

**London - Surrey Borders Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	London - Surrey Borders Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Healthy Volunteers
Chair:	Sir Adrian Baillie
Vice-Chair:	Mr. Derek Cock
Alternate Vice-Chair:	Dr. Mark Weeks
REC Manager:	Barbara Cuddon Mr Atul Patel (until end of August 2015)
REC Assistant:	Ms. Fola Ovie-Afabor
Committee Address:	Research Ethics Committee (REC) London Centre Ground Floor Skipton House 80 London Road London SE1 6LH
Telephone:	0207 972 2568
Email:	nrescommittee.london-surreyborders@nhs.net

Chair's overview of the past year:

2015-2016 was a challenging year for the ethics service as the creation of the new HRA Approval service led to a large number of HRA office staff changing roles. Our committee was not unusual in saying goodbye to its manager mid-way through the year, and we offer our thanks to Atul and wish him well in his new post. Happily, our new manager, Barbara, was appointed without too much of a gap and the disruption to the REC was managed well.

Two valued members left during the period, both due to a change in professional role that left them unable to donate their time. This is an increasing problem - we wish the individuals well, but do wish that NHS employers would be more supportive of our work and enable staff to join committees. On the other hand we are delighted to have also welcomed two new members so our membership level remains acceptable.

We remain a busy REC with an interesting range of studies and a particularly high level of amendments. Because of the wide range of studies that we review, we can't stress enough how grateful we are when researchers attend meetings, which they do more often than not, as this greatly aids our review and improves the process for all involved.

London - Surrey Borders Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Sir Adrian Baillie	Financial Investment Advisor	Lay Plus	01/04/2014	
Ms. Christine Braithwaite	Director of Standards and Policy	Lay Plus	10/02/2015	
Mr. Derek Cock	Chief Pharmacist	Expert	03/02/2007	
Mr. Tobias Davis	Medical Device Specialist	Expert	02/02/2015	
Mr. Dominic Fairclough	Solicitor	Lay Plus	01/04/2009	
Mr David Fitzgerald	Radioisotope Services Manager	Expert	01/11/2014	30/06/2015
Mrs. Anne Laurie	Lecturer in Clinical Communications	Lay	01/06/2007	
Dr. David Lukey	Management Consultant	Expert	02/02/2015	
Dr. Rosemary O'Neil	Senior Lecturer (Statistics and Mathematics)	Lay Plus	01/12/2008	
Dr. Anand Patel	Medical Director (Drug Development)	Expert	01/04/2015	
Ms. Sibonginkosi Sibanda	Advanced Nurse Practitioner	Expert	01/12/2014	
Dr. Elizabeth Smyth	Clinical Research Fellow	Expert	01/05/2015	
Mr. Graham Tate	Tissue Bank Manager	Expert	03/06/2013	
Mrs Jana Wanli	MSc Neuroscience Student	Lay Plus	18/06/2013	06/10/2015
Dr. Mark Weeks	Senior Research Associate	Expert	03/06/2013	

London - Surrey Borders Research Ethics Committee : Members' Declarations of Interest:

