

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	East of England - Cambridge East Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Databases, Establishing Research Tissue Banks, Medical Device Study, Phase 1 Studies in Healthy Volunteers, Phase 1 Studies in Patients
Chair:	Dr Nicki Bannister (until December 2016) Dr Alan Lamont (January 2017 onwards)
Vice-Chair:	Mr Iain Martin (until October 2016) Dr Derek Prater (from April 2017 for 6 months)
Alternate Vice-Chair:	Dr Rebecca Harmston (until February 2017)
REC Manager:	Ms Carolyn Halliwell (until February 2017) Ms Rachel Nelson (from February 2017)
REC Assistant:	Ms Joanne O'Neil (until February 2017) Mr Adam Garretty (from February 2017)
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

The past year has seen a number of changes to the team, in which our REC manager Carolyn has moved on within the service. We wish her well in her career, and welcomed Rachel. We also had a change of chair, wishing Niki Bannister well in her move. Over the course of the year found ourselves saying farewell to Iain Martin, our VC, Rebecca Harmston, our AVC, Jacqueline Cornelissen and Patricia Westcott, all of whose contributions will be missed. A period of recruitment has commenced, and we hope to be up to complement soon, avoiding the need for co-option. The Committee has embraced Proportionate Review, which has further increased to workload on members temporarily. Overall, as new Chair I was made welcome, was pleased to find the whole team working well together, and now look forward to the future with optimism.

East of England - Cambridge East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Niki Bannister	Retired Hospital Doctor	Expert	20/01/2014	31/12/2016
Dr Helen Burns	Retired GP	Expert	05/12/2014	
Dr Alan Calverd	Scientific Consultant	Expert	16/02/2015	
Mrs Ann Colvill	Employment Tribunal Service	Lay	19/01/2016	
Dr Jacqueline Cornelissen	Senior Project Manager - Medical Affairs Research Operations	Lay	01/12/2011	14/11/2016
Dr Rebecca Harmston	Scientific Officer	Lay Plus	01/04/2014	08/02/2017
Dr Alan Lamont	Retired Consultant Oncologist	Expert	01/03/2017	
Mr Iain Martin	Retired RAF Officer	Lay Plus	01/10/2012	18/10/2016
Dr Derek Prater	Pharmacist	Expert	05/05/2015	
Dr Wendi Qian	Statistician	Expert	08/05/2014	
Dr Jessica Santos	Global Compliance & Quality Director	Lay Plus	02/04/2014	
Mrs Patricia Westcott	Retired Oncology Specialist Nurse & Co-ordinator for a Cancer Charity	Lay	22/10/2013	02/02/2017
Dr Joyce Whittington	Psychologist	Expert	02/12/2014	
Miss Suzahn Wilson	Physiotherapist	Expert	10/02/2016	

East of England - Cambridge East Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None	None	None	None

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

Name	Profession	Status	Meeting date attended
Ms Julie Lockhart	PPI Representative	Lay Plus	17/01/2017 21/02/2017
Ms Stephanie Ellis	Civil Servant (Retired)	Lay Plus	19/07/2016
Dr Alan Lamont	Retired Consultant Oncologist	Expert	15/11/2016 17/05/2016

