

**London - Westminster Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## 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>	Dr Alan Ruben
<b>Vice-Chair:</b>	Mr Robert Goldstein
<b>Alternate Vice-Chair:</b>	Mr Michael Puntis
<b>REC Manager:</b>	Ms Rachel Katzenellenbogen
<b>REC Assistant:</b>	Mr Ewan Waters
<b>Committee Address:</b>	4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	0207 104 8012
<b>Email:</b>	nrescommittee.london-westminster@nhs.net

## Chair's overview of the past year:

April 2015 to March 2016.

For the past year the Westminster REC has enjoyed the rare pleasure of the continuous support of an experienced top flight efficient Manager. The professional relationship contrasts vividly with what one had to put up with in years gone by.

An increasing burden on our volunteer members is the volume of documents often submitted with applications for Proportionate Review. Though these applications should be ethically quite straight forward the pile of appended documents that one feels obliged to read through can be extremely burdensome. Though some committee attendance time is allowed, this does not match the reading time required. My most recent favourite ran to 24 bundles! The very short time-scale allowed for consideration of applications places a considerable extra pressure on members who have volunteered to help out by doing these reviews.

## London - Westminster Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Rachel Fay	Research Governance & GCP Manager	Lay	04/01/2016	
Mr Robert Goldstein	Economist	Lay Plus	01/07/2013	
Dr Nourieh Hoveyda	Consultant in Public Health Medicine	Expert	01/09/2014	
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	
Miss Aarti Nandani	Clinical Trials Pharmacist	Expert	27/02/2014	09/02/2016
Dr Yash Patel	Research Project Manager	Expert	23/02/2015	
Mr Michael Puntis	ICU/Anaesthetist	Expert	08/07/2010	
Dr Alan Ruben	GP (Retired)	Expert	01/09/2011	
Miss Ros Stanbury	Ophthalmologist (Retired)	Expert	03/07/2006	
Dr Alan Swann	Occupational Physician	Expert	24/10/2013	
Miss Anna Watson	Highly Specialist Pharmacist - Acute Medicine (Admissions)	Expert	01/11/2014	

## London - Westminster Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

## London - Westminster Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Ms Rachel Fay	GCP and Governance Manager, Joint Research Management Office, Queen Mary University of London and Barts Health NHS Trust.	31/12/2015
Mr Robert Goldstein	Shares in some medical companies	17/05/2015
Dr Nourieh Hoveyda	Medical Assessor at the MHRA.	27/04/2015
Dr Erika Kennington	Head of Research at Asthma UK.	08/07/2015
Mr Christopher Mellor	None	01/04/2015
Mrs Rosemary Morgan	None	23/02/2016
Mr Malcolm Morton	None	23/02/2016
Mr Michael Puntis	None	23/02/2016
Dr Alan Ruben	Chair of Research Ethics Committee, British School of Osteopathy A number of unit trusts shares are held, the individual companies are not known.	21/04/2015
Miss Ros Stanbury	None	24/02/2016
Dr Alan Swann	Occupational Health Physician for Imperial college. Work involves advising on health risk assessments for research projects in biomedical research. Focus is on risks posed to the researchers rather than participants.	27/04/2015
Miss Anna Watson	None.	23/02/2016

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

Month	Date	Number of Members Present at Meeting
April	28/04/2015	8
May	26/05/2015	10
July	28/07/2015	10
August	25/08/2015	7
September	29/09/2015	8
October	27/10/2015	10
November	24/11/2015	9
January	26/01/2016	11
February	23/02/2016	10
March	29/03/2016	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
April	16/04/2015	3
July	16/07/2015	3
August	13/08/2015	3
September	24/09/2015	3
November	19/11/2015	5
December	16/12/2015	3
January	19/01/2016	3
February	18/02/2016	3
March	24/03/2016	3

9 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	17/04/2015	4
May	01/05/2015	3
May	15/05/2015	4
May	29/05/2015	4
June	12/06/2015	4
June	26/06/2015	4
July	17/07/2015	4
August	07/08/2015	4
August	28/08/2015	4
September	25/09/2015	4
October	16/10/2015	4
October	30/10/2015	4

