

**South Central - Hampshire A Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	South Central - Hampshire A 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 Kolstoe
Vice-Chair:	Dr Ronja Bahadori
Alternate Vice-Chair:	Ms Sonia Baryschpolec
REC Manager:	Mrs Maxine Knight (until 28/02/2017) Mrs Claudia Bywater (01/03/2017 until present)
REC Assistant:	Miss Elizabeth Hearn
Committee Address:	Bristol HRA Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

This year we have reviewed 46 full applications with an average meeting attendance of nine members, although we have been as low as seven. We have had a number of members on LOA's and a number of resignations (for a variety of reasons). Although we have so far always found enough members to run the meetings, this has proved to be challenging on a number of occasions.

Meetings themselves are stimulating and we have always run to time, albeit assisted by normally having less than six applications to review. 71% of our decisions are provisional opinions, and I have tried to increase the number of "favourable with additional conditions" decisions in accordance with HRA guidance, the main hindrance to this has been trying to specify suitable conditions for studies that would not require a provisional opinion to come back to me.

Due to our permanent REC Managers maternity leave we have had numerous REC managers covering our meetings and dealing with committee business (5 during the year), and whilst I have been generally impressed by the conduct and abilities of the various individuals, it is likely that the variety of support accounts for 8% of amendments being reviewed outside the 35 day SOP timelines.

South Central - Hampshire A Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Clifford Allen	Corporate Development and Learning	Lay Plus	14/10/2011	07/11/2016
Mr Richard Andoh	Pharmacist	Expert	01/12/2009	
Dr Catherine Angell	Midwife/Lecturer	Expert	01/12/2010	
Mrs Lisa Frances Armstrong	Senior Lecturer Social Work	Lay	14/10/2011	
Dr Ronja Bahadori	Clinical Trial Coordinator	Expert	01/06/2011	
Ms Sonia Baryschpolec	Staff nurse	Expert	01/01/2014	
Dr Mike Gibson	Retired Consultant in Occupational Medicine	Expert	01/12/2015	28/02/2017
Mrs Kathryn Gillanders	Retired Head of Clinical Research	Expert	13/07/2016	
Dr Vasileios Karagiannopoulos	Senior Lecturer in Socio-Legal Studies	Lay Plus	13/07/2016	
Dr Simon Kolstoe	Senior Lecturer in Biochemistry	Expert	01/07/2009	
Dr James MacLean	Associate Professor in Law	Lay Plus	13/07/2016	02/12/2016
Dr Karl Nunkoosing	Principal Psychology Lecturer	Lay	01/10/2014	
Mr Trevor Olding	Clinical Coordinator	Lay	11/03/2013	
Dr Emmanouil Papavasileiou	Research Fellow in International Labour Mobility	Lay Plus	16/09/2016	
Dr Kesava Ananth Ramakrishnan	Consultant, Paediatric Intensive Care Unit (PICU)	Expert	01/01/2014	01/06/2016
Dr Ramya Ramanujachar	Paediatric Oncology Consultant	Expert	27/02/2014	
Ms Helen Ryan	Head of Law	Lay Plus	26/09/2016	
Mrs Margaret Stephens	Senior Specialist, Speech & Language Therapist (Adult Neurology & Elderly Care)	Expert	10/07/2008	

South Central - Hampshire A Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

South Central - Hampshire A Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Canon Ian Ainsworth-Smith	Hospital Chaplain	Lay Plus	12/07/2016
Professor Ron King	Mathematician (Retired)	Lay Plus	10/05/2016

