

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

**Annual Report**

**01 April 2016 - 31 March 2017**



## 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 Georgia Copeland
<b>REC Assistant:</b>	Miss Lindsey Wallace
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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## Chair's overview of the past year:

From April 2016 through to March 2017 the Committee's workload remained at the same level as in the previous year maintaining the enhanced activity associated with the change of name of the committee. Of the applications received nearly 50% were CTIMPs including 20% of the total number of studies that were Phase 1.

As Chairman of the Committee I am extremely grateful for and impressed by the commitment of all Members to the review process. Discussions of applications are always highly rigorous and when researchers attend, and for the most part they do, they seem very reassured by the level of scrutiny their applications receive. A continuing challenge for the Chairman is to keep meetings to time while receiving all the relevant input from those committee members who have invested a significant amount of time in reviewing the extensive amount of documentation associated with each application. Members are mixed in terms of their approach to the review some using electronic others paper format. Overall members are committed to their own development in areas related to ethical review and have completed an array of HRA activities. One Shared Ethical Debate (SHED) was completed in the year. In addition Committee representatives attended Chairs meetings organised for the East of England.

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, were extremely valuable. A more equitable spread of member involvement in sub-committees provided useful experience for the newer members. The further recruitment of new members and the loss of experienced members however mean that a greater spread of involvement remains on the agenda for next year.

Two experienced expert members left the Committee during the year and we thank them for their very valuable inputs to our meetings over the years. As a result of interviews three new members were appointed to the committee one in the reporting period and two more will start early in the next reporting year.

The Committee was well supported by the REC Manager and the REC Assistant and on behalf of the whole committee we thank them both for their hard work on our behalf. In the year Committee meetings moved location and are now held at the Conference Centre of the University of Hertfordshire and this provides an excellent venue from the perspective of members, applicants and the REC managers.

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

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Ruth Barker	Senior Physiotherapist Therapist / Therapies Research Facilitator	Expert	10/02/2016	
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	
Professor Diana Kornbrot	Statistician	Expert	01/09/2016	
Dr Wassim Matta	General Practitioner	Expert	01/04/2013	01/01/2017
Mr Peter Neville	Retired European Patent Attorney	Lay	23/02/2015	
Dr David Rawlins	Retired Pharmaceutical Consultant	Lay	09/08/2016	
Dr Patricia Scott	Principal Lecturer	Expert	22/10/2013	08/03/2017
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	31/05/2016
Dr Melanie Whittick	Pharmacist	Expert	01/04/2013	

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

None

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

Name	Profession	Status	Meeting date attended
Mr Paul Hamilton	Parish Administrator	Lay Plus	11/05/2016
Dr Alan Lamont	Consultant Oncologist	Expert	14/09/2016
Professor Paula McGee	Professor of Nursing	Expert	08/06/2016
Dr Michael Schachter	Clinical Pharmacologist	Expert	11/05/2016
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	20/04/2016 PR
Mr John Aldridge	Retired Senior Lecturer In Nursing	Lay	19/07/2016 Sub- committee
Dr Ian Ross	Retired Consultant Physician	Expert	16/08/2016 Sub- committee

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Miss Ruth Barker	None declared	06/01/2017
Mr David Grayson	None declared	14/12/2016
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.	01/04/2016
Professor Barry Hunt	Trustee and Research Advisor for Ataxia UK Consultant for University of Hertfordshire and Chair of University Ethics Committee	28/03/2017
Diana Kornbrot	Emeritus Professor University of Hertfordshire. Invited referee various grants	25/10/2016
Mr Peter Neville	Wife is a shareholder in BTG plc, a company specialising in development and promotion of new healthcare/pharmaceutical products.	05/01/2017
Dr David Rawlins	Direct shareholdings in GSK, Astra Zeneca, Reneuron and Allergy Therapeutics. Indirect shareholdings via investment funds.	05/01/2017
Dr Patricia Scott	Employee of University of Hertfordshire. Programme Director, Doctorate in Health Research.	05/01/2017
Dr Ian Skidmore	Shareholdings in GSK.	05/01/2017
Ms Helen Street	Current PhD student at Cambridge University.	05/01/2017
Dr Melanie Whittick	Shares in GSK. Originally obtained when working for Glaxo Group Research as member of staff.	30/03/2017

