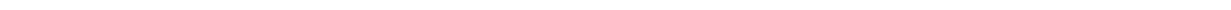


**South East Coast - Surrey Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	South East Coast - Surrey Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	None
Chair:	Professor David-Russel Jones (upto 01/04/2015) Dr Mark Atkins (02/04/2015 – present)
Vice-Chair:	Mrs Chrissie Lawson
Alternate Vice-Chair:	Vacant
REC Manager:	Gemma Oakes (01/03/2015 – 14/12/2015) Maeve Groot Bluemink (14/12/2015 - 06/03/2016) Raj Khullar (07/03/2016 – present)
REC Assistant:	Aliki Sifostratoudaki (01/03/2015 – 14/12/2015) Sadie McKeown-Keegan (14/12/2015 - 06/03/2016) Mr Wai Yeung (07/03/2016 – present)
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
Telephone:	(020) 7104 8053
Email:	nrescommittee.secoast-surrey@nhs.net

Chair's overview of the past year:

The Committee has had another successful and productive year as confirmed by the attached data. We have seen the departure of a number of members and I would like to take this opportunity to thank them for their hard work and support. The committee has continued to function with reduced numbers but I anticipate the introduction of new members shortly will ease this situation. The committee members have continued to be dedicated and thorough in their work, producing high quality evaluations and some lively debate. I would like to thank the staff at the Bristol office for their invaluable support. We look forward to the coming year and the opportunity to make our contribution to facilitating high quality medical research.

Dr Mark Atkins

South East Coast - Surrey Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Mark Atkins	Consultant Virologist	Expert	03/06/2014	
Miss Mary Ayton	Infection Control Adviser	Expert	01/05/2005	01/05/2015
Dr Julia Boyle	Director Surrey CRC/Pharmacologist	Expert	12/01/2011	07/07/2015
Miss Elizabeth Cheshire	Consultant in Emergency Medicine	Expert	01/06/2010	
Dr Benedict Creagh-Brown	Consultant Physician	Expert	08/04/2014	
Mrs Margaret Handyside	Retired Lecturer in Science Education	Lay Plus	18/01/2011	31/01/2016
Ms Wendy Joy	Retired Support Worker	Lay Plus	12/01/2011	
Mrs Chrissie Lawson	Nurse Specialist	Expert	01/05/2006	
Dr Charles Li	Consultant Physician	Expert	12/01/2011	
Miss Deborah Malins	Managing Director (retired)	Lay	19/01/2016	
Mr Michael Morris	Managing Partner of Law Firm	Lay Plus	04/10/2007	
Ms Janet Oakeshott	Retired Specialist Nurse	Lay	01/04/2014	
Mr Michael Pettit	Senior Lecturer in Pharmacy Practice	Expert	10/12/2015	
Dr JHP Powell	Consultant Physician	Expert	01/05/2005	01/05/2015
Prof David Russell-Jones	Professor of Diabetes and Endocrinology	Expert	01/04/2005	01/04/2015
Dr Jane Stuart	Public Health Researcher	Lay	01/10/2011	07/04/2015
Mr Robin Walsh	Retired Professor of Physical Chemistry	Lay	29/05/2013	

South East Coast - Surrey Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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South East Coast - Surrey Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	05/05/2015
Stephanie Ellis	Retired Civil Servant	Lay Plus	03/11/2015, 01/12/2015
Fanny Mitchell	Retired NHS Manager	Lay Plus	01/12/2015

South East Coast - Surrey Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Mark Atkins	Consultant Pathologist for the Doctors Laboratory (TDL) London.	29/08/2015
Dr Benedict Creagh-Brown	NIHR CRN Respiratory lead for KSS RO41 Committee member at RSCN British Thoracic Society member	05/01/2016
Miss Elizabeth Cheshire	Vice President of Leonard Cheshire Disability.	31/03/2016
Ms Wendy Joy	None	10/09/2015
Mrs Chrissie Lawson	None	29/08/2015
Dr Charles Li	None	31/03/2016
Mr Michael Morris	Small shareholder (direct) at Glaxo Smith Kline	26/08/2015
Ms Janet Oakeshott	None	02/09/2015
Mr Robin Walsh	None	20/04/2015
Mr Michael Pettit	None	22/12/2015
Miss Debbie Malins	Small holding of shares in Novartis and GlaxoSmithKline	29/12/2015

