NHS
Health Research Authority

Research Ethics Service

London - Central Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016

Part 1 – Committee Membership and Training

Name of REC:	London - Central Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
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:	Ewan Waters
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Email:	NRESCommittee.London-Central@nhs.net

Chair's overview of the past year:

The Committee continues to function well and reviews a wide range of applications including many CTIMPs, some of which are first-in-patient studies.

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.

We continue to have excellent 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	
Ms Sally Davis	Lawyer/PhD Student	Lay	01/01/2013	16/12/2015
Dr Beverly Donaldson	Academic Research Midwife	Expert	11/02/2014	
Dr Olivia Festy	Industry Collaboration Manager	Lay	14/04/2006	
Mrs Sophie Forsyth	Lawyer	Lay Plus	01/04/2011	
Mr Stephen Gerry	Medical Statistician	Expert	02/04/2015	
Dr Frances Goodhart	Consultant Clinical Psychologist	Expert	01/04/2011	31/03/2016
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	University Lecturer	Expert	23/05/2012	
Dr Gareth Tudor-Williams	Consultant in Paediatric Infectious Diseases	Expert	01/04/2010	

London - Central Research Ethics Committee: Deputy Members

None

London - Central Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Ron Driver	Retired University Lecturer/Statistician	Lay	29/07/2015
Professor Anthony Fox	Pharmaceutical Medicine	Expert	29/07/2015 & 28/10/2015
Dr Lorraine Ludman	Retired Research Psychologist	Lay	27/01/2016
Mrs Marney Williams	Teacher	Lay Plus	26/08/2015

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

Name	Declaration of Interest	Date
Dr Louise Abrams	Insignificant shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research.	27/01/2016
Mr Clive Carsley	None to declare	27/01/2016
Dr Beverly Donaldson	Current role post-doctoral research midwife ICL - investigator in various studies.	26/01/2016
Dr Olivia Festy	Now works for National Institute for Health Research Clinical Research Infrastructure office as Industry Collaboration Manager (since November 2015).Nothing else to declare	01/03/2016
Mrs Sophie Forsyth	None to declare	27/01/2016
Mr Stephen Gerry	Peer reviewer for NIHR HTA and EME funding bodies.	27/01/2016
Dr Frances Goodhart	Small holding of shares in GSK	24/06/2015
Dr Andrew Hilson	None to declare	25/01/2016
Miss Noor Mujahid	None to declare	23/03/2016
Lady Karen Rix	None to declare	27/01/2016
Professor Lewis Spitz	None to declare	27/01/2016
Mr Benjamin Stanfield-Davies	External Examiner - Canterbury Christ Church University	27/01/2016
Dr Gareth Tudor-Williams	Member of the Scientific Steering Committee for the Paediatric European Network for the Treatment of Aids (PENTA) from time to time. Chairs or participates in DSMBs/DMCs for international clinical trials of anti-retrovirals for children with HIV and for vaccine trials in vulnerable populations. Willing to act as specialist referee for paediatric studies including CTIMPs	30/03/2016

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

Month	Date	Number of Members Present at Meeting
April	29/04/2015	8
June	24/06/2015	11
July	29/07/2015	8
August	26/08/2015	8
September	30/09/2015	8
October	28/10/2015	8
November	25/11/2015	8
January	27/01/2016	12
February	24/02/2016	9
March	30/03/2016	9

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
January	13/01/2016	3

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

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	24/04/2015	2
May	08/05/2015	2
May	15/05/2015	3
May	22/05/2015	2
June	05/06/2015	2
June	12/06/2015	2
July	07/07/2015	2
July	17/07/2015	2
July	31/07/2015	2
August	14/08/2015	2
August	24/08/2015	2
September	11/09/2015	2
September	18/09/2015	2
September	25/09/2015	2
October	16/10/2015	2
October	23/10/2015	2
November	09/11/2015	4
November	09/11/2015	2

