

London - Central Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - Central Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in patients
Type of Flag:	Paediatric research, Phase 1 in patients
Chair:	Dr Andrew Hilson
Vice-Chair:	Mr Clive Carsley
Alternate Vice-Chair:	Professor Lewis Spitz
REC Manager:	Elaine Hutchings
REC Assistant:	Mr Ewan Waters – up to April 2016 Miss Gemma Warren – April 2016 – January 2017 Miss Katherine Ashley (February – March 2017 Ms Julie Acourt (01/03/2017 to current date)
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The Committee continues to function well and reviews a wide range of applications particularly many CTIMPs, including several first-in-patient studies, which have raised some interesting issues. Our workload remains high, but we meet our targets.

The Committee remains popular with researchers for its position as well as for the quality of its reviews.

There has inevitably been some change in membership over the year but the Committee members continue to have excellent internal working relationships. Having lost some experienced members, we are looking for new blood. This is helped by having an annual meeting just for training and review of our practice.

We continue to have superb management support from Manchester, and this makes a major contribution to the smooth running of the REC.

London - Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Louise Abrams	Consultant Physician and Clinical Pharmacologist	Expert	10/04/2015	
Mr Clive Carsley	Retired Lawyer	Lay Plus	08/11/2007	
Dr Beverly Donaldson	Academic Research Midwife	Expert	11/02/2014	
Dr Olivia Festy	NHS Navigator	Lay	01/10/2006	
Mrs Sophie Forsyth	Lawyer	Lay Plus	01/04/2011	
Mr Stephen Gerry	Medical Statistician	Expert	02/03/2015	
Dr Andrew Hilson	Consultant in Nuclear Medicine	Expert	01/02/2012	
Miss Noor Mujahid	Student - Masters in Pharmacy	Lay	01/03/2016	
Lady Karen Rix	Retired lawyer	Lay Plus	12/10/2015	
Professor Lewis Spitz	Emeritus Nuffield Professor of Paediatric Surgery	Expert	29/11/2007	
Mr Benjamin Stanfield-Davies	Learning and Education Manager	Expert	23/05/2012	
Dr Gareth Tudor-Williams	Consultant in Paediatric Infectious Diseases	Expert	01/04/2010	
Dr Daniel Wang	Lecturer in Health and Human Rights	Lay Plus	01/07/2016	
Dr Sonya Elizabeth Wright	Retired GP	Expert	01/08/2016	

London - Central Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Jonathan Watkins	Social Worker	Expert	26/10/2016

London - Central Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Louise Abrams	May have a small number of shares in drug companies. However, I do not manage my portfolio.	29/03/2017
Mr Clive Carsley	Shares held through investment manager with discretionary authority.	29/03/2017
Dr Beverly Donaldson	Appointed in January 2016 by the Soapbox Collaborative as a part-time Postdoctoral Research Midwife in The Gambia, to cease on 5 April 2017. Post of Postdoctoral Research Midwife at ICL ceases 31 March 2017; was CI and Co-investigator for a number of studies.	31/03/2017
Dr Olivia Festy	Work in an academic health science centre in London associated with Guys Hospital	31/03/2017
Mrs Sophie Forsyth	None	29/03/2017
Mr Stephen Gerry	Member of trial steering committees, data monitoring committee, reviewers for HTA journal NIHR HTA & EMA grants	31/03/2017
Dr Andrew Hilson	Very small holdings in GSK and AstraZeneca. Possible holdings via Unit Trusts. Nuclear medicine / radiation dose from imaging (I have worked in the field for 40 years, and have served on ARSAC as chair of a research sub-committee).	31/03/2017
Miss Noor Mujahid	Pre- registration pharmacy training at Addenbrookes Cambridge NHS Trust & GlaxoSmithKline (GSK) UK to start 20/06/17.	29/03/2017
Lady Karen Rix	None to declare	29/03/2017
Professor Lewis Spitz	Shares in pharmaceutical industry..	29/03/2017
Mr Benjamin Stanfield-Davies	Head of Clinical Education Nuffield Health. Change in role - formerly Senior Lecturer in University, now Head of Education in a Trust - 30/05/16.	29/03/2017
Dr Gareth Tudor-Williams	Member of the Scientific Steering Committee for the Paediatric European Network for the Treatment of Aids (PENTA).ember of Steering committee, Collaborative HIV in Paediatrics Study (CHIPS). UK surveillance and research programme. Lead clinical scientist for research studies relating to blood borne viruses in children for Imperial College London. Research in children or perinatal studies especially relating to infectious diseases in children.	29/03/2017
Dr Daniel Wang	Nothing to declare	29/03/2017
Dr Sonya Elizabeth Wright	None to declare	29/03/2017

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

Month	Date	Number of Members Present at Meeting
April	27/04/2016	8
June	29/06/2016	10
July	27/07/2016	12
August	31/08/2016	10
September	28/09/2016	11
October	26/10/2016	9
November	30/11/2016	10
January	25/01/2017	11
February	22/02/2017	9
March	29/03/2017	11

