

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

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	East of England - Cambridgeshire and Hertfordshire 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:	Phase I in Healthy Volunteers Phase I in Patients
Chair:	Professor Barry Hunt
Vice-Chair:	Dr Ian Skidmore
Alternate Vice-Chair:	Mr David Grayson
REC Manager:	Miss Georgia Copeland
REC Assistant:	Miss Lindsey Wallace
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

The committee's title was changed from 'Hatfield' to 'Cambridgeshire and Hertfordshire' in December 2014 as part of the process to address the low volume of activity of the full committee. From April 2015 through to March 2016 the Committee reviewed 44 applications this was an increase of over 60% from the previous year suggesting that the name change did have an impact. On the other hand the number of applications that involved phase 1 studies remained at a constant but low level. Some members of the committee expressed concern that this may not reflect a proportionate sharing of these applications between flagged committees. Additionally the expertise of these members is not being used to full potential and ways to enhance the number of phase 1 applications need to be considered. Overall of the 44 applications reviewed about 86% were given a provisional opinion. On occasion it proved difficult for the committee to complete its review within the allocated time slot particularly for complex studies. Amendments to the timing of the meeting agenda will be considered in order to help resolve this over the next year. Meetings continued to be held at the University of Hertfordshire and this remained an excellent venue from the perspective of members, applicants and the REC managers.

Sub-committees established to review substantial amendments had 28 meetings in the reporting period. Attempts to achieve a more equitable spread of member involvement and a consequent wider experience for members did have some effect. The influx of new members and the loss of experienced members however means that a greater spread of involvement remains on the agenda for next year. The Proportionate Review sub-committee met 10 times and reviewed 20 applications; for 2 of these applications referral to a full committee was required. Again for this subcommittee the wider involvement of members is part of an ongoing strategy. For both sub-committees on a small number of occasions it was necessary to co-opt members from other RECs.

As a result of interviews three new members were appointed to the committee in the reporting period and they were warmly welcomed. The Committee was very sorry that three members resigned within the year and thanked them each for their valuable contributions that had spanned many years.

The Committee was well supported by the REC Manager and the REC Assistant. The committee received a summary presentation on the new Health Research Authority application process and an introduction to the HARP member portal for electronic access to applications and substantial amendments.

East of England - Cambridgeshire and Hertfordshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Roger Aubrey	Retired medical doctor	Expert	01/04/2013	08/07/2015
Miss Ruth Barker	Senior Physiotherapist Therapist / Therapies Research Facilitator	Expert	10/02/2016	
Professor Anwar Baydoun	Pharmacologist	Lay	01/04/2013	29/07/2015
Mrs Elspeth Coult	Registered Nurse	Expert	01/04/2013	17/08/2015
Mr David Grayson	Retired Local Government Administrator	Lay Plus	01/04/2013	
Mrs Kornelia Hathaway	Education & Training Manager	Expert	04/03/2015	
Professor Barry Hunt	Pro-Vice Chancellor (International) (Retired)	Expert	01/04/2013	
Dr Wassim Matta	General Practitioner	Expert	01/04/2013	
Mr Peter Neville	Retired European Patent Attorney	Lay	23/02/2015	
Dr Patricia Scott	Senior Lecturer DHRes	Expert	22/10/2013	
Dr Ian Skidmore	Retired Company Director	Lay Plus	01/04/2013	
Ms Helen Street	PHD Candidate	Lay	27/04/2015	
Mrs Jill Troup	Service manager for medicine	Expert	30/09/2015	
Dr Melanie Whittick	Pharmacist	Expert	01/04/2013	

East of England - Cambridgeshire and Hertfordshire Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

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

Name	Profession	Status	Meeting date attended
Ms Carol Alves	Research Quality Facilitator	Expert	12 August 2015
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	11 November 2015 25 May 2015 31 August 2015
Mr John Aldridge	Retired Senior Lecturer in Nursing	Expert	24 June 2015
Dr Michael Sheldon	Retired Clinical Psychologist	Lay	03 August 2015
Dr Sarahjane Jones	Research Fellow	Lay	23 September 2015

