

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South Central - Hampshire A Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPs in Patients - Type III
<b>Type of Flag:</b>	Adults Lacking Capacity Paediatric
<b>Chair:</b>	Dr Simon Kolstoe
<b>Vice-Chair:</b>	Dr Catherine Angell (until 18/12/2015) Dr Ronja Bahadori (18/12/2015 – present)
<b>Alternate Vice-Chair:</b>	Dr Ronja Bahadori (until 18/12/2015) Vacant (18/12/2015 - 05/02/2016) Ms Sonia Baryschpolec (05/02/2016 – present)
<b>REC Manager:</b>	Mrs Maxine Knight
<b>REC Assistant:</b>	Miss Elizabeth Hearn
<b>Committee Address:</b>	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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## Chair's overview of the past year:

The committee has had a busy year reviewing 36 full applications and 32 proportionate review applications along with the normal subcommittee workloads. Committee meetings are attended by 9 members on average reviewing about 5 applications per meeting. Although it is sometimes a challenge to finish the meeting at 8pm, general feedback from the committee suggests that members are enjoying the meeting and finding the discussion stimulating. We welcomed back one member from a leave of absence, had two members leave the committee, and appointed one new physician member. We still struggle in finding lay plus members and often needing to co-opt for this role. Training of committee members seems generally up to date and the span of expertise is ideal. We are, as always, impressed and appreciative of the support provided by our REC managers.

Simon Kolstoe

## 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	
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	
Professor Stewart Bruce-Low	Laboratory Director & Senior Lecturer	Lay Plus	01/11/2010	14/01/2016
Dr Mike Gibson	Retired Consultant in Occupational Medicine	Expert	01/12/2015	
Dr Simon Kolstoe	Senior Lecturer in Biochemistry	Expert	01/07/2009	
Dr Karl Nunkoosing	Principal Psychology Lecturer	Lay	01/10/2014	
Mr Trevor Olding	Clinical Coordinator	Lay	11/03/2013	
Dr Kesava Ananth Ramakrishnan	Consultant, Paediatric Intensive Care Unit (PICU)	Expert	01/01/2014	
Dr Ramya Ramanujachar	Paediatric Oncology Consultant	Expert	27/02/2014	
Mrs Margaret Stephens	Senior Specialist, Speech & Language Therapist (Adult Neurology & Elderly Care)	Expert	10/07/2008	01/07/2015

## 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
Ms Julie Brinton	Speech and Language Therapist	Expert	12/01/2016
Professor Ron King	Mathematician (Retired)	Lay Plus	09/02/2016
Canon Ian Ainsworth-Smith	Hospital Chaplain	Lay Plus	PRSC 21/05/2015

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Clifford Allen	None	29/05/2015
Mr Richard Andoh	None	31/03/2016
Dr Catherine Angell	Ethical review for school of health and social care - Bournemouth University	31/03/2016
Mrs Lisa Frances Armstrong	None	29/05/2015
Ms Sonia Baryschpolec	None	31/03/2016
Professor Stewart Bruce-Low	None	29/05/2015
Dr Simon Kolstoe	None	29/05/2015
Dr Karl Nunkoosing	Occasionally review research proposal for the NIHR and also review research articles for several journals. Principal lecturer in the Dept of Psychology at the University of Portsmouth and conducting research is an aspect of his work. Reviewed research for various funders in the past.	25/02/2016
Mr Trevor Olding	None	29/05/2015
Dr Kesava Ananth Ramakrishnan	None	11/05/2015
Dr Ramya Ramanujachar	None	29/05/2015

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

Month	Date	Number of Members Present at Meeting
May	12/05/2015	10
July	14/07/2015	8
August	11/08/2015	8
October	13/10/2015	7
November	10/11/2015	9
January	12/01/2016	8
February	09/02/2016	10

7 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	23/04/2015	3
May	21/05/2015	4
June	18/06/2015	3
July	23/07/2015	3
August	24/08/2015	3
October	22/10/2015	4
November	19/11/2015	3
December	17/12/2015	3
January	26/01/2016	3
February	23/02/2016	3
March	22/03/2016	3

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

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	15/04/2015	2
April	28/04/2015	2
May	13/05/2015	2
June	09/06/2015	2
June	10/06/2015	3
June	23/06/2015	2
July	07/07/2015	2
July	21/07/2015	2
August	04/08/2015	2
August	25/08/2015	2
September	08/09/2015	2
September	22/09/2015	2
October	06/10/2015	2