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	12/04/2016	3
May	12/05/2016	3
June	16/06/2016	3
July	13/07/2016	3
August	11/08/2016	5
September	16/09/2016	4
October	12/10/2016	5
November	14/11/2016	3
January	19/01/2017	3
February	09/02/2017	3
March	09/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	2
April	22/04/2016	2
April	29/04/2016	2
May	20/05/2016	2
June	08/06/2016	2
June	24/06/2016	2
July	01/07/2016	5
July	15/07/2016	2
July	29/07/2016	2
August	05/08/2016	2

August	19/08/2016	2
August	26/08/2016	2
September	16/09/2016	2
October	07/10/2016	2
October	28/10/2016	2
November	04/11/2016	2
November	18/11/2016	2
November	25/11/2016	3
December	02/12/2016	2
December	16/12/2016	2
December	23/12/2016	2
January	06/01/2017	3
January	13/01/2017	3
January	20/01/2017	2
February	10/02/2017	2
February	17/02/2017	3
March	03/03/2017	3
March	10/03/2017	2
March	17/03/2017	2
March	24/03/2017	2
March	31/03/2017	2

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

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

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

Name	No. of Meetings Attended
Dr Louise Abrams	7
Mr Clive Carsley	9
Dr Beverly Donaldson	6
Dr Olivia Festy	5
Mrs Sophie Forsyth	7
Mr Stephen Gerry	8
Dr Andrew Hilson	10
Miss Noor Mujahid	4
Lady Karen Rix	9
Professor Lewis Spitz	9
Mr Benjamin Stanfield-Davies	5
Dr Gareth Tudor-Williams	8
Dr Daniel Wang	6
Dr Sonya Elizabeth Wright	6

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

Name	No. of Meetings Attended
Dr Louise Abrams	1
Mr Clive Carsley	6
Dr Olivia Festy	4
Mrs Sophie Forsyth	2
Mr Stephen Gerry	2
Miss Sarah Gregory	1
Dr Andrew Hilson	11
Mr Christopher Houston	1
Miss Noor Mujahid	1
Lady Karen Rix	1
Professor Lewis Spitz	7
Dr Sonya Elizabeth Wright	1

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

Name	No. of Meetings Attended
Dr Louise Abrams	1
Mr Clive Carsley	29
Mrs Sophie Forsyth	2
Dr Andrew Hilson	30
Lady Karen Rix	1
Professor Lewis Spitz	6
Mr Benjamin Stanfield-Davies	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Louise Abrams	25/05/2016	London Central REC Training Day
Mr Clive Carsley	25/05/2016	London Central REC Training Day
Mr Clive Carsley	30/06/2016	Equality, Diversity and Human Rights
Dr Beverly Donaldson	25/05/2016	London Central REC Training Day
Dr Olivia Festy	25/05/2016	London Central REC Training Day
Mrs Sophie Forsyth	25/05/2016	London Central REC Training Day
Mr Stephen Gerry	25/05/2016	London Central REC Training Day
Mr Stephen Gerry	04/10/2016	Research Ethics Seminar
Dr Andrew Hilson	25/05/2016	London Central REC Training Day
Dr Andrew Hilson	01/07/2016	Consultant Mandatory Training
Dr Andrew Hilson	01/07/2016	Equality & Diversity
Dr Andrew Hilson	07/11/2016	The Practicalities of Running a REC
Dr Andrew Hilson	01/12/2016	REC National Chairs' training day
Dr Andrew Hilson	27/03/2017	Chairs' Review Programme Workshop
Miss Noor Mujahid	01/06/2016	Human Rights and Global Development
Miss Noor Mujahid	06/08/2016	Information Governance Package
Miss Noor Mujahid	23/09/2016	Medicines Ethics and Practice
Miss Noor Mujahid	31/03/2017	Research Ethics Paris Descartes Laboratories
Lady Karen Rix	10/03/2017	E-consent training
Professor Lewis Spitz	04/07/2016	CTIMP Training
Professor Lewis Spitz	16/02/2017	National Members Training Day
Dr Gareth Tudor-Williams	25/05/2016	London Central REC Training Day
Dr Daniel Wang	01/07/2016	On-line induction training
Dr Sonya Elizabeth Wright	06/12/2016	Committee members induction

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	29	52.73
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.82
Research Database (including renewals)	0	0.00
Others	25	45.45
Total Applications Reviewed	55	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	16
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

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	1.82
Favourable Opinion with Additional Conditions	12	21.82
Unfavourable Opinion	2	3.64
Provisional Opinion	40	72.73
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	55	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	33	60.00
Further Information Favourable Opinion with Additional Conditions	5	9.09
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.82
Favourable Opinion with Additional Conditions	12	21.82
Unfavourable Opinion	2	3.64
Provisional Opinion	1	1.82
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.82
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	55	100

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

Total Applications Reviewed	30
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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	3
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	2
Number of qualitative applications reviewed	1