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

Name	Declaration of Interest	Date
Dr Niki Bannister	Vice Chair of National Governors Association	13/12/2016
Dr Helen Burns	317 ORD shares in GlaxoSmithKline	13/01/2017
Dr Alan Calverd	Director: Radiation Consultancy Services Ltd, Medical Physics Cooperative Ltd, United Open MRI Ltd. Self-employed consultant trading as Quality Associates Ownership or part ownership in all the above. Shareholder in all above and Exhalation Technologies Ltd.	02/12/2016
Mrs Ann Colvill	None declared	13/12/2016
Dr Rebecca Harmston	1. Member of the International Advisory Board for the Research Registry. 2. Member of the Quality in Organ Donation panel (QUOD) Oxford University. 3. Abstract Rater for the National Institute of Health Research. 4. Statinwise Steering Group for the London School of Tropical Medicine. 5. Cell Salvage in Obstetrics with Queen Mary University of London. 6. DECRYPT steering group UEA/Inspire. 7. Member of the CRUK Involvement Network. 8. Adviser on heart related projects for John Radcliffe Hospital. 9. Lay Reviewer for the Cochrane Collaboration. 10. Lay member on the CHIPPS project UEA. Public Member of the PPI group Great Ormond Street Hospital. 12. Lay member of the Children's Burns Research Panel for Bristol University. 13. Lay member on the Health Technology Assessment Maternal, Neonatal and Child Health Panel. 14. Member of the FARR Institute Public and Patient Working Group. 15. Member of the Placental Assessment Predicting Pregnancy Outcome (PAPPO) project with Manchester University. 16. Lay Reviewer for the British Medical Journal. 17. Member of the INSPIRE Adult Panel.	13/01/2017
Dr Alan Lamont	None declared	17/01/2017
Dr Derek Prater	Previously employed by Mundipharma Research Ltd until April 2014. Previously held a Consultancy Agreement with Mundipharma Research Ltd, without any committed hours or obligations of availability or exclusivity until 6th March 2015.	02/12/2016
Dr Wendi Qian	Senior Statistician at Cambridge Clinical Trials Unit.	05/12/2016
Dr Jessica Santos	Global Compliance and Quality Director, Kantar Health, Co-Chair Code of Ethics ISPOR, Ethics Committee member, BHBA, Ethics Network, EphMRA, Small number of shares in GSK	13/12/2016
Mrs Patricia Westcott	None declared	12/12/2016
Dr Joyce Whittington	Shares in GSK and AstraZeneca.	05/12/2016
Miss Suzahn Wilson	None declared	21/06/2016

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

Month	Date	Number of Members Present at Meeting
May	17/05/2016	7
June	21/06/2016	9
July	19/07/2016	7
September	20/09/2016	8
October	18/10/2016	11
November	15/11/2016	10
December	13/12/2016	8
January	17/01/2017	9
February	21/02/2017	8
March	21/03/2017	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	01/04/2016	3
May	01/05/2016	3
June	01/06/2016	3
July	01/07/2016	3
September	01/09/2016	3
October	01/10/2016	3
November	07/11/2016	3
December	01/12/2016	3
January	06/01/2017	3
February	01/02/2017	3

10 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	05/04/2016	2
April	19/04/2016	2
May	03/05/2016	2
May	19/05/2016	2
May	31/05/2016	2
June	14/06/2016	2
June	28/06/2016	2
July	12/07/2016	2
July	26/07/2016	2
August	09/08/2016	2

August	23/08/2016	2
September	06/09/2016	2
September	20/09/2016	2
October	03/10/2016	2
October	04/10/2016	2
October	18/10/2016	2
November	15/11/2016	2
November	29/11/2016	2
December	13/12/2016	2
December	29/12/2016	2
January	10/01/2017	2
January	24/01/2017	2
February	07/02/2017	2
February	21/02/2017	2
March	07/03/2017	2
March	27/03/2017	2

26 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
Dr Niki Bannister	6
Dr Helen Burns	9
Dr Alan Calverd	7
Mrs Ann Colvill	7
Dr Jacqueline Cornelissen	3
Dr Rebecca Harmston	6
Dr Alan Lamont	3
Mr Iain Martin	4
Dr Derek Prater	9
Dr Wendi Qian	5
Dr Jessica Santos	8
Mrs Patricia Westcott	3
Dr Joyce Whittington	7
Miss Suzahn Wilson	4

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

Name	Number of Meetings Attended
Dr Helen Burns	1
Dr Alan Calverd	1
Mrs Ann Colvill	2
Dr Jacqueline Cornelissen	3
Dr Rebecca Harmston	10
Dr Alan Lamont	1
Dr Derek Prater	3
Dr Wendi Qian	2
Dr Jessica Santos	2
Dr Joyce Whittington	3
Miss Suzahn Wilson	1

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

Name	Number of Meetings Attended
Dr Niki Bannister	15
Dr Helen Burns	2
Dr Alan Calverd	3
Mrs Ann Colvill	2
Dr Jacqueline Cornelissen	1