Name	Declaration of Interest	Date
Sir Adrian Baillie	From time to time minor (less than 1%) positions may be held by external fund managers I employ – I have none.	31/03/2016
Sir Adrian Baillie	Trustee Hepatitis C Trust	31/03/2016
Sir Adrian Baillie	Trustee Gawaine Stamp Fund (Small-Medium Charity)	31/03/2016
Sir Adrian Baillie	Shadow Governor Surrey and Sussex Healthcare Trust	31/03/2016
Ms. Christine Braithwaite	Director, Professional Standards Authority. We commission research as part of our work.	13/01/2016
Mr. Derek Cock	Occasional consultancy with Pharma.	31/03/2016
Mr. Derek Cock	Kingston Hospital R & D Committee member. .	31/03/2016
Mr. Derek Cock	Justice of the Peace	31/03/2016
Mr. Derek Cock	Involvement in drug studies at Kingston Hospital.	31/03/2016
Mr. Tobias Davis	Permanent Job Role - Affiliate Quality and Regulatory Head at Roche Diabetes Care UK & Ireland Ltd	13/01/2016
Mr. Dominic Fairclough	None	09/03/2016
Mrs. Anne Laurie	Member and Chair of local women's groups that often fundraise for health and social care, these are the Ladies Circle, Tangent Club and Inner Wheel clubs of Wallington & Carshalton in Surrey.	15/01/2016
Mrs. Anne Laurie	As a lecturer in Clinical Communication working in both a NHS Trust and a London Medical School there may be times when I could possibly come into contact with related interested parties.	15/01/2016
Dr. David Lukey	CEO of Healthcare Innovations Group (HIG) Ltd	13/01/2016
Dr. Rosemary O'Neil	Occasional statistical analysis on ad-hoc basis. There has never been a problem in the past.	26/01/2016
Dr. Anand Patel	Employed by Ipsen Biopharm . Holds shares in Actavis	10/06/2015
Ms. Sibonginkosi Sibanda	Co-Chair, International Council of Nurses, APN/ANP Network (Practice Sub-Group)	26/01/2016
Dr. Elizabeth Smyth	Member drugged therapeutics committee, royal Marsden sub investigator in multiple royal Marsden GI unit clinical trial.	16/03/2016
Dr. Elizabeth Smyth	None.	12/05/2015
Mr. Graham Tate	Advisor to R&D Department at Barts NHS Trust in relation to human tissue issues.	26/01/2016
Dr. Mark Weeks	Research scientist working in pancreatic cancer research, any conflict to know colleagues will be flagged.	16/03/2016

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

Month	Date	Number of Members Present at Meeting
April	08/04/2015	9
May	13/05/2015	12
June	10/06/2015	15
July	08/07/2015	12
September	09/09/2015	10
October	14/10/2015	11
November	11/11/2015	9
December	09/12/2015	10
January	13/01/2016	10
March	09/03/2016	11

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
June	10/06/2015	3
July	08/07/2015	3
November	11/11/2015	3
December	09/12/2015	3
January	13/01/2016	3
February	10/02/2016	3

7 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	08/04/2015	2
April	29/04/2015	4
May	13/05/2015	2
May	26/05/2015	3
June	10/06/2015	2
July	08/07/2015	2
July	29/07/2015	2
August	18/08/2015	2
September	09/09/2015	2
September	23/09/2015	2
October	01/10/2015	2
October	14/10/2015	2
October	28/10/2015	2

November	06/11/2015	2
November	11/11/2015	2
November	25/11/2015	2
November	27/11/2015	2
December	09/12/2015	2
December	23/12/2015	2
January	13/01/2016	2
January	27/01/2016	2
February	25/02/2016	2
March	10/03/2016	2
March	16/03/2016	2
March	30/03/2016	2
March	31/03/2016	2

26 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

Name	Number of Meetings Attended
Sir Adrian Baillie	9
Ms. Christine Braithwaite	7
Mr. Derek Cock	9
Mr. Tobias Davis	10
Mr. Dominic Fairclough	8
Mr David Fitzgerald	3
Mrs. Anne Laurie	9
Dr. David Lukey	9
Dr. Rosemary O'Neil	7
Dr. Anand Patel	5
Ms. Sibonginkosi Sibanda	10
Dr. Elizabeth Smyth	8
Mr. Graham Tate	9
Mrs Jana Wanli	3
Dr. Mark Weeks	3

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

Name	Number of Meetings Attended
Sir Adrian Baillie	2
Mr. Derek Cock	5
Mrs. Anne Laurie	6
Mr. Graham Tate	4
Dr. Mark Weeks	4

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

Name	Number of Meetings Attended
Sir Adrian Baillie	16
Ms. Christine Braithwaite	2
Mr. Derek Cock	9
Mr. Tobias Davis	1
Mr David Fitzgerald	1
Mrs. Anne Laurie	2
Dr. David Lukey	1
Dr. Rosemary O'Neil	4
Dr. Anand Patel	3

