

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

Annual Report

01 April 2017 - 31 March 2018



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 Niki Bannister
Vice-Chair:	Dr Gerry Kamstra
Alternate Vice-Chair:	Dr Shahira Amr from 1 June 2017
REC Manager:	Ms Ellen Swainston
REC Assistant:	Ms Nicola Kohut from 10 July 2017
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

2017-18 was another busy year for the Essex Research Ethics Committee. The workload, especially from subcommittees and Proportionate Review, has increased in burden, and at times we struggled with quoracy. We greatly appreciated the help received from members of other RECs who kindly agreed to be co-opted. A recruitment drive has fortunately been successful in appointing four new members whom we warmly welcomed: Ashok Patnaik, Alison Taylor-Lamb, Susan Smith and Aimee Bambury.

We thanked Melanie Wakelin for her valued contributions to the Committee, and wished her well in moving on. As Chair I have been ably assisted by the Vice Chair, Gerry Kamstra, newly joined by Shahira Amr as AVC, and greatly appreciate all the ongoing support given by our manager Ellen Swainston and everyone in the REC Office.

As one of the few Prison-Flagged committees it was particularly pleasing for us to host a specific training event on research involving prisoners this year. This was well attended by members from other RECs and replaced our June 2017 meeting.

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	
Miss Aimee Bambury	Volunteer Research Assistant	Lay	18/10/2017	
Dr Niki Bannister	Retired Hospital Doctor	Expert	03/01/2017	
Dr Gerry Kamstra	Retired Solicitor	Lay Plus	01/04/2011	
Ms Julie Lockhart	PPI Representative	Lay Plus	01/04/2011	
Dr Ashok Patnaik	Policy Analyst	Lay Plus	01/09/2017	
Dr Susan Smith	Research Adviser / Senior Research Officer	Lay	17/10/2017	
Ms Sarah Starr	Senior Nurse	Expert	01/10/2012	
Dr Andy Stevens	Media Consultant & Retired Principal Lecturer	Lay	01/04/2011	
Mrs Alison Taylor-Lamb	Lecturer	Expert	17/10/2017	
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	05/10/2017

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

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Civil Servant (Retired)	Lay Plus	06/07/2017
Dr Alan Lamont	Retired Consultant Oncologist	Expert	06/07/2017 07/09/2017 15/03/2018 18/09/2017 sub-committee
Reverend Keith Lackenby	Reverend	Lay Plus	15/03/2018

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	05/01/2018
Mr Tony Baker	None declared	08/02/2018
Mrs Alison Taylor-Lamb	None declared	07/12/2017
Miss Aimee Bambury	Works in patient recruitment for St Pancras Clinical Research. A writer for ministryofethics.co.uk	05/12/2017
Dr Niki Bannister	Trustee National Governance Association which occasionally undertakes educational research but not in the field of health or social care	05/01/2018
Dr Gerry Kamstra	No direct shareholdings - there may be indirect holdings through the funds in which my pension is invested.	05/01/2018
Ms Julie Lockhart	Voluntary member of Ambulance Service	05/01/2018
Dr Ashok Patnaik	Currently leading a research project on online health information-seeking behaviour for Healthwatch Essex, which is a charity	23/10/2017
Dr Susan Smith	Member of Research Awards Panel, Crohns and Colitis UK. Employed by University of Essex as a research adviser for NIHR funded research design service East of England which provides advice and support to health and social care researchers developing grant applications. Occasional attendance at various organisations' R&D Committee meetings. Spouse employed by .East and North Herts NHS Trust as Associate Director for Research and Development and is a visiting professor at the University of Hertfordshire.	09/11/2017
Dr Shahira Amr	Medical Advisor @ Ipsen Ltd. Owner Apothecary Management Ltd (not involved in research)	31/03/2018
Ms Sarah Starr	None declared	05/01/2018
Dr Andy Stevens	None declared	05/01/2018
Dr Nkiruka Umaru	Academic and researcher currently working at the University of Hertfordshire	13/11/2017

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

Month	Date	Number of Members Present at Meeting
April	06/04/2017	8
May	04/05/2017	9
July	06/07/2017	8
September	07/09/2017	7
October	05/10/2017	10
November	02/11/2017	9
December	07/12/2017	9
January	11/01/2018	9
February	01/02/2018	8
March	15/03/2018	7