Dr Rebecca Harmston	2
Dr Alan Lamont	5
Mr Iain Martin	8
Dr Derek Prater	2
Dr Wendi Qian	2
Dr Jessica Santos	4
Mrs Patricia Westcott	2
Dr Joyce Whittington	2
Miss Suzahn Wilson	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Niki Bannister	24/05/2016	Introduction to Phase I Research - Trials and Regulation
Dr Niki Bannister	23/09/2016	Local Training Day - Regional
Dr Helen Burns	23/09/2016	Local Training Day - Regional
Mrs Ann Colvill	06/01/2017	Equality and Diversity Training
Mrs Ann Colvill	14/03/2017	Induction Training
Dr Rebecca Harmston	02/04/2016	Research Ethics – Ethical considerations in international Health Research and Special Topic in Research Ethics
Dr Rebecca Harmston	06/04/2016	Handling Health Related Findings in Research
Dr Rebecca Harmston	19/04/2016	Training for Commercial Studies
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
Dr Derek Prater	06/04/2016	Handling Health Related Findings in Research
Dr Derek Prater	29/04/2016	Reviewing the Research Design of Clinical Trials
Dr Derek Prater	29/04/2016	Training for Commercial Studies
Dr Derek Prater	29/04/2016	Training for Non-Commercial Studies
Dr Derek Prater	23/09/2016	Local Training Day - Regional
Dr Derek Prater	16/02/2017	National Member's Training Day
Dr Wendi Qian	07/02/2017	Research and Human Tissue Legislation
Dr Jessica Santos	04/07/2016	CTIMP Training
Dr Jessica Santos	23/09/2016	Regional Training Day - Local
Dr Jessica Santos	16/02/2017	National Member's Training Day
Mrs Patricia Westcott	06/04/2016	Handling Health Related Findings in Research
Dr Joyce Whittington	06/04/2016	Handling Health-Related Findings in Research
Dr Joyce Whittington	09/06/2016	Consent, Payments & Voluntariness
Dr Joyce Whittington	04/07/2016	CTIMP Training Day
Dr Joyce Whittington	16/02/2017	National Member's Training Day
Miss Suzahn Wilson	07/09/2016	Induction for New Members
Miss Suzahn Wilson	09/09/2016	Equality, Diversity and Human Rights

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	18	37.50
Phase 1	1	2.08
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.17
Research Database (including renewals)	2	4.17
Others	25	52.08
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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	6
Number of paediatric applications reviewed	4
Number of device applications reviewed	9
Number of prisoner applications reviewed	1
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	0

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	1	2.08
Favourable Opinion with Additional Conditions	2	4.17
Unfavourable Opinion	1	2.08
Provisional Opinion	44	91.67
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	33	68.75
Further Information Favourable Opinion with Additional Conditions	6	12.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.08
Favourable Opinion with Additional Conditions	2	4.17
Unfavourable Opinion	1	2.08
Provisional Opinion	3	6.25
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	2	4.17
Total	48	100

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

Total Applications Reviewed	25
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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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	6
Number of device applications reviewed	0
Number of qualitative applications reviewed	7

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	8.00
Favourable Opinion with Additional Conditions	2	8.00
No Opinion transfer to full committee for review	1	4.00
Provisional Opinion	17	68.00
Unfavourable Opinion	3	12.00
Total	25	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	46
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	4.17%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	24
Number of completed proportionate review applications for ethical review over 21 days	7
Number of completed proportionate review applications over 21 days as a % of total	29.16%
Number of SSAs (non-Phase 1) reviewed	5
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	103
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.94%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	6.80%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	50.00%
Number of non substantial amendments received	90
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	19
Number of annual progress reports received	57
Number of safety reports received	28
Number of Serious Adverse Events received	0

