NHS
Health Research Authority

Research Ethics Service

East of England - Cambridge South Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	East of England - Cambridge South Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	IRB Registered, Research Involving Children
Chair:	Dr Leslie Gelling
Vice-Chair:	Dr Frank Wells from April 2016 to February 2017
Alternate Vice-Chair:	Dr Ian Dumbelton
REC Manager:	Ms Penelope Gregory from February 2017 Miss Jessica Parfrement from September 2016 to February 2017 Ms Ellen Swainston from April 2016 to September 2016
REC Assistant:	Mr Tadeusz Jones from February 2017 Ms Nicola Kohut from April 2016 to August 2016
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8097 / 0207 104 8101
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Chair's overview of the past year:

The research community has been well-served by the Cambridge South Research Ethics Committee over the past year. Members take great pride in their work and in the quality of the service provided to those submitting applications for ethical review, both applications considered at full meetings and proportionate review applications. This has been helped by continued stability in the Committee's membership. It continues to be a privilege to be the Chair of this Committee.

East of England - Cambridge South Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Richard Aldridge	Retired Lecturer	Lay Plus	21/04/2015	
Mrs Martha Byrne	Director, Clinical & Pharmacoviligance QA	Lay Plus	01/04/2011	
Miss Marilyna Chong	Pharmacist specialist - cancer services	Expert	16/03/2016	
Dr Ian Dumbelton	Retired General Medical Practitioner	Expert	01/04/2011	
Dr Leslie Gelling	Reader in Research Ethics	Expert	01/04/2011	
Mr Colin Green	Drugs & Therapeutics Pharmaceutical Advisor	Expert	01/04/2011	
Mrs Alison Hall	Programme Lead - Humanities	Lay	01/04/2011	
Dr Linda Harvey	Clinical Research Facility Consultant	Lay Plus	24/09/2015	
Mr John Kirkpatrick	Statistician	Expert	11/06/2013	
Miss Angela Palmer	Retired Patent Litigator	Lay Plus	01/04/2011	
Mrs Nikki Phillimore	Antibiotic/infection management pharmacist	Expert	01/04/2011	
Dr Michael Sheldon	Retired Clinical Psychologist	Lay	01/05/2015	
Miss Carol Smee	Regulatory and Ethical Compliance Manager	Lay	01/04/2011	
Mr Phil Tempest	Compliance Manager	Lay	01/04/2011	
Dr Frank Wells	Retired Pharmaceutical Physician	Expert	01/04/2011	27/02/2017
Dr Kate Williams	Senior Research Associate	Lay	01/04/2011	

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

Name	Profession	Status	Meeting date attended
Miss Marilyna Chong	Pharmacist specialist - cancer services	Expert	27/10/2016
Miss Marilyna Chong	Pharmacist specialist - cancer services	Expert	23/02/2017
Miss Marilyna Chong	Pharmacist specialist - cancer services	Expert	25/08/2016

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

None

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

Name	Declaration of Interest	Date
Dr Richard Aldridge	Still actively involved in personally motivated research in image processing	28/04/2016
Mrs Martha Byrne	Director, Clinical & Pharmacovigilance QA, Strategic Advice Astrazeneca Group of Companies including Medimune Science Units. Member of Good Clinical Practice (GCP) Committee Member of Research QA Association (RQA) Share options to buy AstraZeneca shares as a company employee but currently has not exercised that right so does not own shares.	31/03/2017
Dr Leslie Gelling	Reader in Nursing, Anglia Ruskin University Consultant, Clinfield. Editor, Journal of Clinical Nursing	06/12/2016
Mr Colin Green	Very occasionally asked to review studies by HRA (Health Technology Assessment) and NIHR. Unpaid role.	01/12/2016
Mrs Alison Hall	Member of Data Access Committee for METADAC. Employee of PHG Foundation - health policy think tank interested in genomics and other biomedical technologies.	01/12/2016
Dr Linda Harvey	1) Chair of the institute of food research, human research governance committee and act as the Sponsor representative for human studies undertaken by the IFR2) A member of the university of East Anglia, Faculty of Medicine and health sciences research ethics committee and chair of the associated human tissue sub-committee3) A member of the management board for the Norwich biorepository (tissue back) based at the Norfolk and Norwich university hospital	06/12/2016
Mr John Kirkpatrick	Associate Director, PPD (not Board Member).	01/12/2016
Mrs Nikki Phillimore	None declared	01/12/2016
Dr Michael Sheldon	None declared	24/11/2016
Miss Carol Smee	Member of TWIST DX Research Ethics Committee. Regulatory and Ethical Compliance Manager at Wellcome trust, Sanger Institute, Cambridge.Employer Involved in health research.Member of EMBL-EBI Research Ethics Committee (BIAC).	01/12/2016
Dr Frank Wells	None declared	01/12/2016
Dr Kate Williams	Research consultant for the charity Medical Detection Dogs (voluntary position).Volunteer for Hearing Dogs and Guide Dogs. Employee of Cambridge University, Primary Care Unit, this involves working closely with the Cambridge Clinical Trials Unit (CCTU).	01/04/2016
Mr Phil Tempest	Employed by Amgen Ltd. Owns shares in Amgen Ltd and GSK plc	01/07/2016

