

London - Central Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



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:	Julie Acourt
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 be popular with researchers and has received good feedback from them, particularly on the quality and punctuality of reviews.

It has been a challenging year, with some tricky applications, but we have had no complaints! We continue to find high-quality new members, replacing those who have come to the end of their time, but are always happy to consider new applications.

None of this could happen without our excellent support from Manchester, where our business manager is based, who continues to make it all happen.

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	
Dr Kieran Brack	Project Manager	Lay	01/01/2018	
Professor David Caplin	Retired Physicist	Lay	28/02/2018	
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	01/02/2018
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	23/05/2017
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
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	26/07/2017 & 25/10/2017
Mrs Sally Gordon-Boyd	Medical Ethicist	Lay Plus	25/10/2017
Dr Margaret Jones	Retired General Practitioner	Expert	26/07/2017
Mr John Addison	Retired Librarian	Lay Plus	08/02/2018 (PRSC)
Mr David Asher	Retired Pharmacist	Lay	08/03/2018 (PRSC)
Mrs Christine Holly	Retired Librarian	Lay Plus	08/03/2018 (PRSC)

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

Name	Declaration of Interest	Date
Dr Louise Abrams	Shares managed by a bank, unknown which companies they are invested in.	31/03/2018
Dr Kieran Brack	Currently employed as a Senior Clinical Trial Manager at the London School of Hygiene and Tropical Medicine, working within the Clinical Trials Unit.	31/03/2018
Professor David Caplin	College of Optometrists, member of Lay Panel and of Research Committee College of Optometrists, member of Lay Panel and of Research Committee NIHR University College London Hospitals Biomedical Research Centre Inflammation, Immunity and Immunotherapeutic Theme Board, Lay Member	28/02/2018
Mr Clive Carsley	None	31/03/2018
Dr Beverly Donaldson	Currently have casual contract with Imperial College London to undertake qualitative research study (Interviews and Focus Group) with pregnant women at St Mary's Hospital NHS Trust, London	31/03/2018
Mrs Sophie Forsyth	None	31/03/2018
Mr Stephen Gerry	Member of Data Monitoring Committees and Trial Steering Committees. Reviewer for HTA Journal, NIHR HTA and EME grants	30/03/2018
Dr Andrew Hilson	Very small holdings in GSK and AstraZeneca (recommended by financial adviser). 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).	31/03/2018
Miss Noor Mujahid	Pre-registration Pharmacist at GlaxoSmithKline (expected to end 20/07/18)	30/03/2018
Lady Karen Rix	None	30/03/2018
Professor Lewis Spitz	None	31/03/2018
Dr Gareth Tudor-Williams	None	31/03/2018
Dr Daniel Wang	None	30/03/2018
Dr Sonya Elizabeth Wright	Lay member of the City University Senate REC	31/03/2018

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

Month	Date	Number of Members Present at Meeting
April	26/04/2017	9
June	28/06/2017	10
July	26/07/2017	9
August	30/08/2017	10
September	27/09/2017	10
October	25/10/2017	8
November	29/11/2017	9
January	31/01/2018	12
February	28/02/2018	10
March	28/03/2018	12

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
April	24/04/2017	3
May	10/05/2017	3
June	14/06/2017	3
July	13/07/2017	3
August	10/08/2017	3
September	14/09/2017	4
October	12/10/2017	6
November	09/11/2017	5
January	11/01/2018	5
February	08/02/2018	6
March	08/03/2018	4

11 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	25/04/2017	2
May	02/05/2017	2
May	08/05/2017	2
May	19/05/2017	2
May	26/05/2017	4
June	02/06/2017	3
June	16/06/2017	2
June	23/06/2017	2

June	30/06/2017	2
July	07/07/2017	2
July	21/07/2017	2
August	04/08/2017	2
August	11/08/2017	2
August	18/08/2017	2
September	01/09/2017	2
September	08/09/2017	2
September	15/09/2017	3
September	29/09/2017	4
October	06/10/2017	2
October	13/10/2017	2
October	20/10/2017	2
October	27/10/2017	2
November	13/11/2017	2
November	24/11/2017	2
December	01/12/2017	2
December	15/12/2017	2
December	22/12/2017	2
January	12/01/2018	2
January	19/01/2018	2
January	26/01/2018	2
February	09/02/2018	2
February	16/02/2018	2
February	23/02/2018	2
March	02/03/2018	2
March	09/03/2018	2
March	16/03/2018	4
March	23/03/2018	2

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

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

0

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

Name	Number of Meetings Attended
Dr Louise Abrams	6
Dr Kieran Brack	1
Professor David Caplin	2
Mr Clive Carsley	8
Dr Beverly Donaldson	7
Dr Olivia Festy	2
Mrs Sophie Forsyth	8
Mr Stephen Gerry	8
Dr Andrew Hilson	9
Miss Noor Mujahid	4
Lady Karen Rix	8
Professor Lewis Spitz	9
Dr Gareth Tudor-Williams	7
Dr Daniel Wang	8
Dr Sonya Elizabeth Wright	8

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

Name	Number of Meetings Attended
Dr Louise Abrams	3
Mr Clive Carsley	3
Dr Olivia Festy	6
Mrs Sophie Forsyth	5
Dr Andrew Hilson	11
Miss Noor Mujahid	4
Lady Karen Rix	1
Professor Lewis Spitz	3
Dr Daniel Wang	1
Dr Sonya Elizabeth Wright	5

