative Rehabilitation Environments in Acute Stroke (CREATE)	21
16/LO/0372	Scar study	26

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/0640	ADAPTeM	28
15/LO/1001	Patient Reported Outcomes - patients and caregivers (PROACT)	31
15/LO/1276	An evaluation of a service for treating Body Dysmorphic Disorder	22
15/LO/1381	Exercise and Training responses	19
15/LO/1627	Evaluation of the Compass Outreach Service	25
15/LO/1900	Pilot Study to Investigate Response to HRV Challenge in Asthmatics	22
16/LO/0142	The CAPAPAF Study	21
16/LO/0202	Confirmation of pathological complete response (pCR) pre-operatively	26

16/LO/0331	Low-intensity internet delivered cognitive behaviour therapy (iCBT)	27
16/LO/0425	The CAPAPAF Study	22

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0835	Cognitive Mechanisms of a Brief Intervention to Reduce Heavy Drinking	16
15/LO/0836	A non-invasive diagnostic indicator for Hepatocellular carcinoma	15
15/LO/1526	Obs study Patients on Fixed Dose Combination Inhaler for Asthma & COPD	12
15/LO/1696	Macular Hole Imaging by AO-SLO (version 1.0)	14
15/LO/1702	Multiple Rib Fractures	13
15/LO/2191	Rational Prescribing for Children v.1.0	18
16/LO/0201	PERSIST	13
16/LO/0564	Dementia (Post Diagnostic) Digital Platform	18

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/LO/1523	Field testing of an app for exercises after breast cancer surgery	13

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/1026	Return to sport following anterior cruciate ligament reconstruction	11
15/LO/2088	Low platelet blood study	12
16/LO/0193	Molecular studies on gynaecological tumours	7
16/LO/0559	Effective medical care in wound healing. Version 3	13
16/LO/0563	Causes of Breast Tissue Marker Malposition	12

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/1358	MEASUREMENT OF MOTION IN THE IPJ OF THE THUMB WITH PHOTOGRAPHY	10
15/LO/1359	Perceptions of admissions for enteral tube related issues	10
15/LO/2102	Lutonix Global BTK Registry - CL0024-01_v1-04Aug2015	13
15/LO/2103	MRI mapping of intra-abdominal movement in health	14
16/LO/0353	Does pharmacist intervention improve prescribing and pain control?	14

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/LO/1363	Thought suppression and anxiety in treatment-refractory depression: V1	10

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
07/Q1907/52/AM12	MINDACT - EORTC 10041 BIG 3-04 Intergroup Study	11	21/01/2015	17
08/H1107/58/AM16	Phase II study of DAST in metastatic renal cell cancer Version 3.0	Amendment 8 (UK Only), Version	08/09/2015	23
08/H1107/58/AM17	Phase II study of DAST in metastatic renal cell cancer Version 3.0	Substantial Amendment #16	15/12/2015	31
08/H1107/58/AM18	Phase II study of DAST in metastatic renal cell cancer Version 3.0	Substantial Amendment #17	10/02/2016	27
09/H1107/103/AM14	Lenalidomide vs Chlorambucil in patients with B-Cell CLL	18	14/04/2015	20
10/H1107/59/AM17	035 Continuation study	AM17	13/11/2015	14
11/LO/0421/AM01	Immune responses in chronic viral hepatitis	Amendment 2	29/12/2015	28
11/LO/0958/AM06	FAST-Forward	Substantial Amendment 4	21/07/2015	30
11/LO/1588/AM10	MARCH study	Amendment 7.0	28/05/2015	25
12/LO/0635/AM06	Cellular and protein markers of prodromal Alzheimer's Disease	7	15/01/2016	6
12/LO/0830/AM02	Functional imaging of bone metastases in prostate cancer	2	17/09/2015	9
12/LO/1084/AM14	VX12-770-112 Phase 3 rollover study of ivacaftor in CF patients 6yrs+	Ivacaftor Investigator's Broch	06/08/2015	26
12/LO/1383/AM02	Innovation study	Protocol (UK) Version 5.0 22Oc	24/04/2015	15
12/LO/1942/AM08	Joint Hypermobility	Amendment 7 06/02/2015 (our re	06/03/2015	17
12/LO/1981/AM11	Study of T-DM1 vs Herceptin, post surgery for HER2+ Breast Cancer	SA #09 (Protocol V6)	11/01/2016	7
13/LO/0411/AM05	BMRI- CAM 1	AM04	06/08/2015	12
13/LO/0411/AM06	BMRI- CAM 1	Amendment 5	26/11/2015	14
13/LO/0422/AM05	ICG clearance in patients randomised to FOLFOX or FOLFIRI	4	11/12/2015	7
13/LO/0740/AM10	A5481008	Substantial	30/03/2015	23

