

London – Dulwich Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	London – Dulwich Research Ethics Committee	
Type of REC:	REC recognised to review CTIMPS in patients - type iii	
Type of Flag:	Medical Devices	
Chair:	Dr Michael Philpot	
Vice-Chair:	Mr Colin Standfield	
Alternate Vice-Chair:	Dr Thomas Kabir	
REC Manager:	Mr Michael Higgs Mrs Alison O’Kane Miss Stephanie Hill	(January 2016 – present) (August 2015 – December 2015) (until July 2015)
Committee Address:	Health Research Authority Skipton House 80 London Road London SE1 6LH	
Telephone:	020 7104 8113	
Email:	nrescommittee.london-dulwich@nhs.net	

Chair's overview of the past year:

During this report year two long-standing members left the Committee. John Fowler – who I first met on the Guy's Hospital REC in the 1990s - completed his 10 years with London-Dulwich, and Krzysztof Rutkowski resigned to pursue further study. In addition, our Pharmacy expert, Chi Kai Tam, left after a few months to take up a senior post elsewhere. I would like to thank them all for their contribution and wish them well.

We have welcomed two new members, both with experience in clinical trials – Dr. Jiafeng Feng and Dr. Traiani Stari who is also a Statistician. Regular attendance by other stalwart members has ensured that there have been no inquorate meetings.

REC activity has remained stable with 56 new studies and 98 substantial amendments. Provisional opinion is still forms the majority of decisions (84%) but an Unfavourable opinion is rare. REC members continue to see the value in working with researchers to achieve a Favourable outcome. Targets are now being met and there has been a gratifying reduction in the average number of days taken to reach a final decision from 42 days (in 2014-15) to 29 days in this report year. No new applications exceeded 60 days.

Lastly, I would like to thank our REC Manager Stephanie Hill for her hard work during the year before she left to take up a new post. Stephanie had been with the REC since 2012 and provided excellent support to the old and new members. Michael Higgs joined us as REC Manager in January 2016 and impressed us all by his rapid acclimatisation to demands of the post.

London – Dulwich Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Urmi Bapat	Pharmaceutical Physician	Expert	17/07/2014	
Dr Jiafeng Feng	Research Assistant	Lay Plus	01/09/2015	
Mr John Fowler	Policy Manager	Lay Plus	31/05/2005	31/05/2015
Mr Kenny Ip	Clinical Trials Specialist	Lay	01/09/2014	
Dr Thomas Kabir	Public Involvement in Research Manager	Lay	10/02/2010	
Dr Martin Keech	Clinical Project Manager	Lay	22/09/2014	
Dr Erika Kennington	Research Manager	Lay Plus	01/09/2014	05/06/2015
Dr Edward Lavender	GP	Expert	03/12/2014	
Dr Joanne Lawson	Civil Servant	Lay Plus	11/02/2014	
Dr Michael Philpot	Consultant Psychiatrist	Expert	30/12/2007	
Ms Anna Ramberg	Research Development Manager	Lay Plus	01/10/2010	
Mr Krzysztof Rutkowski	Research Nurse	Expert	01/08/2010	09/07/2015
Mr Colin Standfield	Charity Worker	Lay	01/02/2012	
Dr Traiani Stari	Associate Director - Biostatistics	Expert	01/09/2015	
Mr Chi Kai Tam	Pharmacist	Expert	01/03/2015	08/10/2015
Ms Catherine Walton	Consultant Midwife	Expert	30/06/2006	

