

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

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Brighton & Sussex Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPs in patients – type III
<b>Type of Flag:</b>	Research involving adults lacking capacity; Research involving children
<b>Chair:</b>	Dr Simon Walton
<b>Vice-Chair:</b>	Dr John Bull
<b>Alternate Vice-Chair:</b>	Mr Maurice Marchant
<b>REC Manager:</b>	Mr Ryan Erfani-Ghettani Ms Kirsty Shearman (until August 2016)
<b>REC Assistant:</b>	Ms Zuleka Alawi Mr Ian Braddick (until August 2016)
<b>Committee Address:</b>	Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH
<b>Telephone:</b>	02071048308
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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. This year the Committee became flagged to receive studies involving adults who lack capacity and in July the committee underwent a training session in the Mental Capacity Act and research. The committee looks forward to receiving more MCA flagged studies in the future. One of the committee's members Dr Jill Adams transferred to another REC this year and we thank her for all the excellent work she has done for this REC. This year we welcomed the return of Dr Paul Seddon from his sabbatical away from the REC. We are also very fortunate in having Ryan Erfani-Ghettani appointed as our new REC manager and thank him for the help he has provided this year. The vice chairs John Bull and Maurice Marchant have worked unstintingly in supporting the work of the Committee and have led on the review of numerous PR Studies, substantial amendments and safety reports we have received over the year.

## London - Brighton & Sussex Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Jill Adams	GP	Expert	01/03/2011	01/03/2017
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	
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	19/04/2016
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	01/12/2016
Dr Nicola Mason	Consultant Midwife	Expert	None

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

Name	Profession	Status	Meeting date attended

**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	31/03/2017
Dr John Bull	No interests declared.	31/03/2017
Miss Philippa Case	R&D Manager for Sussex Partnership NHS Foundation Trust.	31/03/2017
Mr Gerard Cronin	None	31/03/2017
Mrs Janine Hobbs	None	31/03/2017
Mr Bill Kent	Secretary of a charity that might become involved in the conduct of research.	31/03/2017
Dr Tom Levett	Member of BSUH NHS trust protocol review panel.	31/03/2017
Miss Samantha Lippett	Pharmacist volunteer at Brighton Lusaka Health Link. Member of Brighton & Sussex University Hospitals NHS Trust Infection Research, Audit and Governance Group. Member of Brighton & Sussex University Hospitals NHS Trust Pharmacy Research and Audit Group.	31/03/2017
Mr Maurice Marchant	Member of the Royal Statistical Society and 'Radical Statistics'	31/03/2017
Dr Nicola Mason	Periodic reviewer for NIHR Health Technology Assessment research programme.	31/03/2017
Mrs Carrie Ridley	Senior research nurse at Brighton and Sussex University Hospitals NHS Trust, which acts as a sponsor for research studies. Has a seat on its Operational Management Group Committee.	31/03/2017
Dr Paul Seddon	Lead for Avison III, Kent, Surrey and Sussex NIHR CRN.	31/03/2017
Dr Ruth Stirton	None	31/03/2017
Mrs Kathy Stott	None	31/03/2017
Dr Simon Walton	No interests declared	31/03/2017
Dr Stuart White	<p>Association of Anaesthetists:</p> <ul style="list-style-type: none"> <li>- National Audit co-ordinator</li> <li>- Working Parties on Consent, the Elderly and Dementia</li> <li>-Editor, Anaesthesia</li> </ul> <p>National Institute of Academic Anaesthesia:</p> <ul style="list-style-type: none"> <li>-Research and Grants Committee</li> <li>-HSRC Research Strategy Committee</li> </ul> <p>Fragility Fractures Network:</p> <ul style="list-style-type: none"> <li>-Research Special Interest Group</li> <li>-Anaesthesia Special Interest Group</li> </ul> <p>Research and Audit Federation of Trainees:</p> <ul style="list-style-type: none"> <li>-President, SEARCH</li> </ul> <p>National Hip Fracture Database:</p>	31/03/2017

	<p>-Scientific and Publications Committee</p> <p>Local Investigator:</p> <ul style="list-style-type: none"><li>-SNAP-2</li><li>-HipHOP</li><li>-ASCRIBED</li><li>-HipAttack</li><li>-WHiTE</li></ul>	
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**Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:**