Ms. Sibonginkosi Sibanda	2
Dr. Elizabeth Smyth	1
Mr. Graham Tate	5
Dr. Mark Weeks	8

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Sir Adrian Baillie	19/05/2015	London NREAP Chair's Meeting
Sir Adrian Baillie	26/11/2015	London REC Members' Training day
Ms. Christine Braithwaite	14/04/2015	Equality & Diversity
Ms. Christine Braithwaite	15/06/2015	Committee Members Induction
Ms. Christine Braithwaite	26/11/2015	London REC Members' Training day
Mr. Derek Cock	29/09/2015	Training - Genetic and Genomic Research (previously HTA Advanced)
Mr. Tobias Davis	12/05/2015	Online Induction for new Research Ethics Service Committee members
Mr. Tobias Davis	15/06/2015	Committee Members Induction
Mr. Dominic Fairclough	29/04/2015	Association of Personal Injury Lawyers Annual Conference
Mr. Dominic Fairclough	26/06/2015	AvMA Annual Conference
Mrs. Anne Laurie	26/11/2015	London REC Members' Training Day
Dr. David Lukey	04/06/2015	Online Member Induction
Dr. David Lukey	15/06/2015	Committee Members Induction
Dr. David Lukey	26/11/2015	London REC Members' Training day
Dr. David Lukey	18/02/2016	Training-National Members Training Day
Dr. Rosemary O'Neil	01/04/2015	Equality & Diversity
Dr. Rosemary O'Neil	05/05/2015	Phase 1 Site Visit with other LSB Members
Dr. Rosemary O'Neil	17/12/2015	RSS/HRA co-sponsored workshop for Statistician Members of RECS
Dr. Anand Patel	15/06/2015	Committee Members Induction
Ms. Sibonginkosi Sibanda	20/05/2015	CTIMP Training Day
Ms. Sibonginkosi Sibanda	04/09/2015	Local Training - Joint Oxford Training
Ms. Sibonginkosi Sibanda	26/11/2015	London REC Members' Training day
Dr. Elizabeth Smyth	15/06/2015	Committee Members Induction
Dr. Elizabeth Smyth	27/11/2015	CTIMP Training Day
Mr. Graham Tate	04/09/2015	Local Training - Joint Oxford Training
Mr. Graham Tate	26/11/2015	London REC Members' Training day
Dr. Mark Weeks	26/11/2015	London REC Members' Training day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	12	23.08
Phase 1	4	7.69
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	36	69.23
Total Applications Reviewed	52	100

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

Number of applications made invalid by the REC Manager	5
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	5
Number of device applications reviewed	7
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	2

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	1	1.92
Favourable Opinion with Additional Conditions	14	26.92
Unfavourable Opinion	7	13.46
Provisional Opinion	30	57.69
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	52	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	28	53.85
Further Information Favourable Opinion with Additional Conditions	2	3.85
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	14	26.92
Unfavourable Opinion	7	13.46
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	0	0.00
Total	52	100

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

Total Applications Reviewed	14
------------------------------------	-----------

Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	5
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	3	21.43
Favourable Opinion with Additional Conditions	3	21.43
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	8	57.14
Unfavourable Opinion	0	0.00
Total	14	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	5.20
Number of completed applications for full ethical review	52
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	12
Number of completed applications over 40 days as a % of total	23.08%
Number of days taken to final decision – average (mean)	33
Number of completed proportionate review applications for ethical review	14
Number of completed proportionate review applications for ethical review over 14 days	3
Number of completed proportionate review applications over 14 days as a % of total	21.43%
Number of SSAs (non-Phase 1) reviewed	4
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	25.00%
Number of SSAs (Phase 1) reviewed	6
Number of completed applications for SSA review over 14 days	1
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	16.67%
Number of substantial amendments reviewed	114
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.88%
Number of completed substantial amendments over 28 days	27
Number of completed substantial amendments over 28 days as a % of total substantial amendments	23.68%
Number of modified amendments reviewed	5
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	89
Number of substantial amendments received for	1

information	
Number of substantial amendments received for new sites/PIs	33
Number of annual progress reports received	60
Number of safety reports received	50
Number of Serious Adverse Events received	11
Number of final reports received	24

