

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

Annual Report

01 April 2017 - 31 March 2018



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:	Vacant
Alternate Vice-Chair:	Dr Ian Dumbelton
REC Manager:	Mr George R Martin from February 2018 Ms Penelope Gregory to January 2017
REC Assistant:	Kate Loven from April 2018 George R Martin from December 2017 to January 2018
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

It is a pleasure and a privilege to be the Chair of Cambridge South REC. Members of the Committee work hard to ensure that applicants receive a fair and thorough review of their proposed research. I am confident that the research community is well served by the Committee. Applicants attending meetings are always treated with respect and every effort is made to make the researcher's experience a positive one.

The Committee has a stable membership with a number of members having considerable experience and new members being welcomed on board. I am confident that members feel able to openly express their opinions about applications in a safe and respectful environment. Whilst meetings are always business-like, members are still able to enjoy the Committee work and their interactions with researchers.

The Committee has, for some considerable time, since the retirement of Dr Frank Wells, been without a Vice-Chair. It would be helpful if this could be resolved as soon as possible.

I look forward to another year working with the Committee and with the HRA.

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 & Pharmacovigilance QA	Lay Plus	01/04/2011	
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	Locum 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 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 Marilyn Chong	Pharmacist specialist - cancer services	Expert	25/01/2018
Miss Marilyn Chong	Pharmacist specialist - cancer services	Expert	27/07/2017
Miss Marilyn Chong	Pharmacist specialist - cancer services	Expert	23/11/2017
Miss Marilyn Chong	Pharmacist specialist - cancer services	Expert	22/03/2018
Miss Marilyn Chong	Pharmacist specialist - cancer services	Expert	27/04/2017
Dr Joanne Doleman	Regulatory Compliance Officer	Lay	22/03/2018
Dr Joanne Doleman	Regulatory Compliance Officer	Lay	25/01/2018

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

Name	Profession	Status	Meeting date attended
Dr Niki Bannister	Retired Hospital Doctor	Expert	28/09/2017
Dr Alan Lamont	Retired Consultant Oncologist	Expert	28/09/2017
Dr Elizabeth Lund	Principal Research Scientist, Nutrition and Gastrointestinal Health	Lay	28/09/2017

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

Name	Declaration of Interest	Date
Dr Richard Aldridge	Continues to participate in medical image processing research group	22/03/2018
Mrs Martha Byrne	Director, Clinical & Pharmacovigilance QA, Strategic Advice AstraZenica Group of Companies including Medimmune Sciences Unit Member of Good Clinical Practice (GCP) Committee Member of the Research QA Association (RQA)	24/01/2018
Miss Marilyn Chong	None declared	25/01/2018
Dr Joanne Doleman	Regulatory Compliance Officer for the Wellcome Trust Sanger Institute. Advises scientists at the Wellcome Trust Sanger Institute on their IRAS applications.	03/10/2017
Dr Ian Dumbelton	Governor of Longsands Academy	01/03/2018
Dr Leslie Gelling	Reader in Nursing at Anglia Ruskin University. Deputy Director, Positive Aging Research Institute.	25/01/2018
Mr Colin Green	None declared	25/01/2018
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. Chair of Ethics and Policy Group of British Society for Genomic Medicine. Member of Regulatory and Ethical Working Group of Global Alliance for Genomics and Health. Pending appointment to Ethical Advisory Committee of Genomics England Limited (100,000 Genomes Project).	25/01/2018
Dr Linda Harvey	Chair, University of East Anglia, Faculty of Medicine and Health Sciences Human Tissue Research Ethics Sub-Committee. Vice Chair, University of East Anglia, Faculty of Medicine and health Sciences Research Ethics Committee.	23/01/2018
Mr John Kirkpatrick	Employee of Roche Products Ltd. Shareholdings in Roche Products Ltd.	25/01/2018
Miss Angela Palmer	Receives a pension from GlaxoWellcome. Holds GSK Shares	19/01/2018
Mrs Nikki Phillimore	None declared	20/10/2017
Dr Michael Sheldon	None declared	25/01/2018
Miss Carol Smee	Paid REC Member (consultancy) for Twist DX. Unpaid member of EMBL-EBI Bioethics Internal Advisory Committee (BIAC). Employed as Regulatory Compliance Manager at the Wellcome Sanger Institute. HRA trainer for the courses: 'An Introduction to the HTA' and 'Genetics and Genomics - What RECs should consider'	15/01/2018
Mr Phil Tempest	Employed by Amgen Ltd as Compliance Senior Manager. Owns shares in Amgen Ltd and GSK plc	09/06/2017
Dr Kate Williams	Medical Detection Dogs Charity - Research Consultant. Cambridge University - Senior Research Associate.	25/01/2018