South Central - Hampshire A Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Richard Andoh	None	31/03/2017
Dr Catherine Angell	None	31/03/2017
Mrs Lisa Frances Armstrong	None	06/02/2017
Dr Ronja Bahadori	Working for the Clinical Trials and Research Governance Team at the University of Oxford; providing support to researchers who are planning to set up clinical trials as well as research.	03/02/2017
Ms Sonia Baryschpolec	None	03/02/2017
Mrs Kathryn Gillanders	None	11/08/2016
Dr Vasileios Karagiannopoulos	None	10/02/2017
Dr Simon Kolstoe	Senior Lecturer in Biochemistry & University Ethics Advisor, University of Portsmouth Participate in R&D oversight at the University of Portsmouth Coordinate ethical review at University of Portsmouth Chair MOD research ethics committee Expert ethics reviewer, EU H2020 programme	01/02/2017
Dr James MacLean	Director of PhD Programmes, Southampton Law School, University of Southampton	18/08/2016
Dr Karl Nunkoosing	Principal lecturer in the Dept of Psychology at the University of Portsmouth and conducting research is an aspect of this work. Reviewed research for various funders in the past.	31/03/2017
Mr Trevor Olding	None	09/02/2017
Dr Emmanouil Papavasileiou	Research Fellow, PBS, University of Portsmouth	10/10/2016
Dr Ramya Ramanujachar	None	31/03/2017
Ms Helen Ryan	Academic at the University of Winchester, working within the Law Department. My fields of expertise are medical Law and Ethics, Mental Health Law and Human Rights	06/11/2016
Mrs Margaret Stephens	Work closely with The Stroke Association locally (Dorset and Hampshire) in my role as a speech and language therapist. Work as a senior lecture at the university of Portsmouth and supervise students undertaking research as part of my masters degree Communication difficulties and swallowing difficulties associated with neurological diseases such as a stroke, dementia , MND etc	02/01/2017

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	8
May	10/05/2016	11
June	14/06/2016	8
July	12/07/2016	10
August	09/08/2016	8
October	11/10/2016	9
November	08/11/2016	12
December	13/12/2016	7
January	10/01/2017	8
February	14/02/2017	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	8
April	26/04/2016	3
May	24/05/2016	3
June	28/06/2016	3
July	26/07/2016	3
August	23/08/2016	3
October	25/10/2016	3
November	22/11/2016	3
January	18/01/2017	3
February	22/02/2017	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	28/04/2016	2
May	13/05/2016	2
May	26/05/2016	2
June	10/06/2016	2
June	23/06/2016	3
July	07/07/2016	2
July	21/07/2016	3
August	11/08/2016	2
August	22/08/2016	2

September	08/09/2016	2
September	22/09/2016	2
October	06/10/2016	4
October	10/10/2016	2
October	27/10/2016	2
November	03/11/2016	2
November	17/11/2016	2
December	08/12/2016	2
December	30/12/2016	2
January	06/01/2017	3
January	16/01/2017	2
February	03/02/2017	2
February	17/02/2017	3
March	03/03/2017	2
March	21/03/2017	2

25 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 Clifford Allen	4
Mr Richard Andoh	6
Dr Catherine Angell	6
Mrs Lisa Frances Armstrong	3
Dr Ronja Bahadori	7
Ms Sonia Baryschpolec	7
Dr Mike Gibson	6
Mrs Kathryn Gillanders	4
Dr Vasileios Karagiannopoulos	3
Dr Simon Kolstoe	10
Dr James MacLean	3
Dr Karl Nunkoosing	4
Mr Trevor Olding	9
Dr Emmanouil Papavasileiou	5
Dr Ramya Ramanujachar	8
Ms Helen Ryan	2
Mrs Margaret Stephens	2

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

Name	Number of Meetings Attended
Dr Clifford Allen	3
Mr Richard Andoh	3
Dr Catherine Angell	1
Mrs Lisa Frances Armstrong	2
Dr Ronja Bahadori	6
Ms Sonia Baryschpolec	3
Dr Mike Gibson	1
Dr Simon Kolstoe	6
Dr Karl Nunkoosing	3
Mr Trevor Olding	6
Dr Ramya Ramanujachar	3
Mrs Margaret Stephens	1

