

**East of England - Cambridgeshire and  
Hertfordshire Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	East of England - Cambridgeshire and Hertfordshire Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase I in Healthy Volunteers Phase I in Patients
<b>Chair:</b>	Professor Barry Hunt
<b>Vice-Chair:</b>	Dr Ian Skidmore
<b>Alternate Vice-Chair:</b>	Mr David Grayson
<b>REC Manager:</b>	Miss Victoria Strutt Miss Georgia Copeland – up until March 2018.
<b>REC Assistant:</b>	Miss Daniella Sarno Miss Lindsey Wallace – up until March 2018
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 104 8106
<b>Email:</b>	<a href="mailto:nrescommittee.eastofengland-cambsandherts@nhs.net">nrescommittee.eastofengland-cambsandherts@nhs.net</a>

## Chair's overview of the past year:

From April 2017 through to March 2018 the work load level of the previous year was maintained with nearly two thirds of the applications being CTIMPs including 13% of the total number of studies that were Phase 1.

An additional five studies were reviewed for the Combined Ways of Working Pilot which would not have been captured in the data.

The committee has seen a growth in its membership with five new members joining during the reporting period. One member resigned from the committee. Of the new members two are experts, two lay plus and one lay. Overall the committee is developing a good breadth of expertise and as Chairman of the Committee I am extremely grateful for and impressed by the commitment of all members to the review process. This year we have been involved with the EU Clinical Trials pilot reviewing applications from a portfolio of documents and without a completed IRAS form. This provided the Committee with a new challenge and proved an interesting exercise and we were able to feed back to the HRA on the process.

In February the committee achieved full accreditation from the HRA audit meeting all of the QA standards. We were pleased to receive the congratulations and thanks from HRA officers. In achieving this result the Committee acknowledges the significant contribution from both the REC Manager and the REC Assistant and on behalf of the whole committee we thank them both for their hard work. Towards the end of the period our REC Manager and REC assistant were promoted and we wished them well in their new positions. We were pleased to welcome both the new REC manager and assistant to their first meeting and we look forward to working with them in the future. Committee meetings are now fully established at the Fielder Centre of the University of Hertfordshire and this provides an excellent venue with good facilities for receiving any applicants who attend to present at our meetings.

Sub-committees reviewed substantial amendments and applications for Proportionate Review. The input to these sub-committees of the Vice Chairman and Alternate Vice Chairman, the latter Chairs proportionate reviews, is acknowledged as an extremely important and demanding contribution. The recruitment of new members last year and early in this period is starting to ease the workload of the longer serving members.

## East of England - Cambridgeshire and Hertfordshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Michael John Adams	Retired Consultancy Director	Lay	03/05/2017	
Ms Eva Anthopoulou	Regulatory Sciences Associate	Expert	13/04/2017	
Miss Ruth Barker	Clinical Doctoral Research Fellow Facilitator	Expert	10/02/2016	
Mr Mauro Buraglio	Independent Consultant in Clinical Pharmacology and Clinical Development	Expert	19/12/2017	
Mrs Victoria Jane Clough	Volunteer for the Riding for the Disabled Association	Lay Plus	26/10/2017	
Mr David Grayson	Retired Local Government Administrator	Lay Plus	01/04/2013	
Mrs Kornelia Hathaway	Previous Education & Training Manager	Expert	04/03/2015	
Professor Barry Hunt	Pro-Vice Chancellor (International) (Retired)	Expert	01/02/2013	
Professor Diana Kornbrot	Statistician	Expert	01/09/2016	
Reverend Keith Lackenby	Reverend	Lay Plus	23/03/2018	
Mr Peter Neville	Retired European Patent Attorney	Lay Plus	23/02/2015	31/03/2018
Dr David Rawlins	Retired Pharmaceutical Consultant	Lay	09/08/2016	
Dr Ian Skidmore	Retired Company Director	Lay Plus	01/04/2013	
Ms Helen Street	MPhil Candidate	Lay	27/04/2015	
Dr Melanie Whittick	Pharmacist	Expert	01/04/2013	

## East of England - Cambridgeshire and Hertfordshire Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Professor Ramesh Kapadia	Retired Education Consultant	Lay Plus	12/04/2017
Ms Julie Lockhart	PPI Representative	Lay Plus	12/04/2017 13/09/2017