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

Name	Number of Meetings Attended
Dr Louise Abrams	1
Professor David Caplin	2
Mr Clive Carsley	33
Mrs Sophie Forsyth	1
Dr Andrew Hilson	36

Lady Karen Rix	1
Professor Lewis Spitz	7
Dr Sonya Elizabeth Wright	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Louise Abrams	31/05/2017	London Central Training Day
Dr Louise Abrams	07/06/2017	Equality, Diversity and Human Rights
Dr Kieran Brack	29/06/2017	GCP
Dr Kieran Brack	30/06/2017	Equality and Diversity
Mr Clive Carsley	13/02/2018	The Ethical Issues of Research Involving Children
Dr Beverly Donaldson	31/05/2017	London Central Training Day
Dr Beverly Donaldson	03/06/2017	Equality, Diversity and Human Rights
Dr Olivia Festy	24/06/2017	Equality, Diversity and Human Rights
Mrs Sophie Forsyth	07/04/2017	Reviewing the Research Design of Clinical Trials
Mrs Sophie Forsyth	08/04/2017	Equality Diversity and Human Rights
Mrs Sophie Forsyth	10/04/2017	Research data and Confidentiality e learning course
Mrs Sophie Forsyth	30/03/2018	Medical Devices e-learning module
Mr Stephen Gerry	31/05/2017	London Central Training Day
Dr Andrew Hilson	03/05/2017	Chairs Meeting
Dr Andrew Hilson	31/05/2017	London Central Training Day
Dr Andrew Hilson	06/11/2017	Chairs Meeting
Miss Noor Mujahid	25/04/2017	Committee member induction module
Miss Noor Mujahid	25/04/2017	Equality, Diversity and Human Rights
Lady Karen Rix	31/05/2017	London Central Training Day
Lady Karen Rix	25/07/2017	Equality, diversity and human rights training
Professor Lewis Spitz	31/05/2017	London Central Training Day
Dr Gareth Tudor-Williams	15/05/2017	Law and Ethics In Paediatrics
Dr Daniel Wang	25/04/2017	Equality, Diversity and Human Rights
Dr Daniel Wang	31/05/2017	London Central REC Training Day 31 May 2017
Dr Daniel Wang	16/11/2017	Committee member induction training
Dr Daniel Wang	07/02/2018	Introduction to Phase 1 research - Trials and Regulation
Dr Sonya Elizabeth Wright	25/05/2017	Equality, Diversity and Human Rights
Dr Sonya Elizabeth Wright	05/10/2017	Introduction to Phase 1 Research
Dr Sonya Elizabeth Wright	12/12/2017	National REC Members' Training Day
Dr Sonya Elizabeth Wright	12/12/2017	National Members' Training Day
Dr Sonya Elizabeth Wright	08/03/2018	London RECs Training Day

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	26	46.43
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	30	53.57
Total Applications Reviewed	56	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	15
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	0
Number of qualitative applications reviewed	2

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	17	30.36
Unfavourable Opinion	1	1.79
Provisional Opinion	38	67.86
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	56	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	32	57.14
Further Information Favourable Opinion with Additional Conditions	3	5.36
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	17	30.36
Unfavourable Opinion	1	1.79
Provisional Opinion	3	5.36
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	56	100

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

Total Applications Reviewed	25
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	6
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	12.00
Favourable Opinion with Additional Conditions	1	4.00
No Opinion transfer to full committee for review	3	12.00
Provisional Opinion	17	68.00
Unfavourable Opinion	1	4.00
Total	25	100

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

Average number of applications reviewed per full meeting	5.60
Number of completed applications for full ethical review	56
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	25
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	11
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	203
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 modified amendments reviewed	1
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	115
Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	50
Number of annual progress reports received	125
Number of safety reports received	38
Number of Serious Adverse Events received	0
Number of final reports received	29

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/LO/0578	Investigating views of children with SLCN & SEMH in Haringey schools	25
17/LO/0632	REGAIN V 1.0	26
17/LO/0661	PTI-428-01 - Proteostasis Therapeutics - Cystic Fibrosis	28
17/LO/0701	Assessment of small bowel baseline impedance in healthy participants	23
17/LO/0718	PRECISE-MRI	32
17/LO/1014	LITE, V1	29
17/LO/1016	A Phase II study of the effects of REGN2477 in patients with FOP	30
17/LO/1233	Measuring white blood cell kinetics in vivo using deuterated glucose	20
17/LO/1234	What is a therapeutic conversation in the emergency department?	24
17/LO/1235	Ward based goal-directed fluid therapy (GDFT) in acute pancreatitis	24
17/LO/1410	Exploring patient understanding of voluntary admission experience V1	34
17/LO/1419	The noradrenergic locus coeruleus in healthy ageing and AD	22
17/LO/1421	MSC12790 (PAPAYA)	20
17/LO/1425	Correlation of age with AXLN CT in non-breast cancer patients	23
17/LO/1582	Phase III study of Inclisiran Sodium in participants with ASCVD	27
17/LO/1590	NAC/Adj GEJ Adenocarcinoma with Chemo (XP/FP) vs Chemo + Pembro Study	22
17/LO/1591	The PRIMING study	24
17/LO/1623	17-0301 A Phase 1 Study of Single Ascending Doses of NGM217 in Adults	28
17/LO/1638	ADDID	22
17/LO/1670	Bipolar ablation for the treatment of arrhythmias	23
17/LO/1760	ENVISION: Givosiran in Patients with Acute Hepatic Porphyrias	24
17/LO/1785	Phase 3 1L Study of Pembrolizumab ± Ipilimumab in NSCLC	33
17/LO/1863	Dabrafenib and Trametinib in Paediatric High Grade Glioma	21
17/LO/1958	RCT of Laser therapy for GSM	36
17/LO/1978	NeuroSAFE proof	25
18/LO/0075	D5136C00010 Hestia 4 - Phase I, open-label study of ticagrelor	28
18/LO/0099	Fitusiran in Patients With Hemophilia A or B Without Inhibitory Ab	24
18/LO/0130	Parental experiences of having a child socially transition Version 1	23
18/LO/0144	DT-001-R-004	25
18/LO/0308	Clinical evaluation of a wearable sleep diagnosis technology	26
18/LO/0363	GentleTouch	24
18/LO/0438	ALN-AT3SC-009	32