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	5	16.67
Favourable Opinion with Additional Conditions	8	26.67
No Opinion transfer to full committee for review	4	13.33
Provisional Opinion	12	40.00
Unfavourable Opinion	1	3.33
Total	30	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	5.50
Number of completed applications for full ethical review	55
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	1
Number of completed applications over 40 days as a % of total	1.82%
Number of days taken to final decision – average (mean)	24
Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days (<i>The timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016</i>)	1
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 14 days as a % of total	3.85%
Number of SSAs (non-Phase 1) reviewed	8
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	173
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	5
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.89%
Number of modified amendments reviewed	9
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 non-substantial amendments received	138
Number of substantial amendments received for information	1
Number of substantial amendments received for new	47

sites/PIs	
Number of annual progress reports received	91
Number of safety reports received	67
Number of Serious Adverse Events received	0
Number of final reports received	6

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/LO/0605	Perception of Emotional Expression and Play	25
16/LO/0632	Paternally Inherited Phenotypes in Cholestasis (PIP-C) V2	28
16/LO/0675	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	28
16/LO/0680	SMILE (PENTA 17)	25
16/LO/1004	MIROCALS_H2020/PHRC-N/2014/GB-01_ID-IL-2_Neuro-Inflammation in ALS Pts	20
16/LO/1012	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	27
16/LO/1069	PALbociclib CoLlaborative Adjuvant Study	22
16/LO/1265	Deaths in Children with Epilepsy	26
16/LO/1318	Nucleos(t)ide withdrawal in Hepatitis B virus infection (NUC-B)	20
16/LO/1322	RSV Vaccine in Pregnancy	21
16/LO/1353	Intestinal hypoperfusion and tissue injury in preterm infants V2	27
16/LO/1357	SSAT062 - PK of EFV 400mg once daily in presence of RIF/INH	24
16/LO/1440	UNDISTORT Correction of distortions in diffusion MRI V1.0	20
16/LO/1480	Disclosure Likelihood in People with HIV	50
16/LO/1485	Compassionate Use of Baricitinib to Treat Auto-inflammatory Syndromes	23
16/LO/1489	A pilot study to develop simultaneous PET-MR scanner technology	21
16/LO/1494	Study of Intramuscular Cabotegravir + Rilpivirine in ART naive adults	22
16/LO/1497	Study to Determine Effect of Arginine on Plaque Adhesive Properties	32
16/LO/1637	First-in-human, trial of HuMax-AXL-ADC in patients with solid tumours	23
16/LO/1641	Phase 1/2a to asses PEN-221 in receptor 2 expressing advanced cancers	27
16/LO/1653	F-I-H study of ODM-207 in patients with advanced solid tumours	22
16/LO/1684	PERFORM	28
16/LO/1861	Safety and efficacy study of SOM230 s.c. in Cluster Headaches	22
16/LO/1928	EXERT PCI study	24
16/LO/2106	Phase IB study of Rucaparib and Atezolizumab for gynaecologic cancers	16
17/LO/0039	Collection of Blood Samples to Optimise Immunotherapy Methodologies	23
17/LO/0096	SUSTAIN (205MS305)	20
17/LO/0247	A Phase 1/2 Safety and Tolerability Study of INCAGN01949	26
17/LO/0284	Single doses of GSK3008348 in IPF patients using PET imaging	23
17/LO/0319	Monitoring OrgAn Transplant (MOAT)	26
17/LO/0347	MK-3475 + Chemotherapy as Neoadjuvant and Adjuvant therapy for TNBC	31
17/LO/0369	Metagenomic and Metatranscriptomic Analysis of Clinical Plaque Samples	28

17/LO/0531	The Self and Self-Knowledge after Prefrontal Neurosurgical lesions	21
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1158	Evaluation of Paediatric Care Online UK	33
16/LO/1794	4213 alleviate1: Giving N8-GP by subcutaneous injection	28
16/LO/1874	Canakinumab in paediatric and young adult sickle cell anaemia patients	31
16/LO/2075	PROMISE Feasibility Study	27
17/LO/0105	Automated, quantitative pupil assessment using binocular OCT	22

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/LO/0269	Plasma, Serum & DNA bank from patients with antiphospholipid antibodies	8

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0715	Experiences of School for Patients at Evelina London	29
16/LO/0805	MK-3475-224: MK-3475 in subjects with previously treated HCC	23
16/LO/1082	CC-90011-ST-001	19
16/LO/1321	LA monitoring regime after FICB	19
16/LO/1715	Understanding the musculoskeletal function of lower limb amputees	23
16/LO/1883	ENLIGHTEN	23
16/LO/2007	Hepatitis C Virus- Know Your Status V.1	20
16/LO/2068	Comparison of two ultrasound techniques	20
16/LO/2078	BP29842 – A Phase Ia/Ib Study of RO6874281 in Metastatic Solid Tumors	20
17/LO/0066	A study of AUT00206 in people with schizophrenia; v1	19
17/LO/0085	INNO2VATE-CONVERSION_Version 1.0_dated 06 May 2016	19
17/LO/0301	RSV-F-004 - RSV Vaccine in Healthy Pregnant Women and their Infants	20

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/1680	Fish Oil Supplementation on Maternal Health (FOSMAT)	9
17/LO/0287	Microbiome and Diet	20

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0402	WO39210 - Atezolizumab in patients with renal cell carcinoma	n/a