**East of England - Cambridgeshire and Hertfordshire Research Ethics Committee:  
Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Michael John Adams	Shareholder in GSK. Shareholder in Conva Tec Ltd. Receive pension payments from GSK	26/03/2018
Ms Eva Anthopoulou	Regulatory Sciences Associate at Southwood Research Clinical Projects Assistant - GW Pharmaceuticals (current position) Previously Research Technician at Hammersmith Medicines Research	08/01/2018
Miss Ruth Barker	Clinical Researcher at Royal Brompton and Harefield NHS FT. From April 2018, Imperial College as a Clinical Research Fellow.	20/02/2018
Mrs Victoria Jane Clough	Stroke Association Volunteer Trustee and Secretary of Rosmarinus Charitable Trust	05/01/2018
Mr David Grayson	None declared	12/01/2018
Mrs Kornelia Hathaway	Has shares in GSK	24/11/2017
Professor Barry Hunt	Trustee of and scientific advisor to Ataxia UK. Chair of University of Hertfordshire Ethics Committee	01/03/2018
Dr David Rawlins	Small, direct shareholdings in GSK, Astra Zeneca, Reneuron and Allergy Therapeutics. Indirect shareholdings via funds/investment trusts	08/01/2018
Dr Ian Skidmore	Shares in GSK	21/03/2018
Ms Helen Street	Completing an MPWI by research at the University of Cambridge investigating the Research Governance of Dementia Studies. My membership of the REC is independent of the research.	04/01/2018
Mr Mauro Buraglio	Self-employed consultant. Hold shares in GSK. Peer reviewer for British Journal Clinical Pharmacology.	06/02/2018
Reverend Keith Lackenby	None declared	26/03/2018
Professor Diana Kornbrot	UK Research Councils, Leverhulme Peer Review	07/03/2018

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

Month	Date	Number of Members Present at Meeting
April	12/04/2017	8
May	10/05/2017	8
June	14/06/2017	9
July	12/07/2017	9
August	09/08/2017	9
September	13/09/2017	8
November	08/11/2017	10
December	13/12/2017	11
February	14/02/2018	10
March	14/03/2018	11

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	20/04/2017	3
May	18/05/2017	3
June	22/06/2017	3
July	20/07/2017	3
August	17/08/2017	3
September	21/09/2017	3
October	19/10/2017	3
November	16/11/2017	3
December	21/12/2017	3
February	22/02/2018	3
March	22/03/2018	3

11 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	11/04/2017	2
April	25/04/2017	2
May	09/05/2017	2
May	23/05/2017	2
June	06/06/2017	3
June	20/06/2017	2
July	04/07/2017	2
July	18/07/2017	2
July	21/07/2017	2
August	01/08/2017	2

August	15/08/2017	2
August	29/08/2017	2
September	12/09/2017	2
September	26/09/2017	2
September	29/09/2017	2
October	10/10/2017	2
October	27/10/2017	2
November	07/11/2017	2
November	21/11/2017	2
December	05/12/2017	2
December	19/12/2017	2
January	05/01/2018	2
January	16/01/2018	2
January	30/01/2018	2
February	13/02/2018	2
February	27/02/2018	2
March	12/03/2018	2
March	13/03/2018	2
March	27/03/2018	2
March	30/03/2018	2

30 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**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Michael John Adams	7
Ms Eva Anthopoulou	7
Miss Ruth Barker	6
Mr Mauro Buraglio	2
Mrs Victoria Jane Clough	3
Mr David Grayson	7
Mrs Kornelia Hathaway	7
Professor Barry Hunt	9
Professor Diana Kornbrot	8
Mr Peter Neville	5
Dr David Rawlins	9
Dr Ian Skidmore	9
Ms Helen Street	3
Dr Melanie Whittick	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Michael John Adams	1
Ms Eva Anthopoulou	1
Miss Ruth Barker	1
Mr David Grayson	11
Mrs Kornelia Hathaway	3
Professor Barry Hunt	3
Professor Diana Kornbrot	2
Mr Peter Neville	3
Dr David Rawlins	1
Dr Ian Skidmore	4
Ms Helen Street	2
Dr Melanie Whittick	1