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1157	281102 - Prophylactic and on-demand treatment of cTTP with BAX 930	27
18/LO/0034	DU176b-C-U313_Edoxaban Tosylate in Paediatric Cardiac Diseases	30
18/LO/0235	GBT440-034 - OLE GBT440 in Patients with Sickle Cell Disease	28

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

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

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0579	The use of Botulinum Toxin A in ambulant children with cerebral palsy	22
17/LO/1003	POPPY	21
17/LO/1034	Can TMS be used as a novel intra-operative monitor	21
17/LO/1080	DEA-MVTI	21
17/LO/1158	Pomalidomide in Children and young adults with brain tumors	21
17/LO/1192	iSTEP feasibility and sensitivity for boys with haemophilia	21
17/LO/1407	An Exploration of Schema Modes in Psychosis (V1)	20
17/LO/1427	Antihypertensives to reduce blood pressure variability after stroke	32
17/LO/1744	Tumouroids	23
17/LO/1776	OLT and coagulation	23
17/LO/1806	Phase 3 Study of Pembrolizumab ± Epacadostat in Metastatic NSCLC	23
17/LO/1896	A Phase 1 study of ADCT-502 in patients with advanced solid tumours	20
17/LO/1929	Pembrolizumab+epacadostat & EXTREME regimen 1st line Treat-R/M HNSCC	20
17/LO/1938	Ethnic Communities and Health Outcomes	20
18/LO/0205	THERMIC-3	21
18/LO/0330	Time Lapse Imaging Trial (TILT)	22
18/LO/0424	The use of binocular OCT imaging for the assessment of ocular disease	27

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0476	GN39763 - MTAU9937A in patients with Alzheimer's Disease	27

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0103	Studying thermal and chemical responses in skin	n/a
18/LO/0470	Immune responses to S. pneumoniae in chronic lung disease	n/a
18/LO/0499	Ablation of Ganglionated Plexi in Neurocardiogenic Syncope	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

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
17/LO/0654	Sickle cell disease and cell-free haemoglobin	12
17/LO/0685	Development of a family intervention for delirium in critical care	12
17/LO/0691	Mindful parenting and adolescent's experience of chronic pain	13
17/LO/1004	Crown	13
17/LO/1204	Health seeking behaviours of families with a type 1 diabetic child	19

17/LO/1210	RESCEU: Burden of disease of RSV in older adults, version 1.0	18
17/LO/1559	MR Protocol Development	7
17/LO/1564	Activity after Intervening with Ankle Foot Orthoses V2	12
17/LO/1773	Patient Reported Outcome Measures PROACT-IV (version 1)	6
17/LO/1777	What factors affect breast cancer neoadjuvant chemotherapy efficacy?	15
17/LO/1949	Operational failures in general practice: An observational study	15
17/LO/1962	Cultural Adaptations in Clinical Interactions	14
18/LO/0102	The immune system in the development of hepatobiliary tumours	18
18/LO/0254	Holistic Integrated Lifestyle Service Evaluation	9

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
18/LO/0100	tUS for the detection of complications of AV fistulae	17

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/0808	Intracranial haemorrhage and neurological complications in ECMO	7
17/LO/1767	Outcomes of calf DVTs not treated with anticoagulants	15
18/LO/0406	How do patients in primary care perceive the role of antibiotics ? 1.	12

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
18/LO/0105	RS FIBRO v1.0	17

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/1217	Managing Achilles Pain - a pilot study; version 1.0	14

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0249	PCNorAD	n/a

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
17/LO/1541	Validation of Electrical Ventricular Activation Patterns Using CIPS	10