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

Month	Date	Number of Members Present at Meeting
April	13/04/2016	7
May	11/05/2016	8
June	08/06/2016	8
July	13/07/2016	7
August	10/08/2016	7
September	14/09/2016	7
November	09/11/2016	8
December	14/12/2016	10
February	08/02/2017	7
March	08/03/2017	9

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	20/04/2016	3
May	18/05/2016	3
June	22/06/2016	3
July	20/07/2016	3
August	17/08/2016	3
September	21/09/2016	3
October	19/10/2016	3
November	23/11/2016	3
December	21/12/2016	3
February	16/02/2017	3
March	16/03/2017	3

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

### Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	12/04/2016	2
April	26/04/2016	2
May	03/05/2016	2
May	10/05/2016	2
May	24/05/2016	2
June	07/06/2016	2
June	21/06/2016	2
July	05/07/2016	2
July	19/07/2016	2
August	02/08/2016	2

August	16/08/2016	2
August	30/08/2016	2
September	13/09/2016	2
September	27/09/2016	2
October	11/10/2016	2
October	25/10/2016	2
November	08/11/2016	2
November	22/11/2016	2
December	06/12/2016	2
December	20/12/2016	2
January	03/01/2017	2
January	17/01/2017	2
January	31/01/2017	2
February	14/02/2017	2
February	28/02/2017	2
March	14/03/2017	2

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

#### Details of inquorate meeting held:01 April 2016 - 31 March 2017

None

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

Name	Number of Meetings Attended
Miss Ruth Barker	7
Mr David Grayson	9
Mrs Kornelia Hathaway	3
Professor Barry Hunt	9
Professor Diana Kornbrot	5
Mr Peter Neville	9
Dr David Rawlins	2
Dr Patricia Scott	8
Dr Ian Skidmore	10
Ms Helen Street	4
Dr Melanie Whittick	8

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

Name	Number of Meetings Attended
Miss Ruth Barker	2
Mr David Grayson	11
Mrs Kornelia Hathaway	3
Professor Barry Hunt	3
Mr Peter Neville	2
Dr Patricia Scott	2
Dr Ian Skidmore	3
Ms Helen Street	4
Dr Melanie Whittick	2

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

Name	Number of Meetings Attended
Miss Ruth Barker	3
Mr David Grayson	9
Mrs Kornelia Hathaway	3
Professor Barry Hunt	10
Professor Diana Kornbrot	3
Dr Wassim Matta	2
Mr Peter Neville	3
Dr Patricia Scott	3
Dr Ian Skidmore	10
Ms Helen Street	2
Dr Melanie Whittick	2



**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr David Grayson	09/06/2016	Consent, Payments and Voluntariness workshop
Mr David Grayson	23/09/2016	Local Training Day - Regional
Mr David Grayson	01/12/2016	National Training Day for Committee Chairs
Mrs Kornelia Hathaway	06/04/2016	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Professor Barry Hunt	27/03/2017	Training - Chairs Review Programme Workshop
Mr Peter Neville	16/02/2017	Training - National Members Training Day
Dr David Rawlins	14/03/2017	Committee Members Induction
Dr Patricia Scott	19/04/2016	Research in the ED with respondents who lack capacity to consent
Dr Patricia Scott	01/05/2016	Nuffield Council on Bioethics 2015; Children and Clinical Research
Dr Patricia Scott	23/09/2016	Local Training Day - Regional
Ms Helen Street	06/04/2016	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Dr Wassim Matta	23/09/2016	Local Training Day - Regional