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



Name	Number of Meetings Attended
Ms Eva Anthopoulou	2
Miss Ruth Barker	5
Mr David Grayson	9
Mrs Kornelia Hathaway	4
Professor Barry Hunt	13
Professor Diana Kornbrot	7
Reverend Keith Lackenby	1
Mr Peter Neville	2
Dr David Rawlins	4
Dr Ian Skidmore	10
Ms Helen Street	2
Dr Melanie Whittick	2

**Training 01 April 2017 - 31 March 2018**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Michael John Adams	23/05/2017	Online Induction for new Research Ethics Service Committee Members
Mr Michael John Adams	21/09/2017	Training - Committee Members Induction
Mr Michael John Adams	20/11/2017	Equality Diversity and Human Rights
Ms Eva Anthopoulou	21/05/2017	Equality Diversity and Human Rights
Ms Eva Anthopoulou	21/05/2017	Online Induction for New Member
Ms Eva Anthopoulou	26/06/2017	Training for Commercial Studies
Ms Eva Anthopoulou	27/06/2017	Training for non-commercial studies
Ms Eva Anthopoulou	01/07/2017	Reviewing the Research Design of Clinical Trials
Ms Eva Anthopoulou	29/09/2017	Members Regional Training Day
Ms Eva Anthopoulou	12/12/2017	National Members Training Day
Miss Ruth Barker	24/04/2017	Tissue Governance
Miss Ruth Barker	05/07/2017	Good Clinical Practice
Miss Ruth Barker	17/08/2017	Information Governance
Miss Ruth Barker	11/10/2017	Mental Capacity Act and Deprivation of Liberty Safeguards
Mr Mauro Buraglio	28/02/2018	Ethical Issues in Phase One Research
Mr Mauro Buraglio	07/03/2018	Induction for new Research Ethics Service Committee members
Mr Mauro Buraglio	08/03/2018	Equality Diversity and Human Rights
Mrs Victoria Jane Clough	12/12/2017	Induction for new Research Ethics Service Committee members
Mrs Victoria Jane Clough	28/01/2018	Equality, Diversity and Human Rights
Mr David Grayson	19/05/2017	Buddy/Member for Mike Adams
Mr David Grayson	24/11/2017	Training - HRA National Chairs' Day and Policy Event
Mr David Grayson	20/11/2017	Chairs' Meeting: East of England
Mrs Kornelia Hathaway	29/09/2017	Members Regional Training Day
Mrs Kornelia Hathaway	07/02/2018	Introduction to Phase 1 Research - Trials & Regulation
Professor Diana Kornbrot	25/05/2017	MRC Good learning practice e-module
Dr David Rawlins	15/01/2018	Equality Diversity and Human Rights
Dr Ian Skidmore	22/01/2018	Detailed study of current EMA Guidance on Phase 1

Dr Ian Skidmore	22/01/2018	EU new Clinical Trials Regulations
Dr Ian Skidmore	22/01/2018	Read the Winkler paper J med ethics 2016. Research must benefit human subjects if it is to be permissible
Dr Ian Skidmore	22/01/2018	Read Ennis and Wykes. Br J Psych. 2016 Sense and readability
Dr Ian Skidmore	23/01/2018	Practical Ethics Blog - Please randomise me but don't tell my family.
Ms Helen Street	01/04/2017	Researching and co-authoring a paper looking at the regulation and ethical review of evaluation studies
Ms Helen Street	01/07/2017	Reading papers relating to the ethical issues associated with dementia studies for my MPhil research project
Ms Helen Street	18/01/2018	Equality and Diversity course reading
Dr Melanie Whittick	24/05/2017	Act as Buddy/Mentor for Eva Anthopoulou
Dr Melanie Whittick	29/09/2017	Members Regional Training Day
Professor Barry Hunt	20/11/2017	Chairs' Meeting: East of England

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	18	48.65
Phase 1	5	13.51
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.70
Research Database (including renewals)	1	2.70
Others	12	32.43
<b>Total Applications Reviewed</b>	<b>37</b>	<b>100</b>

**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	1
Number of student applications reviewed	5
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
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	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.70
Unfavourable Opinion	3	8.11
Provisional Opinion	32	86.49
Provisional Opinion Pending Consultation with Referee	1	2.70
<b>Total</b>	<b>37</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	25	67.57
Further Information Favourable Opinion with Additional Conditions	5	13.51
Further Information Unfavourable Opinion	1	2.70
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.70
Unfavourable Opinion	3	8.11
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.70
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.70
<b>Total</b>	<b>37</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>29</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	0
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	13
Number of paediatric applications reviewed	1
Number of device applications reviewed	2
Number of qualitative applications reviewed	3