November	20/11/2015	4
December	18/12/2015	4
January	15/01/2016	4
February	12/02/2016	4
February	29/02/2016	3
March	15/03/2016	4

18 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**

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Rachel Fay	2
Mr Robert Goldstein	10
Dr Nourieh Hoveyda	5
Dr Erika Kennington	5
Mr Christopher Mellor	3
Mrs Rosemary Morgan	8
Mr Malcolm Morton	10
Miss Aarti Nandani	1
Dr Yash Patel	7
Mr Michael Puntis	5
Dr Alan Ruben	9
Miss Ros Stanbury	8
Dr Alan Swann	10
Miss Anna Watson	9

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Robert Goldstein	1
Dr Nourieh Hoveyda	2
Mr Christopher Mellor	4
Mrs Rosemary Morgan	3
Mr Malcolm Morton	3
Dr Yash Patel	3
Mr Michael Puntis	3
Dr Alan Ruben	8
Miss Ros Stanbury	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Robert Goldstein	16
Dr Alan Ruben	17
Miss Ros Stanbury	18
Dr Alan Swann	18
Miss Anna Watson	1



**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Robert Goldstein	07/10/2015	Introduction to Phase I Research - Trials and Regulation
Mr Robert Goldstein	18/02/2016	National Members Training Day
Dr Nourieh Hoveyda	07/05/2015	Introduction to Phase I Research
Dr Nourieh Hoveyda	11/03/2016	Genetic and Genomic Research
Mrs Rosemary Morgan	30/06/2015	Children in Research
Mr Michael Puntis	24/02/2016	Human Tissue Act (Use of human tissue samples in research) - an introductory level
Miss Ros Stanbury	03/02/2016	Handling Health-Related Findings in Research
Miss Ros Stanbury	18/02/2016	National Members Training Day
Dr Alan Swann	12/08/2015	Equality and Diversity

## 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	18	32.14
Phase 1	2	3.57
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.79
Others	35	62.50
<b>Total Applications Reviewed</b>	<b>56</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	18
Number of paediatric applications reviewed	10
Number of device applications reviewed	0
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**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	11	19.64
Unfavourable Opinion	3	5.36
Provisional Opinion	41	73.21
Provisional Opinion Pending Consultation with Referee	1	1.79
<b>Total</b>	<b>56</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	30	53.57
Further Information Favourable Opinion with Additional Conditions	9	16.07
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	11	19.64
Unfavourable Opinion	3	5.36
Provisional Opinion	2	3.57
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>56</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>27</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	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
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	18.52
Favourable Opinion with Additional Conditions	8	29.63
No Opinion transfer to full committee for review	6	22.22
Provisional Opinion	8	29.63
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>27</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>	5.60
<b>Number of completed applications for full ethical review</b>	56
<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>	1.79%
<b>Number of completed applications for full ethical review over 40 days</b>	13
<b>Number of completed applications over 40 days as a % of total</b>	23.21%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of completed proportionate review applications for ethical review</b>	21
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	4.76%
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	1
<b>Number of completed applications for SSA review over 14 days</b>	1
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	100.00%
<b>Number of substantial amendments reviewed</b>	128
<b>Number of completed substantial amendments over 35 days</b>	8
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	6.25%
<b>Number of completed substantial amendments over 28 days</b>	28
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	21.88%
<b>Number of modified amendments reviewed</b>	1
<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 minor amendments received</b>	66
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	29
<b>Number of annual progress reports received</b>	119
<b>Number of safety reports received</b>	42

<b>Number of Serious Adverse Events received</b>	3
<b>Number of final reports received</b>	39

