

**London - London Bridge Research Ethics  
Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - London Bridge Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPS in healthy volunteers – type I REC recognised to review CTIMPS in patients – type III
<b>Type of Flag:</b>	Phase I Studies in Healthy Volunteers
<b>Chair:</b>	Professor David Bartlett
<b>Vice-Chair:</b>	Mr Brady Pohle
<b>Alternate Vice-Chair:</b>	Dr Michael Goggin
<b>REC Manager:</b>	Miss Kirstie Shearman Miss Stephanie Hill(until August 2015)
<b>REC Assistant:</b>	Mr Ian Braddick
<b>Committee Address:</b>	Skipton House 80 London Road London SE1 6LH
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<b>Email:</b>	nrescommittee.london-londonbridge@nhs.net

## Chair's overview of the past year:

RES Committee London - London Bridge is a busy and effective REC. The Committee has maintained a good attendance record giving an average of 10.2 members attending each meeting. No meetings were cancelled. The Committee reviewed a total of 51 applications (4.64 studies per meeting). The highest proportion were clinical trials of investigational medical products. The Committee received a number of informal comments at the meeting congratulating the committee on its friendliness. There were no applications over 60 days and nearly 32% completed in 40 days. We reviewed 113 substantial and 83 minor amendments and 56 safety reports and 90 annual reports. We continue to see most applications on time with few waiting more than 15 minutes for their interview.

The main focus of the committee continues to be CTIMPS and phase 1 comprising 40% of all applications and this trend follows previous years. The majority of the members undertook training.

The members' declarations of interest are listed and if and when any conflict with an application the member leaves the Committee.

## London - London Bridge Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Professor David Bartlett	Honorary Consultant	Expert	22/03/2007	
Mrs Tamsin Brownell	Honorary Research Associate	Lay	22/07/2011	
Dr Frances Dockery	Consultant Physician	Expert	13/02/2012	
Dr Parastou Donyai	Pharmacist (Academic)	Expert	01/02/2016	
Mr David Gallacher	Consultant Physicist	Expert	22/08/2010	
Dr Michael Goggin	Consultant Physician	Expert	03/08/2009	
Dr Nedim Hadzic	Consultant and Honorary Reader in Paediatric Hepatology	Expert	01/08/2010	
Ms Sarah Kaiser	Diversity Practitioner	Lay Plus	24/04/2013	24/10/2015
Ms Kate Melvin	Freelance Qualitative Researcher	Lay Plus	01/10/2015	
Mr Barry Moody	Retired solicitor/partner in law firm	Lay Plus	10/10/2011	
Mr Brady Pohle	Head of Legal Services (Solicitor)	Lay Plus	12/12/2006	
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Expert	06/06/2006	
Ms Jane Smith	Retired medical journal editor (BMJ)	Lay Plus	01/07/2013	
Miss Josephine Studham	Registered Nurse	Expert	25/02/2010	
Mr Paul Tunstell	Pharmacist	Expert	28/03/2006	28/03/2016
Dr Ralph White	Pharmacist	Expert	25/03/2011	

**London - London Bridge Research Ethics Committee : Deputy Members**

<b>Name</b>	<b>Profession</b>	<b>Status</b>	<b>Meeting date attended</b>
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**London - London Bridge Research Ethics Committee : Co-opted Members**

<b>Name</b>	<b>Profession</b>	<b>Status</b>	<b>Meeting date attended</b>
None	n/a	n/a	n/a