## 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	11	25.58
Phase 1	9	20.93
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	23	53.49
<b>Total Applications Reviewed</b>	<b>43</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	4
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	4

**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	4	9.30
Unfavourable Opinion	0	0.00
Provisional Opinion	39	90.70
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>43</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	35	81.40
Further Information Favourable Opinion with Additional Conditions	3	6.98
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	4	9.30
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.33
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>43</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>22</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	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	6
Number of device applications reviewed	2
Number of qualitative applications reviewed	5

**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	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	1	4.55
Provisional Opinion	21	95.45
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>22</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>	4.30
<b>Number of completed applications for full ethical review</b>	43
<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 completed applications for full ethical review over 40 days</b>	7
<b>Number of completed applications over 40 days as a % of total</b>	13.95%
<b>Number of days taken to final decision – average (mean)</b>	35
<b>Number of completed proportionate review applications for ethical review</b>	21
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	4
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	19.05%
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	8
<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>	116
<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 completed substantial amendments over 28 days</b>	4
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	3.45%
<b>Number of modified amendments reviewed</b>	2
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	109

<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	9
<b>Number of annual progress reports received</b>	104
<b>Number of safety reports received</b>	33
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	35

**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>
16/EE/0097	Photo Participatory Courses Delivered at the NHS Recovery College East	59
16/EE/0146	0501 The effects of training on measures of attention and spatial bias	36
16/EE/0161	Nitrite in Hypertrophic Cardiomyopathy (HCM) Study	38
16/EE/0163	First in human study in participants with Pompe disease	38
16/EE/0164	Sense4Families	43
16/EE/0206	Study in Healthy Males to Evaluate Novel Celecoxib Formulation(117779)	37
16/EE/0214	Study to evaluate the PK Profile of PRN1008 MR formulations(QCL117643)	38
16/EE/0217	Phase I study to compare PK of tiotropium products (QCL117786)	25
16/EE/0248	MelaTools-SSM Trial	37
16/EE/0254	A study to compare 2 treatments for the maintenance of COPD	37
16/EE/0257	GMP Validation - Lipoaspiration	30
16/EE/0261	ACT774312 SADMA Study in Healthy Volunteers/ poor CYP2C9 metabolizers	35
16/EE/0297	Phase II Study of a New RIP1 Kinase Inhibitor in Moderate to Severe RA	41
16/EE/0299	PROGRAM	38
16/EE/0305	PRIMETIME	39
16/EE/0322	Understanding and Dealing with Stress (DE-STRESS)	31
16/EE/0328	Abnormal genes and proteins in oral inflammatory diseases v1	37
16/EE/0329	tVNS for episodic aggression: A feasibility and pilot study	27
16/EE/0335	ACT14604	40
16/EE/0356	TRIDENT Study	38
16/EE/0374	Hertfordshire Cohort Study HES follow-up	29
16/EE/0390	Compare PK/PD of study drug and Neulasta® at 2 mg dose (QCL115655)	29
16/EE/0403	Lifestyle and Liraglutide in NASH	33
16/EE/0475	GWEP1675 CBDV	28
16/EE/0483	Illness Perceptions In South Asian Haemodialysis Patients	36
16/EE/0491	EESIS	41
16/EE/0549	FAB in MGD (v4 - 10.02.17)	31
16/EE/0553	RAPPER III - MS	36
17/EE/0037	FCM-P version 1	39
17/EE/0056	Brain Work Recursive Therapy (BWRT) for non-complex trauma	36
17/EE/0057	Exploratory Study of V565 in Ulcerative Colitis Patient Volunteers	32
17/EE/0066	A Phase 1, food effect, bioavailability study of Sotagliflozin	26

17/EE/0097	Ad4HIV	36
17/EE/0100	The Lucy Study	45
17/EE/0101	Altura Post-Market Registry Study: Altitude Registry	42