London - Dulwich Research Ethics Committee: Deputy Members

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

Name	Profession	Status	Meeting date attended
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London – Dulwich Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Urmi Bapat	Employed as Medical Director (UK & Ireland) for the Women's Health division of Gedeon Richter UK Ltd, a pharmaceutical company.	13/01/2016
	Holds shares in Bristol-Myers Squibb Pharmaceuticals	13/01/2016
Dr Jiafeng Feng	Project Manager for NIHR Cardiovascular Healthcare Technologies Co-operative at Guy's and St Thomas' NHS Trust. This includes supporting clinicians, researchers and public in developing medical devices and technologies that address needs in heart disease.	21/09/2015
	Guy's & St Thomas' NHS Foundation Trust employee. Acting department manager for cardiovascular imaging department King's College London which runs various studies on medical devices.	09/03/2016
Mr Kenny Ip	Employed as a Clinical Trials Specialist for Parexel Ltd.	13/01/2016
Dr Thomas Kabir	<ul style="list-style-type: none"> * Staff member at the McPin Foundation * Co-applicant on three NIHR-funded research studies * Visiting researcher, department of psychiatry, Cambridge University * Visiting research, IoPPN, King's College London * Peer reviewer for the journal Research Involvement and Engagement 	09/03/2016
Dr Martin Keech	Holds shares in GlaxoSmithKline and AstraZeneca.	13/01/2016
	Was previously Director and joint owner of Pharmakos Ltd. Company closed in June 2015.	13/01/2016
Dr Edward Lavender	None.	13/01/2016
Dr Joanne Lawson	None.	10/02/2016
Dr Michael Philpot	Member of the Alzheimer's Society.	13/01/2016
Ms Anna Ramberg	Employed as Research Development Manager at City University London and responsible for ethics approvals at this institution.	13/01/2016
Mr Colin Standfield	Member of the NICE appeals panel.	13/01/2016
Dr Traiani Stari	Employed as Associate Director of Biostatistics at Astellas Pharma UK Ltd.	13/01/2016
	Permanent full-time Associate Director of Biostatistics at Astellas Pharmaceuticals	21/09/2015
Ms Catherine Walton	None.	10/02/2016

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

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

10 full committee meetings were held during the reporting period.

Sub-Committee Meetings: 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
	15/04/2015	2
May	07/05/2015	3
	07/05/2015	2
	15/05/2015	2
	19/05/2015	2
	22/05/2015	2
	29/05/2015	3
June	05/06/2015	3
	19/06/2015	5
	19/06/2015	3
	30/06/2015	2
July	15/07/2015	2
	22/07/2015	2
	24/07/2015	2
August	11/08/2015	2
	14/08/2015	2
	17/08/2015	2
September	04/09/2015	2
	07/09/2015	2
	21/09/2015	2
	23/09/2015	2
	28/09/2015	5
October	12/10/2015	2
November	01/11/2015	2
	17/11/2015	2
December	18/12/2015	2
January	08/01/2016	2
February	05/02/2016	2
	19/02/2016	2
	26/02/2016	2
March	04/03/2016	2
	28/03/2016	2

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

Details of inquorate meetings: 01 April 2015 - 31 March 2016

0 inquorate meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Urmi Bapat	6
Dr Jiafeng Feng	5
Mr John Fowler	1
Mr Kenny Ip	8
Dr Thomas Kabir	8
Dr Martin Keech	8
Dr Edward Lavender	10
Dr Joanne Lawson	9
Dr Michael Philpot	9
Ms Anna Ramberg	8
Mr Krzysztof Rutkowski	2
Mr Colin Standfield	9
Dr Traiani Stari	5
Mr Chi Kai Tam	4
Ms Catherine Walton	7

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

Name	Number of Meetings Attended
Dr Urmi Bapat	4
Mr Kenny Ip	2
Dr Thomas Kabir	5
Dr Martin Keech	8
Dr Edward Lavender	4
Dr Joanne Lawson	5
Dr Michael Philpot	33
Ms Anna Ramberg	3
Mr Krzysztof Rutkowski	1
Mr Colin Standfield	3
Dr Traiani Stari	1
Mr Chi Kai Tam	1
Mrs Cathy Walton	6

