

**London - Hampstead Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Hampstead Research Ethics Committee
<b>Type of REC:</b>	Recognised, Type I and Type III
<b>Type of Flag:</b>	Phase I in healthy volunteers, Paediatric
<b>Chair:</b>	Miss Stephanie Ellis
<b>Vice-Chair:</b>	Dr. Manish Saxena
<b>Alternate Vice-Chair:</b>	Mr Paul Hardiman
<b>REC Manager:</b>	Dr Ashley Totenhofer (1 April 2015 – 28 August 2015) Mr Matt Rogerson (1 February 2016 – 31 March 2016)
<b>REC Assistant:</b>	Miss Amber Ecclestone
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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<b>Email:</b>	nrescommittee.london-hampstead@nhs.net

## Chair's overview of the past year:

This year was my fourth year as Chair of Hampstead REC. I am grateful to everyone on the committee for their commitment and helpfulness.

Sadly Dr Ashley Totenhofer our manager has now left but Matt Rogerson has joined as our new manager and he and Amber Ecclestone make a formidably good team. I am pleased to be able to say that researchers have commented on how helpful they have been.

We strive to be a friendly and helpful committee, and Matt and Amber are key to helping the researchers. We recognise that one of the most worrying parts of doing medical research is facing a Research Ethics Committee, especially attending a meeting. It can be a very daunting experience. I am pleased how many researchers come back to us.

Most applications we see are good. The researchers have clearly thought carefully about how to run their research and how to present it.

Sadly there are, as ever, some problems. We continue to see proposals from students who have clearly not been given much support by their supervisors. Because of this their proposals are often far from clear, and this means we have to insist on substantial changes which means the poor student has to put in even more work.

A further common problem is that of research sponsored by pharmaceutical companies based in other countries who do not seem to understand the importance of tailoring their information sheets to what people in this country would understand.

Our Committee continues to work well. I never cease to be impressed by the commitment of the members. They put in a lot of work, not only during the meeting but before hand when they read everything very carefully. Those researchers who attend our meetings see us for only a short time, but they rapidly realise that we have looked at their applications very carefully and can help them improve them still further.

Miss Stephanie Ellis (Chair)

## London - Hampstead Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Waheeb Atia	Retired Consultant Physician	Expert	01/11/2010	
Mrs Jacqueline Birks	Senior Medical Statistician	Expert	12/10/2008	
Dr Rahul Chodhari	Consultant Paediatrician	Expert	03/04/2008	
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	21/01/2013	
Dr Alicia Isabel Etchegoyen	Psychiatrist	Expert	12/11/2013	
Mr Paul Hardiman	Consultant Gynaecologist/Senior Lecturer in Obstetrics and Gynaecology	Expert	01/09/2010	
Dr Michael Jacobs	Retired Academic Pharmacologist	Lay	14/05/2013	
Miss Monica Jefford	Retired Midwife	Expert	31/08/2011	
Miss Mina Karamshi	Specialist Sister in Radiology	Expert	02/11/2010	
Dr Jane Lees-Millais	General Practitioner	Expert	01/07/2011	
Ms Anna Osadcow	Clinical Trials Research Pharmacist	Expert	01/01/2013	
Ms Ann Rosenthal	Literary Consultant (Retired)	Lay Plus	01/01/2014	
Dr. Manish Saxena	Clinical Lecturer and Clinical Research Fellow	Expert	01/07/2013	
Mrs Arlene Renee Seaton	Retired Medical Publisher	Lay Plus	06/02/2013	
Mrs Wendy Spicer	Pharmacist	Expert	01/12/2005	
Dr Latha Padma Weston	Consultant Psychiatrist	Expert	14/12/2011	

## London - Hampstead Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	10/06/2015
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	13/05/2015
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	09/12/2015
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	11/11/2015
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	08/07/2015

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

<b>Name</b>	<b>Profession</b>	<b>Status</b>	<b>Meeting date attended</b>
Mr Malcolm Morton	Retired (Practice Manager)	Lay Plus	Full REC 09/09/2015 SC 02/10/2015