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	04/04/2017	3
May	04/05/2017	9
May	23/05/2017	3
June	13/06/2017	3
July	11/07/2017	3
September	04/09/2017	2
October	10/10/2017	3
November	14/11/2017	3
December	07/12/2017	7
December	12/12/2017	3
January	09/01/2018	3
February	13/02/2018	3
March	06/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	10/04/2017	2
April	24/04/2017	2
May	08/05/2017	2
May	22/05/2017	2
June	05/06/2017	2
June	19/06/2017	2
July	03/07/2017	2
July	17/07/2017	2

July	31/07/2017	2
August	14/08/2017	2
August	28/08/2017	2
September	11/09/2017	2
September	18/09/2017	2
September	25/09/2017	2
October	09/10/2017	2
October	23/10/2017	2
November	06/11/2017	2
December	04/12/2017	2
December	18/12/2017	2
January	08/01/2018	2
January	22/01/2018	2
February	05/02/2018	2
February	19/02/2018	2
March	05/03/2018	2
March	16/03/2018	2
March	19/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

None

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

Name	Number of Meetings Attended
Ms Carol Alves	7
Dr Shahira Amr	6
Mr Tony Baker	6
Miss Aimee Bambury	2
Dr Niki Bannister	8
Dr Gerry Kamstra	10
Ms Julie Lockhart	6
Dr Ashok Patnaik	4
Dr Susan Smith	3
Ms Sarah Starr	9
Dr Andy Stevens	5
Mrs Alison Taylor-Lamb	1
Mrs Jill Troup	4
Dr Nkiruka Umaru	5
Mrs Melanie Wakelin	3

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

Name	Number of Meetings Attended
Ms Carol Alves	5
Dr Shahira Amr	5
Mr Tony Baker	1
Dr Niki Bannister	7
Dr Gerry Kamstra	9
Ms Julie Lockhart	4
Ms Sarah Starr	4
Dr Andy Stevens	6
Mrs Jill Troup	2
Dr Nkiruka Umaru	2
Mrs Melanie Wakelin	3

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

Name	Number of Meetings Attended
Ms Carol Alves	2
Dr Shahira Amr	1
Mr Tony Baker	4
Dr Niki Bannister	15
Dr Gerry Kamstra	12
Ms Julie Lockhart	3
Dr Ashok Patnaik	1
Ms Sarah Starr	3
Dr Andy Stevens	4
Mrs Jill Troup	3
Dr Nkiruka Umaru	2
Mrs Melanie Wakelin	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Ms Carol Alves	01/06/2017	Research in Prisons
Ms Carol Alves	23/10/2017	Acting as buddy to a new REC member
Ms Carol Alves	12/12/2017	National Members Training Day
Dr Shahira Amr	01/06/2017	Research In Prisons
Mr Tony Baker	01/06/2017	Research in Prisons
Miss Aimee Bambury	28/02/2018	Ethical Issues in Phase One Research: An Advanced Training Course
Dr Niki Bannister	01/06/2017	Research in Prisons
Dr Niki Bannister	29/09/2017	Regional Training Day - Nottingham
Dr Niki Bannister	22/05/2017	Chairs' Meeting – East of England
Dr Niki Bannister	20/11/2017	Chairs' Meeting – East of England
Dr Gerry Kamstra	01/06/2017	Research in Prisons
Dr Gerry Kamstra	23/10/2017	Acting as buddy to a new REC member
Dr Gerry Kamstra	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Gerry Kamstra	22/05/2017	Chairs' Meeting – East of England
Dr Gerry Kamstra	20/11/2017	Chairs' Meeting – East of England
Ms Julie Lockhart	01/06/2017	Research in Prisons
Ms Julie Lockhart	06/03/2018	Assessing the Consequences (benefits and harms) of Research
Dr Susan Smith	11/01/2018	Training - Committee Members Induction
Dr Ashok Patnaik	09/10/2017	Ethics in palliative care research
Dr Ashok Patnaik	14/10/2017	Ethics of palliative care research
Ms Sarah Starr	23/10/2017	Acting as buddy to a new starter
Mrs Alison Taylor-Lamb	11/01/2018	Committee Members Induction
Mrs Jill Troup	25/07/2017	REC Members Induction
Dr Nkiruka Umaru	01/06/2017	Research in Prisons
Mrs Melanie Wakelin	01/06/2017	Research in Prisons