## London - London Bridge Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Professor David Bartlett	Lecture consultancies for Unilever, GSK, P&G, and Colgate. Both for acid erosion. Chair of the British Society for Oral & Dental Research.	27/01/2016
Dr Frances Dockery	None.	31/03/2016
Dr Parastou Donyai	Day-to-day work as an academic involves research. Occasionally reviews protocols or journal articles from funders or publishers. Grant from Janssen Cilag (drug research company).	27/01/2016
Mr David Gallacher	Journal of Radiological Protection: member of editorial board of this scientific journal, reviewing papers for publication.	27/01/2016
Dr Michael Goggin	Has Unit Trusts which might be involved with research. Trustee of Alan Squirrel Artificial Kidney Unit Fund, who finance research.	31/03/2016
Dr Nedim Hadzic	Ad hoc consultant for Alnylam Pharmaceuticals, Cambridge, MA, USA and Alexion UK. Associate Editor of J Paediatric Gastroenterology Nutrition. Regular reviewer for a number of international journals	31/03/2016
Ms Kate Melvin	Freelance qualitative researcher so much work focuses on health.	27/01/2016
Mr Barry Moody	Shareholdings in GSK. Volunteer with Prostate Cancer UK (Charity).	27/01/2016
Mr Brady Pohle	Director and Trustee of the Northern Lights Symphony Orchestra (Registered Charity) - not involved in research. Employed at the Royal Free London NHS Foundation Trust.	27/01/2016
Ms Karen Sanders	Member of the LSBU Faculty of Health and Social Care Ethics Committee.	27/01/2016
Ms Jane Smith	None.	27/02/2016
Miss Josephine Studham	Clinical Research Facility Interim Manager at St George's University Hospitals NHS Foundation Trust.	03/03/2016
Dr Ralph White	Director and Owner of PPMLD Ltd. Shares in PPMLD and GSK. Member of Royal Pharmaceutical Society.	27/01/2016

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

Month	Date	Number of Members Present at Meeting
April	22/04/2015	11
May	27/05/2015	10
June	24/06/2015	10
August	26/08/2015	9
September	23/09/2015	9
November	18/11/2015	10
December	16/12/2015	11
January	27/01/2016	11
February	24/02/2016	11
March	23/03/2016	10

10 full 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	14/04/2015	2
April	21/04/2015	2
May	11/05/2015	2
May	20/05/2015	2
May	29/05/2015	2
June	08/06/2015	2
June	17/06/2015	2
June	18/06/2015	2
June	22/06/2015	2
June	25/06/2015	2
July	10/07/2015	2
July	13/07/2015	2
July	15/07/2015	2
July	28/07/2015	2
August	06/08/2015	2
August	14/08/2015	2
August	21/08/2015	2
September	04/09/2015	2
September	18/09/2015	2
September	25/09/2015	2
October	02/10/2015	2
October	08/10/2015	2
October	16/10/2015	2
October	30/10/2015	3
November	09/11/2015	2
November	27/11/2015	2
December	30/12/2015	2

December	30/12/2015	2
December	31/12/2015	2
January	20/01/2016	2
February	20/02/2016	4
March	11/03/2016	2
March	25/03/2016	2

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

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

<b>Date</b>	<b>Reason</b>	<b>Action taken</b>
None	n/a	n/a

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

Name	Number of Meetings Attended
Professor David Bartlett	9
Dr Frances Dockery	8
Dr Parastou Donyai	1
Mr David Gallacher	8
Dr Michael Goggin	9
Dr Nedim Hadzic	4
Ms Sarah Kaiser	2
Ms Kate Melvin	3
Mr Barry Moody	8
Mr Brady Pohle	7
Ms Karen Sanders	8
Ms Jane Smith	9
Miss Josephine Studham	7
Mr Paul Tunstell	9
Dr Ralph White	10

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

Name	Number of Meetings Attended
Professor David Bartlett	18
Mr David Gallacher	1
Dr Michael Goggin	10
Mr Barry Moody	6
Mr Brady Pohle	7
Ms Karen Sanders	3
Ms Jane Smith	12
Miss Josephine Studham	2
Mr Paul Tunstell	5
Dr Ralph White	9



