

**East of England - Essex Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	East of England - Essex Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in patients – type iii
Type of Flag:	Phase 1 Studies in Patients, Research Involving Adults Lacking Capacity, Research Involving Prisoners or Prisons
Chair:	Dr Alan Lamont to 31 December 2016 Dr Niki Bannister from 1 January 2017
Vice-Chair:	Dr Gerry Kamstra
Alternate Vice-Chair:	Mr Alan Edwards to 3 June 2016
REC Manager:	Helen Poole to 31 January 2017 Ellen Swainston from 1 February 2017
REC Assistant:	Adam Garretty to 31 January 2017
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8107
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Chair's overview of the past year:

2016-17 was a busy year for the members of the Essex Research Ethics Committee, which saw a change of Chair in February 2017. A recruitment drive has eased the workload towards the end of the year, especially now that the newer members of the team are settled in place. Both the outgoing and new Chairs have been ably supported by our VC Gerry Kamstra and REC Manager Helen Poole and more recently Ellen Swainston. We wished Helen well in her move to another committee as a part of reorganisation, and welcomed our new manager Ellen shortly after the change. We also gave our best wishes to the outgoing chair, Alan Lamont, who has moved to chair Cambridge East and Alan Edwards who left the Committee.

We were delighted to introduce new members, Carol Alves and Jill Troup, and to have Tony Baker return after a sabbatical.

Overall we have had excellent attendance at our full meetings, and we look forward to a period of stability next year.

East of England - Essex Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Carol Alves	Research Quality Facilitator	Expert	21/04/2015	
Dr Shahira Amr	Pharmacist	Expert	22/07/2014	
Mr Tony Baker	Retired Consultant Head of Medical Physics	Lay	01/04/2011	
Dr Niki Bannister	Retired Hospital Doctor	Expert	03/01/2017	
Mr Alan Edwards	Retired Company Director	Lay Plus	01/04/2011	03/06/2016
Dr Gerry Kamstra	Retired Solicitor	Lay Plus	01/04/2011	
Dr Alan Lamont	Retired Consultant Oncologist	Expert	01/04/2011	03/01/2017 Transferred to Cambridge East REC
Ms Julie Lockhart	PPI Representative	Lay Plus	01/04/2011	
Ms Sarah Starr	Senior Nurse	Expert	01/10/2012	
Dr Andy Stevens	Media Consultant & Retired Principal Lecturer	Lay	01/04/2011	
Mrs Jill Troup	Senior Nurse	Expert	01/06/2016	
Dr Nkiruka Umaru	Pharmacist	Expert	05/05/2015	
Mrs Melanie Wakelin	Independent Statistical Consultant	Expert	11/01/2016	

East of England - Essex Research Ethics Committee: Deputy Members

None

East of England - Essex Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Brendan Laverty	Retired Head of Research Governance	Lay	07/07/2016
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	08/10/2016

East of England - Essex Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Carol Alves	Employed in NHS R&D; Basildon Hospital (incorporating the Essex Cardiothoracic Centre).	01/12/2016
Dr Shahira Amr	Final medical signatory. Employee shares with AbbVie.	01/12/2016
Mr Tony Baker	None declared	01/12/2016
Dr Niki Bannister	Vice chair of National Governors Association	09/02/2017
Dr Gerry Kamstra	No direct shareholdings - there may be indirect holdings through the funds in which my pension is invested.	01/12/2016
Dr Alan Lamont	I do not consider this material. I have retired from medical practice and am no longer GMC licenced to practice, though am retained on the register. I retain retired status membership of The Royal Colleges of Physicians and Radiologists.	01/12/2016
Ms Julie Lockhart	Voluntary member of Ambulance Service	01/12/2016
Ms Sarah Starr	None declared	01/12/2016
Dr Andy Stevens	None declared	01/12/2016
Mrs Jill Troup	Clinical Governance Team Leader in post Jan 16. Isobel Hospice Welwyn Garden City, Herts.	01/06/2016
Dr Nkiruka Umaru	Active researcher within a university organisation.	01/12/2016
Mrs Melanie Wakelin	Independent statistical consultant. Current clients involved in research are QMUL for NIHR funded study sponsored by Newcastle Upon Tyne Hospitals NHS Foundation Trust, Dermal Laboratories Ltd - Hitchin Herts, and Concepta Diagnostics Bedfordshire. Is an independent statistical consultant operating as a sole trader.	01/12/2016

