

**London - Surrey Borders Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



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 STIMPS in patients – type III
Type of Flag:	Phase I Studies in Healthy Volunteers
Chair:	Sir Adrian Baillie
Vice-Chair:	Mr. Derek Cock
Alternate Vice-Chair:	Ms. Christine Braithwaite
REC Manager:	Barbara Cuddon
REC Assistant:	Ms. Fola Ovie-Afabor (February 2016 to July 2016) Ms Zuleka Alawa (July 2016 to January 2017) Ms Marisa Scott (February to May 2017) Miss Patrycja Pysz (May 2017 to date)
Committee Address:	Research Ethics Committee (REC) London Centre Ground Floor Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

2016-2017 was another busy year for the committee, with some challenges having resolved from the year before, and some remaining. We are very glad that our manager, Barbara, remains with the committee and have really appreciated the continuity. It is a shame that her support has changed several times but despite this, disruption to the REC was minimal and managed well.

Within the period membership levels were happily not a concern owing to a concerted recruitment effort by the HRA - we lost only one valued member (due to relocation) and gained two. We are delighted to welcome Dr Khurum Khan and Mr Thomas Morrish to the committee. Unfortunately, a number of members have resigned or come to the end of their terms just after the period, so recruitment will unfortunately need to be back as a major focus in the next period. Despite everyone's best efforts this does remain a challenge - we reiterate our wish that NHS employers would be more supportive of our work and enable staff to join committees.

We have been sadly forced to change venue as our longstanding arrangement with St Helier has come to an end due to the redevelopment of the building in which we met. Skipton House is our new venue which seems to be working for members and researchers geographically, but it is to be hoped that teething issues with the reception at the building have been resolved by the issue of new security cards.

We all enjoy that we are a busy REC with an interesting and varied range of studies, but have noted that there have been a particularly high level of amendments. Still, the work remains important and rewarding.

Because of this 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 Expert	Expert	02/02/2015	
Mr. Dominic Fairclough	Solicitor	Lay Plus	01/04/2009	
Dr Khurum Khan	Clinical Research Fellow	Expert	01/05/2016	
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)	Expert	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	
Dr. Mark Weeks	Senior Research Associate	Expert	03/06/2013	31/05/2016

London - Surrey Borders Research Ethics Committee: Deputy Members

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

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Civil Servant (Retired)	Lay	Proportionate Review Meetings: 18/05/2016, 15/06/2016 and 15/08/2016

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

Name	Declaration of Interest	Date
Sir Adrian Baillie	Trustee of the Gwaine Stamp Fund - a small medical charity	14/03/2017
Sir Adrian Baillie	Shadow Governor Surrey and Sussex Healthcare Trust	14/03/2017
Sir Adrian Baillie	Member of the Organ Donation Committee, SASH	14/03/2017
Sir Adrian Baillie	I have (with my brother in law) a small interest in a Norwegian Biotech Company researching stem cells called Fortuna Fix	14/03/2017
Sir Adrian Baillie	It is possible that from time to time I may have minor shareholding(s) in stock market listed entities in the healthcare centre, or exposure to them through investment funds. At present I can confirm that I do not hold any except (possibly) in accounts that are fully directly managed by external fund managers, although I will have some exposure through index trackers and the like. I have nothing approaching a significant take in any such organisation, nor one that is financially very material to me, personally.	14/03/2017
Sir Adrian Baillie	Trustee of the Hepatitis C Trust	14/03/2017
Ms. Christine Braithwaite	None Declared	06/02/2017
Mr. Derek Cock	Consultancies for Pharma Companies on occasion (Details as per APBI Declaration)	18/01/2017
Mr. Derek Cock	Kingston Hospital R&D	18/01/2017
Mr. Tobias Davis	Employee Regulatory Affairs & Quality Executive-Roche Diabetes Care Ltd	18/01/2017
Mr. Dominic Fairclough	I sit on a board medical committee of a Hospital (Putney)	18/01/2017
Dr Khurum Khan	I am attached to GI & Lymphoma Unit at the Royal Marsden Hospital and they can be involved in Clinical trials sponsored by this unit	01/03/2017
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.	06/02/2017
Mrs. Anne Laurie	As a lecturer in Clinical Communications working in both a NHS Trust and a London Medical School there may be times when I could possible come into contact with related interested parties.	06/02/2017
Dr. David Lukey	CEO of Health Innovations Group LTD (HIG Ltd)	18/01/2017
Dr. Rosemary O'Neil	Occasional involvement with advising on research design – any conflicts of interest will be declared as and when they arise.	07/03/2017
Dr. Anand Patel	Employee of IPSEN (Pharmaceutical Company)	18/02/2017
Dr. Anand Patel	Shareholder of Allergran PLCIPSON Ltd	18/02/2017
Ms. Sibonginkosi Sibanda	Senior Lecturer at London Southbank University- May Be involved in consultancy & Clinical Research projects	18/01/2017
Ms. Sibonginkosi Sibanda	Core Steering Group (CSG) Member International Nurses Council NP/APN Network	18/01/2017