## London - Hampstead Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Waheeb Atia	Member of BMA	31/03/2016
Mrs Jacqueline Birks	None	31/03/2016
Dr Rahul Chodhari	Received Pharma support for unrestricted educational grant to attend paediatric allergy meeting	31/03/2016
Miss Stephanie Ellis	None	31/03/2016
Dr Alicia Isabel Etchegoyen	None	31/03/2016
Dr Michael Jacobs	none	31/03/2016
Miss Monica Jefford	Shareholdings - British Telecom, Iberdola, SSE plc Connection with St Andrew's Church, Coulsdon member, Coulsdon Churches Together Chair, Croydon Churches Floating Shelter volunteer, St Andrew's Church Contact Group Co-ordinator, Croydon Neighbourhood Care Association affiliation, Croydon Adult Social Services User Panel, member Croydon Voluntary Action as above, Bowel Cancer UK volunteer Research Connections with; The Royal Marsden NHS Foundation Trust: i) Patient and Carer Research Review Panel ii) Clinical Research Facility member and studies co-investigator iii) PPI with the Biomedical Research Centre iv) Patient and Carer Advisory Group member Institute of Cancer Research: Trial Management Group member NCRI/N member - Colorectal Clinical Studies Group member SE London Consumer Research Panel member NIHR Clinical Research Network - South London member Imperial College PPI sessions with medical students Guy's and St Thomas' NHS Foundation Trust Chaplain	31/03/2016
Miss Mina Karamshi	None	31/03/2016
Dr Jane Lees-Millais	None	31/03/2016
Ms Anna Osadcow	Advise on pharmaceutical issues to academic sponsor (UCL) on request for CTIMP studies	31/03/2016
Ms Ann Rosenthal	Son, Adam Rosenthal, is a Consultant at UCH. If any research study mentions his name an interest would be declared.	31/03/2016
Mrs Arlene Renee Seaton	Chair of Ethics Committee, IVF Clinic Lister Hospital, Chelsea, London	31/03/2016
Dr Latha Padma Weston	Trustee at Barnet Bereavement Society	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	08/04/2015	13
May	13/05/2015	13
June	10/06/2015	14
July	08/07/2015	8
September	09/09/2015	8
October	14/10/2015	12
November	11/11/2015	11
December	09/12/2015	12
January	13/01/2016	11
February	10/02/2016	12

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	08/04/2015	3
May	20/05/2015	3
June	12/06/2015	3
July	08/07/2015	3
August	13/08/2015	3
September	09/09/2015	3
October	14/10/2015	3
November	11/11/2015	3
December	09/12/2015	3
January	13/01/2016	3
February	10/02/2016	3
March	09/03/2016	3

12 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	17/04/2015	2
May	01/05/2015	2
May	11/05/2015	2
June	02/06/2015	2
June	23/06/2015	2
June	26/06/2015	2
July	02/07/2015	2
July	07/07/2015	2

July	16/07/2015	2
August	10/08/2015	2
August	24/08/2015	2
August	27/08/2015	2
September	11/09/2015	2
October	01/10/2015	2
October	02/10/2015	5
October	15/10/2015	2
October	22/10/2015	3
November	02/11/2015	2
November	16/11/2015	2
December	01/12/2015	2
December	15/12/2015	2
December	21/12/2015	2
January	01/01/2016	2
January	15/01/2016	2
January	26/01/2016	3
January	29/01/2016	2
February	10/02/2016	2
February	16/02/2016	3
February	24/02/2016	2
March	09/03/2016	2
March	23/03/2016	2

32 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>
Dr Waheeb Atia	10
Mrs Jacqueline Birks	6
Dr Victoria Chapman	5
Dr Rahul Chodhari	3
Miss Stephanie Ellis	10
Dr Alicia Isabel Etchegoyen	7
Mr Paul Hardiman	6
Dr Michael Jacobs	7
Miss Monica Jefford	10
Miss Mina Karamshi	8
Dr Jane Lees-Millais	4
Ms Anna Osadcow	7
Ms Ann Rosenthal	8
Dr Manish Saxena	3
Mrs Arlene Renee Seaton	8
Mrs Wendy Spicer	6
Dr Latha Padma Weston	5

**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 Waheeb Atia	1
Dr Victoria Chapman	2
Dr Rahul Chodhari	2
Miss Stephanie Ellis	12
Dr Alicia Isabel Etchegoyen	3
Mr Paul Hardiman	1
Miss Monica Jefford	2
Miss Mina Karamshi	1
Dr Jane Lees-Millais	4
Ms Anna Osadcow	1
Ms Ann Rosenthal	1
Dr Manish Saxena	1
Mrs Arlene Renee Seaton	3
Mrs Wendy Spicer	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Waheeb Atia	3
Dr Victoria Chapman	2
Dr Rahul Chodhari	5
Miss Stephanie Ellis	32
Dr Alicia Isabel Etchegoyen	4
Mr Paul Hardiman	1
Dr Michael Jacobs	2
Miss Monica Jefford	5
Miss Mina Karamshi	1
Dr Jane Lees-Millais	5
Ms Ann Rosenthal	2
Mrs Arlene Renee Seaton	5
Mrs Wendy Spicer	2