Miss Marilyna Chong	None declared	19/04/2016
Dr Ian Dumbelton	None declared	31/03/2017
Miss Angela Palmer	Receives a pension from GlaxoWellcome. Holds GSK Shares	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	28/04/2016	12
May	26/05/2016	14
July	28/07/2016	11
August	25/08/2016	11
September	22/09/2016	10
October	27/10/2016	11
November	24/11/2016	10
January	26/01/2017	13
February	23/02/2017	11
March	23/03/2017	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	01/04/2016	3
May	09/05/2016	4
June	13/06/2016	4
July	11/07/2016	4
August	08/08/2016	3
September	12/09/2016	4
October	10/10/2016	4
February	13/02/2017	4
March	13/03/2017	3

9 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	01/04/2016	2
April	13/04/2016	2
April	29/04/2016	2
May	12/05/2016	2
May	26/05/2016	2
June	10/06/2016	2
June	24/06/2016	2
July	08/07/2016	2
July	22/07/2016	2
August	05/08/2016	2
August	19/08/2016	2
September	02/09/2016	2

September	26/09/2016	2
September	30/09/2016	2
October	14/10/2016	2
November	07/11/2016	2
November	16/11/2016	1
December	01/12/2016	2
December	16/12/2016	2
January	06/01/2017	2
February	03/02/2017	2
February	17/02/2017	2
March	03/03/2017	2
March	17/03/2017	2
March	31/03/2017	2

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

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

None

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

Name	Number of Meetings Attended
Dr Richard Aldridge	7
Mrs Martha Byrne	8
Miss Marilyna Chong	4
Dr Ian Dumbelton	4
Dr Leslie Gelling	8
Mr Colin Green	9
Mrs Alison Hall	7
Dr Linda Harvey	7
Mr John Kirkpatrick	10
Miss Angela Palmer	9
Mrs Nikki Phillimore	6
Dr Michael Sheldon	8
Miss Carol Smee	8
Mr Phil Tempest	5
Dr Frank Wells	7
Dr Kate Williams	6

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

Name	Number of Meetings Attended
Dr Richard Aldridge	2
Mrs Martha Byrne	2
Dr Ian Dumbelton	2
Dr Leslie Gelling	9
Mr Colin Green	1
Mrs Alison Hall	1
Dr Linda Harvey	2
Mr John Kirkpatrick	3
Miss Angela Palmer	2
Mrs Nikki Phillimore	2
Dr Michael Sheldon	1
Miss Carol Smee	2
Mr Phil Tempest	2
Dr Frank Wells	1
Dr Kate Williams	1

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

Name	Number of Meetings Attended
Mrs Martha Byrne	2
Miss Marilyna Chong	1
Dr Ian Dumbelton	1
Dr Leslie Gelling	25
Mrs Alison Hall	1
Mr John Kirkpatrick	1
Dr Frank Wells	17
Dr Kate Williams	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Richard Aldridge	06/04/2016	Quantitative Research Methods and Statistics
Dr Richard Aldridge	26/10/2016	Qualitative Research and Ethical Review
Miss Marilyna Chong	23/09/2016	Members Regional Training Day
Miss Marilyna Chong	30/11/2016	Members Induction
Miss Marilyna Chong	16/02/2017	National Members Training Day
Dr Ian Dumbelton	23/09/2016	Members Regional Training Day
Mr Colin Green	13/07/2016	Equality and Diversity
Mrs Alison Hall	23/09/2016	Members Regional Training Day
Dr Linda Harvey	19/08/2016	E&D
Dr Linda Harvey	16/02/2017	National Members Training Day
Mr John Kirkpatrick	23/09/2016	Members Regional Training Day
Miss Angela Palmer	03/06/2016	NREAP/Chairs meeting
Miss Angela Palmer	23/09/2016	Members Regional Training Day
Mrs Nikki Phillimore	23/09/2016	Members Regional Training Day
Dr Michael Sheldon	23/09/2016	Members Regional Training Day
Miss Carol Smee	06/09/2016	E&D
Miss Carol Smee	07/09/2016	HRA Approval Workshop
Miss Carol Smee	28/09/2016	Sponsorship: Expectations of the HRA
Miss Carol Smee	01/03/2017	Informed Consent for Research
Miss Carol Smee	08/03/2017	Handling health-related findings in research
Mr Phil Tempest	31/01/2017	Review of revised ICH guideline for good clinical practice (E6(R2)
Dr Frank Wells	23/09/2016	Members Regional Training Day
Dr Frank Wells	01/12/2016	National Training Day for Committee Chairs
Dr Kate Williams	06/04/2016	Handling Health-Related Findings in Research