Ms. Sibonginkosi Sibanda	London Southbank University	18/01/2017
Dr. Elizabeth Smyth	Research Fellow in Oncology at Royal Marsden Hospital GI Unit	18/01/2017
Mr. Graham Tate	No Declared Interests	01/03/2017

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

Month	Date	Number of Members Present at Meeting
April	13/04/2016	12
May	11/05/2016	9
June	08/06/2016	10
July	13/07/2016	10
September	14/09/2016	9
October	12/10/2016	13
January	18/01/2017	8
February	15/02/2017	7
March	15/03/2017	10

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	20/04/2016	3
May	18/05/2016	3
June	15/06/2016	3
July	20/07/2016	3
August	15/08/2016	3
September	21/09/2016	3
October	19/10/2016	3
November	16/11/2016	3
December	14/12/2016	3
January	11/01/2017	3
February	08/02/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	2
April	13/04/2016	7
April	28/04/2016	2
May	11/05/2016	2
May	25/05/2016	2
June	08/06/2016	3
June	22/06/2016	2
July	13/07/2016	3
July	27/07/2016	2
August	10/08/2016	2
August	24/08/2016	2

September	14/09/2016	2
September	28/09/2016	2
October	03/10/2016	2
October	12/10/2016	2
October	26/10/2016	3
November	09/11/2016	2
November	23/11/2016	2
December	14/12/2016	3
December	16/12/2016	2
December	28/12/2016	2
January	25/01/2017	3
February	08/02/2017	4
February	22/02/2017	5
March	08/03/2017	2
March	22/03/2017	2

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

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

None

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

Name	Number of Meetings Attended
Sir Adrian Baillie	9
Ms. Christine Braithwaite	7
Mr. Derek Cock	8
Mr. Tobias Davis	9
Mr. Dominic Fairclough	8
Dr Khurum Khan	5
Mrs. Anne Laurie	4
Dr. David Lukey	7
Dr. Rosemary O'Neil	5
Dr. Anand Patel	3
Ms. Sibonginkosi Sibanda	7
Dr. Elizabeth Smyth	7
Mr. Graham Tate	7
Dr. Mark Weeks	2

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

Name	Number of Meetings Attended
Sir Adrian Baillie	1
Ms. Christine Braithwaite	7
Mr. Derek Cock	8
Mr. Tobias Davis	1
Stephanie Ellis	3
Mr. Dominic Fairclough	1
Dr Khurum Khan	1
Mrs. Anne Laurie	1
Dr. David Lukey	3
Dr. Rosemary O'Neil	1
Dr. Anand Patel	1
Ms. Sibonginkosi Sibanda	1
Dr. Elizabeth Smyth	1
Mr. Graham Tate	1
Dr. Mark Weeks	2

