

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

Annual Report

01 April 2017 - 31 March 2018



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 Helen Ryan
REC Manager:	Mrs Claudia Bywater (01/03/2017 until 01/08/2017) Ms Helen Sivey (01/08/2017 until 01/01/2018) Miss Lucy Roberts (01/01/2018 until present)
REC Assistant:	Miss Elizabeth Hearn (until 01/08/2017) Ms Amy Peters (01/08/2017 until 01/01/2018) Alison Doherty (01/01/2018 until present)
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The committee has been working well this year apart from having lost four members. Due to the professional commitments of other committee members we have sometimes struggled to get enough members to meetings, occasionally needing to co-opt in, and in a couple case being delayed starting due to waiting for people to arrive. We have also struggled again with consistency from our REC managers, having three different people over the course of the year as well as three different assistants. This makes continuity of processes quite difficult especially as seen with the organisation of our sub-committees, an issue that led to one of our officers standing down. The committee is also frustrated by the number of telephone attendees and the lack of appropriate conferencing facilities in our venues. Meetings have on the whole run to time and are still enjoyed by all members.

South Central - Hampshire A Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Jill Adams	GP	Expert	27/06/2017	
Mr Richard Andoh	Pharmacist	Expert	01/12/2009	
Dr Catherine Angell	Midwife/Lecturer	Expert	01/12/2010	03/07/2017
Mrs Lisa Frances Armstrong	Senior Lecturer Social Work	Expert	14/10/2011	
Dr Ronja Bahadori	Clinical Trial Coordinator	Expert	01/06/2011	
Ms Sonia Baryschpolec	Staff nurse	Expert	01/01/2014	
Dr James Gavin	Academic (Exercise Physiology)	Lay Plus	06/06/2017	
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	22/05/2017
Dr Simon Kolstoe	Senior Lecturer in Biochemistry	Expert	01/07/2009	
Dr Karl Nunkoosing	Principal Psychology Lecturer	Lay	01/10/2014	19/05/2017
Mr Trevor Olding	Clinical Coordinator	Lay	11/03/2013	
Dr Emmanouil Papavasileiou	Research Fellow in International Labour Mobility	Lay Plus	16/09/2016	17/01/2018
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	
Dr Anja Timm	Senior Research Fellow in Medical Education	Lay Plus	07/07/2017	

South Central - Hampshire A Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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South Central - Hampshire A Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Miss Shelly Glaister-Young	Barrister	Lay Plus	09/05/2017
Reverend Catherine McBride	Vicar	Lay	09/05/2017
Ms Julie Brinton	Retired Speech and Language Therapist	Expert	13/06/2017
Dr Linda Cartwright	Retired Consultant Epidemiologist	Expert	13/03/2018

Dr Thomas Edward Woodcock	Retired Consultant - Intensive Care Unit	Expert	13/03/2018
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South Central - Hampshire A Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Dr Jill Adams	None	29/06/2017
Mrs Lisa Frances Armstrong	External Examiner for the MA in social work at the university of Derby External Examiner for the BA Social Work degree validated by Bath University and run at Wiltshire College. Colleagues or students could apply through the REC for ethical review for their research.	31/03/2018
Dr Ronja Bahadori	Senior Research Support Specialist University of Oxford Review studies for sponsorship on behalf of the University of Oxford and signing off Substantial Amendments.	31/03/2018
Ms Sonia Baryschpolec	Works as a research nurse; occasionally recognises investigators from her Trust.	10/10/2017
Dr James Gavin	Professional member of, and CPD representative for the British Association for Sport and Exercise Sciences (BASES), but no financial assets held. Academic at Bournemouth University Member of British Association of Sport & Exercise Science	06/06/2017
Mrs Kathryn Gillanders	None	31/03/2018
Dr Simon Kolstoe	Chair of MODREC Consultancy: MOD research ethics and governance Senior Lecturer at University of Portsmouth	10/10/2017
Mr Trevor Olding	None	10/10/2017
Ms Helen Ryan	Involved with and about to become a Trustee of Advocates for Children a charity that advises and represents children with SEN and mental health difficulties.	31/03/2018
Dr Anja Timm	Worked at the University of Southampton in the Faculty of Medicine for the past ten years; is the Deputy Head of the Medical Education Development Unit there. A member of the Faculty of Medical Ethics Committee of the University of Southampton..	24/10/2017