Training: 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Urmi Bapat	08/04/2015	Ethics & GCP Forum ICR
	16/09/2015	Equality and Diversity
	06/10/2015	Quantitative Research Methods and Statistics
	03/12/2015	HRA Workshop: Pragmatic or Point of Care Trials
	18/02/2016	National Members Training Day
Dr Jiafeng Feng	26/11/2015	London REC Members' Training day
Mr Kenny Ip	01/04/2015	SDL - private reading: Health Research Authority (2014) Seeking informed consent for simple and efficient trials in the NHS: draft guidance for comment.
	01/06/2015	SDL - private reading: Chapman SJ et al (2014) Discontinuation and nonpublication of surgical randomised controlled trials: observational study. BMJ 349:g6870.
	01/09/2015	SDL - private reading: National Patient Safety Agency (2008) Approval for medical devices research: guidance for researchers, manufacturers, research ethics committees and NHS R&D offices.
	01/03/2016	SDL - private reading: Ennis L & Wykes T (2016) Sense and readability: participant information sheets for research studies. Br J Psychiatry, 208, 189-194.
Dr Thomas Kabir	04/09/2015	Equality and Diversity Training
	26/11/2015	London REC Members' Training day
Dr Martin Keech	26/02/2016	SDL - private reading: Virtue ethics – an old answer to a new dilemma? J R Soc Med 108(2-3)
	26/02/2016	SDL - private reading: Ennis L & Wykes T (2016) Sense and readability: participant information sheets for research studies. Br J Psychiatry, 208
	26/02/2016	SDL - private reading: National Patient Safety Agency (2008) Approval for medical devices research: guidance for researchers, manufacturers, research ethics committees and NHS R&D offices
Dr Edward Lavender	15/08/2015	Equality and Diversity Training
	26/11/2015	London REC Members' Training day
	18/02/2016	National Members Training Day
Dr Joanne Lawson	14/04/2015	SDL - private reading: Misselbrook D (2015) Virtue ethics - an old answer to a new dilemma? J R Soc Med 108(2-3)
	20/04/2015	SDL - private reading: Husain I & Spence D (2015) Can healthy people benefit from health apps? BMJ 350:h1887
	12/02/2016	SDL - private reading: Ennis L & Wykes T (2016) Sense and readability: participant information sheets for research studies. Br J Psychiatry 208
	22/02/2016	SDL - private reading: Carpenter D (2016) HRA Members Training Day - The Virtuous Ethics Committee handout
Dr Michael Philpot	09/09/2015	Equality and Diversity Training
	02/11/2015	National Training Day for Committee Chairs
Ms Anna Ramberg	26/11/2015	London REC Members' Training day
Mr Colin Standfield	26/11/2015	London REC Members' Training day
Dr Traiani Stari	07/09/2015	Equality and Diversity Training
Ms Catherine Walton	16/09/2015	Equality and Diversity Training
	13/01/2016	Assessing the Consequences of Research
	18/02/2016	National 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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	11	19.64
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.79
Others	44	78.57
Total Applications Reviewed	56	100

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	16
Number of paediatric applications reviewed	7
Number of device applications reviewed	11
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	6

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	7	12.50
Unfavourable Opinion	1	1.79
Provisional Opinion	47	83.93
Provisional Opinion Pending Consultation with Referee	1	1.79
Total	56	100
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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	46	82.14
Further Information Favourable Opinion with Additional Conditions	1	1.79
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	7	12.50
Unfavourable Opinion	1	1.79
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
Total	56	100

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

Total Applications Reviewed	0
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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	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	0
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	0

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

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

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

Average number of applications reviewed per full meeting	5.60
Number of completed applications for full ethical review	55
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	6
Number of completed applications over 40 days as a % of total	10.71%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	0
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	5
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non-Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	98
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.02%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.08%
Number of modified amendments reviewed	1
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	69
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	15
Number of annual progress reports received	117
Number of safety reports received	22
Number of Serious Adverse Events received	10
Number of final reports received	39

