

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

Annual Report

01 April 2017 - 31 March 2018



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 Alan Lamont
Vice-Chair:	Vacant Dr Derek Prater (from April 2017 for 6 months)
Alternate Vice-Chair:	Mrs Ann Colvill (from October 2017)
REC Manager:	Ms Rachel Nelson (to May 2017) Mr Tad Jones (from July 2017)
REC Assistant:	Mr Adam Garretty
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

As Chair of Cambridge East Research Ethics Committee I have been very pleased to welcome three new members over the past year, allowing resumption of Proportionate Review which had been temporarily suspended during the year to reduce workload. During that period, though the burden on members was higher than usual during the period of reduced complement, we have been successfully reaccredited, and have had some very positive feedback from researchers.

We appointed Ann Colvill as AVC, and look forward to Victoria Hollamby taking up the role of VC shortly.

The work of the REC continues to be interesting, stimulating and challenging, and we are particularly grateful to our Manager Tad Jones and his assistant Adam Garretty for their high quality support.

East of England - Cambridge East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Philip Bedford	Retired Study Responsible Scientist	Lay	02/02/2018	
Dr Helen Burns	Retired GP	Expert	05/12/2014	
Dr Alan Calverd	Scientific Consultant	Expert	01/03/2015	
Mrs Ann Colvill	Employment Tribunal Service	Lay	07/10/2015	
Mrs Victoria Hollamby	Assistant Research Governance Advisor	Lay Plus	01/04/2017	
Dr Alan Lamont	Retired Consultant Oncologist	Expert	03/01/2017	
Mr Trevor McCann	Retired Strategic Development Consultant	Lay	01/04/2017	
Miss Sophie Newton	Hearing Implant Research Nurse	Expert	01/02/2018	
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	
Dr Joyce Whittington	Psychologist	Expert	02/12/2014	
Miss Suzahn Wilson	Physiotherapist	Expert	10/02/2016	

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

Name	Profession	Status	Meeting date attended
Dr Niki Bannister	Retired Hospital Doctor	Expert	12/12/2017
Mr John Kirkpatrick	Statistician	Expert	16/01/2018
Ms Julie Lockhart	PPI Representative	Lay Plus	16/01/2018

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

Name	Declaration of Interest	Date
Dr Philip Bedford	None declared	07/02/2018
Dr Alan Calverd	Director, Radiation Consultancy Services Ltd; Director, Medical Physics Co-operative Ltd; Shareholder, Aimberry Ltd (MRI facilities- previously United Open MRI Ltd); Shareholder, Exhalation Technologies Ltd	04/01/2018
Mrs Ann Colvill	None declared	16/02/2018
Mrs Victoria Hollamby	Employed by Research Governance Office, School of Clinical Medicine, University of Cambridge	05/01/2018
Dr Alan Lamont	None declared	20/02/2018
Mr Trevor McCann	Shares in GSK. GSK company pension	20/02/2018
Miss Sophie Newton	Responsible for ethics and research framework within ENT department of Addenbrookes. Current investigator on ENT research studies. Also advise colleagues as part of role as NIHR GCP facilitator and PI masterclass facilitator.	19/02/2018
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	04/01/2018
Dr Wendi Qian	Statistician at Cambridge Clinical trials unit. Member of NIHR PFPB committee	20/02/2018
Dr Jessica Santos	Global Compliance and Quality Director, Kantar Health; Co-chair of ISPOR Ethics Committee; Shareholding, GSK.	04/01/2018
Dr Joyce Whittington	Shares in Astra-Zeneca & GSK	16/02/2018

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

Month	Date	Number of Members Present at Meeting
May	16/05/2017	10
July	18/07/2017	9
September	19/09/2017	8
October	17/10/2017	9
November	21/11/2017	9
December	12/12/2017	8
January	16/01/2018	8
February	20/02/2018	12
March	20/03/2018	9

9 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
January	05/01/2018	3
February	05/02/2018	3