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

Month	Date	Number of Members Present at Meeting
April	27/04/2017	10
May	25/05/2017	9
July	27/07/2017	11
August	24/08/2017	10
September	28/09/2017	11
October	26/10/2017	9
November	23/11/2017	11
January	25/01/2018	12
February	22/02/2018	8
March	22/03/2018	9

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
May	08/05/2017	4
June	12/06/2017	4
July	10/07/2017	4
August	14/08/2017	4
September	11/09/2017	4
November	13/11/2017	4
December	11/12/2017	3
January	15/01/2018	4
February	12/02/2018	4
March	13/03/2018	4

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	14/04/2017	2
April	28/04/2017	2
May	12/05/2017	2
May	26/05/2017	2
May	30/05/2017	2
June	09/06/2017	2
June	23/06/2017	2
July	07/07/2017	2
July	21/07/2017	2
August	04/08/2017	2
August	18/08/2017	2

September	01/09/2017	2
September	15/09/2017	2
September	29/09/2017	3
October	13/10/2017	2
October	27/10/2017	2
November	10/11/2017	2
November	24/11/2017	2
December	08/12/2017	2
December	28/12/2017	2
January	12/01/2018	2
February	09/02/2018	2
March	05/03/2018	2
March	12/03/2018	2
March	29/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

None

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

Name	Number of Meetings Attended
Dr Richard Aldridge	7
Mrs Martha Byrne	7
Miss Marilyn Chong	5
Dr Joanne Doleman	2
Dr Ian Dumbelton	3
Dr Leslie Gelling	9
Mr Colin Green	9
Mrs Alison Hall	9
Dr Linda Harvey	7
Mr John Kirkpatrick	5
Miss Angela Palmer	7
Mrs Nikki Phillimore	5
Dr Michael Sheldon	8
Miss Carol Smee	6
Mr Phil Tempest	3
Dr Kate Williams	5

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

Name	Number of Meetings Attended
Dr Richard Aldridge	2
Mrs Martha Byrne	3
Dr Ian Dumbelton	2
Dr Leslie Gelling	10
Mr Colin Green	2
Mrs Alison Hall	3
Dr Linda Harvey	2
Mr John Kirkpatrick	2
Miss Angela Palmer	2
Mrs Nikki Phillimore	1
Dr Michael Sheldon	2
Miss Carol Smee	3
Mr Phil Tempest	3
Dr Kate Williams	2

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

Name	Number of Meetings Attended
Dr Ian Dumbelton	4
Dr Leslie Gelling	25
Mrs Alison Hall	3
Dr Linda Harvey	2
Mrs Nikki Phillimore	2
Dr Michael Sheldon	5
Miss Carol Smee	3
Mr Phil Tempest	4
Dr Kate Williams	3

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Richard Aldridge	12/09/2017	Genetic and Genomic Research (prev HTA Advanced)
Dr Ian Dumbelton	19/09/2017	Equality and Diversity Training
Miss Angela Palmer	12/09/2017	Genetic and Genomic Research (prev HTA Advanced)
Mrs Nikki Phillimore	14/04/2017	Equality and Diversity
Mrs Nikki Phillimore	29/09/2017	Members Regional Training Day
Dr Michael Sheldon	29/09/2017	Members Regional Training Day
Miss Carol Smee	06/09/2017	Equality Diversity and Human Rights
Miss Carol Smee	12/12/2017	Training - National Members Day
Dr Leslie Gelling	22/05/2017	Chairs' Meeting – East of England
Dr Leslie Gelling	02/11/2017	Chairs' Meeting – East of England

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	18	39.13
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	28	60.87
Total Applications Reviewed	46	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	2
Number of student applications reviewed	15
Number of paediatric applications reviewed	13
Number of device applications reviewed	2
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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	6	13.04
Provisional Opinion	40	86.96
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	46	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	36	78.26
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	6	13.04
Provisional Opinion	4	8.70
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	46	100

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

Total Applications Reviewed	29
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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	1
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	17
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	7

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	1	3.45
Favourable Opinion with Additional Conditions	1	3.45
No Opinion transfer to full committee for review	7	24.14
Provisional Opinion	19	65.52
Unfavourable Opinion	1	3.45
Total	29	100

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

Average number of applications reviewed per full meeting	4.60
Number of completed applications for full ethical review	46
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 days taken to final decision – average (mean)	40
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	11
Number of completed proportionate review applications over 21 days as a % of total	52.38%
Number of SSAs (non-Phase 1) reviewed	12
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	8.33%
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	166
Number of completed substantial amendments over 35 days	16
Number of completed substantial amendments over 35 days as a % of total substantial amendments	9.64%
Number of modified amendments reviewed	7
Number of completed modified amendments over 14 days	2
Number of completed modified amendments over 14 days as a % of total modified amendments	28.57%
Number of non substantial amendments received	185
Number of substantial amendments received for information	5
Number of substantial amendments received for new sites/PIs	28
Number of annual progress reports received	99
Number of safety reports received	77
Number of Serious Adverse Events received	3
Number of final reports received	16