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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Professor David Bartlett	19/05/2015	Chairs' NREAP Meeting
Professor David Bartlett	02/11/2015	Chairs' NREAP Meeting
Dr Frances Dockery	22/07/2015	Qualitative Research and Ethical Review
Mr David Gallacher	26/11/2015	London REC Members' Training Day
Dr Michael Goggin	27/11/2015	CTIMP Training Day
Dr Nedim Hadzic	05/02/2016	Reading articles on ethics in medicine; own clinical research study setup. Natural history of AATD.
Ms Kate Melvin	10/02/2016	HRA Induction for REC Members
Mr Barry Moody	13/01/2016	Assessing the consequences (harms and benefits) of research
Mr Brady Pohle	04/09/2015	Joint Oxford Training
Ms Karen Sanders	19/11/2015	Personal Data in Research
Ms Karen Sanders	21/01/2016	Research Involving Adults Who Lack Capacity
Ms Jane Smith	07/10/2015	Introduction to Phase 1 Research - Trials and Regulation
Ms Jane Smith	18/02/2016	National Members' Training Day
Ms Jane Smith	03/03/2016	Qualitative Research and Ethical Review
Miss Josephine Studham	16/03/2016	Training - National Members Training Day
Dr Ralph White	26/11/2015	London REC 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	15	30.00
Phase 1	5	10.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.00
Others	29	58.00
<b>Total Applications Reviewed</b>	<b>50</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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	5

**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	2	4.00
Unfavourable Opinion	2	4.00
Provisional Opinion	46	92.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>50</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	39	78.00
Further Information Favourable Opinion with Additional Conditions	2	4.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	2	4.00
Unfavourable Opinion	2	4.00
Provisional Opinion	4	8.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>50</b>	<b>100</b>

**Table 5: Other Management Information based on the number of completed applications for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.00
<b>Number of completed applications for full ethical review</b>	50
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	17
<b>Number of completed applications over 40 days as a % of total</b>	34.00%
<b>Number of days taken to final decision – average (mean)</b>	37
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<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>	7
<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>	114
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.88%
<b>Number of completed substantial amendments over 28 days</b>	7
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	6.14%
<b>Number of modified amendments reviewed</b>	3
<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>	82
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	31
<b>Number of annual progress reports received</b>	90
<b>Number of safety reports received</b>	56
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	47



**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/0535	Precise study social science programme	41
15/LO/0679	Changes in male fertility during chronic illness	40
15/LO/0680	Evaluating interventions for caregivers	60
15/LO/0683	Effect of palm olein intake on lipid profile and fat deposition	49
15/LO/0684	LEVALS	41
15/LO/0689	1423M0634: S-888711 in CLD Undergoing Invasive Procedures (L-PLUS-2)	42
15/LO/0774	PK & PD of ALN - AAT in healthy volunteers and liver disease patients	40
15/LO/0861	Safety and effectiveness of SAR156597 in the treatment of IPF	49
15/LO/0917	Exploring women's & clinicians views of treatment for BCRL of the arm	49
15/LO/0927	Mixed method study of prostate cancer patient discharge experience v.1	52
15/LO/0942	LOPAC Laser Ablation versus Observation to Prevent Anal Cancer v.1.0	39
15/LO/1063	M14-004 AbbVie DAA's +Ribavirin in HCV Gt1 or 4/HIV Type 1 Coinfection	41
15/LO/1066	ADONIS	25
15/LO/1121	Soul-Deep II: The South London Diabetes and Ethnicity Phenotyping study	28
15/LO/1280	PRIDE- version 2.1	30
15/LO/1326	GON migraine study	57
15/LO/1356	The psychological impact of treatment for oesophageal cancer	33
15/LO/1417	ASCEND	38
15/LO/1422	673-203 HRD Study, Amendment 3, 10-August-2015	44
15/LO/1425	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	29
15/LO/1445	Exploring Young Peoples' Constructions of a FEP	23
15/LO/1667	QST and PET Targeted SCS	55
15/LO/1818	AZD2014 and Palbociclib w/ Horm. Therapy in Pts with Adv. Breast Cancer	38
15/LO/1828	RAINBOW	42
15/LO/1835	PNET 5	39
15/LO/1861	The TWO Study: a prospective study of twins, pregnancy to childhood.	36
15/LO/1916	Phase 1, open-label PET study in healthy volunteers after oral TAK-831	33
15/LO/2011	Optimising Management of Serial and Diffuse Coronary Artery Disease	41
15/LO/2050	PK and Safety of M923 via Auto Injector and Pre Filled Syringe	40
15/LO/2064	The Effect of Sjögren's Syndrome	55
15/LO/2075	Autologous Platelet Adjuncts In Large or Failed Macular Holes	34