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

Name	Number of Meetings Attended
Dr Clifford Allen	2

Mr Richard Andoh	3
Mrs Lisa Frances Armstrong	2
Dr Ronja Bahadori	14
Ms Sonia Baryschpolec	8
Dr Mike Gibson	3
Dr Simon Kolstoe	15
Mr Trevor Olding	4
Dr Ramya Ramanujachar	3
Mrs Margaret Stephens	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Richard Andoh	31/03/2017	Mental Capacity Act, medical negligence and confidentiality Module - Medical law program
Mrs Lisa Frances Armstrong	29/06/2016	Local Training Day - Hampshire B
Mrs Lisa Frances Armstrong	13/07/2016	Attendance at the JSWEC conference 2016, Milton Keynes Presentation of two papers
Mrs Lisa Frances Armstrong	24/08/2016	Attendance at 6th International Conference on Sociology and Social Work Presented 1 paper
Mrs Lisa Frances Armstrong	08/02/2017	Continuing research in to the experience of carers. This requires constant reading regarding ethical practice and specifically the ethics of citizenship
Mrs Lisa Frances Armstrong	08/02/2017	Teaching/lecturing students in law and ethical practice in preparation for social work placement
Mrs Lisa Frances Armstrong	13/02/2017	E&D training online course
Dr Ronja Bahadori	29/06/2016	Local Training Day - Hampshire B
Dr Ronja Bahadori	24/02/2017	Local Training - Bristol REC
Ms Sonia Baryschpolec	02/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Ms Sonia Baryschpolec	01/12/2016	Training - National Training Day for Committee Chairs
Ms Sonia Baryschpolec	21/01/2017	E&D Training.
Ms Sonia Baryschpolec	16/02/2017	National members training day
Ms Sonia Baryschpolec	29/03/2017	The Practicalities of Running a REC - a workshop for Chairs and REC Managers (formerly 'Nuts and Bolts')
Mrs Kathryn Gillanders	15/08/2016	Induction for new Research Ethics Service ONLINE
Mrs Kathryn Gillanders	30/11/2016	Training - Committee Members Induction
Mrs Kathryn Gillanders	16/02/2017	National members training day
Mrs Kathryn Gillanders	20/02/2017	Equality Diversity and Human Rights
Dr Vasileios Karagiannopoulos	14/09/2016	Induction for new members ONLINE
Professor Ron King	02/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Dr Simon Kolstoe	01/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Dr Simon Kolstoe	01/12/2016	National Chairs Training Day

Dr Simon Kolstoe	04/01/2017	MODREC training day
Dr Simon Kolstoe	03/02/2017	E&D Training
Dr James MacLean	15/09/2016	Member Induction
Mr Trevor Olding	29/06/2016	Local Training Day - Hampshire B
Mr Trevor Olding	31/03/2017	Reviewing the Research Design Of Clinical
Dr Ramya Ramanujachar	16/02/2017	National members training day

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	26.09
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	34	73.91
Total Applications Reviewed	46	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	13
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	10
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	6

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	8	17.39
Unfavourable Opinion	5	10.87
Provisional Opinion	33	71.74
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	46	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	32	69.57
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	8	17.39
Unfavourable Opinion	5	10.87
Provisional Opinion	1	2.17
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	46	100

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

Total Applications Reviewed	30
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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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	15
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	8

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	6	20.00
Favourable Opinion with Additional Conditions	4	13.33
No Opinion transfer to full committee for review	4	13.33
Provisional Opinion	15	50.00
Unfavourable Opinion	1	3.33
Total	30	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	4.60
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	12
Number of completed applications over 40 days as a % of total	26.09%
Number of days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	26
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)	16
Number of completed proportionate review applications for ethical review over 21 days	4
Number of completed proportionate review applications over 14 days as a % of total	61.54%
Number of SSAs (non-Phase 1) reviewed	5
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	101
Number of completed substantial amendments over 35 days	8
Number of completed substantial amendments over 35 days as a % of total substantial amendments	7.92%
Number of completed substantial amendments over 28 days	47
Number of completed substantial amendments over 28 days as a % of total substantial amendments	46.53%
Number of modified amendments reviewed	6
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	16.67%