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
17/EE/0146	Reinforcement Learning and Perception in Schizophrenia	32
17/EE/0175	Young SMILES: An intervention for children with mentally ill parents	45
17/EE/0176	Neo-RT	56
17/EE/0177	BOSTON: Open-label Study of SVD versus VD in patients with RRMM	32
17/EE/0179	Exploring the Impact of Trauma in Mental Health Difficulties (V1)	38
17/EE/0220	1368.4 Exploratory trial of BI655130 in patients with active UC	34
17/EE/0221	CC-90001-IPF-001 - safety and efficacy of CC90001 in patients with IPF	40
17/EE/0223	Phase 2b extension study to evaluate NEOD001 in Light Chain (AL)	44
17/EE/0265	TRIPP Study	50
17/EE/0301	BioMarin 190-203	38
17/EE/0303	Effect of MIN-102 in Male Patients with Adrenomyeloneuropathy	39
17/EE/0311	Incremental Dialysis to Preserve Residual Kidney Function	47
17/EE/0318	The Hopes and Expectations of Weight Loss Surgery Candidates	43
17/EE/0334	A novel physiological assessment of the microcirculation in PPCI	56
17/EE/0337	A study using RM-493 in patients with LEPR deficiency obesity	42
17/EE/0338	Regulation of gut inflammation in health and disease	36
17/EE/0340	INTERIM	34
17/EE/0382	PROFILE - personalised medicine in Crohn's disease	40
17/EE/0390	Ambulance-led Sepsis Care: systems and risk factor assessment V1.3	32
17/EE/0403	Mental health and quality of life in women who have had breast cancer	37
17/EE/0430	Asthma Bronchial Challenge: The ABC Study	46
17/EE/0431	Dose Ranging Trial of MK-8591 Given in Combination Therapy	51
17/EE/0433	Feasibility study of mechanisms of psychosis in Prader-Willi syndrome	52
17/EE/0460	PRODOSE Algorithmic Protamine Dosing for Reversal of Heparin after CPB	41
17/EE/0463	Recombinant human parathyroid hormone for hypoparathyroidism in adults	25
17/EE/0475	Fluoride interventions to prevent dental decay in care home residents	24
17/EE/0480	Phase 3 Study of Pembro with/without Epacadostat in 1L Urothelial Carc	37
17/EE/0481	PITHIA	24
18/EE/0032	OSTRICH Study	53
18/EE/0033	Exploration of Smoking Cessation in Dual-Diagnosis Groups	57
18/EE/0034	Study of efficacy and safety of CDZ173 in patients with APDS/ PASLI	44
18/EE/0035	PIPIC - version 0.001	41

18/EE/0047	TAPS01	37
18/EE/0067	NN7088-4410 N8-GP in PTP with Severe Haemophilia A	42
18/EE/0070	Electronic medical device- patient adherence study in COPD patients	47
18/EE/0095	PCR2002 Niraparib Combination Therapies for Prostate Cancer	42

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
17/EE/0174	TRIPP Study	27
17/EE/0222	Predictors of Disordered Eating in Young People with Asthma	29
17/EE/0224	Family adjustment when a member is in Forensic Mental Health setting	29
17/EE/0306	Improvised music to enhance Intensive Interaction version 1	26
17/EE/0356	Cognition in patients with sarcoidosis	28
17/EE/0418	Improvised Music to Enhance Intensive Interaction version 3	27

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0395	Consolidation in typical and atypical learning in childhood	n/a
18/EE/0068	Genetic Investigations of Rare Disorders of Metabolism and/or Growth	n/a
18/EE/0099	CL3-95005-006 SOLSTICE	n/a
18/EE/0101	Improving Nutritional Status In Liver Cirrhosis - Version 1.0	n/a

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
17/EE/0194	Auditory evoked potentials as objective outcome measures V.1.	20
17/EE/0199	A study of pain experienced during successive screening mammography.	16
17/EE/0246	Comparative Brain and Spinal Imaging in MS, NMO and MOG-Ab Disease	26
17/EE/0247	Effects of groove music on movement in Parkinsonian DBS patients	26
17/EE/0249	Circulating microRNAs as biomarkers in MND; version 1.0	25
17/EE/0342	The use of a therapist-made ankle-foot orthosis after stroke	34
17/EE/0344	Use of blood cells in in-vitro characterisation assays	24
17/EE/0345	Can salivary hormone levels be correlated to ovarian response in IVF?	38
17/EE/0372	The experience of recovery following severe tibial fracture	27
17/EE/0374	Long-term Quality of Life and Function after Anterior Resection	32
17/EE/0467	Protect-NOW – Octapharma’s FVIII in PUPs and MTPs	25
17/EE/0515	Does earwax removal by suction result in temporary threshold shift?	20

