

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

Annual Report

01 April 2015 - 31 March 2016



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
Vice-Chair:	Dr Gerry Kamstra
Alternate Vice-Chair:	Mr Alan Edwards
REC Manager:	Helen Poole
REC Assistant:	Rachel Nelson (April-August 2015) Adam Garretty (August 2015 to date)
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

This last year has seemed busier than the 48 full studies reviewed would suggest, probably because in addition to some membership changes we also reviewed 74 Substantial Amendments in the period, and 15 PR applications since formally recommencing this work in October last year.

We are as ever grateful to our much-appreciated REC manager, Helen Poole, now supported by our new REC assistant, Adam Garretty, and welcomed three new members, Nkiruka Umaru, Carol Alves and Melanie Wakelin. They are particularly valued as we also 'lost' Gusztav Belteki to the more conveniently-located Cambridge Central REC, and Tony Baker has taken a break to attend to other commitments. We now look forward to the next year, and some further recruitment.

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	Break in service 01/11/15 – 31/08/16
Dr Gusztav Belteki	Consultant Neonatologist	Expert	01/10/2014	Transferred to Cambridge Central REC 01/01/16
Ms Rachel Burrows	Project Commercial Assistant	Lay Plus	01/04/2011	11/08/2015
Mr Alan Edwards	Retired Company Director	Lay Plus	01/04/2011	
Dr Gerry Kamstra	Retired Solicitor	Lay Plus	01/04/2011	
Dr Alan Lamont	Consultant Oncologist	Expert	01/04/2011	
Ms Julie Lockhart	PPI Representative	Lay Plus	01/04/2011	
Mr. Cian Murphy	PhD Student in Genetics of Heart Disease	Lay	22/09/2014	10/07/2015
Ms Sarah Starr	Senior Nurse	Expert	01/10/2012	
Dr Andy Stevens	Media Consultant & Retired Principal Lecturer	Lay	01/04/2011	
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

Name	Profession	Status	Meeting date attended
None	None	None	None

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

Name	Profession	Status	Meeting date attended
Dr Michael Sheldon	Retired Clinical Psychologist	Lay	01/05/2015
Dr Niki Bannister	Retired Hospital Doctor	Expert	02/04/2015

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

Name	Declaration of Interest	Date
Ms Carol Alves	Employed in R&D Department as Research Quality Facilitator at Basildon and Thurrock University Hospitals NHS Foundation Trust, incorporating the Essex Cardiothoracic Centre	01/12/2015
Dr Shahira Amr	Promotional Affairs Manager (Principal Pharmacist) at Abbvie Ltd. Holds shares in Abbvie Ltd. Connection as an employee with Abbvie Ltd and MsC student at Oxford University (Experimental Therapies).	01/12/2015
Mr Alan Edwards	None declared	01/12/2015
Dr Gerry Kamstra	No direct holdings - there may be indirect holdings through through the funds in which my pension is invested.	01/12/2015
Dr Alan Lamont	Employed as consultant clinical oncologist, conductor of cancer research.	01/12/2015
Ms Julie Lockhart	None declared	01/12/2015
Ms Sarah Starr	None declared	03/12/2015
Dr Andy Stevens	None declared	01/12/2015
Dr Nkiruka Umaru	Practice and academic research interests.	01/12/2015
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, Concepta Diagnostics LTd Beds.I am an independent Statistical Consultant operating as a self trader.Willing to offer specialist advice in statistical aspects of research, especially clinical trial design, non-inferiority studies, blinding and samples size etc.	11/01/2016

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	8
May	07/05/2015	9
June	04/06/2015	9
July	02/07/2015	10
September	03/09/2015	7
October	01/10/2015	10
November	05/11/2015	8
December	03/12/2015	9
February	04/02/2016	8
March	03/03/2016	9

10 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
October	06/10/2015	3
November	10/11/2015	3
December	07/12/2015	3
January	12/01/2016	3
February	09/02/2016	3
March	07/03/2016	3

