

**London - Brighton & Sussex Research Ethics  
Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Brighton & Sussex Research Ethics Committee
<b>Type of REC:</b>	Recognised to review CTIMPs in patients – type iii
<b>Type of Flag:</b>	Research Involving Children Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Simon Walton
<b>Vice-Chair:</b>	Dr John Bull
<b>Alternate Vice-Chair:</b>	Mrs Carrie Ridley
<b>REC Manager:</b>	Miss Nicole Curtis
<b>REC Assistant:</b>	Mr Jake Chambers
<b>Committee Address:</b>	Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH
<b>Telephone:</b>	02071048129
<b>Email:</b>	NRESCcommittee.SECOast-BrightonandSussex@nhs.net

## Chair's overview of the past year:

Brighton and Sussex REC has continued to provide quality ethical review for many different types of study and is flagged to receive studies involving adults who lack capacity and studies involving children. Meetings have been well attended by members who have put a lot of hard effort in to attending meetings and participating in the sub-committee work. We were sad to lose Miss Philippa Case and Miss Samantha Lippett and we are grateful for the help and support they have provided to the committee. We also welcomed a new appointment Dr Caroline Garrett and are very grateful for the expertise she brings to the committee. Also in this period Maurice Marchant stepped down from his role as alternate Vice-Chair and we thank him for all his hard work he has unstintingly done in this role. He was replaced by one of our members Carrie Ridley and with John Bull they have been invaluable in supporting the Chair and the Committee by chairing meetings, PR studies and other subcommittees. This year Nicole Curtis was appointed as the Committee's new REC manager and she has been excellent in her new role and we look forward to working with her in the future.

## London - Brighton & Sussex Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Duncan Angus	Consultant Psychiatrist	Expert	01/03/2011	
Dr John Bull	Consultant Physician (retired)	Expert	01/03/2011	
Miss Philippa Case	Mental Health Nurse	Expert	15/11/2015	30/05/2017
Mr Gerard Cronin	Business Development Manager	Lay Plus	01/03/2011	
Dr Caroline Garrett	Human Tissue Governance Manager and Research Fellow	Lay	01/12/2017	
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	Consultant Geriatrician	Expert	15/11/2015	
Mr Maurice Marchant	Public Health Information Specialist (retired)	Lay Plus	01/03/2011	
Dr Nicola Mason	Consultant Midwife	Expert	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	
Dr Stuart White	Consultant Anaesthetist	Expert	01/03/2011	

## London - Brighton & Sussex Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Miss Samantha Lippett	Lead Microbial Pharmacist	Expert	06/04/2017

## London - Brighton & Sussex Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Retired Civil Servant	Lay Plus	01/06/2017, 02/11/2017

**London - Brighton & Sussex Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Duncan Angus	None declared	31/03/2018
Dr John Bull	Governor Western Sussex Hospitals. Individual Funding panel Coastal West Sussex CCG.	20/03/2018
Mr Gerard Cronin	No Interests declared	23/03/2018
Dr Caroline Garrett	As a part time research fellow and working in a research-active institution, there may be times when I am a co-applicant on a research proposal submitted to the research ethics service however, any such proposal will not be reviewed by the Brighton & Sussex REC	21/12/2017
Mrs Janine Hobbs	No declared interests	21/03/2018
Mr Bill Kent	Secretary of a Charity (reMEMber) which might become involved in the conduct of research	21/03/2018
Dr Tom Levett	Senior Lecturer at Brighton and Sussex Medical School. Sit on the Protocol review panel of Brighton & Sussex University Hospitals	28/03/2018
Mr Maurice Marchant	No declared interests	31/03/2018
Dr Nicola Mason	None	31/03/2018
Mrs Carrie Ridley	Senior Research Nurse (Acute team leader) Brighton and Sussex University Hospitals NHS Trust	23/03/2018
Dr Paul Seddon	Research Lead for Division 3 (Haematology, Genetics, Children and Reproductive health & Childbirth), Kent Surrey & Sussex NIHR Clinical Research Network.	31/03/2018
Dr Paul Seddon	I took retirement from the NHS in Feb 2018 but have returned to the same post in a part-time role on a new contract.	31/03/2018
Dr Ruth Stirton	No declared interests	27/03/2018
Mrs Kathy Stott	None Declared.	31/03/2018
Dr Simon Walton	Legal and General ISA Unit trust (FTSE 100 tracker)	31/03/2018
Dr Stuart White	Lecturer, Overcoming Multiple Sclerosis charity. Associate of Anaesthetists: National Audit co-ordinator; Working Parties on Consent, the Elderly and Dementia; Editor, Anaesthesia, National Institute of Academic Anaesthesia: Research and Grants Committee; HSRC Research Strategy Committee. Fragility Fractures Network: Research Special Interest Group, Anaesthesia Special Interest Group. Research and Audit Federation of Trainees: President, SEARCH. National Hip Fracture Database: Scientific and Publications Committee. Local Investigator: SNAP-2, HipHOP, ASCRIBED, HipAttack, WHITE .	31/03/2018

