

**London - Riverside Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Riverside Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPs in healthy volunteers – Type III REC recognised to review CTIMPs in patients – Type III
<b>Type of Flag:</b>	Phase 1 Studies in Patients and Healthy Volunteers Research involving Children
<b>Chair:</b>	Dr Sabita Uthaya (until 06/07/2015) Dr Margaret Jones (from 07/07/2015 – present)
<b>Vice-Chair:</b>	Dr Margaret Jones (from 01/07/2014 - 07/07/2015) Vacant (from 07/07/2015 – present)
<b>Alternate Vice-Chair:</b>	Vacant (from 01/07/2014 to 12/10/2015) Dr Matthew Hyde (from 12/10/2015)
<b>REC Manager:</b>	Miss Tina Cavaliere
<b>REC Assistant:</b>	Miss Claudia Harrison (until 22/02/2016) Ms Helen Sivey (from 22/02/2016 - present)
<b>Committee Address:</b>	Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
<b>Telephone:</b>	020 7104 8204
<b>Email:</b>	nrescommittee.london-riverside@nhs.net

## Chair's overview of the past year:

The Riverside committee has had another interesting year in which we have been challenged to review and consider a large number of disparate applications. The committee enjoys the variety of differing aspects of medical research and works to promote the interests of all who participate in medical research.

Last year, we lost the services of Dr Sabita Uthaya who has chaired and guided our committee over the last ten years. We owe her a great debt for her excellent and skilful management of our meetings and for the knowledge and experience which she was prepared to share with the committee. We were also saddened to lose the expertise and guidance of a number of valued longstanding members, including John Clifford and Dr Daniel Wood. We send them all our best wishes for the future.

We have been fortunate in welcoming 4 new members to our committee together with several others who have kindly attended on an ad hoc basis. Their interest and enthusiasm brings a freshness to our work and we look forward to their contributions in the future.

Once again, I have to thank our REC Manager, Tina Cavaliere who has been a source of knowledge and encouragement for me when I took over the role of Chair and has, as usual, managed the committee with good humour, patience and efficiency. She has been ably supported by her assistants, Claudia Bywater and Helen Sivey.

Margaret Jones

## London - Riverside Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Anna Bischler	Pharmacist	Expert	01/11/2007	31/12/2015
Dr Ben Braithwaite	General Practitioner	Expert	01/09/2014	01/08/2015
Dr Marina Cecelja	Centre Career Establishment Fellow	Expert	15/12/2015	
Dr Irina Chis Ster	Senior Lecturer In Biostatistics	Expert	02/12/2015	
Mr John Clifford	Dean	Lay Plus	18/05/2005	18/05/2015
Dr Julian Collinson	Consultant Cardiologist	Expert	01/03/2011	
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	01/09/2012	
Dr Linda Feighery	Strategic Publication Lead	Lay	16/11/2015	
Dr Nuria Gonzalez-Circa	Clinical Study Manager	Lay	14/03/2016	
Dr Matthew Hyde	Research Scientist	Lay	01/09/2009	
Dr Margaret Jones	Retired General Practitioner	Expert	26/09/2007	
Ms Alexandra Mancini	Pan London Lead for Neonatal/Palliative Care	Expert	06/04/2009	
Ms Fanny Mitchell	Retired NHS Manager	Lay Plus	01/10/2009	
Mr Kamen Shoylev	Lawyer	Lay Plus	01/12/2011	
Mrs Dinah Smith	Retired Head Teacher	Lay Plus	11/06/2013	
Dr Sabita Uthaya	Consultant Neonatologist	Expert	01/07/2005	06/07/2015
Ms Julia Williams	Senior Producer	Lay Plus	13/06/2013	
Dr Daniel Wood	Clinical Psychologist	Expert	01/09/2009	03/07/2015

## London - Riverside Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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## London - Riverside Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Sally Gordon Boyd	Medical Ethicist	Lay	06/07/2015
Mrs Elayne Nasr	Retired School Matron	Lay Plus	02/11/2015
Dr Michael Schachter	Clinical Pharmacologist	Expert	06/07/2015, 07/03/2016