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0216	Phase IIB study of GS-5745 in participants with Cystic Fibrosis	36
16/EE/0295	Unconscious processes between mothers with ED and their infants	36
16/EE/0492	UROLE trial	35

#### 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
16/EE/0159	Physical (autonomic) symptoms in people living with Lewy Body Dementia	28
16/EE/0388	Chemotherapy Plus Necitumumab in Squamous Non-Small Cell Lung Cancer	28
16/EE/0481	First time in human study of GSK2292767 in healthy volunteers	29
16/EE/0554	AFI-targeted confocal endomicroscopy in Barrett's oesophagus	27

#### 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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Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock
17/EE/0090	GLPG2222-CL-202 In subjects with CF, homozygous for F508del mutation	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
16/EE/0169	Does hearing loss at 4kHz affect speech discrimination in noise?	14
16/EE/0177	New Tests for Remote Monitoring of Cochlear Implants v2.0	11
16/EE/0181	Health burden of hypophosphatasia	11
16/EE/0226	COME on! - What does a wandering mind lead to? (Version 1)	14
16/EE/0227	Pancreas function, physiology, pathology and therapeutics	14
16/EE/0229	Protocol generation for future ultrasound stimulated wound healing	9
16/EE/0275	Prevalence of skin conditions and head lice in children.	14
16/EE/0319	Mindfulness and chronic pain in adolescents	11
16/EE/0321	Pregnant women and midwives' perception about using mobile apps/online	14
16/EE/0323	Diagnostic reasoning in primary care - Version 01	10
16/EE/0365	What is the best method to assess hand swelling?	14
16/EE/0368	Validation of molecular assay for foetal Rh D genotype	10
16/EE/0416	Qualitative interviews to understand the patient experience of MVA	13
16/EE/0461	Evaluation of a Patient Information Leaflet	10
16/EE/0466	Standardising outcome measures in orthodontic trials	9
16/EE/0528	Assessment of cell-free DNA in the management of retinoblastoma	13
16/EE/0560	Distal biceps tendon repair using the BicepsButton	10

17/EE/0068	MR-opt	18
17/EE/0071	Direct III	15
17/EE/0116	Odontogenic tumours as markers for WNT pathway cancers	19
17/EE/0117	m-health technologies for hearing aid users	21

#### Further Information Favourable Opinion with Additional Conditions

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

REC Reference	Title	Number of Days on Clock
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#### 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**

<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/AM22	Genes and mechanisms in type 1 diabetes in the Cambridge BioResource	20	27/09/2016	23
07/H0310/146/AM09	TNF and NFkB signalling in haematologic malignancies - version 1.2	1.13	24/11/2016	6
07/Q0106/63/AM06	Identification and Classification of Circulating Tumour Cells	6	20/09/2016	9
07/Q0106/63/AM07	Identification and Classification of Circulating Tumour Cells	7	09/12/2016	27
08/H0306/21/AM06	CHiC Translational Research in Autoimmune Disease 2 (1.0)	6	07/07/2016	13
08/H0306/32/AM08	CAMPAN 1	6	08/06/2016	27
08/H0311/120/AM33	Ipilimumab compared to placebo in stage III melanoma after surgery	22	18/04/2016	10
08/H0311/120/AM37	Ipilimumab compared to placebo in stage III melanoma after surgery	24	30/01/2017	15
09/H0311/88/AM11	Generation of patient-specific stem cells for CNS disorders	11	17/03/2016	21
10/H0310/28/AM02	A Comparison of Methods of Elevation for Lower Limb Injuries	1	16/03/2016	24
10/H0310/59/AM07	Understanding cognition and action in Pick's disease	3	30/01/2017	19
10/H0311/24/AM01	Healthy volunteer sample donation for in vitro experimentation	1	11/01/2017	18
11/EE/0196/AM02	Early life and environmental determinants of bone microarchitecture	2	10/11/2016	15
12/EE/0058/AM12	Diagnostic urine biomarkers for prostate cancer	8	11/04/2016	16
12/EE/0058/AM13	Diagnostic urine biomarkers for prostate cancer	9	14/02/2017	27
12/EE/0289/AM06	Ex-FACTOR	5	06/12/2016	13
12/EE/0307/AM05	prevalence of pathogenic antibodies in psychosis	4	22/04/2016	14
12/EE/0307/AM06	prevalence of pathogenic antibodies in psychosis	5	25/07/2016	9
12/EE/0307/AM10	prevalence of pathogenic antibodies in psychosis	6	22/11/2016	12
12/EE/0445/AM11	Preoperative intravenous iron to treat anaemia in major surgery	7	25/07/2016	14
12/EE/0525/AM03	Inflammation & Human Memory: Version 1	4	29/04/2016	9
13/EE/0199/AM19	Study of the Safety and Efficacy of Botox® for the Treatment of PE	8	08/09/2016	19
13/EE/0203/AM09	National Cohort Study of Pulmonary Arterial Hypertension	5	11/10/2016	23
13/EE/0214/AM13	A Long Term Follow-up Study of Subjects previously treated with MK5172	08	18/04/2016	9