October	20/10/2015	3
November	10/11/2015	2
November	17/11/2015	2
December	08/12/2015	2
December	22/12/2015	3
January	06/01/2016	2
January	20/01/2016	2
February	10/02/2016	2
February	16/02/2016	2
February	17/02/2016	2
February	24/02/2016	3
February	29/02/2016	2
March	03/03/2016	2
March	24/03/2016	2

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

#### Details of inquorate meeting held:01 April 2015 - 31 March 2016

None

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Clifford Allen	4
Mr Richard Andoh	4
Mrs Lisa Frances Armstrong	4
Dr Ronja Bahadori	6
Ms Sonia Baryschpolec	6
Professor Stewart Bruce-Low	1
Dr Mike Gibson	2
Dr Simon Kolstoe	7
Dr Karl Nunkoosing	6
Mr Trevor Olding	7
Dr Kesava Ananth Ramakrishnan	4
Dr Ramya Ramanujachar	7

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Clifford Allen	4
Mr Richard Andoh	2
Mrs Lisa Frances Armstrong	2
Dr Ronja Bahadori	7
Ms Sonia Baryschpolec	2
Professor Stewart Bruce-Low	1
Dr Simon Kolstoe	4
Dr Karl Nunkoosing	3
Mr Trevor Olding	3
Dr Kesava Ananth Ramakrishnan	4
Dr Ramya Ramanujachar	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Clifford Allen	6
Mr Richard Andoh	3
Mrs Lisa Frances Armstrong	2
Dr Ronja Bahadori	13
Professor Stewart Bruce-Low	2
Dr Simon Kolstoe	17
Dr Karl Nunkoosing	4



Mr Trevor Olding	5
Dr Kesava Ananth Ramakrishnan	5
Dr Ramya Ramanujachar	1

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Clifford Allen	08/12/2015	Hampshire A Training Day
Mr Richard Andoh	08/12/2015	Hampshire A Training Day
Mrs Lisa Frances Armstrong	08/12/2015	Hampshire A Training Day
Dr Ronja Bahadori	08/12/2015	Hampshire A Training Day
Dr Ronja Bahadori	09/12/2015	Training - National Training Day for Committee Chairs
Dr Ronja Bahadori	14/01/2016	National Training Day for chairs
Dr Ronja Bahadori	24/01/2016	E&D online
Ms Sonia Baryschpolec	08/12/2015	Hampshire A Training Day
Dr Mike Gibson	07/12/2015	Hampshire A Training Day
Dr Mike Gibson	10/12/2015	Training - Equality and Diversity (e-learning module)
Dr Simon Kolstoe	03/06/2015	NREAP/chairs meetings
Dr Simon Kolstoe	08/12/2015	Hampshire A Training Day
Dr Karl Nunkoosing	08/12/2015	Hampshire A Training Day
Mr Trevor Olding	08/12/2015	Hampshire A Training Day
Dr Ramya Ramanujachar	08/12/2015	Hampshire A 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	13	36.11
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	23	63.89
<b>Total Applications Reviewed</b>	<b>36</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	5
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

**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	2	5.56
Favourable Opinion with Additional Conditions	6	16.67
Unfavourable Opinion	1	2.78
Provisional Opinion	27	75.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>36</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	26	72.22
Further Information Favourable Opinion with Additional Conditions	1	2.78
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	5.56
Favourable Opinion with Additional Conditions	6	16.67
Unfavourable Opinion	1	2.78
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>36</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>32</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	12
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	7
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

**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	8	25.00
Favourable Opinion with Additional Conditions	4	12.50
No Opinion transfer to full committee for review	2	6.25
Provisional Opinion	18	56.25
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>32</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.14
<b>Number of completed applications for full ethical review</b>	36
<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>	5
<b>Number of completed applications over 40 days as a % of total</b>	13.89%
<b>Number of days taken to final decision – average (mean)</b>	33
<b>Number of completed proportionate review applications for ethical review</b>	30
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	6
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	20.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	6
<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>	122
<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>	17
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	13.93%
<b>Number of modified amendments reviewed</b>	5
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of minor amendments received</b>	50
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	17
<b>Number of annual progress reports received</b>	42