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	6	20.69
Favourable Opinion with Additional Conditions	1	3.45
No Opinion transfer to full committee for review	2	6.90
Provisional Opinion	18	62.07
Unfavourable Opinion	2	6.90
<b>Total</b>	<b>29</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	3.70
<b>Number of completed applications for full ethical review</b>	36
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	40
<b>Number of completed proportionate review applications for ethical review</b>	27
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	3
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	11.11%
<b>Number of SSAs (non-Phase 1) reviewed</b>	19
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	5
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	126
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of modified amendments reviewed</b>	4
<b>Number of completed modified amendments over 14 days</b>	1
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	25.00%
<b>Number of non substantial amendments received</b>	108
<b>Number of substantial amendments received for information</b>	4
<b>Number of substantial amendments received for new sites/PIs</b>	10
<b>Number of annual progress reports received</b>	77
<b>Number of safety reports received</b>	37
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	23

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/EE/0107	Bioequivalence of Diabetes Drug Combinations in Healthy Volunteers	27
17/EE/0153	Social Information Processing in Offenders with ASD	27
17/EE/0160	Debio 1450-111 PK study in healthy volunteers	37
17/EE/0204	BCX7353 as a treatment for acute HAE attacks	31
17/EE/0209	Fluorescence targeted pelvic lymph node mapping	42
17/EE/0240	NAXIVA	36
17/EE/0255	A study to find out if orvepitant is safe to use and reduces coughing	33
17/EE/0264	Efficacy of Durvalumab/Tremelimumab with SoC chemo in metastatic NSCLC	43
17/EE/0291	Phase III trial-pembrolizumab or brentuximab vedotin-Hodgkin Lymphoma	44
17/EE/0295	Trans-cervical balloon catheter and prostaglandin for labour induction	43
17/EE/0317	Study of AZD4573 in Relapsed or Refractory Haematological Malignancies	39
17/EE/0329	Lending a helping hand to very preterm babies Version 1	41
17/EE/0341	Continuous 5-hour IV Infusions of BMS-986231 in Heart Failure Patients	40
17/EE/0355	Imatinib effects on lung vascular dysfunction by stimulation of injury	28
17/EE/0386	Nacubactam and Meropenem in patients with a complicated UTI.	53
17/EE/0387	The MASH Trial	41
17/EE/0389	MONOS	42
17/EE/0450	Preventing NTHi-MCat Infection, a major cause of AECOPD	40
17/EE/0494	EDP1066 Phase 1a/1b study in healthy participants and patients	40
17/EE/0498	Capsaicin 8% patch: a clinical study in Diabetic Peripheral Neuropathy	45
17/EE/0508	Fingerprick Autologous Blood (FAB) in Severe Dry Eye Disease	49
18/EE/0062	Phase 1b Study to Assess LAM-001 in Female Subjects with LAM	49
18/EE/0073	Clozapine-induced OCS in schizophrenia version 1	60
18/EE/0082	Efficacy & Safety of Fasinumab in Low Back Pain & Osteoarthritis	60
18/EE/0092	Study to evaluate the safety & efficacy of 13 weeks of SARM GSK2881078	52

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/EE/0083	Effects of multiple doses of Lu AF35700 on the PK of CYP Substrates	29
17/EE/0256	Language of Pain	46
17/EE/0287	Understanding medication use V1.0	39



17/EE/0502	An extension study to evaluate the safety and tolerability of QCC374	37
18/EE/0066	EXTENDING PRIMARY INDICATED PREVENTION TO IMPROVE PSYCHOSIS OUTCOMES	57

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0207	B7981005_Ph2b_Compare PF-06651600/PF-06700841/PBO in mod/sev UC	51

#### 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/0276	SCENE (Work Package 2)	29

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0150	SCENE (YEAR 1)	26
17/EE/0440	Barts DKC Registry- R	28
17/EE/0441	Barts DKC Registry - BioBank	28

#### 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
17/EE/0427	Co-applying Steroids and Emollients (CaSE trial)	n/a

#### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
18/EE/0065	PSACMEN Study	33

