

London - Westminster Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	London - Westminster Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Healthy Volunteers
Chair:	Mr Robert Goldstein
Vice-Chair:	Mr Michael Puntis
Alternate Vice-Chair:	Mr Malcolm Morton
REC Manager:	Ms Rachel Katzenellenbogen
REC Assistant:	Ms Laila Sarwar
Committee Address:	4 Minshull Street Manchester M1 3DZ
Telephone:	0207 104 8012
Email:	nrescommittee.london-westminster@nhs.net

Chair's overview of the past year:

There has been a reasonable level of ethical debate covering the applications presented to Westminster REC. Members have in most cases demonstrated a good understanding of the issues. The balance of backgrounds and skills of REC members has been such as to allow different viewpoints to be considered. There has been very good support from the REC Manager both administratively and also through guidance on HRA principles and procedures.

The Westminster REC has continued to examine a significant number of clinical drug trials which is one of its main areas of expertise.

The new prescreening assessments by the HRA of research applications are now being shown with each application. In almost all cases these assessments have been helpful and serious overlap with ethical issues has not yet arisen.

Proportionate Reviews have been assessed on a regular basis each month and the email system has worked well and allowed decision and recommendations to be made within the required short time lines.

There have also been a significant number of Substantial Amendments several of which can be dealt with easily and quickly although some have required considered discussion and requests for further information made to applicants. The work load these SAs engender needs to be kept under review. After requests by the Chair to reconsider the current procedure, the REC Manager has introduced a new system of sending out grouped SAs on a Monday which appears to be working well.

Last year Westminster REC had a member shortage which has been a problem facing the REC. That is, the member shortage combined with lack of attendance by some members has affected the ability of Westminster REC to function. The result has been that most REC meetings have required members from other RECs to be coopted. New members have been recruited but this has been balanced by existing members resigning. The REC is therefore still somewhat under strength. The main concern is that the proportion of expert members who have clinical experience is still too low and this needs to be rectified. It is clear that there are instances where expert medical knowledge provides vital input to clarifying the ethical issues arising out of the research application. The two clinicians on the REC may both, for different reasons, have to resign in the next few months leaving the Westminster REC in a critical position.

London - Westminster Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Rasiah Bharathan	Subspecialty Fellow in gynaecological oncology	Expert	01/03/2018	
Mr Calvin Chen	Clinical Research Associate	Expert	28/03/2017	
Ms Rachel Fay	Research Governance & GCP Manager	Lay	04/01/2016	08/06/2017
Mr Robert Goldstein	Chair - Economist	Lay Plus	01/07/2013	
Mrs Jean Gournay	Clinical Psychologist	Expert	01/04/2017	
Dr Erika Kennington	Research Funder	Lay	30/06/2015	
Miss Farinaz Keshavarzi	Pharmacist	Expert	01/12/2017	
Mr Christopher Mellor	Barrister	Lay Plus	06/02/2013	
Mrs Rosemary Morgan	Financial Services	Lay Plus	01/01/2013	
Mr Malcolm Morton	Practice Manager	Lay Plus	31/05/2013	
Dr Michael Newell	Lecturer in Sport and Exercise Nutrition	Expert	01/06/2017	
Dr Yash Patel	Senior Clinical Project Manager	Lay	23/02/2015	
Mr Michael Puntis	Vice-Chair - ICU Anaesthetist	Expert	08/07/2010	
Dr Alan Swann	Occupational Physician	Expert	24/10/2013	
Mrs Anna Szmigin	Principal Pharmacist - Acute Medicine	Expert	01/11/2014	

London - Westminster Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Urmi Bapat	Pharmaceutical Physician	Expert	31/10/2017 27/02/2018
Ms Stephanie Cooper	Solicitor	Lay Plus	25/04/2017
Mrs Marion Cumbers	Librarian	Lay Plus	25/07/2017
Mr Maurice Hoffman	Teacher	Lay Plus	29/08/2017
Dr Joanne Lawson	Civil Servant	Lay Plus	27/03/2018
Ms Ann Rosenthal	Literary Consultant	Lay Plus	31/10/2017
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Expert	27/03/2018
Dr Francesca Silverton	Statistics Teacher	Lay	27/02/2018
Dr Jacqueline Tavabie	General Practitioner	Expert	25/04/2017
Dr Ruth Williams	Consultant Paediatric Neurologist	Expert	27/06/2017 29/08/2017
Dr David Pilling	Consultant Radiologist	Expert	16/03/2017 (sub-committee)

