

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

Annual Report

01 April 2015 - 31 March 2016



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
Alternate Vice-Chair:	Dr Ian Dumbelton
REC Manager:	Ms Ellen Swainston from 1 February 2016 Ms Penelope Gregory to 31 January 2016
REC Assistant:	Miss Nicola Kohut
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	
Email:	nrescommittee.eastofengland-cambridgesouth@nhs.net

Chair's overview of the past year:

East of England - Cambridge South Research Ethics Committee Membership

Name	Profession	Expert or	Dates
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		Lay	Appointed	Left
Dr Richard Aldridge	Retired Lecturer	Lay Plus	21/04/2015	
Mrs Martha Byrne	Director, Clinical & Pharmacovigilance QA	Lay Plus	01/04/2011	
Dr Ian Dumbelton	Retired General Medical Practitioner (Alternate Vice-Chair)	Expert	01/04/2011	
Dr Leslie Gelling	(Chair) 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	Head of Scientific Support	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	(Vice-Chair) Retired Pharmaceutical Physician	Expert	01/04/2011	
Dr Kate Williams	Senior Research Associate	Lay	01/04/2011	
Dr Rashid Zaman	Consultant Psychiatrist and Director of Bedfordshire Centre for Mental Health Research	Expert	01/04/2011	18/02/2016

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

Name	Profession	Status	Meeting date attended
Miss Poonam Dhokia	Medicines Information Pharmacist	Expert	28/05/2015
Miss Poonam Dhokia	Medicines Information Pharmacist	Expert	26/11/2015 (Left on 31/12/2015)
Miss Poonam Dhokia	Medicines Information Pharmacist	Expert	27/08/2015
Miss Marilyna Chong	Pharmacist specialist - cancer services	Expert	Appointed 16/03/2016

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

Name	Profession	Status	Meeting date attended
Dr Rebecca Harmston	Scientific Officer	Lay Plus	24/09/2015

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

Name	Declaration of Interest	Date
Dr Richard Aldridge	Still participates in research that is loosely associated with techniques involved in medical imaging but is no longer a team member of any group working directly on a NHS sponsored grant.	11/05/2015
Mrs Martha Byrne	I am currently working for Astra Zeneca within the Quality Function with oversight of Phase I-IV Research activities. I provide strategic advice to Early Clinical Development and Vendor Management. I am independent of R&D activities and not responsible for operational activities. My role provides oversight of the Regulations for Pharmaceutical Development and Research activities. I am currently Director, Clinical & Pharmacovigilance QA, Strategic Advice Limited share options with AZ (this gives me an option to buy shares) EQAC (European QA Confederation) – Rapporteur for review of EMA legislation and other guidance on behalf of QA societies across Europe since 2011 Addenbrookes Hospital NHS Foundation Trust Cambridge Public Member since 2006 RQA GCP Committee Member since 2003 (RQA – Research Quality Assurance Association providing advice and training for members involved in Research and Development) RQA Member since 1991	28/03/2016
Miss Marilyn Chong	None declared	29/03/2016
Dr Ian Dumbelton	None declared	24/03/2016
Dr Leslie Gelling	Reader in Nursing at Anglia Ruskin University Member of the Royal College of Nursing	24/03/2016
Mr Colin Green	None declared	24/03/2016
Mrs Alison Hall	Head of Humanities, PHG Foundation. This is a charity interested in new genomic technologies as translated into health care. Member of METADAC - data access committee with oversight over data access to longitudinal cohort studies. Chair of Lexicon Task Team for Global Alliance for genomics and Health (GA4GH)	29/03/2016
Dr Linda Harvey	Chair of the Institute of Food Research, Human Research Governance Committee and act as sponsor's representative for human studies undertaken by the IFR. A member of University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee and chair of associated human tissue sub-committee	24/03/2016
Mr John Kirkpatrick	Employee, PPD Global	23/03/2016
Miss Angela Palmer	Holder of GSK shares. Receives pension from GSK	24/03/2016
Mrs Nikki Phillimore	None declared	24/03/2016
Dr Michael Sheldon	None declared	24/03/2016

Miss Carol Smee	Member of TwistDx Research Ethics Committee, Babraham Research Park, Cambridge. Regulatory and Ethical Compliance manager at the Wellcome Trust Sanger Institute, Cambridge.	29/03/2016
Dr Frank Wells	Lead advisor to the Health Research Authority on Integrity, Fraud and Misconduct. Lay member of the University of East Anglia Ethics Committee	31/03/2016
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).	30/03/2016
Mr Phil Tempest	Employed by Amgen Ltd. Owns shares in Amgen Ltd and GSK plc	18/03/2016