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

Name	Declaration of Interest	Date
Mr David Grayson	Member of viewpoint mental health charity	05/01/2016
Mrs Kornelia Hathaway	Holds a small number of shares in GSK PLC. Employed by the Cambridge University Hospitals NHS FT. Active member of the UK Clinical research facilities network.	04/01/2016
Professor Barry Hunt	Member of academic board and ethics committee university of law. Trustee of Ataxia UK. Chairman of University of Hertfordshire Ethics Committee.	09/12/2015
Dr Wassim Matta	None	03/03/2016
Mr Peter Neville	Wife is a shareholder in BTG plc, a company specialising in development and promotion of new healthcare/pharmaceutical products.	05/01/2016
Dr Ian Skidmore	Shareholdings in GSK. Occasional consultancy for biopharm companies on regulatory issues.	09/12/2015
Miss Ruth Barker	Member of R&D at Princess Alexandra Hospital	07/03/2016
Dr Patricia Scott	Programme Director, Doctorate in Health Research, University of Hertfordshire Consultant Editor RCNi Emergency Nurse Journal NIHR Peer Reviewer	20/03/2016
Ms Helen Street	Awarded a PhD studentship by the Alzheimers Society. Currently undertaking a PhD at the Institute of Public Health, University of Cambridge	02/03/2016
Dr Melanie Whittick	Shares in GSK. Originally obtained when working for Glaxo Group Research as member of staff.	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	08/04/2015	8
May	13/05/2015	8
June	10/06/2015	7
July	08/07/2015	9
August	12/08/2015	9
September	09/09/2015	8
November	11/11/2015	8
December	09/12/2015	7
February	03/02/2016	8
March	09/03/2016	9

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	29/04/2015	3
June	24/06/2015	4
July	29/07/2015	3
August	26/08/2015	3
September	23/09/2015	3
November	25/11/2015	3
December	23/12/2015	3
January	20/01/2016	3
February	17/02/2016	3
March	16/03/2016	3

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

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	13/04/2015	3
April	27/04/2015	3
May	11/05/2015	3
May	25/05/2015	3
June	08/06/2015	2
June	22/06/2015	2
July	06/07/2015	2
July	20/07/2015	2
August	03/08/2015	3
August	17/08/2015	3
August	31/08/2015	2

September	14/09/2015	2
September	28/09/2015	2
October	12/10/2015	2
October	26/10/2015	2
November	09/11/2015	2
November	23/11/2015	2
December	07/12/2015	2
December	21/12/2015	2
January	05/01/2016	2
January	19/01/2016	2
February	02/02/2016	2
February	26/02/2016	2
March	01/03/2016	2
March	15/03/2016	2
March	22/03/2016	2
March	30/03/2016	2

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

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

Date	Reason	Action taken
None		

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

Name	Number of Meetings Attended
Dr Roger Aubrey	4
Miss Ruth Barker	1
Mrs Elspeth Coult	1
Mr David Grayson	10
Mrs Kornelia Hathaway	8
Professor Barry Hunt	9
Dr Wassim Matta	5
Mr Peter Neville	9
Dr Patricia Scott	7
Dr Ian Skidmore	9
Ms Helen Street	6
Mrs Jill Troup	1
Dr Melanie Whittick	9

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

Name	Number of Meetings Attended
Professor Anwar Baydoun	1
Mr David Grayson	10
Mrs Kornelia Hathaway	1
Professor Barry Hunt	5
Mr Peter Neville	1
Dr Patricia Scott	2
Dr Ian Skidmore	6
Dr Melanie Whittick	3

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

Name	Number of Meetings Attended
Mr David Grayson	15
Mrs Kornelia Hathaway	1
Professor Barry Hunt	16
Dr Wassim Matta	2
Mr Peter Neville	2
Dr Patricia Scott	2
Dr Ian Skidmore	14
Dr Melanie Whittick	5

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr David Grayson	26/05/2015	NREAP Meeting
Mrs Kornelia Hathaway	17/06/2015	NRES Committee Members Induction
Mrs Kornelia Hathaway	18/02/2016	National members training day
Dr Wassim Matta	25/09/2015	Members Regional Training Day
Mr Peter Neville	17/06/2015	Members Induction
Mr Peter Neville	25/09/2015	Members Regional Training Day
Mr Peter Neville	18/02/2016	National members training day
Ms Helen Street	25/09/2015	Members Regional Training Day
Ms Helen Street	10/02/2016	Committee Members Induction
Dr Melanie Whittick	25/09/2015	Members Regional Training Day
Dr Patricia Scott	01/04/2015	SDL- Supervision of doctoral research students in healthcare
Professor Barry Hunt	01/09/2015	Chair of University Ethics Committee
Professor Barry Hunt	10/11/2015	NREAP Chairs Meeting
Professor Barry Hunt	12/11/2015	World Congress on Orphan Drugs - Geneva 2 day conference