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

Month	Date	Number of Members Present at Meeting
April	11/04/2017	9
May	09/05/2017	8
June	13/06/2017	10
July	11/07/2017	11
August	08/08/2017	8
October	10/10/2017	9
November	14/11/2017	12
January	09/01/2018	8
March	13/03/2018	8

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	25/04/2017	3
May	23/05/2017	3
June	27/06/2017	3
July	25/07/2017	3
August	23/08/2017	3
November	22/11/2017	3
December	27/12/2017	3
January	24/01/2018	3
February	28/02/2018	3
March	28/03/2018	3

10 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	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	16/06/2017	2
July	11/07/2017	2
July	25/07/2017	2
August	08/08/2017	3
September	12/09/2017	2
September	26/09/2017	2
October	10/10/2017	2

October	24/10/2017	2
November	14/11/2017	2
November	28/11/2017	2
December	04/12/2017	2
December	08/12/2017	2
December	12/12/2017	2
December	19/12/2017	2
January	09/01/2018	2
January	16/01/2018	2
January	23/01/2018	2
January	30/01/2018	2
February	06/02/2018	2
February	13/02/2018	2
February	20/02/2018	2
February	23/02/2018	4
February	27/02/2018	2
March	06/03/2018	2
March	13/03/2018	2
March	20/03/2018	2
March	27/03/2018	2

32 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 Jill Adams	5
Mr Richard Andoh	6
Mrs Lisa Frances Armstrong	4
Dr Ronja Bahadori	6
Ms Sonia Baryschpolec	7
Dr James Gavin	7
Mrs Kathryn Gillanders	6
Dr Simon Kolstoe	9
Mr Trevor Olding	8
Dr Emmanouil Papavasileiou	3
Dr Ramya Ramanujachar	4
Ms Helen Ryan	6
Mrs Margaret Stephens	4
Dr Anja Timm	3

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

Name	Number of Meetings Attended
Mr Richard Andoh	2
Mrs Lisa Frances Armstrong	1
Dr Ronja Bahadori	4
Ms Sonia Baryschpolec	2
Dr James Gavin	1
Mrs Kathryn Gillanders	4
Dr Simon Kolstoe	4
Mr Trevor Olding	2
Dr Emmanouil Papavasileiou	1
Dr Ramya Ramanujachar	2
Ms Helen Ryan	4

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

Name	Number of Meetings Attended
Dr Jill Adams	1
Mr Richard Andoh	4
Mrs Lisa Frances Armstrong	3
Dr Ronja Bahadori	13
Ms Sonia Baryschpolec	6

Dr James Gavin	3
Mrs Kathryn Gillanders	3
Dr Vasileios Karagiannopoulos	1
Dr Simon Kolstoe	15
Mr Trevor Olding	4
Dr Emmanouil Papavasileiou	4
Dr Ramya Ramanujachar	1
Ms Helen Ryan	4
Mrs Margaret Stephens	3
Dr Anja Timm	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Jill Adams	12/12/2017	National REC Members' Training Day
Mrs Lisa Frances Armstrong	12/12/2017	Training - National Members
Mrs Lisa Frances Armstrong	31/03/2018	Higher Education Academy Professional Development Course for External Examiners of Honours and Masters programmes
Dr Ronja Bahadori	12/12/2017	National REC Members' Training Day
Ms Sonia Baryschpolec	17/10/2017	Training for new REC Chairs
Ms Sonia Baryschpolec	12/12/2017	National Members' Training Day
Dr James Gavin	25/07/2017	HRA REC Member Induction
Dr James Gavin	12/12/2017	National Members' Training Day
Dr James Gavin	28/02/2018	Training - Ethical Issues in Phase One Research: An Advanced Training Course
Mrs Kathryn Gillanders	12/12/2017	National Members' Training Day
Mrs Kathryn Gillanders	13/02/2018	The ethical issues of research involving children
Dr Vasileios Karagiannopoulos	19/04/2017	Equality Diversity and Human Rights
Dr Simon Kolstoe	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Simon Kolstoe	12/12/2017	National Members' Training Day
Mr Trevor Olding	12/12/2017	National REC Members Training Day
Dr Emmanouil Papavasileiou	04/05/2017	Equality and Diversity
Dr Emmanouil Papavasileiou	12/12/2017	National REC Members' Training Day
Dr Emmanouil Papavasileiou	15/02/2018	HRA Induction Training
Dr Ramya Ramanujachar	29/11/2017	Equality and Diversity
Ms Helen Ryan	19/07/2017	Induction for new Research Ethics Service Committee members
Ms Helen Ryan	19/07/2017	Equality and Diversity
Ms Helen Ryan	25/07/2017	REC Member Induction
Ms Helen Ryan	12/12/2017	National REC Members' Training Day
Mrs Margaret Stephens	28/11/2017	Online Equality & Diversity Module
Mrs Margaret Stephens	12/12/2017	National REC Members' 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	14	31.82
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	30	68.18
Total Applications Reviewed	44	100