6 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	13/04/2015	2
April	27/04/2015	2
May	25/05/2015	2
June	05/06/2015	2
June	12/06/2015	2
July	06/07/2015	2
August	03/08/2015	2
August	19/08/2015	2
August	31/08/2015	2
September	21/09/2015	2
September	28/09/2015	2
October	26/10/2015	2
October	29/10/2015	3
November	09/11/2015	2
November	25/11/2015	2

November	30/11/2015	2
December	14/12/2015	2
January	04/01/2016	2
January	18/01/2016	2
February	01/02/2016	3
February	15/02/2016	2
February	18/02/2016	2
March	07/03/2016	2
March	21/03/2016	2

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

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

Date	Reason	Action taken
None	None	None

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

Name	Number of Meetings Attended
Ms Carol Alves	8
Dr Shahira Amr	7
Mr Tony Baker (break in service 01.11.15 – 31.08.16)	3
Dr Gusztav Belteki (transferred to other REC 01.01.16)	5
Mr Alan Edwards	8
Dr Gerry Kamstra	9
Dr Alan Lamont	10
Ms Julie Lockhart	9
Ms Sarah Starr	8
Dr Andy Stevens	8
Dr Nkiruka Umaru	6
Mrs Melanie Wakelin (started 11.01.16)	2

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

Name	Number of Meetings Attended
Dr Shahira Amr	2
Dr Gusztav Belteki	1
Mr Alan Edwards	3
Dr Gerry Kamstra	2
Dr Alan Lamont	3
Ms Julie Lockhart	2
Ms Sarah Starr	3
Dr Andy Stevens	2

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

Name	Number of Meetings Attended
Ms Carol Alves	1
Dr Shahira Amr	4
Mr Tony Baker	1
Dr Gusztav Belteki	3
Mr Alan Edwards	7
Dr Gerry Kamstra	7
Dr Alan Lamont	17
Ms Julie Lockhart	2
Ms Sarah Starr	3
Dr Andy Stevens	3
Dr Nkiruka Umaru	2

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Ms Carol Alves	12/05/2015	ULearn BTUH Equality and Diversity Course
Ms Carol Alves	26/05/2015	Online Induction for New Research Ethics Committee Members
Ms Carol Alves	24/09/2015	Committee Members Induction
Mr Tony Baker	04/11/2015	Equality and Diversity Training Slides
Dr Gusztav Belteki	28/04/2015	Equality and Diversity (E-Learning Module)
Mr Alan Edwards	26/05/2015	Reading Materials - Ethical Issues regarding Consenting Participants
Mr Alan Edwards	04/11/2015	Equality and Diversity - Reading (module slides)
Dr Gerry Kamstra	24/04/2015	Equality and Diversity (Online Module)
Dr Gerry Kamstra	26/05/2015	NREAP Meeting
Dr Gerry Kamstra	26/05/2015	NREAP Chair's Network Meeting
Dr Alan Lamont	26/05/2015	NREAP Meeting
Dr Alan Lamont	28/06/2015	Equality and Diversity E-Learning Module
Dr Alan Lamont	25/09/2015	Members' Regional Training Day
Ms Julie Lockhart	16/06/2015	Acting as 'Buddy' for New Member - Dr Nkiruka Umaru
Mr. Cian Murphy	01/05/2015	Equality and Diversity (E-learning Module)
Ms Sarah Starr	27/05/2015	Reading Materials - Ethical Issues in Consenting Participants - Various documents
Ms Sarah Starr	17/03/2016	Acting as a 'Buddy'
Dr Andy Stevens	02/05/2015	Equality and Diversity (E-learning module)
Dr Andy Stevens	26/05/2015	Reading Materials - Ethical Issues in Consenting Participants -
Dr Andy Stevens	01/07/2015	Acting as a 'buddy' for Carol Alves
Dr Nkiruka Umaru	24/09/2015	Committee Members' Induction
Dr Nkiruka Umaru	21/01/2016	Research Involving Adults Lacking Capacity (including research in emergency situations)
Mrs Melanie Wakelin	11/02/2016	Equality and Diversity E-Module