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	10	25.64
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.56
Others	28	71.79
Total Applications Reviewed	39	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	4
Number of student applications reviewed	16
Number of paediatric applications reviewed	6
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	4
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	0	0.00
Favourable Opinion with Additional Conditions	6	15.38
Unfavourable Opinion	1	2.56
Provisional Opinion	31	79.49
Provisional Opinion Pending Consultation with Referee	1	2.56
Total	39	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	29	74.36
Further Information Favourable Opinion with Additional Conditions	1	2.56
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	15.38
Unfavourable Opinion	1	2.56
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	2	5.13
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	39	100

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

Total Applications Reviewed	37
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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	1
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	16
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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	2	5.41
Favourable Opinion with Additional Conditions	2	5.41
No Opinion transfer to full committee for review	5	13.51
Provisional Opinion	28	75.68
Unfavourable Opinion	0	0.00
Total	37	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	3.55
Number of completed applications for full ethical review	39
Number of completed applications for full ethical review over 60 days	3
Number of completed applications over 60 days as a % of total	7.69%
Number of days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	32
Number of completed proportionate review applications for ethical review over 21 days	10
Number of completed proportionate review applications over 21 days as a % of total	31.25%
Number of SSAs (non-Phase 1) reviewed	2
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	68
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 modified amendments reviewed	3
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	82
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	21
Number of annual progress reports received	35
Number of safety reports received	31
Number of Serious Adverse Events received	14
Number of final reports received	19

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/EE/0138	Psychoanalytic Parent Infant Psychotherapy Research Version 1	32
17/EE/0139	Post systolic index as a reliable predictor of coronary heart disease	27
17/EE/0140	Factors that promote recovery from an acute episode of psychosis	35
17/EE/0191	Emotional awareness, mentalization and symptom complexity in FND	27
17/EE/0192	Developing a Support Needs Approach for Patients (SNAP2) - Stage 1	20
17/EE/0271	AceFIT – Acetabular Fractures in older patients Intervention Trial.	54
17/EE/0272	The SOUL-D long-term follow-up study	30
17/EE/0275	RECOS	36
17/EE/0279	Women's lived experience of primary tokophobia	26
17/EE/0283	Wise After the Event - Is Rumination Always Bad?	37
17/EE/0363	ElevatIOn HCC101	50
17/EE/0368	Study into the Reversal of Septic Shock with Landiolol (Beta Blockade)	37
17/EE/0376	Anetumab ravtansine thorough ECG and drug interaction study	31
17/EE/0384	A Phase III study to compare Apatinib plus BSC with placebo plus BSC	68
17/EE/0398	Real-time Monitoring of Glucose with MicroEye® & ContinuMon®	27
17/EE/0404	Conceiving Subjectivity, Version 1.0	45
17/EE/0411	Vascular dysfunction as a predictor of Acute Kidney Injury	34
17/EE/0437	AQUILA (54767414SMM3001)	23
17/EE/0448	CHILLY-AF	26
17/EE/0449	MOVE Study	27
17/EE/0455	RUSH2A	31
18/EE/0004	An exploration of stigma in South Asian people with psychosis V1	28
18/EE/0023	JBT101-SSc-002 Efficacy & Safety Study of Lenabasum in SSc	38
18/EE/0027	Perioperative Medicine Inception Cohort Database	40
18/EE/0028	Interpersonal style and perceptions of the secure care environment.	28
18/EE/0038	Parental Anxiety and PTSS in Food Allergy v1.0	33
18/EE/0040	Transforming the mental health treatment of children with epilepsy	58
18/EE/0071	Therapeutic relationships in a Parent-Infant Mental Health Service v.1	47
18/EE/0080	A Single-Dose study of Tedizolid Phosphate in Pediatrics 2<12years	47

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
18/EE/0079	APEX 2 BCX7353 in Prevention of HAE Attacks	45