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

Month	Date	Number of Members Present at Meeting
April	07/04/2016	8
May	05/05/2016	9
June	02/06/2016	7
July	07/07/2016	8
October	06/10/2016	9
November	03/11/2016	8
December	01/12/2016	8
January	12/01/2017	10
February	02/02/2017	9
March	02/03/2017	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	3
May	10/05/2016	3
June	14/06/2016	3
July	12/07/2016	3
August	09/08/2016	3
September	13/09/2016	3
October	11/10/2016	3
December	13/12/2016	3
January	10/01/2017	3
February	02/02/2017	9
March	14/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	18/04/2016	2
May	09/05/2016	2
May	16/05/2016	2
May	30/05/2016	2
June	13/06/2016	2
June	27/06/2016	2
July	11/07/2016	2
July	25/07/2016	2
August	08/08/2016	2
August	30/08/2016	2

September	12/09/2016	2
September	29/09/2016	2
October	20/10/2016	2
October	31/10/2016	2
November	24/11/2016	2
December	14/12/2016	2
January	09/01/2017	2
January	30/01/2017	2
February	13/02/2017	2
February	27/02/2017	2
March	13/03/2017	2
March	27/03/2017	2

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

None

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

Name	Number of Meetings Attended
Ms Carol Alves	8
Dr Shahira Amr	10
Mr Tony Baker	1
Dr Niki Bannister	3
Mr Alan Edwards	3
Dr Gerry Kamstra	10
Dr Alan Lamont	7
Ms Julie Lockhart	10
Ms Sarah Starr	9
Dr Andy Stevens	7
Mrs Jill Troup	5
Dr Nkiruka Umaru	8
Mrs Melanie Wakelin	11

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

Name	Number of Meetings Attended
Ms Carol Alves	4
Dr Shahira Amr	3
Mr Tony Baker	1
Dr Niki Bannister	1
Dr Gerry Kamstra	5
Dr Alan Lamont	7
Ms Julie Lockhart	4
Ms Sarah Starr	5
Dr Andy Stevens	2
Mrs Jill Troup	1
Dr Nkiruka Umaru	4
Mrs Melanie Wakelin	2

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

Name	Number of Meetings Attended
Ms Carol Alves	4
Dr Shahira Amr	3
Dr Niki Bannister	2
Mr Alan Edwards	1
Dr Gerry Kamstra	9
Dr Alan Lamont	12
Ms Julie Lockhart	4
Ms Sarah Starr	3
Dr Andy Stevens	3
Dr Nkiruka Umaru	1
Mrs Melanie Wakelin	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Ms Carol Alves	04/07/2016	CTIMP Training Day
Dr Shahira Amr	16/02/2017	National Members Training Day
Dr Niki Bannister	24/05/2016	Introduction to Phase 1 Research - Trials and Regulation
Dr Niki Bannister	23/09/2016	Local Training Day - Regional
Dr Niki Bannister	29/03/2017	Practicalities of Running a REC
Dr Gerry Kamstra	04/07/2016	CTIMP Training Day
Dr Gerry Kamstra	01/12/2016	National Training Day for Chairs
Dr Gerry Kamstra	29/03/2017	Practicalities of Running a REC
Dr Alan Lamont	23/06/2016	Reading - Children in Clinical Research and Assent (NREAP Materials)
Dr Alan Lamont	23/09/2016	Regional REC Members' Training Day
Ms Julie Lockhart	05/11/2016	Medicines Adherence Online CPD
Ms Sarah Starr	25/04/2016	Patient Handling
Ms Sarah Starr	25/04/2016	Launch Age Discrimination
Ms Sarah Starr	25/04/2016	Launch Approaching Equality and Diversity
Ms Sarah Starr	25/04/2016	Launch Disability Discrimination
Ms Sarah Starr	25/04/2016	Launch Faith, Religion or Belief Discrimination
Ms Sarah Starr	25/04/2016	Launch Race Discrimination
Ms Sarah Starr	25/04/2016	Launch Sex and Sexual Orientation Discrimination
Ms Sarah Starr	27/04/2016	Safeguarding Children E-Learning
Ms Sarah Starr	27/04/2016	Kwango Safeguarding Adults
Ms Sarah Starr	18/05/2016	Virtual Dementia Tour - relevance to MCA flagging
Ms Sarah Starr	30/09/2016	Acting as a 'buddy' for Jill Troup
Ms Sarah Starr	22/02/2017	Deprivation of Liberty Safeguards
Ms Sarah Starr	22/02/2017	Safeguarding Adults
Ms Sarah Starr	22/02/2017	Launch Age Discrimination
Ms Sarah Starr	22/02/2017	Launch Approaching Equality and Diversity
Ms Sarah Starr	22/02/2017	Launch Disability Discrimination
Ms Sarah Starr	22/02/2017	Launch Faith, religion or belief discrimination
Ms Sarah Starr	22/02/2017	Launch Race Discrimination
Ms Sarah Starr	22/02/2017	Launch Sex Discrimination
Ms Sarah Starr	22/02/2017	Launch Sexual Orientation Discrimination
Ms Sarah Starr	22/02/2017	Protecting Information Level 1
Ms Sarah Starr	22/02/2017	Safeguarding Children E-Learning

