

**London - Westminster Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Westminster Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase 1 Studies in Healthy Volunteers
<b>Chair:</b>	Mr Robert Goldstein
<b>Vice-Chair:</b>	Mr Michael Puntis
<b>Alternate Vice-Chair:</b>	No Alternate Vice-Chair appointed at time of report
<b>REC Manager:</b>	Ms Rachel Katzenellenbogen
<b>REC Assistant:</b>	Mr Ewan Waters (01/04/2016-06/03/2017) Ms Laila Sarwar (06/03/2017-31/03/2017)
<b>Committee Address:</b>	4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	0207 104 8012
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## Chair's overview of the past year:

There has been a good level of ethical debate concerning 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.

At this stage, Westminster REC has not seen the new prescreening assessments by the HRA of research applications and so cannot comment on their usefulness and effectiveness.

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. The implication of required REC action over some of the researcher issued annual reports still requires clarification.

Last year Westminster REC had a member shortage which has been the main 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. Two new members have just joined and it is hoped the REC will be brought to full strength in the near future. Of equal concern is that the proportion of expert members who have clinical experience has been falling 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.

## London - Westminster Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Calvin Chen	Clinical Research Associate	Expert	28/03/2017	
Ms Rachel Fay	Research Governance & GCP Manager	Lay	04/01/2016	
Mr Robert Goldstein	Chair - Economist	Lay Plus	01/07/2013	
Dr Nourieh Hoveyda	Consultant in Public Health Medicine	Expert	01/09/2014	13/01/2017
Dr Erika Kennington	Research Funder	Lay	30/06/2015	
Mr Christopher Mellor	Barrister	Lay Plus	06/02/2013	
Mrs Rosemary Morgan	Financial Services (retired)	Lay Plus	01/01/2013	
Mr Malcolm Morton	Practice Manager (Retired)	Lay Plus	31/05/2013	
Dr Yash Patel	Senior Clinical Project Manager	Expert	23/02/2015	
Mr Michael Puntis	ICU/Anaesthetist	Expert	08/07/2010	
Dr Alan Ruben	Chair - Retired GP	Expert	01/09/2011	01/09/2016
Miss Ros Stanbury	Ophthalmologist (Retired)	Expert	03/07/2006	03/07/2016
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
Professor David Caplin	Physicist	Lay	31/01/2017
Dr Jan Downer	Consultant Anaesthetist	Expert	29/11/2016
Mr Stephen Edgar	Designer	Lay Plus	PR SC - 21/07/2016
Miss Shelly Glaister-Young	Barrister	Lay Plus	28/02/2017
Mrs Diana Harvey	Lawyer	Lay Plus	28/02/2017
Mr Maurice Hoffman	Retired Teacher	Lay Plus	28/02/2017
Miss Monica Jefford	Retired Midwife	Expert	30/08/2016 27/09/2016
Dr Edward Lavender	GP	Expert	31/01/2017
Miss Anna Sekula	Nurse	Expert	PR SC - 11/01/2017
Mrs Marney Williams	Teacher	Lay Plus	30/08/2016
Dr Nabila Youssouf	Research Fellow in Clinical Trials	Expert	29/11/2016

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Calvin Chen	Clinical Research Scientist and Associate Project Manager at Mitsubishi Tanabe Pharma Europe LTD.	21/03/2017
Ms Rachel Fay	R&D Manager, Royal Free London NHS Foundation Trust. As part of this work, routinely attend meetings of the North Thames CRN.	31/03/2017
Mr Robert Goldstein	Director of Roskill Ltd. Ownership and small shareholdings in Anaxsys, Microtest Matrices, Michelson Diagnostics and Roskill Ltd.	28/02/2017
Dr Erika Kennington	Head of Research at Asthma UK Board Member of the European Federation of Allergy and Airways Disease Patients Associations.	28/03/2017
Mr Christopher Mellor	None	30/03/2017
Mrs Rosemary Morgan	None	28/03/2017
Mr Malcolm Morton	None	10/01/2017
Dr Yash Patel	Region Specialist – Scholarship Reading Committee, Foreign and Commonwealth Office Employee of the Royal Marsden – Clinical Trials Unit	11/07/2016
Mr Michael Puntis	None	19/02/2017
Dr Alan Ruben	None	26/06/2016
Dr Alan Swann	I am employed by Imperial College as their occupational physician. I am responsible for scrutinising risk assessments of work involving use of human pathogens and advising on measures to protect the health of researchers against risks arising out of their research work. Some of this research is carried out in the NHS and requires ethics approval by a REC.	12/01/2017
Mrs Anna Szmigin	Employed in the NHS as a clinical pharmacist so may rarely come into contact with patients admitted to the hospital who are enrolled in a clinical trust.	04/01/2017