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
01/2/044/AM02	Clinical and molecular analyses of childhood overgrowth syndromes	Substantial Amendment 3	31/01/2018	23
06/MRE02/4/AM14	UK Genetic Prostate Cancer Study (UKGPCS)	Substantial Amendment 13	07/03/2018	33
07/H0718/55/AM14	A Phase I trial of KU-0059436 in solid tumours	Substantial Amendment 12	18/05/2017	4
07/H0718/57/AM08	United Kingdom Adult ITP Registry	Substantial Amendment 5	12/06/2017	15
10/H0718/53/AM15	Phase 2/3 study of Lenalidomide in Diffuse Large B-Cell Lymphoma	Substantial Amendment 12	14/06/2017	12
10/H0718/53/AM16	Phase 2/3 study of Lenalidomide in Diffuse Large B-Cell Lymphoma	Substantial Amendment 13	05/02/2018	24
11/LO/1487/AM40	UKALL 2011	Substantial amendment 31	13/04/2017	14
11/LO/1487/AM46	UKALL 2011	Substantial Amendment 36	06/03/2018	30
11/LO/1860/AM10	Phase I study of AT13148, a novel AGC kinase inhibitor	Substantial Amendment 15	18/07/2017	16
12/LO/0456/AM09	PCD4989g Phase 1 study in patients with solid tumours	Substantial Amendment 10	05/06/2017	29
12/LO/0456/AM10	PCD4989g Phase 1 study in patients with solid tumours	Substantial Amendment 11	28/09/2017	14
12/LO/0456/AM11	PCD4989g Phase 1 study in patients with solid tumours	Substantial Amendment 12	12/01/2018	17
12/LO/1328/AM12	ACE-011-B-THAL-001 Amendment 1 dated 4th May 2012	Substantial Amendment 8	03/07/2017	21
12/LO/1928/AM08	TAPAS Study	Substantial Amendment 4	23/08/2017	19
12/LO/1970/AM06	Understanding pain perception in osteoarthritis(PAPO)	Substantial amendment 6	21/03/2017	8
12/LO/1970/AM07	Understanding pain perception in osteoarthritis(PAPO)	Substantial Amendment 7	23/11/2017	18

12/LO/2018/AM02	Biomarkers in the management of HPV-positive oropharyngeal cancer 1.0	Substantial Amendment 1	30/11/2017	18
13/LO/0208/AM11	A study of Dabrafenib in Participants under 18 with solid tumours	Substantial amendment 9	20/04/2017	7
13/LO/0208/AM12	A study of Dabrafenib in Participants under 18 with solid tumours	Substantial Amendment 10	23/08/2017	19
13/LO/0388/AM22	Phase 3 study to assess efficacy and safety of tocilizumab in GCA	Substantial Amendment 18	12/09/2017	15
13/LO/0388/AM24	Phase 3 study to assess efficacy and safety of tocilizumab in GCA	Substantial Amendment 20	27/02/2018	21
13/LO/0408/AM13	Phase/II_SU011248 L-malate-salt_Advanced GIST in young patients	Substantial Amendment 11	17/10/2017	6
13/LO/1705/AM06	Epilepsy in infancy	Substantial Amendment 2	05/06/2017	13
13/LO/1766/AM21	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	Substantial Amendment 17	01/06/2017	14
13/LO/1766/AM23	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	Substantial Amendment 18	24/07/2017	10
13/LO/1766/AM25	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	Substantial Amendment 19	16/08/2017	19
14/LO/0097/AM02	National Child Development Study	Substantial Amendment 2	14/12/2017	14
14/LO/0103/AM07	ComPAKT: A Phase I trial of olaparib in combination with AZD5363	Substantial Amendment 6	19/01/2018	22
14/LO/0187/AM05	Phase I/II study in advanced solid tumours or multiple myeloma TAS-120	Substantial Amendment 4	06/06/2017	7
14/LO/0187/AM07	Phase I/II study in advanced solid tumours or multiple myeloma TAS-120	Substantial amendment 6	29/08/2017	5
14/LO/0187/AM08	Phase I/II study in advanced solid tumours or multiple myeloma TAS-120	Substantial Amendment 7	02/03/2018	27
14/LO/0250/AM02	Human ex vivo lung perfusion research consortium UK (HELP RCUK)	Substantial Amendment 2	17/07/2015	16
14/LO/0602/AM09	998HB303 Previously Untreated Patients With Severe Haemophilia B	Substantial Amendment 8	07/06/2017	11
14/LO/0602/AM10	998HB303 Previously Untreated Patients With Severe Haemophilia B	Substantial Amendment 9	03/08/2017	27
14/LO/0602/AM11	998HB303 Previously Untreated Patients With Severe	Substantial	03/10/2017	14

	Haemophilia B	Amendment 10		
14/LO/1077/AM01	Virus identification from CSF and Respiratory Samples	Substantial Amendment 1	08/03/2017	20
14/LO/1081/AM11	A Phase 1, Open-Label, Non-Randomized, Dose-Escalating Safety, Tolerability, Pharmacokinetic, and Pharmacodynamic Study of TAS-119 in Patients with Advanced Solid Tumours	Substantial amendment 7	04/05/2017	21
14/LO/1081/AM13	A Phase 1, Open-Label, Non-Randomized, Dose-Escalating Safety, Tolerability, Pharmacokinetic, and Pharmacodynamic Study of TAS-119 in Patients with Advanced Solid Tumours	Substantial amendment 8	04/08/2017	16
14/LO/1122/AM07	PPALM - Palm oil and Pentoxifylline Against Late Morbidity	Substantial Amendment 5	25/04/2017	9
14/LO/1195/AM15	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial Amendment 8	31/05/2017	15
14/LO/1195/AM16	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial Amendment 9	26/09/2017	16
14/LO/1195/AM17	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial Amendment 10	06/02/2018	20
14/LO/1336/AM07	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial Amendment 7	26/06/2017	11
14/LO/1336/AM08	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial amendment 8	10/10/2017	5
14/LO/1407/AM09	TERIKIDS	Substantial Amendment 4	27/04/2017	20
14/LO/1428/AM22	Adjunctive Steroid Combination in Ocular Trauma (ASCOT) Study	Substantial Amendment 14	14/12/2017	14
14/LO/1672/AM11	POLO	Substantial Amendment 8	27/04/2017	18
14/LO/1672/AM12	POLO	Substantial Amendment 9	18/05/2017	22
14/LO/1868/AM08	A Study of BYL719 in patients with pNETs, RCC and breast cancer.	Substantial Amendment 5	05/01/2018	7
14/LO/2041/AM10	AZD6094 in patients with papillary renal cell carcinoma	Substantial Amendment 10	25/05/2017	19
14/LO/2041/AM11	AZD6094 in patients with papillary renal cell carcinoma	Substantial Amendment 11	16/06/2017	10
15/LO/0423/AM06	SSAT064: PK of ABC/3TC/DTG in HIV patients of 60 years and over	Substantial amendment 3	17/02/2017	14