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

Month	Date	Number of Members Present at Meeting
April	23/04/2015	10
May	28/05/2015	9
July	23/07/2015	10
August	27/08/2015	11
September	24/09/2015	12
October	22/10/2015	14
November	26/11/2015	12
January	28/01/2016	13
February	25/02/2016	10
March	24/03/2016	11

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	13/04/2015	5
May	11/05/2015	3
June	08/06/2015	4
July	13/07/2015	3
August	10/08/2015	3
September	14/09/2015	4
October	12/10/2015	4
November	09/11/2015	4
December	14/12/2015	4
January	11/01/2016	4
February	08/02/2016	4
March	14/03/2016	3

12 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	01/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	23/07/2015	2

August	07/08/2015	2
August	21/08/2015	2
September	04/09/2015	2
September	18/09/2015	2
October	01/10/2015	2
October	16/10/2015	2
October	30/10/2015	2
November	13/11/2015	2
November	27/11/2015	2
December	03/12/2015	2
December	11/12/2015	2
December	22/12/2015	2
January	08/01/2016	2
January	22/01/2016	2
February	05/02/2016	2
February	19/02/2016	2
March	04/03/2016	2
March	08/03/2016	2
March	18/03/2016	2

28 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 Richard Aldridge	7
Mrs Martha Byrne	5
Miss Poonam Dhokia	3
Dr Ian Dumbelton	5
Dr Leslie Gelling	10
Mr Colin Green	9
Mrs Alison Hall	9
Dr Linda Harvey	5
Mr John Kirkpatrick	8
Miss Angela Palmer	9
Mrs Nikki Phillimore	7
Dr Michael Sheldon	6
Miss Carol Smee	7
Mr Phil Tempest	4
Dr Frank Wells	8
Dr Kate Williams	6
Dr Rashid Zaman	5

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

Name	Number of Meetings Attended
Mrs Martha Byrne	3
Miss Poonam Dhokia	2
Dr Ian Dumbelton	2
Dr Leslie Gelling	11
Mr Colin Green	2
Mrs Alison Hall	3
Mr John Kirkpatrick	2
Miss Angela Palmer	3
Mrs Nikki Phillimore	2
Dr Michael Sheldon	1
Miss Carol Smee	5
Mr Phil Tempest	2
Dr Frank Wells	3
Dr Kate Williams	3
Dr Rashid Zaman	1

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

Name	Number of Meetings Attended
Dr Ian Dumbelton	1
Dr Leslie Gelling	28
Dr Frank Wells	27

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Richard Aldridge	25/09/2015	HRA Regional Training Day
Dr Richard Aldridge	04/11/2015	Committee Members Induction Training
Mrs Martha Byrne	17/07/2015	Safety Reporting in Clinical Research, Adverse Events
Mrs Martha Byrne	27/07/2015	ENT-BIO-002 Global Bioethics Policy Awareness CBT
Mrs Martha Byrne	10/08/2015	Data Privacy
Mrs Martha Byrne	20/11/2015	AZ Code of Conduct Re-certification
Mrs Martha Byrne	08/12/2015	ENT COC 014 AZ Code of Conduct and Ethical Interactions
Dr Ian Dumbelton	13/01/2016	Assessing the consequences (benefits and harms) of research: A HRA workshop
Dr Leslie Gelling	26/05/2015	NREAP Meeting
Mr Colin Green	26/10/2015	Equality and Diveristy
Mr Colin Green	26/10/2015	Reading - The Haug Paper
Mr Colin Green	26/10/2015	Reading: Article by GS Williams
Mrs Alison Hall	25/09/2015	Members Regional Training Day
Dr Linda Harvey	30/11/2015	Improving healthcare through clinical research
Dr Linda Harvey	11/12/2015	Informed Consent in a Digital Age
Dr Linda Harvey	18/02/2016	National Members Training Day
Dr Linda Harvey	11/03/2016	Genetic and Genomic Research
Miss Angela Palmer	22/07/2015	HRA Qualitative Research & Ethical Review
Mrs Nikki Phillimore	25/09/2015	Members Regional Training Day
Miss Carol Smee	05/10/2015	Training - Equality and Diversity - elearning module
Mr Phil Tempest	23/10/2015	Review of Europeans Medicines Agency
Mr Phil Tempest	23/10/2015	Review of European Medicines Agency document Guideline for good clinical practice E6 (R2)
Mr Phil Tempest	23/10/2015	Review of Ethical considerations for clinical trials
Dr Frank Wells	26/05/2015	NREAP Meeting
Dr Frank Wells	02/07/2015	Equality & Diversity
Dr Frank Wells	09/12/2015	National Training Day for Committee Chairs
Dr Kate Williams	25/09/2015	Regional Members Training Day
Dr Kate Williams	03/12/2015	Pragmatic or Point of Care Trials