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	22.92
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	37	77.08
Total Applications Reviewed	48	100

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	20
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
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	8

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	2	4.17
Favourable Opinion with Additional Conditions	1	2.08
Unfavourable Opinion	2	4.17
Provisional Opinion	43	89.58
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	48	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	42	87.50
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.17
Favourable Opinion with Additional Conditions	1	2.08
Unfavourable Opinion	2	4.17
Provisional Opinion	1	2.08
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	48	100

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

Total Applications Reviewed	15
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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	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	1

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	26.67
Favourable Opinion with Additional Conditions	2	13.33
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	8	53.33
Unfavourable Opinion	1	6.67
Total	15	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	4.80
Number of completed applications for full ethical review	48
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	5
Number of completed applications over 40 days as a % of total	10.42%
Number of days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	15
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	4
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	74
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	2
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.70%
Number of modified amendments reviewed	5
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	68
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	25
Number of annual progress reports received	70

Number of safety reports received	24
Number of Serious Adverse Events received	6
Number of final reports received	16

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/EE/0048	A prison Therapeutic Community's (TC) view about prisoner autonomy	43
15/EE/0113	The nature and extent of bullying in psychiatric services	33
15/EE/0131	AYMES Shake Plus Thickener Tolerance and Acceptability Study	26
15/EE/0134	Social and Personal Constructs of Dementia	48
15/EE/0137	Exploring social networks of cancer survivors in self-management	33
15/EE/0141	Perceptions of work and support needs for people with diagnosis of EOD	40
15/EE/0174	The effects of repeated checking in Mild Cognitive Impairment (MCI)	26
15/EE/0181	Adverse birth outcomes in Pakistani and Bangladeshi women in Luton v1	38
15/EE/0185	A qualitative study of female adolescent self-harm. Version 1	25
15/EE/0188	Possible Selves in First Episode Psychosis (v1)	38
15/EE/0189	POETIC-2 Feasibility	23
15/EE/0190	Is my child naughty or autistic?	38
15/EE/0216	The INDOORS study	37
15/EE/0225	Laryngotracheal injuries following mechanical ventilation	40
15/EE/0227	Non-invasive cardiac output measurement in the Emergency Department	37
15/EE/0244	Acute hospital care for frail older people	25
15/EE/0245	Understanding the experiences of women in the criminal justice system	38
15/EE/0247	NMDA PET in TBI	24
15/EE/0249	Well-being Wheel Feasibility Study, v1	40
15/EE/0259	Rollover study of OPC 34712 in subjects with Alzheimer	38
15/EE/0305	Affective Disorders Research Database	36
15/EE/0317	Early targeted trunk training to improve mobility outcomes post stroke	30
15/EE/0322	Drug-drug interactions between Clobazam and GWP42003-P	40
15/EE/0326	Rituximab + Bendamustine +/- Brentuximab in CD30-Positive DLBCL	39
15/EE/0361	SIS- Southend Imaging Study	34
15/EE/0369	Mirror-Box Imaging Study	37
15/EE/0371	Long term follow-up registry for adolescent and paediatric patients	30
15/EE/0405	Alirocumab/Placebo in Insulin Treated Diabetics with High Cholesterol	35
15/EE/0410	Foot Orthoses- Custom v Off-the-shelf in Rheumatoid Arthritis	42
15/EE/0414	Supporting Prisoners Upon Release Service (SPuRS) (Version 10)	38
15/EE/0443	Positive psychology outcome measures for people with dementia	32
15/EE/0451	GLPG1837-CL-201 in subjects with CF and G551D mutation	41