<b>Number of safety reports received</b>	31
<b>Number of Serious Adverse Events received</b>	22
<b>Number of final reports received</b>	9

**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>
15/SC/0199	ROSE ACS Study	38
15/SC/0231	The Brain Imaging In Dementia study (BRAIID)	36
15/SC/0257	Long term abdominal drains in end stage cirrhosis	43
15/SC/0374	Epidemiology of diabetic retinopathy in type 1 diabetic patients (v1)	29
15/SC/0379	Retrospective case note review of enteral tube related issues (v1)	31
15/SC/0387	ADITEC Flu2	43
15/SC/0397	Amino acid feed children's study NJ002	29
15/SC/0403	EndoSTIM for GORD in asthma	30
15/SC/0409	Abicipar Pegol in Neovascular age related macular degeneration	35
15/SC/0420	Dementia Care and the Arts	31
15/SC/0422	The predictive value of pulse oximetry to diagnose sleep apnoea	34
15/SC/0433	The MultiCath Study	37
15/SC/0559	Central and peripheral blood pressure in stroke	23
15/SC/0605	Measurement of quality of life in carers of people with dementia	29
15/SC/0606	Study of Mirtazapine or Carbamazepine for Agitation in Dementia	28
15/SC/0609	Respiratory Muscle Warm Up Prior to Exercise in Patients with COPD V1	30
15/SC/0628	GP disclosure in sexual health clinics	31
15/SC/0645	People with Depression and Anxiety Experience When Using the Web	48
15/SC/0682	CLARINET FORTE Final Version: 19 May 2015	32
16/SC/0015	LUD2015-005	33
16/SC/0017	Making Drinking Fun	53
16/SC/0018	Study of CTXÄ-4430 in Cystic Fibrosis Patients	30
16/SC/0019	SFX-01 after subarachnoid haemorrhage	27
16/SC/0042	Evaluation of acute care development programme	34
16/SC/0071	Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma	51
16/SC/0072	ADHD and entrainment of neural oscillations in adolescents	32

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0631	AbSeS	29



**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
15/SC/0204	Observational study of BOTOX in Idiopathic Overactive Bladder Patients	34
15/SC/0435	Study examining the effect of Etanercept on inflammation in the brain	29

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
15/SC/0175	'24 Hour Labour Line' - A Qualitative Exploration	30
15/SC/0276	Evaluation of self management workshop for young people with cancer	38
15/SC/0448	Phase III study with Finerenone in Type II Diabetes and DKD, CV	29
16/SC/0008	A qualitative study of stroke Early Supported Discharge v1.0	33
16/SC/0020	PuraStat® for Bleed Control in Endoscopic Submucosal Dissection (v1.0)	25
16/SC/0067	Investigate study drug Arimoclomol with patients diagnosed with NP-C	23

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
15/SC/0579	Platelet Rich Plasma with Hyaluronic Acid in Knee Osteoarthritis	23

**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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**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period****Further Information Favourable Opinion with Standard Conditions**

REC Reference	Title	Number of Days on Clock
15/SC/0263	Carboxyhemoglobin in neonatal sepsis	11
15/SC/0325	Evaluation of Electronic Palliative Care Co-ordination System (EPaCCS)	24
15/SC/0328	Investigation into lung transplant pathophysiology v. 1	17
15/SC/0330	Social Reasoning in People Living with HIV-Infection	16
15/SC/0472	Dizziness, Imbalance and Vision Assessment questionnaire	13
15/SC/0481	The role of lymphocytes in Alopecia Areata	9
15/SC/0530	Transitioning healthcare management from parents to young people	30
15/SC/0533	Effectiveness of GeneX for the management of defects in fractures	12
15/SC/0536	Post-neoadjuvant chemotherapy & inflammatory response in breast cancer	13
15/SC/0653	Assessment of Anticoagulant Activity & Reversal of FactorXa Inhibitors	12
15/SC/0655	Pain associated with Interproximal Enamel Reduction : a RCT	15
15/SC/0726	The accuracy of a dietetic objective assessment of protein intake V3	13
15/SC/0729	Sleep Diagnostics within primary care	11
15/SC/0730	Does Immune Responsiveness to MSU crystals reduce over time?	11
15/SC/0774	Views towards 24-7 consultant presence on maternity unit	13
15/SC/0775	Incorporation of omega-3 fatty acids in healthy humans	14
16/SC/0056	Promoting Breastfeeding v1	14
16/SC/0165	Cognition in multiple sclerosis	15