		Amendment #6, 30 M		
13/LO/0740/AM11	A5481008	1	20/05/2015	33
13/LO/0740/AM17	A5481008	Substantial Amendment #8	27/01/2016	13
13/LO/0801/AM11	Dapagliflozin Effect on Cardiovascular Events	6	05/02/2016	27
13/LO/0801/AM12	Dapagliflozin Effect on Cardiovascular Events	AM07	16/02/2016	29
13/LO/1029/AM02	HIV Bioresource	00220/ 03/2015	20/03/2015	24
13/LO/1082/AM03	RINCAL Trial	5	09/07/2015	18
13/LO/1082/AM04	RINCAL Trial	AM08	29/10/2015	16
13/LO/1302/AM09	Dolutegravir/abacavir/lamivudine vs a standard HIV regimen in females	Substantial Amendment 7	04/05/2015	16
13/LO/1528/AM02	Quality of Life in Survivors of Out of Hospital Cardiac Arrest V1	Amendment number 2 03.03.2015	26/03/2015	21
13/LO/1866/AM05	Cardiac Control of Fear in Brain: relationship to anxiety symptoms	Amendment 4	21/07/2015	15
14/LO/0382/AM02	Effects of shoes in individuals with intermittent claudication	2	18/07/2015	25
14/LO/0438/AM06	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	A_03	21/08/2015	9
14/LO/0438/AM07	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	AM04	05/10/2015	7
14/LO/0669/AM01	PT in PAH	1	06/05/2015	34
14/LO/0753/AM01	Mechanisms of Primary Lymphoedema	1	14/05/2015	27
14/LO/0866/AM03	Evaluating Xilonox in Symptomatic Colo-Rectal Cancer	2014-PT026 version 1.0	24/04/2015	25
14/LO/1025/AM01	Complement mediated allograft nephropathy - version 1	1	22/05/2015	31
14/LO/1312/AM03	The Pregnancy Physiology Pattern Prediction Study (4P)	1	11/04/2015	18
14/LO/1312/AM04	The Pregnancy Physiology Pattern Prediction Study (4P)	AM02	22/09/2015	18
14/LO/1381/AM02	Reformulated raltegravir q.d. (1200 mg) versus raltegravir b.i.d. (400 mg) in ART-na ⁺ ve pts	SA02	27/04/2015	10
14/LO/1381/AM03	Reformulated raltegravir q.d. (1200 mg) versus raltegravir b.i.d. (400 mg) in ART-na ⁺ ve pts	AM03	25/08/2015	6
14/LO/1564/AM04	PANDA	PANDA 02 2015/04/13 (our	13/04/2015	15