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/0539	RAIDER	28
15/LO/0553	OPERO Version 1.0	31
15/LO/0595	CBD - Sleep and Waking Performance	37
15/LO/0808	How does the review process support adults post-stroke?	36
15/LO/0818	Inhaled RNS60 Vapour Study	32
15/LO/0846	MM-0100 RCT205	29
15/LO/0849	Trident–Accolade THR with LFIT head and X3 poly surveillance study	25
15/LO/0952	Effects of exercise on Pompe disease_Version 1	28
15/LO/1003	MINSTREL v1.5	30
15/LO/1016	Phase I study of oral BAY 1143269 given alone or in combination with intravenous doxetacel	40
15/LO/1117	17110 - radium Ra 223 dichloride plus paclitaxel in cancer patients	47
15/LO/1118	BET115521: GSK525762 in Subjects with Solid Tumours	28
15/LO/1159	TiLE – Time Lapse Eeva™	42
15/LO/1203	Influencing Factors on Parent-Infant Psychotherapy	35
15/LO/1484	Contextualising Abortion: A life narrative study of abortion and class	58
15/LO/1500	1199.229 Drug-drug interaction study with nintedanib and pirfenidone	43
15/LO/1692	M15-684 AbbVie 3DAA Regimen in HCV GT1b (GARNET)	44
15/LO/1701	Virtual chromoendoscopy for colitis surveillance	38
15/LO/1825	Open label Phase 1b Qt/QTc study of ARN-509 in CR Prostate Cancer	42
15/LO/1836	TRIGGER Trial Version 1.0	45
15/LO/1985	Mitral TRACER Trial	48
15/LO/2028	TAS3681 in Metastatic Castration Resistant Prostrate Cancer	55
15/LO/2111	Prediction of Extubation Outcome by the Spontaneous Breathing Trial	49
16/LO/0065	Therapy withdrawal in REcovered Dilated cardiomyopathy trial (TRED)	28
16/LO/0080	Exploring the role of the AHR in Gut Immunology	28
16/LO/0397	Phase 1b Dose Escalation + Dose Expansion Study of Demcizumab	45
16/LO/0401	Parents' experience of decision making in PICU	36
16/LO/0423	A CRUK Phase I trial of CCT245737 in patients with advanced cancer	40

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0842	Therapeutic Alliance and the STEPPS Programme	36
16/LO/0422	A CRUK Phase I trial of oral CCT245737 given in combination	40

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
15/LO/1933	Utility of IRIDICA rapid microbial screening in newborn infections	41

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0579	Pk study on fluticasone/ salmeterol combinations (OTT329/214)	35
15/LO/0634	LONGEVITY Study	28
15/LO/0843	Feasibility and efficacy of resistance training in CP. Version 1.	23
15/LO/1360	(duplicate) Community-Based Antimicrobial Resistance Spread - Feasibility Studies	26
15/LO/1444	The Platinum Study - Version 2.0, 9th July 2015	21
15/LO/1534	Early Prolonged Ambulatory Cardiac monitoring in Stroke (EPACS)	26
15/LO/1649	T-cell diversity following intranasal and intramuscular vaccines	27
15/LO/1693	Comparing functional and integrated mental health care (COFI-FU)	27
15/LO/1739	The experience of mastectomy patients on the 23 hour pathway	27
15/LO/1940	Diabetic Foot Ulcer Prevention System (DFUPS)- part 2	28
15/LO/2039	PET scanning in evaluation of vaccine reactogenicity; v1	28
15/LO/2099	INNOVATE	28
16/LO/0063	Imaging NSCLC treatment response to immunotherapy	22
16/LO/0403	EXTREQOL	22