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0554	Cardiac biomarkers in revascularisation in ischaemic cardiomyopathy	29
15/LO/0641	Music during surgery	37
15/LO/0646	The development of a Youth Mental Health Help Seeking decision aid	39
15/LO/0652	BMS AI468-038: Phase 2b HIV-1 Maturation Inhibitor study	33
15/LO/0671	A Prospective, Observational Study of MPS IIIB	54
15/LO/0673	Detecting relapse in schizophrenia using remote sleep monitoring.	35
15/LO/0880	Stress-reactivity in clinical and non-clinical voice hearers	42
15/LO/0928	MitrAI Valve Repair Clinical Trial (MAVERIC Trial)	27
15/LO/0935	The mechanism of oesophageal mucosal protection with sodium alginate	35
15/LO/0978	Development of new PET-MR scanning methods	41
15/LO/1002	Tendinopathy: Treatment effects and mechanisms 1 (Tendinopathy TEAM 1)	47
15/LO/1070	STAR-VT	26
15/LO/1085	Venus P-Valve study, version A, Jan 2015	28
15/LO/1108	Stratified medical and technological approaches to managing chronic orofacial pain patients (V1)	33
15/LO/1110	Effects of neuronal nitric oxide synthase on human cardiac function	34
15/LO/1135	Transitions from paediatric to adult services for sickle cell disease	29
15/LO/1443	Biomarkers and Outcomes in CAA (BOCAA)	38
15/LO/1470	Multidimensional Risk Factor Assessment in Constipation (version 1.0)	44
15/LO/1479	What coming here means to me	37
15/LO/1553	POST 4	28
15/LO/1554	POST 5	28
15/LO/1611	Clinical study to evaluate INTERCEPT RBC in Thalassemia patients v5.0	26
15/LO/1640	SPYRAL HTN-ON MED Study	29
15/LO/1641	SPYRAL HTN-OFF MED Study	29
15/LO/1684	Dietary Interventions for FGS in IBD Version 1	39
15/LO/1700	Care.Know.Do Pilot: Version 1	37
15/LO/1732	VP-VEC-162-0101 - EFFECTS OF RAPID TRANSMERIDIAN TRAVEL	30
15/LO/1827	Evaluating a web-based intervention for maternal postpartum anxiety	36
15/LO/1831	PICUP Research Database 1.0	25
15/LO/1923	The Twelve TMVR Pilot Study	22
15/LO/1950	A Phase IIb/III study of ABT-414 for newly diagnosed glioblastoma	33

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/1974	Anti-atherogenic effects of anti-platelet agents (Version 1)	23
15/LO/1998	DEFINING IMMUNE PATHWAYS DRIVING GUT INFLAMMATION	24
16/LO/0026	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	24
16/LO/0028	EPOC	25
16/LO/0056	Robotic Retinal Dissection Device Study	24
16/LO/0061	Executive Dysfunction Partially Underlies Deficits in Theory of Mind	25
16/LO/0240	Prose - Cosentyx®/Secukinumab/AIN457	19
16/LO/0266	Habitual thinking and resilience in breast cancer survivors	18
16/LO/0284	VOICE PD Views on inpatient care Version 1	19
16/LO/0367	POPIN Study Version 1.5	23
16/LO/0409	Safety and Performance of IRIS V2 System	27
16/LO/0414	Randomised trial of LightPath Imaging in breast cancer surgery	24
16/LO/0436	APRICOT_V1	22
16/LO/0438	An exploration of interventions for severe eating disorders V1.0	22
16/LO/0441	Safety & Performance of Shockwave Coronary Rx Lithoplasty® System	22

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0982	AIRWAY EFFECTS OF TIOTROPIUM IN PATIENTS WITH COPD	43

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

15/LO/1678	OPuS 4 - Long term safety study of avoralstat	23
15/LO/1781	Is alcohol dependence associated with increased 18F Amyvid binding?	23
15/LO/1821	Disrupted Relationships: Psychosis and Connectedness	23
15/LO/1999	FATTY LIVER DISEASE IN HIV	21
16/LO/0002	Patient expectations and outcomes of orthodontic treatment	22
16/LO/0120	Validity & Reliability of Integrated Patient Outcome Scale IPOS-Renal	16
16/LO/0194	WiCS-LV Post Market Surveillance Registry	16