Number of non substantial amendments received	98
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	18
Number of annual progress reports received	32
Number of safety reports received	28
Number of Serious Adverse Events received	13
Number of final reports received	10

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/SC/0197	VAS203/III/1/04_Nostra Phase III Trial	28
16/SC/0216	The OPTIMIST-A Trial	37
16/SC/0245	NIOX VERO Nasal Application in Primary Ciliary Dyskinesia	40
16/SC/0333	An Evaluation of the Solaticare System of Hygienic Care	17
16/SC/0334	Total Haemoglobin In Ventilated patiEnts The 'THrIVE' study	34
16/SC/0350	Ketogenic Diet & Delirium on ICU - A Feasibility Study	29
16/SC/0364	MENOS 4	35
16/SC/0378	Evolocumab in patients with HeFH aged 10-17	33
16/SC/0387	The Merge Study version1.0	43
16/SC/0389	ACADIA ACP-103-032	30
16/SC/0405	Live Music Within a Hospital Ward for Patients with Dementia.V1.1	45
16/SC/0413	Understanding the experience of anxiety in young people with ASD	29
16/SC/0416	D5290C00003 - MEDI8897 Against RSV in Healthy Preterm Infants	27
16/SC/0425	Wild type N. lactamica challenge and eradication pilot study	43
16/SC/0431	MotivATE intervention to increase eating disorders engagement	42
16/SC/0529	Dementia care and the use of multisensory environments in hospital	49
16/SC/0530	Ketogenic diet drink study	43
16/SC/0548	MS200588-0004, Safety & Efficacy of MSB11022 in Rheumatoid Arthritis	44
16/SC/0593	The effect of temporality on communication with patients with dementia	60
16/SC/0594	Observing meal time experiences for people with dementia in hospital	56
16/SC/0599	An investigation of decision making around treatment escalation	40
16/SC/0633	The PROMOTE Study	49
16/SC/0638	Prostate Cancer UK Module 4 Phase 2: Development of a new garment	27
16/SC/0649	Respiratory Monitoring of Intrathecal Baclofen- a Feasibility Study	29
16/SC/0675	Hydration HEALTH	37
17/SC/0002	Feasibility of SSM website and FC in IBD	37
17/SC/0024	Zika virus infection and persistence in body fluids. vers 11, 22 Dec	31
17/SC/0025	Edoxaban vs. VKA in Subjects undergoing Catheter Ablation:ELIMINATE-AF	49
17/SC/0026	IFNopathy natural history study	32
17/SC/0052	RAS in Gait Training for Children and Youth after ABI	27
17/SC/0055	Secukinumab treatment in Juvenile Idiopathic Arthritis	40
17/SC/0067	STOP trial	40

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

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

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SC/0324	StatinWISE	25
16/SC/0330	Supporting family caregivers at end of life	26
16/SC/0353	Bone Microarchitecture in Spinal Cord Injury	24
16/SC/0542	GX30191 Lampalizumab open label extension in geographic atrophy	29
16/SC/0576	Phase 2 study investigating Fibrinogen Supplementation Sources	24
16/SC/0596	CONTRACT	28
17/SC/0015	Effects of Functional Exercise on Fitness and QoL in Cancer Survivors	23
17/SC/0023	V56502: Efficacy, safety, & tolerability of V565 treatment	28

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/SC/0258	MotivATE intervention to increase eating disorders engagement	24
16/SC/0294	v0.1 Fitting of artificial eyes in children with retinoblastoma	28
16/SC/0505	Short term management of patients with dementia admitted to hospital	27
16/SC/0674	Genotyping in patients with primary immunodeficiency	22
17/SC/0064	Decision making in recurrent rectal cancer surgery	23

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/SC/0540	Microbial keratitis: Pathogen identification using impedance cytometry	n/a