2 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	04/04/2017	2
April	24/04/2017	2
May	02/05/2017	2
May	30/05/2017	2
June	07/06/2017	2
June	13/06/2017	2
June	29/06/2017	2
July	11/07/2017	2
July	25/07/2017	2
August	08/08/2017	2
September	05/09/2017	2
September	26/09/2017	2
October	17/10/2017	2
October	31/10/2017	2
November	28/11/2017	2
December	19/12/2017	2
January	09/01/2018	2
January	23/01/2018	2
February	06/02/2018	2
March	06/03/2018	2

March	21/03/2018	2
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21 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
Dr Philip Bedford	2
Dr Helen Burns	6
Dr Alan Calverd	7
Mrs Ann Colvill	7
Mrs Victoria Hollamby	8
Dr Alan Lamont	9
Mr Trevor McCann	7
Miss Sophie Newton	2
Dr Derek Prater	9
Dr Wendi Qian	5
Dr Jessica Santos	7
Dr Joyce Whittington	8
Miss Suzahn Wilson	2

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

Name	Number of Meetings Attended
Mrs Victoria Hollamby	1
Dr Alan Lamont	2
Dr Wendi Qian	1
Dr Jessica Santos	1
Dr Joyce Whittington	1

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

Name	Number of Meetings Attended
Dr Helen Burns	4
Dr Alan Calverd	2
Mrs Ann Colvill	2
Mrs Victoria Hollamby	1
Dr Alan Lamont	21
Dr Derek Prater	2
Dr Wendi Qian	2
Dr Jessica Santos	4
Dr Joyce Whittington	3
Miss Suzahn Wilson	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Philip Bedford	11/02/2018	Induction for new Research Ethics Service Committee members
Dr Philip Bedford	19/02/2018	Equality Diversity & Human Rights
Dr Philip Bedford	26/02/2018	Reviewing the Research Design of Clinical Trials
Dr Philip Bedford	05/03/2018	Research Involving Human Tissue
Dr Philip Bedford	05/03/2018	Ionising radiation
Dr Helen Burns	29/09/2017	Members Regional Training Day
Dr Alan Calverd	12/07/2017	Comments on Room temperature effects
Dr Alan Calverd	18/07/2017	Comments on Fast Field Cycling MRI
Dr Alan Calverd	02/09/2017	Comments on Radiation risk
Dr Alan Calverd	29/09/2017	Regional Training day
Mrs Ann Colvill	04/05/2017	Buddy / Mentor
Mrs Ann Colvill	01/06/2017	Prison Training
Mrs Victoria Hollamby	03/05/2017	Devices and in vitro diagnostic medical device (IVD) workshop
Mrs Victoria Hollamby	16/11/2017	Members induction
Dr Alan Lamont	01/06/2017	Prison Training
Dr Alan Lamont	29/09/2017	Members Regional Training Day
Dr Alan Lamont	17/01/2018	Equality Diversity and Human rights
Dr Alan Lamont	22/01/2018	Informed consent in paediatric research
Dr Alan Lamont	22/01/2018	Informed consent with ALC
Dr Alan Lamont	23/01/2018	GCP (secondary care)
Dr Alan Lamont	25/01/2018	GCP (primary care)
Dr Alan Lamont	22/05/2017	Chairs' Meeting – East of England
Dr Alan Lamont	02/11/2017	Chairs' Meeting – East of England
Mr Trevor McCann	23/05/2017	Online Induction
Mr Trevor McCann	29/09/2017	Members Regional Training Day
Mr Trevor McCann	16/11/2017	Members induction
Mr Trevor McCann	17/01/2018	Equality and Diversity
Miss Sophie Newton	22/02/2018	Equality Diversity and Human Rights
Miss Sophie Newton	22/02/2018	Induction for new Research Ethics Service Committee members
Dr Derek Prater	11/04/2017	EU Data Privacy in 2017: What you need to know
Dr Derek Prater	01/06/2017	Prison Training
Dr Derek Prater	14/07/2017	Research involving participants lacking mental capacity