13/EE/0214/AM15	A Long Term Follow-up Study of Subjects previously treated with MK5172	SA09	11/07/2016	20
13/EE/0214/AM18	A Long Term Follow-up Study of Subjects previously treated with MK5172	12	22/02/2017	26
13/EE/0255/AM05	Digital ulceration as an outcome measure	2	14/07/2016	9
13/EE/0312/AM18	TACTT3	D	26/07/2016	16
13/EE/0312/AM19	TACTT3	E	28/09/2016	28
13/EE/0349/AM04	Extension study for Chronic Myeloid Leukaemia	September 2015	19/04/2016	16
13/EE/0349/AM05	Extension study for Chronic Myeloid Leukaemia	May 2016	16/11/2016	28
13/EE/0431/AM12	Optimal Treatment for OCD (OTO) Version 1.0	6	24/11/2016	34
13/EE/0448/AM11	AMPACT2 - An open-label extension to the TACTT3 study	B	06/09/2016	9
14/EE/0034/AM06	VICTORY AF	4	11/11/2016	8
14/EE/0059/AM02	POST MARKET MULTICENTRIC EVALUATION OF THE AQUESYS XEN IMPLANT	2	25/08/2016	12
14/EE/0097/AM03	MIMIC	3	23/05/2016	17
14/EE/0107/AM01	Neurophysiology and Cognition Following Traumatic Brain Injury	1	17/11/2016	12
14/EE/0189/AM05	The Cognitive Ageing Nutrition and Neurogenesis (CANN) trial.	1.5	23/09/2016	22
14/EE/0219/AM04	The Orange Juice and Cardiovascular Disease Study	3	22/04/2016	14
14/EE/1040/AM02	Nuclear mitochondrial DNA mutations in acute liver failure	1	13/03/2016	8
14/EE/1047/AM04	Randomised study of Adalimumab in subjects with Crohn's Disease	3	28/03/2016	28
14/EE/1048/AM07	ESTEEM	4	27/04/2016	26
14/EE/1048/AM08	ESTEEM	5	29/09/2016	7
14/EE/1048/AM10	ESTEEM	6	27/01/2017	13
14/EE/1098/AM01	A study of novel proteins and pathways in epilepsy	1	11/05/2016	12
14/EE/1121/AM03	The Bioavailability Of sulforaphane from Broccoli Soups study(BOBS)	2	01/06/2016	16
14/EE/1126/AM03	The Babelfish Control study	4	24/06/2016	9
14/EE/1137/AM03	Cohort study investigating haemophilic arthropathy development V0.01	2	19/04/2016	20
14/EE/1221/AM02	UK Clinical Experience with Linacotide for Patients with IBS-C	2	14/06/2016	30
14/EE/1239/AM06	G3215 Single and multiple ascending dose study	5	21/12/2016	26
14/EE/1293/AM04	C-STICH	4	11/04/2016	18
15/EE/0032/AM02	Ticagrelor and Clopdogrel on IMR	14	27/07/2016	20
15/EE/0083/AM05	Validation of laser speckle contrast imaging and thermography	3	22/04/2016	13