Dr Nkiruka Umaru	16/02/2017	National Members Training Day
Mrs Melanie Wakelin	23/09/2016	Regional REC Members' Training Day
Mrs Melanie Wakelin	30/11/2016	Committee Members' Induction

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	11	25.58
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	32	74.42
Total Applications Reviewed	43	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	1
Number of device applications reviewed	3
Number of prisoner applications reviewed	4
Number of applications involving adults unable consent reviewed	7
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

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	1	2.33
Unfavourable Opinion	0	0.00
Provisional Opinion	42	97.67
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	43	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	40	93.02
Further Information Favourable Opinion with Additional Conditions	1	2.33
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.33
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.33
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	43	100

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

Total Applications Reviewed	34
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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	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	19
Number of paediatric applications reviewed	8
Number of device applications reviewed	0
Number of qualitative applications reviewed	8

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	4	11.76
Favourable Opinion with Additional Conditions	1	2.94
No Opinion transfer to full committee for review	5	14.71
Provisional Opinion	21	61.76
Unfavourable Opinion	3	8.82
Total	34	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	3.58
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	2
Number of completed applications over 40 days as a % of total	4.65%
Number of days taken to final decision – average (mean)	32
Number of completed proportionate review applications for ethical review	28
Number of completed proportionate review applications for ethical review over 14 days. (Please note, the timeline for the review of PR applications was extended from 14 to 21 days in December 2016)	7
Number of completed proportionate review applications for ethical review over 21 days.	2
Number of completed proportionate review applications over 14 days as a % of total	28.57%
Number of SSAs (non-Phase 1) reviewed	20
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	96
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.04%
Number of modified amendments reviewed	4
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 non substantial amendments received	84

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	22
Number of annual progress reports received	48
Number of safety reports received	32
Number of Serious Adverse Events received	1
Number of final reports received	13