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

Month	Date	Number of Members Present at Meeting
April	07/04/2015	9
May	05/05/2015	7
June	02/06/2015	8
July	07/07/2015	7
September	01/09/2015	7
November	03/11/2015	8
December	01/12/2015	7
January	05/01/2016	7
February	02/02/2016	8

9 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	07/04/2015	3
May	05/05/2015	3
June	02/06/2015	3
August	04/08/2015	3
September	01/09/2015	3
October	06/10/2015	3
November	03/11/2015	3
December	01/12/2015	3
January	19/01/2016	3
March	01/03/2016	3

10 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	02/04/2015	2
April	10/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	22/05/2015	2
May	29/05/2015	2
June	05/06/2015	2
June	12/06/2015	2
June	19/06/2015	2
June	26/06/2015	2
July	01/07/2015	2

July	10/07/2015	2
July	31/07/2015	2
August	21/08/2015	2
August	28/08/2015	2
September	10/09/2015	2
September	18/09/2015	2
October	19/10/2015	2
October	23/10/2015	2
October	30/10/2015	2
November	06/11/2015	2
November	20/11/2015	2
November	27/11/2015	2
December	11/12/2015	2
January	08/01/2016	2
February	01/02/2016	2
February	10/02/2016	2
March	01/03/2016	2
March	07/03/2016	2
March	14/03/2016	2
March	21/03/2016	2

32 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

Name	Number of Meetings Attended
Dr Mark Atkins	9
Miss Mary Ayton	1
Dr Julia Boyle	3
Dr Benedict Creagh-Brown	5
Mrs Margaret Handyside	3
Ms Wendy Joy	6
Mrs Chrissie Lawson	8
Miss Deborah Malins	1
Mr Michael Morris	8
Ms Janet Oakeshott	8
Mr Michael Pettit	1
Prof David Russell-Jones	1
Dr Jane Stuart	1
Mr Robin Walsh	9

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

Name	Number of Meetings Attended
Dr Mark Atkins	9
Ms Wendy Joy	6
Mrs Chrissie Lawson	10
Mr Michael Morris	2
Prof David Russell-Jones	1
Mr Robin Walsh	2

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

Name	Number of Meetings Attended
Dr Mark Atkins	32
Mrs Chrissie Lawson	30
Prof David Russell-Jones	1
Mr Robin Walsh	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Mark Atkins	02/02/2016	Members' training day
Dr Benedict Creagh-Brown	02/02/2016	Members' training day
Ms Wendy Joy	02/02/2016	Surrey training day
Mrs Chrissie Lawson	29/06/2015	Researcher Day
Mrs Chrissie Lawson	17/08/2015	Online E&D Training
Mrs Chrissie Lawson	09/12/2015	Training - National Training Day for Committee Chairs
Mrs Chrissie Lawson	02/02/2016	Members' training day
Miss Deborah Malins	30/12/2015	Training - Equality and Diversity (e-learning module)
Miss Deborah Malins	22/01/2016	Nuffield Report Summary and recommended actions
Miss Deborah Malins	22/01/2016	Global Health training
Miss Deborah Malins	22/01/2016	Children and Clinical Research
Miss Deborah Malins	02/02/2016	Surrey Members' training day
Miss Deborah Malins	10/02/2016	Training - Committee Members Induction
Ms Fanny Mitchell	18/02/2016	National Training Day
Mr Michael Morris	01/02/2016	Children and Clinical Research
Mr Michael Morris	02/02/2016	Surrey REC Members' training day
Ms Janet Oakeshott	29/06/2015	HRA Researcher Training Day
Ms Janet Oakeshott	24/09/2015	HRA REC Member Induction Training
Ms Janet Oakeshott	24/09/2015	Committee Members Induction
Ms Janet Oakeshott	01/02/2016	E Learning module about the Nuffield Report (3hours)
Ms Janet Oakeshott	02/02/2016	REC training day
Mr Michael Pettit	10/02/2016	Training - Committee Members Induction
Mr Robin Walsh	02/02/2016	Surrey REC 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	0	0.00
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	42	100.00
Total Applications Reviewed	42	100