16/LO/0009	SAD, MAD, PK Study of SC ALN-HBV in healthy volunteers and patients	13
16/LO/0051	A PHASE 1, SAD, MAD, PK and PD STUDY OF ALXN1210 IN JAPANESE SUBJECTS	20
16/LO/0066	EVENTS (version 1.0)	25
16/LO/0075	Prospective, randomised controlled trial of using catheter valve	20
16/LO/0256	Brain Structure and function of children at risk for eating disorders	29
16/LO/0342	Phase I Finasteride Photosensitization Study in Healthy Males v1.0	39
16/LO/0360	The effectiveness of treating PST; feasibility study (V2)	42
16/LO/0384	ImprovE Y1 - Exploring shared decision making in coercive care	46

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0943	Myasthenia Database	40
15/LO/1055	PARSIFAL I	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
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#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1081	Evaluating fatigue in inflammatory bowel disease	23
15/LO/2025	Plaque characterisation by MRI	34

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/1065	HRD, Amendment 1, 17-April-2015	24
15/LO/2040	NEON: Nurture Early for Optimal Nutrition	20

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0329	Grounded theory: Experience Based Co-Design with families	n/a
16/LO/0470	ENRICH peer worker programme to enhance psychiatric discharge	n/a
16/LO/0477	Peri-implant bone changes in post-menopausal osteoporotic women	n/a
16/LO/0516	CASPer	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>
16/LO/0035	RCT IRE Prostate	n/a

<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>
01/11/12/AM02	Development of novel magnetic resonance techniques using normal volunteers	AM 4.0	12/10/2015	4
06/Q0704/18/AM05	Imunopathogenesis of Psoriasis v1	Amendment 1, protocol v2	23/11/2015	25
08/H0804/139/AM03	Molecular and Immunopathogenesis of Melanoma	1	01/07/2015	3
08/H0804/79/AM03	Cone beam computed tomography study 2	AM02	01/07/2015	22
09/H0804/45/AM02	Studying immune cells in ovarian cancer	AM02	15/10/2015	10
09/H0804/92/AM01	Pre-Clinical Development of Cancer Immunotherapy	AM02	14/07/2015	8
10/H0804/21/AM03	Erythrocyte aggregation & haemodynamics	AM03 (Our reference - protocol)	08/03/2016	7
10/H0804/67/AM05	Investigation of limb ischaemia	AM05	22/06/2015	7
11/H0804/10/AM02	The MEGA Haemodynamic study	2	08/09/2015	13
11/LO/1236/AM05	Comorbidities in Severe Psoriasis	4	16/09/2015	2
11/LO/1972/AM09	SentiMAG Multicentre Trial	3	10/03/2015	21
11/LO/1972/AM10	SentiMAG Multicentre Trial	Protocol Version 5.0 dated 13/	03/02/2016	15
12/LO/1977/AM01	Improving outcomes in surgery for brain tumours using advanced MRI	AM01	16/03/2015	33
13/LO/0147/AM04	PrEP-investigating the role of Maraviroc 300mg in protection from HIV	SA4 1	17/03/2015	21
13/LO/0219/AM16	GS-6624 in Subjects with Idiopathic Pulmonary Fibrosis (RAINIER)	12	10/04/2015	17
13/LO/0219/AM18	GS-6624 in Subjects with Idiopathic Pulmonary Fibrosis (RAINIER)	AM14	14/10/2015	4
13/LO/0288/AM01	Evaluation of website for parents of children with Juvenile Arthritis	AM01	29/07/2015	8
13/LO/0288/AM02	Evaluation of website for parents of children with Juvenile Arthritis	AM02	26/10/2015	15