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	10
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	9
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	2

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	5	11.36
Favourable Opinion with Additional Conditions	6	13.64
Unfavourable Opinion	2	4.55
Provisional Opinion	31	70.45
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	44	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	27	61.36
Further Information Favourable Opinion with Additional Conditions	1	2.27
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	11.36
Favourable Opinion with Additional Conditions	6	13.64
Unfavourable Opinion	2	4.55
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	2	4.55
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.27
Total	44	100

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

Total Applications Reviewed	22
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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	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	7
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	0

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	8	36.36
Favourable Opinion with Additional Conditions	1	4.55
No Opinion transfer to full committee for review	1	4.55
Provisional Opinion	12	54.55
Unfavourable Opinion	0	0.00
Total	22	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	4.89
Number of completed applications for full ethical review	43
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	15
Number of completed applications over 40 days as a % of total	34.09%
Number of days taken to final decision – average (mean)	36
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	5
Number of completed proportionate review applications over 21 days as a % of total	23.81%
Number of SSAs (non-Phase 1) reviewed	17
Number of completed applications for SSA review over 25 days	4
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	23.53%
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	125
Number of completed substantial amendments over 35 days	8
Number of completed substantial amendments over 35 days as a % of total substantial amendments	6.40%
Number of completed substantial amendments over 28 days	28
Number of completed substantial amendments over 28 days as a % of total substantial amendments	22.40%
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	80
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	32
Number of annual progress reports received	49
Number of safety reports received	17
Number of Serious Adverse Events received	1

Number of final reports received	11
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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
17/SC/0136	Open Label Evolocumab Study in Patients Aged 10-17yrs with HeFH & HoFH	35
17/SC/0177	Singing for Wellness v1.0	39
17/SC/0189	Measuring Heart & Lung Function in Critical Care	37
17/SC/0191	On-X Aortic Prosthetic Heart Valve Registry	55
17/SC/0232	Javelin DLBCL: Phase 1B/3 study of Avelumab in patients with DLBCL	39
17/SC/0249	Evaluating advice and support for people with emotional distress	45
17/SC/0267	Neuro LTC Study Version 1.0	44
17/SC/0271	RESULT: Reliable, Emergent Solution Using Lipotamase Treatment	56
17/SC/0287	Microwave Ablation in Advanced Melanoma Study (MAAM Study) Version 1	42
17/SC/0336	The VENTILATE study	60
17/SC/0346	First Steps	32
17/SC/0348	CPPROQVLP012_Phase 3_Plant derived Influenza Vaccine in Adults	43
17/SC/0368	Molecular point-of-care 'test and treat' for influenza (FluPOC) v1.0	34
17/SC/0402	HEXI-PREP by Clinell Wipes	41
17/SC/0529	Automated analysis of lung sounds as a predictor of VAP	46
17/SC/0532	Inhaled SNG001 in COPD patients	32
17/SC/0533	ARGO	38
17/SC/0575	Adrenal insufficiency and Hepatorenal syndrome (RAI & HRS)	35
17/SC/0595	Phase 3 study of pimavanserin vs placebo in dementia patients	51
17/SC/0609	Daiichi Sankyo DS8201-A-U201 (DS-8201a)	35
17/SC/0613	The A-STOP Study	38
18/SC/0005	INGR1D	50
18/SC/0008	Improving Prediction of Outcome in Cardiac Arrest - KOCAR	44
18/SC/0012	Video somnography in child brain tumour survivors	49
18/SC/0015	Adjuvant canakinumab vs placebo in stages IB, II-IIIa resected NSCLC	52
18/SC/0138	Outcomes that matter to young people with persistent pain	24
18/SC/0143	GRACE - 208901 - Phase 1 study	37