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

Name	Declaration of Interest	Date
Mr Calvin Chen	Clinical Project Associate Director – Biotechnology in Stevenage Business Park	31/03/2018
Mr Robert Goldstein	Director of Roskill Ltd. Ownership and small shareholdings in some medical companies	28/11/2017
Mrs Jean Gournay	None	31/10/2017
Dr Erika Kennington	Head of Research at Asthma UK	04/01/2018
Miss Farinaz Keshavarzi	None	27/02/2018
Mr Christopher Mellor	None	31/01/2018
Mrs Rosemary Morgan	None	30/01/2018
Mr Malcolm Morton	None	28/11/2017
Dr Michael Newell	Lecturer in Sport and Exercise Nutrition at University of Westminster. College Research Associate at Wolfson College Cambridge.	30/01/2018
Mr Michael Puntis	None	28/11/2017
Dr Alan Swann	None	28/11/2017
Mrs Anna Szmigin	None	30/01/2018

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

Month	Date	Number of Members Present at Meeting
April	25/04/2017	8
June	27/06/2017	8
July	25/07/2017	9
August	29/08/2017	7
September	26/09/2017	7
October	31/10/2017	9
January	30/01/2018	7
February	27/02/2018	7
March	27/03/2018	7

9 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	18/04/2017	3
May	15/05/2017	3
July	17/07/2017	3
August	22/08/2017	3
September	19/09/2017	3
October	17/10/2017	3
November	21/11/2017	3
January	16/01/2018	3
February	20/02/2018	3
March	20/03/2018	3

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

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

Month	Date	Number of Members Present at Meeting
April	07/04/2017	2
April	21/04/2017	3
May	05/05/2017	2
May	19/05/2017	3
June	16/06/2017	3
June	30/06/2017	3
July	14/07/2017	2
July	28/07/2017	2
August	11/08/2017	3
August	25/08/2017	2
September	22/09/2017	3
October	06/10/2017	2
October	20/10/2017	3

November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	15/12/2017	3
January	05/01/2018	3
January	19/01/2018	2
February	02/02/2018	2
February	16/02/2018	2
March	02/03/2018	2
March	16/03/2018	3
March	30/03/2018	2

24 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
Mr Calvin Chen	3
Mr Robert Goldstein	7
Mrs Jean Gournay	5
Dr Erika Kennington	4
Miss Farinaz Keshavarzi	1
Mr Christopher Mellor	4
Mrs Rosemary Morgan	6
Mr Malcolm Morton	5
Dr Michael Newell	4
Mr Michael Puntis	4
Dr Alan Swann	6
Mrs Anna Szmigin	8

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

Name	Number of Meetings Attended
Mr Robert Goldstein	9
Dr Erika Kennington	3
Mr Christopher Mellor	3
Mrs Rosemary Morgan	2
Mr Malcolm Morton	2
Dr Yash Patel	1
Mr Michael Puntis	5
Dr Alan Swann	2
Mrs Anna Szmigin	3

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

Name	Number of Meetings Attended
Mr Robert Goldstein	24
Dr Erika Kennington	4
Mr Christopher Mellor	2
Mrs Rosemary Morgan	3
Mr Malcolm Morton	4
Mr Michael Puntis	8
Dr Alan Swann	6
Mrs Anna Szmigin	6