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

Month	Date	Number of Members Present at Meeting
April	06/04/2017	12
June	01/06/2017	10
July	06/07/2017	12
August	03/08/2017	10
September	07/09/2017	9
November	02/11/2017	8
December	07/12/2017	10
February	01/02/2018	10
March	01/03/2018	9

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	18/04/2017	6
May	16/05/2017	3
June	20/06/2017	3
July	18/07/2017	3
August	15/08/2017	3
October	18/10/2017	3
March	21/03/2018	3

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

### Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	14/04/2017	3
April	28/04/2017	3
May	15/05/2017	2
May	31/05/2017	2
June	15/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	31/07/2017	2
August	15/08/2017	2
August	31/08/2017	2
September	15/09/2017	2
September	29/09/2017	2
October	15/10/2017	2
October	31/10/2017	2
November	15/11/2017	2

November	30/11/2017	2
December	15/12/2017	2
December	31/12/2017	2
January	15/01/2018	2
January	31/01/2018	2
February	14/02/2018	2
February	28/02/2018	2
February	28/02/2018	2
March	15/03/2018	2
March	31/03/2018	2

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

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

None.

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

Name	Number of Meetings Attended
Dr Duncan Angus	5
Dr John Bull	8
Miss Philippa Case	3
Mr Gerard Cronin	8
Dr Caroline Garrett	2
Mrs Janine Hobbs	5
Mr Bill Kent	8
Dr Tom Levett	5
Miss Samantha Lippett	1
Mr Maurice Marchant	8
Dr Nicola Mason	4
Mrs Carrie Ridley	5
Dr Paul Seddon	5
Dr Ruth Stirton	6
Mrs Kathy Stott	4
Dr Simon Walton	5
Dr Stuart White	6

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

Name	Number of Meetings Attended
Dr John Bull	5
Miss Philippa Case	1
Mr Gerard Cronin	4
Mrs Janine Hobbs	1
Mr Bill Kent	1
Dr Tom Levett	1
Miss Samantha Lippett	1
Mr Maurice Marchant	2
Dr Nicola Mason	2
Mrs Carrie Ridley	2
Dr Paul Seddon	1
Dr Simon Walton	2
Dr Stuart White	1

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



<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Duncan Angus	2
Dr John Bull	13
Miss Philippa Case	1
Mr Gerard Cronin	3
Mrs Janine Hobbs	4
Mr Bill Kent	4
Dr Tom Levett	2
Mr Maurice Marchant	3
Mrs Carrie Ridley	4
Dr Ruth Stirton	2
Mrs Kathy Stott	3
Dr Simon Walton	11