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/1468	Patient expectations and outcomes of orthodontic treatment	23

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
16/LO/0098	GROOVE and version 1.1	22

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
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Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q0703/198/AM06	Lymphoid Neogenesis In Rheumatoid Arthritis	3	28/08/2015	10
05/Q0703/198/AM07	Lymphoid Neogenesis In Rheumatoid Arthritis	4	09/11/2015	5
06/Q0703/40/AM15	PEG-IFN ± Lamivudine for chronic HBV infection in children	3	15/02/2016	11
07/Q0703/24/AM05	Improving outcomes in robotic prostate surgery using AR guidance	5	26/02/2015	12
07/Q0703/24/AM06	Improving outcomes in robotic prostate surgery using AR guidance	6	09/02/2016	15
08/H0808/177/AM02	Magnetic damping of nystagmus	2.0	30/04/2015	29
08/H0808/27/AM08	The Welfare of Children of Military Fathers	5.2	01/03/2015	6
08/H0808/27/AM09	The Welfare of Children of Military Fathers	5.3	01/05/2015	5
08/H0808/8/AM05	Barrett's oesophagus optical biopsy with ESS study (BOOST)	Am05	21/01/2015	23
08/H0808/8/AM06	Barrett's oesophagus optical biopsy with ESS study (BOOST)	Am06	21/09/2015	34
09/H0808/15/AM03	Non-invasive biomarkers and paediatric NAFLD v1.0	3.0	03/12/2015	22
09/H0808/98/AM04	Cartiva MOTION Study	D	19/01/2016	11
10/H0808/141/AM02	Longitudinal study non motor symptoms PD: treatment effect/tolerability	1	03/08/2015	8
10/H0808/27/AM05	Zenith TX2 Low-Profile Clinical Study #08-017-02	08-017-06	26/05/2015	22
10/H0808/7/AM21	Cortisol and memory in Alcoholics. Version 1	AM21	19/03/2015	13
10/H0808/7/AM23	Cortisol and memory in Alcoholics. Version 1	10	14/05/2015	6
11/LO/1243/AM02	Childhood blindness: genetic diagnosis for clinical management	2	04/08/2015	9
11/LO/1596/AM04	A RCT of PCI versus no PCI prior to TAVI	4.0	17/04/2015	18
11/LO/1818/AM02	Sensor based assessment of the upper limb following stroke: version 1	AM02	25/06/2015	6
12/LO/0235/AM05	ETOP LUNGSCAPE master protocol and LUNGSCAPE-001-ALK v1.0	3	25/03/2015	13
12/LO/0460/AM06	EURO-CTO	5	11/02/2016	5
12/LO/0588/AM24	MF/F Safety Study in Adolescent and Adult Persistent Asthmatics	1.0	19/11/2015	16
12/LO/0588/AM28	MF/F Safety Study in Adolescent and Adult Persistent Asthmatics	21	14/01/2016	8
12/LO/0588/AM29	MF/F Safety Study in Adolescent and Adult Persistent Asthmatics	AM29	01/03/2016	9
12/LO/0917/AM06	MOVE-IT (Motivational Enhanced Interviewing)	6	11/05/2015	1
12/LO/0917/AM07	MOVE-IT (Motivational Enhanced Interviewing)	7	07/09/2015	10
12/LO/0917/AM08	MOVE-IT (Motivational Enhanced Interviewing)	8	09/12/2015	25
12/LO/0990/AM05	EMTICS	5	07/08/2015	16
12/LO/0993/AM01	CWPS validation of digital pathology.	1	14/08/2015	12