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

15/LO/0654	Community-Based Antimicrobial Resistance Spread - Feasibility Studies	28
15/LO/0929	Dietary salt and blood pressure in haemodialysis patients: Version 1	28
15/LO/1069	Kinesiotaping in Lymphoedema Management (version 1)	28
15/LO/1730	Mitral TRACER Trial	27
15/LO/2109	An Evaluation of the Solaticare System of Hygienic Care	28
16/LO/0062	Use of Electromyography in spinal nerve root blocks under CT guidance	22
16/LO/0316	An Evaluation of the Solaticare System of Hygienic Care	22

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
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 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/0644	MR only radiotherapy planning	18
15/LO/0649	Privacy in activity monitoring of knee surgery patient recovery	18
15/LO/1095	Survey of physical activity in Haemophiliacs and their beliefs.	13
15/LO/1257	Patients' information needs to aid decision making on knee replacement	11

15/LO/2161	SPREE (version 1.0)	13
15/LO/2163	Epidural fat in IIH	14
16/LO/0315	Social Cognition in patients with Non Epileptic Attack Disorder	13

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1253	ACCEPT- Methodology to assess acceptability of paediatric medicines.	14

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
15/LO/2157	Evaluating Outcomes from Genetic Counselling	13
16/LO/0111	Pain management at home following corrective spinal surgery	12
16/LO/0121	Morphological assessment of the ankle Version 1.2	12

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/2017	Testing the usability of the eRAPID system in surgery	15
16/LO/0115	Focused Diffusion Weighted Imaging in Prostate Cancer	12
16/LO/0311	Experiences of living with cancer and functional impairment	8

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/Q0806/34+5/AM01	Neonatal Infection Surveillance Database (neonIN)	1	24/07/2015	33
08/H0806/98/AM04	MM Genetics	4	13/02/2015	19
10/H0806/100/AM25	AZD5363 Safety & Tolerability in Patients with Advanced Solid Tumours	9	07/04/2015	36
10/H0806/118/AM06	CASPS	Protocol Version 5.0	16/04/2015	2
10/H0806/118/AM07	CASPS	6	10/06/2015	15
10/H0806/71/AM17	Carfilzomib in patients with Relapsed Multiple Myeloma	Protocol amendment 5, IB15, IB	18/12/2015	35
11/LO/0350/AM03	Cortical Pain Responses in Human Infants	AM03	24/02/2015	27
11/LO/0619/AM20	E7080 alone or with Everolimus in patients with renal cell carcinoma	AM20	11/11/2014	17
11/LO/0619/AM21	E7080 alone or with Everolimus in patients with renal cell carcinoma	1 2015/10/15	15/10/2015	29
11/LO/1267/AM10	The ATLAS Trial	9	05/05/2015	2
11/LO/1267/AM11	The ATLAS Trial	Substantial Amendment 10	30/09/2015	10
11/LO/2019/AM11	TOPARP	MREC9MHRA4	01/07/2015	20
11/LO/2022/AM09	A phase 1b study of patients with selected advanced solid tumours	Am07	14/04/2015	27
11/LO/2022/AM10	A phase 1b study of patients with selected advanced solid tumours	1	20/11/2015	28
12/LO/0105/AM01	Blood Donation	No1 24 Sep 2015	24/09/2015	16
12/LO/1606/AM03	MPD-RC 112 (Pegasys)	01/04/2015	01/04/2015	35
12/LO/1606/AM05	MPD-RC 112 (Pegasys)	8.0	21/12/2015	7
12/LO/1722/AM13	Helping older women make choices about breast cancer treatment	13	22/06/2015	27