**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
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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0389	Executive Functioning and Self-Management in Adolescents with T1D (1)	13
15/SC/0394	What Helps in 'Self-help'?	10
15/SC/0780	A snapshot study of chronic post-operative breast pain	8
16/SC/0054	Identifying relapse mechanisms in ETV6-RUNX1 ALL patients	7
16/SC/0117	Hallux Valgus Using a Foot Pressure Platform	11
16/SC/0119	3D modelling of pGALS manoeuvres in children. Version 1	8
16/SC/0121	Wilson Disease Standard of Care Treatment Study	6
16/SC/0166	Dental growth rhythms	13

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0322	Event Perception in children with language difficulties	13
15/SC/0777	CLASP: Development of a website to support survivors of cancer V.1	13
16/SC/0055	A software utility for mapping human movement onto game control	12
16/SC/0124	LENA Pilot Investigation v1.0	11

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

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

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

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



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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
03/11/090/AM10	DNA Polymorphisms in Mental Illness	10	09/04/2015	7
03/11/107/AM15	GW572016 and Letrozole versus Letrozole alone in ER and PGR patient	EGF3008 SA 07 28 April 2015	28/04/2015	15
06/Q1702/109/AM20	The pathophysiology of Primary Ciliary Dyskinesia	14	12/07/2015	18
08/H0502/126/AM07	Mechanisms of lung infection and inflammation in respiratory disease	Protocol v 1.5	09/02/2016	14
08/H0502/132/AM37	BH21260- Mircerá® vs. reference ESAs in CKD patients	#33 BH21260 protocol version D	23/03/2015	23
08/H0502/132/AM38	BH21260- Mircerá® vs. reference ESAs in CKD patients	Substantial Amendment 34	12/11/2015	29
08/H0502/165/AM13	Treatment of non alcoholic fatty liver disease with n-3 fatty acids	Substantial Amendment 7	15/10/2015	13
09/H0502/126/AM04	Cortical changes in stroke following rehabilitation (Version 1).	Amendment number 4, 20/03/2015	20/03/2015	35
09/H0502/126/AM05	Cortical changes in stroke following rehabilitation (Version 1).	5	30/09/2015	24
09/H0502/87/AM16	Everolimus with Trastuzumab and Paclitaxel in Advanced Breast Cancer	15	03/09/2015	20
11/SC/0043/AM01	Patients and carers experiences of accessing district nursing services	1	29/06/2015	15
11/SC/0146/AM17	REFRAMED version 1.1	13	27/05/2015	22
11/SC/0169/AM14	Trial of Ipilimumab Versus Placebo in Subjects with Lung Cancer	V.18	10/03/2015	15
11/SC/0230/AM04	Cardiovascular Tissue Studies	3	11/08/2015	20
11/SC/0479/AM15	Carfilzomib for Advanced Refractory Multiple Myeloma European Study	Investigator's Brochure v.15 &	31/03/2015	24
11/SC/0479/AM16	Carfilzomib for Advanced Refractory Multiple Myeloma European Study	4	08/07/2015	29
12/SC/0434/AM09	DPM-CF-204 mannitol in CF aged 6-17 years	4	03/03/2015	33
12/SC/0538/AM18	A Trial of LMTM in Patients with bvFTD (TRx-237-007)	AM 18 Investigator	22/05/2015	27