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/EE/0117	CIAO-II Version 1.0	41
16/EE/0124	ANZMTG 01.09/TROG 08.09 - The RTN2 Study	30
16/EE/0133	Safety study of ATX-GD-59 in subjects with Graves' disease	32
16/EE/0137	Feasibility of perioperative exercise on in older surgical patients	39
16/EE/0145	Non-invasive monitoring	36
16/EE/0183	BI 655064 in patients with active lupus nephritis.	30
16/EE/0190	Prepare-ABC	35
16/EE/0195	CASCADE	35
16/EE/0196	T2GO - Dapagliflozin in T2DM Patients aged 10-24 years	40
16/EE/0202	Haem and Nitrite Study	41
16/EE/0232	Coronary microcirculatory and bioresorbable vascular scaffolds	38
16/EE/0236	The DRINK Randomised Feasibility Trial V1.0	28
16/EE/0237	Moderation Effect of Treatment on Criminal Thinking and Aggression	35
16/EE/0238	Heuristic assessment of health literacy	30
16/EE/0241	RITA-MI	38
16/EE/0243	OTO-104 in Meniere's Disease	29
16/EE/0258	ROME	37
16/EE/0263	Understanding what supports dementia friendly hospital environments v1	27
16/EE/0271	The MAVEN Study	34
16/EE/0272	Pilot study of using video technology with older adults living at home	28
16/EE/0273	Quantifying maternal bone loss during pregnancy	40
16/EE/0284	CHIPPS WP5: Feasibility Study	36
16/EE/0409	Evaluation of a point-of-care whole blood viral load test for HIV	18
16/EE/0414	Watch and Wait	25
16/EE/0420	Outcome evaluation of offender Liaison and Diversion trial schemes	27
16/EE/0441	Self-disgust and Obsessive Compulsive Disorder	23
16/EE/0442	DUBLIN	23
16/EE/0443	MADRID	23
16/EE/0445	Investigating cognitive impairment in PD using PET neuroimaging	25
16/EE/0476	PRaM-GBM	25
16/EE/0501	Examining biofeedback with sexual offenders with a learning disability	33
16/EE/0514	Phase 2/3 ATOMIC Study of MPM to Assess ADI-PEG 20 with PemCis v3	31

17/EE/0001	A Feasibility Study to Evaluate Self-Harm Group in Inpatient Settings	27
17/EE/0005	Is dance cafe effective to improve the life of people with dementia?	28
17/EE/0022	Phase 2 study of MOXR0916 and Atezolizumab for bladder cancer	31
17/EE/0024	Bedside Assessment of Eye Movements in the Cognitively Impaired V1.1	33
17/EE/0038	Phase 2 study of RO7123520 as adjunct therapy for Rheumatoid Arthritis	38
17/EE/0040	ENCIRCLE Emergency Cerclage in Twins at Imminent Risk of preterm birth	27
17/EE/0089	Predicting Outcomes After Oesophagectomy	36
17/EE/0099	Dying inside	34

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0531	Multimodal Imaging in Lewy Body Disorders v1	40

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
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0462	B. Braun Medical Ltd. - Fuchsia	22

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0098	Optimisation of Vitamin D in Care Homes	n/a

Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/EE/0158	Patient barriers to accessing a specialist weight management service	29
16/EE/0160	Promoting reproductive and sexual health among 16-25 years olds.	27
16/EE/0166	Renal Dysfunction in Acute Stroke	19
16/EE/0209	Validation of a risk assessment tool for venous ulcer healing	10
16/EE/0212	Patient & Prescriber views on switching from a biologic to biosimilar	12
16/EE/0213	PROSPECTUS	12
16/EE/0267	Meaning and value of Augmentative and Alternative Communication (1)	10
16/EE/0268	Parents' experiences of the time preceding infant readmission v1.0	9
16/EE/0308	Therapeutic Assessment RCT Long-Term Follow Up	17
16/EE/0347	Factors Influencing Women Smoking in Hull	14
16/EE/0352	Experiences of Participants in a Commercial Weight Loss Scheme	9
16/EE/0401	Enhanced Imaging of the Tissue Structures in the Human Spine	8
16/EE/0456	Vancomycin renal toxicity when given by continuous infusion	12
16/EE/0457	Multiple sclerosis treatment preferences	13
16/EE/0556	Autism Measure for Contextual Information in Early Years Settings V1	12
17/EE/0020	Outcome assessment for rhinosinusitis	11
17/EE/0023	Ascitic weight and girth pre- and post-paracentesis	14
17/EE/0110	Quantification of the dart thrower's motion in wrists with pathology	21
17/EE/0112	Colorectal breath analysis (COBRA)	21

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
16/EE/0306	Common genetic variants in type 1 diabetes	14
16/EE/0405	Diabetic Retinopathy Progression following Bariatric Surgery	8
16/EE/0555	Exploring patients' decision making regarding kidney transplantation	13
17/EE/0018	Estimating incidence of GBS-associated neonatal encephalopathy	10

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/EE/0349	Dupuytren's In SoCietY Outcomes (DISCO)	15