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Ms Anna Bischler	No declarations of interest.	04/01/2016
Dr Marina Cecelja	Carries out peer reviews for grants and journals	04/01/2016
Dr Irina Chis Ster	Member of local ethics committee at St Georges University of London	04/01/2016
Dr Julian Collinson	No declarations of interest.	30/01/2016
Ms Stephanie Ellis	No declarations of Interest.	04/01/2016
Dr Linda Feighery	No declarations of interest.	03/01/2016
Dr Nuria Gonzalez-Circa	No declarations of interest.	31/03/2016
Dr Matthew Hyde	Employed by Imperial College London that is likely to be related to the conduct of research.	04/01/2016
Dr Margaret Jones	Owens a few shares in Smith and Nephew.	04/01/2016
Ms Alexandra Mancini	No declarations of interest.	31/03/2016
Ms Fanny Mitchell	No declarations of interest.	25/01/2016
Mr Kamen Shoylev	No declarations of interest.	31/03/2016
Mrs Dinah Smith	No declarations of interest.	01/01/2016
Ms Julia Williams	No declarations of interest.	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	13/04/2015	11
June	01/06/2015	10
July	06/07/2015	7
August	03/08/2015	9
September	07/09/2015	7
October	05/10/2015	8
November	02/11/2015	10
December	07/12/2015	12
January	04/01/2016	12
March	07/03/2016	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	27/04/2015	3
June	15/06/2015	3

2 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	07/04/2015	2
April	10/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	07/05/2015	2
May	15/05/2015	2
May	27/05/2015	2
June	05/06/2015	2
June	12/06/2015	2
June	19/06/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	17/07/2015	2
July	24/07/2015	2
July	31/07/2015	2
August	07/08/2015	2
August	14/08/2015	2
August	14/08/2015	2
August	21/08/2015	2

August	28/08/2015	2
September	04/09/2015	2
September	11/09/2015	2
September	18/09/2015	2
September	25/09/2015	2
October	02/10/2015	2
October	09/10/2015	2
October	16/10/2015	2
October	23/10/2015	2
October	30/10/2015	2
November	06/11/2015	2
November	13/11/2015	2
November	20/11/2015	2
November	27/11/2015	2
December	04/12/2015	2
December	04/12/2015	2
December	11/12/2015	2
December	18/12/2015	2
December	25/12/2015	2
January	08/01/2016	2
January	15/01/2016	2
January	22/01/2016	2
January	29/01/2016	2
February	05/02/2016	2
February	19/02/2016	2
February	26/02/2016	2
March	04/03/2016	2
March	11/03/2016	2
March	18/03/2016	2
March	25/03/2016	2

49 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 Anna Bischler	3
Dr Ben Braithwaite	2
Dr Marina Cecelja	3
Dr Irina Chis Ster	2
Mr John Clifford	1
Dr Julian Collinson	8
Ms Stephanie Ellis	9
Dr Linda Feighery	3
Dr Matthew Hyde	8
Dr Margaret Jones	9
Ms Alexandra Mancini	5
Ms Fanny Mitchell	7
Mr Kamen Shoylev	8
Mrs Dinah Smith	10
Dr Sabita Uthaya	3
Ms Julia Williams	7
Dr Daniel Wood	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Julian Collinson	1
Ms Fanny Mitchell	1
Mr Kamen Shoylev	1
Dr Sabita Uthaya	2
Dr Daniel Wood	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Anna Bischler	1
Dr Ben Braithwaite	2
Dr Julian Collinson	7
Ms Stephanie Ellis	7
Dr Linda Feighery	1
Dr Matthew Hyde	9
Dr Margaret Jones	39
Ms Alexandra Mancini	4



Ms Fanny Mitchell	5
Mr Kamen Shoylev	5
Mrs Dinah Smith	6
Dr Sabita Uthaya	6
Ms Julia Williams	4
Dr Daniel Wood	2