		Brochure v.		
12/SC/0538/AM19	A Trial of LMTM in Patients with bvFTD (TRx-237-007)	AM19 - SA Prot8	08/09/2015	19
12/SC/0633/AM11	CQGE031B2201: QGE031 in asthma patients on inadequate ICS/LABA	Substantial Amendment 10	04/08/2015	22
12/SC/0687/AM21	PROTOCOL BP28248 PATIENTS WITH MODERATE SEVERITY ALZHEIMER'S DISEASE	AM21 - Substantial Amendment	18/09/2015	9
13/SC/0012/AM10	LOCATE - Local Care and Treatment Evaluation	Substantial Amendment 7	05/10/2015	10
13/SC/0012/AM13	LOCATE - Local Care and Treatment Evaluation	Substantial Amendment 8	18/12/2015	12
13/SC/0014/AM04	Study of flow mediated vasodilation in children with congenital HD.	1.3	12/01/2015	25
13/SC/0174/AM11	Phase IIb, GS-6624 in subjects with primary sclerosing cholangitis	AM11	05/01/2016	16
13/SC/0179/AM07	Stem cells for drug discovery	Substantial Amendment 7	05/07/2015	27
13/SC/0179/AM08	Stem cells for drug discovery	Substantial Amendment 8	10/02/2016	25
13/SC/0182/AM02	GORD in Asthma	3 Date: 08 April 2015	10/04/2015	16
13/SC/0237/AM14	A Trial of LMTM in Patients with Mild AD (TRx-237-005)	IB v16	21/05/2015	33
13/SC/0237/AM15	A Trial of LMTM in Patients with Mild AD (TRx-237-005)	Substantial Amendment - Protoc	07/07/2015	18
13/SC/0237/AM16	A Trial of LMTM in Patients with Mild AD (TRx-237-005)	Substantial Amendment - IBv17.	08/01/2016	19
13/SC/0249/AM08	A phase IIb study of GS-6624 in subjects with compensated cirrhosis	IB v10	05/01/2016	13
13/SC/0259/AM24	Idelalisib + Bendamustine + Rituximab for Previously Treated iNHL	SA10	03/12/2015	8
13/SC/0265/AM03	Measuring long-term outcomes in people with dementia in care homes	Substantial Amendment 3	09/07/2015	28
13/SC/0265/AM04	Measuring long-term outcomes in people with dementia in care homes	Substantial Amendment 4	27/10/2015	28
13/SC/0332/AM25	Takeda TOMM40_301 Alzheimer's Disease study	Substantial	30/03/2015	25

		Amendment 20, 30.0		
13/SC/0332/AM26	Takeda TOMM40_301 Alzheimer's Disease study	21	08/04/2015	16
13/SC/0332/AM29	Takeda TOMM40_301 Alzheimer's Disease study	22	22/05/2015	27
13/SC/0332/AM30	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 23	13/07/2015	27
13/SC/0332/AM31	Takeda TOMM40_301 Alzheimer's Disease study	Substantial Amendment 24	26/08/2015	30
13/SC/0332/AM32	Takeda TOMM40_301 Alzheimer's Disease study	25	10/11/2015	11
13/SC/0332/AM33	Takeda TOMM40_301 Alzheimer's Disease study	SA26	18/02/2016	8
13/SC/0490/AM08	Lebrikizumab in adolescent patients with uncontrolled asthma	Substantial Amendment 5	07/07/2015	25
13/SC/0490/AM09	Lebrikizumab in adolescent patients with uncontrolled asthma	Substantial Amendment 6	03/08/2015	23
13/SC/0490/AM10	Lebrikizumab in adolescent patients with uncontrolled asthma	AM10-SA7	25/09/2015	9
13/SC/0490/AM12	Lebrikizumab in adolescent patients with uncontrolled asthma	Substantial Amendment 8	26/10/2015	15
14/SC/0029/AM11	A Study of GLPG0634 in Patients With Active Crohn's Disease	IB Ed 8 dated 11Feb15	30/03/2015	25
14/SC/0164/AM02	SILENCE Phase 1: Sleep Assessments in the ICU	2: 14th April 2015	14/04/2015	20
14/SC/0178/AM10	The Efficacy and Safety of Idelalisib- Gilead GS-US-312-0123	IB ed 13	26/10/2015	32
14/SC/0184/AM02	Long term safety of QGE031 in allergic asthma patients	2	18/05/2015	29
14/SC/0186/AM03	Tissue analysis for understanding lung diseases	Substantial Amendment 2	03/09/2015	25
14/SC/0234/AM02	3625 SUSTAINâ„„4 Semaglutide vs. Basal Insulin in Type 2 Diabetes	NN9535-3625 Sub Am No01 UK	06/03/2015	31
14/SC/0263/AM04	AWARE II	3	22/09/2015	13
14/SC/0299/AM01	5T4 and its association with outcomes in ovarian cancer	1.0	18/03/2015	32
14/SC/0302/AM02	Lack of awareness of symptoms (anosognosia) in PD	Amendment 1, 26/Mar/2015	26/03/2015	25
14/SC/0302/AM03	Lack of awareness of symptoms (anosognosia) in PD	AM03	16/10/2015	28
14/SC/1031/AM05	AB09004 mild to moderate Alzheimer's disease	3	03/03/2015	22
14/SC/1031/AM08	AB09004 mild to moderate Alzheimer's disease	Substantial Amendment 7	20/08/2015	28
14/SC/1031/AM09	AB09004 mild to moderate Alzheimer's disease	5	02/09/2015	28
14/SC/1031/AM10	AB09004 mild to moderate Alzheimer's disease	Substantial	02/11/2015	20