Month	Date	Number of Members Present at Meeting
April	07/04/2016	12
June	02/06/2016	8
August	04/08/2016	7
September	01/09/2016	9
October	06/10/2016	10
November	03/11/2016	10
December	01/12/2016	10
February	02/02/2017	8

8 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	13/04/2016	3
May	17/05/2016	3
June	21/06/2016	3
July	19/07/2016	3
August	16/08/2016	3
October	18/10/2016	3
November	15/11/2016	3
December	13/12/2016	3
January	17/01/2017	3
February	21/02/2017	3
March	21/03/2017	3

11 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	11/04/2016	2
April	25/04/2016	3
June	01/06/2016	2
June	14/06/2016	2
July	01/07/2016	5
August	01/08/2016	5
September	01/09/2016	3
September	15/09/2016	2
September	20/09/2016	3
October	21/10/2016	2
October	31/10/2016	5
November	15/11/2016	2

November	20/11/2016	2
November	30/11/2016	2
December	15/12/2016	2
December	30/12/2016	2
January	01/01/2017	2
January	13/01/2017	2
January	31/01/2017	2
February	15/02/2017	2
February	28/02/2017	2
March	15/03/2017	3
March	31/03/2017	2

23 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**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Jill Adams	1
Dr Duncan Angus	5
Dr John Bull	7
Miss Philippa Case	5
Mr Gerard Cronin	5
Mrs Janine Hobbs	8
Mr Bill Kent	6
Dr Tom Levett	5
Miss Samantha Lippett	1
Mr Maurice Marchant	5
Mrs Carrie Ridley	7
Dr Paul Seddon	2
Mrs Kathy Stott	7
Dr Simon Walton	6
Dr Stuart White	4

**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 Duncan Angus	2
Dr John Bull	4
Miss Philippa Case	3
Mr Gerard Cronin	5
Mrs Janine Hobbs	3
Mr Bill Kent	3
Dr Tom Levett	3
Mr Maurice Marchant	4
Mrs Carrie Ridley	2
Mrs Kathy Stott	1
Dr Simon Walton	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Duncan Angus	1
Dr John Bull	10
Miss Philippa Case	3
Mr Gerard Cronin	9

Mrs Janine Hobbs	4
Mr Bill Kent	5
Dr Tom Levett	1
Mr Maurice Marchant	11
Dr Nicola Mason	3
Mrs Carrie Ridley	2
Dr Paul Seddon	1
Mrs Kathy Stott	2
Dr Simon Walton	6
Dr Stuart White	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Duncan Angus	07/07/2016	Mental Capacity Act Local Training Day
Dr John Bull	04/05/2016	London Chair's Meeting
Dr John Bull	07/07/2016	Mental Capacity Act Local Training Day
Miss Philippa Case	07/07/2016	Mental Capacity Act Local Training Day
Miss Philippa Case	16/02/2017	National Members Training Day
Mr Gerard Cronin	07/07/2016	Mental Capacity Act Local Training Day
Mrs Janine Hobbs	07/07/2016	Mental Capacity Act Local Training Day
Dr Tom Levett	07/07/2016	Mental Capacity Act Local Training Day
Dr Tom Levett	04/10/2016	Equality and Diversity Training
Mr Maurice Marchant	07/07/2016	Mental Capacity Act Local Training Day
Mrs Carrie Ridley	01/04/2016	HRA Consent and Participant Information Sheet - refresher
Mrs Carrie Ridley	01/04/2016	Active involvement in research as a vocation - working full time as a senior research nurse
Mrs Carrie Ridley	07/07/2016	Mental Capacity Act Local Training Day
Mrs Carrie Ridley	14/07/2016	Equality and Diversity
Dr Ruth Stirton	31/03/2017	Taught research ethics and governance to under-graduate students
Mrs Kathy Stott	31/03/2017	Ionising radiation revision; HRA guidance; Medical Devices research; Research Design revision; MRC toolkit.
Dr Simon Walton	07/07/2016	Mental Capacity Act Local Training Day
Dr Simon Walton	07/11/2016	Chair's Meeting
Dr Stuart White	31/03/2017	Editor's meeting; read a review about improving consent in research in NEJM; read a review about healthcare data collections in BMC Medical Ethics.