Number of final reports received	17
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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/0175	EDITION JUNIOR	36
16/EE/0219	Phase 1b study, JNJ-64052781 with Ibrutinib in B-Cell Malignancies	24
16/EE/0223	LPS14584 - Toujeo vs Tresiba in T2DM	23
16/EE/0235	1199.36 Nintedanib + Sildenafil in advanced IPF	35
16/EE/0259	The EPIC-Norfolk Fifth Health Check (5HC)	34
16/EE/0260	Intermediate phenotypes of impulsivity and compulsivity	41
16/EE/0286	Closed Loop from Onset in Type 1 Diabetes (CLOuD)	24
16/EE/0289	Native tissue repair with surgical pelvic organ pessary - an RCT	23
16/EE/0296	Molecular Imaging Methods in Primary Sjögren's Syndrome	31
16/EE/0346	Optimizing new MR sequences in patients	29
16/EE/0360	Examining predictors of self harm ideation in prisoners	38
16/EE/0421	ATHENA Study	32
16/EE/0436	Glycoprotein VI Receptor in Atrial Fibrillation and Thromboembolism	27
16/EE/0444	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	27
16/EE/0446	Niraparib in men with mCRPC and DNA-repair anomalies	43
16/EE/0453	Phase I Study to Evaluate the Pharmacokinetics of Roxadustat	30
16/EE/0459	VAMP Healthy Volunteer Panel	38
16/EE/0473	Novel ET tubes in Human volunteers	25
16/EE/0490	Mediterranean diet web site	34
16/EE/0494	ReoGlio	22
16/EE/0545	Gastrectomy, eating behaviour and GLP-1	22
16/EE/0546	Barrett's oESophagus Trial 3 (BEST3)	24
16/EE/0550	TICSI version 0.6	26
16/EE/0552	Safety, tolerability, PK & efficacy of LMB763 in patients with NASH	23
17/EE/0008	SNP-based Microdeletion and Aneuploidy RegisTry (SMART)	31
17/EE/0017	Promixin in patients with non-cystic fibrosis bronchiectasis	22
17/EE/0021	Phase I study:MK1454+/-Pembrolizumab-Advanced Solid Tumors/Lymphomas	28
17/EE/0029	BrainCool-Migraine	40
17/EE/0074	Lorlatinib (PF-06463922) Open Label Lung Cancer Study	18
17/EE/0081	PanCO	18
17/EE/0115	A study of FDL169 in subjects with Cystic Fibrosis	32
17/EE/0119	Clinical Records Management System for inflammatory arthritis	26

17/EE/0121	Safety and Tolerability of AZD9898 in Healthy Volunteers & Asthmatics	39
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Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/EE/0234	SSG XXII	30
16/EE/0256	Effect of high intensity exercise on metabolism and insulin response	36
16/EE/0408	Biopsy of Uterine Fibroids of Uncertain Malignant potential	31
17/EE/0026	Clinical Study of an Investigational Intraocular Lens	27
17/EE/0078	PKU Synergy Evaluation	22
17/EE/0082	Studies of mothers with postnatal depression	24

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
16/EE/0334	Research Tissue Bank for MedImmune	22

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/EE/0298	Shearwave and Fibroscan elastography versus biopsy in hepatic fibrosis	20
17/EE/0077	SYNCHRO	15

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/EE/0218	Distinct Experiences in Epilepsy - Version 1	17

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

17/EE/0080	Armo's Randomised Trial Inducing Stimulated T cells	n/a
17/EE/0114	AZFD - Study of LY3314814 in Early Alzheimer's Disease Dementia	n/a
17/EE/0129	Quality of Life among Prostate Cancer Patients on Active Surveillance	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
16/EE/0287	DIALIVE in ACLF	29
16/EE/0547	Retention of Research Database by Partnerships in Care	22

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/0142	Designing lifestyle interventions: what matters for men?	16
16/EE/0198	Emergency Contraceptive Pills (ECP) in the era of 'Safe Sex'	19
16/EE/0199	Barriers and enablers to screening for AMR organisms in hospitals	24
16/EE/0200	COLlectioN Devices to reduce Urine ConTamination (CONDUCT)	28
16/EE/0280	Evaluation of maternal obesity service on pregnancy outcome version 1	21
16/EE/0282	Modulation of persistent inflammation in asthma by drug repositioning	20
16/EE/0381	Implementation, impact & costs of policies for safe staffing	15
16/EE/0382	How to implement NICE recommendations for birthplace in practice?	22
16/EE/0432	Is there a relationship between tinnitus severity and sleep effort?	15
16/EE/0439	Portraits of Pain	10
16/EE/0488	Cytokine guided Robotic Urological Surgery	8

17/EE/0006	Contextualising risk, reducing harm: A Realist Evaluation	23
17/EE/0007	ETNA DUS	25
17/EE/0052	Assessment of sleep on in-patient psychiatry wards	15

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0143	Exploration into the impact of group interventions in a cancer setting	25
16/EE/0283	Periodontal health in patients with acute myocardial infarction	25
16/EE/0438	A survey of mindfulness and self-compassion in IAPT (08.09.2016)	20

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
16/EE/0532	Should all gas transfer measurements be corrected for baseline CO?	12
16/EE/0544	Oral health knowledge, status and adherence post radiotherapy	12