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Duncan Angus	17/07/2017	Safeguarding Adults Level 2
Dr Duncan Angus	17/07/2017	Safeguarding Children Level 3 Core
Dr Duncan Angus	08/03/2018	London REC Members Training Day
Dr John Bull	08/03/2018	London REC Members Training Day
Mr Gerard Cronin	27/03/2018	GCP related to Primary Care
Dr Caroline Garrett	11/01/2018	Online Induction for new Research Ethics Committee members
Dr Caroline Garrett	29/01/2018	Online E&D Training
Mr Maurice Marchant	08/03/2018	London REC Members Training Day
Mr Maurice Marchant	09/03/2018	Online E&D Training
Dr Nicola Mason	28/02/2018	Level 3 Safeguarding Training and Competency Assessment (ESHT)
Dr Nicola Mason	15/03/2018	Surrogacy Seminar as part of national Consultant Midwife Forum
Mrs Carrie Ridley	17/10/2017	REC Chair's Training
Dr Paul Seddon	08/03/2018	London REC Members Training Day
Mrs Kathy Stott	03/04/2017	Equality & Diversity Training
Dr Simon Walton	08/03/2018	London REC Members Training Day
Dr Stuart White	01/04/2017	Active participation as Clinical Investigator on HipHOP study of inoperative blood pressure control and delirium in elderly hip fracture patients
Dr Stuart White	01/04/2017	Active participation as Clinical Investigator on ASCRIBED study of CSF markers of delirium in elderly hip fracture patients
Dr Stuart White	01/04/2017	Active participation as Clinical Investigator on RiiO study of thermoregulation in elderly hip fracture patients
Dr Stuart White	01/04/2017	Co-Chair, AAGBI guidelines on Surgery for patients with dementia
Dr Stuart White	31/05/2017	Equality & Diversity 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	13	33.33
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	26	66.67
<b>Total Applications Reviewed</b>	<b>39</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	3
Number of applications withdrawn prior to the meeting	4
Number of student applications reviewed	11
Number of paediatric applications reviewed	5
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
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**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	2.56
Favourable Opinion with Additional Conditions	5	12.82
Unfavourable Opinion	1	2.56
Provisional Opinion	32	82.05
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>39</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	28	71.79
Further Information Favourable Opinion with Additional Conditions	3	7.69
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.56
Favourable Opinion with Additional Conditions	5	12.82
Unfavourable Opinion	1	2.56
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	1	2.56
<b>Total</b>	<b>39</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>19</b>
------------------------------------	-----------

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

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of qualitative applications reviewed	7

**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	0	0.00
Favourable Opinion with Additional Conditions	1	5.26
No Opinion transfer to full committee for review	8	42.11
Provisional Opinion	10	52.63
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>19</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.33
<b>Number of completed applications for full ethical review</b>	38
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of completed proportionate review applications for ethical review</b>	11
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	3
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	27.27%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	86
<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 modified amendments reviewed</b>	1
<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>	72
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	13
<b>Number of annual progress reports received</b>	56
<b>Number of safety reports received</b>	51
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	6

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0463	SINE Study	29
17/LO/0592	CENTAUR Rollover study	45
17/LO/0845	Mechanisms of Chronic Pain and Fatigue	32
17/LO/0943	The acceptability of wearing activity monitors in people with dementia	28
17/LO/0944	Reata - 402-C-1302 - Pulmonary Hypertension	32
17/LO/0945	SLiPS study (Study of Liraglutide on decreasing Parenteral Support)	25
17/LO/1070	Investigation of Thermal Injury and Intestinal Permeability	55
17/LO/1116	SKIPPAIN ( SecuKinumab-Induced relief from Pain in AxSpA)	40
17/LO/1240	CN001016: Phase 2/3 Study of BMS-986089 in Ambulatory Boys with DMD	35
17/LO/1289	A Phase 2b Ublituximab, TGR-1202, Bendamustine in NHL patients	26
17/LO/1302	Investigating attention patterns in young people with anxiety	29
17/LO/1310	Paediatric cuffed tube study	38
17/LO/1363	SCOPE II	39
17/LO/1461	Study to understand if a vaccine can prevent flare ups of your COPD	29
17/LO/1511	Efficacy & safety of Olaparib in Castration-Resistant Prostate Cancer	36
17/LO/1795	HIV Phylogenetics Acceptability	44
17/LO/2058	WAVECREST PMCF STUDY - CHX_IP015	28
17/LO/2078	Voice-hearing in young people: distress factors and social relating	41
17/LO/2088	MS-OPT Version 1.0 dated 12/10/17	34
18/LO/0172	Parenting while struggling with emotional intensity	35
18/LO/0173	An investigation into hand grip strength as an assessment tool	25
18/LO/0179	MIND-MAPS AD	35
18/LO/0182	Telephone delivered Incentives for Encouraging adherence (TIES) Phase2	35
18/LO/0185	Catric Study (Version 2)	44
18/LO/0189	Functional magnetic resonance imaging of the lacrimal drainage system	30
18/LO/0238	BAViT ver 1	40
18/LO/0370	68Ga-THP-PSMA PET/CT imaging in primary and recurring prostate cancer	49
18/LO/0374	Mycoprotein, resistance training, and hypertrophy (Version 1)	41