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

Number of applications made invalid by the REC Manager	4
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	8
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

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	10	23.81
Unfavourable Opinion	1	2.38
Provisional Opinion	31	73.81
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	42	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	30	71.43
Further Information Favourable Opinion with Additional Conditions	1	2.38
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	10	23.81
Unfavourable Opinion	1	2.38
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
Total	42	100

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

Total Applications Reviewed	23
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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	15
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

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	11	47.83
Favourable Opinion with Additional Conditions	5	21.74
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	7	30.43
Unfavourable Opinion	0	0.00
Total	23	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	4.67
Number of completed applications for full ethical review	42
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	2
Number of completed applications over 40 days as a % of total	4.76%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	23
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	1
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	51
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	42
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	25

Number of safety reports received	0
Number of Serious Adverse Events received	2
Number of final reports received	9

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
15/LO/0596	Study of the effects of Vitamin D on immune responses to Tuberculosis	32
15/LO/0610	The Clarity-Pro Study	34
15/LO/0621	Self-management support for people with long-term conditions v1.0	33
15/LO/0623	Real World Evidence in Diabetes	34
15/LO/0624	In vivo Tau pathology in PSP and CBD	30
15/LO/0733	What is the experience of peer-supported open dialogue service users?	24
15/LO/0796	Neuroimaging predictors of stroke recovery	27
15/LO/0802	High vs standard energy children's drink study FC125	23
15/LO/0804	Adolescents living with HIV project (ALHIV)	24
15/LO/0945	Does nitrate supplementation improve CPX performance / postop recovery	31
15/LO/0977	mHealth for antenatal mental health	29
15/LO/0989	Targeted Nutritional Interventions to Prevent Diabetes	34
15/LO/1189	ASK	20
15/LO/1201	Enhanced management of patients and contact tracing for hepatitis B	17
15/LO/1207	CATCH: Parents and Carers Attending A&E for Children with fever	25
15/LO/1213	IVF Treatment and Child Health Outcomes: A Data Linkage Study	17
15/LO/1368	Effects of a Serratus block on Post-operative Pain in Breast Surgery	53
15/LO/1403	Lycra suit and balance in children/youth with ABI	32
15/LO/1414	Optimisation of neonatal ventilation	36
15/LO/1437	Paternal Weight, Sperm Epigenomics and Fetal Growth	32
15/LO/1438	The GENIUS Study Version 1	31
15/LO/1826	Mechanisms of vocal emotion impairment in schizophrenia	29
15/LO/1849	Capecitabine App in Metastatic Breast Cancer, version 1	29
15/LO/1889	Electrophysiological optimisation	34
15/LO/2063	Vitamin D in CKD - Vascular Function, Structure and Immune Regulation	25
15/LO/2082	The REACT (REtirement in ACTION) study - V1	25
15/LO/2091	SoMoVe v1	39
16/LO/0041	Trace Element Malnutrition in Paediatric Renal Disease	49
16/LO/0064	The Role of Error Signals for Awareness of Cognitive Deficits	40
16/LO/0067	The Management of self-harm in forensic settings	15

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0903	Co-designing Community-Based Diabetes Services for CYP	38

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
15/LO/0793	Training healthcare assistants (HCAs) in Psychological First Aid (PFA)	27
15/LO/0891	Effect of high- and low-fructose diets on intestinal fat production.	27
15/LO/1111	Evaluation of novel HOX-targeted cancer drugs	16
15/LO/1178	The QuaRTUS Study	16
15/LO/1421	London University Study on oral HPV	28
15/LO/1881	Wellbeing in Young People with Epilepsy	20
15/LO/2051	The PRIME Study: Positive tRansitions through the MEnopause	21
15/LO/2101	SPRINTT Project	22
16/LO/0072	Remediation of Social Cognition in Schizophrenia	14
16/LO/0074	Predictors of outcomes and mechanisms of change in STEPPS	14

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/0145	A Mental Health Risk Assessment Questionnaire Study in SLD children	27