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

Month	Date	Number of Members Present at Meeting
April	26/04/2016	10
June	28/06/2016	7
July	26/07/2016	8
August	30/08/2016	9
September	27/09/2016	8
November	29/11/2016	8
January	31/01/2017	8
February	28/02/2017	8
March	28/03/2017	7

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	21/04/2016	3
May	31/05/2016	3
June	23/06/2016	3
July	21/07/2016	6
August	10/08/2016	3
September	14/09/2016	3
October	12/10/2016	3
November	09/11/2016	3
December	14/12/2016	3
January	11/01/2017	3
February	21/02/2017	3
March	21/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	4
April	21/04/2016	3
April	22/04/2016	4
May	20/05/2016	4
June	10/06/2016	4
July	22/07/2016	4
August	12/08/2016	3
August	31/08/2016	3
September	30/09/2016	2
October	14/10/2016	2

October	28/10/2016	2
November	15/11/2016	3
November	28/11/2016	2
November	29/11/2016	3
December	16/12/2016	3
January	13/01/2017	3
January	27/01/2017	3
February	10/02/2017	3
February	24/02/2017	2
March	10/03/2017	2
March	24/03/2017	2
March	30/03/2017	11

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

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

0

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Calvin Chen	1
Ms Rachel Fay	4
Mr Robert Goldstein	8
Dr Nourieh Hoveyda	1
Dr Erika Kennington	6
Mrs Rosemary Morgan	5
Mr Malcolm Morton	6
Dr Yash Patel	6
Mr Michael Puntis	8
Dr Alan Ruben	4
Miss Ros Stanbury	2
Dr Alan Swann	6
Mrs Anna Szmigin	6

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Rachel Fay	1
Mr Robert Goldstein	7
Dr Nourieh Hoveyda	1
Mr Christopher Mellor	2
Mrs Rosemary Morgan	3
Mr Malcolm Morton	6
Dr Yash Patel	7
Mr Michael Puntis	3
Dr Alan Ruben	5
Mrs Anna Szmigin	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Robert Goldstein	20
Dr Erika Kennington	3
Mrs Rosemary Morgan	1
Mr Malcolm Morton	1
Dr Yash Patel	2
Mr Michael Puntis	8
Dr Alan Ruben	8



Miss Ros Stanbury	6
Dr Alan Swann	16
Mrs Anna Szmigin	2

**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Calvin Chen	23/03/2017	Equality Diversity and Human Rights
Ms Rachel Fay	31/12/2016	Equality and Diversity
Mr Robert Goldstein	14/10/2016	Genetic and Genomic Research
Mr Robert Goldstein	01/12/2016	National Training Day for Committee Chairs
Mr Robert Goldstein	16/02/2017	National Members Training Day
Dr Erika Kennington	11/01/2017	Induction for new RES Committee members
Mr Malcolm Morton	31/01/2017	Mental Capacity Act
Dr Yash Patel	30/06/2016	Children in Research
Mr Michael Puntis	16/02/2017	National Members Training Day
Mrs Anna Szmigin	16/02/2017	National Members 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	12	27.27
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	32	72.73
<b>Total Applications Reviewed</b>	<b>44</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
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	6

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	11.36
Favourable Opinion with Additional Conditions	5	11.36
Unfavourable Opinion	0	0.00
Provisional Opinion	33	75.00
Provisional Opinion Pending Consultation with Referee	1	2.27
<b>Total</b>	<b>44</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	25	56.82
Further Information Favourable Opinion with Additional Conditions	9	20.45
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	11.36
Favourable Opinion with Additional Conditions	5	11.36
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
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
<b>Total</b>	<b>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>33</b>
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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	8
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	12
Number of paediatric applications reviewed	7
Number of device applications reviewed	3
Number of qualitative applications reviewed	5

**Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	15.15
Favourable Opinion with Additional Conditions	14	42.42
No Opinion transfer to full committee for review	8	24.24
Provisional Opinion	6	18.18
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>33</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.89
<b>Number of completed applications for full ethical review</b>	44
<b>Number of completed applications for full ethical review over 60 days</b>	1
<b>Number of completed applications over 60 days as a % of total</b>	2.27%
<b>Number of completed applications for full ethical review over 40 days</b>	16
<b>Number of completed applications over 40 days as a % of total</b>	36.36%
<b>Number of days taken to final decision – average (mean)</b>	37
<b>Number of completed proportionate review applications for ethical review</b>	25
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	9
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	36%
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	123
<b>Number of completed substantial amendments over 35 days</b>	2
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.63%
<b>Number of completed substantial amendments over 28 days</b>	33
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	26.83%
<b>Number of modified amendments reviewed</b>	9
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	106
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new</b>	24

<b>sites/PIs</b>	
<b>Number of annual progress reports received</b>	99
<b>Number of safety reports received</b>	37
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	22

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0676	MK-8628 Haematologic Malignancy Trial	37
16/LO/0683	BLADE-PCI	45
16/LO/0702	GP2017 and Humira in moderate to severe active rheumatoid arthritis	39
16/LO/0791	Observational study exploring treatment for women with arm lymphoedema.	45
16/LO/1045	The BARDÁ® Venous Stent - VERNACULAR study	38
16/LO/1124	Loxo NTRK Tumours - LOXO-TRK-15002	34
16/LO/1143	The Coagulation Cascade in IPF	48
16/LO/1258	NorAD Version 1.0	39
16/LO/1310	BI 425809 and placebo in patients with Alzheimer's Disease	49
16/LO/1423	Phase 3 study of Bardoxolone Methyl in patients with CTD-PAH	33
16/LO/1432	ISCoPE - Transverse myelitis	50
16/LO/1484	Parents' Experiences: Landau Kleffner Syndrome: Version 1	40
16/LO/1619	Haemodynamics and physiology underlying low flow aortic stenosis	34
16/LO/1730	Cardiac radionuclide imaging in ventricular arrhythmia	48
16/LO/1732	Moderato-A Double-Blind Randomized Trial	38
16/LO/2035	Integrated short term rehabilitation for thoracic cancer	36
16/LO/2126	EMINENT	37
17/LO/0051	MRI of cardiac arrhythmia substrate in repaired Tetralogy of Fallot	63
17/LO/0120	PAS Pilot Trial	46
17/LO/0138	Infusion Reactions in Autoimmune Disease to Rituximab	48
17/LO/0141	Brain immunity in Tourette	42
17/LO/0150	MRI to guide treatment of abnormal heart rhythms	53
17/LO/0186	Photovoice: Exploring Quality of Care and Safety within Dementia	59
17/LO/0383	Pre- and post-operative procedures in bariatric surgery	28
17/LO/0535	SAVVy version 1.0	15

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0522	How frequently should we see our orthodontic patients?	38
16/LO/0711	Adults with skin cancer: exploring personal experiences (V2)	30
16/LO/1312	A study of IMO-8400 in Patients with Dermatomyositis	43



16/LO/1682	Measuring the metabolic cost of fever	32
16/LO/2107	MRI/CT augmented Guidance for Congenital Cardiovascular Interventions	46
17/LO/0296	BAT II Study version 1.0	39
17/LO/0341	Device optimisation in patients with ACHD	46
17/LO/0546	The Feasibility of Online Mindfulness for Stroke Sufferers - Version 1	43
17/LO/0552	STRATIFY	25

#### Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
16/LO/1138	STRATUS ( SysTemic sclerOsis AbiTUzumab Study )	24
16/LO/1466	PRX-102 compared to Agalsidase Beta in Patients with Fabry Disease	22
16/LO/1483	3D models in congenital heart disease	23
17/LO/0518	Patients' satisfaction when wearing different dentures - a pilot study	23
17/LO/0528	Qualitative study on subsequent pregnancies of teenage mothers	23

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1144	GLIDE: Gastric band and Liraglutide Intervention in Diabetes Evolution	24
16/LO/1306	Bladder changes in different OAB patients and the impact of treatment	28
16/LO/1346	Suffering in a physically unwell homeless population	28
16/LO/1360	Factors influencing women's decision to opt for an unplanned homebirth	28
16/LO/1460	Attitudes	23

#### Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
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<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0772	Is 6 weeks too long for first outpatient review after Cardiac Surgery?	14
16/LO/1714	Balance and balance confidence after stroke. version 1	5
16/LO/1880	Patient outcomes in ulcerative colitis	15
16/LO/2034	Allergy management education v1	11
17/LO/0131	Glycaemic Variability in Haemodialysis	22
17/LO/0137	Incidence of Iatrogenic Damage During Ilizarov Fixation of the Tibia.	20

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Favourable Opinion with Standard Conditions**

REC Reference	Title	Number of Days on Clock
16/LO/1088	Developing tools for managing fatigue in Inflammatory Arthritis v1	10
16/LO/1225	Lifestyle and health in the Hertfordshire Cohort Study	14
16/LO/1388	Signature 2 (extension study)	17
16/LO/2222	Glycaemic control in diabetics with haemoglobin variants Version 2	8
17/LO/0332	Comparison of admission rates between Neonatal Units	15

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0785	Inter and Intra reliability of cardiopulmonary exercise testing in AAA	14
16/LO/0789	ARK_v1	13
16/LO/1080	Impact of Unilateral hearing loss in children	10
16/LO/1238	Human Immunodeficiency Virus Fingerprick Study	11
16/LO/1398	C. difficile in diabetic foot patients	16
16/LO/1512	Development of personalised cancer treatments	9
16/LO/1513	RADAR-CNS: Focus Groups	7
16/LO/1713	Failed Telescopic Rods in the Management of Osteogenesis Imperfecta	4
16/LO/2217	Blood Glucose Performance Test, version A	12
16/LO/2247	Validating a pictorial Epworth Sleepiness Scale questionnaire.	11
17/LO/0086	Cognitive performance after reduction in anti-epileptic medication	12
17/LO/0336	Neuropathic symptoms in idiopathic Parkinson's Disease	21
17/LO/0520	Parental perceptions of the hospital food environment	16
17/LO/0527	In vitro pro- and anticoagulant drug effect and hepatobiliary surgery	19

#### Unfavourable Opinion

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

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

REC Reference	Title	Number of Days on Clock
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<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/Q0702/24/AM18	ENDO-2: Platelet Assay Development; Version 1.3	16	01/02/2016	11
08/H0802/93/AM08	Enquiring About Tolerance (EAT) Study (Version 29.4.08)	7	20/02/2017	34
09/H0802/126/AM07	PRISM CRT Randomised Controlled Trial Version 1.0	5	01/05/2016	28
10/H0802/72/AM05	Vitamin K in osteoporosis	4	07/03/2016	9
11/H0802/5/AM09	Haemodynamic effects of drugs acting on large and small vessels	4	12/12/2016	22
11/LO/0123/AM10	Atopic Dermatitis Anti-IgE Paediatric Trial (ADAPT)	7	11/08/2016	20
11/LO/0854/AM21	Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001	12	22/01/2016	13
11/LO/1955/AM04	Juvenile SLE Investigation V1	3	01/08/2016	7
12/LO/0227/AM02	Flora Twin Study	2.0	06/04/2016	16
12/LO/0893/AM10	Brentuximab Vedotin vs Physician's Choice in Patients with CD30+ CTCL	IB 14	21/10/2016	24
12/LO/1133/AM15	Hydroxychloroquine Trial (HCQ)	Urgent Safety Measure	21/10/2016	22
13/LO/0012/AM02	RESTUS v1	2	16/09/2016	13
13/LO/0701/AM03	Evolution of Systolic Hypertension in Twins UK	2	15/12/2015	22
13/LO/0720/AM15	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	ed. 12.1	18/05/2016	19
13/LO/0980/AM06	Investigation into the role of GTN & RIPC in cardiac surgery	Version 5	01/08/2016	32
13/LO/1050/AM15	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	13	26/04/2016	35
13/LO/1050/AM16	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	Updated radiology assessment	17/11/2016	27
13/LO/1050/AM17	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	13.3	10/11/2016	35
13/LO/1289/AM10	Phase 3 Study KW-0761 Versus Vorinostat in CTCL Patients	7	26/05/2016	32
13/LO/1328/AM21	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	16	24/03/2016	17
13/LO/1328/AM23	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	18	03/05/2016	26
13/LO/1328/AM24	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	19	13/05/2016	24