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Ben Braithwaite	13/04/2015	In-house training - Research in children and young people
Dr Marina Cecelja	10/03/2016	Members Induction
Dr Julian Collinson	27/11/2015	CTIMP Training Day
Ms Stephanie Ellis	08/04/2015	Tutor for training session on MCA for Harrow REC
Ms Stephanie Ellis	13/04/2015	Tutor for Mental Capacity training day for Frenchay REC
Ms Stephanie Ellis	16/04/2015	Tutor for MCA training for SE Coast Surrey REC
Dr Matthew Hyde	12/10/2015	Complex Cases
Dr Margaret Jones	19/10/2015	Ethical Issues in research involving children
Ms Fanny Mitchell	26/11/2015	London REC Members' Training Day
Ms Fanny Mitchell	18/02/2016	National Training Day
Mr Kamen Shoylev	07/10/2015	Introduction into Phase 1 - trials and regulations
Mrs Dinah Smith	07/10/2015	Introduction into Phase 1 - trials and regulations
Ms Julia Williams	13/04/2015	In-house training - Research on Children & young people

## 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	26	56.52
Phase 1	1	2.17
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	19	41.30
<b>Total Applications Reviewed</b>	<b>46</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	11
Number of paediatric applications reviewed	11
Number of device applications reviewed	2
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	1

**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	6	13.04
Favourable Opinion with Additional Conditions	13	28.26
Unfavourable Opinion	1	2.17
Provisional Opinion	26	56.52
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>46</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	22	47.83
Further Information Favourable Opinion with Additional Conditions	2	4.35
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	13.04
Favourable Opinion with Additional Conditions	13	28.26
Unfavourable Opinion	1	2.17
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.17
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.17
<b>Total</b>	<b>46</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>2</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	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	1
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	1

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	100.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>2</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.60
<b>Number of completed applications for full ethical review</b>	45
<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>	2.17%
<b>Number of completed applications for full ethical review over 40 days</b>	4
<b>Number of completed applications over 40 days as a % of total</b>	8.70%
<b>Number of days taken to final decision – average (mean)</b>	31
<b>Number of completed proportionate review applications for ethical review</b>	2
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<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>	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>	129
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	5
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	3.88%
<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 minor amendments received</b>	105
<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	43
<b>Number of annual progress reports received</b>	59

<b>Number of safety reports received</b>	231
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	15

**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/0446	PICU Diary Feasibility Study	38
15/LO/0571	ALERT	54
15/LO/0591	Quality of life in older cancer patients	50
15/LO/0924	A Phase 3 Double Blind Randomised Study of Orally Administered PLX3397	29
15/LO/0940	GS-US-312-0118, Efficacy and Safety with Idelalisib in Combination	38
15/LO/1080	AIM Cards Research Project	31
15/LO/1119	ARTESiA: Apixaban in patients with device-detected sub-clinical AF	26
15/LO/1120	ODYSSEY (Once daily DTG-based ART in young people vs standard therapy)	30
15/LO/1138	SVR SOF Cirrhosis Registry Study	23
15/LO/1143	Measuring physical activity using electronic measurement devices	24
15/LO/1419	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	31
15/LO/1432	RIM4DMD	30
15/LO/1653	CAM2038 in Adult Outpatients with Opioid Use Disorder	37
15/LO/1657	Drisapersen extension study	32
15/LO/1815	Maternal cardiac function in placental complications	31
15/LO/1987	A Trial to Evaluate Terguride in Subjects with CYP2D6 Genotypes.	41
15/LO/2034	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	37
16/LO/0021	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	32
16/LO/0025	simplify	61
16/LO/0303	Pictorial aids at discharge for minor head injury patients V2	36
16/LO/0333	Phase II Study of Pembrolizumab in Advanced Recurrent Ovarian Cancer	36
16/LO/0378	Assessment of social communication in children with visual impairment	33

<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/1582	Comparison of NIRS, PPG and SDF in neonates with NEC.	33
15/LO/2073	KEYNOTE-158	40

<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>
15/LO/0886	232SM201 - Spinal Muscular Atrophy Study	23
15/LO/1236	NEOD001 versus placebo in AL Amyloidosis	25
15/LO/1633	Smart Socket Sensor System	25
15/LO/1635	ABACUS	25
15/LO/1665	Safetxt: a randomised controlled trial of a safer sex intervention	25
15/LO/1808	Vitamin K and folate status of breast fed preterm infants	28