## 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	8	24.24
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	3.03
Research Database (including renewals)	0	0.00
Others	24	72.73
<b>Total Applications Reviewed</b>	<b>33</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	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
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	4

**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	3.03
Favourable Opinion with Additional Conditions	3	9.09
Unfavourable Opinion	2	6.06
Provisional Opinion	27	81.82
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>33</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	22	66.67
Further Information Favourable Opinion with Additional Conditions	4	12.12
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	3.03
Favourable Opinion with Additional Conditions	3	9.09
Unfavourable Opinion	2	6.06
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	3.03
<b>Total</b>	<b>33</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>29</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	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	6
Number of paediatric applications reviewed	6
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

**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	2	6.90
Favourable Opinion with Additional Conditions	8	27.59
No Opinion transfer to full committee for review	7	24.14
Provisional Opinion	12	41.38
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>29</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>	3.67
<b>Number of completed applications for full ethical review</b>	32
<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>	4
<b>Number of completed applications over 40 days as a % of total</b>	12.12%
<b>Number of days taken to final decision – average (mean)</b>	34
<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 timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	13
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	59.09%
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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 completed substantial amendments over 28 days</b>	13
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	15.12%
<b>Number of modified amendments reviewed</b>	3
<b>Number of completed modified amendments over 14 days</b>	1
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	33.33%
<b>Number of non substantial amendments received</b>	83

<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	15
<b>Number of annual progress reports received</b>	104
<b>Number of safety reports received</b>	35
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	45



**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/0681	Phase 3 study of Luspatercept in patients with MDS	34
16/LO/0943	Public Preferences for Vascular Treatment	41
16/LO/0953	Antibiotic Levels in Burn wound Infection (ABLE)	29
16/LO/0993	Biomarkers in Childhood Cancer and Blood Disorders	38
16/LO/0999	Inducing Tolerance in Allergy (ITA)	37
16/LO/1384	Safety and tolerability of secukinumab in 2mL Prefilled syringes	39
16/LO/1461	STARflo TM Glaucoma Implant Clinical Experience Program in Real-World	34
16/LO/1468	Cancer Safety Netting (CASNET)	39
16/LO/1469	4SC-201-6-2015_Phase II trial to evaluate Resminostat	26
16/LO/1548	Risk of corticosteroid induced hyperglycaemia in malignancy	30
16/LO/1555	Study of Terguride Plus Symptomatic Therapy in patients with dcSSc	32
16/LO/1602	Treatment Resistant Infantile Spasms (TRIS Study)	37
16/LO/1611	The HIV brain amyloid study	32
16/LO/1638	Quality of Life After Bladder Cancer (Q-ABC): qualitative interviews	33
16/LO/1767	The Efficacy and Safety of Solanezumab vs Placebo in Prodromal AD	37
16/LO/1780	Validation of MIRROR application for facial paralysis	39
16/LO/1807	Evaluation of dynamic changes in cervical cancer during radiotherapy.	39
16/LO/1811	GA30044 - GDC-0853 v placebo in patients with moderate to severe SLE	32
16/LO/1940	MO29983 - Atezolizumab in patients with Urinary Tract Carcinoma	47
16/LO/2122	EmERGE validation study V3.0	30
16/LO/2132	Nutrient Fortified Foods for Older Hospital Patients	47
17/LO/0151	Environment-aware Listener-optimised Binaural Enhancement of Speech	29

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1929	Model fidelity of early intervention services for psychosis_version 1	40
16/LO/2131	INWARD	37
17/LO/0108	MASTER DAPT	39
17/LO/0147	Chronic Pain Phenotype in Patients with Inflammatory Arthritis	41

**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
16/LO/0684	Women's lived experience of blood glucose management during pregnancy	27

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
16/LO/0570	RIPCORDER 2	27
16/LO/1071	National Autistic Society Quality of Life in autistic adults	28
17/LO/0231	Liver transplantation as a treatment for hepatocellular carcinoma - V1	22

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
16/LO/0630	The experience of service user involvement in risk assessment - V1	27
16/LO/1823	Investigating maladaptive cognitive biases in anxious asthma patients	28