**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>
15/LO/0625	Markers of aneurysm formation and progression	27
15/LO/0692	Survey of Elderly Residential Care Home Residents (SEaRCH)	23
15/LO/0699	Vertex - VX14-661-108 - Cystic Fibrosis	27
15/LO/0896	109MS308 - BG00012 in subjects with SPMS	26
15/LO/0897	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	28
15/LO/1162	Evaluation of lancet blood sampling for radioiodine dosimetry	46
15/LO/1173	Vascular homeostasis and mental stress: sympathetic activity and nNOS	39
15/LO/1181	AFTER	55
15/LO/1192	Trial to evaluate different starting doses (strengths) of ponatinib	51
15/LO/1325	Long term outcomes in patients treated for oesophageal atresia.	44
15/LO/1332	Ecologically valid measure of executive function for children with ASD	33
15/LO/1351	Global longitudinal strain of left ventricle in NSTEMIs	35
15/LO/1361	Cognitive and Neural Networks in Psychiatry	50
15/LO/1569	The UK CAVIAR Study	40
15/LO/1570	IRONWOMAN - Iron therapy for female athletes	35
15/LO/1574	tDCS in treatment of symptoms of schizophrenia	28
15/LO/1575	Gena-99: Human-cl rhFVIII treatment for Haemophilia-A patients	47
15/LO/1581	EORTC1206 Salivary Gland Study	33
15/LO/1622	Collection and storage of conjunctival specimens	42
15/LO/1787	PRM-151G-101	36
15/LO/1941	VP-VEC-162-3106 Tasimelteon in travellers with jet lag disorder	32
15/LO/2189	Understanding factors influencing vaccination uptake	51
15/LO/2205	Social context of anomalous experiences in daily life	40
16/LO/0103	SSAT069: Pharmacokinetic effect of evotaz/microgynon co-administration	44
16/LO/0119	Origins and impacts of EDS in connective tissues and skin	53
16/LO/0281	Cambridge Clinical Informatics eHospital Database	27
16/LO/0285	Vonoprazan-2001 - GERD study	34
16/LO/0309	Biomarkers of neoangiogenesis in Rheumatoid Arthritis	48
16/LO/0418	Barriers to self management support following stroke	32
16/LO/0519	CF patient experiences - lung transplant and palliative care	37

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0696	Brain associates of parent training on ASB in children	30
15/LO/0881	MK-1439A versus ATRIPLA in treatment-naive HIV-1 infected subjects	32
15/LO/1222	Fast Infrared Meibography	36
15/LO/1671	Beliefs about ethnicity, families and cancer V0.1	40
15/LO/1743	Pilot Study for Automated Detection of Atrial Fibrillation after TIA	38
15/LO/1803	LAWT and EP characteristics using CT	32
16/LO/0100	DEFINE-FLOW	72
16/LO/0242	Epizyme EZH202 - Adult	56
16/LO/0310	HySTS (Hybrid Sentinel node Tracer Study)	30

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

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

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0690	Feasibility of a trial of risk reduction in sexual health clinics	22
15/LO/0859	Isotoxic dose escalation for lung cancer radiotherapy using ABC.	21
15/LO/0863	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	21
15/LO/1234	EMG in COPD - factor analysis	23
15/LO/1353	A Phase I Study to Assess Malaria Vaccine R21 with AS01B	23
15/LO/1576	TRACC	23
15/LO/1906	Study to compare Alicaforsen with placebo in patients with Pouchitis	20
15/LO/1920	EIT and NIV Healthy	20
15/LO/1921	EIT AND NIV COPD OHS	20
15/LO/1936	Phase 2 Open Label MGCD265 in patients with NSCLC	20
16/LO/0486	Recovery following total hip replacement: does guidance matter?	22



<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0694	Multicenter Aggression subTyping Research in Conduct Syndromes	22
15/LO/1785	Effects and Safety of Oral Tolvaptan in Children with Low Blood Sodium	24
16/LO/0116	WEALTH, v4	30

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0493	ESPRIT ESP1/SARC025	n/a
16/LO/0521	Ph 1b MEDI4736 for Relapsed/Refractory Diffuse Large B-cell Lymphoma	n/a

<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>
15/LO/0753	Laboratory models of liver, biliary and pancreatic cancer	12
15/LO/0761	Breast cancer, diabetes and diabetes treatment: a feasibility study	13
15/LO/1447	Biomechanically determined interventions for patellofemoral pain	15
15/LO/1448	Psoriasis - A Life Story	14
15/LO/1718	Preferences for mirror image vs true image in facial palsy patients	14
16/LO/0196	Patient and carer information needs on the medical ward	13