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	22.73
Phase 1	4	9.09
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	30	68.18
Total Applications Reviewed	44	100

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
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	6

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	2	4.55
Provisional Opinion	38	86.36
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	44	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	75.00
Further Information Favourable Opinion with Additional Conditions	3	6.82
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	2	4.55
Provisional Opinion	1	2.27
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	1	2.27
Total	44	100

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

Total Applications Reviewed	20
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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	7
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	3
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	2	10.00
Favourable Opinion with Additional Conditions	1	5.00
No Opinion transfer to full committee for review	2	10.00
Provisional Opinion	15	75.00
Unfavourable Opinion	0	0.00
Total	20	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	4.40
Number of completed applications for full ethical review	43
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	2.27%
Number of completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	2.27%
Number of days taken to final decision – average (mean)	32
Number of completed proportionate review applications for ethical review	18
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	3
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	5
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	127
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	3
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.36%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	120
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	14
Number of annual progress reports received	142

Number of safety reports received	24
Number of Serious Adverse Events received	5
Number of final reports received	46

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/EE/0129	Enhance	40
15/EE/0135	CCD-05993AA1-07_Chiesi_COPD_TRISTAR	33
15/EE/0142	Qualitative study of proactive care and restraint reduction	22
15/EE/0171	Effect of Dementia First Aid course on carers' knowledge & competence	37
15/EE/0187	Sex differences in the experiences of Eating Disorder's	27
15/EE/0194	MIMOSA: Morphine in Moderate Obstructive Sleep Apnoea	34
15/EE/0210	Fabry SRT Mono Extension	62
15/EE/0220	2015-AAR-009 Alfapump-albumin replacement therapy V1.0	36
15/EE/0232	The effects of mixed meals on gastric emptying and lipid metabolism	25
15/EE/0233	How is Dementia talked about between and within marital couples?	35
15/EE/0238	The impact of caring for someone with Mild Cognitive Impairment	22
15/EE/0279	Contrast Enhanced Spectral Mammography Study	39
15/EE/0292	POSAG Trial: Prevalence of Obstructive Sleep Apnoea in Glaucoma	36
15/EE/0293	Kinesiotaping in Lymphoedema Management (version 3)	27
15/EE/0294	Changes in neural representations and body perception during pregnancy	30
15/EE/0296	Golden-7	30
15/EE/0310	Personalised cancer risk information to promote behaviour change	31
15/EE/0319	Sirolimus Treatment for PIK3CA Related Overgrowth (PROMISE)	32
15/EE/0329	A Two Part study of AZD8871 in asthmatic and COPD subjects	33
15/EE/0332	Herts and Minds: Supporting the Well-being of Looked After Children V1	39
15/EE/0334	Phase II Study of PBI-4050 in Subjects with Alström Syndrome	40
15/EE/0406	Comparative PK Study of 2 Fluticasone/Salmeterol 250/50 mcg Inhalers	31
15/EE/0408	Role of Innate Lymphoid Cells in Asthma and Allergy	28
15/EE/0440	Hepatic Effects of Right Heart Lesions in ACHD	36
15/EE/0448	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	39
15/EE/0457	Trust and Questioning in the Acute Care Setting	40
15/EE/0466	A study of RO5459072 in people with coeliac disease; v1	32
16/EE/0042	DIAGRAMS, Version 3	34
16/EE/0046	Acceptability and usability of SISOM (version 1.0)	39
16/EE/0049	Developing models of the human musculoskeletal system	37
16/EE/0050	Lived experience of parents caring for a child with breathlessness, v1	37
16/EE/0051	EAGLE FM	34

16/EE/0095	The Modular Protocol For Mental Health: A Pilot Trial	33
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0234	A Phase II Study of Pembrolizumab in Subjects with Gastric Cancer	28
15/EE/0258	Caecal pH as a biomarker for irritable bowel syndrome	27
15/EE/0321	Plerixafor kinetics and radiolabelled neutrophils	36

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0120	Safety, tolerability & PK of JNJ-63623872 in healthy Japanese subjects	21
15/EE/0256	Hertfordshire Birth to Death Cohort Study	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0102	A bioequivalency study of ticagrelor in healthy Japanese subjects	18
15/EE/0198	SURECAN	23