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0253	Exploring retinal pathology using deep learning and eye imaging	11
17/EE/0050	Self Management among Adolescents with type 1 Diabetes in school, V1.0	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/EE/0144	Diagnostic accuracy of POC enzymatic test for NG tube placement.	9
16/EE/0535	The patient's understanding of their role after a heart attack: v1	14
16/EE/0540	Vascular Injury and repair in children with infection	15

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
04/Q0104/129/AM06	Anophthalmia-microphthalmia genetic research study	SA6	12/10/2016	12
08/H0304/19/AM02	Does acupuncture help nausea and vomiting in Palliative Care patients?	SA2	06/07/2016	6
09/H0304/8/AM15	PATENT-2: Long-Term Extension of PATENT-1 Trial	SA12	10/05/2016	9
09/H0304/9/AM12	CHEST-2: Long-Term Extension of CHEST-1 Trial	SA9	10/05/2016	9
10/H0304/64/AM05	Alemtuzumab for ANCA-Associated Refractory Vasculitis	SA6	13/05/2016	15
10/H0304/64/AM06	Alemtuzumab for ANCA-Associated Refractory Vasculitis	SA7	29/09/2016	4
10/H0304/65/AM06	Genes and Platelets version 1	SA2	30/11/2016	17
10/H0304/80/AM07	Molecular imaging of Barrett's oesophagus during endoscopy	SA2	11/10/2016	14
11/EE/0415/AM16	Vismodegib safety study in basal cell carcinoma v1	SA8	11/04/2016	8
11/H0304/3/AM06	The VARSITY Study	SA4	11/05/2016	22
12/EE/0071/AM06	2012-AAR-005 ALFApump vs standard care in ascites treatment V.01	SA4	15/03/2016	17
12/EE/0171/AM33	Belimumab in Idiopathic Membranous Glomerulonephropathy	5	22/06/2016	14
12/EE/0220/AM07	Brain function and treatment response	5	05/12/2016	28
12/EE/0363/AM20	Weight Loss Referrals for Adults in Primary Care (WRAP)	SA12	14/09/2016	13
12/EE/0493/AM03	Guy's & St Thomas' Research Biobanks	SA2	13/05/2016	19
12/EE/0493/AM04	Guy's & St Thomas' Research Biobanks	SA3	17/05/2016	20
13/EE/0331/AM02	Mechanisms of right ventricular adaptation to pressure overload v1	SA1	12/08/2016	21
13/EE/0364/AM09	A Phase 2 Study with Denosumab in Non-Small Cell Lung Cancer	SA4	29/07/2016	10
13/EE/0433/AM06	The Leadless Observational Study	SA4	06/11/2016	12
13/EE/0436/AM09	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	SA4	06/06/2016	27
13/EE/0436/AM11	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	SA6	22/11/2016	24
13/EE/0436/AM13	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	SA 16.02.2017	16/02/2017	19
14/EE/0018/AM03	Human vasodilatory response of GLP-1	SA1	12/08/2016	14