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	14	25.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.79
Research Database (including renewals)	0	0.00
Others	41	73.21
Total Applications Reviewed	**56**	**100**

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	19
Number of paediatric applications reviewed	12
Number of device applications reviewed	3
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	3
Number of qualitative applications reviewed	3

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	1.79
Unfavourable Opinion	4	7.14
Provisional Opinion	51	91.07
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**56**	**100**
Number of studies sent back to full committee meeting for final opinion	1	

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	50	89.29
Further Information Favourable Opinion with Additional Conditions	1	1.79
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	1.79
Unfavourable Opinion	4	7.14
Provisional Opinion	0	0.00
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	0	0.00
Total	**56**	**100**

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

Total Applications Reviewed	**32**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	4
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	4	12.50
Favourable Opinion with Additional Conditions	2	6.25
No Opinion transfer to full committee for review	2	6.25
Provisional Opinion	22	68.75
Unfavourable Opinion	2	6.25
Total	**32**	**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	5.60
Number of completed applications for full ethical review	56
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.79%
Number of completed applications for full ethical review over 40 days	19
Number of completed applications over 40 days as a % of total	33.93%
Number of days taken to final decision – average (mean)	38

Number of completed proportionate review applications for ethical review	29
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)	16
Number of completed proportionate review applications for ethical review over 21 days	5
Number of completed proportionate review applications over 14 days as a % of total	55.17%

Number of SSAs (non-Phase 1) reviewed	12
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%

Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%

Number of substantial amendments reviewed	141
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.42%
Number of completed substantial amendments over 28 days	11
Number of completed substantial amendments over 28 days as a % of total substantial amendments	7.80%

Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	2
Number of completed modified amendments over 14 days as a % of total modified amendments	50.00%

Number of non substantial amendments received	109

Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	28
Number of annual progress reports received	107
Number of safety reports received	78
Number of Serious Adverse Events received	1
Number of final reports received	26

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0136	Quantification of Glioma Malignancy by MRI	28
16/EE/0148	Internet interventions for adults with tinnitus	26
16/EE/0162	Tolerability and patient feedback study of a novel ulnar nerve splint	30
16/EE/0176	Traditional Approach to Management of Endometriosis (TAME) Outcomes	26
16/EE/0180	Femtosecond laser assisted cataract surgery in The NHS - Version1	31
16/EE/0184	MISSION: GliomaS	33
16/EE/0205	MISSION - Prostate	31
16/EE/0215	VR testing of entorhinal-hippocampal function in AD (VIRTECH-AD)	28
16/EE/0225	Fabry Disease: Podocyturia, Non-Invasive Predictor of Renal disease	26
16/EE/0231	Optimal Analgesia Following Metatarsal Surgery	27
16/EE/0233	DECRYPT: Delivery of Cognitive Therapy for Young People after Trauma	38
16/EE/0294	ComparIsoN oF Optimal Hypertension RegiMens (AIM HY-INFORM)	48
16/EE/0314	A comparison of strain imaging and visual assessment in stress echo	44
16/EE/0315	Metformin SGA study version 1.2	40
16/EE/0317	Mitochondrial function in patients undergoing elective hip replacement	37
16/EE/0318	Lithium versus Quetiapine in Depression (LQD study), Version 1	58
16/EE/0324	Prophylatic and Pre-emptive DLI for myeloid malignancies (PRO-DLI)	38
16/EE/0325	M15-550: Venetoclax in Relapsed/Refractory subjects with CLL	34
16/EE/0327	The role of circuit flow during mechanical ventilation of neonates	46
16/EE/0338	Metabolism after surgery v.1	49
16/EE/0355	ICE-T	34
16/EE/0357	Opicapone in clinical practice (OPTIPARK)_V1	38
16/EE/0362	Paediatric Study with Etelcalcetide in Secondary Hyperparathyroidism	34
16/EE/0380	Day and night closed-loop in young people with type 1 diabetes (DAN05)	61
16/EE/0386	The BEACON CRC Study	43
16/EE/0387	KASPAR RCT	35
16/EE/0392	A study using RM-493 in patients with POMC deficiency obesity	58
16/EE/0465	Investigation of neural basis of habit perseveration in OCD	41
16/EE/0468	BBB permeability and Neuro-Inflammation in SVD	37
16/EE/0469	PCOS OSA	39
16/EE/0471	Pituitary changes following obstetric haemorrhage: Version 1	39
16/EE/0502	Biomarkers for Hormone Therapy Response	38