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EE/0389	Development of the Medicines Optimisation Assessment Tool (MOAT) v1	28
16/EE/0111	Dealing with Impasses and Hesitations in Therapy and Supervision.	19

Provisional Opinion

REC Reference	Title	Number of Days on Clock
15/EE/0239	CMO incidence following cataract surgery continuing/stopping PGA drops	n/a

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock
None		

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
15/EE/0416	Safety, pharmacokinetics and pharmacodynamics study of inhaled QBW276 in	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
15/EE/0193	Effect of Goldmann Applanation Tonometry on Biometry Measurements	9
15/EE/0265	A Feasibility study of EEG Neurofeedback in Chronic Migraine	10
15/EE/0267	The Effect of Intradialytic Exercise on Blood Endotoxin Levels	12
15/EE/0300	Patient outcomes following complex musculoskeletal injury	11
15/EE/0301	ECHO: Expanding Communications on Hemophilia-A Outcomes	14
15/EE/0342	Recovery trajectory following colorectal surgery	13
15/EE/0344	Aortic root replacement in bicuspid aortic valve disease_1	14
15/EE/0375	Increasing uptake of cervical screening through behavioural insight	8
15/EE/0376	COMPARE-HIV	14
15/EE/0485	Combined ischaemic conditioning on deceased donor renal transplants	10
16/EE/0038	The Acceptability of Metaphors in the Management of People with MUS	8
16/EE/0039	What is the role of pain in Pulmonary Rehabilitation?	10
16/EE/0076	MR imaging in genetic muscle disease	14

16/EE/0082	Parent's experiences during transition to adolescence in Diabetes	14
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0343	Parent-child Communication in Kidney Disease	14

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0191	The effect of oral iron supplementation on phosphate homeostasis	5
16/EE/0125	TDP-43 pathology in FTLD-TDP and old-age hippocampal sclerosis	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0304	Evaluation of Mechanical Properties of Human Rotator Cuff Tendon	9

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

Provisional Opinion

REC Reference	Title	Number of Days on Clock
None		

Further information response not complete

REC Reference	Title	Number of Days on Clock

None		
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Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
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
05/Q0106/20/AM21	Genes and mechanisms in type 1 diabetes in the Cambridge BioResource	19	29/07/2015	28
07/H0310/146/AM07	TNF and NFkB signalling in haematologic malignancies - version 1.2	1.11	17/06/2015	18
07/H0310/146/AM08	TNF and NFkB signalling in haematologic malignancies - version 1.2	1.12	24/01/2016	16
07/Q0204/65/AM30	Computerised Adaptive Testing for the EORTC QLQ-C30	Substantial Amendment 26	23/03/2015	13
08/H0306/61/AM09	CTCR-OV04	7.0	30/11/2015	28
08/H0306/62/AM03	Identifying biomarkers of renal tubular disorders	3	26/11/2015	21
08/H0311/120/AM29	Ipilimumab compared to placebo in stage III melanoma after surgery	21	30/03/2015	15
08/H0311/120/AM30	Ipilimumab compared to placebo in stage III melanoma after surgery	19	03/06/2015	20
08/H0311/120/AM31	Ipilimumab compared to placebo in stage III melanoma after surgery	20	09/07/2015	20
08/H0311/120/AM32	Ipilimumab compared to placebo in stage III melanoma after surgery	21	09/03/2016	26
09/H0311/88/AM10	Generation of patient-specific stem cells for CNS disorders	10	12/05/2015	14
10/H0306/61/AM03	Platelets for Neonatal Transfusion - study 2 (PlaNiT-2) V1.0	SA#04	19/01/2016	21
10/H0310/59/AM04	Understanding cognition and action in Pick's disease	2nd Amendment V5, 1st July 2015	29/07/2015	28
10/H0311/59/AM04	European Study of Osteoarthritis: The Hertfordshire Cohort Study arm	31.07.15	01/09/2015	28
10/H0311/59/AM05	European Study of Osteoarthritis: The Hertfordshire Cohort Study arm	1.6	30/11/2015	16
11/EE/0142/AM03	Psychometric functions for displacement and static perimetry	3	02/11/2015	7
11/EE/0147/AM04	TEST-BP VERSION: 1.0	3	30/07/2015	19
11/EE/0240/AM01	Multiparametric MRI to assess treatment response in mesothelioma	01	06/01/2016	19
11/EE/0346/AM03	Meiosis in unfertilised human oocytes 1	2	23/12/2015	17