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/EE/0454	Is a blended diet beneficial and safe for gastrostomy fed children?	8
17/EE/0054	Understanding children's experiences of staying in hospital	11
17/EE/0109	Measuring lip scar in cleft lip/palate patients	19

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/EE/0053	Preliminary validation of a new cognitive assessment after TIA	n/a

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
16/EE/0455	GO-0002 Obs Study of Tumor Tissue for Treatment Methadology of NSCLC	11

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
08/H0302/96/AM02	Genetic analysis of inherited retinal degenerations	3	10/11/2016	18
09/H0301/5/AM28	Lenalidomide in patients with B-Cell Chronic Lymphocytic Leukaemia	10.1	28/06/2016	20
09/H0301/5/AM29	Lenalidomide in patients with B-Cell Chronic Lymphocytic Leukaemia	Investigators Brochure Edition	26/08/2016	4
10/H0301/55/AM77	Norfolk DPS	40	20/07/2016	19
10/H0301/64/AM12	Phase III Study of GSK1120212 in BRAF V600E/K positive melanoma	IB update 7.0	10/11/2016	18
10/H0301/64/AM13	Phase III Study of GSK1120212 in BRAF V600E/K positive melanoma	Investigator's Brochure Update	20/01/2017	10
12/EE/0156/AM02	Serotonin's influence on neuronal mechanisms of compulsivity	Amendment 4	04/04/2016	18
12/EE/0274/AM35	CRASH-3 [Version 1.0]	28	28/04/2016	20
12/EE/0274/AM39	CRASH-3 [Version 1.0]	Substantial Amendment 32 2016/	06/09/2016	12
12/EE/0274/AM40	CRASH-3 [Version 1.0]	33	05/12/2016	21
13/EE/0008/AM03	VoxTox - Linking radiation dose at the voxel level with toxicity 1.0	SA2	16/03/2017	11
13/EE/0038/AM21	Haemorrhage alleviation with tranexamic acid [HALT-IT] [Version 1.0]	SA19	24/02/2017	3
13/EE/0063/AM38	Minocycline in Alzheimer's Disease Efficacy (MADE) trial	21	29/07/2016	10
13/EE/0107/AM03	Energy Balance and Sleep in Obesity	3	04/07/2016	7
13/EE/0123/AM11	RHYTHM-I	9	22/09/2016	27
13/EE/0216/AM05	GDC-0068 in Subjects with locally advanced / metastatic adenocarcinoma	Protocol Version 4	31/05/2016	10
13/EE/0235/AM04	Applying the Medical Research Council guidance to evaluate an intervention to support uptake and adherence to antiretroviral therapy for HIV	3	29/01/2016	13
13/EE/0301/AM03	CFS/ME Case series: anxiety	3	02/12/2016	23
13/EE/0345/AM15	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	11	21/04/2016	20