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock
17/LO/0440	A Phase 1 Study to Evaluate ISIS 814907 in Mild Alzheimer's Disease	n/a

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

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0924	Eight week pilot study of HFAO in COPD	5
16/LO/0925	Acceptability of personalised risk-based breast cancer screening v1.0	6
16/LO/0927	Community antibiotics and the development of resistance	11
16/LO/1326	Cardiac-Oncology Toxicity in Breast Cancer	3
16/LO/1335	Non-invasive brain stimulation of cognitive functions	13
16/LO/1521	Retrospective Medical Record Review Study	10
16/LO/1529	Productivity losses & indirect costs after cardiovascular events V1.0	9

16/LO/1897	Kidney transplant monitoring using near infra-red spectroscopy	12
16/LO/2051	Health Needs Assessment for Underserved Populations Version 1.0	6
17/LO/0176	Prevalence of ATTR amyloid in the carpal tunnel	7
17/LO/0276	Impact of Hand-Held Cardiac Ultrasound in General Practice Version 3.1	4

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
16/LO/1183	Detection of Circulating Tumour Cells in Thyroid Cancer (CircuiTT)	8
16/LO/1522	The evaluation of diagnostic management in young febrile infants	9
16/LO/1693	Inhaler Technology Study	3
16/LO/1894	Patient participation in improving general practice	14
17/LO/0466	Phenotyping neonatal Leucocytes Using Mass Spectrometry (PLUMS)	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0728	Audit of factors associated with liver service referral for hep B	6
16/LO/1166	Cardiovascular risk in children and adolescents in ten British towns	9
16/LO/1168	Platelet & micro-particle PL in thrombotic and bleeding disorders	20
16/LO/1178	Medicine Related Problems in Adult Patients with AF on DOACs	3
16/LO/1531	Narratives of Bowel Cancer Screening in Hull	9
16/LO/1884	Medication Adherence in Bariatric Patients	8
16/LO/1887	Pilot study investigating EAMS as fitness measure in cancer patients	14
17/LO/0279	Impact of Prior Care Experience. Version 1.0.	2

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/1708	NHS Health Checks dementia component to all ages pilot project	13

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0454	Use of Thromboelastography in Interventional Radiology	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
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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
06/MRE02/4/AM11	UK Genetic Prostate Cancer Study (UKGPCS)	Substantial Amendment 10	12/10/2016	28
07/H0718/90/AM52	SPIRIT 2 trial in CML	Substantial amendment 45	08/06/2016	20
07/H0718/90/AM58	SPIRIT 2 trial in CML	Substantial amendment 50	21/12/2016	16
07/H0718/90/AM61	SPIRIT 2 trial in CML	Substantial amendment 52	07/03/2017	13
08/H0718/11/AM23	Bevacizumab and standard chemotherapy in childhood soft-tissue sarcoma	Substantial amendment 19	01/02/2017	27
08/H0718/22/AM25	PORTEC-3 - Version 1.0	Substantial Amendment 22	29/11/2016	23
09/H0718/29/AM05	Study of free walking in patients with balance problems	Substantial amendment 6	01/03/2016	17
09/H0718/40/AM06	PANNA v2	Substantial Amendment 5	23/01/2017	23
09/H0718/51/AM53	TORPEDO-CF	Substantial amendment 36	03/03/2016	22
09/H0718/51/AM55	TORPEDO-CF	Substantial Amendment 37	27/10/2016	19
10/H0718/53/AM13	Phase 2/3 study of Lenalidomide in Diffuse Large B-Cell Lymphoma	Substantial Amendment 10	17/06/2016	19
10/H0718/53/AM14	Phase 2/3 study of Lenalidomide in Diffuse Large B-Cell Lymphoma	Substantial Amendment 11	26/10/2016	19
10/H0718/55/AM04	Larynx Cancer Screening With Endoscopic Optical Coherence Tomography	Substantial amendment 2	08/06/2016	28
11/LO/0923/AM20	BO25041 Paed HGG	Substantial Amendment 15	01/02/2017	26
11/LO/1487/AM36	UKALL 2011	Substantial amendment 25	16/06/2016	25
12/LO/0050/AM09	Study of Tadalafil in Children with Pulmonary Arterial Hypertension(a)	Substantial Amendment 7	06/10/2016	15