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0719	Paediatric Tumour Profiling	23
15/LO/1238	CUTHIVAC002	25
15/LO/1239	HIV Once Daily ARV Single Tablet bPI regimen naive patients - AMBER	25
15/LO/1246	MM-141-07-02-02 (CARRIE) Pancreatic Cancer Phase 2	25
15/LO/1399	ILD Controls V1.0	28
15/LO/1410	Undergraduate medical education in general practice	28
15/LO/1729	VX15-770-123 - Cystic Fibrosis study for 3-5 year olds	25
15/LO/2008	MK1439A in treatment naïve HIV1 infected subjects with NNRTI transmitt	24
15/LO/2036	Experiences of Hearing Aid Use; A Qualitative Study	27
16/LO/0006	Safety and Biomarker Study with EPI-589 in Parkinson's Disease	29
16/LO/0018	Approach Bias Modification Training In Bulimia Nervosa	24
16/LO/0023	1. Interval training in IPF	24
16/LO/0443	A multicentre, open-label, randomised ITP study	25

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1142	Faecal screen pre prostate biopsy to reduce complications	22

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<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>
16/LO/0024	STATIN (version 1.0)	n/a

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1072	FASHION : Female Attitudes to Sexuality in Hepatitis c InfectiON	51

*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>

<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>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0815	Development of a lifestyle service pathway in NAFLD	8
15/LO/1126	Use of a cell-line (A1ATD) in metabolism and pathogen research	8

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

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

<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>
04/Q0401/40/AM23	BRAINS	4	21/01/2016	14
07/Q0401/25/AM06	Analysis of specimens from patients with orthopaedic implants	6	13/04/2015	20
08/H0706/100/AM21	Phase II AZD2281 in platinum sensitive serous ovarian cancer	1	10/03/2016	11
08/H0706/61/AM24	CUP-ONE Cancer of unknown primary-1: An NCRN phase II study	(CUP ONE A18)	15/04/2015	23
09/H0706/20/AM07	Genetic basis of craniofacial malformations	4	02/07/2015	24
09/H0706/20/AM08	Genetic basis of craniofacial malformations	No 5 1 October 2015	01/10/2015	14
09/H0706/22/AM40	Aliskiren vs enalapril in chronic heart failure		21/04/2015	29
09/H0706/35/AM09	Immune reconstitution studies in cord blood transplantation. Vn 1.1		04/06/2015	15
09/H0706/90/AM06	DEPICT	Amendment 4	21/10/2015	14
10/H0706/35/AM13	Pain In Neuropathy Study (PINS)		19/02/2015	9
10/H0706/35/AM15	Pain In Neuropathy Study (PINS)	7	10/06/2015	16
10/H0706/65/AM52	ARISTOTLE		31/07/2015	5
10/H0706/65/AM54	ARISTOTLE	SA35	22/12/2015	12
10/H0706/68/AM02	Basal Ganglia Connectivity Version 1.0	Amendment number 3 (AM02)	08/03/2016	8
11/LO/0935/AM09	Personalised Medicine for Morbid Obesity		12/05/2015	10
11/LO/1490/AM09	NO25390 Phase I Paed Melanoma		28/07/2015	3
12/LO/0081/AM11	008: Oral CP-690,550 as Maintenance Therapy for Ulcerative Colitis	Investigator Brochure June 201	27/10/2015	13
12/LO/0082/AM12	009: Open-label Oral CP-690,550 for Treatment of Ulcerative Colitis	SA10	29/10/2015	18
12/LO/1506/AM08	HGS1006-C1121 Phase 3 study of belimumab plus SoC in Lupus Nephritis		16/03/2015	29
12/LO/1898/AM05	INTestinal ischaemia Early REcognition STudy (INTEREST)	Amendment 2, November 13th 201	13/11/2015	16
12/LO/2019/AM05	Breast Screening and Monitoring Study		29/05/2015	6
12/LO/2019/AM06	Breast Screening and Monitoring Study	Amendment 5, 7 September 2015	07/09/2015	2