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	18	31.58
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	39	68.42
Total Applications Reviewed	57	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	5
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	1
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	1	1.75
Favourable Opinion with Additional Conditions	2	3.51
Unfavourable Opinion	5	8.77
Provisional Opinion	49	85.96
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	57	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	48	84.21
Further Information Favourable Opinion with Additional Conditions	1	1.75
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.75
Favourable Opinion with Additional Conditions	2	3.51
Unfavourable Opinion	5	8.77
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	57	100

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

Total Applications Reviewed	36
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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	4
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	5
Number of qualitative applications reviewed	5

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	3	8.33
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	2	5.56
Provisional Opinion	29	80.56
Unfavourable Opinion	2	5.56
Total	36	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	5.70
Number of completed applications for full ethical review	57
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	8
Number of completed applications over 40 days as a % of total	14.04%
Number of days taken to final decision – average (mean)	33
Number of completed proportionate review applications for ethical review	34
Number of completed proportionate review applications for ethical review over 14 days	5
Number of completed proportionate review applications over 14 days as a % of total	14.71%
Number of SSAs (non-Phase 1) reviewed	14
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	146
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.68%
Number of modified amendments reviewed	7
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	125
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	36
Number of annual progress reports received	140

Number of safety reports received	73
Number of Serious Adverse Events received	0
Number of final reports received	24

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/0132	Understanding Consequences	28
15/EE/0152	Regenerative cellular therapies, physiology, pathology and development	28
15/EE/0154	Talking about suicide: Investigating institutional risk assessments	46
15/EE/0160	Overeating study	32
15/EE/0161	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	31
15/EE/0175	Quality assessment of human kidneys by ex-vivo normothermic perfusion	35
15/EE/0200	Brain function for age curves in UK infants	35
15/EE/0201	Circulating Factors in Pulmonary Hypertension	38
15/EE/0204	Safety and efficacy of PVDF (DynaMesh@SIS soft) retropubic slings.	40
15/EE/0209	Evaluation of Clinical Outcomes after the use of SYSTANE HYDRATION	45
15/EE/0255	Molecular Imaging of Multiple Sclerosis (MIMS) v1.1	30
15/EE/0261	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	32
15/EE/0268	(duplicate) Older People's Experience of Urgent and Emergency Care	35
15/EE/0269	IMPACT-CTO STUDY	47
15/EE/0273	Changes in ocular signs and symptoms in patients with ocular hypertension or open-angle glaucoma	32
15/EE/0298	LuCID: Lung Cancer Indicator Detection	33
15/EE/0302	Monaleesa 3 CLEE011F2301 ribiciclib/placebo + fulvestrant	35
15/EE/0307	TASTE	33
15/EE/0308	Alcohol Dependence and Adherence to Medicine (ADAM)	31
15/EE/0341	OPUS-MEN	55
15/EE/0345	Antiseptic Randomised Controlled Trial for Insertion of Catheters v1.0	24
15/EE/0350	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	22
15/EE/0352	Study of CT-P10 in patients with Low Tumour Burden Follicular Lymphoma	35
15/EE/0353	PCYC-1137-CA	34
15/EE/0355	Revusiran in patients with TTR-mediated FAP	24
15/EE/0377	MISSION-liver v1.0	38
15/EE/0378	MISSION-ovary	35
15/EE/0380	On the legal regulation of sex work	37



15/EE/0388	GS-US-370-1296, Study of Gemcitabine& Nab-paclitaxel	38
15/EE/0400	Cryotherapy following rotator cuff repair version 1	32
15/EE/0412	HAUS Study - Phase II	41
15/EE/0426	Exploring patients' experiences of Open Access Follow Up (version 2.0)	37
15/EE/0435	STOP-HCV-1 version 1.0	40
15/EE/0442	Phase III Study of AG-221 in Late Stage AML with IDH2 mutation	30
16/EE/0008	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	28
16/EE/0023	Estimating the loss in quality of life of people with asthma.	29
16/EE/0028	ABROGATE	28
16/EE/0032	ANTLER	39
16/EE/0033	HPF burden of illness Observational patient diary study	26
16/EE/0052	OPUS-DI	27
16/EE/0064	Patient support needs tool for COPD (SNAP1)	39
16/EE/0071	Unravel MGUS	42
16/EE/0073	IOP response to a short-term application of CPAP	33
16/EE/0074	The impact of CPAP on nocturnal IOP	28
16/EE/0096	POSTDIL-STEMI	44
16/EE/0102	Observational Study of Small Fibre Neural Assessment in Diabetes V1.0	33
16/EE/0130	3854 - onsetÂ® 5 insulin pump study	30
16/EE/0132	Novartis ph3: Secukinumab response in Psoriatic Arthritis using PDUS	31