November	18/11/2015	2
November	20/11/2015	2
December	04/12/2015	2
December	15/12/2015	2
January	08/01/2016	2
January	11/01/2016	2
January	13/01/2016	4
January	20/01/2016	2
February	05/02/2016	2
February	12/02/2016	2
February	19/02/2016	2
March	14/03/2016	2
March	24/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

None

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

Name	Number of Meetings Attended
Dr Louise Abrams	7
Mr Clive Carsley	9
Dr Beverly Donaldson	6
Dr Olivia Festy	10
Mrs Sophie Forsyth	6
Mr Stephen Gerry	7
Dr Frances Goodhart	6
Dr Andrew Hilson	10
Lady Karen Rix	3
Professor Lewis Spitz	7
Mr Benjamin Stanfield-Davies	5
Dr Gareth Tudor-Williams	8

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

Name	Number of Meetings Attended
Mr Clive Carsley	1
Dr Andrew Hilson	1
Professor Lewis Spitz	1

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

Name	Number of Meetings Attended
Mr Clive Carsley	30
Dr Olivia Festy	1
Mrs Sophie Forsyth	1
Dr Andrew Hilson	31
Professor Lewis Spitz	3

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Louise Abrams	27/05/2015	What happens behind the scenes?
Dr Louise Abrams	26/11/2015	London REC Members' Training Day
Dr Louise Abrams	18/02/2016	National Members' Training Day
Dr Louise Abrams	11/03/2016	Local Training day London Research Ethics Committees
Mr Clive Carsley	27/05/2015	What happens behind the scenes?
Mr Clive Carsley	26/11/2015	London REC Members' Training Day
Mr Clive Carsley	27/11/2015	CTIMP Training
Dr Beverly Donaldson	27/05/2015	What happens behind the scenes?
Dr Olivia Festy	27/05/2015	What happens behind the scenes?
Mrs Sophie Forsyth	27/05/2015	What happens behind the scenes?
Mrs Sophie Forsyth	27/11/2015	CTIMP Training Day
Mr Stephen Gerry	27/05/2015	What happens behind the scenes?
Dr Frances Goodhart	27/05/2015	What happens behind the scenes?
Dr Andrew Hilson	27/05/2015	What happens behind the scenes?
Dr Andrew Hilson	26/11/2015	London REC Members' Training Day
Dr Andrew Hilson	09/12/2015	National Training Day for Committee Chairs
Lady Karen Rix	10/02/2016	Committee Members' Induction
Professor Lewis Spitz	27/05/2015	What happens behind the scenes?
Mr Benjamin Stanfield-Davies	20/10/2015	Critical Appraisal of Studies
Mr Benjamin Stanfield-Davies	26/11/2015	SPSS Training
Mr Benjamin Stanfield-Davies	02/12/2015	Research Ethics
Dr Gareth Tudor-Williams	29/02/2016	Imperial College Clinical Ethics Committee 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	28	50.91
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	27	49.09
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	5
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	7
Number of device applications reviewed	2
Number of prisoner applications reviewed	1
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	2	3.64
Favourable Opinion with Additional Conditions	11	20.00
Unfavourable Opinion	1	1.82
Provisional Opinion	41	74.55
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**55**	**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	30	54.55
Further Information Favourable Opinion with Additional Conditions	2	3.64
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.64
Favourable Opinion with Additional Conditions	11	20.00
Unfavourable Opinion	1	1.82
Provisional Opinion	8	14.55
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	1	1.82
Total	**55**	**100**

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

Total Applications Reviewed	**4**

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	0
Number of student applications reviewed	0
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
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	0	0.00
Favourable Opinion with Additional Conditions	1	25.00
No Opinion transfer to full committee for review	1	25.00
Provisional Opinion	2	50.00
Unfavourable Opinion	0	0.00
Total	**4**	**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	54
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)	22

Number of completed proportionate review applications for ethical review	3
Number of completed proportionate review applications for ethical review over 14 days	0

Number of completed proportionate review applications over 14 days as a % of total	0.00%

Number of SSAs (non-Phase 1) reviewed	7
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	134
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	2.24%
Number of completed substantial amendments over 28 days	8
Number of completed substantial amendments over 28 days as a % of total substantial amendments	5.97%