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Waheeb Atia	12/10/2015	Managing Complex & Contentious Issues in Research Review
Dr Waheeb Atia	26/12/2015	London Members Training Day
Mrs Jacqueline Birks	17/12/2015	Workshop for REC Statisticians
Miss Stephanie Ellis	08/04/2015	Local Training Day - MCA for Harrow REC
Miss Stephanie Ellis	13/04/2015	Local Training Day - MCA for Frenchay REC
Miss Stephanie Ellis	16/04/2015	Local Training Day - MCA for South East Coast Surrey REC
Miss Stephanie Ellis	01/05/2015	Presentation on RECs for Trainee Clinicians
Miss Stephanie Ellis	02/06/2015	Critical Care Conference
Miss Stephanie Ellis	04/09/2015	Oxford Centre for Diabetes, Endocrinology and Metabolism Training Day
Miss Stephanie Ellis	12/11/2015	Oxford Training Day
Miss Stephanie Ellis	26/11/2015	REC Training Day
Miss Stephanie Ellis	09/12/2015	National Training Day for Chairs
Miss Stephanie Ellis	11/01/2016	MCA Training
Miss Stephanie Ellis	04/02/2016	HRA Training Day
Dr Michael Jacobs	26/11/2015	London Members Training Day
Ms Ann Rosenthal	19/10/2015	Ethical Issues of Research Involving Children
Ms Ann Rosenthal	26/11/2015	Sense about Science

## 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	24	42.86
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	32	57.14
<b>Total Applications Reviewed</b>	<b>56</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	16
Number of paediatric applications reviewed	16
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	4

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	8	14.29
Favourable Opinion with Additional Conditions	12	21.43
Unfavourable Opinion	0	0.00
Provisional Opinion	35	62.50
Provisional Opinion Pending Consultation with Referee	1	1.79
<b>Total</b>	<b>56</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	33	58.93
Further Information Favourable Opinion with Additional Conditions	1	1.79
Further Information Unfavourable Opinion	1	1.79
Favourable Opinion with Standard Conditions	8	14.29
Favourable Opinion with Additional Conditions	12	21.43
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.79
<b>Total</b>	<b>56</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>36</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	1
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	15	41.67
Favourable Opinion with Additional Conditions	2	5.56
No Opinion transfer to full committee for review	5	13.89
Provisional Opinion	13	36.11
Unfavourable Opinion	1	2.78
<b>Total</b>	<b>36</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.60
<b>Number of completed applications for full ethical review</b>	55
<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>	4
<b>Number of completed applications over 40 days as a % of total</b>	7.14%
<b>Number of days taken to final decision – average (mean)</b>	26
<b>Number of completed proportionate review applications for ethical review</b>	31
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	4
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	12.90%
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	136
<b>Number of completed substantial amendments over 35 days</b>	3
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	2.21%
<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>	3.68%
<b>Number of modified amendments reviewed</b>	2
<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>	100
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	41
<b>Number of annual progress reports received</b>	85

<b>Number of safety reports received</b>	15
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	31



**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/0515	SPARE: scalp sparing radiotherapy treatment to the whole brain	17
15/LO/0557	Hypersexuality in neurological disorders.	16
15/LO/0559	Sensitivity and specificity of corneal microscopy in polyneuropathy	17
15/LO/0569	Listen-In	16
15/LO/0749	Effects of 100mg Hydrocortisone injection into Deltoid & Thigh	23
15/LO/0764	Health Behaviour Change in TYA Cancer Survivors	19
15/LO/0828	Viability of prostate cancer patient focus group (PCPFG)	24
15/LO/0833	IBIS 3 Feasibility version 1.0	19
15/LO/0997	Power Up	24
15/LO/1032	Self-disgust in personality disorders V2	21
15/LO/1077	ABC-07	21
15/LO/1090	Neutrophil defects and tooth loss in children	23
15/LO/1100	Blood Pressure in children and young adults with ADPKD	19
15/LO/1134	Parents' Experiences of Therapy EI for Complex Infants	20
15/LO/1149	RACE version 2	21
15/LO/1488	Gift-Surg – Fetal MRI	31
15/LO/1592	QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD	22
15/LO/1679	Impact on CGM on Hypoglycaemia in Type 1 Diabetes	25
15/LO/1680	BioPolyâ„¢ RS Partial Resurfacing Implant	26
15/LO/1681	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	27
15/LO/1832	LENA WP8	26
15/LO/1833	LENA WP9	26
15/LO/1834	LENA WP10	26
15/LO/1885	Patterns of airway infection and inflammation in children	37
15/LO/2100	TAGS	56
15/LO/2162	The oral health of people living with Multiple Sclerosis.	44
16/LO/0017	Phase I/II study - patients with previously treated solid tumours	54
16/LO/0029	Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naive subjects	28
16/LO/0036	GS-9883/F/TAF versus ABC/DTG/3TC in HIV-1, treatment-naive subjects	28
16/LO/0039	Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject	29
16/LO/0058	LAVA- Liver resection surgery versus thermal ablation for CLM	35
16/LO/0188	Plantaris release for non-insertional Achilles tendinopathy	39

