

**London - London Bridge Research Ethics  
Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## 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>	Ms Jane Smith
<b>Alternate Vice-Chair:</b>	Dr Michael Goggin
<b>REC Manager:</b>	Mr Ryan Erfani-Ghettani
<b>REC Assistant:</b>	Ms Zuleka Alawi
<b>Committee Address:</b>	Skipton House 80 London Road London SE1 6LH
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## Chair's overview of the past year:

This completes another successful year for the committee. Four members left, Tamsin Brown, Nedim Hadzic, Brady Pohle and Jo Studham, and we wish them well and thank them for their commitment to ethics. We were quorate for our 10 meetings, with 9.8 members present at each meeting and 3 for proportionate reviews. We had 4.6 applications per meeting, 33.5 of which were CTIMPs and 15% Phase 1 trials. All applications sent back to the chair for review were replied to within 5 working days and many within 24 hours. No study took longer than 60 days, 1 (2.7%) took more than 40 days and the average was 29 days.

Feedback from applicants at the meetings was good with many complimenting the committee. Overall, the committee was busy and successful.

## 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	Lay Member	Lay	22/07/2011	19/09/2016
Dr Frances Dockery	Consultant Physician	Expert	13/02/2012	
Dr Parastou Donyai	Pharmacist (Academic)	Expert	01/02/2016	
Mr David Gallacher	Consultant Physician	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	01/02/2017
Ms Colleen Hubbard	Director of Clinical Marketing	Lay Plus	01/12/2016	
Dr Imran Jawaid	General Practitioner	Expert	01/09/2016	
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	
Ms Elayne Nasr	Retired School Nurse	Lay Plus	06/02/2017	05/08/2017
Mr Brady Pohle	Head of Legal Services (Solicitor)	Lay Plus	12/12/2006	12/12/2016
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	01/09/2016
Dr Ralph White	Pharmacist	Expert	25/03/2011	

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

Name	Profession	Status	Meeting date attended
Dr Urmi Bapat	Pharmaceutical Physician	Expert	22/03/2017
Miss Noor Mujahid	Student – MA Pharmacy	Lay	25/05/2016
Dr Yash Patel	Research Project Manager	Expert	25/05/2016

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Professor David Bartlett	President British Society for Oral and Dental Research.	31/03/2017
Dr Frances Dockery	Member of national fracture liaison service steering group.	31/03/2017
Dr Frances Dockery	Member of the London South Bank University - Health and Social Care Research Ethics Committee.	31/03/2017
Dr Parastou Donyai	Reviews papers for various journals and grants for NIHR and other bodies.	31/03/2017
Mr David Gallacher	On editorial board of Journal of Radiological Protection – this is an Institute of Physics journal. A member of the IoP and the IPEM and Society of Radiological Protection (SRP). The board does not however commission research, but peer reviews scientific papers for the journal, some of which are in the medical field.	31/03/2017
Dr Michael Goggin	Trustee in a charity funding research. Member of Research and Governance Committee of Canterbury Christchurch University.	31/03/2017
Mr Nicholas Harper	Employed by King's College London in Faculty of Life Sciences and Medicine, Department of Perinatal Imaging. Kings is involved in a range of medical research. My department conducts research into maternal, neonatal and paediatric health, typically in the form of observational studies with a clinical imaging intervention.	31/03/2017
Ms Colleen Hubbard	Working on a short-term contract ending April 2017 doing marketing and communications strategy for Parkinson's UK, but does not interact with research arm of charity. Volunteer with the Camden Clinical Commissioning Group.	31/03/2017
Dr Imran Jawaid	Expert Adviser for the NICE Centre for Guidelines. Standing member of a clinical guidelines update committee at the National Institute of Health and Care Excellence. RCGP representative (Antimicrobial Resistance). Member of NICE Diagnostic Services Guideline Committee. Member of Board of Fellows, Map of Medicine, London. Clinical Adviser for the Clinical Innovation and Research Centre Royal College of General Practitioners.	31/03/2017
Ms Kate Melvin	Freelance consultant social researcher. Most work in the field of health services research. Clients have included Department of Health, National Social Marketing Centre, NHS Alliance, Cancer Research UK, the GMC, the National Institute for Clinical Excellence, the Commission for Health Improvements, Primary Care and Hospital Trusts and Clinical Commissioning Groups and Public	31/03/2017