14/EE/0024/AM03	Real time tissue characterisation using mass spectrometry	SA3	10/11/2016	13
14/EE/0062/AM11	Laminate External Support Protocol, Rev 01	SA5	09/09/2016	11
14/EE/0101/AM07	High and low dose of IgPro20 for the maintenance treatment of CIDP	1	08/12/2015	20
14/EE/0130/AM01	Mucosal Cytokines and Chemokines in Vasculitis (MUCYVAS)	SA1	04/04/2016	23
14/EE/0192/AM01	NMES in Patients with Critical Limb Ischaemia	SA1	18/12/2015	26
14/EE/1045/AM02	POSEIDON	Amendment 3 - protocol version	14/06/2016	25
14/EE/1057/AM07	DILfrequency	4	23/06/2016	17
14/EE/1193/AM03	AIRFLOW-1	SA3	20/05/2016	28
14/EE/1193/AM04	AIRFLOW-1	SA4	07/07/2016	32
14/EE/1193/AM07	AIRFLOW-1	SA5		12
14/EE/1200/AM14	MK3475 vs standard treatment in subjects with head and neck cancer	SA10	07/04/2016	20
14/EE/1200/AM15	MK3475 vs standard treatment in subjects with head and neck cancer	SA12	18/11/2016	7
14/EE/1256/AM01	Research Tissue Bank of Synovial Tissue, Synovial Fluid and Blood	Substantial Amendment 01	29/02/2016	28
14/EE/1270/AM01	Archival nervous system tissue and blood collection	SA1	09/11/2016	20
15/EE/0061/AM01	SERVED-Memory; version 2.0	SA1	04/05/2016	9
15/EE/0064/AM03	Community Mental Health Survey 2015	SA2	24/11/2016	19
15/EE/0119/AM01	Influence of chronobiology on Hepatitis B vaccine responses	SA1	03/06/2016	26
15/EE/0218/AM04	SMS - Study of Somatic Mutations using Genome Sequencing	SA3	31/05/2016	33
15/EE/0226/AM01	Oesophageal Squamous cell CARcinoma (OSCAR) study	AM2	07/12/2016	15
15/EE/0324/AM01	Home testing of day and night closed loop with pump suspend feature	SA1	06/06/2016	28
15/EE/0324/AM04	Home testing of day and night closed loop with pump suspend feature	2	10/03/2017	17
15/EE/0335/AM02	COMPARE: a study of haemoglobin testing methods	SA2	06/05/2016	16
15/EE/0335/AM03	COMPARE: a study of haemoglobin testing methods	SA2	15/08/2016	8
15/EE/0379/AM04	Measuring gut permeability in haemodialysis patients	SA3	25/04/2016	16
15/EE/0379/AM05	Measuring gut permeability in haemodialysis patients	SA4	29/10/2016	23
15/EE/0385/AM04	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	2 (updates to IB)	14/03/2016	17
15/EE/0385/AM09	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	SA3	07/06/2016	27
15/EE/0385/AM10	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	SA4	22/07/2016	10
15/EE/0385/AM13	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	SA7	19/12/2016	10

15/EE/0385/AM14	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	7	03/03/2017	13
15/EE/0418/AM03	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	SA03	15/04/2016	26
15/EE/0418/AM04	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	SA4	15/07/2016	12
15/EE/0418/AM05	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	SA5	26/08/2016	11
15/EE/0418/AM06	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	6	28/11/2016	21
15/EE/0419/AM04	Integrated Care Research Study	SA1	22/08/2016	16
15/EE/0421/AM03	MUKSeven	26/04/2016	26/04/2016	27
15/EE/0446/AM02	Phase 3 extension study in patients with lung infections (INS-312).	SA2	10/05/2016	9
15/EE/0446/AM04	Phase 3 extension study in patients with lung infections (INS-312).	SA3	22/09/2016	11
15/EE/0446/AM05	Phase 3 extension study in patients with lung infections (INS-312).	SA4	06/01/2017	25
15/EE/0468/AM02	Response Evaluation of Cancer Therapeutics in Metastatic Breast Cancer	SA1	03/02/2017	26
16/EE/0015/AM01	OAsIs	1	14/06/2016	25
16/EE/0016/AM02	A study to test the safety and efficacy of GSK2269557 in APDS patients	SA1	13/12/2016	16
16/EE/0017/AM01	Cambridge Case:Control Cytosponge II Study	SA1	06/04/2016	18
16/EE/0017/AM02	Cambridge Case:Control Cytosponge II Study	SA2	20/04/2016	21
16/EE/0017/AM03	Cambridge Case:Control Cytosponge II Study	SA3	31/08/2016	9
16/EE/0017/AM04	Cambridge Case:Control Cytosponge II Study	SA4	31/08/2016	9
16/EE/0030/AM01	iQuit in Practice	SA1	21/04/2016	13
16/EE/0030/AM02	iQuit in Practice	SA2	06/01/2017	26
16/EE/0036/AM02	Video Information versus Approved Leaflets for Flexible Cystoscopy	SA1	09/05/2016	9
16/EE/0048/AM03	KFL3502 (Version 1 (protocol version 1, 28 Sep 2015))	SA3	01/02/2017	19
16/EE/0065/AM03	Cholecalciferol in Patients on Dialysis - SIMPLIFIED	SA3	23/10/2016	22
16/EE/0068/AM01	Influence of tranexamic acid on blood loss in total joint replacement	SA1	04/07/2016	19
16/EE/0068/AM02	Influence of tranexamic acid on blood loss in total joint replacement	Urgent Safety Measure	09/02/2017	45