13/LO/0002/AM20	Efficacy & safety of GS-1101 with Ofatumumab in previously treated CLL	SA#12	01/12/2015	8
13/LO/0242/AM07	GE180 and microglial activation in AD and MCI subjects	Amendment 5	10/07/2015	2
13/LO/0254/AM01	Profiling and culturing of neuroblastoma and soft tissue sarcoma cells	SA1	17/12/2015	2
13/LO/0609/AM01	Is triaging effective in H1N1 influenza?		20/07/2015	2
13/LO/0753/AM02	The investigation and treatment of chondro-labral pathology of the hip		21/08/2015	10
13/LO/0753/AM03	The investigation and treatment of chondro-labral pathology of the hip		19/02/2016	12
13/LO/0822/AM08	VinCaP		21/05/2015	9
13/LO/0822/AM10	VinCaP	5	11/02/2016	21
13/LO/0945/AM10	KOGNITO - Kuvan®'s effect in children with phenylketonuria	Change in Sponsor and Protocol	11/12/2015	4
13/LO/1117/AM06	TAVI in Women Registry		05/05/2015	9
13/LO/1152/AM04	An exploratory breast lead interval study (EBLIS)		27/07/2015	6
13/LO/1152/AM05	An exploratory breast lead interval study (EBLIS)	Amendment 5, 03 November 2015	03/11/2015	8
13/LO/1463/AM12	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial	5a	12/08/2015	7
13/LO/1473/AM07	Telaprevir in genotype 3 HCV		31/03/2015	14
13/LO/1473/AM08	Telaprevir in genotype 3 HCV	Amendment 5	21/10/2015	7
14/LO/0022/AM05	Randomised Phase II study in untreated advanced renal cell carcinoma		08/05/2015	18
14/LO/0022/AM06	Randomised Phase II study in untreated advanced renal cell carcinoma	Substantial Amendment - MPDL32	07/07/2015	7
14/LO/0022/AM07	Randomised Phase II study in untreated advanced renal cell carcinoma	6	05/02/2016	31
14/LO/0115/AM04	Imaging Brain Structures in Children with Congenital Hypothyroidism		26/05/2015	10
14/LO/0305/AM03	Investigating healthcare in the construction of disability. Version 2		27/04/2015	20
14/LO/0324/AM07	Pulmaquin® with Non-Cystic Fibrosis Bronchiectasis (ORBIT 3)		21/05/2015	19

14/LO/0339/AM03	The ACORN study: Coping and Relaxation in Pregnancy		27/04/2015	9
14/LO/0339/AM05	The ACORN study: Coping and Relaxation in Pregnancy		04/06/2015	15
14/LO/0343/AM04	PET monitoring for MS therapy		15/07/2015	13
14/LO/0471/AM08	Pulmaquin® with Non-Cystic Fibrosis Bronchiectasis (Orbit 4)		21/05/2015	14
14/LO/0510/AM02	The Lived Experience Of Low Back Pain In Multi-ethnic Leicester, V1		25/03/2015	13
14/LO/0512/AM05	A Clinical Trial to Test if the Drug OPC-108459 is Safe and Effective		25/08/2015	7
14/LO/0528/AM11	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis		14/04/2015	14
14/LO/0528/AM13	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis		14/09/2015	3
14/LO/0528/AM15	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	SA7	05/01/2016	6
14/LO/0795/AM07	Long-term safety study of Z-338 in patients with functional dyspepsia		16/07/2015	27
14/LO/0813/AM03	CanACT feasibility		21/08/2015	5
14/LO/0818/AM06	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC		31/03/2015	8
14/LO/0818/AM09	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC		24/06/2015	14
14/LO/0818/AM12	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	SA06	05/11/2015	12
14/LO/1102/AM01	Helping Urgent Care Users Cope with Distress about Physical Complaints		01/05/2015	26
14/LO/1169/AM03	dHCP		19/03/2015	27
14/LO/1169/AM07	dHCP		01/08/2015	14
14/LO/1194/AM02	Neurophysiology in disorders of glycinergic neurotransmission		27/07/2015	7
14/LO/1293/AM07	Study of Effectiveness and Safety of SD-101 in Subjects with Epidermolysis Bullosa	SA5	23/02/2016	8
14/LO/1387/AM03	GWEP1332 - Study of GWP42003-P in Dravet Syndrome		20/03/2015	13
14/LO/1387/AM05	GWEP1332 - Study of GWP42003-P in Dravet Syndrome		04/06/2015	19
14/LO/1387/AM06	GWEP1332 - Study of GWP42003-P in Dravet Syndrome	6	19/11/2015	11
14/LO/1464/AM01	Natural History of Acute Hepatic Porphyria (AHP)		13/02/2015	13
14/LO/1464/AM02	Natural History of Acute Hepatic Porphyria (AHP)		13/02/2015	27
14/LO/1490/AM06	Study of Nivolumab in patients with Melanoma		01/04/2015	35