18/EE/0019	Heart failure accelerometry	17
18/EE/0061	HPV Biomarkers in Head and Neck Cancer	28
18/EE/0087	Dialysis Decisions (DD) V 1	15
18/EE/0088	Intra- and Inter-Individual Variations In Disease Activity	22

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
17/EE/0197	The impact of gender on the stepped care model of therapy	15

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
18/EE/0060	SHINE: Sensing the Hips of Newborns	14

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0373	Assessing understanding long term medication for chronic pain	21

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0299	Genotype-Phenotype study in CDKL5	n/a
17/EE/0464	Qualitative Enquiry into Womens Experience of LARC	n/a

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
17/EE/0288	Cancer patients experiences of healthcare transition	14

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
00/5/030/AM20	Population based study of genetic predisposition to endometrial cancer	Amendment 20	26/04/2017	11
02/5/042/AM16	A population-based study of genetic predisposition to breast cancer	Amendment 16	26/04/2017	11
08/H0305/29/AM17	Study of AZD2281 (KU-0059436) in Patients with Advanced Ovarian Cancer	SA IB update ed14	16/06/2017	21
09/H0305/84/AM07	1199.26 study of BIBF vs sunitinib in RCC.	SA#05	28/04/2017	10
09/H0305/84/AM09	1199.26 study of BIBF vs sunitinib in RCC.	SA#6	28/07/2017	32
09/H0305/84/AM10	1199.26 study of BIBF vs sunitinib in RCC.	SA7	09/08/2017	20
10/H0305/1/AM23	Multicentre study to determine Predictive and Prognostic Biomarkers	SA9	26/10/2017	25
10/H0305/34/AM22	Phase 3: SGN-35 and BSC vs placebo and BSC in Hodgkin Lymphoma V1	Substantial Amendment 15	23/02/2018	28
11/EE/0198/AM13	Investigation of compulsivity and motivation in disorders of addiction	SA#07	12/04/2017	7
11/EE/0291/AM25	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	SA 07.04.2017	07/04/2017	14
11/EE/0291/AM27	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	Substantial Amendment ICF v12.	20/02/2018	32
11/EE/0311/AM17	MO25455	SA13	06/07/2017	18
11/EE/0311/AM18	MO25455	SA14	26/10/2017	14
11/EE/0483/AM18	BO25430 - Trastuzumab Emtansine (T-DM1) Extension Study	SA14	18/10/2017	29
12/EE/0036/AM21	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	SA7 IB Update	28/06/2017	25
12/EE/0036/AM22	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	8	13/10/2017	21
12/EE/0036/AM23	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	9	20/12/2017	37
12/EE/0089/AM21	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	SA9 IB Update	28/06/2017	25
12/EE/0089/AM22	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in	10	13/10/2017	21

	Ps			
12/EE/0089/AM23	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	11	28/11/2017	13
12/EE/0230/AM09	RITAZAREM: Rituximab vasculitis maintenance study	SA9	27/06/2017	15
12/EE/0230/AM10	RITAZAREM: Rituximab vasculitis maintenance study	SA10	26/07/2017	26
12/EE/0405/AM04	Investigation of Segmental Overgrowth Disorders	6	06/09/2017	35
13/EE/0016/AM05	National Diet and Nutrition Survey (NDNS) Rolling Programme Y6-9	4	15/11/2017	32
13/EE/0016/AM06	National Diet and Nutrition Survey (NDNS) Rolling Programme Y6-9	5	22/01/2018	18
13/EE/0202/AM15	Inter-B-NHL Ritux 2010 - Version 1.0	SA10 2017/08/03	03/08/2017	19
13/EE/0325/AM24	NIHR BioResource - Rare Diseases	17	18/07/2017	21
13/EE/0325/AM25	NIHR BioResource - Rare Diseases	SA 18 14/08/2017	14/08/2017	22
14/EE/0035/AM12	Phase 3 Trial of Fuvestrant(Faslodex®)in women with Breast Cancer	SA07	04/10/2017	15
14/EE/0108/AM10	An evaluation of a water fluoridation scheme in Cumbria	Birth Cohort - SA8	19/09/2017	10
14/EE/1063/AM10	AZD9291 v chemotherapy in NSCLC, following EGFR TKI therapy (AURA3)	8	12/05/2017	20
14/EE/1063/AM12	AZD9291 v chemotherapy in NSCLC, following EGFR TKI therapy (AURA3)	9	25/01/2018	30
14/EE/1112/AM16	100,000 Genomes Project Bioresource - main phase	SA15	15/05/2017	9
14/EE/1112/AM17	100,000 Genomes Project Bioresource - main phase	16	23/10/2017	13
14/EE/1184/AM04	Genomics of diabetic retinopathy in the UK	SA#02 - February 2017	07/02/2017	15
14/EE/1184/AM05	Genomics of diabetic retinopathy in the UK	3	26/06/2017	31
14/EE/1184/AM06	Genomics of diabetic retinopathy in the UK	4	01/09/2017	11
15/EE/0014/AM04	CAM-PLEX	SA#06	24/05/2017	22
15/EE/0014/AM08	CAM-PLEX	9.0	28/11/2017	25
15/EE/0078/AM11	TPP1 Extension	Protocol amendment 4 and IB V8	04/05/2017	22
15/EE/0078/AM13	TPP1 Extension	Protocol Amendment 5	05/05/2017	26
15/EE/0130/AM17	Phase 3 study in patients with lung infections - protocol INS-212	12	14/07/2017	20
15/EE/0132/AM08	Understanding Consequences	SA4	10/09/2017	15