**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/0161	Evaluation of a decision aid prototype for stroke survivors (v1)	21
17/EE/0164	Statin Intolerant Patient:Development of Patient Reported Questionnaire	20
17/EE/0215	An assessment of EE therapy from the service users' perspective.	21
17/EE/0217	Ultrasound estimation of bladder volume in pelvic radiotherapy (v1)	19
17/EE/0270	Changes of thiamine and magnesium induced by knee arthroplasty	13
17/EE/0309	Satisfaction in breast clinic discharge	20
17/EE/0315	SOFIA	20
17/EE/0352	Are unmaintained static air support cushions affecting the patients experience	21
17/EE/0357	A framework to improve medication management with older people	24
17/EE/0391	Objective & Patient-Reported Assessment of Skin grafts & Keystone flap	22
17/EE/0392	Feasibility Study Investigating MIRA	20
17/EE/0393	ORal antibiotics Instead of IntraVenous Antibiotics (ORIIVA)	21
17/EE/0432	Parents' help-seeking behaviour	20
17/EE/0435	Validation of Electrical Ventricular Activation Patterns Using CIPS	19
17/EE/0478	Expression of PMCA in lower limb arteries	15
17/EE/0519	Can referral to ophthalmology be improved by on-line training?	21
17/EE/0520	Sub-profiling of people with spinally referred leg pain	28

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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17/EE/0162	MRI of the fetal body v 1.0	21
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#### 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/0163	D816V KIT mutations in Anaphylaxis	16
17/EE/0269	Why do norovirus pandemics occur?	18
17/EE/0313	ARDA Validation	21
17/EE/0314	Recurrent Infections in Musculoskeletal rheumatic Diseases (RIMED)	19
17/EE/0476	Do HLA-DQ eplet mismatches influence renal transplant outcomes?	20
18/EE/0076	Genomics of acral lentiginous melanoma	21

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/EE/0434	Inpatient music survey	13

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
18/EE/0077	Virtual reality headsets for patients undergoing regional anaesthesia	13
18/EE/0098	CCHFVaccine	14

#### 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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<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
05/Q0106/20/AM23	Genes and mechanisms in type 1 diabetes in the Cambridge BioResource	21	20/10/2017	28
07/H0310/146/AM10	TNF and NFkB signalling in haematologic malignancies - version 1.2	1.14	01/08/2017	35
07/H0311/103/AM09	Healthy volunteer blood donation for in vitro experimentation v1 2007	9	16/05/2017	24
07/H0311/103/AM10	Healthy volunteer blood donation for in vitro experimentation v1 2007	10	15/01/2018	19
07/Q0204/68/AM10	Hertfordshire Sarcopenia Study (HSS) Ver[1.0]May 2007	9	15/06/2017	33
08/H0306/26/AM15	Parkinson's Disease Heterogeneity Study	14	26/05/2017	11
08/H0311/120/AM38	Ipilimumab compared to placebo in stage III melanoma after surgery	25	07/04/2017	20
08/H0311/201/AM05	Generation of patient specific stem cells for liver disease	SA04	09/08/2017	32
09/H0306/36/AM05	Breast Cancer Genome Analysis	4	15/06/2017	19
09/H0311/88/AM13	Generation of patient-specific stem cells for CNS disorders	12	18/01/2018	32
11/EE/0346/AM04	Meiosis in unfertilised human oocytes 1	3	30/03/2017	27
12/EE/0058/AM14	Diagnostic urine biomarkers for prostate cancer	10	04/07/2017	26
12/EE/0136/AM05	Bone Marrow Cells for Cartilage Repair	5	05/04/2017	25
12/EE/0307/AM18	prevalence of pathogenic antibodies in psychosis	Substantial Amendment 7	10/07/2017	18
12/EE/0330/AM02	Multi-National Gilenya Pregnancy Exposure Registry in MS patients	2	07/12/2017	30
12/EE/0446/AM04	Characterisation of ischaemia reperfusion injury in human kidneys	SA 3) November 2017	21/11/2017	13
12/EE/0478/AM03	Investigating Hereditary Cancer Predisposition - IHCAP	5	12/05/2017	19
13/EE/0203/AM12	National Cohort Study of Pulmonary Arterial Hypertension	6	04/08/2017	28
13/EE/0203/AM13	National Cohort Study of Pulmonary Arterial Hypertension	7	04/08/2017	28
13/EE/0214/AM19	A Long Term Follow-up Study of Subjects previously treated with MK5172	13	26/06/2017	8
13/EE/0214/AM22	A Long Term Follow-up Study of Subjects previously treated with MK5172	15	15/11/2017	9