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

Name	Number of Meetings Attended
Sir Adrian Baillie	17

Ms. Christine Braithwaite	5
Mr. Derek Cock	12
Mr. Tobias Davis	3
Mr. Dominic Fairclough	3
Dr Khurum Khan	2
Mrs. Anne Laurie	3
Dr. David Lukey	3
Dr. Rosemary O'Neil	4
Dr. Anand Patel	2
Ms. Sibonginkosi Sibanda	4
Dr. Elizabeth Smyth	4
Mr. Graham Tate	3
Dr. Mark Weeks	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Sir Adrian Baillie	04/05/2016	London NREAP Chairs' Meeting
Ms. Christine Braithwaite	30/06/2016	Chairing Skills Training
Ms. Christine Braithwaite	16/02/2017	National Members Training Day
Mr. Derek Cock	09/06/2016	Consent Payments and Voluntariness Workshop
Mr. Tobias Davis	23/03/2017	Training for commercial Studies
Mr. Tobias Davis	23/03/2017	Training for Non-commercial Studies
Mr. Tobias Davis	24/03/2017	Reviewing the research design of Clinical Trials
Mr. Tobias Davis	24/03/2017	IRAS Training module
Mr. Tobias Davis	30/03/2017	Human Tissue Act
Mr. Tobias Davis	30/03/2017	Guidance on Research involving Medical Devices
Mr. Dominic Fairclough	16/11/2016	Members Training Day - London REC
Dr Khurum Khan	14/06/2016	RES Induction - on line
Dr Khurum Khan	06/12/2016	REC Members Induction Training
Mrs. Anne Laurie	01/09/2016	Ethics & Professionalism with regard to Patients/Relatives/Carers
Dr. David Lukey	16/11/2016	London REC Centre Members Training Day
Dr. Rosemary O'Neil	01/02/2017	Medical Devices Training
Dr. Anand Patel	16/02/2017	Ethical Conduct In recruiting Patients
Dr. Anand Patel	26/02/2017	Guidelines on ethics for Patients
Dr. Anand Patel	28/02/2017	Patient Centricity
Ms. Sibonginkosi Sibanda	16/11/2016	REC Members Training Day - London REC Centre
Dr. Elizabeth Smyth	01/08/2016	Reviewed an Ethics Presentation for upload to the ESMO Oncology PRO website
Dr. Elizabeth Smyth	17/03/2017	ICH GCP Training Course
Mr. Graham Tate	16/11/2016	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	19	42.22
Phase 1	2	4.44
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	24	53.33
Total Applications Reviewed	45	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	1
Number of student applications reviewed	8
Number of paediatric applications reviewed	3
Number of device applications reviewed	3
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	3

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	3	6.67
Favourable Opinion with Additional Conditions	5	11.11
Unfavourable Opinion	2	4.44
Provisional Opinion	34	75.56
Provisional Opinion Pending Consultation with Referee	1	2.22
Total	45	100
Number of studies sent back to full committee meeting for final opinion	1	

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	29	61.70
Further Information Favourable Opinion with Additional Conditions	5	10.64
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.38
Favourable Opinion with Additional Conditions	5	10.64
Unfavourable Opinion	3	6.38
Provisional Opinion	1	2.13
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	2.13
Total	47	100

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

Total Applications Reviewed	29
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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	6
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	10
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

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	5	17.24
Favourable Opinion with Additional Conditions	2	6.90
No Opinion transfer to full committee for review	3	10.34
Provisional Opinion	18	62.07
Unfavourable Opinion	1	3.45
Total	29	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	5.00
Number of completed applications for full ethical review	46
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	4
Number of completed applications over 40 days as a % of total	8.89%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	9
Number of completed Proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 14 days as a % of total	34.62%
Number of SSAs (non-Phase 1) reviewed	4
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	125
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	5
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.00%
Number of modified amendments reviewed	3
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 non substantial amendments received	101

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	32
Number of annual progress reports received	92
Number of safety reports received	114
Number of Serious Adverse Events received	0
Number of final reports received	27