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

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/LO/0858	Quality of life&depression in Chronic kidney disease	12
15/LO/0860	PAM evaluation	12
15/LO/1384	Test-retest validity of the Individual Management Plan Outcome Score.	11
15/LO/1577	Effectiveness of NHS Health Check for patients identified as high risk	7
15/LO/1579	Keeping active	11
15/LO/1958	Molecular Signatures of Ebola Virus Infection in Patients and Cells V1	12
16/LO/0451	Biomarkers and classical Hodgkin lymphoma v1 (BACH)	11

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

15/LO/0635	CS01	14
15/LO/0695	Immunity to the bacterial flora of the upper respiratory tract	10
15/LO/0862	A study of subjective pain on local steroid injection for CTS	12
15/LO/1047	Liverpool ALD bioresource	13
15/LO/1385	Melanomas excised in primary care vs secondary care excision	11
15/LO/1386	Tinnitus after cochlear implantation	11
15/LO/1387	UK infection and cystine stone follow-up - V1.	12
15/LO/1969	Lifestyle Advice in Primary Care Consultations	9
15/LO/2136	RET NAT 01 - Natural History Study in Inherited Retinal Disease	8
15/LO/2138	Socioeconomic inequalities in gastrointestinal infections - Version 1	11
16/LO/0185	Questionnaire about online provision of contraception	13

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1794	Shoulder Impingement Syndrome: A Qualitative Study	11
15/LO/1968	Cardiac Troponin I monitoring pilot study	10
15/LO/2112	Attitudes and perceptions of pregnant women on a dietary intervention	9
16/LO/0452	PEVES V2	11
16/LO/0453	Immune Responses in Human Tonsils (Version 1.0)	11

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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 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
07/Q1909/13/AM02	The use of OMICS Technologies to characterise human cancers	5.4 (AM02)	25/06/2015	2
07/Q1909/13/AM03	The use of OMICS Technologies to characterise human cancers	6.4	15/03/2016	14
09/H0701/49/AM13	Post-marketing, Observational Registry of Humira in Psoriasis Patients	Substantial Amendment 10	04/03/2015	3
11/LO/0109/AM06	Pathophysiological signals of urine in lower urinary tract symptoms	Substantial Amendment 4	09/06/2015	10
11/LO/0476/AM01	Minitub:Prospective Registration Study on Sentinel Node (SN) Positive	Substantial Amendment 1 [UK01]	01/04/2015	2
11/LO/0476/AM02	Minitub:Prospective Registration Study on Sentinel Node (SN) Positive	UK02	16/12/2015	19
11/LO/0987/AM01	Periodontitis and disease progression in Alzheimer's Disease	Substantial Amendment 102	09/05/2015	8
11/LO/1396/AM05	A study of major system reconfiguration in stroke services	1.9	23/11/2015	4
11/LO/1801/AM06	Brain TSPO Function	Substantial Amendment 3	26/03/2015	5
12/LO/0515/AM05	OPTIMA Version 1.0, 08 March 2012	Substantial Amendment 5	09/09/2015	7
12/LO/0910/AM02	RCT of contingency management for abstinence in drug treatment	Substantial Amendment 2	25/03/2015	7
12/LO/1629/AM01	A safety registry for malaria patients treated with Eurartesim	Substantial Amendment 1 Protoc	23/04/2015	1
12/LO/1772/AM01	A European multi-centre Pregnancy Registry for Eurartesim	Substantial Amendment 1 Protoc	18/03/2015	13
13/LO/0057/AM01	Blood-brain barrier permeability in cerebral small vessel disease	Substantial Amendment 1	05/05/2015	2
13/LO/0058/AM03	Improving therapy and outcomes in venous diseases	Substantial	19/06/2015	3