Name of Member	Date	Event(s) attended
Mr Calvin Chen	06/04/2017	Induction for new Research Ethics Service Committee members
Mr Calvin Chen	21/09/2017	Committee Members Induction
Mr Calvin Chen	28/02/2018	Ethical Issues in Phase One Research
Mr Robert Goldstein	03/05/2017	Chair's Meeting
Mr Robert Goldstein	08/08/2017	Equality, Diversity and Human Rights
Mr Robert Goldstein	06/11/2017	Chair's Meeting
Mr Robert Goldstein	24/11/2017	HRA National Chairs' Day and Policy Event
Mr Robert Goldstein	28/11/2017	REC Member training meeting
Mr Robert Goldstein	12/12/2017	National Members Training Day
Mr Robert Goldstein	13/02/2018	Ethical Issues of Research Involving Children
Mrs Jean Gournay	25/04/2017	Review and consideration of the ShED 22 report
Mrs Jean Gournay	16/11/2017	Committee Members Induction
Dr Erika Kennington	16/11/2017	Committee Members Induction
Dr Erika Kennington	28/11/2017	REC Member training meeting
Mr Christopher Mellor	19/05/2017	Reviewed SOPs extracts regarding substantial amendments to facilitate taking part in Sub-Committees
Mr Christopher Mellor	10/06/2017	Reviewed guidance on generic ionising radiation statements for PISs.
Mr Christopher Mellor	17/06/2017	Reviewed REC Member Exchange 8, especially with regard to EU Clinical Trial regulations.
Mr Christopher Mellor	24/06/2017	Reviewed Proportionate Review section of SOPs to facilitate participation in PR meetings
Mr Christopher Mellor	18/01/2018	Reviewed changes to data protection
Mrs Rosemary Morgan	25/04/2017	Review and consideration of the ShED 22 report
Mrs Rosemary Morgan	12/06/2017	Equality and Diversity
Mrs Rosemary Morgan	24/07/2017	Medical Devices
Mrs Rosemary Morgan	29/11/2017	REC Member training meeting
Mr Malcolm Morton	25/04/2017	Review and consideration of the ShED 22 report
Mr Malcolm Morton	28/11/2017	REC Member training meeting
Dr Michael Newell	18/04/2017	Useful information from OMEA #80 regarding PR and different opinions.
Dr Michael Newell	08/06/2017	Read the new Generic Ionising Radiation Risk Statements guidance

Dr Michael Newell	22/06/2017	Read section of Standard Operating Procedures on Proportionate Review and Sub-committees.
Dr Michael Newell	18/01/2018	Read guidance on changes to Data Protection and the impact on RECs and researchers.
Mr Michael Puntis	25/04/2017	Review and consideration of the ShED 22 report
Mr Michael Puntis	12/06/2017	Equality Diversity and Human Rights
Mr Michael Puntis	12/06/2017	Equality & Diversity
Mr Michael Puntis	28/11/2017	REC Member training
Ms Karen Sanders	01/09/2017	Equality & Diversity
Ms Karen Sanders	29/09/2017	East Midlands Member Training Day
Ms Karen Sanders	12/12/2017	National Members Training Day
Dr Alan Swann	25/04/2017	Review and consideration of the ShED 22 report
Dr Alan Swann	18/07/2017	Reviewing Clinical Trials
Dr Alan Swann	28/11/2017	REC Member training
Mrs Anna Szmigin	25/04/2017	Review and consideration of the ShED 22 report
Mrs Anna Szmigin	28/11/2017	REC Member training meeting

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	23	46.94
Phase 1	2	4.08
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	24	48.98
Total Applications Reviewed	49	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	3
Number of student applications reviewed	11
Number of paediatric applications reviewed	3
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	4

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	15	30.61
Unfavourable Opinion	0	0.00
Provisional Opinion	33	67.35
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	49	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	27	55.10
Further Information Favourable Opinion with Additional Conditions	4	8.16
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	15	30.61
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.04
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.04
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	49	100

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

Total Applications Reviewed	22
------------------------------------	-----------

Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

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	22.73
Favourable Opinion with Additional Conditions	3	13.64
No Opinion transfer to full committee for review	1	4.55
Provisional Opinion	13	59.09
Unfavourable Opinion	0	0.00
Total	22	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	5.44
Number of completed applications for full ethical review	49
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)	35
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 21 days as a % of total	14.29%
Number of SSAs (non-Phase 1) reviewed	1
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	1
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	99
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	4
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	116
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	18
Number of annual progress reports received	83
Number of safety reports received	53
Number of Serious Adverse Events received	1
Number of final reports received	16