16/LO/0251	Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial	25
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#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1407	Uterine Transplantation in the Human Setting	26

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/1991	Intraocular Pressure And Tolerability Study SPORT II	48

#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1144	ATX-MTM-001 - Recensus Retrospective Study for Patients with XLMTM	19
15/LO/1578	The role of rehabilitation units in self-medication for older people	21
15/LO/1687	Neural Correlates of Number Processing in preterm children	20
15/LO/2098	INTEREST study	28
15/LO/2116	The TEPIC Study	28
16/LO/0133	Identification and Care of Patients at Risk of Post Stroke Dementia	21
16/LO/0141	INCEPTUS: ATX-MTM-009	21
16/LO/0144	SHP-GCB-402-effect of Velaglycerase alfa on Bones in Gaucher Disease	21

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0567	An exploration of oral nutrition support in Motor Neurone Disease	16
15/LO/0844	An Open-Label, Phase 2 Study of Neratinib in Patients With Solid Tumour	27
15/LO/0904	SSAT063- PK of EFV 400mg once daily during pregnancy in HIV+ women	27
15/LO/0984	PM01183 - CORAIL Trail	20
15/LO/1019	Mood mAPPer	20
15/LO/1477	PRM-151-202	21
15/LO/1485	HIV-1 latent reservoir in co-infections v1	21
15/LO/1585	PB102F03: Extension Study of PRX-102 in Fabry Disease	21
15/LO/1868	StOP Haemophilia A Study	22

15/LO/1975	The Effect of Age on Zostavax Vaccine Response	28
15/LO/2085	Muscle connective tissue in limb development and disease	28
16/LO/0129	Post Marketing study following long term prophylactic Optivate usage	21

#### Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
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#### 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
15/LO/0812	Fasting Protocols for coronary Angiography	19

**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
15/LO/0919	Post Market Data Collection: L-PRP for Chronic Lateral Epicondylitis	9
15/LO/1113	Pilot assessment of the measurement properties of the UAB PRO V1.0	8
15/LO/1254	EMA post-authorisation safety study of influenza vaccine	10
15/LO/1264	Pilot of electronic health promotion in maternity services	5

15/LO/1629	Quality of life and wellbeing in pregnant women and new mothers V1	12
15/LO/1841	The Use of Placenta and Umbilical Cord Derived Stem Cells	18
15/LO/1870	Co- use of prescription and herbal medicines among older adults	18
15/LO/2016	QOL in dialysis patients and carers	15
15/LO/2027	Knowledge mobilisation in critical care	9
15/LO/2159	The influence of CBM-I on generalised anxiety in older adults	13
16/LO/0108	An exploration of the lived experiences of anxiety in those with COPD	10
16/LO/0127	VEST	14
16/LO/0305	Lichen Planus Study	19

#### 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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#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0643	Distress related to visual hallucinations in psychosis and eye disease	14
15/LO/0645	The management of patients with cauda equina syndrome	14
15/LO/0659	Cumulative reduction of oral malodour by a sonic tongue brush	12
15/LO/1084	Reliability of functional outcome measures in neurofibromatosis 1	11
15/LO/1092	NNRD Statistical Methods Version 2	9
15/LO/1109	Women with Benign Breast Disease - Review	7
15/LO/1423	Distress caused by episodic breathlessness in lung cancer	10
15/LO/1428	Patient information technology access in secondary care	9
15/LO/1431	Flow-volume loop monitoring in paediatric airway surgery	10
15/LO/1433	ADONeS Study	10
15/LO/1619	Users' experiences with technology-based mental health treatments (V4)	9
15/LO/1630	Short term morbidity with defunctioning stomas in anterior resection	7
15/LO/2023	Baseline observations for MoRoW-3	10
16/LO/0113	Dental skill mix	7
16/LO/0497	Biomarkers of ageing in serum	8

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0647	New markers and treatment targets in retinoblastoma	13
16/LO/0318	Impact of Loading Pressure on Endothelial Function in Diabetic Foot v1	8

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0473	Improving negative psychological outcomes at breast screening recall	7