15/EE/0452	OAK Study	46
15/EE/0456	CLAHRC-Y2	39
15/EE/0464	LJPC-501 in Patients with Catecholamine-Resistant Hypotension	28
16/EE/0002	Mixed methods evaluation of a dementia-friendly swimming project	34
16/EE/0011	OTO-104 in Meniere's Disease	30
16/EE/0013	GS-9620 + TDF for participants with Chronic Hepatitis B	30
16/EE/0018	A Comparative Study of Hospital Discharge for Homeless People	32
16/EE/0040	GX29915: UTTR1147A in Diabetic Foot Ulcers	32
16/EE/0080	Spatial language processing in early AD	25
16/EE/0099	MASTERS-D 2 version 1.0	28

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
None	None	None

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	None

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0327	An integrated approach to investigate immunosenescence	28
15/EE/0407	A study to estimate the prevalence of drug misuse in pregnancy (v.2)	26

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0325	AYMES Shake Compact	26

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EE/0367	Gastrointestinal symptom questionnaire validation	26

16/EE/0044	Meaning-making following group anger management. Version 1	25
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
15/EE/0331	Experience of Service Users subject to Community Treatment Orders: A case study	n/a

Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
None	None	None

Further information response not complete

REC Reference	Title	Number of Days on Clock
None	None	None

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
None	None	None

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/EE/0390	GALA-5 Long Term Follow up Study	13
15/EE/0436	Comparison of Systolic Rise Time to Duplex as the Gold Standard 1.0	12
16/EE/0024	Time/frequency analysis of heart murmurs, Version 1	5
16/EE/0060	The internal "eating disorder voice" and childhood trauma.	14
16/EE/0061	StAmP Samples Follow on Study	10
16/EE/0062	Validating an inventory for assessment of visual deficits in children	11
16/EE/0104	Significance of GATA3 expression in triple-negative breast cancers	10

16/EE/0109	Human Derived Demineralised Bone Matrix and its Correlative Imaging	8
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
None	None	None

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	None

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0434	Self-Management of Physical activity in people with colorectal cancer	12
15/EE/0470	SF-36 to assess impact of chest-contouring surgery	9
15/EE/0472	What effect does outcome questionnaire have on biofeedback therapy	8
15/EE/0473	RCTs in tuberculosis treatment: patient perception and choice	8

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0391	Golimumab Utilisation And Impact in Patients with AS	10
16/EE/0025	RA patients' knowledge in knowing their numbers (1)	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/EE/0026	Residual blood from anonymous NBS platelet donors for use in assays-V1	14

Provisional Opinion

REC Reference	Title	Number of Days on Clock
None	None	None

Further information response not complete		
REC Reference	Title	Number of Days on Clock
None	None	None

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
None	None	None

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/H0301/85/AM21	AZD2171 Mono/Combitherapy + Lomustine/Lomustine alone; in Glioblastoma	31.03.16	09/04/2015	19
07/H0302/82/AM04	Anti-inflammatory screening protocol using human blood - V.H01	4	20/11/2015	21
09/H0301/5/AM24	Lenalidomide in patients with B-Cell Chronic Lymphocytic Leukaemia	17.04.14	17/04/2015	12
09/H0301/5/AM25	Lenalidomide in patients with B-Cell Chronic Lymphocytic Leukaemia	28.08.15	17/04/2015	26
10/H0301/49/AM07	Early-onset obsessive-compulsive disorder	6	25/02/2016	11
10/H0301/55/AM70	Norfolk DPS	37	23/04/2015	5
10/H0301/55/AM73	Norfolk DPS	38	07/09/2015	14
10/H0301/55/AM74	Norfolk DPS	39	10/09/2015	14
10/H0302/6/AM05	N-ALIVE Pilot	14.05.15	14/05/2015	12
11/EE/0092/AM17	CDI-CS-001B: BAL101553 in Patients with Advanced Solid Tumors(15Feb11)	13.04.15	13/04/2015	15
11/EE/0092/AM18	CDI-CS-001B: BAL101553 in Patients with Advanced Solid Tumors(15Feb11)	20.05.15	20/05/2015	29
11/EE/0092/AM20	CDI-CS-001B: BAL101553 in Patients with Advanced Solid Tumors(15Feb11)	17	09/09/2015	12
11/EE/0092/AM21	CDI-CS-001B: BAL101553 in Patients with Advanced Solid Tumors(15Feb11)	18	29/10/2015	15
11/EE/0092/AM22	CDI-CS-001B: BAL101553 in Patients with Advanced Solid Tumors(15Feb11)	19	24/11/2015	1
11/EE/0092/AM23	CDI-CS-001B: BAL101553 in Patients with Advanced Solid Tumors(15Feb11)	20	17/12/2015	19
11/H0302/7/AM01	ACE Gene polymorphism and hypoglycaemia - Version 01	01	13/08/2015	20
12/EE/0310/AM05	CONCEPTT: version 1.0 [2012_04_25]	3	12/05/2015	15
12/EE/0428/AM01	Transition to young adulthood in Autism Spectrum Disorder	1	29/04/2015	22
12/EE/0455/AM04	Children and young people's views on living with impaired sight	01.04.15	18/03/2015	13
13/EE/0063/AM28	Minocycline in Alzheimer's Disease Efficacy (MADE) trial	19.05.15	18/05/2015	9