16/EE/0503	A personal construct study of Medically Unexplained Symptoms	39
16/EE/0506	Short term outcomes of DCD renal transplantation	51
17/EE/0003	Gravity Study	35
17/EE/0010	Choroidal reflectance camera for the detection of congenital cataracts	36
17/EE/0028	MC-1 Status with Age Using PET	55
17/EE/0031	Preoperative planning practices and quality of Total Hip Replacements	32
17/EE/0034	Astral-3: SGI-110 versus Treatment Choice in Adults with MDS or CMML	53
17/EE/0035	pRFs & Crowding in Amblyopia	31
17/EE/0069	Cooling Study	50
17/EE/0070	Feasibility of MyHealthAvatar in Type 2 diabetes	50
17/EE/0076	The Spinal Cord Injury Move More (SCIMM) study Version 1	46
17/EE/0079	Avacopan in patients with Vasculitis	44
17/EE/0120	The role of Nicotinamide Riboside in mitochondrial biogenesis	52
17/EE/0123	Self- compassion and weight loss in clinically obese adults	32
17/EE/0124	302-Phase 3 study of ALXN1210 VS ECULIZUMAB in adult patients with PNH	55
17/EE/0126	PQR309-005_Efficacy and safety study of PQR309 in primary CNS lymphoma	39
17/EE/0128	Long-term Extension for GEN701 and GEN702	50
17/EE/0130	Is vincristine neurotoxicity related to genotype?	35

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0179	BRAcED: The BRAin tumour Early Detection study	33

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

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

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0463	CLEE011A2404. Ribociclib and Letrozole in HR+, HER- breast cancer	27

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0467	Less to Hold	27
16/EE/0505	Inequalities in access to sexual health services among young people	23
16/EE/0507	Inhaler Research V1	27
17/EE/0030	Biology of the Human Uterus in Pregnancy and Disease	27

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**

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**

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/0150	Informed Consent, What do Patients Want to Know?	18
16/EE/0152	A pilot study to evaluate a soft tissue healing model	19
16/EE/0204	Evaluation of IFU for a creatinine patient meter	15
16/EE/0207	Quality of Life in patients with an ileal anal pouch	12
16/EE/0262	Profiling the impact of the arts on the wellbeing of dementia patients	8
16/EE/0264	Increased osteoclastic activity of the acute Charcot foot	14
16/EE/0301	Parental experiences of 'PremieStart': one year on	8
16/EE/0302	Parental appraisals of injustice in the context of paediatric pain	16

16/EE/0304	Comfort and wearability of Orthodontic Mouthguards	16
16/EE/0342	Effects of weight loss on circulating extracellular vesicles. V1.	21
16/EE/0343	Partosure as a screening marker for spontaneous preterm birth	16
16/EE/0348	Predicting outcomes in contaminated abdominal wall reconstruction	17
16/EE/0395	in vitro models of human blood vessel wall dysfunction v1	31
16/EE/0397	Using hospital admission data to study life course epidemiology	19
16/EE/0400	CCN 1-3 expression by HUVEC in uremic medium	15
16/EE/0407	Home test patient questionnaire development	13
16/EE/0448	Influence and characterisation of excipients applied to human skin.	27
16/EE/0449	Older People's experience of Cognitive Behavioural Therapy	14
16/EE/0450	Hyperpolarized Xenon imaging in patients with cystic fibrosis	22
17/EE/0105	Using the 'Phase of Illness' tool in paediatric palliative care.	23
17/EE/0106	An immunological study of chronic rhinosinusitis. version 1	26