	Health Departments. Working on two NIHR funded projects and a study commissioned by Hackney CCG/GP Confederation.	
Mr Barry Moody	Shares in GlaxoSmithKline. Volunteer with Prostate Cancer UK.	31/03/2017
Ms Karen Sanders	Member of the LSBU Faculty of Health and Social Care Ethics Committee.	31/03/2017
Ms Jane Smith	Has some unit trusts, which almost certainly contain pharmaceutical company shares within them. Has no specific control over those shares	31/03/2017
Dr Ralph White	Director PPMLD Ltd; Shares in GSK.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	27/04/2016	11
May	25/05/2016	9
June	22/06/2016	8
August	24/08/2016	10
September	28/09/2016	11
November	23/11/2016	11
December	14/12/2016	10
January	25/01/2017	10
February	22/02/2017	10
March	22/03/2017	8

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
May	30/05/2016	3
July	01/07/2016	4
July	29/07/2016	3
September	02/09/2016	3
October	07/10/2016	3
November	04/11/2016	3
December	02/12/2016	3
January	06/01/2017	3
February	03/02/2017	3
March	03/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	2
May	08/05/2016	2
May	25/05/2016	2
June	14/06/2016	3
July	01/07/2016	3
August	01/08/2016	2
September	01/09/2016	2
September	22/09/2016	2
October	03/10/2016	2
October	07/10/2016	2
October	17/10/2016	2

November	11/11/2016	3
November	30/11/2016	2
December	15/12/2016	2
December	30/12/2016	2
January	13/01/2017	2
January	31/01/2017	2
February	15/02/2017	2
February	28/02/2017	2
March	15/03/2017	2
March	31/03/2017	2

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

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

None



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

<b>Name</b>	<b>Number of Meetings Attended</b>
Professor David Bartlett	6
Dr Frances Dockery	7
Dr Parastou Donyai	7
Mr David Gallacher	8
Dr Michael Goggin	8
Dr Nedim Hadzic	4
Ms Colleen Hubbard	2
Dr Imran Jawaid	4
Ms Kate Melvin	8
Mr Barry Moody	8
Mr Brady Pohle	6
Ms Karen Sanders	7
Ms Jane Smith	9
Miss Josephine Studham	2
Dr Ralph White	9

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Professor David Bartlett	6
Dr Frances Dockery	1
Mr David Gallacher	2
Dr Michael Goggin	6
Dr Nedim Hadzic	2
Ms Kate Melvin	4
Mr Barry Moody	2
Mr Brady Pohle	2
Ms Karen Sanders	2
Ms Jane Smith	4

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Professor David Bartlett	5
Dr Frances Dockery	2
Dr Parastou Donyai	2
Mr David Gallacher	3
Dr Michael Goggin	9

Ms Kate Melvin	2
Mr Barry Moody	2
Mr Brady Pohle	5
Ms Karen Sanders	3
Ms Jane Smith	6
Miss Josephine Studham	1
Dr Ralph White	5