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0642	Exploring mothers views of fathers staying overnight on postnatal ward	50
17/LO/0657	ITACS Trial	42
17/LO/0658	FOLD:Study Of EARFOLD® For The Treatment Of Prominent Ears	48
17/LO/0683	Evaluating VX-659 Combination Therapy safety & efficacy in CF patients	44
17/LO/1055	Elective rituximab in TTP	36
17/LO/1087	Phase I study to compare the effect of food on the test tablet	38
17/LO/1093	A couple-based psychological intervention for chronic fatigue syndrome	33
17/LO/1143	PIVL repair for lateralised incisional hernia	42
17/LO/1180	Petal	30
17/LO/1202	A multimodal outcome study of eating disorders	26
17/LO/1350	Study PB-102-F50 PRX-102 in Fabry Disease Patients Treated with ERT	35
17/LO/1396	Denture Malodour and Microbiota (DMM)	51
17/LO/1616	The adherence to multivitamins and minerals following duodenal switch.	39
17/LO/1617	Personality, coping and type 1 diabetes management in children.	39
17/LO/1629	Phase 1b study in patients with advanced or solid tumours	32
17/LO/1808	ICON9	36
17/LO/1840	Nitric Oxide Synthase Inhibition on Human Atrial Electrophysiological	36
18/LO/0108	Human Olfactory Ensheathing Cells	35
18/LO/0112	Phase 3b switch study to B/F/TAF FDC in HIV subjects aged >= 65 years	35
18/LO/0116	Prexasertib in Recurrent Ovarian Cancer (JTJN)	34
18/LO/0129	WesFit: The Wessex Fit-4-Cancer Surgery Trial	47
18/LO/0274	Massive Implants the Next Generation (MING)	57
18/LO/0292	Immunological profiling in uterine cancer	39
18/LO/0295	OPTIMA - SAV008-01 - Pilot clinical trial of inhaled Molgramostim	41
18/LO/0319	ANB019-002: ANB019 in Subjects with Generalized Pustular Psoriasis	52
18/LO/0434	Fabry disease study to determine the safety and efficacy of lucerastat	31
18/LO/0448	CALDOSE - 1	45

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1659	Understanding Fontan circulatory failure using exercise CMR	46

18/LO/0071	A-BRAVE Trial	41
18/LO/0104	HYVET 2: Treatment of white coat HYPertension in the Very Elderly	38
18/LO/0309	D4H Study	45

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
17/LO/1391	Psychological Therapy for Complex Post-traumatic Stress Disorder	28

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0988	Social Values, Impression Management Strategies and Psychopathy (V1)	27
17/LO/1040	PISARRO-R	21
17/LO/1046	Response to varying the rate of administration of a fluid challenge	21
17/LO/1059	Ubrogepant in the Acute Treatment of Migraine	27
17/LO/1066	GO-LEVEL	27
17/LO/1226	Melatonin treatment for sleep disturbance in ocular disorders:Sandman	21
17/LO/1353	MICROCHIP	28
17/LO/1411	FRAILCLINIC: Intervention	28
17/LO/1469	A study of RO7020531 in healthy subjects and patients with hepatitis B	24
17/LO/1509	MS-STAT2	27
17/LO/1592	BO39633 - Atezolizumab open label extension study	27
17/LO/1844	PROSPER Study	22
17/LO/1848	Positron lymphography for pre-operative axillary nodal staging	23
18/LO/0294	Experiences of peer relationships in inpatient CAMHS; version 1	24
18/LO/0507	Preserving Antibiotics through Safe Stewardship: PASS	29

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0500	MORPHEUS - GASTRIC CANCER	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
18/LO/0444	The intensive care palliative assessment tool (ICPAT) study	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
17/LO/0648	Development of a Patient Focused Chronic Pain Consultation Aid	17
17/LO/0653	MCD: Increasing Mindfulness and Mindful eating in Bariatric Patients	20
17/LO/0666	Experiences of Childbirth Following Attendance at Relaxation Training	18
17/LO/0831	The evaluation of the use of a Physical Health Plan	23
17/LO/1444	Can we standardize urinary urgency?	15
17/LO/2029	An Assistive Powered Wheelchair: Stage 1 Trial	21
18/LO/0142	Effects of Remote Ischaemic Preconditioning in patients with PVD	18
18/LO/0334	Peripheral blood KIT Mutations in paediatric mastocytosis	19
18/LO/0337	Patient Acceptability of the First Contact Practitioner Role	19
18/LO/0339	Comparison of clinical outcomes of preterms at two tertiary centres	19
18/LO/0477	OPHELIA study - Causes of Gestational Diabetes	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1803	Validation of questionnaires in relation to overcontrol Version 1.2	19
18/LO/0157	NRD to predict COPD exacerbations at home	16