13/EE/0063/AM32	Minocycline in Alzheimer's Disease Efficacy (MADE) trial	17	06/11/2015	24
13/EE/0123/AM10	RHYTHM-I	008	09/11/2015	19
13/EE/0187/AM04	Donepezil in Aneurysmal Subarachnoid Haemorrhage (DASH) Trial	04	22/09/2015	7
13/EE/0216/AM04	GDC-0068 in Subjects with locally advanced / metastatic adenocarcinoma	3.0	14/12/2015	21
13/EE/0296/AM03	The neural basis of gambling cognitions: the role of the opioid system	3	27/04/2015	21
13/EE/0301/AM02	CFS/ME Case series: anxiety	2	28/10/2015	15
13/EE/0328/AM02	Learning from hospital admissions by reviewing patient's records	6	05/11/2015	19
13/EE/0343/AM07	CAPITAL	2	26/02/2016	14
13/EE/0345/AM11	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	7	22/05/2015	21
13/EE/0345/AM12	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	8	14/07/2015	21
13/EE/0345/AM13	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	9	08/09/2015	24
13/EE/0345/AM14	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	SA10	04/03/2016	4
14/EE/0045/AM02	Vitamin D supplementation study	2	14/07/2015	19
14/EE/0152/AM07	1321.3 – reversal of dabigatran by idarucizumab (BI655075).	6	19/06/2015	17
14/EE/0152/AM08	1321.3 – reversal of dabigatran by idarucizumab (BI655075).	7	22/06/2015	13
14/EE/0152/AM09	1321.3 – reversal of dabigatran by idarucizumab (BI655075).	8	17/12/2015	16
14/EE/0169/AM04	VWF-ADAMTS 13 in stroke	1	10/09/2015	24
14/EE/0169/AM06	VWF-ADAMTS 13 in stroke	2	10/02/2016	7
14/EE/1001/AM09	OTO-104 in Meniere's Disease	4	15/01/2016	17
14/EE/1027/AM01	CPAx: Evaluating recovery from critical illness	29.07.15	29/07/2015	13
14/EE/1062/AM01	GYPSIE - Glycoprotein Six in Stroke	03.08.15	03/08/2015	10
14/EE/1076/AM01	An evaluation of a new nonverbal treatment for global aphasia	1	07/05/2015	31
14/EE/1120/AM02	MK-5172/MK-8742 in HCV G1, 4, 6 with Inherited Blood Disorders	02	10/09/2015	28
14/EE/1120/AM03	MK-5172/MK-8742 in HCV G1, 4, 6 with Inherited Blood Disorders	SA03	23/11/2015	27
14/EE/1120/AM05	MK-5172/MK-8742 in HCV G1, 4, 6 with Inherited Blood Disorders	4	26/02/2016	10