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Professor David Bartlett	04/05/2016	London Chairs' Meeting
Professor David Bartlett	07/11/2016	London Chairs' Meeting
Dr Frances Dockery	31/03/2017	Reading RES articles; supervision of half-day placement on ethics for students.
Dr Parastou Donyai	03/01/2017	Communication for research; 5 simple ideas
Dr Parastou Donyai	01/02/2017	Equality and Diversity Training
Dr Parastou Donyai	16/02/2017	National Members Training Day
Mr David Gallacher	16/11/2016	Local Training Day - London REC Members' Training Day
Dr Michael Goggin	16/02/2017	National Members Training Day
Ms Colleen Hubbard	31/03/2017	Online Induction for new members
Dr Imran Jawaid	10/02/2017	Equality and Diversity Training
Ms Kate Melvin	08/09/2016	Equality and Diversity Training
Mr Barry Moody	16/02/2017	National Members Training Day
Ms Karen Sanders	16/11/2016	London REC Members' Training Day
Ms Jane Smith	09/11/2016	Training for New REC Chairs
Ms Jane Smith	16/11/2016	London REC Members' Training Day
Ms Jane Smith	01/12/2016	National Training Day for Committee Chairs
Ms Jane Smith	15/01/2017	Equality and Diversity Training
Dr Ralph White	11/04/2016	Ethics and GCP Forum
Dr Ralph White	04/01/2017	Equality Diversity and Human Rights course
Dr Ralph White	29/03/2017	Ethics and GCP Forum Presentation

## 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	32.61
Phase 1	7	15.22
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	24	52.17
<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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	5
Number of device applications reviewed	3
Number of prisoner applications reviewed	1
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	3

**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	1	2.17
Favourable Opinion with Additional Conditions	4	8.70
Unfavourable Opinion	6	13.04
Provisional Opinion	35	76.09
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	31	67.39
Further Information Favourable Opinion with Additional Conditions	2	4.35
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.17
Favourable Opinion with Additional Conditions	4	8.70
Unfavourable Opinion	6	13.04
Provisional Opinion	2	4.35
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>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>15</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	6
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

**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	1	6.67
Favourable Opinion with Additional Conditions	2	13.33
No Opinion transfer to full committee for review	4	26.67
Provisional Opinion	8	53.33
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>15</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.60
<b>Number of completed applications for full ethical review</b>	46
<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>	1
<b>Number of completed applications over 40 days as a % of total</b>	2.17%
<b>Number of days taken to final decision – average (mean)</b>	29
<b>Number of completed proportionate review applications for ethical review</b>	11
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	4
<b>Number of completed proportionate review applications for review over 21 days</b>	4
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	36.36%
<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>	5
<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>	95
<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>	1.05%
<b>Number of completed substantial amendments over 28 days</b>	11
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	11.58%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	88

<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	14
<b>Number of annual progress reports received</b>	67
<b>Number of safety reports received</b>	50
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	21



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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0241	Safety and tolerability of SC ALN-TTRSCO2 in healthy volunteers	23
16/LO/0524	PK of Simeprevir, Odalasvir and AL-335 in healthy Japanese subjects	26
16/LO/0584	Safety, Tolerability & PK of odalasvir and AL-335 in healthy Japanese	21
16/LO/0853	BI-1206 + anti-CD20 in patients with CD32b positive B-cell malignancy	37
16/LO/0858	BCX7353 in prevention of HAE attacks	31
16/LO/0871	MISSION 2015-05	28
16/LO/0933	REACTION	28
16/LO/0955	Patient Impact of a diagnosis of Non-specific Genital Infection	36
16/LO/1140	The development of a dialogue in open dialogue network meetings	35
16/LO/1304	LEAP	30
16/LO/1442	M15-574 SHARPS study, HS and Adalimumab with Surgery	29
16/LO/1453	Positive Outcomes	37
16/LO/1510	Surgery for cervix cancer follow up questionnaire	33
16/LO/1568	Structure and functional characterisation of human hearts	36
16/LO/1677	DARWIN2	40
16/LO/1696	Safe withdrawal of inhaled steroids in mild or moderate COPD (SWAP)	36
16/LO/1697	MK-3475 in the treatment of Advanced/Metastatic Urothelial Carcinoma	38
16/LO/1701	Olaratumab plus Gemcitabine and Docetaxel in Soft Tissue Sarcoma -JGDL	30
16/LO/2003	Identification of the genes involved in recurrent molar pregnancies	28
16/LO/2032	Drug resistant TB contacts registry	34
16/LO/2043	CA209-649: Nivo/Ipi vs SOC in gastric cancer patients	28
16/LO/2190	PLUM	25
16/LO/2195	TRITON2: A Multicenter, Open-label Phase 2 Study of Rucaparib in mCRPC	27
16/LO/2204	SAD/MAD study of Z944-20-MR7 tablet in healthy adults (QCL117836)	19
17/LO/0068	Fear of illness recurrence in psychosis	32
17/LO/0092	CHELATE STUDY GMPO-131-002	29
17/LO/0130	STATIN	41
17/LO/0203	Microvascular dysfunction - response to exercise and vasodilators	22
17/LO/0266	Immune dysfunction in Chronic Hepatitis B & HCC	24
17/LO/0442	High risk lung health clinic	27
17/LO/0482	A phenomenological study of CTCL patients undergoing a RISCT	27