15/LO/0443/AM15	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial Amendment 10	06/07/2017	18
15/LO/0443/AM16	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial Amendment 11	19/01/2018	18
15/LO/0615/AM10	A Phase II study of ABT-414 for recurrent glioblastoma	Substantial amendment 6	27/03/2017	8
15/LO/0615/AM11	A Phase II study of ABT-414 for recurrent glioblastoma	Substantial Amendment 7	11/05/2017	11
15/LO/0615/AM12	A Phase II study of ABT-414 for recurrent glioblastoma	Substantial Amendment 8	15/08/2017	15
15/LO/0710/AM08	EMBARC:MDV3100-13 Phase3, Enzalutamide, nonmetastatic Prostate Cancer	Substantial amendment 7	06/04/2017	20
15/LO/0710/AM09	EMBARC:MDV3100-13 Phase3, Enzalutamide, nonmetastatic Prostate Cancer	Substantial Amendment 8	09/03/2017	17
15/LO/0711/AM19	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 10	19/04/2017	28
15/LO/0711/AM24	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 12	09/01/2018	17
15/LO/0711/AM25	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial Amendment 13	15/02/2018	20
15/LO/1041/AM07	Gut Hormones in Addiction (GHADD) v1.1	Substantial Amendment 5	20/11/2017	17
15/LO/1044/AM07	ACTICCA-1	Substantial Amendment 5	24/05/2017	13
15/LO/1044/AM08	ACTICCA-1	Substantial Amendment 6	14/09/2017	15
15/LO/1050/AM03	DARWIN1	Substantial Amendment 3	17/11/2017	18
15/LO/1050/AM05	DARWIN1	Substantial Amendment 4	31/01/2018	14
15/LO/1226/AM06	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial Amendment 5	08/09/2017	20
15/LO/1226/AM07	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial Amendment 6	03/11/2017	2
15/LO/1226/AM08	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	Substantial Amendment 7	01/03/2018	20
15/LO/1232/AM04	Simbrinza BID Adjunctive to PGA	Substantial	21/07/2017	14

		Amendment 2		
15/LO/1284/AM11	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial Amendment 9	11/05/2017	11
15/LO/1284/AM13	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial Amendment 10	12/07/2017	23
15/LO/1284/AM14	HuMax [®] -TF-ADC Dose Escalation Safety Study	Substantial Amendment 11	26/10/2017	5
15/LO/1339/AM04	Physician associates in secondary care	Substantial Amendment 1	27/04/2017	9
15/LO/1595/AM08	PRISM	Substantial Amendment 2	13/04/2017	17
15/LO/1598/AM04	WA29767 - A study of Tocilizumab versus placebo in Systemic Sclerosis	Substantial Amendment 4	12/06/2017	14
15/LO/1598/AM05	WA29767 - A study of Tocilizumab versus placebo in Systemic Sclerosis	Substantial amendment 5	02/01/2018	31
15/LO/1600/AM14	GDC-0810 vs fulvestrant in advanced/metastatic ER+/HER2-Breast Cancer	Substantial Amendment 8	14/02/2018	15
15/LO/1760/AM12	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	Substantial Amendment 8	21/04/2017	18
15/LO/1760/AM13	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	Substantial Amendment 9	11/12/2017	11
15/LO/1760/AM14	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	Substantial Amendment 10	20/02/2018	24
15/LO/1796/AM07	Phase 1/2 study of BMN 250 in MPS IIIB patients	Substantial amendment 2	15/11/2017	19
15/LO/1800/AM01	Characterization of the IgE Repertoire and Activity in Asthma, V01	Substantial Amendment 1	18/08/2017	24
15/LO/1807/AM05	CA209-331 Nivolumab vs Chemotherapy in SCLC	Substantial Amendment 4	11/08/2017	15
15/LO/1807/AM06	CA209-331 Nivolumab vs Chemotherapy in SCLC	Substantial Amendment 5	13/02/2018	26
15/LO/1922/AM05	Anakinra vs. Steroids for Gout Attacks in patients with Renal Disease	Substantial Amendment 4	01/07/2017	10
16/LO/0093/AM07	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial Amendment 6	11/04/2017	15
16/LO/0093/AM08	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial Amendment 7	26/06/2017	11