11/EE/0524/AM13	Functional Strength Training for upper limb recovery after stroke	Substantial amendment 7.0	31/03/2015	30
11/EE/0524/AM14	Functional Strength Training for upper limb recovery after stroke	8	04/06/2015	16
12/EE/0372/AM06	Service user journeys and stakeholder experiences	11	22/04/2015	18
12/EE/0389/AM02	Effect of encapsulated nutrients on gut peptide secretion	2	07/05/2015	18
12/EE/0395/AM01	DETECT mTBI	1.0	12/11/2015	21
12/EE/0478/AM02	Investigating Hereditary Cancer Predisposition - IHCAP	2	07/03/2016	23
12/EE/0524/AM02	Cerebral autoregulation in newborn infants undergoing intensive care	2	02/07/2015	28
13/EE/0021/AM12	Does a breathlessness intervention service reduce stress?	10	23/12/2015	8
13/EE/0106/AM07	Prognostic study of carpal tunnel syndrome	4	27/04/2015	14
13/EE/0106/AM08	Prognostic study of carpal tunnel syndrome	5	28/05/2015	11
13/EE/0130/AM01	Quantification of neutrophil accumulation in lung cancer	1	16/09/2015	21
13/EE/0130/AM02	Quantification of neutrophil accumulation in lung cancer	03	11/01/2016	27
13/EE/0176/AM07	Ferumoxytol for Anemia of CKD Trial (FACT)- AMAG-FER-CKD-401	06.05.15	06/05/2015	27
13/EE/0195/AM06	Assessment of gut peptide levels in patients with motility disorders	3	08/07/2015	24
13/EE/0195/AM07	Assessment of gut peptide levels in patients with motility disorders	4	16/12/2015	17
13/EE/0199/AM18	Study of the Safety and Efficacy of Botox® for the Treatment of PE	7	22/06/2015	15
13/EE/0203/AM08	National Cohort Study of Pulmonary Arterial Hypertension	4	23/12/2015	12
13/EE/0214/AM11	A Long Term Follow-up Study of Subjects previously treated with MK5172	07	20/08/2015	13
13/EE/0242/AM04	Helping people with aphasia have better conversations	08.01.16	08/01/2016	14
13/EE/0288/AM11	Automated Monitoring of Symptoms Severity (AMoSS)	5	05/08/2015	14
13/EE/0292/AM10	Blueberry anthocyanin, insulin resistance, vascular health & cognition	4	05/06/2015	23
13/EE/0302/AM04	Exploring mutational signatures in humans	Substantial amendment 4	27/03/2015	7
13/EE/0302/AM05	Exploring mutational signatures in humans	5	05/06/2015	21
13/EE/0310/AM05	Reducing Arthritis Fatigue: Team cognitive-behavioural approach (RAFT)	3.0	08/09/2015	21
13/EE/0312/AM11	TACTT3	Substantial	07/04/2015	7