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0093	FuturePharma	28
17/LO/0097	Precise Study: NG & MG point-of-care test evaluation	35

<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>
16/LO/1135	Use of MDCT aortic root assessment to determine valve sizing in TAVI	27

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0794	RAINBOW extension study	27
16/LO/0908	Efficacy and safety of iNO in Pulmonary Arterial Hypertension, v1.0	26
17/LO/0174	Safety, Tolerability, PK, Immunogenicity & PD of JNJ-64179375	19
17/LO/0420	Proof of Concept study for a dressing glove	22

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0931	Predictors of poor patient satisfaction after hip replacement	26
16/LO/1128	Blood sampling method for sleep studies v1	27
16/LO/2031	Lymphoscintigraphy standards to unravel breast cancer lymphoedema	28
16/LO/2052	R727-CL-1532 Ph4 Praluent, Neurocognitive Funct., Hypercholesterolaemia	28
17/LO/0193	SAD/MAD Phase 1 of the Safety, PK & PD of AST-008 in Healthy Subjects	13
17/LO/0246	AFFECT Education	19

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/2216	Lung-protective ventilation strategies using high resistance ETTs	n/a

17/LO/0311	Adverse Events in Infants Following BCG Vaccination ver 1.0	n/a
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### Provisional Opinion Pending Consultation with Referee

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

REC Reference	Title	Number of Days on Clock
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### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

### Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1072	Impact of an information leaflet on patient anxiety before CSI	9
16/LO/1477	CANDO: prediction of outcomes in epilepsy surgery	13
16/LO/1656	Natural history and biomarkers in autonomic disorders	29
16/LO/1858	COMmunity based PulmonAry rehabiliTation programme (COMPACT) V1	24
16/LO/1863	Sobi.Elocta-002 A-SURE	24
16/LO/2021	Colonic Propionate, Appetite, and Weight Loss	5
17/LO/0062	STUDIOUS	25

### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1478	Impact of patient experience data on acute NHS hospital trusts	7

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1077	Understanding Repeat Attenders for Emergency Care Not Continuing Care	11
16/LO/1654	Impacts on Carers of Patients with SBS-IF	11

<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>
17/LO/0422	Assessment of information retention of orthodontic patients & parents	n/a