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/1256/AM07	PliCath HFTM ECVR System, CIP-0015 Rev. D	11	04/09/2015	27
12/LO/1256/AM08	PliCath HFTM ECVR System, CIP-0015 Rev. D	12	04/11/2015	11
12/LO/1256/AM09	PliCath HFTM ECVR System, CIP-0015 Rev. D	13	04/02/2016	11
12/LO/1368/AM05	Fatigue and Inflammation	5	14/09/2015	5
12/LO/2017/AM06	Brain Imaging in Babies (BIBS)	6	12/03/2015	39
12/LO/2017/AM07	Brain Imaging in Babies (BIBS)	7	10/07/2015	20
12/LO/2034/AM03	Anti-psychotic Medication Side Effects PROM V1	3	28/07/2015	9
13/LO/0145/AM06	CLEOPATRA	5	24/09/2015	12
13/LO/0615/AM06	SGL-110 in patients with platinum-resistant recurrent ovarian cancer	AM06	07/04/2015	8
13/LO/0830/AM07	Lambda/Daclatasvir/Ribavirin for treatment of HCV/HIV co-infection	1	12/12/2014	20
13/LO/0907/AM04	NAPPA (version 1.0)	3	11/03/2015	28
13/LO/1475/AM02	CRT in narrow QRS heart failure with MRI dyssynchrony assessment	3.0	01/04/2015	13
13/LO/1475/AM03	CRT in narrow QRS heart failure with MRI dyssynchrony assessment	4	21/01/2016	23
13/LO/1542/AM01	Haemodynamic Changes After Percutaneous Aortic Valve Intervention	1	11/03/2015	7
13/LO/1542/AM02	Haemodynamic Changes After Percutaneous Aortic Valve Intervention	2	20/06/2015	21
13/LO/1542/AM03	Haemodynamic Changes After Percutaneous Aortic Valve Intervention	3	30/09/2015	15
13/LO/1651/AM05	Evaluation of the NSPCC UK Minding the Baby Programme	Am05	16/06/2015	6
13/LO/1651/AM06	Evaluation of the NSPCC UK Minding the Baby Programme	Am06	04/02/2016	14
13/LO/1838/AM03	deferasirox plus erythropoietin vs erythropoietin alone in MDS	3	14/08/2015	7
14/LO/0052/AM02	MASTER SL clinical study	2	01/07/2015	7
14/LO/0353/AM03	PERIGON Pivotal Trial	1E	22/04/2015	12
14/LO/0389/AM05	BioStent	AM05	20/03/2015	7
14/LO/0389/AM06	BioStent	06	26/05/2015	7
14/LO/0389/AM07	BioStent	07	02/10/2015	24
14/LO/0609/AM04	E5501-G000-310 Thrombocytopenia associated with Liver Disease	ed11	03/03/2015	27
14/LO/0609/AM05	E5501-G000-310 Thrombocytopenia associated with Liver Disease	4	22/06/2015	20
14/LO/0690/AM02	George's Capillary Rarefaction Offspring Study, G-CROS	2	12/07/2015	25
14/LO/0775/AM02	Safety study of dCELL® Meniscus Version 01	01	29/06/2015	6
14/LO/0875/AM02	CtG Huddle	2	15/09/2015	26
14/LO/1125/AM03	Newron phase 1 study treating patients with Parkinson's Disease	AM03	30/09/2015	12
14/LO/1200/AM01	Evaluation of the safety & performance of 2 intradermal safety devices	1	07/08/2015	25
14/LO/1200/AM02	Evaluation of the safety & performance of 2 intradermal safety devices	2	15/09/2015	5
14/LO/1375/AM01	SMART TARGET (Therapy Study)	001	01/08/2015	20