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
16/LO/0423	A Phase 1 trial of SRA737 in subjects with advanced cancer	40
16/LO/0677	CQVM149B2302 to compare QVM149 with QMF149 in patients with asthma	33
16/LO/0708	Evaluating TAS-116 in patients with advanced solid tumours	29
16/LO/0842	Allakos AK001-002 NASAL POLYPOSIS	30
16/LO/0902	PIPS (Psychological Impact of Primary Screening for HPV)	25
16/LO/0915	PReCISE Pilot	28
16/LO/0958	A Phase 1/2 Open-label Study of Orally Administered EPI-506	34
16/LO/1032	Phase 3 open label study with nab-Paclitaxel in patients with NSCLC	34
16/LO/1034	Phase II Trial of MK-3475 in Subjects with mCRPC	26
16/LO/1051	CHAP study	38
16/LO/1052	SST receptor quantitation - NODAGA-JR11 PET/CT in chest NET	34
16/LO/1211	JHL-CLIN-1101-01: JHL1101 versus MabThera in RA	28
16/LO/1262	Self-disgust in eating disorders Version 1.0	21
16/LO/1605	HyPeR: Phase1 - combination of pembrolizumab with guadecitabine	27
16/LO/1640	Fiducial markers for locally advanced lung cancer EBRT	30
16/LO/1679	A Microneurography Test-Retest Study	35
16/LO/1777	MDV3800-13, Open Label, Extended Treatment with Talazoparib	36
16/LO/1779	MDV3800-06 Talazoparib in Men with MCRPC	35
16/LO/1871	SSAT073 PK of Dolutegravir and Darunavir/Cobicistat	27
16/LO/2197	Patient Family Centred Care (PFCC): Living Well to the Very End	46
17/LO/0018	Phase 1/1b study of Medi3726 for castration resistant prostate cancer	50
17/LO/0082	PuraStat®; Post Market Performance during Vascular Surgery	34
17/LO/0088	Effect of barley β -glucan on bile acid excretion and blood cholesterol	43
17/LO/0263	ACE: A Phase I/II trial of AZD5069 in combination with enzalutamide	35
17/LO/0381	ESMI	35
17/LO/0394	Social Networks of Mental Health Service Users	43
17/LO/0441	Phase 3 trial of etoposide/platinum with or without pembrolizumab	31
17/LO/0443	The GENERATE study	35
17/LO/0444	M13-576: Follow-up for 2nd Gen DAA in previous HCV studies	35

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0422	A Phase I trial of oral CCT245737 given in combination	40
16/LO/0685	A Study of Ibrutinib Combination Therapy in Advanced Tumour Patients	38
17/LO/0262	PDR001 in Advanced or Metastatic Non-Functional Neuroendocrine Tumours	37
17/LO/0271	The BEACON study	30
17/LO/0292	H.E.A.R.T Study - Version 1.0	30

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
16/LO/1300	E-support for carers of people with psychosis: Focus groups	19
16/LO/1502	CTC-STOP	21
17/LO/0445	Balancing ACT	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0883	Human salivary O-glycome	21
16/LO/1240	DHEA in Poor Responders (1)	20
16/LO/1315	CHOROID-ROP	20
16/LO/1826	The "Occupation Matters" Experience	23
17/LO/0094	R-PrEP Trial	23

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/0688	Safety Tolerability and PK study of GBR900 in Osteoarthritis Patients	25
16/LO/1650	Epistemic trust in adolescents	35
16/LO/1860	Feasibility study of a Novel Efficacy Assessment Tool (NEAT)	23

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/LO/1818	Balloon inflation and plaque morphology in revascularisation (BURST)	n/a

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
17/LO/0087	Safety and Performance of PRIMA System in dry AMD patients	23

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0705	Development of a POCT for the detection of CMV in Urine	19
16/LO/0731	CAPTURE - Retrospective chart review (Riociguat)	22
16/LO/1147	Changing bowel habits in people with MND	10
16/LO/1149	ACCESS TO SAMPLES FOR DEVELOPMENT OF NEW TESTS FOR PROSTATE CANCER	8
16/LO/1550	Study of caregivers in RA: towards effective support (SOCRATES)	12
16/LO/1552	INITIATE	8
16/LO/1557	Focus Groups and Interviews to inform the development of ePainQ	12
16/LO/2064	Improving the reading experience of people with early-stage dementia 1	13
16/LO/2087	Identifying possible cow's milk protein allergy in children < 2 years.	6
16/LO/2220	EP differences in the South Asian heart	28
17/LO/0075	Validation of two measures for growth hormone deficiency in children	20
17/LO/0078	TREC, KREC, and STELA analysis in adult PID	21
17/LO/0081	The Role of Interoception in Multiple Sclerosis Fatigue	20

17/LO/0084	Survey of healthcare professionals and patients opinions of biosimilar	20
17/LO/0258	Natural history of dural arteriovenous fistula	16