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0234	Dehydr8 and deactiv8	57

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/SC/0180	RCT of parent-based intervention for language delayed 2 to 3 year olds	26
17/SC/0183	The Reliability of a Behavioural Pain Assessment in PDOC	28
17/SC/0511	Sensitivity and specificity of the Wessex Trauma Network Bypass Tool	30
17/SC/0524	ISAIHA- InveStigation of Anaemia in Hospital	24
18/SC/0137	Dapagliflozin during Exercise for the PrevenTion of Hypos (DEPTH)	25

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0342	Structured Exercise Training in Idiopathic Pulmonary Fibrosis	24
17/SC/0398	Pilot trial of Individual Placement Support and chronic pain	17
17/SC/0400	Markers of neuro-inflammation in children with Down syndrome & apnoea	17
17/SC/0406	COMET	17
17/SC/0522	Understanding RSV: Severe disease and the long term consequences	24
18/SC/0018	Perioperative Utilisation of Supplemental Oxygen (PULSE Ox)	39

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/SC/0344	Catric Study (Version 1)	23
18/SC/0140	Whey protein and glycaemia in adults with poor glucose control_V1	21

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
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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
17/SC/0377	Cytosorb filter in patients having surgery for infective endocarditis	n/a
18/SC/0135	Zimuraâ„¸ in Autosomal Recessive Stargardt Disease	n/a

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
17/SC/0282	Fortified Foods in Older Inpatients Version 1	19

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/SC/0214	IRAMP	17
17/SC/0215	Technology assisted outdoor exercise referral monitoring	17
17/SC/0460	Tissue-type MRI of brain tumours	20
17/SC/0680	Mucosal Molecular Mechanisms in Allergic Rhinitis(M3AR)	41
17/SC/0687	Locality based approach to integrated care in Tower Hamlets	29
17/SC/0688	Grip-HD: Handgrip strength and physical ability in haemodialysis v1	36
18/SC/0058	Early markers in biliary atresia (EMBA)	13
18/SC/0059	Oro-facial MoCa	22
18/SC/0114	Understanding activity levels in cardiac transplant patients	23
18/SC/0172	Exercise for Patients with Prostate Cancer	9
18/SC/0174	TRICALS Respiratory Registry	17
18/SC/0177	Magnetic resonance imaging in obesity version 1.0	17

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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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/SC/0218	Lymphocyte development in paediatric HIV infection	14
17/SC/0219	Feasibility of Using Accelerometers in Hospitalised Older Adults	14
17/SC/0266	PAGE - Peritoneal diAlysis and Glucose Exposure V1.2	16
17/SC/0324	A secondary analysis of data from the STOPAH trial	10
17/SC/0374	Oxford Growth Restriction Identification Programme (OxGRIP)	13
17/SC/0375	Detecting seeded protein aggregation in Alzheimer's disease	15
17/SC/0376	The Waiting Room Project	13
17/SC/0378	Clinical Evaluation of OtA© Sensation Solution Care System	15

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0328	Novel biomarker detection from volatile chemical analyses of urine. v1	13