<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>
08/H0804/139/AM04	Molecular and Immunopathogenesis of Melanoma	4	03/08/2016	35
08/H0804/79/AM04	Cone beam computed tomography study 2	v2, 18/05/2016	18/05/2016	10
08/H0804/94/AM02	Regulation of Immunoglobulin Class Switching version 1	2	10/01/2017	28
10/H0804/67/AM06	Investigation of limb ischaemia	6	05/12/2016	6
11/LO/1232/AM03	CRT Perfusion Study	Amendment 2	16/02/2016	17
11/LO/1972/AM11	SentiMAG Multicentre Trial	Amendment 4	22/02/2016	11
12/LO/0776/AM03	Clinical Assessment Study for Pediatric Patients with Achondroplasia	3	14/09/2016	30
12/LO/0776/AM04	Clinical Assessment Study for Pediatric Patients with Achondroplasia	4	09/12/2016	29
12/LO/0776/AM05	Clinical Assessment Study for Pediatric Patients with Achondroplasia	5	03/03/2017	2
12/LO/1897/AM11	Development and evaluations of diagnostic tests for STIs	6	07/11/2016	1
13/LO/0288/AM04	Evaluation of website for parents of children with Juvenile Arthritis	Amendment 4.0	21/04/2016	11
13/LO/0288/AM05	Evaluation of website for parents of children with Juvenile Arthritis	5	05/09/2016	2
13/LO/0691/AM05	Patient-consented samples for STI diagnostic & biomarker evaluation	8b	06/12/2016	28
13/LO/0922/AM04	Measurement of pulse wave velocity	Amendment 2	05/04/2016	21
13/LO/1522/AM08	LTS13632 Long-term phase 2 study of rhASM in ASMD patients	SA-004 V1.0	23/03/2016	18
13/LO/1578/AM12	A longitudinal study of cognition in people over 50	8	29/09/2016	22
13/LO/1578/AM13	A longitudinal study of cognition in people over 50	9	01/03/2017	3
13/LO/1620/AM38	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	Version 2	10/05/2016	6
13/LO/1620/AM41	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	SA16: Patient's compensation,	09/08/2016	7
13/LO/1886/AM12	IPI-145 in subjects with refractory iNHL	10	17/08/2016	15
13/LO/1886/AM13	IPI-145 in subjects with refractory iNHL	11	16/12/2016	13
13/LO/1886/AM14	IPI-145 in subjects with refractory iNHL	12	21/12/2016	21

13/LO/1906/AM15	RA-EXTEND	9	13/01/2017	6
14/LO/0287/AM02	Real time imaging of regulatory T cells in healthy volunteers	1	26/07/2016	36
14/LO/0665/AM08	MK-5172/MK8742 in HCV Subjects on Opiate Substitution Therapy	MK-5172 (Ed 11, 9Jun2016) & MK	08/07/2016	7
14/LO/1107/AM05	Effect of MD1003 in multiple sclerosis	Amendment 5, 05.01	31/05/2016	2
14/LO/1476/AM05	Phase II of RO5520985 in patients with metastatic colorectal cancer	1	01/11/2016	6
14/LO/1495/AM02	Pilot RCT of oxytocin for the treatment of opioid dependence	9	22/09/2016	32
14/LO/1685/AM02	PSORT-D	1	24/08/2016	4
14/LO/1692/AM03	Oxytocin and social functioning in people at high risk for psychosis	3, 01/06/2016	01/06/2016	18
14/LO/1990/AM14	SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients	Amendment 5_v1.0	25/04/2016	9
14/LO/1990/AM16	SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients	ALN-CC5-001, Temporary Halt No	26/05/2016	5
14/LO/1990/AM17	SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients	1.0	22/09/2016	33
14/LO/2011/AM12	DUAL antithrombotic therapy with dabigatran etexilate (RE-DUAL PCI)	Substantial Amendment 9	13/05/2016	8
14/LO/2153/AM03	ORCA-2	Amendment 2.0	23/03/2016	11
15/LO/0114/AM02	Phase I study of MOv18 IgE.	CTA Amendment 08	23/02/2017	33
15/LO/0117/AM02	Vaccination with Adjuvants, Peptides, Elimination of Regulatory Cells.	Amendment 2	16/03/2016	11
15/LO/0117/AM03	Vaccination with Adjuvants, Peptides, Elimination of Regulatory Cells.	3	08/03/2017	22
15/LO/0213/AM02	Cardiovascular effects of renal disease and hypertension in children	Amendment 2	01/04/2016	1
15/LO/0257/AM04	SAFETY, TOLERABILITY, PD AND PK OF IV ALXN1210 IN HEALTHY SUBJECTS	Amendment 3 dated 13 July 2016	13/07/2016	20
15/LO/0535/AM02	Precise study social science programme	4	14/10/2016	8
15/LO/0679/AM01	Changes in male fertility during chronic illness	1.0	01/04/2016	1
15/LO/0684/AM08	LEVALS	5	14/03/2017	8
15/LO/0689/AM02	1423M0634: S-888711 in CLD Undergoing Invasive Procedures (L-PLUS-2)	1	18/01/2017	14