16/LO/0203	Metabolomics of burn tissues	13
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#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1299	The impact of wearing dentures on Eating related quality of life.	14

#### 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
15/LO/1283	Birmingham Behcet's centre: an analysis of an inception cohort	12
15/LO/2059	Testing a new PCR array for forensic DNA recovery	11
15/LO/2068	Emotional writing and wound healing	12
15/LO/2169	The IFR Colon Model	10
16/LO/0579	Tenovus Cancer Choirs	10

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0738	EORTC CAT Full Validation	12
15/LO/0744	Virtual Hospice	11
15/LO/1300	Mixed-species biofilms and silicone device longevity v0.1	12
15/LO/1452	Exploring AMD caregivers' perspective- focus groups	13
15/LO/1457	Antibiotic effects on the bladder microbiome	12
15/LO/2054	Investigating the pathway of type 1 diabetes in childhood	12
16/LO/0190	Identification of protein markers for monitoring colon cancer	7
16/LO/0576	Functional Network Dynamics in Parkinson's Disease: Version 1	9

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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<b>Provisional Opinion</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 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/H0802/104/AM04	Characterisation of inherited skin disorders	4	09/03/2015	5
07/Q0702/2/AM07	Genetic Studies in Osteoporosis & Osteoarthritis	4	17/03/2015	3
07/Q0702/24/AM16	ENDO-2: Platelet Assay Development; Version 1.3	14	01/04/2015	20
07/Q0702/24/AM17	ENDO-2: Platelet Assay Development; Version 1.3	15	01/08/2015	9
09/H0802/126/AM05	PRISM CRT Randomised Controlled Trial Version 1.0	3	28/04/2015	9
09/H0802/126/AM06	PRISM CRT Randomised Controlled Trial Version 1.0	4	10/12/2015	11
09/H0802/5/AM13	UK Pregnancy Better Eating and Activity Trial (UPBEAT)	11	28/08/2015	11
10/H0802/13/AM09	Level of BP control and target organ damage in children with CKD	1.2	24/03/2015	10
10/H0802/34/AM07	Diagnostic Test Of Infections in Patients with Severe Sepsis	002	10/08/2015	2
10/H0802/44/AM04	Diagnostic markers of clinical allergy vs sensitisation to peanut -v.1	2	01/06/2015	7
10/H0802/46/AM10	REVIVED	8	01/05/2015	7
10/H0802/52/AM08	Relationship between nitrate/nitrate handling and glucose tolerance	6	26/10/2015	15
10/H0802/58/AM04	ADVENT-HF Trial (version 1)	1	31/05/2012	22
10/H0802/58/AM05	ADVENT-HF Trial (version 1)	3	02/07/2015	37
10/H0802/6/AM03	Muscle excitability studies in channelopathies	2	20/05/2015	6
10/H0802/72/AM04	Vitamin K in osteoporosis	4	16/07/2015	25
10/H0802/86/AM03	Blood/urine markers of cardiovascular/renal disease in diabetes	2	29/04/2015	21
11/H0802/7/AM05	Bio-markers of Systemic Treatment Outcomes in Psoriasis	4	03/07/2015	15
11/LO/0123/AM08	Atopic Dermatitis Anti-IgE Paediatric Trial (ADAPT)	6	19/06/2015	9
11/LO/0854/AM16	Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001	11	25/07/2015	19
11/LO/0854/AM17	Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001	IB 11, Ad 1	03/08/2015	15
11/LO/0854/AM18	Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001	INT-7	27/04/2015	5
12/LO/0637/AM13	The ARREST trial	1.0	01/10/2015	34
12/LO/0893/AM07	Brentuximab Vedotin vs Physician's Choice in Patients with	5	02/12/2014	24