13/LO/0288/AM03	Evaluation of website for parents of children with Juvenile Arthritis	3.0	11/02/2015	10
13/LO/0527/AM07	APL-1 SAD/ MAD study in healthy subjects	6.0	19/03/2015	24
13/LO/0691/AM03	Patient-consented samples for STI diagnostic & biomarker evaluation	eSTI2 WS3 Protocol_v8_extra sa	04/08/2015	6
13/LO/0736/AM07	GP15-302: Randomised Study To Compare GP2015 and Enbrel in Psoriasis	IB v.4	25/03/2015	16
13/LO/1011/AM03	FLT-PET in HCC	2	15/01/2015	17
13/LO/1120/AM05	Cardiovascular Disease in Chronic Inflammatory Disease's	SA1	17/03/2015	20
13/LO/1290/AM06	M13-102: Follow-up study for DAA therapies in previous HCV studies	AM06	30/06/2015	8
13/LO/1522/AM06	LTS13632 Long-term phase 2 study of rhASM in ASMD patients	1	11/08/2015	7
13/LO/1578/AM08	A longitudinal study of cognition in people over 50	5	01/05/2015	6
13/LO/1578/AM09	A longitudinal study of cognition in people over 50	AM06	12/06/2015	19
13/LO/1578/AM10	A longitudinal study of cognition in people over 50	7	10/09/2015	12
13/LO/1620/AM26	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	SA10	16/06/2015	41
13/LO/1620/AM27	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	4	29/07/2015	5
13/LO/1620/AM31	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	SA12	02/12/2015	29
13/LO/1620/AM33	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	SA13	30/12/2015	16
13/LO/1714/AM07	NOX-H94 in ESA-hyporesponsive anaemia in dialysis patients V2.0	SA06	11/06/2015	10
13/LO/1875/AM01	The pathophysiology of mental stress induced myocardial ischaemia	2.0	01/02/2015	17
13/LO/1886/AM09	IPI-145 in subjects with refractory iNHL	SA08	19/06/2015	3
13/LO/1886/AM10	IPI-145 in subjects with refractory iNHL	AM09	15/12/2015	9
13/LO/1906/AM13	RA-EXTEND	AM17	31/08/2015	15
14/LO/0081/AM09	EMR700461-023: Phase IIb Study of Atacicept in SLE	SA9	08/07/2015	6
14/LO/0094/AM01	Non-invasive determination of left ventricular pressure	SA1	05/05/2015	5
14/LO/0287/AM01	Real time imaging of regulatory T cells in healthy volunteers	1	25/08/2015	2

14/LO/0311/AM03	VIBRaNT	Amendment 4; v4.0; 05 June 201	05/06/2015	4
14/LO/0437/AM01	EMR700461-024: Phase IIb Long-Term Extension Study of Atacicept in SLE	1	13/04/2015	6
14/LO/0437/AM03	EMR700461-024: Phase IIb Long-Term Extension Study of Atacicept in SLE	2	07/05/2015	2
14/LO/0440/AM02	IOL + LRI vs Toric IOL for corneal astigmatism during cataract surgery	2	05/06/2015	5
14/LO/0440/AM03	IOL + LRI vs Toric IOL for corneal astigmatism during cataract surgery	3	26/06/2015	8
14/LO/0440/AM04	IOL + LRI vs Toric IOL for corneal astigmatism during cataract surgery	AM03	08/10/2015	28
14/LO/0448/AM04	Kinematics and Kinetics of cam hip impingement	AM01	11/05/2015	29
14/LO/0566/AM08	Olaparib therapy in high risk HER2 negative BRCA mutated breast cancer	6	23/04/2015	8
14/LO/0566/AM11	Olaparib therapy in high risk HER2 negative BRCA mutated breast cancer	AM08	17/12/2015	12
14/LO/0605/AM01	AZD5312 in patients with advanced cancer	Edition Number 4.0	09/04/2015	6
14/LO/0605/AM02	AZD5312 in patients with advanced cancer	5.0	16/06/2015	20
14/LO/0605/AM03	AZD5312 in patients with advanced cancer	3	08/09/2015	13
14/LO/0665/AM04	MK-5172/MK8742 in HCV Subjects on Opiate Substitution Therapy	SA03 REC Protocol Amendment MK	26/06/2015	12
14/LO/0665/AM07	MK-5172/MK8742 in HCV Subjects on Opiate Substitution Therapy	MK5172 (Ed.10, 24Jul15) & MK87	07/09/2015	3
14/LO/0720/AM01	CMR augmented exercise testing in paediatric pulmonary hypertension	AM01	16/06/2015	3
14/LO/0720/AM02	CMR augmented exercise testing in paediatric pulmonary hypertension	Amendment 2	11/03/2016	2
14/LO/0802/AM01	The Glove Project	AM01	19/08/2015	5
14/LO/0806/AM06	Safety, PK & PD of UCB7665 IV/SC infusion as SAD in healthy subjects	6	15/03/2015	11
14/LO/0806/AM07	Safety, PK & PD of UCB7665 IV/SC infusion as SAD in healthy subjects	Substantial Amendment 5	20/05/2015	13
14/LO/1033/AM04	Gevokizumab Giant Cell Arteritis study	Final version	31/03/2015	16