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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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/SC/0173	How loneliness impacts on patients with COPD (version 1)	29
16/SC/0230	PROM-SA: Development of a QoL tool for patients with severe asthma	32
16/SC/0239	A comparison of two ECBG sampling techniques to ABG sampling	23
16/SC/0289	Electronic data collection of QoL PROMS in Prostate cancer	21
16/SC/0368	What are the psychological effects of Guillain-Barre Syndrome?	19
16/SC/0372	Vascular complications after transradial catheterization	19
16/SC/0426	Explaining the Invisible - V1.1	11
16/SC/0428	REVAMP:Response evaluation in myeloma using 18F-FDG PET/MRI	14
16/SC/0587	Informing Core Outcome Set Development in Cauda Equina Syndrome.	20
16/SC/0591	The impact of a mindfulness course on birthing experiences	19
16/SC/0656	Immune System and Cardiovascular disease	15
16/SC/0700	Attitudes Towards Tobacco and E-Cigarettes V1	19
17/SC/0084	AMINO III	18
17/SC/0087	Pilot Study T1 Diabetes Patients using Automated Monitoring	19

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SC/0589	LUSH (LUng Symptom awareness and Health)	20

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/SC/0367	ATRX IHC in IDH-1 mutated low grade gliomas	11
16/SC/0467	NETL: Pulmonary neuroendocrine tumours	9
16/SC/0468	Patient experiences of out-of-hours point of care blood tests	11
17/SC/0043	Teachable moments and type 2 diabetes	11
17/SC/0138	Oral Health-Related Quality of Life after Dental Treatment under G.A.	20
17/SC/0140	Knowledge and experience of peritoneal dialysis-associated peritonitis	20

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SC/0209	ADRCs for the prevention of anastomotic leak	22
16/SC/0296	Christie Ambassadors v1.0	11
16/SC/0592	EMPIRIC Study	13
16/SC/0699	Synthetic Cannabinoids-effects,treatments and outcomes within the ED.	11

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/SC/0212	Predictors for time to return to play after ankle sprain Version 1	14

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
028/04/t/AM02	RHM OPH0081	Amend No5 Nov 2016	06/12/2016	35
03/11/090/AM14	DNA Polymorphisms in Mental Illness	Amendment 11	03/08/2016	24
05/Q1702/8/AM06	A molecular genetic study of primary open angle glaucoma	Amendment 6 (19th October 2016)	19/10/2016	33
06/Q1702/109/AM23	The pathophysiology of Primary Ciliary Dyskinesia	17	01/12/2016	26
07/H0502/113/AM27	MAVIDOS	2.4	04/07/2016	29
07/H0502/85/AM06	Imprinting disorders in humans	3	24/03/2016	28
08/H0502/132/AM40	BH21260- Mircera® vs. reference ESAs in CKD patients	SA36	09/05/2016	22
08/H0502/132/AM41	BH21260- Mircera® vs. reference ESAs in CKD patients	SA 37	10/11/2016	33
09/H0502/126/AM06	Cortical changes in stroke following rehabilitation (Version 1).	6	27/05/2016	29
09/H0502/58/AM12	OxVALVE	10.0	04/05/2016	32
09/H0502/88/AM05	Prospective cohort study of children with hips dislocated at rest	Substantial Amendment 1/12	08/12/2016	7
11/SC/0048/AM04	The Cellular and Molecular Biology of Brain Tumours	Substantial Amendment 2	08/09/2016	29
11/SC/0111/AM02	Screening and diagnosis of familial kidney diseases	2	30/08/2016	27
11/SC/0169/AM15	Trial of Ipilimumab Versus Placebo in Subjects with Lung Cancer	19	02/03/2016	18
11/SC/0169/AM16	Trial of Ipilimumab Versus Placebo in Subjects with Lung Cancer	Protocol Amendment 13	08/06/2016	33
11/SC/0446/AM17	9HB01EXT - Long-Term Safety and Efficacy of (rFIXFc) Haemophilia B	9HB01EXT	09/03/2016	43
13/SC/0012/AM14	LOCATE - Local Care and Treatment Evaluation	22	11/04/2016	32
13/SC/0012/AM15	LOCATE - Local Care and Treatment Evaluation	SA9	24/04/2016	45
13/SC/0012/AM17	LOCATE - Local Care and Treatment Evaluation	SA10	17/11/2016	24
13/SC/0179/AM09	Stem cells for drug discovery	Substantial Amendment 9	23/06/2016	32
13/SC/0259/AM25	Idelalisib + Bendamustine + Rituximab for Previously Treated iNHL	11	05/04/2016	32