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
17/EE/0113	Recovery from psychosis: a mental health inpatient perspective (1)	26
17/EE/0143	Relational experiences of older individuals with ASD - Version 1	26
17/EE/0286	How the bereaved experience withdrawal of LST in Critical Care.	17
17/EE/0381	VISIT_ICU	22
17/EE/0436	Childhood Bullying in a First Episode Psychosis Population - Version 1	20
18/EE/0046	Feasibility assessment of a new eye-test ("Eyecatcher Lite")	35

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0456	UK-START	25

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
18/EE/0005	Effect on HRCT Endpoints to Glucocorticoid in Pulmonary Sarcoidosis	n/a
18/EE/0081	MK-7264 on cough with induced viral upper respiratory tract infection	n/a

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
17/EE/0148	Socio-demographic factors and HPV in oropharyngeal cancer.	16
17/EE/0196	CAIN457A3403 (SERENA) Secukinumab real-life use in Pso, PsA and AS	19
17/EE/0200	The effect of injectable therapies on quality of life in diabetes	16
17/EE/0202	Homeless patients' experience of GP service in an outreach setting	14
17/EE/0203	MAPS	16
17/EE/0218	Evaluation of IFU for Max Plus LX3 monitoring system	23
17/EE/0219	Stability in Emotional Regulation with Group Exercise (SERGE) Trial	15
17/EE/0250	ContactME-IBS	9
17/EE/0251	Defining the role of the therapist in influencing patient outcomes	19
17/EE/0252	Control of eating after bariatric surgery	23
17/EE/0253	Language & Effective Communication in MDTs V3	14
17/EE/0292	Exploring the networks of frail individuals within a community setting	25
17/EE/0379	Expression pattern of Neurotensin and receptors in colorectal cancer	20
17/EE/0380	Validating novel therapeutic targets in Autoimmune diseases, Version 1	16
17/EE/0417	In-hospital interstage for HLHS and HLHS variants	20
17/EE/0469	Multi-behaviours and Multi-morbidity	23
17/EE/0493	Asymptomatic Small Pancreatic Endocrine Neoplasms (ASPEN Study)	22
17/EE/0500	Research into the problem of drug related litter in Manchester (v1)	25
17/EE/0506	Clinical changes of Inflammatory Rheumatic Disease in Pregnancy study	22
17/EE/0507	Clinical efficacy of an OT pathway in the treatment of DCX injection	28

17/EE/0513	The core outcome set for bereavement research in palliative care	14
18/EE/0015	BOOM Study	20
18/EE/0016	The MENI-FOOT Project	20
18/EE/0020	Digital Intervention Generating Innovation in Prosthetics: DIGITs	45
18/EE/0063	Transitions of Care: The Patient Experience	18
18/EE/0089	Mindfulness, self-compassion and weight management	16
18/EE/0090	Mindfulness, Self-Compassion and Bariatric Surgery	21

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/EE/0470	Impact of compounds on cells from haematological malignancies	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
17/EE/0296	100k Genomes in Africa Study	20
18/EE/0022	Median nerve variation MRI	13

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/EE/0294	DIFUS-T1	12
17/EE/0378	Women's experiences of a maternal obesity service	15