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1561	Preliminary Validation of a High Content Chemosensitivity Assay	12
16/LO/1774	Ketosis in Type 2 Diabetics on SGLT-2 inhibitors	13
16/LO/2243	BCCs Ultrasound Vs Histology Version 6.0	13

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
16/LO/0698	Collection of Chronic Wound Exudate	24
16/LO/1378	Exploring the clinical relevance of LMTK3 in Glioblastoma	10
16/LO/1387	A descriptive study of hypersensitivity pneumonitis patients	9
16/LO/1778	Cognitive Behavioural Therapy for Medicines Related Consultations.	8
16/LO/1936	Anxiety on induction of general anaesthesia	7

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1151	Plantar fasciitis - Prognostic Indicators for Treatment Response	9
16/LO/1371	ArchWire RaCE: Orthodontic Archwires: a Randomised Clinical Trial	11

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0265	CRT devices: Echo vs Electrical optimisation	13

Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 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
08/H0806/80/AM15	Metformin in obese non-diabetic pregnant women Version 1.0	8	20/01/2017	31
10/H0806/115/AM09	Abnormal genes and proteins in inflammatory bowel disease	SA07	12/04/2016	15
10/H0806/118/AM09	CASPS	7	23/02/2016	19
10/H0806/50/AM02	Assessing treatment response in breast cancer with functional imaging	No. 1	01/01/2016	7
10/H0806/71/AM18	Carfilzomib in patients with Relapsed Multiple Myeloma	Change of Sponsor 2016/04/04	04/04/2016	7
10/H0806/71/AM19	Carfilzomib in patients with Relapsed Multiple Myeloma	PIC&CF Update V8.0 18Jul16	15/08/2016	21
11/LO/0180/AM08	KIACTA to prevent kidney function worsening in AA amyloidosis patients	Edition 17	01/09/2015	28
11/LO/0619/AM22	E7080 alone or with Everolimus in patients with renal cell carcinoma	SA20	26/06/2016	18
11/LO/2022/AM12	A phase 1b study of patients with selected advanced solid tumours	SA10	02/08/2016	15
11/LO/2022/AM13	A phase 1b study of patients with selected advanced solid tumours	13	06/10/2016	9
12/LO/0426/AM02	Molecular and cellular pathogenesis of bone marrow failure syndromes	1	01/11/2016	20
12/LO/0434/AM13	Open Label Abiraterone Acetate Long Term Access Study (JNJ-212082)	SA08	21/03/2016	23
12/LO/1081/AM09	GO25632-Phase 3 study for treatment of metastatic breast cancer	23	01/11/2015	28
12/LO/1081/AM11	GO25632-Phase 3 study for treatment of metastatic breast cancer	SA 10	01/11/2016	34
12/LO/1407/AM05	Phase I trial of RO5126766, a dual RAF/MEK inhibitor	SA05	01/02/2016	11
13/LO/0023/AM07	Evaluate the Safety of Long-term Treatment with CNTO328 in MCD	7	05/01/2017	17
13/LO/0596/AM01	Blood donation	1	22/09/2016	14