	in SSc			
15/EE/0117/AM06	Comparison of Active Treatments For IGR:a SRFT/Hitachi trial (CATFISH)	3	06/05/2016	32
15/EE/0117/AM08	Comparison of Active Treatments For IGR:a SRFT/Hitachi trial (CATFISH)	4	17/06/2016	13
15/EE/0117/AM09	Comparison of Active Treatments For IGR:a SRFT/Hitachi trial (CATFISH)	5	02/11/2016	21
15/EE/0125/AM06	REACH: Research Exploring physical Activity in Care Homes	4	24/11/2016	7
15/EE/0135/AM02	CCD-05993AA1-07_Chiesi_COPD_TRISTAR	2	26/04/2016	17
15/EE/0135/AM04	CCD-05993AA1-07_Chiesi_COPD_TRISTAR	4	01/08/2016	16
15/EE/0193/AM01	Effect of Goldmann Applanation Tonometry on Biometry Measurements	1	22/09/2016	19
15/EE/0194/AM04	MIMOSA: Morphine in Moderate Obstructive Sleep Apnoea	2	23/11/2016	28
15/EE/0220/AM03	2015-AAR-009 Alfapump-albumin replacement therapy V1.0	1	28/06/2016	22
15/EE/0232/AM03	The effects of mixed meals on gastric emptying and lipid metabolism	2	02/11/2016	20
15/EE/0234/AM03	A Phase II Study of Pembrolizumab in Subjects with Gastric Cancer	05	20/01/2017	20
15/EE/0292/AM03	POSAG Trial: Prevalence of Obstructive Sleep Apnoea in Glaucoma	2	14/12/2016	28
15/EE/0300/AM02	Patient outcomes following complex musculoskeletal injury	1.4	25/11/2016	26
15/EE/0301/AM03	ECHO: Expanding Communications on Hemophilia-A Outcomes	22	25/10/2016	26
15/EE/0329/AM02	A Two Part study of AZD8871 in asthmatic and COPD subjects	01	20/05/2016	24
15/EE/0332/AM02	Herts and Minds: Supporting the Well-being of Looked After Children V1	2	11/04/2016	35
15/EE/0332/AM03	Herts and Minds: Supporting the Well-being of Looked After Children V1	3	20/07/2016	18
15/EE/0332/AM05	Herts and Minds: Supporting the Well-being of Looked After Children V1	4	28/07/2016	28
15/EE/0332/AM07	Herts and Minds: Supporting the Well-being of Looked After Children V1	5	17/01/2017	15
15/EE/0334/AM01	Phase II Study of PBI-4050 in Subjects with Alström Syndrome	1	31/03/2016	24
15/EE/0334/AM02	Phase II Study of PBI-4050 in Subjects with Alström Syndrome	2	22/08/2016	28
15/EE/0334/AM03	Phase II Study of PBI-4050 in Subjects with Alström Syndrome	3	09/12/2016	12
15/EE/0375/AM01	Increasing uptake of cervical screening through behavioural	1	19/05/2016	28