13/EE/0223/AM02	Investigation of elastographic techniques in soft tissue pathology (1)	2	17/05/2017	28
13/EE/0242/AM05	Helping people with aphasia have better conversations	3	04/04/2017	12
13/EE/0302/AM07	Exploring mutational signatures in humans	6	08/02/2018	15
13/EE/0312/AM23	TACTT3	F	11/12/2017	18
13/EE/0349/AM06	Extension study for Chronic Myeloid Leukaemia	2	07/11/2016	15
13/EE/0349/AM07	Extension study for Chronic Myeloid Leukaemia	01.07.17	01/07/2017	7
13/EE/0397/AM07	NIMRAD (NIMorazole/placebo plus RADiotherapy in head and neck cancer)	6	27/07/2017	21
13/EE/0401/AM04	Pulmonary magnetic resonance imaging in cystic fibrosis [V1.0]	2	27/07/2017	7
13/EE/0401/AM05	Pulmonary magnetic resonance imaging in cystic fibrosis [V1.0]	3	07/11/2017	31
13/EE/0401/AM06	Pulmonary magnetic resonance imaging in cystic fibrosis [V1.0]	4	27/02/2018	33
13/EE/0405/AM03	Diary Study of Auditory Hallucination Triggers in Early Psychosis	1	11/10/2017	14
14/EE/0189/AM06	The Cognitive Ageing Nutrition and Neurogenesis (CANN) trial.	1.6	11/05/2017	35
14/EE/1047/AM06	Randomised study of Adalimumab in subjects with Crohn's Disease	4	26/06/2017	21
14/EE/1068/AM04	JETREA® Drug Utilisation Study (TULIP) TG-MV-017	1	11/05/2017	7
14/EE/1155/AM03	Selective Dorsal Rhizotomy database	1	09/10/2017	13
14/EE/1185/AM09	Study to Evaluate Long Term Effect, Safety & Tolerability of Adalimumab	5	26/06/2017	8
14/EE/1239/AM08	G3215 Single and multiple ascending dose study	6	31/05/2017	21
14/EE/1239/AM09	G3215 Single and multiple ascending dose study	6	31/05/2017	9
14/EE/1239/AM10	G3215 Single and multiple ascending dose study	6	31/05/2017	14
14/EE/1239/AM11	G3215 Single and multiple ascending dose study	7	02/10/2017	26
14/EE/1293/AM06	C-STICH	5	23/03/2017	17
14/EE/1293/AM08	C-STICH	7	18/09/2017	15
14/EE/1293/AM10	C-STICH	9	05/03/2018	6
14/EE/1297/AM03	The BeGIN study: Investigating Outcomes from Breast Cancer	3	03/05/2017	29
15/EE/0032/AM03	Ticagrelor and Clopdogrel on IMR	15.0	15/11/2017	21
15/EE/0076/AM02	Norfolk Arthritis Register	1	12/05/2017	27
15/EE/0194/AM07	MIMOSA: Morphine in Moderate Obstructive Sleep Apnoea	SA03 2017/12/15	15/12/2017	18
15/EE/0210/AM04	Fabry SRT Mono Extension	02	19/09/2016	22
15/EE/0210/AM06	Fabry SRT Mono Extension	3	10/11/2017	8
15/EE/0234/AM05	A Phase II Study of Pembrolizumab in Subjects with Gastric Cancer	7	04/04/2017	30