		Amendment 9		
14/SC/1143/AM02	ATAFUTI	AM03	17/03/2015	24
14/SC/1143/AM03	ATAFUTI	AM04	22/05/2015	32
14/SC/1143/AM05	ATAFUTI	Substantial Amendment 06	29/02/2016	24
14/SC/1171/AM03	Isoprenaline infusion as a method of induction of Atrial Fibrillation	2	24/04/2015	20
14/SC/1171/AM05	Isoprenaline infusion as a method of induction of Atrial Fibrillation	Substantial Amendment 3	09/11/2015	14
14/SC/1183/AM02	Acute fatigue assessment and management (FAME)	3.0	23/03/2015	13
14/SC/1183/AM03	Acute fatigue assessment and management (FAME)	4	24/08/2015	27
14/SC/1183/AM04	Acute fatigue assessment and management (FAME)	5	12/10/2015	19
14/SC/1183/AM05	Acute fatigue assessment and management (FAME)	6	21/12/2015	26
14/SC/1311/AM03	Daptomycin in paediatric patients with AHO (infection of the bone)	Substantial Amendment 1	05/01/2016	12
14/SC/1409/AM02	ART - V1.0	Substantial Amendment 01	24/06/2015	21
14/SC/1409/AM03	ART - V1.0	02	04/09/2015	26
14/SC/1409/AM04	ART - V1.0	NoSA 3	22/02/2016	13
14/SC/1425/AM03	GX29185 Lampalizumab in Geographic Atrophy	2	17/03/2015	22
14/SC/1425/AM07	GX29185 Lampalizumab in Geographic Atrophy	5	17/12/2015	32
14/SC/1455/AM02	ACtiF - Adherence to treatment in adults with Cystic Fibrosis	Substantial Amendment 2	26/06/2015	35
14/SC/1455/AM03	ACtiF - Adherence to treatment in adults with Cystic Fibrosis	Substantial Amendment 3	06/08/2015	20
15/SC/0057/AM04	Clinical experience with cabazitaxel in prostate cancer	1	30/10/2015	21
15/SC/0062/AM02	Diabetes Unmet Need with Basal Insulin Evaluation	1	02/06/2015	13
15/SC/0065/AM04	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	SA3 Protocol	04/06/2015	14
15/SC/0065/AM05	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	4	08/09/2015	22
15/SC/0065/AM06	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	SA05: IB v8.0	27/03/2015	30
15/SC/0065/AM07	MEDI4736 and Tremelimumab in NSCLC (D4191C00004, ARCTIC Study)	SA06	10/02/2016	13
15/SC/0073/AM01	Vitamin D supplementation in impaired fasting glycaemia,	Substantial	29/05/2015	23