15/EE/0152/AM01	Regenerative cellular therapies, physiology, pathology and development	SA1	15/05/2017	9
15/EE/0200/AM03	Brain function for age curves in UK infants	4	02/08/2017	36
15/EE/0201/AM03	Circulating Factors in Pulmonary Hypertension	SA#03	23/05/2017	10
15/EE/0205/AM01	Gastropanel *for early detection of gastric atrophy and gastric cancer	1	05/01/2018	38
15/EE/0241/AM01	S-CORT: Stratification in COloRectal cancer:	SA1	22/09/2017	25
15/EE/0241/AM02	S-CORT: Stratification in COloRectal cancer:	2	24/11/2017	41
15/EE/0253/AM04	The Natural History of Malaria V.1	3	20/09/2017	17
15/EE/0253/AM05	The Natural History of Malaria V.1	SA4	04/10/2017	13
15/EE/0253/AM06	The Natural History of Malaria V.1	5	14/12/2017	36
15/EE/0253/AM07	The Natural History of Malaria V.1	6	21/02/2018	27
15/EE/0268/AM02	(duplicate) Older People's Experience of Urgent and Emergency Care	1	29/11/2017	10
15/EE/0298/AM05	LuCID: Lung Cancer Indicator Detection	3	23/08/2017	14
15/EE/0302/AM08	Monaleesa 3 CLEE011F2301 ribiciclib/placebo + fulvestrant	v.3	19/05/2017	12
15/EE/0308/AM09	Alcohol Dependence and Adherence to Medicine (ADAM)	SA6	02/05/2017	6
15/EE/0308/AM10	Alcohol Dependence and Adherence to Medicine (ADAM)	SA#7	20/06/2017	26
15/EE/0352/AM05	Study of CT-P10 in patients with Low Tumour Burden Follicular Lymphoma	SA4.0	28/06/2017	20
15/EE/0352/AM06	Study of CT-P10 in patients with Low Tumour Burden Follicular Lymphoma	5	12/11/2017	27
15/EE/0353/AM06	PCYC-1137-CA	6	19/09/2017	17
15/EE/0353/AM07	PCYC-1137-CA	7	07/03/2018	18
15/EE/0378/AM02	MISSION-ovary	SA2	16/06/2017	8
15/EE/0435/AM11	STOP-HCV-1 version 1.0	SA#07	28/04/2017	10
15/EE/0435/AM12	STOP-HCV-1 version 1.0	SA#08	20/06/2017	6
15/EE/0435/AM13	STOP-HCV-1 version 1.0	9	17/08/2017	35
15/EE/0435/AM15	STOP-HCV-1 version 1.0	Substantial Amendment 10	22/02/2018	32
15/EE/0442/AM06	Phase III Study of AG-221 in Late Stage AML with IDH2 mutation	Substantial Amendment 2	16/02/2018	29
16/EE/0008/AM05	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	SA#04	25/04/2017	31
16/EE/0008/AM06	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	4	22/08/2017	21
16/EE/0008/AM07	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	5	19/12/2017	38
16/EE/0022/AM06	Implementation of an online relatives toolkit (IMPART study)	3	19/12/2017	37