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0103	The Human Vertebral Endplate: biomechanical study in spinal disorders	42

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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15/EE/0253	The Natural History of Malaria V.1	25
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0374	Developing primary care services for stroke: Qualitative studies	28
16/EE/0053	AddIT Follow Up	26

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EE/0150	Bioavailability of dietary antioxidants in volunteers	27
15/EE/0275	Prognostic markers in kidney transplantation	28
15/EE/0430	Prediction of response to Neoadjuvant therapy in rectal cancer	27
16/EE/0034	Prediction and Assessment of Response to Therapy in Rectal Cancer	22
16/EE/0079	Nutrikinetics of dietary antioxidants in volunteers	26

Provisional Opinion

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

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

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

REC Reference	Title	Number of Days on Clock
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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/0168	Volar plate injury: a comparison of two splinting methods (Version 1)	10
15/EE/0172	Mobile Technology for Nutrition Assessment in AMD (MANAGER2)	9
15/EE/0203	Identification of biomarkers for monitoring prostate cancer	14
15/EE/0205	Gastropanel *for early detection of gastric atrophy and gastric cancer	11
15/EE/0208	Healthcare Professionals using Clinical Holding with Children	8
15/EE/0237	Six Minute Walk Test and post-operative morbidity	10
15/EE/0241	S-CORT: Stratification in COloRectal cancer:	11
15/EE/0285	Validation of RMNST against the PG-SGA for adult oncology outpatients	10
15/EE/0291	Post-op Pain and QoR after day surgery version 1.0	10
15/EE/0313	Sound feedback and body image in Complex Regional Pain Syndrome	14
15/EE/0314	Comparison of antibiotic MIC amongst C diff strains	14
15/EE/0362	Laboratory evaluation of a blood test for measuring free light chains	11
15/EE/0364	Investigating Attitudes towards HIV Pre-Exposure Prophylaxis (PrEP)	15
15/EE/0366	Myasthenia Gravis Development of a PRO Strategy	12
15/EE/0393	STRAT-PD	19
15/EE/0395	Scottish Adherence to Antihypertensive Medication in the Elderly	8
15/EE/0396	CDG testing protocol development using dried blood spots	12
15/EE/0427	Serial Monitoring of Salivary EBV in Multiple Sclerosis v1.0	10
15/EE/0429	Safety and Feasibility of CPET in Head and Neck Cancer Patients	9
15/EE/0475	PTP1B Inhibition: A new target in the treatment of atherosclerosis	16
15/EE/0476	Acceptability of home-based high-intensity interval training	13
16/EE/0019	Preventing Physical Health Illnesses in Mental Health	10
16/EE/0020	Understanding Interprofessional Relationships within a stroke team.	13
16/EE/0021	Comparison of gait analysis of Total and Hemi knee replacement surgery	14
16/EE/0022	Implementation of an online relatives toolkit (IMPART study)	15
16/EE/0057	Patient-practitioner interactions in type 2 diabetes	12
16/EE/0058	Scale-up BP: Evaluation	13

16/EE/0059	Interest and use of technology by individuals with SMI	11
16/EE/0121	Isolation and identification of spiked cancer cells in HNV blood	17

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
15/EE/0163	AKI-Diagnostics	7
15/EE/0207	Preceding paraneoplastic encephalitis in ovarian cancer	6
16/EE/0056	Anaesthetic technique and lung cancer outcomes	12

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
16/EE/0120	Prevalence of sleep disturbance in HIV adult population, Version 1	11
16/EE/0123	PanDA Pancreatic cancer Dietary Assessment study	11