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
17/LO/0671	Are elderly women more susceptible to the risk of developing periphe	18
17/LO/1258	Central neurotoxicity in childhood ALL v1.0	10
17/LO/1605	MRI-based AC for SPECT v1.0	24
17/LO/2026	Wearable for health: 'Bring your own data' for perioperative care	12
18/LO/0475	lymphatic and vascular invasion in SCC tongue v1	20

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1441	SYNC-EDU Version 1	21
17/LO/1446	Perianal Crohn's disease & Patient informational preferences	19
17/LO/2033	Objective neurovascular monitoring in feet of Type 2 diabetes patients	21

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
10/H0802/44/AM07	Diagnostic markers of clinical allergy vs sensitisation to peanut -v.1	3	10/10/2017	21
10/H0802/52/AM13	Relationship between nitrate/nitrate handling and glucose tolerance	9	19/02/2018	24
11/H0802/4/AM07	Regulation of vascular tone in conduit and resistance vasculature	4	30/03/2017	15
11/LO/0854/AM22	Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001	IB Ed 13	26/10/2017	15
11/LO/1296/AM09	Vitamin D in left Ventricular hypertrophy Diabetes (VIVID) Trial.	8	21/02/2018	11
12/LO/0893/AM11	Brentuximab Vedotin vs Physician's Choice in Patients with CD30+ CTCL	15	26/10/2017	10
12/LO/1417/AM01	The Gut-Liver Axis in Liver Disease & Liver Transplantation	1	01/03/2017	33
13/LO/0210/AM03	Vascular Metabolic Phenotyping	2	20/12/2017	34
13/LO/0720/AM17	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	IB Ed 14	10/03/2017	16
13/LO/0720/AM21	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	Change of legal rep	16/10/2017	8
13/LO/1050/AM18	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	IB Ed 14	18/07/2017	29
13/LO/1050/AM19	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	IB Ed 14.1	25/01/2018	35
13/LO/1289/AM12	Phase 3 Study KW-0761 Versus Vorinostat in CTCL Patients	8	24/03/2017	35
13/LO/1796/AM09	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	7	25/04/2017	35
13/LO/1796/AM11	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	9	19/12/2017	16
13/LO/1796/AM12	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	10	14/02/2018	34
14/LO/0100/AM12	APIPPRA version 1.0	4	23/03/2017	15
14/LO/0148/AM03	Dapagliflozin in Type 2 diabetic patients with diabetic nephropathy.	3	09/10/2017	29
14/LO/0306/AM17	Phase IB study of MK3475 in subjects with Select Advanced Solid Tumors	15	13/11/2017	22
14/LO/0801/AM18	IMPRESS Trial version 2.0	5	19/09/2017	34