	insight			
15/EE/0375/AM02	Increasing uptake of cervical screening through behavioural insight	2	11/07/2016	14
15/EE/0448/AM01	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	2	23/03/2016	20
15/EE/0448/AM04	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	4	25/05/2016	14
15/EE/0448/AM08	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	6	19/08/2016	19
15/EE/0448/AM09	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	10	25/11/2016	6
15/EE/0448/AM13	CheckMate401: Nivolumab + Ipilimumab trial of subjects with melanoma	13	13/02/2017	14
15/EE/0466/AM01	A study of RO5459072 in people with coeliac disease; v1	1	29/06/2016	16
15/EE/0466/AM02	A study of RO5459072 in people with coeliac disease; v1	1	20/06/2016	24
15/EE/0485/AM01	Combined ischaemic conditioning on deceased donor renal transplants	2	13/04/2016	18
16/EE/0038/AM01	The Acceptability of Metaphors in the Management of People with MUS	01	31/05/2016	20
16/EE/0038/AM02	The Acceptability of Metaphors in the Management of People with MUS	2	21/11/2016	14
16/EE/0042/AM01	DIAGRAMS, Version 3	1	14/06/2016	22
16/EE/0049/AM02	Developing models of the human musculoskeletal system	1	16/12/2016	16
16/EE/0051/AM01	EAGLE FM	1	08/11/2016	8
16/EE/0082/AM01	Parent's experiences during transition to adolescence in Diabetes	1	27/04/2016	17
16/EE/0146/AM01	0501 The effects of training on measures of attention and spatial bias	1	26/09/2016	22
16/EE/0146/AM02	0501 The effects of training on measures of attention and spatial bias	2	19/01/2017	12
16/EE/0159/AM01	Physical (autonomic) symptoms in people living with Lewy Body Dementia	1	19/07/2016	20
16/EE/0161/AM01	Nitrite in Hypertrophic Cardiomyopathy (HCM) Study	1	02/12/2016	28
16/EE/0163/AM01	First in human study in participants with Pompe disease	1	27/09/2016	6
16/EE/0163/AM02	First in human study in participants with Pompe disease	2	27/10/2016	21
16/EE/0163/AM03	First in human study in participants with Pompe disease	3	06/02/2017	14

16/EE/0177/AM01	New Tests for Remote Monitoring of Cochlear Implants v2.0	1.0	05/10/2016	25
16/EE/0181/AM01	Health burden of hypophosphatasia	1	30/08/2016	14
16/EE/0216/AM01	Phase IIB study of GS-5745 in participants with Cystic Fibrosis	01	22/08/2016	8
16/EE/0248/AM01	MelaTools-SSM Trial	1	02/12/2016	14
16/EE/0254/AM01	A study to compare 2 treatments for the maintenance of COPD	1	03/08/2016	22
16/EE/0254/AM04	A study to compare 2 treatments for the maintenance of COPD	2	08/11/2016	21
16/EE/0261/AM02	ACT774312 SADMAD Study in Healthy Volunteers/ poor CYP2C9 metabolizers	1	20/01/2017	11
16/EE/0297/AM01	Phase II Study of a New RIP1 Kinase Inhibitor in Moderate to Severe RA	1	28/09/2016	16
16/EE/0322/AM01	Understanding and Dealing with Stress (DE-STRESS)	1	09/02/2017	20
16/EE/0329/AM01	tVNS for episodic aggression: A feasibility and pilot study	1	28/10/2016	21
16/EE/0329/AM03	tVNS for episodic aggression: A feasibility and pilot study	2	11/01/2017	17
16/EE/0335/AM02	ACT14604	4	15/02/2017	21
16/EE/0356/AM02	TRIDENT Study	2	08/02/2017	28
16/EE/0403/AM03	Lifestyle and Liraglutide in NASH	0.3	10/01/2017	15
16/EE/0475/AM02	GWEP1675 CBDV	3	06/02/2017	15
16/EE/0481/AM01	First time in human study of GSK2292767 in healthy volunteers	1	10/01/2017	6
98CN01/AM07	EPIC in Norfolk	7	08/11/2016	14

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/EE/0195/AM08	Assessment of gut peptide levels in patients with motility disorders	5	19/04/2016	15

**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
12/EE/0393/AM04/2	Cambridge-Edinburgh Human Imaging and Longitudinal Development study	6	05/05/2016	13



15/EE/0125/AM04/1	REACH: Research Exploring physical Activity in Care Homes	3	18/04/2016	14
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<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
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**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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