	CD30+ CTCL			
12/LO/0893/AM08	Brentuximab Vedotin vs Physician's Choice in Patients with CD30+ CTCL	13	14/01/2016	29
12/LO/1322/AM17	Diabetes prevention using SMS	8	08/06/2015	4
12/LO/1322/AM18	Diabetes prevention using SMS	9	17/06/2015	8
12/LO/1476/AM04	Orteronel (TAK-700) in Castration-Resistant Prostate Cancer Patients	4	27/03/2015	20
12/LO/1476/AM05	Orteronel (TAK-700) in Castration-Resistant Prostate Cancer Patients	ICF Addendum 2	16/04/2015	27
12/LO/1793/AM02	Impella Haemodynamic Support Study	2	09/12/2014	35
12/LO/1793/AM03	Impella Haemodynamic Support Study	3	18/11/2015	10
13/LO/0097/AM08	Phase IIb - GS-6624 in subjects with advanced liver fibrosis	3	05/01/2016	38
13/LO/0387/AM05	Combination therapy in pulmonary hypertension	5	25/03/2015	11
13/LO/0539/AM01	(April) Kisspeptin in pregnancy and gestational diabetes	Amendment 1	10/02/2016	24
13/LO/0570/AM05	The addition of TPV in patients with acute hep C/HIV co-infection	06	26/11/2015	5
13/LO/0704/AM05	A study of allergen extracts in house dust mite associated asthma	IB v11	15/06/2015	35
13/LO/0720/AM13	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	7	01/10/2015	27
13/LO/0720/AM14	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	5.0	26/10/2015	33
13/LO/0755/AM02	Predicting response to CRT using body surface ECG mapping	2	01/04/2015	1
13/LO/0755/AM03	Predicting response to CRT using body surface ECG mapping	3	29/07/2015	6
13/LO/0920/AM02	Developing NE London Cancer Surveillance Project: Distance Monitoring	1	07/09/2015	11
13/LO/0980/AM05	Investigation into the role of GTN & RIPG in cardiac surgery	4	01/05/2015	12
13/LO/1019/AM03	Dose-Ranging Proof of Concept Study of BIIB033 in Relapsing MS	3	20/03/2015	13
13/LO/1019/AM05	Dose-Ranging Proof of Concept Study of BIIB033 in Relapsing MS	IB v6; ICF v4; EoS Questionnaire	22/12/2015	21
13/LO/1050/AM12	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	4	26/03/2015	12
13/LO/1050/AM13	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	12	15/07/2015	26
13/LO/1050/AM14	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	7	18/02/2016	40
13/LO/1066/AM06	Hydrus 4 Study	6	06/07/2015	9
13/LO/1066/AM07	Hydrus 4 Study	7	24/11/2015	7

13/LO/1289/AM07	Phase 3 Study KW-0761 Versus Vorinostat in CTCL Patients	6	06/04/2015	3
13/LO/1328/AM11	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	09	24/04/2015	24
13/LO/1328/AM12	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	10	23/06/2015	30
13/LO/1328/AM19	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	14	29/01/2016	14
13/LO/1332/AM02	Study Evaluating Tolerability and Anti-tumour activity of OPB 111001	IB v5.0	08/05/2015	13
13/LO/1513/AM04	Rituximab Plus Lenalidomide (CC-5013) in Indolent Lymphoma	3	26/03/2015	19
13/LO/1513/AM05	Rituximab Plus Lenalidomide (CC-5013) in Indolent Lymphoma	3	21/10/2015	22
13/LO/1599/AM01	CORAL: Cancer of the Ovary Abiraterone trial	1	28/08/2015	24
13/LO/1599/AM02	CORAL: Cancer of the Ovary Abiraterone trial	2	07/10/2015	28
13/LO/1629/AM04	Pain_OMICs	3	22/01/2016	31
13/LO/1796/AM02	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	2	23/03/2015	25
13/LO/1796/AM04	Ph I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients	3	25/01/2016	32
14/LO/0066/AM06	Pronuts version 1	2	15/04/2015	15
14/LO/0087/AM06	An observational study on clearance on biologics in plaque psoriasis	5	18/06/2015	7
14/LO/0087/AM07	An observational study on clearance on biologics in plaque psoriasis	6	25/02/2016	32
14/LO/0100/AM06	APIPPRA version 1.0	2	25/05/2015	21
14/LO/0148/AM01	Dapagliflozin in Type 2 diabetic patients with diabetic nephropathy.	Substantial Amendment 1	26/11/2015	17
14/LO/0150/AM02	Computer Model Indices to Individualise Heart Failure Treatment	2	27/01/2016	23
14/LO/0220/AM03	PET/MRI Oncological Imaging	1	31/07/2015	17
14/LO/0306/AM05	Phase IB study of MK3475 in subjects with Select Advanced Solid Tumors	SA05	01/04/2015	29
14/LO/0306/AM11	Phase IB study of MK3475 in subjects with Select Advanced Solid Tumors	SA06	01/09/2015	8
14/LO/0306/AM12	Phase IB study of MK3475 in subjects with Select Advanced Solid Tumors	SA07	15/07/2015	23
14/LO/0306/AM13	Phase IB study of MK3475 in subjects with Select Advanced	08	08/10/2015	27