13/LO/0826/AM24	C diffense	SA15	27/07/2016	28
13/LO/0826/AM26	C diffense	SA16	04/10/2016	13
13/LO/0863/AM03	The role of PDE-10A in Parkinson's disease L-dopa-induced dyskinesias.	V2	14/10/2016	27
13/LO/0867/AM10	1199.93 - Nintedanib in mesothelioma	SA8	28/07/2016	24
13/LO/0867/AM12	1199.93 - Nintedanib in mesothelioma	10	14/10/2016	10
13/LO/0867/AM16	1199.93 - Nintedanib in mesothelioma	SA11	13/02/2017	9
13/LO/0983/AM07	GO28625 - Phase II study of MPDL3280A for non-small cell lung cancer	7	06/01/2017	20
13/LO/1081/AM08	PROSPER:MDV3100-14 Phase 3,Enzalutamide,non-metastatic CRPC patients	Version 5.0	16/08/2016	9
13/LO/1083/AM06	C32001 MLN0128 + MLN1117 in advanced non-haematologic malignancies	Substantial amendment 5	06/07/2016	19
13/LO/1083/AM07	C32001 MLN0128 + MLN1117 in advanced non-haematologic malignancies	7	16/09/2016	32
13/LO/1320/AM15	STUDY OF FAI INSERT IN SUBJECTS WITH CHRONIC NON-INFECTIOUS UVEITIS	8	15/04/2016	12
13/LO/1352/AM12	GO28753 Anti-PDL1 in NSCLC	7 2016/09/08	08/09/2016	15
13/LO/1352/AM13	GO28753 Anti-PDL1 in NSCLC	8	16/01/2017	15
13/LO/1365/AM01	MRI scan to investigate micro bleeds in thrombocytopenic patients	1.0	27/01/2016	1
13/LO/1459/AM01	Predictive Biomarkers for Drugs Targeting ALK/p53 in Neuroblastoma	01	29/07/2016	12
13/LO/1482/AM07	MDV3100-10 TBP, Phase 4, Enzalutamide, metastatic CRPC patients	7	05/10/2016	20
13/LO/1616/AM19	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA #13	11/04/2016	23
13/LO/1616/AM21	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA 14 [REC 21]	23/10/2016	10
13/LO/1684/AM08	Direct Flow Medical DISCOVER Registry	#7	14/06/2016	14
13/LO/1850/AM10	Phase 1 advanced cancer study of VS-5584	SA09	06/04/2016	20
13/LO/1850/AM12	Phase 1 advanced cancer study of VS-5584	SA11	06/07/2016	19
13/LO/1850/AM13	Phase 1 advanced cancer study of VS-5584	SA12	08/08/2016	9
14/LO/0080/AM11	Luster PCI32765FLR3001	AM11	07/02/2017	27
14/LO/0259/AM05	RE-AKT	MREC5MHRA2	23/11/2016	29
14/LO/0354/AM02	015 - extension study of CL-503012 in patients with AA	17/09/2015	01/09/2015	28

	Amyloidosis			
14/LO/0481/AM01	Lung HeXeRT	1	01/12/2016	22
14/LO/0503/AM09	Safety and PK of single doses of GBR 900 in healthy adults	AM09	04/05/2016	28
14/LO/1064/AM10	BYM338D2201 A Possible Treatment for Muscle Wasting after Hip Fracture	7	19/04/2016	10
14/LO/1064/AM11	BYM338D2201 A Possible Treatment for Muscle Wasting after Hip Fracture	Substantial Amendment 8	09/05/2016	8
14/LO/1064/AM15	BYM338D2201 A Possible Treatment for Muscle Wasting after Hip Fracture	10	30/11/2016	20
14/LO/1425/AM04	CHM for RUTIs	4	13/04/2016	22
14/LO/1425/AM09	CHM for RUTIs	9 2016/09/02	09/09/2016	24
14/LO/1485/AM06	A study to evaluate SYD985 in advanced or metastatic solid tumours	SA 5	22/09/2016	13
14/LO/1540/AM03	EUREKIX	Substantial Amendment 2	02/08/2016	13
14/LO/1633/AM05	Case-control study of inherited women's cancer	3	13/12/2016	21
14/LO/1800/AM20	Treating pulmonary fibrosis with co-trimoxazole	SA13	26/05/2016	21
14/LO/2024/AM05	A Phase 1 study of oral TVB-2640 in Patients with Solid Tumours	5.0	04/04/2016	28
14/LO/2024/AM07	A Phase 1 study of oral TVB-2640 in Patients with Solid Tumours	1.0	09/06/2016	21
14/LO/2024/AM10	A Phase 1 study of oral TVB-2640 in Patients with Solid Tumours	7	17/10/2016	9
14/LO/2024/AM12	A Phase 1 study of oral TVB-2640 in Patients with Solid Tumours	9	12/01/2017	14
14/LO/2156/AM10	A phase II study of VSN16R for Multiple Sclerosis related spasticity	Substantial Amendment 6	27/04/2016	18
14/LO/2156/AM11	A phase II study of VSN16R for Multiple Sclerosis related spasticity	Substantial Amendment 7	14/06/2016	3
14/LO/2156/AM12	A phase II study of VSN16R for Multiple Sclerosis related spasticity	8.0	25/08/2016	7
14/LO/2156/AM14	A phase II study of VSN16R for Multiple Sclerosis related spasticity	10	22/11/2016	14
14/LO/2188/AM02	K-07 Physica KR Fluoroscopy study	2	21/09/2016	4
14/LO/2225/AM02	(duplicate) modafinil in hypercapnic respiratory failure	2	07/11/2016	15
15/LO/0044/AM04	panRAF	Substantial	06/05/2016	6