14/LO/1033/AM07	Gevokizumab Giant Cell Arteritis study	Final version	28/08/2015	15
14/LO/1043/AM05	LEAVO (Version 1.0)	4.0	08/01/2016	6
14/LO/1079/AM01	Early prediction of preterm birth (Version 1)	Protocol v3.0 13.9.2015	14/09/2015	22
14/LO/1107/AM02	Effect of MD1003 in multiple sclerosis	Amendment 2 v1 2015/08/17	11/09/2015	31
14/LO/1107/AM03	Effect of MD1003 in multiple sclerosis	Amendment 03	26/10/2015	14
14/LO/1476/AM01	Phase II of RO5520985 in patients with metastatic colorectal cancer	V4 February 2015	01/02/2015	21
14/LO/1476/AM02	Phase II of RO5520985 in patients with metastatic colorectal cancer	AM04	08/09/2015	18
14/LO/1495/AM01	Pilot RCT of oxytocin for the treatment of opioid dependence	Final Version	09/03/2015	7
14/LO/1513/AM06	Phase 4 Renal Study in Patients with Treatment-Naive HIV-1	2	22/04/2015	9
14/LO/1692/AM02	Oxytocin and social functioning in people at high risk for psychosis	Am02	01/05/2015	27
14/LO/1708/AM01	Effect of dietary nitrate ingestion in stable angina.	AM01	25/03/2015	5
14/LO/1805/AM02	iFIND- 1. US Data	Amendment 2	01/11/2015	21
14/LO/1806/AM01	iFIND- 2. Further Imaging	AM1	19/05/2015	5
14/LO/1806/AM02	iFIND- 2. Further Imaging	Amendment 3	01/11/2015	20
14/LO/1968/AM01	DNAVAC 001	1.2	26/01/2015	13
14/LO/1968/AM03	DNAVAC 001	Substantial Amendment 2	07/01/2016	0
14/LO/1968/AM04	DNAVAC 001	2	07/01/2016	6
14/LO/1968/AM05	DNAVAC 001	3	25/01/2016	6
14/LO/1990/AM10	SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients	AM04	22/12/2015	13
14/LO/2007/AM09	3 Formulations of Adalimumab (M923, EU & US Sourced Humira)	SA 01	01/04/2015	19
14/LO/2011/AM01	DUAL antithrombotic therapy with dabigatran etexilate (RE-DUAL PCI)	2	12/03/2015	5
14/LO/2011/AM05	DUAL antithrombotic therapy with dabigatran etexilate (RE-DUAL PCI)	4	12/08/2015	2
14/LO/2011/AM07	DUAL antithrombotic therapy with dabigatran etexilate (RE-DUAL PCI)	5	02/09/2015	6
14/LO/2011/AM09	DUAL antithrombotic therapy with dabigatran etexilate (RE-	AM06	07/10/2015	5