16/EE/0032/AM04	ANTLER	SA2	09/08/2017	29
16/EE/0052/AM01	OPUS-DI	1	20/05/2017	23
16/EE/0053/AM04	AdDIT Follow Up	Amendment 4	24/10/2017	27
16/EE/0071/AM04	Unravel MGUS	SA#03	12/06/2017	11
16/EE/0071/AM08	Unravel MGUS	4	19/03/2018	15
16/EE/0103/AM01	The Human Vertebral Endplate: biomechanical study in spinal disorders	SA1	03/01/2018	38
16/EE/0132/AM03	Novartis ph3: Secukinumab response in Psoriatic Arthritis using PDUS	2	18/04/2017	26
16/EE/0132/AM05	Novartis ph3: Secukinumab response in Psoriatic Arthritis using PDUS	3	31/01/2018	35
16/EE/0207/AM01	Quality of Life in patients with an ileal anal pouch	SA#1	18/07/2016	15
16/EE/0207/AM02	Quality of Life in patients with an ileal anal pouch	2	16/01/2018	37
16/EE/0215/AM04	VR testing of entorhinal-hippocampal function in AD (VIRTECH-AD)	SA3	18/01/2018	29
16/EE/0233/AM03	DECRYPT: Delivery of Cognitive Therapy for Young People after Trauma	2	20/01/2018	36
16/EE/0294/AM03	Comparison of Optimal Hypertension Regimens (AIM HY-INFORM)	SA#03	26/05/2017	21
16/EE/0294/AM06	Comparison of Optimal Hypertension Regimens (AIM HY-INFORM)	6	18/01/2018	35
16/EE/0315/AM01	Metformin SGA study version 1.2	SA#01	10/04/2017	13
16/EE/0315/AM02	Metformin SGA study version 1.2	SA#03	11/05/2017	15
16/EE/0315/AM04	Metformin SGA study version 1.2	4	13/11/2017	20
16/EE/0315/AM06	Metformin SGA study version 1.2	5	12/03/2018	15
16/EE/0318/AM06	Lithium versus Quetiapine in Depression (LQD study), Version 1	7	21/09/2017	31
16/EE/0318/AM08	Lithium versus Quetiapine in Depression (LQD study), Version 1	4.0	10/01/2018	28
16/EE/0324/AM04	Prophylactic and Pre-emptive DLI for myeloid malignancies (PRO-DLI)	SA1	19/01/2018	28
16/EE/0325/AM02	M15-550: Venetoclax in Relapsed/Refractory subjects with CLL	0.02.01	22/05/2017	29
16/EE/0327/AM01	The role of circuit flow during mechanical ventilation of neonates	1	29/11/2017	30
16/EE/0357/AM11	Opicapone in clinical practice (OPTIPARK)_V1	SA07	20/09/2017	16
16/EE/0362/AM01	Paediatric Study with Etelcalcetide in Secondary	SA#01	01/06/2017	15

	Hyperparathyroidism			
16/EE/0380/AM02	Day and night closed-loop in young people with type 1 diabetes (DAN05)	2	20/11/2017	20
16/EE/0386/AM03	The BEACON CRC Study	SA02	26/10/2017	25
16/EE/0387/AM04	KASPAR RCT	SA#02	02/06/2017	9
16/EE/0387/AM05	KASPAR RCT	SA03	01/08/2017	23
16/EE/0387/AM06	KASPAR RCT	SA4	18/01/2018	34
16/EE/0392/AM01	A study using RM-493 in patients with POMC deficiency obesity	SA#01	19/04/2017	24
16/EE/0450/AM01	Hyperpolarized Xenon imaging in patients with cystic fibrosis	SA#1	25/07/2017	19
16/EE/0450/AM02	Hyperpolarized Xenon imaging in patients with cystic fibrosis	2	05/09/2017	35
16/EE/0463/AM03	CLEE011A2404. Ribociclib and Letrozole in HR+, HER- breast cancer	SA#02	03/04/2017	21
16/EE/0463/AM06	CLEE011A2404. Ribociclib and Letrozole in HR+, HER- breast cancer	Substantial amendment 03	17/08/2017	25
16/EE/0463/AM07	CLEE011A2404. Ribociclib and Letrozole in HR+, HER- breast cancer	4	22/11/2017	20
16/EE/0468/AM01	BBB permeability and Neuro-Inflammation in SVD	SA#03	14/06/2017	12
16/EE/0469/AM03	PCOS OSA	SA#01	24/04/2017	21
16/EE/0469/AM04	PCOS OSA	SA#2	01/08/2017	25
16/EE/0471/AM01	Pituitary changes following obstetric haemorrhage: Version 1	1	13/11/2017	25
17/EE/0028/AM01	MC-1 Status with Age Using PET	09.06.2017	09/06/2017	16
17/EE/0028/AM02	MC-1 Status with Age Using PET	Substantial Amendment 2	08/08/2017	23
17/EE/0034/AM01	Astral-3: SGI-110 versus Treatment Choice in Adults with MDS or CMML	1	21/11/2017	21
17/EE/0035/AM01	pRFs & Crowding in Amblyopia	1	10/11/2017	25
17/EE/0070/AM01	Feasibility of MyHealthAvatar in Type 2 diabetes	SA#01	12/05/2017	14
17/EE/0076/AM02	The Spinal Cord Injury Move More (SCIMM) study Version 1	SA#02	26/05/2017	11
17/EE/0076/AM03	The Spinal Cord Injury Move More (SCIMM) study Version 1	SA#03	21/06/2017	4
17/EE/0076/AM04	The Spinal Cord Injury Move More (SCIMM) study Version 1	SA#3	20/07/2017	26
17/EE/0076/AM05	The Spinal Cord Injury Move More (SCIMM) study Version 1	SA04	07/08/2017	21
17/EE/0076/AM06	The Spinal Cord Injury Move More (SCIMM) study Version 1	Substantial Amendment 9	16/08/2017	21
17/EE/0076/AM07	The Spinal Cord Injury Move More (SCIMM) study Version 1	6	20/09/2017	28
17/EE/0076/AM08	The Spinal Cord Injury Move More (SCIMM) study Version 1	7	26/09/2017	28