		Amendment 04		
15/LO/0044/AM06	panRAF	5	26/10/2016	6
15/LO/0241/AM01	Children Innovative Debridement Study (CIDS) MW2012-01-01	7	20/01/2017	18
15/LO/0263/AM04	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	SA04	06/07/2016	25
15/LO/0263/AM05	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	SA05	29/08/2016	17
15/LO/0263/AM07	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	7	17/02/2017	14
15/LO/0263/AM08	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	6	31/01/2017	27
15/LO/0553/AM01	OPERO Version 1.0	1	15/10/2016	11
15/LO/0553/AM03	OPERO Version 1.0	3	09/02/2017	2
15/LO/0649/AM05	Privacy in activity monitoring of knee surgery patient recovery	4.25 06 June 2016	06/06/2016	6
15/LO/0649/AM06	Privacy in activity monitoring of knee surgery patient recovery	SA07	08/07/2016	5
15/LO/1016/AM03	Phase I study of oral BAY 1143269 given alone or in combination with intravenous docetaxel in subjects with advanced solid tumors	1	09/11/2016	15
15/LO/1117/AM04	17110 - radium Ra 223 dichloride plus paclitaxel in cancer patients	Amendment change to Sponsor BH	27/05/2016	3
15/LO/1118/AM08	BET115521: GSK525762 in Subjects with Solid Tumours	03	29/04/2016	11
15/LO/1118/AM10	BET115521: GSK525762 in Subjects with Solid Tumours	4	16/12/2016	19
15/LO/1257/AM02	Patients' information needs to aid decision making on knee replacement	2	30/11/2016	30
15/LO/1360/AM01	(duplicate) Community-Based Antimicrobial Resistance Spread - Feasibil	01	25/04/2016	10
15/LO/1360/AM03	(duplicate) Community-Based Antimicrobial Resistance Spread - Feasibil	2	25/08/2016	15
15/LO/1444/AM01	The Platinum Study - Version 2.0, 9th July 2015	Amendment 1	09/05/2016	24
15/LO/1444/AM02	The Platinum Study - Version 2.0, 9th July 2015	2	16/02/2017	6
15/LO/1500/AM06	1199.229 Drug-drug interaction study with nintedanib and pirfenidone	5	15/08/2016	6
15/LO/1500/AM07	1199.229 Drug-drug interaction study with nintedanib and pirfenidone	6	30/01/2017	1
15/LO/1825/AM03	Open label Phase 1b Q1/Q1c study of ARN-509 in CR Prostate	1	09/02/2017	12