14/EE/1163/AM01	Study on subjects affected by agitation associated with Alzheimer's.	1	23/02/2015	6
14/EE/1163/AM02	Study on subjects affected by agitation associated with Alzheimer's.	2	15/05/2015	7
14/EE/1163/AM04	Study on subjects affected by agitation associated with Alzheimer's.	3.0	17/12/2015	21
14/EE/1168/AM03	Gaucherite - A study to classify Gaucher disease	2	11/02/2016	18
14/EE/1235/AM04	A study comparing treatments of severe influenza A	04	27/07/2015	18
14/EE/1235/AM10	A study comparing treatments of severe influenza A	1	28/01/2016	15
14/EE/1275/AM01	Micro-LT: Microcirculation and Liver Transplantation	1	23/03/2015	16
15/EE/0003/AM01	ISIS 304801-CS16 - The COMPASS Study	1	17/06/2015	28
15/EE/0003/AM02	ISIS 304801-CS16 - The COMPASS Study	2	19/08/2015	14
15/EE/0003/AM03	ISIS 304801-CS16 - The COMPASS Study	3.0	14/01/2016	21
15/EE/0003/AM05	ISIS 304801-CS16 - The COMPASS Study	4	09/02/2016	9
15/EE/0011/AM03	ProActive Assessment of Obesity Risk during Infancy Version 1.0	4.0	09/11/2015	21
15/EE/0013/AM03	Phase 1 of Nivolumab in Advanced HCC	SA03	18/01/2016	13
15/EE/0134/AM01	Social and Personal Constructs of Dementia	12.08.15	12/08/2015	13
15/EE/0174/AM01	The effects of repeated checking in Mild Cognitive Impairment (MCI)	1	22/07/2015	13
15/EE/0174/AM02	The effects of repeated checking in Mild Cognitive Impairment (MCI)	2	05/01/2016	20
15/EE/0216/AM01	The INDOORS study	1	18/09/2015	7
15/EE/0247/AM01	NMDA PET in TBI	1	08/12/2015	11
15/EE/0322/AM01	Drug-drug interactions between Clobazam and GWP42003-P	4	05/02/2016	13
15/EE/0326/AM01	Rituximab + Bendamustine +/- Brentuximab in CD30-Positive DLBCL	1	01/12/2015	20
15/EE/0326/AM02	Rituximab + Bendamustine +/- Brentuximab in CD30-Positive DLBCL	SA2	24/12/2015	25
15/EE/0391/AM01	Golimumab Utilisation And Impact in Patients with AS	1	14/03/2016	10
15/EE/0405/AM01	Alirocumab/Placebo in Insulin Treated Diabetics with High Cholesterol	1	04/01/2016	6
16/EE/0011/AM01	OTO-104 in Meniere's Disease	1	11/03/2016	24

Unfavourable opinion

Amendment REC	Title	Version	Date	Number of Days on
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Reference				Clock
08/H0301/98/AM06	The Amaze trial	4	14/04/2015	5
08/H0302/154/AM02	Identification of regulatory systems in pterygial-derived cells	14.08.15	14/08/2015	28
10/H0301/64/AM10	Phase III Study of GSK1120212 in BRAF V600E/K positive melanoma	14.04.15	14/04/2015	6
15/EE/0013/AM01	Phase 1 of Nivolumab in Advanced HCC	SA1	27/05/2015	12
15/EE/0013/AM02	Phase 1 of Nivolumab in Advanced HCC	SA2	28/07/2015	21

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
08/H0301/98/AM06/1	The Amaze trial	Modified amendment	04/05/2015	2
08/H0302/154/AM02/1	Identification of regulatory systems in pterygial-derived cells	2	06/10/2015	0
10/H0301/64/AM10/1	Phase III Study of GSK1120212 in BRAF V600E/K positive melanoma	21.05.15	21/05/2015	7
15/EE/0013/AM01/1	Phase 1 of Nivolumab in Advanced HCC	12.06.15	12/06/2015	0
15/EE/0013/AM02/1	Phase 1 of Nivolumab in Advanced HCC	EC02-CA0	05/10/2015	7

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	n/a

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
None	None	n/a

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	n/a

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None	None	n/a

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	n/a

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	n/a

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	n/a