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

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0265	The impact of HIV on the treatment of anal cancer	12
16/EE/0266	Laboratory studies into the pathology of leukaemia	12
16/EE/0303	Biomarker analysis in pancreatic cancer	12
17/EE/0063	Immune responses to vaccines in African individuals (IRvax)	14

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0451	Economic impact of stroke	12
17/EE/0062	Self-management treatment for fatigue in paediatric multiple sclerosis	10

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/EE/0103	OPERATE study 0001	15
17/EE/0108	MRI quantification of body composition	14

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**

Further information response not complete		
REC Reference	**Title**	**Number of Days on Clock**

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0208	A survey of life experiences and stool sample for IBD patients	12

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**
03/5/076/AM07	UK National Acromeglay database	8	13/07/2016	9
04/5/025/AM16	Recombinant growth hormone treatment in children born SGA version numb	16	09/01/2017	9
07/H0305/61/AM17	The FEMCO Study v1.0	12	01/12/2016	21
09/H0305/84/AM06	1199.26 study of BIBF vs sunitinib in RCC.	SA#3	01/07/2016	7
10/H0305/1/AM18	Multicentre study to determine Predictive and Prognostic Biomarkers	SA7	15/03/2016	26
10/H0305/1/AM21	Multicentre study to determine Predictive and Prognostic Biomarkers	8	08/08/2016	30
10/H0305/34/AM21	Phase 3: SGN-35 and BSC vs placebo and BSC in Hodgkin Lymphoma V1	14	04/10/2016	7
11/EE/0250/AM09	Monitoring Plasma Tumour DNA in Colorectal Cancer (ver 1)	8	27/05/2016	17
11/EE/0250/AM10	Monitoring Plasma Tumour DNA in Colorectal Cancer (ver 1)	Substantial	14/09/2016	17

		Amendment 9		
11/EE/0291/AM23	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	SA - PIS/ICF v10	21/03/2016	4
11/EE/0291/AM24	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	SA IBv12 update	31/01/2017	8
11/EE/0368/AM04	MUST FS	SA3	10/11/2016	5
11/EE/0483/AM12	BO25430 - Trastuzumab Emtansine (T-DM1) Extension Study	SA8	26/05/2016	18
11/EE/0483/AM16	BO25430 - Trastuzumab Emtansine (T-DM1) Extension Study	12	25/01/2017	9
11/H0305/1/AM02	Memory biases in clinical depression and PTSD (MNEMONICS)	2	19/06/2016	35
12/EE/0036/AM17	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	6	28/09/2016	14
12/EE/0036/AM18	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	SA#07 IB Update	15/02/2017	6
12/EE/0089/AM17	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	SA 8.0 - ICD update version 7	13/07/2016	9
12/EE/0089/AM18	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	SA#08 IB update	07/02/2017	15
12/EE/0172/AM03	A study of common and rare genetic variants associated with thinness.	SA2	17/03/2016	20
12/EE/0172/AM04	A study of common and rare genetic variants associated with thinness.	SA#03	06/02/2017	21
12/EE/0271/AM11	SIOP CNS GCT II	SA10	13/06/2016	14
12/EE/0458/AM03	Parents and Young Children under Extreme Stress (PYCES)	Amendment 3, 19.04.16	20/04/2016	22
12/EE/0492/AM11	ARISE (Acid Lipase Replacement Investigating Safety and Efficacy)	SA7	07/04/2016	22
12/EE/0492/AM12	ARISE (Acid Lipase Replacement Investigating Safety and Efficacy)	8	10/08/2016	28
13/EE/0165/AM02	Evaluation of Arterial Inflammation and Function in OSAHS and COPD.	SA2	06/04/2016	18
13/EE/0262/AM01	PROsPeCTs: Promoting recovery from PTSD in Children and Teenagers	SA1	20/04/2016	15
13/EE/0314/AM02	Functional Outcomes Following Anal Cancer Treatment (FOFACT)	2	27/07/2016	31
13/EE/0325/AM17	NIHR BioResource - Rare Diseases	SA13	22/03/2016	15