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
028/04/t/AM03	RHM OPH0081	Amendment number 6- Aug 17	22/09/2017	25
03/11/090/AM16	DNA Polymorphisms in Mental Illness	Substantial Amendment 12	09/11/2017	24
06/Q1702/109/AM24	The pathophysiology of Primary Ciliary Dyskinesia	Amendment 18; July 2017	10/10/2017	28
06/Q1702/99/AM09	Genetics of colorectal tumours	7 25/7/17	26/09/2017	19
08/H0502/29/AM06	Genetics of thyroid tumours	Amendment 6 25/7/17	26/09/2017	19
09/H0502/58/AM13	OxVALVE	Amendment number 11.0 31/10/20	05/12/2017	16
10/H0502/69/AM02	MicroRNA, the gut tight junction and the innate immune system	Amendment 2 040118	29/01/2018	13
11/SC/0204/AM03	Neurological conditions and oncology: immunology and interactions	2	29/01/2018	28
11/SC/0446/AM24	9HB01EXT - Long-Term Safety and Efficacy of (rFIXFc) Haemophilia B	v10	28/03/2017	15
11/SC/0446/AM26	9HB01EXT - Long-Term Safety and Efficacy of (rFIXFc) Haemophilia B	Substantial Amendment 17	15/11/2017	23
12/SC/0686/AM04	The effects of d-cycloserine on learning	Substantial Amendment 2	08/06/2017	23
13/SC/0012/AM18	LOCATE - Local Care and Treatment Evaluation	SA11	12/05/2017	25
13/SC/0012/AM19	LOCATE - Local Care and Treatment Evaluation	26	08/09/2017	25
13/SC/0058/AM02	Assessing the effectiveness of bone anchored hearing aids	Amendment number 2.0	06/07/2017	18
13/SC/0182/AM03	GORD in Asthma	Amendment no: 4 - Date: 27 Nov	27/11/2017	30
13/SC/0332/AM41	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 34 - Upd	25/08/2017	27
13/SC/0332/AM42	Takeda TOMM40_301 Alzheimer's Disease study	SA 35	29/09/2017	35

13/SC/0332/AM44	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 37 - Upd	06/10/2017	45
13/SC/0332/AM45	Takeda TOMM40_301 Alzheimer's Disease study	38	08/02/2018	13
13/SC/0506/AM04	Feasibility Study of a Coping Intervention for Recurrent Miscarriage	Amendment 4 - 2nd October 2017	02/10/2017	19
13/SC/0507/AM01	Impact of inflammation on age related hearing loss.	Amendment 1	13/03/2017	21
14/SC/1004/AM01	Impact of befriending on wellbeing in people suffering from psychosis	149082 9. Befriending research	04/03/2018	15
14/SC/1031/AM19	AB09004 mild to moderate Alzheimer's disease	15 - Voluntary halt to recruit	22/06/2017	21
14/SC/1183/AM08	Acute fatigue assessment and management (FAME)	9	01/02/2017	35
14/SC/1183/AM09	Acute fatigue assessment and management (FAME)	10	18/03/2017	24
14/SC/1409/AM08	ART - V1.0	AM05, 05/03/2018	07/03/2018	13
14/SC/1425/AM10	GX29185 Lampalizumab in Geographic Atrophy	Substantial Amendment #8 - Tem	22/09/2017	26
14/SC/1425/AM11	GX29185 Lampalizumab in Geographic Atrophy	Substantial amendment 9. Updat	01/11/2017	15
14/SC/1425/AM12	GX29185 Lampalizumab in Geographic Atrophy	SA10 - Sponsor Letters - Lampa	21/12/2017	33
15/SC/0065/AM14	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	SA12 - IB Ed11	02/08/2017	34
15/SC/0065/AM15	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	Substantial Amendment 13	14/11/2017	24
15/SC/0082/AM13	HOME-BP	Amendment 9	25/05/2017	23
15/SC/0082/AM14	HOME-BP	10 - 09-06-17	09/06/2017	30
15/SC/0082/AM16	HOME-BP	11	05/12/2017	7
15/SC/0113/AM07	Measuring listening effort and fatigue in hearing impaired individuals	Number:6 31/3/2017	31/03/2017	16
15/SC/0142/AM07	NiPPeR	Amendment 7	12/05/2017	34
15/SC/0175/AM03	'24 Hour Labour Line' - A Qualitative Exploration	2 06.12.2017	15/01/2018	15