12/LO/1328/AM11	ACE-011-B-THAL-001 Amendment 1 dated 4th May 2012	Substantial amendment 7	04/07/2016	17
13/LO/0062/AM06	MIN-001-1203: 2-OHOA in advanced solid tumours, V1.0	Substantial Amendment 4	18/11/2016	21
13/LO/0208/AM10	A study of Dabrafenib in Participants under 18 with solid tumours	Substantial amendment 8	24/01/2017	21
13/LO/0751/AM03	Studying autism and ADHD risks (STAARS)	Substantial amendment 2	18/05/2016	18
13/LO/0986/AM09	A Phase 1/2a study of Oral TSR-011 in Solid Tumors and Lymphomas	Substantial Amendment 5	14/12/2016	27
13/LO/1148/AM03	SPIRIT 3 - study to evaluate best use of TKIs in chronic phase CML	Substantial amendment 3	18/03/2016	15
13/LO/1161/AM01	Is gait speed and sarcopenia prognostic in chronic respiratory disease	Substantial amendment 1	10/03/2016	24
13/LO/1705/AM01	Epilepsy in infancy	Substantial Amendment 1	28/07/2016	25
13/LO/1766/AM16	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	Substantial amendment 13	18/04/2016	20
13/LO/1766/AM17	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	Substantial amendment 14	10/08/2016	14
13/LO/1766/AM19	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	Substantial Amendment 16	07/12/2016	16
14/LO/0092/AM04	OTX015_104	Substantial Amendment 8	09/09/2016	12
14/LO/0103/AM06	ComPAKT: A Phase I trial of olaparib in combination with AZD5363	Substantial Amendment 5	26/10/2016	21
14/LO/0401/AM10	IPTG-01: A new skin cream for impetigo	Substantial Amendment 7	10/10/2016	4
14/LO/0511/AM01	CBT for Insomnia: exploring mode of delivery and sleep outcomes v1	Substantial amendment 1	16/05/2016	17
14/LO/1022/AM02	Prognostic Biomarkers in Epilepsy (ELMO) Study	Substantial amendment 2	20/10/2015	21
14/LO/1066/AM01	SAF001	Substantial Amendment 1	05/09/2016	16
14/LO/1081/AM09	A Phase I study of TAS-119 given as a single agent and in combination	Substantial amendment 6	16/12/2016	22
14/LO/1091/AM11	Alnylam - ALN-TTRSC-003 - TTR Cardiac Amyloidosis	Substantial	08/03/2016	22

		amendment 4		
14/LO/1091/AM12	Alnylam - ALN-TTRSC-003 - TTR Cardiac Amyloidosis	Substantial amendment 5	25/03/2016	7
14/LO/1091/AM15	Alnylam - ALN-TTRSC-003 - TTR Cardiac Amyloidosis	Substantial Amendment 6	07/10/2016	12
14/LO/1091/AM16	Alnylam - ALN-TTRSC-003 - TTR Cardiac Amyloidosis	Substantial Amendment 7	14/10/2016	14
14/LO/1122/AM05	PPALM - Palm oil and Pentoxifylline Against Late Morbidity	Substantial Amendment 4	01/11/2016	22
14/LO/1195/AM09	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial amendment 4	06/05/2016	14
14/LO/1195/AM10	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial amendment 5	20/07/2016	7
14/LO/1195/AM14	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial Amendment 7	05/12/2016	14
14/LO/1336/AM04	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial amendment 4	29/03/2016	15
14/LO/1336/AM05	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial Amendment 5	23/09/2016	19
14/LO/1336/AM06	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial Amendment 6	24/01/2017	21
14/LO/1407/AM06	TERIKIDS	Substantial Amendment 3	18/01/2017	12
14/LO/1428/AM12	Adjunctive Steroid Combination in Ocular Trauma (ASCOT) Study	Substantial amendment 7	23/03/2016	20
14/LO/1467/AM07	Deep and Frequent Phenotyping Feasibility	Substantial amendment 4	17/02/2016	3
14/LO/1553/AM02	5-FU in relapsed Ependymoma v2.0	Substantial Amendment 1	24/05/2017	12
14/LO/1868/AM06	A Study of BYL719 in patients with pNETs, RCC and breast cancer.	Substantial amendment 3	11/07/2016	7
14/LO/1868/AM07	A Study of BYL719 in patients with pNETs, RCC and breast cancer.	Substantial Amendment 4	16/11/2016	7
14/LO/1885/AM03	EDIBLE v1.0	Substantial amendment 2	18/03/2016	14
14/LO/1885/AM04	EDIBLE v1.0	Substantial Amendment 3	13/09/2016	8

14/LO/2041/AM08	AZD6094 in patients with papillary renal cell carcinoma	Substantial Amendment 8	06/06/2016	7
14/LO/2041/AM09	AZD6094 in patients with papillary renal cell carcinoma	Substantial Amendment 9	06/01/2017	27
15/LO/0286/AM05	TRACE mechanistic assessments	Substantial Amendment 3	22/11/2016	15
15/LO/0286/AM06	TRACE mechanistic assessments	Substantial Amendment 4	06/01/2017	35
15/LO/0287/AM04	Boiled Oral Peanut Immunotherapy (The BOPI Study)	Substantial amendment 4	08/04/2016	18
15/LO/0287/AM05	Boiled Oral Peanut Immunotherapy (The BOPI Study)	Substantial Amendment 5	09/02/2017	21
15/LO/0407/AM02	Attention Control Training for Infants at Risk of ADHD (INTERSTAARS)	Substantial amendment 2	12/05/2016	11
15/LO/0423/AM05	SSAT064: PK of ABC/3TC/DTG in HIV patients of 60 years and over	Substantial Amendment 2	29/11/2016	21
15/LO/0443/AM06	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial amendment 5	16/10/2015	23
15/LO/0443/AM11	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial amendment 8	17/06/2016	25
15/LO/0443/AM14	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial amendment 9	25/01/2017	5
15/LO/0460/AM04	SSAT058:Atripla to Eviplera switch in patients without CNS symptoms	Substantial Amendment 3	17/11/2016	8
15/LO/0615/AM08	A Phase II study of ABT-414 for recurrent glioblastoma	Substantial Amendment 5	18/11/2016	21
15/LO/0710/AM04	EMBARK:MDV3100-13 Phase3, Enzalutamide, non-metastatic Prostate Cancer	Substantial Amendment 4	28/07/2016	25
15/LO/0710/AM05	EMBARK:MDV3100-13 Phase3, Enzalutamide, non-metastatic Prostate Cancer	Substantial amendment 5	09/03/2017	12
15/LO/0711/AM10	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 5	01/06/2016	11
15/LO/0711/AM13	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial Amendment 6	27/07/2016	17
15/LO/0711/AM14	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial Amendment 7	03/10/2016	16
15/LO/0711/AM15	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial	04/11/2016	16