13/SC/0332/AM35	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 28	25/05/2016	21
13/SC/0332/AM36	Takeda TOMM40_301 Alzheimer's Disease study	SA 29	25/10/2016	23
13/SC/0332/AM39	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 32	31/01/2017	27
13/SC/0416/AM01	Leukocytes: Inflammation Model Systems (LIMS)	1	03/08/2016	24
13/SC/0490/AM16	Lebrikizumab in adolescent patients with uncontrolled asthma	AM16 2016/07/04	04/07/2016	76
13/SC/0490/AM17	Lebrikizumab in adolescent patients with uncontrolled asthma	AM17	04/11/2016	31
13/SC/0556/AM02	Maps follow up.	Amendment 2	09/02/2017	22
14/SC/0164/AM04	SILENCE Phase 1: Sleep Assessments in the ICU	3	31/05/2016	28
14/SC/1031/AM14	AB09004 mild to moderate Alzheimer's disease	9.0 UK	02/08/2016	20
14/SC/1143/AM06	ATAFUTI	AM 07	23/03/2016	10
14/SC/1143/AM07	ATAFUTI	08	13/06/2016	30
14/SC/1183/AM07	Acute fatigue assessment and management (FAME)	Amendment 8	01/06/2016	32
14/SC/1409/AM07	ART - V1.0	AM04	23/01/2017	14
14/SC/1425/AM08	GX29185 Lampalizumab in Geographic Atrophy	SA6	28/09/2016	35
15/SC/0065/AM08	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	7	04/05/2016	15
15/SC/0065/AM09	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	SA08	29/09/2016	35
15/SC/0065/AM11	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	Amendment 6.0 (Revised CSP ed5)	07/11/2016	39
15/SC/0065/AM13	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	SA11	31/01/2017	34
15/SC/0082/AM06	HOME-BP	Amendment 6	13/04/2016	23
15/SC/0082/AM08	HOME-BP	Amendment 7	20/06/2016	35
15/SC/0082/AM12	HOME-BP	8	01/02/2017	17
15/SC/0113/AM05	Measuring listening effort and fatigue in hearing impaired individuals	Amendment 4	31/03/2016	23
15/SC/0113/AM06	Measuring listening effort and fatigue in hearing impaired individuals	5	25/05/2016	22
15/SC/0142/AM05	NiPPeR	Amendment 5	30/03/2016	32
15/SC/0142/AM06	NiPPeR	Amendment 6, 11 Oct 2016	11/10/2016	24
15/SC/0257/AM05	Long term abdominal drains in end stage cirrhosis	AMO5 31 Oct 2016	31/10/2016	34