	Solid Tumors			
14/LO/0774/AM01	Bumetanide in Hypokalaemic Periodic Paralysis	3	27/07/2015	22
14/LO/0774/AM02	Bumetanide in Hypokalaemic Periodic Paralysis	2	02/11/2015	1
14/LO/0801/AM03	IMPRESS Trial version 2.0	3	04/09/2015	27
14/LO/1059/AM01	Development of Musculoskeletal Model of the PIP Joint	01	31/07/2015	15
14/LO/1087/AM02	Phase 1b study of MLN9708 for treatment of lupus nephritis	4	16/03/2015	6
14/LO/1087/AM03	Phase 1b study of MLN9708 for treatment of lupus nephritis	08	18/08/2015	29
14/LO/1087/AM04	Phase 1b study of MLN9708 for treatment of lupus nephritis	3	04/08/2015	37
14/LO/1165/AM01	Ibrutinib in Combination with Lenalidomide and Rituximab in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	2.0	03/02/2015	15
14/LO/1165/AM04	Ibrutinib in Combination with Lenalidomide and Rituximab in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	4.0	10/11/2015	27
14/LO/1181/AM01	SSAT057: Targeted clinical strategies and LLV in bPI therapy	1	06/07/2015	19
14/LO/1181/AM02	SSAT057: Targeted clinical strategies and LLV in bPI therapy	2	04/01/2016	5
14/LO/1461/AM01	AC-065C202: Raynaud's Phenomenon secondary to Systemic Sclerosis	10	19/02/2015	17
14/LO/1487/AM03	Fluctuation of airway function in children with asthma	1	09/03/2015	26
14/LO/1978/AM01	Tau PET in traumatic brain injury	1	12/11/2015	6
14/LO/2052/AM13	BE Trial of Liquid versus Freeze-dried Pergoveris® - Resubmission	3	23/10/2015	19
14/LO/2066/AM01	A study to evaluate the effect of solithromycin in COPD	1	13/05/2015	6
14/LO/2074/AM01	Histological Features in Testicular Cancers – Effect on Prognosis	Amendment number 1	26/01/2016	23
14/LO/2088/AM01	Assessment of possible benefits of PSG to setup NIV	1.4	08/06/2015	7
14/LO/2313/AM01	Delivering Pulmonary Rehabilitation with Lay Health Workers (DRILL)	1	23/06/2015	11
15/LO/0105/AM01	Development of a Tool to Assess Social Functioning in Dementia	1	05/05/2015	13
15/LO/0105/AM02	Development of a Tool to Assess Social Functioning in Dementia	2	06/10/2015	12
15/LO/0140/AM01	CLEANER 310 3166 in the treatment of venous or mixed leg ulcers	01	08/12/2015	14
15/LO/0144/AM01	Physical activity and exercise capacity in PH	1.0	02/04/2015	9
15/LO/0191/AM01	MRI assessment of CRC hypoxia (MATCH).	1	21/09/2015	28