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

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

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
03/5/059/AM11	RESCUEicp study	SA 19/08/2015 Version 6	19/08/2015	20
03/5/071/AM12	The Million Women Study: Disease Susceptibility in Women	SA#17	12/08/2015	8
04/MRE05/50/AM06	DECIPHER-database of submicroscopic chromosome imbalance & phenotype	6.0	23/11/2015	18
05/MRE05/7/AM18	Depolarisations in acute brain injury	Amendment 17	26/02/2016	7
06/MRE05/39/AM28	HiLo	SA 12	24/07/2015	16
07/H0305/61/AM16	The FEMCO Study v1.0	Amendment 11	29/02/2016	21
07/MRE05/44/AM16	The causes of clonal blood cell disorders	11	09/12/2015	15
08/H0305/45/AM05	Research Study into the genetic causes of PSC	Amendment 4 (SA2)	18/12/2015	23
10/H0305/34/AM17	Phase 3: SGN-35 and BSC vs placebo and BSC in Hodgkin Lymphoma V1	Substantial Amendment - update	24/04/2015	16
10/H0305/34/AM18	Phase 3: SGN-35 and BSC vs placebo and BSC in Hodgkin Lymphoma V1	SA7	10/12/2015	23
10/H0305/9/AM31	Baby Milk Study	SA12	14/04/2015	21
10/H0305/9/AM33	Baby Milk Study	SA13	11/02/2016	10
11/EE/0198/AM12	Investigation of compulsivity and motivation in disorders of addiction	SA6	02/06/2015	25
11/EE/0250/AM08	Monitoring Plasma Tumour DNA in Colorectal Cancer (ver 1)	Substantial amendment 7	02/03/2015	15
11/EE/0291/AM22	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	SA: IB Ed.11, PIS & ICF V9.0	21/10/2015	22
11/EE/0311/AM15	MO25455	SA11 13.10.15	14/10/2015	18
11/EE/0313/AM02	Ethical implications of whole genome studies. Version 1	SA1	23/03/2015	5
11/EE/0357/AM05	Evaluation of the role of inflammation in Chronic Airways Disease	SA5	19/03/2015	8

11/H0305/5/AM02	A genomic study in Uganda	2.0	18/01/2016	4
11/H0305/6/AM02	A genomic study in South Africa	1	18/01/2016	4
11/H0305/7/AM12	AB06006 - Mastocytosis	Substantial Amendment - Update	31/03/2015	21
11/H0305/7/AM14	AB06006 - Mastocytosis	SA09	22/02/2016	25
12/EE/0036/AM15	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	SA - Protocol update 11f-MC-RH	05/10/2015	9
12/EE/0172/AM02	A study of common and rare genetic variants associated with thinness.	SA1	10/03/2016	12
12/EE/0230/AM05	RITAZAREM: Rituximab vasculitis maintenance study	Amendment 5	17/09/2015	8
12/EE/0260/AM08	Gaucher Outcomes Survey [GOS] version 2, 26 September 2011.	Substantial Amendment - Protocol	06/07/2015	27
12/EE/0271/AM08	SIOP CNS GCT II	SA7	27/04/2015	8
12/EE/0271/AM09	SIOP CNS GCT II	SA08	22/09/2015	8
12/EE/0371/AM26	Phase III Study Comparing Betrixiban with Enoxaparin in VTE	SA18	26/05/2015	20
12/EE/0371/AM28	Phase III Study Comparing Betrixiban with Enoxaparin in VTE	Substantial Amendment 20	15/09/2015	14
12/EE/0405/AM03	Investigation of Segmental Overgrowth Disorders	SA3	10/08/2015	9
12/EE/0473/AM01	DREAM TAVI study	SA1	23/03/2015	9
12/EE/0492/AM08	ARISE (Acid Lipase Replacement Investigating Safety and Efficacy)	SA5	28/04/2015	8
12/EE/0492/AM10	ARISE (Acid Lipase Replacement Investigating Safety and Efficacy)	SA#06	01/02/2016	20
13/EE/0110/AM07	(April) Effect of Sulforaphane on prostate CAncer PrEvention (ESCAPE)	SA5	17/03/2015	15
13/EE/0117/AM03	LDE225 and INC424 in Combination in myelofibrosis patients.	SA3	15/04/2015	12
13/EE/0117/AM04	LDE225 and INC424 in Combination in myelofibrosis patients.	SA4	11/03/2016	10
13/EE/0126/AM03	BACE CT-003	SA2	04/08/2015	16
13/EE/0131/AM02	Genomic studies of HIV control in the CASCADE Collaboration	SA2	08/04/2015	12
13/EE/0167/AM04	Study of Ambrisentan in Chronic Thromboembolic Pulmonary Hypertension	Protocol SA 10	26/03/2015	6