Number of modified amendments reviewed	3
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of minor amendments received	55
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	52
Number of annual progress reports received	15
Number of safety reports received	37
Number of Serious Adverse Events received	0
Number of final reports received	9

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0710	EMBARK:MDV3100-13 Phase3, Enzalutamide, nonmetastatic Prostate Cancer	16
15/LO/0711	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	16
15/LO/0740	PH:fACTors influencing decisions about IV prostanoid therapy(PHACT-IV)	17
15/LO/0743	Safety and effects of FP-02.2 - first doses in humans;v1	17
15/LO/1006	Phase II copanlisib in relapsed or refractory DLBCL	25
15/LO/1041	Gut Hormones in Addiction (GHADD) v1.1	37
15/LO/1044	ACTICCA-1	23
15/LO/1050	DARWIN1	18
15/LO/1179	LPS14201 (XRP6258) Cabazitaxel vs abiraterone or enzalutamide in mCRPC	32
15/LO/1226	Phase 1b/2 study of Carfilzomib in relapsed or refractory ALL children	24
15/LO/1228	M15-461 (RUBY-II) - GT 1a or 4 Chronic HCV with Renal Impairment	20
15/LO/1230	ORDIT v0.1	23
15/LO/1232	Simbrinza BID Adjunctive to PGA	37
15/LO/1278	Phase 1B Study of Dexanabinol in Glioblastoma Multiforme Patients	19
15/LO/1284	HuMaxÂ®-TF-ADC Dose Escalation Safety Study	20
15/LO/1319	Thromboprophylaxis in newly diagnosed Multiple Myeloma (TiMM)	17
15/LO/1339	Physician associates in secondary care	32
15/LO/1588	SHEAR-STENT study	34
15/LO/1589	New Biomarkers of Early Myocardial Infarction	21
15/LO/1598	WA29767 - A study of Tocilizumab versus placebo in Systemic Sclerosis	17
15/LO/1600	GDC-0810 vs fulvestrant in advanced/metastatic ER+/HER2- Breast Cancer	17
15/LO/1634	Exploring Child & Family Adjustment to Acquired Brain Injury	17
15/LO/1800	Characterization of the IgE Repertoire and Activity in Asthma, V01	35
15/LO/1922	Anakinra vs. Steroids for Gout Attacks in patients with Renal Disease	18
15/LO/1945	Prophylaxis against acute attacks of Hereditary Angioedema (HAE)	22
16/LO/0088	txt2bhealthy mobile phone based intervention pilot RCT	44
16/LO/0124	Radiance HTN study of ReCor Paradise System in Clinical Hypertension	21
16/LO/0340	MSB11022 in Moderate to Severe Chronic Plaque Psoriasis	27
16/LO/0354	Cygnus	21
16/LO/0366	MISST	28

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/1847	Psychological Analysis of GI Cancer Patients	27
15/LO/1942	Review of drug treatment outcomes	17

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**
15/LO/1760	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	19
15/LO/1807	CA209-331 Nivolumab vs Chemotherapy in SCLC	19

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0615	A Phase II study of ABT-414 for recurrent glioblastoma	16
15/LO/1352	Interviews w/ Parents of Children w/ Disabilities & Sleep Difficulties	22
15/LO/1595	PRISM	16
15/LO/1756	Human Factor and Usability Testing of A Binocular OCT System	19
15/LO/1796	Phase 1/2 study of BMN 250 in MPS IIIB patients	19
15/LO/1908	Phase I/IIa Study of DTP3 in Patients With Advanced Multiple Myeloma	16
15/LO/1954	Quality Of LIfe Tool for IBD (QOLITI)	16
16/LO/0068	Phase 1 trial with Bcl-2 inhibitor S55746 in t(11:14) multiple myeloma	17
16/LO/0091	BETTER-B(Feasibility): BETter TreatmEnts for Refractory Breathlessness	17
16/LO/0432	EUROASPIRE V Survey	16
16/LO/0543	GMP drink for PKU study	16

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0140	Perception of Emotional Expression and Play	20