**Provisional Opinion**

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

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

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

REC Reference	Title	Number of Days on Clock
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16/LO/1504	4Tech PREVENT trial, PREVENT_001/2013	21
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**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/0709	A cognitive restructuring intervention for dental anxiety	11
16/LO/0729	The Burden of Immunoglobulin Treatment	15
16/LO/0936	An investigation into patients' journey in an Intermediate Care service	19
16/LO/0942	Patient evaluation of online information resource on jaw surgery	21
16/LO/1196	Improving Tracheostomy Care	20
16/LO/1368	Family role in rehabilitation	17
16/LO/1549	Patient activation and adherence to follow up in prostate cancer	15
16/LO/2211	Patient Anxiety at CT Colonography (PACT)	11
17/LO/0333	Impact of nausea in pregnancy using technology (INPUT) study	19

<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/0146	Quality of Life in Cystic Fibrosis Intravenous Antibiotic Patients	13
17/LO/0519	Use of waste lipoaspirate tissue to investigate stem & stromal cells	16

<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/0732	Diagnostic classification of B cell acute lymphoblastic leukaemia	6
16/LO/2055	Genetic/functional characterisation of adult ALL	12

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1200	Study of the effects of bariatric surgery in the cardiac performance.	20
16/LO/1369	Fluenz Tetra Enhanced Safety Surveillance 2016 -17	15
16/LO/1546	PROM-COM	19
16/LO/1923	Suicide Deaths in Northern Ireland: Medication and Health Service Use	4
16/LO/2053	Feasibility Study for Emergency Admissions PROMs	12
17/LO/0338	Women's perspectives on a subsequent pregnancy after GDM	16
17/LO/0342	Challenges to Maintaining Glycaemic Control	15
17/LO/0522	Evolutionary conserved determinants of neuronal ageing.	14

<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>
17/LO/0529	3D Reconstruction of Basal Cell Carcinomas (3DBCC)	n/a

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

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

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
08/H1107/58/AM19	Phase II study of DAST in metastatic renal cell cancer Version 3.0	Substantial Amendment #18	03/06/2016	25
08/H1107/58/AM20	Phase II study of DAST in metastatic renal cell cancer Version 3.0	19	16/01/2017	35
09/H1107/103/AM16	Lenalidomide vs Chlorambucil in patients with B-Cell CLL	Revlimid <sup>®</sup> (lenalidomide, CC-50)	20/06/2016	14
09/H1107/107/AM22	Sorafenib vs Placebo in Thyroid Cancer	Sponsor Legal Name Change (Bay	06/07/2016	19
10/H1107/59/AM21	035 Continuation study	14	02/11/2016	5
12/LO/0739/AM08	Cook MyoSite Incorporated AMDC Female SUI Clinical Study--10-019-02_EU	MHRA SA 06	01/06/2016	12
12/LO/1942/AM10	Joint Hypermobility	SA8	06/05/2016	14
12/LO/1981/AM13	Study of T-DM1 vs Herceptin, post surgery for HER2+ Breast Cancer	SA #11 Patient facing newslett	10/05/2016	18
13/LO/0107/AM04	The immunological basis of preterm delivery	Substantial Amendment 3	21/03/2016	20
13/LO/0265/AM01	Long term risk of cervical cancer following HPV infection	Amendment Number 1	05/10/2015	14
13/LO/0572/AM10	Phase III of Two Single tablet regimens in HIV-1 Positive Adults	5	20/01/2017	25
13/LO/0574/AM12	Phase 3 of Two Single tablet regimens in HIV-1 Positive Adults	5	20/01/2017	25
13/LO/0574/AM13	Phase 3 of Two Single tablet regimens in HIV-1 Positive Adults	6	19/01/2017	35
13/LO/0801/AM16	Dapagliflozin Effect on Cardiovascular Events	9	17/01/2017	21
13/LO/0801/AM18	Dapagliflozin Effect on Cardiovascular Events	10	09/03/2017	27
13/LO/1029/AM04	HIV Bioresource	004	16/02/2016	4
13/LO/1115/AM10	PIVOTAL	AM06	10/02/2016	10
13/LO/1115/AM12	PIVOTAL	AM07	28/06/2016	7
13/LO/1115/AM14	PIVOTAL	10	09/01/2017	16
13/LO/1199/AM08	Long Term Safety and Efficacy of Baricitinib in Patients with RA	F	30/01/2017	15