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

17/LO/0618	WO30070 Atezolizumab in advanced or metastatic urothelial carcinoma	46
17/LO/1866	Ablation by Mapping	30
18/LO/0382	Experiences of using NHS patient medicines helplines	40

#### 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
17/LO/1483	Extension of cervical sample collection in the ARTISTIC Trial cohort	25

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1255	Adapted solution focused therapy for people with aphasia (SOFIA trial)	26
17/LO/1311	FluAGE: influenza-specific immunity in chronic HIV infection	26
17/LO/1515	Alzheimer's Carers' Perceptions of Psychological Therapy V1	25
17/LO/1655	ALOHA – A LOnDon HPV Self SAmpling pilot	26
17/LO/1858	GA30066-Open label GDC-0853 in patients with moderate to severe SLE	26

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/2016	BABY SMART (Study of Massage therapy, sleep And neurodevelopMenT)	25

#### 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
17/LO/1150	Safety, Efficacy & Tolerability of ALKS3831 in Schizophrenia 308	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
17/LO/0634	The effect of Community Chaplaincy Listening (version 1)	24
17/LO/0650	Exploring the emotional impact of breastfeeding difficulties.	31
17/LO/1257	Measuring Breathing Airflow Using a Heat Sensitive Camera (ThermFlow)	12
17/LO/1403	Bristol Interstitial lung disease (B-ILD) Tissue collection	20
17/LO/1404	Evaluation of automated pain logging	25
17/LO/1815	Neural correlates of emotional competition	18
18/LO/0496	Motivational interviews; increase patients' physical activity ?	15
18/LO/0504	Understanding Frailty	20

**Further Information Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/LO/0838	Patients' views on outcomes following total knee arthroplasty	10
17/LO/1408	Improving the understanding of intervertebral disc degeneration	16

**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
---------------	-------	-------------------------

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/1252	The connection between uniformity and conformity	20

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

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

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

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

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/Q1907/52/AM16	MINDACT - EORTC 10041 BIG 3-04 Intergroup Study	UK14	06/03/2018	14
08/H1107/58/AM21	Phase II study of DAST in metastatic renal cell cancer Version 3.0	20	30/11/2017	7
09/H1103/50/AM04	HOX proteins in breast and ovarian cancer	Protocol V4	24/10/2017	34
09/H1103/50/AM05	HOX proteins in breast and ovarian cancer	AM05	14/03/2018	15
09/H1107/103/AM18	Lenalidomide vs Chlorambucil in patients with B-Cell CLL	21	24/04/2017	12
09/H1107/103/AM19	Lenalidomide vs Chlorambucil in patients with B-Cell CLL	Revlimid® (lenalidomide, CC-5013) Investigator's Brochure, Edition 22, 03 November 2017	03/11/2017	17
10/H1107/59/AM22	035 Continuation study	IB v15 & PIS/ICF v10	01/12/2017	13
11/LO/0958/AM10	FAST-Forward	6	24/02/2017	20
11/LO/0958/AM13	FAST-Forward	9	21/12/2017	19
12/LO/1164/AM04	Human studies in valve failure	3	15/03/2018	15
13/LO/0374/AM03	Pre U7-53 Study	03	15/03/2017	35
13/LO/0740/AM20	A5481008	9	19/05/2017	22
13/LO/0740/AM22	A5481008	SA10	09/08/2017	26
13/LO/0801/AM20	Dapagliflozin Effect on Cardiovascular Events	11	13/07/2017	7
13/LO/0801/AM21	Dapagliflozin Effect on Cardiovascular Events	SA12 31/10/2017	31/10/2017	31
13/LO/0801/AM23	Dapagliflozin Effect on Cardiovascular Events	SA14	19/12/2017	17
13/LO/1029/AM05	HIV Bioresource	Amendment 05 17/10/2017	17/10/2017	28
13/LO/1108/AM06	UPBEAT TEMPO	Amendment 4.1	25/07/2017	7
13/LO/1115/AM15	PIVOTAL	11	24/03/2017	22
13/LO/1199/AM09	Long Term Safety and Efficacy of Baricitinib in Patients with RA	Amendment 9	17/08/2017	27
13/LO/1199/AM10	Long Term Safety and Efficacy of Baricitinib in Patients with RA	g	11/12/2017	22
14/LO/0438/AM14	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	6	25/04/2017	12
14/LO/0438/AM15	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	7	22/09/2017	10