13/EE/0345/AM16	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	12	16/05/2016	15
13/EE/0345/AM17	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	SA13	27/06/2016	12
13/EE/0345/AM18	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	14	26/08/2016	11
14/EE/0152/AM10	1321.3 – reversal of dabigatran by idarucizumab (BI655075).	9	01/07/2016	4
14/EE/0200/AM06	A clinical study to assess lung fluid using MRI scans	3	13/05/2016	22
14/EE/1120/AM06	MK-5172/MK-8742 in HCV G1, 4, 6 with Inherited Blood Disorders	SA5	08/07/2016	10
14/EE/1163/AM05	Study on subjects affected by agitation associated with Alzheimer's.	4	29/06/2016	16
14/EE/1205/AM01	INFLAME-ICH: pilot study	1	02/06/2016	7
14/EE/1235/AM13	A study comparing treatments of severe influenza A	2016/09/01	01/09/2016	10
15/EE/0003/AM06	ISIS 304801-CS16 - The COMPASS Study	Amend 1	10/06/2016	4
15/EE/0003/AM07	ISIS 304801-CS16 - The COMPASS Study	6	27/07/2016	12
15/EE/0003/AM10	ISIS 304801-CS16 - The COMPASS Study	7	10/10/2016	10
15/EE/0003/AM11	ISIS 304801-CS16 - The COMPASS Study	8	06/12/2016	8
15/EE/0010/AM07	PITCHES: Phase III trial of UDCA in ICP: V1	3	07/04/2016	15
15/EE/0013/AM04	Phase 1 of Nivolumab in Advanced HCC	4	10/01/2017	19
15/EE/0134/AM03	Social and Personal Constructs of Dementia	3	02/11/2016	21
15/EE/0216/AM03	The INDOORS study	2	17/06/2016	10
15/EE/0216/AM04	The INDOORS study	3	27/09/2016	25
15/EE/0244/AM01	Acute hospital care for frail older people	1	15/06/2016	7
15/EE/0247/AM02	NMDA PET in TBI	2	10/05/2016	7
15/EE/0259/AM02	Rollover study of OPC 34712 in subjects with Alzheimer	SA2	10/05/2015	14
15/EE/0322/AM03	Drug-drug interactions between Clobazam and GWP42003-P	3	22/07/2016	18
15/EE/0322/AM04	Drug-drug interactions between Clobazam and GWP42003-P	IB Edition 9	27/09/2016	23
15/EE/0326/AM04	Rituximab + Bendamustine +/- Brentuximab in CD30-Positive DLBCL	SA3	20/05/2016	27
15/EE/0326/AM06	Rituximab + Bendamustine +/- Brentuximab in CD30-Positive DLBCL	SA5	23/12/2016	18
15/EE/0371/AM02	Long term follow-up registry for adolescent and paediatric patients	1	15/06/2016	20
15/EE/0371/AM03	Long term follow-up registry for adolescent and paediatric patients	Protocol Amendment 3	23/08/2016	7

15/EE/0410/AM02	Foot Orthoses- Custom v Off-the-shelf in Rheumatoid Arthritis	Substantial Amendment 1 1.11.2	01/11/2016	23
15/EE/0443/AM01	Positive psychology outcome measures for people with dementia	01	08/06/2016	6
15/EE/0443/AM02	Positive psychology outcome measures for people with dementia	2	19/12/2016	22
15/EE/0451/AM01	GLPG1837-CL-201 in subjects with CF and G551D mutation	Protocol v3.0 dated 14 March 2	01/04/2016	22
15/EE/0451/AM02	GLPG1837-CL-201 in subjects with CF and G551D mutation	02	18/04/2016	15
15/EE/0451/AM04	GLPG1837-CL-201 in subjects with CF and G551D mutation	SA3	17/08/2016	13
15/EE/0452/AM03	OAK Study	2	13/06/2016	10
15/EE/0452/AM04	OAK Study	SA03	29/07/2016	10
15/EE/0452/AM05	OAK Study	4	13/10/2016	16
15/EE/0456/AM01	CLAHRC-Y2	1	26/08/2016	17
15/EE/0464/AM02	LJPC-501 in Patients with Catecholamine-Resistant Hypotension	SA001	06/04/2016	20
15/EE/0464/AM04	LJPC-501 in Patients with Catecholamine-Resistant Hypotension	2	24/11/2016	16
15/EE/0470/AM02	SF-36 to assess impact of chest-contouring surgery	SA1	23/03/2016	14
16/EE/0011/AM04	OTO-104 in Meniere's Disease	SA#3	09/06/2016	5
16/EE/0011/AM06	OTO-104 in Meniere's Disease	SA4	06/09/2016	10
16/EE/0013/AM03	GS-9620 + TDF for participants with Chronic Hepatitis B	26.08.16	26/08/2016	4
16/EE/0013/AM04	GS-9620 + TDF for participants with Chronic Hepatitis B	SA #02	16/02/2017	11
16/EE/0018/AM01	A Comparative Study of Hospital Discharge for Homeless People	Number one	18/07/2016	7
16/EE/0040/AM01	GX29915: UTTR1147A in Diabetic Foot Ulcers	Protocol Amendment v2	13/04/2016	27
16/EE/0040/AM03	GX29915: UTTR1147A in Diabetic Foot Ulcers	Whole Genome Sequencing brochu	04/07/2016	13
16/EE/0040/AM08	GX29915: UTTR1147A in Diabetic Foot Ulcers	SA4	22/11/2016	22
16/EE/0040/AM09	GX29915: UTTR1147A in Diabetic Foot Ulcers	Protocol v3 and ICF v4.0 and P	24/01/2017	6
16/EE/0040/AM10	GX29915: UTTR1147A in Diabetic Foot Ulcers	SA6	06/02/2017	16
16/EE/0060/AM01	The internal "eating disorder voice" and childhood trauma.	1	01/04/2016	8
16/EE/0060/AM02	The internal "eating disorder voice" and childhood trauma.	2	25/08/2016	12