16/EE/0105/AM01	ZOL-A trial	SA1	14/09/2016	8
16/EE/0105/AM02	ZOL-A trial	SA2	25/01/2017	22
16/EE/0114/AM02	Evaluating thromboelastography (TEG) and ETP in sickle adults	SA1	16/05/2016	17
16/EE/0175/AM01	EDITION JUNIOR	SA1	14/09/2016	6
16/EE/0175/AM02	EDITION JUNIOR	SA2	11/10/2016	17
16/EE/0200/AM02	COLlection Devices to reduce Urine ConTamination (CONDUCT)	SA1	09/01/2017	22
16/EE/0219/AM01	Phase 1b study, JNJ-64052781 with Ibrutinib in B-Cell Malignancies	SA1	21/07/2016	35
16/EE/0219/AM02	Phase 1b study, JNJ-64052781 with Ibrutinib in B-Cell Malignancies	SA2	02/09/2016	18
16/EE/0223/AM01	LPS14584 - Toujeo vs Tresiba in T2DM	SA1	05/07/2016	32
16/EE/0223/AM05	LPS14584 - Toujeo vs Tresiba in T2DM	SA3	05/12/2016	14
16/EE/0234/AM01	SSG XXII	SA1	17/08/2016	19
16/EE/0235/AM02	1199.36 Nintedanib + Sildenafil in advanced IPF	SA2	18/08/2016	19
16/EE/0235/AM03	1199.36 Nintedanib + Sildenafil in advanced IPF	SA3	12/09/2016	8
16/EE/0235/AM04	1199.36 Nintedanib + Sildenafil in advanced IPF	SA4	14/03/2017	12
16/EE/0260/AM01	Intermediate phenotypes of impulsivity and compulsivity	SA1	22/12/2016	19
16/EE/0286/AM02	Closed Loop from Onset in Type 1 Diabetes (CLOuD)	1	21/03/2017	6
16/EE/0296/AM01	Molecular Imaging Methods in Primary Sjögren's Syndrome	SA1	15/09/2016	12
16/EE/0438/AM01	A survey of mindfulness and self-compassion in IAPT (08.09.2016)	1	24/11/2016	25
16/EE/0444/AM01	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	SA1	23/12/2016	19
16/EE/0446/AM01	Niraparib in men with mCRPC and DNA-repair anomalies	SA 2	25/01/2017	26
16/EE/0546/AM01	Barrett's oESophagus Trial 3 (BEST3)	SA 1	16/02/2017	18
17/EE/0021/AM02	Phase I study:MK1454+/-Pembrolizumab-Advanced Solid Tumors/Lymphomas	SA2	15/03/2017	12

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/Q0104/2/AM04	CF Registry	SA2	24/01/2017	15
10/H0304/70/AM11	Amyloid imaging of late-life depression and mild cognitive impairment	7	26/09/2016	41

12/EE/0220/AM06	Brain function and treatment response	6	13/02/2017	18
15/EE/0226/AM02	Oesophageal Squamous cell CARcinoma (OSCAR) study	3	02/12/2016	30
15/EE/0385/AM11	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	SA5	02/11/2016	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
15/EE/0226/AM02/1	Oesophageal Squamous cell CARcinoma (OSCAR) study	Mod1 SA3	11/01/2017	15
15/EE/0385/AM11/1	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	SA6	02/12/2016	9

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

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
16/EE/0143	Exploration into the impact of group interventions in a cancer setting	25
16/EE/0199	Barriers and enablers to screening for AMR organisms in hospitals	24
16/EE/0200	COLlectionN Devices to reduce Urine ConTamination (CONDUCT)	28
16/EE/0283	Periodontal health in patients with acute myocardial infarction	25
16/EE/0382	How to implement NICE recommendations for birthplace in practice?	22
17/EE/0006	Contextualising risk, reducing harm: A Realist Evaluation	23
17/EE/0007	ETNA DUS	25

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0304/70/AM11	Amyloid imaging of late-life depression and mild cognitive impairment	7	26/09/2016	41
16/EE/0068/AM02	Influence of tranexamic acid on blood loss in total joint replacement	Urgent Safety Measure	09/02/2017	45

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/EE/0226/AM02/1	Oesophageal Squamous cell CARcinoma (OSCAR) study	Mod1 SA3	11/01/2017	15