		Amendment 6		
13/EE/0312/AM13	TACTT3	New tinnitus advert insert	28/09/2015	16
13/EE/0312/AM14	TACTT3	10/12/15	10/12/2015	27
13/EE/0357/AM03	IMPRESS version 1	3	08/10/2015	21
13/EE/0431/AM04	Optimal Treatment for OCD (OTO) Version 1.0	24.04.15	18/05/2015	8
13/EE/0431/AM06	Optimal Treatment for OCD (OTO) Version 1.0	29.07.15	29/07/2015	27
13/EE/0431/AM08	Optimal Treatment for OCD (OTO) Version 1.0	3	18/09/2015	16
13/EE/0448/AM06	AMPACT2 - An open-label extension to the TACTT3 study	Substantial Amendment 3	07/04/2015	7
13/EE/0448/AM07	AMPACT2 - An open-label extension to the TACTT3 study	B	01/06/2015	7
13/EE/0448/AM08	AMPACT2 - An open-label extension to the TACTT3 study	C	03/11/2015	27
14/EE/0032/AM03	Treating dry eyes and corneal ulcers with fingerprick autologous blood	1	25/05/2015	16
14/EE/0034/AM05	VICTORY AF	Substantial Amendment 3	23/03/2015	21
14/EE/0097/AM02	MIMIC	2	05/08/2015	18
14/EE/0136/AM01	Improving dementia care in African and Caribbean minority ethnic group	1	15/07/2015	20
14/EE/0148/AM04	Women 60 Years and Under, Living and Working with COPD	2	13/04/2015	14
14/EE/0176/AM01	Post-treatment Care Pathway in Long-term Head & Neck Cancer	1	03/12/2015	17
14/EE/0189/AM02	The Cognitive Ageing Nutrition and Neurogenesis (CANN) trial.	3	18/05/2015	8
14/EE/0189/AM03	The Cognitive Ageing Nutrition and Neurogenesis (CANN) trial.	1.3	03/08/2015	18
14/EE/0189/AM04	The Cognitive Ageing Nutrition and Neurogenesis (CANN) trial.	4.0	01/12/2015	21
14/EE/0197/AM03	Predictors of T-wave oversensing study	3	07/04/2015	19
14/EE/0219/AM03	The Orange Juice and Cardiovascular Disease Study	2	27/01/2016	13
14/EE/1047/AM01	Randomised study of Adalimumab in subjects with Crohn's Disease	1	17/06/2015	21
14/EE/1047/AM03	Randomised study of Adalimumab in subjects with Crohn's Disease	2	31/07/2015	25
14/EE/1048/AM02	ESTEEM	Substantial Amendment 2	31/03/2015	14
14/EE/1048/AM05	ESTEEM	3.0	11/12/2015	16
14/EE/1094/AM04	Physical Activity in Haemodialysis Patients	4.0	22/10/2015	27
14/EE/1126/AM02	The Babelfish Control study	2	02/07/2015	14

14/EE/1157/AM03	Exploring the self-management needs of people who have progressive MS	12.06.15	12/06/2015	11
14/EE/1159/AM02	viral hepatitis case-finding in primary care	1	27/05/2015	14
14/EE/1161/AM01	REASSURE: Radium-223 post authorisation safety study	1	05/01/2016	16
14/EE/1185/AM01	Study to Evaluate Long Term Effect, Safety & Tolerability of Adalimumab	1	08/04/2015	21
14/EE/1185/AM03	Study to Evaluate Long Term Effect, Safety & Tolerability of Adalimumab	2	25/06/2015	22
14/EE/1185/AM07	Study to Evaluate Long Term Effect, Safety & Tolerability of Adalimumab	4	22/02/2016	8
14/EE/1188/AM01	Quality of life in glaucoma patients undergoing trabeculectomy	1.0	20/10/2015	26
14/EE/1209/AM03	First Time in human study of RIP1K inhibitor (GSK2982772)	06.05.15	06/05/2015	22
14/EE/1209/AM04	First Time in human study of RIP1K inhibitor (GSK2982772)	3	04/06/2015	14
14/EE/1209/AM06	First Time in human study of RIP1K inhibitor (GSK2982772)	3	09/11/2015	21
14/EE/1221/AM01	UK Clinical Experience with Linaclotide for Patients with IBS-C	1	18/05/2015	17
14/EE/1239/AM02	G3215 Single and multiple ascending dose study	2	07/05/2015	19
14/EE/1239/AM03	G3215 Single and multiple ascending dose study	3	19/05/2015	19
14/EE/1239/AM05	G3215 Single and multiple ascending dose study	Additional visit	12/02/2016	20
14/EE/1244/AM03	Home monitoring to predict exacerbations in Cystic Fibrosis	1	18/04/2015	21
14/EE/1254/AM03	MelMarT - Melanoma Margins Trial - Pilot Study	2	25/11/2015	22
14/EE/1276/AM03	Post-Approval Safety Study of Updated ACCUSOL 35: ACCUPASS	SA1	07/05/2015	28
14/EE/1293/AM01	C-STICH	1	09/07/2015	23
14/EE/1293/AM02	C-STICH	2	03/09/2015	25
14/EE/1297/AM02	The BeGIN study: Investigating Outcomes from Breast Cancer	2	22/06/2015	17
14/EE/1299/AM02	New biomarkers in lupus nephritis	1	25/06/2015	10
14/EE/1299/AM03	New biomarkers in lupus nephritis	2	13/11/2015	7
15/EE/0007/AM03	PERFECTED: Caring for patients with hip-fracture & memory difficulties	3	19/05/2015	7
15/EE/0007/AM06	PERFECTED: Caring for patients with hip-fracture & memory difficulties	6	12/08/2015	19
15/EE/0032/AM01	Ticagrelor and Clopidogrel on IMR	14.08.15	14/08/2015	21
15/EE/0041/AM01	Genetic Study of Neurocognitive Substrates in OCD	1	01/07/2015	18
15/EE/0066/AM02	Fascia Iliaca block and burn donor site pain.(ver. 1)	1	07/01/2016	33
15/EE/0068/AM02	CIMAX (CIMzia in AXial spondyloarthritis).	1	26/01/2016	6
15/EE/0083/AM02	Validation of laser speckle contrast imaging and thermography	1	22/07/2015	12