	version 2.0	Amendment SA001		
15/SC/0082/AM01	HOME-BP	Substantial Amendment 1	23/07/2015	18
15/SC/0082/AM02	HOME-BP	2	19/08/2015	26
15/SC/0082/AM03	HOME-BP	3	01/10/2015	23
15/SC/0082/AM04	HOME-BP	4	02/12/2015	35
15/SC/0082/AM05	HOME-BP	Amendment 5	23/02/2016	7
15/SC/0113/AM01	Measuring listening effort and fatigue in hearing impaired individuals	Number 1 Date: 19/3/2015	19/03/2015	15
15/SC/0113/AM02	Measuring listening effort and fatigue in hearing impaired individuals	Number 2 Date: 24/4/2015	24/04/2015	10
15/SC/0142/AM01	NiPPeR	Substantial Amendment 1	10/06/2015	14
15/SC/0142/AM02	NiPPeR	Substantial Amendment 2	21/08/2015	27
15/SC/0142/AM03	NiPPeR	Substantial Amendment 3	04/11/2015	16
15/SC/0142/AM04	NiPPeR	4	01/12/2015	10
15/SC/0146/AM01	Secukinumab in patients with active Ankylosing Spondylitis	Substantial Amendment 1	02/07/2015	9
15/SC/0175/AM01	'24 Hour Labour Line' - A Qualitative Exploration	1	19/11/2015	11
15/SC/0231/AM01	The Brain Imaging In Dementia study (BRAID)	Substantial Amendment 1	04/01/2016	18
15/SC/0257/AM01	Long term abdominal drains in end stage cirrhosis	AM01	16/09/2015	14
15/SC/0257/AM02	Long term abdominal drains in end stage cirrhosis	AM02	26/10/2015	14
15/SC/0257/AM03	Long term abdominal drains in end stage cirrhosis	AM03	09/02/2016	22
15/SC/0379/AM01	Retrospective case note review of enteral tube related issues (v1)	1	08/12/2015	28
15/SC/0387/AM01	ADITEC Flu2	Substantial Amendment 1	02/10/2015	20
15/SC/0387/AM03	ADITEC Flu2	Substantial Amendment 2	03/02/2016	21
15/SC/0403/AM01	EndoSTIM for GORD in asthma	Substantial Amendment 1	19/01/2016	19
15/SC/0433/AM01	The MultiCath Study	1	17/11/2015	24
15/SC/0433/AM02	The MultiCath Study	Substantial	11/02/2016	33

		Amendment 2		
15/SC/0435/AM01	Study examining the effect of Etanercept on inflammation in the brain	Substantial Amendment 1	30/09/2015	23
15/SC/0448/AM03	Phase III study with Finerenone in Type II Diabetes and DKD, CV	2	16/09/2015	13
15/SC/0448/AM05	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Substantial Amendment 3	13/11/2015	18
15/SC/0448/AM06	Phase III study with Finerenone in Type II Diabetes and DKD, CV	Substantial Amendment 4	22/01/2016	12
15/SC/0682/AM01	CLARINET FORTE Final Version: 19 May 2015	Substantial Amendment 1	25/02/2016	14
15/SC/0775/AM01	Incorporation of omega-3 fatty acids in healthy humans	Amendment 1	29/01/2016	9
15/SC/0775/AM02	Incorporation of omega-3 fatty acids in healthy humans	Amendment 2	19/02/2016	19
16/SC/0015/AM01	LUD2015-005	SA001	03/03/2016	15

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
11/SC/0204/AM02	Neurological conditions and oncology: immunology and interactions	1	01/04/2015	21
14/SC/0016/AM01	Establishing normal oximetry values in infants using Masimo technology	2	09/01/2015	16
14/SC/1065/AM01	Nursing Care Received by Disabled Children During Emergency Admissions	1	28/07/2015	12
14/SC/1170/AM01	CALIBRATE	Amendment 01	02/03/2016	20
14/SC/1425/AM04	GX29185 Lampalizumab in Geographic Atrophy	Substantial Amendment 3	06/05/2015	18
15/SC/0113/AM04	Measuring listening effort and fatigue in hearing impaired individuals	Substantial Amendment 3	05/08/2015	35
15/SC/0481/AM01	The role of lymphocytes in Alopecia Areata	SA01	24/02/2016	28

**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>
08/H0502/5/AM13/1	Long term safety and efficacy of Omnitrope	Modified Amendment 5	10/06/2015	3
11/SC/0204/AM02/2	Neurological conditions and oncology: immunology and interactions	Modified Amendment 1	01/04/2015	11
14/SC/1425/AM04/1	GX29185 Lampalizumab in Geographic Atrophy	Substantial Amendment #3 Modif	06/05/2015	6
15/SC/0113/AM04/1	Measuring listening effort and fatigue in hearing impaired individuals	Modified SA3	02/10/2015	4

<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>
11/SC/0204/AM02/1	Neurological conditions and oncology: immunology and interactions	1 Modified	01/04/2015	7

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
15/SC/0325	Evaluation of Electronic Palliative Care Co-ordination System (EPaCCS)	24
15/SC/0328	Investigation into lung transplant pathophysiology v. 1	17
15/SC/0330	Social Reasoning in People Living with HIV-Infection	16
15/SC/0530	Transitioning healthcare management from parents to young people	30
15/SC/0655	Pain associated with Interproximal Enamel Reduction : a RCT	15
16/SC/0165	Cognition in multiple sclerosis	15

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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