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

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

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

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/Q0501/49/AM35	R-CHOP 14 versus 21	Protocol v9.0	15/03/2016	6
08/H0720/46/AM04	Healthy Control Samples	Amendment 6	04/03/2016	6
08/H0720/87/AM17	Phase I/II study of Abiraterone in ER or AR positive breast cancer	18	07/09/2015	3
09/H0720/123/AM04	Treatment of primary breast cancer using Photodynamic therapy (PDT)	9	06/10/2015	40
09/H0720/132/AM17	Phase 3 study of Lenalidomide in castrate-resistant prostate cancer	Revlimid Investigator's Brochure	15/07/2015	25
09/H0720/8/AM17	THE LONDON COPD EXACERBATION COHORT (The EXCEL Cohort)	Substantial Amendment 1.10 19/	19/03/2015	21
09/H0720/8/AM19	THE LONDON COPD EXACERBATION COHORT (The EXCEL Cohort)	09/H0720/123,	23/10/2015	8
09/H0720/8/AM21	THE LONDON COPD EXACERBATION COHORT (The EXCEL Cohort)	13535/929902/13/3 98/51369	29/02/2016	7
10/H0720/12/AM02	PROFILE Study (Brompton)	Amendment 2 14.01.2016	14/01/2016	35
10/H0720/21/AM12	Study of the aetiology and prodrome of Parkinson's disease	9	02/08/2015	14
10/H0720/21/AM13	Study of the aetiology and prodrome of Parkinson's disease	10	30/11/2015	28
10/H0720/28/AM24	The AIMS Study	NOSA 19	10/04/2015	17
10/H0720/5/AM06	Pulmonary Metastasectomy in Colorectal Cancer (PulMICC)	Version 16	06/03/2015	14
10/H0720/5/AM09	Pulmonary Metastasectomy in Colorectal Cancer (PulMICC)	002 (Protocol Version 17) Date	28/01/2016	8
10/H0720/80/AM04	The UCH Preterm Development Project v1	Amendment 4 25 July 2015	27/07/2015	26
10/H0720/88/AM13	LUME-Lung 3.	Amend September 2015	28/09/2015	21
11/H0720/4/AM03	Remote Ischaemic Preconditioning and Outcome of Liver Transplantation.	2: 03/02/2016	07/03/2016	3

11/LO/0077/AM07	Cognitive Impairment in People with HIV in the European Region(CIPHER)	amendment 5	05/05/2015	21
11/LO/0425/AM13	SYCAMORE	Substantial Amendment v11.0	14/01/2015	15
11/LO/0425/AM14	SYCAMORE	Substantial Amendment v12.0	17/04/2015	1
11/LO/0425/AM15	SYCAMORE	Substantial Amendment v13.0	24/04/2015	3
11/LO/0425/AM16	SYCAMORE	Substantial Amendment v14.0	12/06/2015	11
11/LO/0425/AM17	SYCAMORE	Substantial Amendment v15.0	25/08/2015	15
11/LO/0608/AM16	Phase 2 study of MDV3100 for metastatic prostate cancer	Investigator's Brochure Edition	09/06/2015	10
11/LO/0608/AM17	Phase 2 study of MDV3100 for metastatic prostate cancer	Updated Patient Information Sheet	17/08/2015	3
11/LO/1634/AM03	MRI assessment of small bowel motility	Amendment 3	16/01/2015	14
11/LO/1634/AM04	MRI assessment of small bowel motility	4 25/1/2016	27/01/2016	13
11/LO/1696/AM04	Progression of atherosclerosis in diabetic subjects	4th Amendment	15/04/2015	17
11/LO/2036/AM15	Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib	Protocol Amendment 5 dated Feb	13/03/2015	14
11/LO/2036/AM16	Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib	Protocol Amendment 6	27/04/2015	25
11/LO/2036/AM20	Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib	Substantial Amendment 1	18/01/2016	7
11/LO/2036/AM21	Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib	Substantial Amendment 12	15/03/2016	6
12/LO/0078/AM05	The effects of Early Palliative Care in Mesothelioma	AM05	18/09/2015	4
12/LO/0219/AM05	A pedometer intervention to increase walking in adults: PACE-UP trial	Fourth Significant Amendment	19/06/2015	8
12/LO/0715/AM02	A novel protein biomarker of myocardial damage	Two	14/10/2015	14
12/LO/0803/AM25	AZD5363 in patients with advanced or metastatic breast cancer (BEECH)	D3610C00002 Amendment to new P	07/04/2015	10
12/LO/0803/AM27	AZD5363 in patients with advanced or metastatic breast	D3610C00002	14/05/2015	17