13/LO/1328/AM26	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	21	13/07/2016	25
13/LO/1375/AM05	OvPSYCH 2	3	10/03/2016	5
13/LO/1796/AM06	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	4.0	23/03/2016	13
13/LO/1796/AM08	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	6	22/11/2016	34
14/LO/0087/AM09	An observational study on clearance on biologics in plaque psoriasis	7	18/03/2016	18
14/LO/0100/AM08	APIPPRA version 1.0	2.3	25/04/2016	27
14/LO/0124/AM08	SYNERGY II	4	08/02/2016	28
14/LO/0148/AM02	Dapagliflozin in Type 2 diabetic patients with diabetic nephropathy.	5.3.2	19/07/2016	18
14/LO/0220/AM05	PET/MRI Oncological Imaging	2	05/04/2016	8
14/LO/0220/AM06	PET/MRI Oncological Imaging	Amendment number 3	19/07/2016	35
14/LO/0414/AM02	OPIP	3	04/03/2016	12
14/LO/0414/AM03	OPIP	4	04/05/2016	21
14/LO/0649/AM10	Exercise training for men with localised prostate cancer	09/08/2016	09/08/2016	8
14/LO/0774/AM03	Bumetanide in Hypokalaemic Periodic Paralysis	5	05/05/2016	37
14/LO/0774/AM04	Bumetanide in Hypokalaemic Periodic Paralysis	4	04/10/2016	32
14/LO/0801/AM08	IMPRESS Trial version 2.0	4	13/12/2016	16
14/LO/1087/AM08	Phase 1b study of MLN9708 for treatment of lupus nephritis	31/08/2016	31/08/2016	30
14/LO/1165/AM05	Ibrutinib in Combination with Lenalidomide and Rituximab in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	5	14/03/2016	8
14/LO/1165/AM07	Ibrutinib in Combination with Lenalidomide and Rituximab in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	Amendment 5	01/06/2016	25
14/LO/1165/AM08	Ibrutinib in Combination with Lenalidomide and Rituximab in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	IB 10.1	08/12/2016	7
14/LO/1269/AM01	Recellularisation of tissue allografts (2)	1	12/05/2016	34
14/LO/1487/AM04	Fluctuation of airway function in children with asthma	2.0	04/04/2016	8
14/LO/1723/AM03	Use of Red LED lights for difficult IV access in neonates and infants	4	03/03/2017	28

14/LO/2061/AM03	Positioning in Macular Hole Surgery	2	31/01/2017	23
14/LO/2249/AM01	Hearing deterioration following treatment for head and neck cancer	1	08/04/2016	21
15/LO/0108/AM01	CCMR One	1	25/05/2016	11
15/LO/0119/AM01	NMES and pelvic fracture rehabilitation RCT	2	18/10/2016	22
15/LO/0288/AM07	Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukaemia	4	23/02/2017	22
15/LO/0337/AM03	PORTICO	2	18/04/2016	6
15/LO/0337/AM05	PORTICO	Final version 3. GBR.A.	21/06/2016	21
15/LO/0337/AM06	PORTICO	IB version 14	17/11/2016	20
15/LO/0696/AM03	Brain associates of parent training on ASB in children	2	12/04/2016	31
15/LO/0699/AM04	Vertex - VX14-661-108 - Cystic Fibrosis	4	15/03/2016	10
15/LO/0699/AM06	Vertex - VX14-661-108 - Cystic Fibrosis	3.0	10/06/2016	19
15/LO/0863/AM03	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	Protocol and ICF updates	15/02/2016	25
15/LO/0863/AM04	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	Protocol V5.0	13/05/2016	24
15/LO/0863/AM05	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	5	26/05/2016	24
15/LO/0881/AM05	MK-1439A versus ATRIPLA in treatment-naïve HIV-1 infected subjects	SA04	28/06/2016	14
15/LO/0881/AM09	MK-1439A versus ATRIPLA in treatment-naïve HIV-1 infected subjects	SA07	17/02/2017	6
15/LO/0897/AM15	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	15	25/01/2017	35
15/LO/0897/AM16	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	16	07/03/2017	28
15/LO/1173/AM01	Vascular homeostasis and mental stress: sympathetic activity and nNOS	1	03/02/2016	14
15/LO/1173/AM02	Vascular homeostasis and mental stress: sympathetic activity and nNOS	2	05/07/2016	16
15/LO/1181/AM02	AFTER	2	06/04/2016	12
15/LO/1192/AM03	Trial to evaluate different starting doses (strengths) of ponatinib	3.0	07/11/2016	35
15/LO/1353/AM05	A Phase I Study to Assess Malaria Vaccine R21 with AS01B	4	05/10/2016	21
15/LO/1361/AM02	Cognitive and Neural Networks in Psychiatry	2	01/09/2016	22