Dr Derek Prater	14/07/2017	Medical Devices
Dr Derek Prater	01/08/2017	HTA
Dr Derek Prater	29/09/2017	Members Regional Training Day
Dr Derek Prater	16/10/2017	Research involving exposure to ionising radiation
Dr Derek Prater	30/11/2017	Genetic and Genomic Research
Dr Derek Prater	23/12/2017	Confidentiality and Information Governance Considerations in Research
Dr Wendi Qian	07/05/2017	International Clinical Trials Methodology Conference
Dr Wendi Qian	29/09/2017	Members Regional Training Day
Dr Jessica Santos	01/06/2017	Prison Training
Dr Jessica Santos	12/09/2017	Genetic and Genomic Research
Dr Jessica Santos	12/12/2017	National members training day
Dr Jessica Santos	28/02/2018	Ethical Issues in Phase One Research
Dr Joyce Whittington	05/10/2017	Phase 1 Research
Dr Joyce Whittington	18/01/2018	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Joyce Whittington	23/01/2018	Complex cases
Miss Suzahn Wilson	25/07/2017	Training - 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	10	23.81
Phase 1	3	7.14
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	3	7.14
Research Database (including renewals)	2	4.76
Others	24	57.14
Total Applications Reviewed	42	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	4
Number of paediatric applications reviewed	6
Number of device applications reviewed	5
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	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	5	11.90
Unfavourable Opinion	0	0.00
Provisional Opinion	37	88.10
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	42	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	33	78.57
Further Information Favourable Opinion with Additional Conditions	1	2.38
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	11.90
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.38
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	2	4.76
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	42	100

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

Total Applications Reviewed	5
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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	0
Number of student applications reviewed	2
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	100.00
Unfavourable Opinion	0	0.00
Total	5	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	4.67
Number of completed applications for full ethical review	42
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	27
Number of completed proportionate review applications for ethical review	5
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 21 days as a % of total	60.00%
Number of SSAs (non-Phase 1) reviewed	28
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	3.57%
Number of SSAs (Phase 1) reviewed	2
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	118
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.69%
Number of modified amendments reviewed	7
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	14.29%
Number of non substantial amendments received	84
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	29
Number of annual progress reports received	71
Number of safety reports received	28
Number of Serious Adverse Events received	0
Number of final reports received	14

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/0171	Safety and Efficacy Study in Infants With SBS	24
17/EE/0178	Genetics of Primary IGF-1 deficiency (PIGFD)	9
17/EE/0212	HE4 in primary care.	20
17/EE/0213	Image guided radiotherapy and adaptive brachytherapy for cervix cancer	40
17/EE/0278	Tomato study	37
17/EE/0297	MO39129: Prophylactic Emicizumab in Haemophilia A patients	8
17/EE/0300	Discovering FFC-MRI biomarkers of Alzheimer's disease	34
17/EE/0302	International 'Care Of the Dying Evaluation'	24
17/EE/0304	Environmental and metabolic determinants of binge-eating behaviour	28
17/EE/0364	West Midlands Combined Authority Health-led Trial	33
17/EE/0371	Sheffield City Region Health-led Trial	33
17/EE/0377	SSCART	33
17/EE/0385	Nitrite and Coronary Flow Study	25
17/EE/0394	COOL-AMI EU PIVOTAL TRIAL	27
17/EE/0410	The DDN Study	33
17/EE/0422	M16-098 - Upadacitinib in patients with Ankylosing Spondylitis.	21
17/EE/0429	Evaluation of Lumicitabine in young children hospitalised with RSV	27
17/EE/0454	Individual Placement and Support - Alcohol and Drugs Trial (IPS-AD)	35
17/EE/0472	BeAT-HF	46
17/EE/0474	AdAPT: Adenovirus after Allogeneic Paediatric Transplantation	22
17/EE/0484	5-HT imaging in depression: Version 1.0	26
17/EE/0486	GCSF for Friedreich Ataxia	30
17/EE/0497	EMA401 in reducing 24-hour average pain in PDN (EMPADINE)	33
17/EE/0503	TAU in OCD	31
17/EE/0505	INCLUDED: Improving NHS Care by Understanding and Embracing Diversity	27
18/EE/0007	PK and food effect study of new formulations of tacrolimus (QCL118062)	23
18/EE/0013	PK study of BOS172767 formulations in healthy subjects (QCL118174)	21
18/EE/0025	KHP Cancer Biobank	22
18/EE/0039	Imaging leukocyte accumulation in cancers	24
18/EE/0041	PAN Cancer Early Detection	29
18/EE/0045	Neutrophils in idiopathic pulmonary fibrosis	37
18/EE/0050	CONFIRM CONFIRMation of pathological complete response pre-operatively	27