13/EE/0168/AM04	An Extension Study of a Drug to Treat CTEPH	Protocol SA 7	26/03/2015	6
13/EE/0202/AM07	Inter-B-NHL Ritux 2010 - Version 1.0	4	20/05/2015	25
13/EE/0202/AM10	Inter-B-NHL Ritux 2010 - Version 1.0	5	26/11/2015	6
13/EE/0202/AM11	Inter-B-NHL Ritux 2010 - Version 1.0	SA6 - Restart & Updated Protocol	26/02/2016	4
13/EE/0270/AM04	RELIEF	2.0	04/01/2016	20
13/EE/0274/AM08	2 year use of Aflibercept study for treatment of wet AMD	Substantial Amendment 4	22/06/2015	16
13/EE/0274/AM09	2 year use of Aflibercept study for treatment of wet AMD	SA5 - Early Termination	13/10/2015	16
13/EE/0276/AM08	Phase 3B study assessing SOF/RBV and SOF/PEG/RBV for Genotype 2 or 3 C	SA4	12/05/2015	20
13/EE/0276/AM11	Phase 3B study assessing SOF/RBV and SOF/PEG/RBV for Genotype 2 or 3 C	SA6	10/09/2015	7
13/EE/0325/AM12	NIHR BioResource - Rare Diseases	SA 8.0	25/03/2015	7
13/EE/0325/AM13	NIHR BioResource - Rare Diseases	SA 9.0	17/06/2015	12
13/EE/0325/AM14	NIHR BioResource - Rare Diseases	SA 10.0	14/07/2015	9
13/EE/0325/AM15	NIHR BioResource - Rare Diseases	11	09/10/2015	21
13/EE/0325/AM16	NIHR BioResource - Rare Diseases	SA12	08/02/2016	14
13/EE/0326/AM05	Revacept/CS/02	Substantial Amendment - Study	27/05/2015	14
13/EE/0326/AM06	Revacept/CS/02	Substantial Amendment - Protocol	25/06/2015	14
13/EE/0367/AM13	BI 655066 in patients with Crohn's disease.	SA5	22/04/2015	16
13/EE/0367/AM16	BI 655066 in patients with Crohn's disease.	SA6	18/11/2015	13
13/EE/0377/AM12	Elagolix in the treatment of menstrual bleeding with Uterine Fibroids	Substantial amendment 18.05.20	18/05/2015	25
13/EE/0412/AM02	MOJITO 1.5	4.0	15/01/2016	21
13/EE/0418/AM03	PANDA RCT	Substantial Amendment	27/04/2015	10

		30.04.15		
13/EE/0418/AM04	PANDA RCT	SA3	16/11/2015	12
14/EE/0020/AM07	NEUCHILD (Version 3.0)	Substantial Amendment 5	05/06/2015	24
14/EE/0020/AM09	NEUCHILD (Version 3.0)	SA6 - Protocol Amendment 5	20/07/2015	18
14/EE/0033/AM01	Home based assessment tool for Myasthenia	SA1	16/05/2015	22
14/EE/0035/AM06	Phase 3 Trial of Fuvestrant(Faslodex®)in women with Breast Cancer	Substantial Amendment 07.05.15	07/05/2015	8
14/EE/0035/AM08	Phase 3 Trial of Fuvestrant(Faslodex®)in women with Breast Cancer	22/01/2016	22/01/2016	19
14/EE/0103/AM06	Evaluation of brain 5-HT2C density with PET	SA2	16/12/2015	24
14/EE/0105/AM04	EORTC 26101	SA2	06/08/2015	18
14/EE/0108/AM06	An evaluation of a water fluoridation scheme in Cumbria	SA5	18/03/2015	15
14/EE/0132/AM03	The influence of ivabradine in a healthy volunteer pain model	3.0	23/12/2015	19
14/EE/0179/AM04	CaNCaP02 - CAmbridge Neoadjuvant CAncer of the Prostate Study 2	Amendment 4 (SA2)	26/05/2015	20
14/EE/0204/AM05	Hydrotherapy for Duchenne Muscular Dystrophy (DMD)	5.0	07/12/2015	12
14/EE/1021/AM02	An evaluation of a Prostate Cancer Survivorship Care Programme	SA2	17/08/2015	21
14/EE/1021/AM03	An evaluation of a Prostate Cancer Survivorship Care Programme	SA3	17/08/2015	21
14/EE/1021/AM04	An evaluation of a Prostate Cancer Survivorship Care Programme	SA4	05/11/2015	26
14/EE/1022/AM01	Evaluation of Brief Cognitive Measures in Neurocognitive Disorders	SA01	05/10/2015	11
14/EE/1080/AM02	Dopaminergic modulation of cognition in ADHD	SA2	16/04/2015	15
14/EE/1082/AM11	Linagliptin and Insulin in elderly Type 2 Diabetes patients.	SA5	06/11/2015	25
14/EE/1100/AM05	MelaTools-eCDS	SA#03	02/02/2016	20
14/EE/1112/AM01	100,000 Genomes Project Bioresource - main phase	SA1	31/03/2015	10
14/EE/1112/AM02	100,000 Genomes Project Bioresource - main phase	SA2	25/06/2015	14
14/EE/1112/AM03	100,000 Genomes Project Bioresource - main phase	SA3	26/08/2015	14