13/EE/0325/AM18	NIHR BioResource - Rare Diseases	SA - Amendment 14, 10/06/2016	10/06/2016	14
13/EE/0325/AM20	NIHR BioResource - Rare Diseases	15	19/10/2016	14
13/EE/0325/AM22	NIHR BioResource - Rare Diseases	16	02/02/2017	14
13/EE/0367/AM17	BI 655066 in patients with Crohn's disease.	SA7	16/03/2016	19
13/EE/0415/AM05	Glucose Lowering In Non-diabetic hyperglycaemia Trial (GLINT)	SA 4	01/04/2016	12
13/EE/0418/AM05	PANDA RCT	SA4	21/03/2016	14
14/EE/0069/AM01	Biomarkers of malignancy from pancreatic cysts	SA - Protocol v7 20.01.16	24/02/2016	23
14/EE/0103/AM08	Evaluation of brain 5-HT2C density with PET	3	28/10/2016	7
14/EE/0105/AM08	EORTC 26101	UK08	18/05/2016	14
14/EE/0108/AM08	An evaluation of a water fluoridation scheme in Cumbria	SA6	11/04/2016	21
14/EE/0141/AM01	DREAM GLP-1 Study	SA 1.0	25/03/2016	9
14/EE/0179/AM07	CaNCaP02 - CAmbridge Neoadjuvant CAncer of the Prostate Study 2	SA07	06/06/2016	23
14/EE/0179/AM08	CaNCaP02 - CAmbridge Neoadjuvant CAncer of the Prostate Study 2	8	22/11/2016	22
14/EE/1059/AM01	Genomic Analyses of Endocrine and Neuroendocrine tumours	Version 4 - 12.04.16	12/04/2016	27
14/EE/1063/AM09	AZD9291 v chemotherapy in NSCLC, following EGFR TKI therapy (AURA3)	SA#06	24/03/2017	13
14/EE/1100/AM07	MelaTools-eCDS	SA#4	04/04/2016	8
14/EE/1112/AM09	100,000 Genomes Project Bioresource - main phase	SA9	08/04/2016	22
14/EE/1112/AM10	100,000 Genomes Project Bioresource - main phase	2.6	01/07/2016	18
14/EE/1112/AM11	100,000 Genomes Project Bioresource - main phase	SA11	15/07/2016	18
14/EE/1112/AM12	100,000 Genomes Project Bioresource - main phase	12	17/10/2016	13
14/EE/1112/AM13	100,000 Genomes Project Bioresource - main phase	13	13/01/2017	18
14/EE/1112/AM14	100,000 Genomes Project Bioresource - main phase	SA#14	27/03/2017	7
14/EE/1165/AM08	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects	SA07	17/03/2016	18
14/EE/1165/AM10	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects	SA08 - Temporary Halt	26/05/2016	18
14/EE/1165/AM12	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects	Substantial Amendment 10	02/09/2016	41
14/EE/1165/AM14	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1,	12	21/02/2017	13

	GT2 and GT3 Infected Subjects			
14/EE/1203/AM09	B1481045 Phase III Study of PF-04950615 & Hyperlipidemia/Dyslipidemia.	SA4	06/04/2016	22
15/EE/0014/AM02	CAM-PLEX	SA4	22/03/2016	28
15/EE/0014/AM03	CAM-PLEX	SA#5	29/11/2016	15
15/EE/0019/AM02	Endotoxemia and unexplained inflammation in haemodialysis	SA#2	19/05/2016	13
15/EE/0077/AM04	AXAFA – AFNET 5	23.01.2017	23/01/2017	11
15/EE/0078/AM06	TPP1 Extension	3	22/08/2016	27
15/EE/0078/AM08	TPP1 Extension	SA#04	22/02/2017	8
15/EE/0098/AM01	Apoptotic cells in autoimmune rheumatic disease	2.0	27/07/2016	26
15/EE/0100/AM05	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2, and GT4 Infected Subjects	SA04	06/04/2016	28
15/EE/0100/AM06	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2, and GT4 Infected Subjects	SA05	21/07/2016	15
15/EE/0124/AM01	The accuracy of tests of Eustachian tube function	1	20/10/2016	14
15/EE/0126/AM05	Aldoxorubicin Compared to Investigator's Choice in Soft Tissue Sarcoma	SA1	04/05/2016	22
15/EE/0130/AM15	Phase 3 study in patients with lung infections - protocol INS-212	Substantial Amendment 10	21/09/2016	28
15/EE/0130/AM16	Phase 3 study in patients with lung infections - protocol INS-212	SA#11	06/01/2017	16
15/EE/0132/AM02	Understanding Consequences	SA2	24/03/2016	20
15/EE/0132/AM04	Understanding Consequences	SA2	10/10/2016	6
15/EE/0161/AM08	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	SA3	04/04/2016	9
15/EE/0161/AM10	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	SA#4	26/04/2016	16
15/EE/0161/AM12	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	5	04/08/2016	20
15/EE/0161/AM13	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	sa#6	11/01/2017	9
15/EE/0161/AM14	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	SA7	24/01/2017	28
15/EE/0200/AM02	Brain function for age curves in UK infants	3	15/08/2016	27
15/EE/0253/AM01	The Natural History of Malaria V.1	SA1	16/11/2016	14
15/EE/0253/AM02	The Natural History of Malaria V.1	Substantial	08/03/2017	7