18/EE/0094	Generation of patient-specific stem cells for research into stroke	37
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
18/EE/0001	I-CaPP Programme- Pilot Study-Exploring communication of disease risk	22

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/0354	Obesity Research Biobank Syndicate (ORBIS) - Version 1	21
17/EE/0369	HEAT	21
17/EE/0461	Use of Human Blood Samples in Leukocyte Functional Assays	21
18/EE/0024	Discover TLD	18
18/EE/0093	Urological Symptoms and Pathways to Diagnosis (USP)	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/0468	Long term study of Lumicitabine in young children after RSV infection	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
18/EE/0078	The role of immune cell subsets in cardiovascular disease	n/a
18/EE/0091	MICROBIOME	n/a

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

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
18/EE/0010	Novel segmentation technique of T1 mapping in Pulmonary Hypertension	29
18/EE/0011	Parent/carer Intended Non-Adherence to their Child's Medication Regime	26
18/EE/0048	Bronchoscopic samples for BREATH COPD program	17
18/EE/0049	GENIE Emergency Department Study version 1	20

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
18/EE/0012	Anti-embolism stockings in acute care	28

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

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
06/Q0104/57/AM49	BOXIT - Bladder COX-2 Inhibition Trial	21	08/06/2017	23
10/H0304/64/AM07	Alemtuzumab for ANCA-Associated Refractory Vasculitis	8	31/05/2017	30
10/H0304/66/AM07	Inherited platelet conditions version 1	5	24/03/2017	26
12/EE/0220/AM08	Brain function and treatment response	7	26/07/2017	29
13/EE/0157/AM02	The Centre for Attention, Learning and Memory (CALM)	2	15/12/2017	35
13/EE/0364/AM10	A Phase 2 Study with Denosumab in Non-Small Cell Lung Cancer	5	29/06/2017	22
13/EE/0433/AM07	The Leadless Observational Study	5	07/06/2017	35
13/EE/0433/AM08	The Leadless Observational Study	6	28/11/2017	34
13/EE/0436/AM14	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	5	06/04/2017	29
13/EE/0436/AM15	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	6	10/07/2017	16
13/EE/0436/AM16	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	ICF update 2 for Investigator	27/11/2017	22
14/EE/0018/AM04	Human vasodilatory response of GLP-1	4	20/11/2017	28
14/EE/0024/AM04	Real time tissue characterisation using mass spectrometry	4.0	12/05/2017	28
14/EE/0024/AM05	Real time tissue characterisation using mass spectrometry	5	11/12/2017	32
14/EE/0122/AM04	The Fenland Study - Phase 2	4	20/04/2017	19
14/EE/0122/AM05	The Fenland Study - Phase 2	5	01/11/2017	31
14/EE/0146/AM03	PRICKLE	3.0 protocol V4.0	24/05/2017	33
14/EE/1036/AM01	Digital Speech Recovery from Articulator Movement (DiSArM). Version 1	1	11/01/2017	26
14/EE/1057/AM09	DILfrequency	5	25/10/2017	32
14/EE/1057/AM10	DILfrequency	6	15/12/2017	20
14/EE/1193/AM09	AIRFLOW-1	6	05/10/2017	13
14/EE/1200/AM19	MK3475 vs standard treatment in subjects with head and neck cancer	14	07/04/2017	17
14/EE/1200/AM21	MK3475 vs standard treatment in subjects with head and neck cancer	16	10/10/2017	20
14/EE/1200/AM23	MK3475 vs standard treatment in subjects with head and neck	17	01/03/2018	32