16/LO/0093/AM09	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial Amendment 8	19/09/2017	23
16/LO/0093/AM10	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial Amendment 9	10/10/2017	13
16/LO/0093/AM11	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	Substantial Amendment 10	29/01/2018	18
16/LO/0124/AM05	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	Substantial Amendment 4	20/10/2017	8
16/LO/0124/AM06	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	Substantial Amendment 5	21/03/2018	15
16/LO/0354/AM08	Cygnus	Substantial Amendment 5	21/08/2017	18
16/LO/0354/AM09	Cygnus	Substantial Amendment 6	10/01/2018	14
16/LO/0366/AM01	MISST	Substantial Amendment 1	07/06/2017	9
16/LO/0432/AM25	EUROASPIRE V/ASPIRE-3-PREVENT	Substantial Amendment 25	25/08/2017	17
16/LO/0529/AM07	CORE Trial	Substantial Amendment 3	21/04/2017	16
16/LO/0529/AM09	CORE Trial	Substantial Amendment 4	03/08/2017	27
16/LO/0537/AM08	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	Substantial Amendment 7	26/07/2017	15
16/LO/0632/AM01	Paternally Inherited Phenotypes in Cholestasis (PIP-C) V2	Substantial Amendment 1	24/11/2017	13
16/LO/0675/AM05	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	Substantial Amendment 5	24/04/2017	23
16/LO/0675/AM06	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	Substantial Amendment 6	01/08/2017	9
16/LO/0675/AM10	Phase 2 study of CC-486 alone & combined with Durvalumab in MDS pts	Substantial Amendment 9	19/02/2018	18
16/LO/0680/AM02	SMILE (PENTA 17)	Substantial Amendment 2	28/09/2017	14
16/LO/0805/AM09	MK-3475-224: MK-3475 in subjects with previously treated HCC	Substantial Amendment 4	04/08/2017	15
16/LO/0805/AM10	MK-3475-224: MK-3475 in subjects with previously treated	Substantial	11/10/2017	5

	HCC	amendment 5		
16/LO/0805/AM11	MK-3475-224: MK-3475 in subjects with previously treated HCC	Substantial Amendment 6	23/02/2018	21
16/LO/0925/AM02	Acceptability of personalised risk-based breast cancer screening v1.0	Substantial Amendment 1	18/08/2017	20
16/LO/1004/AM07	MIROCALS_H2020/PHRC-N/2014/GB-01_ID-IL-2_Neuro-Inflammation in ALS Pts	Substantial Amendment 5	29/06/2017	14
16/LO/1004/AM10	MIROCALS_H2020/PHRC-N/2014/GB-01_ID-IL-2_Neuro-Inflammation in ALS Pts	Substantial amendment 6	02/01/2018	17
16/LO/1012/AM03	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	Substantial Amendment 3	16/05/2017	6
16/LO/1012/AM04	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	Substantial Amendment 4	21/06/2017	5
16/LO/1012/AM05	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	Substantial Amendment 5	18/12/2017	10
16/LO/1012/AM06	Study of the the Effects of Tolvaptan in Children and Teens with ADPKD	Substantial Amendment 6	02/02/2018	14
16/LO/1069/AM06	PALbociclib CoLaborative Adjuvant Study	Substantial Amendment 3	20/07/2017	15
16/LO/1069/AM07	PALbociclib CoLaborative Adjuvant Study	Substantial Amendment 4	11/09/2017	16
16/LO/1082/AM03	CC-90011-ST-001	Substantial Amendment 2	23/06/2017	16
16/LO/1082/AM04	CC-90011-ST-001	Substantial Amendment 3	29/09/2017	15
16/LO/1183/AM01	Detection of Circulating Tumour Cells in Thyroid Cancer (CircuiTT)	Substantial Amendment 1	20/04/2017	16
16/LO/1318/AM01	Nucleos(t)ide withdrawal in Hepatitis B virus infection (NUC-B)	Substantial Amendment 1	22/09/2017	17
16/LO/1318/AM02	Nucleos(t)ide withdrawal in Hepatitis B virus infection (NUC-B)	Substantial Amendment 2	04/10/2017	8
16/LO/1322/AM06	RSV Vaccine in Pregnancy	Substantial Amendment 3	29/08/2017	21
16/LO/1357/AM02	SSAT062 - PK of EFV 400mg once daily in presence of RIF/INH	Substantial amendment 2	05/04/2017	3
16/LO/1357/AM05	SSAT062 - PK of EFV 400mg once daily in presence of RIF/INH	Substantial Amendment 5	19/10/2017	12