		Amendment 2		
15/EE/0261/AM07	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	SA - Amendment 7	18/07/2016	22
15/EE/0261/AM08	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	SA10	24/05/2017	13
15/EE/0261/AM10	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	11	17/01/2017	17
15/EE/0302/AM04	Monaleesa 3 CLEE011F2301 ribiciclib/placebo + fulvestrant	SA1	18/04/2016	23
15/EE/0302/AM05	Monaleesa 3 CLEE011F2301 ribiciclib/placebo + fulvestrant	Substantial Amendment 2	28/07/2016	34
15/EE/0307/AM04	TASTE	SA2	31/03/2016	17
15/EE/0308/AM06	Alcohol Dependence and Adherence to Medicine (ADAM)	Substantial Amendment 4	05/09/2016	27
15/EE/0308/AM08	Alcohol Dependence and Adherence to Medicine (ADAM)	SA05	28/02/2017	7
15/EE/0345/AM04	Antiseptic Randomised Controlled Trial for Insertion of Catheters v1.0	3	18/11/2016	13
15/EE/0350/AM07	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	SA04	01/04/2016	12
15/EE/0350/AM11	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	Substantial Amendment 6	20/09/2016	17
15/EE/0350/AM12	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	SA#7	11/01/2017	9
15/EE/0352/AM03	Study of CT-P10 in patients with Low Tumour Burden Follicular Lymphoma	2	01/06/2016	13
15/EE/0352/AM04	Study of CT-P10 in patients with Low Tumour Burden Follicular Lymphoma	3	05/09/2016	30
15/EE/0353/AM02	PCYC-1137-CA	SA2	21/04/2016	21
15/EE/0353/AM03	PCYC-1137-CA	3	16/09/2016	12
15/EE/0353/AM05	PCYC-1137-CA	SA5	15/02/2017	20
15/EE/0355/AM02	Revusiran in patients with TTR-mediated FAP	SA2	12/04/2016	17
15/EE/0355/AM04	Revusiran in patients with TTR-mediated FAP	SA03	06/10/2016	32
15/EE/0355/AM05	Revusiran in patients with TTR-mediated FAP	4	14/10/2016	19
15/EE/0366/AM04	Myasthenia Gravis Development of a PRO Strategy	SA1	04/04/2016	17
15/EE/0412/AM01	HAUS Study - Phase II	SA1	18/03/2016	7
15/EE/0429/AM01	Safety and Feasibility of CPET in Head and Neck Cancer Patients	SA1	10/03/2016	20

15/EE/0435/AM06	STOP-HCV-1 version 1.0	Amendment 3	13/04/2016	15
15/EE/0435/AM09	STOP-HCV-1 version 1.0	5	26/10/2016	12
15/EE/0442/AM02	Phase III Study of AG-221 in Late Stage AML with IDH2 mutation	1	21/12/2016	20
16/EE/0008/AM02	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	SA - Protocol Amendment 1	10/06/2016	17
16/EE/0008/AM03	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	Substantial Amendment 2	08/08/2016	33
16/EE/0008/AM04	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	2	21/12/2016	19
16/EE/0022/AM01	Implementation of an online relatives toolkit (IMPART study)	Substantial Amendment 1 - 22/8	22/08/2016	22
16/EE/0023/AM01	Estimating the loss in quality of life of people with asthma.	Substantial Amendment 1.0	16/05/2016	10
16/EE/0053/AM02	AdDIT Follow Up	SA2	12/01/2017	18
16/EE/0058/AM01	Scale-up BP: Evaluation	SA1	12/05/2016	15
16/EE/0058/AM02	Scale-up BP: Evaluation	2	15/08/2016	28
16/EE/0071/AM01	Unravel MGUS	Substantial Amendment 1	22/09/2016	34
16/EE/0071/AM02	Unravel MGUS	2	12/12/2016	9
16/EE/0073/AM01	IOP response to a short-term application of CPAP	SA1	15/12/2016	9
16/EE/0130/AM02	3854 - onsetÂ® 5 insulin pump study	1	10/10/2016	25
16/EE/0132/AM01	Novartis ph3: Secukinumab response in Psoriatic Arthritis using PDUS	1	16/08/2016	56
16/EE/0162/AM01	Tolerability and patient feedback study of a novel ulnar nerve splint	11.01.2017	11/01/2017	23
16/EE/0215/AM01	VR testing of entorhinal-hippocampal function in AD (VIRTECH-AD)	1	12/10/2016	18
16/EE/0215/AM02	VR testing of entorhinal-hippocampal function in AD (VIRTECH-AD)	2	09/12/2016	9
16/EE/0233/AM01	DECRYPT: Delivery of Cognitive Therapy for Young People after Trauma	1	01/03/2017	17
16/EE/0318/AM01	Lithium versus Quetiapine in Depression (LQD study), Version 1	2.0	26/09/2016	29
16/EE/0318/AM02	Lithium versus Quetiapine in Depression (LQD study), Version 1	3	06/12/2016	20