15/LO/0288/AM03	Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukaemia	Protocol amendment 6 and 7	29/05/2015	7
15/LO/0288/AM05	Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukaemia	3	18/11/2015	12
15/LO/0320/AM01	Open label study for subjects with BRAF V600 Mutation Positive Tumors	PIS/ICF	19/05/2015	3
15/LO/0337/AM01	PORTICO	2.GBR.A	05/08/2015	35
15/LO/0690/AM01	Feasibility of a trial of risk reduction in sexual health clinics	1.0	29/06/2015	24
15/LO/0692/AM01	Survey of Elderly Residential Care Home Residents (SEaRCH)	1	20/10/2015	16
15/LO/0692/AM02	Survey of Elderly Residential Care Home Residents (SEaRCH)	2	15/12/2015	15
15/LO/0696/AM01	Brain associates of parent training on ASB in children	1	03/12/2015	31
15/LO/0699/AM02	Vertex - VX14-661-108 - Cystic Fibrosis	2.0	06/08/2015	28
15/LO/0761/AM01	Breast cancer, diabetes and diabetes treatment: a feasibility study	1.1	29/05/2015	8
15/LO/0863/AM01	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	1	24/06/2015	28
15/LO/0863/AM02	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	2	08/09/2015	38
15/LO/0881/AM01	MK-1439A versus ATRIPLA in treatment-naive HIV-1 infected subjects	01	05/08/2015	15
15/LO/0881/AM02	MK-1439A versus ATRIPLA in treatment-naive HIV-1 infected subjects	2	04/03/2016	28
15/LO/0897/AM01	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	2	16/06/2015	35
15/LO/0897/AM04	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	6	19/08/2015	36
15/LO/0897/AM07	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	9	10/10/2015	15
15/LO/0897/AM08	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	5	10/12/2015	34
15/LO/1181/AM01	AFTER	1	21/12/2015	9
15/LO/1192/AM02	Trial to evaluate different starting doses (strengths) of ponatinib	2.0	17/12/2015	31
15/LO/1353/AM01	A Phase I Study to Assess Malaria Vaccine R21 with AS01B	1	14/10/2015	24
15/LO/1353/AM03	A Phase I Study to Assess Malaria Vaccine R21 with AS01B	SA002	18/01/2016	26
15/LO/1353/AM04	A Phase I Study to Assess Malaria Vaccine R21 with AS01B	3	05/02/2016	7



15/LO/1361/AM01	Cognitive and Neural Networks in Psychiatry	1	21/01/2016	33
15/LO/1787/AM01	PRM-151G-101	5.1	12/02/2016	37

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0802/86/AM04	Blood/urine markers of cardiovascular/renal disease in diabetes	3	12/06/2015	7
13/LO/0089/AM02	Adipose-derived cells in limb ischaemia	2	03/07/2015	35
13/LO/0720/AM11	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	6	28/04/2015	35
13/LO/0720/AM12	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	7	01/10/2015	50
14/LO/0143/AM04	Assessment of 18F-Sodium Fluoride PET/CT as a measure of calcification	3	30/04/2015	17
14/LO/0306/AM07	Phase IB study of MK3475 in subjects with Select Advanced Solid Tumors	6	04/06/2015	35
14/LO/1087/AM05	Phase 1b study of MLN9708 for treatment of lupus nephritis	9	17/08/2015	23

**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
13/LO/0720/AM11/1	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	6	28/04/2015	13

#### Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
16/LO/0100	DEFINE-FLOW	72

**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
15/LO/1447	Biomechanically determined interventions for patellofemoral pain	15

**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
15/LO/1763	A Phase I study to assess the	15

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0802/58/AM05	ADVENT-HF Trial (version 1)	3	02/07/2015	37
13/LO/0097/AM08	Phase IIb - GS-6624 in subjects with advanced liver fibrosis	3	05/01/2016	38
13/LO/0720/AM12	MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients	7	01/10/2015	50
13/LO/1050/AM14	E7080-G000-304 - Unresectable Hepatocellular Carcinoma	7	18/02/2016	40
14/LO/1087/AM04	Phase 1b study of MLN9708 for treatment of lupus nephritis	3	04/08/2015	37
15/LO/0863/AM02	AG348-C-003 Phase II Study in Patients with Pyruvate Kinase Deficiency	2	08/09/2015	38
15/LO/0897/AM04	WO29637. A Study of anti PD-L1 Antibody in Renal Cell Carcinoma (RCC)	6	19/08/2015	36
15/LO/1787/AM01	PRM-151G-101	5.1	12/02/2016	37

**Modified Amendments over 14 day timeline**

<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
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