16/LO/1485/AM03	Compassionate Use of Baricitinib to Treat Auto-inflammatory Syndromes	Substantial Amendment 3	30/06/2017	14
16/LO/1485/AM04	Compassionate Use of Baricitinib to Treat Auto-inflammatory Syndromes	Substantial Amendment 4	25/08/2017	14
16/LO/1489/AM01	A pilot study to develop simultaneous PET-MR scanner technology	Substantial Amendment 1	06/09/2017	21
16/LO/1494/AM08	Study of Intramuscular Cabotegravir + Rilpivirine in ART naive adults	Substantial Amendment 3	28/02/2018	21
16/LO/1529/AM05	Productivity losses & indirect costs after cardiovascular events V1.0	Substantial Amendment 1	28/07/2017	16
16/LO/1637/AM03	First-in-human, trial of HuMax-AXL-ADC in patients with solid tumours	Substantial Amendment 5	26/06/2017	17
16/LO/1637/AM05	First-in-human, trial of HuMax-AXL-ADC in patients with solid tumours	Substantial amendment 5	06/10/2017	9
16/LO/1641/AM04	Phase 1/2a to asses PEN-221 in receptor 2 expressing advanced cancers	Substantial Amendment 3	09/05/2017	18
16/LO/1641/AM05	Phase 1/2a to asses PEN-221 in receptor 2 expressing advanced cancers	Substantial Amendment 4	17/08/2017	18
16/LO/1641/AM06	Phase 1/2a to asses PEN-221 in receptor 2 expressing advanced cancers	Substantial Amendment 5	04/01/2018	17
16/LO/1653/AM03	F-I-H study of ODM-207 in patients with advanced solid tumours	Substantial Amendment 3	16/05/2017	5
16/LO/1653/AM04	F-I-H study of ODM-207 in patients with advanced solid tumours	Substantial amendment 5	08/11/2017	18
16/LO/1653/AM05	F-I-H study of ODM-207 in patients with advanced solid tumours	Substantial Amendment 7	16/02/2018	24
16/LO/1684/AM03	PERFORM	Substantial Amendment 2	19/12/2017	10
16/LO/1693/AM01	Inhaler Technology Study	Substantial Amendment 1	19/04/2017	14
16/LO/1693/AM02	Inhaler Technology Study	Substantial Amendment 2	07/06/2017	19
16/LO/1693/AM03	Inhaler Technology Study	Substantial Amendment 3	24/08/2017	17
16/LO/1693/AM04	Inhaler Technology Study	Substantial Amendment 4	23/11/2017	12
16/LO/1794/AM03	4213 alleviate1: Giving N8-GP by subcutaneous injection	Substantial	24/11/2017	22

		Amendment 1		
16/LO/1861/AM03	Safety and efficacy study of SOM230 s.c. in Cluster Headaches	Substantial Amendment 1	09/01/2018	13
16/LO/1874/AM03	Canakinumab in paediatric and young adult sickle cell anaemia patients	Substantial Amendment 3	21/09/2017	11
16/LO/2051/AM03	Health Needs Assessment for Underserved Populations Version 1.0	Substantial Amendment 3	10/01/2018	19
16/LO/2051/AM05	Health Needs Assessment for Underserved Populations Version 1.0	Substantial Amendment 5	22/02/2018	18
16/LO/2078/AM02	BP29842 – A Phase Ia/Ib Study of RO6874281 in Metastatic Solid Tumors	Substantial Amendment 2	18/05/2017	22
16/LO/2078/AM03	BP29842 – A Phase Ia/Ib Study of RO6874281 in Metastatic Solid Tumors	Substantial Amendment 3	20/07/2017	10
16/LO/2078/AM04	BP29842 – A Phase Ia/Ib Study of RO6874281 in Metastatic Solid Tumors	Substantial Amendment 4	30/08/2017	20
16/LO/2078/AM05	BP29842 – A Phase Ia/Ib Study of RO6874281 in Metastatic Solid Tumors	Substantial Amendment 5	05/02/2018	20
16/LO/2106/AM01	Phase IB study of Rucaparib and Atezolizumab for gynaecologic cancers	Substantial Amendment 1	04/05/2017	12
16/LO/2106/AM02	Phase IB study of Rucaparib and Atezolizumab for gynaecologic cancers	Substantial Amendment 2	27/06/2017	17
16/LO/2106/AM03	Phase IB study of Rucaparib and Atezolizumab for gynaecologic cancers	Substantial amendment 3	27/10/2017	12
17/LO/0039/AM02	Collection of Blood Samples to Optimise Immunotherapy Methodologies	Substantial Amendment 2	18/12/2017	16
17/LO/0066/AM03	A study of AUT00206 in people with schizophrenia; v1	Substantial Amendment 2	19/09/2017	14
17/LO/0085/AM05	INNO2VATE-CONVERSION_Version 1.0_dated 06 May 2016	Substantial Amendment 3	23/03/2018	20
17/LO/0096/AM02	SUSTAIN (205MS305)	Substantial Amendment 2	06/07/2017	18
17/LO/0247/AM01	A Phase 1/2 Safety and Tolerability Study of INCAGN01949	Substantial Amendment 1	01/06/2017	11
17/LO/0247/AM02	A Phase 1/2 Safety and Tolerability Study of INCAGN01949	Substantial Amendment 2	19/07/2017	16
17/LO/0247/AM03	A Phase 1/2 Safety and Tolerability Study of INCAGN01949	Substantial Amendment 3	20/09/2017	25