16/EE/0357/AM05	Opicapone in clinical practice (OPTIPARK)_V1	SA02	04/01/2017	14
16/EE/0380/AM01	Day and night closed-loop in young people with type 1 diabetes (DAN05)	SA#01	01/03/2017	6
16/EE/0387/AM03	KASPAR RCT	SA#01	27/02/2017	16
16/EE/0449/AM01	Older People's experience of Cognitive Behavioural Therapy	SA1	16/12/2016	10
16/EE/0463/AM01	CLEE011A2404. Ribociclib and Letrozole in HR+, HER- breast cancer	SA01	31/01/2017	16
97/5/001/AM27	The Million Women Study	Amendment 29 (substantial)	14/03/2016	20
97/5/001/AM28	The Million Women Study	SA30	22/04/2016	20
97/5/001/AM29	The Million Women Study	31	12/10/2016	19
97/5/001/AM31	The Million Women Study	SA#32	22/02/2017	7
97/5/007/AM36	UKFOCSS UK Familial Ovarian Cancer Screening Study	Researcher Amendment #29	01/06/2016	11
98/5/027/AM20	Epidemiological study of BRCA1 and BRCA2 mutation carriers	SA#21	15/03/2017	8

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/EE/1063/AM06	AZD9291 v chemotherapy in NSCLC, following EGFR TKI therapy (AURA3)	SA5	02/05/2016	20
15/EE/0130/AM14	Phase 3 study in patients with lung infections - protocol INS-212	SA#9	15/04/2016	27
15/EE/0255/AM01	Molecular Imaging of Multiple Sclerosis (MIMS) v1.1	1	05/08/2016	28
15/EE/0298/AM02	LuCID: Lung Cancer Indicator Detection	1	01/07/2016	14
16/EE/0032/AM01	ANTLER	Substantial Amendment 1 - 22/2	22/02/2016	25
16/EE/0266/AM01	Laboratory studies into the pathology of leukaemia	SA#01	14/03/2017	7

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

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/EE/0130/AM14/1	Phase 3 study in patients with lung infections - protocol INS-212	MA of SA#9	09/06/2016	8
15/EE/0255/AM01/1	Molecular Imaging of Multiple Sclerosis (MIMS) v1.1	Mod1 of SA1	15/11/2016	1
15/EE/0298/AM02/1	LuCID: Lung Cancer Indicator Detection	Mod SA1	13/10/2016	21
16/EE/0032/AM01/1	ANTLER	2	22/02/2016	18

Unfavourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0380	Day and night closed-loop in young people with type 1 diabetes (DAN05)	61

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/EE/0395	in vitro models of human blood vessel wall dysfunction v1	31
16/EE/0448	Influence and characterisation of excipients applied to human skin.	27
16/EE/0450	Hyperpolarized Xenon imaging in patients with cystic fibrosis	22
17/EE/0105	Using the 'Phase of Illness' tool in paediatric palliative care.	23
17/EE/0106	An immunological study of chronic rhinosinusitis. version 1	26

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
14/EE/1165/AM12	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects	S/A 10	02/09/2016	41
16/EE/0132/AM01	Novartis ph3: Secukinumab response in Psoriatic Arthritis using PDUS	1	16/08/2016	56

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
15/EE/0298/AM02/1	LuCID: Lung Cancer Indicator Detection	Mod SA1	13/10/2016	21
16/EE/0032/AM01/1	ANTLER	2	22/02/2016	18