	cancer			
14/EE/1257/AM01	Extracorporeal Shockwave therapy for intermittent claudication 1.0	1	20/07/2017	23
15/EE/0017/AM02	Long Bone Diaphyseal Adaptation to Lifetime Loading v.1	1	09/03/2017	27
15/EE/0064/AM04	Community Mental Health Survey 2015	3	05/12/2017	14
15/EE/0153/AM02	PET CT analysis of restenosis after lower limb revascularisation	1	21/06/2017	6
15/EE/0218/AM05	SMS - Study of Somatic Mutations using Genome Sequencing	4	17/03/2017	15
15/EE/0218/AM06	SMS - Study of Somatic Mutations using Genome Sequencing	5	29/06/2017	21
15/EE/0218/AM07	SMS - Study of Somatic Mutations using Genome Sequencing	6	03/11/2017	19
15/EE/0226/AM03	Oesophageal Squamous cell CARcinoma (OSCAR) study	4	01/11/2017	20
15/EE/0373/AM02	Cognitive and neural effects of methylphenidate in children with ADHD	1	09/11/2017	17
15/EE/0385/AM15	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	8	22/05/2017	34
15/EE/0385/AM17	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	11	01/09/2017	6
15/EE/0385/AM18	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	11	20/10/2017	20
15/EE/0385/AM19	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	D419AC00003	12/12/2017	27
15/EE/0385/AM20	Medi4736 and Tremelimumab in Non Small Cell Lung Cancer	Protocol v7	12/03/2018	22
15/EE/0418/AM07	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	7	24/04/2017	22
15/EE/0418/AM10	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	9	22/12/2017	25
15/EE/0421/AM11	MUKSeven	HM15/336/2017121 1	11/12/2017	29
15/EE/0446/AM06	Phase 3 extension study in patients with lung infections (INS-312).	5	02/06/2017	28
15/EE/0446/AM07	Phase 3 extension study in patients with lung infections (INS-312).	6	14/07/2017	10
15/EE/0468/AM03	Response Evaluation of Cancer Therapeutics in Metastatic Breast Cancer	2	31/08/2017	28
16/EE/0015/AM02	OAsIs	2	03/04/2017	26
16/EE/0016/AM06	A study to test the safety and efficacy of GSK2269557 in APDS patients	3	24/10/2017	21
16/EE/0030/AM03	iQuit in Practice	3	22/01/2018	34
16/EE/0048/AM04	KFL3502 (Version 1 (protocol version 1, 28 Sep 2015))	4	11/05/2017	27