14/LO/0801/AM21	IMPRESS Trial version 2.0	6	09/02/2018	24
14/LO/1165/AM10	Ibrutinib in Combination with Lenalidomide and Rituximab in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	5.0	13/12/2017	14
14/LO/1181/AM03	SSAT057: Targeted clinical strategies and LLV in bPI therapy	3	22/06/2017	27
14/LO/1978/AM02	Tau PET in traumatic brain injury	2	01/02/2017	13
15/LO/0108/AM04	CCMR One	4	22/05/2017	7
15/LO/0337/AM07	PORTICO	6	29/08/2017	20
15/LO/0337/AM08	PORTICO	7	14/02/2018	29
15/LO/0696/AM08	Brain associates of parent training on ASB in children	5	17/07/2017	27
15/LO/0863/AM06	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	6	30/08/2017	11
15/LO/0863/AM07	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	7	02/02/2018	29
15/LO/0881/AM11	MK-1439A versus ATRIPLA in treatment-naïve HIV-1 infected subjects	9	06/06/2017	26
15/LO/0881/AM12	MK-1439A versus ATRIPLA in treatment-naïve HIV-1 infected subjects	11	17/07/2017	11
15/LO/0881/AM13	MK-1439A versus ATRIPLA in treatment-naïve HIV-1 infected subjects	12	30/08/2017	24
15/LO/0897/AM17	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	17	28/06/2017	20
15/LO/0897/AM18	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	18	27/11/2017	18
15/LO/1181/AM05	AFTER	4	18/07/2017	31
15/LO/1192/AM07	Trial to evaluate different starting doses (strengths) of ponatinib	6	06/10/2017	18
15/LO/1192/AM09	Trial to evaluate different starting doses (strengths) of ponatinib	7	20/12/2017	16
15/LO/1299/AM01	The impact of wearing dentures on Eating related quality of life.	1	28/03/2017	12
15/LO/1332/AM01	Ecologically valid measure of executive function for children with ASD	1	17/03/2017	31
15/LO/1332/AM02	Ecologically valid measure of executive function for children with ASD	2	18/08/2017	28
15/LO/1569/AM09	The UK CAVIAR Study	8	01/02/2018	35
15/LO/1576/AM03	TRACC	1	20/06/2017	35
15/LO/1576/AM07	TRACC	2	24/01/2018	34
15/LO/1787/AM03	PRM-151G-101	IMPD v10	07/03/2017	19

15/LO/1906/AM12	Study to compare Alicaforsen with placebo in patients with Pouchitis	8	29/06/2017	13
15/LO/1906/AM16	Study to compare Alicaforsen with placebo in patients with Pouchitis	Protocol Amendment 3.2	01/12/2017	21
15/LO/1936/AM02	Phase 2 Open Label MGCD265 in patients with NSCLC	2	18/04/2017	27
15/LO/1936/AM03	Phase 2 Open Label MGCD265 in patients with NSCLC	3	21/07/2017	7
15/LO/1936/AM05	Phase 2 Open Label MGCD265 in patients with NSCLC	4	29/08/2017	11
15/LO/1936/AM07	Phase 2 Open Label MGCD265 in patients with NSCLC	6	06/12/2017	13
15/LO/2054/AM01	Investigating the pathway of type 1 diabetes in childhood	1	20/02/2018	20
16/LO/0242/AM05	Epizyme EZH202 - Adult	IB v7	14/04/2017	23
16/LO/0242/AM06	Epizyme EZH202 - Adult	5	07/08/2017	28
16/LO/0285/AM10	Vonoprazan-2001 - GERD study	7	26/01/2018	14
16/LO/0521/AM08	Ph 1b MEDI4736 for Relapsed/Refractory Diffuse Large B-cell Lymphoma	3	25/08/2017	30
16/LO/0522/AM01	How frequently should we see our orthodontic patients?	1	27/06/2017	22
16/LO/0676/AM05	MK-8628 Haematologic Malignancy Trial	5	27/10/2017	17
16/LO/0702/AM04	GP2017 and Humira in moderate to severe active rheumatoid arthritis	3	06/07/2017	22
16/LO/0791/AM09	Observational study exploring treatment for women with arm lymphoedema.	3.2	25/08/2017	2
16/LO/1124/AM03	Loxo NTRK Tumours - LOXO-TRK-15002	7.2	12/02/2018	35
16/LO/1138/AM03	STRATUS (SysTemic sclerOsis AbiTUzumab Study)	2	26/05/2017	19
16/LO/1138/AM05	STRATUS (SysTemic sclerOsis AbiTUzumab Study)	3	03/11/2017	35
16/LO/1144/AM01	GLIDE: Gastric band and Liraglutide Intervention in Diabetes Evolution	1	27/07/2017	31
16/LO/1225/AM02	Lifestyle and health in the Hertfordshire Cohort Study	1	30/03/2017	28
16/LO/1225/AM03	Lifestyle and health in the Hertfordshire Cohort Study	2	01/10/2017	17
16/LO/1310/AM01	BI 425809 and placebo in patients with Alzheimer's Disease	1	19/01/2018	14
16/LO/1310/AM03	BI 425809 and placebo in patients with Alzheimer's Disease	2	07/03/2018	35
16/LO/1398/AM02	C. difficile in diabetic foot patients	2	17/07/2017	26
16/LO/1423/AM05	Phase 3 study of Bardoxolone Methyl in patients with CTD-PAH	PIS/ICF	01/12/2017	20
16/LO/1466/AM01	PRX-102 compared to Agalsidase Beta in Patients with Fabry Disease	Protocol amendment 4	29/09/2016	15
16/LO/1466/AM02	PRX-102 compared to Agalsidase Beta in Patients with Fabry Disease	5	14/07/2017	17