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/1059	The effect of phenylalanine on appetite	n/a
16/LO/0093	MEDI4736-NHL-001_Phase1/2_Durvalumab_lymphoma/CLL	n/a
16/LO/0288	Vedolizumab IV in the Treatment of PSC (VIADUCT)	n/a
16/LO/0350	The effects of the beach chair position on cerebral haemodinamic	n/a
16/LO/0485	Time-intensive behavioural activation for depression.	n/a
16/LO/0490	A PK & safety study of Regadenoson in CVD paediatric patients	n/a
16/LO/0529	CORE Trial	n/a
16/LO/0537	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	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**
16/LO/0339	Clinical Applicable Pacing Therapies in VT (CAPT –VT)	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/0149	Radiofrequency ablation for gastric antral vascular ectasia	10
16/LO/0157	PLAY Therapy Intervention: Re-Modelling Patient Experience (PLAYTIME)	9

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

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

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

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0162	Patient Priorities in Breast Cancer Research - Version 1	8

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

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

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

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

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**
08/H0718/11/AM20	Bevacizumab and standard chemotherapy in childhood soft-tissue sarcoma	Substantial amendment 16	21/04/2015	6
08/H0718/11/AM21	Bevacizumab and standard chemotherapy in childhood soft-tissue sarcoma	Substantial amendment 17	15/01/2016	21
08/H0718/54+5/AM02	Queen Square Brain Bank for Neurological Disorders (QSBB) and NeuroRes	Substantial amendment 1	29/06/2015	21
08/H0718/64/AM13	A population-based ankylosing spondylitis cohort	Substantial amendment 12	08/06/2015	3
09/H0718/29/AM04	Study of free walking in patients with balance problems	Substantial amendment 4	22/06/2015	9
09/H0718/40/AM05	PANNA v2	Substantial amendment 4	04/02/2015	18
10/H0718/53/AM12	Phase 2/3 study of Lenalidomide in Diffuse Large B-Cell Lymphoma	Substantial amendment 9	13/02/2015	9
11/LO/0095/AM09	FerinjectÂ® for iron deficiency in IPAH patients	Substantial amendment 6	23/06/2015	14
11/LO/0095/AM11	FerinjectÂ® for iron deficiency in IPAH patients	Substantial amendment 8	14/12/2015	20
11/LO/1094/AM17	Intellikine 1117-001	Substantial amendment 12	29/09/2015	2
11/LO/1399/AM14	A Phase I study of MK-8242 in patients with Advanced Solid Tumours	Substantial amendment 11	30/04/2015	42
11/LO/1487/AM24	UKALL 2011	Substantial Amendment 17	16/11/2015	1
11/LO/1487/AM26	UKALL 2011	Substantial Amendment 19	21/12/2015	16
11/LO/1711/AM07	Avastin Colorectal Non-Interventional Study.	Substantial amendment 4	17/02/2015	20
11/LO/1720/AM02	Prospective cohort study of patients with pulmonary embolism Version 1	Substantial amendment 22	22/12/2015	19
11/LO/1860/AM06	Phase I study of AT13148, a novel AGC kinase inhibitor	Substantial	05/10/2015	3