16/EE/0065/AM06	Cholecalciferol in Patients on Dialysis - SIMPLIFIED	6	05/04/2017	19
16/EE/0065/AM16	Cholecalciferol in Patients on Dialysis - SIMPLIFIED	14	19/07/2017	19
16/EE/0065/AM20	Cholecalciferol in Patients on Dialysis - SIMPLIFIED	18	03/10/2017	22
16/EE/0068/AM03	Influence of tranexamic acid on blood loss in total joint replacement	3	03/02/2017	20
16/EE/0068/AM04	Influence of tranexamic acid on blood loss in total joint replacement	4	03/02/2017	27
16/EE/0105/AM03	ZOL-A trial	SA3	26/04/2017	39
16/EE/0105/AM04	ZOL-A trial	4	02/08/2017	36
16/EE/0110/AM01	SPECTRE	1	23/05/2017	32
16/EE/0110/AM02	SPECTRE	2	06/02/2018	29
16/EE/0175/AM04	EDITION JUNIOR	3	05/06/2017	22
16/EE/0234/AM05	SSG XXII	3	30/10/2017	20
16/EE/0235/AM05	1199.36 Nintedanib + Sildenafil in advanced IPF	SA 5	12/05/2017	24
16/EE/0259/AM02	The EPIC-Norfolk Fifth Health Check (5HC)	1	27/03/2017	10
16/EE/0260/AM03	Intermediate phenotypes of impulsivity and compulsivity	2	26/05/2017	27
16/EE/0260/AM04	Intermediate phenotypes of impulsivity and compulsivity	3	11/07/2017	34
16/EE/0283/AM01	Periodontal health in patients with acute myocardial infarction	1	12/10/2017	12
16/EE/0283/AM03	Periodontal health in patients with acute myocardial infarction	2	17/01/2018	27
16/EE/0286/AM03	Closed Loop from Onset in Type 1 Diabetes (CLOuD)	SA2	20/06/2017	15
16/EE/0286/AM04	Closed Loop from Onset in Type 1 Diabetes (CLOuD)	3	27/02/2018	24
16/EE/0346/AM01	Optimizing new MR sequences in patients	1	04/12/2017	21
16/EE/0421/AM02	ATHENA Study	2	11/07/2017	16
16/EE/0444/AM03	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	Protocol Amendment 3.0	22/03/2017	35
16/EE/0444/AM05	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	3.0	10/08/2017	24
16/EE/0444/AM06	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	3.0	25/09/2017	7
16/EE/0446/AM03	Niraparib in men with mCRPC and DNA-repair anomalies	15.05.2017	15/05/2017	12
16/EE/0446/AM04	Niraparib in men with mCRPC and DNA-repair anomalies	Protocol Amendment 3	07/11/2017	30
16/EE/0446/AM05	Niraparib in men with mCRPC and DNA-repair anomalies	4	22/01/2018	29
16/EE/0453/AM01	Phase I Study to Evaluate the Pharmacokinetics of Roxadustat	1	06/04/2017	18
16/EE/0473/AM01	Novel ET tubes in Human volunteers	1.0	25/07/2017	26
16/EE/0494/AM01	ReoGlio		20/07/2017	7

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16/EE/0494/AM02	ReoGlio	C016/150/Docs/20 171130	30/11/2017	14
16/EE/0546/AM02	Barrett's oESophagus Trial 3 (BEST3)	3	03/04/2017	14
16/EE/0546/AM03	Barrett's oESophagus Trial 3 (BEST3)	2	31/03/2017	14
16/EE/0546/AM04	Barrett's oESophagus Trial 3 (BEST3)	SA4	14/06/2017	28
16/EE/0546/AM05	Barrett's oESophagus Trial 3 (BEST3)	5	03/08/2017	15
16/EE/0546/AM07	Barrett's oESophagus Trial 3 (BEST3)	6	07/02/2018	20
16/EE/0550/AM04	TICSI version 0.6	0.8	11/01/2017	14
16/EE/0552/AM03	Safety, tolerability, PK & efficacy of LMB763 in patients with NASH	3	05/07/2017	16
16/EE/0552/AM04	Safety, tolerability, PK & efficacy of LMB763 in patients with NASH	4	15/12/2017	32
16/EE/0552/AM06	Safety, tolerability, PK & efficacy of LMB763 in patients with NASH	5	09/03/2018	25
17/EE/0007/AM02	ETNA DUS	1	01/06/2017	28
17/EE/0021/AM04	Phase I study:MK1454+/-Pembrolizumab-Advanced Solid Tumors/Lymphomas	4	12/10/2017	25
17/EE/0026/AM01	Clinical Study of an Investigational Intraocular Lens	1	07/08/2017	21
17/EE/0026/AM02	Clinical Study of an Investigational Intraocular Lens	2	23/11/2017	26
17/EE/0029/AM01	BrainCool-Migraine	1	05/05/2017	17
17/EE/0050/AM01	Self Management among Adolescents with type 1 Diabetes in school, V1.0	1	18/07/2017	17
17/EE/0074/AM03	Lorlatinib (PF-06463922) Open Label Lung Cancer Study	2	25/05/2017	25
17/EE/0074/AM08	Lorlatinib (PF-06463922) Open Label Lung Cancer Study	4	25/01/2018	28
17/EE/0080/AM05	Armo's Randomised Trial Inducing Stimulated T cells	Protocol Amendment 1.1	18/08/2017	15
17/EE/0080/AM06	Armo's Randomised Trial Inducing Stimulated T cells	3	29/11/2017	19
17/EE/0080/AM07	Armo's Randomised Trial Inducing Stimulated T cells	4	19/01/2018	30
17/EE/0081/AM03	PanCO	2	16/08/2017	35
17/EE/0082/AM01	Studies of mothers with postnatal depression	1	05/12/2017	28
17/EE/0114/AM01	AZFD - Study of LY3314814 in Early Alzheimer's Disease Dementia	14/08/2017	08/08/2017	22
17/EE/0114/AM02	AZFD - Study of LY3314814 in Early Alzheimer's Disease	16/11/2016	18/10/2017	25