15/SC/0199/AM05	ROSE ACS Study	Substantial Amendment 02	12/12/2017	37
15/SC/0231/AM02	The Brain Imaging In Dementia study (BRAID)	Amendment 2, 01 February 2017	06/03/2017	33
15/SC/0409/AM11	Abicipar Pegol in Neovascular age related macular degeneration	Investigator Brochure Edition	26/10/2017	38
15/SC/0409/AM12	Abicipar Pegol in Neovascular age related macular degeneration	7	12/01/2018	19
15/SC/0448/AM16	Phase III study with Finerenone in Type II Diabetes and DKD, CV	5.4.2	09/06/2017	32
15/SC/0448/AM19	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Substantial Amendment #14	22/09/2017	24
15/SC/0448/AM21	Phase III study with Finerenone in Type II Diabetes and DKD, CV	16	21/02/2018	15
15/SC/0559/AM02	Central and peripheral blood pressure in stroke	Amendment 2. 26/10/2017	26/10/2017	26
15/SC/0606/AM07	Study of Mirtazapine or Carbamazepine for Agitation in Dementia	4	10/04/2017	28
15/SC/0606/AM11	Study of Mirtazapine or Carbamazepine for Agitation in Dementia	SYMBAD - amendment 7	18/10/2017	21
16/SC/0015/AM06	LUD2015-005	006	19/06/2017	22
16/SC/0015/AM08	LUD2015-005	LUD2015-005 Substantial Amendm	31/07/2017	28
16/SC/0015/AM09	LUD2015-005	8	21/09/2017	28
16/SC/0015/AM10	LUD2015-005	LUD2015-005 Substantial Amendm	28/12/2017	26
16/SC/0018/AM04	Study of CTXA-4430 in Cystic Fibrosis Patients	Substantial Modification nÂ°4:	23/11/2017	20
16/SC/0019/AM05	SFX-01 after subarachnoid haemorrhage	5	22/03/2017	32
16/SC/0019/AM06	SFX-01 after subarachnoid haemorrhage	Substantial Amendment 6	20/09/2017	27
16/SC/0019/AM08	SFX-01 after subarachnoid haemorrhage	Substantial Amendment 7	08/11/2017	16
16/SC/0019/AM10	SFX-01 after subarachnoid haemorrhage	Updated Patient Documents	15/01/2018	21

16/SC/0019/AM11	SFX-01 after subarachnoid haemorrhage	substantial Amendment 9	11/01/2018	34
16/SC/0020/AM02	PuraStat® for Bleed Control in Endoscopic Submucosal Dissection (v1.0)	Amendment 02 19/10/2017	19/10/2017	17
16/SC/0067/AM04	Investigate study drug Arimoclomol with patients diagnosed with NP-C	IB v3.0	22/03/2017	24
16/SC/0067/AM05	Investigate study drug Arimoclomol with patients diagnosed with NP-C	Protocol amendment v5.0	11/05/2017	32
16/SC/0071/AM04	Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma	SA004_UK_Aug20 17	22/08/2017	26
16/SC/0071/AM06	Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma	1.0	20/12/2017	28
16/SC/0197/AM07	VAS203/III/1/04_Nostra Phase III Trial	7.0	11/10/2017	35
16/SC/0197/AM09	VAS203/III/1/04_Nostra Phase III Trial	IB update, Version 12, dated 2	14/11/2017	15
16/SC/0197/AM10	VAS203/III/1/04_Nostra Phase III Trial	Patient Information Sheets and	08/03/2018	11
16/SC/0209/AM01	ADRCs for the prevention of anastomotic leak	1	27/03/2017	27
16/SC/0324/AM06	StatinWISE	Substantial Amendment 3	24/05/2017	28
16/SC/0324/AM07	StatinWISE	Substantial Amendment 4	14/07/2017	24
16/SC/0364/AM04	MENOS 4	AM03	02/03/2017	35
16/SC/0364/AM06	MENOS 4	AM04	02/06/2017	27
16/SC/0364/AM08	MENOS 4	AM05 18-Sep-2017	18/09/2017	15
16/SC/0378/AM02	Evolocumab in patients with HeFH aged 10-17	2	22/02/2018	14
16/SC/0387/AM03	The Merge Study version1.0	1	08/03/2017	27
16/SC/0389/AM06	ACADIA ACP-103-032	2	22/09/2017	28
16/SC/0389/AM07	ACADIA ACP-103-032	Protocol Amendment 3 UK Specif	08/01/2018	22
16/SC/0416/AM03	D5290C00003 - MEDI8897 Against RSV in Healthy Preterm Infants	AM03	16/05/2017	21
16/SC/0425/AM03	Wild type N. lactamica challenge and eradication pilot study	3	27/04/2017	25