12/LO/1812/AM03	Mechanisms by which obesity predisposes to severe H1N1 infection 1.0	3	12/05/2015	15
12/LO/1825/AM10	Rilotumumab (AMG 102) with ECX in advanced gastric cancer	9	18/03/2015	28
13/LO/0398/AM07	Cancer presentation and diagnosis study	Substantial Amendment 2	17/08/2015	12
13/LO/0528/AM16	Rivaroxaban vs. Vitamin K antagonist in AF patients undergoing a PCI	Substantial Amendment INT 10	07/12/2015	30
13/LO/0665/AM05	Study with secukinumab in palmoplantar psoriasis	5	08/04/2015	22
13/LO/0666/AM07	A clinical study to evaluate secukinumab in Nail Psoriasis	5	30/03/2015	18
13/LO/0826/AM17	C diffense	AM17	05/05/2015	14
13/LO/0863/AM01	The role of PDE-10A in Parkinson's disease L-dopa-induced dyskinesias.	1	07/07/2015	29
13/LO/0867/AM08	1199.93 - Nintedanib in mesothelioma	SA7	16/02/2016	8
13/LO/0935/AM03	A Phase I trial of ONX-0801	2.0	24/06/2015	16
13/LO/0935/AM04	A Phase I trial of ONX-0801	5	11/12/2015	22
13/LO/0983/AM05	GO28625 - Phase II study of MPDL3280A for non-small cell lung cancer	6	06/12/2014	34
13/LO/0983/AM06	GO28625 - Phase II study of MPDL3280A for non-small cell lung cancer	IB7, UKICF V4 and Prot V7	12/11/2015	21
13/LO/1081/AM05	PROSPER:MDV3100-14 Phase 3,Enzalutamide,non-metastatic CRPC patients	SA#5	07/09/2015	15
13/LO/1083/AM04	C32001 MLN0128 + MLN1117 in advanced non-haematologic malignancies	SA#4	30/10/2015	13
13/LO/1320/AM13	STUDY OF FAI INSERT IN SUBJECTS WITH CHRONIC NON-INFECTIOUS UVEITIS	8 2015/07/02	02/07/2015	25
13/LO/1350/AM03	HYBRID	2	27/07/2015	6
13/LO/1352/AM07	GO28753 Anti-PDL1 in NSCLC	4	24/02/2015	27
13/LO/1352/AM09	GO28753 Anti-PDL1 in NSCLC	SA#5	06/01/2016	26
13/LO/1482/AM06	MDV3100-10 TBP, Phase 4, Enzalutamide, metastatic CRPC patients	SA#6	19/10/2015	25
13/LO/1616/AM08	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	7	24/03/2015	24
13/LO/1616/AM10	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	8	25/03/2015	23

13/LO/1616/AM14	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA #10	21/12/2015	32
13/LO/1616/AM18	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA#12	11/03/2016	9
13/LO/1684/AM03	Direct Flow Medical DISCOVER Registry	#4	06/10/2015	22
13/LO/1684/AM04	Direct Flow Medical DISCOVER Registry	#5	14/12/2015	20
13/LO/1850/AM04	Phase 1 advanced cancer study of VS-5584	#4 VS5584101	04/09/2015	28
13/LO/1850/AM05	Phase 1 advanced cancer study of VS-5584	VS-5584-101 3.1	16/12/2015	21
13/LO/1850/AM07	Phase 1 advanced cancer study of VS-5584	5.1	18/02/2016	11
14/LO/0080/AM08	Luster PCI32765FLR3001	Substantial Amendment for INT2	15/09/2015	34
14/LO/0080/AM10	Luster PCI32765FLR3001	AM10	02/03/2016	19
14/LO/0259/AM02	RE-AKT	MREC2MHRA1	24/07/2015	3
14/LO/0503/AM07	Safety and PK of single doses of GBR 900 in healthy adults	4.0	29/09/2015	13
14/LO/0636/AM01	PHANSS-1	Amendment Number 1	22/02/2016	12
14/LO/1064/AM07	BYM338B2201 A Possible Treatment for Muscle Wasting after Hip Fracture	5	25/06/2015	25
14/LO/1064/AM08	BYM338B2201 A Possible Treatment for Muscle Wasting after Hip Fracture	Substantial Amendment 5	07/09/2015	35
14/LO/1064/AM09	BYM338B2201 A Possible Treatment for Muscle Wasting after Hip Fracture	Am06	15/03/2016	8
14/LO/1247/AM01	BF4	2.0	20/11/2015	8
14/LO/1385/AM06	REASURE (Radium-223: Evaluation of Activity and SURrogate REsponse)	REC2/MHRA1	22/02/2016	28
14/LO/1425/AM03	CHM for RUTIs	3	30/11/2015	21
14/LO/1485/AM03	A study to evaluate SYD985 in advanced or metastatic solid tumours	Substantial Amendment 3	04/08/2015	16
14/LO/1485/AM05	A study to evaluate SYD985 in advanced or metastatic solid tumours	Substantial Amendment 4	20/01/2016	24
14/LO/1617/AM06	Type I DM Study	SA05	12/03/2015	24
14/LO/1800/AM06	Treating pulmonary fibrosis with co-trimoxazole	2	13/04/2015	23
14/LO/1804/AM04	A Phase I Study of CAVATAKâ„¢ in Patients with Bladder Cancer	SA03_IB V13 PICF V3	22/09/2015	10