15/LO/0774/AM02	PK & PD of ALN - AAT in healthy volunteers and liver disease patients	ALN-AAT-001, Temporary Halt, 5	23/03/2016	12
15/LO/0774/AM04	PK & PD of ALN - AAT in healthy volunteers and liver disease patients	1	02/03/2017	25
15/LO/0917/AM03	Exploring women's & clinicians views of treatment for BCRL of the arm	3	03/01/2017	9
15/LO/1055/AM04	PARSIFAL I	Protocol Amendment 2	30/06/2016	26
15/LO/1055/AM05	PARSIFAL I	5	05/10/2016	30
15/LO/1055/AM06	PARSIFAL I	3	20/12/2016	22
15/LO/1063/AM05	M14-004 AbbVie DAA's +Ribavirin in HCV Gt1 or 4/HIV Type 1 Coinfection	SA03	23/08/2016	20
15/LO/1121/AM01	Soul-Deep II: The South London Diabetes and Ethnicity Phenotyping study	1	09/12/2016	28
15/LO/1280/AM02	PRIDE- version 2.1	version 3.0	24/05/2016	3
15/LO/1417/AM03	ASCEND	SA-002	29/03/2016	8
15/LO/1425/AM07	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	Protocol 201677 Amendment No.	31/03/2016	29
15/LO/1425/AM08	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	Amendment No 8 Pregnant Subject	21/06/2016	11
15/LO/1425/AM09	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	Investigator's Brochure Edition	08/08/2016	14
15/LO/1425/AM11	Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis	3	17/11/2016	27
15/LO/1818/AM09	AZD2014 and Palbociclib w/ Horm. Therapy in Pts with Adv. Breast Cancer	4	24/08/2016	8
15/LO/1818/AM10	AZD2014 and Palbociclib w/ Horm. Therapy in Pts with Adv. Breast Cancer	4	12/01/2017	21
15/LO/1828/AM09	RAINBOW	6	22/03/2017	7
15/LO/1835/AM03	PNET 5	02	04/10/2016	27
16/LO/0009/AM02	SAD, MAD, PK Study of SC ALN-HBV in healthy volunteers and patients	Amendment 1	16/05/2016	8
16/LO/0009/AM03	SAD, MAD, PK Study of SC ALN-HBV in healthy volunteers and patients	Amendment 2 Date: 10/Aug/2016	10/08/2016	27
16/LO/0009/AM04	SAD, MAD, PK Study of SC ALN-HBV in healthy volunteers and patients	1.0	18/01/2017	13
16/LO/0009/AM05	SAD, MAD, PK Study of SC ALN-HBV in healthy volunteers	1	27/01/2017	14