16/EE/0099/AM01	MASTERS-D 2 version 1.0	SA1	08/02/2017	18
16/EE/0117/AM01	CIAO-II Version 1.0	1 [Protocol 1.2]	06/07/2016	5
16/EE/0133/AM04	Safety study of ATX-GD-59 in subjects with Graves' disease	2	03/11/2016	22
16/EE/0133/AM08	Safety study of ATX-GD-59 in subjects with Graves' disease	5	15/02/2017	12
16/EE/0137/AM01	Feasibility of perioperative exercise on in older surgical patients	4	24/11/2016	29
16/EE/0183/AM02	BI 655064 in patients with active lupus nephritis.	2	04/01/2017	26
16/EE/0190/AM01	Prepare-ABC	01	03/10/2016	16
16/EE/0195/AM01	CASCADE	1	15/09/2016	14
16/EE/0195/AM02	CASCADE	SA02	26/10/2016	28
16/EE/0196/AM01	T2GO - Dapagliflozin in T2DM Patients aged 10-24 years	1	07/10/2016	10
16/EE/0196/AM03	T2GO - Dapagliflozin in T2DM Patients aged 10-24 years	SA2	16/03/2017	12
16/EE/0202/AM01	Haem and Nitrite Study	1	10/10/2016	10
16/EE/0202/AM02	Haem and Nitrite Study	2	10/02/2017	17
16/EE/0236/AM01	The DRINK Randomised Feasibility Trial V1.0	1	06/07/2016	4
16/EE/0236/AM03	The DRINK Randomised Feasibility Trial V1.0	3	03/03/2017	13
16/EE/0243/AM01	OTO-104 in Meniere's Disease	1	22/12/2016	21
16/EE/0243/AM02	OTO-104 in Meniere's Disease	2	01/03/2017	19
16/EE/0271/AM02	The MAVEN Study	1	23/12/2016	13

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q0102/16/AM09	The effects of testosterone on development	10	02/06/2016	18
07/H0307/64/AM05	Magnetoencephalography (MEG) in neurodegenerative disease	4	27/04/2016	23
10/H0301/38/AM04	HDR prostate brachytherapy monotherapy	10.1	10/06/2016	1
13/EE/0175/AM04	CHALK Study. Version 1.	2	05/12/2016	17
15/EE/0134/AM02	Social and Personal Constructs of Dementia	2	04/08/2016	13
16/EE/0040/AM11	GX29915: UTTR1147A in Diabetic Foot Ulcers	SA7	10/03/2017	18
16/EE/0236/AM02	The DRINK Randomised Feasibility Trial V1.0	2	14/12/2016	26

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
05/Q0102/16/AM09/1	The effects of testosterone on development	10	19/07/2016	0
07/H0307/64/AM05/1	Magnetoencephalography (MEG) in neurodegenerative disease	5	22/12/2016	14
13/EE/0175/AM04/1	CHALK Study. Version 1.	1	06/03/2017	13
16/EE/0236/AM02/1	The DRINK Randomised Feasibility Trial V1.0	Modified to amendment 2	11/01/2017	5

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
16/EE/0158	Patient barriers to accessing a specialist weight management service	29
16/EE/0160	Promoting reproductive and sexual health among 16-25 years olds.	27
16/EE/0166	Renal Dysfunction in Acute Stroke	19
16/EE/0349	Dupuytren's In SoCiety Outcomes (DISCO)	15
17/EE/0109	Measuring lip scar in cleft lip/palate patients	19
17/EE/0110	Quantification of the dart thrower's motion in wrists with pathology	21
17/EE/0112	Colorectal breath analysis (COBRA)	21

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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