15/LO/1361/AM03	Cognitive and Neural Networks in Psychiatry	Amendment number 3	23/01/2017	37
15/LO/1569/AM01	The UK CAVIAR Study	1	08/04/2016	14
15/LO/1570/AM01	IRONWOMAN - Iron therapy for female athletes	1	02/11/2016	14
15/LO/1575/AM01	Gena-99: Human-cl rhFVIII treatment for Haemophilia-A patients	1	03/03/2016	25
15/LO/1906/AM02	Study to compare Alicaforsen with placebo in patients with Pouchitis	2	21/03/2016	15
15/LO/1906/AM03	Study to compare Alicaforsen with placebo in patients with Pouchitis	SA#03	14/06/2016	34
15/LO/1906/AM06	Study to compare Alicaforsen with placebo in patients with Pouchitis	SA#04	08/08/2016	28
15/LO/1906/AM09	Study to compare Alicaforsen with placebo in patients with Pouchitis	5	20/09/2016	34
15/LO/1920/AM01	EIT and NIV Healthy	1	09/08/2016	29
15/LO/1936/AM01	Phase 2 Open Label MGCD265 in patients with NSCLC	1	22/06/2016	20
15/LO/2169/AM01	The IFR Colon Model	Amendment number 1	29/06/2016	11
16/LO/0103/AM01	SSAT069: Pharmacokinetic effect of evotaz/microgynon co-administration	1.0	18/04/2016	13
16/LO/0103/AM02	SSAT069: Pharmacokinetic effect of evotaz/microgynon co-administration	2	21/12/2016	13
16/LO/0242/AM01	Epizyme EZH202 - Adult	1	21/04/2016	31
16/LO/0242/AM04	Epizyme EZH202 - Adult	4.0	25/10/2016	35
16/LO/0285/AM01	Vonoprazan-2001 - GERD study	1	15/02/2016	32
16/LO/0285/AM02	Vonoprazan-2001 - GERD study	AM02	29/03/2016	11
16/LO/0285/AM04	Vonoprazan-2001 - GERD study	4	07/09/2016	35
16/LO/0285/AM05	Vonoprazan-2001 - GERD study	5	29/09/2016	32
16/LO/0285/AM06	Vonoprazan-2001 - GERD study	6	01/11/2016	27
16/LO/0521/AM07	Ph 1b MEDI4736 for Relapsed/Refractory Diffuse Large B-cell Lymphoma	Global protocol amendment 1	02/09/2016	28
16/LO/0579/AM01	Tenovus Cancer Choirs	1	14/04/2016	10
16/LO/0676/AM01	MK-8628 Haematologic Malignancy Trial	1	14/07/2016	10
16/LO/0676/AM02	MK-8628 Haematologic Malignancy Trial	02	24/08/2016	17
16/LO/0676/AM03	MK-8628 Haematologic Malignancy Trial	3	16/12/2016	22
16/LO/0683/AM01	BLADE-PCI	1	27/07/2016	12