15/EE/0234/AM07	A Phase II Study of Pembrolizumab in Subjects with Gastric Cancer	10	31/10/2017	15
15/EE/0234/AM08	A Phase II Study of Pembrolizumab in Subjects with Gastric Cancer	11	21/11/2017	30
15/EE/0332/AM08	Herts and Minds: Supporting the Well-being of Looked After Children V1	6	05/05/2017	35
15/EE/0332/AM10	Herts and Minds: Supporting the Well-being of Looked After Children V1	7	08/01/2018	8
15/EE/0334/AM04	Phase II Study of PBI-4050 in Subjects with Alström Syndrome	4	08/08/2017	15
15/EE/0334/AM05	Phase II Study of PBI-4050 in Subjects with Alström Syndrome	5	13/02/2018	35
15/EE/0448/AM14	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	20	09/03/2017	9
15/EE/0448/AM15	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	23.11.17	23/11/2017	31
15/EE/0457/AM03	Trust and Questioning in the Acute Care Setting	2	07/08/2017	6
15/EE/0457/AM04	Trust and Questioning in the Acute Care Setting	3	19/10/2017	20
16/EE/0051/AM04	EAGLE FM	2	20/05/2017	35
16/EE/0051/AM05	EAGLE FM	Substantial Amendment 3	22/11/2017	22
16/EE/0076/AM02	MR imaging in genetic muscle disease	1	28/07/2017	17
16/EE/0095/AM01	The Modular Protocol For Mental Health: A Pilot Trial	1	30/03/2017	13
16/EE/0095/AM02	The Modular Protocol For Mental Health: A Pilot Trial	2	09/06/2017	9
16/EE/0095/AM03	The Modular Protocol For Mental Health: A Pilot Trial	3	11/07/2017	8
16/EE/0097/AM01	Photo Participatory Courses Delivered at the NHS Recovery College East	6	26/07/2017	34
16/EE/0097/AM04	Photo Participatory Courses Delivered at the NHS Recovery College East	05.10.17	05/10/2017	6
16/EE/0097/AM05	Photo Participatory Courses Delivered at the NHS Recovery College East	7	25/10/2017	21
16/EE/0161/AM03	Nitrite in Hypertrophic Cardiomyopathy (HCM) Study	2	07/12/2017	12
16/EE/0163/AM04	First in human study in participants with Pompe disease	4	19/05/2017	33
16/EE/0248/AM02	MelaTools-SSM Trial	2	23/05/2017	28
16/EE/0295/AM01	Unconscious processes between mothers with ED and their infants	1	29/06/2017	10
16/EE/0297/AM03	Phase II Study of a New RIP1 Kinase Inhibitor in Moderate to Severe RA	SA2	23/05/2017	31

16/EE/0297/AM05	Phase II Study of a New RIP1 Kinase Inhibitor in Moderate to Severe RA	3	19/10/2017	17
16/EE/0299/AM02	PROGRAM	2	23/08/2017	12
16/EE/0305/AM04	PRIMETIME	SA01	25/04/2017	25
16/EE/0305/AM07	PRIMETIME	2	02/01/2018	34
16/EE/0322/AM02	Understanding and Dealing with Stress (DE-STRESS)	2	21/07/2017	11
16/EE/0328/AM01	Abnormal genes and proteins in oral inflammatory diseases v1	1	07/06/2017	14
16/EE/0335/AM05	ACT14604	6/USM	15/08/2017	15
16/EE/0335/AM06	ACT14604	7	30/11/2017	27
16/EE/0356/AM05	TRIDENT Study	05.02.18	05/02/2018	21
16/EE/0475/AM04	GWEP1675 CBDV	2	05/04/2017	15
16/EE/0483/AM01	Illness Perceptions In South Asian Haemodialysis Patients	1	01/03/2017	8
16/EE/0491/AM01	EESIS	Protocol revision D	26/07/2017	12
16/EE/0491/AM02	EESIS	2	16/10/2017	22
16/EE/0492/AM01	UROLE trial	01	09/03/2018	21
16/EE/0554/AM01	AFI-targeted confocal endomicroscopy in Barrett's oesophagus	1	17/11/2017	29
17/EE/0066/AM02	A Phase 1, food effect, bioavailability study of Sotagliflozin	1	09/05/2017	12
17/EE/0066/AM04	A Phase 1, food effect, bioavailability study of Sotagliflozin	2	12/06/2017	18
17/EE/0066/AM06	A Phase 1, food effect, bioavailability study of Sotagliflozin	1	21/02/2017	8
17/EE/0066/AM08	A Phase 1, food effect, bioavailability study of Sotagliflozin	1	21/02/2017	7
17/EE/0068/AM01	MR-opt	1	21/03/2017	18
17/EE/0083/AM02	Effects of multiple doses of Lu AF35700 on the PK of CYP Substrates	1	10/03/2017	15
17/EE/0083/AM03	Effects of multiple doses of Lu AF35700 on the PK of CYP Substrates	1	10/03/2017	22
17/EE/0083/AM04	Effects of multiple doses of Lu AF35700 on the PK of CYP Substrates	1	10/03/2017	34
17/EE/0097/AM01	Ad4HIV	AM01	11/08/2017	20
17/EE/0097/AM05	Ad4HIV	05	15/03/2018	18
17/EE/0164/AM01	Statin Intolerant Patient: Development of Patient Reported Questionnaire	1	03/01/2018	7
17/EE/0204/AM01	BCX7353 as a treatment for acute HAE attacks	01	28/07/2017	15
17/EE/0204/AM02	BCX7353 as a treatment for acute HAE attacks	2	28/08/2017	24
17/EE/0204/AM04	BCX7353 as a treatment for acute HAE attacks	04	06/02/2018	35
17/EE/0209/AM01	Fluorescence targeted pelvic lymph node mapping	1	14/09/2017	15
17/EE/0264/AM01	Efficacy of Durvalumab/Tremelimumab with SoC chemo in	1	11/12/2017	10