17/LO/0279/AM02	Impact of Prior Care Experience. Version 1.0.	Substantial Amendment 1	07/11/2017	13
17/LO/0284/AM01	Single doses of GSK3008348 in IPF patients using PET imaging	Substantial Amendment 1	27/06/2017	24
17/LO/0347/AM02	MK-3475 + Chemotherapy as Neoadjuvant and Adjuvant therapy for TNBC	Substantial Amendment 2	22/05/2017	22
17/LO/0347/AM05	MK-3475 + Chemotherapy as Neoadjuvant and Adjuvant therapy for TNBC	Substantial Amendment 4	03/08/2017	27
17/LO/0347/AM06	MK-3475 + Chemotherapy as Neoadjuvant and Adjuvant therapy for TNBC	Substantial Amendment 5	11/10/2017	11
17/LO/0347/AM07	MK-3475 + Chemotherapy as Neoadjuvant and Adjuvant therapy for TNBC	Substantial Amendment 6	02/03/2018	19
17/LO/0369/AM01	Metagenomic and Metatranscriptomic Analysis of Clinical Plaque Samples	Substantial Amendment 1	20/09/2017	26
17/LO/0369/AM02	Metagenomic and Metatranscriptomic Analysis of Clinical Plaque Samples	Substantial Amendment 2	15/12/2017	7
17/LO/0402/AM01	WO39210 - Atezolizumab in patients with renal cell carcinoma	Substantial Amendment 1	28/06/2017	16
17/LO/0402/AM02	WO39210 - Atezolizumab in patients with renal cell carcinoma	Substantial Amendment 2	18/12/2017	10
17/LO/0440/AM02	A Phase 1 Study to Evaluate ISIS 814907 in Mild Alzheimer's Disease	Substantial amendment 1	02/10/2017	7
17/LO/0632/AM01	REGAIN V 1.0	Substantial Amendment 1	02/08/2017	13
17/LO/0685/AM01	Development of a family intervention for delirium in critical care	Substantial Amendment 1	16/06/2017	7
17/LO/1014/AM01	LITE, V1	Substantial Amendment 1	29/09/2017	13
17/LO/1014/AM02	LITE, V1	Substantial Amendment 2	10/01/2018	18
17/LO/1034/AM01	Can TMS be used as a novel intra-operative monitor	Substantial Amendment 1	21/02/2018	30
17/LO/1157/AM01	281102 - Prophylactic and on-demand treatment of cTTP with BAX 930	Substantial Amendment 1	28/09/2017	5
17/LO/1157/AM02	281102 - Prophylactic and on-demand treatment of cTTP with BAX 930	Substantial Amendment 2	27/11/2017	17
17/LO/1158/AM01	Pomalidomide in Children and young adults with brain tumors	Substantial	28/09/2017	14

		amendment 1		
17/LO/1158/AM03	Pomalidomide in Children and young adults with brain tumors	Substantial Amendment 2	16/02/2018	24
17/LO/1210/AM01	RESCEU: Burden of disease of RSV in older adults, version 1.0	Substantial Amendment 1	10/08/2017	13
17/LO/1210/AM03	RESCEU: Burden of disease of RSV in older adults, version 1.0	Substantial Amendment 2	03/10/2017	11
17/LO/1210/AM05	RESCEU: Burden of disease of RSV in older adults, version 1.0	Substantial Amendment 3	20/02/2018	21
17/LO/1235/AM01	Ward based goal-directed fluid therapy (GDFT) in acute pancreatitis	Substantial Amendment 1	26/10/2017	5
17/LO/1582/AM02	Phase III study of Inclisiran Sodium in participants with ASCVD	Substantial Amendment 2	29/01/2018	18
17/LO/1590/AM02	NAC/Adj GEJ Adenocarcinoma with Chemo (XP/FP) vs Chemo + Pembro Study	Substantial amendment 2	26/10/2017	19
17/LO/1590/AM04	NAC/Adj GEJ Adenocarcinoma with Chemo (XP/FP) vs Chemo + Pembro Study	Substantial Amendment 4	22/02/2018	22
17/LO/1744/AM01	Tumouroids	Substantial Amendment 1	05/01/2018	31
17/LO/1760/AM01	ENVISION: Givosiran in Patients with Acute Hepatic Porphyrias	Substantial Amendment 1	14/12/2017	14
17/LO/1785/AM01	Phase 3 1L Study of Pembrolizumab ± Ipilimumab in NSCLC	Substantial Amendment 1	04/01/2018	18
17/LO/1785/AM05	Phase 3 1L Study of Pembrolizumab ± Ipilimumab in NSCLC	Substantial Amendment 03	21/03/2018	22
17/LO/1806/AM01	Phase 3 Study of Pembrolizumab ± Epacadostat in Metastatic NSCLC	Substantial Amendment 1	14/12/2017	14
17/LO/1806/AM02	Phase 3 Study of Pembrolizumab ± Epacadostat in Metastatic NSCLC	Substantial Amendment 3	22/01/2018	15
17/LO/1806/AM03	Phase 3 Study of Pembrolizumab ± Epacadostat in Metastatic NSCLC	Substantial Amendment 4	02/03/2018	32
17/LO/1929/AM01	Pembrolizumab+epacadostat & EXTREME regimen 1st line Treat-R/M HNSCC	Substantial Amendment 2	21/12/2017	32
17/LO/1929/AM02	Pembrolizumab+epacadostat & EXTREME regimen 1st line Treat-R/M HNSCC	Substantial Amendment 3	09/03/2018	31
17/LO/1949/AM01	Operational failures in general practice: An observational study	Substantial Amendment 1	19/01/2018	18

MREC/02/2/91/AM08	British Regional Heart Study: Pathways to Prevention of CVD	Substantial Amendment 6	26/07/2017	24
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Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0711/AM21	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial Amendment 11	24/07/2017	14
MREC/02/2/91/AM09	British Regional Heart Study: Pathways to Prevention of CVD	Substantial Amendment 7	23/11/2017	28

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

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0711/AM21/1	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 11 modified	24/07/2017	8

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

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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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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