17/EE/0079/AM03	Avacopan in patients with Vasculitis	2	08/08/2017	34
17/EE/0079/AM08	Avacopan in patients with Vasculitis	27/01/2017	11/12/2017	44
17/EE/0120/AM01	The role of Nicotinamide Riboside in mitochondrial biogenesis	SA1	04/07/2017	27
17/EE/0120/AM02	The role of Nicotinamide Riboside in mitochondrial biogenesis	2.0	14/11/2017	25
17/EE/0120/AM04	The role of Nicotinamide Riboside in mitochondrial biogenesis	4	07/02/2018	29
17/EE/0124/AM01	302-Phase 3 study of ALXN1210 VS ECULIZUMAB in adult patients with PNH	SA1	29/06/2017	20
17/EE/0124/AM05	302-Phase 3 study of ALXN1210 VS ECULIZUMAB in adult patients with PNH	27/01/2017	06/11/2017	29
17/EE/0124/AM06	302-Phase 3 study of ALXN1210 VS ECULIZUMAB in adult patients with PNH	3	18/12/2017	37
17/EE/0126/AM04	PQR309-005_Efficacy and safety study of PQR309 in primary CNS lymphoma	11/12/2017	20/12/2017	35
17/EE/0126/AM05	PQR309-005_Efficacy and safety study of PQR309 in primary CNS lymphoma	SA6	25/01/2018	22
17/EE/0128/AM01	Long-term Extension for GEN701 and GEN702	01	17/08/2017	25
17/EE/0128/AM02	Long-term Extension for GEN701 and GEN702	2	08/02/2018	33
17/EE/0175/AM01	Young SMILES: An intervention for children with mentally ill parents	SA1	27/07/2017	15
17/EE/0175/AM02	Young SMILES: An intervention for children with mentally ill parents	2	31/08/2017	21
17/EE/0177/AM01	BOSTON: Open-label Study of SVD versus VD in patients with RRMM	SA1	14/08/2017	22
17/EE/0177/AM05	BOSTON: Open-label Study of SVD versus VD in patients with RRMM	3	20/12/2017	37
17/EE/0194/AM01	Auditory evoked potentials as objective outcome measures V.1.	SA#1	20/07/2017	19
17/EE/0221/AM02	CC-90001-IPF-001 - safety and efficacy of CC90001 in patients with IPF	2	14/11/2017	14
17/EE/0301/AM01	BioMarin 190-203	Protocol Amendment 3	28/11/2017	14
17/EE/0303/AM01	Effect of MIN-102 in Male Patients with Adrenomyeloneuropathy	SA1 - Protocol Amendment 1	05/10/2017	11
17/EE/0337/AM01	A study using RM-493 in patients with LEPR deficiency obesity	1	15/01/2018	36
17/EE/0340/AM02	INTERIM	2	12/01/2018	32
17/EE/0342/AM01	The use of a therapist-made ankle-foot orthosis after stroke	SA1	02/11/2017	44

17/EE/0344/AM01	Use of blood cells in in-vitro characterisation assays	1	13/03/2018	21
17/EE/0374/AM01	Long-term Quality of Life and Function after Anterior Resection	1	08/12/2017	32
17/EE/0382/AM02	PROFILE - personalised medicine in Crohn's disease	SA1	18/01/2018	29
17/EE/0431/AM01	Dose Ranging Trial of MK-8591 Given in Combination Therapy	1	12/03/2018	19
17/EE/0463/AM01	Recombinant human parathyroid hormone for hypoparathyroidism in adults	1	14/02/2018	41
97/5/001/AM32	The Million Women Study	SA33	16/08/2017	26
97/5/007/AM38	UKFOCSS UK Familial Ovarian Cancer Screening Study	SA#30	26/04/2017	14
97/5/032/AM15	Familial Gastric Cancer Study.	17	29/11/2017	28
99/5/007/AM21	A population based study of genetic predisposition to Ovarian cancer	SA#21	31/03/2017	24

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/5/025/AM17	Recombinant growth hormone treatment in children born SGA version numb	SA#17	15/06/2017	22
12/EE/0305/AM02	Cortical Reorganisation in CRPS-An EEG Study (Version No.1)	1	28/11/2017	27
14/EE/0108/AM09	An evaluation of a water fluoridation scheme in Cumbria	SA7	09/06/2017	15
15/EE/0161/AM15	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	SA8	21/06/2017	15
15/EE/0350/AM14	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	SA9	21/06/2017	15
16/EE/0022/AM02	Implementation of an online relatives toolkit (IMPART study)	SA#02	20/04/2017	16
16/EE/0180/AM02	Femtosecond laser assisted cataract surgery in The NHS - Version1	SA1	24/01/2018	23
16/EE/0468/AM02	BBB permeability and Neuro-Inflammation in SVD	2	26/10/2017	34
17/EE/0003/AM01	Gravity Study	1	24/10/2017	28
17/EE/0126/AM02	PQR309-005_Efficacy and safety study of PQR309 in primary CNS lymphoma	4	26/06/2017	18