14/EE/1112/AM04	100,000 Genomes Project Bioresource - main phase	SA04	28/09/2015	16
14/EE/1112/AM05	100,000 Genomes Project Bioresource - main phase	SA05	07/12/2015	7
14/EE/1112/AM06	100,000 Genomes Project Bioresource - main phase	6	21/12/2015	18
14/EE/1112/AM07	100,000 Genomes Project Bioresource - main phase	SA07	08/02/2016	14
14/EE/1112/AM08	100,000 Genomes Project Bioresource - main phase	SA8	14/03/2016	7
14/EE/1115/AM04	OBE001 in women undergoing embryo transfer in the context of IVF-ICSI	SA3	19/05/2015	13
14/EE/1149/AM01	ESCAPE-imagING evaluation (ESCAPE-ING)	SA01	29/01/2016	9
14/EE/1165/AM04	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects	SA4	03/06/2015	11
14/EE/1165/AM05	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects	SA05	25/09/2015	3
14/EE/1184/AM01	Genomics of diabetic retinopathy in the UK	SA1	16/11/2015	14
14/EE/1198/AM02	Conversation analysis of back pain consultations	SA2	10/11/2015	20
15/EE/0014/AM01	CAM-PLEX	3.0	04/01/2016	9
15/EE/0016/AM01	Hippocampal and retrosplenial function in MCI patients	1.0	15/12/2015	6
15/EE/0019/AM01	Endotoxemia and unexplained inflammation in haemodialysis	SA1	15/05/2015	7
15/EE/0025/AM01	CHAT:Can HCA Training improve relational care? (feasibility RCT)	SA01	23/07/2015	9
15/EE/0078/AM01	TPP1 Extension	SA1	23/03/2015	34
15/EE/0078/AM02	TPP1 Extension	SA02	24/09/2015	6
15/EE/0078/AM03	TPP1 Extension	SA3	22/10/2015	22
15/EE/0100/AM01	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2, and GT4 Infected Subjects	SA1	27/05/2015	13
15/EE/0100/AM02	MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2, and GT4 Infected Subjects	SA03	28/09/2015	18
15/EE/0130/AM02	Phase 3 study in patients with lung infections - protocol INS-212	SA1	13/05/2015	18
15/EE/0130/AM04	Phase 3 study in patients with lung infections - protocol INS-212	SA3	02/07/2015	12
15/EE/0130/AM05	Phase 3 study in patients with lung infections - protocol INS-212	SA#4	22/07/2015	16
15/EE/0130/AM08	Phase 3 study in patients with lung infections - protocol INS-	SA#5	08/09/2015	10

	212			
15/EE/0132/AM01	Understanding Consequences	SA1 - 10/10/2015	13/10/2015	17
15/EE/0161/AM06	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	SA02	25/02/2016	8
15/EE/0168/AM01	Volar plate injury: a comparison of two splinting methods (Version 1)	SA1	02/07/2015	4
15/EE/0172/AM03	Mobile Technology for Nutrition Assessment in AMD (MANAGER2)	SA1	17/07/2015	6
15/EE/0201/AM01	Circulating Factors in Pulmonary Hypertension	SA01	03/10/2015	4
15/EE/0204/AM03	Safety and efficacy of PVDF (DynaMesh®SIS soft) retropubic slings.	SA01	24/02/2016	20
15/EE/0209/AM01	Evaluation of Clinical Outcomes after the use of SYSTANE HYDRATION	SA1	09/07/2015	24
15/EE/0209/AM05	Evaluation of Clinical Outcomes after the use of SYSTANE HYDRATION	2.0	21/01/2016	19
15/EE/0237/AM01	Six Minute Walk Test and post-operative morbidity	SA01	07/08/2015	14
15/EE/0237/AM03	Six Minute Walk Test and post-operative morbidity	SA2	07/10/2015	9
15/EE/0261/AM02	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	SA1	07/10/2015	9
15/EE/0261/AM03	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	SA02	14/10/2015	16
15/EE/0261/AM05	A Phase 3 Study to Evaluate AMG334 in Episodic Migraine Prevention	SA03 - Protocol Amendment 1	02/12/2015	12
15/EE/0269/AM01	IMPACT-CTO STUDY	1	05/10/2015	11
15/EE/0269/AM02	IMPACT-CTO STUDY	SA02	15/02/2016	18
15/EE/0308/AM01	Alcohol Dependence and Adherence to Medicine (ADAM)	SA1	18/11/2015	11
15/EE/0308/AM03	Alcohol Dependence and Adherence to Medicine (ADAM)	2	23/12/2015	19
15/EE/0345/AM01	Antiseptic Randomised Controlled Trial for Insertion of Catheters v1.0	SA1	30/10/2015	17
15/EE/0350/AM04	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	SA02	23/02/2016	9
15/EE/0352/AM01	Study of CT-P10 in patients with Low Tumour Burden Follicular Lymphoma	1.0	21/01/2016	20