	cancer (BEECH)	Protocol Amendment		
12/LO/0803/AM28	AZD5363 in patients with advanced or metastatic breast cancer (BEECH)	D3610C00002 - formulation change	02/06/2015	23
12/LO/0803/AM32	AZD5363 in patients with advanced or metastatic breast cancer (BEECH)	D3610C00002 Patient Guide and	22/07/2015	18
12/LO/0889/AM04	Time to test of cure for Chlamydia and Gonorrhoea infections (Final)	Amendment 1	11/03/2015	27
12/LO/1411/AM02	NeSST2: The development of a non-invasive Short Synacthen Test	Amendment 2	21/12/2015	13
12/LO/1411/AM04	NeSST2: The development of a non-invasive Short Synacthen Test	Substantial Amendment 3	12/02/2016	13
12/LO/1422/AM03	LuDo	SA02	02/03/2016	3
12/LO/1759/AM11	OuTSMART	Amendment 10	11/08/2015	8
12/LO/1759/AM14	OuTSMART	Amendment 12, 26/11/2015	26/11/2015	21
13/LO/0016/AM03	Baxter 281101: Phase 1 Study of Safety and Pharmacokinetics in TTP	Substantial Amendment #3	18/06/2015	22
13/LO/0171/AM01	Research into IMD patient-derived iPSC. V1	Amendment number 1	05/02/2016	17
13/LO/0482/AM07	Reducing the frequency and severity of voices: AVATAR Clinical Trial	7	11/09/2015	18
13/LO/0634/AM03	Late onset depression: Correlates of dopaminergic function	Substantial Amendment 2	27/03/2015	14
13/LO/0847/AM04	IPF-PRoM Study	V5	03/08/2015	18
13/LO/1104/AM03	PB-102-F02: Extension of the PB-102-F01 study (PRX-102 for ERT in Fabr	IB Edition 3A, UK only	26/07/2015	2
13/LO/1150/AM01	ROLE OF LEFT ATRIAL SITES THAT TRIGGER PULMONARY VEIN ECTOPY IN PAF	Substantial Amendment 1	08/05/2015	28
13/LO/1184/AM04	TheraSphere® vs soc Sorafenib in Hepatocellular Carcinoma with PVT	Investigator's Brochure TheraSphere	29/06/2015	13
13/LO/1321/AM09	GB28547 - Lebrikizumab in patients with idiopathic pulmonary fibrosis	Substantial Amendment #4	29/05/2015	28
13/LO/1321/AM10	GB28547 - Lebrikizumab in patients with idiopathic pulmonary fibrosis	5 - Poster	28/01/2015	12



13/LO/1321/AM11	GB28547 - Lebrikizumab in patients with idiopathic pulmonary fibrosis	6	14/12/2015	27
13/LO/1331/AM01	Does transdermal magnesium correct low serum magnesium?	Substantial Amendment 1	12/05/2015	20
13/LO/1511/AM03	MIC programme: module 2, the interview module.	Amendment 3	07/09/2015	20
13/LO/1520/AM07	Study Of Diabetic Nephropathy with Atrasentan	Sub Amd 06	31/03/2015	17
13/LO/1520/AM08	Study Of Diabetic Nephropathy with Atrasentan	Sub Amd 07	20/04/2015	9
13/LO/1707/AM02	Investigating the pathophysiology of mesenteric infarction	Version 5	01/04/2015	10
13/LO/1712/AM01	MatImms@Imperial: A mother-infant study of immune responses to vaccine	Amendment 1	26/11/2015	7
14/LO/0040/AM01	CONCYST: Needle-based confocal laser endomicroscopy of pancreatic cysts	Amendment 1. 30th January 2016	18/02/2016	19
14/LO/0121/AM06	PAKT	Amendment 5.0	12/06/2015	11
14/LO/0121/AM07	PAKT	Amendment 6.0	22/07/2015	9
14/LO/0521/AM05	Switching to, then stopping treatment with nilotinib for CML patients.	CAMN107AIC05; version 02	20/02/2015	14
14/LO/0521/AM06	Switching to, then stopping treatment with nilotinib for CML patients.	Three	23/09/2015	25
14/LO/0568/AM04	Screening for depression in South Asians with End Stage Renal Disease	Amendment Number 2	18/05/2015	2
14/LO/0568/AM05	Screening for depression in South Asians with End Stage Renal Disease	Amendment number 3 (25/11/15)	11/01/2016	8
14/LO/0892/AM04	Phase 1 study of MEDI4736 in Myelodysplastic Syndrome	Protocol Amendment 2	27/05/2015	27
14/LO/0892/AM05	Phase 1 study of MEDI4736 in Myelodysplastic Syndrome	4	11/11/2015	19
14/LO/1454/AM02	The Scleroderma Patient Centered Intervention Network (SPIN) Cohort	Substantial Amendment 1	28/05/2015	1
14/LO/1459/AM04	Study of MMX <sup>®</sup> Mesalamine/Mesalazine in Paediatric Ulcerative Colitis	Protocol Amendment 3 version 4	09/02/2015	13
14/LO/1536/AM07	261202: BAX855 in children with severe haemophilia A	Substantial Amendment #5	02/04/2015	13
14/LO/1548/AM03	HRQL and Health Behaviours in Paediatric SCD Populations (Version 1)	Version 1C	18/05/2015	20
14/LO/1677/AM01	KOLCOV HF Study	SA01	12/08/2015	20