		amendment 11		
12/LO/0050/AM07	Study of Tadalafil in Children with Pulmonary Arterial Hypertension(a)	Substantial amendment 5	24/06/2015	14
12/LO/0050/AM08	Study of Tadalafil in Children with Pulmonary Arterial Hypertension(a)	Substantial amendment 6	09/03/2016	14
12/LO/0456/AM07	PCD4989g Phase 1 study in patients with solid tumours	Substantial amendment 8	27/05/2015	7
12/LO/0456/AM08	PCD4989g Phase 1 study in patients with solid tumours	Substantial amendment 9	04/12/2015	11
12/LO/1328/AM10	ACE-011-B-THAL-001 Amendment 1 dated 4th May 2012	Substantial amendment 6	23/06/2015	14
12/LO/1514/AM06	LABILE	Substantial amendment 5	01/05/2015	8
12/LO/1514/AM08	LABILE	Substantial amendment 6	14/07/2015	7
12/LO/1611/AM02	The relationship between oral malodour and gum disease	Substantial amendment 2	24/04/2015	7
12/LO/1850/AM05	Spironolactone and Nitrate on arterial function in Type2 Diabetes	Substantial amendment 3	30/07/2015	8
12/LO/1970/AM05	Understanding pain perception in osteoarthritis(PAPO)	Substantial amendment 5	11/11/2015	11
12/LO/1979/AM02	Assessment of fibre structure & function of the heart	Substantial amendment 2	30/07/2015	12
13/LO/0062/AM05	MIN-001-1203: 2-OHOA in advanced solid tumours, V1.0	Substantial amendment 3	28/09/2015	7
13/LO/0208/AM06	A study of Dabrafenib in Participants under 18 with solid tumours	Substantial amendment 6	09/10/2015	26
13/LO/0224/AM02	Reprogramming patient cells to pluripotency for the study of disease	Substantial amendment 2	13/10/2015	20
13/LO/0379/AM01	Optimising motor functions and treatment in Parkinson's disease	Substantial amendment 1	12/12/2014	23
13/LO/0388/AM18	Phase 3 study to assess efficacy and safety of tocilizumab in GCA	IB update 9 Mar 16	09/03/2016	14
13/LO/0408/AM07	PhaseI/II_SU011248 L-malate-salt_Advanced GIST in young patients	Substantial amendment 5	12/05/2015	14
13/LO/0408/AM09	PhaseI/II_SU011248 L-malate-salt_Advanced GIST in young	Substantial	28/05/2015	2

	patients	amendment 8		
13/LO/0408/AM11	PhaseI/II_SU011248 L-malate-salt_Advanced GIST in young patients	Substantial amendment 9	03/09/2015	3
13/LO/0408/AM12	PhaseI/II_SU011248 L-malate-salt_Advanced GIST in young patients	Substantial amendment 10	22/10/2015	6
13/LO/0716/AM12	CL3-78989-005. EYEGUARD-A study	Substantial amendment 9	04/03/2015	11
13/LO/0717/AM10	CL3-78989-006. EYEGUARD-C study	Substantial amendment 9a	04/03/2015	11
13/LO/0928/AM03	Body weight, bile salts, bacteria, and bowel inflammation	Substantial amendment 2	07/01/2015	6
13/LO/1148/AM02	SPIRIT 3 - study to evaluate best use of TKIs in chronic phase CML	Substantial amendment 2	29/01/2016	31
13/LO/1621/AM01	Immunity and Ageing	Substantial amendment 1	28/08/2015	8
13/LO/1766/AM11	EMR 100070-001: Phase I study of MSB0010718C in solid tumours	Substantial amendment 9	11/05/2015	12
13/LO/1766/AM13	EMR 100070-001: Phase I study of MSB0010718C in solid tumours	Substantial amendment 10	28/08/2015	7
13/LO/1766/AM15	EMR 100070-001: Phase I study of MSB0010718C in solid tumours	Substantial Amendment 12	23/11/2015	4
14/LO/0092/AM03	OTX015_104	Amendment 9	20/11/2015	14
14/LO/0097/AM01	National Child Development Study	Substantial amendment 1	18/01/2016	13
14/LO/0103/AM05	ComPAKT: A Phase I trial of olaparib in combination with AZD5363	Substantial amendment 4	24/02/2015	18
14/LO/0187/AM02	PHASE I/II STUDY IN ADVANCED SOLID TUMOURS or MULTIPLE MYELOMA TAS-120	Substantial amendment 2	06/05/2015	27
14/LO/0250/AM01	Human ex vivo lung perfusion research consortium UK (HELP RCUK)	Substantial amendment 1	17/07/2015	18
14/LO/0308/AM01	Serum Archive for Emerging Zoonoses (SAfEZ).	Substantial amendment 1	08/09/2015	4
14/LO/0364/AM04	IL-10 Axis in paediatric IBD	Substantial amendment 4	09/11/2015	24
14/LO/0371/AM01	1970 British Cohort Study	Substantial amendment 1	04/09/2015	6