13/LO/1450/AM04	Pregnancy lifestyle intervention & childhood cardiovascular function	2.0	25/04/2016	30
14/LO/0438/AM13	Cook MyoSite AMDC Fecal Incontinence Clinical Study 09-025	5	15/02/2017	34
14/LO/0866/AM09	Evaluating Xilonox in Symptomatic Colo-Rectal Cancer	SA#5 IMPD, DSUR and IB 2016	29/04/2016	15
14/LO/1381/AM04	Reformulated raltegravir q.d. (1200 mg) versus raltegravir b.i.d. (400 mg) in ART-naïve pts	SA04	12/10/2016	26
14/LO/1898/AM01	Experiences of the wellbeing of people with a high grade glioma	V4	14/04/2016	20
14/LO/1908/AM01	MR-BTC Version 1	4	13/07/2016	23
15/LO/0109/AM01	Action control in Tourette Syndrome and related conditions, version 1	Amendment 1, Protocol version	04/07/2016	27
15/LO/0402/AM12	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	Amendment 6 - ICF Addendum	18/04/2016	14
15/LO/0402/AM13	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	Amendment 7 - CI change	31/05/2016	35
15/LO/0402/AM14	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	Substantial Amendment 7	12/08/2016	35
15/LO/0402/AM15	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	3	02/09/2016	14
15/LO/0402/AM17	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	10	07/10/2016	16
15/LO/0402/AM19	Safety and efficacy of SA4Ag vaccine in lumbar spinal fusion	11	07/02/2017	16
15/LO/0418/AM02	Light Therapy: An Exploratory Trial	Amendment 2	14/07/2016	32
15/LO/0981/AM02	DIPSS Asthma: Development of an asthma home management website	2	13/04/2016	7
15/LO/1018/AM09	OPTIMUM Trial	Am3	29/09/2016	19
15/LO/1018/AM11	OPTIMUM Trial	10	24/11/2016	11
15/LO/1151/AM02	IXORAS S: Ixekizumab in Plaque Psoriasis	RHBS Protocol Amendment (a) 9	31/03/2016	7
15/LO/1151/AM03	IXORAS S: Ixekizumab in Plaque Psoriasis	RHBS ICD update_7Jun2016	07/06/2016	17
15/LO/1151/AM05	IXORAS S: Ixekizumab in Plaque Psoriasis	4	06/10/2016	33
15/LO/1151/AM07	IXORAS S: Ixekizumab in Plaque Psoriasis	5	03/02/2017	21
15/LO/1153/AM06	IPI-145 with rituxumab or obinutuzumab in subjects with untreated FL	Switch of Obinutuzumab (invest	10/05/2016	7
15/LO/1153/AM07	IPI-145 with rituxumab or obinutuzumab in subjects with	Temporary halt of	12/07/2016	14

	untreated FL	the trial in		
15/LO/1153/AM08	IPI-145 with rituxumab or obinutuzumab in subjects with untreated FL	2	09/11/2016	35
15/LO/1153/AM09	IPI-145 with rituxumab or obinutuzumab in subjects with untreated FL	2	08/12/2016	16
15/LO/1163/AM06	1717 - Phase 3b switch study with F/TAF in HIV-1 infected subjects	4	26/09/2016	16
15/LO/1289/AM06	VOYAGER PAD	Substantial Amendment 5: PA4	23/03/2016	18
15/LO/1289/AM07	VOYAGER PAD	Substantial Amendment 6: Amend	07/06/2016	21
15/LO/1289/AM08	VOYAGER PAD	Substantial Amendment 7: New P	26/07/2016	28
15/LO/1302/AM01	OCTOPUS	Substantial Amendment No 1	30/06/2016	21
15/LO/1359/AM02	Perceptions of admissions for enteral tube related issues	Amendment 2	05/04/2016	27
15/LO/1526/AM01	Obs study Patients on Fixed Dose Combination Inhaler for Asthma & COPD	Substantial Amendment 1	27/04/2016	20
15/LO/1666/AM04	Effect of OC459 on the response to rhinovirus challenge in asthma	SA1	15/12/2016	11
15/LO/1669/AM01	Clementia 202	3	10/03/2016	12
15/LO/1669/AM02	Clementia 202	New Patient Items - Dosing Ins	15/06/2016	21
15/LO/1669/AM04	Clementia 202	1	16/08/2016	10
15/LO/1669/AM06	Clementia 202	6	27/10/2016	16
15/LO/1669/AM07	Clementia 202	7	31/01/2017	21
15/LO/1702/AM01	Multiple Rib Fractures	1	18/11/2016	23
15/LO/1887/AM03	The AVICCI study	AVICCI01 Amendment 3.0	13/05/2016	12
15/LO/1892/AM01	EBC MAIN Version 2.0 dated of September 22, 2015	Version 3.0 on 09/11/2015	09/11/2015	28
15/LO/1907/AM03	Minocycline and Depression (MINDEP) study	MINDEP 2.0	22/03/2016	12
15/LO/1907/AM04	Minocycline and Depression (MINDEP) study	3.0	14/10/2016	5
15/LO/2066/AM06	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	SA05	11/08/2016	26