		ref:		
14/LO/1564/AM06	PANDA	Am03	03/06/2015	34
15/LO/0402/AM06	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	Amendment 1 (Revised)	21/08/2015	34
15/LO/0402/AM09	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	AM02 - Protocol Amendment 2	15/09/2015	27
15/LO/0418/AM01	Light Therapy: An Exploratory Trial	Amendment 1	03/02/2016	26
15/LO/0632/AM01	Approaching childbirth aged 35 years and above	1	24/04/2015	13
15/LO/0632/AM02	Approaching childbirth aged 35 years and above	Amendment number 2	27/11/2015	11
15/LO/0981/AM01	DIPSS Asthma: Development of an asthma home management website	1, 25/1/16	25/01/2016	11
15/LO/0990/AM03	Clementia 201	Additional/Updated Patient lte	21/01/2016	17
15/LO/1018/AM02	OPTIMUM Trial	SA01	22/06/2015	34
15/LO/1018/AM06	OPTIMUM Trial	AM02	18/11/2015	8
15/LO/1151/AM01	IXORAS S: Ixekizumab in Plaque Psoriasis	2	25/08/2015	14
15/LO/1153/AM04	IPI-145 with rituxumab or obinutuzumab in subjects with untreated FL	2.0	22/10/2015	11
15/LO/1163/AM03	1717 - Phase 3b switch study with F/TAF in HIV-1 infected subjects	AM01	26/11/2015	33
15/LO/1163/AM04	1717 - Phase 3b switch study with F/TAF in HIV-1 infected subjects	1, Patient Recruitment Materia	11/03/2016	7
15/LO/1289/AM03	VOYAGER PAD	AM03	11/12/2015	27
15/LO/1289/AM04	VOYAGER PAD	Substantial Amendment 4: Site	26/01/2016	6
15/LO/1380/AM01	ADAPTeM	AM01	18/11/2015	18
15/LO/1887/AM01	The AVICCI study	AM02	27/11/2015	19
15/LO/1887/AM02	The AVICCI study	2.1	15/01/2016	6
15/LO/1910/AM01	AMOUR	SA1	21/12/2015	7
15/LO/2066/AM02	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	1.0	28/01/2016	15

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H1101/69/AM06	Non-invasive physiological biomarkers in health and disease	version 8	30/04/2015	27
10/H1101/69/AM07	Non-invasive physiological biomarkers in health and disease	AM08	01/10/2015	34
12/LO/0635/AM05	Cellular and protein markers of prodromal Alzheimer's Disease	AM05	16/10/2015	32
13/LO/0422/AM03	ICG clearance in patients randomised to FOLFOX or FOLFIRI	1 (3.6)	21/07/2015	28
13/LO/1108/AM02	UPBEAT TEMPO	AM02	17/11/2015	34
13/LO/1115/AM07	PIVOTAL	05	29/06/2015	31
13/LO/1261/AM03	DECAN Study	Amendment 3, 21/1/15 (our ref:	18/03/2015	21
13/LO/1261/AM04	DECAN Study	AM04	05/11/2015	22
14/LO/0438/AM05	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	A_02	28/04/2015	24
15/LO/0990/AM01	Clementia 201	Sub Amendment 6, 29th May 2015	14/08/2015	35

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
12/LO/0635/AM05/1	Cellular and protein markers of prodromal Alzheimer's Disease	AM06	17/11/2015	0
13/LO/0422/AM03/1	ICG clearance in patients randomised to FOLFOX or FOLFIRI	3.8 (modified)	21/07/2015	13
13/LO/1115/AM07/1	PIVOTAL	AM05 modified	21/09/2015	13
13/LO/1261/AM04/1	DECAN Study	4	24/12/2015	4
14/LO/0438/AM05/1	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	A_02 (modified)	28/04/2015	13
	Clementia 201	AM06 - Modified	29/05/2015	7

15/LO/0990/AM01/1				
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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
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/0835	Cognitive Mechanisms of a Brief Intervention to Reduce Heavy Drinking	16
15/LO/0836	A non-invasive diagnostic indicator for Hepatocellular carcinoma	15
15/LO/2191	Rational Prescribing for Children v.1.0	18
16/LO/0564	Dementia (Post Diagnostic) Digital Platform	18

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
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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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