14/LO/0602/AM07	998HB303 Previously Untreated Patients With Severe Haemophilia B	Substantial amendment 7	02/10/2015	4
14/LO/0631/AM03	Inner ear and vestibular nuclei histology in SIDS	Substantial amendment 2	22/07/2015	22
14/LO/0638/AM05	A Phase 1/2a study of LON002 in subjects with advanced solid tumours.	Substantial amendment 3	04/06/2015	2
14/LO/0638/AM06	A Phase 1/2a study of LON002 in subjects with advanced solid tumours.	Substantial amendment 4	22/09/2015	5
14/LO/1081/AM03	A Phase I study of TAS-119 given as a single agent and in combination	Substantial amendment 3	15/04/2015	5
14/LO/1081/AM06	A Phase I study of TAS-119 given as a single agent and in combination	Substantial amendment 4	24/08/2015	8
14/LO/1091/AM10	Alnylam - ALN-TTRSC-003 - TTR Cardiac Amyloidosis	Substantial amendment 3	10/12/2015	26
14/LO/1098/AM01	The physiological interactions of reproductive hormones in humans	Substantial amendment 1	09/07/2015	2
14/LO/1122/AM01	PPALM - Palm oil and Pentoxifylline Against Late Morbidity	Substantial amendment 1	02/06/2015	14
14/LO/1122/AM02	PPALM - Palm oil and Pentoxifylline Against Late Morbidity	Substantial amendment 2	04/09/2015	6
14/LO/1122/AM03	PPALM - Palm oil and Pentoxifylline Against Late Morbidity	Substantial amendment 3	29/01/2016	15
14/LO/1195/AM08	997HA306 - Previously Untreated Patients With Severe Haemophilia A	Substantial amendment 3	13/07/2015	33
14/LO/1258/AM01	Is pleural infection associated with longer survival in mesothelioma?	Substantial amendment 1	17/08/2015	7
14/LO/1263/AM02	Morquio A Registry Study (MARS)	Substantial amendment 1	24/10/2014	0
14/LO/1279/AM01	RCT of azithromycin maintenance therapy in Primary Ciliary Dyskinesia	Substantial amendment 1	04/11/2015	8
14/LO/1336/AM02	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial amendment 2	29/06/2015	6
14/LO/1336/AM03	A Phase 1 Study in Patients with Advanced or Metastatic Cancer (JJCA)	Substantial amendment 3	16/12/2015	20
14/LO/1407/AM01	TERIKIDS	Substantial amendment 1	05/10/2015	5

14/LO/1467/AM04	Deep and Frequent Phenotyping Feasibility	Substantial amendment 2	16/04/2015	20
14/LO/1467/AM05	Deep and Frequent Phenotyping Feasibility	Substantial amendment 3	05/06/2015	15
14/LO/1672/AM03	POLO	Substantial amendment 3	08/03/2015	4
14/LO/1672/AM04	POLO	Substantial amendment 4	15/05/2015	45
14/LO/1672/AM07	POLO	Substantial amendment 5	20/08/2015	5
14/LO/1672/AM08	POLO	Substantial amendment 6	07/12/2015	18
14/LO/1868/AM02	A Study of BYL719 in patients with pNETs, RCC and breast cancer.	Substantial amendment 1	30/03/2015	0
14/LO/1868/AM05	A Study of BYL719 in patients with pNETs, RCC and breast cancer.	Substantial amendment 2	18/09/2015	19
14/LO/1876/AM03	MK-8835/PF-PF-04971729 and Sitagliptin Initial Combination Study	Substantial amendment 3	31/03/2015	6
14/LO/1876/AM04	MK-8835/PF-PF-04971729 and Sitagliptin Initial Combination Study	Substantial amendment 4	17/08/2015	7
14/LO/1876/AM05	MK-8835/PF-PF-04971729 and Sitagliptin Initial Combination Study	Substantial amendment 5	01/09/2015	7
14/LO/1876/AM06	MK-8835/PF-PF-04971729 and Sitagliptin Initial Combination Study	Substantial amendment 6	23/10/2015	4
14/LO/1876/AM09	MK-8835/PF-PF-04971729 and Sitagliptin Initial Combination Study	Substantial amendment 7	03/03/2016	13
14/LO/1885/AM02	EDIBLE v1.0	Substantial amendment 1	18/03/2015	6
14/LO/1936/AM01	Online Acceptance and Commitment Therapy for chronic pain	Substantial amendment 1	17/06/2015	28
14/LO/2041/AM03	AZD6094 in patients with papillary renal cell carcinoma	Substantial amendment 3	19/03/2015	6
14/LO/2041/AM05	AZD6094 in patients with papillary renal cell carcinoma	Substantial amendment 5	26/06/2015	10
14/LO/2041/AM06	AZD6094 in patients with papillary renal cell carcinoma	Substantial amendment 6	21/10/2015	4