14/LO/1874/AM01	Evaluation of Physiotherapist and Podiatrist Independent Prescribing	1	11/05/2015	7
14/LO/1996/AM06	VS-6063-104 Phase 1 study in relapsed malignant mesothelioma	Substantial Amendment 2	15/12/2015	20
14/LO/2024/AM01	A Phase 1 study of oral TVB-2640 in Patients with Solid Tumours	1	06/03/2015	30
14/LO/2024/AM04	A Phase 1 study of oral TVB-2640 in Patients with Solid Tumours	UK Amendment 4.0	20/08/2015	32
14/LO/2156/AM01	A phase II study of VSN16R for Multiple Sclerosis related spasticity	1	07/04/2015	24
14/LO/2156/AM06	A phase II study of VSN16R for Multiple Sclerosis related spasticity	Substantial Amendment 4	04/12/2015	22
14/LO/2156/AM07	A phase II study of VSN16R for Multiple Sclerosis related spasticity	5.0	29/02/2016	27
14/LO/2163/AM04	MUK Seven	2.0	29/06/2015	21
14/LO/2188/AM01	K-07 Physica KR Fluoroscopy study	1	28/04/2015	7
14/LO/2225/AM01	(duplicate) modafinil in hypercapnic respiratory failure	1	23/03/2016	25
14/LO/2226/AM03	Gene expression profiles in muscle after immunisation	1	02/03/2015	32
15/LO/0044/AM03	panRAF v1.0	1	30/04/2015	12
15/LO/0263/AM02	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	SA-2	14/08/2015	32
15/LO/0263/AM03	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	CDI-CS-002 SA-3	17/12/2015	21
15/LO/0539/AM01	RAIDER	Amendment 1	18/08/2015	21
15/LO/0595/AM01	CBD - Sleep and Waking Performance	1.0	22/06/2015	25
15/LO/0595/AM03	CBD - Sleep and Waking Performance	SA002	29/09/2015	16
15/LO/0595/AM05	CBD - Sleep and Waking Performance	SA003	02/11/2015	10
15/LO/0649/AM01	Privacy in activity monitoring of knee surgery patient recovery	1	24/06/2015	21
15/LO/0649/AM02	Privacy in activity monitoring of knee surgery patient recovery	2	28/07/2015	21
15/LO/0649/AM03	Privacy in activity monitoring of knee surgery patient recovery	3.0	21/10/2015	16
15/LO/0649/AM04	Privacy in activity monitoring of knee surgery patient recovery	alternative of synchronization	14/01/2016	19
15/LO/0842/AM02	Therapeutic Alliance and the STEPPS Programme	1 01/09/15	01/09/2015	33
15/LO/0843/AM02	Feasibility and efficacy of resistance training in CP. Version 1.	1	06/07/2015	10