		Amendment 8		
15/LO/0711/AM17	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 9	23/02/2017	14
15/LO/0743/AM02	Safety and effects of FP-02.2 - first doses in humans;v1	Substantial amendment 4	20/05/2016	20
15/LO/0743/AM03	Safety and effects of FP-02.2 - first doses in humans;v1	Substantial amendment 5	23/06/2016	21
15/LO/0743/AM04	Safety and effects of FP-02.2 - first doses in humans;v1	Substantial Amendment 6	21/11/2016	16
15/LO/0743/AM06	Safety and effects of FP-02.2 - first doses in humans;v1	Substantial amendment 7	16/03/2017	26
15/LO/1006/AM03	Phase II copanlisib in relapsed or refractory DLBCL	Substantial amendment 3	10/05/2016	4
15/LO/1006/AM04	Phase II copanlisib in relapsed or refractory DLBCL	Substantial Amendment 4	18/08/2016	15
15/LO/1041/AM05	Gut Hormones in Addiction (GHADD) v1.1	Substantial Amendment 3	04/11/2016	22
15/LO/1041/AM06	Gut Hormones in Addiction (GHADD) v1.1	Substantial Amendment 4	15/02/2017	20
15/LO/1044/AM03	ACTICCA-1	Substantial Amendment 3	28/07/2016	18
15/LO/1044/AM05	ACTICCA-1	Substantial Amendment 4	22/12/2016	13
15/LO/1050/AM02	DARWIN1	Substantial amendment 2	15/06/2016	17
15/LO/1179/AM03	LPS14201 (XRP6258) Cabazitaxel vs abiraterone or enzalutamide in mCRPC	Substantial Amendment 2	28/11/2016	21
15/LO/1226/AM02	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial amendment 1	12/05/2016	14
15/LO/1226/AM03	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial amendment 2	19/05/2016	4
15/LO/1226/AM04	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial amendment 3	22/12/2016	21
15/LO/1226/AM05	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial amendment 4	22/03/2017	25
15/LO/1284/AM03	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial amendment 2	26/04/2016	13

15/LO/1284/AM04	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial Amendment 3	05/08/2016	28
15/LO/1284/AM06	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial Amendment 5	02/11/2016	21
15/LO/1284/AM07	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial amendment 6	05/01/2017	28
15/LO/1589/AM03	New Biomarkers of Early Myocardial Infarction	Substantial amendment 3	24/02/2017	8
15/LO/1595/AM01	PRISM	Substantial amendment 1	01/03/2016	21
15/LO/1598/AM02	WA29767 - A study of Tocilizumab versus placebo in Systemic Sclerosis	Substantial amendment 2	20/05/2016	14
15/LO/1598/AM03	WA29767 - A study of Tocilizumab versus placebo in Systemic Sclerosis	Substantial Amendment 3	15/12/2016	27
15/LO/1600/AM02	GDC-0810 vs fulvestrant in advanced/metastatic ER+/HER2-Breast Cancer	Substantial amendment 2	18/03/2016	22
15/LO/1600/AM05	GDC-0810 vs fulvestrant in advanced/metastatic ER+/HER2-Breast Cancer	Substantial amendment 4	24/06/2016	13
15/LO/1600/AM12	GDC-0810 vs fulvestrant in advanced/metastatic ER+/HER2-Breast Cancer	Substantial Amendment 6	21/02/2017	16
15/LO/1760/AM08	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	Substantial Amendment 5	29/04/2016	7
15/LO/1760/AM11	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	Substantial amendment 7	23/03/2017	27
15/LO/1807/AM03	CA209-331 Nivolumab vs Chemotherapy in SCLC	Substantial amendment 2	06/06/2016	15
15/LO/1807/AM04	CA209-331 Nivolumab vs Chemotherapy in SCLC	Substantial Amendment 3	15/12/2016	25
15/LO/1908/AM02	Phase I/IIa Study of DTP3 in Patients With Advanced Multiple Myeloma	Substantial amendment 1	23/05/2016	10
15/LO/1908/AM03	Phase I/IIa Study of DTP3 in Patients With Advanced Multiple Myeloma	Substantial amendment 2	18/07/2016	3
15/LO/1908/AM05	Phase I/IIa Study of DTP3 in Patients With Advanced Multiple Myeloma	Substantial Amendment 3	21/12/2016	28
15/LO/1908/AM06	Phase I/IIa Study of DTP3 in Patients With Advanced Multiple Myeloma	Substantial amendment 4	16/03/2017	27
15/LO/1922/AM01	Anakinra vs. Steroids for Gout Attacks in patients with Renal	Substantial	11/08/2016	10