14/LO/0438/AM16	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	A_08	12/02/2018	20
14/LO/0627/AM01	Long-term follow-up of ARTISTIC cervical screening trial cohort	1	14/06/2017	22
14/LO/1025/AM02	Complement mediated allograft nephropathy - version 1	2	02/01/2018	11
14/LO/1763/AM01	National Syphilis Serum Bank	AM01	15/02/2018	8
15/LO/0218/AM03	Diagnosis of clinically significant prostate cancer	Substantial Amendment 1 - 10/1/18	10/01/2018	31
15/LO/0218/AM04	Diagnosis of clinically significant prostate cancer	v3	06/02/2018	15
15/LO/0402/AM22	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	SA13 26/10/2017	26/10/2017	12
15/LO/0402/AM25	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	SA14 - Closure of NCI site in UK, change of NCI	07/03/2018	14
15/LO/1151/AM08	IXORAS S: Ixekizumab in Plaque Psoriasis	6	28/06/2017	30
15/LO/1289/AM15	VOYAGER PAD	9	21/03/2017	13
15/LO/1302/AM06	OCTOPUS	SA03	08/08/2017	20
15/LO/1446/AM01	1970 British Cohort Study: 2016-17 Survey	SA01	12/07/2017	2
15/LO/1599/AM01	REMAP-AF 1.0	SA01	01/04/2017	17
15/LO/1666/AM05	Effect of OC459 on the response to rhinovirus challenge in asthma	2	04/07/2017	5
15/LO/1669/AM11	Clementia 202	Prot Amt 4 and associated docs	09/02/2018	5
15/LO/1702/AM02	Multiple Rib Fractures	SA02	01/11/2017	28
15/LO/1907/AM06	Minocycline and Depression (MINDEP) study	SA4.0	18/07/2017	8
15/LO/2066/AM14	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	7	24/05/2017	21
15/LO/2066/AM16	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	SA08	10/08/2017	13
15/LO/2066/AM18	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	1	19/10/2017	17
16/LO/0201/AM02	PERSIST	Amendment 2 dated 07-Aug-2017	07/08/2017	8
16/LO/0212/AM03	Collaborative Rehabilitation Environments in Acute Stroke (CREATE)	0.04 (22.08.2017)	08/09/2017	7
16/LO/0212/AM04	Collaborative Rehabilitation Environments in Acute Stroke (CREATE)	0.5	08/03/2018	15
16/LO/0353/AM01	Does pharmacist intervention improve prescribing and pain control?	As per HARP AM01	27/03/2017	34
16/LO/0372/AM01	Scar study	1	26/04/2017	24
16/LO/0681/AM03	Phase 3 study of Luspatercept in patients with MDS	Protocol AM 2	07/09/2017	5