	Cancer			
15/LO/1836/AM04	TRIGGER Trial Version 1.0	3 [REC AM04]	19/07/2016	5
15/LO/1836/AM05	TRIGGER Trial Version 1.0	AM1701/23 (SA4)	07/03/2017	17
15/LO/1985/AM02	Mitral TRACER Trial	001	25/04/2016	22
15/LO/2017/AM02	Testing the usability of the eRAPID system in surgery	1	26/04/2016	22
15/LO/2017/AM04	Testing the usability of the eRAPID system in surgery	Substantial Amendment 2	04/07/2016	28
15/LO/2017/AM06	Testing the usability of the eRAPID system in surgery	6	21/02/2017	15
15/LO/2028/AM03	TAS3681 in Metastatic Castration Resistant Prostrate Cancer	2	24/11/2016	14
15/LO/2028/AM05	TAS3681 in Metastatic Castration Resistant Prostrate Cancer	2	14/10/2016	21
15/LO/2039/AM03	PET scanning in evaluation of vaccine reactogenicity; v1	4	27/09/2016	11
15/LO/2039/AM06	PET scanning in evaluation of vaccine reactogenicity; v1	V5	02/02/2017	20
15/LO/2161/AM05	SPREE (version 1.0)	SA01	07/06/2016	13
15/LO/2161/AM06	SPREE (version 1.0)	2 [REC AM06]	13/10/2016	11
16/LO/0065/AM01	Therapy withdrawal in REcovered Dilated cardiomyopathy trial (TRED)	1	19/09/2016	12
16/LO/0397/AM02	A Phase 1b, Open-Label, Dose Escalation and Expansion Study of Demcizumab Plus Pembrolizumab in Patients with Locally Advanced or Metastatic Solid Tumors	SA01	09/06/2016	7
16/LO/0403/AM10	EXTREQOL	1	05/01/2017	14
16/LO/0422/AM02	A Phase I trial of oral CCT245737 given in combination	1	12/10/2016	6
16/LO/0422/AM03	A Phase I trial of oral CCT245737 given in combination	2	06/03/2017	21
16/LO/0423/AM02	A Phase 1 trial of SRA737 in subjects with advanced cancer	1	12/10/2016	6
16/LO/0423/AM03	A Phase 1 trial of SRA737 in subjects with advanced cancer	2	10/02/2017	28
16/LO/0677/AM02	CQVM149B2302 to compare QVM149 with QMF149 in patients with asthma	2	25/10/2016	24
16/LO/0685/AM01	A Study of Ibrutinib Combination Therapy in Advanced Tumour Patients	1	06/03/2017	24
16/LO/0708/AM01	Evaluating TAS-116 in patients with advanced solid tumours	1	15/09/2016	14
16/LO/0708/AM03	Evaluating TAS-116 in patients with advanced solid tumours	8	22/12/2016	7
16/LO/0842/AM01	Allakos AK001-002 NASAL POLYPOSIS	1	16/09/2016	21
16/LO/0842/AM02	Allakos AK001-002 NASAL POLYPOSIS	2	08/12/2016	15
16/LO/0842/AM05	Allakos AK001-002 NASAL POLYPOSIS	3	02/02/2017	8
16/LO/1032/AM02	Phase 3 open label study with nab-Paclitaxel in patients with NSCLC	SA01	14/03/2017	22
16/LO/1034/AM02	Phase II Trial of MK-3475 in Subjects with mCRPC	2	06/10/2016	18

16/LO/1034/AM04	Phase II Trial of MK-3475 in Subjects with mCRPC	3	20/12/2016	16
16/LO/1151/AM02	Plantar fasciitis - Prognostic Indicators for Treatment Response	1	07/11/2016	10
16/LO/1211/AM01	JHL-CLIN-1101-01: JHL1101 versus MabThera in RA	1	20/10/2016	7
16/LO/1211/AM03	JHL-CLIN-1101-01: JHL1101 versus MabThera in RA	3	06/12/2016	28
16/LO/1300/AM02	E-support for carers of people with psychosis: Focus groups	1	13/12/2016	21
16/LO/1561/AM01	Preliminary Validation of a High Content Chemosensitivity Assay	1.0 November 2016	02/12/2016	4
16/LO/1640/AM01	Fiducial markers for locally advanced lung cancer EBRT	AM01	01/03/2017	26
16/LO/1679/AM01	A Microneurography Test-Retest Study	1	19/01/2017	9
16/LO/1778/AM01	Cognitive Behavioural Therapy for Medicines Related Consultations.	1	15/11/2016	6
17/LO/0018/AM02	Phase 1/1b study of Medi3726 for castration resistant prostate cancer	1	17/03/2017	17

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1425/AM06	CHM for RUTIs	Our AM06	07/06/2016	22

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

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1171/AM05/1	LNP3794 in patients with Advanced Solid Tumours having Mutations	Substantial Amendment 4	30/03/2016	12
14/LO/1425/AM06/1	CHM for RUTIs	5	12/07/2016	6
14/LO/1804/AM05/1	A Phase I Study of CAVATAK in Patients with Bladder Cancer	SA04_Protocol V2.3_Modified Am	08/04/2016	3

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
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
16/LO/0698	Collection of Chronic Wound Exudate	24
16/LO/0731	CAPTURE - Retrospective chart review (Riociguat)	22
16/LO/2220	EP differences in the South Asian heart	28

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
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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