	Disease	Amendment 1		
15/LO/1922/AM02	Anakinra vs. Steroids for Gout Attacks in patients with Renal Disease	Substantial Amendment 2	12/12/2016	27
15/LO/1922/AM04	Anakinra vs. Steroids for Gout Attacks in patients with Renal Disease	Substantial Amendment 3	08/02/2017	15
15/LO/1945/AM02	Prophylaxis against acute attacks of Hereditary Angioedema (HAE)	Substantial amendment 2	30/06/2016	22
15/LO/1945/AM03	Prophylaxis against acute attacks of Hereditary Angioedema (HAE)	Substantial Amendment 3	08/02/2017	27
15/LO/1954/AM01	Quality Of Life Tool for IBD (QOLITI)	Substantial Amendment 1	24/08/2016	5
16/LO/0093/AM01	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial amendment 1	22/01/2016	18
16/LO/0093/AM02	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial amendment 2	20/06/2016	11
16/LO/0093/AM03	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial Amendment 3	27/07/2016	3
16/LO/0124/AM02	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	Substantial amendment 1	13/03/2016	3
16/LO/0124/AM03	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	Substantial Amendment 2	17/10/2016	29
16/LO/0340/AM01	MSB11022 in Moderate to Severe Chronic Plaque Psoriasis	Substantial amendment 1	20/06/2016	28
16/LO/0340/AM03	MSB11022 in Moderate to Severe Chronic Plaque Psoriasis	Substantial Amendment 2	02/12/2016	16
16/LO/0340/AM04	MSB11022 in Moderate to Severe Chronic Plaque Psoriasis	Substantial Amendment 3	23/12/2016	21
16/LO/0354/AM01	Cygnus	Substantial amendment 1	26/04/2016	21
16/LO/0529/AM01	CORE Trial	Substantial Amendment 1	16/08/2016	20
16/LO/0529/AM03	CORE Trial	Substantial Amendment 2	08/12/2016	25
16/LO/0537/AM01	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial amendment 1	27/05/2016	11
16/LO/0537/AM02	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial Amendment 2	08/07/2016	21

16/LO/0537/AM03	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial Amendment 3	26/07/2016	4
16/LO/0537/AM04	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial Amendment 4	28/09/2016	21
16/LO/0537/AM05	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial Amendment 5	31/10/2016	26
16/LO/0537/AM06	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial amendment 6	17/03/2017	17
16/LO/0675/AM02	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	Substantial amendment 2	11/07/2016	10
16/LO/0675/AM03	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	Substantial Amendment 3	18/10/2016	27
16/LO/0675/AM04	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	Substantial Amendment 4	21/11/2016	18
16/LO/0680/AM01	SMILE (PENTA 17)	Substantial amendment 1	21/12/2016	28
16/LO/0805/AM01	MK-3475-224: MK-3475 in subjects with previously treated HCC	Substantial amendment 1	24/06/2016	13
16/LO/0805/AM04	MK-3475-224: MK-3475 in subjects with previously treated HCC	Substantial Amendment 2	24/10/2016	12
16/LO/0805/AM07	MK-3475-224: MK-3475 in subjects with previously treated HCC	Substantial amendment 3	15/03/2017	6
16/LO/0924/AM01	Eight week pilot study of HFAO in COPD	Substantial Amendment 1	16/01/2017	19
16/LO/1004/AM01	MIROCALS_H2020/PHRC-N/2014/GB-01_ID-IL-2_Neuro-Inflammation in ALS Pts	Substantial Amendment 1	29/11/2016	20
16/LO/1004/AM04	MIROCALS_H2020/PHRC-N/2014/GB-01_ID-IL-2_Neuro-Inflammation in ALS Pts	Substantial amendment 3	08/02/2017	27
16/LO/1012/AM01	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	Substantial Amendment 1	24/11/2016	12
16/LO/1012/AM02	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	Substantial Amendment 2	22/12/2016	22
16/LO/1069/AM05	PALbociclib CoLaborative Adjuvant Study	Substantial Amendment 2	31/01/2017	27
16/LO/1082/AM02	CC-90011-ST-001	Substantial amendment 1	24/11/2016	13
16/LO/1322/AM02	RSV Vaccine in Pregnancy	Substantial	27/06/2016	29