16/LO/1466/AM03	PRX-102 compared to Agalsidase Beta in Patients with Fabry Disease	Reimbursement Policy	04/01/2018	7
16/LO/2126/AM07	EMINENT	2	14/11/2017	8
17/LO/0296/AM01	BAT II Study version 1.0	1	19/09/2017	10
17/LO/0552/AM02	STRATIFY	1	16/08/2017	31
17/LO/0552/AM03	STRATIFY	2	03/11/2017	21
17/LO/0657/AM01	ITACS Trial	1	08/11/2017	32
17/LO/0658/AM02	FOLD:Study Of EARFOLD® For The Treatment Of Prominent Ears	1	12/10/2017	22
17/LO/0658/AM03	FOLD:Study Of EARFOLD® For The Treatment Of Prominent Ears	2	19/12/2017	17
17/LO/0683/AM02	Evaluating VX-659 Combination Therapy safety & efficacy in CF patients	2	12/07/2017	14
17/LO/0683/AM05	Evaluating VX-659 Combination Therapy safety & efficacy in CF patients	3	15/09/2017	28
17/LO/0683/AM08	Evaluating VX-659 Combination Therapy safety & efficacy in CF patients	4	01/12/2017	27
17/LO/1040/AM02	PISARRO-R	2	26/09/2017	27
17/LO/1066/AM01	GO-LEVEL	1	02/06/2017	31
17/LO/1066/AM02	GO-LEVEL	2	18/09/2017	14
17/LO/1180/AM01	Petal	1	20/12/2017	17
17/LO/1180/AM02	Petal	2	05/01/2018	14
17/LO/1202/AM01	A multimodal outcome study of eating disorders	1	27/10/2017	11
17/LO/1353/AM01	MICROCHIP	1	12/02/2018	23
17/LO/1469/AM01	A study of RO7020531 in healthy subjects and patients with hepatitis B	1	10/01/2018	9
17/LO/1469/AM02	A study of RO7020531 in healthy subjects and patients with hepatitis B	2	21/03/2018	28
17/LO/1509/AM01	MS-STAT2	1	26/01/2018	34
17/LO/1592/AM01	BO39633 - Atezolizumab open label extension study	1	29/11/2017	29
17/LO/1592/AM02	BO39633 - Atezolizumab open label extension study	2	01/03/2018	35
17/LO/1629/AM01	Phase 1b study in patients with advanced or solid tumours	1	21/03/2018	16
17/LO/1803/AM01	Validation of questionnaires in relation to overcontrol Version 1.2	1	18/01/2018	35
EC00/128/AM06	Eczema Genetics	7	21/03/2017	35

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/LO/1732/AM04	Moderato-A Double-Blind Randomized Trial	2	22/11/2017	16

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/0696/AM05/1	Brain associates of parent training on ASB in children	4 (modified)	27/03/2017	9
15/LO/0699/AM07/1	Vertex - VX14-661-108 - Cystic Fibrosis	7 modified	07/04/2017	3
16/LO/1732/AM04/1	Moderato-A Double-Blind Randomized Trial	2 modified	13/02/2018	13

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/LO/1375/AM07/1	OvPSYCH 2	5 (modified)	12/10/2016	14

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 21 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/0831	The evaluation of the use of a Physical Health Plan	23
17/LO/1605	MRI-based AC for SPECT v1.0	24
18/LO/0477	OPHELIA study - Causes of Gestational Diabetes	26

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
-------------------------	-------	---------	------	-------------------------

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------