	and patients			
16/LO/0051/AM04	A PHASE 1, SAD, MAD, PK and PD STUDY OF ALXN1210 IN JAPANESE SUBJECTS	1	31/08/2016	14
16/LO/0066/AM01	EVENTS (version 1.0)	1.0	19/09/2016	31
16/LO/0066/AM02	EVENTS (version 1.0)	02	04/01/2017	6
16/LO/0241/AM01	Safety and tolerability of SC ALN-TTRSCO2 in healthy volunteers	1	20/12/2016	28
16/LO/0360/AM01	The effectiveness of treating PST; feasibility study (V2)	3	09/12/2016	12
16/LO/0470/AM02	ENRICH peer worker programme to enhance psychiatric discharge	1	29/09/2016	19
16/LO/0524/AM01	PK of Simeprevir, Odalasvir and AL-335 in healthy Japanese subjects	64294178HPC1006 , C15050 SA 2	01/06/2016	1
16/LO/0524/AM03	PK of Simeprevir, Odalasvir and AL-335 in healthy Japanese subjects	4	27/09/2016	22
16/LO/0584/AM01	Safety, Tolerability & PK of odalasvir and AL-335 in healthy Japanese	Amendment 1	25/04/2016	14
16/LO/0584/AM03	Safety, Tolerability & PK of odalasvir and AL-335 in healthy Japanese	4	27/09/2016	22
16/LO/0794/AM02	RAINBOW extension study	1	22/02/2017	6
16/LO/0853/AM01	BI-1206 + anti-CD20 in patients with CD32b positive B-cell malignancy	CTA Amendment 01 dated 20-Jun-	20/06/2016	19
16/LO/0853/AM04	BI-1206 + anti-CD20 in patients with CD32b positive B-cell malignancy	4	02/02/2017	7
16/LO/0858/AM01	BCX7353 in prevention of HAE attacks	1	19/10/2016	28
16/LO/0858/AM03	BCX7353 in prevention of HAE attacks	1.0	24/01/2017	7
16/LO/0871/AM01	MISSION 2015-05	Amendment number 01	08/07/2016	10
16/LO/0871/AM02	MISSION 2015-05	2	01/11/2016	21
16/LO/0908/AM01	Efficacy and safety of iNO in Pulmonary Arterial Hypertension, v1.0	1	25/11/2016	15
16/LO/1072/AM01	Impact of an information leaflet on patient anxiety before CSI	Amendment 1	24/06/2016	10
16/LO/1072/AM02	Impact of an information leaflet on patient anxiety before CSI	2	20/11/2016	4
16/LO/1077/AM03	Understanding Repeat Attenders for Emergency Care Not Continuing Care	3	12/01/2017	18
16/LO/1135/AM01	Use of MDCT aortic root assessment to determine valve sizing	1	05/12/2016	6



	in TAVI			
16/LO/1304/AM01	LEAP	1.0	06/02/2017	22
16/LO/1697/AM02	MK-3475 in the treatment of Advanced/Metastatic Urothelial Carcinoma	SA01	23/12/2016	8
16/LO/1697/AM04	MK-3475 in the treatment of Advanced/Metastatic Urothelial Carcinoma	MK-3475-361	22/03/2017	19
16/LO/1701/AM01	Olaratumab plus Gemcitabine and Docetaxel in Soft Tissue Sarcoma -JGDL	1	17/02/2017	5
16/LO/2043/AM01	CA209-649: Nivo/Ipi vs SOC in gastric cancer patients	1	27/02/2017	3
17/LO/0174/AM01	Safety, Tolerability, PK, Immunogenicity & PD of JNJ-64179375	1	08/03/2017	11

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/LO/0051/AM03	A PHASE 1, SAD, MAD, PK and PD STUDY OF ALXN1210 IN JAPANESE SUBJECTS	Amendment 1 dated 13 July 2016	13/07/2016	29

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

REC Reference	Title	Number of Days on Clock
16/LO/1656	Natural history and biomarkers in autonomic disorders	29
16/LO/1858	COMmunity based PulmonAry rehabiliTation programme (COMPACT) V1	24
16/LO/1863	Sobi.Elocta-002 _ A-SURE	24
17/LO/0062	STUDIOUS	25

**SSAs (non Phase 1) over 25 day timeline**

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0287/AM02	Real time imaging of regulatory T cells in healthy volunteers	1	26/07/2016	36

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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