14/LO/1490/AM07	Study of Nivolumab in patients with Melanoma		03/07/2015	8
14/LO/1490/AM08	Study of Nivolumab in patients with Melanoma		24/09/2015	1
14/LO/1532/AM02	Copanlisib pharmacodynamic study		23/04/2015	18
14/LO/1532/AM03	Copanlisib pharmacodynamic study	Version 3.0	05/08/2015	14
14/LO/1728/AM02	ME-344 plus topotecan in patients with solid tumour cancers		06/05/2015	20
14/LO/1745/AM01	Mitofamily: Genetics, reproduction and biotechnologies_v1_07-14		16/06/2015	21
14/LO/1779/AM03	Incentives for Diabetic eye screening		07/05/2015	17
14/LO/1779/AM04	Incentives for Diabetic eye screening		17/08/2015	8
14/LO/1918/AM01	Next Generation Tests for Latent Tuberculosis Infection		13/08/2015	10
14/LO/1918/AM02	Next Generation Tests for Latent Tuberculosis Infection	NextGen version2	05/10/2015	2
14/LO/1918/AM06	Next Generation Tests for Latent Tuberculosis Infection	SA4	13/01/2016	8
14/LO/1948/AM02	Native T1 Mapping in Rare Diseases		28/07/2015	9
14/LO/1950/AM02	TAK-448-2001, PD TAK448, male type 2 DM, Hypogonadotropic Hypogonadism		17/07/2015	13
14/LO/1950/AM03	TAK-448-2001, PD TAK448, male type 2 DM, Hypogonadotropic Hypogonadism	SA#3	06/11/2015	5
14/LO/2071/AM02	Healthy Start, Happy Start: Helping parents with children's behaviour		13/08/2015	13
14/LO/2119/AM02	Boston Biomedical: The BRIGHTER Study		15/04/2015	12
14/LO/2119/AM04	Boston Biomedical: The BRIGHTER Study		07/07/2015	14
14/LO/2119/AM06	Boston Biomedical: The BRIGHTER Study		26/08/2015	6
14/LO/2126/AM05	PF-03084014 IN PATIENTS WITH ADVANCED TRIPLE-NEGATIVE BREAST CANCER		20/05/2015	8
14/LO/2126/AM06	PF-03084014 IN PATIENTS WITH ADVANCED TRIPLE-NEGATIVE BREAST CANCER		08/06/2015	15
15/LO/0121/AM04	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma		22/07/2015	20
15/LO/0121/AM05	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma		03/08/2015	14
15/LO/0121/AM06	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma		26/08/2015	10
15/LO/0121/AM07	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma	SA10	18/11/2015	2
15/LO/0148/AM02	PROMs Feedback Study		14/05/2015	8
15/LO/0148/AM03	PROMs Feedback Study	SA2	15/01/2016	6