	in SSc			
15/EE/0083/AM04	Validation of laser speckle contrast imaging and thermography in SSc	2	24/09/2015	20
15/EE/0102/AM01	A bioequivalency study of ticagrelor in healthy Japanese subjects	1	29/05/2015	20
15/EE/0103/AM01	Dementia interview study, v1	1	10/07/2015	25
15/EE/0116/AM01	Impacts of passive movements in people with severe multiple sclerosis	1	23/04/2015	21
15/EE/0117/AM01	Comparison of Active Treatments For IGR:a SRFT/Hitachi trial (CATFISH)	1	21/05/2015	13
15/EE/0117/AM05	Comparison of Active Treatments For IGR:a SRFT/Hitachi trial (CATFISH)	2	09/03/2016	13
15/EE/0120/AM01	Safety, tolerability & PK of JNJ-63623872 in healthy Japanese subjects	1	29/04/2015	12
15/EE/0125/AM01	REACH: Research Exploring physical Activity in Care Homes	1	10/08/2015	21
15/EE/0125/AM03	REACH: Research Exploring physical Activity in Care Homes	2	10/12/2015	26
15/EE/0135/AM01	CCD-05993AA1-07_Chiesi_COPD_TRISTAR	1	02/09/2015	13
15/EE/0194/AM01	MIMOSA: Morphine in Moderate Obstructive Sleep Apnoea	1	04/10/2015	28
15/EE/0210/AM01	Fabry SRT Mono Extension	1.0	17/12/2015	15
15/EE/0232/AM02	The effects of mixed meals on gastric emptying and lipid metabolism	001	11/11/2015	8
15/EE/0234/AM01	A Phase II Study of Pembrolizumab in Subjects with Gastric Cancer	03	03/12/2015	28
15/EE/0238/AM01	The impact of caring for someone with Mild Cognitive Impairment	1	05/10/2015	20
15/EE/0267/AM02	The Effect of Intradialytic Exercise on Blood Endotoxin Levels	2	10/02/2016	11
15/EE/0279/AM01	Contrast Enhanced Spectral Mammography Study	SA1	01/03/2016	1
15/EE/0292/AM01	POSAG Trial: Prevalence of Obstructive Sleep Apnoea in Glaucoma	1	21/12/2015	15
15/EE/0296/AM02	Golden-7	4.0	20/11/2015	27
15/EE/0300/AM01	Patient outcomes following complex musculoskeletal injury	1.2	08/12/2015	27
15/EE/0310/AM01	Personalised cancer risk information to promote behaviour change	1	16/11/2015	7
15/EE/0310/AM02	Personalised cancer risk information to promote behaviour change	2	18/12/2015	18
15/EE/0332/AM01	Herts and Minds: Supporting the Well-being of Looked After	SA#01	13/01/2016	28

	Children V1			
98CN01/AM06	EPIC in Norfolk	January 2016	25/02/2016	25

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0306/26/AM14	Parkinson's Disease Heterogeneity Study	13	14/07/2015	27
12/EE/0393/AM04	Cambridge Human Imaging and Longitudinal Development (CHILD) study	Substantial amendment 4	25/08/2015	22
14/EE/1239/AM04	G3215 Single and multiple ascending dose study	5	25/06/2015	13
15/EE/0125/AM04	REACH: Research Exploring physical Activity in Care Homes	3	09/03/2016	35

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
14/EE/1239/AM04/1	G3215 Single and multiple ascending dose study	5	13/07/2015	3

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/EE/0393/AM04/1	Cambridge Human Imaging and Longitudinal Development (CHILD) study	5	14/03/2016	13

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

REC Reference	Title	Number of Days on Clock
15/EE/0210	Fabry SRT Mono Extension	62

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
None		

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None		

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
None		

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Modified Amendments over 14 day timeline

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