	DUAL PCI)			
14/LO/2011/AM11	DUAL antithrombotic therapy with dabigatran etexilate (RE-DUAL PCI)	8	14/03/2016	9
14/LO/2153/AM02	ORCA-2	AM01	07/07/2015	6
15/LO/0213/AM01	Cardiovascular effects of renal disease and hypertension in children	AM01	23/09/2015	10
15/LO/0257/AM01	SAFETY, TOLERABILITY, PD AND PK OF IV ALXN1210 IN HEALTHY SUBJECTS	AM02	02/07/2015	6
15/LO/0306/AM01	Testing a strategy to improve multitasking in Virtual Reality	AM01	15/03/2015	3
15/LO/0535/AM01	Precise study social science programme	Protocol version 3 06.08.2015	06/08/2015	3
15/LO/0683/AM02	Effect of palm olein intake on lipid profile and fat deposition	AM02	16/10/2015	21
15/LO/0684/AM02	LEVALS	1.0	11/06/2015	4
15/LO/0684/AM03	LEVALS	AM02	15/12/2015	7
15/LO/0684/AM04	LEVALS	AM 4	15/02/2016	14
15/LO/0774/AM01	PK & PD of ALN - AAT in healthy volunteers and liver disease patients	AM01	01/12/2015	17
15/LO/0861/AM01	Safety and effectiveness of SAR156597 in the treatment of IPF	1	21/07/2015	5
15/LO/0861/AM02	Safety and effectiveness of SAR156597 in the treatment of IPF	Substantial amendment 2	14/09/2015	8
15/LO/0861/AM04	Safety and effectiveness of SAR156597 in the treatment of IPF	AM03	20/11/2015	29
15/LO/1055/AM02	PARSIFAL I	1	20/01/2016	5
15/LO/1063/AM01	M14-004 AbbVie DAA's +Ribavirin in HCV Gt1 or 4/HIV Type 1 Coinfection	3	02/09/2015	14
15/LO/1063/AM02	M14-004 AbbVie DAA's +Ribavirin in HCV Gt1 or 4/HIV Type 1 Coinfection	AM04	11/11/2015	32
15/LO/1280/AM01	PRIDE- version 2.1	2.2	26/10/2015	4
15/LO/1417/AM01	ASCEND	V1.0	01/02/2016	14
15/LO/1425/AM04	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	Substantial Amendment 3	15/10/2015	3
15/LO/1425/AM05	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	04	29/02/2016	3
15/LO/1667/AM01	QST and PET Targeted SCS	1	29/01/2016	13

15/LO/1818/AM01	AZD2014 and Palbociclib w/ Horm. Therapy in Pts with Adv. Breast Cancer	Amendment 02	03/12/2015	6
15/LO/1828/AM03	RAINBOW	SA 4	25/02/2016	4
15/LO/1828/AM05	RAINBOW	SA 5	11/03/2016	27

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1468/AM03	SPL7013-018 Starpharma Phase 3 study of VivaGel <sup>®</sup> in Bacterial Vaginosis	SA2	05/05/2015	10
14/LO/1476/AM03	Phase II of RO5520985 in patients with metastatic colorectal cancer	5.0	10/02/2016	27
14/LO/1990/AM04	SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients	2	07/08/2015	21
15/LO/0683/AM01	Effect of palm olein intake on lipid profile and fat deposition	1	05/08/2015	28

**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
14/LO/1468/AM03/1	SPL7013-018 Starpharma Phase 3 study of VivaGel <sup>®</sup> in Bacterial Vaginosis	SA3	22/06/2015	11
14/LO/1476/AM03/1	Phase II of RO5520985 in patients with metastatic colorectal cancer	Modified amendment - Protocol	17/03/2016	6
14/LO/1990/AM04/1	SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients	3	18/09/2015	5

#### 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
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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
13/LO/1620/AM26	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	SA10	16/06/2015	41

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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