16/SC/0428/AM02	REVAMP:Response evaluation in myeloma using 18F-FDG PET/MRI	Amendment 3 substantial (with	16/01/2018	16
16/SC/0529/AM01	Dementia care and the use of multisensory environments in hospital	Version 2 02/08/2017	02/08/2017	33
16/SC/0542/AM03	GX30191 Lampalizumab open label extension in geographic atrophy	Substantial Amendment 3 - Temp	22/09/2017	26
16/SC/0542/AM04	GX30191 Lampalizumab open label extension in geographic atrophy	4 (Substantial) – IB v9, Proto	19/10/2017	14
16/SC/0542/AM05	GX30191 Lampalizumab open label extension in geographic atrophy	SA05	21/12/2017	28
16/SC/0548/AM03	MS200588-0004, Safety & Efficacy of MSB11022 in Rheumatoid Arthritis	Substantial Amendment 2: 06/04	06/04/2017	24
16/SC/0576/AM01	Phase 2 study investigating Fibrinogen Supplementation Sources	1	01/01/2017	34
16/SC/0576/AM02	Phase 2 study investigating Fibrinogen Supplementation Sources	2	21/04/2017	19
16/SC/0576/AM03	Phase 2 study investigating Fibrinogen Supplementation Sources	Amendment 003 IB update	30/11/2017	18
16/SC/0589/AM01	LUSH (LUng Symptom awareness and Health)	1.2	23/06/2017	26
16/SC/0596/AM03	CONTRACT	1	20/04/2017	14
16/SC/0596/AM04	CONTRACT	Substantial Amendment 2, 14 Ju	14/07/2017	31
16/SC/0596/AM05	CONTRACT	3, 17 November 2017	11/12/2017	37
16/SC/0596/AM06	CONTRACT	4	07/03/2018	21
16/SC/0633/AM02	The PROMOTE Study	1	21/12/2017	24
16/SC/0638/AM02	Prostate Cancer UK Module 4 Phase 2: Development of a new garment	2 14/06/2017	19/07/2017	41
17/SC/0023/AM05	V56502: Efficacy, safety, & tolerability of V565 treatment	SA2	19/04/2017	16
17/SC/0023/AM06	V56502: Efficacy, safety, & tolerability of V565 treatment	SA3	12/07/2017	26
17/SC/0025/AM02	Edoxaban vs. VKA in Subjects undergoing Catheter Ablation:ELIMINATE-AF	1	21/04/2017	7
17/SC/0025/AM05	Edoxaban vs. VKA in Subjects undergoing Catheter Ablation:ELIMINATE-AF	SA03 2018/01/15	15/01/2018	16

17/SC/0055/AM02	Secukinumab treatment in Juvenile Idiopathic Arthritis	SA1 Amended protocol version	11/04/2017	14
17/SC/0136/AM01	Open Label Evolocumab Study in Patients Aged 10-17yrs with HeFH & HoFH	1	25/09/2017	19
17/SC/0191/AM02	On-X Aortic Prosthetic Heart Valve Registry	Amendment 1 date: 30/10/2017	30/10/2017	30
17/SC/0232/AM02	Javelin DLBCL: Phase 1B/3 study of Avelumab in patients with DLBCL	EC SA2: Avelumab IB7¼ Addition	24/10/2017	20
17/SC/0232/AM05	Javelin DLBCL: Phase 1B/3 study of Avelumab in patients with DLBCL	3	26/01/2018	26
17/SC/0234/AM01	Dehydr8 and deactiv8	1.0	07/10/2017	43
17/SC/0249/AM01	Evaluating advice and support for people with emotional distress	Amendment No.1	13/09/2017	28
17/SC/0271/AM02	RESULT: Reliable, Emergent Solution Using Liprotamase Treatment	Amendment 2, 19-Oct-2017	30/01/2018	13
17/SC/0346/AM01	First Steps	1.0	12/10/2017	41
17/SC/0348/AM01	CPPROQVLP012_Phase 3_Plant derived Influenza Vaccine in Adults	version 1.3_UK	03/10/2017	15
17/SC/0348/AM02	CPPROQVLP012_Phase 3_Plant derived Influenza Vaccine in Adults	Substantial Amendment_Site & P	19/12/2017	12
17/SC/0402/AM01	HEXI-PREP by Clinell Wipes	2	22/11/2017	20
17/SC/0402/AM02	HEXI-PREP by Clinell Wipes	SA3 2018/01/15	17/01/2018	14
17/SC/0522/AM01	Understanding RSV: Severe disease and the long term consequences	1 08/01/2018	18/01/2018	17
17/SC/0532/AM01	Inhaled SNG001 in COPD patients	2	23/02/2018	20
17/SC/0532/AM02	Inhaled SNG001 in COPD patients	SG015 - SA-3	02/03/2018	23
17/SC/0533/AM01	ARGO	1	04/12/2017	16
17/SC/0595/AM03	Phase 3 study of pimavanserin vs placebo in dementia patients	Investigator Brochure, Edition	23/02/2018	20
17/SC/0595/AM04	Phase 3 study of pimavanserin vs placebo in dementia patients	Site 472 closure Local amendme	08/03/2018	26
17/SC/0609/AM01	Daiichi Sankyo DS8201-A-U201 (DS-8201a)	UK specific protocol and ICF S	10/01/2018	18
17/SC/0609/AM03	Daiichi Sankyo DS8201-A-U201 (DS-8201a)	2	23/02/2018	20