	Dementia			
17/EE/0115/AM01	A study of FDL169 in subjects with Cystic Fibrosis	SA-01-EC-(Prot Amd5 GBR amd#4)	10/10/2017	18
17/EE/0115/AM02	A study of FDL169 in subjects with Cystic Fibrosis	SA-03-CA/SA-02	30/01/2018	28
17/EE/0297/AM01	MO39129: Prophylactic Efficacy of Emicizumab in Haemophilia A patients	1	10/01/2018	21
17/EE/0364/AM01	West Midlands Combined Authority Health-led Trial	1	13/02/2018	19
17/EE/0371/AM01	Sheffield City Region Health-led Trial	1	13/02/2018	7
17/EE/0371/AM02	Sheffield City Region Health-led Trial	2	28/02/2018	7
17/EE/0377/AM04	SSCART	3	20/02/2018	27
17/EE/0461/AM01	Use of Human Blood Samples in Leukocyte Functional Assays	1.1	07/12/2017	27
18/EE/0013/AM01	PK study of BOS172767 formulations in healthy subjects (QCL118174)	1	09/02/2018	27

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q0104/133/AM14	Genetics of endocrine tumours	13	12/04/2017	15
08/H0304/56+5/AM06	Papworth Hospital Research Tissue Bank (PHRTB) - Renewal	1	23/10/2017	35
08/h0304/85+5/AM03	Norwich Biorepository (formerly the Partners in Cancer Research Human	3	01/12/2017	31
11/EE/0297/AM04	Isolation of blood-derived progenitor cells	2	08/08/2017	29
14/EE/0137/AM01	Pre-transplant normothermic liver perfusion	1	19/10/2017	30
16/EE/0444/AM04	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	2017/04/13	13/04/2017	24

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline				
Amendment REC	Title	Version	Date	Number of Days on

Reference				Clock
06/Q0104/133/AM14/1	Genetics of endocrine tumours	Amended Version V13	26/01/2018	9
08/h0304/85+5/AM03/1	Norwich Biorepository (formerly the Partners in Cancer Research Human	3	01/12/2017	1
10/H0304/70/AM11/1	Amyloid imaging of late-life depression and mild cognitive impairment	7	09/01/2018	5
11/EE/0297/AM04/1	Isolation of blood-derived progenitor cells	4	16/10/2017	15
12/EE/0220/AM06/1	Brain function and treatment response	Modified SA6	01/04/2017	7
14/EE/0137/AM01/1	Pre-transplant normothermic liver perfusion	2	04/01/2018	8
16/EE/0444/AM04/1	ONO-4474-02 Study to evaluate the efficacy of ONO-4474 in patients	2017/05/16	16/05/2017	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 21 day timeline

REC Reference	Title	Number of Days on Clock
18/EE/0010	Novel segmentation technique of T1 mapping in Pulmonary Hypertension	29
18/EE/0011	Parent/carer Intended Non-Adherence to their Child's Medication Regime	26
18/EE/0012	Anti-embolism stockings in acute care	28

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/EE/0254	A Prospective, Randomized, Controlled, Multi-Center Clinical Study of the\nACRYSOF IQ Extended Depth of Focus (EDF) IOL	27

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
16/EE/0105/AM03	ZOL-A trial	SA3	26/04/2017	39
16/EE/0105/AM04	ZOL-A trial	4	02/08/2017	36

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/EE/0297/AM04/1	Isolation of blood-derived progenitor cells	4	16/10/2017	15