14/LO/2041/AM07	AZD6094 in patients with papillary renal cell carcinoma	Substantial amendment 7	21/10/2015	11
14/LO/2078/AM04	C34-PEG4-Chol - a new fusion inhibitor for the treatment of HIV	Substantial amendment 2	18/08/2015	6
14/LO/2078/AM05	C34-PEG4-Chol - a new fusion inhibitor for the treatment of HIV	Substantial amendment 3	05/10/2015	5
14/LO/2236/AM01	Primary Care Outcomes: Stage 2	Substantial amendment 1	25/06/2015	28
15/LO/0163/AM01	CL3-78989-019. The EYEGUARD-X study.	Substantial amendment 1	20/05/2015	24
15/LO/0285/AM01	The INFECIR-2 Albumin Prevention Study	Substantial amendment 1	30/06/2015	9
15/LO/0285/AM02	The INFECIR-2 Albumin Prevention Study	Substantial amendment 2	10/09/2015	5
15/LO/0286/AM02	TRACE mechanistic assessments	Substantial amendment 1	27/09/2015	2
15/LO/0286/AM03	TRACE mechanistic assessments	Substantial amendment 2	27/12/2015	6
15/LO/0287/AM01	Boiled Oral Peanut Immunotherapy (The BOPI Study)	Substantial amendment 1	29/10/2015	3
15/LO/0287/AM02	Boiled Oral Peanut Immunotherapy (The BOPI Study)	Substantial amendment 2	09/12/2015	1
15/LO/0287/AM03	Boiled Oral Peanut Immunotherapy (The BOPI Study)	Substantial amendment 3	28/01/2016	5
15/LO/0407/AM01	Attention Control Training for Infants at Risk of ADHD (INTERSTAARS)	Substantial amendment 1	28/01/2016	24
15/LO/0443/AM02	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial amendment 2	10/08/2015	8
15/LO/0443/AM04	Pomalidomide in Relapsed or Refractory Multiple Myeloma Patients-MM007	Substantial amendment 4	15/12/2015	5
15/LO/0460/AM03	SSAT058:Atripla to Eviplera switch in patients without CNS symptoms	Substantial amendment 2.0	05/01/2016	14
15/LO/0615/AM02	A Phase II study of ABT-414 for recurrent glioblastoma	Substantial amendment 2	14/09/2015	8
15/LO/0615/AM05	A Phase II study of ABT-414 for recurrent glioblastoma	Substantial amendment 4	01/02/2016	14