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
05/Q0102/16/AM12	The effects of testosterone on development	11	28/02/2018	10
07/H0302/138/AM09	Parkinsonism: incidence and cognitive heterogeneity in Cambridgeshire	SA9	26/05/2017	19
07/H0302/82/AM06	Anti-inflammatory screening protocol using human blood - V.H01	SA5	29/06/2017	15
09/H0301/5/AM30	Lenalidomide in patients with B-Cell Chronic Lymphocytic Leukaemia	SA21	24/04/2017	19
09/H0301/5/AM31	Lenalidomide in patients with B-Cell Chronic Lymphocytic Leukaemia	22	02/02/2018	33
10/H0301/49/AM11	Early-onset obsessive-compulsive disorder	7	25/01/2018	19
10/H0301/55/AM78	Norfolk DPS	SA41	03/10/2017	29
12/EE/0274/AM41	CRASH-3 [Version 1.0]	SA35	05/04/2017	8
12/EE/0310/AM07	CONCEPTT: version 1.0 [2012_04_25]	Amendment 4 29/08/2017	29/08/2017	23
12/EE/0310/AM08	CONCEPTT: version 1.0 [2012_04_25]	SA5	06/11/2017	29
13/EE/0008/AM04	VoxTox - Linking radiation dose at the voxel level with toxicity 1.0	SA3	05/12/2017	30
13/EE/0038/AM26	Haemorrhage alleviation with tranexamic acid [HALT-IT] [Version 1.0]	22	06/10/2017	5
13/EE/0301/AM04	CFS/ME Case series: anxiety	Substantial Amendment 4	04/09/2017	23
13/EE/0343/AM10	CAPITAL	4	15/01/2018	18
13/EE/0385/AM02	Parkinson's Disease and Impulsivity:biological and behavioural markers	SA1	15/12/2017	25
14/EE/1168/AM06	Gaucherite - A study to classify Gaucher disease	SA3	22/08/2017	7
15/EE/0010/AM20	PITCHES: Phase III trial of UDCA in ICP: V1	9	06/02/2018	6
15/EE/0013/AM06	Phase 1 of Nivolumab in Advanced HCC	5	04/10/2017	17
15/EE/0013/AM07	Phase 1 of Nivolumab in Advanced HCC	6	07/02/2018	15
15/EE/0245/AM02	Understanding the experiences of women in the criminal justice system	1	27/04/2017	7
15/EE/0305/AM01	Affective Disorders Research Database	SA 1.2	11/06/2017	26

15/EE/0317/AM06	Early targeted trunk training to improve mobility outcomes post stroke	3	29/12/2017	10
15/EE/0322/AM05	Drug-drug interactions between Clobazam and GWP42003-P	21/04/2017	21/04/2017	20
16/EE/0011/AM12	OTO-104 in Meniere's Disease	8.0	08/05/2017	16
16/EE/0011/AM13	OTO-104 in Meniere's Disease	SA#7	11/07/2017	26
16/EE/0040/AM14	GX29915: UTTR1147A in Diabetic Foot Ulcers	SA - Informed Consent 5.0	28/09/2017	21
16/EE/0040/AM15	GX29915: UTTR1147A in Diabetic Foot Ulcers	SA 4 2017/11/18	17/11/2017	32
16/EE/0124/AM03	ANZMTG 01.09/TROG 08.09 - The RTN2 Study	Substantial Amendment 1	29/08/2017	16
16/EE/0137/AM02	Feasibility of perioperative exercise on in older surgical patients	Substantial Amendment 2	17/07/2017	22
16/EE/0145/AM01	Non-invasive monitoring	SA#1	26/07/2017	11
16/EE/0183/AM03	BI 655064 in patients with active lupus nephritis.	SA3	16/03/2017	16
16/EE/0183/AM05	BI 655064 in patients with active lupus nephritis.	SA 4 Am 5	30/08/2017	16
16/EE/0183/AM06	BI 655064 in patients with active lupus nephritis.	SA 6 2017/12/20	20/12/2017	27
16/EE/0190/AM08	Prepare-ABC	2	01/06/2017	13
16/EE/0190/AM12	Prepare-ABC	SA3	22/11/2017	18
16/EE/0190/AM16	Prepare-ABC	4	09/03/2018	7
16/EE/0195/AM06	CASCADE	SA#4	01/06/2017	5
16/EE/0196/AM04	T2GO - Dapagliflozin in T2DM Patients aged 10-24 years	SA03	27/10/2017	13
16/EE/0232/AM02	Coronary microcirculatory and bioresorbable vascular scaffolds	P02135 Version 7.0	29/11/2017	29
16/EE/0241/AM03	RITA-MI	SA01	25/10/2017	20
16/EE/0241/AM04	RITA-MI	SA02	25/11/2017	21
16/EE/0243/AM05	OTO-104 in Meniere's Disease	N/A	28/04/2017	15
16/EE/0243/AM06	OTO-104 in Meniere's Disease	SA#5	11/07/2017	26
16/EE/0271/AM05	The MAVEN Study	2	09/10/2017	27
16/EE/0349/AM02	Dupuytren's In SoCiety Outcomes (DISCO)	1	13/01/2017	17
16/EE/0443/AM01	MADRID	1	22/05/2017	13
16/EE/0476/AM02	PRaM-GBM	1	13/04/2017	9
16/EE/0501/AM01	Examining biofeedback with sexual offenders with a learning disability	SA01	01/10/2017	7
16/EE/0514/AM04	Phase 2/3 ATOMIC Study of MPM to Assess ADI-PEG 20 with PemCis v3	SA 1 2018/01/24	24/01/2018	10
17/EE/0022/AM01	Phase 2 study of MOXR0916 and Atezolizumab for bladder	1.0	05/05/2017	13