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1588/AM02	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	2	28/05/2015	5
14/LO/1588/AM03	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	2	24/08/2015	3
14/LO/1608/AM02	The GHB Trial	2	30/07/2015	26
14/LO/1615/AM01	Naltrexone Enhanced Addiction Treatment (NEAT)	SA1	23/07/2015	15
14/LO/1615/AM02	Naltrexone Enhanced Addiction Treatment (NEAT)	SA2	13/08/2015	7
14/LO/1615/AM04	Naltrexone Enhanced Addiction Treatment (NEAT)	SA3	03/12/2015	14
14/LO/1730/AM01	Electronic intervention to reduce antibiotic prescribing (eCRT2 Study)	1	06/05/2015	6
14/LO/1751/AM04	Barriers to uptake of diabetes education	1	27/04/2015	15
14/LO/1927/AM02	M14-567 - Study in Subjects with Genotype 3 Chronic HCV infection	0.03	18/02/2015	15
14/LO/1927/AM03	M14-567 - Study in Subjects with Genotype 3 Chronic HCV infection	AM03	10/06/2015	1
14/LO/1927/AM04	M14-567 - Study in Subjects with Genotype 3 Chronic HCV infection	0.03.02	21/10/2015	19
14/LO/1934/AM04	Intervention for Improving Psychological Distress in Dialysis (iDiD)	One	11/05/2015	18
14/LO/1974/AM03	To Assess the Effect of RNS60 and Budesonide in Asthmatic Patients	2.0	26/03/2015	13
14/LO/1974/AM04	To Assess the Effect of RNS60 and Budesonide in Asthmatic Patients	2.3	23/04/2015	4
14/LO/1974/AM05	To Assess the Effect of RNS60 and Budesonide in Asthmatic Patients	SA04	08/06/2015	32
14/LO/1974/AM07	To Assess the Effect of RNS60 and Budesonide in Asthmatic Patients	SA05	30/07/2015	12
14/LO/2067/AM01	Aneurysm-ULTRA	1	21/07/2015	18
14/LO/2129/AM01	The VIOLET study	1	08/06/2015	27
14/LO/2129/AM03	The VIOLET study	2	08/10/2015	6
14/LO/2143/AM02	Cardialen CESS V5	2	08/10/2015	20
15/LO/0020/AM01	REVITA-1 study	1	08/05/2015	28
15/LO/0020/AM02	REVITA-1 study	2	08/07/2015	14
15/LO/0020/AM03	REVITA-1 study	3	11/09/2015	12
15/LO/0047/AM01	Intrinsic PEEP and laryngeal aperture in COPD	AM01	16/06/2015	3
15/LO/0198/AM01	Compassion Focused Therapy for distressing experiences	1	18/05/2015	13
15/LO/0436/AM01	The PREDICT Study	001/2015	07/09/2015	4
15/LO/0652/AM01	BMS A1468-038: Phase 2b HIV-1 Maturation Inhibitor study	01	11/06/2015	26
15/LO/0652/AM02	BMS A1468-038: Phase 2b HIV-1 Maturation Inhibitor study	EC 02	21/08/2015	25
15/LO/0671/AM01	A Prospective, Observational Study of MPS IIIB	1	17/06/2015	20
15/LO/0880/AM01	Stress-reactivity in clinical and non-clinical voice hearers	1	14/08/2015	12
15/LO/0880/AM03	Stress-reactivity in clinical and non-clinical voice hearers	3	09/10/2015	4
15/LO/0982/AM01	AIRWAY EFFECTS OF TIOTROPIUM IN PATIENTS WITH COPD	2	22/10/2015	14
15/LO/1553/AM02	POST 4	2	04/12/2015	10

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/1554/AM01	POST 5	1	08/01/2016	3
16/LO/0061/AM01	Executive Dysfunction Partially Underlies Deficits in Theory of Mind	1.0	01/03/2016	7

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1125/AM02	Newron phase 1 study treating patients with Parkinson's Disease	5	03/06/2015	27

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

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1125/AM02/1	Newron phase 1 study treating patients with Parkinson's Disease	AM05	03/06/2015	13

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
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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
12/LO/2017/AM06	Brain Imaging in Babies (BIBS)	6	12/03/2015	39

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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