	metastatic NSCLC			
17/EE/0264/AM02	Efficacy of Durvalumab/Tremelimumab with SoC chemo in metastatic NSCLC	2	08/02/2018	28
17/EE/0270/AM01	Changes of thiamine and magnesium induced by knee arthroplasty	1	30/10/2017	19
17/EE/0291/AM01	Phase III trial-pembrolizumab or brentuximab vedotin-Hodgkin Lymphoma	01	24/10/2017	18
17/EE/0291/AM04	Phase III trial-pembrolizumab or brentuximab vedotin-Hodgkin Lymphoma	02	11/12/2017	35
17/EE/0295/AM02	Trans-cervical balloon catheter and prostaglandin for labour induction	1	13/10/2017	13
17/EE/0295/AM04	Trans-cervical balloon catheter and prostaglandin for labour induction	SA 2017/12/20	20/12/2017	28
17/EE/0329/AM01	Lending a helping hand to very preterm babies Version 1	1	07/03/2018	12
17/EE/0341/AM04	Continuous 5-hour IV Infusions of BMS-986231 in Heart Failure Patients	1	01/11/2017	8
17/EE/0341/AM06	Continuous 5-hour IV Infusions of BMS-986231 in Heart Failure Patients	4	21/12/2017	15
17/EE/0355/AM04	Imatinib effects on lung vascular dysfunction by stimulation of injury	1.0	24/01/2018	15
17/EE/0357/AM01	A framework to improve medication management with older people	4	08/11/2017	14
17/EE/0357/AM02	A framework to improve medication management with older people	2	07/02/2018	24
17/EE/0387/AM01	The MASH Trial	1.0	08/12/2017	34
17/EE/0434/AM01	Inpatient music survey	1	20/11/2017	30
17/EE/0494/AM02	EDP1066 Phase 1a/1b study in healthy participants and patients	2	16/03/2018	18

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
08/H0311/147/AM02	Volumetric perfusion CT of human tumours using Dual Source CT	Amendment protocol v3.0	14/12/2016	22

12/EE/0393/AM06	Cambridge-Edinburgh Human Imaging and Longitudinal Development study	7	02/02/2017	16
13/EE/0256/AM04	The effects of study participation on patient adherence behaviour	2	18/04/2017	25
16/EE/0299/AM01	PROGRAM	1	05/05/2017	32
16/EE/0481/AM03	First time in human study of GSK2292767 in healthy volunteers	02	08/09/2017	14

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
12/EE/0393/AM06/1	Cambridge-Edinburgh Human Imaging and Longitudinal Development study	8	05/06/2017	14
13/EE/0256/AM04/1	The effects of study participation on patient adherence behaviour	2.1	18/04/2017	15
16/EE/0299/AM01/1	PROGRAM	Modified Amendment SA01	06/07/2017	14
16/EE/0481/AM03/1	First time in human study of GSK2292767 in healthy volunteers	2	09/10/2017	14

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**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
17/EE/0357	A framework to improve medication management with older people	24
17/EE/0391	Objective & Patient-Reported Assessment of Skin grafts & Keystone flap	22
17/EE/0432	Parents' help-seeking behaviour	35
17/EE/0520	Sub-profiling of people with spinally referred leg pain	28

**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
13/EE/0256/AM04/1	The effects of study participation on patient adherence behaviour	2.1	18/04/2017	15