15/LO/2066/AM09	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	9	07/11/2016	7
15/LO/2066/AM10	4222: Oral semaglutide versus sitagliptin in Type 2 Diabetes	1	09/12/2016	25
15/LO/2092/AM03	Developing a symptom list for children with cancer	1	27/02/2017	34
15/LO/2106/AM01	ABC-ONE (Version 1): Trial of BRS use in coronary bifurcation	1	02/09/2016	11
15/LO/2117/AM02	Body composition in pre-pubertal children with cystic fibrosis v1	1	28/11/2016	32
15/LO/2191/AM01	Rational Prescribing for Children v.1.0	SA1	31/07/2016	28
16/LO/0212/AM01	Collaborative Rehabilitation Environments in Acute Stroke (CREATE)	0.03	09/08/2016	13
16/LO/0338/AM01	IMerge Imetelstat in Myelodysplastic syndrome (MDS)	Am 1 Protocol Amendment 1 to	31/05/2016	12
16/LO/0338/AM03	IMerge Imetelstat in Myelodysplastic syndrome (MDS)	1	30/09/2016	27
16/LO/0564/AM01	Dementia (Post Diagnostic) Digital Platform	1	29/08/2016	29
16/LO/0681/AM01	Phase 3 study of Luspatercept in patients with MDS	1	25/08/2016	16
16/LO/0681/AM02	Phase 3 study of Luspatercept in patients with MDS	1.0	21/09/2016	19
16/LO/0999/AM01	Inducing Tolerance in Allergy (ITA)	1	06/09/2016	9
16/LO/0999/AM03	Inducing Tolerance in Allergy (ITA)	2	16/01/2017	21
16/LO/1196/AM02	Improving Tracheostomy Care	1	11/01/2017	25
16/LO/1555/AM01	Study of Terguride Plus Symptomatic Therapy in patients with dcSSc	1	03/03/2017	6
16/LO/1602/AM01	Treatment Resistant Infantile Spasms (TRIS Study)	1	10/02/2017	12
16/LO/1602/AM02	Treatment Resistant Infantile Spasms (TRIS Study)	Amendment 2.0	20/03/2017	10
16/LO/1940/AM01	MO29983 - Atezolizumab in patients with Urinary Tract Carcinoma	1	19/12/2016	14
17/LO/0333/AM02	Impact of nausea in pregnancy using technology (INPUT) study	1.1	23/03/2017	6

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/1164/AM02	Human studies in valve failure	Amendment 2	22/06/2016	27
13/LO/0806/AM02	Lipomodelling of peri-stomal symptomatic skin contour abnormalities	SA 2	21/07/2016	29

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



<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
12/LO/1164/AM02/1	Human studies in valve failure	2.2	31/10/2016	15
13/LO/1108/AM02/2	UPBEAT TEMPO	2 (Modified AM02)	17/11/2015	8

<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>
13/LO/1108/AM02/1	UPBEAT TEMPO	2	17/11/2015	13

**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
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**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
12/LO/1164/AM02/1	Human studies in valve failure	2.2	31/10/2016	15