15/SC/0397/AM02	Amino acid feed children's study NJ002	Amendment 1	10/03/2016	35
15/SC/0409/AM04	Abicipar Pegol in Neovascular age related macular degeneration	150998-006 Amendment 2	28/04/2016	38
15/SC/0409/AM09	Abicipar Pegol in Neovascular age related macular degeneration	Edition 9	01/10/2016	34
15/SC/0433/AM03	The MultiCath Study	Substantial Amendment 3	18/03/2016	29
15/SC/0433/AM04	The MultiCath Study	Amendment 4	13/04/2016	27
15/SC/0433/AM06	The MultiCath Study	Substantial Amendment 5	05/09/2016	14
15/SC/0435/AM03	Study examining the effect of Etanercept on inflammation in the brain	Substantial amendment 02	12/10/2016	35
15/SC/0448/AM08	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Substantial Amendment 6	08/04/2016	29
15/SC/0448/AM09	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Substantial Amendment 7	12/05/2016	27
15/SC/0448/AM10	Phase III study with Finerenone in Type II Diabetes and DKD, CV	8	15/07/2016	24
15/SC/0448/AM11	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Substantial Amendment 9	03/10/2016	32
15/SC/0559/AM01	Central and peripheral blood pressure in stroke		12/05/2016	24
15/SC/0605/AM01	Measurement of quality of life in carers of people with dementia	Amendment 1	27/06/2016	29
15/SC/0606/AM01	Study of Mirtazapine or Carbamazepine for Agitation in Dementia	Amendment 1	22/03/2016	30
15/SC/0606/AM04	Study of Mirtazapine or Carbamazepine for Agitation in Dementia	SYMBAD - amendment 2	04/08/2016	30
15/SC/0682/AM03	CLARINET FORTE Final Version: 19 May 2015	Substantial Amendment 2	27/01/2017	24
15/SC/0730/AM01	Does Immune Responsiveness to MSU crystals reduce over time?	SA1	29/06/2016	27
15/SC/0775/AM03	Incorporation of omega-3 fatty acids in healthy humans	Amendment 3	27/05/2016	24
15/SC/0777/AM01	CLASP: Development of a website to support survivors of cancer V.1	Substantial Amendment 1	22/03/2016	31
16/SC/0015/AM05	LUD2015-005	SA05	16/02/2017	11
16/SC/0017/AM02	Making Drinking Fun	Substantial	26/04/2016	32

		Amendment 1		
16/SC/0018/AM01	Study of CTX-4430 in Cystic Fibrosis Patients	Substantial Amendment 1	27/05/2016	28
16/SC/0018/AM02	Study of CTX-4430 in Cystic Fibrosis Patients	Substantial Modification nÂ°2	22/12/2016	26
16/SC/0018/AM03	Study of CTX-4430 in Cystic Fibrosis Patients	SA03	03/03/2017	27
16/SC/0019/AM01	SFX-01 after subarachnoid haemorrhage	EVG001SAH	21/03/2016	26
16/SC/0019/AM02	SFX-01 after subarachnoid haemorrhage	3	21/03/2016	18
16/SC/0019/AM04	SFX-01 after subarachnoid haemorrhage	EVG001SAH; V4	09/02/2017	7
16/SC/0055/AM01	A software utility for mapping human movement onto game control	Substantial Amendment 1	06/05/2016	16
16/SC/0067/AM01	Investigate study drug Arimoclomol with patients diagnosed with NP-C	Amendment 1	29/04/2016	20
16/SC/0067/AM02	Investigate study drug Arimoclomol with patients diagnosed with NP-C	Protocol Amendment 4.0	18/10/2016	35
16/SC/0067/AM03	Investigate study drug Arimoclomol with patients diagnosed with NP-C	IB v2.0	09/01/2017	10
16/SC/0121/AM01	Wilson Disease Standard of Care Treatment Study	AM01	14/09/2016	35
16/SC/0121/AM02	Wilson Disease Standard of Care Treatment Study	AMENDMENT 1	21/09/2016	37
16/SC/0165/AM02	Cognition in multiple sclerosis	1.3	18/11/2016	49
16/SC/0165/AM03	Cognition in multiple sclerosis	1.4	23/02/2017	8
16/SC/0197/AM03	VAS203/III/1/04_Nostra Phase III Trial	SA 2	07/10/2016	32
16/SC/0324/AM01	StatinWISE	2.0	08/08/2016	14
16/SC/0364/AM03	MENOS 4	AM02	03/01/2017	9
16/SC/0372/AM01	Vascular complications after transradial catheterization	SA 1	23/12/2016	24
16/SC/0389/AM01	ACADIA ACP-103-032	Substantial Amendment 1 dated	18/11/2016	7
16/SC/0389/AM02	ACADIA ACP-103-032	GB Amendment 01 Protocol	15/02/2017	16
16/SC/0416/AM01	D5290C00003 - MEDI8897 Against RSV in Healthy Preterm Infants	AM01	10/11/2016	9
16/SC/0425/AM01	Wild type N. lactamica challenge and eradication pilot study	Amendment 1	07/12/2016	30
16/SC/0425/AM02	Wild type N. lactamica challenge and eradication pilot study	2	01/03/2017	27
16/SC/0426/AM01	Explaining the Invisible - V1.1	1	30/11/2016	24
16/SC/0548/AM01	MS200588-0004, Safety & Efficacy of MSB11022 in	Substantial	09/01/2017	31