		Amendment 3		
13/LO/0238/AM01	DNA Damage and Repair in Coronary Artery Disease (Version 1)	Substantial Amendment 1	20/05/2015	10
13/LO/0314/AM01	Predictors of progression from MCI to AD	1	08/10/2015	12
13/LO/0621/AM01	(May) Specificity of "4 Mountains" spatial memory test for Alzheimer's	1	16/10/2015	27
13/LO/0885/AM03	First-trimester cfDNA testing Version 1	Substantial Amendment dated 12	12/04/2015	6
13/LO/0885/AM06	First-trimester cfDNA testing Version 1	3 (AM06)	04/01/2016	8
13/LO/1349/AM06	eGFR-C	Substantial Amendment 3	22/05/2015	5
13/LO/1349/AM08	eGFR-C	4	01/12/2015	12
13/LO/1398/AM02	Exercise CMR in Pulmonary Arterial Hypertension	Substantial Amendment 2	19/05/2015	2
14/LO/0358/AM06	PK	Substantial Amendment 2	11/05/2015	2
14/LO/0495/AM05	redi: Risk-assessed Exercise & Diet Intervention - Stage I (version 1)	Substantial Amendment 2	26/03/2015	4
14/LO/0525/AM02	Assessing alcohol misuse in cognitive impairment in the elderly.	Substantial ASmendment 2 dated	26/03/2015	13
14/LO/1589/AM01	Developing a model to include patients in benefit-risk assessment	Amendment 01 (AM01)	29/12/2015	7
14/LO/1842/AM01	ENDCaP-C Test Accuracy Study	Amendment No. 1, 28th July 201	28/07/2015	8
14/LO/1928/AM01	Effects of sub-maximal cycling exercise in late-onset Pompe disease	1	02/11/2015	5
14/LO/1977/AM03	Intentional rounding in hospital wards	Substantial amendment dated 17 March 2016	17/03/2016	12
14/LO/2276/AM02	Amyloid PET imaging in the timely diagnosis of Alzheimer's disease	Version 3	17/09/2015	20
15/LO/0030/AM01	Validation of fetal movement sensor	Substantial Amendment 1	25/05/2015	5
15/LO/0038/AM02	STRATA Version 1.0	Substantial	20/05/2015	3

		Amendment 1		
15/LO/0038/AM03	STRATA Version 1.0	Substantial Amendment 2	28/08/2015	6
15/LO/0038/AM06	STRATA Version 1.0	3.0	15/03/2016	12
15/LO/0063/AM01	Surgical outcomes following strabismus surgery in children	Substantial Amendment 1	01/03/2015	4
15/LO/0067/AM01	Nail bed INJury Analysis (NINJA-P) Pilot Study	Substantial Amendment 1	20/04/2015	1
15/LO/0183/AM02	Standard Care versus Triventricular Pacing in Heart Failure (STRIVE HF)	Substantial Amendment 1	15/08/2015	12
15/LO/0184/AM01	Dietary resistant starch from peas for healthy glucose homeostasis	Substantial Amendment 1	29/09/2015	15
15/LO/0185/AM02	EORTC H&N Phase IV	Substantial Amendment 1	19/09/2015	7
15/LO/0596/AM02	Study of the effects of Vitamin D on immune responses to Tuberculosis	Substantial Amendment 1 (Proto	12/10/2015	13
15/LO/0621/AM01	Self-management support for people with long-term conditions v1.0	Substantial Amendment 1	23/06/2015	3
15/LO/0624/AM01	In vivo Tau pathology in PSP and CBD	Substantial Amendment 1	02/07/2015	1
15/LO/0945/AM01	Does nitrate supplementation improve CPX performance / postop recovery	V3 (AM01)	22/12/2015	5
15/LO/1201/AM01	Enhanced management of patients and contact tracing for hepatitis B	Substantial Amendment 1	20/08/2015	6
15/LO/1437/AM01	Paternal Weight, Sperm Epigenomics and Fetal Growth	Substantial amendment 1	24/02/2016	21
15/LO/1881/AM01	Wellbeing in Young People with Epilepsy	Amendment 1, 17/12/2015	17/12/2015	1
15/LO/1881/AM02	Wellbeing in Young People with Epilepsy	2	24/03/2016	11
15/LO/2051/AM02	The PRIME Study: Positive tRanslitions through the MEnopause	1.2	09/03/2016	13
15/LO/2063/AM01	Vitamin D in CKD - Vascular Function, Structure and Immune Regulation	Study Protocol Version 4 (AM01	25/01/2016	6
15/LO/2082/AM01	The REACT (REtirement in ACTion) study - V1	1.2	07/03/2016	23

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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

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 14 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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