14/LO/1739/AM12	PRESIDE (9785-MA-1001)	APL Amendment I (biomarker sub	19/06/2015	17
14/LO/1802/AM02	Exjade new formulation study (Eclipse)	Addition of MDS	09/03/2015	17
14/LO/1970/AM01	Coping with Unusual ExperienceS for 12-18 year olds (CUES+)	1	18/09/2015	7
14/LO/2014/AM03	Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy	Substantial Amendment 3	05/10/2015	10
14/LO/2014/AM04	Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy	Substantial Amendment 4	18/12/2015	24
14/LO/2035/AM06	Alnylam - ALN-TTR02-004 - TTR Mediated Polyneuropathy (FAP)	Protocol Amendment 5	25/09/2015	38
14/LO/2035/AM07	Alnylam - ALN-TTR02-004 - TTR Mediated Polyneuropathy (FAP)	Updated ICF 3.0	18/01/2016	7
14/LO/2037/AM01	Riociguat in diffuse cutaneous systemic sclerosis (dcSSc)	BAY63-2521-16277	04/02/2015	4
14/LO/2037/AM02	Riociguat in diffuse cutaneous systemic sclerosis (dcSSc)	BAY632521/16277 Clinic Poster	15/06/2015	16
14/LO/2166/AM01	A multimodal investigation of treatment enhancers for eating disorders	Amendment one	19/04/2015	11
14/LO/2179/AM02	071101: rVWF in Subjects with Severe VWD Undergoing Surgery	UK EC Substantial Amendment #2	14/05/2015	18
14/LO/2179/AM05	071101: rVWF in Subjects with Severe VWD Undergoing Surgery	UK EC Substantial Amendment #3	21/01/2016	4
14/LO/2182/AM02	TheraSphere in Unresectable Hepatocellular Carcinoma (HCC) TS-103	Amendment 1 IB V3.2	20/02/2015	8
15/LO/0051/AM06	FI intervention study (FINS)	V5.0 7th January 2016	12/01/2016	11
15/LO/0075/AM01	Phase 3 study in treatment-naive HIV-1 infected subjects	Protocol Amendment 018-02	10/02/2015	4
15/LO/0075/AM02	Phase 3 study in treatment-naive HIV-1 infected subjects	Substantial Amendment 2	01/05/2015	10
15/LO/0075/AM03	Phase 3 study in treatment-naive HIV-1 infected subjects	Substantial Amendment 3	29/07/2015	12
15/LO/0075/AM05	Phase 3 study in treatment-naive HIV-1 infected subjects	Substantial Amendment 5	09/03/2016	14
15/LO/0208/AM07	Prevalence of TTR Mutations in Cardiac Amyloidosis	Amendment 2 dated 08Oct15	09/10/2015	25