15/LO/0843/AM03	Feasibility and efficacy of resistance training in CP. Version 1.	2	18/08/2015	24
15/LO/0843/AM04	Feasibility and efficacy of resistance training in CP. Version 1.	AM03	15/02/2016	18
15/LO/0846/AM02	MM-0100 RCT205	Substantial Amendment dated 1s	01/09/2015	33
15/LO/0846/AM03	MM-0100 RCT205	Amendment 2	23/10/2015	21
15/LO/0846/AM04	MM-0100 RCT205	3	26/11/2015	13
15/LO/0952/AM01	Effects of exercise on Pompe disease_Version 1	1	15/07/2015	28
15/LO/0952/AM04	Effects of exercise on Pompe disease_Version 1	amendment 2	25/11/2015	32
15/LO/1003/AM01	MINSTREL v1.5	Amendment No 1	01/02/2016	8
15/LO/1117/AM01	17110 - radium Ra 223 dichloride plus paclitaxel in cancer patients	Substantial Amendment 1	11/09/2015	25
15/LO/1117/AM03	17110 - radium Ra 223 dichloride plus paclitaxel in cancer patients	Amendment 2	23/12/2015	30
15/LO/1118/AM01	BET115521: GSK525762 in Subjects with Solid Tumours	01	21/08/2015	17
15/LO/1118/AM02	BET115521: GSK525762 in Subjects with Solid Tumours	Substantial Amendment 02	14/09/2015	6
15/LO/1253/AM02	ACCEPT- Methodology to assess acceptability of paediatric medicines.	SA01	18/11/2015	30
15/LO/1257/AM01	Patients' information needs to aid decision making on knee replacement	1.0	09/12/2015	22
15/LO/1500/AM03	1199.229 Drug-drug interaction study with nintedanib and pirfenidone	AM03	11/03/2016	25
15/LO/2039/AM01	PET scanning in evaluation of vaccine reactogenicity; v1	Am01	15/03/2016	7

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0806/71/AM15	Carfilzomib in patients with Relapsed Multiple Myeloma	AM15	09/06/2015	34
12/LO/1081/AM08	GO25632-Phase 3 study for treatment of metastatic breast cancer	Substantial Amendment 7 Protoc	14/09/2015	35
13/LO/0867/AM07	1199.93 - Nintedanib in mesothelioma	SA6	28/10/2015	35

13/LO/1320/AM14	STUDY OF FAI INSERT IN SUBJECTS WITH CHRONIC NON-INFECTIOUS UVEITIS	Investigator's Brochure 7	09/11/2015	35
13/LO/1616/AM11	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	9	26/05/2015	21
14/LO/0503/AM05	Safety and PK of single doses of GBR 900 in healthy adults	3	16/03/2015	35
14/LO/1171/AM05	LNP3794 in patients with Advanced Solid Tumours having Mutations	Protocol amendment no. 3 dated	08/01/2016	32
14/LO/1425/AM01	CHM for RUTIs	1 30th September 2015	30/09/2015	26
14/LO/1633/AM01	Case-control study of inherited women's cancer	Amendment 1, 31 July 2015	20/08/2015	35
14/LO/1804/AM05	A Phase I Study of CAVATAK™ in Patients with Bladder Cancer	SA04_protocol v2.3	02/02/2016	20
14/LO/2163/AM03	MUK Seven	2	29/06/2015	28

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

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/1081/AM08/1	GO25632-Phase 3 study for treatment of metastatic breast cancer	6	25/02/2016	5
13/LO/0867/AM07/1	1199.93 - Nintedanib in mesothelioma	SA6 - Modified	28/10/2015	8
14/LO/0503/AM05/1	Safety and PK of single doses of GBR 900 in healthy adults	3	16/03/2015	13
14/LO/1425/AM01/1	CHM for RUTIs	2	30/10/2015	10
14/LO/1633/AM01/1	Case-control study of inherited women's cancer	Amendment 2	22/12/2015	8

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/0644	MR only radiotherapy planning	18
15/LO/0649	Privacy in activity monitoring of knee surgery patient recovery	18
15/LO/2017	Testing the usability of the eRAPID system in surgery	15

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/1601	Feasibility and efficacy of resistance training in CP. Version 1.	32

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/0757	A Phase 1, Double Blind, Rando	35

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0806/100/AM25	AZD5363 Safety & Tolerability in Patients with Advanced Solid Tumours	9	07/04/2015	36

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------