16/LO/0683/AM02	BLADE-PCI	2	21/09/2016	14
16/LO/0683/AM05	BLADE-PCI	Substantial Amendment 4	13/01/2017	31
16/LO/0702/AM01	GP2017 and Humira in moderate to severe active rheumatoid arthritis	20/07/2016	20/07/2016	19
16/LO/0702/AM03	GP2017 and Humira in moderate to severe active rheumatoid arthritis	2	28/02/2017	15
16/LO/0789/AM01	ARK_v1	1	24/05/2016	21
16/LO/0791/AM01	Observational study exploring treatment for women with arm lymphoedema.	1	30/06/2016	11
16/LO/0791/AM03	Observational study exploring treatment for women with arm lymphoedema.	2.1	06/10/2016	24
16/LO/0791/AM05	Observational study exploring treatment for women with arm lymphoedema.	3.0	15/12/2016	14
16/LO/1138/AM01	STRATUS ( SysTemic sclerOsis AbiTUzumab Study )	SA01	01/12/2016	31
16/LO/1306/AM01	Bladder changes in different OAB patients and the impact of treatment	1	20/02/2017	15
16/LO/1312/AM02	A study of IMO-8400 in Patients with Dermatomyositis	1	27/01/2017	24
16/LO/1423/AM01	Phase 3 study of Bardoxolone Methyl in patients with CTD-PAH	Protocol Amendment 2	15/12/2016	15
16/LO/1513/AM01	RADAR-CNS: Focus Groups	1.0	15/12/2016	15
16/LO/1513/AM02	RADAR-CNS: Focus Groups	1.1	06/02/2017	34
16/LO/1732/AM01	Moderato-A Double-Blind Randomized Trial	Amendment 1	06/02/2017	17
16/LO/2126/AM01	EMINENT	1	31/01/2017	17

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/1793/AM04	Impella Haemodynamic Support Study	Amendment 4	14/10/2016	34
13/LO/0720/AM16	MEK162 vs Dacarzabine in NRAS mutation positive melanoma patients	13	15/09/2016	25
13/LO/1375/AM07	OvPSYCH 2	5	12/10/2016	30
14/LO/1723/AM02	Use of Red LED lights for difficult IV access in neonates and infants	1	02/09/2016	34
15/LO/0696/AM05	Brain associates of parent training on ASB in children	3	11/10/2016	25
15/LO/0699/AM07	Vertex - VX14-661-108 - Cystic Fibrosis	Sub Am7_IB (VX-	14/01/2017	32

		661) v8.0		
15/LO/0897/AM10	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	12	25/10/2016	17
15/LO/1787/AM02	PRM-151G-101	Protocol 6.0	15/12/2016	18
15/LO/1906/AM10	Study to compare Alicaforsen with placebo in patients with Pouchitis	SA-06-EC-(social media advert	13/01/2017	28
15/LO/1921/AM01	EIT AND NIV COPD OHS	One	09/08/2016	34
16/LO/0521/AM06	Ph 1b MEDI4736 for Relapsed/Refractory Diffuse Large B-cell Lymphoma	1.0	02/09/2016	34
16/LO/1124/AM02	Loxo NTRK Tumours - LOXO-TRK-15002	6.2	27/01/2017	35

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
13/LO/0720/AM16/1	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	IB Ed 13 (modified)	15/09/2016	14
14/LO/0143/AM04/2	Assessment of 18F-Sodium Fluoride PET/CT as a measure of calcification	3	20/01/2016	12
14/LO/0143/AM04/3	Assessment of 18F-Sodium Fluoride PET/CT as a measure of calcification	4	28/01/2016	12
14/LO/1723/AM02/2	Use of Red LED lights for difficult IV access in neonates and infants	3	16/12/2016	2
15/LO/0897/AM10/1	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	12 (modified)	08/12/2016	12
15/LO/1787/AM02/1	PRM-151G-101	Modified 6.0	13/03/2017	14
15/LO/1906/AM10/1	Study to compare Alicaforsen with placebo in patients with Pouchitis	7	23/02/2017	8
15/LO/1921/AM01/1	EIT AND NIV COPD OHS	1 modified	10/01/2017	14

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on</b>

<b>Reference</b>				<b>Clock</b>
14/LO/1723/AM02/1	Use of Red LED lights for difficult IV access in neonates and infants	2; 3rd November 2016	03/11/2016	14

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

REC Reference	Title	Number of Days on Clock
17/LO/0051	MRI of cardiac arrhythmia substrate in repaired Tetralogy of Fallot	63

**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/0131	Glycaemic Variability in Haemodialysis	22

**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
14/LO/0774/AM03	Bumetanide in Hypokalaemic Periodic Paralysis	5	05/05/2016	37
15/LO/1361/AM03	Cognitive and Neural Networks in Psychiatry	Amendment number 3	23/01/2017	37

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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