17/SC/0613/AM01	The A-STOP Study	Amendment 2 30/01/2018	30/01/2018	14
18/SC/0015/AM01	Adjuvant canakinumab vs placebo in stages IB, II-III A resected NSCLC	1	28/02/2018	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0502/72/AM01	Molecular and Genetic Mechanisms in Pancreatic Carcinoma	Amendment 1.0 03/03/2017	03/03/2017	12
13/SC/0574/AM02	Evaluating the pathogenicity of novel germline RET sequence variants	4	09/10/2017	23
15/SC/0448/AM15	Phase III study with Finerenone in Type II Diabetes and DKD, CV	11	14/03/2017	42
15/SC/0605/AM06	Measurement of quality of life in carers of people with dementia	2	23/02/2017	34
17/SC/0191/AM03	On-X Aortic Prosthetic Heart Valve Registry	Amendment 2 Date: 30/10/2017	30/10/2017	30

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
10/H0502/72/AM01/1	Molecular and Genetic Mechanisms in Pancreatic Carcinoma	Modified to Amendment 1.0 03/0	03/03/2017	9
13/SC/0332/AM38/1	Takeda TOMM40_301 Alzheimer's Disease study	SA31 modified	29/03/2017	5
13/SC/0574/AM02/1	Evaluating the pathogenicity of novel germline RET sequence variants	Version 4 resubmitted (13/12/1)	15/12/2017	19
15/SC/0448/AM15/1	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Modified SA 11	28/04/2017	7
15/SC/0605/AM06/1	Measurement of quality of life in carers of people with dementia	Modified - 3 11/5/17	11/05/2017	5

17/SC/0191/AM03/1	On-X Aortic Prosthetic Heart Valve Registry	3.0	19/12/2017	13
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Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

REC Reference	Title	Number of Days on Clock
17/SC/0680	Mucosal Molecular Mechanisms in Allergic Rhinitis(M3AR)	41
17/SC/0687	Locality based approach to integrated care in Tower Hamlets	29
17/SC/0688	Grip-HD: Handgrip strength and physical ability in haemodialysis v1	36
18/SC/0059	Oro-facial MoCa	22
18/SC/0114	Understanding activity levels in cardiac transplant patients	23

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/SC/0475	A Double-Blind, Placebo-Contro	30
17/SC/0558	An evaluation of the efficacy	35
17/SC/0587	A Double Blind, Randomized, PI	26
17/SC/0594	The First Steps pathway for ta	26

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
13/SC/0332/AM44	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 37 - Upd	06/10/2017	45
15/SC/0199/AM05	ROSE ACS Study	Substantial Amendment 02	12/12/2017	37
15/SC/0409/AM11	Abicipar Pegol in Neovascular age related macular	Investigator	26/10/2017	38

	degeneration	Brochure Edition		
15/SC/0448/AM15	Phase III study with Finerenone in Type II Diabetes and DKD, CV	11	14/03/2017	42
16/SC/0596/AM05	CONTRACT	3, 17 November 2017	11/12/2017	37
16/SC/0638/AM02	Prostate Cancer UK Module 4 Phase 2: Development of a new garment	2 14/06/2017	19/07/2017	41
17/SC/0234/AM01	Dehydr8 and deactiv8	1.0	07/10/2017	43
17/SC/0346/AM01	First Steps	1.0	12/10/2017	41

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0574/AM02/1	Evaluating the pathogenicity of novel germline RET sequence variants	Version 4 resubmitted (13/12/1	15/12/2017	19