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

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/EE/0108/AM09/1	An evaluation of a water fluoridation scheme in Cumbria	MSA#7	09/06/2017	14
15/EE/0161/AM15/1	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	8	21/06/2017	5
15/EE/0350/AM14/1	Empagliflozin as adjunctive to insulin in Type 1 Diabetes (EASE-3)	9	21/06/2017	5
16/EE/0022/AM02/1	Implementation of an online relatives toolkit (IMPART study)	Modified amendment 2	05/06/2017	11
16/EE/0266/AM01/1	Laboratory studies into the pathology of leukaemia	Modified amendment 30.03.2017	28/03/2017	7
17/EE/0126/AM02/1	PQR309-005_Efficacy and safety study of PQR309 in primary CNS lymphoma	4.0	23/05/2017	15

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/EE/0468/AM02/1	BBB permeability and Neuro-Inflammation in SVD	3	26/01/2018	17

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

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/EE/0246	Comparative Brain and Spinal Imaging in MS, NMO and MOG-Ab Disease	26
17/EE/0247	Effects of groove music on movement in Parkinsonian DBS patients	26
17/EE/0249	Circulating microRNAs as biomarkers in MND; version 1.0	25
17/EE/0342	The use of a therapist-made ankle-foot orthosis after stroke	34
17/EE/0344	Use of blood cells in in-vitro characterisation assays	24
17/EE/0345	Can salivary hormone levels be correlated to ovarian response in IVF?	38
17/EE/0372	The experience of recovery following severe tibial fracture	27
17/EE/0374	Long-term Quality of Life and Function after Anterior Resection	32
17/EE/0467	Protect-NOW – Octapharma’s FVIII in PUPs and MTPs	25
18/EE/0061	HPV Biomarkers in Head and Neck Cancer	28
18/EE/0088	Intra- and Inter-Individual Variations In Disease Activity	22

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/EE/0210	A three-arm, Randomised Controlled Trial of the effectiveness and cost-effectiveness of adjunctive medication management and contingency management to enhance adherence to medications for relapse prevention in alcohol dependence	30

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
12/EE/0036/AM23	Study to Evaluate the Efficacy & Safety of LY2439821 Vs	9	20/12/2017	37

	Placebo in Ps			
15/EE/0200/AM03	Brain function for age curves in UK infants	4	02/08/2017	36
15/EE/0205/AM01	Gastropanel *for early detection of gastric atrophy and gastric cancer	1	05/01/2018	38
15/EE/0241/AM02	S-CORT: Stratification in COloRectal cancer:	2	24/11/2017	41
15/EE/0253/AM06	The Natural History of Malaria V.1	5	14/12/2017	36
16/EE/0008/AM07	ISIS 304801-CS17 - Broaden Study - Partial Lipodystrophy	5	19/12/2017	38
16/EE/0022/AM06	Implementation of an online relatives toolkit (IMPART study)	3	19/12/2017	37
16/EE/0103/AM01	The Human Vertebral Endplate: biomechanical study in spinal disorders	SA1	03/01/2018	38
16/EE/0207/AM02	Quality of Life in patients with an ileal anal pouch	2	16/01/2018	37
16/EE/0233/AM03	DECRYPT: Delivery of Cognitive Therapy for Young People after Trauma	2	20/01/2018	36
17/EE/0079/AM08	Avacopan in patients with Vasculitis	27/01/2017	11/12/2017	44
17/EE/0124/AM06	302-Phase 3 study of ALXN1210 VS ECULIZUMAB in adult patients with PNH	3	18/12/2017	37
17/EE/0177/AM05	BOSTON: Open-label Study of SVD versus VD in patients with RRMM	3	20/12/2017	37
17/EE/0337/AM01	A study using RM-493 in patients with LEPR deficiency obesity	1	15/01/2018	36
17/EE/0342/AM01	The use of a therapist-made ankle-foot orthosis after stroke	SA1	02/11/2017	44
17/EE/0463/AM01	Recombinant human parathyroid hormone for hypoparathyroidism in adults	1	14/02/2018	41

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/EE/0468/AM02/1	BBB permeability and Neuro-Inflammation in SVD	3	26/01/2018	17
17/EE/0126/AM02/1	PQR309-005_Efficacy and safety study of PQR309 in primary CNS lymphoma	4.0	23/05/2017	15