15/LO/0273/AM01	Randomised, Phase 3 study for subjects with Early Stage TNBC	IB Ed 9	18/09/2015	10
15/LO/0273/AM02	Randomised, Phase 3 study for subjects with Early Stage TNBC	Substantial Amendment	22/12/2015	20
15/LO/0277/AM02	High flow oxygen with THRIVE results in better oxygenation	vfeb 2016	29/02/2016	5
15/LO/0278/AM01	Harvoni in Adolescents and Children with HCV	Protocol Amendment v2.2	30/04/2015	11
15/LO/0278/AM02	Harvoni in Adolescents and Children with HCV	Protocol Amendment 3 28-May-20	26/06/2015	7
15/LO/0278/AM03	Harvoni in Adolescents and Children with HCV	15/LO/0278/AM03	12/01/2016	37
15/LO/0282/AM03	I1F-MC-RHBE Ixekizumab in patients with active psoriatic arthritis	Substantial Amendment 2	23/10/2015	12
15/LO/0424/AM01	PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers	SSAT055	08/09/2015	18
15/LO/0424/AM03	PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers	SSAT055	12/02/2016	13
15/LO/0464/AM01	The EQUIP Trial	Substantial Amendment 1	26/06/2015	7
15/LO/0467/AM01	The longitudinal effects of endotoxemia in haemodialysis patients	Substantial Amendment 1	15/04/2015	20
15/LO/0467/AM02	The longitudinal effects of endotoxemia in haemodialysis patients	Substantial Amendment 2	10/06/2015	16
15/LO/0467/AM03	The longitudinal effects of endotoxemia in haemodialysis patients	3	18/09/2015	19
15/LO/0557/AM01	Hypersexuality in neurological disorders.	Amendment 1	02/09/2015	14
15/LO/0749/AM01	Effects of 100mg Hydrocortisone injection into Deltoid & Thigh	1	27/01/2016	14
15/LO/0764/AM01	Health Behaviour Change in TYA Cancer Survivors	Amendment 1	26/08/2015	15
15/LO/0833/AM03	IBIS 3 Feasibility version 1.0	1	19/10/2015	15
15/LO/0844/AM01	An Open-Label, Phase 2 Study of Neratinib in Patients With Solid Tumor	SA001	31/07/2015	12
15/LO/0904/AM01	SSAT063- PK of EFV 400mg once daily during pregnancy in HIV+ women	1	17/09/2015	10
15/LO/0919/AM01	Post Market Data Collection: L-PRP for Chronic Lateral Epicondylitis	No 1: Change in Chief Investigator	21/02/2016	16
15/LO/0997/AM01	Power Up	1	16/09/2015	12

15/LO/1077/AM01	ABC-07	1	04/09/2015	7
15/LO/1100/AM01	Blood Pressure in children and young adults with ADPKD	1 18/ 10/2015	22/10/2015	27
15/LO/1144/AM01	ATX-MTM-001 - Recensus Retrospective Study for Patients with XLMTM	Substantial Amendment no.1	17/09/2015	6
15/LO/1433/AM01	ADONeS Study	Substantial Amendment 1	26/08/2015	10
15/LO/1477/AM01	PRM-151-202	PRM-151-202	23/12/2015	19
15/LO/1477/AM03	PRM-151-202	188394/926976/32/947/50742	25/02/2016	5
15/LO/1592/AM01	QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD	One	01/12/2015	14
15/LO/1592/AM02	QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD	Substantial Amendment	26/01/2016	20
15/LO/1592/AM03	QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD	Substantial Amendment 3	28/01/2016	14
15/LO/1629/AM01	Quality of life and wellbeing in pregnant women and new mothers V1	1: 14/01/16	09/02/2016	16
15/LO/1832/AM01	LENA WP8	190138/927499/32/611/50670	15/02/2016	14
15/LO/1833/AM01	LENA WP9	190945/927494/32/934/50758	12/02/2016	12
15/LO/1834/AM01	LENA WP10	192178/927501/32/656/50790	12/02/2016	13
15/LO/2016/AM01	QOL in dialysis patients and carers	Amendment 1.Date: 17.02.16	10/03/2016	35
15/LO/2100/AM01	TAGS	TO-TAS-102-302	16/03/2016	8
16/LO/0029/AM02	Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naive subjects	Protocol Amendment 1	07/03/2016	16
16/LO/0039/AM01	Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject	Update to EC form	19/02/2016	6

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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08/H0720/46/AM03	Healthy Control Samples	Amendment Number 4	16/06/2015	5	
15/LO/0277/AM01	High flow oxygen with THRIVE results in better oxygenation	1	12/10/2015	22	
15/LO/1629/AM02	Quality of life and wellbeing in pregnant women and new mothers V1	2	02/03/2016	03/03/2016	7

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
08/H0720/46/AM03/1	Healthy Control Samples	Amendment 5	17/07/2015	0
15/LO/0277/AM01/1	High flow oxygen with THRIVE results in better oxygenation	Changes made as per recommendation	24/11/2015	11

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

**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
15/LO/1841	The Use of Placenta and Umbilical Cord Derived Stem Cells	18
15/LO/1870	Co- use of prescription and herbal medicines among older adults	18
15/LO/2016	QOL in dialysis patients and carers	15
16/LO/0305	Lichen Planus Study	19

**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
09/H0720/123/AM04	Treatment of primary breast cancer using Photodynamic therapy (PDT)	9	06/10/2015	40
14/LO/2035/AM06	Alynlam - ALN-TTR02-004 - TTR Mediated Polyneuropathy (FAP)	Protocol Amendment 5	25/09/2015	38
15/LO/0278/AM03	Harvoni in Adolescents and Children with HCV	15/LO/0278/AM03	12/01/2016	37

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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