16/LO/0943/AM01	Public Preferences for Vascular Treatment	1	20/04/2017	12
16/LO/0999/AM04	Inducing Tolerance in Allergy (ITA)	4	06/10/2017	9
16/LO/1469/AM01	4SC-201-6-2015_Phase II trial to evaluate Resminostat	4	09/03/2017	21
16/LO/1546/AM01	PROM-COM	SA01	11/09/2017	6
16/LO/1602/AM05	Treatment Resistant Infantile Spasms (TRIS Study)	AM05	19/01/2018	30
16/LO/1611/AM02	The HIV brain amyloid study	Amendment v5 (04.08.17)	04/08/2017	14
16/LO/1611/AM03	The HIV brain amyloid study	V6 06.11.17	06/11/2017	22
16/LO/1780/AM01	Validation of MIRROR application for facial paralysis	Amendment 1 10/10/17	10/10/2017	10
16/LO/1807/AM01	Evaluation of dynamic changes in cervical cancer during radiotherapy.	1	06/12/2017	21
16/LO/1811/AM06	GA30044 - GDC-0853 v placebo in patients with moderate to severe SLE	SA3	20/09/2017	29
16/LO/1811/AM08	GA30044 - GDC-0853 v placebo in patients with moderate to severe SLE	SA4 - Prot v3	27/02/2018	14
16/LO/1923/AM01	Suicide Deaths in Northern Ireland: Medication and Health Service Use	Amendment 1	09/08/2017	20
16/LO/1940/AM04	MO29983 - Atezolizumab in patients with Urinary Tract Carcinoma	4	23/06/2017	24
16/LO/1940/AM06	MO29983 - Atezolizumab in patients with Urinary Tract Carcinoma	6	29/11/2017	16
16/LO/1940/AM07	MO29983 - Atezolizumab in patients with Urinary Tract Carcinoma	7	22/02/2018	19
16/LO/2211/AM02	Patient Anxiety at CT Colonography (PACT)	AM02	09/08/2017	26
17/LO/0108/AM02	MASTER DAPT	N.2_November 29th, 2017	30/11/2017	11
17/LO/0333/AM03	Impact of nausea in pregnancy using technology (INPUT) study	2	07/06/2017	27
17/LO/0338/AM01	Women's perspectives on a subsequent pregnancy after GDM	1	13/10/2017	24
17/LO/0338/AM03	Women's perspectives on a subsequent pregnancy after GDM	Amendment 2, 06/11/2017	13/11/2017	14
17/LO/0463/AM01	SINE Study	1	16/05/2017	22
17/LO/0522/AM01	Evolutionary conserved determinants of neuronal ageing.	Amendment n.1	01/08/2017	2
17/LO/0592/AM01	CENTAUR Rollover study	SA01	06/09/2017	6
17/LO/0618/AM04	WO30070 Atezolizumab in advanced or metastatic urothelial carcinoma	Sub 3	11/09/2017	6

17/LO/0618/AM07	WO30070 Atezolizumab in advanced or metastatic urothelial carcinoma	Amendment 6 (IB v10)	06/12/2017	9
17/LO/0618/AM08	WO30070 Atezolizumab in advanced or metastatic urothelial carcinoma	Substantial Amendment 7 - 7/2/18	07/02/2018	27
17/LO/0845/AM02	Mechanisms of Chronic Pain and Fatigue	AM02	23/11/2017	14
17/LO/0845/AM03	Mechanisms of Chronic Pain and Fatigue	AMD 3	24/01/2018	35
17/LO/1070/AM01	Investigation of Thermal Injury and Intestinal Permeability	SA1	20/12/2017	8
17/LO/1116/AM01	SKIPPAIN ( SecuKinumab-Induced relief from Pain in AxSpA)	SA01 - Change in CI	14/09/2017	18
17/LO/1240/AM01	CN001016: Phase 2/3 Study of BMS-986089 in Ambulatory Boys with DMD	1	29/11/2017	16
17/LO/1240/AM02	CN001016: Phase 2/3 Study of BMS-986089 in Ambulatory Boys with DMD	2	27/02/2018	21
17/LO/1289/AM01	A Phase 2b Ublituximab, TGR-1202, Bendamustine in NHL patients	SA#1 2017/10/26	26/10/2017	15
17/LO/1311/AM01	FluAGE: influenza-specific immunity in chronic HIV infection	1.1	08/11/2017	18
17/LO/1461/AM01	Study to understand if a vaccine can prevent flare ups of your COPD	1	24/11/2017	19
17/LO/1461/AM02	Study to understand if a vaccine can prevent flare ups of your COPD	SA02Substantial Amendment 2: Protocol Admin Change 1	07/03/2018	14

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/LO/1115/AM18	PIVOTAL	AM13	17/11/2017	34

**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
-------------------------	-------	---------	------	-------------------------

13/LO/1115/AM18/1	PIVOTAL	AM13 - modified	06/02/2018	5
-------------------	---------	-----------------	------------	---

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
17/LO/0634	The effect of Community Chaplaincy Listening (version 1)	24
17/LO/0650	Exploring the emotional impact of breastfeeding difficulties.	31
17/LO/1404	Evaluation of automated pain logging	25

**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
-------------------------	-------	---------	------	-------------------------

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------