15/LO/0710/AM01	EMBARK:MDV3100-13 Phase3, Enzalutamide, nonmetastatic Prostate Cancer	Substantial amendment 1	20/07/2015	11
15/LO/0710/AM02	EMBARK:MDV3100-13 Phase3, Enzalutamide, nonmetastatic Prostate Cancer	Substantial amendment 2	07/10/2015	8
15/LO/0711/AM03	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 1	18/08/2015	4
15/LO/0711/AM04	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 2	30/10/2015	10
15/LO/0711/AM08	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial amendment 3	27/01/2016	11
15/LO/0711/AM09	The CHARIOT:PRO Study Protocol REGISTRYALZ0001	Substantial Amendment 4	14/03/2016	13
15/LO/0743/AM01	Safety and effects of FP-02.2 - first doses in humans;v1	Substantial amendment 1	28/10/2015	7
15/LO/1006/AM02	Phase II copanlisib in relapsed or refractory DLBCL	Substantial amendment 2	12/02/2016	12
15/LO/1041/AM01	Gut Hormones in Addiction (GHADD) v1.1	Substantial amendment 1	01/09/2015	5
15/LO/1041/AM02	Gut Hormones in Addiction (GHADD) v1.1	Substantial amendment 2	23/02/2016	14
15/LO/1044/AM02	ACTICCA-1	Substantial amendment 2	13/11/2015	25
15/LO/1050/AM01	DARWIN1	Substantial amendment 1	11/01/2016	5
15/LO/1228/AM01	M15-461 (RUBY-II) - GT 1a or 4 Chronic HCV with Renal Impairment	Substantial amendment 1	18/11/2015	17
15/LO/1284/AM01	HuMaxÂ®-TF-ADC Dose Escalation Safety Study	Substantial amendment 1	15/10/2015	7
15/LO/1589/AM01	New Biomarkers of Early Myocardial Infarction	Substantial amendment 1	26/02/2016	18
15/LO/1598/AM01	WA29767 - A study of Tocilizumab versus placebo in Systemic Sclerosis	Substantial amendment 1	26/02/2016	35
15/LO/1600/AM01	GDC-0810 vs fulvestrant in advanced/metastatic ER+/HER2- Breast Cancer	Substantial amendment 1	18/12/2015	7
15/LO/1634/AM01	Exploring Child & Family Adjustment to Acquired Brain Injury	Substantial amendment 1	03/03/2016	13

15/LO/1760/AM01	MEDI4736 and AZD4547 in treatment of advanced bladder cancer	Substantial amendment 1	29/10/2015	21
15/LO/1796/AM01	Phase 1/2 study of BMN 250 in MPS IIIB patients	Substantial amendment 1	09/12/2015	1
15/LO/1807/AM02	CA209-331 Nivolumab vs Chemotherapy in SCLC	Substantial amendment 1	29/01/2016	10
15/LO/1945/AM01	Prophylaxis against acute attacks of Hereditary Angioedema (HAE)	Substantial amendment 1	14/12/2015	13
16/LO/0157/AM01	PLAY Therapy Intervention:Re-Modelling Patient Experience (PLAYTIME)	Substantial amendment 2	08/02/2016	17

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
06/MRE02/73/AM11	Longitudinal study of infant siblings of children with autism	Substantial amendment 7	28/05/2015	32
06/MRE02/73/AM12	Longitudinal study of infant siblings of children with autism	Substantial amendment 8	19/01/2016	7
07/H0718/90/AM50	SPIRIT 2 trial in CML	Substantial amendment 43	30/10/2015	18
12/LO/0313/AM06	Phase I/IIa FTIH study of GSK2636771 in PTEN- solid tumour patients	Substantial amendment 5	11/03/2015	43
12/LO/1850/AM06	Spironolactone and Nitrate on arterial function in Type2 Diabetes	Substantial amendment 4	20/10/2015	30

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**
6/MRE02/73/AM11/1	Longitudinal study of infant siblings of children with autism	Substantial amendment 2 - modified	28/05/2015	7
12/LO/0313/AM06/1	Phase I/IIa FTIH study of GSK2636771 in PTEN- solid tumour patients	Modified substantial amendment 5	29/07/2015	2
14/LO/0364/AM03/1	IL-10 Axis in paediatric IBD	Substantial amendment 4 modified	27/01/2015	10

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**

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

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

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
11/LO/1399/AM14	A Phase I study of MK-8242 in patients with Advanced Solid Tumours	Substantial amendment 11	30/04/2015	42
12/LO/0313/AM06	Phase I/IIa FTIH study of GSK2636771 in PTEN- solid tumour patients	Substantial amendment 5	11/03/2015	43
14/LO/1672/AM04	POLO	Substantial amendment 4	15/05/2015	45

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