		amendment 1		
16/LO/1322/AM04	RSV Vaccine in Pregnancy	Substantial Amendment 2	20/01/2017	25
16/LO/1335/AM01	Non-invasive brain stimulation of cognitive functions	Substantial Amendment 1	29/09/2016	14
16/LO/1357/AM01	SSAT062 - PK of EFV 400mg once daily in presence of RIF/INH	Substantial Amendment 1	11/10/2016	29
16/LO/1485/AM01	Compassionate Use of Baricitinib to Treat Auto-inflammatory Syndromes	Substantial Amendment 1	06/12/2016	25
16/LO/1485/AM02	Compassionate Use of Baricitinib to Treat Auto-inflammatory Syndromes	Substantial Amendment 2	30/01/2017	26
16/LO/1494/AM01	Study of Intramuscular Cabotegravir + Rilpivirine in ART naive adults	Substantial Amendment 1	19/10/2016	27
16/LO/1494/AM04	Study of Intramuscular Cabotegravir + Rilpivirine in ART naive adults	Substantial Amendment 2	09/02/2017	21
16/LO/1637/AM01	First-in-human, trial of HuMax-AXL-ADC in patients with solid tumours	Substantial Amendment 1	10/01/2017	27
16/LO/1641/AM02	Phase 1/2a to asses PEN-221 in receptor 2 expressing advanced cancers	Substantial Amendment 1	22/12/2016	21
16/LO/1641/AM03	Phase 1/2a to asses PEN-221 in receptor 2 expressing advanced cancers	Substantial amendment 2	23/03/2017	19
16/LO/1653/AM02	F-I-H study of ODM-207 in patients with advanced solid tumours	Substantial amendment 1	28/02/2017	9
16/LO/1684/AM01	PERFORM	Substantial Amendment 1	16/12/2016	24
16/LO/1884/AM01	Medication Adherence in Bariatric Patients	Substantial Amendment 1	17/01/2017	18
16/LO/2078/AM01	BP29842 – A Phase Ia/Ib Study of RO6874281 in Metastatic Solid Tumors	Substantial amendment 1	15/03/2017	6
17/LO/0066/AM01	A study of AUT00206 in people with schizophrenia; v1	Substantial amendment 1	09/03/2017	12
98/2/051/AM02	PHLS collaborative unlinked anonymous survey of salivary antibodies to HIV, hepatitis B core antigen and hepatitis C in injecting drug users in England and Wales	Substantial Amendment 4	22/07/2016	8
98/2/40/AM02	A randomised controlled trial of the effect on breast cancer mortality of annual mammographic screening starting at age 40	Substantial amendment 3	05/07/2016	15

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/LO/0222/AM05	The contribution of exosomes to cardioprotection from RIPC. Version 1	Substantial Amendment 4	06/12/2016	27
14/LO/0187/AM04	Phase I/II study in advanced solid tumours or multiple myeloma TAS-120	Substantial amendment 3	19/02/2016	22
14/LO/1022/AM05	Prognostic Biomarkers in Epilepsy (ELMO) Study	Substantial amendment 3	21/12/2016	27
15/LO/1179/AM01	LPS14201 (XRP6258) Cabazitaxel vs abiraterone or enzalutamide in mCRPC	Substantial Amendment 1	16/06/2016	26
15/LO/1756/AM01	Human Factor and Usability Testing of A Binocular OCT System	Substantial amendment 1	29/06/2016	14
16/LO/0124/AM04	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	Substantial Amendment 3	23/12/2016	26
16/LO/0354/AM06	Cygnus	Substantial Amendment 4	15/11/2016	24
16/LO/0432/AM11	EUROASPIRE V/ASPIRE-3-PREVENT	Substantial Amendment	07/12/2016	27
MREC/02/2/93/AM03	Molecular Genetics of Metabolic and Endocrine Disorders	Substantial amendment 3	01/05/2016	27
MREC/02/2/93/AM04	Molecular Genetics of Metabolic and Endocrine Disorders	Substantial amendment 4	11/10/2016	34

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
06/MRE02/73/AM12/1	Longitudinal study of infant siblings of children with autism	Modification of substantial amendment 8	21/03/2016	3
14/LO/0187/AM04/1	Phase I/II study in advanced solid tumours or multiple myeloma TAS-120	Modification of substantial	19/02/2016	0

		amendment 3		
14/LO/1022/AM05/1	Prognostic Biomarkers in Epilepsy (ELMO) Study	Substantial amendment 3	15/02/2017	2
15/LO/1179/AM01/1	LPS14201 (XRP6258) Cabazitaxel vs abiraterone or enzalutamide in mCRPC	Modification of substantial amendment 1	02/08/2016	8
15/LO/1756/AM01/1	Human Factor and Usability Testing of A Binocular OCT System	Substantial Amendment 1 modified	01/08/2016	11
16/LO/0124/AM04/1	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	Substantial Amendment 3 Modified	01/02/2017	6
16/LO/0354/AM06/2	Cygnus	Substantial Amendment 4 Modified Amendment	19/12/2016	6
16/LO/0432/AM11/1	EUROASPIRE V/ASPIRE-3-PREVENT	Modified substantial amendment 1	16/01/2017	4
MREC/02/2/93/AM04/1	Molecular Genetics of Metabolic and Endocrine Disorders	Substantial amendment 4 modified	03/02/2017	1

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

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

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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