15/EE/0355/AM01	Revusiran in patients with TTR-mediated FAP	SA#1	03/11/2015	13
15/EE/0374/AM03	Developing primary care services for stroke: Qualitative studies	Amendment 3 (SA1)	18/12/2015	24
15/EE/0377/AM01	MISSION-liver v1.0	SA01	01/03/2016	7
15/EE/0378/AM01	MISSION-ovary	SA01	17/02/2016	8
15/EE/0435/AM01	STOP-HCV-1 version 1.0	1.0	21/01/2016	19
97/5/001/AM25	The Million Women Study	Amendment 27	05/03/2015	12
97/5/001/AM26	The Million Women Study	Amendment 28	24/02/2016	7
98/5/023/AM09	The Genetics of Ankylosing Spondylitis	SA9	23/06/2015	14
99/5/007/AM15	SEARCH Cancer Studies(Ovarian)	SA 12 - 03.08.15	03/08/2015	18

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/MRE05/7/AM16	Depolarisations in acute brain injury	Substantial Amendment 15	05/05/2015	21
12/EE/0089/AM11	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	Substantial Amendment 16.06.15	16/06/2015	13
12/EE/0163/AM03	Living with breathlessness (version 1)	SA03	05/08/2015	16
12/EE/0346/AM03	The EPIC-Norfolk Fourth Health Check (4HC)	SA03	18/08/2015	20
12/EE/0371/AM27	Phase III Study Comparing Betrixiban with Enoxaparin in VTE	SA19	01/07/2015	7
13/EE/0181/AM04	PROGENY - Version 1.1	SA 2.0	05/06/2015	9
14/EE/0212/AM04	NIRTURE Follow-up	SA3	10/08/2015	9
14/EE/1203/AM04	B1481045 Phase III Study of PF-04950615 & Hyperlipidemia/Dyslipidemia.	SA3	02/04/2015	13
15/EE/0200/AM01	Brain function for age curves in UK infants	1.0	17/12/2015	5
15/EE/0201/AM02	Circulating Factors in Pulmonary Hypertension	2.0	15/01/2016	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
12/EE/0089/AM11/2	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	Modified Amendment 2	06/10/2015	5
14/EE/0212/AM04/1	NIRTURE Follow-up	Modified Amendment of SA03	01/12/2015	2
14/EE/1203/AM03/1	B1481045 Phase III Study of PF-04950615 & Hyperlipidemia/Dyslipidemia.	Modified Amendment of SA2	31/03/2015	14
14/EE/1203/AM04/1	B1481045 Phase III Study of PF-04950615 & Hyperlipidemia/Dyslipidemia.	Modified Amendment of SA3	11/05/2015	4
15/EE/0200/AM01/1	Brain function for age curves in UK infants	Modified Amendment of SA01	18/01/2016	4
15/EE/0201/AM02/1	Circulating Factors in Pulmonary Hypertension	SA2 - modified	04/02/2016	7

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/EE/0089/AM11/1	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	Modified Amendment of SA	31/07/2015	7
Table 11: Items exceeding timelines				
		16.06		

Full applications for ethical review over 60 day timeline		
REC Reference	Title	Number of Days on Clock

Proportionate review applications for ethical review over 14 day timeline		
REC Reference	Title	Number of Days on Clock

15/EE/0364	Investigating Attitudes towards HIV Pre-Exposure Prophylaxis (PrEP)	15
15/EE/0393	STRAT-PD	19
15/EE/0475	PTP1B Inhibition: A new target in the treatment of atherosclerosis	16
16/EE/0022	Implementation of an online relatives toolkit (IMPART study)	15
16/EE/0121	Isolation and identification of spiked cancer cells in HNV blood	17

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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