	cancer			
17/EE/0022/AM03	Phase 2 study of MOXR0916 and Atezolizumab for bladder cancer	2	23/10/2017	27
17/EE/0038/AM02	Phase 2 study of RO7123520 as adjunct therapy for Rheumatoid Arthritis	SA2	06/06/2017	13
17/EE/0038/AM09	Phase 2 study of RO7123520 as adjunct therapy for Rheumatoid Arthritis	6	07/02/2018	15
17/EE/0040/AM02	ENCIRCLE Emergency Cerclage in Twins at Imminent Risk of preterm birth	Amendment 2	03/01/2018	11
17/EE/0040/AM06	ENCIRCLE Emergency Cerclage in Twins at Imminent Risk of preterm birth	6	06/03/2018	11
17/EE/0098/AM02	Optimisation of Vitamin D in Care Homes	SA1	26/09/2017	17
17/EE/0191/AM01	Emotional awareness, mentalization and symptom complexity in FND	Amendment number 1	21/10/2017	26
17/EE/0203/AM01	MAPS	v1.2	25/10/2017	24
17/EE/0218/AM01	Evaluation of IFU for Max Plus LX3 monitoring system	SA1	14/06/2017	7
17/EE/0218/AM02	Evaluation of IFU for Max Plus LX3 monitoring system	SA2	31/07/2017	17
17/EE/0250/AM03	ContactME-IBS	Substantial Amendment No 1. 11	11/01/2018	20
17/EE/0272/AM01	The SOUL-D long-term follow-up study	1	20/12/2017	36
17/EE/0279/AM01	Women's lived experience of primary tokophobia	SA1	16/11/2017	34
17/EE/0286/AM01	How the bereaved experience withdrawal of LST in Critical Care.	1	03/08/2017	13
17/EE/0378/AM02	Women's experiences of a maternal obesity service	1	25/01/2018	10
17/EE/0381/AM01	VISIT_ICU	1	27/02/2018	17

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/EE/0038/AM06	Phase 2 study of RO7123520 as adjunct therapy for Rheumatoid Arthritis	SA5 18 December 2017	18/12/2017	29
17/EE/0296/AM01	100k Genomes in Africa Study	1	05/02/2018	22

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
16/EE/0040/AM11/1	GX29915: UTTR1147A in Diabetic Foot Ulcers	7	31/03/2017	13
17/EE/0038/AM06/1	Phase 2 study of RO7123520 as adjunct therapy for Rheumatoid Arthritis	5	09/02/2018	7
17/EE/0296/AM01/1	100k Genomes in Africa Study	2	02/03/2018	7

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
17/EE/0384	A Phase III study to compare Apatinib plus BSC with placebo plus BSC	68

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/EE/0218	Evaluation of IFU for Max Plus LX3 monitoring system	23
17/EE/0252	Control of eating after bariatric surgery	23
17/EE/0292	Exploring the networks of frail individuals within a community setting	25
17/EE/0469	Multi-behaviours and Multi-morbidity	23
17/EE/0470	Impact of compounds on cells from haematological malignancies	29
17/EE/0493	Asymptomatic Small Pancreatic Endocrine Neoplasms (ASPEN Study)	22
17/EE/0500	Research into the problem of drug related litter in Manchester (v1)	25
17/EE/0506	Clinical changes of Inflammatory Rheumatic Disease in Pregnancy study	22
17/EE/0507	Clinical efficacy of an OT pathway in the treatment of DCX injection	28
18/EE/0020	Digital Intervention Generating Innovation in ProsThetics: DIGITs	45

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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