	Rheumatoid Arthritis	Amendment 1		
16/SC/0638/AM01	Prostate Cancer UK Module 4 Phase 2: Development of a new garment	1	08/03/2017	21

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q1702/109/AM21	The pathophysiology of Primary Ciliary Dyskinesia	Amendment 15	01/02/2016	28
06/Q1702/109/AM22	The pathophysiology of Primary Ciliary Dyskinesia	16	01/08/2016	35
13/SC/0332/AM38	Takeda TOMM40_301 Alzheimer's Disease study	SA31	12/12/2016	35
14/SC/0016/AM03	Establishing normal oximetry values in infants using Masimo technology	3	27/04/2016	13
14/SC/1183/AM06	Acute fatigue assessment and management (FAME)	Amendment 7	01/03/2016	21
16/SC/0197/AM01	VAS203/III/1/04_Nostra Phase III Trial	Substantial Amendment 1	08/06/2016	34
16/SC/0378/AM01	Evolocumab in patients with HeFH aged 10-17	Substantial Amendment 1	19/10/2016	36

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
06/Q1702/109/AM21 /1	The pathophysiology of Primary Ciliary Dyskinesia	Modified Amendment 15	02/06/2016	13
06/Q1702/109/AM22 /1	The pathophysiology of Primary Ciliary Dyskinesia	Modified Amendment 16	01/08/2016	16
14/SC/1170/AM01/1	CALIBRATE	Modified Amendment 1	22/09/2016	14

15/SC/0481/AM01/1	The role of lymphocytes in Alopecia Areata	Modified Substantial Amendment	24/02/2016	5
16/SC/0197/AM01/1	VAS203/III/1/04_Nostra Phase III Trial	Modified Amendment 1	14/07/2016	11
16/SC/0378/AM01/1	Evolocumab in patients with HeFH aged 10-17	Modified Amendment 1	08/12/2016	14

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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
16/SC/0173	How loneliness impacts on patients with COPD (version 1)	29
16/SC/0209	ADRCs for the prevention of anastomotic leak	22
16/SC/0230	PROM-SA: Development of a QoL tool for patients with severe asthma	32
16/SC/0239	A comparison of two ECBG sampling techniques to ABG sampling	23

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
11/SC/0446/AM17	9HB01EXT - Long-Term Safety and Efficacy of (rFIXFc) Haemophilia B	9HB01EXT	09/03/2016	43
13/SC/0012/AM15	LOCATE - Local Care and Treatment Evaluation	SA9	24/04/2016	45
13/SC/0490/AM16	Lebrikizumab in adolescent patients with uncontrolled asthma	AM16 2016/07/04	04/07/2016	76
15/SC/0065/AM11	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	Amendment 6.0 (Revised CSP ed5)	07/11/2016	39
15/SC/0409/AM04	Abicipar Pegol in Neovascular age related macular degeneration	150998-006 Amendment 2	28/04/2016	38
16/SC/0121/AM02	Wilson Disease Standard of Care Treatment Study	AMENDMENT 1	21/09/2016	37
16/SC/0165/AM02	Cognition in multiple sclerosis	1.3	18/11/2016	49
16/SC/0378/AM01	Evolocumab in patients with HeFH aged 10-17	Substantial	19/10/2016	36

		Amendment 1		
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Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q1702/109/AM22 /1	The pathophysiology of Primary Ciliary Dyskinesia	Modified Amendment 16	01/08/2016	16