15/LO/0153/AM01	NACAH	SA1	15/02/2016	31
15/LO/0173/AM01	Structure/function relationship in glaucoma with 3D perimetric stimuli		25/08/2015	25
15/LO/0349/AM03	Shire SHP602-206 Study to Monitor for the Development of Renal Tumours	Substantial Amendment dated 24	02/12/2015	2
15/LO/0591/AM01	Quality of life in older cancer patients	Amendment 1 14 September 2015	14/09/2015	6
15/LO/0886/AM01	232SM201 - Spinal Muscular Atrophy Study		02/07/2015	19
15/LO/0940/AM02	GS-US-312-0118, Efficacy and Safety with Idelalisib in Combination	3.0	06/11/2015	11
15/LO/0940/AM03	GS-US-312-0118, Efficacy and Safety with Idelalisib in Combination	13.0	26/10/2015	5
15/LO/1138/AM02	SVR SOF Cirrhosis Registry Study	SA2	21/12/2015	21
15/LO/1143/AM01	Measuring physical activity using electronic measurement devices		29/07/2015	5
15/LO/1236/AM03	NEOD001 versus placebo in AL Amyloidosis		06/08/2015	5
15/LO/1238/AM01	CUTHIVAC002		16/07/2015	10
15/LO/1238/AM03	CUTHIVAC002	SA2	25/11/2015	12
15/LO/1239/AM01	HIV Once Daily ARV Single Tablet bPI regimen naA <sup>-</sup> ve patients - AMBER	Amdt 2, Countryspecific for UK	29/09/2015	7
15/LO/1246/AM01	MM-141-07-02-02 (CARRIE) Pancreatic Cancer Phase 2		26/08/2015	7
15/LO/1246/AM02	MM-141-07-02-02 (CARRIE) Pancreatic Cancer Phase 2		23/09/2015	20
15/LO/1419/AM03	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	SA3	21/12/2015	3
15/LO/1432/AM01	RIM4DMD	SA1	15/12/2015	13
15/LO/1653/AM02	CAM2038 in Adult Outpatients with Opioid Use Disorder	Substantial Amendment 3	20/11/2015	19
15/LO/1653/AM03	CAM2038 in Adult Outpatients with Opioid Use Disorder	SA4	13/01/2016	8
15/LO/1653/AM04	CAM2038 in Adult Outpatients with Opioid Use Disorder	SA5	15/02/2016	4
15/LO/1665/AM01	Safetxt: a randomised controlled trial of a safer sex intervention	1	16/11/2015	8
15/LO/1815/AM01	Maternal cardiac function in placental complications	Amendment number 1, 12/12/15	12/12/2015	3
15/LO/1987/AM01	A Trial to Evaluate Terguride in Subjects with CYP2D6 Genotypes.	SA1	14/01/2016	3



15/LO/2008/AM01	MK1439A in treatment naïve HIV1 infected subjects with NNRTI transmitt	1	29/02/2016	15
15/LO/2036/AM01	Experiences of Hearing Aid Use; A Qualitative Study	SA1	13/01/2016	7
15/LO/2073/AM01	KEYNOTE-158	SA1	15/01/2016	7

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/H0706/81/AM18	Molecular basis of chronic inflammatory and degenerative diseases		24/04/2015	10
07/Q0401/25/AM08	Analysis of specimens from patients with orthopaedic implants	AM07	17/02/2016	22
13/LO/1787/AM02	PROFILE Study Version 1.1		16/02/2015	26
14/LO/0113/AM06	AZ D1344C00001 (SUMIT) Uveal Melanoma		08/09/2015	12
14/LO/0115/AM03	Imaging Brain Structures in Children with Congenital Hypothyroidism		30/03/2015	19
14/LO/0115/AM05	Imaging Brain Structures in Children with Congenital Hypothyroidism	Amendment 4.0 13/10/2015	13/10/2015	10
14/LO/1701/AM02	Mechanisms of Intestinal Fibrosis in Crohn's Disease	SA1	14/01/2016	8
14/LO/1918/AM03	Next Generation Tests for Latent Tuberculosis Infection		10/11/2015	7
15/LO/0121/AM01	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma			15

**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
07/H0706/81/AM18/1	Molecular basis of chronic inflammatory and degenerative diseases		18/06/2015	9
12/LO/1443/AM03/1	A Study on Trial Participation in Stem Cell Research. Version 1.1		09/06/2015	8
13/LO/1787/AM02/2	PROFILE Study Version 1.1		29/05/2015	3
14/LO/0113/AM06/1	AZ D1344C00001 (SUMIT) Uveal Melanoma		29/09/2015	3

14/LO/0115/AM03/1	Imaging Brain Structures in Children with Congenital Hypothyroidism		21/04/2015	12
14/LO/0115/AM05/1	Imaging Brain Structures in Children with Congenital Hypothyroidism	Amendment 4.1	08/01/2016	5
14/LO/1701/AM02/1	Mechanisms of Intestinal Fibrosis in Crohn's Disease	Modified to SA1	01/02/2016	1
14/LO/1918/AM03/1	Next Generation Tests for Latent Tuberculosis Infection	Modified Amendment to SA3	24/11/2015	0
15/LO/0121/AM01/2	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma		29/04/2015	14

### 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/0025	simplify	61

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

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

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

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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